Changing young people's attitudes towards effective contraception using mobile phone messaging

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Declaration of own work

I, Ona Lorraine McCarthy, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that I have indicated in the thesis.

Signed:  Date: 6 November 2018

Abstract

Background This thesis involved the development and evaluation of a contraceptive behavioural intervention delivered by mobile phone for young people in Tajikistan, Palestine and Bolivia.

Methods The intervention was developed using behavioral science and evaluated by randomised controlled trial in each country. Outcome data were self-reported at four months. The primary outcome was acceptability of at least one method of effective contraception (N = 570 in Palestine and Tajikistan). In Bolivia, a co-primary outcome was use of effective contraception (N = 1310). Secondary and process outcome data were collected. I conducted a post-hoc change from baseline to follow-up analysis in Tajikistan and Bolivia. Interviews with trial participants were also conducted.

Results Intervention development: the results of the intervention development were similar across the countries. The interventions consist of short messages delivered over four months and include the same ten behaviour change methods. Tajikistan trial: 573 were enrolled and 82% (n = 472) completed follow-up. Intervention content was included on the app, causing contamination. Acceptability: 66% intervention vs 64% control; adjusted OR 1.21 95% CI .80-1.83, p = 0.36. Increase in acceptability from baseline to follow-up: 2% to 65%, p < 0.001. Palestine trial: 578 were enrolled and 80% (n = 464) completed follow-up. Acceptability: 31% intervention vs 17% control; adjusted OR 2.34, 95% CI 1.48-3.68, p < 0.001. Bolivia trial: 640 were enrolled and 67% (n = 429) completed follow-up. Use: 37% intervention vs 33% control; adjusted OR 1.19, 95% CI .80-1.77, p = 0.40. Acceptability: 71.92% intervention vs 62.56% control; adjusted OR 1.49, 95% CI .98-2.28, p = 0.06. Increase in acceptability from baseline to follow-up: 9% to 67%, p < 0.001. Interviews: interviewees highly valued the intervention.

Conclusion The interventions were well-specified, theory-based and tailored to each country. It is likely that the intervention delivered by short messages improves attitudes towards effective contraception.

Acknowledgements

Many colleagues, friends and family supported me through this project. When I submitted this thesis, my supervisor and line manager Professor Cari Free and I had been working closely together for almost six years. I have learned an incredible amount from her over the years and am very grateful for her support and friendship.

Thanks so much to Alison McKinley at IPPF for her support throughout the project and the IPPF Innovation Programme for funding it. Thanks to all of my lovely collaborators at TFPA (Firuza Kulaeva, Ravshan Tokhirov, Salokhiddin Saibov, Zilola Salimova, Zarina Murodova, Rukhshona Jamoliddinova), PFPPA (Amina Stavridis, Ammal Awadallah, Ola Wazwaz, Iman Jado, Hanadi Zghayyer) and CIES (Jhonny López Gallardo, Veronica Osorio Calderon, Dr Alfaro, Carolina Aliaga, Maria Eugenia Torrico). I have learned so much from our partnership. In addition, the IPPF Regional Officers, Marieka Vandeviele, Sarah Standaert, Samia Adada, Shelly Makleff and Silvia Huaynoca have been a huge asset to the project. Thanks to Aptivate for their input during the development field research. And a huge thanks to the recruiters in each country, many of whom were volunteers.

Dr Chris Smith introduced me to Alison and the IPPF Innovation Programme and for provided feedback on my grant proposal. Dr Kathryn Church provided an advisory role in the beginning of my PhD. Drs Phil Edwards and Baptiste Leurent provided statistical support. Phil's experience, statistical oversight and encouragement was extremely helpful. Baptiste always made himself available to assist me with the minute statistical details. Drs Rebecca French and James Lewis kindly agreed to be on my Trial Steering Committee. Their input was very helpful and reassuring.

In addition to her excellent academic advice, my friend and colleague Dr Melissa Palmer monitored the trials while I was on maternity leave, which I am very thankful for. I also thank my friend and office mate Dr Emma Wilson for the laughs and fun through stressful times (we like to get to the bottom of things…). My other office mate Irrfan Ahamed built the database and randomisation system, which was integral to the trials.

I'm pretty sure that my partner Tom could successfully defend my thesis. An artist who has a natural inclination for science, he always responded with considered comments and questions when I subjected him to frequent cathartic monologues related to this project. His

emotional and intellectual support has been invaluable. Our son Miles was born towards the end of this project. Before this, I was preoccupied by the potential adverse effects having a baby during my PhD would have on its completion and my career. After giving birth to Miles I realised that this was nonsense. I have him to thank for giving me perspective.

My sister Leila has been a constant source of support as usual. Ultimately, I have my parents, Mariette and Bruce, to thank for enabling me to develop perseverance, without which I could not have completed this project.

And finally, to the people who are the most important in this project- young people in Tajikistan, Palestine and Bolivia- I hope that your reproductive lives are those that you choose.

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Acronyms and Abbreviations

LMIC	Low and middle income countries
IUD	Intrauterine device
IPPF	The International Planned Parenthood Federation
MA	Member Association
TFPA	The Tajik Family Planning Association
PFPPA	The Palestinian Family Planning and Protection Association
CIES	Centro de Investigación, Educación y Servicios
LSHTM	The London School of Hygiene and Tropical Medicine
CPR	Contraceptive prevalence rate
TAR	Total abortion rate
MICS	Multiple Indicator Cluster Survey
ITU	International Telecommunications Union
ASFRs	Age-specific fertility rates
LARC	Long acting reversible contraception
IM	Intervention Mapping
FGD	Focus group discussion
IBM	Integrated Behavioural Model
BCM	Behaviour change method
OR	Odds ratio
CI	Confidence interval
OC	Oral contraceptives
WHO	World Health Organization
YAE	Youth all engaged!
TOP	Teen Outreach Program
API	Application programming interface

1 Introduction

1.1 Global unintended pregnancy

Worldwide between 2010-2014, an estimated 44% of all pregnancies were unintended, with 56% of these ending in abortion during this period (1). A range of negative consequences are associated with unintended pregnancy. Women with unintended pregnancies can experience decreased psychological well-being (2-10). They initiate antenatal care later than those with intended pregnancies (4, 10-14) and access care less frequently (4, 11, 14). The risk of low birth weight and pre-term birth is higher among children born of unintended pregnancies (15, 16). These children can exhibit behavioural problems more often than children born of intended pregnancies (17). Unintended pregnancy can delay or prevent educational and career advances, which can affect the financial security of the family (18). Unsafe abortions are a consequence of unintended pregnancy where access to safe abortion is limited (19, 20). While unintended pregnancy exists in all countries among women in every socio-economic group, young people in LMIC are at particular risk, with half of pregnancies among women age 15-19 in these regions estimated to be unintended (21). Tajikistan, Bolivia and Palestine, the countries where the research in this thesis was conducted, are three LMIC where adolescents are at risk of unintended pregnancy. The measurement of pregnancy intention, however, is challenging (22, 23) and studies evaluating unintended pregnancy's effects on maternal and child health outcomes are methodologically limited (23). Despite this, it is clear that unintended pregnancy persists as a global health problem (24), with research in low and middle income countries (LMIC) lacking (4, 23).

Meeting unmet need for effective contraception is essential in decreasing unintended pregnancy. A woman who has an unmet need for modern contraception is: of reproductive age (15-49); legally married, cohabiting, in a consensual union or unmarried and sexually active; is not using a modern method of contraception; is fecund and does not want to have a child (or another child) in the next two years or at all (25, 26). Modern contraceptive methods include oral contraceptives, injectables, intra-uterine device (IUDs), implants, the patch, the ring, male and female sterilization, male and female condoms and other barrier methods, modern fertility-awareness methods and emergency contraception (27). 'Effective' contraceptive methods are methods with less than 10% typical use failure rate at 12 months, i.e. all modern methods besides condoms, other barrier methods and modern fertility awareness methods (28-30). While effective methods are available in Tajikistan, Bolivia and Palestine, there remain barriers to use. Despite increasing availability of a variety of

contraceptive methods, thirty-eight million women aged 15-19 in LMIC are sexually active and do not want a child in the next two years, yet 23 million have an unmet need for modern contraception (21). It is estimated that meeting adolescents' unmet need for contraception would reduce unintended pregnancies by six million each year (21).

1.2 Health interventions delivered by mobile phone

Worldwide, there were an estimated 7.7 billion mobile phone subscriptions at the end of 2017, with 6.1 billion in the developing world (31). The ubiquity of mobile phones creates the opportunity for broad intervention delivery. Regarding health intervention delivery, they are now a popular and widely established vehicle and there is growing evidence that interventions delivered by mobile phone can be effective at improving a range of health behaviours (32-47). Health support delivered by mobile phone can be received at a time of the recipient's choosing, which may be important for young people, especially with sensitive topics such as sexual and reproductive health. Because the content of interventions delivered by mobile phone can be standardised and pre-specified, these interventions can be delivered with high fidelity. Such interventions may be more convenient and cheaper to deliver than face-to-face support. Mobile phone interventions can be delivered through a variety of different ways, for example, through voice and text messages (SMS, short message service), mobile applications, instant messages that include videos and images, bi-directional communication with professionals via SMS or a live voice call. Despite the potential to reach many people, systematic reviews have highlighted a lack of high quality efficacy studies evaluating health interventions delivered by mobile phone in LMIC (38, 48, 49).

1.3 The three country project

In 2014, the International Planned Parenthood Federation's (IPPF) Innovation Programme Round 1 put forth a thematic initiative for their Member Associations (MA) titled, "Can you think of a new way to broaden the contraceptive method mix to young people?". Three MAs included a mobile phone element in their proposal: the Tajik Family Planning Association (TFPA), the Palestinian Family Planning and Protection Association (PFPPA), and the Centro de Investigacion, Educacion y Servicios (CIES, Bolivia). Viewing this as an opportunity to create a cross-country project, IPPF refined the aim of Round 1 when seeking a research partner, to focus on developing and evaluating an intervention delivered by mobile phone to broaden contraceptive method choice among young people in each country. In December 2014 I wrote a research proposal in response to this call, as a member of staff at the London School

of Hygiene & Tropical Medicine (LSHTM), under the supervision of Professor Cari Free. In January of 2015, my application was successful, and we began a three year collaboration with IPPF and the three MAs. My thesis is based on this project.

1.4 Roles

IPPF conceived of the aims of the project (to develop and evaluate an intervention delivered by mobile phone to broaden contraceptive method choice in each country) and chose the target population ('young people'). I identified and executed the methods to achieve these aims. During the project, IPPF's role was largely to facilitate good collaboration and to monitor and ensure compliance with the research grant agreement. I led the project as a full time staff member at LSHTM. I was responsible for all the research activities (broadly, the study design, research governance, data collection, data analysis and dissemination). I managed the research activities of the local staff working on the project, which involved frequent remote training, monitoring and planning meetings along with field visits. I trained staff in the field and remotely in qualitative research methods and trial conduct and I monitored the conduct of the trials day to day. I wrote the intervention development and trial protocols and statistical analysis plans, modified the trial database and randomisation system, managed the data, conducted the analysis and interpreted the results.

1.5 Aims and objectives of the thesis

The overall aim of this thesis is to develop and evaluate a contraceptive behavioural intervention delivered by mobile phone for young people in Tajikistan, Palestine and Bolivia.

Specific objectives of this thesis are to:

1. Review the literature on the factors that influence contraceptive use in LMIC
2. Describe the context in each country regarding contraceptive and mobile phone use
3. Review the evidence from trials evaluating individual level interventions for contraception delivered by mobile phone
4. Develop an intervention for contraception delivered by mobile phone in each country, using a systematic approach grounded in behavioural science
5. Evaluate the effect of the intervention by conducting a randomised controlled trial in each country
6. Conduct interviews with trial participants regarding their views of the intervention

7. Discuss the results across the countries to draw conclusions about the efficacy of the intervention

1.6 Structure of the thesis

My thesis is written as a combination of book style and research paper style. My research papers cover the intervention development and evaluation (Chapters 3 and 5-8). Five out of seven of the research papers have been published in peer-reviewed journals (50-54). I have written the other chapters of my thesis in book style.

Chapter 2 provides a background for the research activities. The intervention development approach and results were similar, which is why I published this work in one publication (Chapter 3). In Chapter 4, I describe the theoretical basis of the intervention. The evaluation methods were similar and consisted of a randomised controlled trial in each country. I considered designing one trial stratified by country, but fundamental differences in the trial designs in each country (such as differences in the primary outcome, eligibility and comparison group) precluded this. Consequently, I published one trial protocol for each country. To avoid unnecessary repetition in this thesis, I present the trial protocols combined in Chapter 5, and highlight the differences between the countries. Chapter 5 also presents additional material that was not included in the published protocols. Chapters 6, 7 and 8 present the evaluation results in each country. Chapter 9 presents additional analyses. In Chapter 10 I present a descriptive analysis of the interviews. Finally, in Chapter 11, I summarise the thesis and discuss the challenges, limitations and cross-country implications.

2 Background

2.1 Factors that influence contraceptive use in LMIC

Reasons for contraceptive non-use in LMIC have been well documented across different settings in surveys, quantitative analyses of observational data, qualitative studies and reviews (21, 26, 55-74). These factors can be thought as resting within the individual, such as attitudes, or can be environmental, such as the influence of friends, family and society as well as structural factors. Often, the individual factors are a result of environmental influences.

Lack of access to services and methods (71), family planning education and information (73), and limited choice constrains women's decision-making abilities (62). Pressure to conform to traditional gender roles and value systems where being a wife and mother determines women's status in society can stigmatise contraceptive use (75, 76) and influence contraceptive decision-making (58, 63). For some, attending services constitutes admission of sexually activity, which can threaten reputations and social status (73). These social pressures, including the pressure to bear children soon after marriage, can limit women's self-efficacy in accessing and using contraception (58). Environmental factors such as law, social practices, traditions, religious and cultural constructs can interact with each other, to prevent women from realising their reproductive intentions (22, 77).

Concern about the side effects or health risks of contraception, such as menstrual irregularities and fear of infertility, remain one of the most often cited reasons for not using modern contraception (21, 55, 57, 59, 61-65, 67, 70). The concerns that women have can be due to either their own experience (61), the experiences of those close to them or misinformation (59). Concerns that stem from personal experience, are often responses to side-effects that occur as a result of the way in which the methods work (61). For example, most hormonal methods alter hormone levels to prevent ovulation. While ovulation suppression is the desired effect, some users may experience undesired side-effects associated with some methods such as bleeding changes, nausea, headaches, breast tenderness, mood changes and weight changes (78).

While experienced side-effects are not uncommon, perceptions of side-effects based on misinformation can lead to a generalised fear of contraception (57, 59, 62, 67, 70). Misperceptions about contraceptive methods are beliefs about the effects or purpose of methods that are not supported by current best evidence (59). Common misperceptions that

women express are that contraception causes infertility and cancer and that bleeding changes associated with some methods are harmful to health (59, 63, 73). These beliefs, whether misperceptions or accurate, can be powerful influences on use (61). While there is some indication that lack of awareness of methods has decreased in LMIC (57), lack of accurate knowledge (55, 58, 63, 64, 66), particularly among young people (74), still remains a barrier to use and can likely reinforce misperceptions.

Misperceptions can also be reinforced through provider bias, which can limit women's choice (59, 60). For example, providers may not offer long acting methods to young people based on the misperception that they are contraindicated in this group (59, 60). Restricting women's method options limits their choice which may result in the choice of a less acceptable method, which in turn could lead to discontinuation. Provider bias prevents women from receiving accurate and comprehensive information on the full range of available methods and opportunities to switch if needed.

Perceived risk of pregnancy can also influence the decision to use contraception. Infrequent sex is a common reason women with an unmet need, particularly younger women, give for contraceptive non-use (21, 26, 57). Post-partum amenorrhea, breast feeding or both are also common reasons women with an unmet need provide (26, 57).

Communication and joint decision making has been shown to be associated with greater contraceptive use in both lower income (68, 69) and higher income (72) settings. However, oppositional attitudes towards contraception, either the user's or someone close to them, is a common reason women with an unmet need provide for not using it (26). While some oppositional attitudes are based on previous experience, survey data reveals that many women hold oppositional beliefs before ever trying a method (26).

The above factors and influences on contraceptive use, in varying degrees, have been documented across a wide range of LMIC. The cross-cultural similarities mean that that countries can learn from each other's efforts to tackle the causes of unintended pregnancy (74).

2.2 Context

In this section I report key data on contraceptive use and the fertility rates in each country. Published data on abortion was only available for Tajikistan, the only country of the three

where abortion is legal on request. It is important to note that abortion is known to be underreported in surveys, even in contexts where abortion is legal (79, 80) and published data should interpreted with caution.

2.2.1 Tajikistan

Figure 2.1 Map of Tajikistan

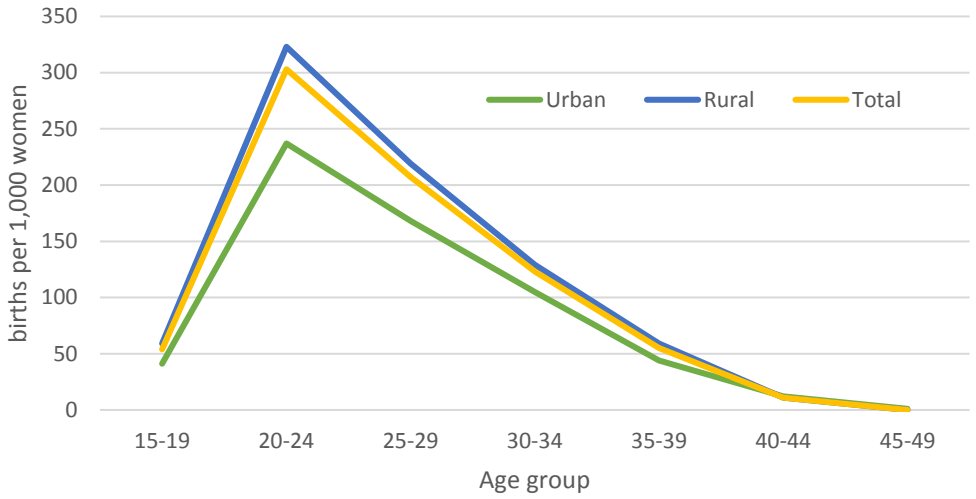
The civil war that followed Tajikistan's independence from the Soviet Union in 1991, had devastating effects on the Tajik economy and health system (81, 82). While economic hardship continues, fundamental reforms to the healthcare system have instigated progressive initiatives, such as the adoption of the Strategic Plan for Reproductive Health in 2004 (83). Despite various reproductive health governmental policy initiatives and strategies, it is still a challenge for Tajik young people to gain accurate information about contraception (84, 85). Women and their partners have limited knowledge about reproductive health and rights and face pressures from family members (85). Provision of reproductive health services is impeded by factors such as lack of access to adequate care, limited health professional capacity and widespread stigma and discrimination (85).

The most reliable source of information about contraceptive use is the 2017 Tajikistan Demographic and Health Survey (DHS), which was published in November of 2018 (all data from the 2017 DHS survey unless referenced otherwise) (86). The survey sample was nationally representative and followed a two-stage design. The first stage involved the selection of 366 clusters (with a probability proportional to their size within each sampling stratum). The second stage involved the selection of 22 households from each cluster (with an equal probability systematic selection process). The final sample included interviews with 10,718 women aged 15-49 in all selected households (a 99% response rate). The sample represents all areas of Tajikistan- urban and rural and for all five regions (Sughd, Dushanbe, Khation, Districts of Republican Subordination and Gorno-Badakhshan Autonomous Oblast).

Awareness contraceptive methods is widespread among women: with 98% of married women aged 15-49 aware of at least one method and married women have heard of an average of seven methods. The top three most well-known methods are the IUD (96%), pill (89%) and the male condom (85%).

The total fertility rate is 3.8 births per woman compared to the total wanted fertility rate of 3.5. Childbearing increases from 54 births per 1,000 women in the 15-19 age group to a peak of 303 births per 1,000 women in the 20-24 age group (Figure 2.2). Age-specific fertility rates are higher among rural women compared to urban women for most age groups.

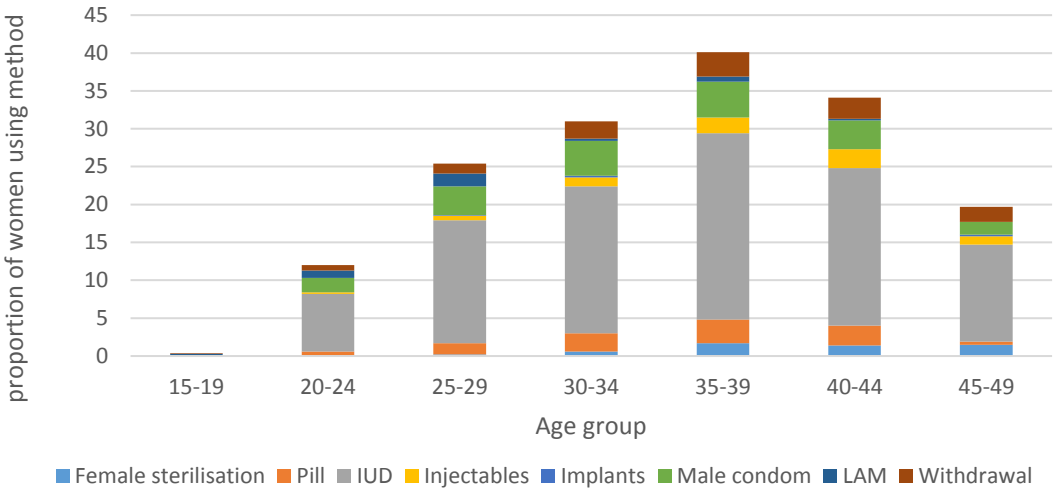
Figure 2.2 Age-specific fertility rates, 2017 (Tajikistan)



Compared to the 2012 survey, contraceptive use in the 2017 changed minimally, whereas there were relatively large changes from the 2005 to the 2012 survey. In the 2012 DHS survey, contraceptive use among married women decreased by around 10% compared to the previous survey conducted in 2005 (from 38% to 28%) (83, 87). Between the two surveys, use of the IUD among all married women decreased by almost 8%. One reason suggested for this decrease is the outward migration of young men into countries such as Russian looking for work; women whose husbands are away may be less likely to use contraception, as they perceive their risk of pregnancy as low. The 2012 survey estimated that that 23% of all married women and 8% of married 15-24 year olds use effective contraception, with the IUD being the most common method used. The contraceptive prevalence rate (CPR) among married women aged 15-49 in the 2017 survey is 29%, with 27% using modern methods. Among all women aged 15-49, the CRP is 21%, with 20% using modern methods. The IUD is the most commonly used method among married women (18%), all women (13%) and in all age groups. Use of contraception increases with age and peaks at 46% among women aged

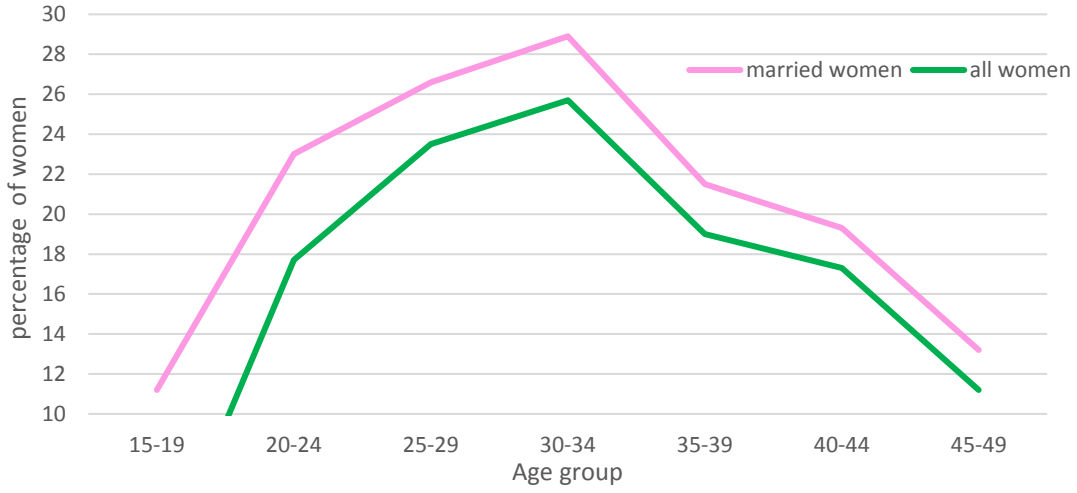
35-39. The IUD is the most commonly used method in all age groups except those aged 15-19, where LAM and the male condom are the most popular.

Figure 2.3 Contraceptive use among all women by age and method, 2017 (Tajikistan)



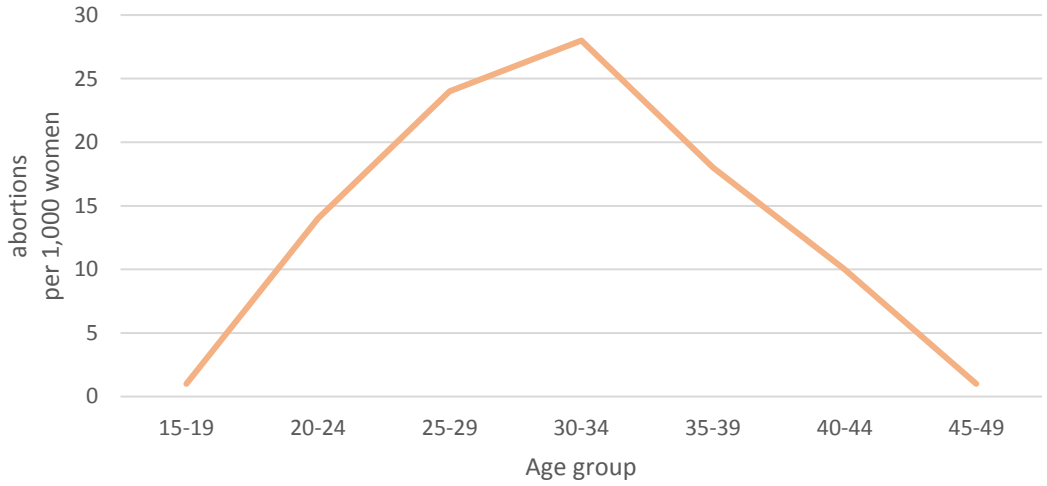
Unmet need for contraception peaks in the 30-34 age group among all women and married women. Unmet need is greatest among married women aged 30-34 (29%), with this age group seeing the largest jump from the previous age group in unmet need for limiting. In the 2012 survey, holding oppositional attitudes towards contraception was the most common reason women with an unmet need provide for not using contraception; 36% of women with an unmet need cited their own opposition and 13% cited their partner's opposition as the reason for not using contraception (26). The next most common reasons were infrequent/no sex (28%) and side effects/health risks/inconvenience (15%) (26).

Figure 2.4 Women with unmet need for contraception by age group and marital status, 2017 (Tajikistan)



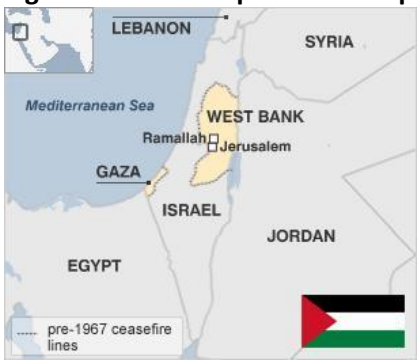
Abortion is legal on request in Tajikistan. Eleven percent of women aged 15-49 have had an induced abortion and the total abortion rate (TAR) 0.5 per woman. In the 2012 DHS survey, the TAR was also 0.5 and 10% of women had had an abortion, indicating stability of the rates in the country (83). The TAR is 0.4 in urban and 0.5 in rural areas. Failure of contraception accounts only for 5% of induced abortions and the main reasons women provided for their decision to have an abortion were concerns about their health (37%) and that the pregnancy was unwanted (36%). The abortion rate increased with age, at 1 per 1,000 among women aged 15-19 and peaking at 28 per 1,000 among women aged 30-34 (Figure 2.5).

Figure 2.5 Abortions per 1,000 women by age group, 2017 (Tajikistan)



2.2.2 Palestine

Figure 2.6 Map of the Occupied Palestinian Territories



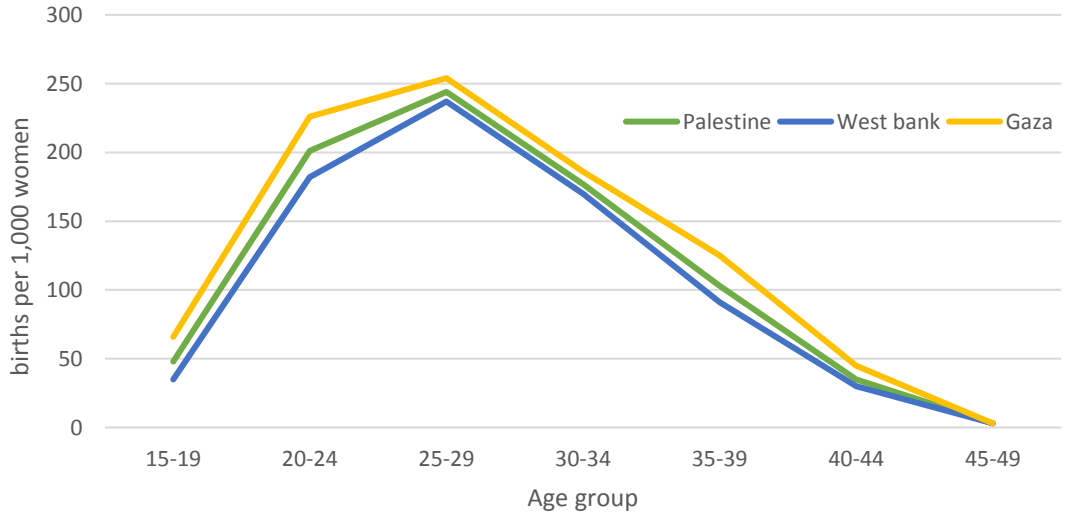
The conflict in the Occupied Palestinian Territories (the West Bank, East Jerusalem and the Gaza Strip, hereafter referred to as 'Palestine') has negatively impacted the health and wellbeing of Palestinians (88-92). More than 20% of communities in Area C have limited access to health facilities, (93), largely due to mobility restrictions imposed upon Palestinians as a result of the conflict (94). The conflict has also had negative effects on reproductive

health and rights in Palestine (22, 94) which has political implications in this context (22, 94). The population is young, with 41% of the population under age 15 and 30% aged 15-29 (95).

The Palestinian Multiple Indicator Cluster Survey (MICS) 2014 provides the most recent data regarding reproductive health (the new survey is due to be completed by the end of 2019), with data regarding contraception available for married women only (96). (All data in this section is from the 2014 MICS unless referenced otherwise.) The MICS was conducted by the Palestinian Central Bureau of Statistics and the Ministry of Health, with support by the United Nations Children's Fund. The sample frame was the Population Housing and Establishment Census 2007 and the Household Listing 2013. There were three questionnaires: household, women and children under five (data in this section relate to the women's questionnaire). From March to April 2014, 13,964 women sampled were eligible and 13,367 were interviewed, representing a 96% response rate.

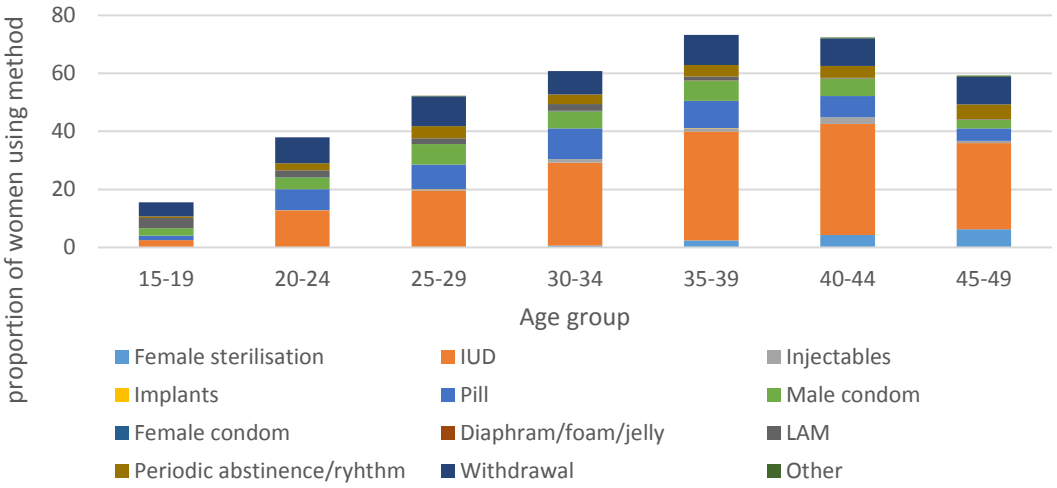
The total fertility rate in 2014 was 4.1 (3.7 for the West Bank and 4.5 for Gaza). The adolescent fertility rate had decreased substantially over the past 20 years, but the current rate of 48 per 1,000 women aged 15-19 remains high for the region (96, 97). The rate in Gaza is almost twice as high as the rate in the West Bank (66 per 1,000 women vs 35 per 1,000 women respectively) (96, 97). The adolescent fertility rate is highly associated with wealth index, with the rate at 86 per 1,000 in the poorest quintile vs 19 per 1,000 women aged 15-19 in the richest quintile. The age-specific fertility rates (ASFRs) by region are presented in Figure 2.7, which reflect a pattern of early childbearing. Fertility is low among adolescents and then sharply rises and peaks to 244 births per 1,000 among women age 25-29.

Figure 2.7 Age-specific fertility rates by region, 2014 (Palestine)



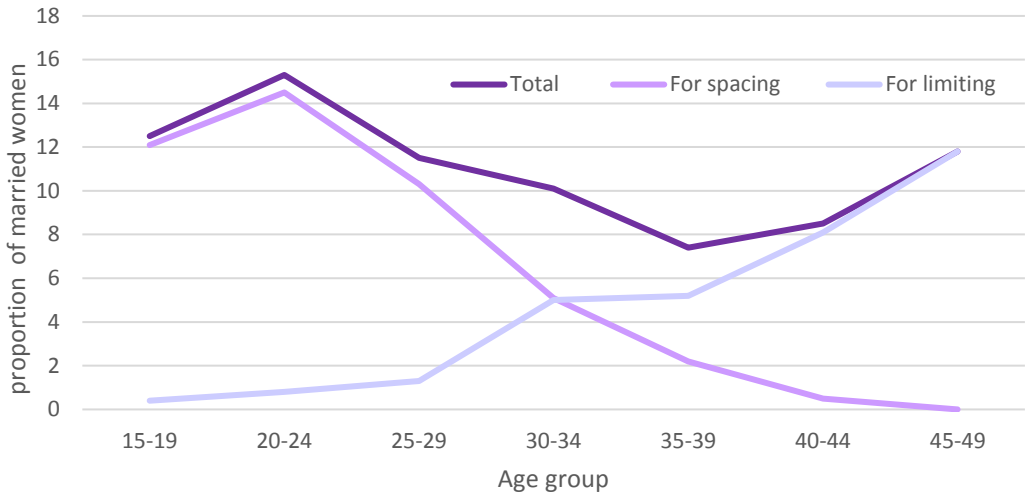
Among married women aged 15-49, the CPR is 57% and modern CRP is 44%. Among married women aged 15-24, the modern CPR is 24% and the effective CPR in the same group is estimated to be 17%. The IUD is by far the most commonly used method among married women of all age groups (Figure 2.8). Married adolescents are the least likely of all age groups to use any form of contraception, with only 15% using any method (10% modern, 6% traditional).

Figure 2.8 Contraceptive use among married women by age and method (Palestine)



In 2014, total unmet need for contraception among married women was highest among women aged 20-24, at just over 15% (Figure 2.9) (96). Unmet need for spacing is also highest in this age group, at close to 15%. Unmet need for limiting surpasses unmet need for spacing in the 30-34 age group. A 2013 study indicated that unmet need is influenced by the availability and quality of services (particularly weak counselling), the availability of a female provider and provider negative attitudes towards family planning (95).

Figure 2.9 Married women with unmet need for contraception by age group (Palestine)



The Palestinian Family Survey 2010 found that among married women not using contraception and not reporting wanting to have a child, the main reasons given for not using contraception were fear of side effects, inconvenience of methods and their husband's opposition (98, 99). Further analysis of this survey data indicates that women are more likely to use contraception and are more likely to use modern contraception when couples agree about using it (98, 99). Spousal communication also increases the odds of contraceptive use (69). Lack of accurate and comprehensive information about contraceptive methods, lack of spousal communication regarding contraception, disapproval of peers and relatives (particularly husbands and mother-in-law), societal pressure to childbear and inadequate family planning services also influence contraceptive use (69, 100-103). Education is also an important factor in this context as Palestinian women who spend more time in education report fewer unintended pregnancies (104).

Data regarding unintended pregnancy in Palestine generally comes from household surveys where married women are asked if their current or last pregnancy was intended at the time that they became pregnant, likely to underestimate the true proportion (104). A 2006 survey estimated that 38% of pregnancies in Palestine are unintended (104, 105). A non-representative study in 2014 and found that 55% of women aged 15–49 years from a community sample (from underserved areas) said that their pregnancy was unintended ('unwanted') and, of these, 26% said that this was because it 'was not their choice'. In a client sample (from service-delivery points), 40% reported unintended pregnancy, with 32% saying that it 'was not their choice' (93).

Abortion in Palestine is criminalised and is legal only to save a woman's life (103, 106). Data on lifetime abortions among married women were collected for married women in the 2014 MICS but are not published. Though there are no reliable estimates of the public health impact of unsafe abortion in Palestine, research conducted by the Safe Abortion Action Fund and PFPPA found that unsafe abortions are "numerous" (103). A qualitative interview study among Palestinian women revealed that limitations to safe abortion access included the legal restrictions, negative social consequences from one's family and community if an abortion is discovered and differential access to abortion depending on location (107).

2.2.3 Bolivia

Figure 2.10 Map of Bolivia

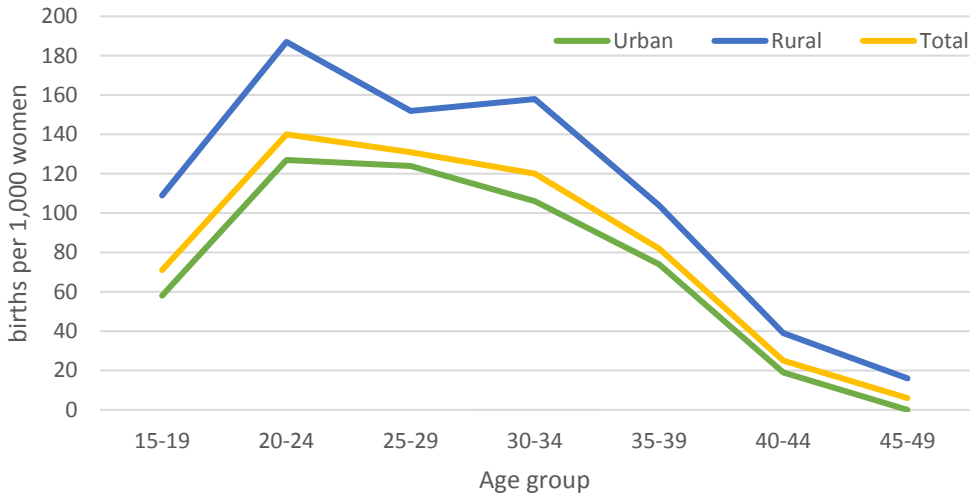
Bolivia is classified as a lower middle-income country, with 60% under the age of 29 (108). While the country has experienced recent economic growth, in 2015 around 39% of people were living below the national poverty line (109). Income inequality is high (109), with substantial inequality between indigenous and nonindigenous populations (110). Although there has been steady improvement, family planning progress in Bolivia has lagged behind other Latin American countries (111). In 2008, there were an estimated 2.4 million people aged 10-19, which equated to 21% of the population (112).

The latest DHS survey is the Encuesta Nacional de Demografía y Salud 2008 (112), which was conducted by the Ministerio de Salud y Deportes, Programa Reforma de Salud and Instituto Nacional de Estadística with technical assistance from Macro International. Data from this survey is nationally representative and used a two-stage sample design: the first stage involved the systematic selection of primary sampling units with probability proportional to their size (the number of households) and the second involved selection of 20 households within each primary sampling unit. Data were collected from February to June 2008 from 19,564 households. Complete interviews were conducted with 16,939 women aged 15-49 (a 96% response rate) and 6,054 men aged 15-64 (a 91% response rate). A more recent Bolivian-lead survey has since been conducted- the Encuesta de Demographia y Salud 2016 (113). The

2016 surveys maintains that the sample design is similar to the 2008 survey to achieve comparability. Data for this survey were collected from May to September 2016. Interviews were conducted with 11,814 women aged 15-49 (a 97% response rate) and 4,975 men aged 15-64 (a 95% response rate). Data in this section are from the latest survey where they were collected.

The total fertility rate in 2016 was estimated to be 2.9 births per woman (113). World Bank indicators (2015) report the adolescent fertility rate to be 70 per 1,000 women aged 15-19 (109) and the 2016 survey reported found a similar rate at 71 per 1,000 (113). The adolescent fertility rate is higher than the rate in Tajikistan and Palestine, at 71 births per 1,000 women and significantly higher among rural women in this age group at 109 births per 1,000 women (113) (Figure 2.11). Sexual abuse is often a factor in adolescent pregnancies, particularly in girls under age 15 (108).

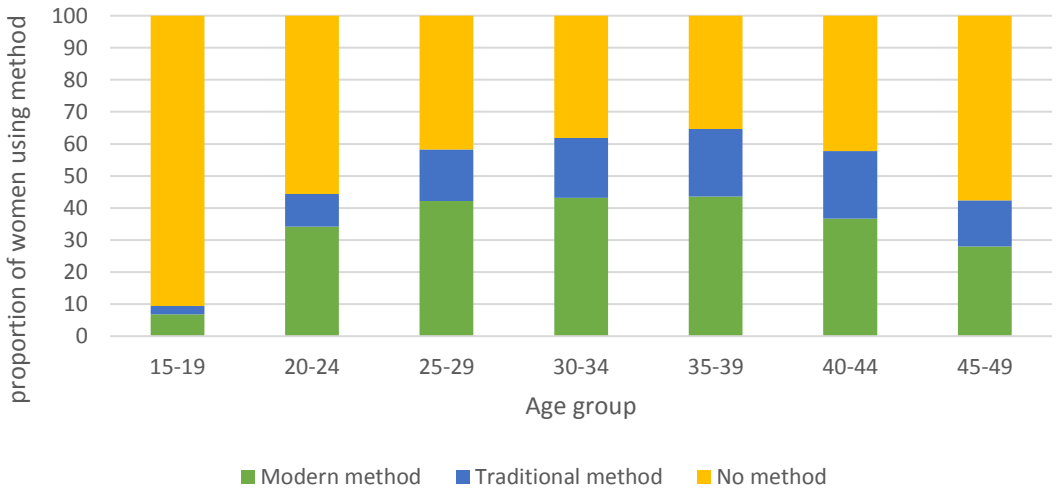
Figure 2.11 Age-specific fertility rates, 2016 (Bolivia)



In 2008, the modern CPR was 35% (40% urban, 28% rural) (112, 114). The 2016 survey found that among unmarried, sexually active women aged 15-19, an estimated 34% were not using any method of contraception (113), which was down from 52% in the 2008 survey (112). The 2008 survey also found that 84.8% of unmarried sexually active women age 15-19 reported not wanting a pregnancy in the next two years, yet only 49% of them reported using any method of contraception. The main reasons these women gave for not using a method were that they were not married (51.5%), had infrequent sex (54.7%) or are not having sex (22.6%). Male condoms and the injection were the most common modern methods reported by this group (19.6% and 6.2% respectively), with 2% reporting that they use withdrawal and 13% using periodic abstinence. According to the 2008 DHS, among women who were married or

have a partner, unmet need for contraception was 20% overall and 38% among women aged 15-19 (112, 114). A 2019 analysis of the 2008 DHS data found that among women of all age groups, use of long acting reversible contraceptive (LARC) methods was highest in the richest wealth quintile at 16% and lowest in the poorest wealth quintile at 2%, an indication of wide inequality (115).

Figure 2.12 Modern and traditional contraceptive use among all women by age group, 2016 (Bolivia)



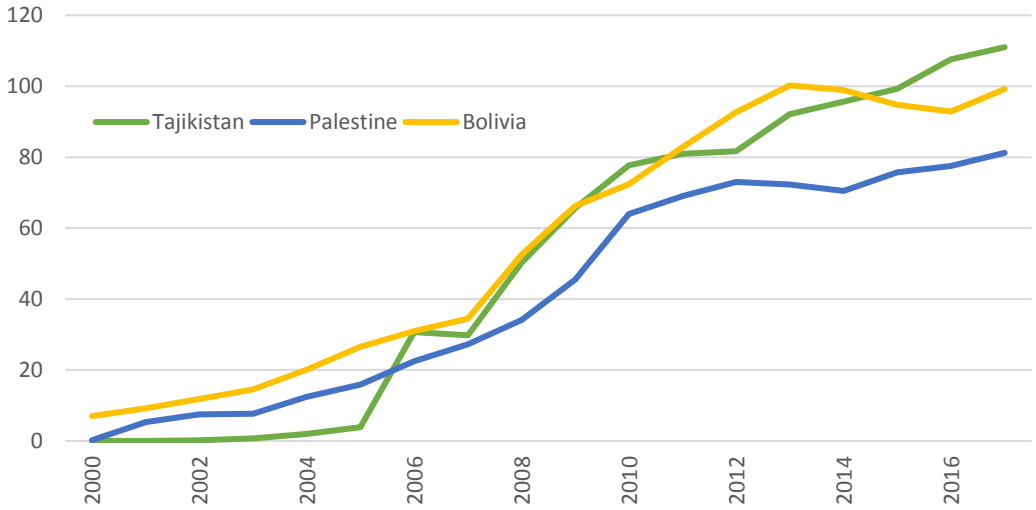
In December 2017 there was brief success in broadening the circumstances in which women can access legal abortion in Bolivia (116). At the time of writing however, abortion in Bolivia is still illegal except in cases of rape, incest and danger to the health of the woman (117). There are no official figures but research suggests that there are likely 100 illegal abortions conducted per day, the majority of which are likely to be unsafe due to the legal restrictions (114).

2.2.4 Mobile phone use in the three countries

While national telecommunication agencies exist in Palestine (the Ministry of Telecommunication and Information Technology) and Bolivia (Autoridad de Regulación y Fiscalización de Telecomunicaciones y Transportes), official and reliable data regarding age-specific mobile phone ownership and usage does not appear to be available in English for the two countries. The 2017 Tajik DHS estimates that 21% of women ages 15-19 and 42% of women aged 20-24 own a mobile phone (86). This project's local partners observed high usage among young people, which is why their original project proposals included a mobile phone component. The International Telecommunications Union (ICU) is the United Nation specialised agency for Information and Communication Technology. ICU data shows a steady

and sharp increase in mobile phone subscriptions in the three countries, particularly from 2007 (Figure 2.13) (118).

Figure 2.13 Mobile phone subscriptions per 100 people (2000-2017)



2.3 Theory and evidence-based approaches to intervention development

Best practice is to develop behaviour change interventions systematically (119-121), allowing for the intervention to be clearly defined. If the determinants of behaviour that an intervention targets and the methods used to alter these determinants are adequately described, it is easier to assess whether the methods are appropriate (122). This transparency also helps with the interpretation of the evaluation and makes adapting effective interventions to different contexts less challenging. Despite this, many descriptions of behaviour change interventions are limited (122). A context-specific, participatory approach to developing family planning interventions for young people makes it more likely that interventions address the specific determinants of the behaviour of the target group (58). Regarding interventions delivered by mobile phone, guidelines have recently been developed to standardise the reporting of the interventions (123).

Along with clear descriptions of the components of interventions and the development process, theories can help explain how interventions work by describing the factors that have been altered to achieve change (124). Though the association between the effectiveness of interventions and the use of theory in their development is unclear (125), theory is recommended as a key component of the development process for this reason (120, 124, 126).

When reviewing what interventions 'work', it is important to not only consider the results of the evaluation, but also to appraise the intervention development and content. This is especially important with interventions delivered by mobile phone because the intervention delivery mechanism (the mobile phone) is often mistakenly considered the active component, with less attention placed on the actual content of the intervention. For example, an intervention delivered by SMS may be effective in one context, but this does not mean that all interventions delivered by SMS are effective; the mobile phone is simply the vehicle for which to reach the target group. If the intervention is well-developed and the active components are well-specified, effective interventions can be adapted and may have a greater chance of being effective in different contexts.

Along with face-to-face interventions, interventions delivered by mobile phone can be theory-based, with some researchers proposing theories or models specifically for 'behaviour change technology' (127-130). Interventions delivered by mobile phone can also include behaviour change methods (general techniques or processes that have been shown to be able to change determinants of behaviour), adapted for delivery by mobile phone (122, 124). While important in the development of all interventions, target group participation in mobile phone intervention development is especially important. This is because the delivery mechanism must be acceptable to the target population and aligned with how they use the technology in order for the intervention to be received as it is intended to be received (131). While mobile phones offer an alternative avenue in which to deliver interventions, greater emphasis is needed on their development, particularly in LMIC (49).

2.4 Mobile phone interventions for contraception: a review of their development, theoretical basis and efficacy

In this section, I review individual-level interventions delivered by mobile phone to improve contraceptive-related outcomes that were evaluated by randomised controlled trial. 'Individual-level' health interventions are interventions that aim to create measurable change in a specific person (132). To identify trials, I started with Smith 2015's Cochrane review "Mobile phone-based interventions for improving contraception use" (133) (see Appendix 1 for the search strategy). The search terms would identify trials of interventions for contraception delivered by phone. The authors excluded trials if they did not include a contraceptive use-related outcome and if they could potentially be delivered by landline

phone. This resulted in five trials that fit their inclusion criteria (134-138). A LSHTM colleague, Dr Melissa Palmer, completed a literature search for a grant proposal using Smith et al's search terms for the period 1 Jan 2015-8 Sept 2017. Dr Palmer identified an additional five trials (44, 139-143) (Trent 2015, was the full publication of a trial that Smith identified, Trent 2013). I ran the same search for the period 1 Sept 2017- 20 September 2018 and identified an additional two trials, one of which was the full publication (144) of a conference abstract identified by Dr Palmer (139) (144, 145). Dr Palmer and I included trials that evaluated a wider range of contraceptive-related outcomes. For example, I included the additional analysis of Castaño 2012 (Hall 2013) as it included knowledge of contraception as an outcome. Smith reports that only one trial was excluded because the outcome measure was not relevant, and this trial would have also been excluded by Dr Palmer and me (the outcome was not related to contraception) (146). In addition, I reviewed four additional Cochrane reviews (147-150), which did not result in the identification of additional trials. Below I present a narrative review the development, theoretical basis and reported results of the 11 trials.

Bull 2016 conducted a cluster RCT in Denver, Colorado, USA to evaluate the effect a mobile phone SMS program called 'Youth all engaged!' (YAE) when delivered alongside a face-to-face program for preventing adolescent births ('Teen Outreach Program', TOP) (44). TOP was delivered by a trained facilitator and consisted of 25 weekly 1-hour sessions covering psychological and behavioural topics such as values clarification, relationships, goal-setting, decision-making, human development and sexuality and community service learning (46). The content of YAE was developed through an iterative consultation process using FGDs with 29 females and 30 males aged 14-18, piloting YAE with 96 participants and post-pilot exit interviews with 12 recipients (46). The authors provide a 'theoretical framework' that depicts how YAE is intended to influence its recipients, e.g. by increasing self-efficacy for contraceptive use and increasing future aspirations. They also provide a table that links the YAE message content to the TOP curriculum and the 'theoretical base' (contraceptive use, future aspirations, etc.). In the trial, YAE + TOP was compared to TOP alone. The authors did not specify the use of behaviour change methods. The behavioural primary outcomes were condom use, contraceptive use, access to care and pregnancy. Analyses were conducted according to randomised arm. There were no statistically significant differences between the groups. Sexually active participants were more likely to be lost to follow-up. The authors identify this as a potential source of bias because YAE or YAE + TOP may be more effective in participants who are at higher risk.

At a Planned Parenthood clinic in Brooklyn, New York, USA, Castaño 2012 conducted a trial of an educational SMS intervention providing information about the oral contraceptive pill (OC) among women under 25 who were using it (134). In the trial, 962 participants attending the clinic were randomised to receive either the intervention messages (one daily message delivered over 180 days) plus routine care or the control, routine care only. The messages were derived from an existing educational information handout that targeted oral contraceptive knowledge regarding the risks, benefits, side effects, use, effectiveness and mechanisms of action. The authors did not report using theory to inform the content of the intervention, suggest why providing information could influence change or report the use of behaviour change methods. The outcomes were various self-reported measures of OC continuation (use at follow-up, no OC interruptions, no missed pills in the past month and OC use at last intercourse). The intervention messages were compared to standard care (clinic contraceptive counselling plus educational handout). The analysis was conducted according to the intention-to-treat principle. The authors used logistic regression to adjust for predictors of continuation. Twenty-nine percent of the trial participants were lost to follow-up. At six months, intervention participants were more likely than control participants to continue use of OCs (adjusted odds ratio 1.44, 95% CI 1.03 to 2.00) and to report that they avoided an interruption in OC use longer than seven days (odds ratio 1.53, 95% CI 1.13 to 2.07) (134, 151). A separate analysis of the trial data showed a very modest improvement in knowledge about contraception among participants receiving the intervention. Knowledge was measured by a 41-item questionnaire covering the following dimensions regarding contraception: mechanism of action, effectiveness, use, side effects, risks, and benefits. Questions were coded 1 for a correct response and 0 for an incorrect response. The mean knowledge score was 23.7 in the control group vs 25.5 in the intervention group ($p < 0.001$) at six months (152).

Harrington 2018's thesis at the University of Washington, USA included the evaluation of family planning-focused post-partum SMS intervention delivered to pregnant, HIV-negative women over the age of 14 years in Kenya (study information from the university website abstract in the absence of published research and response from researchers after attempted contact) (145). The messages were delivered weekly from enrolment to six months post-partum and the platform enabled bidirectional communication with a nurse. The abstract does not provide information regarding the intervention development, inclusion of behaviour change methods or theoretical basis. In the trial, the intervention was compared to 'no SMS'

and the primary outcome was self-reported highly effective contraceptive use. Ninety-eight percent (254/260) of trial participants were included in the analysis. Participants randomised to receive the intervention were more likely to use highly effective contraception at six months post-partum (adjusted risk ratio 1.26, 95% CI 1.04-1.52, p = 0.02).

Hebert 2018 evaluated 'miPlan', a contraceptive counselling mobile app among African American and Latina women aged 15-29 attending four family planning clinics in a 'large Midwestern city' (144). The app content was developed with young African American and Latina patients using a 'human-centred design', where the target group was consulted throughout the app development process (153). The authors state that the Transtheoretical Model of Behavioural Change and the Theory of Planned Behaviour informed the app content, which targeted attitudes, norms and intention regarding contraceptive use, but do not specify the use of behaviour change methods. Participants were randomised to have access to miPlan in the clinic waiting room or to receive the contraceptive clinic visit alone. The study was powered for the outcome 'interest in discussing LARC' (an outcome measured immediately post intervention). Baseline interest was based on a previous pilot study, which was estimated at 25.8%. The authors chose a sample size of 220 participants, which would provide 80% power to detect an absolute increase in interest of 19.2% at the 5% significance level. Outcomes measured at three months were knowledge of contraceptive effectiveness, intention to use LARC and LARC uptake. Two hundred and seven participants were randomised and there was 19% loss to follow-up (the authors did not account for lost to follow-up in the target sample size). The analysis was per protocol. Besides LARC use, which was measured by chart review, all outcomes were self-reported. There were no differences between the groups in any of the outcomes besides in one knowledge question regarding the IUD effectiveness, which more intervention participants answered correctly (52.3% vs 30.8%, p=.001).

A daily SMS stating, "Please remember to take your birth control pill", was the intervention evaluated in Hou 2010's trial conducted at a Planned Parenthood clinic in Boston, USA (136). The authors do not describe how the intervention was developed, whether it contains any behaviour change methods or whether it has any theoretical basis. Eighty-two sexually active women choosing OCs were randomised to the intervention or control (no SMSs). The sample size of eight-two was based on detecting a 1.6-pill improvement on an average of 2.6 missed pills per cycle. The average missed pills per cycle was derived from a previous study that found 2.6 pills on averaged were missed per cycle as measured by an electronic monitoring

device. The outcome was OC adherence measured by electronic monitoring devices with wireless data collection. The analysis was by intention-to-treat and 89% of participants (73/82) had complete outcome data at follow-up. There was no evidence for a difference in mean number of missed pills between the groups.

Mobile for Reproductive Health (m4RH) is an SMS intervention that provides information on the benefits, disadvantages and side effects of nine family planning methods as well as addresses misconceptions about them (142, 154, 155). The authors do not report an explicit theoretical base for the intervention or specify the use of behaviour change methods. However, recipients of m4RH can request to receive 'role model' content- stories about how a person dealt with a particular sexual or reproductive health issue, which could be considered the behaviour change method 'cultural similarity' ('using characteristics of the target group in source, message and channel' (122)). The content was developed based on best practices for health communication programs and is based on the World Health Organization (WHO) Family Planning Handbook. A trial was conducted among male and female new consumers of m4RH in Kenya. New consumers were assigned to either a full-access group or a limited-access group on a rolling basis (each new consumer was assigned to the opposite group that the previous new consumer was assigned to). The authors considered this process effectively random due to the high number of consumers and the large variation in SMS delivery times in Kenya as a result of differences in network coverage and speed. The full-access group had access to all m4RH's components. The limited-access group had access to a clinic locator and general motivational messages about a variety of health topics and no information about family planning methods or role model content. Follow-up data was self-reported, collected by SMS in three 'waves'- 24 hours, six days and three months after the consumer first accessed m4RH. The primary outcome was the number of family planning knowledge questions answered correctly (out of 5), which were asked at the six day follow-up wave. Other outcomes were contraceptive use, communication and service attendance, measured at the three month follow-up wave. The authors did not prespecify a sample size, presumably because the recruitment process would generate many potential recipients to provide follow-up data. Over 13 thousand (n = 13,629) new consumers were randomised. Follow-up response was low with 5,164 (39%) analysed regarding the knowledge questions and 2,863 (21%) analysed regarding the behavioural outcomes. There was a high proportion of missing data within survey waves, which the authors dealt with using multiple imputation. Participants randomised to receive full access of m4RH had a mean knowledge score of 2.19 compared to a mean score of 1.92 in the limited-access arm (p

< .001), which represents a 14% difference. There were no significant differences in the behavioural outcomes.

In Accra, Ghana, Rokicki 2017 conducted a three arm cluster randomised trial among 756 female students aged 14-24 years at 38 schools (140). The schools were randomised to a unidirectional SMS intervention, an interactive SMS intervention and control for 12 weeks. The unidirectional intervention consisted of one reproductive health SMS sent once a week. The interactive intervention consisted of one multiple choice question sent by SMS once a week. When participants responded to the question, they were immediately sent a SMS saying if they answered correctly along with the correct answer and information that corresponded with the unidirectional intervention content. Interactive intervention participants were sent mobile phone credit for every two correct responses. The intervention participants were also sent messages about the benefits of communicating with partners about reproductive health. Participants randomised to the control were sent messages once a week about malaria. Intervention content was developed through focus groups with young people to understand 'the most popular sexual health topics of interest'. The authors do not provide information on the use of theory in the development of the intervention or specify the use of behaviour change methods. The primary outcome of the trial was reproductive health knowledge at three and 15 months, measured by a 24 item quiz. Secondary outcomes were pregnancy, sexual activity and contraceptive use measured at 15 months. All outcomes were self-reported. Follow-up was 95% at both time points and the analysis was by intention to treat. Knowledge was adjusted for the following baseline covariates: knowledge, age, religion, ethnicity, parental completion of secondary school and school size. At three months, average knowledge scores were significantly higher in both intervention groups compared to the control group. At 15 months, the interactive group only had significantly higher mean knowledge score than the control. There were no significant differences in secondary outcomes in the full sample, but both interventions decreased self-reported pregnancy among sexually active participants.

Smith 2015 conducted a trial involving 500 women older than 17 years who sought an induced abortion at Marie Stopes clinics in Cambodia (135). The trial evaluated a mobile phone voice message and counselling intervention to support use of post-abortion contraception (the 'MOTIF' intervention) (156). The authors provide a conceptual framework based on the literature on the determinants of contraceptive use that drew on the COM-B (capability, opportunity and motivation) behavioural system (156-158). MOTIF was developed

by 1) reviewing the literature on contraceptive behavioural interventions 2) conducting 15 interviews and 4 focus group discussions with the target group and 3) consultation with clinicians and organisations involved in mHealth activities in Cambodia (156, 157). The authors do not report the explicit use of behaviour change methods. The intervention consists of six automated, interactive voice messages with counsellor phone support sent three months after an abortion. Participants were allocated to groups by minimisation (by urban or rural clinic) to receive MOTIF or standard post-abortion care, which included post abortion family planning counselling at the clinic. The primary outcome was self-reported use of effective contraception at 4 and 12 months post abortion. Secondary behavioural outcomes were use of LARC, pregnancy, abortion, effective contraceptive use during the study, all self-reported using a questionnaire. Follow-up data was collected for 86% of participants at four months and 66% at 12 months. The results demonstrated an increase in self-reported use of effective contraception at four months in the intervention group compared to the control group (64% vs 46%, RR 1.39, 95% CI 1.17–1.66) and an increase in LARC use at four (29% vs 9%, RR 3.35, 95% CI 2.07-5.40) and 12 months (25% vs 12%, RR 2.08, 95% CI 1.27-3.42).

Trent 2015's trial with women aged 13-21 using the injection at a medical practice in Baltimore, USA evaluated the *Depotext* intervention. *Depotext* consisted of daily SMS injection reminders that started three days before the appointment date plus additional health related messages (143). Control participants received standard care- "patient-initiated support and contact for missed appointments". No details regarding the intervention development, theory or methods for changing behaviour were provided. The researchers set the minimum target sample size to 100 because they needed to conduct the recruitment and follow-up within a nine month period. This number was considered practical and would demonstrate feasibility and acceptability. The primary outcome was injection appointment attendance, which was monitored by an electronic tracking database. Participants randomised to receive the *Depotext* intervention attended closer to their scheduled appointments compared to participants randomised to the control arm for the first injection (*B* = -.75; 95% CI -1.4 to .06 p = .03) but not for the second and third. There was no overall difference in receiving the injection within the on-time window between the intervention and control groups. The authors mention that no overall difference was seen because participants who missed their appointments received additional telephone outreach.

Tsur 2008's intervention consisted of two text messages providing information about the teratogenic risk associated with isotretinoin aimed to increase awareness and contraceptive use among women taking the drug. The authors did not provide information regarding the development or theoretical basis of the intervention and did not mention the use of behaviour change methods. Women aged 16-24 who were taking isotretinoin and called a drug consultation centre seeking advice were randomised by computer-generated random numbers kept in sealed envelopes to receive only the information in the initial phone consultation (control) or mailed written information and the two text messages one and two months after the initial phone consultation (137). The primary outcome was self-reported contraceptive use at three months. The sample size of 100 was based on the ability to detect a 30% absolute increase in use of contraception in the intervention group compared to the control group at the 5% level of significance, with 80% power. Follow-up data was available for 95% of participants (103/108). This small trial in Israel (n = 108) found no evidence for a difference in contraceptive use between the groups.

Sridhar 2015 conducted a trial at the University of California Los Angeles (UCLA) Obstetrics and Gynecology clinic to evaluate *Plan A Birth Control* (Plan ABC) (141). Plan ABC is a mobile app that displays information about the non-permanent contraceptive methods. The content was adapted from three patient information resources used in the clinic, reviewed by family planning academics at UCLA and pilot tested with 40 patients for usability and clarity. There is no explicit theoretical basis for Plan ABC but one of the resources the content is based on mentions motivational interviewing as a component, otherwise, the authors do not mention the use of behaviour change methods. Women aged 18-45 not using contraception were recruited from the clinic waiting room before their appointment. Participants were randomised to receive contraceptive information from a health educator or from Plan ABC. The primary outcome of the trial was the effectiveness of the chosen method. The method chosen was verified by a review of medical records. Secondary outcomes were knowledge of the chosen method and patient satisfaction with counselling. The authors state that 120 participants would provide 80% power detect a 20% absolute increase in the choice of a very effective contraceptive method (40% in the control and 60% in the intervention) at the 5% level of significance. There were no significant differences between the groups in any of the outcomes.

2.4.1 Summary

Out of the 11 trials, eight evaluated interventions delivered primarily by SMS (44, 134, 136, 137, 140, 142, 143, 145), two evaluated interventions delivered by mobile phone app (141, 144) and one evaluated a mobile phone voice message intervention (135). The use of theory was mentioned in the development of only three of the interventions (44, 135, 144) and none mentioned the explicit use of behaviour change methods (although some interventions may have included them, e.g. m4RH). The content of four interventions was developed through iterative consultation with the target group (46, 140, 153, 156). Four trials (135, 140, 142, 145) were conducted in a LMIC.

The primary outcome was knowledge in two trials (140, 142), contraceptive use-related in eight trials (44, 134-137, 141, 143, 145) and 'interest in discussing LARC' in one (144). Six trials reported a beneficial effect of the intervention on the primary outcome compared to the control (134, 135, 140, 142, 143, 145). Only three trials had an objective measure as the primary outcome (136, 141, 143). (Herbert 2018 used chart review to determine LARC use, however outcomes were not specified as primary or secondary and the trial was powered for 'interest in discussing LARC'.) Of the five trials where knowledge of contraception was an outcome (134, 140-142, 144), four showed a beneficial effect of the intervention compared to the control. Both trials where knowledge of contraception was the primary outcome showed a beneficial effect (140, 142). All trials included a use-related outcome, however only three showed a beneficial effect (134, 135, 145).

The evidence suggests that providing accurate information about contraception by mobile phone can increase knowledge about contraception. The evidence regarding contraceptive use is mixed, however, which could be due to the variability in the quality of the intervention development, the content of the intervention and trial methodology. The target group may not have been adequately consulted in the development, which would decrease the likelihood that the content was relevant and acceptable to them (for example, the development details regarding Harrington 2018's intervention are not known). However, adequate consultation with the target group does not guarantee that the intervention will be efficacious, as in Hebert 2018. Heterogeneity in the comparators used in the trials makes it difficult to generalise about the efficacy of the interventions on contraceptive use. For example, Bull 2016's comparator was a very comprehensive evidence-based face-to-face programme (the intervention group received this program plus an additional text message programme) and Castaño 2012's comparator was standard care (clinic contraceptive

counselling plus educational handout). There was no significant difference in use in the Bull trial but there was in the Castaño trial. Despite ample global evidence demonstrating the existence of widespread negative attitudes towards contraception, none of the trials evaluated the effect of the intervention on attitudes towards contraception.

3 Intervention development

3.1 Introduction

This chapter is the research paper that presents the development of the intervention in Tajikistan, Palestine and Bolivia. This work was published in BMC Public Health as an open access article in May 2018 (50) (Appendix 2).

Citation:

(50) McCarthy OL, Wazwaz O, Osorio Calderon V, Jado I, Saibov S, Stavridis A, López Gallardo J, Tokhirov R, Adada S, Huaynoca S, Makleff S, Vandewiele M, Standaert S, Free C. Development of an intervention delivered by mobile phone aimed at decreasing unintended pregnancy among young people in three lower middle income countries. BMC Public Health. 2018; 18(576).

RESEARCH PAPER COVER SHEET

Student Details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Paper already published

Where was the work published?	*BMC Public Health*		
When was the work published?	May 2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed and managed the research, wrote the interventions and the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

3.2 Research paper

3.2.1 Abstract

Background: Unintended pregnancies can result in poorer health outcomes for women, children and families. Young people in low and middle income countries are at particular risk of unintended pregnancies and could benefit from innovative contraceptive interventions. There is growing evidence that interventions delivered by mobile phone can be effective in improving a range of health behaviours. This paper describes the development of a contraceptive behavioural intervention delivered by mobile phone for young people in Tajikistan, Bolivia and Palestine, where unmet need for contraception is high among this group.

Methods: Guided by Intervention Mapping, the following steps contributed to the development of the interventions: (1) needs assessment; (2) specifying behavioural change to result from the intervention; (3) selecting behaviour change methods to include in the intervention; (4) producing and refining the intervention content.

Results: The results of the needs assessment produced similar interventions across the countries. The interventions consist of short daily messages delivered over four months (delivered by text messaging in Palestine and mobile phone application instant messages in Bolivia and Tajikistan). The messages provide information about contraception, target attitudes that are barriers to contraceptive uptake and support young people in feeling that they can influence their reproductive health. The interventions each contain the same ten behaviour change methods, adapted for delivery by mobile phone.

Conclusions: The development resulted in a well-specified, theory-based intervention, tailored to each country. It is feasible to develop an intervention delivered by mobile phone for young people in resource-limited settings.

3.2.2 Background

In developing regions in 2017, an estimated 89 million pregnancies were unintended, that is, were pregnancies that occurred too soon or were not wanted at all (159). Unintended pregnancy is associated with a range of negative health and social consequences, for example, poorer access to antenatal care, increased risk of low birth weight and pre-term

birth, delays in women's educational and career achievements and unsafe abortion (2-20). Women aged 15-24 in low and middle income countries (LMIC) are at particular risk and are more likely to have an unmet need for contraception compared to older women (26). Women with an unmet need for modern contraception are those who want to avoid a pregnancy but currently use no method or use a traditional method (21). It is estimated that meeting adolescents' unmet need for modern contraception would reduce unintended pregnancies by six million each year (21).

Tajikistan, Palestine and Bolivia are three LMIC where women are at high risk of unintended pregnancy. In Tajikistan, women have 0.5 more children than desired, with the total wanted fertility rate at 3.3 births per woman compared to the actual of 3.8 (83). Unmet need for contraception among married 15-24-year-old women is estimated to be 26%, with unmet need for birth spacing the highest among women in this age group compared to women in other age groups (83). In Bolivia, family planning progress has lagged behind other Latin American countries (111). In 2008, unmet need for contraception among women aged 15-19, was estimated to be 38% (112, 114). Among unmarried, sexually active women aged 15-19, 51.9% are not using a method of contraception. Among these women, 84.8% reported not wanting a pregnancy in the next two years, yet only 48.8% of them reported using any method of contraception. In Palestine in 2006, an estimated 38% of pregnancies were unintended (104, 105). In 2014, unmet need for contraception was highest among women aged 20-24, at 15% (96). While the adolescent fertility rate had decreased substantially in Palestine over the past 20 years, the current adolescent fertility rate of 48 per 1,000 women aged 15-19 remains higher than most other countries in the region (96, 97).

The non-permanent 'effective' contraceptive methods have less than 10% typical use failure rate at 12 months, i.e. oral contraceptives, injectables, intra-uterine device (IUDs), implants, the patch and the ring (IUDs and implants being the most effective) (28-30). While effective methods are available in Tajikistan, Bolivia and Palestine, there remain barriers to use. In Tajikistan, oppositional attitudes towards contraception is the most common reason women with a Demographic and Health Surveys-defined (DHS) unmet need (25) provide for not using contraception; 36% of women with an unmet need cite their own opposition and 13% cite their partner's opposition as the reason for not using contraception (26). The next most common reasons are infrequent/no sex (28%) and side effects/health risks/inconvenience (15%) (26). In Bolivia, the main reasons unmarried, sexually active adolescent women who report not wanting a child in the next two years provide for not using a method are

infrequent sex (54.7%) or not married (51.5%) (112, 114). Among married women in Palestine not using contraception and not reporting wanting to have a child, the main reasons given for not using contraception were fear of side effects, inconvenience of methods and their husband's opposition (98, 99).

Mobile phones are now a popular and widely established vehicle to deliver health interventions. There is some evidence from trials that mobile phone-based interventions can improve knowledge about contraception (152, 160) and contraceptive-related behaviours (134, 135, 143, 147, 151, 161). However, all but two of these trials (135, 160) were conducted in the United States and none had low risk of bias (133) according to the Cochrane Collaboration's tool for assessing risk of bias in randomised controlled trials (162).

In January 2015, the London School of Hygiene and Tropical Medicine (LSHTM) started a collaboration with the International Planned Parenthood Federation's (IPPF) Member Associations in Tajikistan, Bolivia and Palestine to develop and evaluate an intervention delivered by mobile phone to enhance contraceptive choice among young people in each country. At this development stage of the project, we included both young women and men because women in these settings have reported that their male partners' attitudes influence their use of contraception. To the best of our knowledge, this research is the first to develop such an intervention for young people in these countries. This project helps fill the research gap regarding the development of mobile phone interventions for contraception in LMIC.

3.2.3 Methods

Intervention development approach

Intervention Mapping (IM) guided the development of the interventions (122, 124). IM is a protocol for the systematic development of health behaviour change interventions. It is a cumulative process that often necessitates moving back and forth through the following steps: (1) needs assessment; (2) specifying behavioural change to result from the intervention; (3) designing the intervention components by selecting behaviour change methods; (4) producing and refining the intervention content; (5) planning intervention implementation and (6) planning intervention evaluation. This paper describes steps 1-4 and compares the results across the countries.

1. Needs assessment

The needs assessment aimed to understand unintended pregnancy and contraceptive use in each context. Activities included 1) establishing a project planning group 2) a literature search 3) focus group discussions (FGDs) and interviews with the target group and 4) interviews with local service providers.

Each country's project planning group was a collaboration between the local partner, the research partner and the three IPPF Regional Offices. The local partners consisted of the Executive Director, Research Assistants, and various other employees of the organisation that contributed to the development process in different capacities. The research partner designed and managed the research. Staff from Regional Offices attended meetings and facilitated communication about the research between the research partner and the local partner.

Relevant articles were identified through the research partner's existing knowledge, recommendations by the local partners, a Google search for grey literature and a search of MEDLINE. The results of the literature search informed the discussion guide used in the FGDs and interviews. Remote meetings were held from February to September 2015 to plan and organise the field research, which took place in July 2015 in Tajikistan, August/September 2015 in Bolivia and October 2015 in the West Bank, Palestine.

The FGDs and interviews with the target group explored their knowledge of and attitudes toward contraceptive methods, perceived barriers in using and confidence in communicating about them (see Appendix 3 for the Target group discussion guide). This information was used to better understand the personal, socio-cultural and socio-economic factors involved in contraceptive use in each setting. The consultations also aimed to understand how amenable young people are to trying new contraceptive methods, their patterns of mobile phone use, preferences for intervention content and views on privacy regarding receiving contraceptive information on their mobile phone. The interviews with providers explored similar topics from a provider perspective (see Appendix 4 for the Provider discussion guide). The research partner trained local research staff in FGD and interview facilitation and research ethics. The number of groups and interviews estimated (up to ten of each) was based on previous intervention development experience (163, 164).

Target group participants were identified by convenience sampling through the local partners' youth volunteer network and services in Dushanbe and Vahdat (Tajikistan), El Alto (Bolivia) and Ramallah, East Jerusalem, Hebron and Bethlehem (Palestine). Women and men were eligible if they were legally able to give independent informed consent (age 14 in Tajikistan, 18 in Bolivia and 18 in Palestine). There was no upper age limit but each local partner focused on recruiting younger participants as this most closely matched the target group 'young people' (165, 166). Providers were affiliated with each local partner.

Each FGD and interview was conducted by a research staff member who was a native speaker of the local language (and in most cases also spoke English) and was attended by a bilingual (English and local language) research staff member who took detailed notes. Immediately after, the facilitator/interviewer relayed the information to the research partner who made detailed notes in English. The FGDs were comprised of participants of the same gender and facilitated by a staff member of the matching gender. The FGDs and interviews were held at the service or at a location hired specifically for this purpose. The FGDs and interviews were audio recorded. The FGDs lasted up to 90 minutes and the interviews lasted up to 60 minutes. Resources allowed only for the FGDs in Bolivia to be transcribed and translated into English. We conducted a descriptive thematic analysis of the FGDs and interviews by examining the discussion notes related to each theme in the discussion guide. An information technology partner consultant based in the United Kingdom reviewed the local mobile phone operators and identified local technology partners.
We depicted the results of the needs assessment visually in a 'logic model of the problem'.

2. Specifying behavioural change

The needs assessment led to the specification of the desired behaviours for target group to accomplish as a result of the intervention (behavioural outcomes) and of the desired changes in the environment to occur as a result of the intervention (environmental outcomes). The performance objectives for the behavioural outcomes were then specified by identifying the smaller actions that are logically required to perform the outcome. The determinants of these actions were specified from the literature search and insights from the FGDs and interviews and behaviour-oriented theories (124). Mapping these against one another in a matrix enabled the identification of the most immediate behaviours that the intervention aims to alter in the individual (change objectives). While the environmental outcomes were specified, it was beyond the scope of the project to develop an intervention to target these conditions

therefore the performance objectives and determinants for the environmental outcomes were not specified.

3. Designing the intervention

This step involved choosing theory-informed behaviour change methods to include in the intervention and deciding how to deliver them (122, 124, 167). Potential methods were identified by considering: 1) authors' report of the methods used in existing effective interventions for contraception (151, 168, 169) and 2) the methods shown to modify each determinant according to the IM taxonomy (122). (The IM taxonomy describes the behaviour change methods that have been shown to modify different types of behavioural determinants.) Throughout the process, the conditions under which the methods can be effective were considered (the 'parameters for effectiveness') (122, 124).

4. Producing and refining the intervention content

The intervention content was written when behavioural change was specified, and the methods and theoretical basis of the intervention were identified. The research partner wrote the initial content. It was then reviewed by the local partner for cultural appropriateness and amended with the research partner. Next, the target group was consulted for their views on the tone, acceptability and comprehensibility of the content. The content was refined with the target group after each consultation and tested until it was acceptable to them.

3.2.4 Results

1. Needs assessment

The factors reported in the published literature that influence contraceptive use and reasons for unmet need in LMIC and in Tajikistan, Bolivia and Palestine are summarised in the Background.

Focus group discussions and interviews with the target group

Eight FGDs each were conducted in Tajikistan and Bolivia and five were conducted in Palestine; one user interview was conducted in Tajikistan, two in Bolivia and four were conducted in Palestine (see FGD and interview demographics in Table 3.1). In Tajikistan and Bolivia, we stopped the FGDs and interviews when no new data emerged in relation to the themes in the discussion guides. The FGDs and interviews coincided with the escalation in

conflict in the West Bank in the first few weeks of October 2015. Due to logistical challenges related to this, we were unable to conduct more than five FGDs in Palestine.

Table 3.1 Focus group discussion and interview demographics

	Tajikistan n = 78 n (%)	**Bolivia n = 64 n (%)**	**Palestine n = 35 n (%)**
Number of participants			
FGD1	10	5	10
FGD2	8	8	Not attended
FGD3	10	10	Not attended
FGD4	8	5	4
FGD5	15	10	3
FGD6	9	10	7
FGD7	9	7	7
FGD8	8	7	Not attended
Interviews	1	2	4
Age			
15-19	37 (47.4)	26 (40.6)	2 (5.7)
20-24	37 (47.4)	36 (56.3)	26 (74.3)
25-30	4 (5.1)	2 (3.1)	5 (14.3)
Missing	0	0	2 (5.7)
Gender			
Male	33 (42.3)	28 (43.8)	13 (37.1)
Female	45 (57.7)	36 (56.3)	22 (62.9)
Missing	0	0	0
Residential area			
City	50 (64.1)	not collected[b]	10 (28.6)
Other[a]	28 (35.9)		24 (68.6)
Missing	0		1 (2.9)
Occupation			
Working	20 (25.6)	4 (6.3)	5 (14.3)
Unemployed	8 (10.3)	0	3 (8.6)
Full-time parent	1 (1.3)	0	3 (8.6)
In education or training	49 (62.8)	60 (93.8)	19 (54.3)
Missing	0	0	5 (14.3)
Pregnancy intention (current)			
Avoid	11 (14.1)	38 (59.4)	13 (37.1)
Unsure/not avoid/do not mind	29 (37.2)	14 (21.9)	18 (5.1)
Not sexually active	30 (38.5)	12 (18.8)	2 (5.7)
Missing	8 (10.3)	0	2 (5.7)
Current method			
None[c]	51 (65.4)	20 (31.3)	13 (37.1)
Condoms only	22 (28.2)	31 (48.4)	3 (8.6)
Withdrawal only	0	1 (1.6)	3 (8.6)
Condoms and withdrawal	2 (2.6)	0	0
Calendar-based only	0	5 (7.8)	2 (5.7)
Effective method[d]	3 (3.8)	5 (7.8)	8 (22.9)
Condoms and calendar-based	0	1 (1.6)	1 (2.9)

	Tajikistan n = 78 n (%)	Bolivia n = 64 n (%)	Palestine n = 35 n (%)
Lactational amenorrhea method only	0	0	1 (2.9)
Condoms and lactational amenorrhea method	0	0	1 (2.9)
Missing	0	1 (1.6)	3 (8.6)

[a] 'Other' in Tajikistan is Vahdat, a large town 10 km outside of the capital Dushanbe; 'Other' in Palestine is village or refugee camp
[b] Participants from El Alto, La Paz or close surrounding areas
[c] Includes participants not sexually active
[d] Oral contraceptives, injectables, intra-uterine device (IUDs), implants, the patch or the ring

Use of mobile phones

Use of mobile phones was nearly ubiquitous in all three countries but there was some variation in terms of the types of phones used and mobile Internet access. Most participants owned a smart phone, and if not, they owned a feature phone. Around five female participants in Vahdat, Tajikistan said that they did not have a mobile phone at all. In Tajikistan and Bolivia, it was more common to have regular mobile Internet access than in Palestine. Of those who owned a smart phone, Android phones were the most popular, with participants in Bolivia saying iPhones were for people of "high status". Participants in Tajikistan and Bolivia accessed the Internet through their phones. A few participants in Tajikistan said that access was sometimes restricted due to insufficient funds to support Internet connectivity. In the rural areas of Tajikistan, mobile Internet connection is expensive, and electricity is restricted to three to five hours a day in the winter, restricting the ability to charge the battery. In Bolivia, participants said that they do not have Internet access on their phones all the time and buy the smallest data package possible to support use of Facebook and WhatsApp. In Palestine, many did not have regular Internet access on their phones and if they did, most access the Internet by Wi-Fi only; those who sometimes access the Internet though their mobile data said that it is common for the connection to be lost.

Contraception support

Participants in all three countries were very enthusiastic about receiving information about contraception on their phone. Participants in Tajikistan thought that acquiring accurate information would improve young people's attitudes towards contraception. In Bolivia, participants expressed very strongly the need for more information and talked about the convenience of being able to look at their phones for contraceptive information without having to ask anyone. In Palestine, while most young people wanted contraceptive information delivered on their mobile phones, female participants were more supportive of

the idea than the male participants. A group of male participants said that they may read the information and benefit from it, but it would be considered a joke and not taken seriously. A male participant said that contraceptive information delivered to phones is new in Palestinian society and that it is important that the information be given in a respectful way as “people feel shame about these issues”.

Intervention delivery preferences and privacy

Participants expressed a range of mobile phone media ideas for intervention delivery, such as videos, pictures and animations. In general, participants preferred to receive contraception support through short message. In Tajikistan, participants thought it was helpful to save the messages to read later at a convenient time and because messages are easy to delete if they want to prevent others seeing them. However, a few were less comfortable receiving support by short message because they were perceived as less private. Bolivian participants, while interested in a variety of intervention delivery modes, preferred information to be sent by simple instant messaging through an app or text messaging. Palestinian participants preferred text messages for intervention delivery, with some saying that they wanted messages delivered by app instant messaging.

Most participants reported that they do not share their phones. Participants in Tajikistan said that if they do share their phone, they lend their phone to friends or family to take photos, play games, listen to music and browse social networks. One female participant in Palestine said that sometimes she asks her children to check her phone when she is busy, and she was concerned that they would see the messages. Another Palestinian participant said that she would share her messages with her husband to “educate him”. A few participants mentioned concerns about others seeing the messages and having information about contraception on their phone, but the majority were not concerned if they can password protect the phone.

Intervention content

Preferences for intervention content were similar across the countries, with some context-specific preferences. In all countries, participants wanted to hear about other people’s experiences, particularly “success stories”, with using contraception. In Bolivia, participants thought that hearing real stories or “testimonies” from people who have had experience using different contraceptive methods would make them feel confident in trying new methods. Some participants in Tajikistan however, did not want information in the form of stories because they value the advice from a specialist over advice from a peer. In Palestine,

participants said that they would trust “scientific” information. Participants in all countries wanted clear and concise information about the advantages and disadvantages of the different methods, how to use them and where they can obtain them. Tajik participants said that the content should not contain difficult terminology and the ‘voice’ should not be young, as this would be perceived as less trustworthy. A female group in Bolivia said that they wanted “little messages” giving advice and not telling them what to do. In terms of frequency, Tajik participants thought that one to two brief messages a day is acceptable, Bolivian participants wanted 1-3 messages a day and Palestinian participants said that they wanted around three messages per day.

Knowledge about contraception

Across the countries, there was a good level of awareness of the effective methods, but a lack of comprehensive knowledge such as the efficacy, advantages and disadvantages of the methods, how to use them and how they work. Participants agreed that young people do not have adequate information about contraception and were curious to know more about the range of methods available.

Attitudes and beliefs towards contraception

Across the countries, participants expressed a range of negative beliefs about effective contraception. Common beliefs were that hormonal contraception (including the non-hormonal IUD) is damaging to the health of the women, not effective in preventing pregnancy, causes heavy and irregular bleeding (IUD), infertility and weight changes. In Bolivia, participants mentioned that the IUD can rust in the uterus and causes cancer and that hormonal contraception makes people “stop being normal”. Tajik participants mentioned that the IUD can grow into the skin. A few female participants in Palestine spoke favourably of the IUD but most thought that the metal in the IUD is harmful and causes an irregular menstrual cycle. A female group in Palestine though that the pill causes anxiety and nervousness.

In Tajikistan and Palestine, most participants approved of the concept of family planning and thought that society did as well. This was mainly because they believed that it helps families plan and assess their economic situation. Palestinian participants thought that it is better to use “natural” methods in the first year of marriage, with a male group saying that using contraception in early marriage will create problems.

Communication about contraception

In Tajikistan and Bolivia, participants expressed a lack of confidence communicating about contraception with partners, parents and providers. Participants in Palestine thought that it was possible to talk to close friends and mothers about contraception. A female Palestinian participant said that it is common for partners to talk about sex before marriage (it was not clear if this was discussion about contraception or just sex). In Tajikistan, a group of male participants said that it can be difficult to talk about contraception with a partner that they have been in a relationship with for a while because they fear that their partner would take offense. A Tajik female group thought that it is difficult to negotiate contraceptive use if they did not want a pregnancy at the time and their partner did. Bolivian participants said that they are confident talking to close friends (friends of opposite gender must be very close) but not confident talking to partners unless they know them very well and trust them. They said that talking about contraception usually happens after they begin a sexual relationship and if a discussion about contraception were initiated too early with a partner, the partner would judge them as promiscuous.

In all countries, participants were not confident talking to providers about contraception because of the cultural stigma surrounding sex before marriage, concerns about confidentiality and fear of being judged. In Bolivia, many participants spoke of negative experiences at services.

Environmental factors

In Tajikistan and Palestine, participants expressed that the strong stigma surrounding sex before marriage in their cultures creates concerns about confidentiality and prevents them from accessing services. In Bolivia, this stigma was implicit, with participants talking about fear of being judged for seeking sexual and reproductive health information and services. Many participants in Bolivia spoke of experiences of being given “bad looks” for attending services (pharmacies and reproductive health services) and fear of feeling embarrassed and ashamed. There was a very strong fear in Tajikistan and Bolivia that others (people in the community) will know that they attended, judge them and spread “rumours”. There was general agreement across the discussions in Palestine that unmarried people accessing services is not accepted and is highly stigmatised. A female group in Palestine felt that they would be judged by providers and they will be asked if they are married or not if they attend a service. They also felt that they would be judged by their community if they went to a service and were not married.

In Palestine and Tajikistan, participants spoke of pressure to begin childbearing soon after marriage (Tajik participants mentioned nine months after). If they do not, they fear that they will be judged and considered unhealthy. Many participants in Palestine talked about the societal pressure from their mother-in-law, friends and neighbours to conceive soon after marriage. If a married woman in Palestine prefers to complete her university degree, participants said that she is pressured to conceive and if she does not, the community assumes that she has fertility problems. A group of female participants in Palestine mentioned that it can be difficult to reach the service because of checkpoints.

Partners and the educational system are environmental agents that also contribute to the problem. This is apparent from participants' report of the lack of partner communication about contraception before sexual activity and their lack of comprehensive knowledge about contraception.

Interviews with service providers

Six interviews with service providers were conducted in Tajikistan (5 doctors and 1 nurse outreach worker) and five were conducted in Bolivia (1 health advisor, 1 educator, 1 nurse and 2 doctors). Due to logistical challenges as a result of the escalation in conflict in the West Bank, only one provider interview was conducted in Palestine.

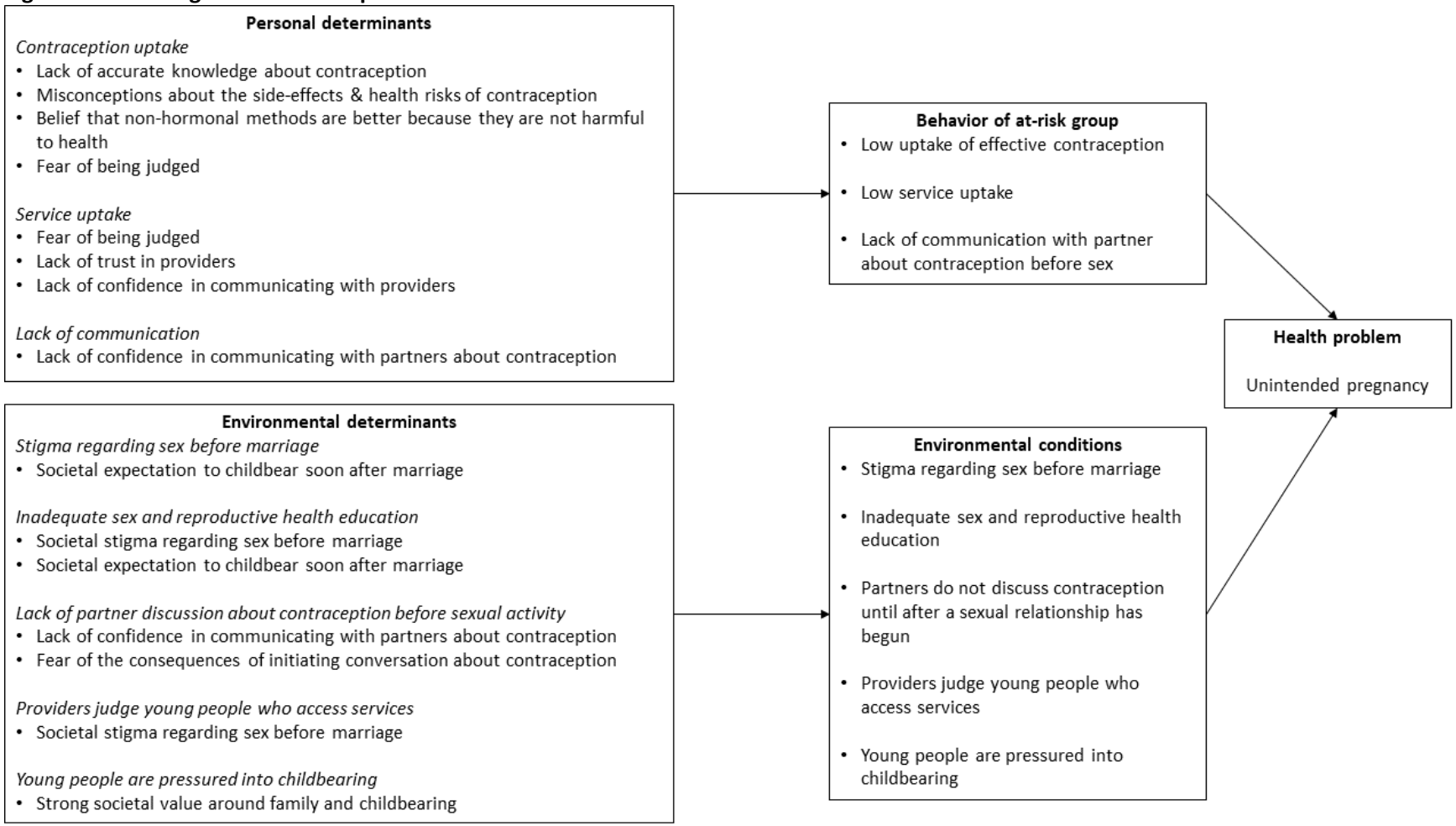
Providers in all countries said that young people are generally aware of the range of methods. However, many said that they do not know how they work or how to use them and want more information on these topics. In Bolivia, lack of information and misinformation is what most providers viewed as the greatest barrier for young people using new methods, along with the cost of contraception.

Providers in Tajikistan and Bolivia thought that young people are eager for more information about contraception and that providing this would help more young people use methods. Bolivian providers also said that more young people would use methods if they were affordable. The Palestinian provider said that in the pre-marital counselling sessions that she conducts, young people ask questions that make it obvious that they are already sexually active. Her perception is that young people want more information because many are having sex before marriage. She thought that providing young people with other people's success stories would help young people try new methods.

Providers in Tajikistan thought that attitudes towards reproductive health are changing and that people are thinking about the consequences of sexual activity before engaging in it. One provider said that young people have a positive attitude towards contraception. Providers said there is a lot of misinformation among young people in Bolivia and that they fear the perceived side effects, such as the infertility they associate with oral contraceptives. The Palestinian provider said that that young people think that the IUD makes them nervous and infertile.

Tajik providers commented on how religion does not accept sexual activity before marriage and that the mother-in-law has a great amount of influence on her daughter-in-law's contraceptive use. Providers said that young people (particularly young unmarried people) do not even try to attend services covertly because they are too concerned that someone will find out. A provider in Bolivia said that barriers stem from problems with the family and that these women are more at risk for early sexual debut. Some providers in Bolivia also mentioned machismo as a barrier in that if a woman is using contraception, men will perceive her as "horny", which is threatening to their masculinity. See Figure 3.1 for the Logic model of the problem.

Figure 3.1 Logic model of the problem



2. Specifying behavioural change: results

Behavioural outcomes

Based on the needs assessment results, we specified the key behavioural and environmental outcomes (Table 3.2).

Table 3.2 Behavioural and environmental outcomes

Behavioural				
1. Young people use effective contraception	2. Young people access reproductive health services	3. Young people communicate with partners about contraception before sexual activity		
Environmental*				
1. Sex before marriage is less stigmatised	2. Young people have access to comprehensive and accurate sexual and reproductive health education	3. Partners discuss contraception before a sexual relationship has begun	4. Providers do not judge young people who access services	5. Young people are not pressured into childbearing

*Not targeted by the mobile phone intervention

Theory, performance objectives and determinants

The Integrated Behavioural Model (IBM) (170) is the overarching framework for the intervention This project's IBM was adapted to include knowledge as a fundamental determinant of behaviour, as in the Information Motivation-Behavioural Skills Model (171) (Chapter 4, Figure 4.2).

Table 3.3 presents the behavioural outcomes, performance objectives and determinants. The literature supports the determinants knowledge (21, 55, 58, 59, 62-64, 66, 71, 73, 74) and attitudes (21, 55, 57, 59, 61-67, 70), as important influences on contraceptive use. It was clear from the needs assessment that accurate information about effective contraception was low. Providing accurate information in a context where there is none or very little, may change people's beliefs. Attitudes and intention were verified by behaviour-oriented theory (170, 172, 173). Personal agency (174) in the IBM is comprised of efficacy (170, 175, 176) and control beliefs (170, 177). The addition of perceived control acknowledges that while a member of the target group may feel confident in using a contraceptive method, they may not feel that they have control over whether they use it.

While intention was identified as a determinant, the intervention does not influence it directly, rather, the intervention aims to influence the behavioural (attitudinal), efficacy and control beliefs identified in the needs assessment, which all influence intention.

Table 3.3 Behavioural outcomes, performance objectives and determinants

Behavioural outcomes	Performance objectives	Determinants
Use effective contraception	po1.1 Choose a method	*Knowledge* about the effective methods
		Attitude towards using effective methods
		Intention to use effective methods
		Personal agency in choosing an effective method
	po1.2 Acquire the method	*Knowledge* of where to get effective contraception
		Attitudes about acquiring effective contraception
		Intention to acquire effective contraception
	po1.3 Use the method correctly	*Knowledge* about how to use effective contraception correctly
		Intention to use effective contraception correctly
		Personal agency in using effective contraception correctly
Access reproductive health services	po2.1 Locate a service	*Knowledge* of where to get effective contraception
		Attitudes about acquiring effective contraception
		Intention to locate a service
	po2.2 Travel to the service	*Intention* to travel to a service
		Personal agency in traveling to a service
	po2.3 Communicate effectively with providers	*Personal agency* in communicating with providers
Communicate with partners about contraception before sexual activity	po3.1 Initiate conversation with partner about contraception	*Attitudes* towards partner's approval of contraception
		Intention to initiate conversation about contraception
		Personal agency in initiating a conversation about contraception
	po3.2 Clearly state own preferences regarding contraception to partner	*Intention* to clearly state contraceptive preferences to partner
		Personal agency in clearly stating contraceptive preferences to partner
	po3.3 Listen to partner's preferences regarding contraception	*Intention* to listen to partner's contraceptive preferences
		Personal agency in listening to partner's contraceptive preferences

Change objectives

Crossing the behavioural outcomes, performance objectives and determinants, it was possible to specify the most immediate behaviours that the intervention aims to alter (see Table 3.4 for a partial matrix and Appendix 5 for the complete matrix). The change objectives for all countries were the same, except for a2.1.3, which only applies to Bolivia, because this was a specific cultural norm that emerged from the needs assessment.

Table 3.4 Partial matrix of change objectives

Performance objective	**Determinants**			
	Knowledge	**Attitudes**	**Intention**	**Personal agency**
Young people will…	*Behavioural outcome 1: Use effective contraception*			
po1.1 Choose a method	k1.1.1 Name the effective methods k1.1.2 Describe how the effective methods work k1.1.3 List the risks & benefits of the range of effective methods	a1.1.1 Express positive attitudes towards the effective methods a1.1.2 Recognise that hormonal methods are not less healthy than non-hormonal methods a1.1.3 Differentiate between real potential side-effects and misconceptions a1.1.4 Recognise that an experience of side-effects in one method may not occur in another method	i1.1.1 Assess options i1.1.2 Express intention to choose effective contraception	pa1.1.0 Express personal agency in choosing an effective method despite fears of being judged by society (married or not married)

3. Designing the intervention components: results

Practical application of the methods

After the needs assessment, through frequent discussions, the project planning groups decided that the intervention would be delivered through short, one-way messages.

Behaviour change methods

Descriptions of the methods used in the effective contraceptive interventions, were limited (134, 135, 143, 161, 178-181). Two of these trials (182, 183) reported using *motivational interviewing*, which could not be successfully delivered though automated messages.

Using the IM taxonomy, we identified methods previously shown to be effective in modifying the determinants (knowledge, attitudes, personal agency) and considered their use for the intervention. Because the methods had to be delivered through short instant message, they required adaptation and there were only two methods from the initial list whose parameters for effectiveness (the conditions under which the methods can be effective) could be fully satisfied (*belief selection* and *tailoring*). While the parameters for most methods could not be fully satisfied, they were used if they could partially or potentially be satisfied. The final methods included in the intervention are (122): *belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective* and *goal setting* (see Appendix 6 for details regarding the behaviour change methods).

4. Producing and refining the intervention content: results

The initial message sets were largely similar across the countries given the similar results of the needs assessment. Feedback from the Tajik partner on the initial set of messages was regarding specifics about the methods available in the country. Feedback from the Bolivian partner was regarding the meaning of some of the messages, which was clarified through discussion. The Palestinian partner's initial feedback was them seeking clarification for the rationale behind some of the messages and suggesting a few changes to maintain cultural sensitivity.

In Tajikistan, thirty-four young people (17 female and 17 male, the majority of whom were volunteers at the organisation) tested the intervention over four rounds. The Bolivia

intervention was also tested over 4 rounds and involved 47 young people (29 female and 18 male) who were a mix of the organisation's 'young leaders', university students who were non-service users and women who were sexually active and did not report using effective contraception. The intervention in Palestine was tested over three rounds with 17 people (eight female and nine male) five of whom were volunteers in the organisation and 12 of whom were non-service users.

In general, feedback across the countries was that the messages were helpful, and they were enthusiastic about the intervention. There were no clear differences in acceptability of the messages by gender. The Tajik volunteers wanted more clarification about how the methods work, which appeared to be for reassurance that they were safe to use. They also said that in general, they wanted the messages to be more "interesting and joyful". Target group feedback in Bolivia was that the messages should be more light-hearted, contain emojis within the messages, "curiosities" about contraception and messages about "pop stars". This contrasted with Palestine, where the target group preferred messages that were "scientific". Palestinian volunteers reported that the messages overall were reassuring and socially acceptable. There were some messages that they said sounded too negative and they suggested rewording to sound more reassuring. The research partner incorporated feedback after each round of testing and tested a revised set of messages in the following round.

Final intervention

The fundamental structure of the intervention is the same across the countries. Each intervention is designed to target the belief-based constructs identified in the needs assessment (instrumental attitude, self-efficacy and perceived control) in relation to contraception use, access to services and communication with partners about contraception. Each intervention provides accurate information about the effective contraceptive methods available in the country and aims to support young people in believing that they can influence their reproductive health. The messages are mapped to their corresponding change objective/s, behaviour change method and behavioural outcome (however, not all messages address a change objective, contain a behaviour change method or target a behavioural outcome).

The interventions contain the same ten behaviour change methods and similar content, with minor contextual variations resulting from the testing (see Table 3.5 for a sample of the intervention messages)

The messages are tailored according to marital status (a proxy for sexual activity) and gender in Tajikistan and Palestine (male messages in Bolivia were not developed due to an early decision that the intervention would be evaluated with women only). The message sets start with 6-7 days of messages with information about what they will receive over the next 120 days, how to stop the messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages. Over the next 112-113 days, intervention recipients receive 0-3 messages a day covering the following: accurate information about the effective methods; short quotes derived from real quotes from the target group regarding their views and experiences using each method; messages targeting specific misconceptions about contraception identified in the needs assessment; messages providing support for communicating with partners about contraception; messages that aim to reassure recipients that it is a provider's job to maintain confidentiality; information about the cost of the different methods and where to obtain contraception and messages emphasising the importance of method switching rather than discontinuation. On day 119 and 120, the message sets include two messages that indicate that the messages have ended and provide reassurance that the information that they provide is confidential.

Table 3.5 Sample intervention messages

Tajikistan	Bolivia	Palestine
Specialists have tested hormonal contraceptives many times and found them to be safe.	Some people think that hormonal methods are less healthy than non-hormonal methods. Hormonal methods are safe.	Some people think that hormonal methods are less healthy than non-hormonal methods. Hormonal methods are safe under medical supervision.
The most effective methods are: pills, IUD, implant and injection. These methods are over 99% effective if used correctly.	The most effective methods are: pills, t-copper (intrauterine dispositive), implant, injection & patch. If used correctly, less than 1 out of 100 women will get pregnant in a year if they use one of these.	The most effective and available methods in Palestine are: pills, IUD, implant, injection, patch. These methods are 99% effective if used correctly.
Some woman may not have a period when on the injection. Some people say that they like not having periods because they can be painful and inconvenient.	Bleeding may change or even stop with the injection. Some people like not having a period.	The bleeding cycle may change or even stop with the injection. Some people like not having a period.

Tajikistan	Bolivia	Palestine
Making decision about contraception with a partner makes it more likely that you will avoid an unintended pregnancy.	Making decision about contraception with a partner makes it more likely that you will avoid an unintended pregnancy.	Making a decision about family planning with your husband helps you avoid an unintended pregnancy.
Providers see young people with different kinds of lifestyles choose contraception.	Providers see young people, married and not-married, all day and help them choose contraception. They want to help rather than judge.	Providers help people of different lifestyles regarding family planning.
Some young people worry that providers will judge them. Remember, it's about your health and you can choose what is right for you.	Some young people worry about being judged by other people too. Your health is what's important. It's your body and your right. 😃.	Remember it's about your health and you have the right to choose what is right for you regardless of how others think and feel.
Think about your situation and what is right for you. If you decide to use contraception without your partner knowing, the IUD and implant are easy to hide.	If you are worried, there are methods that you can use without others knowing.	If your husband disapproves, talk to him about why you believe that it's a good decision for you. The IUD and implant are easy to keep private.

3.2.5 Discussion

Main results

The application of Intervention Mapping resulted in one intervention, tailored for Tajikistan, Bolivia and Palestine. The interventions are well specified, with each step in the development process documented. The needs assessment revealed that mobile phone ownership is widespread in each country and that young people are eager to receive contraceptive support on their mobile phone. Young people lacked comprehensive knowledge about contraception and expresses a range of negative beliefs about effective methods. They expressed a lack of confidence communicating about contraception and mentioned various environmental barriers to use. This study demonstrates that it is feasible to develop an innovative, comprehensible, acceptable intervention delivered by mobile phone with and for young people in resource-limited settings.

Strengths and limitations

A strength of the development is the participatory design. Young people were an integral part of the process and strengthened the intervention. Target group participants were a heterogeneous group, particularly in terms of age, gender and residential area. This is the

only study we are aware of that has used the same approach to develop, in parallel, interventions delivered by mobile phone in three different contexts. Because the intervention content is mapped to the corresponding change objectives and behaviour change methods, it is well specified.

While there were strengths in conducting this multi-country research, it was also a challenge to spread our resources across the three countries. We conducted a pragmatic study using qualitative methods to explore the key themes related to unintended pregnancy and contraceptive use identified in the literature, to inform the development of the intervention. Working in one country would have allowed greater time and resources to conduct a more in depth qualitative study. It is possible that a more in depth, inductive approach could have produced a slightly different intervention. However, it is reassuring that our findings are in line with the global literature.

The needs assessment revealed that there are powerful environmental influences, such as stigma surrounding young people using contraception and pressure to child bear soon after marriage. While not mentioned explicitly by young people, this cultural stigma is likely a result of religious belief that maintains sexual activity is reserved for marriage (Islam in Tajikistan and Palestine and Christianity in Bolivia). A potential limitation of this project is that the delivery mechanism was pre-specified. Targeting these important environmental conditions would likely require a broader intervention than messages delivered by mobile phone.

Another limitation is that the target group was defined at the start of the project. The needs assessment revealed that unmet need is greatest in all three countries in a slightly older age group, i.e. 19-30. Due to funding restrictions, the focus group discussions in Tajikistan and Palestine were not transcribed and translated into English. The research partner who wrote the first draft of the intervention relied on the report of the trained facilitators and note takers.

In Palestine, the increase in conflict that coincided with the fieldwork meant that some FGDs were not well attended and only one provider interview was conducted. A consequence of this is that the views of younger people may not have been adequately explored because only two participants were aged 15-19. However, the message testing provided reassurance that the intervention was appropriate and acceptable.

In Bolivia and Tajikistan, participants in the FGD were members of the youth network or recruited by the youth network. It may be that this group was more informed than people not connected with services in any way. Still, there were widespread negative beliefs and low levels of comprehensive knowledge about contraception. Another way that this may have hindered the development is that this group may be more likely to find a mobile phone intervention for contraception acceptable because they had greater exposure to the topic and therefore may be more comfortable with it. In addition, young people who have no connection with services may have greater confidentiality concerns.

Most participants were either employed or in education or training. The project could have benefitted from the inclusion of more participants in other occupational categories.

It was only possible for the research partner to train each local team remotely in the testing procedures. The research partner relied on their report of the results, some of which were more detailed than others. It is not clear if this variability was due to the testing facilitators, the target population or both. If the project had more time and resources, we would have tested the intervention with a wider range of people (e.g. more at-risk groups and people who were not connected to the youth networks).

Intervention Mapping provides a comprehensive guide for developing complex health interventions targeting both individuals and environmental agents. This project, however, is smaller in scope and targets individuals only. The determinants were not quantitatively verified (184) and their importance or changeability was not assessed. The adaption of the behaviour change methods for delivery by mobile phone and lack of fully accounting for the parameters for effectiveness is likely to result in some loss of meaning (124). While there are various modes in which to deliver content via mobile phones, strictly speaking, it is counter to Intervention Mapping to rule out non-mobile phone options from the start. Despite this, a mobile phone intervention emerged as highly acceptable and appropriate mode of intervention delivery.

Although participants in Bolivia mentioned that cost was a barrier to contraceptive use, the intervention could not address this. Even if the intervention is successful in improving attitudes towards the methods, uptake may not be improved if cost remains a barrier.

Comparisons with existing research

The results of the consultation with the target group align with existing research regarding the attitudinal factors that influence contraceptive use, i.e. that concern about the side effects or health risks are the most commonly expressed beliefs (21, 55, 57, 59, 61-65, 67, 70). Consistent with other research (58, 63, 73, 75, 76), this study confirms similar environmental barriers to contraceptive use, such as stigma regarding sex before marriage and the societal value around family and childbearing. Other research involving young people has shown that participants are willing and eager to receive contraceptive information on their mobile phone (134, 136, 143, 154, 155). While there was variation in mobile Internet access among participants, mobile phone use was nearly ubiquitous. This reflects the global growth of mobile phone subscriptions, which has been slower in LMIC compared to higher income countries but is rising (185).

Implications

The fact that the beliefs identified in the needs assessment were similar to the beliefs in the literature suggests that the intervention is likely to be somewhat generalizable. The approach that we used to develop the intervention was successful in three culturally different settings, which highlights its broad applicability. Adaptation of the intervention to different settings could be more straightforward than usual, because the intervention is well specified.

Conclusions

The intervention development process resulted in one intervention, tailored to three contexts. The process exhibited how similar factors contribute to contraceptive use across three geographically and culturally unique LMIC settings. This project contributes to the field of contraception intervention development and mobile health. It has taken forward the practice of adapting behaviour change methods for delivery by mobile phone. This contribution highlights the importance of developing interventions using a systematic approach. The intervention has been evaluated by randomised controlled trial among men and women aged 16-24 in Tajikistan (54), women aged 18-24 in Palestine (52) and women aged 16-24 in Bolivia (53).

Ethical approval

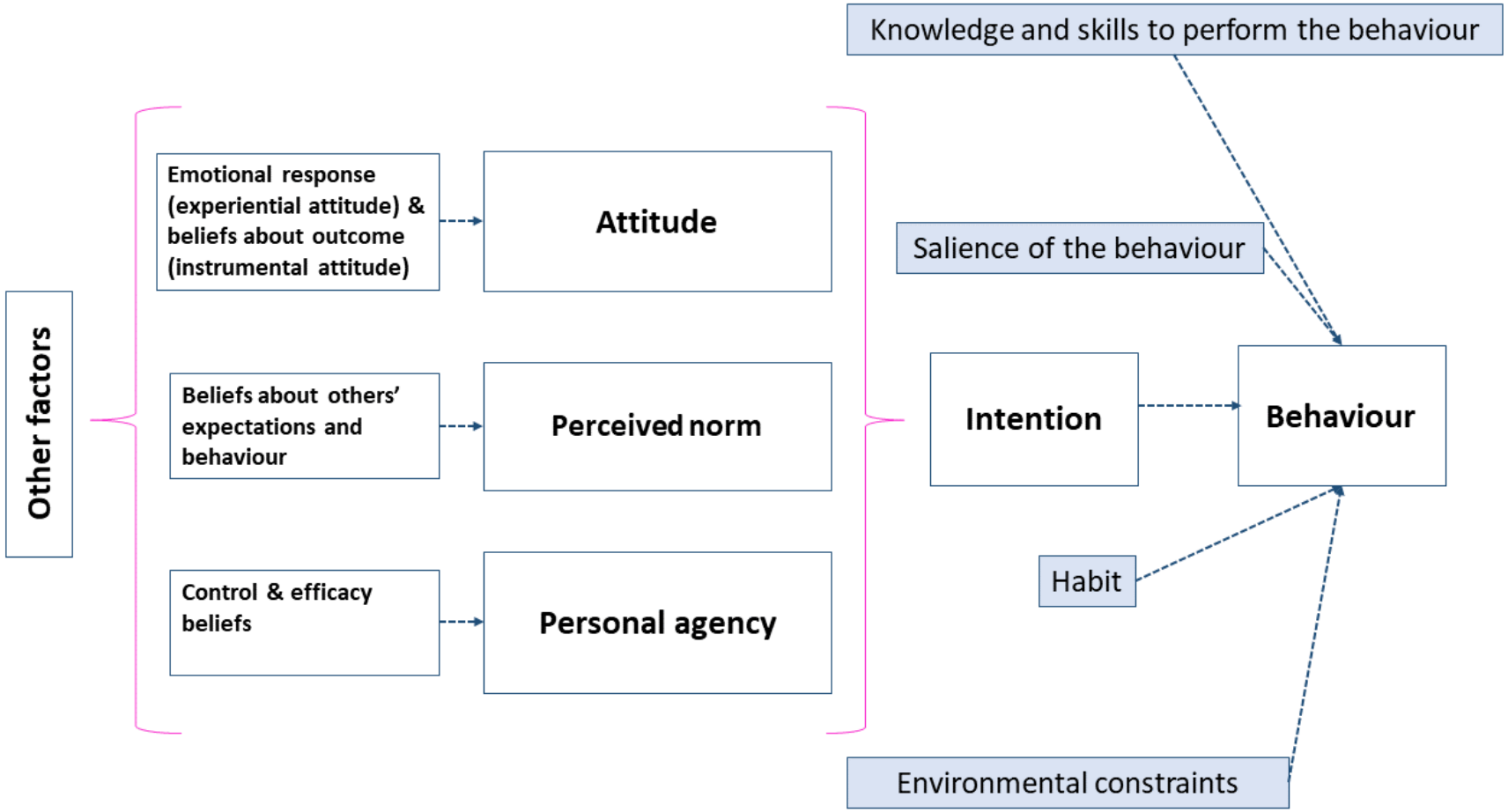
Ethical approval was granted from the London School of Hygiene and Tropical Medicine Observational Research Ethics Committee on 27 April 2015 (reference number 9148), the

Tajik National Scientific and Research Centre on Paediatrics and Child Surgery on 8 June 2015, the State of Palestine Ministry of Health on 1 July 2015 and the Bolivian National Committee of Bioethics on 4 August 2015 (Appendix 7). Participants were given verbal and written information about the study by the FGD facilitator or interviewer. Participants provided written informed consent before providing demographic data and before the focus group discussions and interviews began.

4 The Integrated Behavioural Model

I chose the Integrated Behavioural Model (IBM) as the overarching theory to conceptualise the factors that affect contraceptive use in the three countries (Montaño and Kasprzyk 2015). I chose the IBM because, after reviewing various other models and theories, considering the factors that influence contraceptive that use from my literature review and consultation with the target group, my view was that the constructs included in the IBM most closely represents the determinants of contraceptive use in the three countries. In the IBM and in the models and theories from which it is derived (Theory of Planned Behaviour, Theory of Reasoned Action, Reasoned Action Approach, Social Cognitive Theory), intention is the closest psychological construct to the behaviour. Intention is determined by attitude, perceived norm and personal agency (comprised of self-efficacy and perceived behavioural control) (170). Attitude, perceived norm and personal agency are aggregates of attitudinal, normative, efficacy and control beliefs. There are four additional factors that are important in determining if an intention can result in behavioural performance: knowledge and skills to perform the behaviour, salience of the behaviour, habit and environmental constraints (Figure 4.1)

Figure 4.1 **The Integrated Behavioural Model**



The intervention is designed to target the IBM belief-based determinants. These are: instrumental attitude, self-efficacy and perceived behavioural control. These determinants are aggregates of the beliefs related to contraception use, access to services and communication with partners about contraception. These beliefs were identified in the focus group discussions, interviews and my review of the literature.

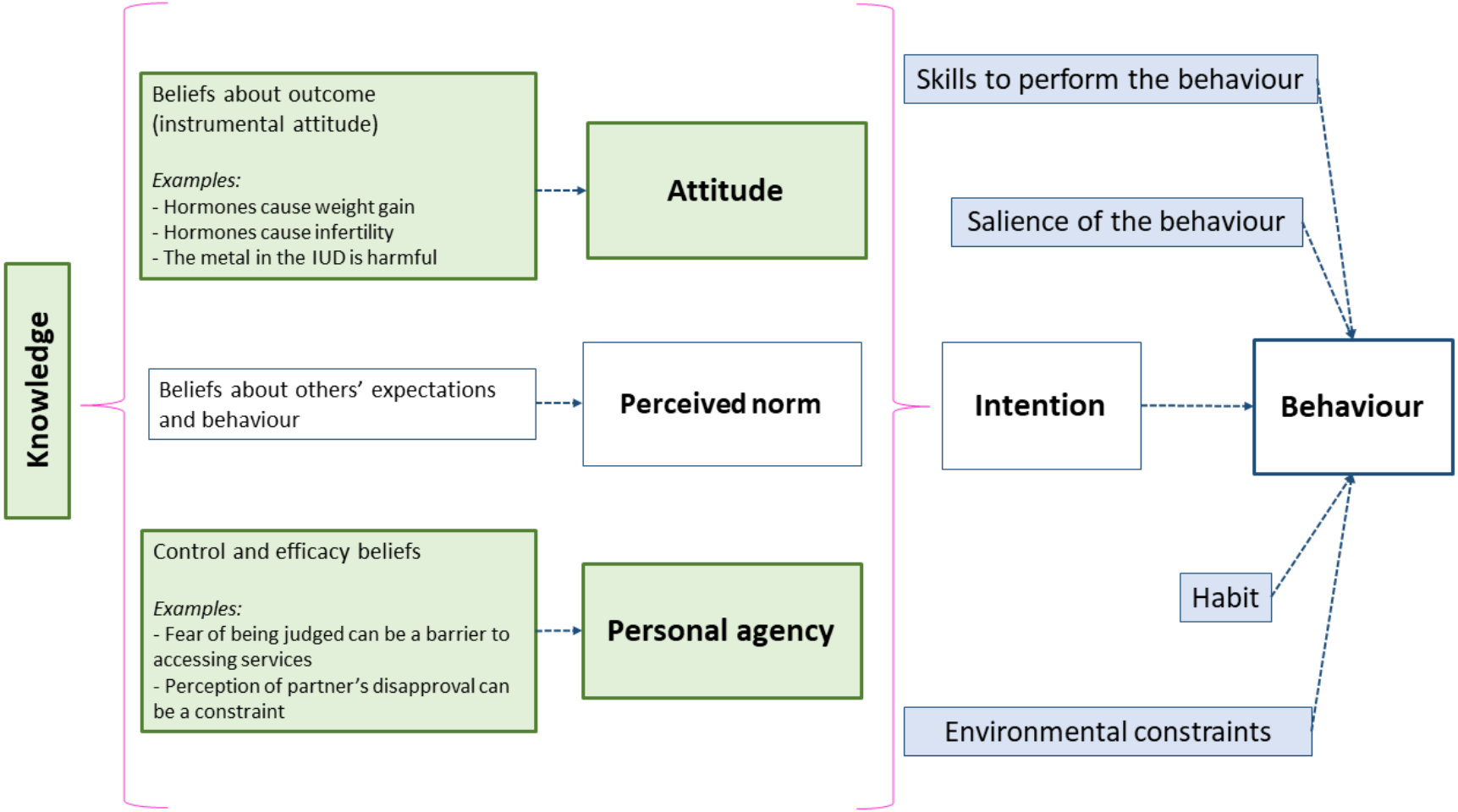
Instrumental attitude is cognitively-based (as opposed to experiential attitude, which is an emotional response) and is determined by beliefs about the outcomes of performing a behaviour, e.g. *"Using hormonal contraception would make me infertile"*. The literature is clear that attitudes influence use of contraception. Attitudinal beliefs, such as concerns about weight gain and infertility due to hormonal contraceptive use, were identified in the consultation with the target group. The intervention is designed to target the specific beliefs.

Personal agency in the IBM follows Bandura's definition- 'bringing one's influence to bear on one's own functioning and environmental events' (174). In the Integrated Behavioural Model, personal agency includes perceived control and self-efficacy, which are similar but distinct. Self-efficacy, from Social Cognitive Theory (175, 176), is an individual's 'degree of confidence in performing a behaviour' (170), e.g. *"I am certain that I can talk to my partner about contraception"*. Perceived control is an individual's 'perception of the degree to which various factors make it easy versus difficult' to perform a behaviour' (170, 177), e.g. *"If my partner disapproved of using contraception, it would be difficult for me to use it".* The intervention provides support in using contraception, talking to a partner about contraception and attending services for contraception, in order to increase self-efficacy in and control over these behaviours.

I have adapted the Integrated Behavioural Model to include knowledge as an equally important construct that is a fundamental determinant of behaviour, as in the Information-Motivation-Behavioural Skills Model (171). In the focus group discussions and interviews, it was clear that accurate information about effective contraception was low. Providing accurate information in a context where there is none or very little, may change people's beliefs. The intervention provides accurate information about the different effective methods.

Figure 4.2 illustrates this project's adapted IBM (the green boxes are the constructs that the intervention targets):

Figure 4.2 **This project's Integrated Behavioural Model**



The intervention content specifically targets the determinants as developed through the Intervention Mapping process. While I have retained perceived norm in the model, the intervention does not target this determinant directly. Perceived norm is composed of injunctive and descriptive norm. Injunctive norm is belief about what others think one should do and descriptive norm is the perception of what others are doing. While the target group expressed normative beliefs about others' expectations and behaviour, it was clear that some perceptions were likely to be accurate (such as the cultural norm of childbearing soon after marriage). I decided that targeting these perceived norms could decrease the credibility of the intervention. However, as the intervention includes real quotes from the target group it is possible that the intervention could influence perceived norms.

5 Evaluation methods

5.1 Introduction

This chapter is based on the three published trial protocols for the evaluation of the intervention in Palestine, Tajikistan and Bolivia. It also contains additional methodological detail, which was not included in the publications. I combined the publications in one chapter to avoid repetition because the methodological approach across the countries is largely the same. I have outlined the differences between the countries in the relevant sections. The Tajikistan protocol was published in BMJ Open in September 2017 (51) (Appendix 8) the Palestine protocol was published in Trials in October 2017 (52) (Appendix 9) and the Bolivia protocol was published in the Journal of Medical Internet Research- Research Protocols in December 2017 (53) (Appendix 10). All articles are open access.

Citations:

(51) McCarthy OL, Leurent B, Edwards P, Tokhirov R, Free C. A randomised controlled trial of an intervention delivered by app instant messaging to increase the acceptability of effective contraception among young people in Tajikistan: study protocol. BMJ Open. 2017;7(9).

(52) McCarthy OL, Wazwaz O, Jado I, Leurent B, Edwards P, Adada S, et al. An intervention delivered by text message to increase the acceptability of effective contraception among young women in Palestine: study protocol for a randomised controlled trial. Trials. 2017;18(1):454.

(53) McCarthy OL, Osorio Calderon V, Makleff S, Huaynoca S, Leurent B, Edwards P, Lopez Gallardo J, Free C. An Intervention Delivered by App Instant Messaging to Increase Acceptability and Use of Effective Contraception Among Young Women in Bolivia: Protocol of a Randomized Controlled Trial. JMIR Res Protoc 2017;6(12):e252. doi:10.2196/resprot.8679

RESEARCH PAPER COVER SHEET

Student Details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Paper already published

Where was the work published?	*Trials*		
When was the work published?	October 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the trial, developed the trial materials and wrote the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

RESEARCH PAPER COVER SHEET

Student Details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Paper already published

Where was the work published?	*BMJ Open*		
When was the work published?	September 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**
* © Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.			

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the trial, developed the trial materials and wrote the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

RESEARCH PAPER COVER SHEET

Student Details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Paper already published

Where was the work published?	*JMIR Research Protocols*		
When was the work published?	December 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the trial, developed the trial materials and wrote the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

5.2 Methods

5.2.1 Study design

In each country, I conducted a parallel-group, individually randomised superiority trial with a 1:1 allocation ratio to evaluate the effect of the intervention in each country. The objective was to establish the effect of the intervention on attitudes towards effective contraception in each country. In Bolivia, an added objective was to establish the effect of the intervention on use of effective contraception.

5.2.2 Eligibility

Tajikistan eligibility

Women and men aged 16-24 who owned a personal Android mobile phone, lived in Tajikistan and could read Tajik or Russian will be eligible to take part.

Palestine eligibility

Women aged 18–24 years, who did not report using effective contraception, owned a personal mobile phone, lived in the West Bank and could read Arabic were eligible to take part. The lower age limit of 18 years was chosen because it is the age in Palestine where people can provide independent informed consent to take part in research.

Bolivia eligibility

Women aged 16 to 24 years who own a personal Android mobile phone and live in La Paz or El Alto and who reported an unmet need for contraception (i.e. were sexually active, not using effective contraception and wanted to avoid a pregnancy) and could read Spanish were eligible to take part.

The upper age limit of 24 years was chosen because this most closely matched the target group ‘young people’ (165), which was identified by the funder. Participants in all countries must also have been willing to receive messages about contraception on their mobile phone.

5.2.3 Recruitment

Tajikistan recruitment

The trial was promoted through the distribution of flyers through TFPA's volunteers and youth partner organisation, TFPA's website and social media sites. Potential participants were provided the link to the enrolment pages of the secure online trial database and randomisation system, where they could read the information sheet and provide informed consent. If they did not have adequate internet access, youth organisation volunteers provided it. Participants had the option of completing the paper-based version of the consent form.

Palestine recruitment

The trial was promoted through PFPPA's service delivery points through outreach sites, the PFPPA website, the distribution of trial promotional material via flyers and social media sites. PFPPA service-delivery points provide: contraceptive methods; counselling for women in psychological, legal and social matters; laboratory tests for both men and women; maternal, antenatal and post-natal care and infertility services (186). The promotional material included brief information about the trial (e.g. who was conducting it, who may be eligible, what participation would involve) with a link to the secure trial database and randomisation system where they could read the information sheet and provide informed consent.

Bolivia recruitment

To achieve a diverse sample, the trial was promoted through a variety or routes: CIES's service delivery points in La Paz and El Alto, the CIES website, flyers distributed through CIES's youth network and social media sites. Potential participants were provided the link to the enrolment pages of the secure online trial database and randomisation system, where they read the participant information sheet and provide informed consent. If they did not have adequate Internet connectivity, youth network volunteers provided this. Participants also had the option of completing the paper-based version of the consent form.

Pre-trial recruitment training

To maximize the chance of recruiting to target, I conducted a pre-trial training in Dushanbe, Bethlehem and La Paz to train local staff on all recruitment procedures. The training included discussions about the practicalities of recruitment with a view to developing the most

appropriate strategies. CIES conducted a similar training with their youth volunteers, who promoted the trial.

All participants also had the option of completing a paper-based version of the consent form. See Appendix 11 for the Information sheets and Appendix 12 for the Consent forms.

5.2.4 Intervention

Similarities in the intervention between the countries

The intervention is informed by the Integrated Behavioural Model (170) and consists of short mobile phone messages providing contraceptive support delivered over four months. The intervention messages provide information about contraception, target beliefs identified in the development phase that influence contraceptive use (e.g. misconceptions about the side effects and health risks of contraception, belief that non-hormonal methods are better because they are not harmful to health) and aim to support young people in believing that they can influence their reproductive health. The intervention contains the following behaviour change methods, adapted for delivery by mobile phone (122): belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting.

Differences in the intervention between the countries

Tajikistan

The intervention was sent through TFPA's 'healthy lifestyles' app. The app itself was to contain basic information about contraception, how to have a 'healthy lifestyle', youth friendly service point locations and no behaviour change methods. The app and the intervention messages were available in Tajik or Russian, according to participants' preference, which they indicated at enrolment.

The messages were tailored according to marital status and gender, resulting in four sets of intervention messages: 1) female-married 2) female-not married 3) male-married 4) male-not married. Most of the messages in the four sets overlap, with minor tailoring so that the messages are relevant to marital status and gender. Marital status was used a proxy for sexual activity because the target group and TFPA considered it inappropriate to ask directly about sexual activity. Based on the development work with the target group, participants received 0-3 messages per day (135 messages for female-not married, 155 messages for female-married, 135 messages for male-not married and 146 messages for male-married) for

120 days. Included in the messages that intervention recipients received were seven control messages about the importance of their participation and reminding them to contact the project coordinator if they change their number.

The message sets started with 6-7 days of messages (11 female-married, 12 female-not married, 12 male-married and 13 male-not married) with general information about the study, such as what they will receive over the next 120 days, how to stop the messages, how to choose specific times to receive the messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages (women only). On the final 2-3 days, the message sets included four messages that indicated that the messages have ended, provided a link to the database to complete the follow-up questionnaire, reassurance that the information that they provide is confidential and a final message stating that their participation helps to determine the best ways to provide reproductive health services in Tajikistan.

Palestine

The intervention was sent by text message and was tailored according to marital status, resulting in two sets of intervention messages: (1) female-married and (2) female-not married. Most of the messages in the two sets overlap, with minor tailoring so that the messages are relevant to marital status (a proxy for sexual activity as in Tajikistan). Participants allocated to the intervention group received zero to three messages per day (113 messages for female-not married and 120 messages for female-married) for 120 days.

The message sets started with 6 days of messages (10 messages for married women and 11 for not-married women) with general information about the study, such as information about what they will receive over the next 120 days, how to stop the messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages. Included in the intervention messages that the intervention recipients receive were seven control messages about the importance of their participation and reminding them to contact the project coordinator if they change their number. On days 119 and 120, the message sets included four messages that indicate that the messages have ended, provided information on how to complete the follow-up questionnaire, reassurance that the information that they provide is confidential and a final message stating that their participation helps to determine the best ways to provide reproductive health services in Palestine.

Bolivia

The intervention messages in Bolivia were sent through the Tú decides app. The app contained standard family planning information and no behaviour change methods. Participants allocated to the intervention group received zero to three messages per day (a total of 183 messages) for 120 days. Included in the 183 messages that intervention recipients receive were seven control messages about the importance of their participation and reminding them to contact the project coordinator if they change their number. The message sets started with 6 days of messages with general information about the study, such as information about what they will receive over the next 120 days, how to stop the messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages. On day 119 and 120, the intervention included 4 messages: one that indicated that the messages have ended, one that provided a link to the database to complete the follow-up questionnaire, one that gave reassurance that the information that they provide is confidential and a final message stating that their participation helps to determine the best ways to provide reproductive health services in Bolivia.

5.2.5 Control

Similarities in the control between the countries

Control participants in all three countries received 16 messages about trial participation over 120 days. The first four days included six messages that introduce the study, as well as provided information about what they will receive over the next 120 days, how to stop the messages and who to contact if they change their number. They then received two messages a month for three months: one about the importance of their participation and one reminding them to contact the project coordinator if they change their number. On day 105, they received one message about the importance of their participation. On day 120, participants received three messages: one that provided information on how to complete the follow-up questionnaire, one that gives reassurance that the information they provide is confidential and a final message stating that their participation helps to determine the best ways to provide reproductive health services in the country.

Differences in the control between the countries

Tajikistan

The control messages were sent through TFPA's Healthy Lifestyles app.

Palestine
The control messages were sent by text messages through the local platform.

Bolivia
The control messages were sent through CIES's Tú decides app.

All participants received usual care (the normal care that a young person would receive if they attended a service in each country) and were free to seek any other support, whether existing or new.

5.2.6 Outcomes

The acceptability primary outcome

In Palestine and Tajikistan, the primary outcome was the proportion of participants reporting that at least one method of effective contraception was acceptable at four months after randomisation ('acceptability'). I chose acceptability as the primary outcome for the following reasons. Sexual activity before marriage is highly stigmatised in all three countries. There is strong cultural pressure to childbear soon after marriage, particularly in Palestine and Tajikistan. I predicted that a significant proportion of participants in the Palestine and Tajik trial sample would be either not married (and not sexually active or not willing to admit that they are) or newly married. Because of this, an objective primary outcome of effective contraceptive use would not be advisable as powering a study for an outcome with a small number of events would make the sample size prohibitively large. In not married/not sexually active young people, the intervention aimed to increase acceptability of the effective methods for when they may want to limit or space their families and could benefit from finding a range of methods acceptable.

In the IBM, intention is the most proximal predictor of behaviour. Apart from measuring the behaviour itself, choosing intention as the primary outcome would have been the best option. However, my view was that intention would have been too abstract for young people in Tajikistan and Palestine, many of whom I thought would not have been sexually active (or not willing to admit that they were). I did not choose personal agency as the primary outcome for similar reasons. Therefore, I chose to measure 'acceptability' as the primary outcome. Acceptability is a composite of the attitudinal beliefs about contraception identified

in the literature and formative work; these are the immediate beliefs that the messages target (instrumental attitude, see this project's IBM, Figure 4.2)

The acceptability of each method was measured by the following stems: Using the [method] …causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy and I would recommend the [method] to a friend. The IUD and implant include an additional stem: The [method] insertion would not be a problem. The response options for each scale were: strongly disagree, disagree, not sure, agree, strongly agree and I do not know what the [method] is. A method was acceptable if participants reported 'agree' or 'strongly agree' for all scales except for '…causes infertility' and '…causes unwanted side effects' stems, for which 'disagree' or 'strongly disagree' denoted acceptability.

Co-primary outcome in Bolivia

In Bolivia, a co-primary outcome was self-reported current use of effective contraception. The formative work in Bolivia indicated that, while sex before marriage is stigmatised as it is in Tajikistan and Palestine, young people were having sex before marriage (or were more willing to admit that they were compared to the other countries).

Secondary outcomes

In Palestine and Tajikistan, a secondary outcome was the proportion reporting current use of effective contraception, which was a co-primary outcome in Bolivia. Secondary outcomes shared across the countries were, for each contraception methods, the proportion reporting that each effective contraception method is acceptable (acceptability of individual methods); the proportion reporting use (or partner's use in Tajikistan) of effective contraception at any time during the four months (discontinuation); the proportion reporting attending a sexual health service during the four months (service uptake); the proportion reporting that they became pregnant (or partner in Tajikistan) and they did not want to become pregnant during the study (unintended pregnancy); and the proportion reporting having an abortion (or partner in Tajikistan) during the study (induced abortion).

Process outcomes

The process outcomes were: knowledge of effective contraception; perceived norms in relation to using and communicating with partners about contraception; personal agency in using (women only) and communicating with partners about contraception; intention to use effective contraception (women only) and intervention dose received.

Measuring the Integrated Behavioural Model constructs

[This section was not included in the published protocols.]

I first reviewed the existing validated scales measuring psychological constructs related to contraception but did not find any that were suitable (187). For example, the "Contraceptive Attitude Scale" (in Fisher 2010 (187), p179) includes items that do not reflect the aim of the messages and with 32 items, was prohibitively long. Likewise, the "Contraceptive Utilities, Intention and Knowledge Scale" and the "Contraceptive Self-efficacy Scale" (in Fisher 2010 (187), p180 and p188) do not measure what the intervention targeted. In most of the measures that I identified, many items were also not culturally appropriate. Therefore, in the absence of existing validated measures, I constructed the scales used to measure instrumental attitude (the acceptability primary outcome), perceived behavioural control, self-efficacy, injunctive norm and descriptive norm in relation to use, accessing services and communicating with partner, based on guidelines for measuring IBM constructs (170, 188, 189). I used the method for measuring 'generalised intention' because this is most commonly used in research involving individual's health behaviour (188). I kept intention to just one item (intention to use contraception) and did not include every change objective in the questionnaires in the interest of keeping the questionnaire as short as possible.

For instrumental attitude (acceptability), I listed the most common perceived advantages and disadvantages of performing each behaviour (use, accessing services and communicating with partners) (Table 5.1). For perceived norms, I considered the most important people or groups of people who would approve or disapprove of each behaviour. The sources of normative influence that I identified were: parents, siblings, family, friends, neighbors, mother-in-law, family-in-law. I could not include an item for each, so I chose the most important. I had originally included the wording 'most people like me' but testing in Tajikistan suggested that 'my friends' would be better. For perceived behavioural control, I identified the perceived barriers or facilitating factors that could make performing each behaviour easier or more difficult. For self-efficacy, I determined the perceived factors that would make people more confident in performing each behaviour. I chose the main constraints that apply to all the countries. Being newly married did not come up strongly in Bolivia, but I included it in the Bolivian questionnaire for consistency across the countries.

I worded the scales in accordance with the IBM guidelines, however it was necessary to adapt the wording for measuring instrumental attitude (acceptability) so that it also applied to men

as well as women. For example, I changed “If I used the pill, it would cause fertility problems” to “The pill causes fertility problems”. I included the common belief across the countries, that contraception causes infertility, as its own item. I grouped the other various negative beliefs about contraception into “harmful side-effects” to make the measure applicable across the three countries. I did not include the belief that hormones cause weight gain because the messages say “most” women do not gain weight, and this item therefore would be difficult to interpret.

We tested the scales for face validity with the target group in each country. The project coordinators asked young people to complete the scales and then asked them why they answered how they answered. They also asked them if they had any difficulty answering any items and how to reword if necessary. The items were translated from English to Tajik, Russian, Arabic and Spanish by native speakers and then back translated into English.

Table 5.1 Specific issues regarding the IBM constructs identified in needs assessment

	Use	***Access services***	***Communication***
(Attitude) Positive or negative beliefs about the behaviour	- Hormones cause weight gain, menstrual changes and infertility - Natural methods are better because they don't have side-effects - The pill contains harmful chemicals, causes anxiety and nervousness - The IUD makes women nervous, causes heavy bleeding, infertility, causes an irregular menstrual cycle, back pain - The metal in the IUD is harmful - The injection causes weight gain - If you use contraception, you will worry less if you have sex - Should not use if not married - Using contraception in early marriage will cause problems	Providers judge young people	Should be a shared decision between partners to use contraception
(Norms) Sources of normative influence about the behaviour	- Parents - Siblings - Family - Friends - Neighbors - Mother-in-law - Family-in-law	- Provider - Society/community - Village/neighbours will find out - Pharmacists make YP feel uncomfortable, providers at clinic more relaxed	- Partner - Society/ community
(Personal agency) Factors that make it easier or harder to perform the behaviour (facilitators and constraints)	- Being newly married can make it difficult to use contraception - Hearing about other's positive experiences would facilitate use - If friends have used a method and report that it does not affect health (including fertility), this would facilitate use - Having accurate information would facilitate use	- Feeling of being judged by providers (mainly pharmacists) - People in village will judge you if not married - Partner doesn't approve	If newly married, could cause problems

5.2.7 Data collection

Baseline data

At baseline, we measured the acceptability of effective contraception and collected the following personal and demographic data: full name; mobile phone number; email address; date of birth; marital status; number of children; ethnicity; occupation; education level; current pregnancy intention; current method of contraception and how they heard about and enrolled in the study. In Palestine, 'residence' was used instead of ethnicity in because PFPPA's believed that most people in Palestine would consider themselves 'Palestinian' and that 'residence' is a more meaningful demographic indicator. In Palestine we also asked participants what the time that they preferred to receive the messages. See Appendix 13 for the baseline questionnaires.

Follow-up data

At four months, we measured the primary, secondary and process outcomes and collected the following data via the follow-up questionnaire: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else who took part in the study and if so, whether they read each other's messages (contamination); whether they experienced physical violence since being in the study and whether anything good or bad happened as a result of receiving the messages. We collected data on physical violence because the intervention involves a sensitive topic and is delivered in a context where intimate partner violence is a public health concern. If participants did not complete the questionnaire themselves, local research staff unaware of participants' allocation contacted them to collect their data. See Appendix 14 for the follow-up questionnaires.

Methods to improve follow-up data collection

I conducted training regarding the follow-up procedures with relevant staff in each country. The training emphasised the importance of ensuring that participants understand that participation involves completing a four month questionnaire and to potentially receiving daily messages about contraception for four months. The control messages, also sent to participants allocated to the intervention, were an effort to keep participants engaged. Staff contacted non-responders multiple times for their follow-up data. Follow-up ended six months after the last participant was randomised or after staff attempted to contact all non-responders at least three times, whichever came first.

Building the trial database and randomisation system

[This section was not included in the published protocols.]

The trial database and randomisation system was used in the three trials. While the architecture of the system was built, it required modifications to fit each trial. I completed all the non-coding work myself (the coding work was completed by the systems developer). This involved extensive content management, testing and reformatting to include the following pages for each country in each local language (in Cyrillic script for Tajik and Russian in Tajikistan and Arabic script for Palestine): landing, eligibility, information sheet, consent, baseline questionnaire and follow-up questionnaire.

5.2.8 Allocation and protecting against bias

Randomisation occurred immediately after baseline data was submitted on the trial database and randomisation system. The allocation sequence was generated by the remote computer-based randomisation software, ensuring that investigators are unaware of allocation before participants are randomised. Due to the nature of the intervention, participants would have been aware of the allocation soon after they started receiving the messages. Local research staff collecting outcome data were not made aware of allocation unless this was revealed to them by the participant. I was masked to treatment allocation until after all analyses were conducted.

5.2.9 Intervention delivery

Palestine

After randomisation, the trial database and randomisation system sent the local SMS platform the following information: allocation, time slot (participants could choose to receive messages from 10:00 to 13:59, 14:00 to 18:59, or both), mobile phone number and marital status. The platform sent the intervention or control messages, according to allocation. Messages sent were recorded by the local platform and were monitored by me and a colleague at LSHTM.

Tajikistan and Bolivia

After participant baseline data was entered, a confirmation of enrolment screen provided instructions on how to install the app. When participants installed the app, they were prompted to enter the mobile phone number they entered on the baseline questionnaire. In

Tajikistan, the trial database and randomisation system then sent the local app platform the following information: gender, marital status, language preference, allocation and date of enrolment. In Bolivia, the system sent only the allocation to the local app platform. Participants then had access to the app and received either the control or intervention messages, according to their allocation. Within the app, participants could choose when they wanted to receive the messages and they could also stop the messages. If participants installed the app after 13:00 in Tajikistan, they received the first message the following day. Otherwise, they received the first message on the day of enrolment. In Bolivia, participants received the first message the day after they install the app.

5.2.10 Sample size

Palestine and Tajikistan

The Palestine and Tajik trials were powered to detect a 15% increase in acceptability of effective contraception in the intervention group compared with the control group. Other studies have found smaller increases in behaviour with similar interventions, for example, Castaño et al (134). Because attitudinal change is likely to be easier to achieve than behavioural change, we decided to power the trial to detect a larger difference. Four hundred and fifty-four participants would have allowed for 90% power to detect a 15% absolute increase in acceptability, assuming 50% acceptability in the control group (i.e., 50% in the control vs 65% in the intervention, an odds ratio of 1.86). Fifty per cent baseline acceptability was used in the absence of published data on acceptability in these contexts. If the actual baseline acceptability was higher or lower than 50%, the trials would still be sufficiently powered to detect an absolute difference of 15%. For example, if the proportion in the control arm was 75%, there would be 90% power to detect an absolute difference of 12% (corresponding to 87% acceptability in the intervention group and an odds ratio of 2.23). Allowing for 20% loss to follow-up, we aimed to randomised 570 people in Palestine and 570 in Tajikistan.

Bolivia

Smith et al's trial evaluating a post abortion mobile phone intervention using voice messages and counsellor support found that 18% more women in the intervention arm than in the control arm were using effective contraception at 4 months (64% versus 46%, relative risk 1.39, 95% CI 1.17–1.66) (135). If Smith and colleagues' trial observed a larger increase in contraceptive uptake, as it involved women who had just had an abortion, we powered our

trial to detect a smaller absolute difference of 10% uptake in effective contraception at four months. The proportion of women aged 16 to 24 years in a partnership living in La Paz or El Alto using effective contraception was estimated to be around 44% (190). A total of 1048 participants would provide 90% power to detect a 10% increase in effective contraception, assuming 44% use in the control group (i.e. 44% in the control vs 54% in the intervention, corresponding to an odds ratio of 1.49). Allowing for 20% loss to follow-up, we aimed to randomise 1310 people.

5.2.11 Data management

I did not convene a data monitoring and ethics committee, as the intervention provided support and was unlikely to produce adverse effects. I convened a PhD trial steering committee, who agreed to take on the monitoring of ethical aspects of the trials.

Personal details entered onto the trial database and randomisation system were stored on LSHTM's secure server. Personally identifiable information exported from the database was stored separately from anonymized research data. Participant mobile phone numbers, but no other personal details, were stored in the local platform that sends the messages through the app. Any signed paper consent forms and questionnaires were kept in a local data enclave. All data arising from the study was kept confidential and accessible only to researchers directly involved in it. Personally identifiable data was not kept longer than necessary and was deleted within three months following study completion. I will retain primary research data for ten years following study completion.

Data export and analysis preparation

[This section was not included in the published protocols.]

The data entered onto the trial database was stored on LSHTM's server. I exported the data, which was in the local script, into excel spreadsheets. I then imported the data into Stata 15 and wrote do files to translate the Cyrillic script (both Tajik and Russian), Arabic and Spanish data into English. When this was complete, I labelled and coded all variables the same across the countries.

5.2.12 Analysis

General statistical considerations

The analysis of the data in each country followed the plan specified below. There were no interim analyses and therefore no stopping rules. I analysed participant data according to the arm that they were allocated to and included only participants with complete outcome data in the primary analysis (a complete case analysis). All statistical tests were two-sided. I reported all effect estimates with a 95% confidence interval and associated p-value. Statistical significance was considered at the 5% level, (but interpreted with caution in Bolivia considering the two primary outcomes). I used Stata 15 for analyses.

Loss to follow-up

To investigate whether loss to follow-up differed by arm in each country, I reported this descriptively and used a chi-squared test. I used logistic regression to compare baseline characteristics of participants who completed four month follow-up against participants who did not. I reported predictors of loss to follow-up and investigated whether the effect of these differed by arm by testing for an interaction.

Assumptions about missing data

The complete-case analysis assumes that missing data for participants who did not complete follow-up are similar to data from participants who completed follow-up, conditionally on baseline covariates included in the analysis model (i.e. that data are missing at random) (191). If participants who completed follow-up are more likely to use effective contraception and to find an effective method acceptable compared with those who are lost to follow-up, the observed proportion may overestimate use and acceptability (191).

It is reasonable to assume that participants who did not complete follow-up would be similar to participants that did not find a method acceptable at four months. For example, a participant that resides in a Bedouin camp typically has inadequate access to services and education, which are likely associated with whether or not they complete follow-up (they may be more difficult for staff to reach over the phone due to poor mobile phone connectivity in certain areas and/or they may find it more difficult to travel to service to complete the paper follow-up questionnaire). In turn, this demographic may also be less likely to find a method acceptable than participants that reside in the city as they may have more firmly held misconceptions about hormonal contraception due to less exposure to

sexual and reproductive health education. In this case, the overestimation would be modest (191).

Missing data on the acceptability outcome scales

[The following paragraph was not included in the published protocols.]

The acceptability of each method (pill, IUD, injection, implant and patch) was measured by five-six ordinal scales. If data was missing on any scale associated with a method, that method could not be acceptable. In this case, acceptability for the method was coded as missing. The acceptability outcome was complete if all scales for each method were complete *or* if there was missing data for some methods but at least one method was acceptable. For example, if a participant had missing data for all methods except for one, and this method was acceptable, the primary outcome would be complete. The acceptability outcome was not complete if there was missing data for some methods, complete data for at least one method, but this method was unacceptable.

Missing covariates

The database required all items on the baseline questionnaire to be submitted to proceed to the random allocation. Therefore, there were no missing baseline covariates.

Principal analyses

Descriptive analysis

I reported a flow diagram of trial participation, as recommended in the Consolidated Standards of Reporting Trials (CONSORT) guidelines (192). I reported the baseline characteristics by treatment arm. I also explored the baseline factors associated with retention (see loss to follow-up section above).

Analysis of the primary outcome

The primary outcome acceptability of at least one method of effective contraception and co-primary outcome use (Bolivia) were binary. I reported the crude proportion who reported that at least one method was acceptable in each group and the crude proportion who reported using effective contraception in each group. I estimated the difference between the groups using logistic regression and reported the odds ratio along with the 95% confidence interval and p-value for evidence against the absence of intervention effect from the model. I adjusted the primary analysis regression for baseline covariates likely to be associated with the outcome in order to improve the efficiency of the analysis and avoid chance imbalances

(193). The pre-specified covariates that I adjusted for were: use (Tajikistan only, using effective contraception/not using effective contraception); pregnancy intention (Palestine and Tajikistan only, wants to avoid a pregnancy/other); gender (Tajikistan only, female/male) age (16-19 years/20-24 years in Tajikistan and Bolivia and 18-19 years/20-24 years in Palestine), number of children (0/≥1), highest education level completed (university/other) and acceptability of effective contraception at baseline (at least one method acceptable/no methods acceptable). In Bolivia, the primary outcomes were analysed individually, and no formal multiplicity correction was applied, but interpretation took into account the multiple tests if only one of the two outcomes reached the 5% significance level. I also reported the crude odds ratio between arms.

Analysis of the secondary outcomes

The analysis of the secondary outcomes was similar to the analysis of the primary outcome. I estimated the difference between the groups using logistic regression, reported odds ratios with 95% confidence intervals and p-values. All regressions were adjusted for the pre-specified covariates as above (although with the acceptability of individual methods, the outcome at baseline replaced acceptability of effective contraception).

Analysis of the process outcomes

The process outcomes perceived norms, personal agency and intention were comprised of ordinal scales. I analysed each scale individually using ordered logistic regression to estimate proportional odds ratios. For knowledge, each correct answer received one point. The points were summed, and an overall score was produced. I used linear regression to test for a difference in mean scores between the arms.

To assess the 'dose' of the intervention that the intervention participants received, I analysed the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages. I reported this descriptively.

Additional analyses

Sensitivity analyses

I conducted sensitivity analyses regarding the missing data. In the first sensitivity analysis, I considered that data are not missing at random; that participants lost to follow-up did not find at least one method acceptable and that participants lost to follow-up were not using an effective method of contraception (Bolivia). In the second, I adjusted for the main baseline

predictors of missingness. Sensitivity analyses were adjusted for the pre-specified covariates as above.

Subgroup analyses

Recognising that the trials are not powered to detect effect differences in subgroups, I conducted an exploratory subgroup analyses for the primary outcomes to determine whether the intervention effect varied by baseline characteristics. The pre-specified subgroups were: gender (Tajikistan only, female/male) age (split at the median); marital status (married/not married); number of children (0/≥1); ethnicity (Tajikistan only, Tajik/other); residence (Palestine and Tajikistan, city/other) geographical location (El Alto/La Paz); occupation (in education/other) and highest education level completed (university/other). Within the pre-specified subgroups, I assessed heterogeneity of treatment effect with a test for interaction (194-198). I presented interaction test p-values, but I interpreted them with caution, due to the exploratory nature, the multiple tests performed and the low power of the interaction test. I estimated odds ratios along with 95% CIs for each subgroup without p-values. As these were exploratory analyses of potentially influential characteristics that are not justified a priori, I did not hypothesize effect directions.

Contamination

To assess the potential for contamination, I reported the proportion of control group participants that read another participant's messages and the proportion of intervention participants whose messages were read by another participant.

5.2.13 Ethical approval

The trials were granted ethical approval by the LSHTM Interventions Research Ethics Committee on 16 May 2016, by the Tajik National Scientific and Research Centre on Paediatrics and Child Surgery under the Ministry of Health on 15 April 2016, by the State of Palestine Ministry of Health Primary Health Care and Public Health Directorate on 9 May 2016 and by La Comisión de Ética de la Investigación del Comité Nacional de Bioética on 20 September 2016 (Appendix 15).

6 Tajikistan evaluation results

6.1 Introduction

This chapter is the research paper that presents the results of the randomised controlled trial in Tajikistan. This work was published in *Reproductive Health* as an open access article in May 2018 (54) (Appendix 16).

Citation:

McCarthy, O; Ahamed, I; Kulaeva, F; Tokhirov, R; Saibov, S; Vandewiele, M; Standaert, S; Leurent, B; Edwards, P; Palmer, M; Free, C; (2018) A randomized controlled trial of an intervention delivered by mobile phone app instant messaging to increase the acceptability of effective contraception among young people in Tajikistan. Reproductive health, 15 (1). p. 28. ISSN 1742-4755 DOI: https://doi.org/10.1186/s12978-018-0473-z

RESEARCH PAPER COVER SHEET

Student details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Paper already published

Where was the work published?	*Reproductive Health*		
When was the work published?	February 2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed and managed the trial, conducted the analysis and wrote the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

6.2 Research paper

6.2.1 Abstract

Background

Unintended pregnancy is associated with poorer health outcomes for women and their families. In Tajikistan, around 26% of married 15-24 year old women have an unmet need for contraception. There is some evidence that interventions delivered by mobile phone can affect contraceptive-related behaviour and knowledge. We developed an intervention delivered by mobile phone app instant messaging to improve acceptability of effective contraceptive methods among young people in Tajikistan.

Methods

This was a randomized controlled trial among Tajik people aged 16-24. Participants allocated to the intervention arm had access to an app plus intervention messages. Participants allocated to the control arm had access to the app plus control messages. The primary outcome was acceptability of at least one method of effective contraception at four months. Secondary outcomes were use of effective contraception at four months and during the study, acceptability of individual methods, service uptake, unintended pregnancy and induced abortion. Process outcomes were knowledge, perceived norms, personal agency and intention. Outcomes were analysed using logistic and linear regression. We conducted a pre-specified subgroup analysis and a post-hoc analysis of change in acceptability from baseline to follow-up.

Results

573 participants were enrolled. Intervention content was included on the app, causing contamination. 472 (82%) completed follow-up for the primary outcome. There was no evidence of a difference in acceptability of effective contraception between the groups (66% in the intervention arm vs 64% in the control arm, adjusted OR 1.21, 95% CI .80-1.83, p=0.36). There were no differences in the secondary or process outcomes between groups. There was some evidence that the effect of the intervention was greater among women compared to men (interaction test p=0.03). There was an increase in acceptability of effective contraception from baseline to follow-up (2% to 65%, p<0.001).

Conclusions

The whole intervention delivered by instant messaging provided no additional benefit over a portion of the intervention delivered by app pages. The important increase in contraceptive acceptability from baseline to follow-up suggests that the intervention content included on the app may influence attitudes. Further research is needed to establish the effect of the intervention on attitudes towards and use of effective contraception among married/sexually active young people.

Trial registration: Clinicaltrial.gov NCT02905513

Date of registration: 14 September 2016

Key words

Randomized controlled trial, Tajikistan, Contraception, Smart phone, Reproductive health, Young adults

Plain English summary

Unintended pregnancy is associated with poor health and social outcomes for women and their families. Despite wide availability of contraception, many women globally face barriers in realizing their fertility desires. A woman has an unmet need for modern contraception if she wants to avoid a pregnancy but currently uses no method or a traditional method. In Tajikistan, unmet need for contraception is approximately 26% among married 15-24 year olds. Oppositional attitudes towards contraception (both their own and others') is a common reason women provide for not using contraception.

We developed an intervention delivered by mobile phone to increase the acceptability of effective contraception among young people in Tajikistan. The intervention was developed with young people using an established approach grounded in behavioural science. We conducted a randomized controlled trial to evaluate the effect of the intervention on acceptability of effective contraception. Participants allocated to the intervention group had access to an app plus the intervention messages. Participants allocated to the control group had access to the app plus control messages. The app contained a proportion of the intervention messages that targeted knowledge of and attitudes towards effective contraception. This was different from what was planned in the trial protocol.

The intervention instant messages did not have an added benefit over the app with regards to any of the outcomes. When data from both groups were analysed together, there was a large increase in acceptability of effective contraception from baseline to follow-up (2% at baseline to 65% at follow-up). While we cannot attribute this increase unequivocally to the intervention content, it suggests that providing accurate information and targeting beliefs that influence contraceptive use may be sufficient in changing attitudes towards these methods among young people in Tajikistan. Further research is needed to reliably establish the effect of the intervention on attitudes towards and use of effective contraceptive methods among married/sexually active young people.

6.2.2 Background

Unintended pregnancy persists as a global health problem, with people in lower income countries experiencing them at a higher rate (24). Unintended pregnancy is associated with a multitude of negative health and economic outcomes for women and their families (3, 4, 7, 10, 12, 15, 16, 18, 199, 200). It is estimated that modern contraceptive use currently prevents 307 million unintended pregnancies each year in developing regions (159). Satisfying unmet need for modern contraception in these regions would reduce unintended pregnancies by 74% (159). A woman has an unmet need for modern contraception if she wants to avoid a pregnancy but currently uses no method or a traditional method (201).

Despite a number of governmental policy initiatives and strategies aimed at improving reproductive health in Tajikistan, young people in the country face challenges in gaining accurate information about contraception and in accessing services (84, 85). The 2012 Tajikistan Demographic and Health Survey is the most reliable resource for family planning data in the country at present (83). The survey estimates that Tajik women have an average of half a child more than their desired number, implying that if unintended pregnancies were avoided, the total fertility rate would be 3.3 births per woman rather than the actual 3.8 (83). The effective contraceptive methods available in Tajikistan are oral contraceptive pills (OCs), intrauterine devices (IUDs), injectables and implants (‘effective methods are methods with a less than 10% typical use failure rate at 12 months (28-30)). Though these methods are available, around 26% of married 15-24 year old women have an unmet need for contraception (83). Unmet need is the highest between the ages of 20 to 29 (26). The main reason women with an unmet need provide for not using contraception are oppositional attitudes towards contraception, both their own and others’ (26). The next common reasons

relate to low perceived pregnancy risk and negative attitudes about the methods, such as fear of side-effects (26).

Over the past few decades, the dramatic global increase in mobile phone ownership has engendered enthusiasm amongst researchers and health care providers regarding the use of mobile phones for health care delivery (32-41, 43, 47). Trials have provided some evidence that interventions delivered by mobile phone can improve contraceptive-related behaviours (134, 135, 143, 161) and knowledge (140, 142, 152), however others have failed to find an effect (44, 136, 137, 202). The London School of Hygiene and Tropical Medicine (LSHTM) and the Tajik Family Planning Association (TFPA), a Member Association of the International Planned Parenthood Federation (IPPF) collaborated to develop and evaluate an intervention delivered by mobile phone to improve attitudes towards the effective contraceptive methods among young people in Tajikistan.

To evaluate the intervention, we conducted a randomized controlled trial from November 2016 to July 2017. This paper reports the results of the trial. To the best of our knowledge, this is the first trial to evaluate a contraceptive behavioural intervention delivered by mobile phone in Tajikistan. The results contribute to an understanding about how to help young people in Tajikistan avoid unintended pregnancies.

6.2.3 Methods

The methods reported in this section were first published in the trial protocol (51) and the statistical analysis plan (203).

Study design and participants

This was a parallel group, individually randomized superiority trial with a 1:1 allocation ratio. The aim of this trial was to assess the effect of the intervention on the acceptability of effective contraceptive methods among young people in Tajikistan. Participants were eligible to take part in the trial if they were between the ages of 16 and 24, owned a personal Android mobile phone, lived in Tajikistan, could provide informed consent and could read Tajik or Russian. Participants must also have been willing to download a mobile phone app and receive instant messages about contraception through the app. Participants provided informed consent though the secure online trial database and randomization system. All participants received usual care (the normal care that a young person would receive if they

attended a sexual and reproductive health service in Tajikistan) and were free to seek any other support.

Intervention and control

The intervention was developed with young Tajik people in 2015-2016 guided by an established approach grounded in behavioural science (124). It consisted of short mobile phone instant messages delivered through TFPA's 'healthy lifestyles' app over four months. It was informed by the Integrated Behavioural Model (IBM) (170) and contained 10 behaviour change methods (BCM) (belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting) (122), adapted for delivery by mobile phone. The messages provided information about contraception, targeted beliefs identified in the development phase that influence contraceptive use and aimed to support young people in believing that they can influence their reproductive health.

The messages are tailored according to marital status and gender, resulting in four sets of messages (female-married, female-not married, male-married and male-not married). The majority of the messages in the four sets are the same, with minor tailoring so that the messages are relevant to these groups. (Marital status was used as a proxy for sexual activity because the target group and TFPA considered it inappropriate to ask directly about sexual activity.) Further details about the intervention are presented in the trial protocol (51) and in a forthcoming intervention development publication.

Contamination

Participants allocated to the intervention arm had access to the app plus the intervention instant messages. Participants allocated to the control arm had access to the app plus control instant messages about trial participation. Contrary to what was planned in the trial protocol (51), the app contained intervention content. The app was intended to contain only basic information about contraception and no behaviour change methods. This contamination occurred due to a misunderstanding between the partners collaborating in the research.

The app contraception pages included just under a third of the intervention content. Specifically, 57% of the female-married intervention messages that provide accurate information about the effective contraceptive methods and 36% of the messages that use the

BCM 'belief selection' were included on the app. Forty-four percent of the female-married intervention content included on the app used the same words as the intervention messages (56% did not use the same words but was very similar and conveyed the same meaning). The intervention content included on the app aimed to help individuals: name the effective methods, describe how the effective methods work, list services that provide effective contraception, list the risks and benefits of the effective methods, describe how methods are used, express positive attitudes towards the effective methods and differentiate between real potential side-effects and misconceptions about the methods.

Allocation and intervention delivery

After providing informed consent, participants completed the baseline questionnaire through the database and randomization system. The allocation sequence was generated by the remote computer-based randomization software. Randomization occurred immediately after baseline data was submitted. All participants downloaded the app immediately after they submitted their baseline data. The delivery of the intervention (and control) instant messages began on the same day if participants downloaded the app before 13:00 and the following day if they downloaded it after 13:00.

Protecting against bias

Due to the nature of the intervention, participants would have been aware of the allocation soon after they started receiving the messages. Local research staff collecting outcome data were masked to allocation unless the participant revealed it to them. Researchers that analysed the data were masked to treatment allocation.

Outcomes

Primary outcome

The primary outcome was the proportion of participants reporting that at least one method of effective contraception was acceptable at four months post randomization. The primary outcome measure was constructed based on guidelines for measuring IBM constructs (170, 188, 189) and tested for face validity with the target group. The acceptability of each method was measured by the following stems: Using the [method] *…causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy* and *I would recommend the [method] to a friend*. The IUD and implant include an additional stem: *The* [method] *insertion would not be a problem*. The response options for each scale were strongly disagree, disagree, not sure, agree, strongly agree and I do not know what the

[method] is. A method was acceptable if participants reported 'agree' or 'strongly agree' for all scales except for '…causes infertility' and '…causes unwanted side effects' stems, for which 'disagree' or 'strongly disagree' indicated acceptability.

Secondary outcomes

Secondary outcomes were: use (or partner's use) of effective contraception; acceptability of individual methods; use (or partner's use) of effective contraception at any time during the four months; service uptake; unintended pregnancy and induced abortion.

Process outcomes

The process outcomes were: knowledge of effective contraception; perceived norms in relation to using and communicating with partners about contraception; personal agency in using (women only) and communicating with partners about contraception; intention to use effective contraception (women only) and intervention dose received. Details about the scales used to measure knowledge, perceived norm, personal agency and intention are reported in the trial protocol (51).

Data collection

Data was collected at baseline and at four months post-randomization using questionnaires. At baseline, we collected personal and demographic data and acceptability of at least one method of effective contraception (using the same scales as the primary outcome measure). All baseline data was entered onto the trial database system by the participant on their mobile phone. At four month follow-up, we collected all outcomes and the following data: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that took part in the study and if so, if they read each other's messages; if they stopped the messages; if they experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages. An instant message that included a link to the database to complete the follow-up questionnaire was sent to all participants through the app four months after downloading the app. If participants did not complete the follow-up questionnaire themselves, local research staff contacted them by telephone to collect their data.

Sample size

The trial was powered to detect a 15% increase in acceptability of effective contraception in the intervention group compared with the control group. Four hundred and fifty-four

participants allowed for 90% power to detect a 15% absolute increase in acceptability, assuming 50% acceptability in the control group (i.e. 50% in the control vs 65% in the intervention, an odds ratio of 1.86). Allowing for 20% loss to follow-up, we aimed to randomize 570 people.

Statistical analysis

The trial protocol was accepted for publication on 21 July 2017 (51) and the statistical analysis plan was publicly released on 16 August 2017 (203). The analysis was conducted using Stata 15. Analyses were according to randomized arm and only participants with complete outcome data were included in the principal analysis. All statistical tests were two-sided and considered significant at the 5% level. Unmasking occurred on 29 August 2017, after the analyses outlined within the analysis plan were complete.

Loss to follow-up and missing data

We used a chi-squared test to investigate whether loss to follow-up differed by arm. We used logistic regression to compare baseline characteristics of participants that completed follow-up against participants that did not. We investigated whether predictors of loss to follow-up differed by arm by testing for an interaction.

6.2.4 Principal analysis

Analysis of the primary outcome

We compared the proportion that reported that at least one method was acceptable in each group using logistic regression. We report the crude and adjusted odds ratio (OR) along with the 95% confidence interval (CI) and p-value. We adjusted the primary analysis regression for the following pre-specified baseline covariates: pregnancy intention (wants to avoid/other); gender (female/male); age (16-19/20-24); highest education level completed (university/other) and acceptability of effective contraception (at least one method acceptable/no methods acceptable) (51, 203).

Analysis of the secondary outcomes

The analysis of the secondary outcomes was similar to the analysis of the primary outcome. We estimated the difference between the groups using logistic regression and report odds ratios with 95% CIs and p-values. Regressions were adjusted for the baseline covariates

pregnancy intention, gender, age, education level and acceptability (of at least one method or with acceptability of individual methods, of the corresponding method).

Analysis of the process outcomes

The process outcomes perceived norms, personal agency and intention were comprised of ordinal scales. Each scale was analysed individually using ordered logistic regression to estimate proportional ORs. For knowledge, each correct answer received one point. The points were summed and an overall score was produced. We used linear regression to test for a difference in mean scores between the arms. To assess the 'dose' of the intervention that the intervention participants received, we analysed the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages.

Additional analyses

Sensitivity analyses

We conducted two sensitivity analyses regarding the missing data. In the first, we considered that participants lost to follow-up did not find at least one method acceptable. In the second, we adjusted for the main baseline predictors of missingness. Both sensitivity analyses were adjusted for the baseline covariates pregnancy intention, gender, age, education level and acceptability.

Subgroup analysis

We conducted an exploratory subgroup analysis for the primary outcome to determine if the intervention effect varied by baseline characteristics. The pre-specified subgroups were gender (female/male); age (split at the median); marital status (married/not married); number of children (0/1+); ethnicity (Tajik/other); occupation (in education/other); highest education level completed (university/other) and pregnancy intention (wants to avoid/other). Within the subgroups, we assessed heterogeneity of treatment effect with a test for interaction (194-198). We estimated ORs along with 95% CIs for each subgroup.

Contamination

To assess the potential for contamination, we report the proportion of control group participants that reported that they read another participant's messages and the proportion of intervention participants that reported that their messages were read by another participant.

Change from baseline

In addition to the analyses specified in the statistical analysis plan, we tested for a change in the primary outcome from baseline to follow-up, using McNemar's χ^2 test for paired data. This post hoc non-randomized analysis was conducted to explore the increase in acceptability overall, as the app included intervention content (see discussion).

6.2.5 Results

Recruitment, randomization, exclusions

Between 16 November 2016 and 1 March 2017, there were 580 randomizations. During the analysis, we discovered that five participants enrolled and were randomized twice. For the three participants that were allocated to the same arm on both randomizations, we kept them in the analysis using the baseline data from their first record. For the two participants that were allocated to different arms, we excluded them from the analysis. This resulted in 573 participants included in the trial (see discussion).

Two hundred and seventy-five participants were allocated to the intervention arm and 298 participants were allocated to the control arm (Figure 6.1). No participants withdrew from the trial after allocation.

Baseline characteristics

Baseline characteristics of trial participants are reported in Table 6.1. Mean age was 20 years, and 53% were male. Ninety-four percent were not married (259/573), and only 2% (13/573) found at least one method of effective contraception acceptable. Characteristics were similar between the two groups.

Table 6.1 Baseline characteristics (Tajikistan)

		Control N = 298 % (n)	**Intervention** N = 275 % (n)	**All participants** N = 573 % (n)
Age	mean [sd]	20.00 [2.41]	19.93 [2.24]	19.98 [2.33]
	16-19	53.02 (158)	56.73 (156)	54.80 (314)
	20-24	46.98 (140)	43.27(119)	45.20(259)
Gender	female	45.97(137)	47.27 (130)	46.60 (267)
	male	54.03 (161)	52.73 (145)	53.40 (306)
Marital status	married	6.71 (20)	5.82 (16)	6.28 (36)
	not-married	93.29 (278)	94.18 (259)	93.72 (537)
Number of children	0	95.64 (285)	97.09 (267)	96.34 (552)
	1	2.01 (6)	2.18 (6)	2.09 (12)

		Control N = 298 % (n)	Intervention N = 275 % (n)	All participants N = 573 % (n)
	2 or more	2.35 (7)	0.73 (2)	1.57 (9)
Ethnicity	Tajik	92.62 (276)	93.82 (258)	93.19 (534)
	Russian	2.35 (7)	0.36 (1)	1.40 (8)
	Uzbek	5.03 (15)	5.45 (15)	5.24 (30)
	other	0 (0)	0.36 (1)	0.17 (1)
Occupation	school	17.79 (53)	17.09 (47)	17.45 (100)
	university	68.46 (204)	70.55 (194)	69.46 (398)
	working	10.74 (32)	10.55 (29)	10.65 (61)
	training	0.67 (2)	0 (0)	0.35 (2)
	parent	0.34 (1)	0 (0)	0.17 (1)
	not working	1.68 (5)	1.82 (5)	1.75 (10)
	university & working	0.34 (1)	0 (0)	0.17 (1)
Highest level of education completed	primary	12.75 (38)	13.09 (36)	12.91 (74)
	secondary	66.11 (197)	59.64 (164)	63.00 (361)
	university	19.46 (58)	25.82 (71)	22.51 (129)
	other	1.68 (5)	1.45 (4)	1.57 (9)
Current pregnancy intention (‘*Do you want a pregnancy now?)*	yes	3.02 (9)	4.00 (11)	3.49 (20)
	no	12.42 (37)	5.82 (16)	9.25 (53)
	unsure	1.01 (3)	0.73 (2)	0.87 (5)
	not married*	83.56 (249)	89.45 (246)	86.39 (495)
Baseline method	none	31.88 (95)	29.45 (81)	30.72 (176)
	male condom	2.01 (6)	1.09 (3)	1.57 (9)
	IUD**	0.67 (2)	0 (0)	0.35 (2)
	not married*	65.10 (194)	69.09 (190)	67.02 (384)
	LAM***	0 (0)	0.36 (1)	0.17 (1)
	other	0.34 (1)	0 (0)	0.17 (1)
At least one effective method is acceptable	yes	2.68 (8)	1.82 (5)	2.27 (13)
	no	97.32 (290)	98.18 (270)	97.73 (560)
Pill acceptability	yes	1.34 (4)	0.73 (2)	1.05 (6)
	no	98.66 (294)	99.27 (273)	98.95 (567)
IUD acceptability	yes	1.34 (4)	0 (0)	0.70 (4)
	no	98.66 (294)	100 (275)	99.30 (569)
Injection acceptability	yes	0.67 (2)	1.45 (4)	1.05 (6)
	no	99.33 (296)	98.55 (271)	98.95 (567)
Implant acceptability	yes	0.34 (1)	0.73 (2)	0.52 (3)
	no	99.66 (297)	99.27 (273)	99.48 (570)

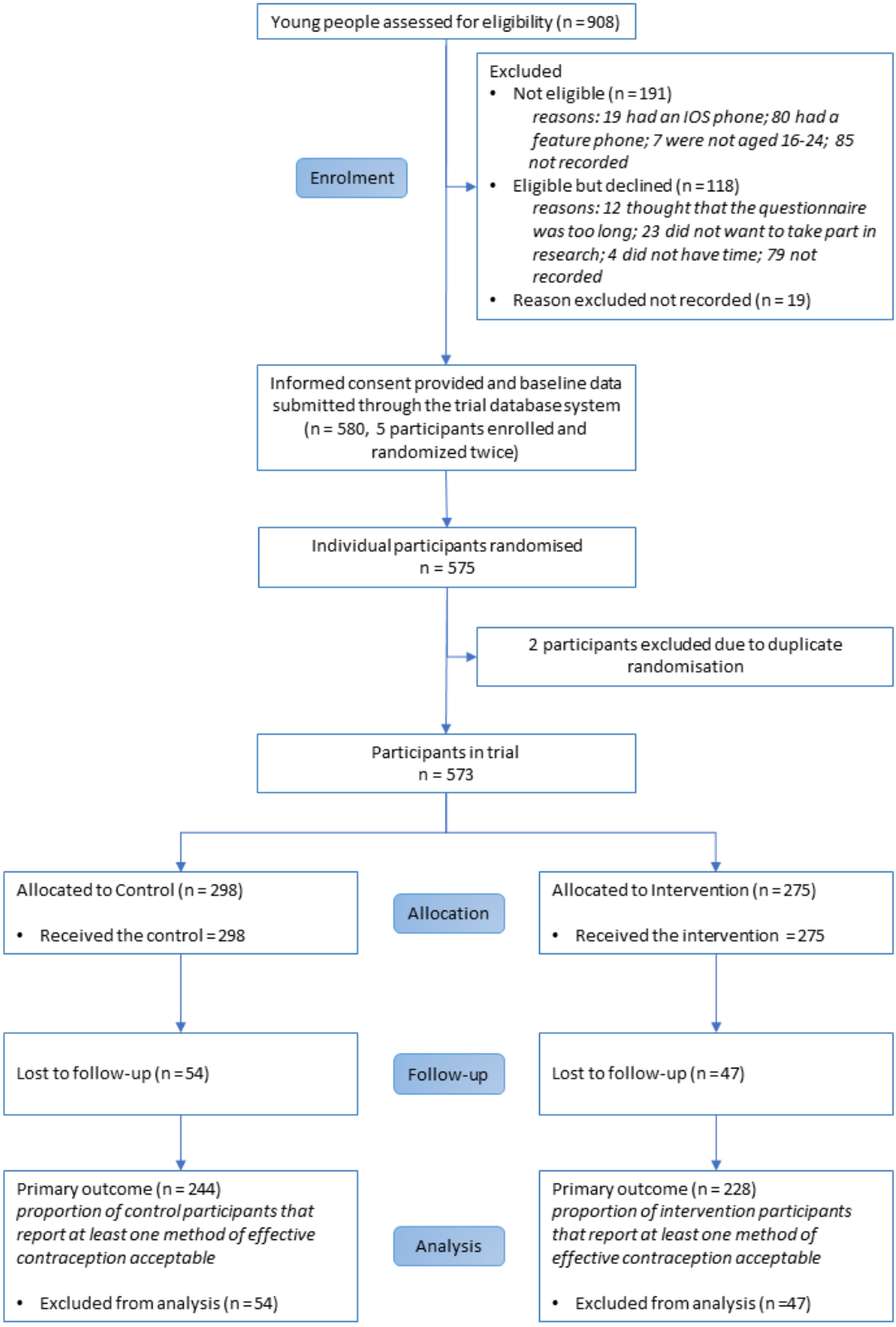
*The response ‘not married’ was used as a proxy for not being sexually active.
**IUD = intrauterine device
***LAM = Lactational amenorrhea method

Loss to follow-up

Four hundred and seventy-six participants total (83%) contributed follow-up data. Four hundred and seventy-two participants (82%) completed the trial follow-up for the primary outcome (intervention, n = 228; control, n =244) (Figure 6.1).

Retention did not differ between the arms (83% in the intervention vs 82% in the control, p=0.75). The main predictors of retention were male gender (OR 1.78, p=0.01), Tajik ethnicity (OR 2.22, p=0.03) and having completed a level of education lower than university at enrolment (OR 1.79, p=0.02). The effect of these predictors did not differ by arm (interaction test p-values: gender, p=0.72; ethnicity, p=0.41; education level, p=0.98). Detailed characteristics of follow-up completers and non-completers are reported in Appendix 17.

Figure 6.1 CONSORT diagram (Tajikistan)



Primary outcome

In the intervention arm, 66% (151/228) reported that at least one method of contraception was acceptable compared to 64% (156/244) in the control arm (Table 6.2). There was no evidence of a difference in acceptability between the groups (crude OR 1.11, 95% CI .76-1.62, p = 0.60; adjusted OR 1.21, 95% CI .80-1.83, p = 0.36).

Table 6.2 Primary outcome (Tajikistan)

	Control N = 244 % (n)	**Intervention** N = 228 % (n)	**OR (95% CI)**	**p-value**
At least one effective method is acceptable*	63.93 (156)	66.23 (151)	1.21 (.80-1.83)	0.36

**adjusted for pregnancy intention, gender, age, education level and acceptability at baseline*

Secondary outcomes

There were no significant differences in any of the secondary outcomes between the groups (Table 6.3).

Table 6.3 Secondary outcomes (Tajikistan)

	Control % (n/N)	**Intervention** % (n/N)	**OR (95% CI)**	**p-value**
Use of effective contraception*	3.66 (9/246)	1.30 (3/230)	.35 (.06-1.42)	0.18
Pill acceptability**	56.56 (138/244)	60.53 (138)	1.32 (.88-2.00)	0.18
IUD acceptability**	52.87 (129/244)	51.32 (117/228)	1.00 (.67-1.50)	0.98
Injection acceptability**	54.51 (133/244)	55.26 (126/228)	1.14 (.76-1.70)	0.52
Implant acceptability**	48.77 (119/244)	48.68 (111/228)	1.08 (.73-1.59)	0.71
Effective contraceptive use during the 4 months*	2.88 (7/243)	1.76 (4/227)	.61 (.13-2.42)	0.62
Service uptake+ (attended a service one or more times)	10.29 (25/243)	7.93 (18/227)	.76 (.39-1.46)	0.41
Unintended pregnancy+	0 (0)	0 (0)	-	-
Induced abortion+	0 (0)	0 (0)	-	-

**based on unadjusted exact logistic regression, due to small numbers*
***adjusted for pregnancy intention, gender, age, education level and the corresponding method acceptability at baseline*

[+]adjusted for pregnancy intention, gender, age, education level and acceptability at baseline

Process outcomes

There were no significant differences in any of the process outcomes between the groups (Table 6.4).

Table 6.4 Process outcomes (Tajikistan)

		Control % (n/N)	**Intervention** % (n/N)	**proportional OR*** (95% CI), p-value
Knowledge of effective contraception		Mean = 4.00 [sd = 2.04]	Mean = 4.08 [sd = 2.02]	.08** (-.29-.44), 0.69
My friends would use the pill, IUD, injection or implant if they wanted to prevent pregnancy	strongly disagree	3.70 (9/243)	1.33 (3/226)	1.40 (.97-2.01), 0.07
	disagree	4.53 (11/243)	5.31 (12/226)	
	not sure	17.28 (42/243)	16.37 (37/226)	
	agree	64.61 (157/243)	59.29 (134/226)	
	strongly agree	9.88 (24/243)	17.70 (40/226)	
My friends would talk to their husband/wife about contraception if they wanted to prevent a pregnancy	strongly disagree	1.23 (3/243)	1.33 (3/226)	1.09 (.76-1.57), 0.64
	disagree	5.35 (13/243)	6.64 (15/226)	
	not sure	16.05 (39/243)	15.93 (36/226)	
	agree	65.02 (158/243)	59.29 (134/226)	
	strongly agree	12.35 (30/243)	16.81 (38/226)	
If you wanted to use the pill, IUD, injection or implant, how easy would it be for you to use it? (women only)	very difficult	7.62 (8/105)	5.83 (6/103)	1.43 (.87-2.34), 0.16
	difficult	17.14 (18/105)	9.71 (10/103)	
	not sure	27.62 (29/105)	29.13 (30/103)	
	easy	38.10 (40/105)	43.69 (45/103)	
	very easy	9.52 (10/105)	11.65 (12/103)	
If you wanted to talk to your husband/wife about contraception, how easy would it be for you to talk to him/her?	very difficult	3.70 (9/243)	3/10 (7/226)	1.22 (.86-1.73), 0.26
	difficult	6.17 (15/243)	7.52 (17/226)	
	not sure	14.81 (36/243)	14.16 (32/226)	
	easy	60.49 (147/243)	53.10 (120/226)	
	very easy	14.81 (36/243)	22.12 (50/226)	
If you wanted to use the pill, IUD, injection or implant, how certain are you that you could use it? (women only)	very certain I could not	2.86 (3/105)	5.83 (6/103)	.99 (.60-1.63), 0.96
	certain I could not	6.67 (7/105)	7.77 (8/103)	
	not sure	38.10 (40/105)	32.04 (33/103)	
	certain I could	40.00 (42/105)	41.75 (43/103)	
	very certain I could	12.38 (13/105)	12.62 (13/103)	

		Control % (n/N)	**Intervention** % (n/N)	**proportional OR*** (95% CI), p-value
If you wanted to talk to your husband/wife about contraception, how certain are you that you could talk to him/her?	very certain I could not	1.23 (3/243)	2.65 (6/226)	1.10 (.78-1.53), 0.60
	certain I could not	13.17 (32/243)	12.39 (28/226)	
	not sure	16.46 (40/243)	16.81 (38/226)	
	certain I could	50.62 (123/243)	44.25 (100/226)	
	very certain I could	18.52 (45/243)	23.89 (54/226)	
I intend to use the pill, IUD, injection or implant	strongly disagree	4.76 (5/105)	2.91 (3/103)	1.37 (.84-2.25), 0.21
	disagree	10.48 (11/105)	12.62 (13/103)	
	not sure	31.43 (33/105)	25.24 (26/103)	
	agree	39.05 (41/105)	34.95 (36/103)	
	strongly agree	14.29 (15/105)	24.27 (25/103)	
Number of messages read	all		32.16 (73/227)	
	most		43.61 (99/227)	
	some		18.50 (42/227)	
	none		5.73 (13/227)	
Proportion of intervention participants that stopped the intervention			29.07 (66/227)	

**estimated from ordered logistic regression*
***mean difference*

Potential for contamination

Three percent (8/243) of control participants said that they read the messages of someone else in the study. Nine percent (21/227) of intervention participants said that someone else in the study read their messages.

Participants' report of physical violence during the study

Overall, 0.85% (4/470) reported that they experienced physical violence since being in the study (0.41% in the control and 1.32% in the intervention, Pearson's chi^2 p = 0.28).

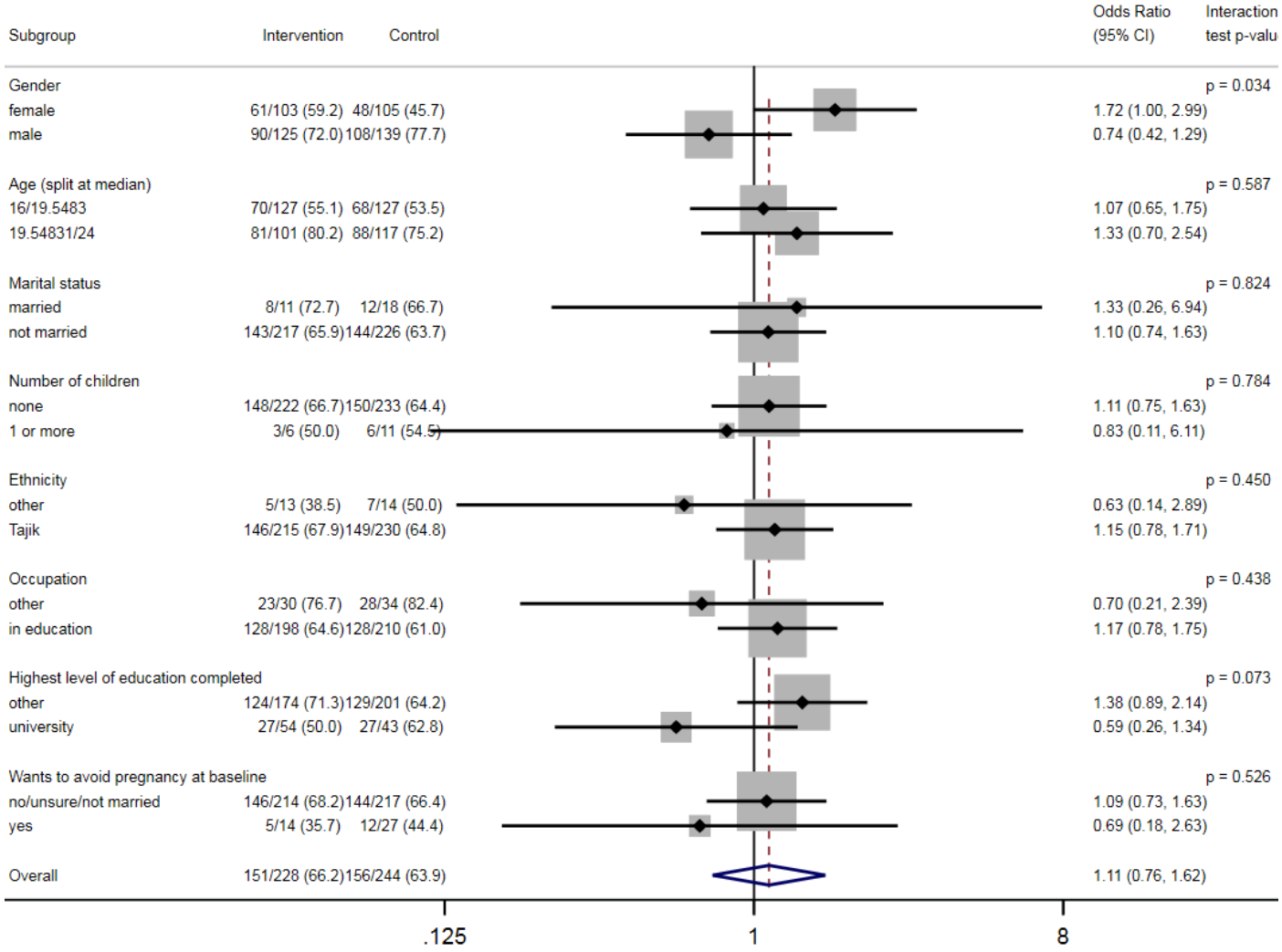
Sensitivity analyses

The effect of the intervention on the primary outcome observed in the principal analysis did not change when we considered participants lost to follow-up did not find at least one method acceptable (OR 1.20, 95% CI .84-1.73, p=0.31) or when we adjusted the model for the predictors of missingness (OR 1.21, 95% CI .80-1.85, p=0.35).

Subgroup analysis

There was some evidence that the effect of the intervention was greater among women compared to men (interaction test p=0.03) (Figure 6.2).

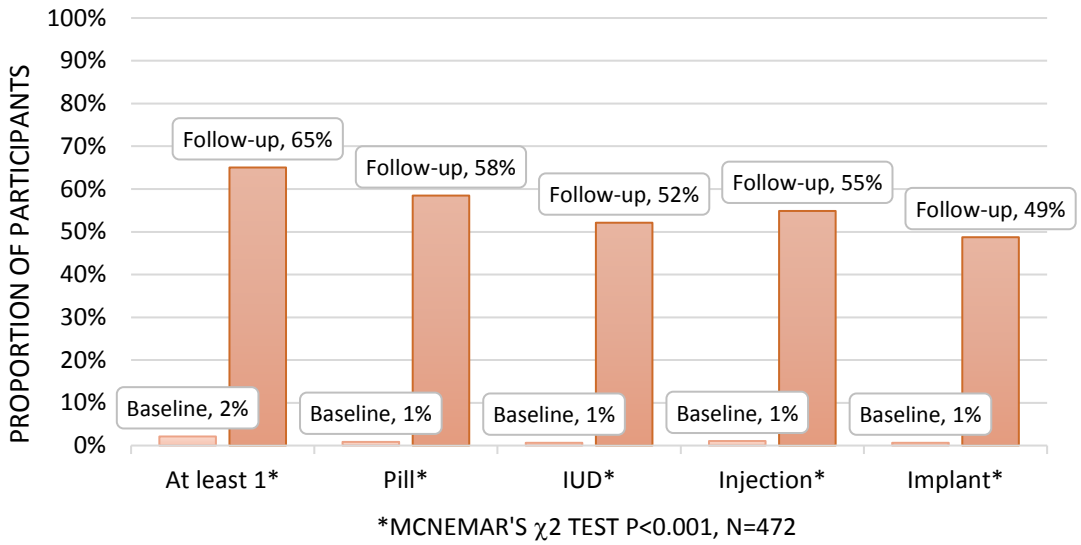
Figure 6.2 Intervention effect on acceptability of effective contraception, by subgroups (Tajikistan)



Change from baseline analysis

Among the 472 participants who completed follow-up 2% (n=10) thought that at least one method was acceptable at baseline, which increased to 65% at follow-up (n=307, p<0.001) (Figure 6.3). Acceptability for the individual methods increased from 1% at baseline to 49%-58% at follow-up (p<0.001).

Figure 6.3 Method acceptability at baseline and follow-up (Tajikistan)



6.2.6 Discussion

Main results

Contrary to what was planned in the trial protocol, the app contained intervention content. Both intervention and control participants received intervention content targeting knowledge and attitudes towards effective contraception, including the BCM 'belief selection'. The trial therefore evaluated the effect of the whole intervention with all ten BCMs (belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting) delivered by instant messaging, compared to a proportion of the intervention delivered on the app pages with the BCM belief selection.

The trial found no evidence of a difference in acceptability of at least one effective contraceptive method between the intervention and control groups. There was also no evidence of a difference in any of the secondary and process outcomes between the groups (use of effective contraception, service uptake, knowledge, perceived norms, personal agency and intention to use effective contraception). This indicates that the intervention content delivered by the intervention messages only (includes nine additional BCMs targeting

attitudes and personal agency) did not have an additional benefit over the app regarding these outcomes. The subgroup analysis suggests that the intervention delivered by instant messaging could be more effective among women compared to men. When data from both groups were analysed together, there was a large statistically significant increase in acceptability from baseline to follow-up.

Comparisons with other research

Trials that have evaluated interventions delivered by mobile phone to improve contraceptive-related outcomes have had mixed results (44, 134-137, 140, 142, 143, 152, 161, 202). We are conducting trials in Bolivia and Palestine that are evaluating the effect of interventions similar to the Tajik intervention on acceptability and use of effective contraception (52, 204). The results of the three trials together should contribute to a better understanding of the effect of the intervention evaluated in this Tajik trial.

Our trial shows no additional benefit on the outcomes from the nine BCMs deliver by instant messaging. No previous research reports the effectiveness of these BCMs aimed at improving contraceptive-related outcomes delivered by mobile phone (133).

Ongoing trials of interventions delivered by mobile phone to improve reproductive health are measuring participants' experience of violence during their participation in the trial (52, 204, 205). In this Tajik trial, we found no association between the intervention and experience of violence. While this is reassuring, both groups had access to the app, so we are unable to assess the effect of the app on partner violence.

Strengths and limitations

The trial conduct has a number of strengths. We recruited our target number of participants and were able to collect follow-up data for an acceptable proportion of them, given that the sample size allowed for 20% loss. We developed and tested a remote trial database and randomization system, which successfully generated and concealed the allocation sequence and achieved well-balanced groups. An important limitation is that the app included intervention content, as discussed above. This constitutes a protocol deviation and the trial was therefore not able to answer the primary question it aimed to answer. Because the self-reported acceptability scales were collected by telephone by the research staff, participants may have been more likely to report positive attitudes than they were at baseline where they

completed the questionnaire by themselves on their phones. Regarding the large increase in acceptability from baseline to follow-up, we cannot rule out the possibility that at least a portion of this increase was due to participation in the trial as opposed to the intervention itself; participants were aware that the trial involved changing attitudes towards contraception. Five participants enrolled and were randomized twice.

There were inconsistencies in participants' self-reporting of marital status. The proportion that responded 'not married' to the current pregnancy intention (495/573, 86%) and the baseline method question (384/573, 67%) is lower than the proportion that responded 'not married' when asked directly about their marital status (537/573, 94%). We cannot say why these inconsistencies occurred. However, we can speculate that some participants who responded 'not married' to the marital status question were sexually active and responded to the other two questions with responses other than 'not married'.

Thirty six percent of people assessed for eligibility (328/908) were excluded from the study. The reason for ineligibility was not recorded for 85 people, which could limit the generalizability of the trial findings. While the recording of this information was not complete, of those that are known, the majority appear to have been excluded because they did not have an Android phone (n = 99). If those who did not own a smartphone were less likely to find at least one method of effective contraception acceptable, this could have affected the generalizability of the results. Smartphone ownership is rapidly increasing however, and ownership could be an option for a greater proportion of young people across different socioeconomic communities in the near future.

Implications of the findings

The finding that the intervention instant messages did not have an additional benefit over the app along with the large increase in acceptability from baseline to follow-up suggests that participants read the app contraception pages. It may be that in a context such as Tajikistan, where young people have limited access to information and support about reproductive health, they are willing to read static app pages about this topic. In comparison, a trial in the United Kingdom found that young people did not engage heavily with a sexual and reproductive health website (206, 207). In contexts such as the United Kingdom where information and support are more accessible, interventions delivered on app pages and websites may be utilized less frequently than in contexts such as Tajikistan.

Because the intervention content included on the app aimed to improve knowledge of and attitudes towards effective contraception, it is not surprising that there was no evidence of a difference between the groups regarding these outcomes. Though the large increase in acceptability from baseline to follow-up cannot be unequivocally attributed to the intervention content, an increase this large suggests that the intervention content included on the app at least was partially effective in improving attitudes towards the effective methods. Because the intervention is well-specified, we were able to identify the components of the intervention that may have been effective in producing this change (accurate information and targeting beliefs using the BCM belief selection) (122, 124).

Despite the contamination that occurred, intervention participants received content that control participants did not. The secondary outcomes use and service uptake and the process outcomes personal agency and intention are related to the content that only intervention participants received. There are a number of potential explanations for why we did not observe a difference between the groups in these outcomes. The first is that the BCMs targeting these outcomes did not work. This could have been because the conditions under which the methods have been shown to be effective were not fully satisfied (122, 124). In addition, because a large proportion of meaning comes from visual cues in face-to-face interaction (124), some of the meaning of the BCMs may have been lost when delivered by mobile phone. For example, the BCM 'guided practice' requires skill demonstration, enactment and individual feedback. While the intervention messages demonstrated and provided instruction, we were not able to observe the participant enacting the behavior or to provide individual feedback. This may have resulted in a loss of effectiveness of the BCM. Another explanation is that intervention could be more effective on these secondary and process outcomes with people where the behaviour is salient, such as with those who are married/sexually active or soon to be. In this trial however, only 6% (36/573) were married/sexually active, which was too small to explore this possibility. Alternatively, the app alone may have been effective in influencing these secondary and process outcomes; in the Tajik context, providing accurate information from a credible source and targeting the pre-identified beliefs may be sufficient. Finally, these secondary and process outcomes could have be so strongly influenced by environmental conditions (e.g. stigma regarding sexual activity before marriage and pressure to bear children) that they were not amenable to change by a mobile phone intervention only.

While caution is necessary in interpreting the results of the subgroup analysis, it suggests that the whole intervention delivered by instant messaging could be more effective among women compared to men. The trials in Bolivia and Palestine involve women only so the results should provide additional evidence of the intervention's effectiveness in women.

We are currently conducting qualitative interviews with trial participants to explore their experiences in receiving the intervention and app content. If participants were positive about receiving the intervention messages, this could support the delivery of the messages with the download of the app. The fact that the intervention is already developed and therefore inexpensive to deliver, plus the fact that it does not appear to cause harm, also supports the delivery of the messages with the download of the app.

Conclusions

This trial demonstrated that the whole intervention delivered by app instant messaging provided no additional benefit over a portion of the intervention delivered by the app pages. An analysis of participants randomized to the control and intervention groups together showed a large significant increase in acceptability from baseline to follow-up. Further research is needed to establish the effect of the intervention on attitudes towards and use of effective contraceptive methods among married/sexually active young people.

7 Palestine evaluation results

7.1 Introduction

This chapter includes the results of the Palestine randomised controlled trial. I submitted the manuscript to *Trials* on 24 August 2018. At the time of thesis submission in November 2018, the manuscript was under review.

RESEARCH PAPER COVER SHEET

Student details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Prepared for publication, but not yet published

Where is the work intended to be published?	*Trials*
Please list the paper's authors in the intended authorship order:	McCarthy OL, Zghayyer H, Stavridis A, Adada S, Ahamed I, Leurent B, Edwards P, Palmer M, Free C
Stage of publication	**Submitted**

Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed and managed the trial, conducted the analysis and wrote the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

7.2 Research paper

7.2.1 Abstract

Background

Research has shown that mobile phone contraceptive behavioral interventions can increase knowledge and use of contraception, but other studies have failed to demonstrate a beneficial effect. The objective of this trial was to estimate the effect of a contraceptive behavioral intervention delivered by mobile phone text message on young Palestinian women's attitudes towards effective contraception.

Methods

We conducted a randomized controlled trial among women aged 18-24 years not using an effective method of contraception living in the West Bank. The intervention group received the intervention messages. The control group received messages about trial participation. The primary outcome was acceptability of at least one method of effective contraception at four months. Secondary outcomes were use of effective contraception at four months and during the study, acceptability of individual methods, service uptake, unintended pregnancy and abortion. Process outcomes included knowledge, perceived norms, personal agency and intention. We analyzed the outcomes using logistic and linear regression.

Results

578 participants were enrolled and 464 (80%) completed follow-up at 4 months. Intervention group participants were more likely to find at least one method of effective contraception acceptable (31% in the intervention group vs. 17% in the control group, adjusted OR 2.34, 95% CI 1.48-3.68, $p < 0.001$). They had a higher mean knowledge score, were more likely to find individual methods acceptable, to agree that their friends would use an effective method and to intend to use an effective method compare to participants in the control group.

Conclusions

The intervention can improve attitudes, knowledge perceived norms and intention to use effective contraception among young women in Palestine. Future implementation research is needed.

Trial registration: ClinicalTrials.gov Identifier NCT02905461

Date of registration: 14 September 2016

URL of trial registry record: https://clinicaltrials.gov/ct2/show/NCT02905461

World Health Organization Trial Registration Data Set:
http://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT02905461

Keywords

Palestine, Contraception, mHealth, Family Planning, Young adults

7.2.2 Background

Unintended pregnancy continues to be a global health problem (24). Women with an unmet need for modern contraception account for an estimated 84% of all unintended pregnancies in developing regions (159). Satisfying unmet need for modern contraception is essential in avoiding unintended pregnancies and identifying the barriers that prevent people from using the methods can help achieve this (26, 201).

Sexual and reproductive health in the State of Palestine (the West Bank, East Jerusalem and the Gaza Strip, hereafter referred to as 'Palestine') has been negatively affected by the conflict (22, 94). It is estimated that 38% of pregnancies are unintended (104), with unmet need for contraception peaking among women aged 20-24, at 15% (96). While the adolescent fertility rate had decreased substantially over the past 20 years, the current adolescent fertility rate of 48 per 1,000 women aged 15-19 remains higher than most other countries in the region (96, 97). The Palestinian Family Survey 2010 found that among married women not using contraception and not reporting wanting to have a child, the main reasons given for not using contraception were fear of side effects, inconvenience of methods and their husband's opposition (98, 99).

Mobile phones are commonly used to deliver health behavioral support (36-41, 43). In Palestine, delivering contraceptive support by mobile phone may be an advantageous mode by which to reach people in the substantial area that is underserved with regard to sexual and reproductive health services (93). There is some evidence from trials that interventions delivered by mobile phone can improve contraceptive use (134, 135, 143, 161) and

knowledge (140, 142, 152), however other trials have not found a beneficial effect (44, 136, 137, 202).

The London School of Hygiene and Tropical Medicine (LSHTM) and the Palestinian Family Planning and Protection Association (PFPPA) developed a contraceptive behavioral intervention in Palestine delivered by mobile phone (50). This paper reports the results of the evaluation of the intervention.

7.2.3 Methods

The methods are summarized in this section. Detailed methods are published in the trial protocol (52) and the statistical analysis plan (208).

Aim, study design and participants

This was a parallel group, individually randomized trial with a 1:1 allocation ratio. The aim was to assess the effect of the intervention on attitudes towards the non-permanent effective contraceptive methods (28-30) available in Palestine (oral contraceptive pills (OCs), intrauterine devices (IUDs), injectables, implants and the patch). Women were eligible to take part if they were between 18 and 24 years, did not report using an effective method of contraception, owned a personal mobile phone, lived in the West Bank and could read Arabic. We recruited participants through PFPPA's service delivery points and outreach sites in Jerusalem, Bethlehem, Halhoul and Ramallah.

Intervention and control

The intervention consisted of short mobile phone text messages, tailored to marital status, delivered over four months (50). The intervention messages contained information and 10 behavior change methods (BCM) (122), adapted for delivery by mobile phone. Participants allocated to the intervention group received the intervention text messages and participants allocated to the control group received control messages about trial participation. Details regarding the development of the intervention can be found in the intervention development publication (50) and the trial protocol (52).

Allocation and intervention delivery

The online trial database and randomization system generated the allocation sequence and randomization occurred immediately after the baseline data were submitted by clinic

research staff. The system sent the Palestinian texting platform the allocation, preferred time slot for message delivery, mobile phone number and marital status.

Protecting against bias

Participants would have been aware of the allocation after they started receiving the messages. Research staff collecting outcome data were masked to allocation unless the participant revealed it to them. Researchers who analyzed the data were masked to treatment allocation.

Outcomes

Primary outcome

The primary outcome was the proportion of participants reporting that at least one method of effective contraception was acceptable at four months post randomization. The acceptability of each method was measured by the following stems: Using the [method] …causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy and I would recommend the [method] to a friend. The IUD and implant include an additional stem: The [method] insertion would not be a problem for me. The response options for each stem were: 'strongly disagree', 'disagree', 'not sure', 'agree', 'strongly agree' and 'I do not know what the [method] is'. A method was acceptable if participants reported agree or strongly agree for all stems except for …causes infertility and …causes unwanted side effects, for which disagree or strongly disagree indicated acceptability (52).

Secondary outcomes

Secondary outcomes were: use of effective contraception at four months and during the study; acceptability of individual methods; service uptake, unintended pregnancy and abortion.

Process outcomes

The process outcomes were: knowledge of effective contraception; perceived norms and personal agency in relation to using and communicating with partners about contraception; intention to use effective contraception and intervention dose received.

Data collection

At baseline, we collected personal and demographic data and the primary outcome via self-completed paper questionnaire. At four-month follow-up we collected all outcomes. Staff masked to treatment allocation collected the follow-up data verbally by telephone.

Sample size

The trial was powered to detect a 15% absolute increase in acceptability of effective contraception in the intervention group compared to the control group. Four hundred and fifty-four participants would provide 90% power to detect a 15% absolute increase in acceptability, at the 5% significance level, assuming 50% acceptability in the control group. We allowed for 20% loss to follow-up and aimed to randomize 570 participants.

Statistical analysis

The trial protocol was accepted for publication on September 14, 2017 (52) and the detailed statistical analysis plan was publicly released before conducting the data analysis, on November 7, 2017 (208). Analyses were conducted according to randomized group and only participants with complete outcome data were included in the principal analysis. All statistical tests were two-sided and considered significant at the 5% level. The analysis was conducted using Stata 15. Unmasking occurred on February 6, 2018, after the analyses outlined within the analysis plan were completed on masked data.

Loss to follow-up and missing data

We used a chi-squared test to investigate whether loss to follow-up differed by trial arm. We used logistic regression to compare baseline characteristics of participants who completed follow-up with participants who did not. We investigated whether predictors of loss to follow-up differed by trial arm by testing for an interaction.

Principal analysis

Analysis of the primary outcome

We compared the proportion of participants that reported that at least one method was acceptable in each trial arm using logistic regression. We report the crude and adjusted odds ratio (OR) along with a 95% confidence interval (CI) and p-value. We adjusted the primary analysis regression for pre-specified baseline covariates (52, 208).

Analysis of the secondary outcomes

The analysis of the secondary outcomes was similar to the analysis of the primary outcome, although with acceptability of the individual methods, the acceptability of that method at baseline replaced the acceptability of at least one method at baseline as a covariate.

Analysis of the process outcomes

The process outcomes perceived norms, personal agency and intention were each comprised of ordinal scales. Each scale was analyzed individually using ordered logistic regression. For knowledge, we used linear regression to assess the difference in the mean scores between the groups. To quantify the 'dose' of the intervention that the intervention participants received, we analyzed the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages, along with our monitoring data.

Additional analyses

Sensitivity analyses

We conducted two sensitivity analyses to account for missing data. In the first, we considered that all participants lost to follow-up did not find at least one method acceptable. In the second, we adjusted for the main baseline predictors of missingness. Both sensitivity analyses were adjusted for the baseline covariates as above.

Subgroup analysis

We conducted an exploratory subgroup analysis for the primary outcome with pre-specified subgroups (208). Within the subgroups, we assessed heterogeneity of the estimated treatment effect with a test for interaction (197, 198). We estimated ORs with 95% CIs for each subgroup.

Contamination

We report the proportion of control group participants that reported that they read another participant's messages and the proportion of intervention participants that reported that their messages were read by another participant.

Report of physical violence

We report the proportion of participants in each group that reported experiencing physical violence during the study.

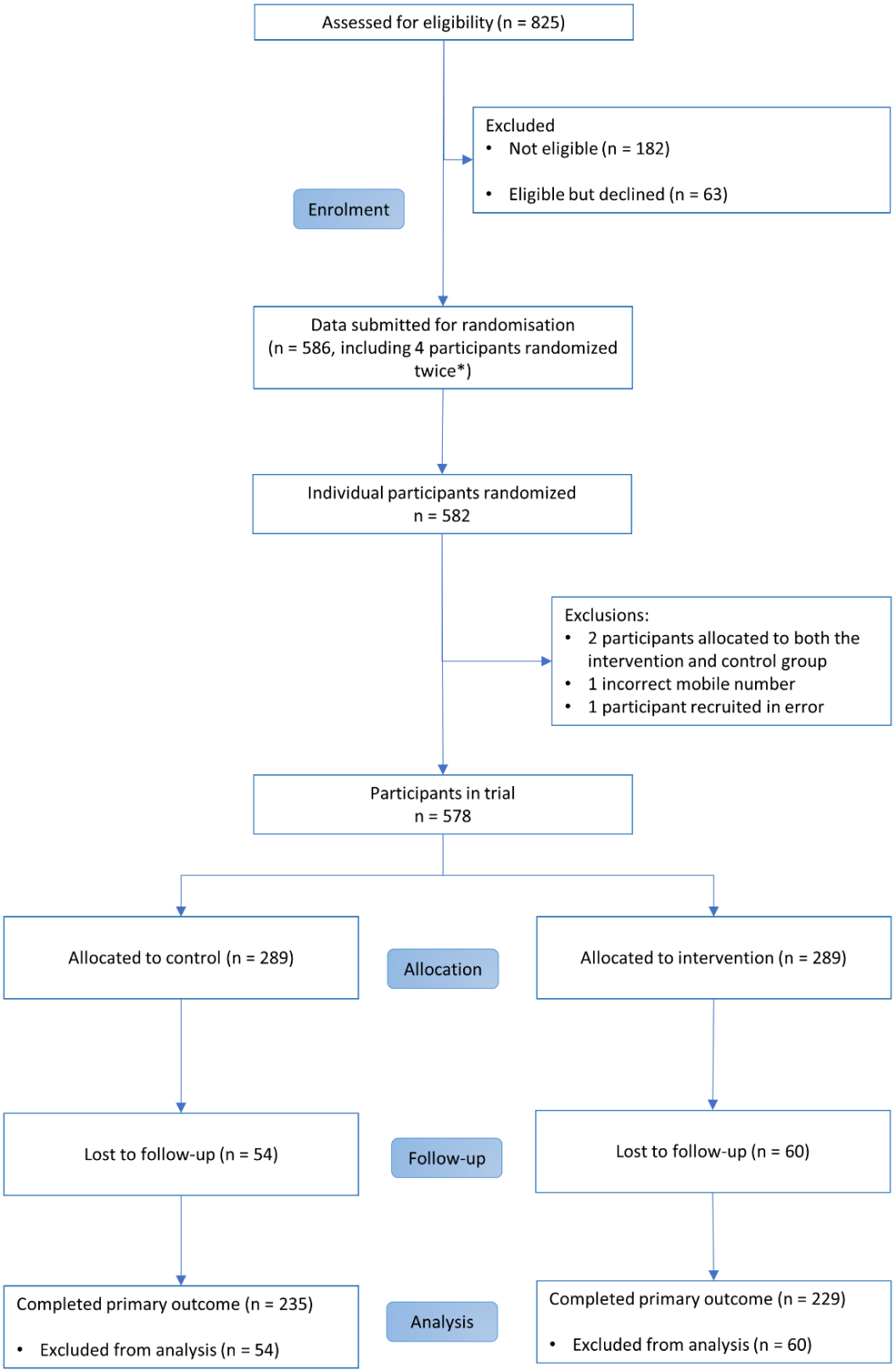
7.2.4 Results

Recruitment, randomization, exclusions

Between December 8, 2016 and July 22, 2017, there were 586 randomizations by the system. During the trial follow-up, we discovered that four participants enrolled and were randomized twice. For the two participants who were allocated to the same group on both randomizations, we kept them in the trial using the baseline data from their first record (the system allowed only one follow-up record). We excluded the two participants who were allocated to different groups from the analysis.

In addition, one record was excluded because the participant's incorrect mobile number was entered onto the database (the correct record and number was kept) and another record was excluded because the participant was recruited in error (the participant was using the IUD and was therefore ineligible). This resulted in 578 participants included in the trial (Figure 7.1). Two hundred and eighty-nine participants were allocated to the intervention group and to the control group. No participants withdrew from the trial after allocation.

Figure 7.1 CONSORT diagram (Palestine)



*2 participants allocated to the same group on both randomizations and 2 participants allocated to different groups

Baseline characteristics

Baseline characteristics of trial participants are reported in Table 7.1. Mean age was 21 years, and 71% (409/578) were aged 20-24 years. Sixty percent were not married (259/573) and only 8% (47/578) found at least one method of effective contraception acceptable. Characteristics were largely similar between the two groups, however, almost twice as many participants in the control group reported that at least one method of effective contraception was acceptable at baseline compared to the intervention group (10.38% in the control vs 5.88% in the intervention, see discussion).

Table 7.1 Baseline characteristics (Palestine)

		Control N = 289 % (n)	**Intervention** N = 289 % (n)	**All participants** N = 578 % (n)
Age	mean [sd]	21.36 [1.77]	21.18 [1.75]	21.27 [1.76]
	18-19	25.95 (75)	32.53 (94)	29.24 (169)
	20-24	74.05 (214)	67.47 (195)	70.76 (409)
Marital status	married	40.48 (117)	38.75 (112)	39.62 (229)
	not-married	59.52 (172)	61.25 (177)	60.38 (349)
Number of children	0	72.32 (209)	79.58 (230)	75.95 (439)
	1	16.26 (47)	10.73 (31)	13.49 (78)
	2 or more	11.42 (33)	9.69 (28)	10.55 (61)
Residence	city	46.71 (135)	47.75 (138)	47.23 (273)
	village	48.10 (139)	46.71 (135)	47.40 (274)
	camp	4.15 (12)	4.84 (14)	4.50 (26)
	Bedouin community	1.04 (3)	0.69 (2)	0.87 (5)
Occupation	school	1.73 (5)	0.35 (1)	1.04 (6)
	university	48.44 (140)	52.60 (152)	44.64 (258)
	working	5.19 (15)	3.46 (10)	4.33 (25)
	training	14.88 (43)	15.92 (46)	15.22 (88)
	parent	22.49 (65)	20.07 (58)	20.59 (119)
	not working	5.88 (17)	6.57 (19)	6.23 (36)
	university & working	0.35 (1)	0.35 (1)	0.35 (2)
	university & parent	0.69 (2)	-	0.35 (2)
	school & parent	0.35 (1)	0.35 (1)	0.35 (2)
	working, training & parent	-	0.35 (1)	0.17 (1)
Highest level of education completed	primary	0.69 (2)	0.69 (2)	0.69 (4)
	secondary	22.84 (66)	21.11 (61)	21.97 (127)
	university	66.09 (191)	66.44 (192)	66.26 (383)
	technical	10.38 (30)	11.76 (34)	11.07 (64)
Current pregnancy intention (‘*Do you want a pregnancy now?)*	yes	16.26 (47)	20.07 (58)	18.17 (105)
	no	25.61 (74)	24.57 (71)	25.09 (145)
	unsure	4.15 (12)	1.38 (4)	2.77 (16)
	not married [a]	53.98 (156)	53.98 (156)	53.98 (312)
Baseline method	none	39.45 (114)	41.52 (120)	40.48 (234)
	male condom	0.69 (2)	0.69 (2)	0.69 (4)
	not married [a]	53.63 (155)	54.33 (157)	53.98 (312)
	calendar	1.04 (3)	0.35 (1)	0.69 (4)
	LAM [b]	3.11 (9)	1.38 (4)	2.25 (13)

		Control N = 289 % (n)	Intervention N = 289 % (n)	All participants N = 578 % (n)
	withdrawal	2.08 (6)	1.38 (4)	1.73 (10)
	other	-	0.35 (1)	0.17 (1)
At least one effective method is acceptable	yes	10.38 (30)	5.88 (17)	8.13 (47)
	no	89.62 (259)	94.12 (272)	91.87 (531)
Pill acceptability	yes	3.81 (11)	3.11 (9)	3.46 (20)
	no	96.19 (278)	96.89 (280)	96.54 (558)
IUD [c] acceptability	yes	4.50 (13)	1.73 (5)	3.11 (18)
	no	95.50 (276)	98.27 (284)	96.89 (560)
Injection acceptability	yes	1.38 (4)	1.38 (4)	1.38 (8)
	no	98.62 (285)	98.62 (285)	98.62 (570)
Implant acceptability	yes	3.11 (9)	1.73 (5)	2.42 (14)
	no	96.89 (280)	98.27 (284)	97.58 (564)
Patch acceptability	yes	0.69 (2)	0.35 (1)	0.52 (3)
	no	99.31 (287)	99.65 (288)	99.48 (575)

[a] the response 'not married' was used as a proxy for sexual activity
[b] LAM Lactational amenorrhea method
[c] IUD Intrauterine device

Loss to follow-up

Four hundred and sixty-four participants (80%) completed the trial follow-up for the primary outcome (control, n = 235; intervention, n = 229) (Figure 7.1). Retention did not differ between the groups (81% in the control and 79% in the intervention group, Pearson's chi squared test p = 0.53). The main predictor of retention was completion of university at enrolment (OR 1.80, 95% CI 1.18-2.73, p = 0.01). The effect of this predictor of retention did not differ by group (interaction test p = 0.78). Detailed characteristics of follow-up completers and non-completers are reported in Appendix 18.

Primary outcome

In the intervention group, 31% (71/229) reported that at least one method of contraception was acceptable compared to 17% (40/235) in the control group (Table 7.2). Participants in the intervention group had 2.34 times the odds of finding at least one method of effective contraception acceptable compared to participants in the control group (adjusted OR 2.34, 95% CI 1.48-3.68, p < 0.001; crude OR 2.19, 95% CI 1.41-3.40, p < 0.001).

Table 7.2 Primary outcome (Palestine)

	Control N = 235 % (n)	Intervention N = 229 % (n)	adjusted OR (95% CI)	p-value
	17.02 (40)	31.00 (71)		< 0.001

At least one effective method is acceptable*			2.34 (1.48-3.68)	

*adjusted for pregnancy intention, age, number of children, education level and acceptability at baseline

Secondary outcomes

The odds of finding the IUD, injection, implant, patch and a LARC method were greater in the intervention group compared to the control group and were statistically significant (Table 7.3). The odds of using effective contraception was also greater in the intervention group, however this could likely have occurred by chance.

Table 7.3 Secondary outcomes (Palestine)

	Control % (n/N)	**Intervention** % (n/N)	**adjusted OR (95% CI)**	**p-value**
Use of effective contraception*	8.51 (20/235)	8.73 (20/229)	1.42 (.66-3.07)	0.37
Pill acceptability**	4.68 (11/235)	6.11 (14/229)	1.39 (.61-3.16)	0.44
IUD acceptability**	6.38 (15/235)	13.97 (32/229)	2.76 (1.41-5.40)	0.003
Injection acceptability**	1.70 (4/235)	5.68 (13/229)	3.16 (.99-10.08)	0.05
Implant acceptability**	5.53 (13/235)	11.79 (27/229)	2.46 (1.19-5.07)	0.02
Patch acceptability**	2.55 (6/235)	10.04 (23/229)	4.17 (1.63-10.64)	0.003
LARC acceptability**	11.91 (28/235)	23.14 (53/229)	2.49 (1.48-4.18)	0.001
Effective contraceptive use during the 4 months*	8.09 (19/235)	10.04 (23/229)	1.95 (.90-4.25)	0.09
Service uptake* (attended a service one or more times)	37.02 (87/235)	42.79 (98/229)	1.38 (.94-2.04)	0.10
Unintended pregnancy*	3.11 (9/289)	2.42 (7/289)	.75 (.27-2.10)	0.59
Induced abortion*	2.55 (6/235)	1.31 (3/229)	.47 (.11-1.95)	0.30

*adjusted for pregnancy intention, age, number of children, education level and acceptability at baseline

**adjusted for pregnancy intention, age, number of children, education level and the corresponding method acceptability at baseline

Process outcomes

Participants in the intervention group had a higher mean knowledge score, were more likely to agree that their friends would use an effective method and were more likely to respond

that they intend to use an effective method compare to participants in the control group (Table 7.4).

Table 7.4 Process outcomes (Palestine)

		Control % (n/N)	Intervention % (n/N)	proportional OR [a] (95% CI), p-value
Knowledge of effective contraception		Mean = 2.13 [sd = 1.42]	Mean = 2.63 [sd = 1.66]	0.50 [b] (0.22-0.78), 0.001
My friends would use the pill, IUD, injection or implant if they wanted to prevent pregnancy	strongly disagree	0.85 (2/235)	0.44 (1/229)	1.46 (1.00-2.13), 0.05
	disagree	9.36 (22/235)	5.68 (13/229)	
	not sure	21.70 (51/235)	17.03 (39/229)	
	agree	62.13 (146/235)	70.74 (162/229)	
	strongly agree	5.96 (14/235)	6.11 (14/229)	
My friends would talk to their husband about contraception if they wanted to prevent a pregnancy	strongly disagree	-	-	0.92 (0.63-1.34), 0.66
	disagree	2.55 (6/235)	2.62 (6/229)	
	not sure	18.30 (43/235)	19.65 (45/229)	
	agree	66.38 (156/235)	65.94 (151/229)	
	strongly agree	12.77 (30/235)	11.79 (27/229)	
If you wanted to use the pill, IUD, injection or implant, how easy would it be for you to use it?	very difficult	0.85 (2/235)	1.31 (3/229)	1.26 (0.89-1.78), 0.19
	difficult	9.79 (23/235)	8.73 (20/229)	
	not sure	48.94 (115/235)	41.05 (94/229)	
	easy	35.32 (83/235)	46.29 (106/229)	
	very easy	5.11 (12/235)	2.62 (6/229)	
If you wanted to talk to your husband about contraception, how easy would it be for you to talk to him?	very difficult	1.28 (3/235)	1.75 (4/229)	0.83 (0.59-1.17), 0.29
	difficult	7.23 (17/235)	9.61 (22/229)	
	not sure	17.87 (42/235)	17.47 (40/229)	
	easy	51.49 (121/235)	52.84 (121/229)	
	very easy	22.13 (52/235)	18.34 (42/229)	
If you wanted to use the pill, IUD, injection or implant, how certain are you that you could use it?	very certain I could not	1.28 (3/235)	0.87 (2/229)	1.19 (0.84-1.68), 0.33
	certain I could not	4.68 (11/235)	4.37 (10/229)	
	not sure	43.40 (102/235)	39.74 (91/229)	
	certain I could	43.83 (103/235)	47.16 (108/229)	
	very certain I could	6.81 (16/235)	7.86 (18/229)	

		Control % (n/N)	Intervention % (n/N)	proportional OR [a] (95% CI), p-value
If you wanted to talk to your husband about contraception, how certain are you that you could talk to him?	very certain I could not	-	-	1.05 (0.73-1.50), 0.80
	certain I could not	2.55 (6/235)	3.49 (8/229)	
	not sure	18.72 (44/235)	11.79 (27/229)	
	certain I could	53.62 (126/235)	63.32 (145/229)	
	very certain I could	25.11 (59/235)	21.40 (49/229)	
I intend to use the pill, IUD, injection, implant or patch	strongly disagree	2.13 (5/235)	2.62 (6/229)	1.85 (1.29-2.65), 0.001
	disagree	13.62 (32/235)	4.37 (10/229)	
	not sure	24.68 (58/235)	18.34 (42/229)	
	agree	51.06 (120/235)	63.76 (146/229)	
	strongly agree	8.51 (20/235)	10.92 (25/229)	
Number of messages read	all		62.88 (144/229)	
	most		21.83 (50/229)	
	some		11.35 (26/229)	
	none		3.93 (9/229)	
Proportion of intervention participants that stopped the intervention			3.93 (9/229)	

[a] estimated from ordered logistic regression

[b] mean difference

Potential for contamination

Seventeen percent (39/235) of control participants said that they read the messages of someone else in the study. Seventeen percent (40/229) of intervention participants said that someone else in the study read their messages.

Report of physical violence

In the intervention group, 0.87% (2/229) reported that they experienced physical violence since being in the study vs 2.13% (5/235) in the control group (Fisher's exact test p=0.45).

Participants' report of anything good or bad that happened during the study

Most intervention participants that answered this question (193/229) said that they benefitted from the messages, mainly from the increase in information and awareness about the methods. No participants reported any serious negative events that happened during the study.

Sensitivity analyses

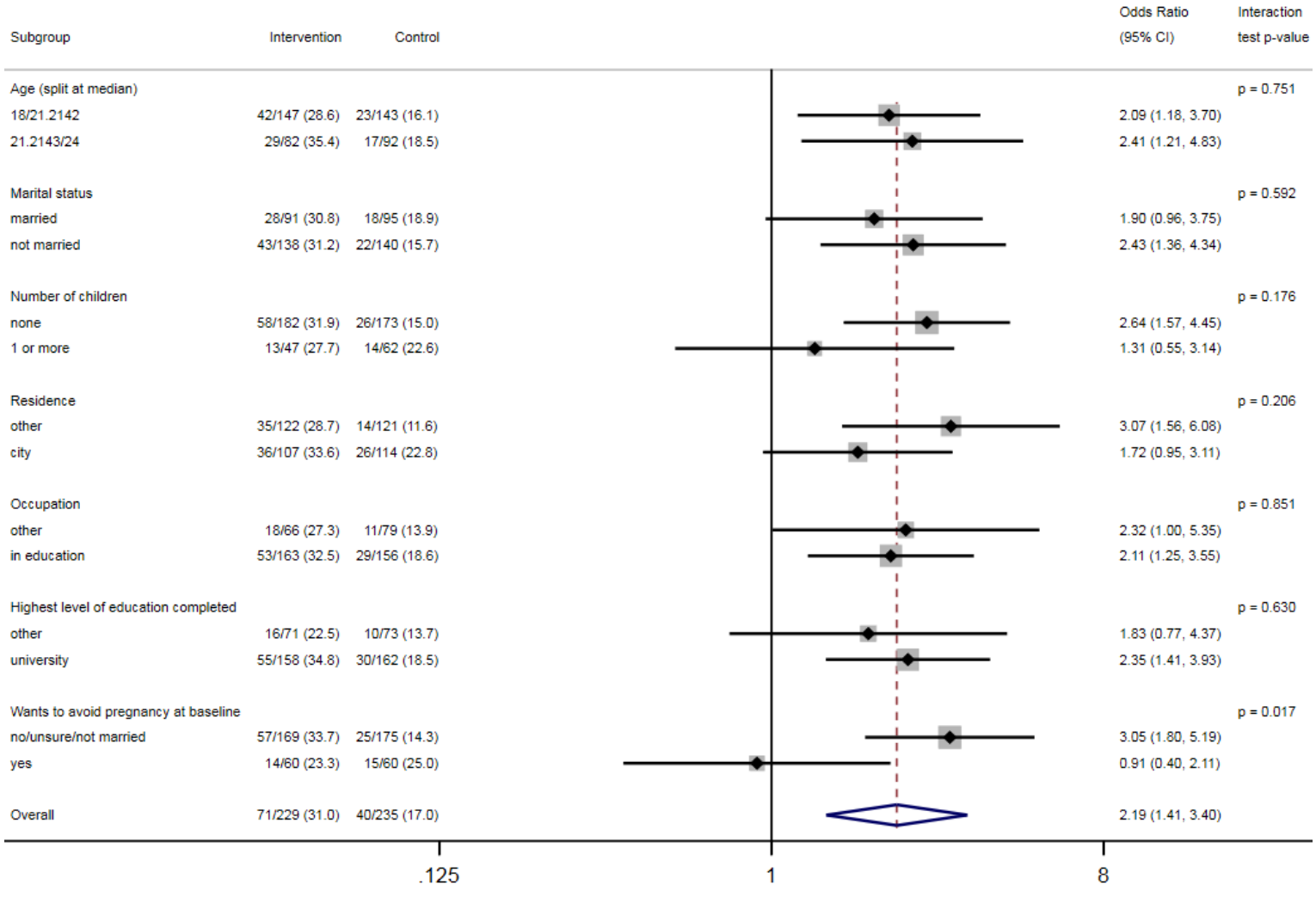
The effect of the intervention on the primary outcome observed in the principal analysis (adjusted OR 2.34, 95% CI 1.48-3.68, $p < 0.001$) moved slightly towards the null when we considered participants lost to follow-up did not find at least one method of effective contraception acceptable (OR 2.13, 95% CI 1.37-3.30, $p = 0.001$).

The strongest baseline predictor of retention was having completed university. This was already adjusted for in the primary analysis and the sensitivity analysis model was the same as the primary analysis.

Subgroup analysis

The effect of the intervention was greater among participants who did not want to avoid a pregnancy at baseline (includes participants who are not married/not sexually active, unsure about their pregnancy intention and who report wanting a pregnancy) at baseline compared to participants that did (interaction test $p = 0.02$) (Figure 7.2).

Figure 7.2 Intervention effect on acceptability of effective contraception, by subgroups (Palestine)



Intervention delivery

After the trial commenced, there were two technical problems with the local platform that resulted in participants not being sent the full intervention. Based on the data available from the local platform, 40% of intervention participants were sent 90% or more of the intervention messages and 8% of intervention participants were sent less than 70% of the messages.

7.2.5 Discussion

Main results

The results of this trial demonstrated that the intervention improved young women's attitudes towards effective contraception in Palestine. The trial results also suggest that the intervention moderately improves knowledge about effective contraception, perceived norms about friends using effective contraception and intention to use effective contraception. The subgroup analysis suggests that that the intervention may be more effective among women who do not report wanting to avoid a pregnancy.

Comparisons with other research

The results of this Palestine trial are in line with research that has found mobile phone interventions can increase contraceptive knowledge (140, 142, 152). Previous research has demonstrated that interventions delivered by mobile phone can improve contraceptive use (134, 135, 143, 161). This current trial did not find evidence for a difference in use between the groups, although this study did not have enough statistical power for this outcome. This is the first trial that we are aware of that has shown that a contraceptive behavioral intervention delivered by mobile phone messaging can increase intention to use effective contraception. A similar intervention was evaluated by trial in Tajikistan (54) and Bolivia with young people (manuscript in preparation). A post hoc change from baseline to follow-up analysis of all participants in Tajikistan demonstrated a large increase in acceptability (54).

Strengths and limitations

An important strength of this trial is that we recruited to target and achieved greater than 80% follow-up for the primary outcome. Our trial database and randomization system concealed the allocation sequence and achieved well-balanced groups overall. There was, however, some imbalance in acceptability at baseline, but this was adjusted for in the

primary analysis and had little effect on the results when not controlled for. The sensitivity analysis confirmed that our results were robust to different missing data assumptions.

The main limitation of the trial is that the whole intervention was not delivered to all participants due to technical problems with the local platform, so our result can only tell us the effect of partial receipt of the intervention. The self-reported primary outcome collected by telephone by research staff may have meant that participants were more likely to report positive attitudes at follow-up compared to baseline where they provided data by paper questionnaire. Most participants were university-educated. The inclusion participants from a wider range of socio-economic backgrounds would have improved the generalizability of the results.

Meaning and implications of the findings

The intervention effect estimated in this trial is likely to be conservative due to the moderate level of potential contamination and the fact that an estimated 60% of intervention participants were not sent the full intervention.

The finding that the intervention may be more effective among women who do not explicitly want to avoid a pregnancy compared to those who do, could relate to exposure to information about contraception. Women who explicitly want to avoid a pregnancy at baseline may already have formed positive attitudes towards the effective methods. Indeed, the level of acceptability at baseline was higher among participants wanting to avoid a pregnancy compared to those who did not want to avoid a pregnancy or were unsure (12% vs 7%), reducing the potential for improvement.

Acceptability among intervention participants remained relatively low, at 31%. Further analysis of the individual scales that comprise the primary outcome measure and the qualitative work could help clarify why the intervention did not improve acceptability to a greater extent.

The results indicate that implementation of the intervention in Palestine could be beneficial. More research is needed to understand how implementation would work in a non-trial context. If the intervention is made available, the local platform will need regular monitoring and maintenance to ensure that the intervention is delivered as intended.

7.2.6 Conclusions

This trial demonstrated that the intervention more than doubled the odds of finding at least one method of effective contraception acceptable. This result along with the lack of evidence that it is associated with any harm, supports the implementation of the intervention in Palestine. Future research is needed to determine how to enable successful implementation and to evaluate the efficacy of the intervention on use of effective contraception and unintended pregnancy in Palestine.

8 Bolivia evaluation results

8.1 Introduction

This chapter includes the results of the Bolivia randomised controlled trial. I finished preparing this manuscript in September 2018. Because I reference the Palestine trial results in the discussion, I plan on submitting the manuscript to the *Journal of Medical Internet Research* when the Palestine trial paper is accepted for publication.

RESEARCH PAPER COVER SHEET

Student details

Student	Ona L McCarthy
Principal Supervisor	Professor Cari Free
Thesis Title	Changing young people's attitudes towards effective contraception using mobile phone messaging

Prepared for publication, but not yet published

Where is the work intended to be published?	*Journal of Medical Internet Research*
Please list the paper's authors in the intended authorship order:	McCarthy OL, Aliaga C, Torrico ME, López Gallardo J, Huaynoca S, Ahamed I, Leurent B, Edwards P, Palmer M, Free C
Stage of publication	**Not yet submitted**

Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed and managed the trial, conducted the analysis and wrote the manuscript.

Student Signature: [redacted] **Date:** 6 November 2018

Supervisor Signature: [redacted] **Date:** 6 November 2018

8.2 Research paper

8.2.1 Abstract

Background

Unintended pregnancy is associated with poorer health outcomes for both women and their children. Fulfilling unmet need for contraception is essential in avoiding unintended pregnancies. Although the most effective methods of contraception are available in Bolivia, unmet need among women aged 15-19 is estimated to be 38% (2008) and the adolescent fertility rate is 71 per 1,000 women (2016). Mobile phones are a popular mode by which to deliver health behaviour support. The London School of Hygiene & Tropical Medicine and the Centro de Investigación, Educación y Servicios in Bolivia developed a contraceptive behavioural intervention for young Bolivian women delivered by mobile phone. The intervention development was guided by behavioural science and consists of short instant messages sent through an app over four months.

Objective

The objective of this trial was to evaluate the effect of the intervention on young Bolivian women's use of and attitudes towards the effective contraceptive methods available in Bolivia (oral contraceptive pills, intrauterine devices, injectables, implants and the patch).

Methods

This was a parallel group, individually randomised superiority trial with a 1:1 allocation ratio. Women were eligible if they were aged 16-24, owned a personal Android mobile phone, lived in La Paz or El Alto, reported an unmet need for contraception (i.e. are sexually active, not using effective contraception and want to avoid a pregnancy) and could read Spanish. The target sample size was 1310 participants. Participants allocated to the intervention arm had access to an app with standard family planning information plus intervention messages. Participants allocated to the control arm had access to the same app plus control messages. Co-primary outcomes were use of effective contraception and acceptability of at least one method of effective contraception at four months. Secondary outcomes were use of effective contraception during the study, acceptability of the individual methods, service uptake, unintended pregnancy and abortion. Process outcomes included knowledge, perceived norms, personal agency and intention. Outcomes were analyzed using logistic and linear

regression. We also asked participants if they experienced physical violence since joining the study.

Results

640 participants were enrolled and 67% (n= 429) contributed follow-up data for the co-primary outcome, use of effective contraception. There was no evidence that use differed between the groups (33% in the control arm vs 37% in the intervention arm, adjusted OR 1.19, 95% CI 0.80-1.77, p = 0.40). There was a borderline significant effect regarding the acceptability outcome (63% in the control arm vs 72% in the intervention arm; adjusted OR 1.49, 95% CI 0.98-2.28, p = 0.06). There were no statistically significant differences in any of the secondary or process outcomes. Intervention dose received was low. In the control group, 3% reported experiencing physical violence compared to 2% in the intervention group (Fisher's exact test p=0.75).

Conclusions

This trial was unable to provide definitive conclusions regarding the effect of the intervention on use and acceptability of effective contraception due to under recruitment. While we cannot strongly recommend implementation, the results suggest that it would be safe and may increase acceptability of effective contraception if the intervention messages were offered alongside the download of the app.

Trial registration: ClinicalTrials.gov Identifier NCT02905526

Date of registration: 14 September 2016

Keywords: Bolivia, Contraception, Mobile phone, Cell phone, Reproductive health, Young adults

8.2.2 Introduction

Unintended pregnancy is associated with numerous poorer health outcomes for both women and their children (2, 4, 12, 15, 16). Satisfying unmet need for contraception is essential in helping women avoid unintended pregnancies, which requires an understanding of the barriers to use in specific settings (26). In Bolivia, a 2008 survey reported that 84% of sexually

active women between the ages of 15-19 wanted to avoid a pregnancy, yet only 49% of these women reported using any contraceptive method (112). A more recent survey (2016) reported that the adolescent fertility rate was 71 per 1,000 women (113). While 'effective' contraceptive methods are available in Bolivia (methods with less than 10% typical use failure at 12 months) (28-30), unmet need among women aged 15-19 was estimated to be 38% in 2008 (112, 114). The (non-permanent) effective methods available in Bolivia are oral contraceptive pills (OC), intrauterine devices (IUD), injectables, implants and the patch.

The option of delivering health interventions by mobile phone has gained popularity, particularly over the last decade (32-43). Randomised controlled trials have provided evidence that interventions delivered by mobile phone can improve contraceptive use (134, 135, 145) and knowledge (134, 140, 142, 144). Other trials however, have not found a beneficial effect (44, 136, 137, 141, 143).

The London School of Hygiene & Tropical Medicine and the Centro de Investigación, Educación y Servicios (CIES) in Bolivia developed a contraceptive behavioural intervention for young Bolivian women delivered by mobile phone (50). We developed the intervention guided by an established approach grounded in behavioural science (124). The intervention is informed by the Integrated Behavioural Model (170) and consists of short instant messages sent through CIES's 'Tú decides' application (app) over four months. In this report we present the results of the evaluation of the intervention by randomized controlled trial. The aim of the trial was to establish if the intervention increases young Bolivian women's use and acceptability of the effective contraceptive methods.

8.2.3 Methods

The methods reported in this section were first published in the trial protocol (53) and the statistical analysis plan (209).

Study design and participants

This was a parallel group, individually randomized superiority trial with a 1:1 allocation ratio that evaluated the effect of the intervention delivered by CIES's app. Women were eligible to take part if they were aged 16-24, owned a personal Android mobile phone, lived in La Paz or El Alto, reported an unmet need for contraception (i.e. are sexually active, not using effective

contraception and want to avoid a pregnancy) and could read Spanish. Participants must also have been willing to download the app and receive messages about contraception on their mobile phone. Participants provided informed consent though the secure online trial database and randomization system.

Intervention and control

The intervention was developed with young Bolivian people in 2015-2016 (50). The intervention provided accurate information about contraception, targeted the beliefs identified in the development phase that influence contraceptive use, and aimed to support young women in believing that they can influence their reproductive health. The messages contained 10 behaviour change methods, adapted for delivery by mobile phone (122): belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting (please see the protocol (53) and the intervention development publication (50) for a detailed description of the intervention). The Tú decides app itself contained standard family planning information and no behaviour change methods. Participants allocated to the intervention arm had access to the app plus the intervention instant messages. Participants allocated to the control arm had access to the app plus control instant messages about trial participation. All participants received usual care were free to seek any other support, whether existing or new.

Allocation and intervention delivery

After providing informed consent, participants completed the baseline questionnaire through the database and randomization system. The allocation sequence was generated by the remote computer-based randomization software. Randomization occurred immediately after baseline data were submitted. All participants downloaded the app immediately after they submitted their baseline data. The messages commenced within 24 hours after participants downloaded the app.

Protecting against bias

Due to the nature of the intervention, participants would have been aware of the allocation soon after they started receiving the messages. Local research staff collecting outcome data were masked to allocation unless the participant revealed it to them. Researchers who analyzed the data were masked to treatment allocation.

Outcomes

Co-primary outcomes

The co-primary outcomes at four months post randomization were: 1) self-reported current use of effective contraception and 2) the proportion of participants reporting that at least one method of effective contraception was acceptable. The primary outcome measure was constructed based on guidelines for measuring IBM constructs (170, 188, 189) and tested for face validity with the target group. The acceptability of each method was measured by the following stems: "Using the [method] …causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy" and "I would recommend the [method] to a friend". The IUD and implant include an additional stem: "The [method] insertion would not be a problem for me". The response options for each stem were "strongly disagree", "disagree", "not sure", "agree", "strongly agree" and "I do not know what the [method] is". A method was acceptable if participants reported "agree" or "strongly agree" for all scales except for "…causes infertility" and "…causes unwanted side effects" stems, for which "disagree" or "strongly disagree" indicated acceptability (53).

Secondary outcomes

Secondary outcomes were: use of effective contraception during the study; acceptability of individual methods; service uptake; unintended pregnancy and abortion.

Process outcomes

The process outcomes were: knowledge of effective contraception; perceived norms and personal agency in relation to using and communicating with partners about contraception; intention to use effective contraception and intervention dose received.

Data collection

Data were collected at baseline and at four months post-randomization using questionnaires. At baseline, we collected personal and demographic data and the co-primary outcome acceptability. At follow-up we collected all outcomes plus the following: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that had also participated in the study and if so, if they read each other's messages; if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages. An instant message that included a link to the database to complete the follow-up questionnaire was sent to all

participants through the app four months after downloading the app. If participants did not complete the follow-up questionnaire themselves, local research staff unaware of participants' allocation contacted them by telephone to collect their data.

Sample size

The trial was powered to detect a 10% absolute difference in use of effective contraception between the intervention and control group at four months. One thousand and forty-eight participants provided 90% power to detect a 10% absolute difference, at the 5% significance level, assuming 44% use in the control group vs 54% in the intervention group (corresponding to an odds ratio of 1.49). Allowing for 20% loss to follow-up, we aimed to enrol and randomize 1310 people.

Statistical analysis

The trial protocol was accepted for publication on November 3, 2017 (53) and the detailed statistical analysis plan was publicly released on November 7, 2017 (209). Analyses were according to randomized arm and only participants with complete outcome data were included in the principal analysis. All statistical tests were two-sided and were considered significant at the 5% level. The analysis was conducted using Stata 15. Unmasking occurred on February 6, 2018, after the analyses outlined within the analysis plan were complete on masked data.

Loss to follow-up and missing data

We used a chi-squared test to investigate evidence for whether losses to follow-up differed by trial arm. We used logistic regression to compare the baseline characteristics of participants who completed follow-up with those participants who did not. We investigated whether predictors of loss to follow-up differed by trial arm by testing for an interaction.

Principal analysis

Analysis of the co-primary outcomes

We compared the proportion that reported using a method of effective contraception or finding at least one method acceptable between the groups using logistic regression. We report the crude and adjusted odds ratio (OR) along with the 95% confidence interval (CI) and p-value. The primary analysis was adjusted for the following pre-specified baseline covariates:

age (16-19/20-24), number of children (0/≥1), education level (university/other) and acceptability of effective contraception at baseline (at least one method acceptable/no methods acceptable) (51, 203).

Analysis of the secondary outcomes

The analysis of the secondary outcomes was similar to the analysis of the primary outcome, although for the acceptability of the individual methods, the acceptability of that method at baseline replaced the acceptability of at least one method at baseline as a covariate.

Analysis of the process outcomes

The process outcomes comprised ordinal scales. Each scale was analyzed individually using ordered logistic regression to estimate proportional ORs. For knowledge, each correct answer received one point. The points were summed, and an overall score was produced for analysis. We used linear regression to test for a difference in the mean scores between the trial arms. To assess the 'dose' of the intervention that the intervention participants received, we analyzed the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages.

Additional analyses

Sensitivity analyses

We conducted two sensitivity analyses allowing for the missing data. In the first analysis (an 'extreme case' analysis), we considered that all participants lost to follow-up did not use an effective method of contraception or did not find at least one method acceptable. In the second analysis, we adjusted for the main baseline predictors of missingness. Both sensitivity analyses were adjusted for the baseline covariates, as above.

Subgroup analysis

We conducted an exploratory subgroup analysis for each co-primary outcome to determine if the intervention effect varied by baseline characteristics. The pre-specified subgroups were: age (split at the median); marital status (married/not married); number of children (0/≥1); geographical location (El Alto/La Paz); occupation (in education/other) and education level (university/other). Within the subgroups, we assessed heterogeneity of treatment effect with a test for interaction (194-198). We estimated ORs with 95% CIs for each subgroup.

Contamination

To assess the potential for contamination, we report the proportion of control group participants that reported that they read another participant's messages and the proportion of intervention participants that reported that their messages were read by another participant.

Report of physical violence

We report the proportion of participants in each group that reported experiencing physical violence during the study.

8.2.4 Results

Recruitment, randomization, exclusions

Between March 1, 2017 and July 29, 2017, there were 645 randomizations by the system. Follow-up ended on February 8, 2018. During the trial follow-up, we discovered that three participants enrolled and were randomized twice. For the one participant that was allocated to the same arm on both randomizations, we kept this participant in the analysis using the baseline data from their first record. For the two participants that were allocated to different arms, we excluded them from the analysis. This resulted in 640 participants included in the trial.

Three hundred and twenty-one participants were allocated to the intervention arm and 319 participants were allocated to the control arm (Figure 8.1).

Baseline characteristics

Baseline characteristics of trial participants are reported in Table 8.1. Mean age was 20 years. Ninety percent (579/640) did not have children and only 8% (26/640) found at least one method of effective contraception acceptable. Characteristics were similar between the two groups.

Table 8.1 Baseline characteristics (Bolivia)

		Control N = 319 % (n)	**Intervention** N = 321 % (n)	**All participants** N = 640 % (n)
Age	mean [sd]	20.42 [2.56]	20.27 [2.58]	20.35 [2.57]
	16-19	47.02 (150)	51.40 (165)	49.22 (315)
	20-24	52.98 (169)	48.60 (156)	50.78 (325)

		Control N = 319 % (n)	Intervention N = 321 % (n)	All participants N = 640 % (n)
Marital status	married	4.39 (14)	5.61 (18)	5.00 (32)
	not-married	95.61 (305)	94.39 (303)	95 (608)
Number of children	0	91.85 (293)	89.10 (286)	90.47 (579)
	1	5.02 (16)	6.54 (21)	5.78 (37)
	2 or more	3.13 (10)	4.36 (14)	3.75 (24)
Indigenous origin (ethnicity)	Aymara	56.74 (181)	55.76 (179)	56.25 (360)
	Guarani	0.31 (1)	0.93 (3)	0.63 (4)
	Quechua	4.08 (13)	1.87 (6)	2.97 (19)
	other	3.13 (10)	3.12 (10)	3.13 (20)
	none	35.74 (114)	38.32 (123)	37.03 (237)
Occupation	school	19.12 (61)	18.07 (58)	18.59 (119)
	university	55.17 (176)	56.39 (181)	55.78 (357)
	working	9.40 (30)	11.21 (36)	10.31 (66)
	training	5.96 (19)	5.30 (17)	5.63 (36)
	not working	1.25 (4)	1.25 (4)	1.25 (8)
	working & studying	9.10 (29)	7.79 (25)	8.44 (54)
Highest level of education completed	primary	5.96 (19)	4.05 (13)	5.00 (32)
	secondary	71.16 (227)	73.21 (235)	72.19 (462)
	university	21.32 (68)	19.31 (62)	20.31 (130)
	technical	1.57 (5)	3.43 (11)	2.50 (16)
Baseline method	none	75.24 (240)	80.06 (257)	77.66 (497)
	male condom	14.42 (46)	11.21 (36)	12.81 (82)
	female condom	2.82 (9)	1.25 (4)	2.03 (13)
	other	7.52 (24)	7.48 (24)	7.5 (48)
At least one effective method is acceptable	yes	8.15 (26)	8.10 (26)	8.13 (52)
	no	91.85 (293)	91.90 (295)	91.88 (588)
Pill acceptability	yes	0.63 (2)	1.56 (5)	1.09 (7)
	no	99.37 (317)	98.44 (316)	98.91 (633)
IUD [a] acceptability	yes	1.88 (6)	1.25 (4)	1.56 (10)
	no	98.12 (313)	98.75 (317)	98.44 (630)
Injection acceptability	yes	2.82 (9)	1.87 (6)	2.34 (15)
	no	97.18 (310)	98.13 (315)	97.66 (625)
Implant acceptability	yes	1.57 (5)	3.12 (10)	2.34 (15)
	no	98.43 (314)	96.88 (311)	97.66 (625)
Patch acceptability	yes	3.45 (11)	2.49 (8)	2.97 (19)
	no	96.55 (308)	97.51 (313)	97.03 (621)

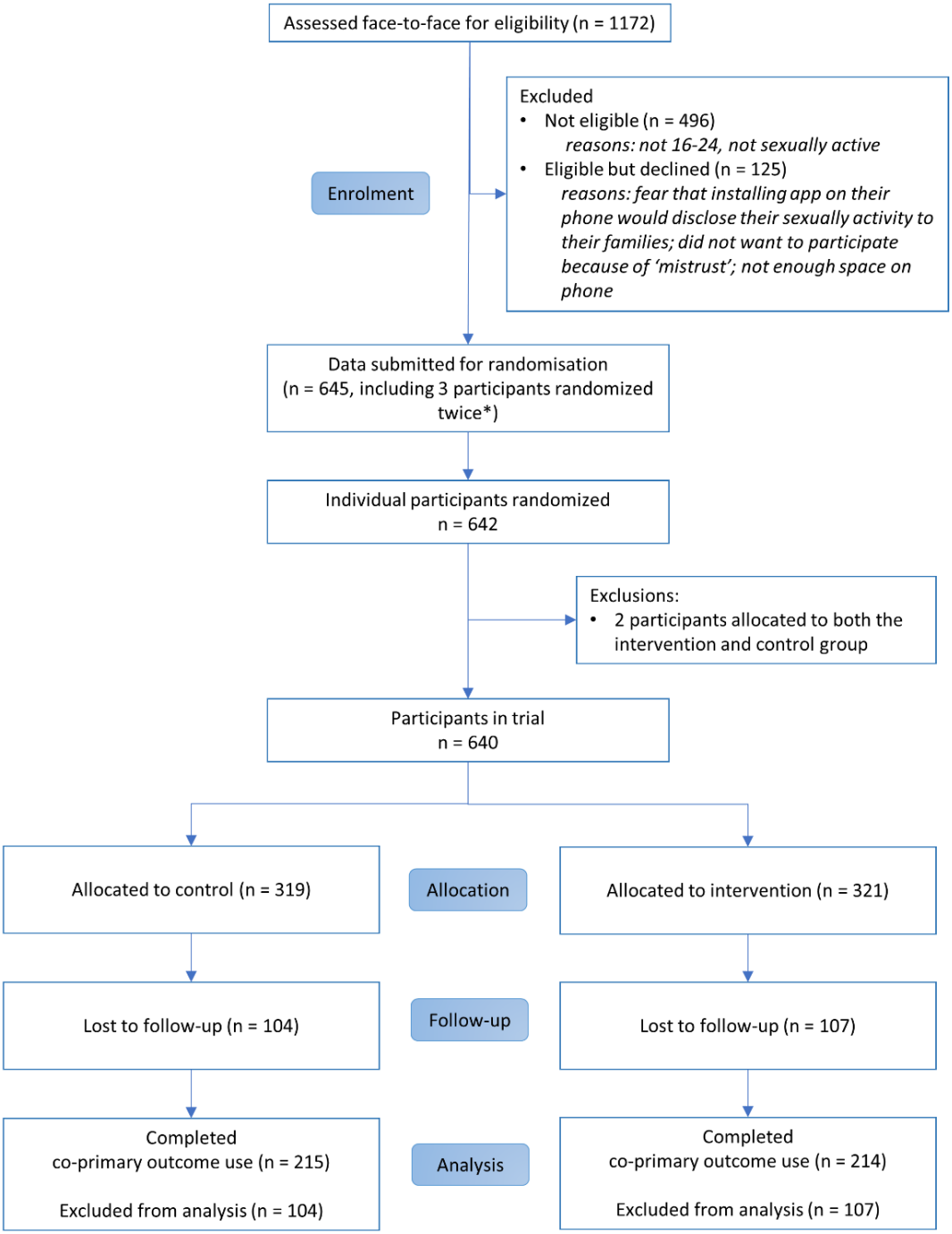
[a] IUD Intrauterine device

Loss to follow-up

Four hundred and twenty-nine participants (67%) completed the trial follow-up for the co-primary outcome use (control, n = 215; intervention, n = 214) and 406 (63%) completed follow-up for the co-primary outcome acceptability (control, n = 203; intervention, n = 203) (Figure 1). Retention did not differ between the arms (66.64 % in the control and 63.24% in the intervention arm, p = 0.92). Among participants who completed the use co-primary

outcome, the strongest predictor of retention was being aged 20-24 (OR 1.33, 95% .96-1.86, p = 0.09). There was some evidence that the effect of this predictor differed by arm (interaction test p = 0.09). Detailed characteristics of participants who completed follow-up and those that did not are reported in Appendix 19.

Figure 8.1 CONSORT diagram (Bolivia)



*1 participant allocated to the same group on both randomizations and 2 participants allocated to different groups

Primary outcomes

In the intervention arm, 37.38% (80/214) reported use of effective contraception compared to 33.49% (72/215) in the control arm (Table 8.2). There was no evidence of a difference in use between the groups (crude OR 1.19, 95% CI .80-1.76, p = 0.40; adjusted OR 1.19, 95% CI .80-1.77, p = 0.40).

In the intervention arm, 71.92% (146/203) reported that at least one method of contraception was acceptable compared to 62.56% (127/203) in the control arm (Table 8.2). There was borderline evidence of a difference in acceptability between the groups (crude OR 1.53, 95% CI 1.01-2.33, p = 0.05; adjusted OR 1.49, 95% CI .98-2.28, p = 0.06).

Table 8.2 Co-primary outcomes (Bolivia)

	Control N = 215 % (n/N)	**Intervention** N = 214 % (n/N)	**adjusted OR (95% CI)**	**p-value**
Use of effective contraception*	33.49 (72/215)	37.38 (80/214)	1.19 (.80-1.77)	0.40
At least one effective method is acceptable*	62.56 (127/203)	71.92 (146/203)	1.49 (.98-2.28)	0.06

* adjusted for age, number of children, education level and acceptability at baseline

Secondary outcomes

There were no significant differences in any of the secondary outcomes between the groups (Table 8.3).

Table 8.3 Secondary outcomes (Bolivia)

	Control % (n/N)	**Intervention** % (n/N)	**adjusted OR (95% CI)**	**p-value**
Pill acceptability**	25.24 (52/206)	28.50 (59/207)	1.19 (.76-1.85)	0.45
IUD acceptability**	20.87 (43/206)	26.70 (55/206)	1.37 (.86-2.19)	0.18
Injection acceptability**	37.98 (79/208)	44.93 (93/207)	1.30 (.88-1.94)	0.19
Implant acceptability**	30.58 (63/206)	31.71 (65/205)	1.03 (.68-1.58)	0.89
Patch acceptability**	45.67 (95/208)	52.40 (109/208)	1.31 (.89-1.93)	0.17
LARC acceptability**	51.96 (106/204)	58.54 (120/205)	1.31 (.88-1.93)	0.18

	Control % (n/N)	**Intervention** % (n/N)	**adjusted OR (95% CI)**	**p-value**
Effective contraceptive use during the 4 months*	36.19 (76/210)	35.44 (73/206)	.94 (.62-1.40)	0.76
Service uptake* (attended a service one or more times)	52.38 (110/210)	45.37 (93/205)	.74 (.50-1.10)	0.14
Unintended pregnancy	0.31 (1/319)	0 (0/321)	-	-
Induced abortion***	1.44 (3/209)	0.49 (1/205)	.34 (.01-4.24)***	0.64

** adjusted for age, number of children, education level and acceptability at baseline*
*** adjusted for age, number of children, education level and the corresponding method acceptability at baseline*
**** unadjusted exact logistic regression*

Process outcomes

There were no significant differences in any of the process outcomes between the groups (Table 8.4).

Table 8.4 Process outcomes (Bolivia)

		Control % (n/N)	**Intervention** % (n/N)	**proportional OR*** (95% CI), p-value
Knowledge of effective contraception		Mean = 4.31 [sd = 1.86]	Mean = 4.48 [sd = 1.79]	.17** (-.19-.53), 0.36
My friends would use the pill, IUD, injection or implant if they wanted to prevent pregnancy	strongly disagree	0.98 (2/205)	0 (0/202)	1.17 (.73-1.88), 0.51
	disagree	3.41 (7/205)	0.99 (2/202)	
	not sure	14.15 (29/205)	15.35 (31/202)	
	agree	77.56 (159/205)	79.70 (161/202)	
	strongly agree	3.90 (8/205)	3.96 (8/202)	
My friends would talk to their partner about contraception if they wanted to prevent a pregnancy	strongly disagree	0.49 (1/205)	0 (0/202)	1.33 (.91-1.94), 0.15
	disagree	8.29 (17/205)	6.93 (14/202)	
	not sure	38.54 (79/205)	33.17 (67/202)	
	agree	51.22 (105/205)	58.42 (118/202)	
	strongly agree	1.46 (3/205)	1.49 (3/202)	
If you wanted to use the pill, IUD, injection or implant, how easy would it be for you to use it?	very difficult	1.95 (4/205)	0.99 (2/202)	.98 (.64-1.51), 0.93
	difficult	11.71 (24/205)	12.38 (25/202)	
	not sure	8.29 (17/205)	8.42 (17/202)	
	easy	72.68 (149/205)	73.76 (149/202)	
	very easy	5.37 (11/205)	4.46 (9/202)	
If you wanted to talk to your partner about contraception, how easy would it be for you to talk to him?	very difficult	0.49 (1/205)	3.47 (7/202)	.71 (.48-1.06), 0.09
	difficult	10.73 (22/205)	13.37 (27/202)	
	not sure	16.10 (33/205)	12.38 (25/202)	
	easy	62.44 (128/205)	67.33 (136/202)	
	very easy	10.24 (21/205)	3.47 (7/202)	
If you wanted to use the pill, IUD, injection or implant, how certain are you that you could use it?	very certain I could not	0.98 (2/205)	0.99 (2/202)	1.01 (.66-1.55), 0.97
	certain I could not	0.98 (2/205)	0.99 (2/202)	
	not sure	16.59 (34/205)	17.82 (36/202)	
	certain I could	73.66 (151/205)	70.79 (143/202)	
	very certain I could	7.80 (16/205)	9.41 (19/202)	

		Control % (n/N)	**Intervention** % (n/N)	**proportional OR*** (95% CI), p-value
If you wanted to talk to your partner about contraception, how certain are you that you could talk to him?	very certain I could not	0 (0/204)	1.98 (4/202)	.87 (.58-1.30), 0.49
	certain I could not	4.41 (9/204)	2.97 (6/202)	
	not sure	22.55 (46/204)	22.28 (45/202)	
	certain I could	64.22 (131/204)	67.82 (137/202)	
	very certain I could	8.82 (18/204)	4.95 (10/202)	
I intend to use the pill, IUD, injection, implant or patch	strongly disagree	1.47 (3/204)	0.99 (2/202)	.74 (.50-1.10), 0.14
	disagree	6.86 (14/204)	7.92 (16/202)	
	not sure	8.82 (18/204)	14.85 (30/202)	
	agree	65.69 (134/204)	61.88 (125/202)	
	strongly agree	17.16 (35/204)	14.36 (29/202)	
Number of messages read	all		6.31 (13/206)	
	most		19.42 (40/206)	
	some		45.63 (94/206)	
	none		28.64 (59/206)	
Proportion of intervention participants that stopped the intervention			11.22 (23/205)	

*estimated from ordered logistic regression

**mean difference

Potential for contamination

One percent (2/209) of control participants said that they read the messages of someone else in the study. Four percent (8/205) of intervention participants said that someone else in the study read their messages.

Report of physical violence

Three percent (6/207) of participants in the control group and 2% (4/202) in the intervention group reported that they experienced physical violence since being in the study (Fisher's exact test p = 0.75).

Intervention dose

Twenty-six percent of intervention reported that they read all or most of the intervention messages, with 29% stating that they read none of the messages. Eleven percent reported that they stopped the intervention messages. Reasons intervention participants provided for not reading the messages or deinstalling the app were: concerns about confidentiality, the app took up too much space on their phone, there were too many messages and some messages were repetitive. Nineteen percent (39/206) of the intervention participants that answered the open-ended question "Did anything good or bad happened as a result of receiving the messages?" said that they did not receive any messages.

Participants' report of anything good or bad that happened during the study

Almost half of intervention participants that answered this question (97/206) reported something positive about the messages. The most common comment was that they learned new information. One participant said that they got pregnant and another said that they had 'a scare due to carelessness'.

Sensitivity analyses

When we considered that participants who were lost to follow-up did not use an effective method or find an effective method acceptable, the effects observed in the principal analysis were reduced (use: OR 1.14 95% CI .79-1.64, p = 0.48, acceptability: OR 1.26, 95% CI .92-1.74, p = 0.15).

The strongest predictor of retention was being aged 20-24. Age was a baseline covariate so the model in the second sensitivity analysis (adjusting for the main baseline predictors of missingness) is the same as the primary analysis model.

Subgroup analysis

There was no evidence that the effect of the intervention differed within the different levels of the subgroups (Figure 8.2 and Figure 8.3).

Figure 8.2 Intervention effect on use of effective contraception, by subgroups (Bolivia)

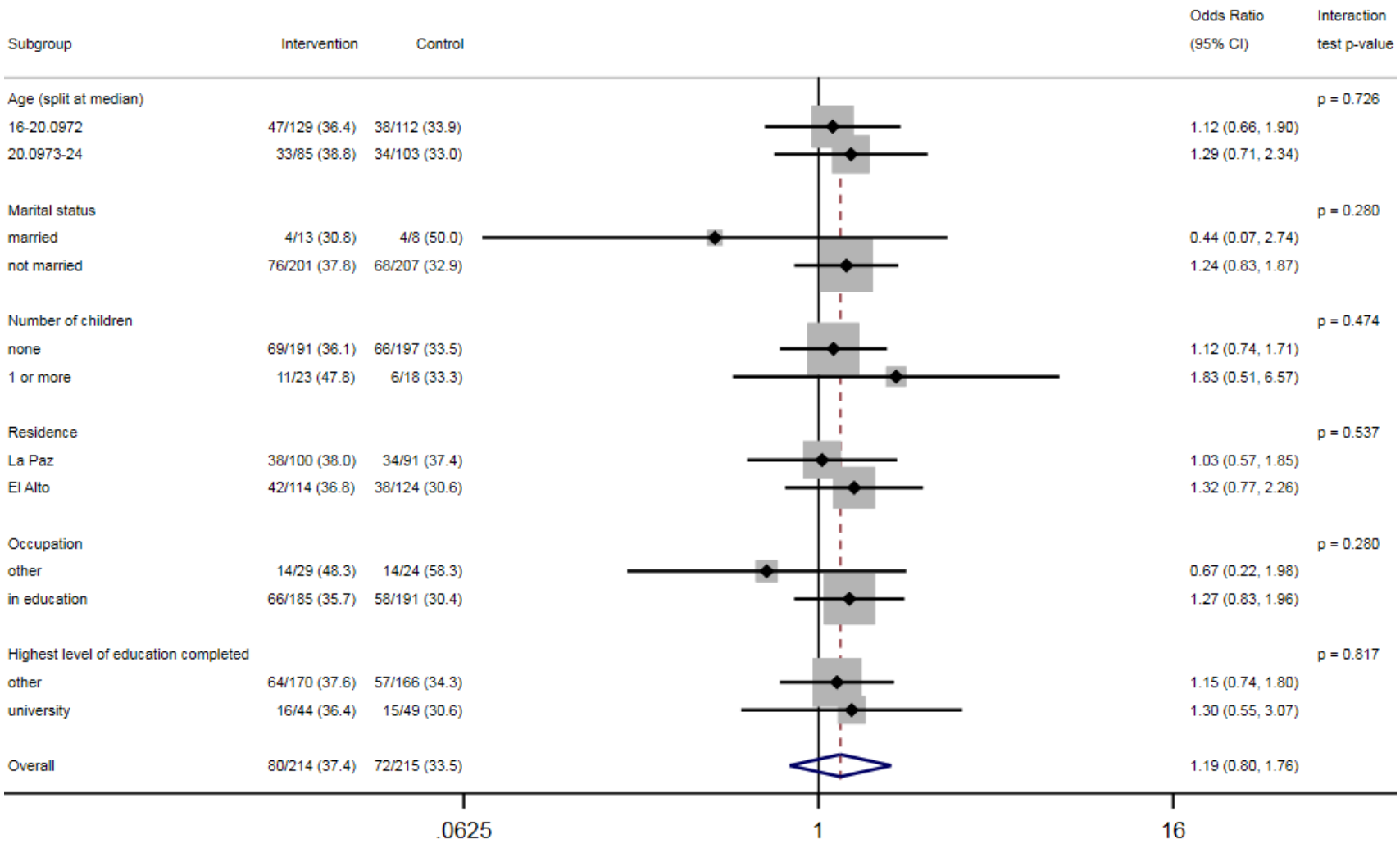
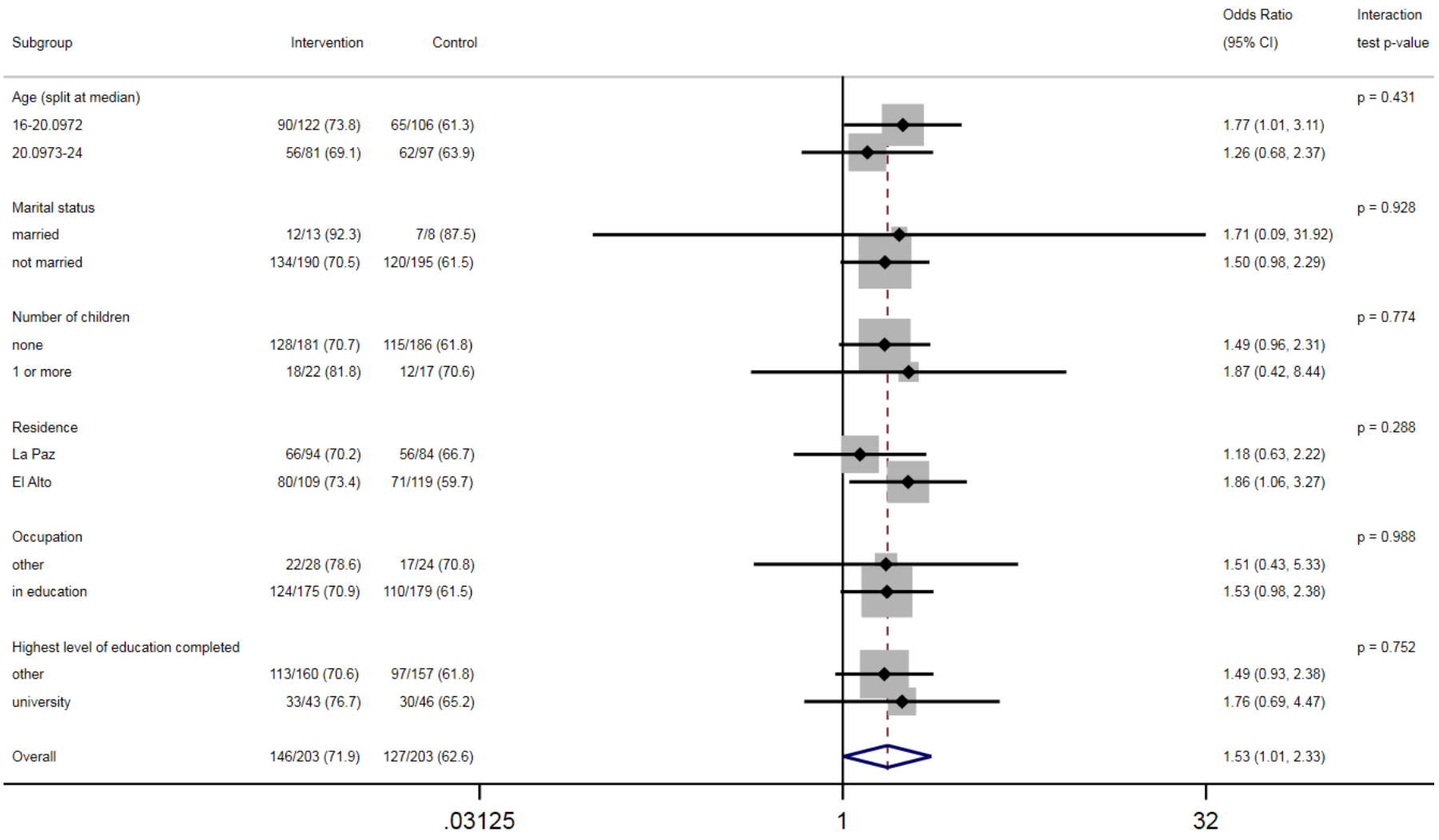


Figure 8.3 Intervention effect on acceptability of effective contraception, by subgroups (Bolivia)



8.2.5 Discussion

Principal results

The trial was underpowered to detect a difference in contraceptive use. While use was higher in the intervention group, the difference was not statistically significant. There was a borderline significant effect regarding the acceptability co-primary outcome, which favored the intervention group. No statistically significant differences between the groups in any of the secondary or process outcomes were observed. The intervention dose received was low, based on participants' report.

Strengths and limitations

The main limitations of this trial were that we did not recruit to target and achieved less than 80% follow-up completion. While effect estimates or both primary outcomes favored sending the intervention messages with the Tú decides app, the differences between the groups were smaller than we expected. The recruitment and follow-up challenges meant that the trial was underpowered and therefore unable to produce unequivocal estimates regarding the effect of sending the intervention messages in addition to the app (with 429 participants, the trial had 54% power to detect a 10% absolute difference in use of effective contraception between the groups).

The low dose of the intervention is likely to have reduced the effect estimates. Only 26% of the participants reported that they read all or most of the intervention messages, with 29% reporting that they read none of the messages. This could have contributed to the smaller than anticipated observed differences.

Despite the limitations, this study had several strengths. Our trial database and randomization system generated and concealed the allocated and achieved well-balanced groups. There was no evidence that the intervention was associated with an increase in self-reported violence. However, we cannot determine the effect of the app on partner violence because both groups had access to it. Despite this, it is reassuring that the self-reported prevalence in this trial was low (2%).

Comparisons with existing research

Trials evaluating contraceptive behavioural interventions delivered by mobile phone have had mixed results (44, 134-137, 140-145), with some showing an improvement in contraceptive use (134, 135, 145) and knowledge (134, 140, 142, 144). The results of this current trial are consistent with our trials of similar intervention among young people in Tajikistan (54) and Palestine (52). In the Palestine trial, participants who received the intervention were more than twice as likely to find at least one method of contraception acceptable (OR 2.34, 95% CI 1.48-3.68, $p < 0.001$). There were also improvements in knowledge, acceptability of individual methods, perceived norms about friends using contraception, and intention to use contraception compared to the control group (trial publication under review). In the Tajikistan trial there was contamination between the intervention and control group and no differences found between the groups. Because of this, we conducted a post hoc change from baseline analysis, which showed a large statistically significant increase in acceptability from baseline to follow-up (2% at baseline to 65% at follow-up, $p < 0.001$). Although we cannot infer causality from this analysis, the results are consistent with the intervention content being at least partially effective at changing attitudes towards effective contraception in Tajikistan. The Tajik and Palestinian trials also did not suggest that the intervention was associated with an increase in violence.

Implications of the findings

The uncertainty regarding the efficacy of the intervention means that we cannot strongly recommend implementation in Bolivia. However, the results suggest that the intervention messages increase acceptability of effective contraception if they were offered alongside the download of the Tú decides app and would not cause harm if done so.

Conclusions

This trial was unable to determine unequivocally if the intervention was effective at increasing use and acceptability of effective contraception among young women with an unmet need in Bolivia. The intervention messages when delivered in addition to an app providing standard family planning information may moderately improve acceptability.

9 Additional analyses

9.1 Internal consistency and predictive validity of the acceptability measure

In the sections, 'The acceptability primary outcome' and 'Measuring the Integrated Behavioural Model constructs' of the Methods chapter, I detail the process of how I constructed the acceptability primary outcome measure and tested it for face validity with the target group. To summarise- I first reviewed the existing validated scales but did not find one that was suitable. In the absence of a pre-existing scale, I constructed scales based on guidelines for measuring the Integrated Behavioural Model construct, instrumental attitude (170, 188, 189). I tested the scales for face validity with young people in each country. In this section, I present an assessment of the measure's internal consistency and predictive validity.

To assess the internal consistency of the measure, I computed Cronbach's alpha for the acceptability of each method using follow-up data for the three countries combined. I used the follow-up data because a large proportion of participants at baseline responded that they did not know what the methods were (pill 30%; IUD 26%; injection 38%; implant 48%; patch 46%). I recoded the response 'I do not know what the *method* is' to the midpoint on the scale. The Cronbach's alpha for each method acceptability was the following: pill = .73; IUD = .85; injection = .84; implant = .84 and patch = .86.

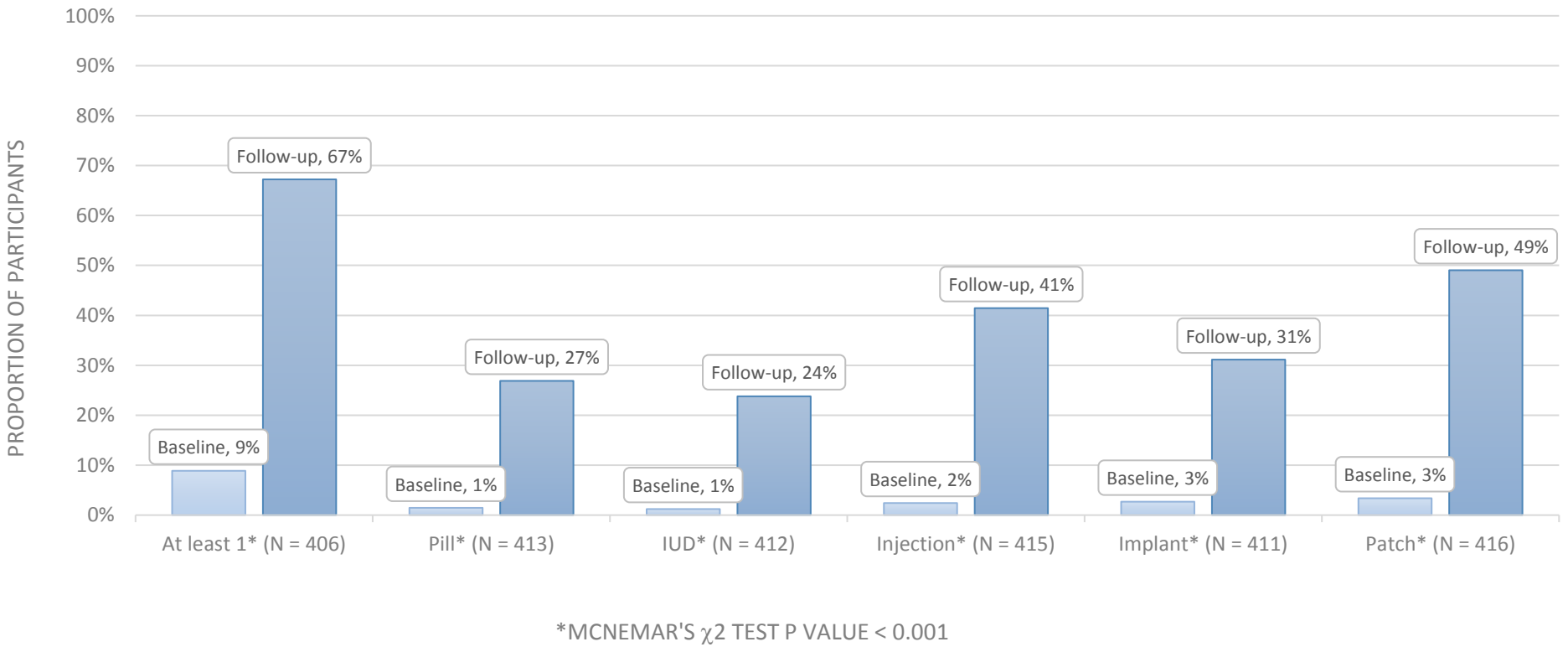
I also conducted analyses to give an indication of the predictive validity of the acceptability measure. In the absence of a gold standard measure of acceptability of effective contraception, I assessed whether the measure was associated with intention to use and current use of effective contraception. As with the data used to compute Cronbach's alpha, I analysed the follow-up data for the three countries combined, however included only women in these analyses (because only women were asked about intention to use contraception in the Tajik trial and the Palestine and Bolivia trials only included women). Participants who found at least one method of acceptable had 3.76 times the odds of reporting that they intend to use an effective method ($p < 0.001$, 95% CI 2.82-5.01). Participants who found at least one method of acceptable had 5.45 times the odds of reporting that they currently use an effective method ($p < 0.001$, 95% CI 3.81-7.80).

These two analyses indicate that the acceptability outcome measure demonstrates internal consistency and predictive validity.

9.2 Bolivia secondary analysis of trial data

I conducted a change from baseline analysis for the co-primary outcome acceptability using McNemar's $\chi 2$ test for paired data. I conducted this post-hoc non-randomised analysis in addition to the analyses specified in the trial protocol 1) because the low recruitment and follow-up produced equivocal results and 2) so that it could be compared to the Tajik trial, which also was not conducted as the protocol specified. Among the 406 participants that completed follow-up for the co-primary outcome acceptability, 9% (n = 36) thought that at least one method of effective contraception was acceptable at baseline. At follow-up, this increased to 67% (n = 273, $p < 0.001$). Acceptability of each of the individual methods also increased from baseline to follow-up (Figure 9.1).

Figure 9.1 Method acceptability at baseline and follow-up (Bolivia)



9.3 Cost analysis

Table 9.1 displays the estimates of developing, maintaining/monitoring and sending the intervention. The cost of developing each county's intervention is based on the amount that each local partner was provided for the project ($200,000 USD) plus the amount provided to LSHTM to develop the intervention (approximately $200,000 USD, which is half of the total provided for the entire project), divided by three. This cost is a one-off, upfront cost that other settings would not incur if they adapted the existing intervention. The cost of maintaining and monitoring the intervention is based on our experience of the annual cost of maintaining an app/web-based texting platform.

I then compared these costs to the difference between the control and intervention groups in the proportion who found at least one method acceptable and the proportion who reported using an effective method at four month follow-up. Based on this difference, I estimated the cost per user.

Table 9.1 Cost analysis

(Figures are in US dollars)		**TFPA**	**PFPPA**	**CIES**
Estimated cost of developing the intervention[1]		$267,000	$267,000	$267,000
Estimated cost of maintaining & monitoring the intervention per year[2]		$5,000	$5,000	$5,000
Estimated cost of sending the intervention messages per recipient		n/a	$2.97[3]	n/a
Difference between the groups at four month follow-up	*at least one method acceptable[4]*	**2%** (int. = 66%, control = 64%)	**14%** (int. = 31%, control = 17)	**9%** (int. = 72%, control = 63%)
	use[5] of an effective method	n/a[6] (int. = 1%, control = 4%)	**.22%** (int. = 8.73%, control = 8.51%)	**4%** (int. = 37%, control = 33%)
Potential number of people who would benefit per <u>1,000</u> intervention recipients; cost per person	*acceptability of effective contraception*	20 $250 per person	140 $39 per person	90 $56 per person
	use of effective contraception	n/a[6]	2.2 $2,276 per person	40 $125 per person
Potential number of people who would benefit	*acceptability of effective contraception*	200 $25 per person	1400 $6.57 per person	900 $5.60 per person

per <u>10,000</u> intervention recipients; cost per person				
	use of effective contraception	n/a[6]	22 $230 per person	400 $12.50 per person
Potential number of people who would benefit per <u>100,000</u> intervention recipients; cost per person	*acceptability of effective contraception*	2,000 $2.50 per person	14,000 $3.33 per person	9,000 $0.56 per person
	use of effective contraception	n/a[6]	220 $25.69 per person	4,000 $1.25 per person

1 Calculated using the amount provided to each local partner (200,000 USD) plus the amount provided to LSHTM to develop the intervention (200,000 USD, which is half of the total provided for the entire project), divided by three
2 Calculated based on our experience of the annual cost of maintaining an app/web-based texting platform
3 Palestine incurs the additional cost of sending the messages via SMS. There are approximately 110 messages per recipient. It costs approximately $272 USD to send 10,000 messages ($0.027 USD per message)
4 Caveat: While in the direction of benefit, the trial results did not demonstrate that the intervention increased acceptability of effective contraception in Tajikistan or Bolivia
5 Caveat: While in the direction of benefit in Palestine and Bolivia, the trial results did not demonstrate that the intervention increased contraceptive use in any of the countries
6 The proportion reporting use of effective contraception at follow-up was higher in the control group in Tajikistan, so not meaningful to calculate the costs

Estimating the cost per user was relatively straightforward in Palestine because the control group only received messages about trial participation. In Tajikistan and Bolivia however, the control group received information about contraception on the app. This has limited the additional benefit of the intervention, which would not be the case if it was compared to a population who received no information. This means that the cost estimates provided are conservative (i.e. that the actual cost is less per person). The cost per person is contingent on scale; the more people who are sent the intervention, the lower the cost per person who would benefit.

These illustrations assume that the intervention is effective, although the trial results only found the intervention to be effective in Palestine (in improving the acceptability of effective contraception). While acceptability was in the right direction in Tajikistan and Bolivia, the results could have occurred by chance. Likewise with regard to use of effective contraception, while it was in the direction of benefit in Palestine and Bolivia, the trial results did not demonstrate that the intervention increased contraceptive use in any of the countries.

10 Interviews with trial participants

10.1 Aim

In this chapter I present a basic, descriptive report of the semi-structured interviews conducted in each country. The aim of the interviews was simply to gather participant views of the intervention (see Appendix 20 for the discussion guides).

10.2 Methods

10.2.1 Eligibility

Participants were eligible for the interview study if they had consented at enrolment to be contacted about being interviewed and if they had either completed follow-up or had all follow-up attempts and were considered non-responders.

10.2.2 Participants

I designed a purposive sample in each country by first listing potential selection criteria in Tajikistan (because the Tajik interviews were completed before the Palestine and Bolivia interviews) and why I was considering each variable (210). The initial criteria that I considered were: age, gender, ethnicity, occupation, education level, intention at baseline, method at baseline, number of children, marital status and acceptability outcome at follow-up (Table 10.1).

Table 10.1 Purposive sample initial selection criteria for Tajikistan

Criteria	Why considered
Age	to ensure a balanced demographic sample
Gender	to ensure balance and because attitudes towards contraception are likely to be influenced by gender
Ethnicity	hypothesised that acceptability may be influenced by ethnicity or residence; to ensure balanced sample
Occupation	hypothesised that people in school or university may find the methods more acceptable because they want to delay
Education level	hypothesised that people who completed university may find methods more acceptable; to ensure balanced sample
Intention at baseline	hypothesised that people who want to avoid a pregnancy at baseline are more likely to find methods acceptable
Method at baseline	people already using (or partner using in Tajikistan) effective contraception may be more likely to find at least one acceptable
Number of children	hypothesised that people who have had at least one child may be more likely to find at least one acceptable

Criteria	Why considered
Marital status	being married may influence acceptability
Outcome	to gain views about the intervention from participants who found at least one acceptable and those that found none acceptable

Next, I prioritised the criteria by listing the variables in order of importance (Table 10.2).

Table 10.2 Selection criteria in order of importance

Primary importance	Secondary importance	Tertiary importance
Age (16-19/20-24)	Number of children* (0/1+) (proxy for marital status)	Ethnicity
Gender (female/male)	Occupation** (in education/other) (proxy for education)	Method at baseline
Outcome (acceptable/not acceptable)	Intention at baseline (wants to avoid/other)	

* In Tajikistan, education level and occupation were correlated
** In Tajikistan number of children and marital status were correlated

I decided on a sample size of up to 20 interviews in each country. This was based on my previous experience conducting interviews with trial participants that indicated that around 20 would be sufficient to better understand participant experiences (211) and a pragmatic decision given the time and resource constraints of the project. I based the selection criteria for Palestine and Bolivia on the selection criteria for Tajikistan, but in Palestine number of children replaced gender (because the trial included women only) and Bolivia included only age and the acceptability outcome because few participants in the sample were married or had children. I then created a sample matrix for each country.

Tajikistan

Because of the contamination in the trial, I decided that it would be beneficial to interview control participants as well as intervention participants. Since most of the interviews were conducted after I discovered the contamination, I amended the discussion guide to understand how intervention participants viewed the effect of the messages compared to the contraception information on the app. This included questions about what intervention participants learned from the app pages, if the app pages influenced them in any way and how the app pages and messages differed. I also created a control discussion guide that was based on the intervention guide but did not include questions regarding the messages (Appendix 20).

Table 10.3 Trial interview sample (Tajikistan)

	Intervention				Control			
	At least one acceptable		None acceptable		At least one acceptable		None acceptable	
	Female	Male	Female	Male	Female	Male	Female	Male
16-19	2	2	1	2			1	1
20-24	1	1	2	1	1	2	1	
Other	1 female, 16-19, randomised twice to different arms, received intervention, not followed-up				1 male, 20-24, non-responder			

Palestine

All interviews in Palestine were conducted with intervention participants. This was because control participants only received messages about trial participation.

Table 10.4 Trial interview sample (Palestine)

	At least one acceptable		None acceptable	
	0 children	1+ children	0 children	1+ children
18-19	3	0	5	0
20-24	3	3	3	3

Bolivia

My intention was that the interview sample in Bolivia would include 75% intervention participants and 25% control participants. I wanted to interview control participants as well to explore whether the standard family planning information provided on the app itself influenced control participants' attitudes, knowledge, agency, behaviour and intention.

Generating a list of participants to interview

Based on the selection criteria, I generated a list of potential interviewees in each country. At this point, I was still masked to treatment allocation in Palestine and Bolivia, so I generated two lists, by masked allocation group (e.g. group D, group C). I assigned each trial

identification number an interview identification number. My unmasked colleague Dr Palmer then labelled the groups to control or intervention, password protected the spreadsheet and sent the list to the interviewers, so that I remained masked.

10.2.3 Interviews

I conducted remote interview trainings with the research staff member conducting the interviews in each country. The training included obtaining informed consent, interviewing techniques such as probing and use of non-verbal listening skills. The interviewers provided verbal and written information about the study (see the Interview information sheet in Appendix 21) and then the interviewees provided written informed consent (Appendix 22). The interviewers audio recorded the interviews, made notes in English from listening to the recording, and sent the notes to me, identifying participants only by their interview identification number. I gave feedback to the interviewers regarding the quality of their report and then sent another batch of interview participant IDs to complete using the procedure described above with Dr Palmer. The goal was for the interviews in all three countries to be completed by the end of November 2017. Tajikistan and Palestine completed 20 and Bolivia had completed five by this date. In addition, the interviewer in Bolivia left the organisation around the time my maternity leave commenced in December 2017, meaning that the new interviewer had not received my training (although had access to my training documents) and did not receive the feedback that I was able to provide the interviewers in Tajikistan and Palestine. I did not receive the additional interviews from Bolivia until March 2018, while I was still on maternity leave.

10.2.4 Analysis

By country, I grouped the interview data in a spreadsheet according to discussion guide theme. I then reported the data for each theme.

10.3 Results

10.3.1 Tajikistan

Receiving the messages and confidentiality

All intervention participants were positive about receiving the messages. One participant said that she liked the way that the information was divided into different parts so that it is easier to memorise. Most participants thought that the number and frequency of the messages was

just right, with a few saying that there should be more, sent for longer than four months. Participants said that they saved the messages to reread later. The only non-positive comment was that the message content about efficacy of the different methods was repetitive. Most control participants liked having the app on their phones. One control participant said that he found it boring to read the text on the app pages.

Most intervention and control participants were not concerned about confidentiality. Four participants did not want their parents or friends to know that they had the app on their phone. Three of these participants said that they had positive discussions with their parents about contraception. For example, one participant said that her mother was interested in the pill, so she showed her the messages. Her mother then had a "positive attitude toward her daughter and the app" (my quotes of interviewer's notes).

Knowledge

All participants said that they learned a lot about the methods. All control participants said that they read the app contraception pages. Many participants, both intervention and control, said that the new information improved their beliefs about contraceptive methods.

Attitudes

Most participants said that the accurate knowledge they gained from the app or the app and messages improved their attitudes towards contraception. Participants mentioned that the content (both on the app and the messages) made them realise the importance of talking to their partner about contraception. They said that the messages helped them distinguish between facts and myths. A few participants said that they were not aware of the different methods before the study, so they had no attitudes towards them. Most however, said that they had basic awareness of the different methods and had heard of the various myths about them and that the information on the app and in the messages improved their attitudes towards them.

> "Before participation at the study, I had negative attitude about some kinds of contraception and thought they are more likely harmful than useful" *Intervention participant, id 15703, female, aged 20, no methods acceptable at follow-up*

Agency

Most participants said that the new knowledge they gained helped them feel more confident either in using or communicating about contraception.

Behaviour and intention

No participants said that their behaviour changed as a result of the app or messages but reiterated that they improved their attitudes towards contraception. Most said that the content changed their intention or "future behaviour", in that they intend to use contraception and talk to future wives/husbands about family planning.

Environment

Nine participants said that there were no barriers to taking care of their reproductive health. Other participants talked about husbands and relatives being barriers to using contraception. One participant held a rather pessimistic view regarding environmental barriers in Tajik society:

> "The main barrier in reproductive sphere is the society and its influence to the individual. Society somehow does not let people to do what they want to do with regard to their reproductive health. For example, I want to go to a service, but I cannot, because I am worried about what others will think of me. This barrier cannot be overcome. We cannot change society's attitude". *Intervention participant, id 15855, female, aged 17, at least one method acceptable at follow-up*

The contraception app content vs the messages

Views on the differences between the app and the messages were very mixed. Some participants preferred the content on the app because it provided more information than the messages. Others appreciated the short daily messages and thought it convenient to read little by little each day. These participants wanted the messages to continue for longer than four months. Participants said that the messages reminded them about the app and that without them, they would forget that the app was on their phone. However, another participant said that the fixed page was more convenient because they didn't have to wait for the messages. One participant said that the app contraception content read like a brochure and seemed boring. This same participant said that the messages were the same as the app but contained stories, which made her prefer the messages.

Other

Most participants said that the app and messages should be available to all young people in Tajikistan. One participant said however, that it would be difficult for the app to be accepted in Tajik society:

> "This application is useful and I think each young person has to has access to this application. However, if to take into account our mentality, it would be difficult to some young people to use it, as their parents will be against of this kind of application, if they discover it." *Intervention participant, id 15528, aged 19, male, at least one method acceptable at follow-up*

10.3.2 Palestine

Receiving the messages and confidentiality

Besides the few participants that mentioned receiving too many messages at once due to the period where there were technical problems with the texting system, participants were very enthusiastic about receiving the messages and spoke of waiting eagerly to receive the messages.

> "I used to read the messages right away even if I'm with people. I read all the messages and I used to wait eagerly to receive them." *id 15394, aged 24, 2+ children, at least one method acceptable at follow-up*

> "I loved the messages very much, it was an important source to get information from. I was longing to know and receive more messages and information. I didn't face any trouble. And the number of them were appropriate and each method was explained appropriately, and clarified. I used to read the messages right away. And I used to read each method in one package when all received." *id 20114, aged 20, 1 child, no methods acceptable at follow-up*

A few participants said that they deleted the messages after reading them but most mentioned saving the messages to reread later. Some even wrote the messages elsewhere:

> "All the messages I received are still in my mobile, and I wrote all of them in my special notebook." *id 15296, aged 24, 0 children, no methods acceptable at follow-up*

All participants said that they had no confidentiality concerns with receiving the messages. The interviews indicated that most parents were aware that their daughter was participating in the study. Participants said that they discussed the messages with a wide range of people

(e.g. husband, mother and father, mother-in-law, husband's sister, wife of husband's brother, aunt, sister, cousin, brother's wife and friends).

> "Once my husband read a message and I felt that he become happy because the messages raised his awareness about the topics. My husband and I took a discussion on a message received about the IUD; if it's the best option or not to use. As a result, we took a decision to choose the IUD, but I still need more information about it." *id 16373, aged 21, 1 child, no methods acceptable at follow-up*

> "And I read the messages to my friends who are participating also in the study and they didn't receive any message about this topic and they were sad. And so I had to send them all the messages." *id 20114, aged 20, 1 child, no methods acceptable at follow-up*

> "My mother was excited to know the information" *id 15848, aged 19, 0 children, at least one method acceptable at follow-up*

One participant appeared to not receive the intervention messages.

Knowledge

All participants except for the one that appeared to not receive the intervention said that the messages increased their knowledge about contraception. Participants frequently referred to misinformation:

> "The most important thing is not to accept any random information from anyone because it's not scientific and safe enough. And I have to directly take it just from the health providers. When I took the contraception (pills) my mother in law, sister and my father used to warn me and scare me to stop using it. My father was totally against me using the pills….Through the messages my thoughts totally changed about the contraception and I'm convinced that the people are stupid." *id 15715, aged 22, 0 children, at least one method was acceptable at follow-up*

> "People are thinking that it (OCs) cause infertility especially after having the first child. I'm so sorry to say that people don't know and they don't believe in science and just they are stuck in what they know." *id 20114, aged 20, 1 child, no methods acceptable at follow-up*

Participants mentioned that they had heard of the IUD and OCs, but for many, the implant and patch were new:

> "I didn't know about all the different methods of contraception before the study. I had heard about the IUD, pills and the injection before the study, however I only

> heard about the implant and patch through the messages. Before the study I thought that contraception causes infertility. But now I know that it is safe to use it and it is actually a way for women to care for their health. In addition, in the past I wasn't sure I would use a family planning method, although I use to think about, but now I am certain that I will use contraception in the future, since now I am convinced that it is safe." *id 15837, aged 19, 0 children, at least one method acceptable at follow-up*

The above quote illustrates how the acquisition of new, accurate information changed the participant's beliefs about contraception and intention to use it.

One participant, while she learned new information, felt that the messages should be more detailed:

> "Most of the messages I received were about contraceptive methods and I got great information from them. All the messages were very important and some of the information were new to me but all of them lacked details." *id 18572, aged 19, 0 children, no methods acceptable at follow-up*

Overall, participants felt that they learned a lot of useful information from the messages, which piqued their interest in learning more and in using methods either now or in the future.

Attitudes

Participants spoke mainly about how the information that they learned from the messages changed their beliefs.

> "Before the study I wasn't convinced to use pills but after I participated in the study my information has been corrected and my thinking has changed." *id 15394, aged 24, 2+ children, at least one method acceptable at follow-up*

> "I was constantly thinking about contraceptive methods and I encouraged my sister to use an effective contraception method. The study enhanced my concepts on this issue and my beliefs also changed and encouraged me to use them comfortably in the future." *id 15837, aged 19, 0 children, at least one method acceptable at follow-up*

Although, one participant said that her attitudes did not change, because she had a positive attitude towards contraception before the study:

> "Nothing changed because I believed in this issue before I participated in the study. In my opinion having one child is enough, having children doesn't mean we have to have many children. The study encouraged me even more to use contraception methods in the future and I will use the implant." *id 15592, aged 22, 0 children, at least one method acceptable at follow-up*

Participants spoke of the messages not only improving their attitudes towards contraception but also generating interest and enthusiasm for the topic:

> "Before the study I wasn't interested but now it's very important. I didn't have lots of information before I participated in this study, but now I have wide knowledge regarding the study…this subject was very embarrassing to me but now I accept it normally." *id 15361, aged 23, 0 children, at least one method acceptable at follow-up*

One participant mentioned feeling that the messages were from a trustworthy source. She spoke of feeling fearful about using contraception before the study, because of myths she heard in her community:

> "Before the study I used to take the information I wanted through the internet. I liked the way that I receive the messages through mobile. Now I have all the messages saved and I will read them. The most important point, for me is the source of the messages was from a trustworthy association… Before the study, my husband and I had fears regarding the usage of contraceptive methods such as pills because maybe its causes fetal malformations. Also we had fears about the IUD, as we had heard from the people that its causes infertility. The environment where I live in, is a lagging environment and the people are not educated and most of them are against using contraception method." *id 17656, 23, 2+ children, 0 methods acceptable at follow-up*

Agency

Besides the participant who appeared not to have received the messages and the participant who said that she had a positive view about contraception before the study, all participants said that their confidence regarding contraceptive methods improved. Participants spoke of feeling fearful before the study, but after the study feeling confident in using contraception and talking to their partners about it:

> "Yes, sure my confidence changed a lot. Now the fear to use the contraception methods is gone and I'm ready to use them now. In addition I have lot information about the methods this is why I'm not afraid to use them. Right now I have a control on myself to use the methods, also my husband want me to use these methods. I didn't try to talk with my husband about this issue before the study. But now I talk to him smoothly and he accepts the information easily." *id 16276, aged 24, 0 children, no methods acceptable at follow-up*

Participants spoke about lack of trust in the methods before the study, stemming from misinformation in the community:

> “I didn’t trust them before, because I used to hear wrong information about them from the people which increased my fear. But after my participation in this study everything changed and my trust increased now for using the contraception. Before my participation in this study I hadn’t any trust to talk in this topic. But now after the I got training and participated in this study I have a wide knowledge and much information in this topic, in addition much bravery in discuss it and without any hesitate." *id 15296, aged 24, 0 children, no methods acceptable at follow-up*

The participant who did not receive the intervention messages was the only participant to express lack of confidence in using methods:

> “I know that all the methods have side effects and I have a fear of use them, and because I hear the people around me talking about them." *id 15300, aged 24, 1 child, no methods acceptable at follow-up*

One participant said that her family was encouraging her to use contraception, but she was afraid. It was receiving the intervention messages that changed her views:

> "Before the study I wasn’t confident in using contraceptives. My mother in law and my husband wanted me to take the pills after I gave birth to my first child, but I refused because I was afraid if I did I would not be able to become pregnant again. Through the discussions with my mother in law and other people I started to consider using a contraceptive. It was with me reading the messages that I received that finally convinced me that using a contraception was a good choice." *id 15394, aged 24, 2+ children, at least one method acceptable at follow-up*

One participant even said that her participation in the study influenced her personality by making her feel less shy and more willing to take part in other activities:

> “Before the study I was too shy and didn’t like to participate in any activity. But after I participated in this study and I liked it, also my personality started to change. Now I’m ready to participate in other activities and be a volunteer at other associations and similar associations.” *id 16965, aged 18, 0 children, at least one method acceptable at follow-up*

One participant spoke specifically about her communication self-efficacy improving after the study:

> "Before the study I wasn't able to discuss and talk about the contraceptive methods because I wasn't sure about my information. Now after the study my confidence related to this subject is 100% and I'm able to discuss confidentially without any hesitation." *id 15361, aged 23, 0 children, at least one method acceptable at follow-up*

Behaviour and intention

Many participants said that the messages increased their intention to use contraception in the future:

> "Before the study I had fears and worries from using the contraceptive methods, but after it my confidence increased because I have more information about them, moreover I have a strong intention of using them in the future." *id 15362, aged 23, 0 children, at least one method acceptable at follow-up*

Some participants said that the messages had encouraged them to use contraception and were currently doing so:

> "I went to the clinic and to the pharmacy to use the pills. The messages have encouraged me to use the pills with full confidence and without any fears and I intend to use the injection in the future." *id 20114, aged 20, 1 child, no methods acceptable at follow-up*

Participants also spoke about how taking part in the study lead to discussions with their partners:

> "Before the study I didn't talk a lot with my husband about using effective contraception, only we discussed that probability to use the IUD. Now after I got more information and knowledge about the topic and discussed it with my husband we reached the result to most likely use the IUD." *id 16373, aged 21, 1 child, no methods acceptable at follow-up*

They also felt that the messages helped them dispel myths they heard about the methods in their communities and families and helped them talk about contraception in general:

> "Now I openly talk with my sisters and advise them on using contraceptives. Moreover, I'm ready to give advice for anyone I know and correct her/his information, especially many people thinking that these methods cause infertility." *id 15837, aged 19, 0 children, at least one method acceptable at follow-up*

> "I became more courageous and less shy to talk about this topic with my sisters and brother's wife, I can now openly participate in discussion with them about this topic. I have also discussed with my friends and colleagues in the institute where I study regarding the messages I received." *id 18133, aged 21, 0 children, no methods acceptable at follow-up*

> "I talk about this topic with my colleagues at work. I have a friend and I advised her to use the IUD. Now I know the difference about the correct and wrong information when talking about the IUD. I discuss as well with my friends and my colleagues because some of them use the pills." *id 17656, aged 23, 2+ children, no methods acceptable at follow-up*

> "I have been discussing more with my husband, mother in law and family more vigorously and insistently. I'm so insist that I take the decision for me and my husband only. And nobody has the right to interfere in my private life. But unfortunately, most of their convictions contradict my convictions, and it's so difficult to change their thoughts and believes. For sure in the future I will use the IUD, because if I want to use the pills it would be a problem because I'm afraid to forget using them at the same time." *id 15715, aged 22, 0 children, at least one method acceptable at follow-up*

In contrast to the positive comments from the other participants, the participant who did not receive the messages expressed fear regarding the use of the IUD:

> "In the past I was thinking to use the IUD but I heard that he causes problems. So now I have a fear to use it because I heard that it has side effects." *id 15300, aged 24, 1 child, no methods acceptable at follow-up*

Environment

A few participants spoke of family members pressuring them to have children:

> "All my family is against me and my husband and friends as well, I have 8 sisters all of them against me except one who is ten years older than me. And all of them are surprised because I don't want to give birth now. My family is a traditional one therefore they like the big family and to keep giving birth and having a lot of children. For me it's enough to have three children and this is what I want. But my family wants me to keep giving birth as long as I am able to do that and have no obstacles preventing me to keep giving birth." *id 15715, aged 22, 0 children, at least one method acceptable at follow-up*

One participant said that her wider family was unsupportive of her using contraception, but her mother was supportive of her and encouraged her to use contraception so that she could continue her studies:

> "There are family members who have always advised me not to use any form of contraceptive methods before having another child (second one), and they say that using them causes infertility and other problems. On the contrary my mother advised me not to have another child before continuing my studies in the University. The most important point is what my husband and I agree on about this topic." *id 16373, aged 21, 1 child, no methods acceptable at follow-up*

However, most participants said that they did not face any environmental obstacles regarding family planning:

> "I didn't face any obstacles nor won't face any in the future preventing me from taking care of my sexual and reproductive health." *id 17606, aged 18, 0 children, no methods acceptable at follow-up*

One participant spoke of societal pressure to have more children, but felt that she could cope with it:

> "Nothing prevents me to take care of my health. I wanted to use the IUD after the first child but the people and the society pressure advised me to have at least two kids and then I can put the IUD. My husband wants more kids but I refused that because it's a huge responsibility and I can't bear it. Now he accepted my opinion and agreed with me to use the IUD for five years and after that we can have more kids." *id 18704, aged 23, 2+ children, at least one method acceptable at follow-up*

One participant reflected on societal barriers have led to her current situation, which she is not satisfied with:

> "Having more kids is an obstacle for me in being able to care for my sexual and psychological health. I regretted having a second child. Nothing is preventing me from taking care of my health and going to receive related services. For a while my husband was not working and we could not afford for me to get an IUD, but when he got work, I took money from him and went to put the IUD. The society thinking in this topic is backward, and all the society needs more awareness. People just keep having children without thinking, they just want to have more children. I'm very upset because I have no life except my marriage and kids. I want to work because I'm educated but my husband doesn't cooperate with me in that and he objects to me working." *id 15394, aged 24, 2+ children, at least one method acceptable at follow-up*

Recommendations

Participants in general thought that the messages should provide more details about the methods, with many wanting more messages sent over a longer time period.

> "More detailed information and increase the number of messages. Extend the period of the participation in the study to be more than four months. Send messages for

> married women and single women, age 16 and above. I think the messages should be offered for all young females and males, but more focused on females. As a result, early marriage would decrease." *id 17606, aged 18, 0 children, no methods acceptable at follow-up*

Participants thought that the messages should be sent to a wide range of people, e.g. mothers, mothers-in-law, people in rural areas and young people.

> "I would like to advice to send these messages to all young people. Because it is a really important issue. In addition we have an opportunity to change their ideas and concepts about this topic." *id 18572, aged 19, 0 children, no methods acceptable at follow-up*

Participants also spoke about the need to send messages to young people in particular because of the problem of early marriage in society:

> "It would be good to increase the number of the messages…for all youth from age 16-20 because we have early marriage phenomena." *id 15361, aged 23, 0 children, at least one method acceptable at follow-up*

> "Send the messages to mothers especially who have been married for a long time. Publish and circulate such messages in schools and educate students from age 14 to avoid early marriage. The messages should go to all young females and males to educate about this important topic. Some males don't know anything about sexual reproductive health particularly issues related to women." *id 18081, aged 19, 0 children, no methods acceptable at follow-up*

One participant thought that the messages should include counselling for married women to convince their husbands to allow them to use contraception:

> "The messages should include psychological counselling for married women to be able convince their husband to use the contraception and avoid or prevent repeated pregnancies spaced too close together. The prominent masculine society believes that the women's role is only to reproduce.…Our streets do not need any more children, one child is enough." *id 15592, aged 22, 0 children, at least one method acceptable at follow-up*

10.3.3 Bolivia

I sent instructions with the list of potential participants in which to interview, according to randomised arm, as I did with Tajikistan and Palestine. Bolivia returned interviews for four intervention participants and 15 control participants, labelled with the interview id as requested. Upon reviewing the interviews, it transpired that the opposite discussion guide

was used in nine interviews (the control guide was used for two intervention participants and the intervention guide was used for seven control participants). In five interview reports with control participants, it appeared that they received the intervention messages. There was nothing in the trial data, however, that suggested that control participants received the intervention messages, so this is most likely a labelling error. One file was named 'Interview ID 67' but was labelled 'Interview 6' within the document. These recording and reporting discrepancies meant that I did not have confidence that the reports corresponded to the correct participant id. In two interview reports with intervention participants, it appeared that they did not receive messages. This is consistent with the trial data that suggested some intervention participants did not receive the intervention messages. In addition, the interview reports were very sparse and read more like short responses to a questionnaire.

For the reasons above, it was not possible to achieve the aim of the interviews and therefore I have not reported them as I have done with the Tajikistan and Palestine interviews. For the one interview with an intervention participant where the intervention discussion guide was used, and it was clear that they received the messages (*id 17535, aged 18, at least one method acceptable at follow-up, was not using effective contraception at follow-up*), the participant said that she did not read the app pages because she did not have time. She preferred the intervention messages because they were "short and concrete". She liked receiving the messages because they contained new information. She approved of the number of messages and did not have confidentiality concerns. She spoke about learning a lot about the IUD, and how this new information changed her thinking. Before she thought that the IUD and other methods were harmful but after receiving the messages, she did not believe this anymore. The participant also reported that she feels more confident because she has more information. She said that she intends to speak with her partner but her behaviour, however, did not change.

10.4 Discussion

Overall, from the intervention recipients' perspective, it appears that the increase in knowledge that resulted from the intervention (delivered by the messages in Palestine and the messages and app contraception pages in Tajikistan) was the active component. This fits with this project's theoretical model in that knowledge influences attitudes (Figure 4.2). Participants in Tajikistan and Palestine were very positive about the intervention content. Most did not have concerns about confidentiality and many spoke about how their confidence in using contraception improved and how they intend to use it.

A strength of this descriptive report of the interviews in Tajikistan and Palestine is that it enriches the understanding of how the intervention affected attitudes, knowledge, agency, behaviour and intention among trial participants. The reports provide a qualitative insight into the experience of the trial participants. Another strength is that the samples include participants that vary demographically, so that the views of a range of participants were represented.

There were several limitations of this report. Because I was not able to conduct the interviews myself, the interviewees were not probed as often as they would have been, had I conducted the interviews. The interviews were not transcribed verbatim and back translated. The quotes were the interviewer's interpretation/translation. The reporting variability in the notes between the two countries meant that I have reported the results differently; in Palestine, the notes were more like interview transcripts, so I was able to report more quotes. In some sections of the Tajikistan notes, it was difficult to tell if the text was the interpretation of the interviewer rather than what the interviewee intended. For example, in the below excerpt, it was not clear if it was the interviewer's opinion that the interviewee had the 'wrong interpretation' or if this was the interviewee's opinion:

> Before the study, as it was already mentioned, he had wrong interpretation regarding some kinds of contraception methods. Mostly it has changed because of the information he got from the messages and the app contraception page. (*id 15550*)

Also, the meaning occasionally was not clear as exhibited by the excerpt below:

> The participant mentioned that despite the sexual behavior, active or passive, people have to talk with each other about contraception. (*id 15929*)

When the meaning was unclear, I would ignore the text rather than attempt to discern what was meant, because it was not possible to clarify this with the interviewers.

Despite the limitations, the interviews provide a useful insight into how the participants view the effect of the intervention. It was clear that the Tajikistan and Palestine participants were very enthusiastic about the intervention messages (and the app itself in Tajikistan). From the participants' point of view, the intervention messages and the app in Tajikistan increased knowledge, which led to an improvement in attitudes towards the effective methods, intention to use them and confidence in using and communicating with partners about the effective methods. Likewise, in Palestine, participants viewed the messages as increasing their knowledge about effective contraception, which improved their attitudes towards the methods, agency in using and communicating with partners about them, intention to use the methods and some participants attributed their use of effective contraception. In Tajikistan, the messages sent through the app seemed to serve to remind participants about the app. This reminder appeared to boost engagement with the app itself. As intervention content was also on the app, participants could have received a greater dose of the intervention compared to the Palestine participants because they had the option to read the intervention content in an alternative way.

The interviews suggest that the provision of accurate information from a trustworthy source in a context where there is none or very little, influenced participants' beliefs and intention and potentially also their behaviour.

11 Discussion

11.1 Summary of the thesis

In Chapter 1 I introduced the health problem that is the ultimate focus of this thesis, (unintended pregnancy), described the origin of the three country-project and outlined my thesis. In Chapter 2 I reviewed the literature on the main factors that influence contraceptive use in LMIC and describe the context in each country regarding contraceptive and mobile phone use. I also reviewed trials of interventions delivered by mobile phone, with a focus on the development, theoretical basis and reported efficacy of the interventions. These chapters provide a background for the research activities that I described in detail through my research papers in Chapters 3 and 5-8.

Chapter 3 consists of the published research paper that details the development of the intervention. Intervention Mapping provided a useful guide for theory-based participatory intervention development. The results of the intervention development were similar across the countries. The process produced an acceptable and highly-specified individual-level contraceptive intervention delivered by mobile phone, tailored for each country.

In Chapter 4 I described the Integrated Behavioural Model in more detail, which is the theoretical basis of the intervention. Because the evaluation methods were largely similar, I combined the three published trial protocols in Chapter 5, highlighting the methodological differences. In this chapter I also present additional information that was not included in the published protocols on how I constructed the trial outcome measures and how I built the baseline and follow-up trial databases.

Chapters 6, 7 and 8 present the trial results in each country. In Tajikistan, intervention content was included on the app, causing contamination. There was no evidence that the intervention and control groups were different regarding acceptability of effective contraception (66% intervention vs 64% control; adjusted OR 1.21 95% CI .80-1.83, p = 0.36). Because of the contamination, I conducted a post-hoc analysis of change in acceptability of effective contraception from baseline to follow-up using data from all participants who completed the primary outcome together, which showed an increase from 2% to 65% ($p < 0.001$). The Palestine trial recruited to target, achieved 80% follow-up response for the primary outcome acceptability and found that intervention recipients had 2.34 times the

odds of finding at least one method acceptable compared to the control group (95% CI 1.48-3.68, $p < 0.001$). In Bolivia, recruitment and follow-up was challenging and we did not meet our targets. Consequently, the results were equivocal. The odds ratio of 1.19 for use of effective contraception (33% in the control and 37% in the intervention) observed in the Bolivia trial, however, would be worthwhile, if it were true. While there was a substantial increase in self-reported use in both arms, this could be because young women already interested in using effective contraception were more likely to take part than those that had no interest. When the results of the three trials are considered together, it seems likely that the intervention content is effective at increasing acceptability across different contexts.

In Chapter 9 I presented three additional analyses. The first was a psychometric evaluation of the acceptability outcome measure, which indicated that the measure has internal consistency and predictive validity. The second was a post-hoc change from baseline to follow-up analysis in Bolivia. As in Tajikistan, this analysis showed a large increase in acceptability from baseline to follow-up (9% to 67%, $p < 0.001$). The third was a cost-analysis, which provides a financial guide for adapting the intervention to other settings.

Finally, in Chapter 10, I reported my descriptive analysis of the interviews conducted with trial participants in each country. Participants in Tajikistan and Palestine were very enthusiastic about the intervention content (delivered by SMS in Palestine and by app instant message and through the static app pages in Tajikistan). While I was not able to meaningfully analyse the Bolivia interviews due to the lack of clarity in the reports overall, the reports were consistent with the trial results that indicate that some intervention participants did not receive the intervention messages. Drawing on the interviews and trial results in Tajikistan and Palestine and the theoretical framework, it is likely that accurate information about contraception provided by a trustworthy source changed people's attitudes by increasing their knowledge.

11.2 Challenges and opportunities

One of the main challenges throughout the course of this project was communicating scientific research principles to the local partners so that they were able to conduct the research according to protocol. This was the first randomised controlled trial that the local partners had been involved in. Adding to this challenge was the fact that my first language was not the same as either of the partners' first language (although in Palestine, the United

States-born Finance Director frequently attended meetings, which was an asset). By varying degrees, at different points in the project, the language differential made it a challenge to ensure mutual understanding. It was this challenge that resulted in the contamination in the Tajik trial. Further complicating the language differential was the challenge of managing the research remotely. Had I been based locally, I would have had more in-person contact with the partners, which would have helped facilitate mutual understanding.

Delivering the interventions to the correct participants by mobile phone was a major technical challenge. It took months and many meetings involving the LSHTM systems developer and the local platform developers in each country to integrate the application programming interface (API) (written by the LSHTM systems developer) that connected the LSHTM-based randomisation system to the local platform that sends the messages. After the API was integrated, we tested it repeatedly with test mobile numbers in each country, making sure that numbers randomised to the control receive the control messages and that numbers randomised to the intervention received the intervention messages. We also tested the timing of the message delivery, fixing the technical problems as they arose. We did not start trial recruitment until I was satisfied that the process was working. Despite this, technical problems arose in the Palestine and Bolivia trials after they commenced. In the Bolivia trial, I did not become aware of the message delivery problem until I analysed the data and discovered that 19% of intervention participants who answered the free text question in the follow-up questionnaire said that they did not receive any messages. Unfortunately, it was not possible to investigate this problem further at the point of discovery.

The technical problems in Palestine, however, were discovered in real time. Because the messages were delivered by SMS, we were able to monitor their delivery through the online SMS delivery platform. So that I remained masked to allocation, only Dr Palmer had access to the online platform. Each week during recruitment, she would extract the mobile numbers from the platform. I would then check the mobile numbers against the mobile numbers on the LSHTM-based randomisation system. Occasionally, we discovered that there were numbers on the LSHTM system that were not on the Palestine platform, meaning that baseline data was entered and randomisation occurred, but the information was not received by the Palestine platform. In these cases, the LSHTM systems developer pushed the numbers from the LSHTM system until they were received. Participants were due to receive the first

message the day after their baseline data was submitted. This problem resulted in a delay to the start of the messages among some participants.

There was also a technical problem with the delivery of the messages from the local Palestine platform. The online delivery platform interface displayed all messages that were scheduled, sent and failed. In addition to checking the mobile numbers, Dr Palmer monitored the message delivery. About a month into the trial, she noticed that there were a significant number of messages that were displaying as “scheduled” to be sent on a day in the past, seemingly indicating that the messages had not been sent or failed. After correspondence with the local developer, we came to understand that this problem was caused by the Microsoft server, however we were unable to ascertain the details. The local developer then switched to a new server, which resulted in messages not being sent and, among some participants, in receiving many messages at once. A separate problem also occurred later in the trial where the local developer stopped the server without warning, because their contract with PFPPA ended. This also resulted in some participants not receiving messages. The result of these problems was that many intervention participants did not receive the full intervention, meaning that the effect estimate in the trial is likely conservative.

These technical problems highlight the importance of monitoring the delivery of the intervention to ensure fidelity, which is even more important when interventions are scaled-up but may not always be possible. Rokicki 2017 also experienced technical problems with intervention delivery in their trial and estimated that their intention to treat analysis was conservative (140).

It was inevitable that there would be different priorities within the diverse group of people that were involved in this project. For our local partners, it is understandable that service delivery, rather than the research, was their main priority. Considering this, it is not surprising that Bolivia did not want to extend recruitment (this was offered to them as my maternity leave would have enabled the recruitment period to continue). They were working to a specific timetable and wanted their app to be made widely available in Bolivia as soon as possible.

IPPF’s role was to facilitate communication and joint decision making between LSHTM and the local partners and to monitor and ensure compliance with the research grant agreement.

They also conceived of the aim of the project, including the choice of the three countries. The factor that linked the countries when this project was conceived was that each country included a mobile phone component in their original proposals. This unconventional approach to conceiving of a research project meant that my role was very work-intensive as I led three intervention development and evaluation research projects in the time that is normally planned for one. Despite the challenges, through frequent remote meetings, email correspondences, field visits, humour and complex discussions, the research was conducted to a relatively high standard in Tajikistan and Bolivia and a high standard in Palestine. I benefitted professionally and personally from the opportunity to work with partners in different contexts with a range of backgrounds.

11.3 Limitations

There are several limitations to this thesis. One is in relation to the self-reported outcome measures. Because they are self-reported, they are more likely to be biased than if the outcomes were objective, such as clinic verified use of contraception. Sexual activity before marriage is stigmatised in all countries and in Tajikistan and Palestine, it was clear from the formative work that if young people were sexually active and not-married, they would not admit to it. This precluded the option of an objective primary outcome in Tajikistan and Palestine. Not-married young people in Bolivia did admit to sexual activity in the formative work, therefore we could justify including use as a co-primary outcome in this country.

While the questionnaires were tested with the target groups for face validity, I did not have the time or resources to conduct a questionnaire validation study. The additional psychometric analysis of the individual method acceptability measures suggests that the measure has internal consistency and predictive validity. However, a measure validation study is warranted. In deciding how to score the acceptability measure, I decided that it was better to avoid false positives; for a method of effective contraception to be acceptable, participants had to choose ‘agree’ or ‘strongly agree’ to the positively worded stems and ‘disagree’ or ‘strongly disagree’ to the negatively worded stems. In other words, for participants to score ‘acceptable’ for a method, they must have unequivocally thought the method acceptable. An example of a problem with the scoring is that it is possible that an individual could believe that a method had unwanted side effects but would still use it because they felt that the benefit of using it outweighed the risks (that is, an unintended pregnancy is more unwanted than the perceived side effect). This is exemplified by the

interviews in Palestine. Quite a few interview participants who did not find at least one method acceptable at follow-up indicated that they had positive attitudes and intended to use a method. The scoring means that the measurement of acceptability is likely underestimated. While this does not have implications regarding the effect of the intervention relative to the control, it means that in the samples overall, the true acceptability may have been higher at baseline and at follow-up.

Another limitation is the contamination in Tajikistan. Had the contamination not occurred I could comment with greater confidence about the efficacy of the intervention across different contexts. Related to this, is the low follow-up and under-recruitment in Bolivia. Had we been able to produce more precise estimates, I could conclude more about the generalisability of the intervention across the three very different contexts.

A further limitation relates to the contexts in which the interventions were delivered. The environmental constraints such as societal pressure to marry and start a family early are extremely influential and were not targeted by this intervention. The trials were designed to evaluate the effect of the intervention on acceptability of effective contraception among young people (and on use in Bolivia). In young non-sexually active people, the intervention aims to improve their attitudes towards the effective methods so that they have greater choice when they want to limit or space their future families. Further work could involve a longer follow-up period where we can observe effects of the intervention on desired family size.

11.4 Cross-country considerations

Despite the limitations, there are inferences can be made about the generalisability of the intervention when the results of the three trials are considered together. It is very likely that the intervention delivered by short messages through a mobile phone improves attitudes towards effective contraception across different contexts. The degree to which it does however, depends on what is offered as usual care. For example, when the comparator is no family planning information, as in the Palestine trial, the intervention more than doubled acceptability in the intervention arm. There was also a beneficial effect of the intervention on attitudes, knowledge and intention. However, when usual care is standard family planning information provided on a mobile app, as in the Tajik and Bolivia trials, the intervention is likely to be moderately more effective. In this thesis, the difference however, cannot be

precisely estimated, due to the contamination that occurred in Tajikistan and the low recruitment and follow-up in Bolivia.

The results of the trials can also help to clarify the components of the intervention were the most effective. For example, in the Tajik trial, the large increase in acceptability from baseline to follow-up and the lack of evidence of a difference between the groups suggests that the intervention content included on the app alone can change attitudes. The Bolivia trial results suggest that standard family planning support delivered on app pages may change attitudes and that the intervention delivered by instant message through the app may moderately boost this effect. The post-hoc change from baseline analysis that I conducted among all trial participants in Tajikistan and Bolivia suggests that simply providing accurate information from a credible source might be all that is needed to produce dramatic improvements in attitudes towards effective contraception.

An alternative explanation for the improvement in attitudes at follow-up across the countries could be due to the Hawthorne effect (212). That is, it is possible that participants were more likely to report positive attitudes towards effective contraception because they were aware that it was the trial's topic. Participants were aware of the trial's topic when they completed the baseline questionnaire and baseline acceptability was very low (2% in Tajikistan, 8% in Palestine and 8% in Bolivia). It is possible that exposure to contraceptive-related content during the trial however, primed intervention participants' awareness of the trial topic. This effect could have occurred among control participants in Tajikistan and Bolivia, because the app contained contraceptive information. Another contributing factor to the observed increase in acceptability could have been that people who chose to participate were people already wanting more information about contraception, so they could have been more receptive to the intervention than someone who was not seeking information about contraception.

While it is likely that the intervention can improve attitudes, changing behaviour (use of effective contraception) is more difficult, or at least more difficult to measure objectively. According to the project's theoretical model, the performance of the behaviour requires it to be salient and requires the removal of the environmental barriers. Young people may not find contraceptive use a salient behaviour if they either are not sexually active or are sexually active and want to conceive or feel pressured to conceive. As mentioned in the Limitations

section, the environmental barriers, such as pressure to start a family, are not targeted by the intervention.

Overall, there was not much difference between the groups regarding the process outcomes across the countries. It was clear from the interviews in Palestine and Tajikistan, that participants who received the intervention content felt that their agency regarding contraceptive use increased and attributed this to the increase in knowledge that they received from the intervention. This is also reflected in the theoretical model. Despite this, there was no statistically significant difference in agency in any of the countries. One explanation for this is that agency is a difficult construct to measure and the scales were not validated. In addition, the translation of the behaviour change methods for delivery by mobile phone may have resulted in loss of meaning. Likewise, for perceived norms, the lack of difference overall could have been due to the non-validated scales. Alternatively, changing norms regarding contraception may require more intervention than a mobile phone is able to provide.

Intervention infidelity was an issue in Palestine as technical problems were discovered through delivery monitoring and in Bolivia as they were discovered through the open ended follow-up question data. In Tajikistan, while there was nothing in the open-ended follow-up question that indicated that there were intervention delivery problems, we cannot be certain that intervention participants received the intervention as intended. With most individual level mobile phone interventions, you cannot verify that the intervention has been received by the intended recipient, so any beneficial effects observed could be considered conservative. Table 11.1 illustrates what the intervention and control group were intended to receive in each country and what they received. (N.B. we cannot know what participants 'received' only what was sent or what was included on the app.)

Table 11.1 Intervention and control in each country

		Tajikistan	**Palestine**	**Bolivia**
Intervention	*intended*	intervention instant messages, sent through the app	intervention text messages	intervention instant messages, sent through the app
	*received**	no indication that intervention was sent not as intended	40% of intervention participants were sent 90% or more	at least 19% intervention participants did not receive any

			of the intervention messages and 8% of intervention participants were sent less than 70% of the messages	messages (according to self-reported data)
Control	*intended*	access to app with standard FP information 16 messages about trial participation usual care, free to seek any other support, whether existing or new	 16 messages about trial participation usual care, free to seek any other support, whether existing or new	access to app with standard FP information 16 messages about trial participation usual care, free to seek any other support, whether existing or new
	*received**	intervention content was included on the app, causing contamination	as intended	as intended

* We cannot know what participants 'received' only what was sent or what was included on the app

11.5 Implications

The implications of the research conducted in this thesis mainly relate to the practical aspects of developing and delivering behavioural interventions by mobile phone. The contamination in the Tajik trial offered an unintentional insight into what BCMs were effective. The trial demonstrated that there was no additional benefit of the nine extra BCMs delivered by the messages only, over information and the BCM 'belief selection' delivered on the app contraception pages. This could have been the result of several factors such as the parameters for effectiveness of the methods not being met and the potential loss of meaning when adapted for delivery by mobile phone. The no additional benefit of the additional nine BCMs, when considered alongside the change from baseline analyses in the Tajik and Bolivia trial that showed large increases in acceptability and the favourable results of the Palestine trial, implies that providing accurate information plus addressing the beliefs of the target group is likely enough to improve attitudes towards effective contraception. In other words,

not all the BCMs were needed. What matters most appears to be the needs assessments, where the beliefs of the target groups are identified and addressed in the intervention.

This thesis has demonstrated the importance of using theory in the development of interventions. In adapting the IBM for this project, based on what was learned from the intervention development work, I added knowledge as a fundamental determinant of an individual's beliefs, which influences intention and ultimately behaviour (Figure 4.2). Explicating the IBM alongside the development of the intervention, provided a structure from which to develop the intervention content. It also enabled me to hypothesise how the intervention was expected to work, i.e. by influencing knowledge, attitudes and personal agency. When considering the results of the evaluations, it was useful to refer to the IBM, which suggested that improving knowledge indeed was necessary to improve people's attitudes towards effective contraception.

The implications regarding the delivery of interventions delivered by mobile phone contrast with what is widely assumed about such interventions, that is, that they are cheap and easy to deliver. The technical challenges that we encountered demonstrate that thorough and dedicated testing and monitoring of the delivery is required, which is neither cheap nor easy. LSHTM managed the testing in all three countries and performed the monitoring of the intervention delivery in Palestine during this project. These functions would need to be performed by trained local staff if the intervention is adapted in different contexts.

Globally, many effective interventions fail to reach the population that can benefit from them, due in large part to inadequate knowledge translation of research findings (213). Mobile phone-based interventions in particular are often piloted but lack a sufficient evidence base to inform implementation (214). PFPPA and I plan to conduct qualitative research among young people and environmental agents (e.g. husbands, wives and partners, parents, siblings, mothers-in-law, community and religious leaders, teachers, government officials, PFPPA staff and health care providers) to understand the barriers to successful implementation and adoption of the intervention. We will then make the intervention available on their website, and evaluate the implementation by measuring adoption, feasibility, fidelity, coverage and sustainability. Ultimately, future research would establish the effect of the intervention on unintended pregnancy.

Adapting and implementing the intervention for different contexts should be relatively straightforward. This is because the cross-country beliefs about contraception identified in the intervention development work were similar to the beliefs in the global literature, which indicates that the intervention is likely generalizable. In addition, the intervention is well-specified. Adaptation would only require a few focus groups and interviews with the target group in the new context to verify that the local beliefs broadly align with the intervention. Minor tailoring for contextual differences and cultural appropriateness would then be necessary.

While it is likely that the intervention can improve attitudes towards effective contraception in different contexts, it is unclear how this attitudinal change leads to contraceptive use. Reflecting on this project's theoretical model (Figure 4.2) an improvement in attitudes towards effective contraception is necessary for use of the methods to increase. Attitudinal change then influences intention to perform the behaviour, which is the most proximal determinant of the behaviour. Even if there is evidence that the intervention increases intention to use contraception (as demonstrated by the Palestine trial), whether or not the behaviour is actually performed depends on the presence, absence and overall influence of the factors in the model that influence the behaviour directly, i.e. having the skills to perform the behaviour, how salient the behaviour is to the individual, habits and the existence of environmental constraints. In this project, it was clear that stigma regarding sexual activity conducted outside of marriage- whether explicit (e.g. admission of sexual activity) or implicit (e.g. clinic attendance)- and the pressure to bear children, are powerful cultural barriers to contraceptive uptake in all three countries. It is likely that a broader intervention that targets multiple environmental agents (e.g. parents, schools, community organisations/leaders, governmental agencies) is needed to create the conditions necessary to facilitate larger changes in individual contraceptive use.

11.6 Retrospective consideration of the thesis

I am fortunate to have had the opportunity to base my PhD on a dynamic project regarding a topic that I feel passionately about. It is difficult to consider what I would do differently if I had the chance to conduct the project again because there was so much learning involved, on everyone's part, which is valuable. One thing I can say that I would do differently however, is that, although I thoroughly explained to the Tajik partner that in a randomised controlled trial, control participants do not receive any intervention content, I would say explicitly that

none of the intervention messages should be included on the app. I would then insist on reviewing the content of the app before the trial began.

Other things that I would do differently require additional funds, which we did not have. For example, I would have hired maternity cover staff to monitor the conduct of the interviews in Bolivia. I would have also had all interviews transcribed and translated into English. Finally, I would not assume that the partners were as motivated by the research as I was.

11.7 Conclusions

The development of the intervention resulted in a well-specified, theory-based intervention, tailored to each country. This work demonstrated that it is feasible to develop an intervention delivered by mobile phone for young people in different settings. The thesis also takes forward the process of adapting behaviour change methods for delivery by mobile phone.

This thesis adds to the body of evidence regarding the efficacy of contraceptive interventions delivered by mobile phone, demonstrating that an intervention delivered by mobile phone messaging changed knowledge and acceptability of and intention to use effective contraception. The trials in Tajikistan and Bolivia suggest that providing accurate, comprehensive information that addresses the beliefs of the target groups, delivered from a trustworthy source, may be enough to change attitudes about effective contraception in contexts where young people have little accurate information. In addition, my thesis has also demonstrated that achieving high fidelity in interventions delivered by mobile phone is not as simple as is currently widely assumed. The trials were the first in each country to evaluate an intervention of its kind. The clear benefit in Palestine, suggestive benefit in Tajikistan and Bolivia and lack of evidence that is associated with negative outcomes, supports the implementation of the intervention in each country. Implementation research could maximise the benefits of the intervention in each country and the intervention can be adapted and delivered in other contexts.

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13 Appendices

Appendix 1. Search strategy

(phone adj3 call*).mp. OR ((cell* or mobile or smart or google or nexus or iphone) adj3 (phone* or telephone*)).mp. OR smartphone*.mp. OR smart-phone*.mp. OR (blackberr* not extract).mp. OR (black-berr* not extract).mp. OR ((mobile adj3 health) not (van* or unit*)).mp. OR mhealth.mp OR m-health.mp OR e-health*.mp. OR ehealth*.mp. OR (electronic adj health).mp. OR (mobile adj3 technol*).mp. OR ((mobile or smartphone or smart-phone or phone or software) adj3 app*).mp. OR MMS.mp. OR multimedia messaging service.mp OR SMS.mp. OR short messag* service.mp OR (text* adj messag*).mp. OR text-messa*.mp. OR voice messag*.mp. OR interactive voice response.mp OR IVR.mp. OR Telemedicine/ OR cellular phone/ or text messaging/

AND

(contracept* or (family adj planning) or (Birth adj control)).mp. OR condom.mp. OR (OC adj pill).mp. OR (depot medroxyprogest* or NET EN or Mesigyna or Cyclofem).mp. OR (intrauterine system or intra-uterine system or IUS or intrauterine device or intra-uterine device or IUD).mp. OR (vasectomy or sterilisation or sterilization or (tubal adj ligation)).mp. OR ((vaginal adj ring) or cycletel or cycle-tel or abstain or abstinen* or lactational amenorr*).mp OR (pregnan* or abortion).mp OR exp Contraception/ OR exp Contraceptive Devices/ OR exp Pregnancy, Unplanned/ OR exp Pregnancy, Unwanted/ OR exp Abortion, Induced/ OR (NORPLANT or implanon or Femplant).mp.

limit to (clinical trial or randomized controlled trial or controlled clinical trial) [Limit not valid in Global Health,PsycINFO; records were retained]

limit to yr="2017 -Current"

Appendix 2. Intervention development publication

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BMC Public Health

RESEARCH ARTICLE Open Access

Development of an intervention delivered by mobile phone aimed at decreasing unintended pregnancy among young people in three lower middle income countries

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Abstract

Background: Unintended pregnancies can result in poorer health outcomes for women, children and families. Young people in low and middle income countries are at particular risk of unintended pregnancies and could benefit from innovative contraceptive interventions. There is growing evidence that interventions delivered by mobile phone can be effective in improving a range of health behaviours. This paper describes the development of a contraceptive behavioural intervention delivered by mobile phone for young people in Tajikistan, Bolivia and Palestine, where unmet need for contraception is high among this group.

Methods: Guided by Intervention Mapping, the following steps contributed to the development of the interventions: (1) needs assessment; (2) specifying behavioural change to result from the intervention; (3) selecting behaviour change methods to include in the intervention; (4) producing and refining the intervention content.

Results: The results of the needs assessment produced similar interventions across the countries. The interventions consist of short daily messages delivered over 4 months (delivered by text messaging in Palestine and mobile phone application instant messages in Bolivia and Tajikistan). The messages provide information about contraception, target attitudes that are barriers to contraceptive uptake and support young people in feeling that they can influence their reproductive health. The interventions each contain the same ten behaviour change methods, adapted for delivery by mobile phone.

Conclusions: The development resulted in a well-specified, theory-based intervention, tailored to each country. It is feasible to develop an intervention delivered by mobile phone for young people in resource-limited settings.

Keywords: Intervention development, Intervention mapping, mHealth, Tajikistan, Bolivia, Palestine, Contraception, Family planning

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Background

In developing regions in 2017, an estimated 89 million pregnancies were unintended, that is, were pregnancies that occurred too soon or were not wanted at all [1]. Unintended pregnancy is associated with a range of negative health and social consequences, for example, poorer access to antenatal care, increased risk of low birth weight and pre-term birth, delays in women's educational and career achievements and unsafe abortion [2–20]. Women aged 15–24 in low and middle income countries (LMIC) are at particular risk and are more likely to have an unmet need for contraception compared to older women [21]. Women with an unmet need for modern contraception are those who want to avoid a pregnancy but currently use no method or use a traditional method [22]. It is estimated that meeting adolescents' unmet need for modern contraception would reduce unintended pregnancies by 6 million each year [22].

Tajikistan, Bolivia and Palestine are three LMIC where women are at high risk of unintended pregnancy. In Tajikistan, women have 0.5 more children than desired, with the total wanted fertility rate at 3.3 births per woman compared to the actual of 3.8 [23]. Unmet need for contraception among married 15–24-year-old women is estimated to be 26%, with unmet need for birth spacing the highest among women in this age group compared to women in other age groups [23]. In Bolivia, family planning progress has lagged behind other Latin American countries [24]. In 2008, unmet need for contraception among women aged 15–19, was estimated to be 38% [25, 26]. Among unmarried, sexually active women aged 15–19, 51.9% are not using a method of contraception. Among these women, 84.8% reported not wanting a pregnancy in the next 2 years, yet only 48.8% of them reported using any method of contraception. In Palestine in 2006, an estimated 38% of pregnancies were unintended [27, 28]. In 2014, unmet need for contraception was highest among women aged 20–24, at 15% [29]. While the adolescent fertility rate had decreased substantially in Palestine over the past 20 years, the current adolescent fertility rate of 48 per 1000 women aged 15–19 remains higher than most other countries in the region [29, 30].

The non-permanent 'effective' contraceptive methods have less than 10% typical use failure rate at 12 months, i.e. oral contraceptives, injectables, intra-uterine device (IUDs), implants, the patch and the ring (IUDs and implants being the most effective) [31–33]. While effective methods are available in Tajikistan, Bolivia and Palestine, there remain barriers to use. In Tajikistan, oppositional attitudes towards contraception is the most common reason women with a Demographic and Health Surveys-defined (DHS) unmet need [34] provide for not using contraception; 36% of women with an unmet need cite their own opposition and 13% cite their partner's opposition as the reason for not using contraception [21]. The next most common reasons are infrequent/no sex (28%) and side effects/health risks/inconvenience (15%) [21]. In Bolivia, the main reasons unmarried, sexually active adolescent women who report not wanting a child in the next 2 years provide for not using a method are infrequent sex (54.7%) or not married (51.5%) [25, 26]. Among married women in Palestine not using contraception and not reporting wanting to have a child, the main reasons given for not using contraception were fear of side effects, inconvenience of methods and their husband's opposition [35, 36].

Mobile phones are now a popular and widely established vehicle to deliver health interventions. There is some evidence from trials that mobile phone-based interventions can improve knowledge about contraception [37, 38] and contraceptive-related behaviours [39–44]. However, all but two of these trials [38, 42] were conducted in the United States and none had low risk of bias [45] according to the Cochrane Collaboration's tool for assessing risk of bias in randomised controlled trials [46].

In January 2015, the London School of Hygiene and Tropical Medicine (LSHTM) started a collaboration with the International Planned Parenthood Federation's (IPPF) Member Associations in Tajikistan, Bolivia and Palestine to develop and evaluate an intervention delivered by mobile phone to enhance contraceptive choice among young people in each country. At this development stage of the project, we included both young women and men because women in these settings have reported that their male partners' attitudes influence their use of contraception. To the best of our knowledge, this research is the first to develop such an intervention for young people in these countries. This project helps fill the research gap regarding the development of mobile phone interventions for contraception in LMIC.

Methods

Intervention development approach

Intervention Mapping (IM) guided the development of the interventions [47, 48]. IM is a protocol for the systematic development of health behaviour change interventions. It is a cumulative process that often necessitates moving back and forth through the following steps: (1) needs assessment; (2) specifying behavioural change to result from the intervention; (3) designing the intervention components by selecting behaviour change methods; (4) producing and refining the intervention content; (5) planning intervention implementation and (6) planning intervention evaluation. This paper describes steps 1–4 and compares the results across the countries.

Needs assessment

The needs assessment aimed to understand unintended pregnancy and contraceptive use in each context.

Activities included 1) establishing a project planning group 2) a literature search 3) focus group discussions (FGDs) and interviews with the target group and 4) interviews with local service providers.

Each country's project planning group was a collaboration between the local partner, the research partner and the three IPPF Regional Offices. The local partners consisted of the Executive Director, Research Assistants, and various other employees of the organisation that contributed to the development process in different capacities. The research partner designed and managed the research. Staff from Regional Offices attended meetings and facilitated communication about the research between the research partner and the local partner.

Relevant articles were identified through the research partner's existing knowledge, recommendations by the local partners, a Google search for grey literature and a search of MEDLINE. The results of the literature search informed the discussion guide used in the FGDs and interviews. Remote meetings were held from February to September 2015 to plan and organise the field research, which took place in July 2015 in Tajikistan, August/September 2015 in Bolivia and October 2015 in the West Bank, Palestine.

The FGDs and interviews with the target group explored their knowledge of and attitudes toward contraceptive methods, perceived barriers in using and confidence in communicating about them (see Additional file 1 for the target group discussion guide). This information was used to better understand the personal, socio-cultural and socio-economic factors involved in contraceptive use in each setting. The consultations also aimed to understand how amenable young people are to trying new contraceptive methods, their patterns of mobile phone use, preferences for intervention content and views on privacy regarding receiving contraceptive information on their mobile phone. The interviews with providers explored similar topics from a provider perspective (see Additional file 2 for the provider discussion guide). The research partner trained local research staff in FGD and interview facilitation and research ethics. The number of groups and interviews estimated (up to ten of each) was based on previous intervention development experience [49, 50].

Target group participants were identified by convenience sampling through the local partners' youth volunteer network and services in Dushanbe and Vahdat (Tajikistan), El Alto (Bolivia) and Ramallah, East Jerusalem, Hebron and Bethlehem (Palestine). Women and men were eligible if they were legally able to give independent informed consent (age 14 in Tajikistan, 18 in Bolivia and 18 in Palestine). There was no upper age limit but each local partner focused on recruiting younger participants as this most closely matched the target group 'young people' [51, 52]. Providers were affiliated with each local partner.

Each FGD and interview was conducted by a research staff member who was a native speaker of the local language (and in most cases also spoke English) and was attended by a bilingual (English and local language) research staff member who took detailed notes. Immediately after, the facilitator/interviewer relayed the information to the research partner who made detailed notes in English. The FGDs were comprised of participants of the same gender and facilitated by a staff member of the matching gender. The FGDs and interviews were held at the service or at a location hired specifically for this purpose. The FGDs and interviews were audio recorded. The FGDs lasted up to 90 min and the interviews lasted up to 60 min. Resources allowed only for the FGDs in Bolivia to be transcribed and translated into English. We conducted a descriptive thematic analysis of the FGDs and interviews by examining the discussion notes related to each theme in the discussion guide. An information technology partner consultant based in the United Kingdom reviewed the local mobile phone operators and identified local technology partners.

We depicted the results of the needs assessment visually in a 'logic model of the problem'.

Specifying behavioural change

The needs assessment led to the specification of the desired behaviours for target group to accomplish as a result of the intervention (behavioural outcomes) and of the desired changes in the environment to occur as a result of the intervention (environmental outcomes). The performance objectives for the behavioural outcomes were then specified by identifying the smaller actions that are logically required to perform the outcome. The determinants of these actions were specified from the literature search and insights from the FGDs and interviews and behaviour-oriented theories [47]. Mapping these against one another in a matrix enabled the identification of the most immediate behaviours that the intervention aims to alter in the individual (change objectives). While the environmental outcomes were specified, it was beyond the scope of the project to develop an intervention to target these conditions therefore the performance objectives and determinants for the environmental outcomes were not specified.

Designing the intervention

This step involved choosing theory-informed behaviour change methods to include in the intervention and deciding how to deliver them [47, 48, 53]. Potential methods were identified by considering: 1) authors' report of the methods used in existing effective interventions for contraception [43, 54, 55] and 2) the methods

shown to modify each determinant according to the IM taxonomy [48]. (The IM taxonomy describes the behaviour change methods that have been shown to modify different types of behavioural determinants.) Throughout the process, the conditions under which the methods can be effective were considered (the 'parameters for effectiveness') [47, 48].

Producing and refining the intervention content

The intervention content was written when behavioural change was specified and the methods and theoretical basis of the intervention were identified. The research partner wrote the initial content. It was then reviewed by the local partner for cultural appropriateness and amended with the research partner. Next, the target group was consulted for their views on the tone, acceptability and comprehensibility of the content. The content was refined with the target group after each consultation and tested until it was acceptable to them.

Results

Needs assessment

The factors reported in the published literature that influence contraceptive use and reasons for unmet need in LMIC and in Tajikistan, Bolivia and Palestine are summarised in the Background.

Focus group discussions and interviews with the target group

Eight FGDs each were conducted in Tajikistan and Bolivia and five were conducted in Palestine; one user interview was conducted in Tajikistan, two in Bolivia and four were conducted in Palestine (see FGD and interview demographics in Table 1). In Tajikistan and Bolivia, we stopped the FGDs and interviews when no new data was emerging in relation to the themes in the discussion guides. The FGDs and interviews coincided with the escalation in conflict in the West Bank in the first few weeks of October 2015. Due to logistical challenges related to this, we were unable to conduct more than five FGDs in Palestine.

Use of mobile phones

Use of mobile phones was nearly ubiquitous in all three countries but there was some variation in terms of the types of phones used and mobile Internet access. Most participants owned a smart phone, and if not, they owned a feature phone. Around five female participants in Vahdat, Tajikistan said that they did not have a mobile phone at all. In Tajikistan and Bolivia, it was more common to have regular mobile Internet access than in Palestine. Of those who owned a smart phone, Android phones were the most popular, with participants in Bolivia saying iPhones were for people of "high status". Participants in Tajikistan and Bolivia accessed the Internet through their phones. A few participants in Tajikistan said that access was sometimes restricted due to insufficient funds to support Internet connectivity. In the rural areas of Tajikistan, mobile Internet connection is expensive and electricity is restricted to three to 5 hours a day in the winter, restricting the ability to charge the battery. In Bolivia, participants said that they do not have Internet access on their phones all the time and buy the smallest data package possible to support use of Facebook and WhatsApp. In Palestine, many did not have regular Internet access on their phones and if they did, most access the Internet by Wi-Fi only; those who sometimes access the Internet though their mobile data said that it is common for the connection to be lost.

Contraception support

Participants in all three countries were very enthusiastic about receiving information about contraception on their phone. Participants in Tajikistan thought that acquiring accurate information would improve young people's attitudes towards contraception. In Bolivia, participants expressed very strongly the need for more information and talked about the convenience of being able to look at their phones for contraceptive information without having to ask anyone. In Palestine, while most young people wanted contraceptive information delivered on their mobile phones, female participants were more supportive of the idea than the male participants. A group of male participants said that they may read the information and benefit from it but it would be considered a joke and not taken seriously. A male participant said that contraceptive information delivered to phones is new in Palestinian society and that it is important that the information be given in a respectful way as "people feel shame about these issues".

Intervention delivery preferences and privacy

Participants expressed a range of mobile phone media ideas for intervention delivery, such as videos, pictures and animations. In general, participants preferred to receive contraception support through short message. In Tajikistan, participants thought it was helpful to save the messages to read later at a convenient time and because messages are easy to delete if they want to prevent others seeing them. However, a few were less comfortable receiving support by short message because they were perceived as less private. Bolivian participants, while interested in a variety of intervention delivery modes, preferred information to be sent by simple instant messaging through an app or text messaging. Palestinian participants preferred text messages for intervention delivery, with some saying that they wanted messages delivered by app instant messaging.

Table 1 Focus group discussion and interview demographics

	Tajikistan *n* = 78 n (%)	Bolivia *n* = 64 n (%)	Palestine *n* = 35 n (%)
Number of participants			
FGD1	10	5	10
FGD2	8	8	Not attended
FGD3	10	10	Not attended
FGD4	8	5	4
FGD5	15	10	3
FGD6	9	10	7
FGD7	9	7	7
FGD8	8	7	Not attended
Interviews	1	2	4
Age			
15–19	37 (47.4)	26 (40.6)	2 (5.7)
20–24	37 (47.4)	36 (56.3)	26 (74.3)
25–30	4 (5.1)	2 (3.1)	5 (14.3)
Missing	0	0	2 (5.7)
Gender			
Male	33 (42.3)	28 (43.8)	13 (37.1)
Female	45 (57.7)	36 (56.3)	22 (62.9)
Missing	0	0	0
Residential area			
City	50 (64.1)	not collected[b]	10 (28.6)
Other[a]	28 (35.9)		24 (68.6)
Missing	0		1 (2.9)
Occupation			
Working	20 (25.6)	4 (6.3)	5 (14.3)
Unemployed	8 (10.3)	0	3 (8.6)
Full-time parent	1 (1.3)	0	3 (8.6)
In education or training	49 (62.8)	60 (93.8)	19 (54.3)
Missing	0	0	5 (14.3)
Pregnancy intention (current)			
Avoid	11 (14.1)	38 (59.4)	13 (37.1)
Unsure/not avoid/ do not mind	29 (37.2)	14 (21.9)	18 (5.1)
Not sexually active	30 (38.5)	12 (18.8)	2 (5.7)
Missing	8 (10.3)	0	2 (5.7)
Current method			
None[c]	51 (65.4)	20 (31.3)	13 (37.1)
Condoms only	22 (28.2)	31 (48.4)	3 (8.6)
Withdrawal only	0	1 (1.6)	3 (8.6)
Condoms and withdrawal	2 (2.6)	0	0
Calendar-based only	0	5 (7.8)	2 (5.7)
Effective method[d]	3 (3.8)	5 (7.8)	8 (22.9)
Condoms and calendar -based	0	1 (1.6)	1 (2.9)
Lactational amenorrhea method only	0	0	1 (2.9)
Condoms and lactational amenorrhea method	0	0	1 (2.9)
Missing	0	1 (1.6)	3 (8.6)

[a]'Other' in Tajikistan is Vahdat, a large town 10 km outside of the capital Dushanbe; 'Other' in Palestine is village or refugee camp
[b]Participants from El Alto, La Paz or close surrounding areas
[c]Includes participants not sexually active
[d]Oral contraceptives, injectables, intra-uterine devices (IUDs), implants, the patch or the ring

Most participants reported that they do not share their phones. Participants in Tajikistan said that if they do share their phone, they lend their phone to friends or family to take photos, play games, listen to music and browse social networks. One female participant in Palestine said that sometimes she asks her children to check her phone when she is busy and she was concerned that they would see the messages. Another Palestinian participant said that she would share her messages with her husband to "educate him". A few participants mentioned concerns about others seeing the messages and having information about contraception on their phone but the majority were not concerned if they can password protect the phone.

Intervention content

Preferences for intervention content were similar across the countries, with some context-specific preferences. In all countries, participants wanted to hear about other people's experiences, particularly "success stories", with using contraception. In Bolivia, participants thought that hearing real stories or "testimonies" from people who have had experience using different contraceptive methods would make them feel confident in trying new methods. Some participants in Tajikistan however, did not want information in the form of stories because they value the advice from a specialist over advice from a peer. In Palestine, participants said that they would trust "scientific" information. Participants in all countries wanted clear and concise information about the advantages and disadvantages of the different methods, how to use them and where they can obtain them. Tajik participants said that the content should not contain difficult terminology and the 'voice' should not be young, as this would be perceived as less trustworthy. A female group in Bolivia said that they wanted "little messages" giving

advice and not telling them what to do. In terms of frequency, Tajik participants thought that one to two brief messages a day is acceptable, Bolivian participants wanted 1–3 messages a day and Palestinian participants said that they wanted around three messages per day.

Knowledge about contraception

Across all of the countries, there was a good level of awareness of the effective methods, but a lack of comprehensive knowledge such as the efficacy, advantages and disadvantages of the methods, how to use them and how they work. Participants agreed that young people do not have adequate information about contraception and were curious to know more about the range of methods available.

Attitudes and beliefs towards contraception

Across the countries, participants expressed a range of negative beliefs about effective contraception. Common beliefs were that hormonal contraception (including the non-hormonal IUD) is damaging to the health of the women, not effective in preventing pregnancy, causes heavy and irregular bleeding (IUD), infertility and weight changes. In Bolivia, participants mentioned that the IUD can rust in the uterus and causes cancer and that hormonal contraception makes people "stop being normal". Tajik participants mentioned that the IUD can grow into the skin. A few female participants in Palestine spoke favourably of the IUD but most thought that the metal in the IUD is harmful and causes an irregular menstrual cycle. A female group in Palestine though that the pill causes anxiety and nervousness.

In Tajikistan and Palestine, most participants approved of the concept of family planning and thought that society did as well. This was mainly because they believed that it helps families plan and assess their economic situation. Palestinian participants thought that it is better to use "natural" methods in the first year of marriage, with a male group saying that using contraception in early marriage will create problems.

Communication about contraception

In Tajikistan and Bolivia, participants expressed a lack of confidence communicating about contraception with partners, parents and providers. Participants in Palestine thought that it was possible to talk to close friends and mothers about contraception. A female Palestinian participant said that it is common for partners to talk about sex before marriage (it was not clear if this was discussion about contraception or just sex). In Tajikistan, a group of male participants said that it can be difficult to talk about contraception with a partner that they have been in a relationship with for a while because they fear that their partner would take offense. A Tajik female group thought that it is difficult to negotiate contraceptive use if they did not want a pregnancy at the time and their partner did. Bolivian participants said that they are confident talking to close friends (friends of opposite gender must be very close) but not confident talking to partners unless they know them very well and trust them. They said that talking about contraception usually happens after they begin a sexual relationship and if a discussion about contraception were initiated too early with a partner, the partner would judge them as promiscuous.

In all countries, participants were not confident talking to providers about contraception because of the cultural stigma surrounding sex before marriage, concerns about confidentiality and fear of being judged. In Bolivia, many participants spoke of negative experiences at services.

Environmental factors

In Tajikistan and Palestine, participants expressed that the strong stigma surrounding sex before marriage in their cultures creates concerns about confidentiality and prevents them from accessing services. In Bolivia, this stigma was implicit, with participants talking about fear of being judged for seeking sexual and reproductive health information and services. Many participants in Bolivia spoke of experiences of being given "bad looks" for attending services (pharmacies and reproductive health services) and fear of feeling embarrassed and ashamed. There was a very strong fear in Tajikistan and Bolivia that others (people in the community) will know that they attended, judge them and spread "rumours". There was general agreement across the discussions in Palestine that unmarried people accessing services is not accepted and is highly stigmatised. A female group in Palestine felt that they would be judged by providers and they will be asked if they are married or not if they attend a service. They also felt that they would be judged by their community if they went to a service and were not married.

In Palestine and Tajikistan, participants spoke of pressure to begin childbearing soon after marriage (Tajik participants mentioned 9 months after). If they do not, they fear that they will be judged and considered unhealthy. Many participants in Palestine talked about the societal pressure from their mother-in-law, friends and neighbours to conceive soon after marriage. If a married woman in Palestine prefers to complete her university degree, participants said that she is pressured to conceive and if she does not, the community assumes that she has fertility problems. A group of female participants in Palestine mentioned that it can be difficult to reach the service because of checkpoints.

Partners and the educational system are environmental agents that also contribute to the problem. This is apparent

from participants' report of the lack of partner communication about contraception before sexual activity and their lack of comprehensive knowledge about contraception.

Interviews with service providers

Six interviews with service providers were conducted in Tajikistan (5 doctors and 1 nurse outreach worker) and five were conducted in Bolivia (1 health advisor, 1 educator, 1 nurse and 2 doctors). Due to logistical challenges as a result of the escalation in conflict in the West Bank, only one provider interview was conducted in Palestine.

Providers in all countries said that young people are generally aware of the range of methods. However, many said that they do not know how they work or how to use them and want more information on these topics. In Bolivia, lack of information and misinformation is what most providers viewed as the greatest barrier for young people using new methods, along with the cost of contraception.

Providers in Tajikistan and Bolivia thought that young people are eager for more information about contraception and that providing this would help more young people use methods. Bolivian providers also said that more young people would use methods if they were affordable. The Palestinian provider said that in the premarital counselling sessions that she conducts, young people ask questions that make it obvious that they are already sexually active. Her perception is that young people want more information because many are having sex before marriage. She thought that providing young people with other people's success stories would help young people try new methods.

Providers in Tajikistan thought that attitudes towards reproductive health are changing and that people are thinking about the consequences of sexual activity before engaging in it. One provider said that young people have a positive attitude towards contraception. Providers said there is a lot of misinformation among young people in Bolivia and that they fear the perceived side effects, such as the infertility they associate with oral contraceptives. The Palestinian provider said that that young people think that the IUD makes them nervous and infertile.

Tajik providers commented on how religion does not accept sexual activity before marriage and that the mother-in-law has a great amount of influence on her daughter-in-law's contraceptive use. Providers said that young people (particularly young unmarried people) do not even try to attend services covertly because they are too concerned that someone will find out. A provider in Bolivia said that barriers stem from problems with the family and that these women are more at risk for early sexual debut. Some providers in Bolivia also mentioned machismo as a barrier in that if a woman is using contraception, men will perceive her as "horny", which is threatening to their masculinity.

See Fig. 1 for the logic model of the problem.

Specifying behavioural change: Results

Behavioural outcomes

Based on the needs assessment results, we specified the key behavioural and environmental outcomes (Table 2).

Theory, performance objectives and determinants

The Integrated Behavioural Model (IBM) [56] is the overarching framework for the intervention. This project's IBM was adapted to include knowledge as a fundamental determinant of behaviour, as in the Information-Motivation-Behavioural Skills Model [57] (Fig. 2).

Table 3 presents the behavioural outcomes, performance objectives and determinants. The literature supports the determinants knowledge [22, 58–67] and attitudes [22, 58, 60–64, 68–72], as important influences contraceptive use. It was clear from the needs assessment that accurate information about effective contraception was low. Providing accurate information in a context where there is none or very little, may change people's beliefs. Attitudes and intention were verified by behaviour-oriented theory [56, 73, 74]. Personal agency [75] in the IBM is comprised of efficacy [56, 76, 77] and control beliefs [56, 78]. The addition of perceived control acknowledges that while a member of the target group may feel confident in using a contraceptive method, they may not feel that they have control over whether they use it.

While intention was identified as a determinant, the intervention does not influence it directly, rather, the intervention aims to influence the behavioural (attitudinal), efficacy and control beliefs identified in the needs assessment, which all influence intention.

Change objectives

Crossing the behavioural outcomes, performance objectives and determinants, it was possible to specify the most immediate behaviours that the intervention aims to alter (see Table 4 for a partial matrix and Additional file 3 for the complete matrix). The change objectives for all countries were the same, except for a2.1.3, which only applies to Bolivia, because this was a specific cultural norm that emerged from the needs assessment (Additional file 3).

Designing the intervention components: Results

Practical application of the methods

After the needs assessment, through frequent discussions, the project planning groups decided that the intervention would be delivered through short, one-way messages.

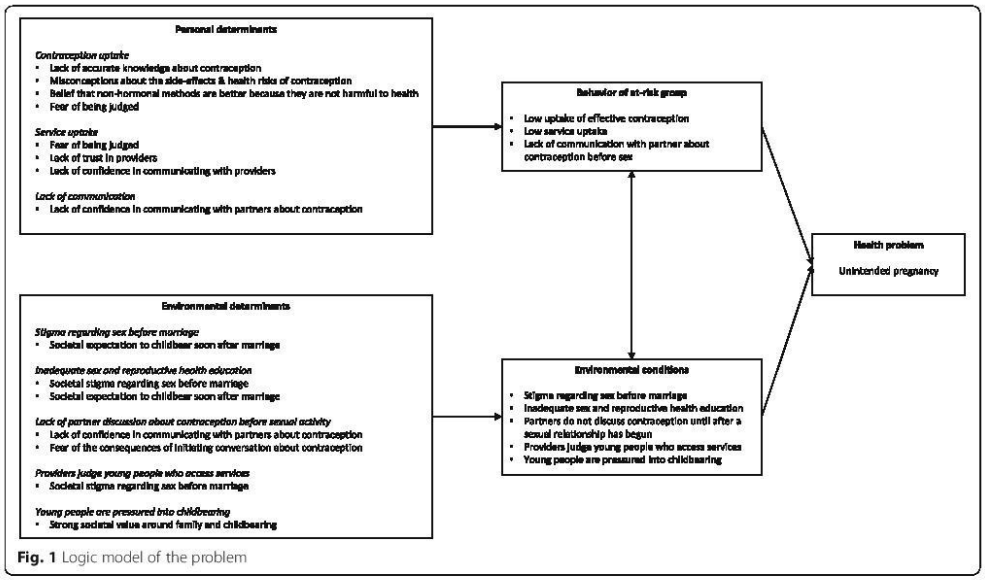

Fig. 1 Logic model of the problem

Behaviour change methods

Descriptions of the methods used in the effective contraceptive interventions, were limited [39–42, 79–82]. Two of these trials [83, 84] reported using *motivational interviewing*, which could not be successfully delivered though automated messages.

Using the IM taxonomy, we identified methods previously shown to be effective in modifying the determinants (knowledge, attitudes, personal agency) and considered their use for the intervention. Because the methods had to be delivered through short instant message, they required adaptation and there were only two methods from the initial list whose parameters for effectiveness (the conditions under which the methods can be effective) could be fully satisfied (*belief selection* and *tailoring*). While the parameters for most methods could not be fully satisfied, they were used if they could partially or potentially be satisfied. The final methods included in the intervention are [48]: *belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective* and *goal setting* (see Additional file 4 for details regarding the behaviour change methods).

Producing and refining the intervention content: Results

The initial message sets were largely similar across the countries given the similar results of the needs assessment. Feedback from the Tajik partner on the initial set of messages was regarding specifics about the methods available in the country. Feedback from the Bolivian partner was regarding the meaning of some of the messages, which was clarified through discussion. The Palestinian partner's initial feedback was them seeking clarification for the rationale behind some of the messages and suggesting a few changes to maintain cultural sensitivity.

Table 2 Behavioural and environmental outcomes

Behavioural				
1. Young people use effective contraception	2. Young people access reproductive health services		3. Young people communicate with partners about contraception before sexual activity	
Environmental[a]				
1. Sex before marriage is less stigmatised	2. Young people have access to comprehensive and accurate sexual and reproductive health education	3. Partners discuss contraception before a sexual relationship has begun	4. Providers do not judge young people who access services	5. Young people are not pressured into childbearing

[a]Not targeted by the mobile phone intervention

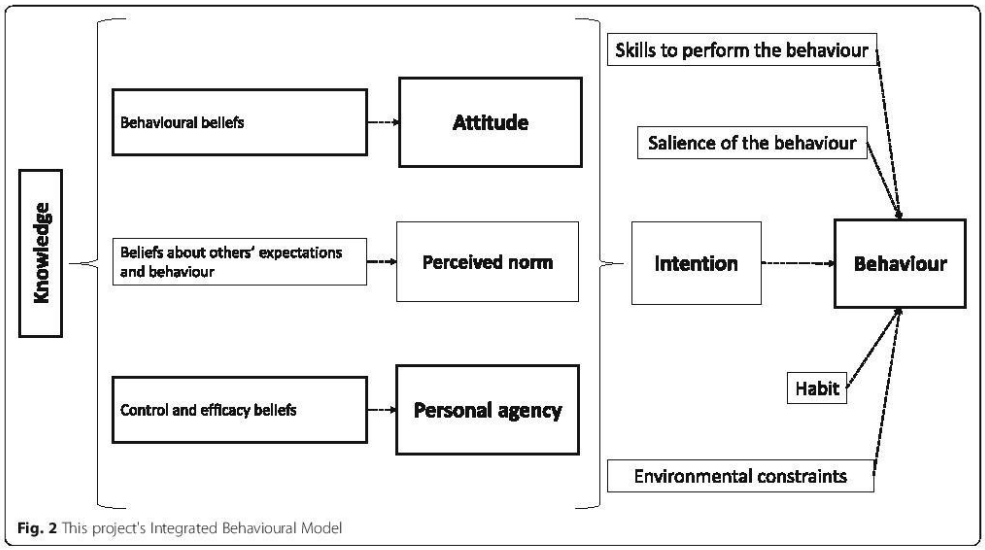

Fig. 2 This project's Integrated Behavioural Model

In Tajikistan, 34 young people (17 female and 17 male, the majority of whom were volunteers at the organisation) tested the intervention over four rounds. The Bolivia intervention was also tested over 4 rounds and involved 47 young people (29 female and 18 male) who were a mix of the organisation's 'young leaders,' university students who were non-service users and women who were sexually active and did not report using effective contraception. The intervention in Palestine was tested over three rounds with 17 people (eight female and six male) five of whom were volunteers in the organisation and 12 of whom were non-service users.

In general, feedback across the countries was that the messages were helpful and they were enthusiastic about the intervention. There were no clear differences in acceptability of the messages by gender. The Tajik volunteers wanted more clarification about how the methods work, which appeared to be for reassurance that they were safe to use. They also said that in general, they wanted the messages to be more "interesting and joyful". Target group feedback in Bolivia was that the messages should be more light-hearted, contain emoji's within the messages, "curiosities" about contraception and messages about "pop stars". This was in contrast to Palestine, where the target group preferred messages that were "scientific". Palestinian volunteers reported that the messages overall were reassuring and socially acceptable. There were some messages that they said sounded too negative and they suggested rewording to sound more reassuring. The research partner incorporated feedback after each round of testing and tested a revised set of messages in the following round.

Final intervention

The fundamental structure of the intervention is the same across the countries. Each intervention is designed to target the belief-based constructs identified in the needs assessment (instrumental attitude, self-efficacy and perceived control) in relation to contraception use, access to services and communication with partners about contraception. Each intervention provides accurate information about the effective contraceptive methods available in the country and aims to support young people in believing that they can influence their reproductive health. The messages are mapped to their corresponding change objective/s, behaviour change method and behavioural outcome (however, not all messages address a change objective, contain a behaviour change method or target a behavioural outcome).

The interventions contain the same ten behaviour change methods and similar content, with minor contextual variations resulting from the testing (see Table 5 for a sample of the intervention messages).

The messages are tailored according to marital status (a proxy for sexual activity) and gender in Tajikistan and Palestine (male messages in Bolivia were not developed due to an early decision that the intervention would be evaluated with women only). The message sets start with 6–7 days of messages with information about what they will receive over the next 120 days, how to stop the

Table 3 Behavioural outcomes, performance objectives and determinants

Behavioural outcomes	Performance objectives	Determinants
Use effective contraception	po1.1 Choose a method	*Knowledge* about the effective methods
		Attitude towards using effective methods
		Intention to use effective methods
		Personal agency in choosing an effective method
	po1.2 Acquire the method	*Knowledge* of where to get effective contraception
		Attitudes about acquiring effective contraception
		Intention to acquire effective contraception
	po1.3 Use the method correctly	*Knowledge* about how to use effective contraception correctly
		Intention to use effective contraception correctly
		Personal agency in using effective contraception correctly
Access reproductive health services	po2.1 Locate a service	*Knowledge* of where to get effective contraception
		Attitudes about acquiring effective contraception
		Intention to locate a service
	po2.2 Travel to the service	*Intention* to travel to a service
		Personal agency in traveling to a service
	po2.3 Communicate effectively with providers	*Personal agency* in communicating with providers
Communicate with partners about contraception before sexual activity	po3.1 Initiate conversation with partner about contraception	*Attitudes* towards partner's approval of contraception
		Intention to initiate conversation about contraception
		Personal agency in initiating a conversation about contraception
	po3.2 Clearly state own preferences regarding contraception to partner	*Intention* to clearly state contraceptive preferences to partner
		Personal agency in clearly stating contraceptive preferences to partner
	po3.3 Listen to partner's preferences regarding contraception	*Intention* to listen to partner's contraceptive preferences
		Personal agency in listening to partner's contraceptive preferences

messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages. Over the next 112–113 days, intervention recipients receive 0–3 messages a day covering the following: accurate information about the effective methods; short quotes derived from real quotes from the target group regarding their views and experiences using each method; messages targeting specific misconceptions about contraception identified in the needs assessment; messages providing support for communicating with partners about contraception; messages that aim to reassure recipients that it is a provider's job to maintain confidentiality; information about the cost of the different methods and where to obtain contraception and messages emphasising the importance of method switching rather than discontinuation. On day 119 and 120, the message sets include two messages that indicate that the messages have ended and provide reassurance that the information that they provide is confidential.

Discussion

Main results

The application of Intervention Mapping resulted in one intervention, tailored for Tajikistan, Bolivia and Palestine. The interventions are well specified, with each step in the development process documented. The needs assessment revealed that mobile phone ownership is widespread in

Table 4 Partial matrix of change objectives

	Determinants			
Performance objectives				
	Knowledge	Attitudes	Intention	Personal agency
Young people will…	*Behavioural outcome 1: Use effective contraception*			
po1.1 Choose a method	k1.1.1 Name the effective methods k1.1.2 Describe how the effective methods work k1.1.3 List the risks & benefits of the range of effective methods	a1.1.1 Express positive attitudes towards the effective methods a1.1.2 Recognise that hormonal methods are not less healthy than non-hormonal methods a1.1.3 Differentiate between real potential side-effects and misconceptions a1.1.4 Recognise that an experience of side-effects in one method may not occur in another method	i1.1.1 Assess options i1.1.2 Express intention to choose effective contraception	pa1.1.0 Express personal agency in choosing an effective method despite fears of being judged by society (married or not married)

each country and that young people are eager to receive contraceptive support on their mobile phone. Young people lacked comprehensive knowledge about contraception and expresses a range of negative beliefs about effective methods. They expressed a lack of confidence communicating about contraception and mentioned various environmental barriers to use. This study demonstrates that it is feasible to develop an innovative, comprehensible, acceptable intervention delivered by mobile phone with and for young people in resource-limited settings.

Strengths and limitations

A strength of the development is the participatory design. Young people were an integral part of the process and strengthened the intervention. Target group participants were a heterogeneous group, particularly in terms of age, gender and residential area. This is the only study we are aware of that has used the same approach to develop, in parallel, interventions delivered by mobile phone in three different contexts. Because the intervention content is mapped to the

Table 5 Sample intervention messages

Tajikistan	Bolivia	Palestine
Specialists have tested hormonal contraceptives many times and found them to be safe.	Some people think that hormonal methods are less healthy than non-hormonal methods. Hormonal methods are safe.	Some people think that hormonal methods are less healthy than non-hormonal methods. Hormonal methods are safe under medical supervision.
The most effective methods are: pills, IUD, implant and injection. These methods are over 99% effective if used correctly.	The most effective methods are: pills, t-copper (intrauterine dispositive), implant, injection & patch. If used correctly, less than 1 out of 100 women will get pregnant in a year if they use one of these 🔒	The most effective and available methods in Palestine are: pills, IUD, implant, injection, patch. These methods are 99% effective if used correctly.
Some woman may not have a period when on the injection. Some people say that they like not having periods because they can be painful and inconvenient.	Bleeding may change or even stop with the injection. Some people like not having a period.	The bleeding cycle may change or even stop with the injection. Some people like not having a period.
Making decision about contraception with a partner makes it more likely that you will avoid an unintended pregnancy.	Making decision about contraception with a partner makes it more likely that you will avoid an unintended pregnancy.	Making a decision about family planning with your husband helps you avoid an unintended pregnancy.
Providers see young people with different kinds of lifestyles choose contraception.	Providers see young people, married and not-married, all day and help them choose contraception. They want to help rather than judge.	Providers help people of different lifestyles regarding family planning.
Some young people worry that providers will judge them. Remember, it's about your health and you can choose what is right for you.	Some young people worry about being judged by other people too. Your health is what's important. It's your body and your right 😊.	Remember it's about your health and you have the right to choose what is right for you regardless of how others think and feel.
Think about your situation and what is right for you. If you decide to use contraception without your partner knowing, the IUD and implant are easy to hide.	If you are worried, there are methods that you can use without others knowing.	If your husband disapproves, talk to him about why you believe that it's a good decision for you. The IUD and implant are easy to keep private.

corresponding change objectives and behaviour change methods, it is well specified.

While there were strengths in conducting this multi-country research, it was also a challenge to spread our resources across the three countries. We conducted a pragmatic study using qualitative methods to explore the key themes related to unintended pregnancy and contraceptive use identified in the literature, to inform the development of the intervention. Working in one country would have allowed greater time and resources to conduct a more in depth qualitative study. It is possible that a more in depth, inductive approach could have produced a slightly different intervention. However, it is reassuring that our findings are in line with the global literature.

The needs assessment revealed that there are powerful environmental influences, such as stigma surrounding young people using contraception and pressure to child bear soon after marriage. While not mentioned explicitly by young people, this cultural stigma is likely a result of religious belief that maintains sexual activity is reserved for marriage (Islam in Tajikistan and Palestine and Christianity in Bolivia). A potential limitation of this project is that the delivery mechanism was pre-specified. Targeting these important environmental conditions would likely require a broader intervention than messages delivered by mobile phone.

Another limitation is that the target group was defined at the start of the project. The needs assessment revealed that unmet need is greatest in all three countries in a slightly older age group, i.e. 19–30. Due to funding restrictions, the focus group discussions in Tajikistan and Palestine were not transcribed and translated into English. The research partner who wrote the first draft of the intervention relied on the report of the trained facilitators and note takers.

In Palestine, the increase in conflict that coincided with the fieldwork meant that some FGDs were not well attended and only one provider interview was conducted. A consequence of this is that the views of younger people may not have been adequately explored because only two participants were aged 15–19. However, the message testing provided reassurance that the intervention was appropriate and acceptable.

In Bolivia and Tajikistan, participants in the FGD were members of the youth network or recruited by the youth network. It may be that this group was more informed than people not connected with services in any way. Still, there were widespread negative beliefs and low levels of comprehensive knowledge about contraception. Another way that this may have hindered the development is that this group may be more likely to find a mobile phone intervention for contraception acceptable because they had greater exposure to the topic and therefore may be more comfortable with it. In addition, young people who have no connection with services may have greater confidentiality concerns.

Most participants were either employed or in education or training. The project could have benefitted from the inclusion of more participants in other occupational categories.

It was only possible for the research partner to train each local team remotely in the testing procedures. The research partner relied on their report of the results, some of which were more detailed than others. It is not clear if this variability was due to the testing facilitators, the target population or both. If the project had more time and resources, we would have tested the intervention with a wider range of people (e.g. more at-risk groups and people who were not connected to the youth networks).

Intervention Mapping provides a comprehensive guide for developing complex health interventions targeting both individuals and environmental agents. This project, however, is smaller in scope and targets individuals only. The determinants were not quantitatively verified [85] and their importance or changeability was not assessed. The adaption of the behaviour change methods for delivery by mobile phone and lack of fully accounting for the parameters for effectiveness is likely to result in some loss of meaning [47]. While there are various modes in which to deliver content via mobile phones, strictly speaking, it is counter to Intervention Mapping to rule out non-mobile phone options from the start. Despite this, a mobile phone intervention emerged as highly acceptable and appropriate mode of intervention delivery.

Although participants in Bolivia mentioned that cost was a barrier to contraceptive use, the intervention could not address this. Even if the intervention is successful in improving attitudes towards the methods, uptake may not be improved if cost remains a barrier.

Comparisons with existing research

The results of the consultation with the target group align with existing research regarding the attitudinal factors that influence contraceptive use, i.e. that concern about the side effects or health risks are the most commonly expressed beliefs [22, 58, 60–63, 68–72]. Consistent with other research [59, 62, 66, 86, 87], this study confirms similar environmental barriers to contraceptive use, such as stigma regarding sex before marriage and the societal value around family and childbearing. Other research involving young people has shown that participants are willing and eager to receive contraceptive information on their mobile phone [39, 41, 88–90]. While there was variation in mobile Internet access among participants, mobile phone use was nearly ubiquitous. This reflects the global growth of mobile phone subscriptions, which has been slower in LMIC compared to higher income countries but is rising [91].

Implications

The fact that the beliefs identified in the needs assessment were similar to the beliefs in the literature suggests that the intervention is likely to be somewhat generalizable. The approach that we used to develop the intervention was successful in three culturally different settings, which highlights its broad applicability. Adaptation of the intervention to different settings could be more straightforward than usual, because the intervention is well specified.

Conclusions

The intervention development process resulted in one intervention, tailored to three contexts. The process exhibited how similar factors contribute to contraceptive use across three geographically and culturally unique LMIC settings. This project contributes to the field of contraception intervention development and mobile health. It has taken forward the practice of adapting behaviour change methods for delivery by mobile phone. This contribution highlights the importance of developing interventions using a systematic approach. The intervention has been evaluated by randomised controlled trial among men and women aged 16–24 in Tajikistan (results published) [92], women aged 18–24 in Palestine and women aged 16–24 in Bolivia [93] (results forthcoming).

Additional files

Additional file 1 The discussion guide used in focus group discussions and interviews with the target group. (PDF 380 kb)

Additional file 2 The discussion guide used in interviews with providers. (PDF 289 kb)

Additional file 3 The matrix that displays the change objectives by crossing the determinants and performance objectives. (PDF 354 kb)

Additional file 4 The behaviour change methods included in the intervention, the basis upon which they were selected, determinants, parameters for effectiveness, and how the parameters were taken into account. (PDF 193 kb)

Abbreviations

FGD: Focus group discussion; IBM: Integrated Behavioural Model; IM: Intervention Mapping; IPPF: International Planned Parenthood Federation; LMIC: Low and middle income countries; LSHTM: the London School of Hygiene and Tropical Medicine

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Availability of data and materials

The field notes or transcripts from the focus group discussions and interviews used during the current study and consent forms are available from the corresponding author on reasonable request.

Authors' contributions

OLM Designed and managed the research, wrote the interventions and the manuscript. OW Facilitated the research that informed the development of the intervention in Palestine. VOC Facilitated the research that informed the development of the intervention in Bolivia. IJ Facilitated the research that informed the development of the intervention in Palestine, provided programmatic input regarding the intervention development. SS Facilitated the research that informed the development of the intervention in Tajikistan, provided programmatic input regarding the intervention development. AS Facilitated the research that informed the development of the intervention in Palestine, provided programmatic input regarding the intervention development. Took overall local responsibility for the project. JLG Provided programmatic input regarding the intervention development in Bolivia. Took overall local responsibility for the project. RT Facilitated the research that informed the development of the intervention in Tajikistan, provided programmatic input regarding the intervention development. Took overall local responsibility for the project. SM, SH, MV, SS, SA contributed to planning discussions regarding the research activities, which facilitated the conduct of the research. CF Provided guidance regarding the development of the intervention. Took overall academic responsibility for the project. All authors revised the work, approved the version to be published and agree to be accountable for all aspects of the work.

Ethics approval and consent to participate

Ethical approval was granted from the London School of Hygiene and Tropical Medicine Observational Research Ethics Committee on 27 April 2015 (reference number 9148), the Tajik National Scientific and Research Centre on Paediatrics and Child Surgery on 8 June 2015, the State of Palestine Ministry of Health on 1 July 2015 and the Bolivian National Committee of Bioethics on 4 August 2015.

Participants were given verbal and written information about the study by the FGD facilitator or interviewer. Participants provided written informed consent before providing demographic data and before the focus group discussions and interviews began.

Competing interests

The authors declare that there are no competing interests.

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Appendix 3. Target group discussion guide

1. Introduction

- We would like to hear about young people's experiences and thoughts about contraception so that we can best help them
- We also would like to know what young people about receiving contraceptive support by mobile phone
- Don't have to take part if you don't want to
- There are no right or wrong answers
- I am here to facilitate the discussion, I'm not an expert on the issues
- We are interested in a range of views, so it's ok to disagree with each other
- Check again that they are ok with audio recording, explain confidentiality and anonymity
- It will last up to 90 mins (up to 60 mins for interview)
- You can leave when you want without having to give a reason
- You don't have to talk about anything you don't want to talk about

2. Informed consent

- Give them two copies of the consent, one is for them and one for CIES
- Ask them to initial each box, print, sign and date
- They don't have to add their number if they don't want to

3. Demographic questionnaire

- This information is anonymous, your name won't be on it
- It's so we can describe the kinds of people we've talked to

Rules (for focus group):

- Please respect each other's confidentiality by not sharing anything with anyone outside the group that might identify people in the group
- Respect each other's opinions
- Don't interrupt
- Please one person speak at a time so that we can understand the recording
- Can take phone calls (please leave the room for the conversation)
- Any questions before I ask you to provide consent and fill out a questionnaire?

4. Game

- Ideas: each person says their name and then one thing about themselves and then people guess if it's true or false, each person says their name and something about themselves and each person has to remember what the people before them have said, another game that you may know of

START RECORDER

5. Technology & information

Aim: to understand patterns of technology use and what tools they use to access information (general and contraception)

- Where do young people get their information from? [If you wanted to find out about something, where would you go (e.g. websites, apps, friends, books, friends, parents]?
- Do you own a phone? [How many? What type? How often do you replace your main phone? (if they don't own one) Do you use someone else's phone?]

- Do you share your phone ever? [e.g. with friends or family. If yes, how do you keep things on your phone private?]
- What do you use your phone for? [if apps, which ones?]
- Do you have access to the internet? [where, how and when?]
- When do you get information from your phone? [are there times that you can't get info from your phone?]
- **[MUST ASK] What would young people think about receiving contraceptive information about on their mobile phone?**
- How helpful is contraception support on your phone if someone is not having sex?
- How would you like to receive contraceptive support on your phone? (e.g. text, app, voice message, instant message)

To change and add for the next group/interview:

6. Knowledge

Aim: to find out how much they know about the range of methods so we can identify any gaps in knowledge

- What kinds of contraception do young people know about? [show images of different methods, ask about traditional methods]
- What do you know about them (the methods that they named)? [How do you use (methods)?]
- How do young people find out about contraception? [Where would you go to find out more? How do your friends learn about it?]
- Would young people like more information about contraception? [how would you like to receive this information?]
- (F) If you have gone to a reproductive health centre/youth friendly centre, what have the providers told you about the different types of contraception?
- How easy do you think is it for a woman to get pregnant if they are not using any contraception?
- How easy do you think it is for a woman to get pregnant if they are just using condoms?

To change and add for the next group/interview:

7. Attitudes

Aim: to identify misconceptions, biases, perceptions and stigma surrounding contraception.

- What do people in Bolivia think about people who use contraception? [Why do you think this? Married/unmarried]
- What do young people think about contraception? [How many of your friends use it? What kinds do they use?]
- Show images of different methods and ask what they think about each.
- What concerns (if any) do you have about these different methods? [Do you think any of them are harmful? (if yes- which ones? Why do you think this?)]
- Who should take responsibility for contraception? [you, your partner or both?]
- What do you think about unmarried young people having sex? [Why? Different for females & males?]
- How does contraception make you feel/would contraception make you feel about sex? [more or less pleasurable? Why?]

To change and add for the next group/interview:

8. Barriers

Aim: to explore things that may prevent them from using contraception.

- How common it is for young people to use contraception? [ones have you/they used? What was your/their experience using the different methods? If not common, ask why not]
- What kinds of problems (if any) do you or other people have with using contraception?
- How easy is it for young people to get to the clinic/mobile service? [rural/urban]
- How do you think providers feel about an unmarried person asking for contraception?
- A young woman in her teens just got married. How acceptable is it for her to wait to get pregnant?
- What role does religion play in how acceptable contraception is? [does this influence how you feel about it?]
- What do you think about women making decisions on their own about contraception? [how easy/hard is it for them? Why do you think this?]
- Does the cost of contraception prevent people from using it?
- (F) If your partner didn't approve of contraception, would you use it anyway? [how important is it that your partner approves?]

To change and add for the next group/interview:

9. Communication

Aim: to understand how confident they are talking to partners and others about their reproductive needs and preferences.

- How confident are young people with talking to their partner about contraception? [what would help them feel more confident?]
- How do young people feel about talking to staff at the clinic about contraception? [F- are young women comfortable talking to them on their own? Why/why not?]
- How confident are young people with talking to their friends about contraception?
- How confident are young people with talking to their parents about contraception?
- If a young woman told her partner that she wanted to use contraception but her (male) partner said he didn't want to, what would happen?
- Imagine a friend of yours is having sex and doesn't want a pregnancy at this time. What would you say to her/him?

To change and add for the next group/interview:

10. Trying new methods

Aim: to get a sense for how open they are to trying new methods and how confident they feel about trying them.

- (F) If a young person wanted to try a new method, how confident would they be about trying it? [how easy/difficult would it be? What would prevent you from trying it?]
- (F) What would help young people feel more confident trying new methods? [show images if they don't respond]
- What would need to change to make people feel more confident in using contraception?
- What kinds of contraception do you think young people would be interested in trying?

To change and add for the next group/interview:

11. Intervention content & privacy

Aim: to find out how the intervention can be supportive & easy to understand.

- What kinds of messages should we send? [e.g. educational, stories and quotes from other people about using contraception, ideas about how to talk about contraception with your partner, images, etc.]
- What kinds of messages should we not send?
- What concerns would young people have about receiving messages like these on your mobile phone?

- How many messages should we send each day (if it was delivered by text or instant message)?

To change and add for the next group/interview:

12. Wrap up

- Thinking about all that we talked about today, what do you feel is the most important? [why?]
- What we've talked about today will help us provide the best contraceptive support by mobile phone
- LAST QUESTION- if you were part of a study, would you come to the service so that the researchers could check your contraceptive use?
- Any questions or comments?
- Thank you! (if they want any more information, show our contact details again)

Appendix 4. Provider discussion guide

The interviews with service providers will explore their perceptions of the target group's knowledge of, attitudes towards and barriers to using different contraceptive methods. We will also ask for their views of the socio-cultural, socio-economic and structural factors involved in method choice.

1. Introduction

- We are asking people to help us develop content for a mobile phone contraceptive intervention.
- We'd like to hear about your experiences and thoughts about the service users' contraceptive use.
- We also would like to know what you think about receiving contraceptive support by mobile phone.
- Check again that they are ok with audio recording, explain confidentiality and anonymity
- It will last up to 60 mins
- Can take phone calls if you need to
- You can leave when you want without having to give a reason. You don't have to talk about anything you don't want to talk about. Any questions before we start?

2. Informed consent

- Give them two copies of the consent, one is for them and one for CIES
- Ask them to initial each box, print, sign and date
- They don't have to add their number if they don't want to

3. Demographic questionnaire

- This information is anonymous, your name won't be on it
- It's so we can describe the different people we've talked to

4. Knowledge

Aim: to find out their perceptions regarding users' knowledge about the range of methods

- What kinds of contraception do you think that the service users know about?
- What don't they know about? [why do you think they don't know about them?]
- Do you think service users want more information about contraception? [if yes- how would they like to receive this information? Why do you think this? If no, why not?]
- Where do you think users get information in general? [e.g. online web forums, friends, books]
- Where do they get information about contraception?
- What do service users think about contraception in general?
- What do users think about (name each method)? [why do they have these views?]
- What do users say about different methods? [have they expressed any concerns, e.g. side effects?]

To change and add for the next interview:

5. Attitudes

Aim: to find out their perceptions regarding user's attitudes towards contraception

- What methods do you think are best for young people? [why? Married/unmarried]
- What methods do you think are not appropriate for young people? [why? Married/unmarried]
- What would you recommend for a young unmarried women who wants contraception? [why?]
- What is the best method for a young woman in a relationship who has never been pregnant but wants a family someday? [why?]

- Are there any methods that you think are unsafe? Why do you think this? [Is this your experience or have you heard this from other people?]
- How safe are IUDs? [Why do you think this?]

To change and add for the next interview:

6. Barriers

Aim: to find out what they think prevents users from using contraception.

- What prevents service users from using effective contraception?
- How acceptable is contraception in Bolivia
- How does (religion, women's status in society, stigma, social-disapproval in general) influence contraception use? [Do you think this can change and if so, how?]
- What kinds of problems do people have with using contraception? [financial, supply, access, language]
- What influence do parents/friends have on users' choice?
- How important is it partner approval in people's choice?
- What would need to change to make people feel more confident in using effective contraception?

To change and add for the next interview:

7. Communication

Aim: to find out what they think about the frequency and quality of users' communication about contraception with partners & providers

- What kinds of things do you discuss with a person who is looking for contraception? [married & not married]
- What kinds or methods do you suggest for them? [Ask why for each and ask why they do not recommend others. How do they respond?]
- How comfortable to users seem when they talk to you about contraception?

To change and add for the next interview:

8. Trying new methods

Aim: to hear providers' opinions on how open people are to trying new methods

- What would help young people feel more confident trying new methods?

To change and add for the next interview:

9. Technology

Aim: to hear their views on user acceptability of a mobile phone intervention.

- Do you think young people would like to receive information by mobile phone? [why or why not? If yes, what kind of information?]
- How would you see a mobile phone intervention fitting into the services that you provide?

To change and add for the next interview:

10. Wrap up

- Thinking about all that we talked about today, what do you feel is the most important? [why?]
- What we've talked about today will help us provide the best contraceptive support by mobile phone
- Any questions or comments?
- Thank you! (if they want any more information, show our contact details again)

Appendix 5. Matrix of change objectives

	Determinants			
Performance objectives				
	Knowledge	**Attitude**	**Intention**	**Personal agency**
Young people…	*Behavioral outcome 1: Use effective contraception*			
po1.1 Choose a method	k1.1.1 Name the effective methods k1.1.2 Describe how the effective methods work k1.1.3 List the risks & benefits of the range of effective methods	a1.1.1 Express positive attitudes towards the effective methods a1.1.2 Recognise that hormonal methods are not less healthy than non-hormonal methods a1.1.3 Differentiate between real potential side-effects and misconceptions a1.1.4 Recognise that an experience of side-effects in one method may not occur in another method	i1.1.1 Assess options i1.1.2 Express intention to choose effective contraception	pa1.1.0 Express personal agency in choosing an effective method despite fears of being judged by society (married or not married)
po1.2 Acquire the method	k1.2.0 List services that provide effective contraception	a1.2.1/a2.1.1 Question whether not attending a service because of fear of being judged by providers is worth the risk of unintended pregnancy a1.2.2 Question whether not using effective contraception because of fear of being judged by society (whether married or unmarried) is worth the risk of unintended pregnancy a1.2.3 Recognise that it is better to withhold assumptions about the affordability of contraception until the price has been confirmed by the service	i1.2.0 Express intention to acquire effective contraception	

	Determinants			
Performance objectives				
	Knowledge	**Attitude**	**Intention**	**Personal agency**
po1.3 Use the method correctly	k1.3.0 Describe how methods are used		i1.3.0 Express intention to use effective contraception	pa1.3.0 Express personal agency in using methods correctly
	Behavioral outcome 2: Access reproductive health services			
po2.1 Locate a service	k1.2.0/2.1.0 List services that provide effective contraception	a2.1.1/a1.2.1 Question whether not attending a service because of fear of being judge by providers is worth the risk of unintended pregnancy a2.1.2 Understand that it is fundamental to providers' job to maintain confidentiality (B)a2.1.3 Debate cultural norm of not accessing services until something is wrong	i2.1.0 Express intention to locate a service	
po2.2 Travel to the service			i2.2.0 Plan travel to the service i2.2.1 Recognise that it is possible for young people (married or not married) to travel to services while preserving privacy	pa2.2.0 Express personal agency in travelling to the service
po2.3 Communicate effectively with providers				pa2.3.0 Express personal agency in communicating with providers
	Behavioral outcome 3: Communicate with partners about contraception before sex			
po3.1 Initiate conversation with partner		a3.1.1 Question whether refraining from initiating a conversation about contraception with a partner is worth the risk of unintended pregnancy	i3.1.0 Express intention to initiate conversation about effective contraception with partners	pa3.1.0 Express personal agency in initiating a conversation about

	Determinants			
Performance objectives				
	Knowledge	**Attitude**	**Intention**	**Personal agency**
		(B)a3.1.3 Assess whether having sex without using effective contraception is really a “proof of love”		effective contraception with partners
po3.2 State own fertility preferences			i3.2.0 Express intention to clearly state own fertility preferences with partner	pa3.2.0 Express personal agency in clearly stating own fertility preferences to partner
po3.3 Listen to partner’s fertility preferences			i3.3.0 Express intention to listen to partner’s fertility preferences	pa3.3.0 Express personal agency in listening to partners talk about their fertility preferences

Appendix 6. Behaviour change methods

Method	Definition	The basis upon which the method was selected	Determinant	Parameters	How the parameters were taken into account
Belief selection	Using messages designed to strengthen positive beliefs, weaken negative beliefs and introduce new beliefs	Theory of planned behaviour, Reasoned action approach	Knowledge, Attitude	Requires investigation of the current attitudinal, normative and efficacy beliefs of the individual before choosing the beliefs on which to intervene	Beliefs targeted were identified in the needs assessment
Facilitation	Creating an environment that makes the action easier or reduces barriers to action	Social cognitive theory, suitability for delivery by text message	Intention, Personal agency	Requires real changes in the environment instead of perceptions of the environment; requires the identification of barriers and facilitators and the power for making the appropriate changes.	Cannot produce real changes in the environment but provides advice on how they can change their environment to remove barriers
Anticipated regret	Stimulating individuals to focus on their feelings after unintended risky behaviour, before any losses actually materialise	Theory of planned behaviour, Reasoned action approach	Knowledge, Attitude, Intention, Personal agency	Stimulation of imagery; assumes a positive intention to avoid the risky behaviour	Cannot be certain that the individual intends to avoid the behaviour. However, the intervention aims to influence intention.
Guided practice	Prompting individuals to rehearse and repeat the behaviour various times, discuss the experience and provide feedback	Social cognitive theory	Intention, Personal agency	Subskill demonstration, instruction and enactment with individual feedback; requires supervision by an experienced person	Cannot provide feedback or supervision. However, real quotes from the target group will help participants compare themselves with an example of a

Method	Definition	The basis upon which the method was selected	Determinant	Parameters	How the parameters were taken into account
					conversation that went well.
Verbal persuasion	Using messages that suggest that the participant possesses certain capabilities	Social cognitive theory	Intention, Personal agency	Credible source	Individuals will know that the messages are coming from the organisation and were written the organisation, the University of London and young people
Tailoring	Matching the intervention or components to previously measured characteristics of the participant	Needs assessment	Knowledge	Tailoring variable or factors related to behaviour change (such as stage) or to relevance (such as culture)	The intervention is based on the needs assessment and is tailored according to marital status and gender
Cultural similarity	Using characteristics of the target group in source, message and channel	Needs assessment	Attitude	Using surface characteristics of the target group enhances receptivity. Socio-cultural characteristics leads to a more positive reception of the message.	Quotes from people in the target group are used
Arguments	Using a set of one or more meaningful premises and a conclusion	Suitability for delivery by text message	Attitudes, Intention, Personal agency	Arguments need to be new	Cannot be certain that all arguments were new to individuals but they might be
Shifting perspective	Encouraging taking the perspective of the other	Needs assessment	Personal agency	Initiation from the perspective of the individual; needs imaginary competence	Cannot be certain that that the individual has imaginary competence. The needs assessment revealed lack of

Method	Definition	The basis upon which the method was selected	Determinant	Parameters	How the parameters were taken into account
					confidence in communicating with providers so this method prompts individuals to see the situation from the providers' perspective.
Goal setting	Prompting planning what the person will do, including a definition of goal-directed behaviours that results in the target behaviour	Suitability for delivery by text message	Intention	Commitment to the goal; goals that are difficult but available within the individual's skill level	Cannot know if individuals are committed to the goal or if it is within their skill level. However, it might be.
Accurate information provision		Information-Motivation-Behavioural Skills Model; not a method, and generally not an important predictor of behaviour, but in contexts where knowledge is low, providing information may influence behaviour	Knowledge		

Appendix 7. Intervention development ethical approval letters

LSHTM

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Keppel Street, London WC1E 7HT
United Kingdom
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www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

LSHTM

27 April 2015 27 April 2015

Dear ,

Study Title: mHealth to enhance contraceptive choice- Intervention development

LSHTM ethics ref: 9148

Thank you for your application for the above research, which has now been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Information Sheet	v1 FGD Information sheet		1
Investigator CV	Cari Free CV	22/04/2013	n/a
Investigator CV	Chris Smith CV	01/01/2015	n/a
Information Sheet	v1 Interview information sheet (user)	23/03/2015	1
Information Sheet	v1 Interview information sheet (provider)	23/03/2015	1
Information Sheet	v1 Workshop Information sheet	23/03/2015	1
Information Sheet	v1 Interview Information sheet (Aptivate- both)	23/03/2015	1
Information Sheet	v1 FGD Consent form	23/03/2015	1
Information Sheet	v1 Interview Consent form (both)	23/03/2015	1
Information Sheet	v1 Workshop Consent form	23/03/2015	1
Information Sheet	v1 Interview Consent form (Aptivate- both)	23/03/2015	1
Investigator CV	Ona McCarthy CV	23/03/2015	n/a
Protocol / Proposal	v1 Demographic questionnaire (user)	23/03/2015	1
Protocol / Proposal	v1 Demographic questionnaire (provider)	23/03/2015	1
Protocol / Proposal	Development protocol (ethics)	23/03/2015	ethics
Protocol / Proposal	v1 FGD & Interview (user) topic guide	23/03/2015	1
Protocol / Proposal	v1 Interview topic guide (provider)	23/03/2015	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

Tajikistan

ВАЗОРАТИ ТАНДУРУСТӢ ВА ҲИФЗИ ИҶТИМОИИ АҲОЛИИ ҶУМҲУРИИ ТОҶИКИСТОН

МУАССИСАИ ДАВЛАТИ МАРКАЗИ ҶУМҲУРИЯВИИ ИЛМИЮ КЛИНИКИИ ПЕДИАТРӢ ВА ҶАРРОҲИИ КӮДАКОНА

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ И СОЦИАЛЬНОЙ ЗАЩИТЫ НАСЕЛЕНИЯ РЕСПУБЛИКИ ТАДЖИКИСТАН

ГОСУДАРСТВЕННОЕ УЧРЕЖДЕНИЕ РЕСПУБЛИКАНСКИЙ НАУЧНО - КЛИНИЧЕСКИЙ ЦЕНТР ПЕДИАТРИИ И ДЕТСКОЙ ХИРУРГИИ

ҶУМҲУРИИ ТОҶИКИСТОН ш. Душанбе, х. И.Сомонӣ 59, бинои 7 тел.:(992) 2365250, 2365851

«08» июня 2015г. № 1/73

Г-же Она Мак Карти
Научному сотруднику Лондонского
Института гигиены и тропической медицины

Государственное Учреждение республиканский научно исследовательский центр педиатрии и детской хирургии ГУ РНИЦП и ДХ выражает свое уважение Институту гигиены и тропической медицины Лондона за содействие по оценке и внедрению новых методологий в области медицины в Таджикистане.

ГУ РНИЦП и ДХ организует и планирует весь спектр научных исследований в области здоровья детей в возрасте 0-18 лет и может представить годами накопленный опыт в организацию и реализацию данного исследования «Использование новых технологий по улучшению информированности населения по здравоохранению».

Все представленные исследовательские инструменты (12файлов) включая протокол по этике Лондонского института гигиены и тропической медицины изучены и утверждены для проведения оценки. Также изучены и допущены к исследованию про файлы исследовательской команды в составе 5 человек:

- Она МакКарти (Ona McCarthy)
- ЭлисонМакКими (Alison McKinley)
- Эли Булбоул (Elly Boulboul)
- Марко Самастур (Marko Samastur)
- Мариека Вандевиле (Marieka Vandewiele)

В связи с тем, что ГУ РНИЦП и ДХ является государственным учреждением, отвечающим за все исследования и внедрения новых технологий в области педиатрии в Таджикистане, просим вас представить итоги исследования и производить публикации по исследованию только по согласованию с нашим учреждением.

Наши наилучшие пожелания в предстоящем исследовании.

Директор ГУ РНИЦП [redacted] Набиев З.Н.

Palestine

State of Palestine
Ministry of Health
Primary Health Care & Public Health Directorate

دولة فلسطين
وزارة الصحة
الإدارة العامة للرعاية الصحية الأولية والصحة العامة

التاريخ: 2015/7/1

To Whom it may concerns

Subject: Survey on m.health to enhance contraceptive choice

kindly , note that the ministry of health is encouraging and supporting different NGOs to full fill the requirement of primary health care stratiges in the country. one of these strategies is to support surveys and researches in different aspects of different programs related to PHC to help policy makers in having their decisions .

For the a/m subject, MOH is giving the green light to the Palestinian Family Planning & Protection Association to start taking into consideration the following requirement :

1. all messages should be reviewed and approved by MOH technical committee
2. all messages should be issued and sent to the people > 18 years
3. results of the survey should be evaluated jointly with Palestinian MOH before dissemination.

Dr. Asad Ramlawi
[redacted]
DG PHC & PH

State of Palestine
Ministry of Health
Primary Health Care & Public Health Directorate

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Bolivia

COMITÉ NACIONAL DE BIOETICA

Comisión de ética de la investigación

CERTIFICADO DE AVAL ÉTICO

A quien corresponda:

La Comisión de Ética de la Investigación del Comité Nacional de Bioética (CEI-CNB), tiene a bien informar que fue presentado a la CEI-CNB, para su revisión y aval ético el proyecto de **Investigación "Salud Móvil para mejorar la elección de métodos anticonceptivos"** , por el CENTRO DE INVESTIGACIÓN, EDUCACIÓN Y SERVICIOS (CIES) . THE LONDON SCHOOL OF HIGIENE AND TROPICAL MEDICINE (LSHTM , LONDRES , EL REINO UNIDO)
Dicho proyecto fue evaluado bajo la normativa internacional, que indica los criterios éticos que se toman en cuenta para todo proyecto de investigación que involucra seres humanos:

1. Validez científica (diseño metodológico bien formulado)
2. Selección equitativa de la muestra (tomando en cuenta principalmente a grupos vulnerables)
3. Validez social (pertinencia, atingencia y relevancia del proyecto)
4. Relación Riesgo/Beneficio (viendo que el riesgo sea mínimo y mayor el beneficio para los sujetos de estudio)
5. El Consentimiento Informado (documento redactado de una manera clara, comprensible y lo suficientemente informativo para el sujeto de investigación)

Una vez verificadas las correcciones hechas por el investigador Principal, en base a las observaciones de la CEI, es que se tiene a bien certificar que el mencionado proyecto cumple con todos los requisitos éticos arriba mencionados, por lo que los miembros de la CEI-CNB dan el respectivo AVAL ÉTICO al proyecto **"Salud Móvil para mejorar la elección de métodos anticonceptivos"** el mismo que puede proseguir con su ejecución.

[redacted]

Dra. Ingrid Gaby Melgarejo Pomar
COORDINADOR
Comité Nacional de Bioética

La Paz, 4 de Agosto 2015

Appendix 8. Tajikistan trial protocol publication

Open Access Protocol

BMJ Open

A randomised controlled trial of an intervention delivered by app instant messaging to increase the acceptability of effective contraception among young people in Tajikistan: study protocol

Ona McCarthy,[1] Baptiste Leurent,[2] Phil Edwards,[1] Ravshan Tokhirov,[3] Caroline Free[1]

To cite: McCarthy O, Leurent B, Edwards P, *et al*. A randomised controlled trial of an intervention delivered by app instant messaging to increase the acceptability of effective contraception among young people in Tajikistan: study protocol. *BMJ Open* 2017;**7**:e017606. doi:10.1136/bmjopen-2017-017606

► Prepublication history and additional material for this paper are available online. To view please visit the journal (http://dx.doi.org/10.1136/bmjopen-2017-017606).

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ABSTRACT

Introduction Women in lower income countries experience unintended pregnancies at a higher rate compared with women in higher income countries. Unintended pregnancy is associated with numerous poorer health outcomes for both women and their children. In Tajikistan, an estimated 26% of married individuals aged 15–24 years have an unmet need for contraception. The strong cultural value placed on childbearing and oppositional attitudes towards contraception are major barriers to contraceptive uptake in the country. Mobile phone ownership is widespread in Tajikistan. The option of receiving reproductive health support on your personal phone may be an appealing alternative to attending a clinic, particularly for young people. The London School of Hygiene & Tropical Medicine and the Tajik Family Planning Association have partnered to develop and evaluate a contraceptive behavioural intervention delivered by mobile phone. The intervention was developed in 2015–2016 guided by behavioural science. It consists of short instant messages sent through an app over 4 months, contains information about contraception and behaviour change methods.

Methods and analysis This randomised controlled trial is designed to evaluate the effect of the intervention on self-reported acceptability of effective contraception at 4 months. 570 men and women aged 16–24 years will be allocated with a ratio of 1:1 to receive the intervention messages or the control messages about trial participation. The messages will be sent through the Tajik Family Planning Association's 'healthy lifestyles' app, which contains basic information about contraception.

Ethics and dissemination The trial was granted ethical approval by the London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee on 16 May 2016 and by the Tajik National Scientific and Research Centre on Paediatrics and Child Surgery on 15 April 2016. The results of the trial will be submitted for publication in peer-reviewed academic journals and disseminated to study stakeholders.

Trial registration number Clinicaltrial.gov NCT02905513.

Date of registration 14 September 2016.

WHO trial registration dataset http://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT02905513

Strengths and limitations of this study

- ► The intervention was developed using an established approach grounded in behavioural science.
- ► Participants must own a personal Android phone to receive the intervention, which means that the sample may not represent young people from a broad socioeconomic spread.
- ► The randomised trial design will allow us to conclude that an observed effect was due to the intervention.
- ► This is the first trial to evaluate an intervention for contraception delivered by mobile phone for young people in Tajikistan.

INTRODUCTION

Globally in 2012, an estimated 85 million pregnancies (approximately 40% of all pregnancies) were unintended.[1] Women in lower income countries experience more unintended pregnancies than in higher income countries, with a rate of 54 per 1000 women compared with 44 per 1000 women, respectively.[1] Unintended pregnancy is associated with numerous poorer health and outcomes for both women and their children[2] including decreased psychological well-being[3–11] and delay in initiating antenatal care.[5 11–15] Children born of unintended pregnancies are at a higher risk of low birth weight and preterm birth.[16 17] A woman has an unmet need for modern contraception if they want to avoid a pregnancy but currently use no method or a traditional method.[18] Fulfilling unmet need for contraception is essential in decreasing unintended pregnancy; however, in 2014, an estimated 225 million women in low-income and middle-income countries had an unmet need for modern contraception.[18]

The civil war that followed Tajikistan's independence from the Soviet Union in 1991

had devastating effects on the Tajik economy and health system.[19 20] While economic hardship continues, fundamental reforms to the healthcare system have instigated progressive initiatives, such as the adoption of the Strategic Plan for Reproductive Health in 2004.[21] With regard to family planning data, the Tajikistan Demographic and Health Survey (DHS) 2012 is the most reliable source at present.[21] Effective contraception methods are those with a less than 10% typical use failure rate at 12 months.[22–24] The effective methods available in Tajikistan are oral contraceptive pills, intrauterine devices (IUDs), injectables and implants. While there is some concern about the suitability of the progestogen-only injection for adolescents, adolescents are eligible to use the same methods as adults; age alone is not a contraindication for use.[25] Despite the availability of the effective methods in Tajikistan, it is estimated that 26% of married individuals aged 15–24 years have an unmet need for contraception. Total unmet need peaks at age 25–29, reflecting the cultural norm of early family completion.

The 2012 DHS survey estimated that around 23% of all married women and 8% of married individuals aged 15–24 years report using an effective method, the IUD being the most popular.[21] Eighty-three per cent of induced abortions (all age groups) occur in women not using any method.[21] The total wanted fertility rate is reported to be 3.3 compared with the actual of 3.8, indicating that woman have 0.5 children more than desired.[21] Oppositional attitudes towards contraception are a barrier to use in Tajikistan; 36% of women with an unmet need cite their own opposition and 13% cite their partner's opposition as the reason for not using contraception.[26] Other reasons married women with an unmet need gave for not using contraception were infrequent/no sex (28%) and side effects/health risks/inconvenience (15%).[26]

Health interventions delivered by mobile phone are increasingly popular.[27–37] With sensitive topics such as reproductive health, the ability to receive information on a personal mobile phone may be an appealing alternative to attend a clinic. While there is some evidence from high-income countries that mobile phone-based interventions can increase contraceptive-related behaviours[38–40] and knowledge,[41] none of the trials evaluating these interventions had a low risk of bias[42] according to the Cochrane Collaboration's tool for assessing risk of bias in randomised controlled trials.[43] The tool assesses risk over multiple domains of bias, that is, selection, performance, detection, attrition, reporting and other bias. To the best of our knowledge, there is only one trial conducted in a non-high income country (Cambodia). This trial found an effect of postabortion voice messaging with telephone counselling support on effective contraceptive use.[44]

The London School of Hygiene and Tropical Medicine (LSHTM) and the Tajik Family Planning Association (TFPA), a member association of the International Planned Parenthood Federation (IPPF), are collaborating to evaluate an intervention delivered by mobile phone for young men and women in Tajikistan to increase the acceptability of effective contraception. In Tajikistan in 2015, there were 98.6 mobile phone subscriptions per 100 people,[45] with 64% owning a smartphone.[46] The intervention was developed in 2015–2016 guided by an evidence-based approach grounded in behavioural science.[47] The approach involved consultation with the target group to identify attitudinal barriers to contraceptive use and an iterative process of writing intervention content, testing with the target group and refining. This development work indicated that short messages delivered by mobile phone could be an acceptable way to provide contraceptive support to young people.

The aim of this publication is to present the protocol for the evaluation of the intervention by randomised controlled trial. The trial is designed to evaluate the effect of the intervention on young Tajik people's self-reported acceptability of the effective contraception methods available in Tajikistan. To the best of our knowledge, this will be the first trial evaluating an intervention delivered by mobile phone designed to increase the acceptability of effective contraception in Tajikistan.[42]

METHODS AND ANALYSIS

Design

This study is a parallel group, individually randomised superiority trial with a 1:1 allocation ratio evaluating the effect of an intervention delivered by mobile phone application (app). Participants randomised to the intervention arm will have access to the app and will receive the intervention instant messages. Participants randomised to the control arm will have access to the app and receive control instant messages about trial participation.

Eligibility criteria

Women and men aged 16–24 years, who own a personal Android mobile phone and live in Tajikistan, can provide informed consent and can read Tajik or Russian will be eligible to take part. Participants must be willing to receive messages about contraception on their mobile phone.

Recruitment

The trial will be promoted through the distribution of flyers through TFPA's volunteers and youth partner organisation, TFPA's website and social media sites. Potential participants will be provided the link to the enrolment pages of the secure online trial database and randomisation system, where they will read the participant information sheet (online supplementary file 1) and provide informed consent (online supplementary file 2). If they do not have adequate internet access, youth organisation volunteers will provide it. Participants will also have the option of completing the paper-based version of the consent form.

To maximise the chance of recruiting to target, LSHTM conducted a pretrial training in Dushanbe to train local staff on all recruitment procedures. The training included a discussion about the practicalities of recruitment with a

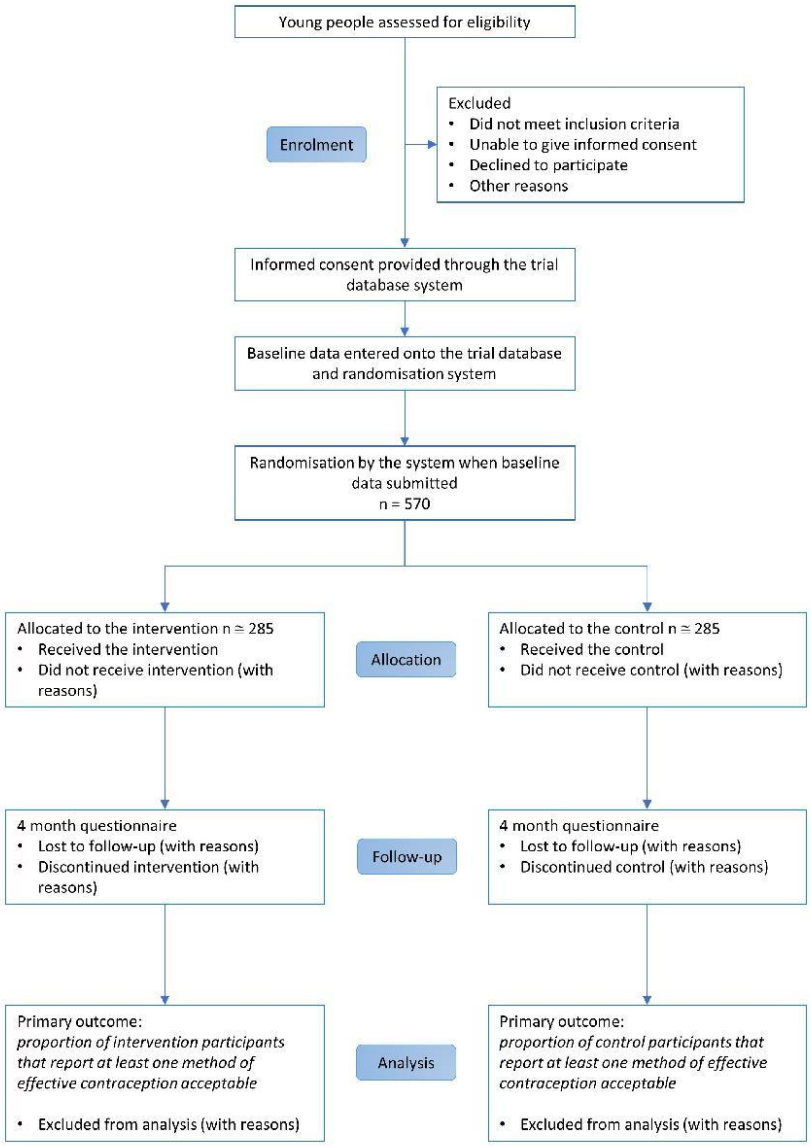

Figure 1 CONSORT diagram.

view to developing the most appropriate strategies (ie, the distribution of flyers, an advertisement on TFPA's website and social media sites).

We will report the number of people assessed for eligibility, number of people excluded before randomisation, number of participants randomised, number of people allocated to the intervention and number of people who completed the follow-up and analyse (figure 1).

Intervention

The intervention is informed by the Integrated Behavioural Model[48] and consists of short mobile phone app instant messages that provide contraceptive support delivered over 4 months sent through TFPA's 'healthy lifestyles' app. The intervention messages provide information about contraception, target beliefs identified in the development phase that influence contraceptive use (eg,

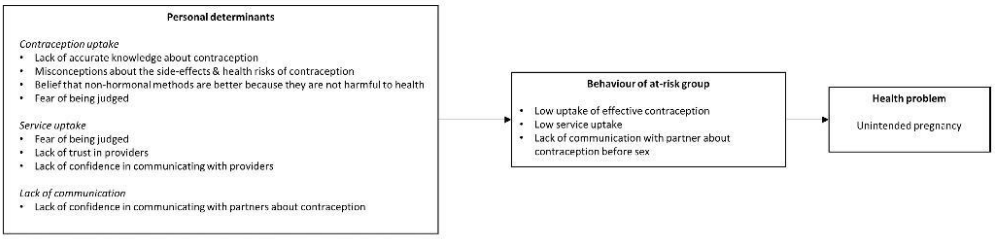

Figure 2 Logic model of the problem.

misconceptions about the side effects and health risks of contraception and belief that non-hormonal methods are better because they are not harmful to health) and aim to support young women in believing that they can influence their reproductive health (see figure 2 for the logic model of the problem). The intervention provides accurate information about contraception and contains the following behaviour change methods,[49] adapted for delivery by mobile phone: belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting. The app itself contains basic information about contraception, how to have a 'healthy lifestyle', youth friendly service point locations and contains no behaviour change methods. The app and the intervention messages are available in Tajik or Russian, according to participants' preference, which is indicated at enrolment.

The messages are tailored according to marital status and gender, resulting in four sets of intervention messages: (1) female-married, (2) female-not married, (3) male-married and (4) male-not married. Most of the messages in the four sets overlap, with minor tailoring so that the messages are relevant to marital status and gender. Marital status is used as a proxy for sexual activity because the target group and TFPA considered it inappropriate to ask directly about sexual activity. Based on the development work with the target group, participants receive 0–3 messages per day (135 messages for female-not married, 155 messages for female-married, 135 messages for male-not married and 146 messages for male-married) for 120 days. Included in the messages that intervention recipients receive are seven control messages about the importance of their participation and reminding them to contact the project coordinator if they change their number.

The message sets start with 6–7 days of messages (11 female-married, 12 female-not married, 12 male-married and 13 male-not married) with general information about the study, such as what they will receive over the next 120 days, how to stop the messages, how to choose specific times to receive the messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages (women only). On the final 2–3 days, the message sets include four messages that indicate that the messages have ended, provide a link to the database to complete the follow-up questionnaire, reassurance that the information that they provide is confidential and a final message stating that their participation is helping to determine the best ways to provide reproductive health services in Tajikistan.

Details regarding the development of the intervention and intervention description will be reported in a forthcoming publication.

CONTROL

Participants allocated to the control group will have access to the same app pages as the intervention group. Control participants will also receive 16 messages about trial participation over 120 days. The first 4 days include six messages that introduce the study, provide information about what they will receive over the next 120 days, how to stop the messages and who to contact if they change their number. They will then receive two messages a month for 3 months—one about the importance of their participation and one reminding them to contact the project coordinator if they change their number. On day 105, they will receive one message about the importance of their participation. On day 120, participants will receive three messages that provide information on how to complete the follow-up questionnaire, reassurance that the information that they provide is confidential and a final message stating that their participation is helping to determine the best ways to provide reproductive health services in Tajikistan.

All participants will receive usual care (the normal care that a young person would receive if they attended a service in Tajikistan) and will be free to seek any other support, whether existing or new. TFPA's app is part of 'usual care' for the purpose of the trial and will be 'new usual care' after the trial.

OUTCOMES

Primary outcome

The primary outcome is the proportion of participants reporting that at least one method of effective contraception is acceptable at 4 months postrandomisation. In the absence of an existing validated measure of acceptability that was appropriate for this context, the primary

outcome measure was constructed based on guidelines for measuring IBM constructs[48 50 51] and tested for face validity with the target group. The acceptability of each method is measured by the following stems: 'Using the [method] …causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy and I would recommend the [method] to a friend'. The IUD and implant include an additional stem: 'The [method] insertion would not be a problem for me. The response options for each scale are: strongly disagree, disagree, not sure, agree, strongly agree and I do not know what the [method] is. A method is acceptable if participants report 'agree' or 'strongly agree' for all scales except for '…causes infertility' and '…causes unwanted side effects' stems, for which 'disagree' or 'strongly disagree' denotes acceptability (items 1–22 in online supplementary file 3 and items 4–25 in online supplementary file 4).

Secondary outcomes

Secondary outcomes are: the proportion reporting current use (or partner's use) of effective contraception (use of effective contraception); the proportion reporting that each method of effective contraceptive method is acceptable (acceptability of individual methods); the proportion reporting use (or partner's use) of effective contraception at any time during the 4 months (discontinuation); the proportion reporting attending a sexual health service during the 4 months (service uptake); the proportion reporting that they became pregnant and did not want a pregnancy during the study (unintended pregnancy); and the proportion reporting having (or partner having) an abortion during the study (induced abortion).

Process outcomes

The process outcomes are: knowledge of effective contraception; perceived norms in relation to using and communicating with partners about contraception; personal agency in using (women only) and communicating with partners about contraception; and intention to use effective contraception (women only) and intervention dose received.

DATA COLLECTION

Data will be collected at baseline and at 4 months postrandomisation using questionnaires, which we tested for face validity with 27 people from the target group. We asked people to comment on the length of the questionnaires, the comprehensibility of the questions, the meaning of the scales and suggestions for improvement. All data will be entered onto the trial database system, which is on LSHTM's secure server. At both time points, participants can either fill out a paper-based version of the questionnaire at the recruitment site, provide the data over the phone with research staff or enter data directly onto the online system, according to their preference. If participants provide their questionnaire data by paper or over the telephone, research staff will enter these data onto the system.

Baseline data collected

At baseline we will measure the primary outcome and collect the following personal and demographic data: full name, mobile phone number, email address, date of birth, gender, marital status, number of children, ethnicity, occupation, education level, current pregnancy intention, current method and how they found out about the study (online supplementary file 3).

Follow-up data collected

At 4 months, we will measure the primary, secondary and process outcomes and collect the following data: if participants report using an effective method, where they obtained it, current pregnancy intention, whether they knew someone else that took part in the study and, if so, if they read each other's messages (contamination), if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages (online supplementary file 4).

If participants do not complete the questionnaire themselves, local research staff will contact them to collect their data. For participants that report use of effective contraception at follow-up, local research staff will attempt to locate the service records to objectively verify use.

Methods to maximise follow-up response

The pretrial training also included training in follow-up procedures. It emphasised the importance of ensuring that participants understand that participation involves completing a 4-month questionnaire and to potentially receiving daily messages about contraception for 4 months. The control messages, also sent to participants allocated to the intervention, are an effort to keep participants engaged. Staff will contact non-responders up to three times for their follow-up data. Follow-up will end 6 months after the last participant has been randomised or after staff has attempted to contact all non-responders three times, whichever comes first.

See figure 3 for the schedule of enrolment, interventions and assessments.

Allocation and protecting against bias

Randomisation will occur immediately after baseline data is submitted on the trial database and randomisation system. The allocation sequence is generated by the remote computer-based randomisation software, ensuring that investigators are unaware of allocation before it occurs. Due to the nature of the intervention, participants will be aware of the allocation soon after they start receiving the messages. Local research staff collecting outcome data will not be made aware of allocation unless this is revealed to them by the participant. Researchers that analyse the data will be masked to treatment allocation.

		STUDY PERIOD						
		Enrolment	Allocation	Post-allocation				Close-out
	TIMEPOINT	0	0	Month 1	Month 2	Month 3	Month 4	6 months after last participant randomised
ENROLMENT	Eligibility screen	√						
	Informed consent	√						
	Baseline data completion	√						
	Baseline data entry	√						
	Allocation		√					
INTERVENTIONS	Contraceptive app instant messages (0-3 messages per day for 120 days)		● →				→	
	App instant messages not about contraception (16 messages over 120 days)		● →				→	
ASSESSMENTS	Baseline data: primary outcome, personal and demographic data	√						
	Follow-up data: primary, secondary and process outcomes*						√	√

*Plus: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that took part in the study and if so, if they read each other's messages (contamination); if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages

Figure 3 Schedule of enrolment, interventions and assessments.

Intervention delivery

After participant baseline data has been entered, a confirmation of enrolment screen will provide instructions on how to install the app. When participants install the app, they will be prompted to enter the mobile phone number they entered on the baseline questionnaire. The trial database and randomisation system will then send the local app platform the following information: gender, marital status, language preference, allocation and date of enrolment. Participants will then have access to the app and will receive either the control or intervention messages, according to their allocation. Within the app, participants can choose when they want to receive the messages and they can also stop the messages. If participants install the app after 13:00, they will receive the first message the following day.

Sample size

The trial is powered to detect a 15% increase in acceptability of effective contraception in the intervention group compared with the control group. Other studies have found smaller increases in behaviour with similar interventions, for example, Castaño *et al*.[39] Because attitudinal change is likely to be easier to achieve than behavioural change, we decided to power the trial to detect a larger difference. Four hundred and fifty-four participants will allow for 90% power to detect a 15% absolute increase in acceptability, assuming 50% acceptability in the control group (ie, 50% in the control vs 65% in the intervention, an OR of 1.86). Fifty per cent baseline acceptability is used in the absence of published data on acceptability in this context. If the actual baseline acceptability is higher or lower than 50%, the trial is still sufficiently powered to detect an absolute difference of 15%. For example, if the proportion in the control arm is 75%, there will be 90% power to detect an absolute difference of 12% (corresponding to 87% acceptability in the intervention group and an OR of 2.23). Allowing for 20% loss to follow-up, 570 people will be randomised.

DATA MANAGEMENT

We did not convene a Data Monitoring and Ethics Committee as the intervention provides support and is unlikely to produce adverse effects. We have convened a Trial Steering Committee, and they have agreed to take on the monitoring of ethical aspects of the trial. The trial sponsor may audit the trial according to their own risk assessment and schedule.

Personal details entered onto the trial database and randomisation system will be stored on LSHTM's secure server. Personally identifiable information exported from the database will be stored separately from anonymised research data. Participants' mobile phone numbers, but no other personal details, will be stored in the local platform that sends the messages through the app. Any signed paper consent forms and questionnaires will be kept in a data enclave at TFPA. All data arising from the study will be kept confidential and only accessible to researchers directly involved in it. Personally identifiable data will not be kept longer than necessary and will be deleted within 3 months following study completion. We will retain primary research data for 10 years following study completion.

ANALYSES

General statistical considerations

The analysis of the data will follow the plan specified below. There will be no interim analyses and therefore no stopping rules. All analyses will be according to randomised arm, and only participants with complete outcome data

will be included in the primary analysis (a complete case analysis). All statistical tests will be two sided. All effect estimates will be reported with a 95% CI and associated p value. Statistical significance will be considered at the 5% level. Analyses will be conducted using Stata 15.

Loss to follow-up

To investigate whether loss to follow-up differs by arm, we will report this descriptively and use a χ^2 test. We will use logistic regression to compare baseline characteristics of participants that completed 4-month follow-up against participants that did not. We will report predictors of loss to follow-up and investigate whether the effect of these differs by arm by testing for an interaction.

Assumptions about missing data

As we are not aware of similar trials, it is not possible to investigate the pattern of missing data. The complete case analysis assumes that missing data for participants that did not complete follow-up are similar to data from participants that completed follow-up, conditionally based on baseline covariates included in the analysis model (ie, that data is missing at random).[52] If participants that complete follow-up are more likely to find an effective method acceptable compared with those that are lost to follow-up, the observed proportion may overestimate acceptability.[52]

Missing covariates

The database requires all items on the baseline questionnaire to be submitted to randomise. Therefore, there will be no missing baseline covariates.

Primary analysis

Descriptive analysis

We will report a flow diagram of trial participation, as recommended in the CONSORT guidelines.[53] We will report the baseline characteristics by treatment arm. We will also explore the baseline factors associated with retention (see above).

Analysis of the primary outcome

The primary outcome is binary, and we will compare the crude proportion reporting at least one method is acceptable in each group. We will estimate the difference between the groups using logistic regression and will report the OR along with the 95% CI and p value for evidence against the absence of intervention effect from the model. The primary analysis regression will be adjusted for baseline covariates likely to be associated with the outcome in order to improve the efficiency of the analysis and avoid chance imbalances.[54] These prespecified covariates that we will adjust for are: use (using effective contraception/not using effective contraception); pregnancy intention (wants to avoid/other); gender (female/male), age (16–19/20–24 years); number of children (0/1+); highest education level completed (university/other) and acceptability of effective contraception at baseline (at least one method acceptable/no methods acceptable). We will also report the crude OR between arms.

Analysis of the secondary outcomes

The analysis of the secondary outcomes will be the similar to the analysis of the primary outcome. We will estimate the difference between the groups using logistic regression, report ORs with 95% CIs and p values. All regressions will be adjusted for the prespecified covariates as above (although with the acceptability of individual methods, the outcome at baseline will replace acceptability of effective contraception).

Analysis of the process outcomes

The process outcomes perceived norms, personal agency and intention are comprised of ordinal scales. Each scale will be analysed individually using ordered logistic regression to estimate proportional ORs. For knowledge, each correct answer will receive one point. The points will be summed, and an overall score will be produced. We will use linear regression to test for a difference in mean scores between the arms.

To assess the 'dose' of the intervention that the intervention participants received, we will analyse the number of messages that participants reported to have read (all, most, some and none) and whether they stopped the messages. This will be reported descriptively.

Additional analyses

Sensitivity analyses

We will conduct sensitivity analyses regarding the missing data. In the first sensitivity analysis, we will consider that data are not missing at random and that participants lost to follow-up did not find at least one method acceptable. In the second, we will adjust for the main baseline predictors of missingness. Both sensitivity analyses will be adjusted for the pre-specified covariates as above.

Subgroup analysis

Recognising that the trial is not powered to detect effect differences in subgroups, we will conduct exploratory subgroup analyses for the primary outcome to determine if the intervention effect varies by baseline characteristics. The prespecified subgroups are: gender (female/male); age (split at the median); marital status (married/not married); number of children (0/1+); ethnicity (Tajik/other); occupation (in education/other); highest education level completed (university/other) and pregnancy intention (wants to avoid/other). Within the prespecified subgroups, we will assess heterogeneity of treatment effect with a test for interaction.[55–59] Interaction test p values will be presented but will be interpreted with caution, due to the exploratory nature, the multiple tests performed and the low power of the interaction test. We will estimate ORs along with 95% CIs for each subgroup without p values. As this is an exploratory analysis of potentially influential characteristics that are not justified a priori, we will not hypothesise effect directions.

Contamination

To assess the potential for contamination, we will report the proportion of control group participants that read

another participant's messages and the proportion of intervention participants whose messages were read by another participant.

Participants' rights and safety

Participants will have the right to withdraw at any time during their involvement, without having to give a reason. Participants can withdraw by contacting the project coordinator. Acting on participants' requests to withdraw from the trial, participants' status will be changed to 'withdrawn', and the person will be excluded from the list of participants that are due to follow-up. Participants' participation and personal identifiable data will remain confidential and research data will be anonymised.

In the development phase, we explored young people's views on confidentiality about receiving messages on their mobile phone. While the large majority of participants reported that they were not concerned about receiving messages about contraception on their phone, it is possible that some participants will want to keep the messages confidential from certain people (eg, partner and parents) and that these people might view the messages. The messages remind participants that they can delete the messages and provide instructions on how to keep the messages private. Towards the beginning of the intervention, a message provides female participants with information on support services that they can contact if they feel unsafe as a consequence of the messages being read. (This information will not be provided for male participants as TFPA advised that male participants not feeling safe as a consequence of the messages being read is not culturally realistic.) We will review physical violence during participants' involvement in the trial reported on the follow-up questionnaire.

DISCUSSION

The results of this trial will provide evidence for the effect of the intervention on young Tajik women and men's attitudes towards effective contraception. The analysis of the secondary and process outcomes may provide evidence for the effect of the intervention on use of effective contraception, attitudes towards the individual effective methods, service use, unintended pregnancy, induced abortion and on the psychological processes that may have been altered by the intervention.

As the intervention will be delivered through TFPA's Android app, participants are required to own a personal Android mobile phone. While the formative work indicated that the majority of young people in Tajikistan did own a personal Android mobile phone, those who do not own a smartphone may be those who are less likely to find at least one method of effective contraception acceptable. However, considering the rapid increase in smartphone ownership, it is reasonable to assume that ownership will be an option for a greater proportion of young people across different socioeconomic communities in the coming years.

The trial is assessing the effect of sending instant messages containing behaviour change methods in addition to the app; it is not assessing the effect of the app itself. It is possible that the app, which provides basic information about contraception, could increase the acceptability of effective contraception. If the app itself is very effective, the added benefit of the instant messages will be lower.

If the trial demonstrates that the intervention increases the acceptability of effective contraception in Tajikistan, the results could inform the design of a trial to evaluate the effect of the intervention on unintended pregnancy.

PROTOCOL AMENDMENTS

Any important changes to the protocol will be submitted to the LSHTM Interventions Research Ethics Committee as an amendment. Trial documentation will be updated accordingly and will be implemented once the Committee has approved the changes. OLM will communicate any changes relevant to local staff.

DISSEMINATION

The research results will be cowritten by LSHTM and TFPA and submitted for publication in peer-reviewed academic journals. We will adhere to the International Committee of Medical Journal Editors authorship criteria. We will disseminate findings to all the study stakeholders.

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Contributors OM designed and managed the trial, developed the trial materials and wrote the manuscript. RT contributed to discussions and decisions regarding the design of the trial, assisted in the development of the trial material and facilitated trial implementation. RT also took overall local responsibility for the trial. BL and PE provided advice regarding the statistical analysis. CF provided guidance regarding the trial design and implementation. All authors revised the work, approved the version to be published and agree to be accountable for all aspects of the work.

Funding The trial is supported by the International Planned Parenthood Federation (IPPF) Innovation Programme. IPPF had some influence over the study design (MV and SS) but will have no involvement in the data collection or analysis.

Competing interests None declared.

Patient consent Detail has been removed from this case description/these case descriptions to ensure anonymity. The editors and reviewers have seen the detailed information available and are satisfied that the information backs up the case the authors are making.

Ethics approval The trial was granted ethical approval by the LSHTM Interventions Research Ethics Committee on 16 May 2016 and by the Tajik National Scientific and Research Centre on Paediatrics and Child Surgery under the Ministry of Health on 15 April 2016.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

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BMJ Open

A randomised controlled trial of an intervention delivered by app instant messaging to increase the acceptability of effective contraception among young people in Tajikistan: study protocol

Ona McCarthy, Baptiste Leurent, Phil Edwards, Ravshan Tokhirov and Caroline Free

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Appendix 9. Palestine trial protocol publication

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Trials

STUDY PROTOCOL Open Access

An intervention delivered by text message to increase the acceptability of effective contraception among young women in Palestine: study protocol for a randomised controlled trial

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Abstract

Background: Unintended pregnancy can negatively impact women's lives and is associated with poorer health outcomes for women and children. Many women, particularly in low- and middle-income countries, continue to face obstacles in avoiding unintended pregnancy. In the State of Palestine, a survey conducted in 2006 estimated that 38% of pregnancies are unintended. In 2014, unmet need for contraception was highest among young women aged 20–24 years, at 15%.
Mobile phones are increasingly being used to deliver health support. Once developed, interventions delivered by mobile phone are often cheaper to deliver than face-to-face support. The London School of Hygiene and Tropical Medicine and the Palestinian Family Planning and Protection Association have partnered to develop and evaluate a contraceptive behavioural intervention for young women in Palestine delivered by mobile phone. The intervention was developed guided by behavioural science and consists of short, mobile phone text messages that contain information about contraception and behaviour change methods delivered over 4 months.

Methods: We will evaluate the intervention by conducting a randomised controlled trial. Five hundred and seventy women aged 18–24 years, who do not report using an effective method of contraception, will be allocated with a 1:1 ratio to receive the intervention text messages or control text messages about trial participation. The primary outcome is self-reported acceptability of at least one method of effective contraception at 4 months. Secondary outcomes include the use of effective contraception, acceptability of individual methods, discontinuation, service uptake, unintended pregnancy and abortion. Process outcomes include knowledge, perceived norms, personal agency and intervention dose received. Outcomes at 4 months will be compared between arms using logistic regression.

Discussion: This trial will determine the effect of the intervention on young women's attitudes towards the most effective methods of contraception. If the intervention is found to be effective, the intervention will be implemented widely across Palestine. The results could also be used to design a larger trial to establish its effect on unintended pregnancy.

Trial registration: ClinicalTrials.gov, ID: NCT02905461. Registered on 14 September 2016.

Keywords: Palestine. Contraception, Mobile phone, Cell phone, Reproductive health, Young adults

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Background

In 2012, an estimated 85 million pregnancies worldwide were unintended, half of which ended in abortion [1]. Women who have unintended pregnancies can experience decreased psychological wellbeing [2–10], initiate antenatal care later than those with intended pregnancies [4, 10–14] and access care less frequently [4, 11, 14]. There is a higher risk of low birth weight and pre-term birth among children born of unintended pregnancies [15, 16] and these children can exhibit behavioural problems more often than children born of intended pregnancies [17]. Unintended pregnancy can also impact the social wellbeing of parents and families. It can delay or prevent educational and career achievements, which can impact the financial security of the family [18]. Unsafe abortions are a consequence of unintended pregnancy where access to safe abortion is limited [19, 20]. Satisfying unmet need for modern contraception reduces unintended pregnancies and identifying the barriers to non-use is crucial in achieving this [21, 22].

The conflict in the State of Palestine (the West Bank, East Jerusalem and the Gaza Strip, hereafter referred to as 'Palestine') has negatively impacted the health and wellbeing of Palestinians [23–25]. The conflict has also had negative effects on reproductive health in Palestine [26, 27]. Data regarding unintended pregnancy in Palestine generally comes from household surveys where only married women (sexual activity before marriage is stigmatised in Palestinian culture) are asked if their current or last pregnancy was intended at the time that they became pregnant [28]. Effective contraception methods are those with a less than 10% typical use-failure rate at 12 months [29–31]. The (non-permanent) effective methods available in Palestine are oral contraceptive pills (OCs), intrauterine devices (IUDs), injectables, implants, and the patch. Despite the availability of these methods, a 2006 survey estimated that 38% of pregnancies in Palestine are unintended [28, 32].

In 2014, the unmet need for contraception was highest among young women aged 20–24 years, at 15% [33]. The modern contraceptive prevalence rate among married women aged 15–24 years is estimated to be 24% and the effective rate in the same group is estimated to be 17% [33]. Barriers to contraceptive uptake are lack of accurate and comprehensive information about a range of contraceptive methods, lack of spousal communication regarding contraception, peers' and relatives' (particularly husband and mother-in-law) disapproval of contraception, societal pressure to bear children early in marriage and inadequate family planning services [34–38]. Attitudes, such as perceived inconvenience and fear of the side effects of contraceptive methods along with husbands' opposition, are common reasons married women provide for not using contraception [39, 40]. Education also is a factor in this setting as Palestinian women who spend more time in education report fewer unintended pregnancies [28]. A non-representative study in 2014 and found that 55% of women aged 15–49 years from a community sample (from underserved areas) said that their pregnancy was unintended ('unwanted') and, of these, 26% said that this was because it 'was not their choice'. In a client sample (from service-delivery points), 40% reported unintended pregnancy, with 32% saying that it 'was not their choice' [41].

Mobile phones are increasingly being used to deliver health support over a range of health behaviours [42–52]. In sensitive areas, such as reproductive and sexual health, short messages delivered by mobile phone may be advantageous as they have the potential to be read at a time and place of the recipient's choosing. The support can be non-judgemental and is often more convenient and cheaper to deliver than face-to-face support. In Palestine, where there is a substantial area that is underserved with regard to sexual and reproductive health services [41], delivering contraceptive support by mobile phone may be a particularly advantageous mode by which to reach people. Those that do have access to services may find the barriers outlined above difficult to overcome and may also benefit from mobile phone support. While there is some evidence from high-income countries that mobile phone-based interventions can increase contraceptive-related behaviours [53–55] and knowledge [56], none of the trials evaluating these interventions had a low risk of bias [57]. To the best of our knowledge, there is only one trial conducted in a non-high-income country (Cambodia); this trial found that post-abortion voice messaging with telephone counselling support increased effective contraceptive use [58].

A systematic approach to developing behaviour change interventions is recommended [59–61] as it allows for the intervention to be clearly defined. The London School of Hygiene and Tropical Medicine (LSHTM) and the Palestinian Family Planning and Protection Association (PFPPA), a Member Association of the International Planned Parenthood Federation (IPPF), are collaborating to evaluate a contraceptive behavioural intervention delivered by mobile phone for young women in Palestine. We developed the intervention guided by an established approach based on behavioural science [62]. Among other activities, the approach involved consultation with young people, which explored their knowledge of, attitudes towards, and barriers in, using contraception; specifying behavioural change; identifying behaviour change methods and producing the intervention content through an interactive process of writing, testing with young people and refining.

In Palestine, mobile phone ownership is high, with 92% of all adults owning a mobile phone and among people aged 18–34 years, 73% report owning a smartphone [63]. However, the intervention development

process revealed that many young people in Palestine did not have regular Internet access on their mobile phones. Those who sometimes access the Internet though their mobile data said that it is common for the connection to be lost. Because of this and because many of the young people we consulted with preferred it, we identified short messaging service (SMS) as the most appropriate mode of intervention delivery.

This randomised controlled trial will evaluate the effect of the intervention on young women's attitudes towards the (non-permanent) effective contraceptive methods available in Palestine: OCs, IUDs, the injection, the implant, and the patch. Sexual activity before marriage is highly stigmatised in Palestine and there is strong cultural pressure to bear children soon after marriage. While it is estimated that 24% of women are married before age 18 years [33], a significant proportion of participants in the study population will likely be either not married (and not sexually active or not willing to admit that they are) or newly married. Because of this, an objective primary outcome of effective contraceptive use would not be advisable as powering a study for an outcome with a small number of events would make the sample size prohibitively large. In not-married/not-sexually-active young women, the intervention aims to increase acceptability of the effective methods for when they may want to limit or space their families and could benefit from finding a range of methods acceptable.

This will be the first trial evaluating an intervention delivered by mobile phone that is designed to increase the acceptability of effective contraception in Palestine [57]. The results of the study will contribute to the growing body of research on the utility of mobile phones as an intervention-delivery mechanism and contribute to the evidence base for contraceptive interventions for young women in Palestine.

Methods

Study design

This study is a parallel-group, individually randomised superiority trial with a 1:1 allocation ratio evaluating the effect of a contraceptive intervention delivered by mobile phone text messaging compared with control text messages about trial participation. The objective of this research is to establish the effect of the intervention on young women's attitudes towards effective contraception in Palestine.

Eligibility criteria

Women aged 18–24 years, who do not report using effective contraception, own a personal mobile phone, live in the West Bank, can provide informed consent and can read Arabic will be eligible to take part. The lower age limit of 18 years was chosen because it is the age in Palestine where people are able to provide independent informed consent to take part in research. The upper age limit of 24 years was chosen because this most closely matched the target group 'young people' [64] which was identified by the funder. Participants must also be willing to receive messages about contraception on their mobile phone.

Recruitment

The trial will be promoted through PFPPA's service-delivery points through outreach sites, the PFPPA website, the distribution of trial promotional material via flyers and social media sites. PFPPA service-delivery points provide: contraceptive methods; counselling for women in psychological, legal and social matters; laboratory tests for both men and women; maternal, antenatal and post-natal care and infertility services [65]. The promotional material includes brief information about the trial (e.g. who is conducting it, who may be eligible, what participation would involve) with a link to the secure trial database and randomisation system.

To maximize the chance of recruiting to target, LSHTM conducted a pre-trial training in Bethlehem to train local staff on all recruitment procedures. The training included discussions about the practicalities of recruitment with a view to developing the most appropriate strategies.

We will report the number of people assessed for eligibility, excluded before randomisation, the number of participants randomised, allocated to the intervention, completed follow-up and analysed (Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) diagram).

Intervention

The intervention is informed by the Integrated Behavioural Model [66] and consists of short mobile phone text messages providing contraceptive support delivered over 4 months. The intervention messages provide information about contraception, target beliefs identified in the development phase that influence contraceptive use (e.g. misconceptions about the side effects and health risks of contraception, belief that non-hormonal methods are better because they are not harmful to health) and aim to support young women in believing that they can influence their reproductive health. The intervention provides accurate information about contraception and contains the following behaviour change methods, adapted for delivery by mobile phone [67]: belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting.

The messages are tailored according to marital status, resulting in two sets of intervention messages: (1) female-married and (2) female-not married. Most of the

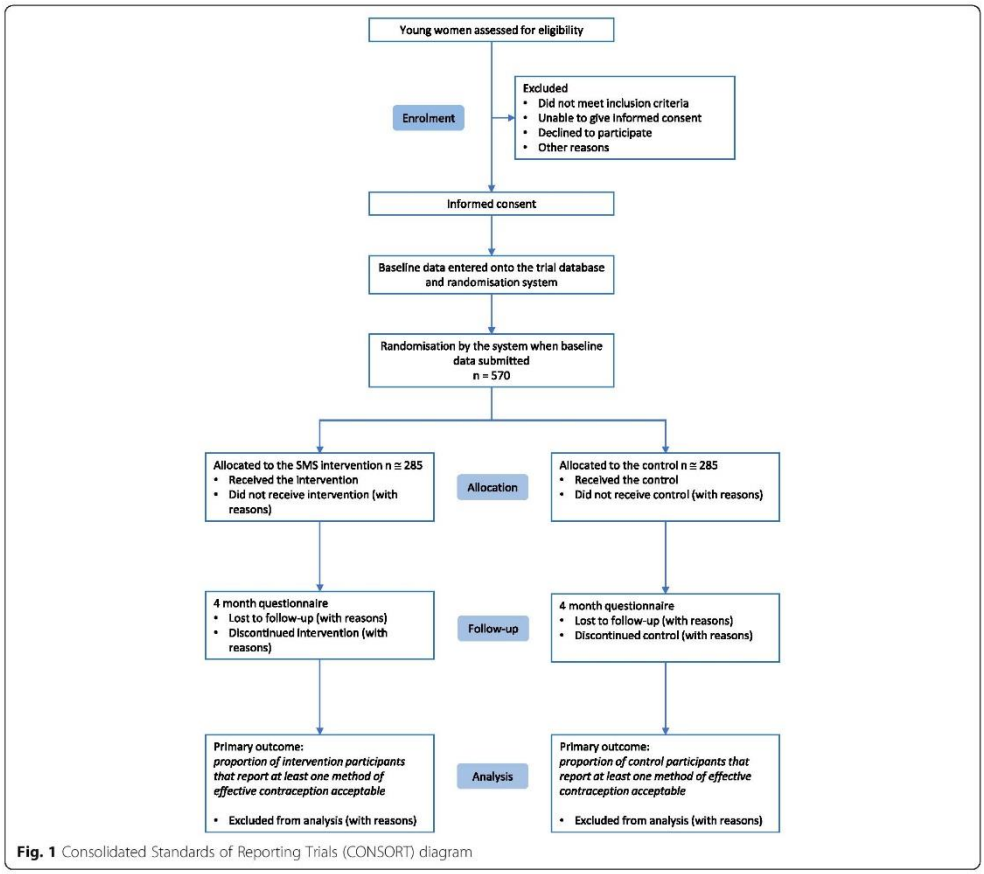

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) diagram

messages in the two sets overlap, with minor tailoring so that the messages are relevant to marital status (a proxy for sexual activity). Participants allocated to the intervention group receive zero to three messages per day (113 messages for female-not married and 120 messages for female-married) for 120 days.

The message sets start with 6 days of messages (10 messages for married women and 11 for not-married women) with general information about the study, such as information about what they will receive over the next 120 days, how to stop the messages, who to contact if they change their number, how to keep the messages private and information about who to call if they feel unsafe as a result of someone reading the messages. Included in the intervention messages that the intervention recipients receive are seven control messages about the importance of their participation and reminding them to contact the project coordinator if they change their number. On days 119 and 120, the message sets include four messages that indicate that the messages have ended, provide information on how to complete the follow-up questionnaire, reassurance that the information that they provide is confidential and a final message stating that their participation is helping to determine the best ways to provide reproductive health services in Palestine.

Details regarding the development of the intervention and intervention description will be reported in a forthcoming publication.

Control

Participants allocated to the control group receive 16 messages over 120 days. The first 4 days include six messages that introduce the study, provide information about what they will receive over the next 120 days, how

to stop the messages and who to contact if they change their number (e.g. 'Thank you for joining. This study is being conducted by Palestinian Family Planning and Protection Association'; 'Over the next 4 months, we will send you a few messages a month'). They will then receive two messages a month for 3 months – one about the importance of their participation and one reminding them to contact the project coordinator if they change their number (e.g. 'Your participation in the study is a way to actively be involved in matters that affect your life. Thanks'; 'If you change your number, please contact X to let us know'). On day 105, participants will receive one message about the importance of their participation ('Your participation helps in reducing inequalities in reproductive health for youth'). On day 120, they will receive three messages that provide information on how to complete the follow-up questionnaire, reassurance that the information that they provide is confidential and a final message stating that their participation is helping to determine the best ways to provide reproductive health services in Palestine (e.g. 'It is time to complete the final questionnaire. Research staff will call you in few days or you can complete it here LINK'; 'You are helping us determine the best ways to provide reproductive health services in Palestine').

All participants will receive usual care and will be free to seek any other support, whether existing or new.

Outcomes

Primary outcome

The primary outcome is the proportion of participants reporting that at least one method of effective contraception is acceptable at four months post randomisation. The acceptability of each method is binary (acceptable/not acceptable), but is derived from ordinal data from the following stems: Using the [method]… causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy and I would recommend the [method] to a friend. The IUD and implant include an additional stem: The [method] insertion would not be a problem for me. The response options for each scale are: strongly disagree, disagree, not sure, agree, strongly agree and I do not know what the [method] is. A method is acceptable if participants report 'agree' or 'strongly agree' for all scales except for '…causes infertility' and '…causes unwanted side effects' stems, for which 'disagree' or 'strongly disagree' denotes acceptability (items 1-27 in Additional file 1 and items 4-30 in Additional file 2).

Secondary outcomes

Secondary outcomes are: the proportion reporting current use of effective contraception (use of effective contraception); the proportion reporting that each effective contraceptive method is acceptable (acceptability of individual methods); the proportion reporting use of effective contraception at any time during the four months (discontinuation); the proportion reporting attending a sexual health service during the four months (service uptake); the proportion reporting that they became pregnant and did not want to become pregnant during the study (unintended pregnancy); the proportion reporting having an abortion during the study (induced abortion).

Process outcomes The process outcomes are: knowledge of effective contraception; perceived norms and personal agency in relation to using and communicating with partners about contraception; intention to use effective contraception and intervention dose received.

Data collection

Data will be collected at baseline and at 4 months post randomisation using questionnaires, which we tested for face validity with the target group. We asked people to comment on the length of the questionnaires, the comprehensibility of the questions, the meaning of the scales and suggestions for improvement. All data will be entered onto the trial database and randomisation system, which is on LSHTM's secure server. At both time points, participants can either fill out a paper-based version of the questionnaire at the recruitment site, provide the data over the phone with research staff or enter data directly onto the online system, according to their preference. If participants provide their questionnaire data by paper or over the phone, research staff will enter this data onto the system.

Baseline data collected

At baseline we will measure the primary outcome and collect the following personal and demographic data: full name; mobile phone number; email address; date of birth; marital status; number of children; residence; occupation; education level; current pregnancy intention; current method; how they heard about and enrolled in the study and the time that they prefer to receive the messages (see Additional file 1).

Follow-up data collected

At 4 months, we will measure the primary, secondary and process outcomes and collect the following data: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that took part in the study and, if so, if they read each other's messages (contamination); if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages (see Additional file 2).

Staff unaware of partcipants' allocation will contact participants by phone to collect the follow-up data (participants can also complete the questionnaire online or attend the service). For participants who report use of effective contraception at follow-up, local research staff will attempt to locate the service records to objectively verify use.

Methods to improve the quality of data collection

Closer to the start of follow-up, we will conduct a 'follow-up refresher' with staff who will collect follow-up data over the phone. This training will re-emphasise how to collect the follow-up data in a neutral, standardised way. Staff will also be given a suggested script and guidelines to follow when gathering the data.

Methods to maximize follow-up response

The pre-trial training also included training in follow-up procedures. It emphasised the importance of ensuring that participants understand that participation involves completing a 4-month questionnaire and to potentially receiving daily messages about contraception for 4 months. The control messages, also sent to participants allocated to the intervention, are an effort to keep participants engaged. Staff will contact non-responders up to three times for their follow-up data. Follow-up will end 6 months after the last participant has been randomised or after staff have attempted to contact all non-responders three times, whichever comes first.

See Fig. 2 for the schedule of enrolment, interventions and assessments.

Allocation and protecting against bias

Randomisation will occur immediately after baseline data is submitted on the trial database and randomisation system. Participants will receive the first message the day after they install the app. The allocation sequence is generated by the remote, computer-based randomisation software, ensuring that investigators are unaware of allocation before participants are randomised. Due to the nature of the intervention, participants will be aware of the allocation soon after they start receiving the messages. Local research staff collecting outcome data will not be aware of allocation unless this is revealed to them by the participant. Researchers who analyse the data will be masked to treatment allocation.

Intervention delivery

After randomisation, the trial database and randomisation system will send the local SMS platform the following information: allocation, time slot (participants can choose to receive messages from 10:00 to 13:59, 14:00 to 18:59, or both), mobile phone number and marital status. The platform will send the intervention or control messages. Messages sent will be recorded by the local platform and will be monitored.

Sample size

The trial is powered to detect an increase in acceptability of effective contraception. Four hundred and fifty-four participants will allow for 90% power to detect a 15% absolute increase in acceptability, assuming 50% acceptability in the control group (i.e. 50% in the control vs. 65% in the intervention, corresponding to an odds ratio of 1.86). The sample size was calculated using the

		STUDY PERIOD						
		Enrolment	Allocation	Post-allocation				Close-out
	TIMEPOINT	0	0	Month 1	Month 2	Month 3	Month 4	6 months after last participant randomised
ENROLMENT	Eligibility screen	√						
	Informed consent	√						
	Baseline data completion	√						
	Baseline data entry	√						
	Allocation		√					
INTERVENTIONS	Contraceptive text message intervention (0-3 messages per day for 120 days)		→	→	→	→	→	
	Text messages not about contraception (16 messages over 120 days)		→	→	→	→	→	
ASSESSMENTS	Baseline data: primary outcome, personal and demographic data	√						
	Follow-up data: primary, secondary and process outcomes*						√	√

*Plus: if participants report using an effective method, where the obtained it; current pregnancy intention; whether they knew someone else that took part in the study and if so, if they read each other's messages (contamination); if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages

Fig. 2 Schedule of enrolment, interventions and assessments. *Plus: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that took part in the study and, if so, if they read each other's messages (contamination); if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages

statistical software Stata 15.0 (syntax: power twoproportions .50 .65, test(chi2) power(0.9)) [68]. A 50% acceptability baseline is used in the absence of published data on acceptability in this context. If the actual baseline acceptability is higher or lower than 50%, the trial is still sufficiently powered to detect an absolute difference of 15%. For example, if the proportion in the control arm is 75%, there will be 90% power to detect an absolute difference of 12% (corresponding to 87% acceptability in the intervention group and an odds ratio of 2.23). Allowing for 20% loss to follow-up, 570 people will be randomised.

Data management

We did not convene a Data Monitoring and Ethics Committee as the intervention provides support and is unlikely to produce adverse effects. However, we have convened a Trial Steering Committee and they have agreed to take on the monitoring of ethical aspects of the trial. The trial sponsor may audit the trial according to their own risk assessment and schedule.

Personal details entered onto the trial database and randomisation system will be stored on LSHTM's secure server. Personally identifiable information exported from the database will be stored separately from anonymised research data on an LSHTM computer. Participant mobile phone numbers, but no other personal details, will be stored in the local platform that sends out the text messages. Signed paper Consent Forms and questionnaires will be kept in a data enclave at PFPPA. All data arising from the study will be kept confidential and is only accessible to researchers directly involved in it. Personally identifiable data will not be kept longer than necessary and will be deleted within 3 months following study completion. We will retain primary research data for 10 years following study completion.

Analyses

General statistical considerations

The analysis of the data will follow the plan specified below. There will be no interim analyses and, therefore, no stopping rules. All analyses will be according to randomised arm and only participants with complete outcome data will be included in the primary analysis (a complete case analysis). All statistical tests will be two-sided. All effect estimates will be reported with a 95% confidence interval and its associated p value. Statistical significance will be considered at the 5% level. Analyses will be conducted using the latest version of Stata.

Loss to follow-up

To investigate whether loss to follow-up differs by arm, we will report this descriptively and use a chi-squared test. We will use logistic regression to compare baseline characteristics of participants who completed 4-month follow-up against participants who did not. We will report predictors of loss to follow-up and investigate whether the effect of these differs by arm by testing for an interaction.

Assumptions about missing data

As we are not aware of similar trials, it is not possible to investigate the pattern of missing data. The complete case analysis assumes that missing data for participants who did not complete follow-up are similar to data from participants who did complete follow-up, conditionally on baseline covariates included in the analysis model (i.e. that data is missing at random (MAR)) [69]. If participants who complete follow-up are more likely to find an effective method acceptable compared to those that are lost to follow-up, the observed proportion may overestimate acceptability [69]. European Union guidance on missing data in clinical trials highlights this limitation of MAR among others [70]. The guidance states, however, that 'under reasonable assumptions' the estimate of treatment effect is unlikely to be biased 'to an important degree'. We will conduct the principal analysis under a MAR assumption (conditionally on the adjustment variables in the model), then perform sensitivity analysis under different assumptions for the missing data, as explained below.

Missing covariates

The database requires all items on the baseline questionnaire to be submitted to randomisation. Therefore, there will be no missing baseline covariates.

Principal analyses

Descriptive analysis We will report a flow diagram of trial participation, as recommended in the CONSORT guidelines [71]. We will report the baseline characteristics by treatment arm. We will also explore the baseline factors associated with retention (see above).

Analysis of the primary outcome The primary outcome is binary and we will compare the crude proportion reporting that at least one method is acceptable in each group. We will estimate the difference between the groups using logistic regression and will report the odds ratio along with the 95% confidence interval and its p value for evidence against the absence of intervention effect from the model. The primary analysis regression will be adjusted for baseline covariates likely to be associated with the outcome in order to improve the efficiency of the analysis and avoid chance imbalances [72]. These pre-specified covariates that we will adjust for are: pregnancy intention (wants to avoid/other); age (18–19/20–24 years); number of children (0/1+); highest

education level completed (university/other) and acceptability of effective contraception at baseline (at least one method acceptable/no methods acceptable). We will also report the crude odds ratio between arms.

Analysis of the secondary outcomes The analysis of the secondary outcomes will be the similar to the analysis of the primary outcome. We will estimate the difference between the groups using logistic regression, report odds ratios with 95% confidence intervals and their p values. All regressions will be adjusted for the pre-specified covariates as above (although with the acceptability of individual methods, the outcome at baseline will replace acceptability of effective contraception).

Analysis of the process outcomes The process outcomes perceived norms, personal agency and intention are comprised of ordinal scales. Each scale will be analysed individually using ordered logistic regression to estimate proportional odds ratios. For knowledge, each correct answer will receive 1 point. The points will be summed and an overall score will be produced. We will use linear regression to test for a difference in mean scores between the arms.

To assess the 'dose' of the intervention that the intervention participants received, we will analyse the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages. This will be reported descriptively.

Additional analyses

Sensitivity analyses We will conduct sensitivity analyses regarding the missing data assumptions. In the first sensitivity analysis, we will consider that data are not MAR, and that all participants lost to follow-up did not find at least one method acceptable. In the second, we will adjust for the main baseline predictors of missingness. Both sensitivity analyses will be adjusted for the pre-specified covariates as above.

Subgroup analysis Recognising that the trial is not powered to detect effect differences in subgroups, we will conduct exploratory subgroup analyses for the primary outcome to determine if the intervention effect varies by baseline characteristics. The pre-specified subgroups are: age (split at the median); marital status (married/not married); number of children (0/1+); residence (city/other); occupation (in education/other); highest education level completed (university/other) and pregnancy intention (wants to avoid/other). Within the pre-specified subgroups, we will assess heterogeneity of treatment effect with a test for interaction [73–77]. Interaction test p values will be presented but will be interpreted with caution due to the exploratory nature, the multiple tests performed and of the low power of the interaction test. We will estimate odds ratios along with 95% CIs for each subgroup without p values. As this is an exploratory analysis of potentially influential characteristics that are not justified a priori, we will not hypothesise effect directions.

Contamination To assess the potential for contamination, we will report the proportion of control group participants who read another participant's messages and the proportion of intervention participants whose messages were read by another participant.

Analysis of pooled trial data We are conducting trials of similar interventions in two other countries. If the results of the other trials are available, we will conduct the principal analyses on the pooled dataset.

Participants' rights and safety

Participants will have the right to withdraw at any time during their involvement, without having to give a reason. Participants can withdraw by contacting the project coordinator. Acting on participants' requests to withdraw from the trial, participants' status will be changed to 'withdrawn', the text messages will stop and the person will be excluded from the list of participants who are due follow-up. Participants will be able to stop text messages, but choose to continue with the trial follow-up. Participants' participation and personal identifiable data will remain confidential and research data will be anonymised.

In the formative work, we explored young people's views on confidentiality about receiving messages on their mobile phone. While the large majority of participants did not report that they were concerned about receiving messages about contraception on their mobile phone, it is possible that some participants will want to keep the messages confidential from certain people (e.g. partner, parents) and that these people might view the messages. The messages remind participants that they can delete the messages and provide instructions on how to keep the messages private. We will provide information on support services that they can contact if they feel unsafe because of the messages being read. We will review physical violence during participants' involvement in the trial reported on the follow-up questionnaire.

Discussion

The results of this trial will provide evidence for the effect of the intervention on young Palestinian women's attitudes towards effective contraception. The analysis of the secondary and process outcomes may provide evidence for the effect of the intervention on the use of effective contraception, attitudes towards the individual effective methods, service use, unintended pregnancy,

induced abortion and on the psychological processes hypothesised to influence contraceptive use.

There are a number of limitations of this trial. The main limitation is that the primary outcome is self-reported. As sexual activity before marriage is highly stigmatised in Palestine, this precluded the option of an objective primary outcome in the study population. We expect that a significant proportion of participants in the trial will not be married and either will not be sexually active, or will be unwilling to admit if they are. Powering a study for uptake of contraception in a population, which will likely result in a small number of outcome events, would make the sample size prohibitively large. In not married/not sexually active young women, the intervention aims to improve attitudes towards the most effective methods, so that they will find a wider range of methods acceptable if they want to choose a method in the future.

While local research staff are not made aware of allocation, there is a chance that the participants could reveal to local research staff collecting outcome data the group that they were allocated to. Staff are trained in asking questions in a standardised way. As the communities from which the trial participants derive are close, we anticipate that there will be some degree of contamination but we cannot predict the extent of it. We are measuring the potential for contamination at 4-month follow-up and will consider this when interpreting the results. In absence of further data, we have powered the trial to detect an absolute difference of 15% in the proportion of participants finding at least one method of effective contraceptive acceptable. The trial will have a lower power if the intervention has a smaller effect.

Trial status

Recruitment commenced on 8 December 2016 and is will be complete by 31 July 2017. The estimated completion date for the final participant recruited (final data collection date for the primary outcome) is January 2018.

Additional files

Additional file 1: Baseline questionnaire. Questionnaire completed after informed consent and before randomisation. (DOCX 16 kb)

Additional file 2: Follow-up questionnaire. Questionnaire completed 4 months after randomisation. (DOCX 20 kb)

Additional file 3: Trial Information Sheet. Participant Trial Information Sheet. (DOCX 18 kb)

Additional file 4: Trial Consent Form. Participant Trial Consent Form. (DOCX 27 kb)

Abbreviations

CONSORT: Consolidated Standards of Reporting Trials diagram; OC: Oral contraceptive pill; IUD: Intrauterine device; LSHTM: The London School of Hygiene and Tropical Medicine; PFPPA: the Palestinian Family Planning and Protection Association; IPPF: The International Planned Parenthood Federation.; MAR: Missing at random; SMS: Short messaging service

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Funding

The trial is supported by the International Planned Parenthood Federation Innovation Programme. IPPF had some influence over the study design (SA) but will have no involvement in the data collection or analysis.

Availability of data and materials

The datasets used and analysed during the current study will be available from the corresponding author on reasonable request.

Protocol amendments

Any important changes to the protocol will be submitted to the LSHTM Interventions Research Ethics Committee as an amendment. Trial documentation will be updated accordingly and will be implemented once the committee has approved the changes. OM will communicate any changes relevant to local staff.

Dissemination

The research results will be co-written by LSHTM and PFPPA and submitted for publication in peer-reviewed, academic journals. We will adhere to the International Committee of Medical Journal Editors' authorship criteria. We will disseminate findings to all the study stakeholders. The IPPF Arab World Regional Office will disseminate the results in the Arab World Region and will conduct activities for regional learning and sharing of the project results.

World Health Organization trial registration dataset

http://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT02905461.

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Author's contributions

OM designed and managed the trial, developed the trial materials and wrote the manuscript. OW, IJ and AS assisted in the development of the trial material and facilitated trial implementation. AS also took overall local responsibility for the trial. BL and PE provided advice regarding the statistical analysis. SA provided programmatic and logistical input regarding the project. CF provided guidance regarding the trial design and implementation. All authors revised the manuscript, approved the final version, and agree to be accountable for all aspects of the work.

Author's information

Not applicable

Ethics approval and consent to participate

The trial was granted ethical approval by the LSHTM Interventions Research Ethics Committee on 16 May 2016 and by the State of Palestine Ministry of Health Primary Health Care and Public Health Directorate on 9 May 2016. Informed consent will be taken either by PFPPA recruitment staff or participants can read the Information Sheet (see Additional file 3) and provide informed consent (see Additional file 4) themselves online through the system.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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Appendix 10. Bolivia trial protocol publication

Protocol

An Intervention Delivered by App Instant Messaging to Increase Acceptability and Use of Effective Contraception Among Young Women in Bolivia: Protocol of a Randomized Controlled Trial

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Abstract

Background: Unintended pregnancy is associated with numerous poorer health outcomes for both women and their children. Fulfilling unmet need for contraception is essential in avoiding unintended pregnancies, yet millions of women in low- and middle-income countries continue to face obstacles in realizing their fertility desires. In Bolivia, family planning progress has improved in recent decades but lags behind other countries in the region. Unmet need for contraception among women aged 15 to 19 years is estimated to be 38%, with the adolescent fertility rate at 70 per 1000 women. Mobile phones are an established and popular mode in which to deliver health behavior support. The London School of Hygiene & Tropical Medicine and the Centro de Investigación, Educación y Servicios in Bolivia have partnered to develop and evaluate a contraceptive behavioral intervention for Bolivian young women delivered by mobile phone. The intervention was developed guided by behavioral science and consists of short instant messages sent through an app over 4 months.

Objective: The objective of this study is to evaluate the effect of the intervention on young women's use of and attitudes toward the most effective contraceptive methods.

Methods: We will allocate 1310 women aged 16 to 24 years with an unmet need for contraception in a 1:1 ratio to receive the intervention messages or the control messages about trial participation. The messages are sent through the Tú decides app, which contains standard family planning information. Coprimary outcomes are use and acceptability of at least one effective contraceptive method, both measured at 4 months.

Results: Recruitment commenced on March 1, 2017 and was completed on July 29, 2017. We estimate that the follow-up period will end in January 2018.

Conclusions: This trial will evaluate the effect of the intervention on young women's use of and attitudes toward the (nonpermanent) effective contraception methods available in Bolivia.

Trial Registration: ClinicalTrials.gov NCT02905526; https://clinicaltrials.gov/ct2/show/NCT02905526 (Archived by WebCite at http://www.webcitation.org/6vT0yIFfN)

(JMIR Res Protoc 2017;6(12):e252) doi:10.2196/resprot.8679

KEYWORDS

behavior change; Bolivia; young adult; adolescent; contraception behavior; smartphone; cell phone; reproductive health

Introduction

The desire to limit and space childbirth has increased in recent decades, yet many women continue to face obstacles in avoiding unintended pregnancies [1]. Unintended pregnancy is associated with numerous poorer health outcomes for both women and their children [2]. Women with unintended pregnancies are more likely to experience depression and anxiety [3-11], and to initiate prenatal care later [5,11-15] and less frequently [5,12,15]. Unintended pregnancies also increase the risk of low birth weight and preterm birth [16,17]. With young women in particular, unintended pregnancy can delay or prevent educational and career achievements, which can affect future financial security [2]. Where safe abortion is restricted, unintended pregnancies can increase the occurrence of unsafe abortions [18,19]. Satisfying unmet need for contraception is essential in avoiding unintended pregnancy, which requires an understanding of the reasons for nonuse in particular contexts [20].

Bolivia is classified as a lower middle-income country. While the country has experienced recent economic growth, in 2015 around 39% of people were living below the national poverty line [21]. Income inequality is high [21], with substantial inequality between indigenous and nonindigenous populations [22]. Compared with other countries in the region, in Bolivia, progress in family planning has lagged behind [23]. Effective contraception methods are those with a less than 10% typical-use failure rate at 12 months [24-26]; the (nonpermanent) effective methods available in Bolivia are oral contraceptive pills, intrauterine devices, injectables, implants, and the patch. Despite the availability of these methods, the 2008 Bolivian Demographic and Health Survey estimated unmet need among women aged 15 to 19 years to be 38% [27,28]. World Bank indicators for 2015 report the adolescent fertility rate to be 70 per 1000 women aged 15 to 19 years [21]. Abortion is illegal in Bolivia except in cases of rape, incest, and danger to the health of the woman [29]. While there are no official figures on induced abortion, research suggests that around 100 illegal abortions are carried out per day [27], the majority of which are likely to be unsafe due to the legal restrictions on abortion in the country. A survey in 2008 found that, among unmarried sexually active women aged 15 to 19 years, 84% reported wanting to avoid a pregnancy in the next 2 years, but only 49% reported using any contraceptive method [28]. The main reasons given for not using contraception were not being married (52%) (sex before marriage is stigmatized in Bolivia) or having infrequent sex (55%) [28].

Mobile phones are now an established and popular mode in which to deliver health interventions [30-41]. An advantage of using mobile phones to deliver health support is that content can be received at a time of the recipient's choosing, which may be particularly important with sensitive topics such as sexual and reproductive health. Mobile phone interventions can be delivered through a variety of ways: through voice messages, text messages, mobile apps, instant messages that include videos and images, or bidirectional teleconsultation with health care professionals via text message or a live voice call, to name just a few. While there is some evidence from high-income countries that mobile phone-based interventions can increase contraceptive use [42-44] and knowledge [45], none of the trials evaluating these interventions had a low risk of bias [46]. To the best of our knowledge, only 1 trial has been conducted in a nonhigh-income country (Cambodia); this trial found that postabortion voice messaging with telephone counselling support increased effective contraceptive use at 4 months [47]. Since 2007, mobile phone ownership in Bolivia has increased sharply, with 92 mobile phone subscriptions per 100 people in 2015 [48], which is likely to be higher among younger people.

The London School of Hygiene & Tropical Medicine (LSHTM) and the Centro de Investigación, Educación y Servicios (CIES), a Member Association of the International Planned Parenthood Federation (IPPF), are collaborating to evaluate a contraception intervention delivered by mobile phone for young women in Bolivia. The intervention is informed by integrated behavioral model [49], consists of short mobile phone app instant messages, and is delivered over 4 months through CIES's Tú decides app. The intervention messages provide accurate information about contraception and include 10 behavior change methods [50]. It was developed through collaboration between LSHTM, CIES, and young people in La Paz and El Alto, Bolivia, with the support of the IPPF Western Hemisphere Region. The collaboration involved various activities aimed at understanding young people's knowledge of, attitudes toward, and barriers faced in using contraception and preferences for intervention delivery. Guided by behavioral science [51], the intervention was produced through an iterative process of writing, testing with the target group, and refining.

We present the protocol for the evaluation of the intervention by randomized controlled trial. The aim of the trial is to establish whether the intervention increases young Bolivian women's use and acceptability of effective contraceptive methods.

Methods

Study Design

This study is a parallel-group, individually randomized superiority trial with a 1:1 allocation ratio evaluating the effect of an intervention delivered by mobile app. Participants randomly allocated to the intervention arm will have access to the app and will receive the intervention instant messages. Participants randomly allocated to the control arm will have access to the app and receive control instant messages about trial participation.

Eligibility Criteria

Women aged 16 to 24 years who own a personal Android mobile phone and live in La Paz or El Alto, and who report an unmet need for contraception (ie, are sexually active, are not using effective contraception, and want to avoid a pregnancy), can provide informed consent, and can read Spanish will be eligible to take part. Participants must also be willing to receive messages about contraception on their mobile phone.

Recruitment and Setting

To achieve a diverse sample, we will promote the trial through a variety of routes: CIES's service delivery points in La Paz

and El Alto, the CIES website, flyers distributed through CIES's youth network, and social media sites. Potential participants will be provided the link to the enrollment pages of the secure online trial database and randomization system, where they can read the participant information sheet (Multimedia Appendix 1) and provide informed consent (Multimedia Appendix 2). (The information sheet and consent form will be provided to potential participants in Spanish. The English versions are included here for the purposes of publication.) If they do not have adequate Internet connectivity, youth network volunteers will provide this. Participants will also have the option of completing the paper-based version of the consent form.

To maximize the chance of recruiting to target, LSHTM conducted a pretrial training in La Paz to train local staff on all recruitment procedures. The training included discussions about the practicalities of recruitment with a view to developing the most appropriate strategies. CIES conducted a similar training with their youth volunteers, who will promote the trial.

We will report the number of people assessed for eligibility, the number excluded before randomization, and the number of participants randomly allocated to the intervention, who completed follow-up, and who were analyzed (Figure 1).

Intervention

In addition to providing accurate information about contraception (including the dual protection that condoms offer), the intervention messages target beliefs identified in the development phase that influence contraceptive use (eg, specific misconceptions about the side effects and health risks of contraception) and aim to support young women in believing that they can influence their reproductive health. The messages contain the following behavior change methods, adapted for delivery by mobile phone [50]: belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective, and goal setting. The Tú decides app itself contains standard family planning information and no behavior change methods.

Participants allocated to the intervention group will receive 0 to 3 messages per day (a total of 183 messages) for 120 days. Included in the 183 messages that intervention recipients receive are 7 control messages about the importance of their participation and reminding them to contact the project coordinator if they change their number.

The message sets start with 6 days of messages with general information about the study, such as information about what they will receive over the next 120 days, how to stop the messages, who to contact if they change their number, how to keep the messages private, and information about who to call if they feel unsafe as a result of someone reading the messages.

On days 119 and 120, the intervention includes 4 messages: 1 that indicates that the messages have ended, 1 that provides a link to the database to complete the follow-up questionnaire, 1 that gives reassurance that the information they provide is confidential, and a final message stating that their participation is helping to determine the best ways to provide reproductive health services in Bolivia.

Details regarding the development and a description of the intervention will be reported in a forthcoming publication.

Control

Participants allocated to the control group will have access to the same Tú decides app pages as the intervention group. Control participants will also receive 16 messages about trial participation over 120 days. The first 4 days include 6 messages that introduce the study, as well as providing information about what they will receive over the next 120 days, how to stop the messages, and who to contact if they change their number. They then receive 2 messages a month for 3 months: 1 about the importance of their participation and 1 reminding them to contact the project coordinator if they change their number. On day 105, they will receive 1 message about the importance of their participation. On day 120, participants will receive 3 messages: 1 that provides information on how to complete the follow-up questionnaire, 1 that gives reassurance that the information they provide is confidential, and a final message stating that their participation is helping to determine the best ways to provide reproductive health services in Bolivia.

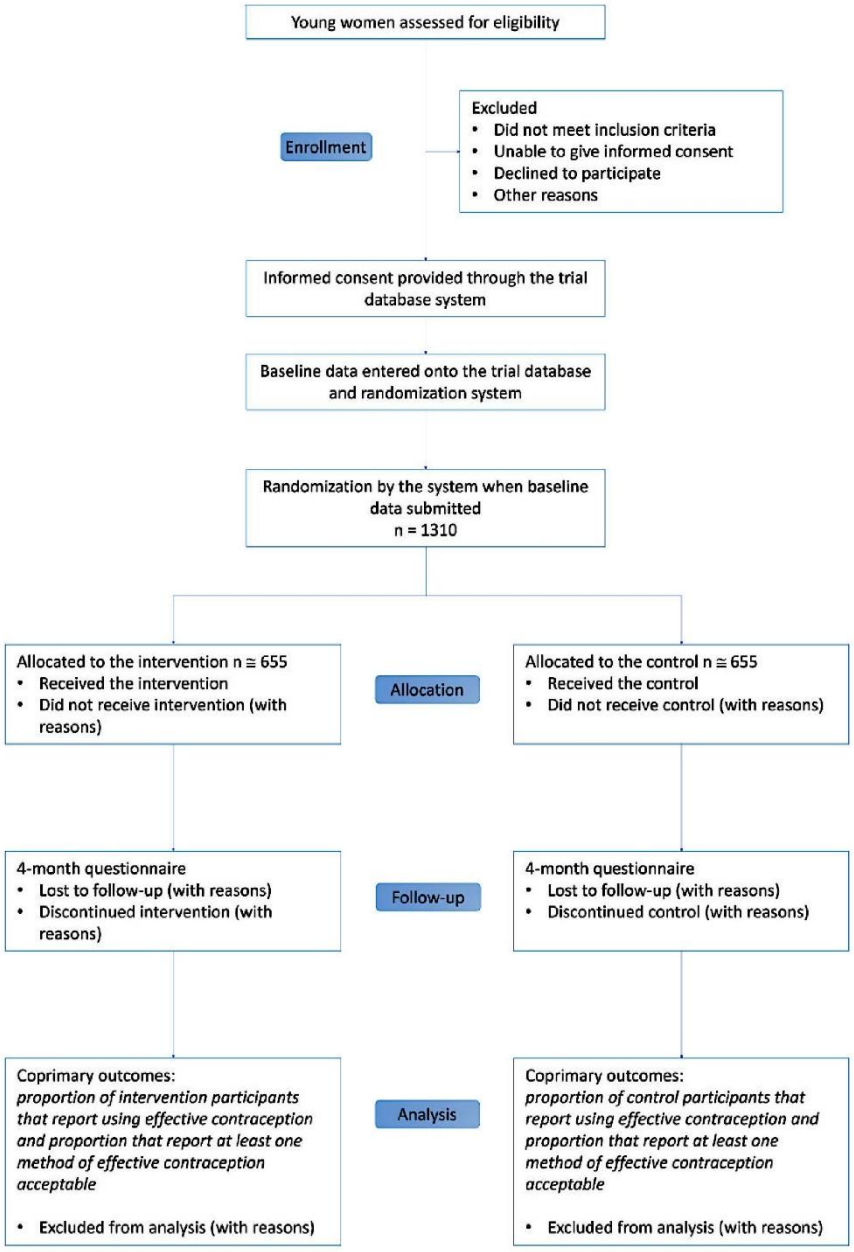
All participants will receive usual care and will be free to seek any other support, whether existing or new.

Outcomes

Primary Outcomes

The coprimary outcomes are self-reported current use of effective contraception and the proportion of participants reporting that at least one method of effective contraception is acceptable at 4 months after randomization. Because a validated measure of acceptability appropriate for this context did not exist, we constructed the primary outcome measure based on guidelines for measuring integrated behavioral model constructs [49,52,53] and tested its face validity with the target group. The acceptability of each method is measured by the following stems: "Using the [method]...causes infertility,...causes unwanted side effects,...is easy,...is a good way to prevent pregnancy" and "I would recommend the [method] to a friend." Intrauterine device and implant acceptability is measured by an additional stem: "The [method] insertion would not be a problem for me." The response options for each scale are "strongly disagree," "disagree," "not sure," "agree," "strongly agree," and "I do not know what the [method] is." A method is acceptable if participants report "agree" or "strongly agree" for all scales except for the "...causes infertility" and "...causes unwanted side effects" stems, for which "disagree" or "strongly disagree" denotes acceptability (items 1-27 in Multimedia Appendix 3 and items 4-30 in Multimedia Appendix 4).

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.



Secondary Outcomes

Secondary outcomes are, for each contraception method, the proportion reporting that each effective contraception method is acceptable (acceptability of individual methods); the proportion reporting use of effective contraception at any time during the 4 months (discontinuation); the proportion reporting attending a sexual health service during the 4 months (service uptake); the proportion reporting that they became pregnant and they did not want to become pregnant during the study

(unintended pregnancy); and the proportion reporting having an abortion during the study (induced abortion).

Process Outcomes

The process outcomes are knowledge of effective contraception; perceived norms and personal agency in relation to using contraception and communicating with partners about contraception; intention to use effective contraception; and intervention dose received.

Data Collection

We will collect data at baseline and 4 months postrandomization using questionnaires. The questionnaires were written in English, translated into Spanish by a native speaker from Bolivia, and then tested for face validity with the target group. We asked 21 young women to comment on the length of the questionnaires, the comprehensibility of the questions, the meaning of the scales, and suggestions for improvement. All data will be entered onto the trial database system, which is on LSHTM's secure server. At both time points, participants can fill out a paper-based version of the questionnaire at the recruitment site, provide the data over the phone with research staff, or enter data directly onto the online system, according to their preference. If participants provide their questionnaire data by paper or over the telephone, research staff will enter these data onto the system.

Baseline Data Collected

At baseline we will measure the acceptability of effective contraception (a coprimary outcome) and collect the following personal and demographic data via the baseline questionnaire: full name; mobile phone number; email address; date of birth; marital status; number of children; ethnicity; occupation; highest education level completed; residence; current method of contraception; and how they found out about the study (Multimedia Appendix 3).

Follow-Up Data Collected

At 4 months, we will measure the primary, secondary, and process outcomes and collect the following data via the follow-up questionnaire: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else who took part in the study and, if so, whether they read each other's messages (contamination); whether they have experienced physical violence since being in the study; and whether anything good or bad happened as a result of receiving the messages (Multimedia Appendix 4). We are collecting data on physical violence because the intervention involves a sensitive topic and is delivered in a context where intimate partner violence is a public health concern. If participants do not complete the questionnaire themselves, local research staff will contact them to collect their data. For participants who report use of effective contraception on the follow-up questionnaire, local research staff will attempt to locate the service records to objectively verify use.

Methods to Maximize Follow-Up Response

The pretrial training also included training in follow-up procedures. It emphasized the importance of ensuring that participants understand that participation involves completing a 4-month questionnaire and potentially receiving daily messages about contraception for 4 months. The control messages, also sent to participants allocated to the intervention, are an effort to keep participants engaged. Staff will contact nonresponders up to 3 times for their follow-up data. Follow-up will end 6 months after the last participant has been randomized or after staff has attempted to contact all nonresponders 3 times, whichever comes first. See Figure 2 for the schedule of enrollment, interventions, and assessments.

Figure 2. Schedule of enrollment, interventions, and assessments.

		STUDY PERIOD						
		Enrollment	Allocation	Postallocation				Closeout
	TIMEPOINT	*0*	*0*	*Month 1*	*Month 2*	*Month 3*	*Month 4*	*6 months after last participant randomized*
ENROLLMENT	Eligibility screen	√						
	Informed consent	√						
	Baseline data completion	√						
	Baseline data entry	√						
	Allocation		√					
INTERVENTIONS	Contraceptive app instant messages (0-3 messages per day for 120 days)		—	—	—	—	→	
	App instant messages not about contraception (16 messages over 120 days)		—	—	—	—	→	
ASSESSMENTS	Baseline data: primary outcome, personal and demographic data	√						
	Follow-up data: primary, secondary, and process outcomes*						√	√

*Plus: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that took part in the study and if so, if they read each other's messages (contamination); if they have experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages

Allocation and Protection Against Bias

Randomization will occur immediately after baseline data are submitted on the trial database and randomization system. The allocation sequence is generated by the remote computer-based randomization software, ensuring that investigators are unaware of allocation before participants are randomized. Due to the nature of the intervention, participants will be aware of the allocation soon after they start receiving the messages. Local research staff collecting outcome data will not be made aware of allocation unless this is revealed to them by the participant. Researchers who analyze the data will be masked to treatment allocation.

Intervention Delivery

After participant baseline data have been entered, a confirmation of enrollment screen will provide instructions on how to install the app. When participants install the app, they will be prompted to enter the mobile phone number they entered on the baseline questionnaire. The trial database and randomization system will then send the allocation to the local app platform. Participants will then have access to the app and receive either the control or intervention messages, according to their allocation. Within the app, participants can choose when they want to receive the messages, and they can also stop the messages. Participants will receive the first message the day after they install the app.

Sample Size

A trial evaluating a postabortion mobile phone intervention using voice messages and counsellor support found that 18% more women in the intervention arm than in the control arm were using effective contraception at 4 months (64% vs 46%, relative risk 1.39, 95% CI 1.17-1.66) [47]. Assuming that Smith and colleagues' trial observed a larger increase in contraceptive uptake, as it involved women who had just had an abortion, we powered our trial to detect a smaller absolute difference of 10% uptake in effective contraception at 4 months.

The proportion of women aged 16 to 24 years in a partnership living in La Paz or El Alto using effective contraception is estimated to be around 44% [54]. A total of 1048 participants will allow us to have 90% power to detect a 10% increase in effective contraception, assuming 44% use in the control group (ie, 44% in the control vs 54% in the intervention, corresponding to an odds ratio of 1.49). Allowing for 20% loss to follow-up, we will randomly allocate 1310 people.

Data Management

We did not convene a data monitoring and ethics committee, as the intervention provides support and is unlikely to produce adverse effects. We have convened a trial steering committee, and they have agreed to take on the monitoring of ethical aspects of the trial. The trial sponsor may audit the trial according to their own risk assessment and schedule.

Personal details entered onto the trial database and randomization system will be stored on LSHTM's secure server. Personally identifiable information exported from the database will be stored separately from anonymized research data. Participant mobile phone numbers, but no other personal details, will be stored in the local platform that sends the messages through the app. Any signed paper consent forms and questionnaires will be kept in a data enclave at CIES. All data arising from the study will be kept confidential and accessible only to researchers directly involved in it. Personally identifiable data will not be kept longer than necessary and will be deleted within 3 months following study completion. We will retain primary research data for 10 years following study completion.

Ethical Approval

The trial was granted ethical approval by LSHTM Interventions Research Ethics Committee on May 16, 2016 and by La Comisión de Ética de la Investigación del Comité Nacional de Bioética on September 20, 2016. The trial is registered by ClinicalTrials.gov (NCT02905526).

Protocol Amendments

Any important changes to the protocol will be submitted to the LSHTM Interventions Research Ethics Committee as an amendment. Trial documentation will be updated accordingly and will be implemented once the Committee has approved the changes. LSHTM will communicate any changes relevant to local research staff.

Dissemination

The research results will be cowritten by LSHTM and CIES and submitted for publication in peer-reviewed academic journals. We will adhere to the International Committee of Medical Journal Editors authorship criteria. We will disseminate findings to all the study stakeholders and policy makers in Bolivia.

Analyses

General Statistical Considerations

The analysis of the data will follow the plan specified below. There will be no interim analyses and therefore no stopping rules. We will analyze participant data according to the arm that they were allocated to and will include only participants with complete outcome data in the primary analysis (a complete-case analysis). All statistical tests will be 2-sided. We will report all effect estimates with a 95% confidence interval and associated *P* value. Statistical significance will be considered at the 5% level, but interpreted with caution considering the 2 primary outcomes. We will use the latest version of Stata (StataCorp LLC) for analyses.

Loss to Follow-Up

To investigate whether loss to follow-up differs by arm, we will report this descriptively and use a chi-square test. We will use logistic regression to compare baseline characteristics of participants who completed 4-month follow-up against participants who did not. We will report predictors of loss to follow-up and investigate whether the effect of these differs by arm by testing for an interaction.

Assumptions About Missing Data

As we are not aware of similar trials, it is not possible to investigate the pattern of missing data. The complete-case analysis assumes that missing data for participants who did not complete follow-up are similar to data from participants who

completed follow-up, conditionally on baseline covariates included in the analysis model (ie, that data are missing at random) [55]. If participants who complete follow-up are more likely to use effective contraception and to find an effective method acceptable compared with those who are lost to follow-up, the observed proportion may overestimate use and acceptability [55].

Missing Covariates

The database requires all items on the baseline questionnaire to be submitted in order to proceed to the random allocation. Therefore, there will be no missing baseline covariates.

Principal Analyses

Descriptive Analysis

We will report a flow diagram of trial participation, as recommended in the Consolidated Standards of Reporting Trials (CONSORT) guidelines [56]. We will report the baseline characteristics by treatment arm. We will also explore the baseline factors associated with retention (see above).

Analysis of the Primary Outcome

Both coprimary outcomes are binary, and we will compare the crude proportion who report using effective contraception in each group and the crude proportion who report that at least one method is acceptable in each group. We will estimate the difference between the groups using logistic regression and will report the odds ratio along with the 95% confidence interval and *P* value for evidence against the absence of intervention effect from the model. The primary analysis regression will be adjusted for baseline covariates likely to be associated with the outcome in order to improve the efficiency of the analysis and avoid chance imbalances [57]. The prespecified covariates that we will adjust for are age (16-19 years/20-24 years), number of children (0/≥1), highest education level completed (university/other), and acceptability of effective contraception at baseline (at least one method acceptable/no methods acceptable). Primary outcomes will be analyzed individually, and no formal multiplicity correction will be applied, but interpretation will take into account the multiple tests if only 1 of the 2 outcomes reaches the 5% significance level. We will also report the crude odds ratio between arms.

Analysis of the Secondary Outcomes

The analysis of the secondary outcomes will be the similar to the analysis of the primary outcome. We will estimate the difference between the groups using logistic regression, and report odds ratios with 95% confidence intervals and *P* values. All regressions will be adjusted for the prespecified covariates as above (although, with the acceptability of individual methods, the outcome at baseline will replace acceptability of effective contraception).

Analysis of the Process Outcomes

The process outcomes perceived norms, personal agency, and intention comprise ordinal scales. We will analyze each scale individually using ordered logistic regression to estimate proportional odds ratios. For knowledge, each correct answer will receive 1 point. The points will be summed and an overall score will be produced. We will use linear regression to test for a difference in mean scores between the arms.

To assess the "dose" of the intervention that the intervention participants received, we will analyze the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages. We will report this descriptively.

Additional Analyses

Sensitivity Analyses

We will conduct sensitivity analyses regarding the missing data. In the first sensitivity analysis, we will consider that data are not missing at random; that participants lost to follow-up did not find at least one method acceptable; and that participants lost to follow-up were not using an effective method of contraception. In the second, we will adjust for the main baseline predictors of missingness. Both sensitivity analyses will be adjusted for the prespecified covariates as above.

Subgroup Analysis

Recognizing that the trial is not powered to detect effect differences in subgroups, we will conduct exploratory subgroup analyses for the coprimary outcomes to determine whether the intervention effect varies by baseline characteristics. The prespecified subgroups are age (split at the median); marital status (married/not married); number of children (0/≥1); geographic location (El Alto/La Paz); occupation (in education/other); and highest education level completed (university/other). Within the prespecified subgroups, we will assess heterogeneity of treatment effect with a test for interaction [58-62]. Interaction test *P* values will be presented but will be interpreted with caution, due to the exploratory nature, the multiple tests performed, and the low power of the interaction test. We will estimate odds ratios along with 95% CIs for each subgroup without *P* values. As this is an exploratory analysis of potentially influential characteristics that are not justified a priori, we will not hypothesize effect directions.

Contamination

To assess the potential for contamination, we will report the proportion of control group participants who read another participant's messages and the proportion of intervention participants whose messages were read by another participant.

Analysis of Pooled Trial Data

We are conducting trials of a similar intervention in 2 other countries. If the results of the other trials are available, we will conduct the principal analyses on the pooled dataset.

The datasets used and analyzed during this study are available from the corresponding author on reasonable request.

Participants' Rights and Safety

Participants will have the right to withdraw at any time during their involvement, without having to give a reason. Participants can withdraw by contacting the project coordinator. Acting on a participant's request to withdraw from the trial, we will change the participant's status to "withdrawn" and exclude the person from the list of participants who are due for follow-up.

Participants' participation and personal identifiable data will remain confidential and research data will be anonymized.

In the formative work, we explored young people's views on confidentiality about receiving messages on their mobile phone. While the majority of participants did not report concerns regarding receiving messages about contraception on their mobile phone, it is possible that some participants will want to keep the messages confidential from certain people (eg, partner, parents) and that these people might view the messages. The messages remind participants that they can delete the messages and provide instructions on how to keep the messages private. We will provide participants with information on support services that they can contact if they feel unsafe as a consequence of the messages being read. We will review physical violence during participants' involvement in the trial reported on the follow-up questionnaire.

Results

Recruitment commenced on March 1, 2017 and was completed on July 29, 2017. The estimated completion date for the final participant recruited (final data collection date for the primary outcome) is January 2018.

Discussion

Among young women in La Paz and El Alto with an unmet need, the results of this trial will provide evidence for the effect of the intervention on their use of and attitudes toward effective contraception. The analysis of the secondary and process outcomes may provide evidence for the effect of the intervention on attitudes toward the individual effective methods, service use, unintended pregnancy, induced abortion, and the psychological processes that may have been altered by the intervention.

Because this trial is being conducted among young women with an unmet need for contraception in a context where information about contraception is low, it is reasonable to assume that enrolling in the trial will be popular. While this is an advantage with regard to meeting the recruitment target, it is possible that participants will tell their friends about the trial and that they will also enroll. While this is desired in a nontrial context, this could lead to contamination if the intervention messages are shared with control participants during the trial. To minimize this, participants will not be recruited through schools.

Because the intervention is being delivered through the Tú decides app, participants must own a personal Android mobile phone to take part in the trial. Although the intervention development work indicated that the majority of young people in Bolivia own a personal Android mobile phone, not everyone in the target group will. It may be that young people less likely to use and to find contraceptive methods acceptable are more likely to not own an Android phone, which would limit the generalizability of the findings. Smartphone ownership continues to increase rapidly, however, so it is likely that a greater proportion of young people from different socioeconomic communities will be able to receive the intervention in the future.

The trial will assess the effect of sending instant messages containing behavior change methods in addition to the app; it is not assessing the effect of the app itself. It is possible that the app, which provides standard family planning information, could have an effect on effective contraceptive use and acceptability of effective contraception. If the app itself is very effective, the added benefit of the instant messages will be lower. The results of the study will add to current research on mobile phones for intervention delivery and will determine whether mobile phones can be an important adjunct to sexual and reproductive health service provision in Bolivia.

Acknowledgments

The authors would like to thank Alison McKinley from IPPF for her support over the course of the project.

The trial is supported by the IPPF Innovation Programme. IPPF had some influence over the study design (SM and SH) but will have no involvement in the data collection or analysis.

Members of the trial steering committee at LSHTM are Dr James Lewis, Senior Lecturer, co-Deputy Director of the Centre for Evaluation, and Dr Rebecca French, Senior Lecturer of Sexual and Reproductive Health.

The guarantor at LSHTM is Patricia Henley, Quality & Governance Manager.

Authors' Contributions

OLM designed and managed the trial, developed the trial materials, and wrote the manuscript. VOC contributed to discussions and decisions regarding the design of the trial, assisted in the development of the trial material, and facilitated trial implementation. SM and SH contributed to discussions regarding the design of the trial. BL and PE provided advice regarding the statistical analysis. JLG took overall local responsibility for the trial. CF provided guidance regarding the trial design and implementation. All authors revised the work, approved the version to be published, and agree to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Trial information sheet.

[PDF File (Adobe PDF File), 197KB - resprot_v6i12e252_app1.pdf]

Multimedia Appendix 2

Trial consent form.

[PDF File (Adobe PDF File), 264KB - resprot_v6i12e252_app2.pdf]

Multimedia Appendix 3

Baseline questionnaire.

[PDF File (Adobe PDF File), 369KB - resprot_v6i12e252_app3.pdf]

Multimedia Appendix 4

Follow-up questionnaire.

[PDF File (Adobe PDF File), 488KB - resprot_v6i12e252_app4.pdf]

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Abbreviations

CIES: Centro de Investigación, Educación y Servicios
CONSORT: Consolidated Standards of Reporting Trials
IPPF: International Planned Parenthood Federation
LSHTM: London School of Hygiene & Tropical Medicine

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Appendix 11. Trial participant information sheets

Tajikistan

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?
The study is testing whether sending instant messages providing information and support helps change young people's attitudes towards the most effective methods of contraception. The messages are sent through the Tajik Family Planning Alliance's (TFPA) health promotion app.

Who is organising and funding the study?
The study is being conducted by TFPA and the London School of Hygiene & Tropical Medicine (LSHTM). TFPA provides high quality sexual and reproductive health services in Tajikistan. LSHTM is a world-leading centre for research and postgraduate education in public and global health. The study is funded by the International Planned Parenthood Federation (IPPF).

Why have I been chosen?
You are aged 16-24, own a personal mobile phone and live in Tajikistan.

Do I have to take part?
No, you do not have to take part. It is your choice. If you choose not to take part, all the services you receive will continue as normal.

What will happen if I take part?
After you have had all of your questions answered and if you decide to take part, we will ask you to complete a consent form. We will then ask you to complete a confidential questionnaire that asks you to provide details about yourself, such as name and date of birth. The questionnaire also asks for your feelings and attitudes towards contraception. Completing the questionnaire will take 5-10 minutes. You can complete the consent and questionnaire on our secure and confidential study website or by filling out a paper version.

After you have completed the questionnaire, you will receive a code on your phone to download TFPA's app. **An automated computer system will put you into one of two groups by chance (randomly)**:

> Group 1: One group will have access to TFPA's app and receive 0 to 3 instant messages a day about contraception over 4 months.
>
> Group 2: The other group will have access to TFPA's app and will not receive the instant messages.

At the end of the study, 4 months after joining, we will ask you to complete the questionnaire again. This is to see how things may have changed. You can complete the 4-month questionnaire on our secure and confidential study website (this is mobile phone friendly too), by filling out a paper version at the service or by providing your answers to the research staff over the phone.

Will you compensate me for taking part?
Unfortunately, we are not able to offer you something for taking part. You do not have to pay for the app.

What are the alternatives?
You do not have to take part.

What are the possible disadvantages of taking part?

Completing the questionnaires will take some of your time. It is possible that the messages that we send could be read by someone else. If you are concerned about this, you could lock your phone and delete the messages after you read them. You can choose the times that you want to receive the messages.

What are the possible advantages of taking part?
You may find the messages helpful and enjoy the experience of taking part in research. You can add your participation in the study to your resume.

What if I do not want to take part anymore?
You can stop receiving messages by (method to be determined). You can leave the study at any time by contacting the Project Coordinator (details below). You do not have to give a reason for wanting to leave the study. Leaving the study will not affect the services that you receive.

What if there is a problem?
You can talk to the Project Coordinator at any time (details below).

Will my taking part be confidential?
Yes. Your answers to the questionnaires will be stored anonymously and your contact details and will be kept confidential and separate from your answers to the questionnaires. You will be assigned a unique study number when you join the study. We will not inform your parents, partner or anyone else about your involvement in this research. With your permission, will search TFPA records to check for any services you may have received during your time in the study.

What will happen with the results of this study?
We will share the results through publication in journals and through conference presentations. If you would like to know the results of the study, please contact the team (details below) and we will share them with you. Your name will not be used in the results of this study.

If the results of the study show that the messages have helped, they will be made available to all young people in Tajikistan.

Who has reviewed this study?
The London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee and the Tajikistan National Scientific and Research Centre on Paediatrics and Child Surgery (NSRCP&CS).

Thank you for taking the time to consider taking part

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Palestine

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?
The study is testing whether SMS messages providing information and support helps change young women's attitudes towards the most effective methods of contraception.

Who is organising and funding the study?
The study is being conducted by the Palestinian Family Planning and Protection Association (PFPPA) and the London School of Hygiene & Tropical Medicine (LSHTM). PFPPA provides high quality sexual and reproductive health services in the Palestinian Authority. LSHTM is a world-leading centre for research and postgraduate education in public and global health. The study is funded by the International Planned Parenthood Federation (IPPF).

Why have I been chosen?
You are female, aged 18-24, do not report using effective contraception, own a personal mobile phone and live in the West Bank.

Do I have to take part?
No, you do not have to take part. It is your choice. If you choose not to take part, all the services you receive will continue as normal.

What will happen if I take part?
After you have had all of your questions answered and if you decide to take part, we will ask you to complete a consent form. We will then ask you to complete a confidential questionnaire that asks you to provide details about yourself, such as name and date of birth. The questionnaire also asks for your feelings and attitudes towards contraception. Completing the questionnaire will take 5-10 minutes. You can complete the consent and questionnaire on our secure and confidential study website or by filling out a paper version.

After you have completed the questionnaire, **an automated computer system will put you into one of two groups by chance (randomly)**:

> Group 1: One group will receive 0 to 3 text messages a day about contraception over 4 months.
>
> Group 2: The other group will receive SMS messages that are not about contraception. This group will receive one message a month for 4 months.

At the end of the study, 4 months after joining, we will ask you to complete the questionnaire again. This is to see how things may have changed. You can complete the 4-month questionnaire on our secure and confidential study website, by filling out a paper version at the service or by providing your answers to the research staff over the phone.

Will you compensate me for taking part?
Unfortunately, we are not able to offer you something for taking part. You do not have to pay for the messages that you receive.

What are the alternatives?
You do not have to take part.

What are the possible disadvantages of taking part?
Completing the questionnaires will take some of your time. It is possible that the messages that we send could be read by someone else. If you are concerned about this, you could lock your phone and

delete the messages after you read them. You can choose the times that you want to receive the messages.

What are the possible advantages of taking part?
You may find the messages helpful and enjoy the experience of taking part in research. You can add your participation in the study to your resume. You can add your participation in the study to your resume.

What if I do not want to take part anymore?
You can stop receiving messages by texting 'stop'. You can leave the study at any time by contacting the Project Coordinator (details below). You do not have to give a reason for wanting to leave the study. Leaving the study will not affect the services that you receive.

What if there is a problem?
You can talk to the Project Coordinator at any time (details below).

Will my taking part be confidential?
Yes. Your answers to the questionnaires will be stored anonymously and your contact details and will be kept confidential and separate from your answers to the questionnaires. You will be assigned a unique study number when you join the study. We will not inform your parents, partner or anyone else about your involvement in this research. With your permission, will search PFPPA records to check for any services you may have received during your time in the study.

What will happen with the results of this study?
We will share the results through publication in journals and through conference presentations. If you would like to know the results of the study, please contact the team (details below) and we will share them with you. Your name will not be used in the results of this study.

If the results of the study show that the messages have helped, they will be made available to all young people in the West Bank.

Who has reviewed this study?
The London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee and the State of Palestine Ministry of Health.

Thank you for taking the time to consider taking part

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Bolivia

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?

The study is testing whether sending instant messages providing information and support helps change young people's attitudes towards the most effective methods of contraception. The messages are sent through CIES Salud Sexual - Salud Reproductiva (CIES) sexual and reproductive health promotion app.

Who is organising and funding the study?

The study is being conducted by CIES and the London School of Hygiene & Tropical Medicine (LSHTM). CIES provides high quality sexual and reproductive health services in Bolivia. LSHTM is a world-leading centre for research and postgraduate education in public and global health. The study is funded by the International Planned Parenthood Federation (IPPF).

Why have I been chosen?

You are: female, aged 16-24, have had sex in the past 6 months, want to avoid a pregnancy at the moment, are not using effective contraception, own a personal android mobile phone and live in El Alto or La Paz.

Do I have to take part?

No, you do not have to take part. It is your choice. If you choose not to take part, all the services you receive will continue as normal.

What will happen if I take part?

After you have had all of your questions answered and if you decide to take part, we will ask you to complete a consent form. We will then ask you to complete a confidential questionnaire that asks you to provide details about yourself, such as name and date of birth. The questionnaire also asks for your feelings and attitudes towards contraception. Completing the questionnaire will take 5-10 minutes. You can complete the consent and questionnaire on our secure and confidential study website or by filling out a paper version.

After you have completed the questionnaire, you will receive a code on your phone to download CIES's app. **An automated computer system will put you into one of two groups by chance (randomly)**:

> Group 1: One group will have access to CIES's app and receive 0 to 3 instant messages a day about contraception over 4 months.
>
> Group 2: The other group will have access to CIES's app and will not receive the instant messages.

At the end of the study, 4 months after joining, we will ask you to complete the questionnaire again. This is to see how things may have changed. You can complete the 4-month questionnaire on our secure and confidential study website (this is mobile phone friendly too), by filling out a paper version at the service or by providing your answers to the research staff over the phone.

Will you compensate me for taking part?

Unfortunately, we are not able to offer you something for taking part. You do not have to pay for the app.

What are the alternatives?

You do not have to take part.

What are the possible disadvantages of taking part?

Completing the questionnaires will take some of your time. It is possible that the messages that we send could be read by someone else. If you are concerned about this, you could lock your phone and

delete the messages after you read them. You can choose the times that you want to receive the messages.

What are the possible advantages of taking part?
You may find the messages helpful and enjoy the experience of taking part in research. You can add your participation in the study to your resume.

What if I do not want to take part anymore?
You can stop receiving messages by (method to be determined). You can leave the study at any time by contacting the Project Coordinator (details below). You do not have to give a reason for wanting to leave the study. Leaving the study will not affect the services that you receive.

What if there is a problem?
You can talk to the Project Coordinator at any time (details below).

Will my taking part be confidential?
Yes. Your answers to the questionnaires will be stored anonymously and your contact details and will be kept confidential and separate from your answers to the questionnaires. You will be assigned a unique study number when you join the study. We will not inform your parents, partner or anyone else about your involvement in this research. With your permission, will search CIES records to check for any services you may have received during your time in the study.

What will happen with the results of this study?
We will share the results through publication in journals and through conference presentations. If you would like to know the results of the study, please contact the team (details below) and we will share them with you. Your name will not be used in the results of this study.

If the results of the study show that the messages have helped, they will be made available to all young people in Bolivia.

Who has reviewed this study?
The London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee and the Bolivian National Research Ethics Committee.

Thank you for taking the time to consider taking part

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Appendix 12. Trial consent forms

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		Please initial here
1.	I have read the Information sheet for the above study (v1 19.02.16) or it has been read to me. I have had the opportunity to consider the information in it.	
2.	I have had the opportunity to ask questions and I am happy with the answers that you gave me.	
3.	I understand that I do not have to take part if I do not want to.	
4.	I understand that the information that I provide will remain confidential and will only be used for this study. Only the research team will have access to this information.	
5.	I agree to the study researchers searching TFPA clinic records to check for any services that I may have received during my participation in the study.	
6.	I understand that I am free to leave the study at any time without having to give a reason. I understand that this will not affect the services that I receive.	
7.	**I consent to take part in the above study.**	
	(optional) I agree to be contacted about taking part in a short interview	

Name of participant (print) Signature of participant Date

Statement by person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of the consent form has been given to the participant.

Name of person taking consent (print) Signature of person taking consent Date

Palestine

Project Coordinator: Ola Wazwaz, Palestinian Family Planning and Protection Association (PFPPA), Industrial Zone, Wadi Al-Joze, Jerusalem, Palestine, + 9722-6280630, ipc@pfppa.org

Principal Investigator: Ona McCarthy, The London School of Hygiene and Tropical Medicine, Department of Population Health, Keppel St, WC1E 7HT, London, United Kingdom, ona.mccarthy@lshtm.ac.uk

	Please initial here
4. I have read the Information sheet for the above study (v2 06.08.16) or it has been read to me. I have had the opportunity to consider the information in it.	
5. I have had the opportunity to ask questions and I am happy with the answers that you gave me.	
6. I understand that I do not have to take part if I do not want to.	
5. I understand that the information that I provide will remain confidential and will only be used for this study. Only the research team will have access to this information.	
8. I agree to the study researchers searching PFPPA clinic records to check for any services that I may have received during my participation in the study.	
9. I understand that I am free to leave the study at any time without having to give a reason. I understand that this will not affect the services that I receive.	
10. **I consent to take part in the above study.**	
(optional) I agree to be contacted about taking part in a short interview	

Name of participant (print) Signature of participant Date

Statement by person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of the consent form has been given to the participant.

Name of person taking consent (print) Signature of person taking consent Date

Bolivia

Project Coordinator: Maria Eugenia Torrico, CIES Salud Sexual - Salud Reproductiva, Calle 6 de Obrajes Nro. 614 – Casilla 9935, (591-2) 2788162, maeugenia@cies.org.bo

Principal Investigator: Ona McCarthy, The London School of Hygiene and Tropical Medicine, Department of Population Health, Keppel St, WC1E 7HT, London, United Kingdom, ona.mccarthy@lshtm.ac.uk

	Please initial here
7. I have read the Information sheet for the above study (v3 02.11.16) or it has been read to me. I have had the opportunity to consider the information in it.	
8. I have had the opportunity to ask questions and I am happy with the answers that you gave me.	
9. I understand that I do not have to take part if I do not want to.	
6. I understand that the information that I provide will remain confidential and will only be used for this study. Only the research team will have access to this information.	
11. I agree to the study researchers searching CIES clinic records to check for any services that I may have received during my participation in the study.	
12. I understand that I am free to leave the study at any time without having to give a reason. I understand that this will not affect the services that I receive.	
13. **I consent to take part in the above study.**	
(optional) I agree to be contacted about taking part in a short interview	

Name of participant (print)	Signature of participant	Date

Statement by person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of the consent form has been given to the participant.

Name of person taking consent (print)	Signature of person taking consent	Date

Appendix 13. Baseline questionnaires

Tajikistan

	Using the pill…						
1	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
2	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
3	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
4	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
6	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
7	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
8	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
9	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	The IUD insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
	Using the injection…						
12	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
13	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
14	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
15	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is

16	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
17	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
18	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
19	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
20	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is

23	What is your first name?						
24	What is your last name?						
25	What is your mobile number?						
26	What is your email address?						
27	What day were you born?	Day	Month	Year			
28	Are you?	Female	Male				
29	Are you?	Married	Not married				
30	How many children do you have?	0	1	2+			
31	Are you? (check all that apply)	Tajik	Russian	Kyrgyz			
		Uzbek	Kazak	Other			
32	Are you? (check all that apply)	At school	At university	Working	Training		
		Full time parent	Not working	Long-term sick			

33	What is the highest level of education that you have completed?	Primary	Secondary	University	Technical education		
34	Do you want a pregnancy <u>now</u>?	Yes	No	Unsure	Not married		
35	What method of contraception are you or your partner using <u>now</u> (check all that apply)?	None	Injection	Male condom	IUD	Not married	
		Implant	Pill	Female condom	Calendar-based method	LAM	
		Withdrawal	Patch	Ring	Other method		
36	How did you find out about this study?	Facebook	OK	Youth service	TFPA website	Friend	Flyer/poster
							Other

Palestine

	Using the pill…						
1	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
2	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
3	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
4	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
6	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
7	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
8	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
9	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	The IUD insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
	Using the injection…						
12	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
13	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is

14	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
15	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
16	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
17	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
18	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
19	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
20	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
	Using the patch…						
23	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
24	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
25	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
26	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is

27	I would recommend the patch to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is

28	What is your first name?						
29	What is your last name						
30	What is your mobile number?						
31	What is your email address?						
32	What day were you born?	Day	Month	Year			
33	Are you?	Married	Not married				
34	How many children do you have?	0	1	2 or more			
35	Where do you live?	City	Village	Camp	Bedouin		
36	Are you? (check all that apply)	At school	At university	Working	Training		
		Full time parent	Not working	Long-term sick			
37	What is the highest level of education that you have completed?	Primary	Secondary	University	Technical education		
38	Do you want a pregnancy <u>now</u>?	Yes	No	Unsure	Not married		
39	What method of contraception are you using <u>now</u> (check all that apply)?	None	Injection	Male condom	IUD	Not married	
		Implant	Pill	Female condom	Calendar-based method	LAM	
		Withdrawal	Patch	Ring	Other method		
40	How did you hear about this study?	Facebook	PFPPA service delivery point	PFPPA website	Friend/family	Flyer/poster	Other

41	How did you enrol in this study?	PFPPA Jerusalem	PFPPA Bethlehem	PFPPA Halhoul	PFPPA Hebron	PFPPA Ramallah	Youth friendly service	Online
42	What times do you prefer to receive messages?	10-2	2-6		10-6			

Bolivia

	Using the pill…						
1	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
2	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
3	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
4	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
6	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
7	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
8	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
9	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	The IUD insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
	Using the injection…						
12	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
13	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
14	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
15	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
16	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
17	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
18	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
19	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is

20	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
	Using the patch…						
23	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
24	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
25	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
26	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
27	I would recommend the patch to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is

28	What is your first name?						
29	What is your last name?						
30	What is your mobile number?						
31	What is your email address?						
32	What day were you born?	Day	Month	Year			
33	Are you?	Married	Not married				
34	How many children do you have?	0	1	2+			
35	You identify with some indigenous origin, mark as appropriate	Aymara	Quechua	Guarani	Ninguno	Otro	
36	Are you? (check all that apply)	At school	At university	Working	Training	Not working	
37	What is the highest level of education that you have completed?	Primary	Secondary	University	Technical education		

38	Where do you live?	El Alto	Norte La Paz	Central La Paz	Sur La Paz		
39	What method of contraception are you or your partner using <u>now</u> (check all that apply)?	None		Male condom			
				Female condom	Calendar-based method	LAM	
		Withdrawal			Other method		
40	How did you find out about this study?	Facebook	CIES El Alto	CIES La Paz	CIES website	Friend	Flyer/poster
							Otro

Appendix 14. Follow-up questionnaires

Tajikistan

FEMALE							
1	What method of contraception are you using now (check all that apply)?	None	Injection	Male condom	IUD	Not married	
		Implant	Pill	Female condom	Calendar-based method	LAM	
		Withdrawal	Patch	Ring	Other method		
2	Where did you get this method?	Not married	Not using a method	Reproductive health centers	Health centers		
		Drugstore	NGO	I do not know			
3	Do you want a pregnancy now?	Yes	No	Not sure	Not married	No, I am currently pregnant	
	Using the pill…						
4	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
6	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
7	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
8	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
9	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
12	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
13	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
14	The IUD insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is

	Using the injection…						
15	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
16	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
17	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
18	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
19	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
20	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
23	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
24	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
25	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is

26	Have you become pregnant <u>since joining the study</u>?	Yes	No	Not married		
27		Yes	No	Not sure	Not married	

	Did you want to become pregnant during the study?					
28	Have you had a termination (abortion) since joining the study?	Yes	No	Not married		
29	What method of contraception have you used during the study (check all that apply)?	None	Injection	Male condom	IUD	Not married
		Implant	Pill	Female condom	Calendar-based method	LAM
		Withdrawal	Patch	Ring	Other method	
30	How many times have you attended a sexual health service since you joined the study 4 months ago?	0	1	2+		
31	How many messages did you read?	All	Most	Some	None	
32	Did you stop the messages?	Yes	No			
33	Do you know anyone else in the study?	Yes	No			
34	Did they read the messages that we sent you?	Yes	No	I do not know anyone in the study		
35	Did you read the messages that we sent them?	Yes	No	I do not know anyone in the study		
36	Have you experienced physical violence since being in the study?	Yes	No			
37	Did anything good or bad happen as a result of receiving the messages? If so, please summarise here:					

38	Hormonal contraception is more effective at preventing pregnancy than condoms alone	Disagree	Agree	Do not know		
39	The pill is taken once a month	Disagree	Agree	Do not know		
40		Disagree	Agree	Do not know		

	The IUD lasts for 6 months					
41	The injection is given once a year	Disagree	Agree	Do not know		
42	The implant can stay under the skin for 10 years	Disagree	Agree	Do not know		
43	I know where to go to get contraception	Disagree	Agree	Do not know		

If you are not married, please imagine that you are and try to answer the following questions:

44	My friends would use the pill, IUD, injection or implant if they wanted to prevent pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
45	My friends would talk to their husband about contraception if they wanted to prevent a pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

46	If you wanted to use the pill, IUD, injection or implant, how easy would it be for you to use it?	Very difficult	Difficult	Not sure	Easy	Very easy
47	If you wanted to talk to your husband about contraception, how easy would it be for you to talk to him?	Very difficult	Difficult	Not sure	Easy	Very easy

48	If you wanted to use the pill, IUD, injection or implant, how certain are you that you could use it?	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could
49	If you wanted to talk to your husband about contraception,	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could

	how certain are you that you could talk to him?					

50	I intend to use the pill, IUD, injection or implant	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

MALE						
1	What method of contraception is your wife using <u>now</u> (check all that apply)?	None	Injection	Male condom	IUD	Not married
		Implant	Pill	Female condom	Calendar-based method	LAM
		Withdrawal	Patch	Ring	Other method	
2	Where did your wife get this method?	Not married	Not using a method	Reproductive health center	Health center	
		Drugstore	NGO	I do not know		
3	Do you want a pregnancy <u>now</u>?	Yes	No	Not sure	Not married	No, my wife is currently pregnant

	Using the pill…						
4	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
6	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
7	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
8	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
9	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
12	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
13	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
14	The IUD insertion would	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is

	not be a problem						
	Using the injection…						
15	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
16	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
17	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
18	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
19	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
20	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
23	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
24	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
25	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is

26	Has your wife become pregnant since joining this study?	Yes	No	Not married		
27	Did she want to become pregnant during the study?	Yes	No	Not sure	Not married	
28	Has your wife had a termination (abortion) since	Yes	No	Not married		

	joining the study?					
29	What method of contraception has your wife used during the study (check all that apply)?	None	Injection	Male condom	IUD	Not married
		Implant	Pill	Female condom	Calendar-based method	LAM
		Withdrawal	Patch	Ring	Other method	Unsure
30	How many times have you attended a sexual health service since you joined the study 4 months ago?	0	1	2+		
31	How many messages did you read?	All	Most	Some	None	
32	Did you stop the messages?	Yes	No			
33	Do you know anyone else that took part in the study?	Yes		No		
34	Did they read the messages that we sent you?	Yes		No	I do not know anyone in the study	
35	Did you read the messages that we sent them?	Yes		No	I do not know anyone in the study	
36	Have you experienced physical violence since being in the study?	Yes		No		
37	Did anything good or bad happen as a result of receiving the messages? If so, please summarise here:					

38	Hormonal contraception is more effective at preventing pregnancy than condoms alone	Disagree	Agree	Do not know		
39	The pill is taken once a month	Disagree	Agree	Do not know		

40	The IUD lasts for 6 months	Disagree	Agree	Do not know		
41	The injection is given once a year	Disagree	Agree	Do not know		
42	The implant can stay under the skin for 10 years	Disagree	Agree	Do not know		
43	I know where to get contraception	Disagree	Agree	Do not know		
If you are not married, please imagine that you are and try to answer the following questions:						
44	My female friends would use the pill, IUD, injection or implant if they wanted to prevent pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
45	My friends would talk to their wife about contraception if they wanted to prevent a pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

46	If you wanted to talk to your wife about contraception, how easy would it be for you to talk to her?	Very difficult	Difficult	Not sure	Easy	Very easy

47	If you wanted to talk to your wife about contraception, how certain are you that you could talk to her?	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could

Palestine

1	What method of contraception are you using <u>now</u> (check all that apply)?	None	Injection	Male condom	IUD	Not married
		Implant	Pill	Female condom	Calendar-based method	LAM
		Withdrawal	Patch	Ring	Other method	
2	Where did you get this method?	PFPPA Jerusalem	PFPPA Bethlehem	PFPPA Halhoul	PFPPA Hebron	PFPPA Ramallah
		MoH clinic	UNRWA	Not using a method	I do not know	Not married
3	Do you want a pregnancy <u>now</u>?	Yes	No	Not sure	Not married	

	Using the pill…						
4	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
6	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
7	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
8	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
9	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
12	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
13	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is

14	The IUD insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
	Using the injection…						
15	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
16	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
17	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
18	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
19	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
20	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
23	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
24	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
25	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is

	Using the patch…						
26	causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
27	causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
28	is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
29	is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
30	I would recommend the patch to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is

31	Have you become pregnant <u>since joining this study</u>?	Yes	No	Not married		
32	Did you want to become pregnant <u>during this study</u>?	Yes	No	Not sure	Not married	
33	Have you had a termination (abortion) <u>since joining this study</u>?	Yes	No	Not married		
34	What method of contraception have you used <u>during this study</u> (check all that apply)?	None	Injection	Male condom	IUD	Not married
		Implant	Pill	Female condom	Calendar-based method	LAM
		Withdrawal	Patch	Ring	Other method	
35	How many times have you attended a sexual health service since you joined this study 4 months ago?	0	1	2 +		

36	How many messages did you read?	All	Most	Some	None	
37	Did you stop the messages?	Yes	No			
38	Do you know anyone else in the study?	Yes	No			
39	Did they read the messages that we sent you?	Yes	No	I do not know anyone in the study		
40	Did you read the messages that we sent them?	Yes	No	I do not know anyone in the study		
41	Have you experienced physical violence since being in the study?	Yes	No			
42	Did anything good or bad happen as a result of receiving the messages? If so, please summarise here:					

43	Hormonal contraception is more effective at <u>preventing pregnancy</u> than condoms alone	Disagree	Agree	Do not know
44	The pill is taken once a month	Disagree	Agree	Do not know
45	The IUD lasts for 6 months	Disagree	Agree	Do not know
46	The injection is given once a year	Disagree	Agree	Do not know
47	The implant can stay under the skin for 10 years	Disagree	Agree	Do not know

48	A new patch is worn each week for 3 weeks, then no patch for the 4th week	Disagree	Agree	Do not know
49	I know where to get contraception	Disagree	Agree	Do not know

If you are not married, please imagine that you are and try to answer the following questions:						
50	My friends would use the pill, IUD, injection, implant or patch if they wanted to prevent pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
51	My friends would talk to their husband about contraception if they wanted to prevent a pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

52	If you wanted to use the pill, IUD, injection, implant or patch, how easy would it be for you to use it?	Very difficult	Difficult	Not sure	Easy	Very easy
53	If you wanted to talk to your husband about contraception, how easy would it be for you to talk to him?	Very difficult	Difficult	Not sure	Easy	Very easy

54	If you wanted to use the pill, IUD, injection, implant or patch, how certain are you that you could use it?	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could
55	If you wanted to talk to your husband about contraception, how certain are you that you could talk to him?	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could

56	I intend to use the pill, IUD, injection, implant or patch	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

Bolivia

1	What method of contraception are you using now (check all that apply)?	None	Injection	Male condom	IUD	Not sexually active
		Implant	Pill	Female condom	Calendar-based method	LAM
		Withdrawal	Patch	Ring	Other method	
2	Where did you get this method?	CIES El Alto	CIES La Paz	Other service	Not using a method	I do not know
3	Do you want a pregnancy now?	Yes	No	Not sure	Not sexually active	

	Using the pill…						
4	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
5	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
6	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
7	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
8	I would recommend the pill to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the pill is
	Using the IUD…						
9	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
10	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
11	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
12	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
13	I would recommend the IUD to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
14	The IUD insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the IUD is
	Using the injection…						

15	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
16	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
17	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
18	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
19	I would recommend the injection to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the injection is
	Using the implant…						
20	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
21	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
22	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
23	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
24	I would recommend the implant to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
25	The implant insertion would not be a problem	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the implant is
	Using the patch…						
26	…causes infertility	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
27	…causes unwanted side-effects	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is

28	…is easy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
29	…is a good way to prevent pregnancy	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is
30	I would recommend the patch to a friend	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	I do not know what the patch is

31	Have you become pregnant since joining this study?	Yes	No	Not sexually active			
32	Did you want to become during this study?	Yes	No	Not sure	Not sexually active		
33	Have you had a termination (abortion) since joining this study?	Yes	No	Not sexually active			
34	What method of contraception have you used during this study (check all that apply)?	None	Injection	Male condom	IUD	Not sexually active	
		Implant	Pill	Female condom	Calendar-based method	LAM	
		Withdrawal	Patch	Ring	Other method		
35	How many times have you attended a sexual health service since you joined the study 4 months ago?	0	1	2+			
36	How many messages did you read?	All	Most	Some	None		
37	Did you stop the messages?	Yes	No				
38	Do you know anyone else in the study?	Yes	No				
39	Did they read the messages that we sent you?	Yes	No	I do not know anyone in the study			
40	Did you read the messages that we sent them?	Yes	No	I do not know anyone in the study			
41	Have you experienced physical violence since being in the study?	Yes	No				

42	Did anything good or bad happen as a result of receiving the messages? If so, please summarise here:

43	Hormonal contraception is more effective at preventing pregnancy than condoms alone	Disagree	Agree	Do not know		
44	The pill is taken once a month	Disagree	Agree	Do not know		
45	The IUD lasts for 6 months	Disagree	Agree	Do not know		
46	The injection is given once a year	Disagree	Agree	Do not know		
47	The implant can stay under the skin for 10 years	Disagree	Agree	Do not know		
48	A new patch is worn each week for 3 weeks, then no patch for the 4th week	Disagree	Agree	Do not know		
49	I know where to get contraception	Disagree	Agree	Do not know		

50	My friends would use the pill, IUD, injection, implant or patch if they wanted to prevent pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
51	My friends would talk to their partner about contraception if they wanted to prevent a pregnancy.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

52	If you wanted to use the pill, IUD, injection, implant or patch, how easy would it be for you to use it?	Very difficult	Difficult	Not sure	Easy	Very easy
53	If you wanted to talk to your partner about contraception, how easy would it be for you to talk to him?	Very difficult	Difficult	Not sure	Easy	Very easy

54	If you wanted to use the pill, IUD, injection, implant or patch, how certain are you that you could use it?	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could
55	If you wanted to talk to your partner about contraception, how certain are you that you could talk to him?	Very certain I could not	Certain I could not	Not sure	Certain I could	Very certain I could

56	I intend to use the pill, IUD, injection, implant or patch	Strongly disagree	Disagree	Not sure	Agree	Strongly agree

Appendix 15. Trial ethical approval letters

LSHTM- Tajikistan

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Ona McCarthy
LSHTM

16 May 2016

Dear Ona

Study Title: A randomised controlled trial of a mobile phone-based intervention to enhance contraceptive choice in Tajikistan

LSHTM Ethics Ref: 10998

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Covering Letter	10998 Clarification		
Investigator CV	Cari Free CV	22/04/2013	1
Information Sheet	v1 TFPA trial information sheet	19/02/2016	1
Information Sheet	v1 TFPA consent	19/02/2016	1
Information Sheet	v1 TFPA interview info sheet	19/02/2016	1
Information Sheet	v1 TFPA Interview Consent	19/02/2016	1
Investigator CV	22.02.16 OM CV	22/02/2016	1
Protocol / Proposal	v2 TFPA Trial Protocol 09.03.16	09/03/2016	2
Sponsor Letter	Tajikistan LSHTM Sponsorship letter	17/03/2016	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Page 1 of 2

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

LSHTM-Palestine

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Ona McCarthy
LSHTM

16 May 2016

Dear Ona

Study Title: A randomised controlled trial of a mobile phone-based intervention to enhance contraceptive choice in Palestine

LSHTM Ethics Ref: 10831

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Covering Letter	10831 Clarification		
Investigator CV	Cari Free CV	22/04/2013	1
Information Sheet	v1 PFPPA trial information sheet	19/02/2016	1
Information Sheet	v1 PFPPA consent	19/02/2016	1
Information Sheet	v1 PFPPA interview info sheet	19/02/2016	1
Information Sheet	v1 PFPPA Interview consent	19/02/2016	1
Investigator CV	22.02.16 OM CV	22/02/2016	1
Protocol / Proposal	v3 PFPPA Trial Protocol 09.03.16	09/03/2016	3
Sponsor Letter	Palestine LSHTM Sponsorship letter	17/03/2016	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

LSHTM-Bolivia

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Observational / Interventions Research Ethics Committee

Ona McCarthy
LSHTM

16 May 2016

Dear Ona

Study Title: A randomised controlled trial of a mobile phone-based intervention to enhance contraceptive choice in Bolivia

LSHTM Ethics Ref: 10999

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Covering Letter	10999 Clarification		
Investigator CV	Cari Free CV	22/04/2013	1
Information Sheet	v1 CIES trial information sheet	19/02/2016	1
Information Sheet	v1 CIES consent	19/02/2016	1
Information Sheet	v1 CIES Interview info sheet	19/02/2016	1
Information Sheet	v1 CIES Interview Consent	19/02/2016	1
Investigator CV	22.02.16 OM CV	22/02/2016	1
Protocol / Proposal	v2 CIES Trial Protocol 09.03.16	09/03/2016	2
Sponsor Letter	Bolivia LSHTM Sponsorship letter	17/03/2016	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

Tajikistan

ВАЗОРАТИ ТАНДУРУСТӢ ВА ҲИФЗИ ИҶТИМОИИ АҲОЛИИ ҶУМҲУРИИ ТОҶИКИСТОН
МУАССИСАИ ДАВЛАТИИ МАРКАЗИ ҶУМҲУРИЯВИИ ИЛМИЮ КЛИНИКИИ ПЕДИАТРӢ ВА ҶАРРОҲИИ КӮДАКОНА

ҶТ, 734026, ш. Душанбе, к.И.Сомонӣ 59, биной 7, тел. 236-52-50, 236- 58-51 www.pediatria.tj

« 15 » апреля 2016 г. **№ 1/85**

Г-же Она Мак Карти
Научному сотруднику Лондонского
Института гигиены и тропической медицины

Государственное Учреждение республиканский научно исследовательский центр педиатрии и детской хирургии ГУ РНИЦП и ДХ выражает свое уважение Институту гигиены и тропической медицины Лондона за содействие по оценке и внедрению новых методологий в области медицины в Таджикистане.

ГУ РНИЦП и ДХ организует и планирует весь спектр научных исследований в области здоровья детей в возрасте 0-18 лет и может представить годами накопленный опыт в организацию и реализацию данного исследования «Использование повых технологий по улучшению информированности населения по здравоохранению».

В рамках трехстороннего исследования представленный со стороны ТАПС Протокол «Организации и планирования исследования эффекта использования мобильных технологий для усиления контрацептивного выбора, случайным и контрольным методом в Таджикистане» изучены и утверждены для проведения оценки. Также изучены и допущены к исследованию профайлы исследовательской команды в составе 5 человек:

- Она МакКарти
- Элисон МакКими
- Эли Булбоул
- Марко Самастур
- Мариека Ванде Виле

В связи с тем, что ГУ РНИЦП и ДХ является государственным учреждением, отвечающим за все исследования и внедрения новых технологий в области педиатрии в Таджикистане, просим вас представить итоги исследования и производить публикации по исследованию только по согласованию с нашим учреждением.

Наши наилучшие пожелания в предстоящем исследовании.

Директор [redacted] **З.Н. Набиев**

Palestine

09-MAY-2016 15:55 From: To:6261675 Page:1/1

State of Palestine
Ministry of Health
Public Health Directorate

دولة فلسطين
وزارة الصحة
الإدارة العامة للصحة العامة

Ref.: 147/2016

التاريخ: 9/5/2016

Palestinian Family Planning and Protection association

Greeting,

Subject: A randomized controlled trail of a mobile phone-based intervention to enhance contraceptive choice in Palestine

Based on your letter No. 2016/Gos,sL/5 dated on 6/4/2016, regarding the above mentioned subject, please note that MOH is supporting NGOs in the field of research and other issues serving the health and public health of our civilian.
Based on that we approve the study mentioned above from 1/6/2016 to 30/6/2018, take into consideration the following:

1- Full commitment of IPPF of Massages that already agreed and signed with MOH.
2- Provide the MOH with the results of the study after completion.

Regards,

[redacted]

Dr. Yasser Bouziya

Acting Director General Of
Public Health Directorate

- Deputy Minister of Health.
- Director of community health dep.
- Director of health & promotion dep.

Tel.: 00970 2 2958927
Fax: 00970 2 2958566
P.O. Box: 752 Ramallah

هاتف: 00970 2 2958927
فاكس: 00970 2 2958566
ص. ب.: 752 / رام الله

Bolivia

COMITÉ NACIONAL DE BIOÉTICA

Comisión de ética de la investigación

AVAL ETICO

A quien corresponda:

La Comisión de Ética de la Investigación del Comité Nacional de Bioética (CEI-CNB), tiene a bien informar que fue presentado a la CEI-CNB, para su revisión y aval ético el proyecto: **ENSAYO CONTROLADO ALEATORIO: INTERVENCIÓN BASADA EN LA TELEFONÍA MÓVIL PARA MEJORAR LA ELECCIÓN DE MÉTODOS ANTICONCEPTIVOS EN BOLIVIA** por el Centro de Investigación, Educación y Servicios (CIES) y London School of Hygiene and Tropical Medicine (LSHTM, Londres, El Reino Unido) y cuyo responsable es la D***ra. Verónica Osorio Calderón.***

El Comité de Ética de la Investigación ha revisado la propuesta y realizo observaciones sugirió ciertas modificaciones y aclaraciones, las cuales quedaron subsanadas por la investigador principal y cuya constancia consta en los archivo de la Comisión.

Por tanto se tiene a bien certificar que el proyecto: **EVALUACION DEL PROYECTO: ENSAYO CONTROLADO ALEATORIO: INTERVENCION BASADA EN LA TELEFONÍA MÓVIL PARA MEJORAR LA ELECCIÓN DE MÉTODOS ANTICONCEPTIVOS EN BOLIVIA** cumple con todos los requisitos éticos, por lo que los miembros de la CEI-CNB le otorgan el respectivo AVAL ÉTICO para la prosecución en su ejecución.

Atentamente

[redacted]

COMITE NACIO TICA
COMISION DE ETICA IGACION

Dra. **INGRID GABY MELGAREJO POMAR**
COORDINADOR

La Paz, septiembre 20 2016

c.c. Arch.

Appendix 16. Tajikistan trial publication

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Reproductive Health

RESEARCH Open Access

A randomized controlled trial of an intervention delivered by mobile phone app instant messaging to increase the acceptability of effective contraception among young people in Tajikistan

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Abstract

Background: Unintended pregnancy is associated with poorer health outcomes for women and their families. In Tajikistan, around 26% of married 15–24 year old women have an unmet need for contraception. There is some evidence that interventions delivered by mobile phone can affect contraceptive-related behaviour and knowledge. We developed an intervention delivered by mobile phone app instant messaging to improve acceptability of effective contraceptive methods among young people in Tajikistan.

Methods: This was a randomized controlled trial among Tajik people aged 16–24. Participants allocated to the intervention arm had access to an app plus intervention messages. Participants allocated to the control arm had access to the app plus control messages. The primary outcome was acceptability of at least one method of effective contraception at 4 months. Secondary outcomes were use of effective contraception at 4 months and during the study, acceptability of individual methods, service uptake, unintended pregnancy and induced abortion. Process outcomes were knowledge, perceived norms, personal agency and intention. Outcomes were analysed using logistic and linear regression. We conducted a pre-specified subgroup analysis and a post-hoc analysis of change in acceptability from baseline to follow-up.

Results: Five hundred and seventy-three participants were enrolled. Intervention content was included on the app, causing contamination. Four hundred and seventy-two (82%) completed follow-up for the primary outcome. There was no evidence of a difference in acceptability of effective contraception between the groups (66% in the intervention arm vs 64% in the control arm, adjusted OR 1.21, 95% CI .80–1.83, $p = 0.36$). There were no differences in the secondary or process outcomes between groups. There was some evidence that the effect of the intervention was greater among women compared to men (interaction test $p = 0.03$). There was an increase in acceptability of effective contraception from baseline to follow-up (2% to 65%, $p < 0.001$).

(Continued on next page)

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Conclusions: The whole intervention delivered by instant messaging provided no additional benefit over a portion of the intervention delivered by app pages. The important increase in contraceptive acceptability from baseline to follow-up suggests that the intervention content included on the app may influence attitudes. Further research is needed to establish the effect of the intervention on attitudes towards and use of effective contraception among married/sexually active young people.

Trial registration: Clinicaltrial.gov NCT02905513. Date of registration: 14 September 2016.

Keywords: Randomized controlled trial, Tajikistan, Contraception, Smart phone, Reproductive health, Young adults

Plain English summary

Unintended pregnancy is associated with poor health and social outcomes for women and their families. Despite wide availability of contraception, many women globally face barriers in realizing their fertility desires. A woman has an unmet need for modern contraception if she wants to avoid a pregnancy but currently uses no method or a traditional method. In Tajikistan, unmet need for contraception is approximately 26% among married 15–24 year olds. Oppositional attitudes towards contraception (both their own and others') is a common reason women provide for not using contraception.

We developed an intervention delivered by mobile phone to increase the acceptability of effective contraception among young people in Tajikistan. The intervention was developed with young people using an established approach grounded in behavioural science. We conducted a randomized controlled trial to evaluate the effect of the intervention on acceptability of effective contraception. Participants allocated to the intervention group had access to an app plus the intervention messages. Participants allocated to the control group had access to the app plus control messages. The app contained a proportion of the intervention messages that targeted knowledge of and attitudes towards effective contraception. This was different from what was planned in the trial protocol.

The intervention instant messages did not have an added benefit over the app with regards to any of the outcomes. When data from both groups were analysed together, there was a large increase in acceptability of effective contraception from baseline to follow-up (2% at baseline to 65% at follow-up). While we cannot attribute this increase unequivocally to the intervention content, it suggests that providing accurate information and targeting beliefs that influence contraceptive use may be sufficient in changing attitudes towards these methods among young people in Tajikistan. Further research is needed to reliably establish the effect of the intervention on attitudes towards and use of effective contraceptive methods among married/sexually active young people.

Background

Unintended pregnancy persists as a global health problem, with people in lower income countries experiencing them at a higher rate [1]. Unintended pregnancy is associated with a multitude of negative health and economic outcomes for women and their families [2–11]. It is estimated that modern contraceptive use currently prevents 307 million unintended pregnancies each year in developing regions [12]. Satisfying unmet need for modern contraception in these regions would reduce unintended pregnancies by 74% [12]. A woman has an unmet need for modern contraception if she wants to avoid a pregnancy but currently uses no method or a traditional method [13].

Despite a number of governmental policy initiatives and strategies aimed at improving reproductive health in Tajikistan, young people in the country face challenges in gaining accurate information about contraception and in accessing services [14, 15]. The 2012 Tajikistan Demographic and Health Survey is the most reliable resource for family planning data in the country at present [16]. The survey estimates that Tajik women have an average of half a child more than their desired number, implying that if unintended pregnancies were avoided, the total fertility rate would be 3.3 births per woman rather than the actual 3.8 [16]. The effective contraceptive methods available in Tajikistan are oral contraceptive pills (OCs), intrauterine devices (IUDs), injectables and implants ('effective methods are methods with a less than 10% typical use failure rate at 12 months [17–19]). Though these methods are available, around 26% of married 15–24 year old women have an unmet need for contraception [16]. Unmet need is the highest between the ages of 20 to 29 [20]. The main reason women with an unmet need provide for not using contraception are oppositional attitudes towards contraception, both their own and others' [20]. The next common reasons relate to low perceived pregnancy risk and negative attitudes about the methods, such as fear of side-effects [20].

Over the past few decades, the dramatic global increase in mobile phone ownership has engendered enthusiasm amongst researchers and health care

providers regarding the use of mobile phones for health care delivery [21–32]. Trials have provided some evidence that interventions delivered by mobile phone can improve contraceptive-related behaviours [33–36] and knowledge [37–39], however others have failed to find an effect [40–43]. The London School of Hygiene and Tropical Medicine (LSHTM) and the Tajik Family Planning Association (TFPA), a Member Association of the International Planned Parenthood Federation (IPPF) collaborated to develop and evaluate an intervention delivered by mobile phone to improve attitudes towards the effective contraceptive methods among young people in Tajikistan.

To evaluate the intervention, we conducted a randomized controlled trial from November 2016 to July 2017. This paper reports the results of the trial. To the best of our knowledge, this is the first trial to evaluate a contraceptive behavioural intervention delivered by mobile phone in Tajikistan. The results contribute to an understanding about how to help young people in Tajikistan avoid unintended pregnancies.

Methods

The methods reported in this section were first published in the trial protocol [44] and the statistical analysis plan [45].

Study design and participants

This was a parallel group, individually randomized superiority trial with a 1:1 allocation ratio. The aim of this trial was to assess the effect of the intervention on the acceptability of effective contraceptive methods among young people in Tajikistan. Participants were eligible to take part in the trial if they were between the ages of 16 and 24, owned a personal Android mobile phone, lived in Tajikistan, could provide informed consent and could read Tajik or Russian. Participants must also have been willing to download a mobile phone app and receive instant messages about contraception through the app. Participants provided informed consent though the secure online trial database and randomization system. All participants received usual care (the normal care that a young person would receive if they attended a sexual and reproductive health service in Tajikistan) and were free to seek any other support.

Intervention and control

The intervention was developed with young Tajik people in 2015–2016 guided by an established approach grounded in behavioural science [46]. It consisted of short mobile phone instant messages delivered through TFPA's 'healthy lifestyles' app over 4 months. It was informed by the Integrated Behavioural Model (IBM) [47] and contained 10 behaviour change methods (BCM) (belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting) [48], adapted for delivery by mobile phone. The messages provided information about contraception, targeted beliefs identified in the development phase that influence contraceptive use and aimed to support young people in believing that they can influence their reproductive health.

The messages are tailored according to marital status and gender, resulting in four sets of messages (female-married, female-not married, male-married and male-not married). The majority of the messages in the four sets are the same, with minor tailoring so that the messages are relevant to these groups. (Marital status was used as a proxy for sexual activity because the target group and TFPA considered it inappropriate to ask directly about sexual activity.) Further details about the intervention are presented in the trial protocol [44] and in a forthcoming intervention development publication.

Contamination

Participants allocated to the intervention arm had access to the app plus the intervention instant messages. Participants allocated to the control arm had access to the app plus control instant messages about trial participation. Contrary to what was planned in the trial protocol [44], the app contained intervention content. The app was intended to contain only basic information about contraception and no behaviour change methods. This contamination occurred due to a misunderstanding between the partners collaborating in the research.

The app contraception pages included just under a third of the intervention content. Specifically, 57% of the female-married intervention messages that provide accurate information about the effective contraceptive methods and 36% of the messages that use the BCM 'belief selection' were included on the app. Forty-four percent of the female-married intervention content included on the app used the same words as the intervention messages (56% did not use the same words but was very similar and conveyed the same meaning). The intervention content included on the app aimed to help individuals: name the effective methods, describe how the effective methods work, list services that provide effective contraception, list the risks and benefits of the effective methods, describe how methods are used, express positive attitudes towards the effective methods and differentiate between real potential side-effects and misconceptions about the methods.

Allocation and intervention delivery

After providing informed consent, participants completed the baseline questionnaire through the database

and randomization system. The allocation sequence was generated by the remote computer-based randomization software. Randomization occurred immediately after baseline data was submitted. All participants downloaded the app immediately after they submitted their baseline data. The delivery of the intervention (and control) instant messages began on the same day if participants downloaded the app before 13:00 and the following day if they downloaded it after 13:00.

Protecting against bias

Due to the nature of the intervention, participants would have been aware of the allocation soon after they started receiving the messages. Local research staff collecting outcome data were masked to allocation unless the participant revealed it to them. Researchers that analysed the data were masked to treatment allocation.

Outcomes

Primary outcome

The primary outcome was the proportion of participants reporting that at least one method of effective contraception was acceptable at 4 months post randomization. The primary outcome measure was constructed based on guidelines for measuring IBM constructs [47, 49, 50] and tested for face validity with the target group. The acceptability of each method was measured by the following stems: Using the [method] *…causes infertility, …causes unwanted side effects, …is easy, …is a good way to prevent pregnancy* and *I would recommend the [method] to a friend*. The IUD and implant include an additional stem: *The* [method] *insertion would not be a problem*. The response options for each scale were strongly disagree, disagree, not sure, agree, strongly agree and I do not know what the [method] is. A method was acceptable if participants reported 'agree' or 'strongly agree' for all scales except for '…causes infertility' and '…causes unwanted side effects' stems, for which 'disagree' or 'strongly disagree' indicated acceptability.

Secondary outcomes

Secondary outcomes were: use (or partner's use) of effective contraception; acceptability of individual methods; use (or partner's use) of effective contraception at any time during the 4 months; service uptake; unintended pregnancy and induced abortion.

Process outcomes The process outcomes were: knowledge of effective contraception; perceived norms in relation to using and communicating with partners about contraception; personal agency in using (women only) and communicating with partners about contraception; intention to use effective contraception (women only) and intervention dose received. Details about the scales used to measure knowledge, perceived norm, personal agency and intention are reported in the trial protocol [44].

Data collection

Data was collected at baseline and at 4 months post-randomization using questionnaires. At baseline, we collected personal and demographic data and acceptability of at least one method of effective contraception (using the same scales as the primary outcome measure). All baseline data was entered onto the trial database system by the participant on their mobile phone. At 4 month follow-up, we collected all outcomes and the following data: if participants report using an effective method, where they obtained it; current pregnancy intention; whether they knew someone else that took part in the study and if so, if they read each other's messages; if they stopped the messages; if they experienced physical violence since being in the study and if anything good or bad happened as a result of receiving the messages. An instant message that included a link to the database to complete the follow-up questionnaire was sent to all participants through the app 4 months after downloading the app. If participants did not complete the follow-up questionnaire themselves, local research staff contacted them by telephone to collect their data.

Sample size

The trial was powered to detect a 15% increase in acceptability of effective contraception in the intervention group compared with the control group. Four hundred and fifty-four participants allowed for 90% power to detect a 15% absolute increase in acceptability, assuming 50% acceptability in the control group (i.e. 50% in the control vs 65% in the intervention, an odds ratio of 1.86). Allowing for 20% loss to follow-up, we aimed to randomize 570 people.

Statistical analysis

The trial protocol was accepted for publication on 21 July 2017 [44] and the statistical analysis plan was publicly released on 16 August 2017 [45]. The analysis was conducted using Stata 15. Analyses were according to randomized arm and only participants with complete outcome data were included in the principal analysis. All statistical tests were two-sided and considered significant at the 5% level. Unmasking occurred on 29 August 2017, after the analyses outlined within the analysis plan were complete.

Loss to follow-up and missing data

We used a chi-squared test to investigate whether loss to follow-up differed by arm. We used logistic regression to compare baseline characteristics of participants that completed follow-up against participants that did not. We investigated whether predictors of loss to follow-up differed by arm by testing for an interaction.

Principal analysis

Analysis of the primary outcome

We compared the proportion that reported that at least one method was acceptable in each group using logistic regression. We report the crude and adjusted odds ratio (OR) along with the 95% confidence interval (CI) and *p*-value. We adjusted the primary analysis regression for the following pre-specified baseline covariates: pregnancy intention (wants to avoid/other); gender (female/male); age (16–19/20–24); highest education level completed (university/other) and acceptability of effective contraception (at least one method acceptable/no methods acceptable) [44, 45].

Analysis of the secondary outcomes

The analysis of the secondary outcomes was similar to the analysis of the primary outcome. We estimated the difference between the groups using logistic regression and report odds ratios with 95% CIs and *p*-values. Regressions were adjusted for the baseline covariates pregnancy intention, gender, age, education level and acceptability (of at least one method or with acceptability of individual methods, of the corresponding method).

Analysis of the process outcomes

The process outcomes perceived norms, personal agency and intention were comprised of ordinal scales. Each scale was analysed individually using ordered logistic regression to estimate proportional ORs. For knowledge, each correct answer received one point. The points were summed and an overall score was produced. We used linear regression to test for a difference in mean scores between the arms. To assess the 'dose' of the intervention that the intervention participants received, we analysed the number of messages that participants reported to have read (all, most, some, none) and whether they stopped the messages.

Additional analyses

Sensitivity analyses

We conducted two sensitivity analyses regarding the missing data. In the first, we considered that participants lost to follow-up did not find at least one method acceptable. In the second, we adjusted for the main baseline predictors of missingness. Both sensitivity analyses were adjusted for the baseline covariates pregnancy intention, gender, age, education level and acceptability.

Subgroup analysis

We conducted an exploratory subgroup analysis for the primary outcome to determine if the intervention effect varied by baseline characteristics. The pre-specified subgroups were gender (female/male); age (split at the median); marital status (married/not married); number of children (0/1+); ethnicity (Tajik/other); occupation (in education/other); highest education level completed (university/other) and pregnancy intention (wants to avoid/other). Within the subgroups, we assessed heterogeneity of treatment effect with a test for interaction [51–55]. We estimated ORs along with 95% CIs for each subgroup.

Contamination

To assess the potential for contamination, we report the proportion of control group participants that reported that they read another participant's messages and the proportion of intervention participants that reported that their messages were read by another participant.

Change from baseline

In addition to the analyses specified in the statistical analysis plan, we tested for a change in the primary outcome from baseline to follow-up, using McNemar's χ^2 test for paired data. This post hoc non-randomized analysis was conducted to explore the increase in acceptability overall, as the app included intervention content (see Discussion).

Results

Recruitment, randomization, exclusions

Between 16 November 2016 and 1 March 2017, there were 580 randomizations. During the analysis, we discovered that five participants enrolled and were randomized twice. For the three participants that were allocated to the same arm on both randomizations, we kept them in the analysis using the baseline data from their first record. For the two participants that were allocated to different arms, we excluded them from the analysis. This resulted in 573 participants included in the trial (see Discussion).

Two hundred and seventy-five participants were allocated to the intervention arm and 298 participants were allocated to the control arm (Fig. 1). No participants withdrew from the trial after allocation.

Baseline characteristics

Baseline characteristics of trial participants are reported in Table 1. Mean age was 20 years, and 53% were male. Ninety-four percent were not married (259/573), and only 2% (13/573) found at least one method of effective

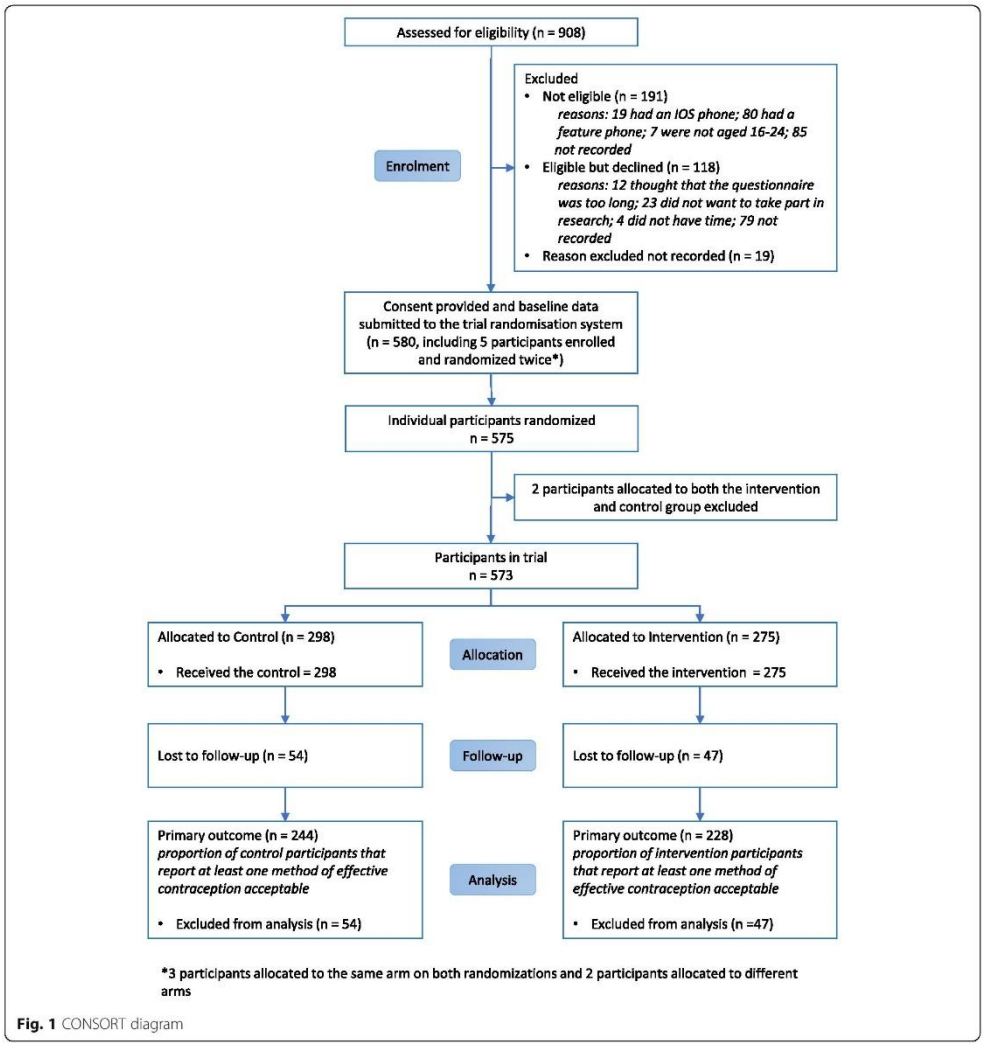

Fig. 1 CONSORT diagram

contraception acceptable. Characteristics were similar between the two groups.

Loss to follow-up

Four hundred and seventy-six participants total (83%) contributed follow-up data. Four hundred and seventy-two participants (82%) completed the trial follow-up for the primary outcome (intervention, $n = 228$; control, $n = 244$) (Fig. 1). Retention did not differ between the arms (83% in the intervention vs 82% in the control, $p = 0.75$). The main predictors of retention were male gender (OR 1.78, $p = 0.01$), Tajik ethnicity (OR 2.22, $p = 0.03$) and having completed a level of education lower than university at enrolment (OR 1.79, $p = 0.02$). The effect of these predictors did not differ by arm (interaction test p-values: gender, $p = 0.72$; ethnicity, $p = 0.41$; education level, $p = 0.98$). Detailed characteristics of follow-up completers and non-completers are reported in Additional file 1.

Table 1 Baseline characteristics

		Control N = 298, % (n)	Intervention N = 275, % (n)	All participants N = 573, % (n)
Age	mean [sd]	20.00 [2.41]	19.93 [2.24]	19.98 [2.33]
	16–19	53.02 (158)	56.73 (156)	54.80 (314)
	20–24	46.98 (140)	43.27(119)	45.20(259)
Gender	female	45.97(137)	47.27 (130)	46.60 (267)
	male	54.03 (161)	52.73 (145)	53.40 (306)
Marital status	married	6.71 (20)	5.82 (16)	6.28 (36)
	not-married	93.29 (278)	94.18 (259)	93.72 (537)
Number of children	0	95.64 (285)	97.09 (267)	96.34 (552)
	1	2.01 (6)	2.18 (6)	2.09 (12)
	2 or more	2.35 (7)	0.73 (2)	1.57 (9)
Ethnicity	Tajik	92.62 (276)	93.82 (258)	93.19 (534)
	Russian	2.35 (7)	0.36 (1)	1.40 (8)
	Uzbek	5.03 (15)	5.45 (15)	5.24 (30)
	other	0 (0)	0.36 (1)	0.17 (1)
Occupation	school	17.79 (53)	17.09 (47)	17.45 (100)
	university	68.46 (204)	70.55 (194)	69.46 (398)
	working	10.74 (32)	10.55 (29)	10.65 (61)
	training	0.67 (2)	0 (0)	0.35 (2)
	parent	0.34 (1)	0 (0)	0.17 (1)
	not working	1.68 (5)	1.82 (5)	1.75 (10)
	university & working	0.34 (1)	0 (0)	0.17 (1)
Highest level of education completed	primary	12.75 (38)	13.09 (36)	12.91 (74)
	secondary	66.11 (197)	59.64 (164)	63.00 (361)
	university	19.46 (58)	25.82 (71)	22.51 (129)
	other	1.68 (5)	1.45 (4)	1.57 (9)
Current pregnancy intention (*'Do you want a pregnancy now?'*)	yes	3.02 (9)	4.00 (11)	3.49 (20)
	no	12.42 (37)	5.82 (16)	9.25 (53)
	unsure	1.01 (3)	0.73 (2)	0.87 (5)
	not married[a]	83.56 (249)	89.45 (246)	86.39 (495)
Baseline method	none	31.88 (95)	29.45 (81)	30.72 (176)
	male condom	2.01 (6)	1.09 (3)	1.57 (9)
	IUD[b]	0.67 (2)	0 (0)	0.35 (2)
	not married[a]	65.10 (194)	69.09 (190)	67.02 (384)
	LAM[c]	0 (0)	0.36 (1)	0.17 (1)
	other	0.34 (1)	0 (0)	0.17 (1)
At least one effective method is acceptable	yes	2.68 (8)	1.82 (5)	2.27 (13)
	no	97.32 (290)	98.18 (270)	97.73 (560)
Pill acceptability	yes	1.34 (4)	0.73 (2)	1.05 (6)
	no	98.66 (294)	99.27 (273)	98.95 (567)
IUD acceptability	yes	1.34 (4)	0 (0)	0.70 (4)
	no	98.66 (294)	100 (275)	99.30 (569)
Injection acceptability	yes	0.67 (2)	1.45 (4)	1.05 (6)
	no	99.33 (296)	98.55 (271)	98.95 (567)
Implant acceptability	yes	0.34 (1)	0.73 (2)	0.52 (3)
	no	99.66 (297)	99.27 (273)	99.48 (570)

[a]The response 'not married' was used as a proxy for not being sexually active
[b]*IUD* Intrauterine device
[c]*LAM* Lactational amenorrhea method

Primary outcome

In the intervention arm, 66% (151/228) reported that at least one method of contraception was acceptable compared to 64% (156/244) in the control arm (Table 2). There was no evidence of a difference in acceptability between the groups (crude OR 1.11, 95% CI .76–1.62, $p = 0.60$; adjusted OR 1.21, 95% CI .80–1.83, $p = 0.36$).

Secondary outcomes

There were no significant differences in any of the secondary outcomes between the groups (Table 3).

Process outcomes

There were no significant differences in any of the process outcomes between the groups (Table 4).

Potential for contamination

Three percent (8/243) of control participants said that they read the messages of someone else in the study. Nine percent (21/227) of intervention participants said that someone else in the study read their messages.

Participants' report of physical violence during the study

Overall, 0.85% (4/470) reported that they experienced physical violence since being in the study (0.41% in the control and 1.32% in the intervention, $p = 0.57$).

Sensitivity analyses

The effect of the intervention on the primary outcome observed in the principal analysis did not change when we considered participants lost to follow-up did not find

Table 2 Primary outcome

	Control N = 244, % (n)	Intervention N = 228, % (n)	OR (95% CI)	*p*-value
At least one effective method is acceptable[a]	63.93 (156)	66.23 (151)	1.21 (.80–1.83)	0.36

[a]adjusted for pregnancy intention, gender, age, education level and acceptability at baseline

Table 3 Secondary outcomes

	Control % (n/N)	Intervention % (n/N)	OR (95% CI)	*p*-value
Use of effective contraception[a]	3.66 (9/246)	1.30 (3/230)	.35 (.06–1.42)	0.18
Pill acceptability[b]	56.56 (138/244)	60.53 (138)	1.32 (.88–2.00)	0.18
IUD acceptability[b]	52.87 (129/244)	51.32 (117/228)	1.00 (.67–1.50)	0.98
Injection acceptability[b]	54.51 (133/244)	55.26 (126/228)	1.14 (.76–1.70)	0.52
Implant acceptability[b]	48.77 (119/244)	48.68 (111/228)	1.08 (.73–1.59)	0.71
Effective contraceptive use during the 4 months[a]	2.88 (7/243)	1.76 (4/227)	.61 (.13–2.42)	0.62
Service uptake[c] (attended a service one or more times)	10.29 (25/243)	7.93 (18/227)	.76 (.39–1.46)	0.41
Unintended pregnancy[c]	0 (0)	0 (0)	–	–
Induced abortion[c]	0 (0)	0 (0)	–	–

[a]based on unadjusted exact logistic regression, due to small numbers
[b]adjusted for pregnancy intention, gender, age, education level and the corresponding method acceptability at baseline
[c]adjusted for pregnancy intention, gender, age, education level and acceptability at baseline

at least one method acceptable (OR 1.20, 95% CI .84–1.73, $p = 0.31$) or when we adjusted the model for the predictors of missingness (OR 1.21, 95% CI .80–1.85, $p = 0.35$).

Subgroup analysis

There was some evidence that the effect of the intervention was greater among women compared to men (interaction test $p = 0.03$). (Fig. 2).

Change from baseline analysis

Among the 472 participants who completed follow-up 2% ($n = 10$) thought that at least one method was acceptable at baseline, which increased to 65% at follow-up ($n = 307$, $p < 0.001$) (Fig. 3). Acceptability for the individual methods increased from 1% at baseline to 49%–58% at follow-up ($p < 0.001$).

Discussion

Main results

Contrary to what was planned in the trial protocol, the app contained intervention content. Both intervention and control participants received intervention content targeting knowledge and attitudes towards effective contraception, including the BCM 'belief selection'. The trial therefore evaluated the effect of the whole intervention with all ten BCMs (belief selection, facilitation, anticipated regret, guided practice, verbal persuasion, tailoring, cultural similarity, arguments, shifting perspective and goal setting) delivered by instant messaging, compared to a proportion of the intervention delivered on the app pages with the BCM belief selection.

The trial found no evidence of a difference in acceptability of at least one effective contraceptive method between the intervention and control groups. There was also no evidence of a difference in any of the secondary and process outcomes between the groups (use of effective contraception, service uptake, knowledge, perceived norms, personal agency and intention to use effective contraception). This indicates that the intervention content delivered by the intervention messages only (includes nine additional BCMs targeting attitudes and personal agency) did not have an additional benefit over the app regarding these outcomes. The subgroup analysis suggests that the intervention delivered by instant messaging could be more effective among women compared to men. When data from both groups were analysed together, there was a large statistically significant increase in acceptability from baseline to follow-up.

Comparisons with other research

Trials that have evaluated interventions delivered by mobile phone to improve contraceptive-related outcomes have had mixed results [33–43]. We are conducting trials in Bolivia and Palestine that are evaluating the effect of interventions similar to the Tajik intervention on acceptability and use of effective contraception [56, 57]. The results of the three trials together should contribute to a better understanding of the effect of the intervention evaluated in this Tajik trial.

Our trial shows no additional benefit on the outcomes from the nine BCMs deliver by instant messaging. No previous research reports the effectiveness of these BCMs aimed at improving contraceptive-related outcomes delivered by mobile phone [58].

Ongoing trials of interventions delivered by mobile phone to improve reproductive health are measuring participants' experience of violence during their participation in the trial [56, 57, 59]. In this Tajik trial, we found no association between the intervention and experience of violence. While this is reassuring, both groups had access to the app so we are unable to assess the effect of the app on partner violence.

Table 4 Process outcomes

		Control % (n/N)	Intervention % (n/N)	proportional OR* (95% CI), *p*-value
Knowledge of effective contraception		Mean = 4.00 [sd = 2.04]	Mean = 4.08 [sd = 2.02]	.08** (−.29–.44), 0.69
My friends would use the pill, IUD, injection or implant if they wanted to prevent pregnancy	strongly disagree	3.70 (9/243)	1.33 (3/226)	1.40 (.97–2.01), 0.07
	disagree	4.53 (11/243)	5.31 (12/226)	
	not sure	17.28 (42/243)	16.37 (37/226)	
	agree	64.61 (157/243)	59.29 (134/226)	
	strongly agree	9.88 (24/243)	17.70 (40/226)	
My friends would talk to their husband/wife about contraception if they wanted to prevent a pregnancy	strongly disagree	1.23 (3/243)	1.33 (3/226)	1.09 (.76–1.57), 0.64
	disagree	5.35 (13/243)	6.64 (15/226)	
	not sure	16.05 (39/243)	15.93 (36/226)	
	agree	65.02 (158/243)	59.29 (134/226)	
	strongly agree	12.35 (30/243)	16.81 (38/226)	
If you wanted to use the pill, IUD, injection or implant, how easy would it be for you to use it? (women only)	very difficult	7.62 (8/105)	5.83 (6/103)	1.43 (.87–2.34), 0.16
	difficult	17.14 (18/105)	9.71 (10/103)	
	not sure	27.62 (29/105)	29.13 (30/103)	
	easy	38.10 (40/105)	43.69 (45/103)	
	very easy	9.52 (10/105)	11.65 (12/103)	
If you wanted to talk to your husband/wife about contraception, how easy would it be for you to talk to him/her?	very difficult	3.70 (9/243)	3/10 (7/226)	1.22 (.86–1.73), 0.26
	difficult	6.17 (15/243)	7.52 (17/226)	
	not sure	14.81 (36/243)	14.16 (32/226)	
	easy	60.49 (147/243)	53.10 (120/226)	
	very easy	14.81 (36/243)	22.12 (50/226)	
If you wanted to use the pill, IUD, injection or implant, how certain are you that you could use it? (women only)	very certain I could not	2.86 (3/105)	5.83 (6/103)	.99 (.60–1.63), 0.96
	certain I could not	6.67 (7/105)	7.77 (8/103)	
	not sure	38.10 (40/105)	32.04 (33/103)	
	certain I could	40.00 (42/105)	41.75 (43/103)	
	very certain I could	12.38 (13/105)	12.62 (13/103)	
If you wanted to talk to your husband/wife about contraception, how certain are you that you could talk to him/her?	very certain I could not	1.23 (3/243)	2.65 (6/226)	1.10 (.78–1.53), 0.60
	certain I could not	13.17 (32/243)	12.39 (28/226)	
	not sure	16.46 (40/243)	16.81 (38/226)	
	certain I could	50.62 (123/243)	44.25 (100/226)	
	very certain I could	18.52 (45/243)	23.89 (54/226)	
I intend to use the pill, IUD, injection or implant	strongly disagree	4.76 (5/105)	2.91 (3/103)	1.37 (.84–2.25), 0.21
	disagree	10.48 (11/105)	12.62 (13/103)	
	not sure	31.43 (33/105)	25.24 (26/103)	
	agree	39.05 (41/105)	34.95 (36/103)	
	strongly agree	14.29 (15/105)	24.27 (25/103)	
Number of messages read	all		32.16 (73/227)	
	most		43.61 (99/227)	
	some		18.50 (42/227)	
	none		5.73 (13/227)	
Proportion of intervention participants that stopped the intervention			29.07 (66/227)	

*estimated from ordered logistic regression
**mean difference

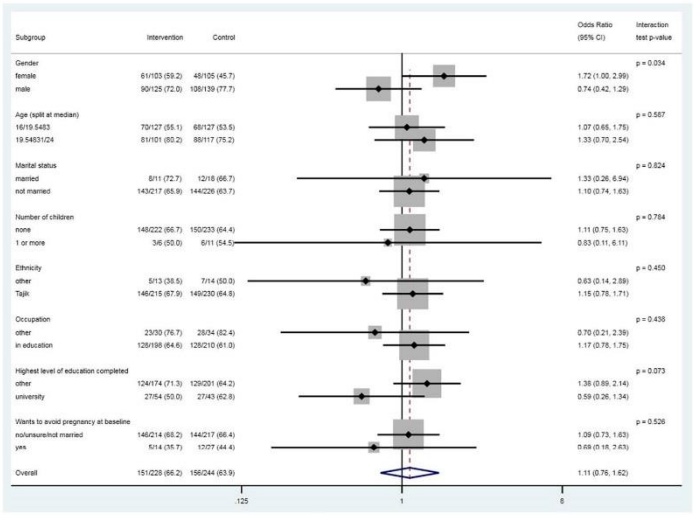

Fig. 2 Primary outcome by pre-specified subgroups

Strengths and limitations

The trial conduct has a number of strengths. We recruited our target number of participants and were able to collect follow-up data for an acceptable proportion of them, given that the sample size allowed for 20% loss. We developed and tested a remote trial database and randomization system, which successfully generated and concealed the allocation sequence and achieved well-balanced groups. An important limitation is that the app included intervention content, as discussed above. This constitutes a protocol deviation and the trial was therefore not able to answer the primary question it aimed to answer. Because the self-reported acceptability scales were collected by telephone by the research staff, participants may have been more likely to report positive attitudes than they were at baseline where they completed the questionnaire by themselves on their phones. Regarding the large increase in acceptability from baseline to follow-up, we cannot rule out the possibility that at least a portion of this increase was due to participation in the trial as opposed to the intervention itself; participants were aware that the trial involved changing attitudes towards contraception. Five participants enrolled and were randomized twice.

There were inconsistencies in participants' self-reporting of marital status. The proportion that responded 'not married' to the current pregnancy intention (495/573, 86%) and the baseline method question (384/573, 67%) is lower than the proportion that responded 'not married' when asked directly about their marital status (537/573, 94%). We cannot say why

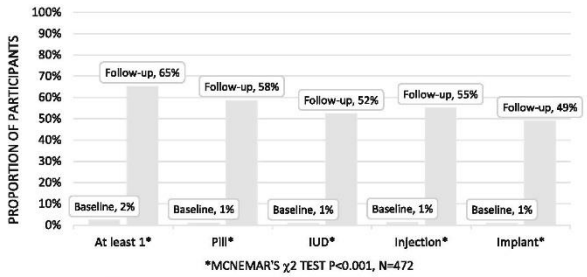

Fig. 3 Method acceptability at baseline and follow-up

these inconsistencies occurred. However, we can speculate that some participants who responded 'not married' to the marital status question were sexually active and responded to the other two questions with responses other than 'not married'.

Thirty six percent of people assessed for eligibility (328/908) were excluded from the study. The reason for ineligibility was not recorded for 85 people, which could limit the generalizability of the trial findings. While the recording of this information was not complete, of those that are known, the majority appear to have been excluded because they either did not have an Android phone ($n = 99$). If those who do not own a smartphone are less likely to find at least one method of effective contraception acceptable, this could affect the generalisability of the results. Smartphone ownership is rapidly increasing however, and ownership could be an option for a greater proportion of young people across different socioeconomic communities in the near future.

Implications of the findings

The finding that the intervention instant messages did not have an additional benefit over the app along with the large increase in acceptability from baseline to follow-up suggests that participants read the app contraception pages. It may be that in a context such as Tajikistan, where young people have limited access to information and support about reproductive health, they are willing to read static app pages about this topic. In comparison, a trial in the United Kingdom found that young people did not engage heavily with a sexual and reproductive health website [60, 61]. In contexts such as the United Kingdom where information and support are more accessible, interventions delivered on app pages and websites may be utilized less frequently than in contexts such as Tajikistan.

Because the intervention content included on the app aimed to improve knowledge of and attitudes towards effective contraception, it is not surprising that there was no evidence of a difference between the groups regarding these outcomes. Though the large increase in acceptability from baseline to follow-up cannot be unequivocally attributed to the intervention content, an increase this large suggests that the intervention content included on the app at least was partially effective in improving attitudes towards the effective methods. Because the intervention is well-specified, we were able to identify the components of the intervention that may have been effective in producing this change (accurate information and targeting beliefs using the BCM belief selection) [46, 48].

Despite the contamination that occurred, intervention participants received content that control participants did not. The secondary outcomes use and service uptake and the process outcomes personal agency and intention are related to the content that only intervention participants received. There are a number of potential explanations for why we did not observe a difference between the groups in these outcomes. The first is that the BCMs targeting these outcomes did not work. This could have been because the conditions under which the methods have been shown to be effective were not fully satisfied [46, 48]. In addition, because a large proportion of meaning comes from visual cues in face-to-face interaction [46], some of the meaning of the BCMs may have been lost when delivered by mobile phone. For example, the BCM 'guided practice' requires skill demonstration, enactment and individual feedback. While the intervention messages demonstrated and provided instruction, we were not able to observe the participant enacting the behavior or to provide individual feedback. This may have resulted in a loss of effectiveness of the BCM. Another explanation is that intervention could be more effective on these secondary and process outcomes with people where the behaviour is salient, such as with those who are married/sexually active or soon to be. In this trial however, only 6% (36/573) were married/sexually active, which was too small to explore this possibility. Alternatively, the app alone may have been effective in influencing these secondary and process outcomes; in the Tajik context, providing accurate information from a credible source and targeting the pre-identified beliefs may be sufficient. Finally, these secondary and process outcomes could have be so strongly influenced by environmental conditions (e.g. stigma regarding sexual activity before marriage and pressure to bear children) that they are not amenable to change by a mobile phone intervention only.

While caution is necessary in interpreting the results of the subgroup analysis, it suggests that the whole intervention delivered by instant messaging could be more effective among women compared to men. The trials in Bolivia and Palestine involve women only so the results should provide additional evidence of the intervention's effectiveness in women.

We are currently conducting qualitative interviews with trial participants to explore their experiences in receiving the intervention and app content. If participants were positive about receiving the intervention messages, this could support the delivery of the messages with the download of the app. The fact that the intervention is already developed and therefore inexpensive to deliver, plus the fact that it does not appear to cause harm, also supports the delivery of the messages with the download of the app.

Conclusions

This trial demonstrated that the whole intervention delivered by app instant messaging provided no additional benefit over a portion of the intervention delivered by the app pages. An analysis of participants randomized to the control and intervention groups together showed a large significant increase in acceptability from baseline to follow-up. Further research is needed to establish the effect of the intervention on attitudes towards and use of effective contraceptive methods among married/sexually active young people.

Additional file

Additional file 1 Baseline data by follow-up status. Baseline characteristics by follow-up completion. The baseline characteristics of the participants that completed the primary outcome and the baseline characteristics of participants that did not complete the primary outcome. (DOCX 17 kb)

Abbreviations

BCM: Behaviour change method; CI: Confidence interval; IPPF: International Planned Parenthood Federation; LSHTM: London School of Hygiene & Tropical Medicine; OR: Odds ratio; TFPA: Tajik Family Planning Association

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Availability of data and materials

The anonymised dataset used and analysed for the current study are available from the corresponding author.

Authors' contributions

OLM designed and managed the trial, conducted the analysis and wrote the manuscript. FK coordinated and conducted the trial recruitment and follow-up and contributed to planning discussions regarding the trial. RT facilitated trial implementation, contributed to planning discussions regarding the trial and took overall local responsibility for the project. SSa facilitated trial implementation and contributed to planning discussions regarding the trial. MV and SSt contributed to planning discussions regarding the trial. IA developed the trial database and randomization system. BL provided advice regarding the statistical analysis and reviewed the Stata analysis code. PE provided oversight regarding the statistical analysis. MP reviewed the primary outcome Stata analysis code. CF provided guidance regarding the trial design and took overall academic responsibility for the project. All authors revised the work, approved the version to be published and agree to be accountable for all aspects of the work.

Ethics approval and consent to participate

Ethical approval was granted from the London School of Hygiene and Tropical Medicine Observational Research Ethics Committee on 27 April 2015 (reference number 9148), the Tajik National Scientific and Research Centre on Pediatrics and Child Surgery on 8 June 2015.

All participants provided informed consent before providing baseline data and randomization.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Appendix 17. Baseline characteristics by follow-up status (Tajikistan)

		Primary outcome completers		Primary outcome non-completers		All participants	
		Control	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
		N = 244	N = 228	N = 54	N = 47	N = 298	N = 275
		% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
Age	mean [sd]	20 [2.44]	20 [2.35]	19.73 [2.29]	19.80 [1.65]	20.00 [2.41]	19.93 [2.24]
	16-19	52.05 (127)	55.70 (127)	57.41 (31)	61.70 (29)	53.02 (158)	56.73 (156)
	20-24	47.95 (117)	44.30 (101)	42.59 (23)	38.30 (18)	46.98 (140)	43.27(119)
Gender	female	43.03 (105)	45.18 (103)	59.26 (32)	57.45 (27)	45.97(137)	47.27 (130)
	male	56.97 (139)	54.82 (125)	40.74 (22)	42.55 (20)	54.03 (161)	52.73 (145)
Marital status	married	7.38 (18)	4.82 (11)	3.70 (2)	10.64 (5)	6.71 (20)	5.82 (16)
	not-married	92.62 (226)	95.18 (217)	96.30 (52)	89.36 (42)	93.29 (278)	94.18 (259)
Number of children	0	95.49 (233)	97.37 (222)	96.30 (52)	95.74 (45)	95.64 (285)	97.09 (267)
	1	2.05 (5)	1.75 (4)	1.85 (1)	4.26 (2)	2.01 (6)	2.18 (6)
	2 or more	2.46 (6)	0.88 (2)	1.85 (1)	0 (0)	2.35 (7)	0.73 (2)
Ethnicity	Tajik	94.26 (230)	94.30 (215)	85.19 (46)	91.49 (43)	92.62 (276)	93.82 (258)
	Russian	2.05 (5)	0.44 (1)	3.70 (2)	0 (0)	2.35 (7)	0.36 (1)
	Uzbek	3.69 (9)	5.26 (12)	11.11 (6)	6.38 (3)	5.03 (15)	5.45 (15)
	other	0 (0)	0 (0)	0 (0)	2.13 (1)	0 (0)	0.36 (1)
Occupation	school	16.39 (40)	17.54 (40)	24.07 (13)	14.89 (7)	17.79 (53)	17.09 (47)
	university	68.85 (168)	69.30 (158)	66.67 (36)	76.60 (36)	68.46 (204)	70.55 (194)
	working	11.89 (29)	12.28 (28)	5.56 (3)	2.13 (1)	10.74 (32)	10.55 (29)
	training	0.41 (1)	0 (0)	1.85 (1)	0 (0)	0.67 (2)	0 (0)
	parent	0.41 (1)	0 (0)	0 (0)	0 (0)	0.34 (1)	0 (0)
	not working	1.64 (4)	0.88 (2)	1.85 (1)	6.38 (3)	1.68 (5)	1.82 (5)
	university & working	0.41 (1)	0 (0)	0 (0)	0 (0)	0.34 (1)	0 (0)
Highest level of education completed	primary	12.70 (31)	13.16 (30)	12.96 (7)	12.77 (6)	12.75 (38)	13.09 (36)
	secondary	68.44 (167)	62.28 (142)	55.56 (30)	46.81 (22)	66.11 (197)	59.64 (164)
	university	17.62 (43)	23.68 (54)	27.78 (15)	36.17 (17)	19.46 (58)	25.82 (71)
	other	1.23 (3)	0.88 (2)	3.70 (2)	4.26 (2)	1.68 (5)	1.45 (4)
Current pregnancy intention	yes	3.69 (9)	3.07 (7)	0 (0)	8.51 (4)	3.02 (9)	4.00 (11)
	no	11.07 (27)	6.14 (14)	18.52 (10)	4.26 (2)	12.42 (37)	5.82 (16)
	unsure	0.41 (1)	0.44 (1)	3.70 (2)	2.13 (1)	1.01 (3)	0.73 (2)

		Primary outcome completers		Primary outcome non-completers		All participants	
		Control N = 244 % (n)	**Intervention** N = 228 % (n)	**Control** N = 54 % (n)	**Intervention** N = 47 % (n)	**Control** N = 298 % (n)	**Intervention** N = 275 % (n)
('*Do you want a pregnancy now?)*	not married*	84.84 (207)	90.35 (206)	77.78 (42)	85.11 (40)	83.56 (249)	89.45 (246)
Baseline method	none	28.28 (69)	25.88 (59)	48.15 (26)	46.81 (22)	31.88 (95)	29.45 (81)
	male condom	1.64 (4)	1.32 (3)	3.70 (2)	0 (0)	2.01 (6)	1.09 (3)
	IUD**	0.82 (2)	0 (0)	0 (0)	0 (0)	0.67 (2)	0 (0)
	not married*	68.85 (168)	72.37 (165)	48.15 (26)	53.19 (25)	65.10 (194)	69.09 (190)
	LAM***	0 (0)	0.44 (1)	0 (0)	0 (0)	0 (0)	0.36 (1)
	other	0.41 (1)	0 (0)	0 (0)	0 (0)	0.34 (1)	0 (0)
At least one effective method is acceptable	yes	2.46 (6)	1.75 (4)	3.70 (2)	2.13 (1)	2.68 (8)	1.82 (5)
	no	97.54 (238)	98.25 (224)	96.30 (52)	97.87 (46)	97.32 (290)	98.18 (270)
Pill acceptability	yes	1.23 (3)	0.44 (1)	1.85 (1)	2.13 (1)	1.34 (4)	0.73 (2)
	no	98.77 (241)	99.56 (227)	98.15 (53)	97.87 (46)	98.66 (294)	99.27 (273)
IUD acceptability	yes	1.23 (3)	0 (0)	1.85 (1)	0 (0)	1.34 (4)	0 (0)
	no	98.77 (241)	100 (228)	98.15 (53)	100 (47)	98.66 (294)	100 (275)
Injection acceptability	yes	0.82 (2)	1.32 (3)	0 (0)	2.13 (1)	0.67 (2)	1.45 (4)
	no	99.18 (242)	98.68 (225)	100 (54)	97.87 (46)	99.33 (296)	98.55 (271)
Implant acceptability	yes	0.41 (1)	0.88 (2)	0 (0)	0 (0)	0.34 (1)	0.73 (2)
	no	99.59 (243)	99.12 (226)	100 (54)	100 (47)	99.66 (297)	99.27 (273)

*The response 'not married' was used as a proxy for not being sexually active

**IUD = intrauterine device

***LAM = Lactational amenorrhea method

Appendix 18. Baseline characteristics by follow-up status (Palestine)

		Primary outcome completers		Primary outcome non-completers		All participants	
		Control N = 235 % (n)	**Intervention** N = 229 % (n)	**Control** N = 54 % (n)	**Intervention** N = 60 % (n)	**Control** N = 289 % (n)	**Intervention** N = 289 % (n)
Age	mean [sd]	21.38 [1.73]	21.18 [1.70]	21.29 [1.97]	21.18 [1.93]	21.36 [1.77]	21.18 [1.75]
	18-19	24.68 (58)	32.75 (75)	31.48 (17)	31.67 (19)	25.95 (75)	32.53 (94)
	20-24	75.32 (177)	67.25 (154)	68.52 (37)	68.33 (41)	74.05 (214)	67.47 (195)
Marital status	married	40.43 (95)	39.74 (91)	40.74 (22)	35.00 (21)	40.48 (117)	38.75 (112)
	not-married	59.57 (140)	60.26 (138)	59.26 (32)	65.00 (39)	59.52 (172)	61.25 (177)
Number of children	0	73.62 (173)	79.48 (182)	66.67 (36)	80.00 (48)	72.32 (209)	79.58 (230)
	1	13.62 (32)	10.92 (25)	27.78 (15)	10.00 (6)	16.26 (47)	10.73 (31)
	2 or more	12.77 (30)	9.61 (22)	5.56 (3)	10.00 (6)	11.42 (33)	9.69 (28)
Residence	city	48.51 (114)	46.72 (107)	38.89 (21)	51.67 (31)	46.71 (135)	47.75 (138)
	village	47.23 (111)	48.1 (112)	51.85 (28)	38.33 (23)	48.10 (139)	46.71 (135)
	camp	3.40 (8)	3.93 (9)	7.41 (4)	8.33 (5)	4.15 (12)	4.84 (14)
	Bedouin community	0.85 (2)	0.44 (1)	1.85 (1)	1.67 (1)	1.04 (3)	0.69 (2)
Occupation	school	2.13 (5)	0.44 (1)	-	-	1.73 (5)	0.35 (1)
	university	50.21 (118)	55.02 (126)	40.74 (22)	43.33 (26)	48.44 (140)	52.60 (152)
	working	4.26 (10)	3.06 (7)	9.26 (5)	5.00 (3)	5.19 (15)	3.46 (10)
	training	12.34 (29)	14.85 (34)	25.93 (14)	20.00 (12)	14.88 (43)	15.92 (46)
	parent	22.8 (54)	19.65 (45)	20.37 (11)	21.67 (13)	22.49 (65)	20.07 (58)
	not working	6.38 (15)	6.11 (14)	3.70 (2)	8.33 (5)	5.88 (17)	6.57 (19)
	university & working	0.43 (1)	0.44 (1)	-	-	0.35 (1)	0.35 (1)
	university & parent	0.85 (2)	-	-	-	0.69 (2)	-
	school & parent	0.43 (1)	-	-	1.67 (1)	0.35 (1)	0.35 (1)
	working, training & parent	-	0.44 (1)	-	-	-	0.35 (1)
	primary	0.43 (1)	0.87 (2)	1.85 (1)	-	0.69 (2)	0.69 (2)
	secondary	21.70 (51)	19.21 (44)	27.78 (15)	28.33 (17)	22.84 (66)	21.11 (61)

		Primary outcome completers		Primary outcome non-completers		All participants	
		Control N = 235 % (n)	**Intervention** N = 229 % (n)	**Control** N = 54 % (n)	**Intervention** N = 60 % (n)	**Control** N = 289 % (n)	**Intervention** N = 289 % (n)
Highest level of education completed	university	68.94 (162)	69.00 (158)	53.70 (29)	56.67 (34)	66.09 (191)	66.44 (192)
	technical	8.94 (21)	10.92 (25)	16.67 (9)	15.00 (9)	10.38 (30)	11.76 (34)
Current pregnancy intention (‘*Do you want a pregnancy now?)*	yes	16.60 (39)	20.52 (47)	14.81 (8)	18.33 (11)	16.26 (47)	20.07 (58)
	no	25.53 (60)	26.20 (60)	25.93 (14)	18.33 (11)	25.61 (74)	24.57 (71)
	unsure	4.26 (10)	1.75 (4)	3.70 (2)	-	4.15 (12)	1.38 (4)
	not married [a]	53.62 (126)	51.53 (118)	55.56 (30)	63.33 (38)	53.98 (156)	53.98 (156)
Baseline method	none	41.28 (97)	43.23 (99)	31.48 (17)	35.00 (21)	39.45 (114)	41.52 (120)
	male condom	0.85 (2)	0.87 (2)	-	-	0.69 (2)	0.69 (2)
	not married [a]	52.34 (123)	52.84 (121)	59.26 (32)	60.00 (36)	53.63 (155)	54.33 (157)
	calendar	0.85 (2)	0.44 (1)	1.85 (1)	-	1.04 (3)	0.35 (1)
	LAM [b]	2.55 (6)	1.31 (3)	5.56 (3)	1.67 (1)	3.11 (9)	1.38 (4)
	withdrawal	1.70 (4)	0.87 (2)	1.85 (1)	3.33 (2)	2.08 (6)	1.38 (4)
	none-withdrawal	0.43 (1)	-	-	-	-	-
	other	-	0.44 (1)	-	-	-	0.35 (1)
At least one effective method is acceptable	yes	9.36 (22)	5.24 (12)	14.81 (8)	8.33 (5)	10.38 (30)	5.88 (17)
	no	90.64 (213)	94.76 (217)	85.19 (46)	91.67 (55)	89.62 (259)	94.12 (272)
Pill acceptability	yes	3.40 (8)	2.62 (6)	5.56 (3)	5.00 (3)	3.81 (11)	3.11 (9)
	no	96.60 (227)	97.38 (223)	94.44 (51)	95.00 (57)	96.19 (278)	96.89 (280)
IUD [c] acceptability	yes	4.26 (10)	0.87 (2)	5.56 (3)	5.00 (3)	4.50 (13)	1.73 (5)
	no	95.74 (225)	99.13 (227)	94.44 (51)	95.00 (57)	95.50 (276)	98.27 (284)
Injection acceptability	yes	1.28 (3)	1.31 (3)	1.85 (1)	1.67 (1)	1.38 (4)	1.38 (4)
	no	98.72 (232)	98.69 (226)	98.15 (53)	98.33 (59)	98.62 (285)	98.62 (285)
Implant acceptability	yes	2.55 (6)	1.31 (3)	5.56 (3)	3.33 (2)	3.11 (9)	1.73 (5)
	no	97.45 (229)	98.6 (226)	94.44 (51)	96.67 (58)	96.89 (280)	98.27 (284)
Patch acceptability	yes	0.85 (2)	0.44 (1)	-	-	0.69 (2)	0.35 (1)
	no	99.15 (233)	99.56 (228)	100 (54)	100 (60)	99.31 (287)	99.65 (288)

[a] the response ‘not married’ was used as a proxy for sexual activity

[b] LAM Lactational amenorrhea method

[c] IUD Intrauterine device

Appendix 19. Baseline characteristics by follow-up status (Bolivia)

		Primary outcome use completers		Primary outcome use non-completers		All participants	
		Control N = 215 % (n)	**Intervention** N = 214 % (n)	**Control** N = 104 % (n)	**Intervention** N = 107 % (n)	**Control** N = 319 % (n)	**Intervention** N = 321 % (n)
Age	mean [sd]	20.69 [2.54]	20.32 [2.61]	19.87 [2.50]	20.17 [2.53]	20.42 [2.56]	20.27 [2.58]
	16-19	42.33 (91)	51.40 (110)	56.73 (59)	51.40 (55)	47.02 (150)	51.40 (165)
	20-24	57.67 (124)	48.60 (104)	43.27 (45)	48.60 (52)	52.98 (169)	48.60 (156)
Marital status	married	3.72 (8)	6.07 (13)	5.77 (6)	4.67 (5)	4.39 (14)	5.61 (18)
	not-married	96.28 (207)	93.93 (201)	94.23 (98)	95.33 (102)	95.61 (305)	94.39 (303)
Number of children	0	91.63 (197)	89.25 (191)	92.31 (96)	88.79 (95)	91.85 (293)	89.10 (286)
	1	5.58 (12)	7.01 (15)	3.85 (4)	5.61 (6)	5.02 (16)	6.54 (21)
	2 or more	2.79 (6)	3.74 (8)	3.85 (4)	5.61 (6)	3.13 (10)	4.36 (14)
Indigenous origin (ethnicity)	Aymara	59.53 (128)	55.61 (119)	50.96 (53)	56.07 (60)	56.74 (181)	55.76 (179)
	Guarani	0.47 (1)	0.47 (1)	-	1.87 (2)	0.31 (1)	0.93 (3)
	Quechua	3.72 (8)	2.34 (5)	4.81 (5)	0.93 (1)	4.08 (13)	1.87 (6)
	other	2.79 (6)	2.80 (6)	3.85 (4)	3.74 (4)	3.13 (10)	3.12 (10)
	none	33.49 (72)	38.79 (83)	40.38 (42)	37.38 (40)	35.74 (114)	38.32 (123)
Occupation	school	15.35 (33)	16.82 (36)	26.92 (28)	20.56 (22)	19.12 (61)	18.07 (58)
	university	57.21 (123)	57.01 (122)	50.96 (53)	55.14 (59)	55.17 (176)	56.39 (181)
	working	9.77 (21)	12.62 (27)	8.65 (9)	8.41 (9)	9.40 (30)	11.21 (36)
	training	5.12 (11)	5.61 (12)	7.69 (8)	4.67 (5)	5.96 (19)	5.30 (17)
	not working	1.40 (3)	0.93 (2)	0.96 (1)	1.87 (2)	1.25 (4)	1.25 (4)
	university & working	8.84 (19)	6.07 (13)	4.81 (5)	9.35 (10)	7.52 (24)	7.17 (23)
	school & working	0.93 (2)	0.47 (1)	-	-	0.63 (2)	0.31 (1)
	training & working	1.40 (3)	0.47 (1)	-	-	0.94 (3)	0.31 (1)
Highest level of education completed	primary	4.65 (10)	3.74 (8)	8.65 (9)	4.67 (5)	5.96 (19)	4.05 (13)
	secondary	70.70 (152)	73.36 (157)	72.12 (75)	72.90 (78)	71.16 (227)	73.21 (235)
	university	22.79 (49)	20.56 (44)	18.27 (19)	16.82 (18)	21.32 (68)	19.31 (62)
	technical	1.86 (4)	2.34 (5)	0.96 (1)	5.61 (6)	1.57 (5)	3.43 (11)
Baseline method	none	73.95 (159)	79.44 (170)	77.88 (81)	81.31 (87)	75.24 (240)	80.06 (257)
	male condom	14.88 (32)	10.75 (23)	13.46 (14)	12.15 (13)	14.42 (46)	11.21 (36)

		Primary outcome use completers		Primary outcome use non-completers		All participants	
		Control N = 215 % (n)	**Intervention** N = 214 % (n)	**Control** N = 104 % (n)	**Intervention** N = 107 % (n)	**Control** N = 319 % (n)	**Intervention** N = 321 % (n)
	female condom	3.26 (7)	1.40 (3)	1.92 (2)	0.93 (1)	2.82 (9)	1.25 (4)
	calendar	1.40 (3)	2.80 (6)	-	0.93 (1)	0.94 (3)	2.18 (7)
	withdrawal	0.47 (1)	-	0.96 (1)	-	0.63 (2)	-
	male & female condom	0.93 (2)	-	-	-	0.63 (2)	-
	calendar & withdrawal	-	0.47 (1)	-	0.93 (1)	-	0.62 (2)
	other	-	-	5.77 (6)	3.74 (4)	0.63 (2)	-
At least one effective method is acceptable	yes	8.37 (18)	9.35 (20)	7.69 (8)	5.61 (6)	8.15 (26)	8.10 (26)
	no	91.63 (197)	90.65 (194)	92.31 (96)	94.39 (101)	91.85 (293)	91.90 (295)
Pill acceptability	yes	0.93 (2)	1.87 (4)	-	0.93 (1)	0.63 (2)	1.56 (5)
	no	99.07 (213)	98.13 (210)	100 (104)	99.07 (106)	99.37 (317)	98.44 (316)
IUD [a] acceptability	yes	1.40 (3)	1.40 (3)	2.88 (3)	0.93 (1)	1.88 (6)	1.25 (4)
	no	98.60 (212)	98.60 (211)	97.12 (101)	99.07 (106)	98.12 (313)	98.75 (317)
Injection acceptability	yes	2.70 (6)	1.87 (4)	2.88 (3)	1.87 (2)	2.82 (9)	1.87 (6)
	no	97.21 (209)	98.13 (210)	97.12 (101)	98.13 (105)	97.18 (310)	98.13 (315)
Implant acceptability	yes	1.86 (4)	3.27 (7)	0.96 (1)	2.80 (3)	1.57 (5)	3.12 (10)
	no	98.14 (211)	96.73 (207)	99.04 (103)	97.20 (104)	98.43 (314)	96.88 (311)
Patch acceptability	yes	3.72 (8)	2.80 (6)	2.88 (3)	1.87 (2)	3.45 (11)	2.49 (8)
	no	96.28 (207)	97.20 (208)	97.12 (101)	98.13 (105)	96.55 (308)	97.51 (313)

[a] IUD = Intrauterine device

Appendix 20. Trial interviews: Discussion guides

Tajikistan-intervention group guide

Introduction

- Thank you for agreeing to the interview. The purpose of the interview is to understand how it was for you to receive the messages. This is so we can understand better how they may have influenced people.
- Please be as honest as possible. If things have not changed for you, we would like to know that. There are no right or wrong answers.
- You don't have to talk about anything that you don't want to talk about.
- The interview will last up to 60 minutes and you can end the interview at any time.
- Check again that they are ok with audio recording, explain confidentiality and anonymity

START RECORDER

"Just to clarify that when I ask about the 'messages' I mean the instant messages that were sent to you though the app."

Receiving the messages

1) What was it like to receive the messages?
2) Did you have any trouble receiving them? [were there any times that the messages couldn't be delivered?]
3) What did you think about the number of messages you received? [too many/too little/just right? Why?]
4) What did you do when you received a message? [e.g. did you read it right away, save it for a time when you were alone, etc.?]
5) How many of the messages did you read? [All of them, some, none? Why?]
6) Did you stop the messages? [Why? When did you stop them, i.e. very early on, in what month?]
7) Did you keep the messages or delete them? [Which ones did you keep or delete? Why?]
8) Did you re-read any of the messages? [Which ones? Why?]

Confidentiality

1) Were you concerned about others seeing the text messages? [If yes, how did you deal with it?]
2) Did anyone else read your messages? [Who was this person? How did you feel about it?]
3) Did you discuss information in the messages with anyone? [Who was this person? How did you feel about this?]
4) Did anything unwanted happen as a consequence of receiving the messages?

Knowledge

1) What did you learn from the messages? [what was the most important thing that you learned from the messages? Why was this the most important?]
2) How has what you learned changed how you think & feel about effective contraception (IUD, pill, injection, implant)? [How did the messages change your views?]

Attitudes

1) What did you think about using effective contraception before the study? Have your beliefs changed? How have they changed and why?
2) What did you think about going to a service contraception before the study? Has that changed? How has it changed and why?
3) What did you think about talking to a partner about contraception before the study? Has that changed? How has it changed and why?

Agency

1) How has your confidence in using contraception changed since being in the study? [Why do you think it has changed? Do you feel you have control over using contraception?]

2) How do you feel about going to a service for contraception now? Has this changed? Why? Do you feel like you could go there if you wanted to? Why?
3) How has your confidence in talking to partners about confidence changed since being in the study? Do you feel like you can talk about it if you want to? Why/how?
4) Did you talk to your partner before about contraception? Have you talked to them now? Do you feel that you have control over talking to your partner?

Behaviour and intention

1) Have the messages influenced your behaviour in any way? [What changed? Why?]
2) Did you intend to use effective contraception (including the IUD) before the study? Do you intend to ever use it? [Why has this changed?]
3) What about going to a service? Have you been since joining the study? Do you intend to go sometime?
4) And talking to a partner- have you talked about contraception? Do you intend to sometime?

Environment

1) Is there anything that prevents you from doing what you want to do with regard to your reproductive health? How is this a barrier? Can it be overcome? How?
2) All of these things- using, going to a service, talking to a partner- if you intend to do them, is there anything that is preventing you from doing them now?

The app

1) Did you deinstall the app? [if yes, why?]
2) What did you think of the app contraception pages? [did you read all, some, most or none of them?]

[if they read the app contraception pages]:

3) What did you learn from the app contraception pages?
4) Did the app contraception pages influence you in any way? [What changed? Why?]
5) How were the app contraception pages and the messages different? [Did you prefer one over the other? Why/why not?]

Wrap up

- What advice do you have about how we could improve the messages?
- Would you recommend the messages to other people? [Who? Why?]
- Do you think that all young people should be offered these messages? Why?
- Thinking about all that we talked about today, what do you feel is the most important?
- Anything else to add?
- Thank you, you've been a big help! (if they want any more information, show our contact details again)

Tajikistan-control group guide

Introduction

- Thank you for agreeing to the interview. The purpose of the interview is to understand how you found the app contraception pages.
- Please be as honest as possible. If things have not changed for you, we would like to know that. There are no right or wrong answers.
- You don't have to talk about anything that you don't want to talk about.
- The interview will last up to 60 minutes and you can end the interview at any time.
- Check again that they are ok with audio recording, explain confidentiality and anonymity
-

START RECORDER

Having the app on your phone

1) What was it like to have the app on your phone?

2) Did you deinstall the app? [if yes, why?]

Confidentiality

3) Were you concerned about others seeing the app on your phone? [If yes, how did you deal with it?]
4) Did anyone else look at the app on your phone? [Who was this person? How did you feel about it?]
5) Did you discuss information in the app with anyone? [Who was this person? How did you feel about this?]
6) Did anything unwanted happen as a consequence of having the app on your phone?

Knowledge

7) Did you read the app contraception pages? [why/why not?]

8) [If they read the app contraception pages]

9) What did you think of the app contraception pages? [did you read all, some, most or none of them?]
10) What did you learn from the app contraception pages? [what was the most important thing that you learned? Why was this the most important?]
11) How has what you learned changed how you think & feel about effective contraception (IUD, pill, injection, implant)? [How did the app change your views?]

Attitudes

12) What did you think about using effective contraception before the study? Have your beliefs changed? How have they changed and why?
13) What did you think about going to a service contraception before the study? Has that changed? How has it changed and why?
14) What did you think about talking to a partner about contraception before the study? Has that changed? How has it changed and why?

Agency

15) How has your confidence in using contraception changed since being in the study? [Why do you think it has changed? Do you feel you have control over using contraception?]
16) How do you feel about going to a service for contraception now? Has this changed? Why? Do you feel like you could go there if you wanted to? Why?
17) How has your confidence in talking to partners about confidence changed since being in the study? Do you feel like you can talk about it if you want to? Why/how?
18) Did you talk to your partner before about contraception? Have you talked to them now? Do you feel that you have control over talking to your partner?

Behaviour and intention

19) Have the app influenced your behaviour in any way? [What changed? Why?]
20) Did you intend to use effective contraception (including the IUD) before the study? Do you intend to ever use it? [Why has this changed?]
21) What about going to a service? Have you been since joining the study? Do you intend to go sometime?
22) And talking to a partner- have you talked about contraception? Do you intend to sometime?

Environment

23) Is there anything that prevents you from doing what you want to do with regard to your reproductive health? How is this a barrier? Can it be overcome? How?
24) All of these things- using, going to a service, talking to a partner- if you intend to do them, is there anything that is preventing you from doing them now?

Wrap up

- What advice do you have about how we could improve the app?
- Would you recommend the app to other people? [Who? Why?]
- Do you think that all young people should be offered the app? Why?
- Thinking about all that we talked about today, what do you feel is the most important?
- Anything else to add?
- Thank you, you've been a big help! (if they want any more information, show our contact details again)

Palestine

Introduction

- Thank you for agreeing to the interview. The purpose of the interview is to understand how it was for you to receive the messages. This is so we can understand better how they may have influenced people.
- Please be as honest as possible. If things have not changed for you, we would like to know that. There are no right or wrong answers.
- You don't have to talk about anything that you don't want to talk about.
- The interview will last up to 60 minutes and you can end the interview at any time.
- Check again that they are ok with audio recording, explain confidentiality and anonymity

START RECORDER

Receiving the messages

1) What was it like to receive the messages?
2) Did you have any trouble receiving them? [were there any times that the messages couldn't be delivered?]
3) What did you think about the number of messages you received? [too many/too little/just right? Why?]
4) What did you do when you received a message? [e.g. did you read it right away, save it for a time when you were alone, etc.?]
5) How many of the messages did you read? [All of them, some, none? Why?]
6) Did you stop the messages? [Why? When did you stop them, i.e. very early on, in what month?]
7) Did you keep the messages or delete them? [Which ones did you keep or delete? Why?]
8) Did you re-read any of the messages? [Which ones? Why?]

Confidentiality

9) Were you concerned about others seeing the text messages? [If yes, how did you deal with it?]
10) Did anyone else read your messages? [Who was this person? How did you feel about it?]
11) Did you discuss information in the messages with anyone? [Who was this person? How did you feel about this?]
12) Did anything unwanted happen as a consequence of receiving the messages?

Knowledge

13) What did you learn from the messages? [what was the most important thing that you learned from the messages? Why was this the most important?]
14) How has what you learned changed how you think & feel about effective contraception (IUD, pill, injection, implant, patch)? [How did the messages change your views?]

Attitudes

15) What did you think about using effective contraception before the study? Have your beliefs changed? How have they changed and why?
16) What did you think about going to a service contraception before the study? Has that changed? How has it changed and why?
17) What did you think about talking to a partner about contraception before the study? Has that changed? How has it changed and why?

Agency

18) Has your confidence change since being in the study? [How has it changed? Why do you think it has changed? Do you feel you have control over using contraception?]
19) How do you feel about going to a service for contraception now? Has this changed? Why? Do you feel like you could go there if you wanted to? Why?
20) Has your confidence in talking to partners about contraception changed since being in the study? [How has it changed? Why do you think it has changed? Do you feel like you can talk about it if you want to? Why/how?]

21) Did you talk to your partner before about contraception? Have you talked to them now? Do you feel that you have control over talking to your partner?

Behaviour and intention

22) Have the messages influenced your behaviour in any way? [What changed? Why?]
23) Did you intend to use effective contraception (including the IUD) before the study? Do you intend to ever use it? [Why has this changed?]
24) What about going to a service? Have you been since joining the study? Do you intend to go sometime?
25) And talking to a partner- have you talked about contraception? Do you intend to sometime?

Environment

26) Is there anything that prevents you from doing what you want to do with regard to your reproductive health? How is this a barrier? Can it be overcome? How?
27) All of these things- using, going to a service, talking to a partner- if you intend to do them, is there anything that is preventing you from doing them now?

Wrap up

- What advice do you have about how we could improve the messages?
- Would you recommend the messages to other people? [Who? Why?]
- Do you think that all young people should be offered these messages? Why?
- Thinking about all that we talked about today, what do you feel is the most important?
- Anything else to add?
- Thank you, you've been a big help! (if they want any more information, show our contact details again)

Bolivia-intervention group guide

Introduction

- Thank you for agreeing to the interview. The purpose of the interview is to understand how it was for you to receive the messages. This is so we can understand better how they may have influenced people.
- Please be as honest as possible. If things have not changed for you, we would like to know that. There are no right or wrong answers.
- You don't have to talk about anything that you don't want to talk about.
- The interview will last up to 60 minutes and you can end the interview at any time.
- Check again that they are ok with audio recording, explain confidentiality and anonymity

START RECORDER

"Just to clarify that when I ask about the 'messages' I mean the instant messages that were sent to you though the app."

Receiving the messages

1) What was it like to receive the messages?
2) Did you have any trouble receiving them? [were there any times that the messages couldn't be delivered?]
3) What did you think about the number of messages you received? [too many/too little/just right? Why?]
4) What did you do when you received a message? [e.g. did you read it right away, save it for a time when you were alone, etc.?]
5) How many of the messages did you read? [All of them, some, none? Why?]
6) Did you stop the messages? [Why? When did you stop them, i.e. very early on, in what month?]
7) Did you keep the messages or delete them? [Which ones did you keep or delete? Why?]
8) Did you re-read any of the messages? [Which ones? Why?]

Confidentiality

9) Were you concerned about others seeing the text messages? [If yes, how did you deal with it?]
10) Did anyone else read your messages? [Who was this person? How did you feel about it?]
11) Did you discuss information in the messages with anyone? [Who was this person? How did you feel about this?]
12) Did anything unwanted happen as a consequence of receiving the messages?

Knowledge

13) What did you learn from the messages? [what was the most important thing that you learned from the messages? Why was this the most important?]
14) How has what you learned changed how you think & feel about effective contraception (IUD, pill, injection, implant)? [How did the messages change your views?]

Attitudes

15) What did you think about using effective contraception before the study? Have your beliefs changed? How have they changed and why?
16) What did you think about going to a service contraception before the study? Has that changed? How has it changed and why?
17) What did you think about talking to a partner about contraception before the study? Has that changed? How has it changed and why?

Agency

18) How has your confidence in using contraception changed since being in the study? [Why do you think it has changed? Do you feel you have control over using contraception?]

19) How do you feel about going to a service for contraception now? Has this changed? Why? Do you feel like you could go there if you wanted to? Why?
20) How has your confidence in talking to partners about confidence changed since being in the study? Do you feel like you can talk about it if you want to? Why/how?
21) Did you talk to your partner before about contraception? Have you talked to them now? Do you feel that you have control over talking to your partner?

Behaviour and intention

22) Have the messages influenced your behaviour in any way? [What changed? Why?]
23) Did you intend to use effective contraception (including the IUD) before the study? Do you intend to ever use it? [Why has this changed?]
24) What about going to a service? Have you been since joining the study? Do you intend to go sometime?
25) And talking to a partner- have you talked about contraception? Do you intend to sometime?

Environment

26) Is there anything that prevents you from doing what you want to do with regard to your reproductive health? How is this a barrier? Can it be overcome? How?
27) All of these things- using, going to a service, talking to a partner- if you intend to do them, is there anything that is preventing you from doing them now?

The app

28) Did you deinstall the app? [if yes, why?]
29) What did you think of the app contraception pages? [did you read all, some, most or none of them?]
30) [if they read the app contraception pages]:
31) What did you learn from the app contraception pages?
32) Did the app contraception pages influence you in any way? [What changed? Why?]
33) How were the app contraception pages and the messages different? [Did you prefer one over the other? Why/why not?]

Wrap up

- What advice do you have about how we could improve the messages?
- Would you recommend the messages to other people? [Who? Why?]
- Do you think that all young people should be offered these messages? Why?
- Thinking about all that we talked about today, what do you feel is the most important?
- Anything else to add?
- Thank you, you've been a big help! (if they want any more information, show our contact details again)

Bolivia-control group guide

Introduction

- Thank you for agreeing to the interview. The purpose of the interview is to understand how you found the app contraception pages.
- Please be as honest as possible. If things have not changed for you, we would like to know that. There are no right or wrong answers.
- You don't have to talk about anything that you don't want to talk about.
- The interview will last up to 60 minutes and you can end the interview at any time.
- Check again that they are ok with audio recording, explain confidentiality and anonymity

START RECORDER

Having the app on your phone

1) What was it like to have the app on your phone?

2) Did you deinstall the app? [if yes, why?]

Confidentiality

3) Were you concerned about others seeing the app on your phone? [If yes, how did you deal with it?]
4) Did anyone else look at the app on your phone? [Who was this person? How did you feel about it?]
5) Did you discuss information in the app with anyone? [Who was this person? How did you feel about this?]
6) Did anything unwanted happen as a consequence of having the app on your phone?

Knowledge

7) Did you read the app contraception pages? [why/why not?]

8) [If they read the app contraception pages]

9) What did you think of the app contraception pages? [did you read all, some, most or none of them?]
10) What did you learn from the app contraception pages? [what was the most important thing that you learned? Why was this the most important?]
11) How has what you learned changed how you think & feel about effective contraception (IUD, pill, injection, implant)? [How did the app change your views?]

Attitudes

12) What did you think about using effective contraception before the study? Have your beliefs changed? How have they changed and why?
13) What did you think about going to a service contraception before the study? Has that changed? How has it changed and why?
14) What did you think about talking to a partner about contraception before the study? Has that changed? How has it changed and why?

Agency

15) How has your confidence in using contraception changed since being in the study? [Why do you think it has changed? Do you feel you have control over using contraception?]
16) How do you feel about going to a service for contraception now? Has this changed? Why? Do you feel like you could go there if you wanted to? Why?
17) How has your confidence in talking to partners about confidence changed since being in the study? Do you feel like you can talk about it if you want to? Why/how?
18) Did you talk to your partner before about contraception? Have you talked to them now? Do you feel that you have control over talking to your partner?

Behaviour and intention

19) Have the app influenced your behaviour in any way? [What changed? Why?]
20) Did you intend to use effective contraception (including the IUD) before the study? Do you intend to ever use it? [Why has this changed?]
21) What about going to a service? Have you been since joining the study? Do you intend to go sometime?
22) And talking to a partner- have you talked about contraception? Do you intend to sometime?

Environment

23) Is there anything that prevents you from doing what you want to do with regard to your reproductive health? How is this a barrier? Can it be overcome? How?
24) All of these things- using, going to a service, talking to a partner- if you intend to do them, is there anything that is preventing you from doing them now?

Wrap up

- What advice do you have about how we could improve the app?
- Would you recommend the app to other people? [Who? Why?]
- Do you think that all young people should be offered the app? Why?
- Thinking about all that we talked about today, what do you feel is the most important?
- Anything else to add?
- Thank you, you've been a big help! (if they want any more information, show our contact details again)

Appendix 21. Trial interviews: Participant information sheets

Tajikistan

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?
We would like to ask you what you think about the messages that you received while taking part in the randomised controlled trial. We'd like to understand how the messages may have affected you. This will help us better understand how and why the intervention may have worked.

Who is organising and funding the study?
The study is being conducted by TFPA and the London School of Hygiene & Tropical Medicine (LSHTM). TFPA provides high quality sexual and reproductive health services in Tajikistan. LSHTM is a world-leading centre for research and postgraduate education in public and global health. The study is funded by the International Planned Parenthood Federation (IPPF).

Why have I been chosen?
You have taken part in the randomised controlled trial and receive the contraception messages.

Do I have to take part?
No, you do not have to take part. It is your choice. If you choose not to take part, all the services you receive will continue as normal.

What will happen if I take part?
If you decide to take part, a study researcher will arrange a time for you to come to TFPA at your convenience. You will be interviewed by the Project Coordinator. With your permission, the interview will be audio recorded. You will not be named on the recording. We will ask you about your experiences with receiving the messages and how it may have influenced how you think and feel about contraception.

What do I have to do?
If you decide to take part, we will ask you to complete the consent form.

How long will it take?
The interview will take up to 60 minutes. You can stop the interview at any time.

Will you compensate me for taking part?
We will offer transportation reimbursement.

What are the alternatives?
You do not have to take part.

What are the possible disadvantages of taking part?
The study will take some of your time. Because the interview is about contraception, we will be talking about sexual and reproductive health. You do not have to share anything that you are not comfortable sharing. You do not have to give us a reason for not sharing.

What are the possible advantages of taking part?
You may enjoy taking part in the research, sharing your experiences and knowing that your participation can help us understand how best to support young people. You can add your participation in the study to your resume.

What if I do not want to take part anymore?
You can end the interview at any time by telling the interviewer that you'd like to stop. You do not have to give a reason for ending the interview. Ending the interview will not affect the services that you receive.

What if there is a problem?
You can talk to the Project Coordinator at any time (details below).

Will my taking part be confidential?
Yes. We will not share any information about you with anyone outside of the research team. Your comments will be anonymous (they will be identified by a research number only). The audio recording will be kept on a password protected computer. No one else besides the research team will listen to the recording. You will not be named in the recording.

What will happen with the results of this study?
Your name will not be used in the results of this study. Your views will help us understand how the intervention may have supported young people. We will share the results through publication in journals and through presenting at conferences. If you would like to know the results of the study, please contact the team (details below) and we will share them with you.

If the results of the study show that the messages have helped, they will be made available to all young people in Tajikistan.

Who has reviewed this study?
The London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee and the Tajikistan National Scientific and Research Centre on Paediatrics and Child Surgery (NSRCP&CS).

Thank you for taking the time to consider taking part

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Palestine

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?
We would like to ask you what you think about the messages that you received while taking part in the randomised controlled trial. We'd like to understand how the messages may have affected you. This will help us better understand how and why the intervention may have worked.

Who is organising and funding the study?
The study is being conducted by the Palestinian Family Planning and Protection Association (PFPPA) and the London School of Hygiene & Tropical Medicine (LSHTM). PFPPA provides high quality sexual and reproductive health services in the Palestinian Authority. LSHTM is a world-leading centre for research and postgraduate education in public and global health. The study is funded by the International Planned Parenthood Federation (IPPF).

Why have I been chosen?
You have taken part in the randomised controlled trial and have received the contraception messages.

Do I have to take part?
No, you do not have to take part. It is your choice. If you choose not to take part, all the services you receive will continue as normal.

What will happen if I take part?
If you decide to take part, a study researcher will arrange a time for you to come to PFPPA at your convenience. You will be interviewed by the Project Coordinator. With your permission, the interview will be audio recorded. You will not be named on the recording. We will ask you about your experiences with receiving the messages and how it may have influenced how you think and feel about contraception.

What do I have to do?
If you decide to take part, we will ask you to complete the consent form.

How long will it take?
The interview will take up to 60 minutes. You can stop the interview at any time.

Will you compensate me for taking part?
We will offer transportation reimbursement.

What are the alternatives?
You do not have to take part.

What are the possible disadvantages of taking part?
The study will take some of your time. Because the interview is about contraception, we will be talking about sexual and reproductive health. You do not have to share anything that you are not comfortable sharing. You do not have to give us a reason for not sharing.

What are the possible advantages of taking part?
You may enjoy taking part in the research, sharing your experiences and knowing that your participation can help us understand how best to support young people.

What if I do not want to take part anymore?
You can end the interview at any time by telling the interviewer that you'd like to stop. You do not have to give a reason for ending the interview. Ending the interview will not affect the services that you receive.

What if there is a problem?
You can talk to the Project Coordinator at any time (details below).

Will my taking part be confidential?
Yes. We will not share any information about you with anyone outside of the research team. Your comments will be anonymous (they will be identified by a research number only). The audio recording will be kept on a password protected computer. No one else besides the research team will listen to the recording. You will not be named in the recording.

What will happen with the results of this study?
Your name will not be used in the results of this study. Your views will help us understand how the intervention may have supported young people. We will share the results through publication in journals and through presenting at conferences. If you would like to know the results of the study, please contact the team (details below) and we will share them with you.

If the results of the study show that the messages have helped, they will be made available to all young people in the West Bank.

Who has reviewed this study?
The London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee and the State of Palestine Ministry of Health.

Thank you for taking the time to consider taking part

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Bolivia

We are inviting you to take part in a research study. Before you decide, it is important that you know why we are doing the study and what is involved. Please read the following information carefully.

What is the study?
We would like to ask you what you think about the messages that you received while taking part in the randomised controlled trial. We'd like to understand how the messages may have affected you. This will help us better understand how and why the intervention may have worked.

Who is organising and funding the study?
The study is being conducted by CIES and the London School of Hygiene & Tropical Medicine (LSHTM). CIES provides high quality sexual and reproductive health services in Bolivia. LSHTM is a world-leading centre for research and postgraduate education in public and global health. The study is funded by the International Planned Parenthood Federation (IPPF).

Why have I been chosen?
You have taken part in the randomised controlled trial and have received the contraception messages.

Do I have to take part?
No, you do not have to take part. It is your choice. If you choose not to take part, all the services you receive will continue as normal.

What will happen if I take part?
If you decide to take part, a study researcher will arrange a time for you to come to CIES at your convenience. You will be interviewed by the Project Coordinator. With your permission, the interview will be audio recorded. You will not be named on the recording. We will ask you about your experiences with receiving the messages and how it may have influenced how you think and feel about contraception.

What do I have to do?
If you decide to take part, we will ask you to complete the consent form.

How long will it take?
The interview will take up to 60 minutes. You can stop the interview at any time.

Will you compensate me for taking part?
We will offer transportation reimbursement.

What are the alternatives?
You do not have to take part.

What are the possible disadvantages of taking part?
The study will take some of your time. Because the interview is about contraception, we will be talking about sexual and reproductive health. You do not have to share anything that you are not comfortable sharing. You do not have to give us a reason for not sharing.

What are the possible advantages of taking part?
You may enjoy taking part in the research, sharing your experiences and knowing that your participation can help us understand how best to support young people. You can add your participation in the study to your resume.

What if I do not want to take part anymore?
You can end the interview at any time by telling the interviewer that you'd like to stop. You do not have to give a reason for ending the interview. Ending the interview will not affect the services that you receive.

What if there is a problem?
You can talk to the Project Coordinator at any time (details below).

Will my taking part be confidential?
Yes. We will not share any information about you with anyone outside of the research team. Your comments will be anonymous (they will be identified by a research number only). The audio recording will be kept on a password protected computer. No one else besides the research team will listen to the recording. You will not be named in the recording.

What will happen with the results of this study?
Your name will not be used in the results of this study. Your views will help us understand how the intervention may have supported young people. We will share the results through publication in journals and through presenting at conferences. If you would like to know the results of the study, please contact the team (details below) and we will share them with you.

If the results of the study show that the messages have helped, they will be made available to all young people in Bolivia.

Who has reviewed this study?
The London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee and the Bolivian National Research Ethics Committee.

Thank you for taking the time to consider taking part

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Appendix 22. Trial interviews: Consent forms

Tajikistan

Project Coordinator: **Firuza Kulaeva**, the Tajik Family Planning Alliance (TFPA), 10 Rudaki Avenue, TC 'Sadbarg', 7th floor, Dushanbe, +992 (918) 69-9925, tfpa.inpro@gmail.com

Principal Investigator: Ona McCarthy, The London School of Hygiene and Tropical Medicine, Department of Population Health, Keppel St, WC1E 7HT, London, United Kingdom, ona.mccarthy@lshtm.ac.uk

	Please initial here
10. I have read the Information sheet for the above study (v1 19.02.16) or it has been read to me. I have had the opportunity to consider the information in it.	
11. I have had the opportunity to ask questions and I am happy with the answers that you gave me.	
12. I understand that I do not have to take part if I do not want to.	
7. I understand that what I say will be written about but my real name will not be used.	
14. I understand that I do not have to talk about anything that I do not want to talk about.	
15. I understand that I am free to end the interview at any time without having to give a reason. I understand that this will not affect the services that I receive.	
16. **I consent to take part in the above study.**	

Name of participant (print) Signature of participant Date

Statement by person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of the consent form has been given to the participant.

Name of person taking consent (print) Signature of person taking consent Date

Palestine

Project Coordinator: Hanadi Zghayyer, Palestinian Family Planning and Protection Association (PFPPA), Industrial Zone, Wadi Al-Joze, Jerusalem, Palestine, + 9722-6280630, ipc@pfppa.org

Principal Investigator: Ona McCarthy, The London School of Hygiene and Tropical Medicine, Department of Population Health, Keppel St, WC1E 7HT, London, United Kingdom, ona.mccarthy@lshtm.ac.uk

		Please initial here
1.	I have read the Information sheet for the above study (v1 19.02.16) or it has been read to me. I have had the opportunity to consider the information in it.	
2.	I have had the opportunity to ask questions and I am happy with the answers that you gave me.	
3.	I understand that I do not have to take part if I do not want to.	
4.	I understand that what I say will be written about but my real name will not be used.	
5.	I understand that I do not have to talk about anything that I do not want to talk about.	
6.	I understand that I am free to end the interview at any time without having to give a reason. I understand that this will not affect the services that I receive.	
7.	**I consent to take part in the above study.**	

Name of participant (print) Signature of participant Date

Statement by person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of the consent form has been given to the participant.

Name of person taking consent (print) Signature of person taking consent Date

Bolivia

Project Coordinator: Verónica Osorio Calderón, CIES Salud Sexual - Salud Reproductiva, Calle 6 de Obrajes Nro. 614 – Casilla 9935, (591-2) 2788162, vosorio@cies.org.bo

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	Please initial here
1. I have read the Information sheet for the above study (v1 19.02.16) or it has been read to me. I have had the opportunity to consider the information in it.	
2. I have had the opportunity to ask questions and I am happy with the answers that you gave me.	
3. I understand that I do not have to take part if I do not want to.	
4. I understand that what I say will be written about but my real name will not be used.	
5. I understand that I do not have to talk about anything that I do not want to talk about.	
6. I understand that I am free to end the interview at any time without having to give a reason. I understand that this will not affect the services that I receive.	
7. **I consent to take part in the above study.**	

Name of participant (print) Signature of participant Date

Statement by person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of the consent form has been given to the participant.

Name of person taking consent (print) Signature of person taking consent Date