Video-augmentation of the Informed Consent Process in Mental Health Research: an Exploratory Study from India

Abhijit Nadkarni[a,b*], Sheena Wood[b], Ankur Garg[b], Danielle Fernandes[b], Ethel D'Souza[b], Urvita Bhatia[b,c]

[a]London School of Hygiene & Tropical Medicine, Keppel Street, London, UK WC1E 7HT
[b]Addictions Research Group, Sangath, Porvorim, Goa, India
[c]Oxford Brookes University, Oxford, UK

Word count (excluding references, tables, and other supplementary materials): 2233

*Corresponding author: abhijit.nadkarni@lshtm.ac.uk ; H No 451 (168), Bhatkar Waddo, Socorro, Bardez, Porvorim, Goa 403501 Tel-00917798889723

Human subjects protection statement: The institutional review board (IRB) of the implementing organisation approved the study.

Accepted for Publication

Abstract

Only around 50-75% of individuals fully understand the various aspects of informed consent in research. The aim of our study was to examine whether supplementing the conventional paper-based informed consent process with an audiovisual aid improves participants' understanding of the informed consent process and the information conveyed to them. Participants from two mental health/substance use intervention development studies were recruited for this study through consecutive sampling. They were then administered the traditional paper information and consenting process by itself or in combination with a video depicting the procedures of the study. Subsequently a bespoke questionnaire was administered to assess the participants' understanding of the information conveyed to them about the parent study. The various domains of the questionnaire were compared between those who were administered the two different consenting processes using the chi square test. 27 (58.7%) participants were administered the traditional consenting process and 19 were administered the video-supplemented consenting process. The video-supplemented consenting process was not superior to the traditional paper-based informed consent process on any of the domains examined. In settings with participants having a limited education, and in research involving people with mental health or substance use problems, further research is necessary to identify of contextually relevant best practices for the informed consent process.

Key words: Informed consent, mental health research, India

Accepted for Publication

1.1 Introduction

All researchers have to ensure that their research does not adversely affect the physical, social and psychological well-being of the participants; and this includes anticipation and mitigation of any potential harmful consequences for participants. According to the International Council for Harmonisation Good Clinical Practice guidelines, all research involving human participants must be preceded by informed consent, a process by which "a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate" (Manti and Licari, 2018). Thus the concept of 'informed consent' is built on the pillars of autonomy, self-determination and the affirmation of human rights and respect for human dignity. This includes the freedom and the responsibility of the individual to take decisions and an acceptance of the consequences of the research, after understanding all the relevant facts and risks involved. While there is a broad agreement over the principles of informed consent, the assumptions behind what constitutes the ability to provide informed consent has complex underpinnings of social constructs such as 'competent'.

Despite the critical nature of this process in research, only around 50-75% of individuals fully understand the various aspects of informed consent such as the nature of the study, their right to refuse to participate, their right to withdraw at any time, and the direct benefits of participation (Falagas et al., 2009; Tam et al., 2015). Researcher-side challenges that affect the validity of the informed consent process include poor communication techniques, limited time spent discussing the consent process and study details, and employing complex medical jargon and lengthy consent documents (Kadam, 2017). Besides these complexities of most consent processes, participant factors that adversely affect comprehension of the consenting process include older age, cognitive impairment, low educational attainment, and poor literacy skills (Paasche-Orlow et al., 2005; Raich et al., 2001; Sugarman et al., 1998). Many of these factors apply to informed consent processes in mental health research, especially in low- and middle-income countries (LMICs), where research volunteers are often from lower socio-economic backgrounds, illiterate, unfamiliar with the conduct of medical research, and have different views on disease causality (Lynöe et al., 2001).

Over the years, a number of innovative interventions have been utilised to modify the conventional paper-based informed consent process with the goal of increasing participants' comprehension of the information provided. These include video and computer multimedia, enhanced consent

Accepted for Publication

forms (improving readability, simplifying vocabulary, removing redundant information/shortening the form, using larger font, etc.), extended informed consent discussion, test/feedback (participants are tested on the material and given feedback on incorrect answers), and combinations of such interventions (Flory and Emanuel, 2004; Nishimura et al., 2013). The evidence for these interventions is mixed. Multimedia interventions rarely resulted in improved comprehension, but in some studies decreased participants' anxiety after consent, increased satisfaction and tolerability, helped increase retention of knowledge and increased willingness to participate (Cohn and Larson, 2007; Philippe et al., 2006). Simplified consent forms often did not improve comprehension (Flory and Emanuel, 2004), but were considered easier to read and less frightening (Nishimura et al., 2013). On the other hand, extended discussion and consent education interventions (e.g. use of prompts to assist in mastering the information) often significantly improved comprehension (Flory and Emanuel, 2004; Nishimura et al., 2013).

Evidence about the benefits of using such interventions with people having mental health/substance use problems in a LMIC context is limited. The aim of our exploratory study was to examine whether supplementing the conventional paper-based informed consent process with an audiovisual aid improves participants' understanding of the informed consent process and the information conveyed to them. We chose an audiovisual intervention because multimedia helps translate complex study information into an understandable and visually appealing format that is suitable for low-health-literacy participants and for illiterate or marginally literate participants. In addition, effective use of audio-visual tools in combination with printed materials enables study participants to manage information overload through repetition and reinforcement and cater to diverse learning abilities of participants.

2.1 Material and Methods

2.1.1 Setting

Goa (population 1.4 million) is a state in western India and has better socioeconomic indicators compared to most other states in the country. This study was nested within two ongoing research studies ("parent studies") in educational institutions, workplaces and healthcare settings. The two parent studies were evaluating the acceptability and feasibility of (a) integrating tele-psychiatry into primary care, and (b) delivering a brief intervention for hazardous drinking through text messaging or recorded calls.

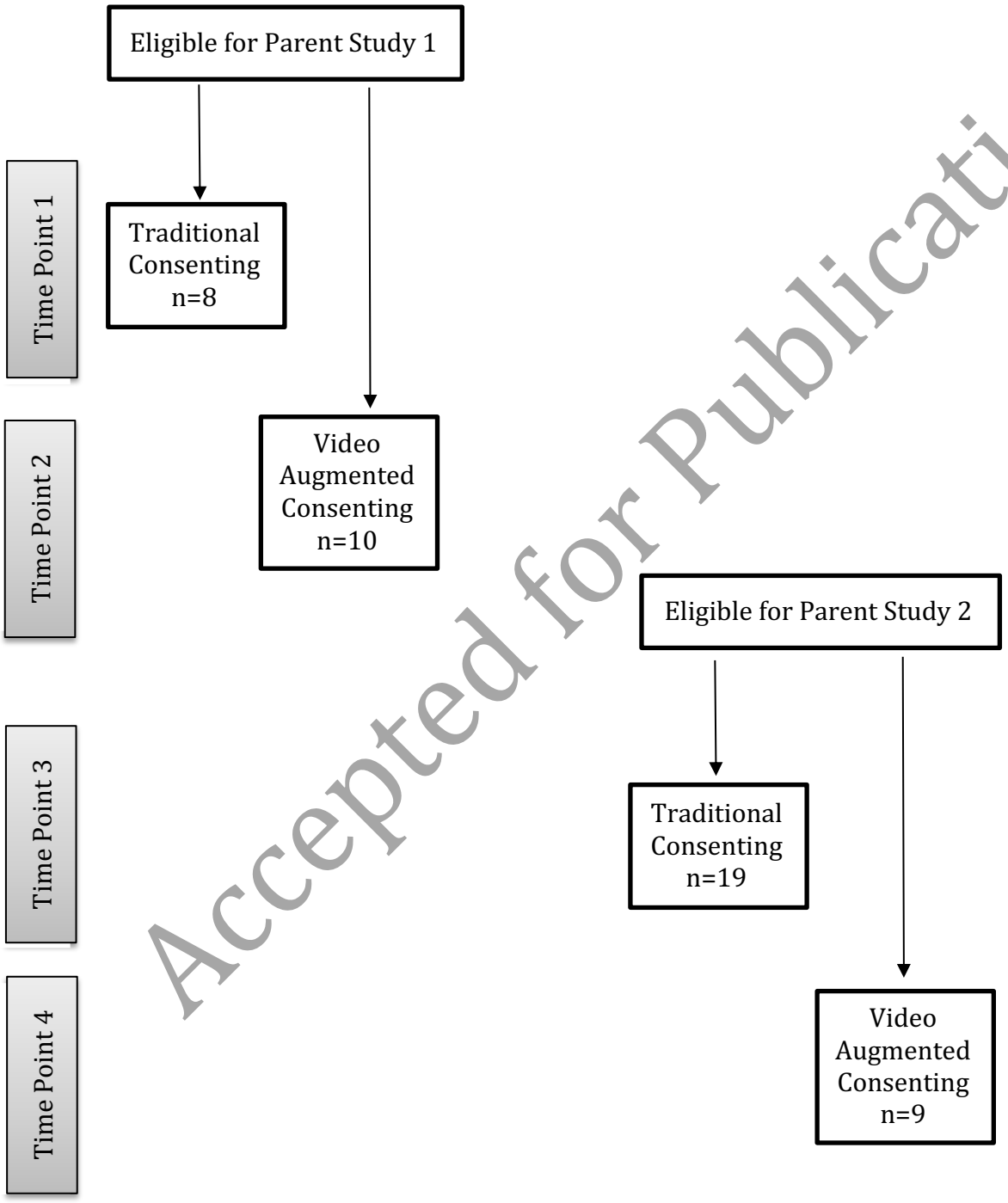
2.1.2 Sample

Accepted for Publication

The participants in this study were a sub-sample from the two parent studies described above and hence needed to fulfil the eligibility criteria for those studies. Broadly, these were adults (≥18 years) with one of the following- (1) Common Mental Disorders defined as those identified through General Health Questionnaire (GHQ 12) (Golderberg and Williams, 1988) as having a score of 4 and above, (2) Severe Mental Disorders diagnosed through a clinical assessment by a psychiatrist, and (3) Alcohol Use Disorders defined as hazardous, harmful or dependent drinkers, identified through the Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993) with a score of 8 and above. The formal diagnosis was confirmed after the consultation with the psychiatrist in Parent Study 1. As Parent Study 2 was designed to provide an intervention for hazardous drinking the total score on AUDIT was considered as confirmed diagnosis as routinely done while delivering brief interventions. Potential participants who did not have the capacity to consent for participation in the parent study were not recruited. Figure 1 is a representation of how the sample for this study was derived from the parent studies.

Accepted for Publication

Figure 1: Study Recruitment



Accepted for Publication

2.1.3 Procedures

The participants were recruited through consecutive sampling in which all eligible participants who consented for either of the parent studies were invited to participate in this study. For each parent study, recruitment into the consenting intervention groups was done sequentially in batches i.e. the first group of participants recruited for this study was administered the traditional paper information and consenting process and the subsequent group of participants recruited were additionally administered the video depicting the procedures of the study. As this was an exploratory study the sample size was not informed by formal power calculations. We followed a convenience sampling strategy and recruitment in each group was stopped based on feasibility.

Participants who were eligible for either of the two parent studies were administered the consenting process by a trained health assistant using one of the following methods: a) Method A: traditional paper information sheet and discussion about the study, or b) Method B: Method A supplemented by a video depicting the procedures of the respective parent study. The information sheet provided details such as information on the study objectives and design, details of participation, role of participants, voluntary nature of participation, detailed description on how confidentiality will be maintained, freedom to withdraw from the study, risks and benefits of participation, use of the data, details of the funding agency and implementing organisation, and contact details of investigators. The video of the first parent study provided visually represented details of procedures outlined in the information sheet which were depicted through a series of skits. This included scenes of a participant interacting with the mobile-based intervention, a participant wishing to withdraw from the study being reassured that he would not face any negative consequences, and researchers removing identifying details before sharing the findings of the study. The video of the other parent study provided details of the study procedures including providing information through the information sheet, recruitment into the study and a tele-psychiatry session in progress. The videos were produced in-house; and the scripts as well as the videos were reviewed and approved internally by mental health experts in the team including psychiatrists and psychologists. The videos were reviewed to ensure that all the relevant content was included and was communicated in a clear and understandable manner. The information sheet and videos were available in English and Konkani (the vernacular language in the study setting) and administered in the language chosen by the participant.

Accepted for Publication

2.1.4 Data

Sociodemographic data (age, marital status, employment status, and educational status) was collected as a part of baseline assessments in the parent studies. Immediately after the participant signed the consent form for the parent study, the health assistant obtained their consent for the sub-study described in this paper and administered a structured questionnaire (Appendix 1). The questionnaire was designed to assess their understanding of the information conveyed to them about the parent study. The items in the questionnaire were adapted from the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) tool (a reliable and valid short form adaptation of the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR)), widely accepted as the best assessment tool for measuring capacity to consent to research, as well as from tools used in other studies that evaluated interventions to enhance the informed consent process (Campbell et al., 2008; Dresden and Levitt, 2001; Jeste et al., 2007; Kass et al., 2009).

This included questions that covered their understanding of the following domains:

1. Purpose of the study,
2. That participation is voluntary and that participants are allowed to change their decision about participating at any point without any adverse consequences to them,
3. That the information was provided to assist autonomous decision making,
4. Study procedures,
5. Potential risks and benefits associated with participation in the study,
6. The confidential and secure nature of the research data and that any published data would be aggregated and anonymous, and

Additionally, they were also asked to rate the following on a four or five point Likert scale:

1. Whether they felt that they had enough information to make a good decision about whether to participate (Strongly agree to Strongly disagree),
2. Ease of understanding study details (Very easy to Very difficult), and
3. Ease of understanding what they were expected to do as part of the study (Very easy to Very difficult).

2.1.5 Analysis

Accepted for Publication

Descriptive statistics were used to analyse the data using Stata SE 14. The socio-demographic characteristics were compared between a) the two parent studies, and b) between those who were administered the two different consenting processes. The various domains of the questionnaire listed above were compared between those who were administered the two different consenting processes. T-test and chi square test were used to compare continuous and categorical variables respectively.

2.1.6 Ethics

Both the parent studies and the consent sub-study were approved by the ethics committee of the host institution.

3.1 Results

Of the 46 participants in the consent study, 18 (39.1%) were from one parent study and the rest were from the other (Table 1). Participants from one parent study were significantly older and had a greater proportion who were married, illiterate, and employed, compared to the other study. 27 (58.7%) participants were administered the traditional consenting process while the rest were administered the video-supplemented consenting process. There were no significant socio-demographic and clinical differences between these two groups (Table 2). Although the conventional paper-based consenting process performed better than the video-supplemented consenting process on the various domains studied, none of the differences between the two groups were statistically significant (Table 3).

Table 1: Sociodemographic and clinical profile of participants in the parent studies

Variable	**Total N=46**	**Parent study 1 N=18 (39.1%)**	**Parent study 2 N=28 (60.9%)**	**Chi^2/t**	**p**
Mean age in years (SD)	36.1 (15.4)	48.6 (10.5)	28.0 (12.4)	5.8374	<0.001
Marital status					
Presently married	22 (47.8)	14 (63.6)	8 (36.4)	10.6316	0.001
Never married/divorced/separated/widow(er)	24 (52.2)	4 (16.7)	20 (83.3)		
Educational status					
Literate (any formal education)	43 (93.5)	15 (34.9)	28 (65.1)	4.9922	0.03
Illiterate	3 (6.5)	3 (100.0)	0 (0)		

Accepted for Publication

Employment status					
Employed/Homemaker	29 (63.0)	17 (58.6)	12 (41.4)	12.5149	<0.001
Unemployed/Student/Retired	17 (37.0)	1 (5.9)	16 (94.1)		
Diagnosis					
Common mental disorder	13 (28.3)	13 (72.2)	-	-	-
Severe mental disorder	1 (2.2)	1 (5.6)	-		
Alcohol use disorder	1 (2.2)	1 (5.6)	-		
Mental disorder unspecified	3 (6.5)	3 (16.7)	-		
Hazardous drinking	28 (60.9)	-	28 (100)		

Table 2: Sociodemographic and clinical profile of participants who were administered the two different consenting processes

Variable	**Total N=46**	**Consent without video N=27 (58.7%)**	**Consent with video N=19 (41.3%)**	**Chi^2/t**	**p**
Mean age in years (SD)	36.1 (15.4)	34.1 (16.0)	38.8 (14.5)	-1.0269	0.31
Marital status					
Presently married	22 (47.8)	13 (48.2)	9 (47.4)	0.0027	0.96
Never married/divorced/separated/widow(er)	24 (52.2)	14 (51.9)	10 (52.6)		
Educational status					
Literate (any formal education)	43 (93.5)	25 (92.6)	18 (94.7)	0.0841	0.77
Illiterate	3 (6.5)	2 (7.4)	1 (5.3)		
Employment status					
Employed/Homemaker	29 (63.0)	16 (59.3)	13 (68.4)	0.4018	0.53
Unemployed/Student/Retired	17 (37.0)	11 (40.7)	6 (31.6)		
Diagnosis					
Common mental disorder	13 (28.3)	5 (18.5)	8 (42.1)	5.3665	0.25
Severe mental disorder	1 (2.2)	1 (3.7)	0 (0)		
Alcohol use disorder	1 (2.2)	0 (0)	1 (5.3)		

Accepted for Publication

Mental disorder unspecified	3 (6.5)	2 (7.4)	1 (5.3)		
Hazardous drinking	28 (60.9)	19 (70.4)	9 (47.4)		

Table 3: Comparison of the performance of the two consenting processes

Variable	**Total N=46**	**Consent without video N=27 (58.7%)**	**Consent with video N=19 (41.3%)**	**Chi^2**	**p**
Understood the aim of the study	29 (63.0)	17 (63.0)	12 (63.2)	0.0002	0.99
Understood they do not have to consent if they do not want to	34 (73.9)	20 (74.1)	14 (73.7)	0.0009	0.98
Understood that they are allowed to change their mind about participation at any stage	32 (69.6)	19 (70.4)	13 (68.4)	0.02	0.89
Understood that information was given so that they could decide freely about participation	42 (91.3)	26 (96.3)	16 (84.2)	2.0517	0.15
Correctly identified $\geq$2 activities that they would have to do as a part of the study	28 (60.9)	14 (51.9)	14 (73.7)	2.2318	0.14
Correctly identified all possible benefits to themselves	17 (37.0)	10 (37.0)	7 (36.8)	0.0002	0.99
Understood that data would be kept confidential	46 (100.0)	27 (100.0)	19 (100.0)	-	-
Understood that all results would be anonymised	31 (67.4)	19 (70.4)	12 (63.2)	0.264	0.61
Understood that it was not compulsory to consent	26 (63.4)	16 (72.7)	10 (52.6)	1.7746	0.18
Strongly agreed that they had enough information to make a decision	30 (73.2)	18 (81.8)	12 (63.2)	1.8084	0.18
Reported that it was very difficult to understand details of the study	1 (2.44)	0 (0)	1 (5.3)	1.1868	0.28

Accepted for Publication

Reported that it was easy to understand their role in the study	38 (92.7)	21 (95.5)	17 (89.5)	0.5378	0.46

4.1 Discussion

The consenting process in human participants research is intended to ensure that individuals understand the purpose, risks, and benefits of the proposed study so that they can make an informed decision about participation. Thus, informed consent is predicated on potential participants adequately understanding the information provided to them. However, evidence over the years suggests that approximately only half of research participants adequately understand information such as the aim of a given study, the nature of voluntariness, the freedom to withdraw, and the risks and benefits of the study (Falagas et al., 2009). Several interventions have been tested to enhance understanding and to plug this major gap in the key component of research, designed to uphold the ethical principle of autonomy. Our study is the first from India, and possibly other LMICs to pilot one such intervention in participants with mental health/substance use problems. We did not find any significant advantage of a video-supplemented consenting process over the traditional paper-based informed consent process.

A close examination of consenting procedures in mental/substance use disorders research is crucial as such disorders can interfere with some of the key conditions that need to be met for informed consent. Specifically, these disorders can prevent patients from understanding the nature and purposes of the study, prevent them from choosing decisively, or prevent them from communicating their consent. For example, the indifference or hopelessness associated with depression might prevent a patient from choosing decisively. Similarly, in conditions such as schizophrenia, the associated cognitive deficits and psychotic symptoms such as delusions and hallucinations impair the abilities needed to make informed decisions, and also make them susceptible to coercion (Palmer and Savla, 2007). In substance use disorders research, individuals may consent to participation in the study under influence of the substance and consequently cognition and capacity to consent may be impaired. In summary, certain symptoms inherent to mental health conditions, such as impaired understanding and reasoning, conceptual disorganisation, and cognitive deficits, such as executive functioning and verbal memory, strongly influence decision-making capacity and consequently affect the informed consent process (Zayas et al., 2005).

Accepted for Publication

Over the years, several innovations such as multimedia, extended discussions or immediate feedback quizzes, have been tested to determine their impact on understanding of information provided during the consenting process (Flory and Emanuel, 2004). Interventions such as enhanced consent forms and extended discussion interventions have been demonstrated to be effective, but the evidence on the effectiveness of multimedia interventions has been mixed (Campbell et al., 2004; Hoffner et al., 2012; Kass et al., 2009; Matsui et al., 2012; Nishimura et al., 2013; Tamariz et al., 2013). There remains much uncertainty about the effect of audio-visual informed consent interventions. There is some evidence that such interventions may slightly improve understanding and participant satisfaction with the information provided, but may make little or no difference to rate of participation or willingness to participate (Synnot et al., 2014). It is important to also foreground our findings in individuals with mental health or substance use problems against the evidence base of similar studies examining the informed consent process in individuals with other health conditions in India. An example of one such study is a clinical trial investigating an anti-rabies monoclonal antibody which compared the traditional consenting procedures with an audio-visual consenting method. The audiovisual method resulted in overall better comprehension as well as specific domains such as 'rights and confidentiality' (Figer et al., 2017). Thus, our findings add to the mixed evidence base about the utility of audio-visual informed consent information, and are particularly crucial because they involve a particularly vulnerable population in a LMIC, an under-represented group in research examining the consenting process.

Our exploratory findings indicate that a multi-media component does not add any further advantage to the traditional paper-based informed consent process. This supports the evidence that extended discussion is the most parsimonious and consistent method of improving understanding rather than adding a multimedia component. This indicates that good dialogue is the most critical component of the consenting process, as it provides opportunities for questions and deeper interaction and allows for a more meaningful relationship to be established between the participant and the researcher. However, this hypothesis will need more detailed exploration as our study is limited by the heterogeneity of diagnoses in included participants and small sample size. Additionally, our findings, and that of other similar studies, are not unequivocal in the conclusions that can be drawn. That raises questions about how consent documents and processes are formulated, designed, and evaluated; and these will need to be addressed in future research. While we await definitive responses to these critical questions there are certain good practices that could be followed in low-literacy settings and these include writing the consent form at a basic reading level, explaining the written document using low health-literacy techniques (e.g.

Accepted for Publication

avoiding jargon, highlighting key areas), using visual aids to enhance participant understanding of key components in the consent form, and using teach-back techniques to establish participant understanding prior to recruitment in the study.

Our study had a number of limitations, the most important being the small sample size. Additionally, we did not randomise participants into the two groups, thus introducing the potential for bias. However, the absence of significant socio-demographic differences between the two groups indicates the success of our efforts to create a non-biased sample within the limitations posed by the feasibility of conducting such a nested study. Finally, social desirability responses are a possibility as the questionnaire about the consenting procedures was administered by the same research workers who implemented the informed consent procedures.

Despite these limitations our research makes an important contribution to the study of understanding the informed consent process. Despite appropriate scrutiny by ethics committees, deficiencies still exist in informed consent processes. Such deficiencies might be even greater in LMICs where participants in research studies often come from diverse backgrounds, including having a limited education, and in research involving people with mental health or substance use problems, both of which can be accompanied by cognitive difficulties. In such settings, our exploratory findings have the potential to stimulate research in the identification of contextually relevant best practices for the informed consent process. In the meanwhile, in the absence of clear evidence demonstrating the superiority of one modality over others, the choice should be based on the feasibility and acceptability to researchers and participants. However, at the very least, particular attention should be paid to implementing procedures that are accessible to populations with limited literacy and health education and/or are at increased risk for poor comprehension due to cognitive difficulties and other vulnerable populations such as minor children.

Accepted for Publication

References

Campbell, F.A., Goldman, B.D., Boccia, M.L., Skinner, M., 2004. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: a comparison of print, video, and computer-based presentations. Patient education and counseling 53, 205-216.

Campbell, H.M., Raisch, D.W., Sather, M.R., Segal, A.R., Warren, S.R., Naik, R., 2008. Impact of a clinical trials information handbook on patient knowledge, perceptions, and likelihood of participation. IRB: Ethics & Human Research 30, 6-14.

Cohn, E., Larson, E., 2007. Improving participant comprehension in the informed consent process. Journal of nursing scholarship 39, 273-280.

Dresden, G.M., Levitt, M.A., 2001. Modifying a standard industry clinical trial consent form improves patient information retention as part of the informed consent process. Academic Emergency Medicine 8, 246-252.

Falagas, M.E., Korbila, I.P., Giannopoulou, K.P., Kondilis, B.K., Peppas, G., 2009. Informed consent: how much and what do patients understand? The American Journal of Surgery 198, 420-435.

Figer, B., Chaturvedi, M., Thaker, S., Gogtay, N., Thatte, U., 2017. A comparative study of the informed consent process with or without audiovisual recording. The National medical journal of India 30, 262.

Flory, J., Emanuel, E., 2004. Interventions to improve research participants' understanding in informed consent for research: a systematic review. Jama 292, 1593-1601.

Golderberg, D., Williams, P., 1988. A user's guide to the General Health questionnaire. NFER-Nelson, Windsor, UK.

Hoffner, B., Bauer-Wu, S., Hitchcock-Bryan, S., Powell, M., Wolanski, A., Joffe, S., 2012. "Entering a clinical trial: Is it right for you?" A randomized study of the clinical trials video and its impact on the informed consent process. Cancer 118, 1877-1883.

Jeste, D.V., Palmer, B.W., Appelbaum, P.S., Golshan, S., Glorioso, D., Dunn, L.B., Kim, K., Meeks, T., Kraemer, H.C., 2007. A new brief instrument for assessing decisional capacity for clinical research. Archives of general psychiatry 64, 966-974.

Kadam, R.A., 2017. Informed consent process: A step further towards making it meaningful! Perspectives in clinical research 8, 107.

Accepted for Publication

Kass, N.E., Sugarman, J., Medley, A.M., Fogarty, L.A., Taylor, H.A., Daugherty, C.K., Emerson, M.R., Goodman, S.N., Hlubocky, F.J., Hurwitz, H.I., 2009. An intervention to improve cancer patients' understanding of early-phase clinical trials. Irb 31, 1.
Lynöe, N., Hyder, Z., Chowdhury, M., Ekström, L., 2001. Obtaining informed consent in Bangladesh. New England Journal of Medicine 344, 460-461.
Manti, S., Licari, A., 2018. How to obtain informed consent for research. Breathe 14, 145-152.
Matsui, K., Lie, R.K., Turin, T.C., Kita, Y., 2012. A randomized controlled trial of short and standard-length consent forms for a genetic cohort study: is longer better? Journal of epidemiology, 1203220305-1203220305.
Nishimura, A., Carey, J., Erwin, P.J., Tilburt, J.C., Murad, M.H., McCormick, J.B., 2013. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC medical ethics 14, 28.
Paasche-Orlow, M.K., Jacob, D.M., Powell, J.N., 2005. Notices of Privacy Practices: a survey of the Health Insurance Portability and Accountability Act of 1996 documents presented to patients at US hospitals. Medical care, 558-564.
Palmer, B.W., Savla, G.N., 2007. The association of specific neuropsychological deficits with capacity to consent to research or treatment. Journal of the International Neuropsychological Society 13, 1047-1059.
Philippe, F., Meney, M., Larrazet, F., Ben, F.A., Dibie, A., Meziane, T., Folliguet, T., Delahousse, P., Lemoine, J., Laborde, F., 2006. Effects of video information in patients undergoing coronary angiography. Archives des Maladies du Coeur et des Vaisseaux 99, 95-101.
Raich, P.C., Plomer, K.D., Coyne, C.A., 2001. Literacy, comprehension, and informed consent in clinical research. Cancer investigation 19, 437-445.
Saunders, J.B., Aasland, O.G., Babor, T.F., de la Fuente, J.R., Grant, M., 1993. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. Addiction 88, 791-804.
Sugarman, J., McCrory, D.C., Hubal, R.C., 1998. Getting meaningful informed consent from older adults: a structured literature review of empirical research. Journal of the American Geriatrics Society 46, 517-524.
Synnot, A., Ryan, R., Prictor, M., Fetherstonhaugh, D., Parker, B., 2014. Audio-visual presentation of information for informed consent for participation in clinical trials. Cochrane Database of Systematic Reviews.
Tam, N.T., Huy, N.T., Thoa, L.T.B., Long, N.P., Trang, N.T.H., Hirayama, K., Karbwang, J., 2015. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Bulletin of the World Health Organization 93, 186-198H.
Tamariz, L., Palacio, A., Robert, M., Marcus, E.N., 2013. Improving the informed consent process for research subjects with low literacy: a systematic review. Journal of general internal medicine 28, 121-126.
Zayas, L.H., Cabassa, L.J., Perez, M.C., 2005. Capacity-to-consent in psychiatric research: Development and preliminary testing of a screening tool. Research on Social Work Practice 15, 545-556.

Accepted for Publication

Accepted for Publication

Appendix

Questionnaire used in parent study A

Informed Consent Comprehension Questionnaire

*Indicates correct answer

1. What is the purpose of the study that was just described to you?
    a. To develop a culturally appropriate mobile-based intervention to be delivered to people who drink riskily*
    b. To determine what types of help risky drinkers need
    c. To screen patients to see if they have any alcohol-related problems
    d. Don't know

2. You have to be in this study even if you do not want to participate.
    a. True
    b. False*
    c. Don't know

3. Once you decide to join the study that was just described to you, you are not allowed to change your mind.
    a. True
    b. False*
    c. Don't know

4. You were given information about the study so you can freely decide whether or not to participate.
    a. True*
    b. False
    c. Don't know

5. If you participate in this study, what are some of the things that you may be asked to do? You may select more than one.
    a. Receive text messages about drinking behaviour and its related health and social effects*
    b. Respond to text messages about your drinking behaviour*
    c. Receive personalized messages about your drinking behaviour*
    d. Answer survey or interview questions about your health or experiences receiving text messages from this program*

6. Question for the facilitator (not to be read or shown to the participant): The participant was able to indicate two or more responses in question 5.
    a. Yes
    b. No

7. What is a possible benefit of this study?
    a. You will contribute to our understanding of how to improve access to treatment for people with hazardous drinking habits
    b. You may feel better in your day to day life due to decreased consumption of alcohol
    c. You will receive payment or other incentives in exchange for participation
    d. Both A and B*
    e. Don't know

8. All of the data collected about you, including personal information and your text message responses, will not be disclosed.
    a. True*
    b. False
    c. Don't know

9. Results from the study, with information that could identify you such as your name, may be published in medical journals.
    a. True
    b. False*
    c. Don't know

10. As a student at this school/employee of this factory/patient at this facility, you must sign this consent form.
    a. True
    b. False*
    c. Don't know

"Now I'm going to read you another set of statements. After I read each statement, I'd like you to rank the extent to which you agree with each statement on a scale from 1 to 5, with 1 meaning you strongly disagree and 5 meaning you strongly agree."

Accepted for Publication

11. I had enough information to make a good decision about whether to participate in the study.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree

12. It was easy to understand the details of the study.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree

13. It was easy to understand what I would be expected to do as part of the study.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree

Questionnaire used in parent study B

Informed Consent Comprehension Questionnaire

*Indicates correct answer

1. What is the purpose of the study that was just described to you?
    a. Understand how tele-psychiatry can be integrated into primary care*
    b. Test a new treatment for a mental health problem via tele-psychiatry
    c. Screen patients to see if they have any mental health problems
    d. Don't know

2. Do you have to be in this study if you do not want to participate?
    a. Yes
    b. No*
    c. Don't know

3. In the study that was just described to you, once people decide to join, they are not allowed to change their mind. Is that true or false?
    a. True
    b. False*
    c. Don't know

4. You were given information about the study so you can freely decide whether to participate. Is that true or false?
    a. True*

Accepted for Publication

b. False
c. Don't know

5. If you participate in this study, what are some of the things that you will be asked to do?
   If they can name two of the following, mark this question correct. If they can only name one or none, make this question incorrect.
   a. Attend a consultation with a psychiatrist through the internet
   b. Receive medication prescribed by a psychiatrist
   c. Receive counselling from the IMPACT counsellor based at your PHC
   d. Attend follow up appointments with a psychiatrist through the internet
   e. Answer survey or interview questions about my health or my experiences receiving tele-psychiatry

6. What is a risk or discomfort that you may experience if you participate in this study?
   a. You may feel upset when discussing details of your illness or life experiences*
   b. You may risk physical injuries while undergoing psychiatric treatment at the PHC
   c. Your counsellor or psychiatrist might speak to other people about your illness without your permission
   d. Don't know

7. What is a possible benefit of this study?
   a. You will contribute to our understanding of how to improve access to treatment for people with mental illness
   b. You may feel better in your day to day life due to the psychiatric care you receive
   c. You will receive payment or other incentives in exchange for participation
   d. Both A and B*
   e. All of the above
   f. Don't know

8. Will my personal medical information, such as notes from my session with the psychiatrist, be kept as confidential as possible?
   a. Yes*
   b. No
   c. Don't know

9. Results from the study, with information that could identify you such as your name, may be published in medical journals. Is that true or false?
   a. True
   b. False*
   c. Don't know

10. Do you have to sign this consent form if your doctor or counsellor gives it to you?
    a. Yes

Accepted for Publication

b. No*
c. Don't know

"Now I'm going to read you another set of statements. After I read each statement, I'd like you tell me whether you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with the statement."

11. In the study I just told you about, you felt like you had enough information to make a good decision about whether to participate.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1	2	3	4

"I'm going to ask you a few more questions now about the consent form for the research study I just told you about. Please answer the following questions using a scale from 1 to 5."

12. On a scale of 1-5, how hard or easy did you think it was to understand the details of the study? 5 means it was very hard to understand, and 1 means it was really easy to understand.

1	2	3	4	5

13. On a scale of 1-5, how hard or easy did you think it was to understand what you would be expected to do as part of the study? 5 means it was very hard to understand, and 1 means it was really easy to understand.

1	2	3	4	5

Accepted for Publication