




BMJ Open Improving rural and regional access to long-acting reversible contraception and medical abortion through nurse-led models of care, task-sharing and telehealth (ORIENT): a protocol for a stepped-wedge pragmatic cluster-randomised controlled trial in Australian general practice

Danielle Mazza ,¹ Mridula Shankar ,¹ Jessica R Botfield ,¹ Jessica E Moulton ,¹ Samantha Paubrey Chakraborty ,¹ Kirsten Black,² Jane Tomnay,³ Deborah Bateson ,⁴ Jody Church,⁵ Tracey-Lea Laba,^{5,6} Jessica Kasza ,⁷ Wendy V Norman ^{8,9}

To cite: Mazza D, Shankar M, Botfield JR, *et al.* Improving rural and regional access to long-acting reversible contraception and medical abortion through nurse-led models of care, task-sharing and telehealth (ORIENT): a protocol for a stepped-wedge pragmatic cluster-randomised controlled trial in Australian general practice. *BMJ Open* 2023;**13**:e065137. doi:10.1136/bmjopen-2022-065137

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-065137>).

Received 26 May 2022

Accepted 22 February 2023



© Author(s) (or their employer(s)) 2023. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Professor Danielle Mazza;
Danielle.Mazza@monash.edu

ABSTRACT

Introduction Women living in rural and regional Australia often experience difficulties in accessing long-acting reversible contraception (LARC) and medical abortion services. Nurse-led models of care can improve access to these services but have not been evaluated in Australian general practice. The primary aim of the ORIENT trial (ImprOving Rural and regional accEss to long acting reversible contraceptiON and medical abortion through nurse-led models of care, Tasksharing and telehealth) is to assess the effectiveness of a nurse-led model of care in general practice at increasing uptake of LARC and improving access to medical abortion in rural and regional areas.

Methods and analysis ORIENT is a stepped-wedge pragmatic cluster-randomised controlled trial. We will enrol 32 general practices (clusters) in rural or regional Australia, that have at least two general practitioners, one practice nurse and one practice manager. The nurse-led model of care (the intervention) will be codesigned with key women's health stakeholders. Clusters will be randomised to implement the model sequentially, with the comparator being usual care. Clusters will receive implementation support through clinical upskilling, educational outreach and engagement in an online community of practice. The primary outcome is the change in the rate of LARC prescribing comparing control and intervention phases; secondary outcomes include change in the rate of medical abortion prescribing and provision of related telehealth services. A within-trial economic analysis will determine the relative costs and benefits of the model on the prescribing rates of LARC and medical abortion compared with usual care. A realist evaluation will provide contextual information regarding model implementation informing considerations for scale-up. Supporting nurses to work to their

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The nurse-led intervention will be developed using principles of codesign and will be implemented with the support of clinical upskilling, individualised peer-to-peer support through educational outreach and participation in an online national community of practice, to encourage model adoption and promote sustainability.
- ⇒ The collection of primary and secondary outcome data on long-acting reversible contraception and medical abortion prescriptions will be complemented by process evaluation data to highlight the contextual and behavioural factors supporting or impeding model implementation, which will be important for considerations of national scale-up.
- ⇒ Participating general practices may not be representative of the wider regional and rural general practice population as trial participation is contingent on clinicians' interest in delivering women's reproductive healthcare, including through a model that utilises general practitioner and practice nurse task-sharing and supports nurses to work to their full scope of practice.
- ⇒ The timeline for recruitment of general practices and participation in trial activities may be negatively affected by the ongoing impact of the COVID-19 pandemic on the functioning of the Australian primary healthcare system; the trial team will use direct and indirect recruitment methods emphasising the potential for the trial to introduce efficiencies in care delivery models in general practice.

full scope of practice has the potential to increase LARC and medical abortion access in rural and regional Australia.

Ethics and dissemination Ethics approval was obtained from the Monash University Human Research Ethics Committee (Project ID: 29476). Findings will be disseminated via multiple avenues including a knowledge exchange workshop, policy briefs, conference presentations and peer-reviewed publications.

Trial registration number This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN1262200086763).

INTRODUCTION

In Australia, women in rural areas are significantly more likely to experience an unintended pregnancy than women living in metropolitan areas, for reasons that include a lack of access to contraception services and geographical isolation.^{1 2} Long-acting reversible contraceptives (LARCs), including the contraceptive implant and hormonal and copper intrauterine devices (IUDs), are more than 99% effective at preventing pregnancies,³ however many women do not have an accurate understanding of these methods⁴ and may never have been offered the option of LARCs by clinical providers.⁵ Inaccurate or insufficient provider and patient knowledge, compounded by limited pathways to insertion, are key addressable factors prevalent in regional and rural areas, which contribute to low access and uptake.⁶

When pregnancies occur that may be unintended or unwanted, many women in rural and regional areas also have limited knowledge of or access to medical abortion care.⁷ Medical abortion is a safe, effective and non-invasive alternative to surgical abortion, and in Australia can be undertaken in the privacy of the woman's home up to 9 weeks' gestation⁸ using a combined regimen of mifepristone and misoprostol (MS-2 Step) available at a subsidised cost via the government-funded Pharmaceutical Benefits Scheme (PBS) (a component of Medicare, the national scheme providing healthcare access to Australian residents).⁹ When compared with surgical abortion, medical abortion reduces the need to travel to specialised clinics in metropolitan areas and the cost and disruption that this may entail. Integration of medical abortion services into primary healthcare can reduce disparities faced by women living outside major metropolitan cities,¹⁰ and enable contraceptive and other comprehensive women's health services to be provided to this priority population.¹¹ However only approximately 10% of general practitioners (GPs) in Australia are currently registered to prescribe medical abortion¹² and large areas of rural and regional Australia have no GPs offering this service.¹³

Nurse-led models of care

International public health bodies such as the WHO recommend enabling additional cadres of healthcare providers, including nurses, to deliver contraception and abortion services through rational redistribution of tasks and expansion of clinical scope and team-based approaches to service delivery (defined as task shifting

or task-sharing).^{14 15} These recommendations are based on robust synthesis of global evidence demonstrating the safety and effectiveness of care provided by a range of mid-level and lower-level cadres. Optimising health worker roles through these service delivery models has also been shown to increase coverage, yield high patient satisfaction, improve workflow efficiencies and be cost saving demonstrating benefit to patients, providers and health systems.^{16–18}

Considerations for nurse-led care for LARC and medical abortion in Australia

In Australia, peak national bodies have also called for increasing nurse insertions of the contraceptive implant in primary care¹⁹ in order to increase access. While there is currently no government rebate for nurse implant insertion, training for nurses to insert and remove implants is available through various organisations providing clinical education in Australia.²⁰ Nurses are supportive of initiatives that enable them to work to their full scope of practice to deliver reproductive healthcare,^{10 21} and evidence exists which demonstrates the feasibility and patient acceptability of nurse-led models in contraception and abortion care in rural community health centres²² and family planning clinics.^{23 24} However, nurse-led models in relation to LARC and medical abortion are yet to be evaluated in the Australian general practice setting, despite nurse-led models of care involving tailored patient education, clinical support and care coordination being applied successfully in general practice for chronic disease management, diabetes education and mental health casework.^{25–27}

Separately, the use of telehealth (using information and communications technologies to deliver health services) has been shown to be effective in overcoming geographical barriers for women seeking healthcare services in Australia,^{28 29} the USA³⁰ and Europe.³¹ In response to the COVID-19 pandemic, the Australian government introduced Medicare rebates more widely for GP telehealth consultations, including specifically for provision of sexual and reproductive healthcare.³² Consumers, including those in rural and remote Australia have described the value of these rebates as increasing accessibility, choice and flexibility to healthcare.³³ These expanded provisions present a timely opportunity to integrate a telehealth model of service provision into nurse-led task-sharing models to increase access to contraception and abortion services for women living in rural and regional locations.

Need for a trial

Nurse-led interventions for delivery of LARC and medical abortion in Australian general practice are lacking. Bridging this evidence gap through the design, delivery and evaluation of a nurse-led model that incorporates innovations such as task-sharing and telehealth services in rural and regional general practices has the potential to address current barriers to equity in access to these essential reproductive health services.

The ORIENT trial will assess the effectiveness and cost-effectiveness of an intervention aimed at expanding the scope of care of practice nurses (PNs) to increase uptake of LARCs and access to medical abortion through general practice clinics in rural and regional areas. Using process evaluation methods we will generate contextual information on intervention implementation to help explain the outcome findings and to inform considerations for national scale-up.

Trial aims and hypothesis

The primary aim of the ORIENT trial is to assess the effectiveness of a nurse-led model of care (involving task-sharing, and where appropriate implant insertion by nurses and use of telehealth) in general practice for improving women's uptake of LARC and access to medical abortion in rural and regional areas.

The secondary aims are to:

1. Codesign a nurse-led model of care for LARC provision and medical abortion in rural and regional general practice.
2. Evaluate the implementation of the nurse-led model using realist evaluation approaches.
3. Evaluate the cost-effectiveness of the intervention compared with usual care.

Our primary hypothesis is that implementation of the nurse-led intervention will increase prescribing rates of LARC and access to medical abortion for women in rural and regional Australia.

The primary outcome of the ORIENT trial is the change in the rate of LARC prescribing comparing control and intervention phases; secondary outcomes include change in the rate of medical abortion prescribing and provision of related telehealth services.

METHODS AND ANALYSES

Trial design

The ORIENT trial is a pragmatic cluster-randomised controlled trial (RCT) with a stepped-wedge approach (figure 1). We chose a stepped-wedge approach because it offers a more powerful design than a traditional parallel RCT due to the expected high heterogeneity within individual clusters in their delivery of women's health services and because it offers the most feasible and appropriate design to implement the intervention across clusters.³⁴ It is also more likely to enhance sustainability because it allows for reflexivity and refinement of the intervention as clusters move through the trial (pragmatism).

The cluster will be the general practice. The comparator in this trial will be usual practice, that is, care that is routinely provided in daily practice. Figure 2 describes the trial flow diagram.

Trial setting

The ORIENT trial will be conducted in general practices located in rural or regional areas across Australia. We will determine practice geographical location by linking practice postcodes to the Modified Monash Model (MMM) geographical classification that categorises all areas in Australia into remoteness categories ranging from MM 1 (metropolitan areas) to MM 7 (very remote communities).³⁵ We will aim to include practices that are located in areas rated as MM 2 (ie, live within 20 km of a town with 500 000+ people) to MM 7 (ie, very remote). Recruitment of eligible practices will begin in mid 2022 and will continue until sample size is achieved.

Eligibility criteria

Eligible practices must be located in rural or regional Australia (MM 2–7), and have at least two GPs, a PN (registered nurse) and a practice manager commit to

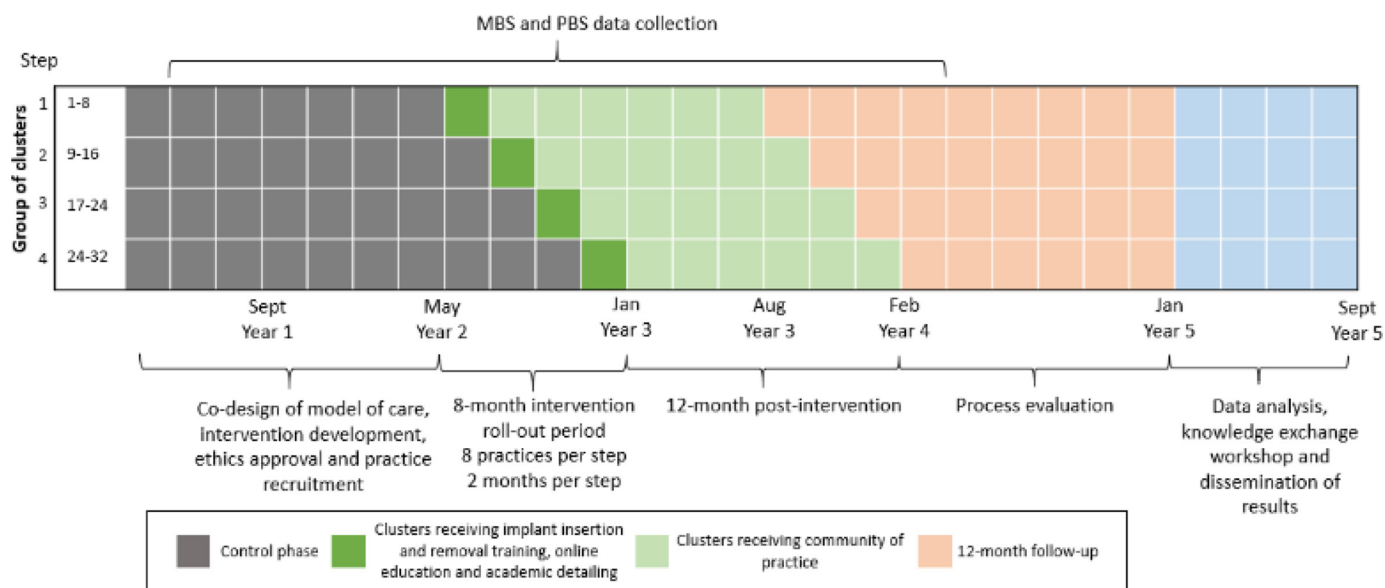


Figure 1 Stepped wedge diagram for the ORIENT randomised trial. MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Scheme.

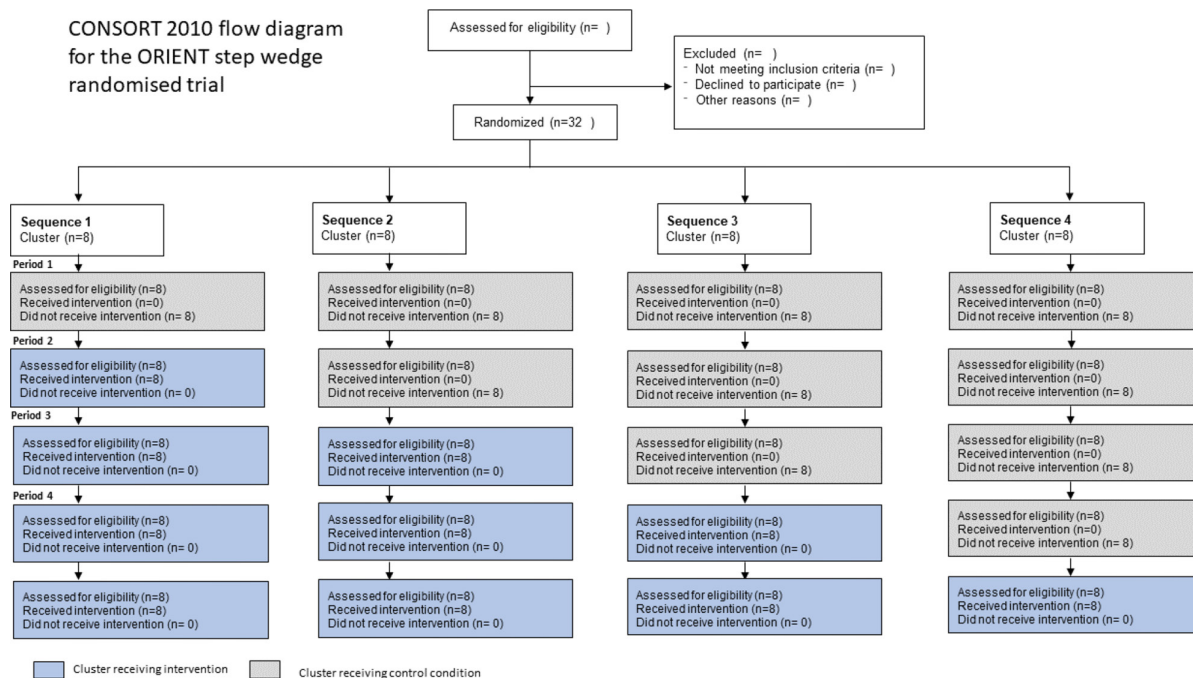


Figure 2 CONSORT 2010 flow diagram of the ORIENT stepped wedge randomised trial. CONSORT, Consolidated Standards of Reporting Trials

participation. General practices who are already implementing a similar model of care will not be eligible.

Sample size

The sample size requirements were calculated based on the primary outcome of LARC prescriptions. We expect a baseline rate of three LARC prescriptions per 1000 GP surgery visits and anticipate a conservative increase of 33% in these rates, based on the 50% increase found in the ACCORD trial^{36,37}; that is, an increase from 3 per 1000 surgery visits to 4 per 1000 surgery visits. With participation of an average of two GPs per cluster, and assuming an intraclass correlation coefficient of 0.15,³⁶ a practice dropout rate of 25% and a two-sided type 1 error of 5%, a sample size of 32 general practices (clusters) has 80% power and to detect a 33% change in LARC prescribing, assuming 900 GP visits in each practice in each month. Power calculations were completed using PASS 16 Power Analysis and Sample Size Software (2018), and verified using the stepped wedge user-written command in Stata.³⁸

Practice recruitment

We will use multiple strategies to recruit practices into the trial. These will include contacting GPs listed in the Australasian Medical Publishing Company commercial database. GPs practicing in rural and regional Australia will be sent a letter of invitation via email and/or facsimile with a link to submit an expression of interest. Non-responders will be sent a reminder 1 week later, followed by a phone call 2 weeks after the original invitation letter is sent out to the practice.

We will also employ indirect strategies for recruitment through established networks and discipline-specific professional organisations such as the Primary Health

Networks (PHNs), Australian Primary Nurse Association and Royal Australian College of General Practitioners, among others, who will advertise the trial through newsletters and their social media handles.

Practices that express an interest and satisfy the inclusion criteria will have the opportunity to speak with trial recruitment staff (either by phone or videoconference) who will explain the trial in detail and obtain informed consent. These are proven methods for GP recruitment^{37,39} that we have successfully used in studies of similar complexity, including two previous RCTs in general practice.^{36,40}

Randomisation and intervention assignment

Once all practices have been consented, the project statistician will perform stratified randomisation using a computer minimisation programme to allocate clusters (general practices) to receive the intervention in four steps (figure 2).⁴¹ The purpose of the stratification is to balance allocation of clusters with respect to location (regional or rural) and IUD insertion status (one or more GPs in the practice currently inserting IUDs). All clusters will be notified of the step that they have been randomised to by study staff at the same point in time prior to implementation of the first step. At the beginning of each step, eight practices will receive intervention support activities (clinical upskilling, an educational outreach session, and access to an online community of practice). Each step will be separated by a period of 8 weeks.

Intervention

Intervention development: co-design of nurse-led model

The nurse-led model of care will be developed using the experience-based codesign methodology and toolkit,

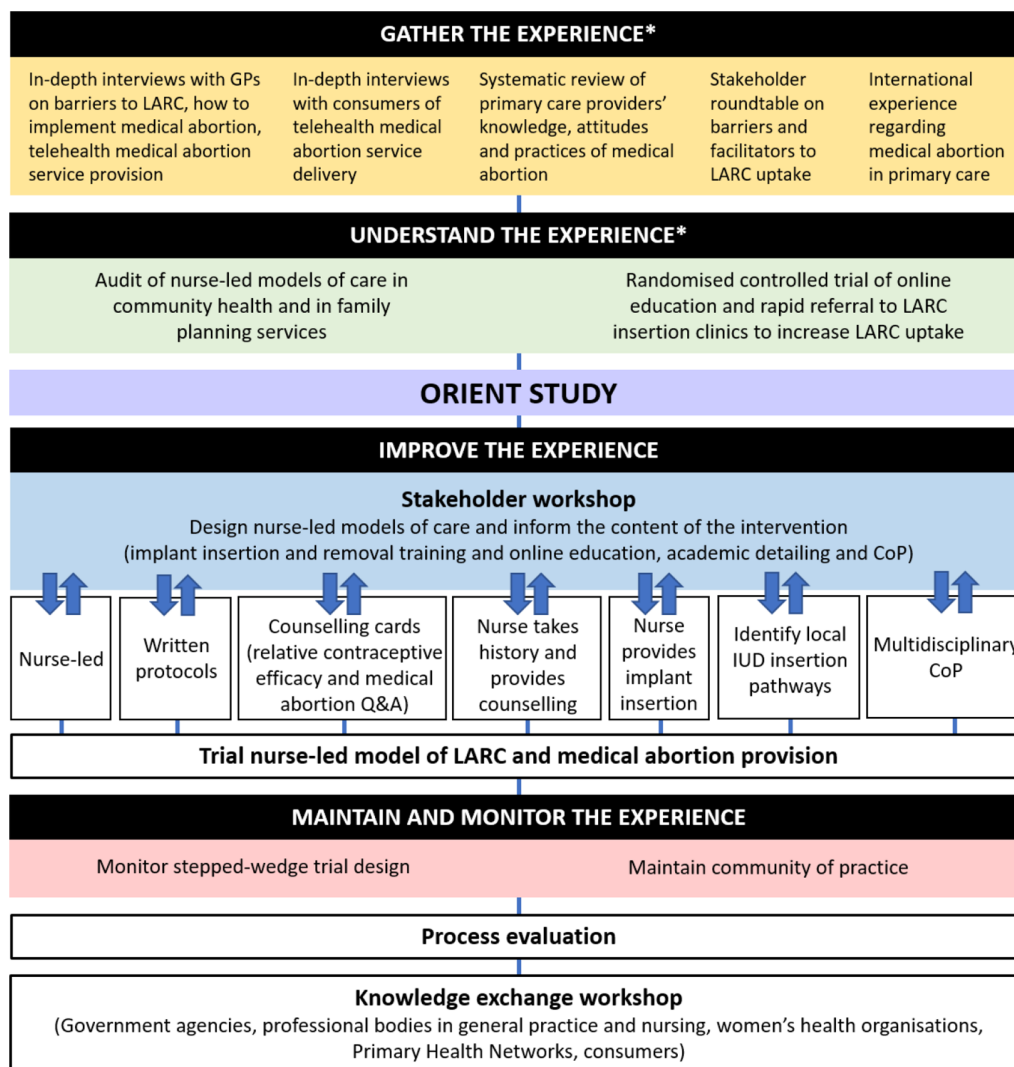


Figure 3 Design of the ORIENT nurse-led model of care with guidance from the consumers health forum of Australia experience-based codesign methodology and toolkit. *Completed domains. CoP, community of practice; GPs, general practitioners; LARC, long-acting reversible contraception.

made available by the Consumers Health Forum of Australia⁴² to support the collaborative development of healthcare services that places user experience at the centre (figure 3). This innovative approach to consumer and health professional engagement will ensure that the ORIENT intervention addresses consumer needs, is evidence-based, feasible, sustainable and offers the best chance of success. Through our extensive research, we have gathered patient and provider experience^{5 43–46} and systematically reviewed the literature.²¹ We have been able to understand the lived experience and patient journeys of consumers through audits of existing nurse-led models of care in community health and family planning settings²² and a large RCT of online education and rapid referral to LARC insertion.³⁶ Altogether, these data will inform a codesign workshop with clinicians (nurses and doctors), consumers and key stakeholders that focuses on improving the experience by designing nurse-led models of care for LARC and medical abortion that involve implant insertion and/or care coordination by nurses

(as appropriate) and can be implemented through face-to-face consultations or via telehealth in general practice.⁴⁷ A detailed protocol for this activity is described in Moulton *et al.*⁴⁷

Intervention support

Implementing the nurse-led model in each practice involves engaging a range of stakeholders with varying needs and capabilities. Intervention support will include addressing gaps in clinical knowledge and establishing or altering practice systems and workflows⁴⁸; and offering continued education and peer-support to address emerging clinical concerns and build clinician confidence in implementing the model.⁴⁹ We will use a 'bundle' of implementation methods, with demonstrated feasibility from our previous studies,^{36 50} to support the implementation and delivery of the nurse-led model of care.

1. Clinical upskilling: PNs and GPs who have not previously undertaken implant training will participate in an online accredited implant insertion and removal



training programme. Participants will be encouraged to identify local IUD insertion referral pathways where there is not an IUD inserter in the practice. Additionally, GPs will complete online medical abortion training to become certified prescribers of MS-2 Step. PNs will undertake online training modules on LARC and medical abortion.

2. Academic detailing (henceforth referred to as educational outreach): an educational outreach session, modelled on the successful approach adopted by the National Prescribing Service (NPS),⁵¹ will be used to discuss implementation strategies for delivery of the nurse-led model, and to introduce the GPs and PNs to the online community of practice. Each session will be facilitated by an educational visitor from the NPS and two clinical opinion leaders. GPs and PNs with experience delivering LARC and medical abortion services, will be recruited as opinion leaders and provided with online training on academic detailing and the ORIENT nurse-led model of care. Each team of facilitators (one educational visitor and one GP and one PN opinion leader) will facilitate single 60 min online educational outreach sessions to eight individual practices. At least 2 weeks prior to the delivery of each session, GP and nurse participants will each receive a pre-session pack containing: (1) a 'detailing aid' with a customisable work plan to document how the model of care will be implemented in each practice, a summary billing options informational sheet and an infographic of the model of care for easy reference, and (2) a brief 3 min video introducing the nurse-led model of care and the steps involved for setting up and delivering LARC and medical abortion services using the model.
3. Participation in an online community of practice (CoP): The Australian Contraception and Abortion Primary Care Practitioner Support Network (AusCAPPs) is a national online community for GPs, PNs and pharmacists, that has been modelled after a successful Canadian CoP,⁴⁹ and provides resources, training and online clinical support and advice regarding provision of LARC and medical abortion services. By creating professional networks of healthcare providers who share clinical and experiential knowledge to foster learning, participation in AusCAPPs can help overcome isolation in management of clinical problems, and aid implementation of new models of care.⁵² For GP and PN participants in the ORIENT trial, AusCAPPs will provide access to clinical experts and a range of resources addressing clinical challenges, system issues and patient concerns to assist GPs and PNs to implement the nurse-led model in their practice.

Participant retention

To facilitate retention of participants in the trial, trial staff will provide personalised guidance and assistance on navigating all components of the intervention support activities to participating GPs and PNs. Practice managers will be formally enrolled into the trial to serve as the

key liaison between the practice and the trial team and will be encouraged to participate in the educational outreach session for their practice. To facilitate engagement throughout the trial, trial staff will send bimonthly email updates to all participants. The email will include a reminder to access the AusCAPPs CoP for expert support and resources to implement the intervention. GPs will receive US\$500 and PNs will receive US\$200 on completion of the intervention support activities. Practice managers will receive a US\$100 gift card for their involvement as the practice liaison. Separately, at the end of the trial, each practice will receive \$500 for time given to the study.

Outcomes

Primary outcome

Our primary outcome is the change in the rate of LARC prescribing across participating practices. Since all clusters will eventually receive the intervention, data from clusters in control phases (usual care) will be compared with data from clusters that have received the intervention. At enrolment, we will ask participants for permission to access data about subsidised GP dispensed prescriptions for the hormonal IUD and implant from Services Australia, which is the government agency that administers the national healthcare scheme (Medicare). Copper IUDs are not currently subsidised; however, their use is minimal,⁵³ and as such they will not be included in this study. The number of consultations undertaken by the GP during each period will also be obtained from Medicare and used as denominators for the rate calculations.

Secondary outcomes

Secondary outcomes will capture the effect of the nurse-led model by assessing the rate of MS-2 Step prescribing and telehealth services provided by GPs. We will use PBS data on MS-2 Step prescriptions by participating GPs and Medicare Benefits Schedule (MBS) telehealth item numbers for time-based and sexual and reproductive healthcare consultations to assess secondary outcomes.

The trial uses GP prescription data for calculation of primary and secondary outcomes as services that are delivered by PNs in collaboration with and on behalf of GPs are billed and recorded under the supervising GP's Medicare provider number.

Evaluation

Fidelity checking of educational outreach sessions

Fidelity checking is a method of assessing if the intervention is delivered as designed and intended.⁵⁴ Checking fidelity allows the outcomes to be mapped back to the intervention and helps determine whether the intervention is scalable. Recordings of all 32 educational outreach sessions will be transcribed and deidentified. A fidelity checking tool will be developed, piloted and refined for assessment of the recordings. The transcripts and logbook notes of key challenges and issues reported by

participants from each session maintained by the educational visitor will be qualitatively analysed using Braun and Clarke's 6-phase theoretical framework for reflexive thematic analysis.⁵⁵ This analysis will help identify key themes, concerns and issues raised by participants during the session in relation to the implementation of the nurse-led model.

Process evaluation

We will use the Realist Evaluation model⁵⁶ and quantitative and qualitative methods to understand 'what worked for whom in what circumstances and why'. This evaluative framework examines context, mechanism and outcomes and will consist of:

1. GPs and PNs completing a pre-trial and post-trial knowledge, attitudes and practices (KAP) survey to identify changes that occurred and barriers and facilitators to implementing the nurse-led model in practice
2. Semistructured phone interviews with 60 randomly selected GPs, PNs and practice managers (20 each) to assess their perceptions of the research and intervention process, the impact on their practice, any new perspectives and concepts gained through participation and to identify factors that can assist in scale-up. PNs will also be asked to invite two women (patients) each (one consulted about contraception and one about medical abortion) during the intervention period to participate in an interview with the trial team about their experience of the model of care.
3. A content analysis of participant posts on the community of practice and digital analytics to assess engagement with peers and patterns of use.

Economic evaluation

A within-trial economic evaluation from the Australian health provider perspective will be conducted to determine the relative costs and benefits of the nurse-led model of care on the prescribing rates of LARC and medical abortion compared with usual care.

Costs will be determined by estimating (1) the cost of the intervention (eg, training, resources) and (2) the direct costs of prescribing LARC or medical abortion (eg, initial and subsequent consultation times, including telehealth consultations, additional training, drug costs). Data on resource use during the trial, including staff time for LARC and medical abortion provision, will be obtained where appropriate, via aggregated Medicare data and via surveys administered at three time points (baseline, 6 months and 12 months postintervention delivery) to GP and nurse participants, costed at prevailing market rates. Using well-established health economic principles,⁵⁷ and accounting for clustering and time, the differences in costs will be compared with changes in the primary and secondary outcome measures (rates of LARC and medical abortion prescribing and telehealth consultations) between the nurse-led model of care and usual care. Sensitivity analyses will be conducted to explore the robustness and validity of the cost-effectiveness results

and any uncertainty around mean costs and outcome measures.

Data management

Primary and secondary PBS and MBS outcome data will be retrieved for analysis only after trial completion. Data from the educational outreach sessions and qualitative interviews will be recorded and together with all other trial generated data, will be stored in electronic password-protected trial folders accessible only to authorised team members. The KAP surveys will be conducted electronically using REDCap software.^{58 59} Data integrity will be enforced through a variety of mechanisms, including referential data rules, valid values, range and consistency checks. All personal identifiers will be removed and if applicable replaced with unique IDs prior to analyses.

Blinding

This is an open pragmatic trial. Participants will become aware of their entry into the intervention phase by virtue of their participation in the activities supporting intervention implementation. Trial personnel administering and coordinating trial activities will also be unmasked to intervention allocation. Analyses of primary and secondary outcome data (PBS prescriptions and MBS item numbers for telehealth services) will be conducted post hoc by a statistician who is not blinded to the timepoints when individual practices entered the intervention phase.

Statistical methods

Primary and secondary analyses

We will use Poisson regression models for the main analyses of the primary and secondary outcomes. These models will include random effects for practice/cluster and fixed effects for time, stratification factors and intervention status.

Missing data

As the GP and PN level data are longitudinal samples, a missing data analysis will be done on each longitudinal dataset and investigations made for predictors of missingness. These investigations will examine the effect of key demographic and other factors particularly on the presence of missing outcomes. If outcome data are found to be likely to not be missing completely at random, then multiple imputations will be applied using the predictors for missingness.

Monitoring

Harms and risks

We do not anticipate any harms to GP or PN participants because of their involvement in this trial. Abortion and contraception are essential reproductive health services that are within the scope of primary care practice in Australia. We acknowledge that these issues may be considered sensitive for some, however the risk of this being the case for ORIENT participants who have voluntarily consented to participate in this trial is very low. We have developed an ethics-approved risk management



and distress protocol which outlines our approach to minimise emotional distress arising from participation, and steps that will be taken by project staff to respond to such situations should they arise. Primary and secondary outcome data on LARC and MS-2 Step prescriptions and related telehealth services will be accessed from Services Australia at the end of the trial period; given the absence of any interim data collection, a data monitoring committee has not been established.

Ethics and protocol amendments

Ethics approval for this trial has been obtained from the Monash University Human Research Ethics Committee (Project ID: 29476). Any significant protocol modifications affecting study design, eligibility criteria, data collection, outcomes and/or analyses will first be approved by all study investigators, and communicated to the Ethics Committee via an amendment. Trial modifications will also be updated in the Australian New Zealand Clinical Trials Registry.

Patient and public involvement

We will involve consumer and health professionals in the development of the nurse-led model of care through application of the experience-based codesign methodology described earlier. Additional consumer input during development of implementation support activities will be sought via the SPHERE Centre of Research Excellence in Sexual and Reproductive Health for Women in Primary Care Consumer Advisory Group and others who will be invited to provide feedback on materials or participate in interviews. Consumers will also form an integral part of stakeholder engagement for dissemination activities and plans for scale-up.

Dissemination and assessment of scalability

The integration of key partners and stakeholders from conceptualisation and design and throughout the trial optimally positions our work for end of grant knowledge transfer and rapid research translation. In Year 5, our partners and invited representatives from government and non-government agencies will participate in a knowledge exchange workshop where outcome data from the intervention, process evaluation and economic evaluation will be presented and inform the development of a national plan for scalability. Scale-up will likely be influenced by PHNs across Australia because their prescribed objectives are to improve population health and access issues through general practice. Consequently, we will invite representatives from PHNs to participate in the knowledge exchange workshop. Project outcomes will be reported in policy briefings to facilitate research translation and disseminated through SPHERE's national communication network as well as through conference presentations at major national and international primary care and practice nursing meetings and via peer-reviewed publications in journals in clinical and public health-focused journals.

DISCUSSION

In Australia, the use of LARC and medical abortion as effective strategies to prevent and respond to unintended and unwanted pregnancies remains hampered by disparities in geographical availability and access. Women living in rural and regional areas are disadvantaged by their reduced exposure to accurate information, poor proximity of services and complicated referral pathways, with a resulting need to travel long distances and bear associated costs to exercise reproductive choice.^{7 60} Nurse-led models involving task-sharing have been effective in improving access to these services in community healthcare settings but are yet to be trialled in general practice. The ORIENT trial aims to build on this promising evidence by assessing the effectiveness of a nurse-led model of care for LARC and medical abortion in general practice to increase uptake of contraception and improve access to medical abortion for women in rural and regional areas.

The design and delivery of this intervention addresses several barriers to LARC and medical abortion service provision in Australian primary care. The nurse-led model will be codesigned with healthcare providers, consumers and other stakeholders to optimise patient experience and model applicability for the contexts in which it will be implemented. The mode will need to be flexible and able to be tailored to suit existing workflows within individual practices. To address the often-cited barrier of poor awareness of service availability,⁹ the model will incorporate resources and recommendations. These will include strengthening partnerships with allied health services, to raise visibility and hence demand among patient populations and the broader community. The team-based approach to service provision with patient education, care coordination and where appropriate, implant insertion by nurses will encourage primary care providers to offer care to their full scope of practice. This will occur through rational distribution and sharing of tasks making the delivery of these multiphase services more time efficient for the clinicians involved. Although we will not differentiate between geographical classification when recruiting (ie, MM2–MM7), recruitment will occur across all states and territories to increase diversity.

Importantly, implementation of this intervention is supported by key activities that have proven to be successful in improving clinical practice in prior research studies.^{52 61–63} GPs and PNs will be provided with accredited training on LARC and medical abortion to enhance their clinical competencies to provide this care. The educational outreach session will be critical to the discussion of practical strategies for customisation of the model to suit individual practices. Clinical opinion leader advice on overcoming anticipated logistical and clinical challenges based on real-world experiences is designed to strengthen motivation and confidence in model implementation. Finally, a key barrier expressed by GPs, particularly in the case of medical abortion, is concern regarding professional isolation and a lack of support to deliver this care. The online community of practice—with its

interactive elements that include a discussion forum for clinical questions and sharing information, webinars and podcasts, case studies, a resource library and a growing directory of members enabling the building of online peer networks, partnerships and referral pathways—will help to promote and sustain model implementation through and beyond the ORIENT trial period.

Results of the ORIENT trial will assess the effectiveness and cost-effectiveness of a nurse-led model of care in general practice at increasing LARC uptake and access to medical abortion services for women living in rural and regional areas of Australia. The accompanying findings of the economic and process evaluations will provide insight into cost-effectiveness of the model for the primary healthcare system and the contextual and/or behavioural factors that support or impede model implementation. Collectively, these outcomes will be critical to taking an empirically informed approach to model scale-up and contributing to national and international scholarship on improving availability and accessibility of contraception and abortion services through service delivery innovations in primary care.

Author affiliations

¹Faculty of Medicine Nursing and Health Sciences, Department of General Practice, Monash University, Clayton, Victoria, Australia

²Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia

³Department of Rural Health, University of Melbourne, Melbourne, Victoria, Australia

⁴Obstetrics, Gynaecology and Neonatology, University of Sydney, Sydney, New South Wales, Australia

⁵Centre for Health Economics Research and Evaluation, University of Technology Sydney Faculty of Health, Ultimo, New South Wales, Australia

⁶Clinical and Health Sciences, University of South Australia, Adelaide, South Australia, Australia

⁷School of Public Health and Preventive Medicine, Monash University, Clayton, Victoria, Australia

⁸Department of Family Practice, The University of British Columbia, Vancouver, British Columbia, Canada

⁹Faculty of Public Health and Policy, Public Health, Environments & Society, London School of Hygiene and Tropical Medicine, London, UK

Twitter Danielle Mazza @Danielle_Mazza; SPHERE_CRE, Jessica R Botfield @Jess_Botfield, Jessica E Moulton @jessicamoulton_, Samantha Paubrey Chakraborty @SamanthaC_22, Kirsten Black @KirstenIsIaB, Jessica Kasza @JessKasza and Wendy V Norman @wvnorman

Acknowledgements We thank Kevin McGeechan for his contributions to the conception of the trial and initial statistical advice related to the draft protocol. We also wish to thank Asvini Subasinghe and Kellie Hamill for providing input and reviewing early drafts of this manuscript.

Contributors DM, KB, JT, DB, TL and WVN conceived and drafted the trial design and trial protocol. TL and JC led the economic evaluation methodology. MS, JRB, JEM and SPC refined and updated the protocol under the direction of DM, KB, JT, DB, TL, JK and WVN. All authors reviewed and approved the final manuscript before submission.

Funding This work was supported by the Medical Research Future Fund (MRFF) grant number MRF 1200453.

Competing interests DM has received research and conference attendance funding, speaker fees and been an advisory board member for Bayer, Organon and MSD. DB has provided education for doctors sponsored by Bayer and Organon and has been an advisory board member for Bayer, Organon and MSD. DB has never received personal remuneration for these services. During this study WVN was a member of the Board of Directors of the Society of Family Planning. She receives family planning research grants from Canadian and UK

governments and not for profit associations, none of which are related to this project.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Danielle Mazza <http://orcid.org/0000-0001-6158-7376>

Mridula Shankar <http://orcid.org/0000-0002-4652-6396>

Jessica R Botfield <http://orcid.org/0000-0001-6157-9739>

Jessica E Moulton <http://orcid.org/0000-0001-7172-9470>

Samantha Paubrey Chakraborty <http://orcid.org/0000-0002-9708-4532>

Deborah Bateson <http://orcid.org/0000-0003-1035-7110>

Jessica Kasza <http://orcid.org/0000-0002-8940-0136>

Wendy V Norman <http://orcid.org/0000-0003-4340-7882>

REFERENCES

- 1 Kruss J, Gridley H. Country women are resilient but. . . : family planning access in rural Victoria. *Aust J Rural Health* 2014;22:300–5.
- 2 Rowe H, Holton S, Kirkman M, *et al*. Prevalence and distribution of unintended pregnancy: the understanding fertility management in Australia national survey. *Aust N Z J Public Health* 2016;40:104–9.
- 3 Trussell J. Understanding contraceptive failure. *Best Pract Res Clin Obstet Gynaecol* 2009;23:199–209.
- 4 Garrett CC, Keogh LA, Kavanagh A, *et al*. Understanding the low uptake of long-acting reversible contraception by young women in Australia: a qualitative study. *BMC Womens Health* 2015;15:72.
- 5 Mazza D, Harrison C, Taft A, *et al*. Current contraceptive management in Australian general practice: an analysis of beach data. *Med J Aust* 2012;197:110–4.
- 6 Mazza D, Bateson D, Frearson M, *et al*. Current barriers and potential strategies to increase the use of long-acting reversible contraception (LARC) to reduce the rate of unintended pregnancies in Australia: an expert roundtable discussion. *Aust N Z J Obstet Gynaecol* 2017;57:206–12.
- 7 Doran FM, Hornibrook J. Barriers around access to abortion experienced by rural women in New South Wales, Australia. *Rural Remote Health* 2016;16:3538.
- 8 Goldstone P, Walker C, Hawtin K. Efficacy and safety of mifepristone-buccal misoprostol for early medical abortion in an Australian clinical setting. *Aust N Z J Obstet Gynaecol* 2017;57:366–71.
- 9 Mazza D, Burton G, Wilson S, *et al*. Medical abortion. *Aust J Gen Pract* 2020;49:324–30.
- 10 Downing SG, Cashman C, Russell DB. Ten years on: a review of medical terminations of pregnancy performed in a sexual health clinic. *Sex Health* 2017;14:208–12.
- 11 Department of Health. *National women's health strategy 2020-2030*. Department of Health, Commonwealth of Australia, 2018.
- 12 Marie Stopes Australia. *Situational report: sexual and reproductive health rights in Australia Melbourne*. Australia: Marie Stopes Australia, 2021.
- 13 Subasinghe AK, McGeechan K, Moulton JE, *et al*. Early medical abortion services provided in Australian primary care. *Med J Aust* 2021;215:366–70.
- 14 WHO. *Abortion care guideline*. Geneva: World Health Organization, 2022.
- 15 WHO. *Health worker roles in providing safe abortion care and post-abortion contraception*. Geneva, Switzerland: World Health Organization, 2015.
- 16 Sjöström S, Kopp Kallner H, Simeonova E, *et al*. Medical abortion provided by nurse-midwives or physicians in a high resource setting: a cost-effectiveness analysis. *PLoS One* 2016;11:e0158645.
- 17 Casey M, O'Connor L, Cashin A, *et al*. An overview of the outcomes and impact of specialist and advanced nursing and midwifery practice, on quality of care, cost and access to services: a narrative review. *Nurse Educ Today* 2017;56:35–40.

- 18 Desborough J, Bagheri N, Banfield M, *et al.* The impact of general practice nursing care on patient satisfaction and enablement in Australia: a mixed methods study. *Int J Nurs Stud* 2016;64:108–19.
- 19 Sexual Health and Family Planning Australia. Time for a change: increasing the use of long acting reversible contraceptive methods in Australia; 2013.
- 20 Garrett CC, Williams H, Keogh L, *et al.* Is there a role for practice nurses in increasing the uptake of the contraceptive implant in primary care?: survey of general practitioners and practice nurses. *Sex Health* 2016;13:241–7.
- 21 Subasinghe AK, Deb S, Mazza D. Primary care providers' knowledge, attitudes and practices of medical abortion: a systematic review. *BMJ Sex Reprod Health* 2019;bmjsrh-2019-200487.
- 22 Tomnay JE, Coelli L, Davidson A, *et al.* Providing accessible medical abortion services in a Victorian rural community: a description and audit of service delivery and contraception follow up. *Sex Reprod Healthc* 2018;16:175–80.
- 23 Botfield JR, Lacey S, Fleming K, *et al.* Increasing the accessibility of long-acting reversible contraceptives through nurse-led insertions: a cost-benefit analysis. *Collegian* 2020;27:109–14.
- 24 Fleming K, Cheng Y, Botfield J, *et al.* Inclusion of intrauterine device insertion to registered nurses' scope of clinical practice. *Collegian* 2019;26:28–32.
- 25 Harris MF, Harris-Roxas B, Knight AW. Care of patients with chronic disease: achievements in Australia over the past decade. *Med J Aust* 2018;209:55–7.
- 26 Mahomed R, St John W, Patterson E. Understanding the process of patient satisfaction with nurse-led chronic disease management in general practice. *J Adv Nurs* 2012;68:2538–49.
- 27 Furler JS, Blackberry ID, Walker C, *et al.* Stepping up: a nurse-led model of care for insulin initiation for people with type 2 diabetes. *Fam Pract* 2014;31:349–56.
- 28 Hyland P, Raymond EG, Chong E. A direct-to-patient telemedicine abortion service in Australia: retrospective analysis of the first 18 months. *Aust N Z J Obstet Gynaecol* 2018;58:335–40.
- 29 LaRoche KJ, Wynn LL, Foster AM. "We've got rights and yet we don't have access": exploring patient experiences accessing medication abortion in Australia. *Contraception* 2020;101:256–60.
- 30 Grossman D, Grindlay K. Safety of medical abortion provided through telemedicine compared with in person. *Obstet Gynecol* 2017;130:778–82.
- 31 Aiken AR, Gomperts R, Trussell J. Experiences and characteristics of women seeking and completing at-home medical termination of pregnancy through online telemedicine in Ireland and Northern Ireland: a population-based analysis. *BJOG* 2017;124:1208–15.
- 32 Department of Health. COVID-19 temporary MBS telehealth services. Department of Health, Australian Government; 2021.
- 33 Toll K, Spark L, Neo B, *et al.* Consumer preferences, experiences, and attitudes towards telehealth: qualitative evidence from Australia. *PLoS One* 2022;17:e0273935.
- 34 Hemming K, Haines TP, Chilton PJ, *et al.* The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015;350:h391.
- 35 Department of Health. Modified monash model: Australian government. 2020. Available: www.health.gov.au/health-workforce/health-workforce-classifications/modified-monash-model
- 36 Mazza D, Watson CJ, Taft A, *et al.* Increasing long-acting reversible contraceptives: the Australian contraceptive choice project (Accord) cluster randomized trial. *Am J Obstet Gynecol* 2020;222:S921.
- 37 Mazza D, Black K, Taft A, *et al.* Increasing the uptake of long-acting reversible contraception in general practice: the Australian contraceptive choice project (Accord) cluster randomised controlled trial protocol. *BMJ Open* 2016;6:e012491.
- 38 Hemming K, Girling A. A menu-driven facility for power and detectable-difference calculations in stepped-wedge cluster-randomized trials. *The Stata Journal* 2014;14:363–80.
- 39 Enticott JC, Shawyer F, Brophy L, *et al.* The PULSAR primary care protocol: a stepped-wedge cluster randomized controlled trial to test a training intervention for general practitioners in recovery-oriented practice to optimize personal recovery in adult patients. *BMC Psychiatry* 2016;16:451.
- 40 Mazza D, Chakraborty S, Camões-Costa V, *et al.* Implementing work-related mental health guidelines in general practice (improve): a protocol for a hybrid III parallel cluster randomised controlled trial. *Implement Sci* 2021;16:77.
- 41 Scott NW, McPherson GC, Ramsay CR, *et al.* The method of minimization for allocation to clinical trials. A review. *Control Clin Trials* 2002;23:662–74.
- 42 Dawda P, Knight A. *Experience-based co-design: a toolkit for Australia*. Australia: Consumers Health Forum of Australia, 2018.
- 43 Deb S, Subasinghe AK, Mazza D. Providing medical abortion in general practice: general practitioner insights and tips for future providers. *Aust J Gen Pract* 2020;49:331–7.
- 44 Fix L, Seymour JW, Sandhu MV, *et al.* At-home telemedicine for medical abortion in Australia: a qualitative study of patient experiences and recommendations. *BMJ Sex Reprod Health* 2020;46:172–6.
- 45 Mazza D, Seymour JW, Sandhu MV, *et al.* General practitioner knowledge of and engagement with telehealth-at-home medical abortion provision. *Aust J Prim Health* 2021;27:456–61.
- 46 Thompson T-A, Seymour JW, Melville C, *et al.* An observational study of patient experiences with a direct-to-patient telehealth abortion model in Australia. *BMJ Sex Reprod Health* 2022;48:103–9.
- 47 Moulton JE, Mazza D, Tomnay J, *et al.* Co-design of a nurse-led model of care to increase access to medical abortion and contraception in rural and regional general practice: a protocol. *Aust J Rural Health* 2022;30:876–83.
- 48 Moulton JE, Subasinghe AK, Mazza D. Practice nurse provision of early medical abortion in general practice: opportunities and limitations. *Aust J Prim Health* 2021;27:427–30.
- 49 Dunn S, Munro S, Devane C, *et al.* A virtual community of practice to support physician uptake of a novel abortion practice: mixed methods case study. *J Med Internet Res* 2022;24:e34302.
- 50 Harris MF, Parker SM, Litt J, *et al.* Implementing guidelines to routinely prevent chronic vascular disease in primary care: the preventive evidence into practice cluster randomised controlled trial. *BMJ Open* 2015;5:e009397.
- 51 Gadzhanova SV, Roughead EE, Bartlett MJ. Improving cardiovascular disease management in Australia: NPS MedicineWise. *Med J Aust* 2013;199:192–5.
- 52 Wieringa S, Engebretsen E, Heggen K, *et al.* How knowledge is constructed and exchanged in virtual communities of physicians: qualitative study of mindlines online. *J Med Internet Res* 2018;20:e34.
- 53 Grzeskowiak LE, Calabretto H, Amos N, *et al.* Changes in use of hormonal long-acting reversible contraceptive methods in Australia between 2006 and 2018: a population-based study. *Aust N Z J Obstet Gynaecol* 2021;61:128–34.
- 54 Carroll C, Patterson M, Wood S, *et al.* A conceptual framework for implementation fidelity. *Implement Sci* 2007;2:40.
- 55 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
- 56 Pawson R, Greenhalgh T, Harvey G, *et al.* Realist review -- a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy* 2005;10 Suppl 1:21–34.
- 57 Gray A, Clarke PM, Wolstenholme JL, *et al.* *Applied methods of cost-effectiveness analysis in healthcare*. Oxford: Oxford University Press, 2010.
- 58 Harris PA, Taylor R, Minor BL, *et al.* The redcap consortium: building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.
- 59 Harris PA, Taylor R, Thielke R, *et al.* Research electronic data capture (redcap) -- a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
- 60 Shankar M, Black KI, Goldstone P, *et al.* Access, equity and costs of induced abortion services in Australia: a cross-sectional study. *Aust N Z J Public Health* 2017;41:309–14.
- 61 Flodgren G, O'Brien MA, Parmelli E, *et al.* Local opinion leaders: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2019;6:CD000125.
- 62 Kulbokas V, Hanson KA, Smart MH, *et al.* Academic detailing interventions for opioid-related outcomes: a scoping review. *Drugs Context* 2021;10:2021-7-7.
- 63 Fischer MA. Academic detailing in diabetes: using outreach education to improve the quality of care. *Curr Diab Rep* 2016;16:1–6.