EXPLANATORY STATEMENT

(For General Practices)

Project ID: 29476

Project title: The ORIENT study: imprOving Rural and regIonal accEss to long acting reversible contraceptioN and medical abortion through nurse-led models of care, Tasksharing and telehealth

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Your practice is invited to take part in the ORIENT study. Please read this Explanatory Statement in full before deciding whether or not to participate. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

Research rationale and approach

Australian women living in rural and regional areas have higher rates of unintended pregnancies and face difficulties accessing long acting reversible contraception (LARC), such as intrauterine devices and implants, and early medical abortion (EMA).

The ORIENT study will test the effectiveness of a collaborative nurse-led model of care in general practice, involving optimal use of clinical upskilling, GP-nurse task sharing and telehealth services to increase access to LARC and EMA for women living in rural and regional Australia. This nurse-led model has been co-designed with end users, rural primary care practitioners and our key partner stakeholders.

Who can participate in this research?

We are recruiting general practices located in regional and rural Australia.

To be eligible to participate in the ORIENT study, your general practice must have at least two GPs and a practice nurse willing to participate in the study, and a practice manager who will serve as the study liaison.

What does participation entail?

Participating general practices will be encouraged and supported to deliver the nurse-led model of LARC and EMA care with the assistance of an ***implementation bundle*** targeted to GPs and practice nurses. Each practice will be randomly allocated to one of four implementation clusters, and each cluster will receive access to the bundle in a stepwise fashion. We anticipate that the first cluster will receive access to the bundle in early/mid 2022.

The implementation bundle will consist of the following components:

1. Free, accredited online implant insertion and removal training (if not previously undertaken) for GPs and nurses (approximately 3 hours).
2. Online MS-2 Step prescriber training for GPs (approximately 2 hours)

3. Free, accredited online LARC and EMA education for nurses (approximately 3 hours)
4. Educational outreach for the practice (GP, nurse and practice manager) via a single online 60-minute session
5. Enrolment of GPs and nurses into an Australia-wide virtual Community of Practice for access to clinical experts, discussions with like-minded clinicians and resources to support delivery of LARC and EMA services within general practice. This activity is self-paced.

Participating GPs, nurses and practice managers will also be asked to complete short surveys at various time points in the study period. Each survey should take no more than 10-15 minutes to complete.

Participation Reimbursement

GPs and staff nurses who enrol in the trial and complete all necessary components of the intervention bundle will be financially compensated for their time. Specifically, GPs will receive $500 and PNs will receive $200 upon confirmation that they have completed all training components and participated in the educational outreach session. Practice managers will receive a $100 gift card for their participation in educational outreach and for serving as the study liaison. Separately, at the end of the trial, each participating practice will receive a single reimbursement of $500 for administrative time needed to provide access to data for assessment of trial outcomes.

Source of funding

This research study is funded by a Medical Research Future Fund (MRFF) Primary Health Care Research grant. There are no declarable conflicts of interest.

Consenting to participate in the project and withdrawing from the research

You may express your interest to take part in this study via the QR code and link (https://redcap.link/jdcgo0n4) or by emailing orient.trial@monash.edu. Your practice's participation in the study will begin once participating GPs, practice nurse and practice manager have signed the consent form.

Participation in this study is completely voluntary. If you agree to participate, you can withdraw from the study at any time. If your practice decides after commencing the trial that you/they do not wish to continue, then you/they do not need to do so. There will be no negative consequences associated with refusal or withdrawal from participation.

If you do wish to withdraw from the study you will need to complete and sign the "Participant withdrawal of consent form" which can be provided by an ORIENT researcher. We will retain any data collected prior to withdrawal for future studies unless otherwise indicated.

Possible benefits and risks to participants

The nurse-led model of care and its implementation will equip primary care health professionals located in rural and regional areas with the resources, networks, knowledge and skills to improve reproductive health outcomes for women. A key outcome of the ORIENT study will be to examine not only the impact on LARC uptake and EMA access, but the feasibility and economic viability of a nurse-led model. The intervention (if proven) can be scaled up nationally to decrease unplanned pregnancy and improving reproductive health outcomes for women through improving access to LARC methods and EMA.

Collected data will be de-identified, thereby minimizing the risk of loss of confidentiality. Separately, you may be at risk of psychological distress when discussing abortion and contraception service delivery. In order to mitigate this risk, we have a distress protocol which offers reassurance of the aims of the project and confidentiality of the data. If you wish to speak to someone about any discomfort you experience you may contact Lifeline (13 11 14) and/or the

project manager of the ORIENT study who can also provide you with the contact information of appropriate mental health services based on your personal preferences.

Confidentiality

All aspects of this study, including results, will be strictly confidential and only the principal researchers will have access to information provided by participants. No individual data will be disclosed and all data will be de-identified for analysis and reporting.

Storage of data

Any data collected will be stored on a secure drive on the Monash server. All electronic data (e.g. participant databases) will be password protected and will only be accessible by the researchers. Where non-Monash University parties require access, secure data exchange methods will be used such as password protected USB drives, encrypted files, or a secure Dropbox folder. Survey data will be collected via REDCap (browser-based platform housing survey data) and will be stored on a password-protected electronic database.

Any written data will be compiled onto a MS Word document and stored on Monash University password-protected computers and disposed of after five years in line with university protocol.

Use of data for other purposes

Secondary use of data increases the value of your data. The aggregated de-identified data collected may be used for purposes other than this study where ethics approval has been granted.

Results

The rate of LARC prescribing will be our primary outcome using data from Medicare on PBS dispensed LARC prescriptions. We will also assess the rate of MS2Step prescribing (the combined pack of mifepristone/misoprostol prescribed for medical abortion) and the rate of telehealth services under the MBS.

We expect to present de-identified findings from the study at conference(s) and publish our findings in peer-reviewed journals. Abstracts of conference presentations or links to journal publications will be directly shared with you via email or post. Participants can also contact Mridula Shankar (Project Manager) at mridula.shankar@monash.edu to request a copy of published results or for any further information regarding the study.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

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Thank you,

Professor Danielle Mazza