EXPLANATORY STATEMENT
(PHARMACIES & PHARMACISTS)

Project ID:	34563		
Project title:	Quality family planning services in community pharmacy: Expanding pharmacists' scope of practice (The ALLIANCE Trial)		
Chief Investigator:	Professor Danielle Mazza	**Trial Manager:**	Dr Anisa Assifi
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You are invited you to participate in the ALLIANCE Trial, which is being conducted by the SPHERE Centre of Research Excellence in Sexual and Reproductive Health for Women in Primary Care (Department of General Practice, Monash University). Please read this Explanatory Statement in full before deciding whether or not to participate in this research.

If you would like further information, you can contact the Project Manager on ALLIANCE.trial@monash.edu or 03 9905 0545

What does the research involve?
The ALLIANCE Trial provides an opportunity to **increase contraceptive knowledge, access and use** among women presenting to pharmacies for the emergency contraceptive pill (ECP) or early medical abortion medicines (MS-2 Step), and may reduce their chances of a future unintended pregnancy. To achieve this, pharmacists will **implement the ALLIANCE intervention** in their pharmacy.

THE INTERVENTION
- Person-centred, effectiveness-based **contraceptive counselling** (in a private consultation room)
- **+/- a referral** to a contraception provider
- These consultations (approx. 20 mins) will be **remunerated to the pharmacist**

REIMBURSEMENTS
- **Each pharmacy will receive $1500** ($1000 in total paid to participating pharmacist(s) and $500 to the practice) at the end of the trial; and
- In the intervention phase, pharmacists will receive **$56 for very consultation +/- referral**.

IMPLEMENTATION SUPPORT
Participating pharmacists will receive the following 'bundle' of activities to implement the intervention:
- accredited **online education (Level 3 CPD Points)** – a module developed by PSA to train pharmacists on how to provide the intervention and educate on relevant theories
- tailored **academic detailing** session **(Level 3 CPD Points)** - co-designed with stakeholders, this session will introduce pharmacists to the ALLIANCE intervention, provide pharmacists with resources on how to implement the intervention in their pharmacy, identify referral pathways and introduce and enrol the pharmacists into the online community of practice
- **identification of referral pathways** to contraception prescribers
- participation in an **online community of practice** (AusCAPPS) - providing access to resources, networks, case studies and more

STEPPED-WEDGE CLUSTER RANDOMISED TRIAL
All pharmacists will provide a period of **usual care** (for between two and 14-months) before being transitioned to the **intervention phase**. During the two-month **transition phase**, pharmacists will gain access to and complete the implementation support activities and implement the intervention in their pharmacy. Pharmacists will undertake

additional **research-related tasks** throughout the entire duration of their participation in the trial. These tasks include but are not limited to:

- screening + recruiting eligible women (3 to 12 women per month), completing associated administrative tasks (approx. 15 mins per patient) and upholding ethical research conduct at all times;
- adhering to ALLIANCE standard operating procedures (e.g. pertaining to recruitment, billing, referral, etc.) and ensuring all non-participating pharmacy employees/colleagues are aware of the nature of the project, your participation and when necessary, support project activities;
- regularly reviewing and updating processes + clinical knowledge during the intervention phase; and
- liaising with and reporting any issues for resolution to the ALLIANCE Clinical Trial Coordinator.

Towards the end of the trial, we will invite a random selection of pharmacists to undertake an audio-recorded **interview about their experience** of providing the intervention. At this time, pharmacists will receive detailed information about this aspect of the study and the fullest opportunity to make an informed decision about their participation and sign a consent form if they choose to participate, or decline without any negative consequences.

Why were you chosen for this research?

You are invited to join the trial if you meet the eligibility criteria as follows:

- pharmacy located in metropolitan, regional or rural NSW, VIC or NT;
- Quality Care Pharmacy Program-accredited (https://www.qcpp.com/);
- private consultation room on premises;
- has at least one pharmacist who works 30+ hrs/week willing to commit to participation;
- participating pharmacist(s) is accredited to dispense MS-2 Step; and
- consent from the pharmacy owner has been obtained.

All pharmacists employed at participating pharmacies will have the option of taking part, this is not mandatory.

Consenting to participate in the project and withdrawing from the research

Participation in this study is completely voluntary and you are not under any obligation to participate. If you agree to participate, you can withdraw participation of yourself or your whole pharmacy (pharmacy owner only) at any time using an online withdrawal form. There will be no negative consequences for refusal or withdrawal from participation.

Pharmacy owners must first submit a consent form as approval of the pharmacy practice's participation in the project. Each pharmacist from the pharmacy that wishes to join the trial must also sign a consent form.

Possible benefits and risks to participants

Pharmacists in the trial will have access to resources and supports developed to reduce barriers to the provision of contraceptive counselling in pharmacies as described by pharmacists in previous Australian research, and improve patient care outcomes.

Potential risks to pharmacists are anticipated to be no more than discomfort. Pharmacists may experience discomfort or inconvenience when implementing new skills and research related tasks in their practice. They may also experience discomfort when interacting with patients in certain circumstances (e.g. if patients become distressed or agitated during recruitment or their participation) though no greater than experienced in normal practice. Key stakeholders have been consulted allowing us to develop processes and resources and ALLIANCE tasks have been built into existing pharmacy procedures (e.g. the Pharmaceutical Society of Australia referral template), to assist in the acceptability to consumers throughout the intervention process, thereby reducing the potential risks.

Source of funding
This trial is funded by the MRFF Quality, Safety and Effectiveness of Medicine Use and Medicine Intervention by Pharmacists Grant Opportunity (MRFQI000057). There are no declarable conflicts of interest.

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 shared, and all data will be de-identified before being included in analyses or reported.

Storage of data
All data collected will be stored separately from the consent form, electronic data will be password-protected and stored on the Monash server. This data will only be accessed by the researchers. Where non-Monash University parties require access (e.g. for secondary analyses), a de-identified version of the data will be sent by secure data exchange methods, such as encrypted files, or secure Australian servers. All digital data will be stored securely 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
We expect to present de-identified findings from the study at conferences and publish our findings in a peer-reviewed journal. Participants can contact the ALLIANCE team via email to request a copy of the published results.

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):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
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Thank you,

Professor Danielle Mazza