











BMJ Open Expanding community pharmacists' scope of practice in relation to contraceptive counselling and referral: a protocol for a pragmatic, stepped-wedge, cluster randomised trial (ALLIANCE)

Danielle Mazza ¹, Anisa Rojanapenkul Assifi ¹, Safeera Yasmeen Hussainy ^{1,2}, Deborah Bateson ³, Stefanie Johnston,⁴ Jane Tomnay ⁵, Jessica Kasza ⁶, Jody Church ⁷, Luke E Grzeskowiak ^{8,9}, Lisa Nissen ¹⁰, Sharon Tracey Cameron ^{11,12}

To cite: Mazza D, Assifi AR, Hussainy SY, *et al.* Expanding community pharmacists' scope of practice in relation to contraceptive counselling and referral: a protocol for a pragmatic, stepped-wedge, cluster randomised trial (ALLIANCE). *BMJ Open* 2023;**13**:e073154. doi:10.1136/bmjopen-2023-073154

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2023-073154>).

Received 24 February 2023
Accepted 21 August 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 Improving access to effective contraception has the potential to reduce unintended pregnancy and abortion rates. Community pharmacists could play an expanded role in contraceptive counselling and referral to contraceptive prescribers particularly when women are already attending community pharmacy to obtain emergency contraceptive pills (ECPs) or to have medical abortion (MA) medicines dispensed. The ALLIANCE trial aims to compare the subsequent uptake of effective contraception (hormonal or intrauterine) in women seeking ECP or MA medicines, who receive the ALLIANCE community pharmacy-based intervention with those who do not receive the intervention.

Methods and analysis ALLIANCE is a stepped-wedge pragmatic cluster randomised trial in Australian community pharmacies. The ALLIANCE intervention involves community pharmacists delivering structured, patient-centred, effectiveness-based contraceptive counselling (and a referral to a contraceptive prescriber where appropriate) to women seeking either ECPs or to have MA medicines dispensed. Women participants will be recruited by participating pharmacists. A total of 37 pharmacies and 1554 participants will be recruited. Pharmacies commence in the control phase and are randomised to transition to the intervention phase at different time points (steps). The primary outcome is the self-reported use of effective contraception at 4 months; secondary outcomes include use of effective contraception and the rate of pregnancies or induced abortions at 12 months. A process and economic evaluation of the trial will also be undertaken.

Ethics and dissemination Ethical approval has been obtained from the Monash University Human Research Ethics Committee (#34563). An explanatory statement will be provided and written consent will be obtained from all participants (pharmacy owner, pharmacist and women) before their commencement in the trial. Dissemination will occur through a knowledge exchange workshop, peer-

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The quality family planning services and referrals in community pharmacy: expanding pharmacists' scope of practice (ALLIANCE) trial will implement a novel pharmacist-delivered contraceptive counselling approach.
- ⇒ The trial builds on the successful ACCORd and Bridge-It trials, training pharmacists through an on-line educational module and creating referral pathways to contraceptive prescribers.
- ⇒ Known barriers to the provision of contraceptive care by community pharmacists in the current Australian context have been addressed in the implementation support activities, reducing potential pharmacist hesitancy.
- ⇒ As codesign methods were used in developing the intervention and implementation support, we anticipate that the intervention will have both immediate and sustainable impact across metropolitan, regional and rural regions.
- ⇒ A limitation of the study is that participating pharmacists may not be representative of the wider population as trial participation is contingent on pharmacists' provision of emergency contraceptive pills and medical abortion and interest in delivering contraceptive counselling.

reviewed journal publications, presentations, social media and conferences.

Trial registration number ACTRN12622001024730.

INTRODUCTION

Preventing unintended pregnancy is an important public health imperative and a key focus of Australia's National Women's Health Strategy 2020–2030.¹ In Australia, 40% of



women experience an unintended pregnancy during their lifetime, and one in three of these results in abortion.^{2,3} The cost of an unintended pregnancy in Australia was estimated to be \$A7.2 billion in 2020, with 56% of total costs borne either directly or indirectly on the woman experiencing the unintended pregnancy.² Where contraception has not been used at all, incorrectly or fails, emergency contraception can be taken after intercourse to reduce the likelihood of conception. The emergency contraceptive pill (ECP), levonorgestrel and ulipristal acetate, is available in pharmacies without a prescription in Australia. Guidelines emphasise that ongoing effective contraception following the provision of ECP is critical for reducing the risk of subsequent unintended pregnancies.^{4,5} However only one in five ECP encounters in pharmacies involve questions about current contraceptive use and only one in three involve counselling regarding the importance of ongoing contraception.⁶

In Australia, a combination pack of mifepristone and misoprostol is registered for use for an early medical abortion (EMA) up to 9 weeks' gestation. The provision of effective reversible contraception following abortion is recognised by the WHO as a key component of abortion care.⁷ Delayed contraceptive provision postabortion is associated with greater odds of repeat unintended pregnancy.^{8–12} A national study of Australian dispensing data found only 35% of women use effective hormonal contraception following the supply of medical abortion (MA) medicines, and that the rate of repeat EMA was halved among those who received long-acting reversible contraception (LARC) and reduced by a third for those who received other hormonal contraceptive methods.¹³ These findings are consistent with international literature.^{12,14}

High-quality contraceptive counselling involves the provision of comprehensive information (including efficacy, potential side effects, safety and cost) on available contraceptive choices.¹⁵ Access to high-quality accurate contraceptive counselling and methods have the potential to reduce unintended pregnancy and abortion rates. However, such counselling is difficult to access, with many Australian women having poor knowledge of all their contraceptive options.^{16–18}

Community pharmacists are an untapped resource for increasing access to health information. There are approximately 5700 community pharmacies across Australia delivering highly-accessible professional health services, medicines and health advice.¹⁹ Community pharmacists are consistently seen by consumers as a trusted and valued part of the healthcare system and in regional areas, 65% of Australians live within 2.5 km of a pharmacy.¹⁹ Expanding community pharmacists' scope of practice has the potential to benefit rural and regional communities, where access to health professionals and health outcomes are lower than in metropolitan areas. Studies in the USA and the UK have found that community pharmacist expanded scope of practice in sexual and reproductive healthcare have improved women's access and continuation of effective contraceptive methods.^{20–23}

In a national Australian survey, almost 40% of community pharmacists report daily or weekly requests for contraceptive advice, demonstrating that many women perceive the pharmacy as an appropriate setting to obtain contraceptive information.²⁴ Pharmacists demonstrated a high level of willingness and interest in providing more comprehensive contraceptive counselling, but identified key barriers such as: lack of payment for providing such counselling; the need for additional education and training; the need for protocols and resources to assist them to deliver counselling and lack of confidence.²⁴ Consumers in Australia have also described a need to trust that pharmacists are knowledgeable, non-judgemental, appropriately trained and provide credible information and advice.^{25,26}

The ALLIANCE trial proposes that expanding pharmacists' scope of practice, while simultaneously addressing known barriers to expanding this scope, could improve women's use of effective contraception and reduce the rate of subsequent unintended pregnancies among women presenting to pharmacies for ECP or EMA. The trial is informed by the successful ACCORD and Bridge-It trials.^{20,27} The ALLIANCE trial will build on the feasibility of: (1) the intervention, retention rates and use of self-reported outcome measures demonstrated in ACCORD, translating the ACCORD intervention into the community pharmacy setting and (2) recruiting community pharmacists and women at the point of ECP provision demonstrated in Bridge-It.

The aim of ALLIANCE is to compare the subsequent uptake of effective contraception (hormonal or intrauterine) in women seeking ECP or MA medicines, who receive the ALLIANCE community pharmacy-based intervention with those who do not receive the intervention. The effectiveness of the proposed intervention as well as acceptability of the intervention, patient outcomes and cost-effectiveness will be assessed.

The primary objective is to determine if the intervention results in increased utilisation of hormonal or intrauterine contraception by women 4 months after the provision of the ECP or MA medicines. The secondary objectives are to evaluate:

1. The subsequent unintended pregnancy and abortion rates and continued use of effective contraception (hormonal or intrauterine) at 12-month postdelivery of the ALLIANCE community pharmacy-based intervention.
2. The implementation of the ALLIANCE intervention.
3. The cost-effectiveness of the ALLIANCE community pharmacy-based intervention.

METHODS AND ANALYSIS

Methodological approaches

The ALLIANCE Trial is a hybrid type 2 effectiveness-implementation designed trial, with a focus on determining the effectiveness of the intervention, and feasibility and impact of the implementation related activities.²⁸ The Reach, Effectiveness, Adoption, Implementation and

| METHOD | REACH | EFFECTIVENESS | ADOPTION | IMPLEMENTATION | MAINTENANCE |
|----------|---|---|---|--|---|
| ACTIVITY | <p>We will review and monitor the extent that pharmacies remain engaged in the intervention and tailor the intervention to increase engagement</p> <p>Will review and monitor the number of women to receive the intervention</p> | <p>We will assess the effectiveness through examining contraceptive use and unintended pregnancy as per the listed outcomes</p> | <p>We will evaluate the implementation, feasibility and acceptability of the intervention by interviewing pharmacists and consumers</p> | <p>We have already engaged with consumers and key stakeholders to design the trial and will continue to do so to plan for implementation</p> | <p>If successful, we will assess the capability and capacity of key partners to sustain delivery of the intervention after the trial period</p> |

Figure 1 Application of the Reach, Effectiveness, Adoption, Implementation and Maintenance (Re-AIM) framework to ALLIANCE.

Maintenance (RE-AIM) framework theoretically underpins the ALLIANCE trial to cocreate an intervention that effects the clinical and implementation outcomes necessary for achieving sustainability and scalability.^{29 30} This framework has been used to develop public health initiatives and considers the elements RE-AIM, which we have applied to the ALLIANCE trial in figure 1.³⁰ We will use the realist evaluation model to address the three key process evaluation questions: (1) what aspects of the intervention were effective or deleterious, (2) when (and in what context) were these benefits and drawbacks experienced and (3) by whom were these benefits and drawbacks experienced by.³¹

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist for reporting on trial protocols was used to develop this protocol.³² The Template for Intervention Description and Replication (TIDieR) checklist for intervention description was also used in this protocol and replaced the intervention section in the SPIRIT checklist.³³

Trial design

We will undertake a pragmatic cluster randomised controlled trial (RCT) using a stepped-wedge approach. A cluster randomised design is necessary since the intervention is applied at the level of the pharmacy, with pharmacists receiving access to the intervention as outlined below, while outcomes are measured on the individual women who present at each pharmacy. With the

stepped-wedge approach all pharmacists in participating pharmacies will be exposed to the known positive effects of the intervention (facilitating recruitment and retention). The stepped-wedge approach is a more powerful design than a traditional parallel cluster trial in this setting.³⁴ A stepped-wedge approach is likely to result in enhanced sustainability as it allows for reflexivity, reflection and refinement of the intervention as clusters move through the trial (pragmatism). Figure 2 depicts the trial flow chart.

Study setting

The trial will be conducted in community pharmacies across two Australian states and one territory—New South Wales (NSW), Victoria (VIC) and the Northern Territory (NT).

Eligibility criteria

Eligible pharmacies will be Quality Care Pharmacy Programme (QCPP)-accredited community-based pharmacies located within metropolitan, regional or rural areas of NSW, VIC or NT; have a private consultation room within their premises; at least one pharmacist (working ≥30 hours a week) willing to commit to participation; participating pharmacist(s) is accredited to dispense MA medicines; and the pharmacy owner has consented to the pharmacy's participation.³⁵ QCPP is a quality assurance programme that aims to ensure that community pharmacists provide high-quality, safe and consistent professional

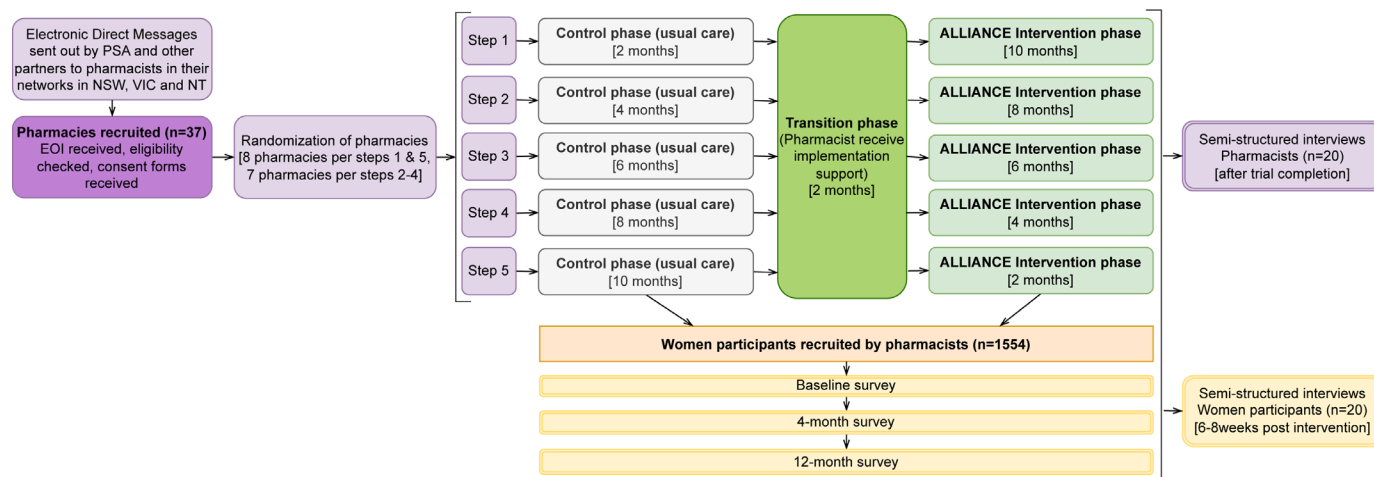


Figure 2 Trial flow chart. EOI, expression of interest; NSW, New South Wales; NT, Northern Territory; PSA, Pharmaceutical Society of Australia; VIC, Victoria.

services and customer care in line with the national Quality Care Community Pharmacy Standard.^{35 36}

Women attending the pharmacy to obtain, for themselves, an ECP or with a script for MA medicines will be invited to participate in the trial by the pharmacist. Consistent with current emergency contraception guidelines, there will be no age restriction on participation; women who require interpreting services will be excluded.³⁷ In this trial, we use the term ‘women’ when referring to study participants. However, the experience of an unintended pregnancy is not limited to cisgender, heterosexual women. We acknowledge that not all individuals who need to access an ECPs or EMA identify as a woman.

Recruitment

Recruitment of pharmacists will be facilitated by our partner organisations through the following approaches:

- ▶ The Pharmaceutical Society of Australia (PSA) will send an electronic direct mail (EDM) containing information about the trial and seeking expressions of interest for participation on two separate occasions 2 weeks apart to all community pharmacists located in NSW, VIC and the NT.
- ▶ Australian Pharmaceutical Industries (API) will send an EDM containing information about the trial and seeking expressions of interest for participation on two separate occasions 2 weeks apart to all Priceline pharmacies in NSW, VIC and the NT.
- ▶ Information about the trial and invitations to participate will be distributed through Supercare Pharmacies and Ramsay Pharmacy networks via email.
- ▶ Our partners, the Gippsland Primary Health Network, Jean Hailes for Women’s Health, Centre for Excellence in Rural Sexual Health (CERSH), Family Planning Organisations in NSW, VIC and the NT, PSA and API will raise awareness about the ALLIANCE trial through their newsletters, websites and social media.

Previous community pharmacy trials have used similar approaches to recruit large numbers of pharmacies (>77) with recruitment rates of 57%.^{20 38} Pharmacists interested

in participating can complete an online expression of interest form. The project team will contact interested pharmacists/pharmacy owners to answer questions and ensure they meet the inclusion criteria. The pharmacy owner and each participating pharmacist will need to complete a e-consent form. When consent forms are received, enrolment in the trial will be confirmed and further instructions provided.

Women presenting to the pharmacy to obtain an ECP or with a script for MA medicines will be invited to participate in the trial by participating pharmacists. Signs will be displayed in the pharmacy informing consumers that the pharmacy is participating in a study and they might be invited to join when requesting certain medicines. The pharmacist will inform all potential participants about the study, and provide them with a plain language study summary to read while they wait for their medicine. By scanning a QR code on the study summary, using their personal device, they can read the full explanatory statement and access the e-consent form. When the person’s medicine is ready for collection, the pharmacist will dispense the medicine as usual and answer any questions. Those willing and eligible will complete the e-consent form. It is not expected that differential recruitment of women will occur when a pharmacy is in the control versus the intervention phases as we do not expect on average that women will present to the pharmacy for ECP or MA medicines more than once during the course of the trial.

Randomisation

Randomisation will be carried out by the trial statistician who will not be involved in recruitment. Stratified randomisation will allocate clusters (pharmacies) to receive the intervention in 5 steps using a computer generated minimisation procedure, with 7–8 pharmacies crossing from control to intervention at each step (figure 3) to balance allocation of clusters with respect to state and location (regional/rural and metropolitan).³⁹ As all clusters eventually receive the intervention, data from the

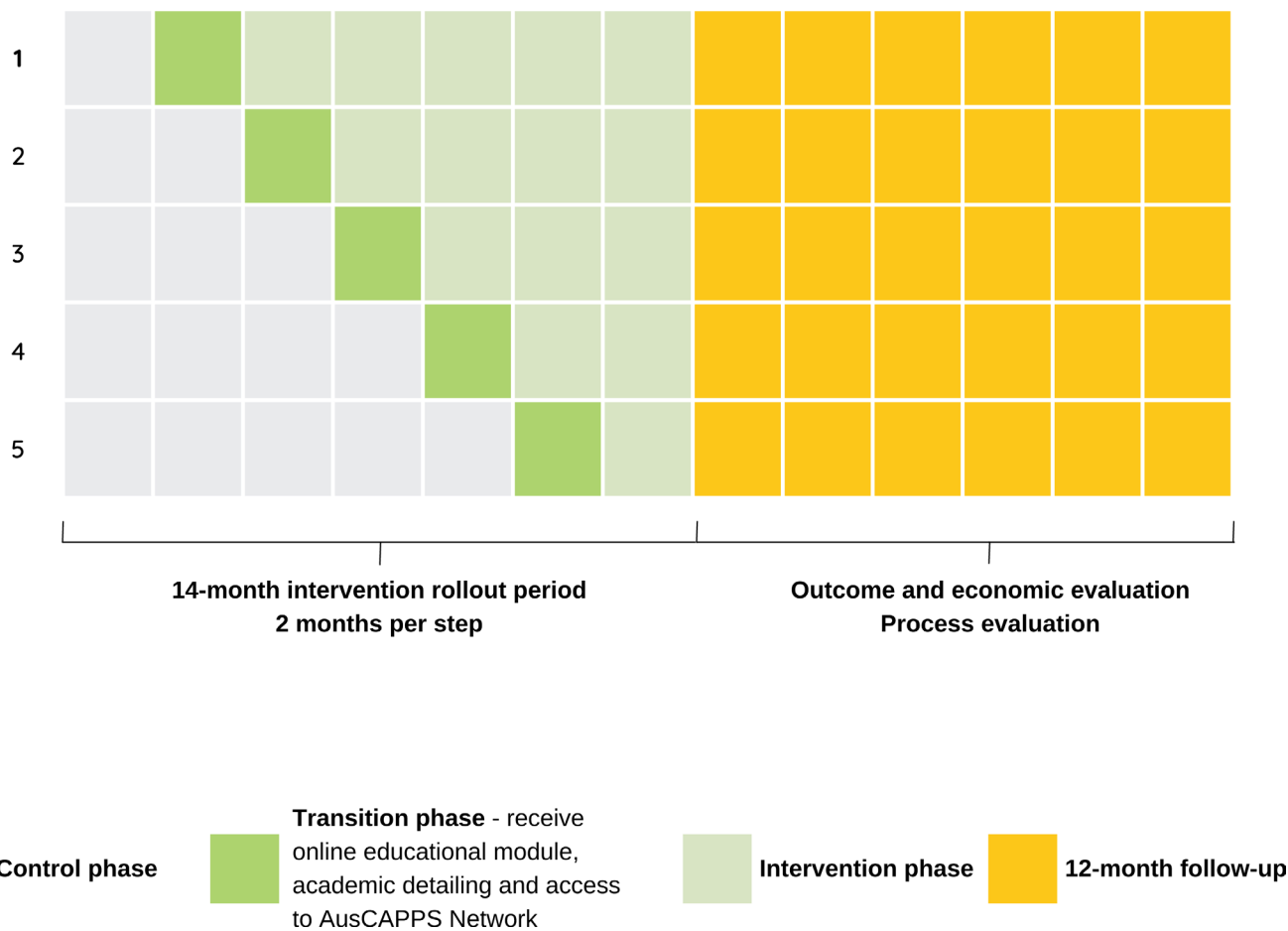


Figure 3 The ALLIANCE stepped-wedge trial design.

control phases (usual care) will be compared with data from intervention phases, with appropriate adjustment for time and clustering effects. There will be a 2-month transition phase when each pharmacy cluster receive access to implementation support. We will collect data from women participants during the control, transition and intervention phases to ensure sustained recruitment of women participants in each pharmacy throughout the trial. Data collected during the transition phase will not contribute to the final analysis (due to the changes in intervention occurring during this phase). Pharmacies will be randomised once all 37 pharmacies have been recruited.

Control phase: 'usual care'

All recruited pharmacies will commence in the control phase and provide a period of 'usual care'. Women recruited to the ALLIANCE trial during the period of usual care will receive standard medicines counselling. The length of the control phase will be determined by the randomised step each pharmacy is allocated, ranging from 2 to 10 months.

Intervention phase

The ALLIANCE trial includes the ALLIANCE intervention and implementation support (figure 4). The ALLIANCE intervention involves the delivery of structured,

patient-centred, effectiveness-based contraceptive counselling in a consultation a pharmacist has with the patient about their ongoing contraceptive needs and options. The consultation will take place in a private consultation room within the pharmacy. If appropriate, a referral to a contraceptive prescriber (general practitioner (GP) and/or local LARC inserter), using PSA's referral template, will be provided to the patient at the end of the consultation.

Pharmacists will be remunerated at a rate of US\$56 per consultation. This amount reflects the nature of the consultation compared with US\$66.53 currently provided for a MedsCheck initial consultation.⁴⁰ At the end of the trial, pharmacies will also be remunerated a total of US\$1500 for their participation in the trial of which US\$1000 will be paid directly to participating pharmacist(s) and US\$500 to the pharmacy.

Participating pharmacists will receive a bundle of implementation support activities to facilitate intervention roll out. Pharmacists will gain access to these activities during the 2-month transition phase. The bundle will comprise:

An online educational module

Participating pharmacists will be required to complete an accredited online education module on contraception and structured, person-centred effectiveness-based contraceptive counselling. The module will be developed

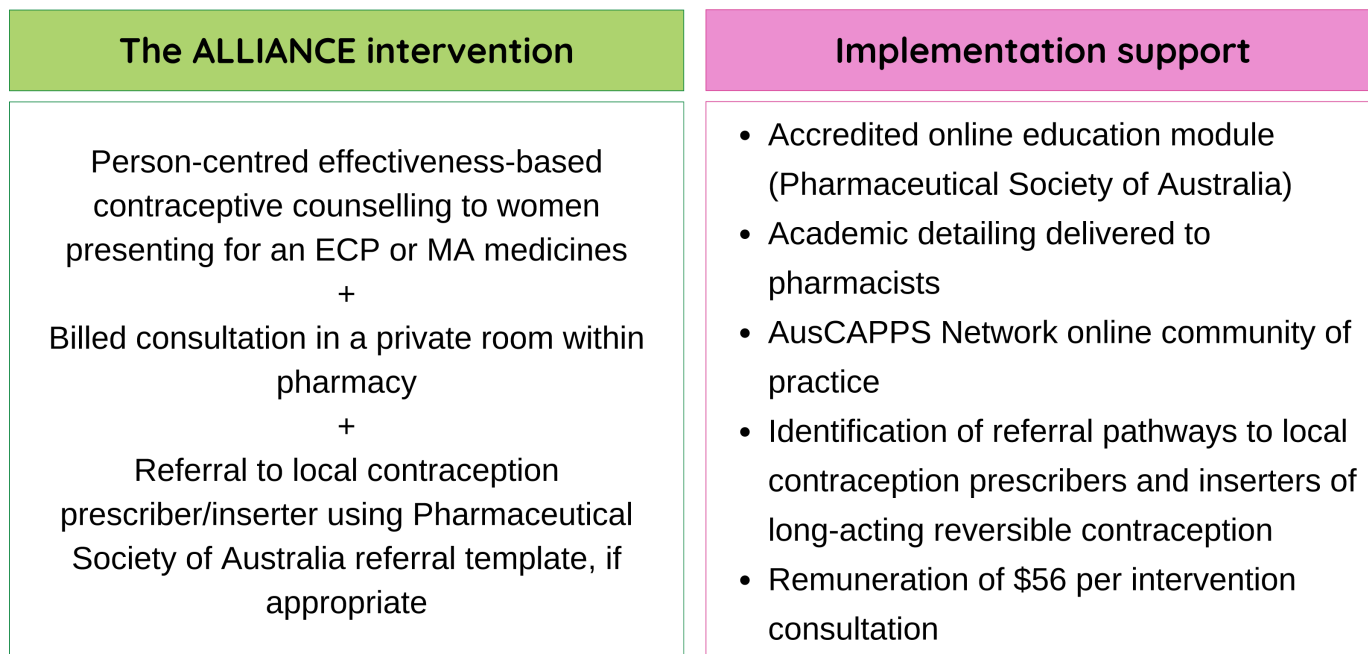


Figure 4 The ALLIANCE intervention and implementation support. ECP, emergency contraceptive pill; MA, medical abortion.

in partnership with PSA and will draw on the educational resources developed in the ACCORD trial.²⁷

Academic detailing

Academic detailing is a cost-effective method to improve the quality of care delivered by primary care practitioners and a novel approach in pharmacy settings to bring about professional behaviour change.^{41–43} Each pharmacy cluster will take part in a virtual 1-hour detailing session, with the aim of supporting pharmacists to prepare themselves and their pharmacy to implement and deliver the intervention, reducing potential implementation challenges. The detailing is modelled on the National Prescribing Service (NPS) approach and was codesigned with consumers, pharmacists and other key stakeholders during a stakeholder workshop in June 2022.⁴⁴ It will introduce the intervention and involve sharing resources, identifying referral pathways and enrolling pharmacists in the AusCAPPS online community of practice (COP).⁴⁵

The academic detailers will be pharmacists who are experts in academic detailing as former NPS trainers.⁴⁶ After being provided with training on the ALLIANCE approach the academic detailers will conduct the detailing with the pharmacists.

Linking with contraception prescribers

Interlinking and integrating pharmacy services with GPs and other healthcare prescribers aids the implementation of contraceptive counselling services, enabling pharmacists to refer women for ongoing care.^{47 48} Participating pharmacists will be required to identify and liaise with a local prescriber or contraception inserter regarding their participation in the trial. This is necessary for instances where women do not have an identifiable GP they feel

comfortable consulting with about contraception or where their GP does not perform LARC insertions.

Participation in the AusCAPPS COP

AusCAPPS is an online COP supporting primary care practitioners (GPs, practice nurses and community pharmacists) to deliver contraception and MA services.⁴⁵ It offers an accessible web-based portal to support practitioners, who may feel isolated in dealing with clinical problems, to create networks and implement new approaches to care.⁴⁵ COPs have successfully been used in Australia to improve evidence-based care, and in Canada to support contraception and abortion care.^{49 50} Pharmacists will be enrolled in AusCAPPS, providing them with access to existing interactive content on effective contraceptive methods, EMA, contraceptive counselling and online resources. AusCAPPS will enable pharmacists to develop a shared repertoire of resources and ways of addressing recurring problems (ie, a shared practice).

Sample size and power calculation

The study requires 35 pharmacies (clusters) and 1260 women participants to detect an increase in the use of effective contraception use from 35% to 50% with 80% power and a two-sided level of significance of 5%. An intraclass correlation of 0.1 is assumed as observed in the ACCORD study.²⁷ The ALLIANCE trial will recruit a total of 37 pharmacies, and 1554 women participants (7 in each pharmacy in each of the 6 non-transition trial periods, allowing for a drop-out rate at the women participant level of 14% and at the pharmacy level of 5%). The sample size calculation assumes that no data are collected from women participants during the transition phases and was conducted using the Shiny CRT app.⁵¹

Data collection methods and outcomes

The primary outcome of the ALLIANCE trial is the self-reported use of effective contraception (hormonal or intrauterine) at 4 months. The secondary outcomes are as follows:

- ▶ The use of effective contraception (hormonal or intrauterine) and the rate of pregnancies or abortions at 12 months.
- ▶ Implementation and experience of the intervention and the impact on practice, new perspectives and concepts, and scalability.
- ▶ The cost-effectiveness of the intervention as compared with the control.

Outcome evaluation

Women participants will complete a baseline, 4-month and 12-month online survey (online supplemental file 1). These surveys are based on the Bridge-It Trial baseline and 4-month surveys, modified for the Australian context.⁴⁸ The surveys will be open for 4 weeks with three reminders via email/text message and a phone call.

A 4-month follow-up was elected as this was considered to be sufficient time for participants to act on referrals and allow for consultations related to LARC insertion. This was the same time period used in the Bridge-It trial on which our study builds on. Having the same follow-up time periods (4 months and 12 months) as the Bridge-It trial allows for comparison.

Data collection from participating women will occur as follows:

- ▶ Baseline survey—a link to the online survey will be sent to participants via email/text message once their e-consent form has been submitted. On completion participants will receive a US\$20 e-gift card.
- ▶ Four-month survey—a link to the online survey will be sent to participants via email/text message 4 months post enrolment. On completion, participants will receive a US\$30 e-gift card.
- ▶ Twelve-month survey—a link to the online survey will be sent to participants via email/text message 12 months post enrolment. On completion, participants will receive a US\$30 e-gift card.

Process evaluation

We will use data from the following sources and methods to undertake a process evaluation of the trial:

- ▶ The academic detailing sessions will be recorded and academic detailers will be asked to complete a log after each session, describing comments and issues raised by pharmacists and their own reflections and learnings from the session. These data will be collated by the project team to inform pragmatic changes to the educational content and/or intervention as necessary, and will be formally analysed for fidelity and synthesised for reporting.
- ▶ Information from AusCAPPS on ALLIANCE pharmacist engagement on the discussion page (eg, what they have posted, what posts they have liked, commented

on) over the duration of the intervention will be collected. All participating pharmacists are informed about the evaluation during recruitment and signup. Additionally, as part of AusCAPPS signup, all individuals are asked whether they consent to take part in research.

- ▶ Pharmacists who consented to be followed-up will be contacted via email/phone/text message at the end of the trial and invited to participate in a 45–60 min semistructured virtual/phone interview. Maximum variation sampling will be used to select pharmacies, this will be based on what step they were randomised into, their location (metro or regional/rural) and what state they are located. Where more than one pharmacist is participating in a pharmacy only one will be interviewed to assess: their perceptions of the research and intervention process; the impact on their practice, new perspectives and concepts gained through participation; and what factors they believe can assist in scale up. Pharmacists will read the explanatory statement and sign the e-consent form prior to the interview. Participating pharmacists will receive a US\$100 e-gift card.
- ▶ Women participants who consented to be followed up will be contacted via email/phone/text message to participate in a semistructured virtual/phone interview 6–8 weeks after receiving the intervention, to assess their experiences of the ALLIANCE intervention. Women will read the explanatory statement and sign the e-consent form prior to the interview. Participants will receive a US\$40 e-gift card.

Economic evaluation

The economic evaluation will compare the costs and benefits of the ALLIANCE intervention and implementation strategy compared with usual care. Health outcomes will be measured in terms of changes in (1) effective contraception use at 4 months and (2) the rate of pregnancy and/or abortions at 12 months based on patient-reported effectiveness. The costs of the ALLIANCE intervention will encompass all aspects of the intervention including costs of delivering the bundle of implementation support (eg, development and provision of training programme and resources), direct costs of providing an ECP and MA medicines, and direct costs of providing counselling and subsequent contraception (eg, pharmacist training and academic detailing costs, usual care and intervention consultation time including referral and follow-up support with contraception prescribers). We will use data collected daily from pharmacists during the trial and the women participant surveys to estimate healthcare usage. Reporting will follow the Consolidated Health Economic Evaluation Reporting Standards statement.⁵²

Data management and monitoring

All pharmacies, pharmacists and women participants will be allocated a unique code. Participants' surveys will be completed in REDCap, an electronic data capture tool

hosted and managed by Helix (Monash University).^{53 54} Semistructured interview data will be audio recorded, transcribed and stored as MS Word documents and pharmacist's engagement data on the AusCAPPs COP will be obtained from the AusCAPPs team. All electronic data will be kept in an electronic password-protected file over a database accessible by a secure connection protocol (HTTPS) over the Internet to authorised individuals. A weekly report on missing data or specific errors in the data will be reviewed by the project team for advice on action.

Analysis

Analysis of trial outcomes

The results of the trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension for the stepped wedge cluster RCTs.⁵⁵ Participant demographics will be described by pharmacy and by study period. The primary analysis will include data from all eligible participants, where the intervention will be assumed to have been implemented in accordance with the trial schematic. All available primary and secondary binary outcomes will be analysed at the patient level using mixed-effects regression models with a binary distribution and an identity link function, with random effects for pharmacy and fixed effects for time, stratification factors and intervention status. Results will be presented as risk differences and 95% CIs; if models fail to converge, the log or logit link functions will be used, with risk or ORs reported. The sensitivity of inference for the effect of the intervention to different within-cluster correlation structures will be assessed.⁵⁶ If the primary outcome is missing for more than 5% of women, multiple imputation will be conducted, where available, outcomes available at each survey will be included in imputation models for outcomes obtained at other surveys. In complete-case analyses, all available data will be included (ie, last known data for an outcome will not be carried forward). Analyses will be conducted in R (V.4.2.1 or later) and/or Stata (V.17 or later) as appropriate.

Process evaluation

Qualitative analysis of in-depth interviews with both pharmacists and patients will be recorded and transcribed verbatim. Participants will be deidentified during transcription. These deidentified transcripts will be analysed in NVivo; pharmacist and patient data will be analysed separately. Coders will familiarise themselves with the datasets, then undertake a reflexive thematic analysis.⁵⁷ Thematic analysis is undertaken with the aim of ensuring credibility and trustworthiness of the final coding frame. A deductive approach will be undertaken whereby the transcripts will first be coded and then organised within the relevant themes of the framework. Constant comparison will be carried out to ensure that the analysis represents all perspectives and negative ('deviant') cases.⁵⁸

Economic evaluation

A within-trial cost-effectiveness analysis will evaluate the incremental costs and benefits of the ALLIANCE intervention and implementation strategy from an Australian healthcare perspective. Cost-effectiveness will be assessed as the ratio of the incremental costs of the intervention per additional unit of health benefit and expressed using the incremental cost-effectiveness ratio (ICER). Using well-established health economic principles, the ICERs will be plotted on a cost-effectiveness plane and compared against similar interventions.⁵⁹ Bootstrapping will be used to estimate a distribution around the mean costs and outcomes and to calculate confidence intervals around the ICER. Robustness of the results will be conducted using one-way sensitivity analyses around key variables and a probabilistic sensitivity analysis to estimate the joint uncertainty in all parameters. The evaluation will not incorporate the benefits and cost savings of preventing pregnancy, as this is well established.

Harms

To minimise any potential risk, a distress protocol outlining how to support pharmacists, women participants and researchers as well as counselling services contact information has been developed to guide the research team.

Auditing

Auditing of trial practices will be conducted through fortnightly meetings of the project team.

Study and participant timeline

Pharmacy recruitment commenced in October 2022. Women participants recruitment commenced in March 2023 and will run for 14 months—the length of the intervention rollout. Data collection continues for 12 months postintervention rollout.

Stakeholder engagement

The governance structure of ALLIANCE is described in figure 5 and involves trial investigators, the project team, consumers and partners from academia, industry, clinician professional groups with interests in women's sexual and reproductive health in primary care. The four committees are: a steering committee (providing advice for clinical and political strategy), the executive team (responsible for the overarching aims and deliverables of the project), an intervention advisory group (providing advice on content and delivery of intervention and intervention support) and project team (responsible for project implementation).

Patient and public involvement

Consumers, health professionals (including pharmacists) and industry and clinical professional groups will be involved in the study. A codesign stakeholder workshop carried out in June 2022 focused on improving the experience and developing the academic detailing session. Established consumer and pharmacy advisory circles will



Figure 5 ALLIANCE governance structure.

be accessed for the purpose of gaining feedback about recruitment, data collection and aspects of the intervention and intervention support activities.

Ethics and dissemination

Research ethics approval

Ethical approval has been obtained from the Monash University Human Research Ethics Committee (#34563). Registration for the project's intervention has been obtained from the Australian and New Zealand Clinical Trial Registry (ACTRN12622001024730).

Consent

Pharmacists and women participants will be given an explanatory statement outlining the trial's aims, the right to withdraw and the voluntary nature, risks and benefits of participation. Written consent will be obtained from pharmacy owners and participating pharmacists before the commencement of the trial and interviews, and from women participants before the commencement of the baseline survey or delivery of the intervention and interviews (online supplemental file 2).

Confidentiality and access to data

Data collected from pharmacists and women participants will be deidentified and kept as electronic files in password-protected project files on the University's secure network. Only the ALLIANCE investigators and project team will have access to data during the project for research purposes.

Dissemination

Findings from the trial will be disseminated via peer-reviewed journal publications, presentations, social media, domestic and international conferences and through author, partner and stakeholder networks. At

project completion, partners and representatives from government and non-government organisations will be invited to participate in a knowledge exchange forum where the trial outcomes from the intervention and the economic evaluation will be presented.

DISCUSSION

The ALLIANCE trial builds on the highly successful ACCORD and Bridge-It trial, delivering key elements of both trials in responding to the growing need to improve the provision of effectiveness based contraceptive counselling in the community pharmacy setting to relevant the risk of unintended pregnancy in Australia. A recommendation from the 2023 Australian senate inquiry into the universal access to reproductive healthcare was for all health professionals working in the field of sexual and reproductive healthcare to work to their 'full scope of practice in a clinically safe way'.⁶⁰ The ALLIANCE trial is anticipated to provide new evidence to inform health system improvement globally by broadening the scope of practice of community pharmacists in the provision of sexual and reproductive health services in primary care—alongside addressing the Australian senate inquiry's recommendation.

Pharmacists participating in the ALLIANCE trial may not be representative of the wider pharmacist population as trial participation is not only contingent on pharmacists' provision of ECPs and MA but also their interest in sexual and reproductive health. Government changes to pharmacy practice, funding mechanisms and regulations have increased pressures on a health workforce still recovering from workforce shortages due to the COVID-19 pandemic. This may present challenges in meeting target sample size of women participants. Ongoing engagement between the project team, the ALLIANCE pharmacy participants and professional groups aims to minimise the effects on the study.

While numerous patient-focused models of practice (eg, smoking cessation, diabetes and cardiovascular screening and care, chlamydia testing) and several models of medicines reviews have been developed and trialled in community pharmacies in recent decades, there has been little focus on the provision of contraceptive counselling.⁶¹ The ALLIANCE trial will build on the principles established in the implementation of some of these models (ie, pharmacist education to support implementation, the requirement to have a private consulting room or space to deliver the service and the expanded service attracting a fee). The intervention will help drive a more integrated approach to health service delivery by helping women access health information and referral pathways at time points when it is most relevant to them, improving their access to effective contraception in a timelier manner. The intervention can be rapidly scaled nationally, addressing the key government priorities of decreasing unintended pregnancy and improving reproductive health outcomes for women.¹ The trials assessment of the cost-effectiveness of the ALLIANCE intervention and implementation strategy will provide vital support to inform policy

decisions on the value of funding community pharmacists to provide this intervention.

Author affiliations

¹SPHERE NHMRC Centre of Research Excellence, Department General Practice, School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

²Pharmacy Department, Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia

³The Daffodil Centre, Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia

⁴Pharmaceutical Society of Australia, Parkville, Victoria, Australia

⁵Centre for Excellence in Rural Sexual Health, University of Melbourne, Shepparton, Victoria, Australia

⁶School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

⁷Centre for Health Economics Research and Evaluation, University of Technology Sydney, Ultimo, New South Wales, Australia

⁸College of Medicine and Public Health, Flinders University, Adelaide, South Australia, Australia

⁹SAHMRI Women and Kids, South Australian Health and Medical Research Institute Limited, Adelaide, South Australia, Australia

¹⁰Centre for the Business & Economics of Health, The University of Queensland, Brisbane, Queensland, Australia

¹¹Obstetrics and Gynaecology, University of Edinburgh, Edinburgh, UK

¹²Sexual and Reproductive Health, NHS Lothian, Edinburgh, UK

Twitter Danielle Mazza @Danielle_Mazza, Anisa Rojanapenkul Assifi @anisaassifi, Safeera Yasmeen Hussainy @SafeeraHussainy, Deborah Bateson @DrDebBateson, Jessica Kasza @JessKasza, Luke E Grzeskowiak @LukeGrzeskowiak, Lisa Nissen @nissen_l and Sharon Tracey Cameron @CameronSharon

Contributors DM conceived the ALLIANCE trial and led its development and design. ARA prepared the manuscript. DM, SYH, DB, SJ, JT, JK, JC, LEG, LN and STC were involved in the development of the protocol. JK provided support for the development of the statistical analysis plan. DM, ARA, SYH, DB, SJ, JT, JK, JC, LEG, LN and STC edited and approved the final manuscript.

Funding This trial is funded by the Medical Research Future Fund—Quality, Safety and Effectiveness of Medicine Use and Medicine Intervention by Pharmacists grant ID: MRFQI000057.

Competing interests None declared.

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.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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>

Anisa Rojanapenkul Assifi <http://orcid.org/0000-0001-5295-4074>

Safeera Yasmeen Hussainy <http://orcid.org/0000-0003-1418-8078>

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

Jane Tomnay <http://orcid.org/0000-0003-4907-3107>

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

Jody Church <http://orcid.org/0000-0001-9584-8431>

Luke E Grzeskowiak <http://orcid.org/0000-0001-8554-4696>

Lisa Nissen <http://orcid.org/0000-0001-5826-4605>

Sharon Tracey Cameron <http://orcid.org/0000-0002-1168-2276>

REFERENCES

- 1 Department of Health. *National Women's Health Strategy 2020-2030*. Canberra: Department of Health, Australian Government, 2018.
- 2 Organon. Impact of unintended pregnancy. NSW, Australia Organon; 2022.
- 3 Taft AJ, Shankar M, Black KI, *et al*. Unintended and unwanted pregnancy in Australia: a cross-sectional, national random telephone survey of prevalence and outcomes. *Med J Aust* 2018;209:407–8.
- 4 Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. 2013. Available: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm> [Accessed 21 Feb 2021].
- 5 The Faculty of Sexual and Reproductive Healthcare. FSRH clinical guideline: emergency contraception. 2020. Available: <https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017> [Accessed 21 Feb 2021].
- 6 Collins JC, Schneider CR, Moles RJ. Emergency contraception supply in Australian pharmacies after the introduction of Ulipristal acetate: a mystery shopping mixed-methods study. *Contraception* 2018;98:243–6.
- 7 World Health Organization. *Abortion care guideline*. Geneva: World Health Organization, 2022.
- 8 Goodman S, Hendlish SK, Reeves MF, *et al*. Impact of immediate postabortal insertion of Intrauterine contraception on repeat abortion. *Contraception* 2008;78:143–8.
- 9 Hognert H, Kopp Kallner H, Cameron S, *et al*. Immediate versus delayed insertion of an etonogestrel releasing implant at medical abortion—a randomized controlled equivalence trial. *Hum Reprod* 2016;31:2484–90.
- 10 Raymond EG, Weaver MA, Tan Y-L, *et al*. Effect of immediate compared with delayed insertion of etonogestrel implants on medical abortion efficacy and repeat pregnancy: a randomized controlled trial. *Obstet Gynecol* 2016;127:306–12.
- 11 Reeves MF, Smith KJ, Creinin MD. Contraceptive effectiveness of immediate compared with delayed insertion of Intrauterine devices after abortion: a decision analysis. *Obstet Gynecol* 2007;109:1286–94.
- 12 Rose SB, Lawton BA. Impact of long-acting reversible contraception on return for repeat abortion. *Am J Obstet Gynecol* 2012;206:37.
- 13 Grzeskowiak LE, Rumbold AR, Subasinghe A, *et al*. Long-acting reversible contraception use after medical abortion is associated with reduced likelihood of a second medical abortion. *Med J Aust* 2022;216:476–7.
- 14 Kilander H, Alehagen S, Svedlund L, *et al*. Likelihood of repeat abortion in a Swedish cohort according to the choice of post-abortion contraception: a longitudinal study. *Acta Obstet Gynecol Scand* 2016;95:565–71.
- 15 Fox E, Reyna A, Malcolm NM, *et al*. Client preferences for contraceptive counseling: a systematic review. *Am J Prev Med* 2018;55:691–702.
- 16 Dixon SC, Herbert DL, Loxton D, *et al*. 'As many options as there are, there are just not enough for me': contraceptive use and barriers to access among Australian women. *Eur J Contracept Reprod Health Care* 2014;19:340–51.
- 17 Dorney E, Botfield JR, Robertson S, *et al*. Acceptability of the copper intrauterine device as a form of emergency contraception in New South Wales, Australia. *Eur J Contracept Reprod Health Care* 2020;25:114–9.
- 18 Goldhammer DL, Fraser C, Wigginton B, *et al*. What do young Australian women want (when talking to doctors about contraception) *BMC Fam Pract* 2017;18:35.
- 19 The Pharmacy Guild of Australia. *National Rural Health Commissioner's discussion paper for consultation: Rural allied health quality, access and distribution - options for Commonwealth policy reform and investment*. The Pharmacy Guild of Australia, 2019.
- 20 Cameron ST, Glasier A, McDaid L, *et al*. Use of effective contraception following provision of the Progestogen-only pill for women presenting to community pharmacies for emergency contraception (Bridge-it): a pragmatic cluster-randomised crossover trial. *Lancet* 2020;396:1585–94.

- 21 Rodriguez MI, Skye M, Edelman AB, *et al.* Association of pharmacist prescription and 12-month contraceptive continuation rates. *Am J Obstet Gynecol* 2021;225:647.
- 22 Rodriguez MI, Edelman AB, Skye M, *et al.* Association of pharmacist prescription with dispensed duration of hormonal contraception. *JAMA Netw Open* 2020;3:e205252.
- 23 Rodriguez MI, Biel FM, Swartz JJ, *et al.* Pharmacists' experience with prescribing hormonal contraception in Oregon. *J Am Pharm Assoc (2003)* 2018;58:608–13.
- 24 Buckingham PLM, Hussainy S, Soon J, *et al.* Improving access to quality contraceptive counselling in community Pharmacy: examining the knowledge, attitudes and practices of community pharmacists in Australia. *BMJ Sex Reprod Health* 2023;49:87–96.
- 25 Hussainy S, Ghosh A, Mc Namara KP, *et al.* Findings from ACCESS (Accessing contraception for emergency supply study): a qualitative study exploring barriers and facilitators to accessing the emergency contraceptive pill from community pharmacies in Australia. 15th World Congress on Public Health; Melbourne, Australia.2017
- 26 Dev T, Amos N, Buckingham P, *et al.* Women's perceptions of over-the-counter contraception in Australia; 2020.
- 27 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.
- 28 Landes SJ, McBain SA, Curran GM. An introduction to effectiveness-implementation hybrid designs. *Psychiatry Res* 2020;283:112630.
- 29 Glasgow RE, Estabrooks PE. Pragmatic applications of RE-AIM for health care initiatives in community and clinical settings. *Prev Chronic Dis* 2018;15:E02.
- 30 Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM framework: rationale and methods. *BMC Health Serv Res* 2018;18:177.
- 31 Pawson R, Tilley N. *Realist Evaluation*. London: SAGE Publishing, 1997.
- 32 Chan A-W, Tetzlaff JM, Altman DG, *et al.* SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
- 33 Hoffmann TC, Glasziou PP, Boutron I, *et al.* Better reporting of interventions: template for intervention description and replication (Tidier) checklist and guide. *BMJ* 2014;348:bmj.g1687.
- 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 The Pharmacy Guild of Australia. Quality care Pharmacy program ACT. Australia The Pharmacy Guild of Australia; 2023. Available: <https://www.qcpp.com/home> [Accessed 03 Jan 2023].
- 36 The Pharmacy Guild of Australia. *Quality Care Community Pharmacy Standard AS 85000:2017*. Sydney, Australia: Standards Australia, 2017.
- 37 Pharmaceutical Society of Australia. *Guidance for provision of a Pharmacist Only medicine - Emergency contraception*. Canberra: Pharmaceutical Society of Australia, 2018.
- 38 Department of Health. Health literacy project: Department of health [Australian Government]. Available: <https://6cpa.com.au/resources/fifth-agreement-rd/health-literacy-project/> [Accessed 21 Feb 2021].
- 39 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.
- 40 Pharmaceutical Society of Australia. Guidelines for pharmacists providing Medscheck and diabetes Medscheck services. Available: <https://my.psa.org.au/s/article/Guidelines-for-pharmacists-providing-MedsCheck-and-Diabetes-MedsCheck-services> [Accessed 21 Feb 2021].
- 41 Fischer MA. Academic detailing in diabetes: using outreach education to improve the quality of care. *Curr Diab Rep* 2016;16:98.
- 42 Mostofian F, Ruban C, Simunovic N, *et al.* Changing physician behavior: what works? *Am J Manag Care* 2015;21:75–84.
- 43 Quanbeck A, Brown RT, Zgierska AE, *et al.* A randomized matched-pairs study of feasibility, acceptability, and effectiveness of systems consultation: a novel implementation strategy for adopting clinical guidelines for opioid prescribing in primary care. *Implement Sci* 2018;13:21.
- 44 Gadzhanova SV, Roughead EE, Bartlett MJ. Improving cardiovascular disease management in Australia: NPS Medicinewise. *Med J Aust* 2013;199:192–5.
- 45 Mazza D, James S, Black K, *et al.* Increasing the availability of long-acting reversible contraception and medical abortion in primary care: the Australian contraception and abortion primary care practitioner support network (Auscapps) cohort study protocol. *BMJ Open* 2022;12:e065583.
- 46 Weekes LM, Blogg S, Jackson S, *et al.* NPS Medicinewise: 20 years of change. *J Pharm Policy Pract* 2018;11:19.
- 47 Buss VH, Shield A, Kosari S, *et al.* The impact of clinical services provided by community pharmacies on the Australian Healthcare system: a review of the literature. *J of Pharm Policy and Pract* 2018;11.
- 48 Patterson S, McDaid L, Saunders K, *et al.* Improving effective contraception uptake through provision of bridging contraception within community pharmacies: findings from the bridge-it study process evaluation. *BMJ Open* 2022;12:e057348.
- 49 Barnett S, Jones SC, Bennett S, *et al.* A virtual community of practice for general practice training: a preimplementation survey. *JMIR Med Educ* 2016;2:e13.
- 50 Norman WV, Guilbert ER, Okpaleke C, *et al.* Abortion health services in Canada: results of a 2012 national survey. *Can Fam Physician* 2016;62:e209–17.
- 51 Hemming K, Kasza J, Hooper R, *et al.* A Tutorial on sample size calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials using the shiny CRT calculator. *Int J Epidemiol* 2020;49:979–95.
- 52 HuserEAU D, Drummond M, Petrou S, *et al.* Consolidated health economic evaluation reporting standards (CHEERS) statement. *BMC Med* 2013;11:80.
- 53 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.
- 54 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.
- 55 Hemming K, Taljaard M, McKenzie JE, *et al.* Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. *BMJ* 2018;363:k1614.
- 56 Kasza J, Forbes AB. Inference for the treatment effect in multiple-period cluster randomised trials when random effect correlation structure is misspecified. *Stat Methods Med Res* 2019;28:3112–22.
- 57 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
- 58 Byrne D. A worked example of Braun and Clarke's approach to reflexive thematic analysis. *Qual Quant* 2022;56:1391–412.
- 59 Drummond MF, Sculphr MJ, Claxton K, *et al.* *Methods for the economic evaluation of health care programmes, 4th ed.* Oxford: Oxford University, Press, 2015.
- 60 The Senate. *Ending the postcode lottery: Addressing barriers to sexual, maternity and reproductive healthcare in Australia*. Canberra: Commonwealth of Australia, 2023.
- 61 McMillan SS, Wheeler AJ, Sav A, *et al.* Community Pharmacy in Australia: a health Hub destination of the future. *Res Social Adm Pharm* 2013;9:863–75.