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, Anisa Rojanapenkul Assifi, Safeera Yasseen Hussain, Deborah Bateson, Stefanie Johnston, Jane Tomnay, Jessica Kasza, Jody Church, Luke E Grzeskowiak, Lisa Nissen, Sharon Tracey Cameron

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-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. In Australia, 40% of...
women experience an unintended pregnancy during their lifetime, and one in three of these results in abortion.2–5 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.6 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.7–12 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.19Expanding 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 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
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
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 ECP 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
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. 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...
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 co-designed 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 intracluster 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). 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. 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. 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. 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.

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. 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 post-intervention 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
Ethics and dissemination

Research ethics approval
Ethical approval has been obtained from the Monash University Human Research Ethics Committee (#94563). 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
9SA/IMRI 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 Rojanapenk Asfisi @anisaaasfisi, Saeera Yaseen Hussainy @SaeeraHussainy, Deborah Bateson @DrDebBateson, Jessica Kasza @JessKasza, Luke E Grzeskowiak @LukeGrzeskowiak, Lisa Nissen @lnissen_1 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: MRFQ000057.

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 Rojanapenk Asfisi http://orcid.org/0000-0001-5295-4074
Saeera Yaseen 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

REFERENCES
2Organon. Impact of unintended pregnancy. NSW, Australia Organon; 2022.
BMC Open: first published as 10.1136/bmjopen-2023-073154 on 31 August 2023. Downloaded from http://bmjopen.bmj.com/ on October 23, 2023 by guest. Protected by copyright.
Baseline Survey

We would be very grateful if you could spend some time filling out this confidential questionnaire. It will take about 5-10 minutes to complete. The questionnaire asks about your background, previous pregnancy, use of contraceptive methods, and your experience at the pharmacy.

Please answer the questions below as best as you can. If you run out of time, you can always save your responses and come back to complete the questionnaire later.

What is your date of birth?

Do you use a language besides English at home?

- Yes
- No, only English

Please specify what other language do you speak (apart from English)

Are you of Aboriginal or Torres Strait Islander origin?

- Yes
- No
- Prefer not to say

Which medicine were you buying when you were invited to participate in this project?

- Levonorgestrel (e.g. Postrelle, Levonelle) - emergency contraceptive pill
- Ulipristal acetate (e.g. EllaOne) - emergency contraceptive pill
- An emergency contraceptive pill (name unknown)
- Abortion medicines (MS-2 Step)

Select all methods of contraception you have ever used:

- Partner had a vasectomy
- Hormonal intrauterine device (Hormonal IUD) e.g. Mirena, Kyleena
- Copper intrauterine device (Copper IUD)
- Implant e.g. Implanon
- Contraceptive injection e.g. Depo Provera
- Contraceptive ring e.g. NuvaRing
- Combined hormonal contraceptive ("the pill" containing two hormones) e.g. Microgynon, Yasmin, Diane, Levlen ED
- Progestogen only pill ("minipill" containing one hormone) e.g. Noriday, Microlut, Slinda
- Male condom
- Female condom
- Diaphragm
- Natural family planning (monitoring of temperature, calendar, urine tests, etc.)
- Withdrawal ("pull-out") method
- Other method of contraception
- I have never used any method

Please say what other methods of contraception you have used

Before your recent use of [medicine] (before you entered this study)...

Had you ever taken an emergency contraceptive pill?

- Yes
- No
- Unsure
Had you ever given birth?
- Yes
- No
- Unsure

Had you ever had an abortion?
- Yes
- No
- Unsure

Did you talk to the pharmacist about your options for contraceptive methods during your visit?
- Yes
- No
- Unsure

Which state was the pharmacy in?
- NSW
- VIC

What suburb was the pharmacy in?
- Albion Park
- Albury
- Ballina
- Berry
- Cabramatta
- Griffith
- Jerrabomberra
- Menai
- Miranda
- Mulgoa
- Newcastle
- North Sydney
- Penrith
- Port Macquarie
- Sydney
- Tamworth
- Warrawong
- Windsor
- Woonona
- Yass

Which pharmacy did you go to?
- Albion Park Rail Pharmacy
- Award Pharmacy Albury
- Blooms The Chemist Windsor
- Chemist Warehouse Sydney Hyde Park
- Cincotta Discount Chemist Warrawong
- Doc's MegaSave Chemist
- Drews Pharmacy
- Flynn's Beach Pharmacy
- Chemist Warehouse, Griffith
- Menai Compounding Discount Drug Store
- Mulgoa Pharmacy
- Priceline Ballina
- Priceline Pharmacy Cabramatta
- Priceline Pharmacy Woonona
- Priceline Pharmacy Yass
- Ramsay Pharmacy Parkside Plaza
- Soul Pattinson Chemist
- Tamworth Discount Drugstore
- TerryWhite Chemmart Penrith Compounding
- The Berry Pharmacy
What suburb was the pharmacy in?
- Bacchus Marsh
- Ballarat
- Bendigo
- Drouin
- Glen Waverley
- Hampton East
- Horsham
- Melbourne
- Mildura
- Mornington
- Port Fairy
- Strathfieldsaye
- Sunshine
- Swan Hill
- Tarneit
- Wantirna South

Which pharmacy did you go to?
- Bacchus Marsh UFS Pharmacy
- Barts the Chemist
- Bendigo UFS Pharmacies View Street
- Bendigo UFS Pharmacies Strathfieldsaye
- Chemist Discount Centre Drouin
- Chemist Warehouse Mildura
- Community Care Chemist North Geelong
- Direct Chemist Outlet Riverdale
- HealthSmart Pharmacy VCCC
- Marraboor Pharmacy
- Mornington Village Pharmacy
- Pharmacy Neo Port Fairy
- Priceline Pharmacy Horsham
- Priceline Pharmacy Knox
- Priceline Pharmacy The Glen
- Priceline Pharmacy Sunshine Marketplace
- Sturt Street UFS Pharmacy

Thank you for taking the time to complete this questionnaire. Your participation is very much appreciated. The last question below relates to your participation in this project.

We will send your gift card to the phone number or email address you have provided to us in your consent form.

Please indicate how you would like to receive your $20 gift card:
- By text message
- By email
4-Month Survey

We would be very grateful if you could spend some time completing this anonymous questionnaire. It will take between 5-10 minutes to complete. It asks about your circumstances at the time you entered the study, your use of contraceptive methods, and your experience of taking part in this study.

Please answer the questions below as best you can. If you run out of time, you can always save your responses and come back to complete the questionnaire later.

Section A. When you entered the study

Which medicine were you buying at the time you entered this study?
- An emergency contraceptive pill
- Abortion medicines (MS-2 Step)

This question asks about your circumstances around the time you went to get the emergency contraceptive pill from the pharmacy four months ago (when you entered this study). Please note: ‘Contraception’ includes anything you did, took or used to avoid becoming pregnant. Withdrawal (“pull-out”) method, contraceptive pills (“the pill”) and condoms are some examples.

In the month before I entered the study...
(Please select the statement which most applies to you)
- I/we were not using contraception
- I/we were using contraception, but not on every occasion
- I/we always used contraception, but know that the method had failed (i.e. broke, moved, came off, came out, not worked etc) at least once
- I/we always used contraception

The next two questions ask about your circumstances around the time you became pregnant. Please think of your pregnancy four months ago, just before you entered this study. Please note: ‘Contraception’ includes anything you did, took or used to avoid becoming pregnant. Withdrawal (“pull-out”) method, contraceptive pills (“the pill”) and condoms are some examples.

In the month that I became pregnant...
(Please select the statement which most applies to you)
- I/we were not using contraception
- I/we were using contraception, but not on every occasion
- I/we always used contraception, but knew that the method had failed (i.e broke, moved, came off, came out, not worked etc) at least once
- I/we always used contraception
What contraceptive method(s) were you using at that time? (Please tick all methods you used at least once)

- Partner had a vasectomy
- Hormonal intrauterine device (Hormonal IUD) e.g. Mirena, Kyleena
- Copper intrauterine device (Copper IUD)
- Implant e.g. Implanon
- Contraceptive injection e.g. Depo Provera
- Contraceptive ring e.g. NuvaRing
- Combined hormonal contraceptive ("the pill" containing two hormones) e.g. Microgynon, Yasmin, Diane, Levlen ED
- Progestogen only pill ("minipill" containing one hormone) e.g. Noriday, Microlut, Slinda
- Male condom
- Female condom
- Diaphragm
- Natural family planning (monitoring of temperature, calendar, urine test etc)
- Withdrawal

What other method of contraception had you used?
__________________________________

Section B. Information at the pharmacy and contraception

Below are some questions that ask about your experience at the pharmacy four months ago (when you entered this study), and your use of contraception afterwards.

At that time, did you talk to the pharmacist about your contraceptive options (i.e. methods you could start using either at the time or after you took [medicine])?

○ Yes  ○ No

Did the pharmacist give you any written information about your options for contraceptive methods?

○ Yes  ○ No

Did the pharmacist tell you about online information such as a website on contraceptives?

○ Yes  ○ No

Please specify what online information was given
__________________________________

Did the pharmacist give you any information about clinics or GPs where you could get a prescription or a contraceptive method supplied?

- Verbal only
- Written only
- Both written and verbal
- None

Do you feel satisfied with the information and/or advice the pharmacist gave you about your contraceptive options?

- Very satisfied
- Quite satisfied
- Neither
- Quite dissatisfied
- Very dissatisfied

Have you used an emergency contraceptive pill or MS-2 Step in the four months since entering the study?

- Yes, emergency contraceptive pill
- Yes, MS-2 Step
- Yes, both
- No

Please tell us how many times approximately
__________________________________
What method(s) of contraception (if any) are you using now?
(please select all that you are currently using or usually use when you have sex)

- Tubal ligation
- Partner had a vasectomy
- Hormonal intrauterine device (Hormonal IUD) e.g. Mirena, Kyleena
- Copper intrauterine device (Copper IUD)
- Implant e.g. Implanon
- Contraceptive injection e.g. Depo Provera
- Contraceptive ring e.g. NuvaRing
- Combined hormonal contraceptive ("the pill" containing two hormones) e.g. Microgynon, Yasmin, Diane, Levlen ED
- Progestogen only pill ("minipill" containing one hormone) e.g. Noriday, Microlut, Slinda
- Male condom
- Female condom
- Diaphragm
- Natural family planning (monitoring of temperature, calendar, urine tests etc)
- Withdrawal ("pull-out") method
- Other method of birth control
- I am not using any method of contraception

Please state what other method of birth control you are using __________________________________

When did you start using these contraceptive method(s)? (Please tick)

- The same day that I took the emergency pill/abortion medicines
- The day after I took the emergency pill/abortion medicines
- With the start of my next period after the emergency pill/abortion medicines
- Other

Please specify the approximate date __________________________________

Where did you get the current method(s) of contraception that you are using?
(Please select all that apply)

- GP clinic
- Family planning/sexual health clinic
- Gynaecologist
- Other

Please tell us where you got contraception from __________________________________

We are interested to know why you are not using prescribed contraception (e.g. "the pill", implant etc)
(Please select all that apply)

- Not currently sexually active
- I am worried about side effects
- I cannot use contraception due to medical reasons
- Difficult to get an appointment for GP or family planning/sexual health clinic appointment
- Difficult to find time to get to GP or family planning/sexual health clinic appointment
- I am pregnant/trying for a baby
- I am not decided on what method I want to use
- Other

Please tell us why __________________________________
How satisfied are you with your current contraceptive use?
- Very satisfied
- Satisfied
- Neither
- Dissatisfied
- Very dissatisfied

Contraceptive Counselling

When you went to the pharmacy four months ago (when you entered this study), did you talk to the pharmacist about any of the contraceptive methods below? (Please select all the methods you remember talking or hearing about)

- Tubal ligation or hysterectomy
- Hormonal IUD
- Copper IUD
- Implant e.g. Implanon
- Contraceptive injection e.g. Depo Provera
- Contraceptive ring e.g. NuvaRing
- Combined hormonal contraceptive pill ("the pill")
- Progestogen only pill ("minipill")
- Male condom
- Female condom
- Diaphragm
- Natural family planning
- Withdrawal ("pull-out") method
- Other method of birth control
- Did not talk to the pharmacist about contraceptive methods

Please state what

After talking to the pharmacist, which contraceptive method were you most interested in using? (Please tick one)

- Tubal ligation or hysterectomy
- Hormonal IUD
- Copper IUD
- Implant e.g. Implanon
- Contraceptive injection e.g. Depo Provera
- Contraceptive ring e.g. NuvaRing
- Combined hormonal contraceptive pill ("the pill")
- Progestogen only pill ("minipill")
- Male condom
- Female condom
- Diaphragm
- Natural family planning
- Withdrawal ("pull-out") method
- I was not interested in using any of these methods

Referral

Did the pharmacist give you a 'referral' to get an appointment for contraception? (a letter to take to a health service to get a form of contraception)

- Yes
- No
- I cannot remember
When did you make an appointment for contraception? (Please tell us approximately)
- The same day that I took the emergency pill/abortion medicines
- The day after I took the emergency pill/abortion medicines
- Within 1 month after the emergency pill/abortion medicines
- 1-2 months after the emergency pill/abortion medicines
- 2-3 months after the emergency pill/abortion medicines
- 3-4 months after the emergency pill/abortion medicines
- I have not made an appointment

Do you intend to use the referral to get an appointment for contraception?
- Yes
- No
- Unsure

Did you use the referral to make this appointment?
- Yes
- No

Why is this the case? (Please select all that apply)
- I prefer to see my usual GP for contraception
- I prefer to attend another family planning/sexual health service for contraception
- Other

Please tell us why
____________________________________

What was the length of time between the date you contacted the clinic and the date of your appointment? (Please tell us approximately)
- Less than a week
- 1-2 weeks
- More than 2 weeks
- 1 month or longer

Please tell us how long approximately
____________________________________

Were you prescribed a method of contraception at that visit?
- Yes
- No

Is this the contraceptive method you are currently using?
- Yes
- No

Were you prescribed the method of contraception that YOU preferred at that visit?
- Yes
- No

Please tell us why the clinic did not provide you with a method you preferred.
- I cannot use the method that I preferred due to medical/health reasons
- Not enough staff or time to provide my preferred method at that visit
- I was/am still deciding which method to use
- I needed to make a second appointment to get my preferred method
- Staff would not provide me with it because I could have been pregnant
- I cannot afford by preferred contraception
- Other
<table>
<thead>
<tr>
<th>Please tell us why</th>
<th>Tubal ligation or hysterectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hormonal IUD</td>
</tr>
<tr>
<td></td>
<td>Copper IUD</td>
</tr>
<tr>
<td></td>
<td>Implant e.g. Implanon</td>
</tr>
<tr>
<td></td>
<td>Contraceptive injection e.g. Depo Provera</td>
</tr>
<tr>
<td></td>
<td>Contraceptive ring e.g. NuvaRing</td>
</tr>
<tr>
<td></td>
<td>Combined hormonal contraceptive pill (&quot;the pill&quot;)</td>
</tr>
<tr>
<td></td>
<td>Progestogen only pill (&quot;minipill&quot;)</td>
</tr>
<tr>
<td></td>
<td>Diaphragm</td>
</tr>
</tbody>
</table>

What was the method that you preferred but did not get at the appointment? (Please select all that apply)
# 12-Month Survey

We would be very grateful if you would spend some time completing this anonymous questionnaire. It will take between 5-10 minutes to complete. It asks about your use of birth control (contraception), recent pregnancies, and your experience of taking part in this study.

Please answer the questions below as best you can. It’s okay to leave a question blank if you’re unable to answer. If you run out of time, you can always save your responses and come back to complete the questionnaire later.

## Section A. Contraceptive use

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
</table>
| Have you used an emergency contraceptive pill or MS-2 Step in the 12 months since entering the study? | Yes, emergency contraceptive pill  
Yes, MS-2 Step  
Yes, both  
No |
| Please tell us how many times approximately                                | ____________________________________________________________________ |
| What method(s) of contraception (if any) are you using now?  
(please select all that you are currently using or usually use when you have sex) | Partner had a vasectomy  
Hormonal intrauterine device (Hormonal IUD) e.g. Mirena, Kyleena  
Copper intrauterine device |
| Please state what                                                         | ____________________________________________________________________ |
| When did you start using these contraceptive method(s)?                  | The same day that I took the emergency pill-abortion medicines  
The day after I took the emergency pill-abortion medicines  
With the start of my next period after the emergency pill-abortion medicines  
Other |
| Please specify the approximate date                                       | ____________________________________________________________________ |
| Where did you get the current method(s) of contraception that you are using?  
(please select all that apply) | GP clinic  
Family planning/sexual health clinic  
Gynaecologist  
Other |
| Please tell us where you got contraception from                          | ____________________________________________________________________ |
We are interested to know why you are not using prescribed contraception (e.g. "the pill", implant etc) (please select all that apply)

- Not currently sexually active
- I am worried about side effects
- I cannot use contraception due to medical reasons
- Difficult to get an appointment for GP or family planning/sexual health clinic appointment
- Difficult to find time to get to GP or family planning/sexual health clinic appointment
- I am pregnant/trying for a baby
- I am not decided on what method I want to use
- I cannot afford my preferred contraception
- Other

Please tell us why

______________________________

How satisfied are you with your current contraceptive use?

- Very satisfied
- Satisfied
- Neither
- Dissatisfied
- Very dissatisfied

Section B. Referral

Did the pharmacist give you a 'referral' to get an appointment for contraception? (a letter to take to a health service to get a form of contraception)

- Yes
- No
- I cannot remember

When did you make an appointment for contraception? (please tell us approximately)

- The same day that I took the emergency pill-abortion medicines
- The day after I took the emergency pill-abortion medicines
- Within 1 month after the emergency pill-abortion medicines
- 1-2 months after the emergency pill-abortion medicines
- 2-3 months after the emergency pill-abortion medicines
- 3-4 months after the emergency pill-abortion medicines
- I have not made an appointment

Do you intend to use the referral to get an appointment for contraception?

- Yes
- No
- Unsure

Did you use the referral to make this appointment?

- Yes
- No

Why is this the case? (Please select all that apply)

- I prefer to see my usual GP for contraception
- I prefer to attend another family planning/sexual health service for contraception
- Other

Please tell us why

______________________________
What was the length of time between the date you contacted the clinic and the date of your appointment?  
(please tell us approximately)  
☐ Less than a week  
☐ 1-2 weeks  
☐ More than 2 weeks  
☐ 1 month or longer  

Please tell us how long approximately  
__________________________________

Were you prescribed a method of contraception at that visit?  
☐ Yes  
☐ No

Is this the contraceptive method you are currently using?  
☐ Yes  
☐ No

Were you prescribed the method of contraception that YOU preferred at that visit?  
☐ Yes  
☐ No

Please tell us why the clinic did not provide you with a method you preferred.  
☐ I cannot use the method that I preferred due to medical/health reasons  
☐ Not enough staff or time to provide by preferred method at that visit  
☐ I was/am still deciding which method to use  
☐ I needed to make a second appointment to get my preferred method  
☐ Staff would not provide me with it because I could have been pregnant  
☐ I cannot afford my preferred contraception  
☐ Other  

Please tell us why  
__________________________________

What was the method that you preferred but did not get at the appointment?  
☐ Tubal ligation or hysterectomy  
☐ Hormonal intrauterine device (Hormonal IUD)  
☐ Copper intrauterine device (Copper IUD)  
☐ Implant  
☐ Contraceptive injection  
☐ Combined hormonal contraceptive pill or ring  
☐ Progestogen only pill ("minipill")  
☐ Male or female condom  
☐ Diaphragm

Section C. Recent pregnancy

Have you been pregnant since you entered the study 12 months ago?  
☐ Yes  
☐ No

Please tell us about all the pregnancies you have had since you entered the study 12 months ago.  
(please select all that apply)  
☐ I am currently pregnant  
☐ I had a miscarriage  
☐ I had an abortion  
☐ I had an ectopic pregnancy  
☐ Other  

Please provide details  
__________________________________

Below are some questions that ask about your circumstances and feelings around the time you became pregnant. Please think of your current (or most recent) pregnancy when answering the questions below.
In the month that I became pregnant...  
(please tick the statement which most applies to you)

- I/we were not using contraception  
- I/we were using contraception, but not on every occasion  
- I/we always used contraception, but knew that the method had failed (i.e. broke, moved, came off, came out, not worked etc) at least once  
- I/we always used contraception  

In terms of becoming a parent (first time or again), I feel that my pregnancy happened at the...  
(please select the statement which most applies to you)

- Right time  
- Ok, but not quite the right time  
- Wrong time  

Just before I became pregnant...  
(please select the statement which most applies to you)

- I intended to get pregnant  
- My intentions keep changing  
- I did not intend to get pregnant  

Just before I became pregnant...  
(please select the statement which most applies to you)

- I wanted to have a baby  
- I had mixed feelings about having a baby  
- I did not want to have a baby  

In the next question, we ask about your pregnancy partner. (This might be (or have been), a partner you live with, husband, boyfriend, or someone you've had sex with once or twice.)

Before I became pregnant...  
(please select the statement which most applies to you)

- My partner and I had agreed that we would like me to be pregnant  
- My partner and I had discussed having children together, but hadn't agreed for me to get pregnant  
- We never discussed having children together
CONSENT FORMS
(PHARMACY OWNERS & PHARMACIST)

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
Department of General Practice

Project Manager:
Dr Anisa Assifi
Department of General Practice
Email: Alliance.trial@monash.edu

[Survey intro in REDCap is the Explanatory Statement]

Name of pharmacy_____________________________________
Postcode_____________________________________

Do you confirm that (pharm_name) meets the trial requirements as outlined in the Explanatory Statement?
1) Located in a metropolitan/regional/rural area in NSW, NT or Vic
   1 Yes
   0 No
2) QCPP accredited
3) Private consultation room on premises
4) Employs at least one 0.8FTE+ pharmacist(s) willing to participate
5) The pharmacy owner consents to the pharmacy participating

Please select the consent form you wish to complete
1 Consent form for individual pharmacists, intending to participate in the ALLIANCE trial only
2 Consent form for pharmacy owners, to approve participation of a pharmacy practice in the ALLIANCE trial only

[The 2 consent forms (pharmacy practices and individual pharmacists) will be accessed via the same link and branching logic will direct to the appropriate form in REDCAP]

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby give my consent to participate in this project.

CONSENT FORM FOR PHARMACY OWNERS

<table>
<thead>
<tr>
<th>As the owner of (pharm_name) (pharm_postcode) I consent to:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist employees participating in all aspects of the ALLIANCE Trial and undertaking research-related tasks including but not limited to those outlined in the Explanatory Statement (as discussed with the ALLIANCE Project Manager) during usual work hours</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The implementation of ALLIANCE Standard Operating Procedures in the pharmacy for the purposes of the trial, such as participant recruitment + billing procedures and the display of ALLIANCE patient resources and promotional materials</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Liaising with the ALLIANCE project team and receiving correspondence via email and phone</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
CONSENT FORM FOR INDIVIDUAL PHARMACISTS

As pharmacist employed by {pharm_name} (pharm_postcode), I consent to:

- Participating in all aspects of the ALLIANCE trial and implementing trial activities including but not limited to tasks outlined in the Explanatory Statement (as discussed with the ALLIANCE Project Manager)
- Liaising with the ALLIANCE project team regarding any aspect of my participation and receiving correspondence via email and phone
- Undertaking research tasks during usual work hours, although I acknowledge that some tasks may need to be undertaken outside of usual work hours (e.g. educational module, questionnaires, etc.)
- To take part in an interview towards the end of the trial (if randomly selected)

I acknowledge the following:

a) Taking part in this study is entirely my choice. I am free to withdraw the pharmacy from the project at any time without explanation and there will be no negative consequences associated with refusal or withdrawal from participation.

b) I may be invited to participate in an in-depth audio-recorded interview about my experiences in this study. (I acknowledge that my participation in the interview is voluntary - I will be given detailed information about the study and the fullest opportunity to make an informed decision about whether to participate or decline the invitation without any negative consequences to me).

c) This project is for the purpose of research and not for profit.

d) All information about me and/or the pharmacy listed above that is gathered due to my participation in this project will be collected, analysed and kept for the purpose of this project.

e) That research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way. The researchers have agreed not to reveal my identity and personal details.

f) I am required to alert the ALLIANCE project team (and authorities, if applicable) if serious events associated with my pharmacy’s participation in the ALLIANCE Trial occur.

Name of pharmacy owner (if different from above)

Signature ___________________________ Date __________

[REDCap message]

Thank you for signing the consent form to participate in the ALLIANCE trial. If you do not hear from us within 7 days, please feel free to contact the ALLIANCE team at ALLIANCE.trial@monash.edu.

Have a nice day!
CONSENT FORM  
(CONSUMERS)

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  
Department of General Practice

Project Manager:  
Dr Anissa Assifi  
Department of General Practice  
Email: alliance.trial@monash.edu

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby give my consent to participate in this project.

I acknowledge the following:

a) Taking part in this study is entirely my choice. I can refuse to take part or change my mind at any time and there will be no negative consequences.
b) I may be invited to participate in an in-depth audio recorded interview about my experiences in this study, in two months’ time.
c) This project is for the purpose of research and not for profit.
d) All information about me that is gathered due to my participation in this project will be collected, analysed and kept for the purpose of this project.
e) Research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

I consent to the following:

| Taking part in the ALLIANCE trial |
| Completing the surveys as requested by the research team |
| Receiving reminders to complete surveys via text, email and/or phone call |
| My de-identified data collected in this trial may be used for future research projects related to this trial, where ethics approval has been granted. |
| To take part in an interview (if randomly selected) |
| Being contacted by the researchers about data related to me and my participation when it is absolutely necessary (e.g. if data or forms are missing) |

☐ YES, I consent

Name of participant:

Phone number:  
Email address:

Preferred contact method (please circle):  
Call  
Text  
Email

Preferred day (please circle):  
Mon  
Tues  
Wed  
Thurs  
Fri  
Sat  
Sun