



The female condom: How acceptable is it to Australian women?

Participant Information Sheet

Coordinating Principal Investigator: Jessica Botfield
Other Investigators: Deborah Bateson, Sarah Fenwick, Jane Estoesta

1. Study overview

Family Planning NSW is conducting a study to better understand the acceptability of the female condom for Australian women. We are seeking volunteers willing to try out the female condom and provide their feedback via an online survey (and optional phone interview).

This document tells you about the study and what your participation would involve. Participation in this study is entirely voluntary.

You can participate if you are:

- Female
- Aged 16 years or over
- Heterosexually active
- Live in New South Wales

2. What does participation involve? *Participating in the study will involve three easy steps:*

Step 1:

Short eligibility survey: To check your eligibility and register your interest, you will be asked to complete a short online survey. In the survey you will be asked a few questions to confirm that you are eligible to participate. You will also be asked to provide your email address/mobile/postal address.

NB: your contact information will not be linked to your other responses. If you choose to continue with the study and complete the feedback survey, those responses will not be linked to the responses of this survey.

Step 2:

Try the female condom: If you are eligible to participate, we will post you 3 female condoms (FC2 Female Condoms®). We will post these to the address you include in the survey above, in discrete plain packaging. Or, you can pick up from your nearest FPNSW clinic if easier for you or if you do not want to provide a postal address.

Step 3:

Feedback survey: Try out the female condom and send us your feedback via an online survey. We'll email and/or text you the survey link after we've sent you the female condoms. We'll also send you two reminders after the initial one in case the study has slipped your mind. After these 3 reminders you will not receive any further emails/texts from us.

Step 4: Optional

Phone interview: Have more to say? Great! We are offering the opportunity for individuals to participate in a short phone interview with a member of the research team. During the phone call we'd like to get a better understanding of your views about the female condom.

You can decide to participate in an interview at any time by contacting the research team. We'll also include the option to indicate your interest at the end of the short eligibility survey (Step 1). The interview will take approximately 10 minutes, and will be audio-recorded with your consent and transcribed afterwards. No identifying information will be asked in the interview.

3. Do I have to take part in this study?

Your participation in this study is voluntary. You can choose not to participate or to stop at any time without giving any reason and without any consequences. Your decision to participate or not will not affect your relationship with Family Planning NSW. If you decide to take part in the study and then change your mind later, you are free to withdraw at any time.

4. What are the possible benefits of taking part?

You will receive no personal benefits from participating in this study, apart from receiving three free female condoms. However your feedback will be invaluable at helping us to better understand the acceptability of the female condom for women in Australia.

5. What risks are involved if I participate?

Choosing to participate in a contraception study is an important personal decision. When using the female condom for the purpose of this study, we recommend that you still continue with your regular contraception. Making changes to your primary method of contraception should always be discussed first with your health care professional.

Note the female condom cannot be used at the same time as the male condom.

When used correctly the female condom is up to 95% effective at preventing pregnancy. This means that approximately 5 women out of every 100 women who use the female condom for a year will become pregnant. If not used perfectly, then approximately 20 women in every 100 may fall pregnant in a year. The female condom also provides protection against STIs for men and women.

Female condoms can be combined with other methods of contraception including contraceptive pills, vaginal rings, contraceptive injections, implants and IUDs. This provides effective contraception and prevents STIs at the same time.

If you are concerned that you used the female condom incorrectly, or it became dislodged or broke during sex, the emergency contraceptive pill (ECP) is available from pharmacies. The ECP can be used within 120 hours to reduce the risk of unintended pregnancy (but it is more effective the sooner it is taken). More information on this can be found here:

<https://www.fpnsw.org.au/health-information/contraception/emergency-contraception>

If you are worried that you might be at risk of pregnancy or an STI, you can also make an appointment to see your GP or your nearest FPNSW clinic (<https://www.fpnsw.org.au/clinics>) to talk to a doctor or nurse. You can also contact FPNSW Talkline for free on 1300 658 886 Monday to Friday, 8:30am-5pm or via email talkline@fpnsw.org.au.

6. How will the information collected be used?

Only the named researchers will have access to study data. All data will be password encrypted and stored on the Family Planning NSW's secure server. Hard copies will be stored in a locked filing cabinet at FPNSW Ashfield head office. All research documents will be retained for five years and then destroyed.

Any identifying information about you will be removed from any data collected. You will not be identifiable in any publications.

When the study is finished, all the findings will be collated and a summary of the findings will be made available in a short report on the FPNSW website. The findings will also form the basis of publications in scientific journals and presentations at local and international conferences.

7. How is this study being funded?

This study is an investigator-initiated study which is being partially funded by the Female Health Company (\$5,000 USD). This means that the idea for the study originated from the research team and is being led by us. Glyde is providing the supply of 1,500 FC2 Female Condoms[®]. The Female Health Company and Glyde will have no input into the results or publication of the results. There are no conflicts of interest relating to the relationship between researchers and commercial partners to declare.

8. What if I have any questions, concerns or complaints?

If you have any questions about the study or your participation, please contact Jessica Botfield on 8752 4334 or at researchcentre@fpnsw.org.au

For any complaints about the study, please contact the Family Planning NSW Ethics Executive Officer, Sarah Wright, at ethics@fpnsw.org.au or (02) 8752 4352.

Note the ethical aspects of this study have been approved by the Family Planning NSW Ethics Committee (approval number: R2018-08).

9. Information and support

If you would like more information on the female condom or other contraceptive methods, you can contact FPNSW Talkline on 1300 658 886 Monday to Friday, 8:30am-5pm or via email talkline@fpnsw.org.au

If you have been impacted by domestic or family violence and abuse and require support, you can call 1800 737 732.

Remember:

The female condom can only be used once. It cannot be used with the male condom. If you feel that the female condom has not worked properly, or you have forgotten to use it, the Emergency Contraceptive Pill can be used to reduce the risk of pregnancy.

