

PARTICIPANT INFORMATION AND CONSENT FORM (PICF)

Sexual Health Unit, School of Population Health, University of Melbourne

Full Project Title: Female University Student Study (FUSS)

Principal Researchers: Katherine Fethers and Catriona Bradshaw

1. Introduction

You are invited to take part in this research project. This is because you are a female aged between 17-21 years of age at Melbourne University. The research project aims to understand how common a genital infection called bacterial vaginosis (BV) is in young Australian women, and how it may be related to different types of sexual activity or factors such as contraceptive use. We hope this research will lead to improvements in treatment for BV.

This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

The purpose of this project is to understand how common BV is in young women in Australia and how it is related to sexual activity and other factors such as contraceptives. In BV a woman's usual healthy vaginal bacteria (in particular lactobacillus bacteria) are replaced by an overgrowth of mixed bacteria. BV is common, and studies have shown it affects 10-30% of women in countries such as the United Kingdom and United States. However, we do not know how common it is in Australian women. BV may cause symptoms of an abnormal vaginal discharge or odour (smell). However, more than half the women with BV do not have any symptoms so are often unaware of the infection. In most women BV has no complications, but it can cause miscarriage, premature birth and pelvic infections, and can increase a woman's risk of getting sexually transmitted infections (STIs). Current recommended treatment for BV is with oral or vaginal antibiotics. Studies have shown that while these treatments cure 70-80% of women within a month, up to half experience recurrence of BV within 6 months of treatment. Importantly, we don't know why this happens. Some previous studies suggest BV may be related to sexual activity or even be sexually transmitted, however this remains unproven. Our research aims to understand how BV is related to sexual activity in order to develop more effective treatment and to prevent the complications associated with BV for women.

We will be asking 500 women aged 17-21 years of age to participate in this study at Melbourne University. The results of this research will be used by the researcher Katherine Fethers to obtain a PhD in medicine.

3. What does participation in this research involve?

Participation in this project will involve completing a questionnaire that will be coded and does not have your name on it. We will be asking you personal questions so that we can understand how BV develops and is spread between people. The questionnaire takes 5 to 10 minutes to complete. We will ask you to collect a swab from the vagina in the privacy of a toilet. Studies have shown that women find this easy and acceptable, and often prefer it to a doctor taking a swab. We will give you clear written instructions on how to collect a swab. It will only take a minute and this swab will be tested for BV. We will ask you on your consent form how you would like to be told about your result. If you have BV we will then arrange for you to have antibiotic treatment either through our clinical service, Melbourne Sexual Health Centre (MSHC) or through your GP if you prefer. We will give you a free study number to phone us to discuss any concerns about sexual health, including BV and STIs. We will be able to arrange for you to be reviewed at MSHC, a confidential service near the university that provides STI and HIV testing, and medication for free if it is required. In recognition of the time and commitment to the study we will be giving women a Coles-Myer voucher for \$25.

This study is the initial part of a longer study where we would like to follow up women every 3 months for a year to see how many women develop BV and what factors or practices may be related to the development of BV. We will ask you to tell us on your consent form whether you agree to be contacted by a researcher to discuss participating in this longer study. If you do not wish to participate in the longer study then you will be able to tell us on your consent form, but you can still participate in the short study today.

We will also ask you on the consent form whether you agree to storage of your swab in a laboratory freezer for future testing for known or possible causes of BV. We do not understand the cause of BV, and if research in the future shows it may be a newly discovered micro-organism (eg bacteria or virus), then we would like to be able to test stored samples from this study. Again if you do not wish us to do this you will be able to tell us on the consent form and still participate in the study today.

4. What are the possible benefits?

Possible benefits for you personally from involvement in this study include being tested for BV and access to expert advice regarding sexual health. Researchers in this study are physicians who have a particular expertise in sexual health. We will provide a free number for you to discuss any sexual health concerns you may have, and we can arrange for you to be seen by a doctor at MSHC if that is needed. If you chose to participate in the longer one year study then we will be able to tell you whether BV occurs using a convenient home-based method. We will be able to arrange immediate treatment at any stage for BV if needed. Participation in this study may not give you any personal benefit other than knowing that you are involved in a study that is part of improving current treatment of BV for women.

5. What are the possible risks?

Self-collection of vaginal swabs is a simple and painless procedure. This method has been used in numerous studies and in situations where women prefer to not to be examined. We will provide clear instructions and diagrams and there is no risk associated with this procedure. Participants will be asked to complete questionnaires during the study that include questions on sexual practices. This information is sensitive, and the sole purpose of these questions is to try and understand how sexual activity may lead to the development or spread of BV. The nature of the questionnaires will be discussed with you at enrolment by a female researcher who recognises the personal and sensitive nature of

these questions. If you become upset or distressed as a result of your participation in this research, we will be able to arrange for you to have counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team. We have trained counsellors in place at MSHC, but we have also provided contact information for the experienced counsellors at the Centre against Sexual Assault (CASA) below if you have had any unwanted sexual experiences including sexual assault in the past and have not received counselling or medical review and wish to do so. The toll free number for the Centre Against Sexual Assault is 1800 806 292.

Your confidential information will be respected and protected. This information will be stored with a code only and information linking the code with your personal identity will be kept separately in a locked cabinet in a different room and accessible only to study investigators. Your personal identifying information will only be used to give you your results.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you decide to withdraw, please notify a member of the research team. This notice will allow the person or the research supervisor to inform you if there are any special requirements linked to withdrawing. If you decide to leave the project, the researchers would like to keep (the personal and health information about you) that have been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the research project. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers or Melbourne University.

7. How will I be informed of the final results of the project?

Participants will be told if BV has been detected within a fortnight of the swab being collected. When the study is complete will be look at how common BV is in the whole study group, and whether specific practices are related to BV. We expect the overall results to be available a year after we start the study. We plan to publish these results in a medical journal, but they will be published in such a way that no person can be identified (eg. 5% of 500 women had BV). Following completion of the project, a copy of the overall results can be made available to you. Please indicate if you would like this on the Consent Form.

8. What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of providing you with your swab result. Your information can only be disclosed with your permission, except as required by law. Your questionnaires will be labelled with a code, date of collection and date of birth only. A listing connecting your name with this code will be stored in a locked cupboard, available only to research staff in the research unit. Data will be stored indefinitely in accordance with the Melbourne University policy on the management of research data and records. We plan to publish the findings of this study in a medical journal and present them at medical conferences, so that other doctors will understand the results. This will be done in a manner that pools all the results – no individual could be identified.

9. Can I access research information kept about me?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information. Further, in accordance with regulatory guidelines, the information collected in this research project will be kept for a minimum of 5 years after publication. You must be aware that the information may become de-identified at some point and access to information about you after this point will not be possible.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the University of Melbourne. This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Consent

I have read this document, *FUSS Version 1.2, dated 1 November 2007*, and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.

I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Please indicate how you would prefer to be contacted in this study by ticking a box and giving us your contact details so we can provide results of your BV test (*give more than one option if possible so we can be sure that we notify you if BV is detected. If you can, write number 1, 2 or 3 next to each of the options to indicate the order you prefer to be contact in*)

- Mobile or telephone number.....
- Email
- Post.....

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I consent to be contacted by a researcher to discuss possible involvement in a longer trial of BV Yes No

I consent to the storage and use of vaginal swabs provided by me for use in further research as described in this Participant Information Yes No

I would like to be sent a copy of the overall study findings at the end of the study Yes No

If so please tick your preferred method of contact post or email

Participant's Name (printed)

Signature

Date

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed)

Signature

Date

12. Who can I contact?

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

a) If you want any further information concerning this project, or if you have any questions at any stage, you can contact the principal researcher on Dr Katherine Fethers on 93416247 or Dr Catriona Bradshaw 9341 6253

You can also contact us for free on 1800 458406

b) If you have any complaints about any aspect of the project, the way it is being conducted or any general questions about being a research participant, then you may contact: Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax 9347 6739.