Summary of your journey through the study

At your pessary appointment
You will be assessed for suitability for the TOPSY study
Information about the study will be given

If you are a new pessary user
You receive a call 2 weeks after appointment to assess eligibility and willingness
and answer any questions

If you are an existing pessary user
Eligibility and potential willingness to participate will be assessed and questions answered

You will complete a consent form and baseline questionnaire
Your study group will be randomly selected

Standard Pessary Care Group
You receive follow up care at your usual place of care (appointment every 4-6 months) for 18 months

Pessary Self-management Group
You receive a teaching appointment,
follow-up phone call + phone support as needed
Follow up appointment at 18 months

Questionnaires
You complete a questionnaire after 6, 12 and 18 months

TOPSY

A study comparing self-management with standard care for women using a vaginal pessary for prolapse

Participant Information Leaflet

for the TOPSY study

Introduction

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. A member of your "local TOPSY research team" (from your usual place of care) will go through the information sheet with you and answer any questions that you have. Please ask us if anything is unclear or if you would like more information. Take the time you need to decide whether or not you wish to take part.

Why are we doing the study?

Pelvic organ prolapse is a common condition that often leads to women having symptoms that interrupt their day to day life. One treatment that some women receive for pelvic organ prolapse is a vaginal pessary. However, it is not clear how to support women once their pessary is in place. One option is that women attend an appointment approximately every four to six months to have their pessary changed: this is called standard pessary care. Another option is that women are taught how to remove and re-insert their pessary at home: this is called pessary self-management. At the moment there is no evidence to tell us which of these is better for women. Therefore this study aims to compare standard pessary care with pessary self-management to find out which is better at improving women's quality of life when they are using a vaginal pessary for treatment of pelvic organ prolapse.

If you have any further questions about the study at any stage, please feel free to contact:

Associate Professor Carol Bugge
Chief Investigator TOPSY Study
Faculty of Health Sciences & Sport
University of Stirling
FK9 4LA
01786 466109
carol.bugge@stir.ac.uk

or

Dr Kirsteen Goodman
Trial Manager
NMAHP Research Unit
Glasgow Caledonian University
G4 0BA
0141 331 3516
Kirsteen.goodman@gcu.ac.uk

If you would like information about research more generally please contact:

Professor Jayne Donaldson
Dean of Faculty of Health Sciences and Sport
University of Stirling
FK9 4LA
Jayne.Donaldson@stir.ac.uk

Information about the study is available on the following web site:

https://w3.abdn.ac.uk/hsru/TOPSY

Thank you for reading this and considering taking part in this study.

The University's Data Protection Officer is Joanna Morrow, Deputy Secretary. If you have any questions relating to data protection these can be addressed to data.protection@stir.ac.uk in the first instance.

If you remain unhappy, you have the right to lodge a complaint against the University regarding data protection issues with the Information Commissioner's Office (https://ico.org.uk/concerns/).

Taking part in this study does not affect your normal legal rights. Whether or not you take part, you will retain the same legal rights as any other patient in the NHS (which include professional indemnity insurance for negligence).

What will happen to the results of the study?

The results will help us to understand women's experiences of pessary treatment for pelvic organ prolapse and how effective different kinds of pessary care are. We hope that the results will be published in a number of journals so that others can read and learn from the results of the study. If you wish, when the study is complete we will send you a summary of the findings.

Can I contact a member of the research team for further information?

If you have received this information leaflet you will be offered an opportunity to speak with a researcher on the telephone. They will be able to provide further information on this study, answer any of your questions and tell you about the next steps should you wish to continue with being part of this study.

Why have I been invited to take part?

You have been asked to take part because you are a woman with pelvic organ prolapse who uses a pessary as treatment. We hope to include women who are new to using a pessary and women who have been using their pessary for a while. We are aiming to involve 330 women in the study. Half of the women will receive standard pessary care. The other half of the women will receive a pessary self-management programme.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information leaflet to keep and be asked to sign a consent form.

If you decide to take part you are free to withdraw at any time without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the care you receive at any time. If you are self-managing and withdraw you will be re-referred for NHS care. You will not be paid any expenses for your involvement in this study, however a five pound gift voucher will be sent to you with your 18 month questionnaire.

A small number of people who do not want to take part in the TOPSY study can still take part in an interview study if they would like to. If this applies to you, you will be given a separate information leaflet to take home with you. You can discuss this further with members of your local TOPSY research team or TOPSY researchers.

What will happen to me if I take part in the TOPSY study?

At your scheduled pessary appointment, or by post, a member of the local TOPSY research team from your usual place of care will introduce you to the study. You will receive an invitation letter, this leaflet and an expression of interest form. Please return the expression of interest form in the stamped addressed envelope provided.

If you reply that you are interested in taking part someone from your "local TOPSY research team" based at your usual place of care will contact you to discuss the study further, answer any questions you may have and to check if you are eligible to take part. If you are eligible and agree to take part you will be asked to complete a consent form and fill out a questionnaire. You will be allocated at random to one of the two groups. You will have a 50% chance of being in either group.

Women in the **standard pessary care group** will be followed up in the usual way; usually every four to six months. At the appointment their pessary will usually be removed and replaced.

Women in the **pessary self-management group** will be given a one-to-one teaching session with a health professional (eg a nurse) that will last approximately 30 minutes. During that session women will be taught how to remove, clean and re-insert their pessary and will be given the chance to practice this.

Women in the self-management group will receive a follow up telephone call approximately two weeks later to check they have managed to remove, clean and re-insert their pessary at least once in those two weeks.

What are the possible disadvantages or risks of taking part?

We do not anticipate any risks to you from being involved in the study. Pessaries are widely used in the NHS as treatment for pelvic organ prolapse. Both pessary self-management and standard pessary care are already used within the NHS. Your participation in the study is therefore only to help us compare these types of care and should not involve any additional risk. Women in the self-management group are asked to remove, clean and re-insert their pessary at least once every six months. They will also receive a leaflet outlining possible complications to look out for. Some of the questions we ask you during the study may seem personal or of a sensitive nature but the information is important to help us fully understand the effects of your pessary care.

Only those involved in the research will be permitted access to any of the files or data. When the results are published, this will be done in such a way that you will not be identifiable. If quotes from an audio-recording or interview are used for reports, you will not be identifiable. If during the study you are no longer able to take part, all relevant data collected prior to this will be retained confidentially.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to members of your local TOPSY research team or you can contact the TOPSY study office who will do their best to address your concerns. In the first instance contact: **Kirsteen Goodman,** Trial Manager (telephone: 0141-331-3516) or you can email TOPSY@gcu.ac.uk.

Legal basis for processing personal data

As part of the project we will be recording personal data relating to you. This will be processed in accordance with the General Data Protection Regulation (GDPR); **Article 6(1)(e).** Under GDPR the legal basis for processing your personal data will be the official authority of the University.

How long will I be involved in the study?

You will be involved in the study for 18 months. You will remain under the care of your local centre for the 18 months of the study.

We will send the last questionnaire to you 18 months after you enter the study. After the study has ended, your future pessary care plans will be discussed and agreed with your local clinical team.

The research team may want to know how you are doing after the study has finished (e.g. in 3-5 years time). In this case to avoid asking you further questions about your pessary care, we would like to access the information that is already held about you electronically by the NHS, for example by your GP or hospital. This information would be looked at by authorised members of the research team. We would tell NHS Digital (who hold your information) your personal details (including name, date of birth, NHS number and address) so they can identify the correct information to send us. If you agree with this please initial the appropriate statement on the consent form.

They will also receive an information leaflet about possible complications and a local telephone number they can call if they experience any difficulties.

Women in the self-management group are asked to remove, clean and re-insert their pessary at least once every six months.

Some self-management teaching sessions and some follow up telephone calls may be audio recorded to find out if the teaching is being delivered as intended. If you are happy with this you will be asked to initial the relevant statement on the consent form. The audio-recordings will be transcribed and anonymised. The recordings will be destroyed at the end of the study. A small number of women in each group will also be invited to take part in an interview study. An additional Information Leaflet and consent form will be given to those selected for interview. If you are willing to hear more about the interview study you will be asked to initial the relevant statement on the consent form.

All women in both groups will receive questionnaires for completion at 6, 12 and 18 months into the study and these can be completed and returned by post **or** completed on your computer or smart phone (you can pick your preferred option).All women will have a pessary appointment at 18 months after they start the study.

If you became pregnant during the study, you would not continue in the study and your pessary use would be discussed with your local care team. The data we have collected from you up to this point will be used in any data analysis conducted for the study.

What are the possible benefits of taking part?

The pessary care you receive may help to manage your pelvic organ prolapse and improve your quality of life. Taking part in the study will not benefit you further but the information we get from this study may help improve the care of women with a pessary in the future.

Will the information I provide be kept confidential?

Yes. All information collected about you will be kept strictly confidential. Paper records will be kept in a locked filing cabinet. Computerised data will be kept on a password protected computer.

Your rights

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information:

https://www.stir.ac.uk/about/faculties-and-services/policy-and-planning/legal-compliance/data-protectiongdpr/gdpr-policy-and-guidance/

Who is organising and funding the study?

The study is sponsored by the University of Stirling, based in the UK, and is being funded by the National Institute for Health Research.

The research is being carried out by a group of experienced doctors, nurses, physiotherapists and researchers along with women who have pelvic organ prolapse. The study has been approved by the West of Scotland Research Ethics Committee and all local NHS sites involved.

We will be using information from you and your medical records in order to undertake this study and the University of Stirling will act as the data controller for this study. This data will contain your name, age, contact details and medical notes relating to your prolapse. Your contact details will be used to send you study related materials (such as questionnaires). Your personal data will be securely shared with Glasgow Caledonian University and the Centre for Healthcare Randomised Trials at the University of Aberdeen who are responsible for the study's database.

We will also notify your GP about your study participation. This means that the University of Stirling is responsible for looking after your information and using it properly. The University of Stirling will keep identifiable information about you for **5 years** after the study has finished in a secure location. After the time, all information will be securely destroyed.