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peppy trial

Prolapse management: Effectiveness of PFMT plus PessarY

Participant Information Leaflet

for the PEPPY study

A study comparing pelvic floor muscle training plus vaginal pessary with pelvic floor muscle training alone for management of pelvic organ prolapse

Introduction

We'd like to invite you to take part in our research study. Deciding to join the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. A member of the PEPPY research team (either at the NHS centre you are attending or from the Trial Office) will go through this information leaflet with you and answer any questions you have. Please ask us about anything that is unclear and tell us if you would like more information. Please use the contact details on Page 11 to get in touch with us. Take the time you need to decide whether or not you wish to take part. A summary of your journey through the study, should you take part, is provided on Page 12.

Although we use the term women within this leaflet, this study is open to individuals of all gender identities who are referred for Pelvic Floor Muscle Training for prolapse.

Why are we doing the study?

Pelvic organ prolapse is a common condition that can cause symptoms that interrupt a woman's day-to-day life. Pelvic floor muscle training (PFMT) supervised by a specialist physiotherapist is an option often used to improve prolapse symptoms. A vaginal pessary, a support device inserted into the vagina to hold the prolapsed organs in place, can also improve prolapse symptoms. PFMT and pessary are used together by some healthcare professionals, however we don't know if this combination is beneficial for women. Therefore, this study aims to find out if using supervised PFMT and a pessary together works better than PFMT alone at reducing prolapse symptoms and improving women's quality of life.

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 has been referred for PFMT as treatment. We are aiming to involve around 550 women in the study. Half of the women will receive both supervised PFMT and a pessary together. The other half of the women will receive PFMT alone. Which of the two groups you are in will be decided at random.

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 asked to sign a consent form. This may be a paper or an electronic consent form. You can choose. For electronic consent forms a link will be sent to your email address for you to complete and once completed a copy of the consent form and this participant information leaflet will be emailed to you as your personal copy.

What if I change my mind?

If you agree to take part, you can change your mind at any time and your usual care won't be affected. Please contact the clinical team (e.g. your doctor, physiotherapist or nurse) or the Trial Office if you are finding it hard to take part. They may be able to help you.

What will happen if I say I want to stop taking part?

If you decide to stop taking part, your clinical team will explain treatment options available to you going forward. You won't have to explain to anyone why you want to stop. However, if you do feel able to tell us about your experience in the study it can perhaps help the research team learn and improve what we do.

What will taking part involve?

A member of the clinical team from your usual place of care will introduce you to the study, either by sending you information by post or by speaking to you at your scheduled clinic appointment. You will receive an invitation letter, this leaflet and an Expression of Interest Form. Please complete and return the Expression of Interest Form in the pre-paid reply envelope provided or give it back to the staff member who gave you the information in clinic.

If you reply saying that you are interested in taking part someone either from the team based at your usual place of care or at the Trial Office will contact you to discuss the study. They will answer your questions and 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 (either via a paper form or an electronic form). After you have completed these you will be allocated at random, by a computer, to one of the two groups. This may be done face-to-face when you are in clinic. You will have a 50% chance of being allocated to either of the two groups and therefore you must be willing to accept, and stick to, the treatment plan you are allocated to:

Group 1: Women in the PFMT and pessary group will have a 16-week PFMT programme involving 5 physiotherapist appointments (3 hours total) and a daily pelvic floor muscle home exercise programme, and have a vaginal pessary fitted (1 hour maximum fitting time). The pessary can be kept in or removed and re-inserted from time to time depending on what you prefer.
Group 2: Women in the PFMT group will have a 16-week PFMT programme involving 5 physiotherapist appointments (3 hours total) and a daily pelvic floor muscle home exercise programme.

The PFMT programme in both groups will involve attending 5 appointments, with at least 3 appointments being face to face, some involving internal assessments of your pelvic floor muscles. Internal assessments are usual for women having PFMT. Others appointments can be by telephone. The PFMT programme will be individualised for you and progressed at each appointment at your pace. Between each appointment you will be asked to complete a daily diary for one week to record the pelvic floor exercises you did, and when you used your pessary (if you are in the pessary group).

Women in both groups will receive questionnaires to complete at 6 and 12 months into the study. You can complete and return these by post **or** on your computer or smart phone (you can pick your preferred option). Women in the pessary group will stop pessary use 2 weeks before completing these questionnaires. The pessary can be removed and re-inserted in clinic if necessary. All women attend

a 1 hour clinic appointment at 12 months to have an internal assessment of their pelvic floor muscles and to measure their prolapse severity.

You will **not** be paid any expenses for your involvement in this study, however a £10 gift card will be sent to you with the 12 month questionnaire.

If you become pregnant, you would not continue in the study and your prolapse care would be discussed with your local care team. The data collected from you up to this point would be used in any study data analysis.

Some appointments may be audio-recorded to find out about how your care is being delivered. If you are happy with this you will be asked to indicate this on your consent form. Audio-recordings will be transcribed and information that could identify you will be removed. The recordings will be destroyed at the end of the study.

An additional information leaflet and consent form will be sent to a small number of women to offer more information about taking part in interviews. On your consent form you will be asked if you are interested in taking part in an interview with a researcher.

You can say no to having an appointment audio-recorded and/or the interview and still be part of the study.

How long will I be involved in the study?

You will be involved in the study for 12 months. You will remain under the care of your local NHS centre for the 12 months of the study.

We will send the last questionnaire to you 12 months after you enter the study. After the study has ended, your future 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 to 5 years' time). In this case, to avoid asking you further questions about your prolapse 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 the NHS bodies 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 us accessing this information you can indicate your agreement on your consent form. You can also indicate on the consent form whether or not you are willing to be contacted in future about other relevant research.

What are the possible benefits of taking part?

The PFMT and 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 collect in this study may help improve the care of other women with pelvic organ prolapse in the future.

What are the possible disadvantages or risks of taking part?

We do not anticipate any risks to you from being involved in the study. Supervised PFMT and pessaries are widely used in the NHS as treatments for prolapse. Your participation in the study is therefore to help us understand if using a pessary in addition to PFMT is more effective than PFMT alone when treating prolapse. Therefore, no additional risk should be involved. 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 care.
Only those involved in the research will have access to any of the files or data. When the results are published, this will be done in a way that means you will not be identified. If quotes from an audio-recording or interview you were involved in are used for reports, you will not be identified. If you decide to withdraw from this study, we will keep and continue to use all you previously collected data.

Who is organising and funding the study?

The study is sponsored by Glasgow Caledonian University, based in Scotland, UK, and is being funded by the National Institute for Health and Care Research. The research is being carried out by a team 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 4 and all local NHS centres involved.

How will we use information about you?

We will be using information from you and your medical records in order to undertake 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 the Centre for Healthcare Randomised Trials at the University of Aberdeen who are responsible for the study's database. People who do not need to know who you are will not be able to see your name and contact details. Your data will have a code number unique to you instead.

We will keep all information about you safe and secure. Other researchers may wish to access *anonymous* data from this study for future research. If this is the case, they would be expected to submit a full application with a reasonable request to the research team and follow legal, data protection and ethical guidelines. It will not be possible to identify you from this data. The information will only be used for the purpose of health and care research and cannot be used to contact you or affect your care.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Glasgow Caledonian University will keep identifiable information about you for a maximum of **5 years.** The study data will then be fully anonymised and securely archived or destroyed.

Legal basis for processing personal data

As part of the study 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.

Will the information I provide be kept confidential?

Yes. All information you provide will be kept strictly confidential. Paper records will be kept in a locked filing cabinet. Electronic data held in our databases will be kept on a password protected computer.

What are your choices about how your information is used?

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information on this link:
https://www.gcu.ac.uk/aboutgcu/universitygovernance/data-protection

What if something goes wrong?

If you have a concern about any aspect of this study, you can speak to members of your local research team or contact the Trial Office. We will do our best to address your concerns. In the first instance contact: Dr Catriona O'Dolan, Trial Manager (telephone: 0141-331-8355

If you have any questions relating to data protection these can be addressed to the University's Data Protection Officer by e-mailing dataprotection@gcu.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 by e-mailing 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 PFMT with or without a pessary for pelvic organ prolapse, and how effective each of these options is in reducing symptoms of prolapse. The results can be shared in a variety of ways, such as on social media and published in clinical and academic journals. No directly identifiable personal data will be used in any reports or publications that come from 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 member of the research team about it. They will be able to provide further information on the research, answer any of your questions and tell you about the next steps should you wish to take part.

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

Professor Suzanne Hagen **OR** **Dr Catriona O'Dolan**
Chief Investigator **Trial Manager**
Research Centre for Health (ReaCH) ReaCH
School of Health & Life Sciences (SHLS) SHLS
Glasgow Caledonian University (GCU) GCU
G4 0BA G4 0BA
0141 331 8104 0141 331 8355
s.hagen@gcu.ac.uk PEPPY@gcu.ac.uk

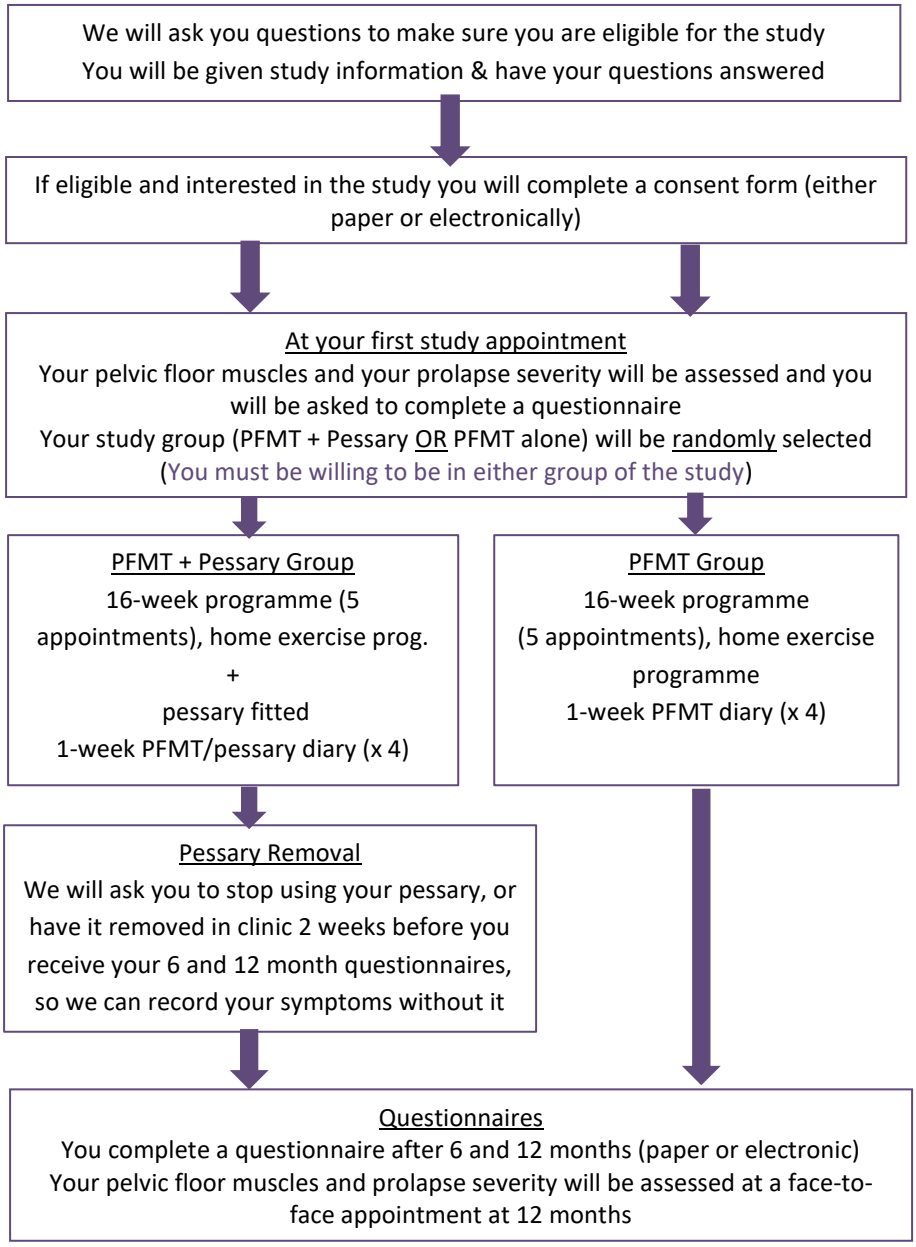
If you would like information about research at GCU more generally please contact:

Professor Anita Simmers
Dean, School of Health and Life Sciences
Glasgow Caledonian University
G4 0BA
Anita.Simmers@gcu.ac.uk

Information about the study is available on the following web site or by scanning the QR code below:
https://www.peppy-trial.co.uk/

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

Summary of your journey if you decide to take part



Meet the PEPPY Team

The PEPPY Team involves researchers and health care professionals working across a number of universities and hospitals in Scotland, England, Wales and Northern Ireland.

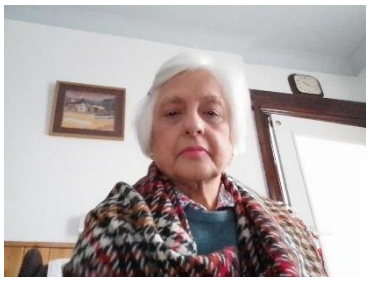
We are fortunate to have a number of public and patient advisors in our team to help guide our research, some of whom are pictured below. We thank them for their invaluable contributions

Curie

Margaret

Bridgette

Angela



Reshma

The research is coordinated from Glasgow Caledonian University in Glasgow, Scotland led by Professor Suzanne Hagen and Professor Carol Bugge.

Some of the team at Glasgow are pictured below


GCU
Glasgow Caledonian University
Research Centre for Health (ReaCH)