Feel-Good Study:

Female Empowerment through Enhanced Living: a comparison of vaginal continence devices and pelvic floor muscle training (PFMT) to PFMT alone for female stress urinary incontinence: a feasibility and pilot study

Chief Investigator: Professor Mohamed Abdel-Fattah

Participant information leaflet

Invitation to take part

We would like to invite you to take part in a research study called FEEL-GOOD. The FEEL-GOOD study is a research study looking at treatments for stress urinary incontinence in women.

Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve.

The first part of the Participant Information Leaflet tells you the purpose of the study and what will happen to you if you take part.

Then, in the second part, we will give you more detailed information about how the study is run.

Please take time to read the information carefully, which has been written with the help of patient representatives with stress urinary incontinence and with colleagues at Bladder Health UK and Women's Voices at the Royal College of Obstetrics and Gynaecology. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to take part or not.

Our contact details can be found at the end of this leaflet.

Part 1 – the purpose of the study and what will happen if you take part

Stress urinary incontinence

Urinary incontinence is the unintentional leakage of urine. There are different types of urinary incontinence. The type being studied in this research is called stress urinary incontinence (sometimes shortened to SUI). This is the unintentional passing of urine during physical activity (exercise, dancing), or when sneezing/ coughing/ laughing, etc. It may be caused by weakness of the pelvic floor muscles that support the bladder and the urethra (the urethra is the tube that allows the urine to exit the body).

Currently in the UK, the recommended initial treatment for stress urinary incontinence is pelvic floor muscle training supervised by a physiotherapist. This consists of programme of exercises to improve the pelvic floor muscle strength, power, relaxation or a combination of these.

There are also devices that have been developed to treat stress incontinence. They are called “vaginal continence devices” or “intravaginal pessaries” as they are inserted into the vagina. They stay in place for as long as needed. They are made of silicone or plastic and they are intended to support the bladder neck, the urethra and pelvic floor muscles.

What is the purpose of the research study?

In the FEEL-GOOD study, we will compare supervised pelvic floor muscle training only to supervised pelvic floor muscle training with a vaginal continence device (VCD), in the management of stress incontinence in women.

The FEEL-GOOD study is a “feasibility and pilot study” – we do a study like this when we want to check whether it is possible to carry out a larger study.

We would like to understand what issues will encourage or stop women and their healthcare providers to take part in FEEL-GOOD and a possible larger study in the future. We also aim to understand what results are important from both women’s and healthcare professionals’ opinions. This helps us design the larger study and also helps us decide how many women would need to take part to ensure that it provides a reliable result.

The FEEL-GOOD study will run for approximately 2 years. We aim to recruit around 74 women from a small number of hospitals across the UK. Women who take part in the study will be in the study for approximately 6 months.

What would taking part involve?

In the FEEL-GOOD study, everyone will have supervised pelvic floor muscle training, half will also receive a vaginal continence device.

If you decide to take part in this research study, you will be randomly allocated to one of the two study groups mentioned above. Being randomised means that neither you nor your doctor or healthcare team will decide which treatment you receive. But after you have been randomised, we will tell you which group you are in. You will either:

- Be in the group who will receive a vaginal continence device AND have supervised pelvic floor muscle training

  OR

- Be in the group who will have supervised pelvic floor muscle training.

There is an equal chance that you will be placed into either treatment group. This helps make sure that the research study compares groups of similar individuals where the only difference is the treatment given.

Before you make a decision about whether or not to take part, please read the information in this leaflet and ask any questions that you want. Our contact details are at the end of this leaflet and you can use these to get in touch with us.

If you do decide to take part, we will ask you to complete a consent form confirming that you are happy to take part.

You can complete this consent form during your clinic appointment at the hospital, during a follow-up visit to the hospital, or at home. You can complete a paper copy of the consent form, or you can complete it online using a computer, tablet or mobile phone. If you would like to take part, please tell a member of the healthcare team during your clinic appointment and they will give you a copy of the consent form. Alternatively, you can contact the study team (details at the end of this leaflet) to ask for a copy of the consent form. Once you have completed the consent form, we will give you a copy to keep.

We will also ask you to complete a questionnaire about you, your bladder problems and how they affect your quality of

life (this should take about 20 minutes). If you complete the consent form at home, you can also complete the questionnaire at home and post this back to us with the consent form. If you complete the consent form online, you can also complete the questionnaire online.

We will then randomly allocate you to one of the two study groups. Whichever group you are in, we will add you to the waiting list for supervised pelvic floor muscle training. This will be offered in line with the NHS standard clinical care in your hospital and will be with a physiotherapist. If you are allocated to the group that also receives a vaginal continence device, this will usually be prescribed by your GP or by the hospital doctor. You should start using this close to or at the time of your physiotherapy appointment. The vaginal continence device is designed so that women can put it in and remove independently (like a tampon); however, some women may need help the first time to learn how to insert it. The physiotherapist or the nurse in your GP surgery can help you with this if needed. You will have the opportunity to raise any concerns you may have about insertion and use of these devices with the physiotherapist, the study team or your GP/nurse.

At three and six months after you have agreed to take part in the study, we will ask you to complete a questionnaire to tell us how things are. Each questionnaire will take about 30 minutes to complete. The questionnaire will ask about your bladder problems and how they impact on your quality of life. They will also ask about your experience with the treatment you received as well as any side effects you might have had. Some of the questions in the questionnaire may seem personal or of a sensitive nature but the information is important to help us fully understand the

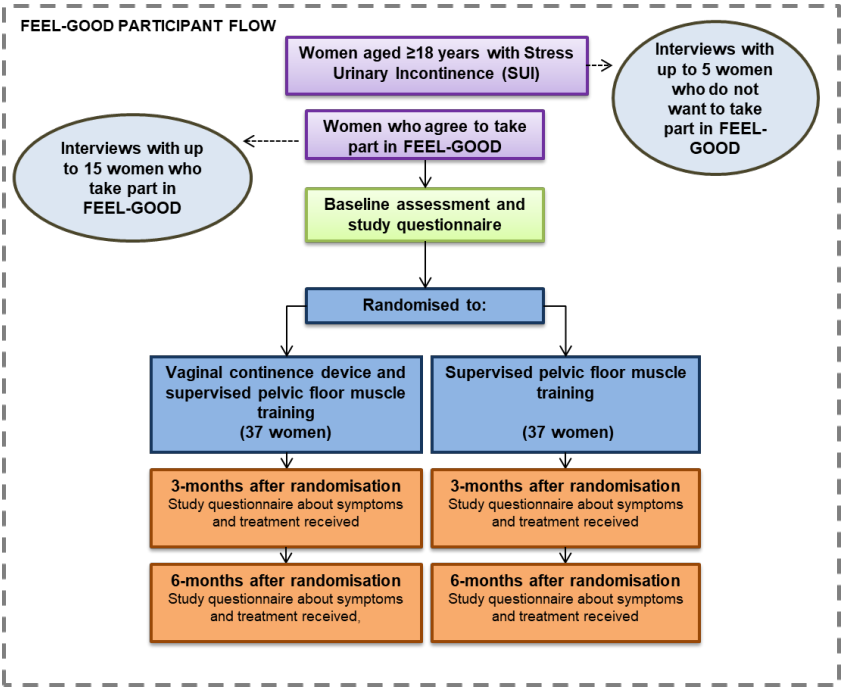
effects of your treatment. But if there are questions you do not want to answer you can leave them blank.

When you join the study, we will ask how you would prefer to complete questionnaires – by post or online.

We will also collect some information from your hospital medical records about your physiotherapy appointments, the vaginal continence device used, and any problems that you may have as a result of the physiotherapy or the device.

If you take part in the study, we will ask if you would like to be contacted in the future about other relevant ethically approved research. This is optional. If you agree to this, we (the FEEL-GOOD study team) would contact you about such research and you could decide if you wanted to take part or not. We would never share your contact details without your permission.

We also hope to interview between 9 and 15 women who agree to take part in the FEEL-OOD study and up to 5 women who decide not to take part. Interviews will take around 40 minutes and will be done either on the telephone or using MS Teams. These interviews will help us understand what issues encourage or stop women taking part and what outcomes (or results) are important to women receiving treatment for urinary leakage. All of this information is summarised in the FEEL-GOOD participant flow diagram below.



What are the possible benefits of taking part?

You may not benefit personally from taking part. By taking part, however, you may be helping us to inform the treatment of future women with stress urinary incontinence. The results of this study will help us plan a larger study, which in turn will help plan effective services offered by the NHS in the future.

What are possible disadvantages, risks and side effects when taking part?

We do not think that there are any possible disadvantages to you. All procedures and techniques are already being used in the NHS to treat patients with stress urinary incontinence. Taking part in the FEEL-GOOD study will

help us assess these procedures and should not involve any **additional** risk to you.

Whichever group you are in, your treatments will be offered by competent and trained clinicians.

It is important to remember that there are risks related with every treatment. You will be informed of any potential risks as part of your routine clinical care. Steps are always taken to ensure that these risks are kept to a minimum. The known side effects associated with pelvic floor muscle training and vaginal continence devices (which are not related to taking part in the study) are:

- pelvic floor muscle discomfort,
- low back pain,
- tummy pain/ discomfort,
- vaginal pain/ discomfort/ irritation,
- the vaginal device coming out on its own,
- vaginal discharge,
- unexpected vaginal bleeding or bleeding when removing the device
- urinary or vaginal infections,
- unable to pass urine which requires catheter in the bladder

If it is the wrong size, the vaginal continence device might fall out. If this happens you can try a different size or type of device - please contact the research nurse for more information about this (contact details at the end of this leaflet).

Do I have to take part?

No. It is entirely up to you whether or not you take part. Please take as much time as you need to make this decision. You can read this information leaflet as many times as you wish and ask your doctor and/or research nurse as many questions as you like.

If you decide that you do not want to take part, you will receive standard NHS care for stress urinary incontinence as per standard practice in your local hospital.

You can decide at any time to withdraw from the study without giving a reason. This decision will not affect the standard of care you are receiving now or in the future. If you make this decision, you should continue attending appointments with your consultant and/or GP as part of your standard care.

If you decide to withdraw from this research study, we will keep and continue to use all your previously collected data. We will, however not collect any further data about you. This information will remain confidential and will not be used for any other purpose. To protect your rights, we will use the minimum identifiable information possible.

Part 2 - more information about how the study is run

What happens when the research study stops?

If the study is stopped earlier than expected for any reason, we will tell you and arrange continuing care for you.

If you were allocated to the group who had the supervised pelvic floor muscle training only, you will be given the opportunity to discuss and trying a vaginal continence device. The local team at your centre will discuss this with you if this is something you want to consider.

If you were allocated to the group who had the supervised pelvic floor muscle training and a vaginal continence device, you might want to continue to use the device. You can discuss this with your clinical team.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the FEEL-GOOD Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

What if there is a problem?

If you have a question or concern about the study, you can ask to speak with the research team who will do their best to answer your questions. Contact details for your local study nurse and the Study Office can be found on the last

page of this information leaflet. If you wish to complain formally or have any concerns about any aspects of the way you have been approached or treated during this study, you can do this through the normal NHS Complaints Procedure. Contact details are available at the end of this leaflet.

We do not expect any harm to come to you by taking part in this study. In the event that something does go wrong, and you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study. Contact details can be obtained from the FEEL-GOOD study office.

If you are harmed due to someone's negligence, then as a patient of the NHS, you may have grounds for legal action. You may have to pay for your legal costs yourself.

The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information which is collected about you for the purpose of this research study will be handled in strict confidence and securely stored by the University of Aberdeen.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name, contact details (address, telephone and email address (if available)), and

your NHS or CHI number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Aberdeen is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Handling it confidentially.

- Storing it securely with access restricted to authorised people directly involved in the study. We will store any information recorded on paper in locked cabinets. Any information held electronically will be protected with passwords.

Your data will not be shared outside the UK.

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.

We will keep your study data for a maximum of 6 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dpa@abdn.ac.uk
- by ringing us on 01224 272596
- at www.abdn.ac.uk/about/privacy/

What will happen to the results of the study?

The results of the study will help us to plan a larger study. The larger study will help make recommendations on treatments for patients with stress urinary incontinence. We will publish the results of this study in scientific journals and present the information at appropriate meetings. You will

not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

Who is organising and funding the study?

This study is sponsored by the University of Aberdeen who have overall responsibility for the management of the study. The study is funded by the Chief Scientist Office in Scotland. The research is being carried out by a group of experienced healthcare professionals and researchers from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by South Central - Hampshire A Research Ethics Committee The Research and Development Department of your local hospital has also reviewed and approved the study.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the FEEL-GOOD study. Please ask us if you have questions or would like more information about the study.

Further information and contact details

If you have any questions or would like any more information, please contact:

FEEL-GOOD study office
Centre for Healthcare Randomised Trials (CHaRT),
University of Aberdeen
Health Sciences Building
Foresterhill
Aberdeen AB25 2ZD
Tel: 01224 438103 / 01224 438181 / 01224 438405
Email: feelgoodstudy@abdn.ac.uk
Web: https://w3.abdn.ac.uk/ace/feelgood

Or the local FEEL-GOOD team:

(Add contact details)

For information about the normal NHS complaints procedure, please contact:

(add details for local PALS or PASS)

Support Groups:
Bladder Health UK (Registered charity 1149973)
Kings Court
17 School Road
Birmingham
B28 8JG
Tel: 0121 702 0820
Email: info@bladderhealthuk.org
Web: https://bladderhealthuk.org/