Queen Margaret
University
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Information Sheet for Potential Participants – Focus Groups

About this Document

This has been written to tell you about a research project and help you decide if you want to take part. You can ask questions about anything you are not sure about, and you can take your time to think about it. This page provides a summary. Pages 2-6 explain the study in more detail.

Study Title

Lifestyle in Perimenopause: Exploring a Community Intervention (Long title: Exploring Impacts of an Existing Multi-Disciplinary Community Intervention to Support Health and Lifestyle in Menopause and Perimenopause)
The study has been reviewed by Queen Margaret University Nursing and Paramedic Science Divisional Ethics Committee and approved on 16/09/2024. A favourable Ethical opinion was given by South East Scotland Research Ethics Committee 02 on 19/12/2024.

Invitation and Summary

My name is Becca Freeden and I am a postgraduate student from the School of Health Sciences at Queen Margaret University (QMU) in Edinburgh. As part of my course, I am undertaking a research project for my thesis. This study will look at how perimenopause and menopause affect daily life and lifestyle, and whether a course like “Menopause Walk with a Doc” can help with this. Activities that improve health can be challenging to fit into everyday life, and I would like to learn more about this.

I am looking for volunteers to participate in the project. You are welcome to take part if you were assigned female sex at birth and are aged 35 and over (or younger and have experienced premature menopause).

If you agree to participate in the study, you will be invited to the Health Agency about two months after the “Menopause Walk with a Doc” course to take part in a focus group – a small group of people who will have a recorded discussion about their experiences of the course together.

In this research study, we (me and my supervisors at QMU) will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it and/or for future research.

We will make sure no one can work out who you are from the reports we write.

What is the Research about?

This research is funded by the Lydia Osteoporosis Project (LOP) (lydiaosteoporosis.org). LOP is an organisation based at Queen Margaret University with a focus on osteoporosis as a public health issue. Projects run by LOP include investigating awareness of osteoporosis among healthcare workers and improving moving and handling practices to reduce the risk of fracture.

Osteoporosis is a condition which makes bones more fragile and more likely to fracture (another word for break). A fracture can have serious impacts on quality of life and independence. A person can reduce their risk of developing osteoporosis by making changes to their lifestyle, such as improving their diet, taking part in exercise, and stopping smoking.

The “Menopause Walk with a Doc” course includes lots of different ways to improve lifestyle and could be helpful in the prevention of osteoporosis and other conditions. Through this study, I hope to gather information on the impact of the course on your lifestyle and wellbeing. This will be helpful in understanding what services can help to support others experiencing menopause in the future.

There will be a maximum of 8 people taking part in the focus group. Everyone who is doing the “Menopause Walk with a Doc” course is welcome to take part in the research, but it is completely optional. can still take part in the course without participating in the research. There will be no impact on your attendance at the course or any other health or legal impact if you choose not to take part in the research.

What would taking part involve?

About two months after the “Menopause Walk with a Doc” course we will meet at the Health Agency in a group of up to eight people who all took part in the course. The purpose of the focus group is to record the things you say about the experience to help us understand how menopause affects your life and whether taking part in the course impacted your life.

Here are some examples of the questions I will ask:

1. Shall we go around the room and talk about what brought each of us to the course?
2. How much did you know about menopause before you started the course?
    a. Did you consider yourself as perimenopausal or menopausal before you started?
3. What did you learn from the course?
    a. Did you learn something that surprised you?
4. Were there any impacts on your day-to-day life?
5. Were there any negatives from attending the course?
6. Is there anything that wasn’t included that you would like to have experienced?
7. Is there anything else you would like to tell me?

The discussion will be recorded on a handheld audio recorder, a Philips Pocket Memo LFH9600. This recorder is password-protected and recordings are encrypted to AES256 standard, as required by NHS Lothian research standards.

This session will last about 2 hours.

Do I have to take part?

No.

If you do not want to take part, it will not stop you from joining the “Menopause walk with a Doc” course and no other part of your medical care or legal rights will be affected.

If you do decide to take part in the research but then change your mind, that is also fine and you do not need to give a reason. Please let me know as soon as possible if you want your information withdrawn from the study. I will remove all of your data if analysis has not yet begun. If analysis has begun, it may not be possible to remove all of your data. Therefore, it is important to let me know as soon as possible if you have decided to withdraw your consent.

What are the possible benefits of taking part?

There are no benefits to taking part but some people who have tried out the methods have found it helpful to reflect on their experiences. The results may help health services decide if courses like this one can help people in menopause in future.

What are the possible disadvantages of taking part?

Some of the questions may be upsetting as they ask about the experience of perimenopause/menopause and stressors you may experience. I will be prepared to help you answer the questions in a way that is comfortable for you and you can request to do things differently. I will provide you with a list of support organisations and other sources of support you may need.

There is a risk that what is shared in the group may be disclosed by group members. Therefore, when we are sharing in the group work, I will ask you all to keep everything that we share confidential.

How will the results be shared?

The results may be published in a journal, presented at a conference, or presented in poster format at the Health Agency and other interested health services and to other people experiencing perimenopause and menopause. You will not be identifiable in any of the results.

I would like to share a summary of the findings with you once I have finished the research. I have given you the option to give me your email address or home address on the consent form if you would like me to send it to you.

How will your information be stored?

Any information you give me on forms will be securely stored and deleted once I have moved it on to digital files, where I will ensure it will not be possible to identify you. These files will be stored securely on Queen Margeret University servers and will only be accessible to my supervisors, Dr Karen Matthews and Prof Cathy Bulley, and me. Your name will be replaced with a participant number, and it will not be possible for you to be identified in any of the reports I write.

Queen Margaret University is the sponsor of this research and is responsible for looking after your information. A representative of the sponsor might look at the data to see that everything is being done correctly. They won’t look at the data for any other reason.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, contact details, and date of birth. We will use this information to do the research or to check your records to make sure that the research is being done properly. If you consent to us letting them know, your GP will be informed that you are taking part in the research.

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 participant number instead.

We will keep all information about you safe and secure by:

- Storing paper copies of forms and audio recorder with recordings on it in a locked drawer in a department that is only accessible to QMU staff with a keycard
- Transferring information to a digital format as soon as possible (within one month) and securely destroying paper copies and deleting audio files from the audio recorder.
- All digital folders require multi-factor authentication to access and files with personally identifiable information will be password-protected
- Digital information with personally identifiable information will be kept separate from the information from your discussions
- All personally identifiable information will be securely deleted once I have shared the research findings
- All non-identifiable information will be securely deleted after five years

All of the research team are responsible for keeping your information confidential. However, it is important to let you know that if you share information that suggests that you or others are at risk of harm, I have a duty of care to tell the relevant authorities.

International transfers

Your data will not be shared outside the UK.

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 purpose 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 be able to choose if your data saved from this study can be used in future research.

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

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

- by asking one of the research team
- by sending an email to BFreeden@qmu.ac.uk, or QMU Data Protection Officer – LKerr2@qmu.ac.uk

- by ringing us on 0750 717 6557
- By visiting the NHS Health Research Authority website at www.hra.nhs.uk/patientdataandresearch

Concerns and Complaints

If you have any concerns or complaints, please contact Dr Karen Matthews via email at KMatthews@qmu.ac.uk

If you would like to contact an independent person who knows about this project but is not involved in it, you are welcome to contact Anne Wysock. Contact details are given below.

You will receive a £10 voucher for participating in the research.

If you have read and understood this information sheet, any questions you had have been answered, and you would like to take part in the study, please now see the consent form.

Contact details of the researcher

Name of researcher: Becca Freeden

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Contact details of the independent adviser:

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