PARTICIPANT INFORMATION SHEET

iCAREiMOVE -- an online programme to improve wellbeing and movement in menopause

Thank you for taking part in the PROTECT Study. We would now like to invite you to take part in the above sub-study led by the University of Exeter and iCareiMove. Before you decide whether to participate 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 friends and relatives if you wish. Please ask a member of the research team if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. If you decide to take part, you may keep this information sheet.

What is the purpose of the study? Menopause is a normal life stage, but for many women it brings physical, emotional and psychological symptoms that can affect daily life. These include sleep problems, low mood, joint pain, fatigue and difficulties with concentration.

There is good evidence that lifestyle approaches can help women manage menopause more effectively. Regular physical activity, particularly strength and balance exercises, can improve physical function and support bone and muscle health after menopause. Exercise can also reduce low mood and stress, which are common during menopause. Breathing, relaxation and mindfulness practices further help reduce stress and improve sleep. These are now recognised by national health policy as first-line strategies for menopause care, alongside or instead of medication, however despite this, many women do not have access to these activities to support them during menopause.

Online programmes offer a promising solution to this, as they allow women to take part at home, at times that suit their symptoms, work and caring responsibilities. However, there is still limited evidence about how online menopause programmes work in practice, especially those that combine exercise and wellbeing.

The iCareiMove Menopause Intervention is a 12-week online programme combining guided movement, breathing and relaxation. It is based on evidence that exercise and stress management improve physical and emotional wellbeing during menopause. The programme has been designed to be safe, flexible and accessible for mid-life women with different energy levels, symptoms and life pressures.

We are asking for volunteers to try out the online programme and provide us with feedback on how you found the videos, whether they were easy to access and follow, and what could be improved. This will help us plan for a larger study using the intervention to improve emotional wellbeing.

Why have I been invited to take part? You have been invited to take part because you have previously consented to take part in the PROTECT Study. We are giving you the opportunity to take part in this sub-study because it may help us to develop an online intervention to support women experiencing menopausal symptoms.

Female participants over the age of 40 are being invited from the PROTECT study to take part in this sub-study.

Do I have to take part?

It is up to you to decide whether or not to take part in this sub-study. If you decide to take part, you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your participation in the PROTECT Study.

What will happen if I take part? If you choose to take part in the sub-study you will be:

- Asked to fill in a short questionnaire, which will take approximately 5-10 minutes. The first part of the questionnaire will ask about your physical health and exercise using very similar questions that you have already answered as part of the main PROTECT study. This will enable us to ensure you are safe and eligible to follow the online movement videos. The second part will ask about menopause symptoms you may or may not experience and your wellbeing.

- If you are able and willing to take part, you will be contacted by a member of the iCAREiMOVE team to discuss the online videos and workbook, the range of exercises and answer any questions you may have.

- You will then be asked to use the online videos and online manual 2-3 x per week for 12 weeks. Each video lasts an hour and can be done entirely in your own time, at your own pace, and you are free to pause or stop at any time.

- The programme is designed for people who are comfortable with light to moderate physical activity, including breathing exercises, stretching and movement. Each video will provide guided and structured movement, breathing and mindfulness support. Each video follows a core seven-step exercise component, that moves from:

1) 'Mobility' -- including breathing exercises and stretches

2) 'Standing Strong'-- simple movements and stretches whilst standing

3) 'Wall Element' -- simple movements and stretches against a wall

4) 'To the Floor' -- including lunges and kneeling exercises

5) 'On the Mat' -- including simple yoga positions and stretches

6) 'Power Down- guided breathing exercises and mindfulness

7) 'Rise Up'- gentle standing sequence

- You will be able to contact the iCAREiMOVE team for support at any time, and will also have the option to join an established iCAREiMOVE facebook community to receive further information and support regarding menopause, however this is entirely optional.

- At the end of 12 weeks, you will be asked to complete an anonymous online questionnaire to let us know how you found the course, and how it could be improved. If you provide consent, we will contact you about a follow up online discussion group to gather participants understanding of participants experiences of the programme.

What are the possible benefits and risks of taking part?

Taking part in this study involves breathing exercises and light to moderate physical activity, similar to exercises that many people do as part of everyday life. The exercises have been designed to be low impact and suitable for people to follow independently. The iCAREiMOVE exercises have been used over the last 20 years with thousands of people, including older adults, people with neurological conditions and those who are at risk of falls, with no difficulties, and are designed to be gentle, safe and completed at your own pace. You are able to stop at any time and only do the exercises you feel completely comfortable with. You may find it hard to make time to follow the videos, and this is completely fine, as you are able to go at your own pace and stop at any time, and part of the study is to ask how people find the videos and course.

As with any physical activity, there is a small risk of minor discomfort or injury. This may include:

- Temporary muscle soreness or stiffness

- Mild joint discomfort

- Fatigue

- Feeling light-headed or experiencing hot flushes during or after exercise

Some menopausal women experience symptoms such as joint stiffness, fatigue, or hot flushes, which may affect how exercise feels on a given day. Serious adverse events are **not expected** given the low intensity of the activities, but cannot be completely ruled out.

Reducing risk

Several steps are in place to minimise risk:

- Participants will complete a health screening questionnaire before taking part to identify any reasons why the exercises may not be suitable.

- The online videos and workbook will provide clear exercise guidance, including instructions on correct technique, pacing, and progression.

- You will be encouraged to exercise at a level that feels comfortable for you and to take breaks as needed.

- Guidance will be provided on when to stop exercising, for example if you experience any pain, dizziness, chest discomfort, or feel unwell.

Your safety during the study

Because the exercise is unsupervised, you will be asked to:

- Exercise in a safe environment of your choosing

- Follow the guidance provided

- Stop exercising immediately if you feel unwell or experience any pain or discomfort and seek appropriate medical help

- Contact GP or call 111 for non-emergency concerns

- Call 999 in an emergency (e.g. chest pain, dizziness)

- If you sustain an injury or experience any symptoms out of usual GP hours, call 111 for non-emergency advice, or attend accident and emergency or call 999 in an emergency (e.g. chest pain, dizziness)

- Seek medical advice before taking part if this is recommended during screening

In the unlikely event you do experience any discomfort during the programme, we will also ask that contact the iCareiMove team as soon as possible using the email or telephone contact details provided during the screening discussion.

There is an extremely small risk that some people may find certain questions regarding menopausal symptoms and wellbeing difficult to answer. You should only answer those questions that you are comfortable with. You do not need to answer any questions that you are not sure about, or you do not wish to

Many previous participants in the iCAREiMOVE intervention, that has been done over the last 20 years both face to face and as an online group, have found it enjoyable and beneficial to their wellbeing, therefore there is potential that you may also find the course of benefit

The main advantage of this research is that participants will be taking part in an important study that could help develop an online programme to provide valuable menopause support.

<u>What will happen to the data I provide?</u>

The University of Exeter is the sponsor for this study. In working with the PROTECT Study team we will be using information from you in order to undertake this study and will act as data controller. This means that we are responsible for looking after your information and using it properly. The PROTECT Study team will keep identifiable information about you and following your consent will share your contact details with the iCAREiMOVE team. To safeguard your rights, we will use the minimum personally-identifiable information possible. All identifiable information about you will be securely stored on encrypted University of Exeter servers and only accessible to members of the research team.

You will be given a code and the screening questionnaire, menopause and wellbeing data will be stored securely under this code. The code linking you to this data will be stored separately by the PROTECT team, and destroyed 4 weeks after the final optional group discussion session, at which point all data will be anonymous. Anonymised feedback information collected as part of this study will be kept for 5 years in accordance with the PROTECT Study privacy policy. For more information about how the PROTECT Study uses your personal data, please see the PROTECT Study privacy policy.

If you agree to take part in the online discussion group, we will securely record the session and then transcribe the discussion removing all identifying information and destroy the recording 4 weeks after the group meeting. At this stage all the information from the group will be anonymous, and you will not be able to be identified.

Individuals from the University of Exeter may look at your research records to check the accuracy of the research study. The only people in the University of Exeter who will have access to information that identifies you will be people who need to contact you to discuss issues directly relating to the study or audit the data collection process.

Will participation be kept confidential?

Your data will be processed in accordance with the General Data Protection Regulation (GDPR). All of the data collected as part of this project will be regarded as strictly confidential and will be held securely until the research is finished. No study data will be available in any identifiable format to anyone outside of the immediate research team. We may share anonymised data from this study with other researchers, within the remit of PROTECT study policy and following necessary approvals.

All data for analysis will be anonymised. In reporting on the research findings, we will not reveal the names of any participants. All research staff are provided with training regarding GDPR and University of Exeter standards for handling data. Any data provided electronically will be stored on a database on a restricted server only accessible by specified members of the research team who have been given authorisation to access the database.

Questions, comments and requests about your personal data can be sent to:

The Administrator

PROTECT Study

College House 1.23

St Luke's Campus

The University of Exeter

Exeter, EX1 2LU

United Kingdom

Alternatively, you may also contact the University of Exeter's Data Protection Officer who is responsible for monitoring compliance with relevant legislation in relation to personal data, by emailing dataprotection@exeter.ac.uk.

You have the right to lodge a complaint with the Information Commissioner's Office at www.ico.org.uk/concerns.

What if I change my mind about taking part?

Your decision to participate in this study is voluntary. You can withdraw from the study at any time without giving a reason by logging into your PROTECT Study account and clicking on the Withdraw from Study option in the Manage Account section of the website. Alternatively, you can contact the PROTECT Study helpdesk by emailing support.protect@exeter.ac.uk or by telephoning 01392 725010. By withdrawing you are making the decision not to provide any further information or responses to the study and you will not receive any further communications about it. However, if you withdraw from the study, we will retain all anonymised data that we have collected up to the time you withdraw. This includes all anonymised data from questionnaires.

Who is organising this study?

This sub-study is being led by University of Exeter and iCAREiMOVE, nested within the main PROTECT Study, which is led by the University of Exeter, King's College London and South London and Maudsley NHS Trust.

This study has been granted full ethical approval from the University of Exeter Medical School Ethics Committee (Application ID 12103159).

Contact for further information

If you have any questions or require more information about this study, please contact the PROTECT helpdesk by emailing support.protect@exeter.ac.uk.

What if there is a problem?

If you wish to complain or have concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact the University of Exeter Medical School Ethics Committee (uemsethics@exeter.ac.uk).

Additional information and Frequently Asked Questions are available on the PROTECT Study website. If this does not answer your query you can contact the PROTECT Study team by calling 01392 725010.

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

Consent to Take Part

- I confirm that I have read and understand the Participant Information Sheet version V2.0 dated 30/04/2026 for the above study, sponsored by the University of Exeter. I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I consent to the processing of my personal information for the purposes explained to me via the Participant Information Sheet. I understand that such information will be handled and stored in accordance with GDPR and other Data Protection Laws.
- I give my consent for the PROTECT team to share my contact details with iCareiMove researchers to contact me for the study.
- I understand that taking part in this study involves light to moderate physical activity, including breathing exercises, stretching and movement.
- I understand that, as with any physical activity, there is a small risk of minor discomfort, such as muscle soreness, joint discomfort or fatigue.
- I understand that the exercises will be unsupervised and that I am expected to follow the guidance provided in the online videos and exercise in a safe environment.
- I understand that I should stop exercising immediately if I feel unwell, experience pain, dizziness, chest discomfort, or any other concerning symptoms.
- I understand that I should seek medical advice before taking part if this is recommended during the screening process.
- I understand that my information may be subject to review by responsible individuals from the University of Exeter for monitoring and audit purposes.
- If I choose to withdraw, I understand that all anonymised data will be retained in the study up to the point of my withdrawal, and no further data will be collected.
- I agree to take part in the study.