Participant Information Booklet

A lifestyle programme involving exercise, diet and health education in the treatment of symptoms experienced during perimenopause.

*Please note: if you would like this information in a research format (i.e., not adapted for easy readability) then this is available by contacting the lead investigator on the details below. The information provided is the same, but the way it is presented differs.

For more information about this study, please contact Edel Flynn: edel.flynn@TUS.ie

You are being invited to take part in this **Lifestyle Programme** for women aged 45-55

Before you decide, it is important for you to **read this information** booklet so you understand **why the study is being carried out** and **what it will involve.**

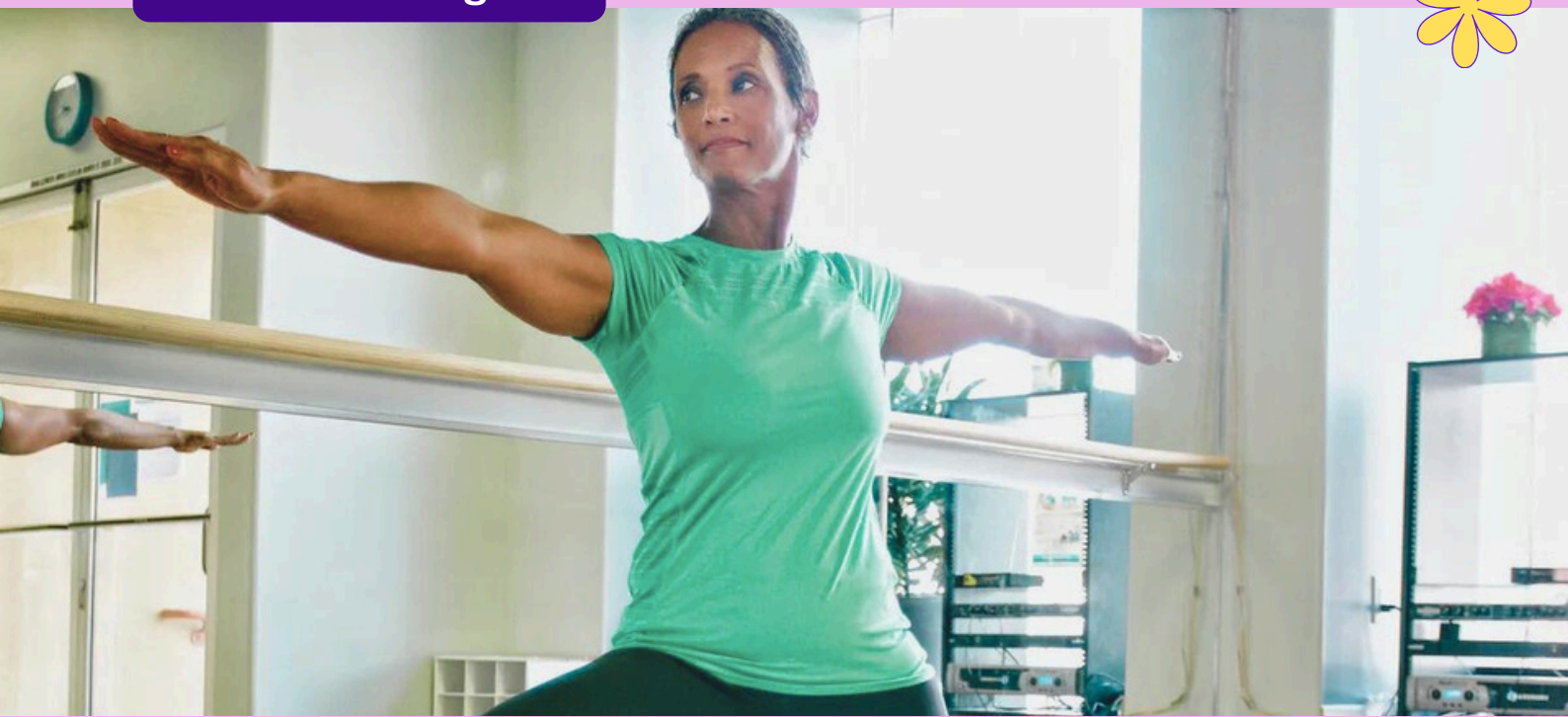
This booklet will tell you about the **purpose, risks, and benefits** of this research study.

Reading this booklet, discussing it with others, and/or asking any questions you might have will help you decide **whether you would like to take part.**

If there is **anything that you are not clear about**, we will be happy to explain it to you.

Please take **as much time as you need** to read it

In addition to this participant information booklet, there will also be a voluntary one-hour, in-person, recruitment workshop in TUS (date TBC) that will provide you with further study details and an opportunity to ask any questions that you might have to the lead investigator.



What is the purpose of this study?

The menopause is described as the time when **menstrual cycle function ceases** and a whole year has gone by without having a period. In the years leading up to menopause (commonly known as perimenopause) many women start to experience **changes to their natural menstrual cycle,** and this can be accompanied by **a wide and diverse range of symptoms.**

These symptoms can often **interfere with a woman's daily activities** and **impact her overall health, well-being, and quality of life.**

Some lifestyle adjustments such as, **exercise and dietary changes, as well as health education** are becoming increasingly considered as potential methods to improve a woman's experience of symptoms during this life stage and her health and wellbeing beyond menopause. However, at the moment **research in this area is lacking.**

Therefore, the aim of this study is to examine the effectiveness (i.e., does the study work?) and scalability (can the study be rolled out nationally) of a lifestyle programme involving **exercise, diet, and health education on symptoms experienced during perimenopause.**

Am I able to take part?

You are able to take part if you are...

- Between the ages of 45 and 55 years old
- Experiencing a spontaneous perimenopause (i.e., the reproductive phase in a woman's life occurring before menopause)
- Beginning to experience some menopause-related symptoms within the last month
- Sedentary OR low active for the last three months (i.e., do not meet the World Health Organization's minimum activity guidelines/ participation in occasional and/or incidental physical activity)
- Free from any health-related conditions (e.g., cancer, hypertension, osteoporosis, and cardiovascular disease)
- Free from any injury in the past six months.

**Please note: before you can take part in this study you will need to meet all the above criteria, which will be assessed through a screening questionnaire.*

Women who are currently using **hormonal replacement therapy,** other types of **medications/hormonal contraception**, as well as **natural products, herbal remedies**, and **complimentary therapies** are also welcome to take part.

What will I be asked to do if I do take part?

Firstly, you will be randomly put into either...

1. The experimental group; or
2. The control group

Experimental group

If you are put into the experimental group you will take part in **18 x 30-minute group sessions** over the six weeks (two classes per week either in-person or online) - consisting of 6 x 30-minute **menopause education workshop** and 12 x 30-40 minutes of **functional training. One weekend workshop (2-3 hours)** including a coffee morning will be a blend of **health education talks and discussions (19 total sessions).**

The menopause workshops will cover **topics specific to this life stage** (such as the basics of menopause, the benefits of exercise and nutrition, mental health and well-being etc.) and will be delivered by experts in these areas.

The functional training section of these sessions will be focused on a combination of **bodyweight and resistance-based exercises** and will be delivered by a qualified instructor. Exercises such as squats, planks and push ups will be instructed - along with modifications and progressions to suit your pace and physical ability. In addition to this type of exercise, participants will also be **encouraged to achieve the general aerobic activity guidelines** for this age group (you will choose from different types of exercise such as brisk walking, cycling, swimming and can change this throughout). You will also be encourage to adopt healthy eating practices

Weekly overview for experimental group:

Week	Activities
1	**General:** Goal to achieve 30 mins of aerobic exercise 3 x per week **Session 1:** Functional training class **Session 2:** Functional training class **Session 3:** Education class
2	**General:** Goal to achieve 30 mins of aerobic exercise 3 x per week **Session 1:** Functional training class **Session 2:** Functional training class **Session 3:** Education class
3	**General:** Goal to achieve 30 mins of aerobic exercise 3 x per week **Session 1:** Functional training class **Session 2:** Functional training class **Session 3:** Education workshop
4	**General:** Goal to achieve 30 mins of aerobic exercise 3/5 x per week **Session 1:** Functional training class **Session 2:** Functional training class **Session 3:** Education workshop **Weekend:** Coffee morning and GP-led talks (HRT & sexual health)
5	**General:** Goal to achieve 30 mins of aerobic exercise 3/5 x per week **Session 1:** Functional training class **Session 2:** Functional training class **Session 3:** Education workshop
6	**General:** Goal to achieve 30 mins of aerobic exercise 3/5 x per week **Session 1:** Functional training class **Session 2:** Functional training class **Session 3:** Education workshop

What will I be asked to do if I do take part? Continued...

Control group

If you are put into the control group you will **continue to follow your usual exercise and nutrition patterns.**

In addition, at the end of the six-weeks you will be offered a guaranteed place on our next installment of the lifestyle programme.

Will I be in the experimental group or the control group?

We choose who goes into what group **randomly,** the same as tossing a coin, so that it is as fair as possible. Therefore, you **have a 50/50 chance** of being in the experimental group. If you are in the control group after the six weeks you will then be offered a **guaranteed place on our next instalment of the lifestyle programme** (so everyone will eventually have access to the programme). **Both groups are really important for the study,** without the control group we would not know if the programme has been effective!

Tasks for participants:

Both participants in the experimental group and the control group will take part in the following tasks at certain points throughout the study. These will be completed both at TUS Athlone and possibly at home depending on the task.

Pre/Post the six week study

- Measures such as body composition, height and weight.
- Monitored physical activity levels with an “Activpal”; an accelerometer that is placed on the upper leg. This tracks step count and time spent sitting, walking and moving, based on the position of the leg. It does not track or store any personal information.
- Physical activity questionnaire.
- Food diary for 3 days .
- Menopause rating scale to assess symptoms
- Menopause-specific health literacy questionnaire
- Follow up at 3- and 6- months post-intervention to determine lifestyle habits

During the study

- Menopause rating scale to assess symptoms (1 x per week)
- Participant workbook tasks
- Evaluation of your progress

At the very end of the study, participants in the experimental group will also take part in an **interview** which will ask them about their experience (i.e., what did you like and dislike about the programme) of the study.

Frequently asked questions:

Do I have to take part?

No, **participation in this study is not mandatory.** You are under no obligation to take part, and you will not experience any loss of benefit or penalty if you choose not to participate. Your **participation is voluntary** so it is up to you whether you would like to take part.

What if I change my mind?

The research you take part in will be most valuable if few people withdraw from it, so please discuss any concerns you might have with the investigators. But, if you do change your mind you can **discontinue your involvement** in the study **whenever you choose**, without informing any of the research team. Please note that if you decide to discontinue in the study any data already collected might still be used in the final analysis. Please remember that all data are anonymous/pseudonymous, so your individual data will not be identifiable in any way.

Are there any possible disadvantages in taking part?

As with any participation in exercise, **there is some risk of injury and post exercise muscle soreness.** Additionally, extra strain is placed on the cardiovascular system. To counteract/reduce these potential risks, **control procedures have been put in place.** The procedures in this investigation are no more rigorous than what is typically experienced when following the recommended guidelines for exercise in this age group.

Has the study been approved?

Yes. The study has been **approved and received full ethical approval by the Research Ethics Committee** in the Technological University of the Shannon, Midlands Midwest.

Will my taking part be kept confidential and anonymous, and how will my data be stored?

Yes, data collected from you in this study will be **confidential.** All data will be dealt with under the strictest of guidelines and stored/deleted according with **university/national GDPR guidelines.** Additionally, any data collected from you will be **anonymous/pseudonymous.** You will be allocated a unique participant code that will be used to identify any data that you provide. Your name and other personal details will not be associated with your data, for example, any signed informed consent forms will be stored separately. Only the research team will have access to any identifiable information.

Are there any possible disadvantages in taking part?

The general findings might be reported in a **scientific journal or presented at a research conference, and other dissemination sources** (i.e., infographic) but they will always remain anonymous/pseudonymous.

Who is organising and funding the study?

The study is being organised by The Technological University of the Shannon. This project is funded by UPMC Sports Medicine and UPMC Institute for Health, UPMC Ireland. In addition, Westmeath Sports Partnership are also involved in the study. A pilot version of this study was previously performed in South East Technological University with involvement of Waterford Sports Partnership.

What happens if there is a problem during the study?

If you are unhappy about anything during or after your participation, you should contact the principal investigator in the first instance. If you feel this is not appropriate, you should contact the **Chairperson of the Technological University of the Shannon ethics committee** stating the full title and principal investigator of the study.

If you have any further questions after reading this booklet, please contact **Edel Flynn: edel.flynn@tus.ie** OR **Dr Patricia Heavey: patricia.heavey@tus.ie**

Thank you for taking your time to read this booklet!