

Plain Language Statement

Research Study Title: MenoWell: A 6-week online exercise and health education programme for women in all stages of menopause.

Principal Investigator:

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Purpose of this Research Study:

An increasing number of women in Ireland will live a large proportion of their lives in the menopause, and many will seek advice regarding menopausal symptoms and the management of same. The purpose of this research study is to increase menopause knowledge and education and increase participation in multimodal (aerobic, resistance, flexibility and balance) exercise which is extremely important for managing and mitigating the physiological adaptations experienced by women throughout the menopausal transition and post-menopause. This research study will provide one 40-minute online menopause-specific health education workshop per week, in addition to two 40-minute online age- and ability-appropriate, menopause-specific exercise classes per week, for a period of 6 weeks for perimenopausal, menopausal, and post-menopausal women living in county Laois. This research study is designed and delivered by a team of clinical and/or exercise physiologists, a registered associate nutritionist, qualified exercise instructors and a certified athletic therapist.

Procedures Involved in the Research Study

Screening: If you are interested in taking part in this research study, you will be asked to complete the physical activity readiness questionnaire for everyone (PAR-Q+). This questionnaire screens for injuries and illnesses that will determine your suitability for the study. Please note, if you have unstable angina and/or heart failure, you will be unable to participate in this research study.

Pre- and Post-Intervention Testing: Pre- and post-intervention testing will occur the week before and the week after the 6-week intervention (week 0 and week 7) respectively, at Portarlinton Community Centre in county Laois.

A. Physical Tests

60-second modified or box push-up test: This test will examine your upper body muscular fitness (strength, power and endurance). The two different push-up techniques will be demonstrated to you in advance of the test (box push-up or modified

push-up). You will be asked to perform as many push ups as you can in 60 seconds with good technique in your chosen positioning.

60-second sit-to-stand test: This test will examine your lower body muscular fitness (strength, power and endurance). You will be asked to sit on a sturdy chair, stand up into a full upright position and then return to the seated position on your chair. This is one repetition. You will be asked to do this as many times as possible in 60 seconds. You will be given a choice of two versions of this test. The easier version allows you to place your hands on your thighs while moving from a seated position to a standing position so that your hands can assist the movement. The more difficult version of this test requires you to place your hands across your chest so that you cannot use your hands for support as you move from a seated to standing position.

30-second bilateral, eyes closed balance test: This test measures your balance on both sides of the body. You will be asked to stand close to an empty wall for this test so you can support yourself if needed. We will assess your balance while standing on your left foot first, followed by standing on your right foot. You will be asked to place your hands across your chest and slowly lift your right foot off the ground so it hovers forward. You will then be asked to close your eyes and the timer will begin. The test will finish and the timer will stop if you put your right foot back on the floor or lose your balance and touch the wall before reaching the 30-second limit. You will be asked to repeat this test on the opposite side, by lifting your left foot.

Sit and reach test: This test measures flexibility, particularly of the hamstrings (the group of muscles at the back of the thigh). You will be asked to sit on the floor, with your legs stretched out straight ahead and place the soles of your feet flat against a sit-and-reach box. You will be asked to reach forward and push the measuring portion or yardstick of the sit-and-reach box forward, without a jerking movement, and ensuring your legs stay straight.

6-minute walk test: This test will give us very important information on how well your heart and lungs are working and will determine your level of physical fitness before the intervention begins. This test measures the maximum distance you can walk in 6 minutes and this distance is measured in meters. One cone is placed at 0m (cone A) and a second cone is placed 20m from here (cone B). You will be required to walk from cone A to cone B and back to cone A as many times as possible in 6 minutes.

Countermovement jump test: The countermovement jump is a measure of lower-body power and the jump mat will be used to record the height that you can jump. You will be asked to stand upright, as still as possible with your weight evenly distributed over both feet standing on the jump mat, with your hands on your hips. When ready, you will be asked to squat down until your knees are bent at 90 degrees and then immediately jump vertically as high as possible. You will then land on the ground with both feet at the same time. This is repeated 3 times with a minimum of 90 seconds break between each jump.

B. Questionnaires

Menopause Rating Scale: You will be asked to complete this 11-item subjective questionnaire that explores the presence and severity of menopausal symptoms.

Menopause Knowledge and Education Questionnaire: You will be asked to complete this 5-item questionnaire to share details on your previous sources and thoughts of menopause information.

M1 Questionnaire: You will be asked to complete this single-item measure (M1) questionnaire which asks you to detail your frequency of physical activity.

World Health Organisation Five Wellbeing (WHO-5) Index: You will be asked to complete this 5-item questionnaire which is a self-reported measure of current mental wellbeing.

Perceived physical activity (LIVAS: Lichamelijke Vaardigheden Schaal) questionnaire: You will be asked to complete this 10-item questionnaire to assess your perceptions of physical abilities in comparison to people of the same age.

6-Week Intervention

Following the completion of pre-intervention testing, you will start your 6-week online intervention of health education and exercise training. You will be asked to attend one * 40-minute live online menopause-specific health workshop per week and two * 40-minute live online menopause-specific multimodal exercise classes per week, for a total of 6 weeks. These sessions will be delivered using Zoom. You will be asked to turn on your camera during the live online exercise classes so we can monitor your technique. There will be an on-demand library of exercise classes if you cannot complete any of the live exercise classes that week. The health education workshops will also be recorded and made available on-demand.

The health education workshops will be focused on changes in muscle, bone and heart health, in addition to sleep, nutrition and self-care during the menopausal transition and post-menopause and the practical lifestyle behaviours to manage and counteract these changes to promote wellness.

In the exercise classes, you will select the intensity (or effort) that you work at. For the most part of the intervention, you will not use any equipment in the exercise classes; you will simply perform a range of aerobic, strength, flexibility and balance exercises using your own body weight. As the intervention progresses and your fitness and strength levels increase, you may be given the option to use small pieces of equipment including resistance bands and light hand weight.

Following the 6-week intervention, you will be asked to attend a post-intervention testing session in Portarlinton Community Centre to repeat the same tests and determine if there are any changes.

Potential Risks

Exercise does carry a risk of injury, such as a pulled muscle, muscle soreness or in extreme cases abnormal heart rhythm, heart attack or death. To minimise these risks, you will be asked to complete a PAR-Q+ to determine your suitability for the study.

You may need to obtain medical clearance from your GP. All pre- and post-testing sessions and online exercise sessions will include an appropriate warm-up and cool down (15 minutes) and stretching to reduce the risk of injury. You will also receive education on exercise intensity and be advised to exercise at an intensity that is appropriate for you. You will be provided with colour coded rate of perceived exertion (RPE) cards (green = low intensity, orange = moderate intensity, red = high intensity) and instructed on how to use these during the online exercise sessions when exercise instructors ask for an exercise intensity check. You will be monitored throughout pre- and post-testing and online exercise classes by a team of trained professionals, including a clinical exercise physiologist and phase IV cardiac rehabilitation specialist. You will be asked to have your phone beside you during all online exercise classes in case we need to contact you privately. If you have any complex cardiovascular conditions, you will be provided with a heart rate monitor and taught how to record your heart rate and be given advice on the heart rate ranges you need to stay within during the online exercise classes.

Benefits of Participation

Following the completion of the 6-week intervention, you will be provided with a full report of your results from the pre- and post-intervention tests, which will include feedback on the changes, if any, that occurred. You may experience increases in strength, fitness, balance and flexibility, nutrition knowledge and menopause knowledge. All the tests and exercise classes will be provided free of charge and will be delivered by trained professionals.

Privacy Notice

DCU Data Protection Officer: Mr. Martin Ward (data.protection@dcu.ie, Tel: 01-700 5118 or 01-700 8257)

Confidentiality of Data

All data will be stored and handled in compliance with GDPR guidelines. You will be provided with an ID number at the start of the research study so all data collected (hardcopy or electronic) will be recorded, stored, and published anonymously so you cannot be identified. The electronic document containing your name, corresponding ID number, and email address will be stored on a restricted-access DCU Google Drive folder that can only be accessed by the study investigators. This data file will be deleted 12 months after the completion of this research study. All hardcopy data we gather will be stored in a locked filing cabinet in a locked office that can only be accessed by the study investigators. All hard copies will be destroyed *via* shredding 12 months after the study is completed. All anonymised electronic data will be stored on a restricted-access DCU Google Drive folder that can only be accessed by the study investigators for the purpose of analysing the findings. This anonymised electronic data will be kept indefinitely for publication purposes. Confidentiality of information provided can only be protected within the limitations of the law. It is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions.

Voluntary Participation

Your participation in this research study is voluntary. You may withdraw from the research study until the point at which all data becomes anonymised (12 months after the completion of this research study) by contacting any of the study investigators by email or phone. There will be no penalty for withdrawing from this research study and this will not affect your relationship with DCU, EduFIT or Laois Sports Partnership.

Funding

This research study has received funding from Sport Ireland in partnership with the Laois Sports Partnership (LSP).

If you have any questions at any time, please contact:

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Dr Diane Cooper, info@edufit.ie

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Ruth Kavanagh ANutr. MSc., ruth@edufit.ie

If you would like information on the results of this research study, this information will be provided once you email any of the researchers above.

If you have concerns about this study and wish to contact an independent person, please contact:

The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation Support, Dublin City University, Dublin 9. Tel 01-700 8000, e-mail rec@dcu.ie