ISRCTN15365883 https://doi.org/10.1186/ISRCTN15365883

A study exploring the impact of a digital health programme on improving dietary and physical activity habits in midlife women

Submission date
16/06/2023

Recruitment status
No longer recruiting

Registration date
23/06/2023

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Eating a healthy diet and staying physically active have been found to help reduce various symptoms experienced by women during peri-post/menopause. These symptoms can include hot flushes, fatigue, sleep disturbances, difficulty concentrating, mood swings, anxiety, and weight gain. Researchers have developed a specialised lifestyle program specifically designed for women in midlife, aiming to improve their diet and increase physical activity. However, there is limited knowledge about the factors that influence the success of these lifestyle improvements in midlife women. This study aims to test if a digital health lifestyle behaviour change program designed for mid-life women is practical, appropriate for the population and engaging. This feedback will help refine the program for future studies and make it available to more women throughout the UK.

Who can participate:
Women aged between 40 and 65 years old and who reside in the UK

What does the study involve?
The study involves a 21-day dietary and physical activity programme where participants will be given resources to help them improve healthy eating and increase their physical activity levels. The programme includes a digital health application called mEMA, designed to interact with the participants five times daily for 14 days. These short interactions have been designed to assist in developing healthy eating including decreasing consumption of caffeinated and alcoholic beverages, increasing hydration, and consumption of fruit and vegetables as well as physical activity (e.g., daily steps) habits. The mEMA app also includes advice on healthy eating, physical activity, and menopause specifically tailored to midlife women and developed by a qualified nutritionist, an exercise physiologist, and an NHS GP. This advice is available at all times during the 14-day programme.
The participants will be provided a wrist-worn Garmin fitness tracker, to keep track of well-being, sleep, and physical activity. Using the Garmin Connect application, the participants can join walking challenges with other Garmin fitness tracker users and view their daily physical activity and sleep summaries captured by their Garmin fitness tracker.

During the first 7-day baseline measurements, the study participants will be asked to complete a survey and wear the fitness tracker at all times to record their daily physical activity and sleep. For the following 14 days after baseline, the participants will use the mEMA app (to read education content and respond to daily surveys) and continue to wear the fitness tracker at all times. Finally, immediately after the study concludes (i.e., on day 22), the programme participants will be asked to complete a post-study survey (same as the pre-study baseline survey) and a questionnaire to share their experiences from the programme (e.g., what they liked, what they did not like).

What are the possible benefits and risks of participating?
Participants will receive a fitness tracker which they will be able to keep after the programme concludes. This fitness tracker will provide information about their physical activity levels, daily step count, and sleep. After the baseline week, participants will have access to advise on healthy eating, physical activity, and menopause, specifically tailored to midlife women. By taking part in this study, participants will be providing invaluable information and knowledge which can be used to develop and design effective dietary and physical activity programmes for women in midlife.

Where is the study run from?
The study is run primarily on virtual platforms (e.g., Microsoft Teams) to increase access to the programme and reach participants from all over the UK. The study was designed when there were restrictions in place as a result of COVID-19.

When is the study starting and how long is it expected to run for?
November 2022 to July 2023

Who is funding the study?
University of Westminster (UK)

Who is the main contact?
Ms Hana Sediva, H.Sediva@westminster.ac.uk (UK)

Contact information

Type(s)
Principal investigator

Contact name
Ms Hana Sediva

ORCID ID
https://orcid.org/0000-0002-5166-3053

Contact details
University of Westminster - Cavendish Campus
115 New Cavendish Street
London
United Kingdom
W1B 2HW
+447773572311
h.sediva@westminster.ac.uk

Type(s)
Scientific

Contact name
Dr Sanjoy Deb

ORCID ID
https://orcid.org/0000-0001-7797-8224

Contact details
External Supervisor
Anglia Ruskin University - Cambridge Campus
East Road
Cambridge
United Kingdom
CB1 1PT
None provided
Sanjoy.Deb@aru.ac.uk

Type(s)
Scientific

Contact name
Dr Tina Cartwright

ORCID ID
https://orcid.org/0000-0003-3416-468X

Contact details
University of Westminster
London
United Kingdom
W1B 2HW
+44 (0)20 7911 5000 ext 69067
t.cartwright@westminster.ac.uk

Type(s)
Scientific

Contact name
Prof Louise Thomas

ORCID ID
https://orcid.org/0000-0003-4235-4694

Contact details
Director of Studies
University of Westminster - Cavendish Campus
115 New Cavendish Street
London

United Kingdom
W1B 2HW
+44 (0)20 7911 5000 ext 64607
l.thomas3@westminster.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
v1.0

Study information

Scientific Title
An exploration of the impact of a digital health programme on dietary and physical activity behaviours in midlife women: a feasibility study

Acronym
DHIMW

Study objectives
A digital health-promoting lifestyle intervention is feasible and acceptable among midlife women

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/03/2023, LAS College Research and Knowledge Exchange Ethics Committee (115 New Cavendish Street, London, W1B 2HW, United Kingdom; +447773572311; voicula@westminster.ac.uk), ref: ETH2223-0933

Study design
Interventional non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Improving dietary and physical activity behaviours in women in midlife (aged 40 - 65 years)

Interventions
This feasibility trial aims to implement and evaluate a 21-day intervention programme to improve healthy eating and increase physical activity in women in midlife (aged 40-65 years). A mixed-methods design will be applied to fulfil the evaluation aims.

Sample: As this intervention will be a feasibility trial, one group of women will be recruited, all of whom will receive the intervention and evaluation procedures.

Hypotheses: The components of the intervention will be acceptable and feasible amongst women in midlife.

Recruitment: Women who are eligible to participate will be approached primarily via two recruitment strategies: Purposive sampling and snowball sampling. Purposive sampling will involve the researcher participating in events on menopause, women's health, and femtech. Other community engagements will include speaking about the research project to groups or organisations represented by women in midlife. Snowball sampling will be used to strengthen social support during the programme so that friends, colleagues, and relatives can experience the programme together and support one another. Less emphasis will be placed on recruitment through advertising the study on social media. The study will be made available to the general public via social media advertisements, such as Twitter and menopause-related groups on Facebook. The recruitment flyer will also be shared with GPs, alternative therapies practitioners (e.g., acupuncturists), and nutritionists specialising in menopause.

Potential participants who contact the researcher regarding the study will be sent a Participant Information Sheet (PIS), and an invitation to schedule a short meeting with the researcher. An individual Microsoft Teams session will be scheduled based on each participant's preference and availability. In this session, the researcher will further explain the study and address any questions the participants may have about the study. The researcher will at the same time screen the potential participants to verify their eligibility to participate in the study. If eligible, the participants will be sent a link to sign the Informed Consent.

Informed consent: The Informed Consent form will be developed and stored in Qualtrics survey software, which is available to the researcher under the University of Westminster licencing. The participants will be asked to provide their shipping address and preferred Garmin fitness tracker size to fit their wrists.

Shipment of Garmin fitness trackers: Once the participants sign the Informed Consent and provide their shipping address, their fitness tracker will be shipped using Royal Mail first class service.

Study setup instructions: The participants will be issued a unique Participant ID (generated by the mEMA app) to access the mEMA app and to identify themselves in all surveys. They will also be issued a unique log-in for the Garmin Connect app for the duration of the study. They will be also provided with set-up instructions, both written and video recorded, to complete their setups of the Garmin fitness tracker, Garmin Connect app, and mEMA app. The researcher will set up individual Teams sessions to validate the participants' settings and connectivity of the study technologies and to further train the participants on the study by guiding the participants through completing a test survey in the mEMA app. The participants will select their preferred study start date, which will be on a Monday of any week between May 22nd and July 10th 2023. It is, therefore, required that all participants complete the study by July 31st.

Group assignments:
The participants will be assigned to groups based on their preferred start date for baseline and the intervention phase. Each group will consist of 1 to 20 participants. The group assignments will not be known to the participants, although to strengthen social support, email communication during the programme will be addressed to the group, with only the first names of the group members being revealed.

Baseline phase:
Once each individual baseline technology setup verification session is completed, participants begin their baseline on the chosen Monday of their baseline week. This phase lasts 7 days and is completed on the Sunday of the same week. In this phase, the participants will be required to:
1. Wear the provided Garmin fitness tracker at all times to record their physical activity and sleep
2. Complete the pre-study baseline survey, consisting of 8 sections, including:
2.1. General demographics, lifestyle, and technology use
2.2. Menopause-related quality-of-life, using The Menopause-Specific Quality-of-Life Questionnaire (MENQOL™)
2.3. Food frequency, using the Short-form food frequency questionnaire (SFFFQ)
2.4. The Dutch eating behaviour questionnaire (DEBQ)
2.5. Physical activity frequency, using the Physical activity questionnaire (IPAQ-SF)
2.6. Physical activity behaviours, using the Behavioural regulation in exercise questionnaire (BREQ-2)
2.7. Pittsburgh Sleep Quality Index (PSQI) questionnaire
2.8. Physical Activity Readiness Questionnaire (PARQ)

In addition, the participants will be further trained by receiving two scheduled mEMA surveys /messages (i.e., the day before baseline, and the day before the intervention phase) to experience triggered survey type, which will be used 5 times daily in the intervention phase.

Intervention phase:
Following the baseline phase, the participants begin their 14-day intervention phase, typically on a Monday of each participant's chosen week. During the intervention phase, the participant will be required to complete the following:
1. Wear the provided Garmin fitness tracker at all times to record their physical activity and sleep.
2. Answer 5 surveys daily available in the mEMA app. The timings for the daily EMA surveys can be customised for each participant, and generally will be offered at the following times and duration:
2.1. Morning: 7:30 am (with reminders every 30-minutes) until 9:00 am
2.2. Late morning: 11:00 am (with reminders every 30-minutes) until 12:30 pm
2.3. Early afternoon: 1:30 pm (with reminders every 30-minutes) until 3:00 pm
2.4. Late afternoon: 3:30 pm (with reminders every 30-minutes) until 5:00 pm
2.5. Evening: 7:30 pm (with reminders every 30-minutes) until 9:00 pm
3. Review education content on healthy eating, physical activity, and menopause, available in the EMA app on-demand at all times.

Post-intervention phase:
The day after completing the intervention phase (this will be typically a Monday, Day 22), the participants will receive their final EMA message congratulating them on completing the study and reminding them to complete the following:
1. Post-study survey (same as pre-study baseline survey, excluding PARQ)
2. Programme evaluation/exit questionnaire (adapted from Theoretical Framework of Acceptability (TFA) Questionnaire) to share their experience from the programme (i.e., what they liked, what they did not like)
3. Uninstall the mEMA app from their phone
4. Disconnect their Garmin fitness tracker from their study-provided Garmin Connect account. The participants will have the option to create their own Garmin Connect account to continue using their Garmin fitness tracker

Evaluation (exit) questionnaire:
A specific study evaluation questionnaire will be administered to gauge how participants feel about the intervention, the EMA surveys, and wearing the fitness tracker. The questionnaire is based on the Technology Acceptability Questionnaire (TAQ). Those participants who withdraw during the 3-week programme will also be invited to complete the study evaluation questionnaire.

Statistical analysis of the secondary outcomes will include:
1. Descriptive statistics
2. ANOVA on pre-/post-study survey data
3. Multilevel modelling (MLM) will be used for the longitudinal measurements taken on the sample of participants for 21 days.
The MLM will be a 2-level model, with the lower Level 1 describing the changes in each participant over time (i.e., within-person). Level 2 will describe the differences between individuals. Therefore, each individual's personal trajectory will be described by two variables: the individual, and the time within each individual. Predictors for the best-performing MLM model will be identified.

Intervention Type
Behavioural

Primary outcome(s)
The following feasibility aspects of the study are measured using:
1. Recruitment rate: the number of participants who are recruited, represented as a percentage of the number of participants who show interest, at baseline
2. Attrition rate: the percentage of participants who withdraw after signing Informed Consent at 3 weeks.
3. Retention rate: the percentage of participants who complete all programme components and evaluation measurements at 3 weeks
4. Compliance rates: represented by:
4.1. Percentage of participants who fully comply with wearing the provided accelerometer measured using a recorded minimum of 8-hrs of daily Garmin data at 3 weeks
4.2. Percentage of participants who record daily physical activity and sleep, measured using recorded 24-hr daily Garmin data at 3 weeks
4.3. Percentage of participants who complete daily mEMA surveys (each prompt even if not all subsections) at 3 weeks
4.4. Percentage of participants who review mEMA education content at 3 weeks
4.5. Percentage of participants who complete the study surveys at 1 week, and at 3 weeks
4.6. Percentage of patients who complete the evaluation (exit) questionnaire at 3 weeks
5. Response rate: represented by
5.1. The percentage of daily completed surveys out of the total number of surveys administered to the participant over the entire study period. Responses will be considered complete if the participants answer every question on the sub-surveys
5.2. The amount of time spent reading the mEMA education content on healthy eating, physical activity, and menopause
5.3. Wearing the Garmin fitness tracker for at least 8-hrs daily for 3 weeks
The mean response rate for the sample will be computed as the arithmetic mean of the participant's individual response rates.
6. Acceptability of the study to all participants measured using the evaluation (exit) questionnaire (based on TFA), including measured items and quotes from the participants, immediately after completing their 21-day programme

Key secondary outcome(s))
1. Number of daily steps walked, measured using accelerometer at baseline (a 7-day average), and daily for 14 days during the intervention period.
2. Minutes of moderate-intensity activity measured using an accelerometer at baseline (a 7-day average), and daily for 14 days during the intervention period. A pre-study baseline and post-study questionnaire (IPAQ-SF) will also capture this self-reported data.
3. Sleep length and quality (reduced awake time) measured using an accelerometer at baseline (a 7-day average), and daily for 14 days during the intervention period. A pre-study baseline and post-study questionnaire (PSQI) will also capture this self-reported data.
4. Hydration measured daily using mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (SFFFQ) will also capture this self-reported data.
5. Caffeinated beverage intake measured daily using mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (SFFFQ) will also capture this self-reported data.
6. Alcoholic beverage consumption measured daily using mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (SFFFQ) will also capture this self-reported data.
7. Consumption of portions of fruit and vegetables measured daily using mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (SFFFQ) will also capture this self-reported data.
8. Number of skipped meals measured daily using mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (SFFFQ) will also capture this self-reported data.
9. Number of snacks consumed measured daily using mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (SFFFQ) will also capture this self-reported data.
10. Menopausal symptoms, specifically fatigue, measured using daily using the mEMA surveys for 14 days. A pre-study baseline questionnaire and post-study questionnaire (MENQOL) will also capture this self-reported data.

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Women who are between ages 40 – 65 years
2. Women who are UK residents
3. Ability to converse in English

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

40 years

Upper age limit
65 years

Sex
Female

Total final enrolment
37

Key exclusion criteria
1. Treatment for a serious mental health condition
2. Pregnancy, or trying to get pregnant
3. Serious life-threatening illness (i.e., cancer, heart failure)
4. Currently enrolled in another lifestyle study
5. Inability to converse in English
6. Unable to wear a fitness tracker on the wrist for 21 consecutive days, for a minimum of 8 hours /day
7. Unable to refrain from wearing any other fitness trackers or lifestyle apps (specifically for diet and physical activity), for the duration of the study
8. Unable to engage in the study for 21 consecutive days without the need to travel internationally.

Date of first enrolment
13/04/2023

Date of final enrolment
07/07/2023

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University of Westminster
115 New Cavendish Street
London
United Kingdom
W1W 6UW

Sponsor information

Organisation
University of Westminster

ROR
https://ror.org/04ycpbx82

Funder(s)

Funder type
University/education

Funder Name
University of Westminster

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/04/2023	20/06/2023	No	Yes