

Participant Information Sheet

1. Research Title: An exploration of the impact of a digital health intervention on dietary and physical activity behaviours in midlife women.

2. Who are we?

My name is Hana Sediva, and I am a PhD student and researcher in the Department of Nutrition, School of Life Sciences, at the University of Westminster, UK. This research is being supervised by Prof. Louise Thomas, Dr Tina Cartwright, and Dr Claire Robertson at the University of Westminster. We are conducting this study to investigate how women in midlife (aged 40 – 65 years) experience digital health technology intended to support them in improving healthy eating and taking regular physical activity.

3. Invitation

You are invited to take part in this research project. Before you decide to do so, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and decide whether you wish to take part. Please feel free to ask the research team if there is anything unclear and/ or if you would like more information.

4. What is the purpose of the study?

By conducting this research, we hope to better understand the experiences of midlife women using digital technology (apps and fitness trackers) that is designed to support them in improving their dietary and physical activity behaviours. These experiences will help us to develop tailored strategies to support women's health in this life stage.

5. What will I be asked to do?

1. You will be asked to wear a Garmin fitness tracker on your wrist for three weeks (21 days) so that we can measure your daily physical activity and sleep. You will be asked to wear the device for 8 hours/day, as a minimum, but ideally at all times, including when you sleep. You may take the device off when you shower if you prefer. We will provide you with a Garmin Vivosmart4 device at the beginning of the study.
2. You will be asked to complete a survey at the beginning and end of the study. You will be asked questions about your experiences with managing a healthy lifestyle, including diet and physical activity and any challenges you might have experienced recently (in the last 14 days) in maintaining a healthy lifestyle and managing symptoms that may be due to menopause. The survey should take no longer than 20 minutes to complete.
3. In the first 7 days of wearing the Garmin device, (the pre-study baseline period), we will only collect your physical activity and sleep data. You will be asked not to change anything in your typical daily routine. At the end of this initial 7 days, and for the 14 days of the study, we will provide you with additional content. You will receive prompts through the Garmin device to support you with regular physical activity.

4. After the 7 days pre-study baseline, you will be provided with an app called Ilumivu EMA, where you can access educational content about ways to improve your healthy diet and regular exercise. You will be asked about your daily experiences with eating and physical activity through this app for the next 14 days of the study. These daily questions about your eating and physical activity should take no longer than 5 minutes to complete.
5. At the end of the study, we will ask about your experiences with the digital technology, and the content provided during the study. Your input will help us make future improvements. This 'exit' survey should take no longer than 5 minutes to complete.

6. Why have I been invited?

You have been invited because you are a woman aged 40 – 65 years and your experiences and perspectives on maintaining healthy lifestyle at midlife will be greatly valued.

7. Do I have to take part in the study?

No. It is up to you to decide whether or not you want to take part after having read this information. If you decide to take part, you will be asked to sign a 'consent form'. You should only sign the form if you feel you fully understand the project. If you decide to take part, you are free to stop at any time without giving a reason.

8. What will happen to me if I decide to take part?

If you want to take part, please email Hana Sediva (h.sediva@westminster.ac.uk). She will then contact you to arrange a convenient time to discuss the research in more detail and to arrange a date to start the study. The discussion will take place online, using Microsoft Teams, a meeting application that can be downloaded for free. You will be sent an online meeting invitation. After the short meeting where you will be able to ask questions about the study, you will be given the 'consent form'. You only sign this form if you agree to take part in the **study**.

You will be provided with a unique study ID to use in all surveys during the study. You will be sent the Garmin device to your preferred address through the post. The researcher will meet with you to explain how to set up your Garmin device and training you to use the Ilumivu EMA app.

You will be provided with a link to complete a pre-study (baseline) survey, using your unique study ID. You will begin wearing your Garmin fitness tracker on your wrist for the first 7 days (at all times) to establish your typical daily physical activity and sleep routine (baseline). We will use this baseline data (collected in the first 7 days) to measure changes in your diet, physical activity, and sleep over the next 14 days of the study.

On Day 1 of the 14-day study period, you will be given access to the Ilumivu EMA app where you can access educational content on physical activity and diet, specifically tailored to women in midlife. The content will be curated by a certified PhD nutritionist and an NHS GP. You will also be asked survey questions up to 5 times daily, throughout the 14 days. You will continue to wear your Garmin device for the duration of the study.

On Day 15 of the 14-day study period, you can stop wearing your Garmin device and the Ilumivu EMA app will be de-activated. You will be asked to complete the same survey that you will be provided at the beginning of the study. This survey will establish your final post-study changes in diet, physical activity, sleep, and menopausal symptoms. Additionally, we

will ask you to complete a short 'exit' survey where you can share with us your experiences from the study (e.g., how you liked the content, how you found the frequency and complexity of the prompts, what worked and what didn't work for you)

9. Do I have to answer all the survey questions?

If you feel uncomfortable answering any of the questions, you do not have to do so. Remember, if you want to withdraw from the study at any point, you are free to do so without giving a reason.

10. Do I have to wear the Garmin fitness tracker?

If you feel uncomfortable wearing the Garmin fitness tracker for a minimum of 8 hours per day for the study, you do not have to do so, and you can withdraw from the study. Remember, you can withdraw from the study at any point, without giving a reason.

11. What if I decide to withdraw after the study ends?

You are free to leave the study at any time. If you decide to leave after the study ends, your survey and Garmin data will be destroyed, and we will not use your exit survey quotes in the project if you tell us not to. However, we cannot remove your quotes once the project is complete.

12. Are there any possible disadvantages or risks of taking part?

Participating in the research is not anticipated to cause you any discomfort. You do not have to answer any questions you do not wish to. Wearing a Garmin fitness tracker on your wrist should not cause any discomfort. If you however find it uncomfortable to wear, you may stop wearing it temporarily and resume wearing it for at least 8 hours per day. If you would like to stop wearing it completely, we will help you withdraw from the study (see Section 10). Please see Section 12 for the benefits of taking part.

13. What are the possible benefits of taking part?

Those taking part in the study will receive access to education material on healthy diet for women in midlife. The appropriateness of the education content is based on scientific guidelines, developed by a qualified nutritionist, and reviewed by a GP.

Results may be used in the future to improve support and services for women in midlife. If you wish, you can receive information on the results of the research. Please indicate on the consent form if you would like to receive this information. Furthermore, the study findings may provide an opportunity to develop the research further into a commercial solution that is widely available to midlife women.

14. Will I be reimbursed?

Yes. You will be able to keep the Garmin fitness tracker after you complete the study **if you wear the device 24/7 for the duration** of the 7-day pre-study baseline and 14-day study period (21 days in total).

15. What happens if the research study stops earlier than expected?

Should the research stop earlier than planned, we will tell you and explain why.

16. Will my taking part in the study be kept confidential?

Yes. You will not need to provide your name at any point in the study. Your responses to the survey questions will be kept strictly confidential and you will be assigned a unique study identifier so be assured none of your responses or anything you say can lead back to you.

All data use is strictly within the terms of the Data Protection Act (DPA 2018). Any information you provide is confidential and will be used solely for the purpose of this project. All material, including surveys, will be identified with codes only. The assignment of unique identifiers to your name and address, for the purpose of mailing the Garmin device to you will be stored separately to ensure anonymity and confidentiality.

All data collected by the Ilumivu EMA app, including your Garmin biometric data and your answers to daily questions (self-reported data), will be confidential and your name will not be used. You will be assigned a unique identifier by Ilumivu to access the EMA app.

All collected data will be entered into a computer under each code so that none of the data on the computer contains information that could identify you. The computer and data file will be password protected. All personally identifiable information, including all emails, will be destroyed 5 years after completing the PhD or associated publications. No paper copies of files will be stored.

17. Will I be recorded, and how will the recorded media be used?

Your initial meeting will be audio-recorded using Microsoft Teams so that you can review the instructions and anything that will be explained to you, after the meeting, if you wish. You will be provided with a link to download the recording. Recordings are stored securely on the University of Westminster servers and will only be identifiable via participant number. Files will be saved in a separate file and password protected so that it will not be possible to match the participant information with the data. The data will be deleted once the PhD project and publications arising from it have been completed.

18. What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?

The research team and a small group of seven midlife women who have greatly contributed to the design of this digital health study have carefully selected and curated the survey questions. This group of women also completed system testing of the content that you will experience. The intention of having a larger group of women experience the digital health study is so that we can learn about what techniques work and do not. With that, our future studies can help many other women improve their diet and physical activity.

Responses to the survey questions and the feedback on the experience from the study participants will help us determine whether the design of the digital health solution meets the needs of women in midlife. Your full participation, including wearing your Garmin fitness tracker at all times and answering all survey questions (pre, during, and post study) will greatly improve the accuracy of our findings. With a lot of missing data from the fitness tracker and answered survey questions, we will not be able to accurately determine what strategies used in the study were the most effective. With inaccurate information, we may not be able to provide effective solution that meets the needs of midlife women.

Our ultimate goal of this study is to contribute to evidence-based research investigating the most effective method to promote healthy lifestyle behaviours to improve midlife women's health and wellbeing.

19. What will happen to the results of this study?

The results of the study will be part of the doctoral researcher's PhD thesis. Results of the research may be published in scientific journals and/or presented at conferences. You will not be identified in any report or publication.

20. Who is organising and funding the study?

This study is organised and carried out at the University of Westminster as part of a PhD research project.

21. Who has reviewed the study?

The research has been reviewed and approved by the College Research Ethics Committee (LASCREC), ethics application **ETH2223-0933**, College of Liberal Arts and Sciences, University of Westminster.

22. Further information and contact details

Ms Hana Sediva (Doctoral Researcher), School of Life Sciences, University of Westminster.
Email: h.sediva@westminster.ac.uk

If you would like additional information about the project, you can contact:

Professor Louise Thomas (Director of Studies), School of Life Sciences, University of Westminster. Email: L.Thomas3@westminster.ac.uk

If the researcher cannot answer your queries or complaints, you can contact:

Professor Brendon Noble (Head of School), School of Life Sciences, University of Westminster. Email: B.Noble@westminster.ac.uk

You can also contact:

Dr Aurora Voiculescu (chair of the Research Ethics Committee CREC), College of Liberal Arts and Sciences, University of Westminster.

Email: a.voiculescu@westminster.ac.uk

Thank you for considering taking part.