



PARTICIPANT INFORMATION SHEET

“The outcome and economic evaluation of a health screening and digital therapeutics intervention in the workplace.”

Dear Volunteer,

Study Purpose: Evaluating the Health and Economic Impact of a Digital Health Intervention Using Wearable Technology

Introduction:

You are invited to take part in a research study examining the effects of a digital health intervention that incorporates wearable technology. This study aims to assess both the health outcomes and the economic impact of using wearable devices to monitor and support health improvements in the workplace.

This information sheet provides details about the study, including its purpose, what participation involves, and how your data will be handled. Please take your time to read it carefully and feel free to ask any questions before deciding whether to participate.

What is the study about?

This study aims to determine whether real-time health information from wearable technology, combined with support from online applications and on-site health screening, can influence behavioural lifestyle changes that improve health outcomes. Additionally, it will assess the economic impact of this intervention on health management.

What will I have to do?

The intervention will take place over a 12-month period. You may be randomly assigned to either the intervention or control group.

Before participating, you will be required to complete the Physical Activity Readiness Questionnaire (PAR-Q), which is used to identify individuals who may be at higher risk of adverse events when starting a moderate to vigorous exercise program. The completed forms will be reviewed by Dr Ciaran Cosgrave, MD (Director of Sports and Exercise Medicine at UPMC Sports Surgery Clinic, Gulliver's Business Park, Santry, Dublin). To ensure confidentiality, only your study ID number will be used on the PAR-Q form, meaning Dr Cosgrave will not be able to directly identify you.

Data Collection & Study Timeline

The intervention will include five data collection points, both online and on-site:

- Month 0 (Baseline)
- Month 3
- Month 6
- Month 9
- Month 12 (Final assessment)

Participation Requirements:

- Online Health Surveys: You will be asked to complete surveys online, which will take 30 minutes.
- On-Site Data Collection: At Month 0 (Baseline), you will attend a session lasting 40 minutes, where your Fitbit device will be set up, and technological support will be provided.
- Subsequent On-Site Check-ins (Months 3, 6, 9, and 12): These sessions will take approximately 15 minutes each and will include measuring height, weight, and blood pressure.

We aim to minimise the time burden on participants while ensuring comprehensive data collection.

Control Group Participation

If you are assigned to the control group, you will:

- Complete physiological and survey testing at Month 0 and Month 12 only.
- Not receive health literacy prompts from the *My Patient Space* app.
- Receive a Fitbit watch at baseline testing, which you will keep.

Additional Participation

You may also be invited to participate in a short interview before and after the study to share your experience with the intervention.

What are the benefits?

By participating in this study, you will:

- Increase your health literacy through educational videos.
- Gain valuable insights into your current health status compared to recommended norms.
- Have the opportunity to improve your health scores, supported by trained professionals.
- Receive real-time feedback on your physical activity levels and health metrics through wearable technology, which aims to motivate and empower you to be more physically active.

What if I do not want to take part?

Participation in this study is entirely voluntary. You may choose not to take part or withdraw at any time, without any consequences.

What happens to the information?

Your data will be pseudonymised, meaning your name and contact details will be replaced with an ID code. A separate document linking your ID to your name and contact information will be securely stored on the University of Limerick's OneDrive account of the Principal Investigator (CMD).

All collected information will be kept private, securely stored, and protected. Your name will not appear on any study documents or results. The data will be retained for seven years, after which it will be permanently destroyed.

Who else is taking part?

Approximately 150 participants will be recruited for this study, with an expected gender distribution of 50% ($\pm 10\%$) female. Participants must be aged 18 to 65 years.

Exclusion Criteria

You may not be eligible to participate if you:

- Have cardiovascular conditions (e.g., uncontrolled hypertension, recent heart attack/stroke).
- Require specialist medical intervention that limits physical activity.
- Have had major surgery or ongoing treatments in the last six months.
- Are pregnant.
- Do not own a smartphone (required for Fitbit data syncing).
- Refuse to wear a Fitbit device for the study duration.
- Decline data collection via the Fitbit app and My Patient Space app.
- Do not pass the Physical Activity Readiness Questionnaire (PAR-Q) screening.
- Are already involved in a structured workplace health program with similar components.
- Have a history of poor engagement in previous digital health studies.

What if something goes wrong?

In the unlikely event of any issues during the study:

- The study will be paused immediately until both the researcher and participant are ready to proceed.
- If necessary, the session may be stopped completely.
- Participants are free to withdraw at any time.
- In the event of a medical concern, only a qualified medical doctor can determine if a participant is cleared to continue in the study.

What happens at the end of the study?

At the conclusion of the study:

- All collected information will remain anonymous, with no participant names included in any results.
- A presentation of the overall study findings will be given to all participants.
- The study results will be prepared for publication in academic journals.

What if I have more questions or do not understand something?

If you have any questions about the study, you are encouraged to contact the research team. It is important that you feel all your questions have been answered before deciding to participate.

What happens if I change my mind during the study?

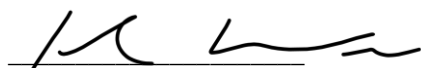
If, at any stage, you decide you no longer wish to participate, you are free to withdraw at any time, with no consequences for your decision.

Contact Details Project Investigators.

Principal Investigator	Other Investigator	Other Investigator
Prof. Ciaran MacDonncha PESS Dept Faculty of Education and Health Sciences University of Limerick ciaran.macdonncha@ul.ie	John Windle Doctoral Candidate PESS Dept, University of Limerick Windle.John@ul.ie	Dr. Aileen Murphy School of Economics University College Cork Aileen.Murphy@ucc.ie

Thank you for taking the time to read this. I would be grateful if you would consider participating in this study. If you are happy to participate, please sign the consent form.

Yours sincerely,



John Windle

This research study has received Ethics approval from the Education and Health Sciences Research Ethics Committee (2024_06_16_EHS).

If you have any concerns about this study and wish to contact someone independent, you may contact:

Chair Education and Health Sciences Research Ethics Committee

EHS Faculty Office

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