



Participant Information Sheet – Pilot Randomised Controlled Trial (RCT)

You are invited to participate in a research project called *STOP*. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information and do not hesitate to ask any questions about anything that might not be clear to you. Make sure that you are happy with what the project proposes before you participate.

1. Background

The *STOP* project aims to provide remote monitoring and assistance to persons with obesity through the foundation of an innovative platform, supporting better nutrition under the supervision of Healthcare Professionals.

The *STOP* project has received funding from the European Commission to promote new approaches that can support weight management and healthy lifestyles, through the creation of an online platform. This will benefit the healthcare service and inspire organisations providing services in this area to offer better services. As part of this project, there is a pilot randomised controlled trial (RCT), which you are invited to participate.

We are interested in contacting and interacting with people live with obesity because we want to develop a solution that is informed and guided by people live with it. The *STOP* project *pilot RCT study* aims to test if an online portal is effective for supporting weight loss in people who are overweight or obese. We want to learn more about your needs and preferences and your view on different options available in terms of technology.

2. What is the pilot Randomised Controlled Trial (RCT)?

A randomized controlled trial (RCT) determines the effectiveness of an

intervention, in this case, whether this newly developed system is effective for weight loss.

- Participants will be part of a two-armed trial by being randomly selected into one of the two groups using a computer randomized program.
- The **intervention group** will consist of adults who are overweight or obese using the newly developed system.
- The **control group** will consist of adults who have a BMI of over 25 not using the system.
- The duration of the intervention is **three months**.
- The primary outcome is **percentage weight loss**.
- Data will be collected at three points for both groups at baseline (month 0), month 1, month 2, and month 3.

2. What is required?

We need a total of 60 adults with a BMI over 25 to participate in this feasibility study. If you decide to participate in this RCT pilot study, you will be required to:

- You will be asked to provide consent to participate in this study.
- You will be asked to measure and provide details on your height and weight
- Demographic information, for example, on your gender and age, will be collected.
- All necessary information on participation will be emailed and collected online from our team.
- You will be randomly allocated into one of two groups. If you are in the intervention group, you will be asked to use the online portal for three months and if you are in the control group, you will not have to use the portal.
- You will need to record your weight and height at three data collection points at baseline (month 0), month 1, month 2, and month 3.
- After one month you will be asked to complete an online survey to provide feedback on your experience with the online portal.

3. Will my information be safe? (Confidentiality)

All of the information you give us will be kept confidential. We will not record your names or contact details on any identifiable information. All data storing will adhere to the GDPR 2018 guidelines.

We do intend to produce papers on our work. This is how we let other researchers interested in this type of work know what we are doing and learn from our experiences. Whilst the information you give us will inform our work and therefore our papers, you will in no way be identifiable as no personal details or medical information is required for the publication of the results from the project.

It would be really helpful if you would work with us to develop the STOP system. However, as a participant you retain no intellectual or financial rights to any product that may be generated as a result of the project.

Please note that if any participant makes a disclosure that is required by law to be reported, then the research team will bring this to the attention to the authorities at the earliest opportunity.

This research project has received ethical approval from Ulster University Research Ethics Committee.

4. What will happen to my information/data?

The information you provide will help us make sure the online portal is effective. It will specially determine the effectiveness of the newly developed system for adults who are overweight and obese. The findings from this project will be used to write research papers that will contribute to the existing body of literature by the addition of this new knowledge, and will also be used to inform the sample size for a larger study.

5. What are the benefits for taking part in this research?

- You will be part of a group of people who will be the first to try out this new technology and your experiences can help develop it further.
- You will be part of a project, which will contribute to new knowledge on this topic.



6. Contact Details

If you would like further information or to discuss participating in this project, please do not hesitate to contact:

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Thank you for considering this request