

ImpulsePal: A Feasibility Study Participant Information Sheet

We are inviting you to take part in a research project running in the local area over the next year. To help you decide if you want to take part, we want to explain:

- Why the research is being done, and
- What it will involve for you to take part.

One of our research team will be happy to answer any questions you may have before you make a final decision. In the meantime, please read the information below and feel free to discuss it with others, such as family, friends, or your GP.

We hope that you feel that you can help us with this study, but there is absolutely no obligation to do so. You are free to decide whether you take part, and if you do take part, you can stop at any time without giving reason. If you don't want to take part, but do want help with weight management, your GP may be able to refer you to other programmes in the area.

What are we doing?

We are conducting a research study to find out whether using a smartphone app to help people manage food cravings would be able to help support people who want to lose weight. We have developed a free smartphone app-based weight loss programme that we would like to try out. This app has been developed specifically to help manage cravings or 'impulses' that usually result in unhealthy eating and overeating. To help us to do this research, we are looking for adults with a Body Mass Index of between 30 and 45kg/m² who wish to lose some weight and have a smartphone that runs on the Android operating system version 2.3 (Gingerbread) or higher.

Why have I been invited?

As we are interested in recruiting people who are interested in losing weight, we have asked Health Promotion Devon to write to people who are taking part in one of the weight management services that they recommend. They have not passed on any of your personal or contact details to us at this stage and we will only be able to contact you, if you complete the reply slip that came with your invitation letter.

What is the purpose of the research?

This research aims to try out a newly developed smartphone app to see if it can help people to reduce unhealthy eating and overeating. If people do find this useful, then we

will use the information from this research to further develop the app and to test its effectiveness in a further research study.

Can I take part in this study?

To be involved, you must

- Be at least 16 years old
- Be overweight and want to lose weight. For this study, we need people with a Body Mass Index (BMI) of 30-45. Roughly speaking, a BMI of 30 is 12 stone for a 5ft 3in person, or 15 stone for a 5ft 10in person.
- Have a smartphone that runs on the Android operating system version 2.3 (Gingerbread) or higher.
- Be in reasonable physical and mental health (we may need to check any medical issues with your GP).
- Not be pregnant or planning to be pregnant in the next year.
- Not have any serious medical conditions that require a very strict dietary plan.
- Be willing and able to attend study meetings (up to 5 brief meetings with our researcher over the next year).
- Not be taking part in any other research project involving weight management or treatments for weight.

What will happen if I take part?

1. If you return the reply slip that came with your invite letter. We will contact you by telephone. We will discuss the study with you and answer any questions you may have. We'll then ask you some questions to check that you can take part. If you are still happy to take part, we will arrange a meeting at the University of Exeter or at your home if you prefer. We will send you some questionnaires to complete before the meeting.
2. At the meeting you will be able to ask any further questions you have about the study. We will then ask you to sign a consent form to say that you agree to take part in the study. Following this, we will measure your weight and height and ask for your completed questionnaires.
3. After this we will divide people into two groups that we want to compare: To make sure that the groups are as similar as possible to each other, each person will be put into a group by chance (randomly).
 - One group will be asked to use the ImpulsePal app straight away
 - A second group (the control group) will not be using the ImpulsePal straight away, but will simply follow their programmes as referred to by the Health Promotion Devon hub.

If you are allocated to the control group, you will be provided with the app at the end of the study, if you wish. If you are allocated to the ImpulsePal group we will ask you to try and use the app for a minimum of four weeks alongside your 12-

week weight management programme. Some components of the app will require your attention several times per week, whereas other components you may use whenever you feel necessary.

4. After the initial visit you will be asked to return for follow-up visits after 1 month and after 3 months. We are also hoping to get funding to extend the study to collect further data at six and twelve months. We will let you know if the study has been extended or not at least a month before the 6 months has expired. You will be contacted nearer each time point to arrange a meeting. We will measure your weight and ask you to complete some of the questionnaires again.
5. You may also be invited to take part in an interview about your experience of taking part in the study after one month and at three months from your first visit (or if you are in the control group, only after 3 months.) The first interview should take around 40 to 60 minutes and will be recorded. The 3 month interview will be a brief telephone call and should only take about 10 to 15 minutes.
6. We will send a single follow up reminder letter and may try to contact you by phone if you do not attend for a follow up appointment, but you are free to withdraw from the study at any time. After the study we will send you a summary of what we found, if you are interested.
7. If you are in the ImpulsePal group, data will be collected via the app. This data is anonymous, through the use of identifier numbers. We will only collect data concerning your use of the app. This will include how often you use the app, what parts of the app you use, how long you use it for at a time, and some information about the tasks you get involved in while on the app. No information outside of what you do with the ImpulsePal app will be able to be collected.

What are the potential benefits of taking part?

Using our app may help you to lose weight and thereby reduce your risk of long term health problems. The research will help to increase our understanding of how food cravings work and can be addressed and this may be useful for the development of more effective approaches to weight management in the wider population.

For this reason, we hope that your participation will be of benefit to you, and will also help improve the way we support other people who want to lose weight in the future. However, it is important for you to know that we cannot guarantee that you will lose weight on this programme. Finally, as a thank you for your participation, if you complete the study (at the 3 month visit) you will be entered into a prize draw to win a £50 voucher (a choice of Amazon or Marks & Spencer). If the study is extended to 12 months, there will be an additional prize draw if you complete the 12 month visit.

What are the potential risks of taking part?

To the best of our knowledge we do not think that there are any risks involved. The programme does not involve taking medications or doing anything that is likely to cause you harm.

Who is organising the research?

The study is being organised by Miss Samantha van Beurden who is a PhD researcher at the University of Exeter Medical School. Her academic supervisors for this research at the University of Exeter are Prof Colin Greaves, Dr Jane Smith, and Prof Charles Abraham. Miss van Beurden is undertaking this research as part of her academic training.

Will my taking part in the study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Your contact details will be held at the University of Exeter Medical School and will not be passed on to any other researchers. These will only be available to the supervisory team mentioned above, and will be used only to contact you in relation to the study. Other members of the research team from the University of Exeter will be able to view any written or recorded information that you give us during the study. However, this data will be labelled with an identifier number only, not your name – in other words, your data will be anonymous. Your name and other personal details will not be able to be identified from any papers or reports that are produced. Any data collected through the ImpulsePal will be stored on University of Exeter secure servers. The research team will have access to this anonymous data (unique identifiers are again used) which will be used to help refine the app. We will follow ethical and legal practice, and all information about you will be handled in confidence.

What if there's a problem?

If you have a health problem or any complaint relating to taking part in this study, please contact the lead researcher:

Miss Samantha van Beurden MSc (PhD researcher)

University of Exeter Medical School, College House, St Luke's Campus, Exeter, EX1 2LU.

Tel: 01392 726440. Email: s.b.vanbeurden@exeter.ac.uk

Or the PhD supervisor

Associate Prof Colin Greaves (PhD supervisor and co-researcher)

University of Exeter Medical School, Smeall Building, St Luke's Campus, Exeter, EX1 2LU.

Tel: 01392 722751. Email: c.j.greaves@exeter.ac.uk

If you would prefer to speak to someone in the University who is independent of the study, you can contact Gail Seymour, who deals with concerns or complaints of people taking part in research run by the University of Exeter:

Mrs Gail Seymour (Research Ethics and Governance Manager)

Research and Knowledge Transfer, Rennes Drive, Exeter, EX4 4RN
Tel: 01392 726621. Email: g.m.seymour@exeter.ac.uk

What happens next?

If you are interested in taking part in this study, please return the reply slip in the enclosed postage-paid envelope. Our researcher will then contact you to confirm arrangements before you are due to meet them. If you are happy that you have received enough information about the research after reading this and discussing it with others and the researcher, you will be asked to sign a consent form during your first visit. You will be able to change your mind about taking part at any point if you wish. If you would like further information, have any questions or would like to discuss taking part in the study further before the researcher visits please contact:

Miss Samantha van Beurden, MSc (PhD researcher)
University of Exeter Medical School, St Luke's Campus, Exeter, EX1 2LU
Email: S.B.vanBeurden@Exeter.ac.uk
Telephone: 01392 726440

Thank you very much for your interest in this study. Please keep this information sheet for future reference if you decide to take part.