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ImpulsePal: A feasibility study of to aid the planning of a randomised controlled trial and refinement of a smartphone app-based intervention to support weight loss

Submission date
16/04/2018

Recruitment status
No longer recruiting

Registration date
18/04/2018

Overall study status
Completed

Last Edited
16/05/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obesity continues to be a growing burden to society and healthcare providers. It increases the risk of chronic health problems such as heart disease, diabetes, and other diseases. Weight loss can greatly reduce the risk of such health problems. Interventions to promote weight loss are available. However, people often struggle to lose weight, despite strong intentions to do so. This is thought to be due at least to food choices that occur impulsively with little conscious awareness. Based on the views of people struggling with weight management, behaviour change experts and published research, an intervention has been developed to help people develop skills to modify the influence of impulses or “food cravings” on their eating behaviour. ImpulsePal is a smartphone app that focuses on training people to identify when (and where) cravings are likely to occur and to use several techniques to gain more control over them. The aims of the study are to develop and refine the intervention, to test the feasibility of delivering this intervention alongside several existing weight loss programmes, and to evaluate recruitment, retention, and other procedures that will be used in a future larger study of the intervention.

Who can participate?
People aged 16 and over with a body mass index (BMI) of 30kg/m2 or more

What does the study involve?
Participants are randomly allocated to one of two groups (an intervention group and a control group). The intervention group receive the ImpulsePal app and the control group are provided with access to the ImpulsePal app after the end of their study participation. Changes in body weight and other outcomes of interest are measured at 1 and 3 months after the start of the study. Participants are interviewed about their experiences of using the ImpulsePal app as well as their experiences of the research procedures, to help make both the intervention itself and the planned future study more acceptable and effective.

What are the possible benefits and risks of participating?
Possible benefits include weight loss and associated health benefits as well as health benefits associated with reduced sugar intake.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
April 2015 to October 2017

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19486

Study information

Scientific Title
ImpulsePal: A feasibility study to aid the planning of a randomised controlled trial and refinement of a smartphone app-based intervention to support weight loss

Acronym
ImpulsePal

Study objectives
Obesity continues to be a growing burden to society and healthcare providers. It increases the risk of chronic health problems such as heart disease, diabetes, and other diseases. Weight loss can greatly reduce the risk of such health problems. Interventions to promote weight loss are available. However, people often struggle to lose weight, despite strong intentions to do so. This is thought to be due, at least to food choices occur impulsively with little conscious awareness. Based on the views of people struggling with weight management, behaviour change experts, and published research we have developed an intervention to help individuals develop skills to modify the influence of impulses or “food cravings” on their eating behaviour. ImpulsePal focuses on training people to identify when (and where) cravings are likely to occur and to use several techniques to gain more control over them. This study will recruit 90 people with a body mass index (BMI) of 30kg/m2 or more. The purposes of the study are a) to develop and refine the intervention n) to test the feasibility of delivering this intervention alongside several existing weight loss programmes and c) to evaluate recruitment, retention, and other procedures that will be used in a future randomised controlled trial of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South-West Exeter, 21/06/2015, REC ref: 15/SW/0181 and SSA ref: 15/SW/0216

Study design
Randomised; Both; Design type: Process of Care, Physical, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Public Health, Primary sub-specialty: Public health; UKCRC code/ Disease: Metabolic and Endocrine/ Obesity and other hyperalimentation

Interventions
Participants were randomised in a 2:1 allocation ratio to the intervention or waiting list control group.
The intervention group received the ImpulsePal app following randomisation and the control group were provided with access to the ImpulsePal app at the end of their study participation.
Participants were requested to take part in a baseline assessment and one- and three-month follow-up assessments.
Participants will be interviewed about their experiences of using the ImpulsePal app as well as their experiences of the research procedures. This will help make both the intervention itself, and the planned future trial, more acceptable and effective.

Intervention Type
Other

Primary outcome measure
For this feasibility RCT, the main outcomes of interest were:
1. Uptake rate (percentage of participants eligible to take part consenting to be randomised)
2. Retention rate (the percentage of randomised individuals providing data at three months)
3. The standard deviation of weight loss at three months of follow up
Other feasibility outcomes of interest were measures-completion rates (the percentage of randomised participants who completed each measure at each time point) and acceptability of the intervention and the study procedures (percent satisfied with the ImpulsePal app and study procedures).

Primary outcome for main trial (weight) was measured to estimate standard deviations to inform sample size calculation. Weight was measured objectively using calibrated Seca 899 weighing scale at baseline, 1 month, and 3 months. Height was measured using the Seca 213 portable stadiometer at baseline only to calculate BMI.

Secondary outcome measures
Secondary outcomes for the full-scale trial were also measured as follows:
1. Unhealthy snack food/drink consumption was measured using a 7-day recall 11-item food frequency questionnaire (FFQ) adapted from a questionnaire used by Churchill and Jessop (Churchill & Jessop, 2011) at baseline, 1 month, and 3 months
2. Frequency of overeating was measured using the three items from the Eating Disorder Examination Questionnaire (EDE-Q) referring to the frequency of overeating episodes and loss of control and the number of days uncontrolled eating occurred (over a period of 28 days)

Process measures for use in the full-scale trial were also used to assess their feasibility as follows:
1. Impulsiveness was measured using the short form Barratt Impulsiveness Scale (BIS-Q)
2. Food cravings were measured using the short form Food Cravings Questionnaire -Trait (FCQ-T-reduced)
3. Sensitivity to the food environment was measured using the Power of Food Scale (PFS)
4. Self-efficacy was measured using a constructed self-efficacy questionnaire which includes items referring to situations where food temptations and cravings commonly arise which make it difficult to stick to a healthy eating goal (as identified through service user involvement)
5. Fidelity checks in terms of the delivery, receipt, and enactment of the separate intervention components

Overall study start date

11/04/2015

Completion date
20/10/2017

Eligibility

Key inclusion criteria
People were eligible to take part if they:
1. Were at least 16 years old
2. Had a BMI of 25kg/m2 or more
3. Owned an Android-based smartphone
4. Lived within a travelling distance (up to 40 minutes) from Exeter, UK

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 88; UK Sample Size: 88

Total final enrolment
88

Key exclusion criteria
People who:
1. Are excluded by eligibility criteria of Health Promotion Devon (see 171)
2. Are currently pregnant
3. BMI of ≥45 kg/m2. When a person reaches a BMI of 45kg/m2 lifestyle modification is more complex and
challenging, requiring specialist (Tier 3) services or bariatric surgery may be recommended (National Institute for
Health and Clinical Excellence, 2006), making it unsuitable for them to take part in the current study
3. Do not speak or understand written English
4. Are participating in concurrent interventional research which may overburden the patient or confound data collection (e.g., another weight loss trial)

Date of first enrolment
01/09/2015

Date of final enrolment
24/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
United Kingdom
EX4 4RN

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: NIHR-CDF-2012-05-259

Results and Publications

Publication and dissemination plan
Results have been presented at UKSBM in December 2017 and the manuscript is ready for submission to now (16/04/2018).

Intention to publish date
16/07/2018

Individual participant data (IPD) sharing plan
The data generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	17/07/2015	18/04/2018	No	Yes
Protocol file	version V3	07/10/2015	18/04/2018	No	No
Results article	results	30/04/2019	01/05/2019	Yes	No
HRA research summary			28/06/2023	No	No