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People regulating themselves to achieve weight loss (Prevail Trial)

Submission date
29/11/2018

Recruitment status
No longer recruiting

Registration date
13/12/2018

Overall study status
Completed

Last Edited
03/11/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study tests a newly developed weight loss intervention that aims to make daily self-weighing a more effective tool for weight loss. The intervention guides participants through a self-regulation process after self-weighing: participants will be asked to track their weight measurements using a weight loss tracker. They will receive daily questionnaires asking them to plan a weight loss action for each day. On a weekly basis they will be asked to reflect on how their behaviours might explain their weight change and to evaluate the weight loss actions they used throughout the week.

Who can participate?
People aged 18 or over with a Body Mass Index (BMI) of 30 kg/m2 or over

What does the study involve?
Participants are randomly allocated to the treatment group or the control group. In the treatment group participants receive the new intervention, in the control group they are asked to simply weigh themselves daily. Participants attend two meetings with the research team, one at the start of the study and one at follow-up. At the first meeting participants, weight, height and body composition are measured. They also complete a questionnaire asking for their demographic background and previous experiences of weighing themselves. They then follow the assigned intervention for 8 weeks. After completing the intervention, participants in the treatment group receive a questionnaire by email asking about their opinions on the intervention components. At the follow-up meeting participants' weight and body composition are measured again. The changes in weight and body composition are compared across the control and treatment groups to see whether the treatment group lost more weight. Some participants in the intervention group are interviewed about their experiences in the study.

What are the possible benefits and risks of participating?
Everyone taking part in the study will receive an intervention that has the potential to help with losing weight. Everybody will also receive information about how to weigh oneself in the best way to achieve reliable results. Participants will be sent a lay summary of the results after analysis is completed. Daily weighing carries no specific health risks. Recent studies have shown that self-weighing leads to higher body satisfaction as well as decreases in depression levels.

The researchers are therefore confident that self-weighing does not pose a risk for our participants. However, they realise that there is a theoretical risk that people with eating disorders might be adversely affected by daily weight measurements. They therefore decided to exclude this population group from the study.

Where is the study run from?
Nuffield Department of Primary Care Health Sciences (UK)

When is the study starting and how long is it expected to run for?
March 2018 to June 2019

Who is funding the study?
NIHR CLAHRC Oxford (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

11/2018

Study information

Scientific Title
A proof of concept trial of a self-regulation intervention for weight loss

Acronym
PREVAIL

Study objectives
A behavioural intervention that guides users through a self-regulation process following self-weighing is more effective for weight loss than simple daily weighing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority, 20/11/2018, REC ref: 18/SC/0482

Study design
Single-centre individually randomised open two-arm parallel-group design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Please contact us via email to request a participant information sheet

Health condition(s) or problem(s) studied
Obesity

Interventions
All eligible participants will be randomised with an allocation ratio of 1:1 to the self-regulation intervention or control group after consent has been taken. A randomisation sequence, stratified by GP and using stratified block randomisation with randomly varying block sizes of 2 and 4 will be generated using a computer algorithm at http://www.randomization.com. Allocations will be concealed in numbered, sealed envelopes by an independent researcher in the department and handed to the researcher who will conduct the baseline visit with the participants.

Participants in the treatment group will be guided through a self-regulation process following self-weighing for eight weeks. Participants will be asked to weigh themselves every day using provided standard body scales and keep track of their weight loss progress using a freely available weight-tracking app. They will be sent automated daily self-regulation prompts via email using the online software Qualtrics. The prompt will ask participants to plan a specific weight loss action for the day (e.g. do not eat between meals). They will be asked to specify how they are going to perform the action and think about any cues they might use to remind themselves of the task. They will then be prompted to construct if-then plans to account for potential barriers. Participants will be asked to choose a category of actions (e.g. actions surrounding physical activity) at the beginning of the week and will be offered action plans within this category for the whole week. By the end of the week, they will thus be able to make conclusions about the effectiveness of this category of actions. On a weekly basis, participants will receive an email with feedback on the weeks progress. The email will also include a link to another self-regulation prompt using the online software Qualtrics, in which participants will be asked to reflect on their behaviour throughout the week and try to explain observed weight changes. The questionnaire will also ask participants to reflect on the effectiveness of the week' s strategy (i.e., category of actions), and whether they would like to continue using this category of actions in the future. At the start of the next week, participants will be encouraged to keep performing effective weight loss actions while trying out a new set of actions. After the eight weeks of the intervention are finished, participants will be sent a final online questionnaire via email (Qualtrics), which asks them about their opinion regarding the usefulness of the intervention components.

Participants in the control group will be asked to weigh themselves daily for eight weeks. Participants will receive special body scales, which are equipped with a SIM card and automatically transfer their weight measurements to a secure research server via the 3G/4G network. This data is used to assess adherence to daily weighing in the control group.

Intervention Type
Behavioural

Primary outcome measure
The early effectiveness of a self-regulation intervention compared to unsupported daily weighing for weight loss, measured through change in body weight between baseline and 2 months follow-up by condition

Secondary outcome measures
1. The usage and effectiveness of the self-regulation intervention components, measured across the two months of the study through:
1.1. Adherence to intervention components, assessed through weight records and daily action-planning/weekly evaluation questionnaires
1.2. Action plan use and evaluation, based on information from daily and weekly questionnaires, and 2 months follow-up interviews
2. Participant experiences of the self-regulation intervention for weight loss, measured at 2 months follow-up through:
2.1. Liking and perceived effectiveness of intervention features based on 2 months follow-up interviews
2.2. Barriers and unmet needs for successful weight loss, assessed in 2 months follow-up interviews

Overall study start date

15/03/2018

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Body Mass Index ≥30 kg/m2
4. Ownership of an Apple or Android smartphone

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Unable to understand English
2. Measures body weight more than once a week
3. Currently or recently (within 3 months of study entry) attended a weight management programme or currently participating in another weight loss study
4. Lost more than 5% of current body weight in the last six months
5. Had bariatric surgery, or scheduled for bariatric surgery
6. Pregnant, or planning to become pregnant during the course of the study
7. Have an electronic medical implant, such as a pacemaker
8. Have ever had or been diagnosed with an eating disorder
9. Patients that the GP judges not able to meet the demands of either treatment programme or measurement schedule. This may include severe medical problems not listed above or severe psychiatric problems including substance misuse that make following the treatment programme or adhering to the protocol unlikely

Date of first enrolment
14/01/2019

Date of final enrolment

22/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Primary Care Health Sciences
Radcliffe Primary Care Building
Radcliffe Observatory Quarter
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Sponsor information

Organisation
University of Oxford / Clinical Trials and Research Governance (CTRG)

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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR CLAHRC Oxford

Results and Publications

Publication and dissemination plan
The trial results will be published and all who meet the criteria for authorship will be listed as authors. Results will also be presented at lay and scientific forums. There are no plans to publish any other materials from the study.

Intention to publish date
31/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as they may contain information that could compromise research participant privacy. Quantified data from the trial, such as weight measurements, may be published as supplemental material to the main outcome paper. All data will be held securely on a departmental drive and will only be accessible by members of the trial management group.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version V1.0	21/10/2019	28/10/2019	No	No
Protocol article	protocol	08/12/2019	22/10/2020	Yes	No
Results article	results	01/09/2020	03/11/2020	Yes	No
HRA research summary			28/06/2023	No	No