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Evaluating a planner to aid a community weight management programme

Submission date
13/12/2013

Recruitment status
No longer recruiting

Registration date
07/01/2014

Overall study status
Completed

Last Edited
17/01/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Reducing death and diseases associated with being overweight is a crucial public health goal. The aim of this study is to test the how well a very brief psychological intervention [a type of planner called a volitional help sheet (VHS)] helps to boost the effects of a community weight management programme and produce additional weight loss in a group of overweight and obese people. The VHS helps people act on their good intentions through the formation of simple IF-THEN plans that encourage a link between a critical situation (i.e., when tempted to eat) and an appropriate response (e.g., then I will remove things from my home that remind me of eating). The VHS has been used successfully to promote a range of health activities; this study will find out if using a booster after the initial VHS will further improve weight management.

Who can participate?
Adult men and women currently participating in a community-based weight management programme run by Bolton NHS Foundation Trust will be invited to participate.

What does the study involve?
Participants will be randomly allocated to either complete a VHS planner or to another planner that acts as a comparison (i.e., control) at the start of their weight management programme. After 5 weeks they will be randomly allocated for the second time to either the VHS planner or the comparison planner. Thoughts and feelings about eating and weight management, source of motivation and weight will be measured at 5 weeks, 3 months, 6 months and 12 months after starting the programme.

What are the possible benefits and risks of participating?
Participants who complete a VHS may benefit from their participation by losing more weight than if they took part in the weight management programme alone. There are no risks to taking part in the study.

Where is the study run from?
The weight management programmes from which participants will be recruited are held in health centres, community centres and work places in the Bolton area, Greater Manchester, UK.

When is the study starting and how long is it expected to last?
July 2014 to September 2017

Who is funding the study?
The study is funded by the University of Manchester, 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
N/A

Study information

Scientific Title
A randomised controlled trial to evaluate the weight loss volitional help sheet in an overweight and obese population attending a community-based weight management programme

Study objectives

The main hypotheses are that:
1. at Week 5 the group (i) (completed VHS planner at start and halfway through programme) and group (ii) (VHS planner at start of programme and comparison planner halfway through the programme) will have greater weight loss than the other two conditions.
2. at Week 10 group (i) will have greater weight loss than the other 3 conditions
3. at Week 10 the group (ii) and group (iii) (comparison planner at start of the programme and VHS planner halfway through the programme) will have greater weight loss than group (iv), the control group (comparison planner at start and halfway through programme)

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Greater Manchester West, 16/01/2014, ref: 13/NW/0888

Study design
Randomised controlled trial with the between-persons factor of condition with four levels

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
A psychological health intervention on an overweight and obese population

Interventions
Participants will be randomised to two groups: volitional help sheet (VHS) planner and a comparison planner (control). After five weeks, they will again be randomised to the above two groups. The four study arms are:
1. VHS planner at the start and halfway through the programme
2. VHS planner at the start of the programme and comparison planner halfway through the programme
3. Comparison planner at the start of the programme and VHS planner halfway through the programme
4. Comparison planner at the start and halfway through the programme (control)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight loss at the end of the weight management programme (objectively measured weight)

Secondary outcome measures
Current:
1. Self-regulation strategies used at T2 and T3 (action control scale from Sniehotta et al., 2005)
2. Eating habit scale at T2 and T3 (Self-reported habit index adapted from Verplanken & Orbell, 2003)
3. Situations experienced and strategies used at T3 (self-report questionnaire from Armitage, 2013)

Weight loss and waist circumference measured at 3 months after the start of the programme.

Previous:
1. Weight loss and waist circumference at five weeks (T2) into the weight management programme (objectively measured)
2. Intentions to lose weight measured using a two-item questionnaire from Armitage, 2013 at T2 and T3 (at the end of the weight management programme)
3. Weight loss self-efficacy at T2 and T3 (a four-item questionnaire from Armitage, 2013)
4. Self-regulation strategies used at T2 and T3 (action control scale from Sniehotta et al., 2005)
5. Eating habit scale at T2 and T3 (Self-reported habit index adapted from Verplanken & Orbell, 2003)
6. Source of motivation for weight loss at T2 and T3 (weight loss treatment self-regulation questionnaire; Williams et al., 2013)
7. Situations experienced and strategies used at T3 (self-report questionnaire from Armitage, 2013)

Weight loss and waist circumference measured at 3, 6 and 12 months after the start of the programme.

Overall study start date
01/07/2014

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Adult
2. Able to understand written and verbal English
3. Competent to provide informed consent
4. Attending a community-based weight management programme run by Bolton NHS Foundation Trust

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
179

Key exclusion criteria
1. Unable to understand written and verbal English
2. Not competent to provide informed consent

Date of first enrolment
01/07/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Centre for Health Psychology
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
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Oxford Road
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester (UK) - Manchester Centre for Health Psychology

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		17/01/2019	17/01/2019	No	No
HRA research summary			28/06/2023	No	No