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Personalized weight loss trial comparing motivational interventions for losing weight and being more active

Submission date
29/06/2016

Recruitment status
No longer recruiting

Registration date
18/07/2016

Overall study status
Completed

Last Edited
12/11/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
In England, two thirds of the adult population is overweight, with almost 25% of adults being classed as obese and numbers rising. Obesity costs the public £11.4 billion every year and presents a serious danger to individuals, leading to long-term health conditions such as heart disease and diabetes. It is well founded that the best way of losing weight is to combine a reduced-calorie diet with increased exercise but people often struggle to stay motivation for long enough to get lasting results. Self-help treatments and commercial programs tend to be ineffective in the long-term, with many regaining the weight they have lost soon after. Repeated failures to keep weight off can be disheartening and so effective support is needed to help people stay motivated over the longer term, developing lasting habits of healthy eating and regular exercise. A well-established counselling approach called motivational interviewing (MI) has proven to be effective for improving weight loss, but its long-term benefits are quite small. There is an urgent need for better techniques to sustain weight loss over the longer term. A new treatment called Functional Imagery Training (FIT) delivers motivational interviewing in a completely new way, building the client's motivation and confidence by training them to create and rehearse emotionally-charged mental images about their personal goal and how they will achieve it. To make healthy goals more vivid, realistic and concrete, participants are repeatedly encouraged to imagine the benefits of working towards their goals, focusing most on those benefits that will happen right away. The aim of this study is to compare the effectiveness of FIT and MI at helping people to keep off the weight they lose.

Who can participate?
Overweight adults.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive an hour-long face-to-face session of MI, focusing on either diet or physical activity changes (participant’s choice). One week later, participants undertake a 45 minute MI session via telephone with a focus on the same area as chosen in the first session. Two weeks later participants receive 10-20 minute-long booster calls every two weeks for three months and then

monthly until the six month follow up to discuss progress, new goals or any issues they are facing. Those in the second group receive an hour-long face-to-face session of FIT, focusing on either diet or physical activity changes (participant's choice). Participants also receive a 45 minute FTI telephone session two weeks later and booster calls in the same regimen as those in the first group. Participants in this group are also given the opportunity to download an app to help them with imagery training (looking at images to reinforce their mental imagery training). At the start of the study, and then again after six and 12 months, participants in both groups are weighted and measured around the weight to assess their weight loss. Participants also complete a range of questionnaires at the start of the study and after six months to assess their diet and activity levels.

What are the possible benefits and risks of participating?
Participants may benefit from increasing their physical activity levels and losing weight. There are no notable risks involved with participating in this study.

Where is the study run from?
Plymouth University (UK)

When is the study starting and how long is it expected to run for?
September 2014 to December 2016

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

Who is the main contact?
1. Miss Linda Solbrig (public)
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2. Professor Jackie Andrade (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FITWEIGHTRCT1

Study information

Scientific Title
Comparison of Functional Imagery Training and Motivational Interviewing for weight loss and increasing physical activity

Study objectives
Functional Imagery Training (FIT) will be more effective than Motivational interviewing for achieving and sustaining weight and increasing physical activity levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty Research Ethics Committee, Health and Human Sciences, Plymouth University, 23/03/2015, ref: 14/15-389

Study design
Single-centre two-arm partially blinded randomized controlled trial

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 contact details to request a participant information sheet.

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

Interventions
Participants are randomized to one of two groups using web-based randomisation software (https://www.randomizer.org/).

Motivational Interviewing (MI) group:
Participants receive one hour of MI, either focused around diet change or physical activity changes (participant led), in a face to face session. One week later they receive another MI session delivered via phone (around 45 minutes) with a focus on diet or physical activity, dependent on what they had chosen to discuss in their first session. They receive fortnightly booster calls starting two weeks after session two (10-20 minutes) giving opportunity to discuss progress, new goals or any issues participants might be facing. The MI group has no app support.

Functional Imagery Training (FIT) group: Participants receive one hour of FIT, either focused around diet change or physical activity changes (participant led), in a face to face session. One week later they receive another FIT session delivered via phone (around 45 minutes) with a focus on diet or physical activity, dependent on what they had chosen to discuss in their first session. They receive fortnightly booster calls starting two weeks after session two (10-20 minutes) giving opportunity to discuss progress, new goals or any issues participants might be facing. Participants in the FIT group are given the option to download an app to help them with imagery training via practice audios, goal setting options and the opportunity to upload motivational photos.

Follow up for all participants involves coming back to the same laboratory, at six months, to be weighed and measured by research assistants or placement students, not by the original experimenter, to achieve partial blinding. They will meet with the experimenter afterwards to receive £15 payment for taking part and to have a debrief. They will also be given the opportunity to find out what the other group were doing and are offered whichever treatment they had not received.

Intervention Type
Other

Primary outcome measure
Weight loss is determined by measuring weight (kg) and waist circumference (cm) at baseline, 6 and 12 months.

Secondary outcome measures
1. Physical activity is measured using the International Physical Activity Questionnaire (IPAQ-short) during session one and one week before follow up at six months
2. Diet is measured using the Food Frequency Questionnaire during session one and one week before follow-up at six months
3. Use of goal imagery is measured using the Thought Frequency Scale at home baseline, one week before session one and the first booster call at the end of trial week four
4. Quality of Life is measured using the QoLIAD (Global Quality of Life Assessment) during session one and one week before follow-up at six months
5. Treatment expectancy/credibility is measured using Credibility/Expectancy Questionnaire after the second session at the end of week two
6. Self-efficacy for exercise is measured using Exercice Self-Efficacy Scale (SCI) one week before session one (lab baseline) at home baseline and at the end of week four after the first booster call
7. Participant experience is measured using the participant experience questionnaire at follow-up
8. Self-efficacy for diet is measured using WELQ (Weight Efficacy Lifestyle Questionnaire)

Overall study start date
15/09/2014

Completion date
18/12/2016

Eligibility

Key inclusion criteria
1. BMI of or above 25
2. Females and males
3. Must be age 18 or above

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Pregnancy
2. History of eating-disorders

Date of first enrolment
01/04/2016

Date of final enrolment
10/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Plymouth University
Link Building
Drake Circus
Plymouth
United Kingdom
PL4 8AA

Sponsor information

Organisation
NIHR CLAHRC Southwest Peninsula (PenCLAHRC)

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Sponsor type
Research organisation

Website

http://clahrc-peninsula.nihr.ac.uk/contact

ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
NIHR CLAHRC Southwest Peninsula (PenCLAHRC)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The raw data are available at https://zenodo.org/record/1120364.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019		Yes	No