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Weight Loss Maintenance in Adults

Submission date
11/01/2010

Recruitment status
No longer recruiting

Registration date
12/01/2010

Overall study status
Completed

Last Edited
19/04/2016

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
Interventions for maintaining weight loss have limited effectiveness, and weight regain is common. This study will test a 12-month intervention with three main parts: motivational interviewing (MI), self-regulation and peer support. Since motivation is likely to be important in weight maintenance we propose to use an intervention based on MI. MI is a counselling style which has been shown to be an effective way to get people to change, as well as maintain behaviour change, even when the MI given is brief. The second feature, self-regulation, consists of weighing yourself regularly and monitoring your eating and drinking. Finally, peer support and social support have been identified as important in weight loss and maintenance of weight loss. We hope to encourage peer support amongst people who take part in this study. Some studies have emphasized the importance of long-term intervention and follow-up, but it remains unclear how intensive this should be and how it is best delivered, therefore both an intensive and a less intensive version of the intervention will be tested.

Who can participate?
Obese adults aged 18 – 70 who have lost at least 5% of their body weight during the last 12 months

What does the study involve?
Participants are randomly allocated into three groups: an intensive intervention group, a less intensive intervention group, and a control group. The two intervention groups receive a 12-month intervention. Participants in the intensive intervention group attend six one-to-one MI sessions (60 minutes) tailored to their needs, delivered every 2 weeks for 3 months either in their homes or a locally hired venue. For the final 9 months of the intervention participants receive monthly brief MI-based telephone calls (20 minutes). Feedback is given, along with information on diet and exercise. Participants are also encouraged to 'self-monitor' by weighing themselves weekly and monitoring their diet. Following on from the end of the face-to-face MI sessions, participants also attend peer-supported group sessions (1.5 hours) once a month for four months at local community or sports centres. At the initial group session participants discuss diet and exercise are share problems and tips with their peers. Participants are invited to bring along a 'buddy' and are allotted a small 'buddy group' who are encouraged to meet between these group sessions. The participants are weighed and receive personal feedback. Participants in the less intensive intervention group have two face-to-face tailored MI sessions two weeks apart and after that an MI-based telephone call at 6 months and one at 12 months,

lasting around 20 minutes. They are also encouraged to self-monitor their weight and diet and the peer group sessions are the same format as the intensive intervention group. The control group are given an information pack describing lifestyle changes to maintain weight loss. Patients in all groups are still able to access usual care, e.g. weight loss groups. The main outcome on which groups are compared is Body Mass Index (BMI) at 2 years after the end of the intervention, taking into account BMI at the start of the study and previous weight loss. Other outcomes include: waist circumference and waist-to-hip ratio, body fat distribution, physical activity, diet, and the proportion maintaining their weight loss. We also conduct semi-structured interviews with participants to examine their views of the intervention and to compare those who maintained weight with those who put weight back on. Finally, we assess the cost of any achieved benefits for each of the intervention groups. Participants are assessed during the intervention at 6 months and followed up just after the intervention is complete and then 12 and 24 months from the end of the intervention.

What are the possible benefits and risks of participating?
This study is being undertaken to find out if this treatment is helpful for people who are trying to maintain the weight they have lost. As well as helping us answer this question, we hope that taking part in the study could help participants to maintain any weight loss they have already achieved, or even help them to lose further weight if that is what they wish to do. They may also improve their overall health.

Where is the study run from?
Cardiff University School of Medicine (UK)

When is the study starting and how long is it expected to run for?
April 2010 to March 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Sharon Simpson
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Study website
http://medicine.cf.ac.uk/wilma/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/44/04

Study information

Scientific Title
A randomised controlled trial of a 12-month multi-component intervention versus a less intensive version on study participants' maintenance of weight loss

Acronym
WILMA

Study objectives
Does a 12-month multi-component intervention or a less intensive version of it enable study participants' to maintain weight lost (prior to study entry) three years from randomisation?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/084404
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/52947/PRO-08-44-04.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Three-arm individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://medicine.cf.ac.uk/media/filer_public/2012/02/23/wilma_participant_information_sheet_1_v20.pdf

Health condition(s) or problem(s) studied
Obesity/public health/behaviour change

Interventions
1. Intense intervention - six one-to-one motivational interviewing (MI) sessions plus four group sessions and 11 brief MI phone calls
2. Less intense intervention - two one-to-one MI sessions plus four group sessions and two brief MI phone calls

The total duration of treatrment is 12 months in both intervention arms and the total duration of follow up is 3 years from randomisation for all study participants.

Intervention Type
Behavioural

Primary outcome measure
BMI at 3 years from randomisation

Secondary outcome measures
1. Waist circumference, measured at baseline, post intervention, 12 months and 24 months after the end of the intervention
2. Waist to hip ratio, measured at baseline, post intervention, 12 months and 24 months after the end of the intervention
3. Body fat distribution, measured at baseline, post intervention, 12 months and 24 months after the end of the intervention
4. Self-report physical activity, collected at baseline, 6 months (during intervention), post-intervention, 12 month follow-up after end of intervention and 24 months after the end of the intervention
5. Proportion maintaining weight loss, measured post-intervention and at 12 and 24 months after intervention
6. Self report dietary intake, collected at baseline, 6 months (during intervention), post-intervention, 12 month follow-up after end of intervention and 24 months after the end of the intervention
7. Health-related quality of life, collected at baseline, 6 months (during intervention), post-intervention, 12 month follow-up after end of intervention and 24 months after the end of the intervention
8. Health resource usage, collected at baseline, 6 months (during intervention), post-intervention, 12 month follow-up after end of intervention and 24 months after the end of the intervention
9. Binge eating, measured post-intervention and at 12 and 24 months after intervention
10. Psychological well being and duration of participation and drop out from intervention, measured post-intervention and at 12 and 24 months after intervention

Overall study start date
01/04/2010

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Obese adults aged 18 - 70 years, either sex
2. Current or previous body mass index (BMI) of 30 or above
3. Lost at least 5% body weight (by pharmacological, lifestyle and/or behavioural methods) during the last 12 months
4. Independent verification of weight loss

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
950

Key exclusion criteria
1. Unable to comply with study protocol, e.g., due to mental health problems, terminal illness or competence in English
2. Pregnant women

Date of first enrolment
01/04/2010

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University School of Medicine
Cardiff
United Kingdom
CF14 4YS

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
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Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No
Results article	results	18/12/2015		Yes	No