# Weight Loss Maintenance in Adults

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
11/01/2010		Protocol		
Registration date 12/01/2010	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/04/2016	Nutritional, Metabolic, Endocrine			

## 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 SimpsonSA@cf.ac.uk

## Contact information

**Type(s)**Scientific

Contact name

Dr Sharon Simpson

#### Contact details

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## Additional identifiers

Protocol serial number 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

#### Study type(s)

Treatment

## 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(s)

BMI at 3 years from randomisation

## Key secondary outcome(s))

- 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

### 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

#### Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

### 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)

#### **ROR**

https://ror.org/03kk7td41

## Funder(s)

## Funder type

Government

## Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2015		Yes	No
Results article	results	18/12/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes