

# Evaluating a planner to aid a community weight management programme

<b>Submission date</b> 13/12/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/01/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?  
Dr Tracy Epton  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

## 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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

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

## Sponsor information

**Organisation**  
University of Manchester (UK)

**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

**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?
<a href="#">Basic results</a>		17/01/2019	17/01/2019	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No