

# Peer-Support Weight Action Programme (SWAP)

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| <b>Submission date</b><br>10/10/2012   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol<br><input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results<br><input type="checkbox"/> Individual participant data |
| <b>Registration date</b><br>12/10/2012 | <b>Overall study status</b><br>Completed                       |   |
| <b>Last Edited</b><br>04/04/2019       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine |   |

## Plain English summary of protocol

### Background and study aims

About 42% men and 32% women in England are overweight [body mass index (BMI) 25 kg/m<sup>2</sup> or over] and some 24% are obese (BMI 30 kg/m<sup>2</sup> or over). The prevalence (percentage of a population affected at a given time) of obesity has increased and is expected to rise further. Ill health resulting from obesity is responsible for about 10% of morbidity and mortality in the UK and costs the NHS about 7 billion pounds annually. Obesity is associated with a number of adverse health conditions including cardiovascular disease, Type 2 diabetes, osteoarthritis and a number of cancers. Weight loss has been shown to improve many of these illnesses, and reduce the risk of early death.

An increasing number of people are in need of interventions (treatment) to help them to lose weight. General Practitioners (GPs) are encouraged to measure BMI and monitor patients with a BMI of 30 kg/m<sup>2</sup> or greater. Such patients are expected to be recommended healthy eating and physical activity, and to receive drug therapy and/or a referral to a practice nurse or dietician, if indicated. Current treatments have modest effects which can be beneficial, but are likely to be lost once the medication is stopped. Surgical interventions are more successful but are currently expensive and unsuitable for large scale use. Dietary interventions on their own have only uncertain effects and brief routine interventions within primary care have generally reported disappointing results. More intensive behavioural interventions generate a small but sustainable weight loss, which can have significant and clinically worthwhile long term health benefits. Such interventions however are normally limited to commercial or research context. Weight management in overweight individuals who seek help normally requires changes to their habitual lifestyle which are difficult to implement and maintain without specialist input, structure and support. The Weight Action Programme (WAP) is a weight loss intervention that was developed over several years through client feedback and testing in deprived communities. It provides people with tools to maintain a healthy lifestyle, with weekly individualized tasks, and peer support group sessions. The proposed study has been designed to establish whether WAP maintains its effects long term, and whether it helps people more than current best practice GP advice.

### Who can participate?

Participants (330 overweight adults) will be referred from general practice.

### What does the study involve?

Participants will be randomly assigned to WAP or to a session with a trained nurse who will

provide weight management advice modelled on the current best practice in primary care. The WAP will provide weekly sessions for 8 weeks, followed by monthly maintenance sessions for one year. The nurse will provide an initial 20 - 30 minute intervention followed by three further sessions over 8 weeks, accompanied by standard written materials and referrals to local physical activity programmes. Both the WAP and the nurse appointments will be run from GP surgeries. Weight loss over one year will be measured. Other measures concerning the participants health, exercise levels, and health behaviours will also be collected.

What are the possible benefits and risks of participating?

The main benefit to the participant is the chance to try a safe treatment that could enhance the likelihood of achieving and maintaining a beneficial weight loss. We do not foresee any potential risks to participants.

Where is the study run from?

The study is being conducted by researchers from Queen Mary University of London which includes experts who have extensive experience in developing and testing interventions to help people change their health behaviours.

When is the study starting and how long is it expected to run for?

The study recruitment started in September 2012 and recruitment is expected to finish in March 2014.

Who is funding the study

The study is being funded by the National Institute for Health Research - Health Technology Assessment Programme (NIHR-HTA).

Who is the main contact?

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## Contact information

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 09/127/34, QMUL051211

**Study information****Scientific Title**

A peer-support weight action programme to supplement brief advice in general practice

**Acronym**

SWAP

**Study objectives**

The proposed study will determine whether a promising group-based weight management program (Weight Action Programme; WAP) targeting underprivileged groups has a long-term effect that is over and above the effect of a 'best practice' weight management intervention that is provided in primary care by practice nurses.

More details can be found at <http://www.hta.ac.uk/project/2552.asp>

Protocol can be found at <http://www.hta.ac.uk/protocols/200901270034.pdf>

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee London - Central, 03/02/2012, ref: 12/LO/0122

**Study design**

Randomised 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 contact [k.myers@qmul.ac.uk](mailto:k.myers@qmul.ac.uk) to request a patient information sheet

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

Obesity/weight management

**Interventions**

Experimental Group: The Weight Action Program (WAP)

WAP is a multi-modal health behavior modification intervention that has been modified and improved through client feedback over the past 5 years. It includes the standard elements of cognitive behavioural interventions, including information on healthy eating and caloric content of food, self-monitoring, cue management, provision of opportunities for exercise and close monitoring of exercise levels. Novel elements include a range of concrete and verifiable tasks agreed individually with each participant, and motivational interventions to ensure adherence to the new lifestyle changes. A range of guidelines for the treatment of obesity report that the best results are achieved with a combination of diet, physical activity and behavioural support. WAP combines all three components.

WAP comprises 8 weekly sessions, followed by monthly follow-up visits lasting up to 1 hour each. The target weight loss is one pound (0.45 kg) per week. Two advisors will be conducting WAP sessions in groups of 10 to 20 participants. Participants will be sent text messages to remind them of the session dates and times.

Control Group: Routine intervention as typically provided in primary care

The control intervention will be modelled on best-practice intervention in primary care, derived from discussions with GPs and Practice Nurses and incorporating national guidelines and NHS materials (e.g. Raising the issue of weight gain).

Participants will receive weight management intervention from a trained study nurse in 4 sessions delivered over 8 weeks. The initial session will take 20-30 minutes; the follow-up session may be briefer, as per usual practices.

**Intervention Type**

Behavioural

**Primary outcome measure**

Change in weight over 12 months from enrollment into the study. A researcher that is blind to treatment allocation will measure weight at 12 months.

**Secondary outcome measures**

1. Change in BMI
2. Waist circumference
3. Proportion of participants losing at least 5% of baseline body weight
4. Changes in healthy eating
5. Changes in physical activity and changes in food craving

All measures at 12 months will be collected by a researcher that is blind to treatment allocation.

**Overall study start date**

03/09/2012

**Completion date**

06/02/2015

## Eligibility

**Key inclusion criteria**

1. Adults, aged 18 years and older
2. BMI of 30 kg/m<sup>2</sup> or over, or BMI of 28 kg/m<sup>2</sup> or over
3. Co-morbidities referred from general practice

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

330

**Key exclusion criteria**

1. Inability to read/write/understand English
2. BMI over 45
3. Lost more than 5% of their body weight in the previous 6 months
4. Women who are pregnant
5. Clients taking psychiatric medications (these medications can have a significant effect on weight and psychiatric illness also makes follow-up and adherence to long-term programs difficult)
6. Clients who are not registered with a GP
7. Currently involved in a research project
8. Clients who cannot speak or understand English

**Date of first enrolment**

24/09/2012

**Date of final enrolment**

28/01/2014

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Health and Lifestyle Research Unit**

55 Philpot Street

London

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## Sponsor information

**Organisation**

Queen Mary University of London (UK)

**Sponsor details**

Joint research management office

Queen Mary Innovation Centre

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**Sponsor type**

University/education

**ROR**

<https://ror.org/026zzn846>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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**

Other

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/10/2016   |            | Yes            | No              |
| <a href="#">Results article</a> | results | 02/04/2019   | 04/04/2019 | Yes            | No              |