

# Skills for weight loss maintenance

<b>Submission date</b> 26/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/09/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Obesity is a medical term used to describe someone who is very overweight. It is generally caused by eating too much and doing too little exercise. Being obese can lead to a number of serious and potentially life-changing conditions including type 2 diabetes, coronary heart disease, some cancers (e.g. breast and bowel cancers) and stroke. It can also affect a person's mental well-being, leading to low self-esteem and depression. Interventions (treatments) are available to promote weight loss and so reduce the risks for these diseases. However, people often regain the lost weight, and there is uncertainty about how best to support long term weight loss maintenance. Based on the views of people that are able to maintain their weight loss, and of providers and commissioners of weight management services, as well as published research, we have developed an intervention to help people develop skills for weight loss maintenance (SkiM). SkiM focuses on self-managing thoughts, feelings and other influences on behaviour; and changing habits. In this study with 90 participants, we will evaluate the feasibility of combining this intervention with several existing weight loss programmes, provided by organisations commissioned to deliver community based weight management services. The purposes of the study are to develop a feasible weight management programme that specifically addresses weight loss maintenance, and to evaluate recruitment, retention, and other methodological strategies that will be used in a later study.

### Who can participate?

Adults with a body mass index over 30kg/m<sup>2</sup>.

### What does the study involve?

The intervention involves group based or one-to-one support, alongside a self-help manual to help the participants develop and practice skills required for weight loss maintenance, while also being on a weight loss programme. Body weight, physical activity levels and other outcomes of interest are measured at the start of the study 6 months and 12 months after the end of the programme. Participants and the programme providers will be interviewed about their experiences of the programme in order to help us make it more acceptable or more effective.

### What are the possible benefits and risks of participating?

Previous experience by the research group using similar behaviour change strategies in studies suggests that the risk of harm from participation is low. The focus of the programme is promotion of both healthy eating and levels of physical activity appropriate for the individual.

Public and service user consultations have been used to check that proposed programme is regarded as reasonable and feasible. Procedures are in place to ensure monitoring for, and timely reporting of, any adverse incidents, and an independent medical team will assess any reports of adverse events and make recommendations for trial conduct following them. The programme does involve exploration of personal issues by the individual and in one-to-one or group situations. Some of these are potentially sensitive, such as body image, emotions that lead to overeating, and personal and social relationships that can influence eating and physical activity behaviours. The self help manual, which encourages self reflection, is written by academics with expertise in health psychology and counselling, and reviewed by a Public and Patient Involvement (PPI) group gathered for this study. Group based and one-to-one work will be facilitated by practitioners trained and experienced in weight management and behaviour change, who will themselves be supervised by, and receive any necessary support from, their own managers and the research team. Contact details of the Study Manager and Principal Investigator will be made available to all participants so that any concerns may quickly be brought to their attention. The University also has a research related complaints procedure in place for any participant wishing to speak to someone independent of the study.

Where is the study run from?  
University of Exeter Medical School (UK)

When is the study starting and how long is it expected to run for?  
January 2015 to April 2018

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

Who is the main contact?  
Dr Leon Poltawski

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Leon Poltawski

**Contact details**  
University of Exeter Medical School  
Medical School - Primary Care  
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St Luke's  
Heavitree Road  
Exeter  
United Kingdom  
EX2 8GW

# Additional identifiers

## Protocol serial number

19465

# Study information

## Scientific Title

Skills for weight loss Maintenance (SkiM): the feasibility of an intervention to support weight loss maintenance, and of a trial to evaluate it

## Acronym

SkiM

## Study objectives

The purposes of the study are to develop a feasible weight management programme that specifically addresses weight loss maintenance, and to evaluate recruitment, retention, and other methodological strategies that will be used in a randomised control trial of the intervention.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Southwest-Exeter REC, 15/06/2015, ref: 171313

## Primary study design

Interventional

## Study design

Non-randomised; Interventional and Observational; Design type: Prevention, Treatment, Qualitative

## Study type(s)

Treatment

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

Topic: Primary Care, Metabolic and endocrine disorders; Subtopic: Metabolic and Endocrine (all Subtopics), Primary care; Disease: Metabolic & Endocrine (not diabetes), All Diseases

## Interventions

SkiM. Behaviourally focused, using group, 1:1 and self-learning materials to develop and practice skills required for weight loss maintenance, while participating in a weight loss programme. Follow Up Length: 18 month(s); Study Entry : Registration only

## Intervention Type

Other

## Primary outcome(s)

Weight; Timepoint(s): baseline, post-intervention (6 months) and follow-up (12 and 18 months)

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

1. Physical activity by accelerometry; Timepoint(s): baseline, post-intervention (6 months), follow-up (12 months)
2. Process measures by questionnaire; Timepoint(s): baseline, post-intervention (6 months), follow-up (12 and 18 months)
3. Waist circumference; Timepoint(s): baseline, post-intervention (6 months), follow-up (12 and 18 months)

### **Completion date**

30/04/2018

## **Eligibility**

### **Key inclusion criteria**

1. Adults (aged at least 18 years)
2. BMI between 30kg/m<sup>2</sup> ( $\geq 27.5$ kg/m<sup>2</sup> for South Asian and Black African/Caribbean heritage populations) and 50kg/m<sup>2</sup>
3. Meet the eligibility criteria for entry to Tier 2 weight management services delivered by our Providers

The different BMI value for South Asian Black African/Caribbean heritage populations is based on recommendations by the National Institute of Health and Care Excellence (NICE), on who should receive weight management support. It reflects the fact that different ethnic groups have different risk levels because of their obesity, even if they have the same BMI.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

All

### **Key exclusion criteria**

We will not offer participation to people who

1. Are currently pregnant, planning to be pregnant during the study period, or have given birth in the preceding 6 months
2. Have a mental disability or low literacy preventing engagement with the intervention
3. Are deemed by their GP to be unable to participate in the study for any other reason (e.g. serious uncontrolled medical condition, psychiatric disorder, diagnosis of dementia, life threatening illness)
4. Are unable to make own arrangements to travel to intervention venue

5. Currently participating in another weight management programme (e.g. commercial weight loss programme)
6. Are participating in other health research, as this may overburden the participant or confound data collection

**Date of first enrolment**

01/08/2015

**Date of final enrolment**

31/10/2016

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Exeter University Medical School (lead)**

St Luke's Campus

Magdalen Road

Exeter

United Kingdom

EX1 2LU

**Study participating centre**

**Westbank Healthy Living Centre**

Farm House Rise

Exeter

United Kingdom

EX6 8AT

**Study participating centre**

**Torbay and Southern Devon Health and Care NHS Trust**

4th Floor Union House

Union Street

Torquay, Devon

United Kingdom

TQ1 3YA

## **Sponsor information**

## Organisation

University of Exeter Medical School

## ROR

<https://ror.org/03yghzc09>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	qualitative sub-study on maintaining weight loss	28/04/2020	17/09/2024	Yes	No
<a href="#">Protocol file</a>	version 9.1	30/08/2016	19/10/2022	No	No