

Skills for weight loss maintenance

Submission date 26/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/09/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" 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/m².

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
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United Kingdom
EX2 8GW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/01/2014

Completion date

30/04/2018

Eligibility

Key inclusion criteria

1. Adults (aged at least 18 years)
2. BMI between 30kg/m² (≥ 27.5 kg/m² for South Asian and Black African/Caribbean heritage populations) and 50kg/m²
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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 80; UK Sample Size: 80; Description: 40 people in two consecutive cohorts. Each cohort comprises 4 groups of 10 receiving a group-based intervention.

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

England

United Kingdom

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

Sponsor details
Department of Primary Care
Smeall Building
St. Luke's Campus
Magdalen Road
Exeter
England
United Kingdom
EX1 2LU

Sponsor type
University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol file	version 9.1	30/08/2016	19/10/2022	No	No
Other publications	qualitative sub-study on maintaining weight loss	28/04/2020	17/09/2024	Yes	No