# Lighten Up weight maintenance study

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
18/02/2014		[X] Protocol		
Registration date 31/03/2014	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/03/2021	Nutritional, Metabolic, Endocrine			

## Plain English summary of protocol

Background and study aims

There are a range of programmes that help people to lose weight, however most people tend to put weight back on. We need to find simple strategies that we can give to the public to help them maintain their weight, that are also cost effective. One simple strategy may be to ask people to weigh themselves on a daily basis to identify changes in their weight. The aim of this study is to investigate the effect of a brief intervention focused on self-weighing on weight change compared to a usual care group.

#### Who can participate?

Only people that have taken part in the Birmingham Lighten Up weight loss service, have been weighed at least once during weeks 9-12 of the 12 weeks and have lost at least 5% of their starting weight at the end of their weight loss programme. They must be 18 years or more and own a mobile phone or landline phone that can receive SMS text messages.

#### What does the study involve?

Participants will be randomly allocated to one of two groups: usual care group or intervention group. The usual care group will receive a hints and tips leaflet about weight maintenance behaviours. The intervention group will receive the same hints and tips leaflets, weighing scales, and will also receive support telephone calls at weeks zero, two and four, that encourage daily self-weighing, together with reminder text messages every other day for the first four weeks, reducing to twice weekly thereafter. Both groups will be weighed at the start f the study, three and 12 months and asked to complete brief questionnaires.

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

We cannot promise that participants will maintain weight loss, but similar programmes have helped people in the past. We do not predict any risks or side-effects from the weight maintenance programmes offered in this study. Should participants become pregnant during the study they should no longer take part in the study.

#### Where is the study run from?

The study is run from the University of Birmingham in partnership

When is the study starting and how long is it expected to run for? April 2014 to March 2017

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

Who is the main contact? Dr Amanda Dalev a.daley@bham.ac.uk

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Amanda Daley

#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

Protocol 1

## Study information

#### Scientific Title

Lighten Up weight maintenance study: a randomised controlled trial

## Acronym

LIMIT

## Study objectives

The primary aim of this study is to evaluate the effectiveness and cost effectiveness of a brief behavioural intervention delivered by non specialist staff to promote regular self weighing to prevent weight regain after intentional weight loss. The intervention will be compared with usual care.

## Ethics approval required

#### Old ethics approval format

#### Ethics approval(s)

University of Birmingham

#### 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 use the contact details to request a patient information sheet

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

Weight management

#### **Interventions**

Usual care group

The usual care group will receive the standard Lighten Up maintenance leaflet sent to their home address. The leaflet is very brief with some advice prepared by NHS Birmingham. It mostly consists of a series of bullet points. Other than for follow up, there will be no other contact with the usual care group.

#### Intervention group

Participants will receive a set of weighing scales and instructed to weigh themselves daily and record it on the record card provided. Participants will also receive three follow-up calls at zero, two and four weeks to encourage self-weighing. They will also receive reminder text messages every other day for the first four weeks, reducing to twice weekly thereafter

## Intervention Type

Behavioural

#### Primary outcome measure

Mean weight change at 12 months follow up.

#### Secondary outcome measures

- 1. The proportion of participants in the intervention and usual care groups who regain less than 1 kg from their weight at the end of the weight loss programme at three and 12 month follow up.
- 2. Mean weight change at three months (post maintenance intervention) follow up.

3. The cost to the NHS per kg, and per kg/m2, of the additional weight loss maintained for the intervention compared to usual care at 12 months, the cost per quality adjusted life years (QALY) during the intervention period and cost per predicted lifetime QALYs gained.

4. The occurrence of adverse effects including uncontrolled eating, emotional eating and weight preoccupation.

## Overall study start date

01/04/2014

#### Completion date

31/03/2017

## Eligibility

#### Key inclusion criteria

- 1. Aged 18 years or more.
- 2. People who have attended and therefore been weighed at their Lighten Up weight loss programme at least once during weeks 9-12 of the 12 week programme.
- 3. People who have lost at least 5% of their starting weight at the end of their weight loss programme. This can be later verified objectively as all participants are weighed by service providers at the start and end of their weight loss programme.
- 4. Own a mobile phone or landline phone that can receive SMS text messages.

#### Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

## Target number of participants

560 participants

#### Total final enrolment

583

## Key exclusion criteria

- 1. Unable to understand English
- 2. Women who are known to be pregnant or intending to become pregnant during the study

#### Date of first enrolment

01/04/2014

#### Date of final enrolment

31/03/2017

## **Locations**

#### Countries of recruitment

England

B15 2TT

**United Kingdom** 

Study participating centre University of Birmingham Birmingham United Kingdom

## Sponsor information

#### Organisation

University of Birmingham (UK)

## Sponsor details

Edgbaston Birmingham England United Kingdom B15 2TT

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resgoviras@lists.bham.ac.uk

## Sponsor type

University/education

#### **ROR**

https://ror.org/03angcq70

## Funder(s)

## Funder type

Government

#### **Funder Name**

Public Health Research Programme Reference: 12/179/09

## Alternative Name(s)

NIHR Public Health Research Programme, PHR

## **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

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	04/06/2015		Yes	No
Results article	results	01/04/2019	04/03/2021	Yes	No