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Lighten Up weight maintenance study

Submission date
18/02/2014

Recruitment status
No longer recruiting

Registration date
31/03/2014

Overall study status
Completed

Last Edited
04/03/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

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 Daley
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Contact information

Type(s)
Scientific

Contact name
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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

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
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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?
Protocol article	protocol	04/06/2015		Yes	No
Results article	results	01/04/2019	04/03/2021	Yes	No