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Evaluation of a text supported weight maintenance programme Lighten Up Plus following a weight reduction programme in the Lighten Up service in Birmingham.

Submission date
26/11/2012

Recruitment status
No longer recruiting

Registration date
18/12/2012

Overall study status
Completed

Last Edited
15/02/2016

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study to measure the effectiveness of a service that is designed to help people maintain their weight after attending a weight loss programme. Our aim is to understand how a SMS-text messaging based weight maintenance programme to encourage self-weighing compares to a brief telephone supported programme in terms of weight change after 3 and 9 months after the end of the 12 week weight-loss programme. The studys findings should help to improve the future design of interventions for overweight people.

Who can participate?
Participants who have completed the 12-week Lighten Up weight management programme aged over 18.

What does the study involve?
All participants eligible for the study will have attended a 12 week weight loss programme. Participants will be randomised to receive weekly text (SMS) based support encouraging weight maintenance or standard care (telephone support post weight loss intervention and information about effective weight maintenance strategies). Participants receiving text based support will be requested to send weight measurements by text. Data will be collected at 3 and 9 months.

What are the possible benefits and risks of participating?
Participants in either treatment arm will receive support to help maintain their current weight. There are no known risks in taking part in this study.

Where is this study run from?
University of Birmingham in collaboration with Birmingham and Solihull NHS Cluster.

When is the study starting and how long is it expected to run for?
Recruitment will begin in January 2013. Participants will be enrolled on the study for 9 months,

and there will be a follow up period where intend to explore the attitudes of participants in relation to the support they received.

Who is funding the study?
Birmingham and Solihull NHS Cluster (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Lighten Up Plus- V1

Study information

Scientific Title
Evaluation of a text supported weight maintenance programme Lighten Up Plus following a weight reduction programme: a randomised controlled trial.

Acronym
Lighten Up Plus

Study objectives
It is hypothesised that participants receiving text (SMS) support will maintain their weight or gain less weight compared to those receiving standard care. The null hypothesis is that there will be no difference between treatment groups.

Ethics approval required

Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 20/11/2012, ref: 12/WM/0372

Primary study design
Interventional

Study design
Randomised controlled trial with patients individually allocated to one of two weight maintenance programmes. Qualitative interviews will explore the experience of the intervention.

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Treatment for people who are overweight/obese

Interventions
Usual care: Telephone support at end of free weight loss programme and at 3 months with hints and tips leaflet about effective weight maintenance strategies;

Text intervention: usual care plus texts at weekly interventions. Texts will ask for the participant s weight and will respond with one of three options:

1. Weight maintenance or weight loss from previous reported weight congratulatory message and encouragement to keep up the good work;
2. Small gain for one or two weeks in succession advice to be careful about diet and increase physical activity
3. Gain for three or more weeks in succession offer of telephone support session

The initial support session will be with a member of the call centre staff who will remind them about their strategies for weight loss. If they continue to gain weight they can then be referred on to a health trainer.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Difference between baseline weight and independently measured weight at nine months following randomisation.

Key secondary outcome(s)
1. Self-reported weight loss at 3 months following randomisation, which will be collected by the Lighten Up call centre by telephone (or questionnaire for people not-contactable by phone)
2. BMI at 9 months and percentage of people achieving 5% loss of body weight from the start of their Lighten Up programme.

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Aged ≥18
2. People who have a final (week 12) weight recorded or attended the Lighten Up weight management service for a minimum of 9 sessions and have had a weight measured within the past 2 weeks
3. Has access to scales to weigh self
4. Owns a phone (mobile or land-line).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Unable to understand English
2. Women who are known to be pregnant
3. People who attended the My Choice pharmacy programme
4. Not willing to be randomised
5. People who have dropped out of the Lighten Up service prior to week 9

Date of first enrolment
01/01/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Birmingham and Solihull NHS Cluster (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Birmingham and Solihull NHS Cluster (UK)

Results and Publications

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?
Results article	results	12/02/2016		Yes	No