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Weight loss maintenance intervention for obese adults after clinically significant weight loss

Submission date
20/03/2014

Recruitment status
No longer recruiting

Registration date
20/03/2014

Overall study status
Completed

Last Edited
08/05/2019

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
More and more people are becoming overweight which is a major problem worldwide. One in four adults in the UK is overweight. Being overweight can contribute to chronic illness, absence from work and reduced life expectancy. Many people manage to successfully lose weight, but often put it back on after a while. The aim of this study is to see if a new approach to weight loss maintenance can help people keep off the weight they have lost in the long term.

Who can participate?
Participants must be 18 years or older, have intentionally lost at least 5% of body weight in the last 12 months, and still weigh at least 5% less than they did previously.

What does the study involve?
After consent has been given, measurements will be taken which include weight, hip/waist circumference and body fat measurements, and an assessment of the level of physical activity. Questionnaires will also be completed. Participants will then be randomly selected to receive either the new approach, which includes a personal support session with a weight loss maintenance expert, or a less intense means of support in the form of a quarterly newsletter. The new approach has been developed by using digital scales and mobile phones that can access the internet. This approach can be tailored to each individual to help maintain weight loss. Information will be collected from participants which will help the team understand any changes in behaviour around maintaining weight loss. Questionnaires will be completed by participants and the level of physical activity will be assessed. Participants are in the study for a total of 12 months, but the new approach or newsletter will administered for the first 6 months of that time period only. At 6 months after study entry, participants will be sent a package of questionnaires which are to be completed and posted back to the team. At 12 months, participants will meet with a Research Team member again and the baseline measurements will be repeated.
Participants receiving the new approach will be asked to weigh themselves daily (at a regular, convenient time) on the scales provided; those receiving the less intense support will also be given scales. If participants forget to weigh themselves on more than one occasion, they will be

prompted to do so by text message. Weight measurements will be received by a central computer at Newcastle University, which will trigger the automatic delivery of messages individually tailored to the participant. Participants receiving the new approach will be asked to attend a personal support session to discuss weight maintenance plans, set goals and evaluate physical activity and food intake. Based on the goals set in this session, participants will receive a weekly text-message link to a small set of electronic weekly 'diary' questions about physical activity and eating goals. Participants who regain weight will be supported by information sent by text message, and a team member will also be available to speak with participants on the phone to give extra support.

What are the possible benefits and risks of taking part?
Participants may not benefit directly, although there may be benefit from some assistance with weight loss maintenance efforts. In addition, participants will have access to weight loss maintenance support, and the use of state of the art equipment. Participation will also help the team to find out how useful the approach is in helping participants to maintain weight loss and may be beneficial to those in the future. There are no physical risks in taking part in the study, although participants may not like the volume or type of text messages received, although these will be kept to a minimum.

Where is the study run from?
The research is organised by Dr Falko Sniehotta (Chief Investigator) and his team of staff in the Institute of Health and Society at Newcastle University.

When is the study starting and how long is it expected to run for?
March 2014 to June 2015.

Who is funding the study?
The research has been funded by a grant from the Medical Research Council as part of the National Prevention Research Initiative. The study is sponsored by Public Health England.

Who is the main contact?
Miss Jane Barnes
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Contact information

Type(s)
Scientific

Contact name
Dr Falko Sniehotta

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16355

Study information

Scientific Title
A randomised, controlled trial with internal pilot of a weight loss maintenance intervention for obese adults after clinically significant weight loss

Acronym
NU:LEVEL

Study objectives
This is a randomised, controlled trial of a scalable, digital weight loss maintenance intervention to recruit participants from the community, who have lost at least 5% of body weight in the last 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Derby, 06/02/2014, ref: 14/EM/0069

Study design
Randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Participants will be randomised to receive either the new intervention or to receive a quarterly newsletter. Weight will be recorded daily (scales provided to participants) which are able to send weight data to a central server. Daily support will be given to those who receive the new intervention delivered as a combination of automated messages in response to weighing data or weekly questionnaires, delivered as text messages or mobile web content (text message with internet link), text messages generated by the intervention team and individual telephone calls. Full intervention is provided for 6 months. After six months, only the fully automatised components will be continued until the end of the study. Participants are followed up at 12 months. Economic and Psychological data will be collected at the beginning and end of the participant's involvement in the study.

Weight monitoring system, remote weight monitoring scales to record daily weight of participants; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Power analysis and sample considerations: In order to detect a 2.5kg difference between the groups at 12 months, given a Type 1 error rate of 5% and assuming a standard deviation of weight gain of 6kg with 90% statistical power, two groups of 122 participants providing data on the primary outcome will be required; assuming a rate of 15% loss to follow-up. A total sample size of 288 participants recruited and randomised will be required.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight change (in kg) from baseline at 12 months post randomisation

Secondary outcome measures
Measures will be taken at baseline (in addition to service use, socioeconomic and demographic variables

Overall study start date
24/03/2014

Completion date
01/06/2015

Eligibility

Key inclusion criteria

1. Providing written informed consent for study participation prior to any study specific procedures
2. Aged 18 years or older (no upper limit)
3. Initial Body Mass Index (prior to weight loss) of 30 or higher (28 or higher for individuals of South Asian descent, i.e. with both parents of Indian, Sri Lankan, Pakistani or Bangladeshi origin or a combination thereof)
4. Written verification of at least 5% of weight lost in the last 12 months by a physician, weight loss counsellor or friend
5. Access to a mobile feature phone or smart phone with internet access to receive reminder messages regarding weight recordings, feedback and intervention assessments
6. Ability to use a standing scale for weight measurements
7. Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 288; UK Sample Size: 288

Total final enrolment
288

Key exclusion criteria
1. Previous participation in pilots of this study
2. Inability to give informed consent
3. Individuals who have lost weight due to illness or surgical procedures, including bariatric procedures
4. Women who are pregnant or planning to become pregnant in the next year
5. Mothers who are breastfeeding
6. Current involvement in other intervention studies
7. Inability to understand written material or telephone conversations in English
8. Diagnosis of anorexia nervosa, bulimia nervosa or purging disorder, or screen positive for symptoms of any of these disorders eating at baseline
9. Diagnosis of any condition which may interfere with increasing mild to moderate physical activities such as walking. Baseline weight of over 175 kg (due to the measurement range of the scales)
10. Inability to use mobile phone technology
11. Travel; i.e. moving out of the area, long-term travel abroad or out of the area

Date of first enrolment
24/03/2014

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4AX

Sponsor information

Organisation
Public Health England (PHE) (UK)

Sponsor details
Respiratory Diseases Department
Centre for Infectious Disease Surveillance and Control (CIDSC)
61 Colindale Avenue
London
United Kingdom
NW9 5EQ

Sponsor type
Government

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC); Grant Codes: MR/J000477/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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	22/09/2015		Yes	No
Results article	results	07/05/2019	08/05/2019	Yes	No
HRA research summary			28/06/2023	No	No