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Evaluation of an internet-based weight loss intervention

Submission date
25/10/2012

Recruitment status
No longer recruiting

Registration date
26/10/2012

Overall study status
Completed

Last Edited
29/03/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity has become a major public health concern with the situation now being referred to as an obesity epidemic. Evidence suggests that traditional primary care treatments (one to one consultations with dieticians or practice nurses) are costly, ineffective and present high attrition rates. These findings suggest that a change in current primary care approaches is required. Therefore research is needed to investigate alternative methods in relation to obesity. This study aims to examine the feasibility and acceptability of using the internet as a method of providing weight management in the NHS.

Who can participate?
The two population groups that will be targeted are men with diabetes and post-partum women with a body mass index (BMI) >30 kg/m2 and <40kg/m2.

What does the study involve?
The web based intervention will deliver consultations, through dietitians and exercise experts, to participants identified as obese via a website (after an initial face to face consultation). The website will also allow participants to enter food intake, physical activity and interact (via messages) with other users. This internet intervention will be compared with a group who will receive usual care through the NHS/GP practice. Comparisons between the internet and usual care groups will be made to identify how acceptable and feasible the intervention is to the participants.

What are the possible benefits and risks of participating?
Participants may lose weight during the course of the programme. There is a possible inconvenience of giving up time to take part in data collection during the course of the programme.

Where is the study run from?
Participants will be recruited from GP Practices within the catchment area of County Durham and Darlington NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The study is now starting the recruitment stage (November), which will be open to participants for the next 5 months (end of March), and then participants will be required to take part in the project for 12 months.

Who is funding the study?
County Durham and Darlington NHS Foundation Trust (UK)

Who is the main contact?
Anna Sherrington
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13414

Study information

Scientific Title
Evaluation of an internet-based weight loss intervention: a randomised trial

Study objectives
Obesity has become a major public health concern. Evidence suggests that traditional primary care treatments are costly, ineffective and report high attrition rates. These findings suggest that a change in current primary care approaches is required. Therefore research is needed to investigate alternative methods for weight loss. This study is a pilot randomised controlled trial

that aims to examine using the internet as a method of providing weight management in the NHS.

Target groups for the study are men with diabetes and post partum women. Both these groups have been shown to have low attendance rates for in person consultations. The web based intervention will deliver dietitian and exercise expert consultations to participants diagnosed as obese (Body Mass Index greater than or equal 30 and less than 40 kg/m2) via a website (after an initial face to face consultation). This internet intervention will be compared with a group who will receive usual care (consisting of either no specific treatment or face to face dietitian or practice nurse consultation). Comparisons between the internet and face to face groups will be made in relation to recruitment, retention, attrition and adherence rates to identify how acceptable and feasible the intervention is to the participants.

Participants will be recruited from GP Practices within the catchment area of County Durham and Darlington NHS Foundation Trust (collaborators on the project). The project will take a mixed method approach with outcomes such as weight being recorded, as well as a qualitative study of participants and stakeholders views. The participants will be required to be in the study for a period of twelve months. Participants randomised to the intervention arm will be asked to input daily food intakes and physical activity data, receive feedback from the dietitian and may take part in an interview.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Central Research Ethics Proportionate Review Sub Committee, First MREC approval date 09/08/2012, ref: 12/EE/0361

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Obesity

Interventions

Participants randomised to the internet based weight loss intervention will meet with a dietitian once face to face. After the initial meeting participants will only receive guidance via a website through web based messages. Exercise experts will also give consultations during the 12 month intervention.

Baseline, 3 months and 12 months data collection will be taken. Participants will be reminded to wear the accelerometers for 4-7 days before there next measurement date.

Intervention Type
Behavioural

Primary outcome measure
Participant Involvement (recruitment, attrition, retention) at baseline, 3 months and 12 months

Secondary outcome measures
1. 24 hour diet recall at baseline, 3 months and 12 months
2. Acceptability Interviews between 6 and 12 months
3. Anthropometric measures (weight, body fat percentage, waist circumference and BMI) at baseline, 3 months and 12 months
4. Predictors of behaviour change at baseline, 3 months and 12 months
5. Quality of life questionnaire at baseline, 3 months and 12 months

Overall study start date
22/10/2012

Completion date
01/04/2014

Eligibility

Key inclusion criteria
Two target groups:
1.Women who have had a baby (from 3 months up to 2 years after childbirth) and, who currently have a body mass index (BMI) >≈30 and <40 kg/m2. Women should have previously had a BMI >≈30 and <40 kg/m2 before pregnancy.
2. The other target group are men who have been diagnosed with type 2 diabetes and have a BMI >≈30 and <40 kg/m2.
3. Participants must have access to the internet (this can be in any location [home, office, public location] or on any device [desktop computer, laptop or mobile phone])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Patients over BMI 40 kg/m2. When a patient reaches a BMI 40kg/m2 lifestyle modification may no longer be appropriate and bariatric surgery may be recommended (National Institute for Health and Clinical Excellence, 2006), making it unsuitable for them to take part in the study.
2. Patients unable to access the internet
3. Patients unable to give written informed consent in English. These patients would be excluded as they would be unable to randomise to the internet intervention which is only available in English. The resources are not available to use a translator in this study or produce the web-based resources in other languages.
4. Patients identified by their GP as having a contraindication making the weight loss intervention inappropriate to recommend
5. Patients who are currently pregnant will be excluded from the study

Date of first enrolment
22/10/2012

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Baddily Clarke Building
Newcastle upon Tyne
United Kingdom
NE2 4AX

Sponsor information

Organisation
County Durham and Darlington NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03vamsh08

Funder(s)

Funder type
Research organisation

Funder Name
UK Clinical Research Collaboration (UK)

Results and Publications

Publication and dissemination plan
A study results paper will be submitted for publication by the end of 2016.

Intention to publish date
31/12/2016

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	27/03/2018		Yes	No