ISRCTN21244703 https://doi.org/10.1186/ISRCTN21244703

Positive Online Weight Reduction Study (POWeR2)

Submission date
16/03/2012

Recruitment status
No longer recruiting

Registration date
16/03/2012

Overall study status
Completed

Last Edited
27/01/2017

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
Obesity is a growing major threat to public health, but there is limited evidence for interventions that could easily be applied, with relatively little training, in primary care, where most obesity is managed. The internet could potentially provide an ideal way to give patients interactive advice based on their personal situation and progress, with the support of a nurse to oversee, encourage, advise patients as necessary. Among obese patients in primary care, we aim to estimate the effectiveness and cost-effectiveness of a) an internet based behavioural intervention with face to face support as needed and b) an internet behavioural intervention with minimal face to face support.

Who can participate?
If you are registered with one of the recruiting GP practices you may be written to, or your general practitioner (GP) or Practice Nurse may ask you if you would like to take part if you attend an appointment with them. You must have a Body Mass Index (BMI) of over 30 or 28 with high blood pressure or high cholesterol, to take part in the study.

What does the study involve?
In order to take part in this study you must have regular access to the internet at home, at work or possibly a public place such as a library. First of all you will attend a screening appointment with your practice nurse, where some measurements will be made and a blood sample taken. All patients in the study will have these same measurements made again 6 months and 12 months after this first appointment. There are three possible groups that you could be randomly allocated to:
Web Intervention with nurse support- if in this group you will use the POWeR2 website and also visit the practice nurse at 2 weeks, 6 weeks and 3 months after the first visit. You may have four extra visits if needed.
Web intervention with minimal nurse support if in this group you will use the POWeR2 website and have a brief visit with the practice nurse at 2 weeks and then have three online contacts from the nurse at 1, 2, and 3 months and up to 2 telephone calls.
Very brief advice and follow up if you are in this group the practice nurse will give you some brief advice about a healthy diet and physical activity. You will only visit the practice nurse at 6 and 12 months for weight measurement and a blood sample.

What are the possible benefits and risks of participating?
By taking part in this study there is a chance that you will lose weight. Making gradual changes to your diet or physical activity levels should not present any risks to you, although if you are diabetic you may need to alter your medications, your practice nurse will advise you if this is necessary. If you have any questions or concerns about your health or your medications while on the programme, the practice nurse will be available to advise you.

Where is the study run from?
The study is co-ordinated from the Dept. of Primary Medical Care, University of Southampton. Patients will be recruited from about 44 practices within Southern England.

When is the study starting and how long is it expected to run for?
The study will begin recruiting patients from February 2013, for 6 months. Patients recruited into the study will be in the study for 12 months.

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment Programme (UK)

Who is the main contact?
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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
HTA 09/12/19, 11939

Study information

Scientific Title
Positive Online Weight Reduction Study (POWeR2): a randomised controlled trial

Acronym
POWeR2

Study objectives
Among obese patients in primary care, to estimate the effectiveness and cost-effectiveness of
1. An internet based behavioural intervention with face to face support as needed and
2. An internet behavioural intervention with minimal face to face support

This is the resulting randomised trial from the pilot study registered under ISRCTN31685626.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Southampton B First MREC, 19/12/2011, ref: 11/SC/0455

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

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

Interventions
1. Control, very brief advice and follow up
2. Web and minimal nurse support, minimal face to face contact with nurse;
3. Web and nurse support, Web intervention with intensive nurse support
Follow-up length: 12 month(s); study entry: single randomisation only

Intervention Type

Behavioural

Primary outcome measure
Outcome measure (08/12/2015):
1. The average weight reduction over 12 months, measured blind to randomisation group using Tanita digital scales measured at baseline, 6, and 12 months.
2. A secondary analysis of weight is the number of individuals who maintain a clinically important 5% weight reduction measured using Tanita digital scales measured at 6 and 12 months.

Original outcome measure:
Weight measured at baseline, 6, and 12 months

Secondary outcome measures
1. Food and drink consumption measured using Food Frequency Questionnaires at baseline, 6, and 12 months
2. Physical activity measured using the Godin physical activity questionnaire at baseline, 6, and 12 months
3. Waist circumference in cm measured by tape measure at baseline, 6, and 12 months
4. Blood pressure (BP) in mm Hg measured using a validated Omron device at baseline, 6, and 12 months
5. Serum Glucose and HbA1c in mmol/l measured at baseline, 6, and 12 months
6. Serum lipids (cholesterol/HDL/LDL/triglyceride) in mmol/l measured at baseline, 6, and 12 months
7. Body composition measured using Tanita digital scales to document percentage body fat measured at baseline, 6, and 12 months
8. Serum Liver function tests (AST,ALT,GGT) measured in IU/l to monitor non-alcoholic fatty liver disease at baseline, 6, and 12 months
9. Serum Ferritin in ug/l measured at 12 months
10.A modified version of the Patient Enablement Instrument measured by self-report questionnaire at baseline and 12 months
11. EQ-5D for Health economic analyses measured by self-report questionnaire at baseline, 6, and 12 months.
12. Health service resource use measured from documentation in the medical records in the 12 months prior to randomisation and the 12 months following
13. Reported activities undertaken to lose weight measured by self-report questionnaire at 12 months

Overall study start date
01/02/2013

Completion date
02/09/2013

Eligibility

Key inclusion criteria
Adult male and female patients with a body mass index (BMI) over 30 (or 28 with hypertension or or hypercholesterolaemia)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 700; UK Sample Size: 700; Description: 15-20 patients per practice from 44 practices

Key exclusion criteria
1. Current mental health problems
2. Very ill or unable to change diet
3. Pregnancy or breastfeeding
4. Perceived inability to walk 100 metres

Date of first enrolment
01/02/2013

Date of final enrolment
02/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Head of Research Governance
Room 4055/Building 37
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SO30 3JB

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (ref: 09/12/19)

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

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?

Results article	results	01/10/2016	Yes	No
Results article	results	01/01/2017	Yes	No