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Positive Online Weight Reduction Study (POWeR)

Submission date	Recruitment status
02/02/2011	No longer recruiting
Registration date	**Overall study status**
02/02/2011	Completed
Last Edited	**Condition category**
03/06/2014	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9575

Study information

Scientific Title
Positive Online Weight Reduction Study (POWeR): a randomised multicentre interventional prevention/process of care trial

Acronym
POWeR

Study objectives
Obesity is a major and rapidly rising public health threat. Recent NICE guidelines provide recommendations to implement lifestyle changes (diet and exercise) supported by behavioural techniques. Unfortunately, an average practice will have more than 1000 patients with obesity, and most practice staff have neither the training nor the time to implement intensive obesity management programmes based on 1:1 counselling, or even group counselling, to cope with such numbers. The problem will become worse as the obesity epidemic progresses. By providing an intervention which requires fewer resources for training and for intervention this study will allow a much greater group of patients to benefit both locally and nationally.

We have developed written behavioural manuals for both patient and practitioner. This study will create a less resource intensive intervention to support behavioural change by converting these materials into web format, taking advantage of a grant to our group which supports the development of generic web programming for behavioural interventions. After materials have been converted to web format, and are acceptable to patients and practitioners, we will then explore the impact of different levels of nurse support required to achieve effective weight change.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IOW, Portsmouth and SE Hampshire Research Ethics Committee approved on the 13th September 2010 (ref: 10/H0501/46)

Study design
Randomised multicentre interventional prevention/process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

Not available in web format, please use the contact details below 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
Phase 1:
Study 1: In-depth interviews will be carried out with up to 30 patients from 3 - 4 GP practices to elicit views of the intervention materials (including reactions to content and usability).

Study 2: Up to 5 focus groups will be held for health professionals with practice nurses and GPs from 10 - 20 practices. Participants will be invited to use the training materials and patient website prior to taking part in the focus group to stimulate discussion of the issues relating to content, format and feasibility.

Phase 2:
Pilot RCT: Patients will be offered:
1. Web access and email support
2. Minimal face to face support
3. Intensive face to face visits
4. Normal care

GP records will be reviewed for cost-effectiveness.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight, measured at baseline, one month and end of study (6 months)

Secondary outcome measures
1. EQ5D, measured at baseline, one month and 6 months
2. Food Frequency Questionnaire, measured at baseline, one month and 6 months
3. Godin Leisure Time Physical Activity Questionnaire, measured at baseline, one month and 6 months
4. GP record review, measured at the end of the study
5. Physical measurements, measured at baseline, one month and 6 months

Overall study start date
01/12/2010

Completion date
31/05/2013

Eligibility

Key inclusion criteria

1. Patients aged over 18 years, either gender
2. Body mass index (BMI) greater than or equal to 30 (or 28 with hypertension or hypercholesterolaemia) documented in the GP case records

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Planned sample size: 265

Key exclusion criteria
1. Current major mental problems (difficulty completing outcomes)
2. Very ill/unable to change diet (e.g. severe left ventricular failure [LVF])
3. Pregnancy/breast feeding
4. Perceived inability to walk 100 metres (i.e. physical activity difficult)

Date of first enrolment
01/12/2010

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Medical Care
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Primary Medical Care
Aldermoor Health Centre
Aldermoor Close
Southampton
England
United Kingdom
SO16 5ST

Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0808-17077)

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	21/05/2014	Yes	No