# Positive Online Weight Reduction Study (POWeR)

Submission date	Recruitment status	Prospectively registered
02/02/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/02/2011	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
03/06/2014	Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mrs Susan Broomfield

#### Contact details

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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