# National Service Framework Targets for Mental Health and Coronary Heart Disease (CHD): Obesity as an Eating Disorder - Weight Management Programme

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
07/09/2015	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Kath Sharman

#### Contact details

The Manor Clinic 18 Ridgeway Road Sheffield United Kingdom S12 2ST

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0071121999

# Study information

#### Scientific Title

National Service Framework Targets for Mental Health and Coronary Heart Disease (CHD): Obesity as an Eating Disorder - Weight Management Programme

#### **Study objectives**

Can a combined holistic therapeutic approach to weight loss achieve weight reduction and empower clients to promote healthier lifestyles physiologically, psychologically and sociologically?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

GP practice

#### Study type(s)

Quality of life

#### 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

Nutritional, Metabolic, Endocrine: Obesity

#### **Interventions**

Qualitative and quantitative methods will be used:

Questionnaires will be the main quantitative measure.

Qualitative data will be collected from 12 participants using semi-structured interviews and narrative approaches, to encapsulate the participants perspective of the strengths and limitations of the study (What helped and what hindered their process?).

Focus Groups will be held monthly with a representative of the Primary Healthcare Team, Counsellors, GPs, patients and therapists involved.

#### Intervention Type

#### Phase

**Not Specified** 

#### Primary outcome measure

Changes will be assessed at varied time points during the study period. In view of the multiple aims of the project, a range of outcome measures will be utilised. These have been selected for their relevance to this particular client group, sensitivity to change, psychometric properties and clinical (as well as research) utility. The formal outcome measures will be substantiated and supplemented by descriptions of the services offered and the development of the service.

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

02/10/2002

#### Completion date

01/10/2003

# Eligibility

#### Key inclusion criteria

There are 33 practices within the South East Primary Care Trust (SE PCT). GPs will be asked to recruit a total of 280 participants (8-9 patients per practice)

- 1. Identified as 'obese patient' (Obesity is most commonly defined by clinicians in terms of body mass index (BMI). A desirable BMI is considered to be in the region of 20 to 25. Anything above this is defined as 'obese')
- 2. BMI >30
- 3. Gender, both males or females accepted
- 4. Age over 16 years, no maximum
- 5. Commitment to the research process for 18 months
- 6. May have mild/moderate chronic illness, diabetes, CHD, irritable bowel syndrome (IBS), back pain
- 7. May have mild/moderate psychological disorders including anxiety and depression

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

16 Years

#### Sex

Both

## Target number of participants

#### Key exclusion criteria

- 1. Pregnancy
- 2. Psychiatric illness, psychosis, schizophrenia
- 3. Patients who are already taking weight reduction medication
- 4. Metabolic dysfunction, ie thyroid problems, hormonal dysfunction

#### Date of first enrolment

02/10/2002

#### Date of final enrolment

01/10/2003

## Locations

#### Countries of recruitment

England

United Kingdom

## Study participating centre

The Manor Clinic

Sheffield United Kingdom S12 2ST

# Sponsor information

#### Organisation

Department of Health (UK)

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

#### Website

http://www.doh.gov.uk

# Funder(s)

## Funder type

Research council

#### Funder Name

Sheffield Health and Social Research Consortium (UK)

# **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