

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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

Other

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 Years

Sex

All

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

United Kingdom

England

Study participating centre

The Manor Clinic

Sheffield

United Kingdom

S12 2ST

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Research council

Funder Name

Sheffield Health and Social Research Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration