ISRCTN12343040 https://doi.org/10.1186/ISRCTN12343040

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 [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 07/09/2015	**Condition category** Nutritional, Metabolic, Endocrine	

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
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

Other

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