

Evaluation of weight reduction programmes in the "Lighten Up" service in South Birmingham primary care trust (PCT)

Submission date 19/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/03/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/12/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Version 4

Study information

Scientific Title

Evaluation of weight reduction programmes in the "Lighten Up" service in South Birmingham primary care trust (PCT): a randomised controlled trial

Acronym

Lighten Up

Study objectives

The weight loss programmes (Weight Watchers®, Slimming World, Rosemary Conley, NHS Size Down, pharmacy and general practice provision) will each achieve significantly greater weight loss at 3 months follow-up than the comparison group of exercise at a leisure centre. There will be no differences between the weight loss services in weight loss at 3 months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Birmingham Research Ethics Committee, approved on 19/12/2008 (ref: 08/H1207/331)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

Obesity

Interventions

Participants will be allocated to one of the following eight arms:

1. Commercial weight loss programme: Weight Watchers
2. Commercial weight loss programme: Slimming World

3. Commercial weight loss programme: Rosemary Conley
4. Size Down (NHS community-based group programme)
5. Pharmacy-led obesity services
6. General practice service
7. Choice of intervention (1 to 6 above)
8. Comparator: Exercise advice + membership to leisure centre (Participants in this group will not be provided with any specific exercise programme)

Total duration of interventions: 12 weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Weight at 3 months follow-up

Secondary outcome measures

1. Weight loss at 1 year
2. Self-reported physical activity using the International Physical Activity Questionnaire-Short version (IPAQ-Short) at 3 and 12 months
3. Percentage weight loss at 3 months and 1 year

Overall study start date

26/01/2009

Completion date

03/01/2011

Eligibility

Key inclusion criteria

1. Aged at least 18 years, both males and females
2. Body mass index greater than or equal to 30 (based on data recorded via NHS Quality and Outcomes Framework [QoF])
3. Identified by GP as medically competent to enter the programme evaluation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

740

Key exclusion criteria

1. Unable to understand English
2. Women who are known to be pregnant
3. Not willing to be randomised

Date of first enrolment

26/01/2009

Date of final enrolment

03/01/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Unit of Public Health, Epidemiology and Biostatistics

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

NHS South Birmingham (UK)

Sponsor details

c/o Dr Jim O'Brien

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Kings Norton

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United Kingdom

B38 8SS

Sponsor type

Government

Website

<http://www.southbirminghampct.nhs.uk/>

Funder(s)

Funder type

Government

Funder Name

NHS South Birmingham (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/11/2011		Yes	No