

'Shape Up-LD': Piloting a manualised weight management programme for overweight and obese persons with mild-moderate learning disabilities

Submission date 31/05/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/03/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Obese people weigh more than is healthy for them. Losing weight can make a person healthier, feel better about themselves and improve quality of life. Studies show that being obese is more common in people with learning disabilities (LD) compared with the general population. However, most programmes designed to help people lose weight are not designed for people with LD. Working with the charity Weight Concern we developed a lifestyle programme (Shape Up) to help people lose weight. Shape Up is used throughout the UK and has now been adapted by learning disability (LD) specialists so that it can help people with LD. A small group tried out 'Shape Up-LD' and found it helped them lose weight and was enjoyable. The aim of this study is to see if we can design a bigger project to measure how well 'Shape Up-LD' works.

Who can participate?

People with mild to moderate LD who are overweight (and their carers).

What does the study involve?

Participants will be randomly allocated either to take part in the Shape Up-LD programme or to receive usual care.

What are the possible benefits and risks of participating?

'Shape Up-LD' may help participants to lose weight. If the results of this study are positive we will apply for funding for a larger study. We will change the Shape Up-LD materials in response to our findings, making them available to services. This study is important because evidence-based weight management services designed for people with LD are not currently available, and being obese can have a negative impact on health and quality of life.

Where is the study run from?

University College London (UK)

When is the study starting and how long is it expected to run for?
The study started in June 2012 and will run until November 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Rebecca Beeken
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11973

Study information

Scientific Title
'Shape Up-LD': A randomised pilot study of a manualised weight management programme for overweight and obese persons with mild-moderate learning disabilities

Acronym
Shape Up-LD

Study objectives

Shape Up, a weight management programme specifically designed for adults with learning disabilities (LD) is feasible and a more effective than usual care in helping overweight and obese service users with mild-moderate LD reduce body weight.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South West- Cornwall & Plymouth, Proportionate Review Sub-Committee; First MREC approval date 05/04/2012, ref: 12/SW/0089

Study design

Randomised; Interventional; Design type: Treatment

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 to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network, Metabolic and Endocrine; Subtopic: Learning difficulties development disorders, Metabolic and Endocrine (all Subtopics); Disease: Learning difficulties, Metabolic & Endocrine (not diabetes)

Interventions

Participants are randomised to Shape Up-LD or usual care.

Shape Up-LD: A LD tailored version of Shape-Up; a manualised healthy lifestyle programme that helps service users learn new behaviours to manage their weight. This population-specific version of Shape Up was developed through a partnership between local users with LD, specialist dietitians and other LD professionals within the PCT, and a psychologist and a dietitian from Weight Concern. The original Shape Up programme ran for 8 weeks, however based on field testing and prior experience of interventions in LD; the programme has been extended to 12 weeks. Follow Up Length: 6 month(s)

Intervention Type

Behavioural

Primary outcome measure

Feasibility outcomes at 12 weeks

Secondary outcome measures

1. Attitudes to healthy behaviours at baseline, 12 weeks, 6 months
2. Blood pressure at baseline, 12 weeks, 6 months
3. Body Fat at baseline, 12 weeks, 6 months
4. Costs at baseline, 12 weeks
5. Knowledge & behaviour change at baseline, 12 weeks, 6 months
6. Mental health at baseline, 12 weeks, 6 months
7. Quality of life at baseline, 12 weeks, 6 months
8. Self esteem at baseline, 12 weeks, 6 months
9. Waist circumference at baseline, 12 weeks, 6 months
10. Weight at baseline, 12 weeks, 6 months

Overall study start date

01/06/2012

Completion date

01/11/2014

Eligibility

Key inclusion criteria

1. LD in mild to moderate range (assessed by a scoring system for Ability & Development scale (Cooper, 1997)
2. Overweight, Body Mass Index (BMI>25)
3. Adults, male and female, upper age limit 100 years, lower age limit 18 years
4. Living in the community
5. If receiving regular care, then the presence of a carer (paid or informal) who is willing to participate in the intervention
6. Ability to attend the weekly Shape-Up sessions

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria

1. Acute mental illness requiring hospitalisation
2. Severe LD
3. Substance misuse

- 4. A confirmed diagnosis of Prader-Willi syndrome
- 5. Not living in the community

Date of first enrolment

01/06/2012

Date of final enrolment

01/11/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

WC1E 7HB

Sponsor information

Organisation

Camden and Islington NHS Foundation Trust (UK)

Sponsor details

R&D Room 3-17

3rd Floor West Wing

St Pancras Hospital St Pancras Way

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United Kingdom

NW1 OPE

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03ekq2173>

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Protocol article	protocol	12/03/2013		Yes	No
Results article	results	01/02/2019		Yes	No