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WEight Loss in Learning Disabilities and Obesity (WELLDO): A weight loss intervention for adults with learning disabilities and obesity

Submission date
30/01/2014

Recruitment status
No longer recruiting

Registration date
12/03/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Individuals with learning disabilities experience health inequalities and poorer access to evidence-based health care than the general population. Adults with learning disabilities are at increased risk of obesity but there is little evidence to inform weight management interventions in clinical services. This study aims to test the TAKE 5 multi-component weight management intervention. This study is based on the results from a feasibility study that found that TAKE 5 was acceptable to adults with learning disabilities and carers, and reported significant positive changes in risk factors associated with chronic disease including body weight, waist circumference and physical activity levels.

Who can participate?
Men and women with learning disabilities and obesity. All the participants will be 18 years of age and above and have a body mass index greater than or equal to 30 kg/m2.

What does the study involve?
Individuals who consent to participate in this study will be randomly allocated to one of two groups. One group will take part in the TAKE 5 intervention and the other group will receive a healthy lifestyle intervention (Waist Winners Too) in use in NHS Greater Glasgow and Clyde. We will examine whether there is a change in participants body weight, physical activity and quality of life over a 12-month period.

What are the possible benefits and risks of participating?
The study aims to support participants to lose 5% of their initial body weight. Studies have shown that this level of weight loss has the following potential benefits: 50% reduction in risk of diabetes, cholesterol is reduced by 10%, blood pressure is reduced by 10/20 mmHg, reduction in risk of chronic disease including ischaemic heart disease, stroke and certain cancers, increased life expectancy by 12-18 months and improved well-being and quality of life. No major risks are expected from taking part in the study, based on the findings from an initial study trying out the interventions.

Where is the study run from?
The study has been set up by the University of Glasgow (UK).

When is the study starting and how long is it expected to run for?
June 2013 to September 2016.

Who is funding the study?
The study is funded by the Equally Well Fund by the Scottish Government, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A single-blind, randomised controlled trial of a weight loss intervention for adults with learning disabilities and obesity

Acronym
WELLDO

Study objectives
To determine the feasibility of a full-scale clinical trial of the TAKE 5 multi-component weight management program in comparison with a comparator intervention.

Secondary objectives:
1. Can adults with learning disabilities and obesity be recruited to a randomised study of the TAKE 5 intervention, versus a comparator healthy lifestyles intervention, and what attrition rates are observed at six and 12 months post-randomisation?
2. What are the distributions of study outcomes in the two intervention groups at the end of the intervention period?
3. Are the outcomes in the two groups consistent with the interventions having a clinically important effect on study outcomes, and/or being cost-effective?
4. Would it be feasible to carry out a full-scale clinical trial to determine clinical outcomes and cost-benefit of the TAKE 5 intervention, what difficulties would need to be overcome and what sample size would be required?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 16/12/2013, ref: 13/SS/0229

Study design
Single centre single blind randomised controlled design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Obesity

Interventions
After collection of baseline data, participants will be randomly allocated to one of the two study groups: TAKE 5 or Waist Winners Too. Individuals recruited may live together and/or be supported by the same family or paid carers. These factors would make it difficult to randomise people living together, for example, to different arms of the study. Cluster randomisation will therefore be used.

TAKE 5 and Waist Winners Too have both been developed and piloted in Glasgow. Both programs have both been shown to be acceptable to adults with learning disabilities and shown to be effective in helping them to lose weight.

Both interventions are 12 months in duration and consist of two phases:
Phase one an initial weight loss phase of approximately six months.
Phase two a weight maintenance phase of six months.

TAKE 5
TAKE 5 is an individual intervention, involving family, or paid carers, to support adults with a learning disability where appropriate.

The participant, supported by a carer where appropriate, will be offered nine sessions, over a six month period, centred on: Dietary change to create a daily negative energy balance of 600 kilocalories/day; gradually increasing physical activity levels to the recommended 30 minutes of accumulated physical activity, at least five days per week; reducing sedentary behaviours to less than four hours per day on average. To achieve these aims behavioural principles are incorporated into the intervention including motivational interviewing, self-monitoring, stimulus control and goal setting.

The second phase of the intervention, the weight maintenance phase is designed to support participants to develop new knowledge and skills relevant to weight maintenance, maintain phase one weight loss and to prevent weight regain. Phase two comprises six sessions, taking place once a month and is based on the Glasgow and Clyde Weight Management Service intervention. These sessions will focus on: maintaining a healthy balanced diet and general information on healthy eating as recommended by the Food Standards Agency e.g. food labeling, healthy snacks, eating breakfast regularly; behavioural methods that will support participants to maintain lifestyle changes e.g. problem solving techniques, lapse and relapse prevention mechanisms, recognition of high risk situations, encouragement of carers for peer and family support; regular self-monitoring of body weight and food intake; reducing sedentary behaviour and increasing time spent active.

Waist Winners Too:
Waist Winners Too is a healthy lifestyle education program. The participant, supported by a carer, will be offered the same number of face-to-face sessions (15) as in TAKE 5. The first weight loss phase is centred on: eating a balanced healthy diet based on the Traffic Light System; public health recommendations on physical activity and sedentary behaviour, and information on alcohol and other drinks.

The second phase of the Waist Winners Too intervention, the weight maintenance phase is designed to support participants to ensure participants have retained knowledge gained during the weight loss intervention and support on-going monitoring of diet and weight. Participants will have an opportunity to ask questions about the healthy lifestyle information they have received and discuss positive changes they have been able to make, and barriers to change they have experienced.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Body weight is measured using data collected at baseline, 6 months post randomisation and 12 months post randomisation

Key secondary outcome(s))
1. Weight loss of 5% or more of initial body weight (Yes/No)
2. Change in BMI
3. Change in waist circumference
4. Change in percentage body fat
5. Mean percentage time per day spent engaged in moderate/vigorous intensity physical activity, measured by accelerometers

6. Mean percentage time per day spent engaged in light intensity physical activity, measured by accelerometers
7. Mean percentage time per day spent engaged in sedentary behaviour, measured by accelerometers
8. Quality of life as measured by the EQ-5D

Data will be collected at baseline, 6 months post randomisation and 12 months post randomisation.

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. A learning disability
2. Over 18 years old (there is no upper age limit)
3. Body mass index (BMI) greater than or equal to 30 kg/m2
4. Able to walk independently
5. Not currently on a prescribed or restricted diet e.g. for phenylketonuria or diabetes
6. No intentional weight loss over the previous 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals with genetic syndromes, Prader Willi syndrome, Cohen syndrome or Bardet- Biedl syndrome (need a specific program to support weight loss)
2. Currently taking part in another research study
3. Pregnant
4. Taking medication prescribed for the purpose of weight loss or over the counter medication designed for weight loss

Date of first enrolment
01/02/2014

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Institute of Health and Wellbeing
Glasgow
United Kingdom
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Scottish Government (UK) - Equally Well Fund

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	12/01/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes