ISRCTN50975609 https://doi.org/10.1186/ISRCTN50975609

A pilot study to inform future research into the use of ankle weights with adults who are learning disabled

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/02/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Melanie Chapman

Contact details
Research Associate
Quality, Research & Service Development Team
Manchester Learning Disability Partnership
Fenham
5 Moorfield Road
West Didsbury
Manchester
United Kingdom
M20 8UZ
+44 (0)161 438 1620
melanie.chapman@manchester.gov.uk

Additional identifiers

Protocol serial number
N0644185913

Study information

Scientific Title
A pilot study to inform future research into the use of ankle weights with adults who are learning disabled

Study objectives
1. There is a lack of research evaluating the use of ankle weights with adults who are learning disabled. Therefore there is a need for a pilot study to inform the sample size and methodology of future research in this area. The principal research objective is therefore to inform the power calculations and methodology of a future study to evaluate the use of ankle weights with adults who are learning disabled.
2. The study also aims to indicate whether the use of ankle weights leads to increased health benefits when used in a walking group. The health benefits to be measured are percentage body fat, Body Mass Index, waist circumference, cardiovascular function, and rate of perceived exertion (how hard someone feels they are working during exercise).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Obtained 26/07/06 from Tameside & Glossop LREC (Ref 06/Q1402/46).
Local research governance approval for Central Manchester PCT and South Manchester PCT via ReGrouP Obtained 04/09/06 (Ref RMG/06/080).

Study design
Pilot study with pretest-posttest control group design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Learning disorders

Interventions
Purpose: This is a pilot study intended to inform the power calculations and methodology of a larger study. Whilst the pilot may provide some indication of the impact of the use of ankle weights, a larger study would aim to determine whether the use of ankle weights leads to increased health benefits for adults who are learning disabled.

Design: Pretest-posttest control group design. One group receives treatment whilst the other does not. Participants are tested before and after the intervention (ie ankle weights). The amount of change indicates the effect of the intervention.

Hypotheses:
1. Participants wearing ankle weights will show a greater reduction in percentage body fat than those who do not wear ankle weights

2. Participants using the ankle weights will show more health improvements than those not using the ankle weights.

Participants: Members of a walking group who walk regularly as a group on a weekly basis. Walking group members who agree to take part will be assigned to two groups:

Condition 1: (N=5 maximum) will walk without ankle weights
Condition 2: (N=5 maximum) will use ankle weights when walking

Allocation to groups: Gender and initial percentage body fat are likely to impact on the change in percentage body fat over time. Therefore, before people are randomly allocated to groups, the effects of gender and baseline body fat will be controlled through matching. The random assignment will be carried out using SPSS by a researcher who has no knowledge of participants.

Those people who are not assigned to the ankle weights group will wear a Velcro ankle band.

Intervention:
The intervention group participants will wear ankle weights for six months. All participants will begin with a weight of 0.5 kg. Should an individuals Rate of Perceived Exertion score (see below) plateau (i.e. the same score over a two month period) the person will wear a weight of 1 kg. Should the Rate of Perceived Exertion score plateau again over a two month period the person will wear a weight of 1.5 kg. The maximum weight worn will be 1.5 kg.

Measures:
Baseline measurements will be taken before people are allocated to groups. These measures will include demographic information (Gender and age, medication, health conditions), and initial measures of the outcomes to be measured. A number of outcome measures will be taken to indicate changes in health risk (as indicated by overweight) and physical fitness.

Outcome measures will be taken at baseline (twice to ensure the reliability and stability of the baseline measures), then monthly for six months. A brief questionnaire will be used at these time points to ask participants who are wearing ankle weights how participants felt about walking whilst wearing weights (e.g. comfort of weights). In order to control for potential confounding variables participants will also be asked to complete an exercise diary at baseline outlining the type and duration of exercise usually taken over a week. At each data collection time point participants and carers will also be asked if there have been any changes in exercise taken, medication or a persons health that may impact on the outcomes being measured.

Data storage and analysis:
Data will be stored and analysed using the Statistical Package for the Social Sciences (SPSS, v12. 0, 2003). Data provided to the researcher will be anonymous and data will be stored on a password protected NHS computer network drive in accordance with the Data Protection Act.

Power calculations indicate that the number of people currently attending the walking group is too small to carry out meaningful statistical analysis between groups. Data analysis will include descriptive statistics to show (i) individual changes in percentage body fat over time, and (ii) the number and proportion of people for whom there is an improvement in percentage body fat and other health outcomes and the number and proportion for whom outcomes worsen.

Sharing of findings:
Findings from the study will be shared with service providers and commissioners. Verbal and accessible written feedback will be provided to participants on findings of study.

Involvement of research participants in the design of the research: people who attend the walking group have been asked for their feedback on the data collection forms and asked what they think about the research. This has led to descriptions of symptoms of physical exertion being developed and changes to the layout of the forms. The group members have been positive about the research idea.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome measure will be percentage body fat (i.e. the percentage of total body weight that is fat). Body fatness is associated with morbidity and mortality. Percentage body fat will be measured using Tanita body fat scales; these scales use bioelectrical impedance and have been demonstrated to be accurate at measuring percentage body fat (Ohno, Nishisaka, & Ikeda, 1998; Utter, Nieman, Ward, & Butterworth, 1999).

Key secondary outcome(s))
Additional outcome measures are:
Body Mass Index (BMI): is a measure of the degree of overweight, in relation to an individuals height (Height/weight2). BMI is a predictor of morbidity and mortality due to numerous chronic diseases and predicts more variance in health risk than does Waist Circumference alone (Janssen, Katzmarzyk, & Ross, 2004).

Waist circumference (WC): is a measure of abdominal obesity gained using a tape measure (Aronne & Segal, 2002). It relates closely to BMI yet is a simpler measure to obtain. It is the best indicator of changes in intra-abdominal fat during weight loss (Lean, Han, & Morrison, 1995). A higher WC measurement indicates higher health risk and the addition of waist circumference to BMI predicts a greater variance in health risk than does BMI alone (Janssen et al., 2004).

Cardiovascular function: Resting systolic and diastolic blood pressure and heart rate measurements will be taken at each time point using a sphignomanometer.

Rate of Perceived Exertion (RPE): Perceived Physical exertion is a measure of how hard someone feels they are working during exercise and should decrease as a persons fitness level improves (Borg, 1998). RPE will be measured using the OMNI Picture System of Perceived Exertion (Robertson, 2004). The OMNI walking to running scale will be used: this has a set of picture and verbal cues in conjunction with a numerical rating scale of 0 to 10 (with 0 being 'not tired at all' and 10 being 'very, very tired'). Research studies have established the validity and reliability of the scales (Robertson, 2004).
Participants will indicate how they feel on the walking scale (a copy of the scale is provided in the protocol Appendix). The physiotherapy technicians will make a judgement about how tiring those participants who have difficulty using the rating scale felt during the walk via physical signs of exertion (i.e. breathing, sweating, ease of talking) - a key has been developed to ensure consistency in how physical signs of exertion are interpreted by physiotherapy technicians.

Talk test: As the OMNI picture system has not been validated with learning disabled adults and some adults may not be able to indicate how they feel on the scales, the physiotherapy technicians will carry out an objective talk test with participants during the walk. Someone who

is active at a light intensity level should be able to sing whilst carrying out an activity. Someone who is active at a moderate intensity should be able to carry out a conversation comfortably while engaging in an activity. If a person is too tired or out of breath to carry on a conversation the activity is considered vigorous (Centers for Disease Control and Prevention, 2005).

Number of steps taken during the walking group walk will be measured. Participants will wear pedometers Yamax Digi-walker SW-200 pedometers (consistently rated in the top ten by independent research reviews (Cavill, 2005).

Completion date
04/05/2007

Eligibility

Key inclusion criteria
1. Participants will be learning disabled adults who attend a walking group
2. All participants will have had a health check to ensure there are no health reasons for not wearing ankle weights

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Person does not wish to take part
2. Person finds walking with weights problematic (eg due to balance, gait, fitness level, comfort, allergic reaction)

Date of first enrolment
04/09/2006

Date of final enrolment
04/05/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Research Associate
Manchester
United Kingdom
M20 8UZ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Greater Manchester Primary Care RM&G Partnership (ReGroup) - UK

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration