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# Embedding sustainable physical activities into the everyday lives of adults with intellectual disabilities

**Submission date**
26/03/2012

**Recruitment status**
No longer recruiting

**Registration date**
18/04/2012

**Overall study status**
Completed

**Last Edited**
07/10/2014

**Condition category**
Mental and Behavioural Disorders

[ ] 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
People with intellectual disability have a right to good health and a healthy lifestyle but they are less physically active than the general community. Without adequate physical activity they will continue to have poorer quality of life and higher risk of ill-health.
Time-limited (typically 12-week) structured physical activity programs produce short-term fitness, strength, and endurance benefits in adults with intellectual disability, but no study has reported on sustained improvements or long-term lifestyle change.
Exercise that is potentially highly sustainable is lifestyle physical activity, such as walking for transport. However, even adults with intellectual disability who are more active (e.g., via walking) may not carry out their physical activity with enough intensity for desired health benefits to be seen.
People with intellectual disability need personal support to organise and take part in exercise. There is a ready source of such support: the staff of disability service organisations that already provide daily (usually 24-hour) support to their clients. No research has focused on staff support of either low-moderate-intensity lifestyle physical activity programs or moderate-vigorous-intensity structured exercise training, and disability service staff do not currently have the skills to support such activity. Crucially, research on Active Support has shown that (a) appropriate personal support strongly increases participation in functional everyday activities by adults with intellectual disability, and (b) carers can be trained to provide it.
The aim of the study is to significantly improve the physical activity, fitness and well-being of adults with intellectual disability by increasing their everyday physical activity and exercise levels, in a manner that is sustainable long-term. This study will compare two approaches to disability staff support of physical activity (lifestyle approach and structured exercise training) with a control group that takes part in assessments only.

Who can participate?
Participants are ambulatory adults with intellectual disability between the ages of 18-55 years who complete a screening questionnaire and if necessary obtain medical clearance saying they can safely participate in the exercise program.
Participants are recruited through participating disability service agencies in Sydney, Australia.

To enrol, participants are given written information about the study, and then provide their written informed consent (or the consent of their guardian if they cannot consent for themselves).

What does the study involve?
All participants will do some tests. The same tests will be done at 3 different times: 1) at the start of the study, 2) after 3 months, and 3) again 6 months after that. These tests are physical tests (physical activity, fitness, strength) and checklists done by interview (physical activity, activities at home, skills and behaviour, depression, support from others for physical activity, and attitudes and beliefs about exercise). Health diaries will also be filled in to measure health service costs.
Physical tests involve walking for six minutes, and riding an exercise bike, using simple equipment to measure strength. To measure body fat participants have x-ray (DEXA) scans. Participants also stand on a monitor in bare feet for a few seconds to measure body fat. For a week participants will wear 2 small monitors; a motion sensor (accelerometer) to record physical activity and a lightweight multi-sensor armband that measures energy use.
After these tests are done for the first time, participants are randomly put into one of 3 groups: a control group or one of the two intervention groups in which participants will do regular physical activity and exercise.
Control group Participants only need to do all the tests again at 3 months, and again 6 months after that.
Lifestyle approach group - Participants will do 150 minutes per week of planned, low-moderate-intensity physical activity with support from disability staff trained to use Active Support techniques. One session a week will be with the support of an exercise professional.
Structured exercise training group - Participants will do 150 minutes per week of moderate-vigorous-intensity exercise, with the first 12-weeks delivered by exercise professionals, and later implementation supported by disability staff. The group meets 3 times per week for 1-hour sessions.

What are the possible benefits and risks of participating?
Benefits - Physical activity and exercise are known to be good for health and wellbeing. This means that people may benefit by taking part in the lifestyle physical activity group or the structured exercise program group and doing regular physical activity and exercise.
Risks - Exercise and exercise testing involve the risk of discomfort such as breathlessness, tiredness, sweating, rapid heartbeat, post-exercise joint or muscle discomfort, and muscle soreness. These risks and discomforts will be minimised through a) screening before physical assessment, b) supervision in a safe environment, and c) individually tailoring physical activity and exercise to each participants current abilities. DEXA scans are commonly performed and safe however there are possible side-effects. Participants will be exposed to some X-ray radiation. At most, this is as much as with a chest X-ray. If there is a possibility that a participant is pregnant she cannot take this test.

Where is the study run from?
The intervention (exercise and physical activity) takes place in participants homes and local communities. The tests all take place at The University of Sydney, Cumberland Campus at Lidcombe (Australia).

When is the study starting and how long is it expected to run for?
The study began in July 2011. Participants enrol in one of up to 5 waves. Waves will start every 6 months or so. Final follow-up (9-month assessment) of the last wave will take place in early 2014.

Who is funding the study?
The main funding comes from the National Health and Medical Research Council in Australia. Two disability service organisations (House With No Steps and Lorna Hodgkinson Sunshine Home) are also giving smaller amounts.

Who is the main contact?
Professor Roger Stancliffe
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Roger Stancliffe

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
13821

# Study information

### Scientific Title
Embedding sustainable physical activities into the everyday lives of adults with intellectual disabilities: a randomised controlled trial

### Study objectives
The objective of this trial is to evaluate effects of two approaches to increase physical activity and exercise in adults with intellectual disability:
1. Lifestyle Physical Activity Program and
2. Structured Exercise Program

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Human Research Ethics Committee, The University of Sydney, 27/05/2011, Protocol No: 05-2011 /13821

## Study design
Three-arm randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## 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
Physical activity in adults with intellectual disability

## Interventions
Lifestyle Physical Activity Program
150 minutes per week of low- to moderate-intensity physical activity will accumulate through everyday activities with support from disability care staff. We will deploy individually tailored low- to moderate-intensity physical activities into the daily lives of adults with intellectual disability so that these activities are enjoyable (e.g., X-Box Kinnect) or serve a functional purpose (e.g., walking for transport).

Structured Exercise Program
This intervention involves 150 minutes per week of moderate-vigorous-intensity structured exercise sessions. Exercise classes will take place 3 days per week with 3 to 6 participants in each group. The program will comprise 30 to 45 minutes of cardiovascular exercise and 15 to 20 minutes of muscular strength and endurance exercise conducted three times per week. Exercise intensity will progress from 40%-50% of heart rate reserve to 50%-70% of heart rate reserve.

Controls
Assessment only, no treatment (i.e., physical activity as usual).

## Intervention Type
Other

## Phase

Not Applicable

### Primary outcome measure
Treatment outcome variables:
1. Aerobic fitness: Submaximal Exercise Aerobic Fitness Test using an isokinetic cycle ergometer
2. Energy Expenditure using a multi-sensor armband, Sensewear
3. Intellectual Disability: International Physical Activity Questionnaire (IPAQ)
All assessments conducted at baseline, 3 months and 9 months.

Safety outcome variables:
1. Adverse Events
2. Incident reports by disability service providers

### Secondary outcome measures
1. Physical activity compliance log
2. Index of Participation in Domestic Life (IPDL)
3. Exercise intensity and compliance using Sensewear armband during the training programs
4. Exercise intensity using Polar Heart Rate Monitor during exercise sessions
5. Active Living using an Actigraph accelerometer
6. Isometric tests of muscle strength
7. Six-minute walk test
8. Health Economics Number of hospitalisations, medical consultations (and other medical services), medications
9. Health Utilities Index 2-3
10. Weight, height, and Body mass Index (BMI)
11. Body fat using Dual-emission X-ray absorptiometry (DEXA) scan and Innerscan Body Composition Monitor
12. Glasgow Depression Scale
13. Self-Efficacy for Activity for persons with Intellectual Disabilities (SE-AID) scale
14. Social Support for Activity for persons with Intellectual Disabilities (SS-AID) scale
15. Exercise Perceptions Scale
All assessments conducted at baseline, 3 months and 9 months

### Overall study start date
04/07/2011

### Completion date
30/06/2014

## Eligibility

### Key inclusion criteria
1. Adult men and women with intellectual disability between the ages of 18-55 years
2. Sedentary for the past 12 months or longer
3. Reside within a 1.5-hour commute to the intervention site
4. Signed informed consent in accordance with the ethics requirements
5. Sufficient ambulation to participate in assessments such as 6-minute walk test

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
55 Years

### Sex
Both

### Target number of participants
102

### Key exclusion criteria
1. Contraindications to participating in exercise programs, or outcome assessments, as advised by the primary care physician and/or ineligible according to American College of Sports Medicine criteria
2. Judged at risk of self-harm by the disability service provider care staff

### Date of first enrolment
04/07/2011

### Date of final enrolment
30/06/2014

## Locations

### Countries of recruitment
Australia

### Study participating centre
**Faculty of Health Sciences**
Lidcombe
Australia
NSW 1825

## Sponsor information

### Organisation
University of Sydney Research Office (Australia)

### Sponsor details

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### Sponsor type
Government

### ROR
https://ror.org/0384j8v12

## Funder(s)

### Funder type
Government

### Funder Name
National Health and Medical Research Council (Australia) Partnership Grant APP1012692

### Funder Name
House With No Steps (Australia)

### Funder Name
Lorna Hodgkinson Sunshine Home (Australia)

## 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 | 05/10/2014 | | Yes | No |