ISRCTN43594228 https://doi.org/10.1186/ISRCTN43594228

Intellectual Disability, Exercise and Aging: The IDEA study

Submission date
11/02/2019

Recruitment status
No longer recruiting

Registration date
19/02/2019

Overall study status
Completed

Last Edited
20/09/2021

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
Adults with intellectual disability (ID), as shown by several studies, have decreased fitness, lower rates of physical activity (PA) and are more obese compared to persons without ID. People with ID that participate in PA and health promoting programs based on physical exercise and knowledge about healthy habits produce more positive attitudes toward exercising properly and, at the same time, reported improved social relationships.
In the present study, we assess the effects of two specific exercise programmes in older adults (> 40 years old) with ID. The aim of this study is to see if the proposed PA programs will improve fitness and to find out which one of the exercise programmes will promote greater benefits to the participants.

Who can participate?
Anyone between the ages of 40 and 75 years with mild to moderate ID, speaks Spanish/Catalan, and is able to do physical exercise can take part.

What does the study involve?
The adults included in the intervention programs will train for 6 months, 3 times a week, 90 minutes per session. The control group will receive 3 visits per week to control if they continue with their daily routines at their respective centres.

What are the possible benefits and risks of participating?
Short term benefits for the participants include reduced cardiovascular risk. All participants will receive informed feedback after the end of the study regarding health factors, health risk identification and increase in fitness and health.
Long term benefits will not only apply to the participants but to the community they come from. With this study we will aim to analyse the effects of different modalities of exercise to prevent non-communicable diseases and to inform the different public and private sectors about the benefits of these activities for the group of seniors with intellectual disabilities.
Participants will be instructed to inform research staff of any adverse events that might occur as a result of participation in baseline tests, intervention and follow-up.
Some risks that might be associated with the specific procedures are:
• In completion of the questionnaire, participants may experience anxiety or boredom

• There is a risk for cardiac events during exercise testing
• Injuries during the tests
• Risks of cardiac events during the PA sessions
• Participants might experience some discomfort during the PA sessions, such as muscle soreness or stiffness.
If some participant suffers some discomfort during the research study or during the evaluations or the testing session, they are going to have the opportunity to discuss it with the principal investigator or the supervisor the same day. In case the participant might need more counselling, the participant will be referred to his/her general practitioner to further discuss the possible cause of discomfort

Where is the study run from?
The study will be running from the Faculty of Psychology, Education and Sports Blanquerna. University Ramon Llull.

When is the study starting and how long is it expected to run for?
December 2018 to December 2022 (updated 20/09/2021, previously: December 2021)

Who is funding the study?
Ministry of Economy and Competitiveness (MINECO), Paseo de la Castellana, 162, Madrid, 28046

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DEP2017-86862-C2-1-R

Study information

Scientific Title
Effects of different exercise modalities to improve health-related fitness variables in older adults with intellectual disability: A randomised controlled trial

Acronym
IDEA

Study objectives
Sprint interval training is better than continuous aerobic training to improve health-related fitness variables in older adults with intellectual disability

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2018, Research Ethics Committee of the University Ramon Llull (Claravall 1-3. 08022 Barcelona; +34 902 053 010; info@url.edu), ref: CER URL 2017_2018_008

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Seniors (> 40 years old) with a mild or moderate intellectual disability.

Interventions
Participants will be randomly allocated into the aerobic and resistance training (CPAP) group, sprint interval training program (SIT) group and control group. The CPAP group and the SIT group will participate in the intervention programs for 6 months, 3 times a week, 90 minutes per session and the control group will receive 3 visits per week to control if they continue with their daily routines at their respective centres. All baseline assessments will be repeated at the end of the intervention (6th month), counting from the beginning of the PA programs, and 12 months after the baseline measurements (6-months post-intervention follow-up). Medical screening, functional, physiological, QoL and cardiovascular tests will be performed. Once the 6 months follow-up is finished, and knowing that physical activity (PA) promotes health improvements, participants from the control group will be offered to be part of a PA program (CPAP or SIT) during the last 6 month of the project.

A stratified randomisation design will be used to incorporate characteristics of: sex of participants (2 level factor: male/female) and intellectual disability level (2 level factor: mild /moderate). This is a single-centre study.

Intervention Type
Behavioural

Primary outcome(s)
Maximal aerobic capacity measured using a precalibrated cycle ergometer (Excalibur, LODE, Groningen, The Netherlands), cycling at 50 rpm. After a one-minute period cycling at 0 watts, participants will follow a 10 watt/min ramp protocol up to exhaustion. Oxygen uptake and carbon dioxide production will be measured by an automatic gas analysis system. Measures will be taken at baseline (i.e. prior to randomization), 6 months after randomization (end of the interventions) and 12 months after randomization.

Key secondary outcome(s))
1. Health-related fitness measurements (strength, balance, flexibility).
1.1 Handgrip strength will be measured using a Jamar Hand Dynamometer.
1.2 Isometric strength of the lower limbs will be measured with a Chronojump force sensor.
1.3 To assess the balance we will use de following tests: the single leg stand test (SLST). The participants stand on a single leg. The maximum time will be set to 30 s.
1.4 Postural sway of the centre of pressure will be assessed with a pressure platform (Podoprint Balance Platform, Namrol, Barcelona, Spain). All participants will perform a double leg stance with opened and closed eyes.
1.5 Dynamic balance will be assessed by using the timed up and go test (TUGT). The test consists on rising from an armless chair with a seat height of ~46cm without using the arms, walking 9m and going back to the chair sitting again.
1.6 Flexibility will be assessed using the chair seat-and-reach test. Shoulder flexibility will be measured using the functional shoulder rotation test.
2. Resting blood pressure, aortic pulse wave velocity and augmentation index will be determined using the SphygmoCor Xcel (AtCor Medical).
3. Anthropometry: Weight, height, body mass index, waist and hip circumference and, fat and fat-free mass.
4. Physical activity and sedentary time, measured using ActiGraph accelerometers.
5. Chronic illness will be obtained from the participant medical files.
6. Interviews with seniors and parents or tutors and their staff will be held and quality of life of the participants will be measured using the Personal Outcome Scale.
All measurements will be performed at baseline (i.e. prior to randomization), 6 months after randomization (end of the interventions) and 12 months after randomization.

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Aged over 40 years and under 76 years (as of 01-12-2018)
2. Mild to moderate intellectual disability (ID).
3. Able to participate in activities in groups of 10 seniors with ID.
4. Able to conduct physical activities.

5. Able to wear an accelerometer for several days.
6. Able to walk independently.
7. Able to perform all the physical fitness measurements.
8. Declaration of physician that the senior with ID is able to perform physical activities safely.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Severe or profound ID.
2. Atlantoaxial instability.
3. Contraindications to exercise.
4. Medication that may have an important effect on the participants' response to exercise.
5. Unable to communicate in Spanish/Catalan.
6. Unable to provide written informed consent.
7. Parents or legal representative of the participants did not provide written informed consent.

Date of first enrolment
07/01/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Spain

Study participating centre
Faculty of Psychology, Education and Sport Blanquerna - University Ramon Llull.
34th Cister Street
Barcelona
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Sponsor information

Organisation
Ministry of Economy and Competitiveness (MINECO)

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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	20/08/2020	24/08/2020	Yes	No