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Comparing the effect of three exercise and wellness programmes on balance and fall prevention in physically inactive adults with learning disabilities

Submission date
28/12/2018

Recruitment status
No longer recruiting

Registration date
03/01/2019

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
One challenge a modern society faces is to provide vulnerable and ageing adults who have learning disabilities with appropriate support for improving balance when standing and walking. Balance is an important part of physical fitness and fall prevention. The aim of this study was to investigate the effect of 16 weeks of three different Special Olympics physical activity programmes on balance and fall reduction in adults with learning difficulties.

Who can participate?
Adults with mild or moderate learning difficulties who are physically inactive and have had at least one fall in the past 4 months.

What does the study involve?
The participants were randomly allocated to one of three groups. One group took part in 16 weeks of balance-targeted exercises and workshops on topics including active and healthy ageing. The second group took part in 16 weeks of a wellness programme that included general fitness exercises, yoga and advice on nutrition and healthy lifestyles. The third group took part in Special Olympics training.

What are the possible benefits and risks of participating?
Participants might improve their physical fitness and balance. They receive extra support during the balance training to reduce the risk of falling. People with medical problems that might be affected by the training were not included in the study.

Where is the study run from?
Special Olympics Slovenia

When is the study starting and how long is it expected to run for?

Who is funding the study?
The investigators will pay for any additional costs involved in the trial.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
SpecialOlympics SloveniaRCT/01

Study information

Scientific Title
The impact of multicomponent programmes on balance and fall reduction in adults with intellectual disabilities: a randomised controlled trial

Study objectives
The Special Olympics physical activity programme will improve balance and will reduce falls in adults with intellectual disabilities

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific and Ethics Committee of the Republic Slovenia, Ministry for Health (Ljubljana, Slovenia), December 2017, ref: 0120-598/2017/7

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Physically inactive adults with intellectual disabilities who have poor balance and a history of falls

Interventions

The Special Olympics (SO) Slovenia programme provided a list of all adult athletes in their programme who, despite the designation, were physically inactive (600 median minutes/week); SO Games Management System software and HAP FF data were used for this purpose. The list of 180 Special Olympics athletes with intellectual disabilities (ID) who are categorized as being inactive and having a high fall frequency (1 fall or more in the past 4 months) was derived from the HAP FF data (in October 2017 for inactive adults with ID and with fall history) compiled of all 1674 (both physically inactive and active) Slovenian SO athletes older than 18 years. PA (physical activity) level was determined according International Physical Activity Questionnaire – long form.

The stratified random sampling was used for recruitment using the Slovenian SO database (SO Games Management System software) and HAP FF data. A randomization list was prepared by the independent statistician using random permuted blocks. This technique ensured that equal numbers of inactive adults with ID within each stratum were randomized to each intervention (restricted stratified randomization). All 150 participants were randomly selected from predetermined strata that correlated with variables in the study (from 79 national SO member programmes within Slovenia, representing both urban and rural areas across all geographic regions in Slovenia). An important feature of stratified randomization was the use of random permuted blocks, which ensured that equal numbers of adults with Down syndrome, cerebral palsy, autism spectrum disorder, Prader Willi syndrome, attention deficit hyperactivity disorder, and others with mild and moderate ID within each stratum were randomized to each intervention group. Stratification of variables known to influence outcome was carried out in our RCT design. Stratified randomization procedures have taken athletes' characteristics into account in order to equalize the groups according to the previously-mentioned variables. Our purpose was to reduce sampling error and to increase the external validity of the study.

We used double-blind RCT to make sure the selected people with ID did not know in which of the three programmes they were involved. Even those who tested the participants were unaware of in which group they were. In order to eliminate bias from results, none of the directly-involved parties knew which group the adults with ID were allocated to (study or control). Due to the increased control of confounding variables, participants were not included in other therapeutic or recreational activities or in any other physical activity (during the study period) that might influence the results.

There were 75 men and 75 women in total, with 39 right-handed and 11 left-handed participants in each group of the three groups of 50.

In each group only 1 recruit was using assistive devices.

Participants with mild and moderate ID were assessed at two stages: before starting interventions (before stratified randomization) and after 4 months of involvement in 3 specific SO programmes.

Assessment included measuring of static/dynamic balance and reporting frequency of falls at baseline (i.e. prior to randomization) and after 16 weeks of randomization. Balance was tested using the Fun Fitness battery test (a functional reach test and a single leg stance test with eyes opened/closed; Bainbridge et al., 2013). The functional reach test was done 1 hour after the physical activity programme in order to avoid the influence of tiredness. All the assessments were carried out individually in well-lit, quiet, air-conditioned rooms.

Once a week (for 60 min), the MBSEP group (experimental group 1) received a multicomponent balance-specific exercise programme described in detail elsewhere (Rugelj 2016) under the guidance of a physiotherapist (with specialization in neurodevelopmental physiotherapy); twice a week (each time for 60 min), they participated in an individual programme under the supervision of a PT student and in line with WHO guidelines (Evenhuis et al. 2000; World Health Organization 2000). MBSEP was designed as group-based physiotherapy program with lectures and counseling on healthy, active aging by the social gerontologist based on the World Health Organization guidelines for 2015-2030, incorporating behavioural-change principles as critical elements for initiating and maintaining a structured and multifaceted physical activity in adults with ID. The MBSEP programme included 36 sessions. These were delivered in a community setting (in a gymnasium situated in a local community sports centre) and in collaboration /partnership between SO Slovenia and Alma Mater Europaea ECM (under the patronage of the European Academy of Science and Arts).
Special Olympics athletes in the MBSEP group were provided with regular SO athletic training according to the Special Olympics Coach's Guide for Athletics once a week under the guidance of a certified SO coach (60 min) and twice a week individually (60 min) according to the same instructions given by the coach.

The Wellness group (experimental group 2) received regular SO athletic training according to the Special Olympics Coach's Guide for Athletics once a week under the guidance of a certified SO coach (60 min) and twice a week individually (60 min) according to the same instructions given by the coach.
The healthy lifestyle component of the Wellness programme provided tips and information for athletes and coaches for leading a healthy and active lifestyle through regular physical activity (fitness sessions), healthy nutrition, and proper hydration. Wellness was conducted in a community setting under the guidance of a fitness instructor once a week (60 min) and comprised 12 sessions in total delivered in a community setting in a local fitness centre, a nutritionist (4 lectures on the topics of healthy eating and hydration), and 4 yoga sessions (4 x 60 min balance exercises) in a community spa centre. The fitness session involves treadmill walking or running (15 min) and dynamic exercises (35 min – leg press, bench press, vertical traction, shoulder press, lower back, leg extension, biceps curl, triceps pushdown, abdominal curls), and stretching and cooling-down exercises according to Mendonca et al., 2011.

The control group received regular SO training under the guidance of a certified SO coach once a week (60 min) and twice a week individually (60 min) according to the Special Olympics Coach's Guide for Athletics. Each session included warming up, running, stretching, event-specific training and cooling down.

The coaches in the Wellness and MBSEP groups were recruited with each athlete with ID. Each coach agreed to participate in each of regular meetings (only for experimental groups) with the participant, and to support the participant in a multicomponent programme in community settings.

Intervention Type
Behavioural

Primary outcome(s)
Frequency of falls at baseline (i.e. prior to randomization) and 16 weeks after randomization

Key secondary outcome(s))

Static and dynamic balance tested using the Fun Fitness battery test (a functional reach test and a single leg stance test with eyes opened/closed; Bainbridge et al., 2013) at baseline (i.e. prior to randomization) and 16 weeks after randomization. . The functional reach test was done 1 hour after the physical activity programme in order to avoid the influence of tiredness. All the assessments were carried out individually in well-lit, quiet, air-conditioned rooms.

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years
2. Mild or moderate ID (ID is diagnosed using medical data)
3. Physically inactive (do not reach the World Health Organization recommendations on weekly physical activity level)
4. Experienced one or more falls in the 4 months previous to the study
5. No restraints in terms of World Health Organization recommendations on physical activity (i.e. with mandatory general practitioner clearance to participate in a physical activity programme
6. Ambulatory (i.e. able to walk independently)
7. Ability to consent – potential participants were either judged by their SO coach to be competent to give informed consent or had a guardian with power of attorney. The ID individuals or their legal guardians had given informed consent in writing. If a guardian signed informed indicated consent but the individual with ID did not want to participate, the individual was not enrolled.
8. Adequate communication – potential participants should be able to communicate preferences (e.g. whether they liked or disliked exercise), wants (e.g. whether they wanted to exercise more, to do physical activity for balance), and needs (e.g. assistance with physical activities regimes, transportation issues) through spoken language 9. Living with parents or in supported living (institutions, small group homes)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. People with severe or profound ID who could not understand the instructions and were not able to understand the meaning and purpose of the study
2. Atlantoaxial instability
3. Other limitations (guidelines from their primary care physician)
4. No fall history
6. Health concerns:
6.1. Restraints according to World Health Organization recommendations on physical activity (mandatory general practitioner clearance to participate in a physical activity programme)
6.2. Uncontrolled hypertension, severe heart disease, cancer, diabetes or vestibular disorders
6.3. Double diagnosis (ID and psychiatric disorder) who are currently being treated for depression or schizophrenia

Date of first enrolment
14/12/2017

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
Slovenia

Study participating centre
Special Olympics Slovenia
Samova ulica 9
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Special Olympics Slovenia

ROR
https://ror.org/04581yq69

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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?
Results article		20/03/2020	10/09/2021	Yes	No
Participant information sheet		03/01/2019	03/01/2019	No	Yes