ISRCTN82341588 https://doi.org/10.1186/ISRCTN82341588

Improving physical activity among older adults with intellectual disabilities by a structured day care program

Submission date
21/09/2012

Recruitment status
No longer recruiting

Registration date
23/10/2012

Overall study status
Completed

Last Edited
23/01/2014

Condition category
Other

[_] 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:
The aim of our study is to improve the physical activity level in seniors with an intellectual disability. Regular physical activity is very important to their health and is specifically important for the prevention and reduction of falls and functional limitations. We developed a new physical activity program and we determined if it indeed improved the physical activity and health of the seniors.

Who can participate?
People with a mild or moderate intellectual disability, aged 45 years and older.

What does the study involve?
The physical activity program will be conducted in the participants day care centers. Day care centers will be randomly allocated to participate in the program or serve as a control group. Those who participate in the study will be divided into two groups. One group will conduct the physical activity program for eight months, three times a week. The program includes education about the importance of physical activity to their health and performing physical activities. The other group will conduct normal activities at the day care center as usual; there will be no changes in their daily program.

What are the possible benefits and risks of participating?
Participants will learn about the importance of physical activity and increase their self-confidence and enjoyment in participating in physical activities. Participants who will actively perform the physical activities, will become more healthy and their fitness may increase and they will feel more flexible and fit. Before the program starts, the general practitioner will be asked to provide a medical advice about participating safely. If no positive advice is provided, the participant cannot continue in the program. Heart-rate monitors will be used to evaluate the heart-rate changes during the activities. If there are falls or other undesirable situations, the researcher, the conductors and physical therapist and or the general practitioner will discuss the continuation of the program.

Where is the study run from?
Ipse de Bruggen and Amarant en Abrona

When is study starting and how long is it expected to run for?
The study started in March 2010 and the last health measurements were taken in October 2011.

Who is funding the study?
The Netherlands Organization for Health Research and Development ref: 57000003

Who is the main contact?
Professor Heleen M Evenhuis
h.evenhuis@debruggen.nl

Contact information

Type(s)
Scientific

Contact name
Mrs Marieke van Schijndel-Speet

Contact details
Erasmus Medical Center Rotterdam
Department of Intellectual Disability Medicine
PO box 2040
Rotterdam
Netherlands
3000 CA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
57000003 / 62-614000-98-006_02

Study information

Scientific Title
Improving physical activity among older adults with a mild or moderate intellectual disability by a structured day care program: a cluster randomized trial

Acronym
IPAD-ID

Study objectives

The physical activity level of participants will improve, whereas the physical activity level of the control group remains on the same (low) level.
The physical fitness level of participants will remain equal or will improve a little, whereas the physical fitness level of the control group remains equal or declines. This hypothesis is also applicable to the secondary outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erasmus University Medical Center Ethics Committee, 03 December 2009 ref: NL 29573.078.09

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Seniors with a mild or moderate intellectual disability with a low physical activity level. Also a low fitness level is to be expected.

Interventions
Participants:
1: physical activity program, during eight months, three times a week, 45 minutes per time AND
2: an education program, during eight months, two times a week, 45 minutes per time

Control group: No intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physical activity (Steps per day)

Secondary outcome measures
1. Motor fitness (strength, balance, walking speed)
2. Cardio respiratory fitness (blood pressure, aerobic capacity)
3. Morphological fitness (weight, waist circumference, skin fold measurements)
4. Metabolic fitness (glucose, cholesterol)
5. Functioning in daily life (mobility, ADL, IADL, depression, functional deterioration)
6. Chronic illness
7. Quality of life
8. Interviews with seniors and/or their staff (Motivation, Quality of life)
9. Physical measurements on seniors (Motor fitness, Cardio respiratory fitness, Morphological fitness, Metabolic fitness, Functioning in daily life),
10. Questionnaires to be filled in by staff (Functioning in daily life)
11. Medical files (Chronic illness)

Overall study start date
01/03/2010

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. Aged 50 years and over (1-9-2010), maximum 75 years old
2. Mild or moderate intellectual disability
3. Being able to participate in activities in groups of around 10 seniors with ID
4. Being able to conduct physical activities after demonstration by staff
5. Being able to wear a pedometer during several days
6. Having sufficient visual function to performing fitness measurements
7. Declaration of physician that the senior is able to perform physical activities safely, in view of his medical condition

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160 participants: 80 participants and 80 controls

Key exclusion criteria
1. Seniors with moderate or severe pain when moving will be excluded from the study
2. Seniors with an active lifestyle will be excluded from the study (more than 7500 steps per day)

Date of first enrolment
01/03/2010

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center Rotterdam
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
The Netherlands Organization for Health Research and Development (Netherlands)

Sponsor details
Laan van Nieuw Oost- Indie 334
The Hague
Netherlands
2593 CE

Sponsor type
Government

Website
http://www.zonmw.nl/en/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name

The Netherlands Organization for Health Research and Development (Netherlands) ref: 57000003

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	12/08/2013		Yes	No