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The power-assisted exercise intervention in people with profound intellectual and multiple disabilities

Submission date 07/10/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/10/2016	**Overall study status** Completed	
Last Edited 07/12/2021	**Condition category** Other	

Plain English summary of protocol

Background and study aims

One of the most vulnerable groups of people is those with profound intellectual and multiple disabilities (PIMD). PIMD involves severe intellectual impairment (very low intelligence and limited understanding) as well as multiple physical disabilities, which may include problems with vision, hearing and the ability to walk independently. Furthermore, these people may also have various general health problems, such as epilepsy, obstipation (severe or complete constipation), low levels of alertness, sleeping problems and mental health problems. This means that they are usually completely dependent on others, often living in facilities that are able to provide 24 hour care. Many studies have shown the benefits of physical activity on both the body and mind. The aim of this study is to see if a power-assisted exercise program (exercise using exercise machines that moves the body safely and effectively) is acceptable for those with PIMB, and to find out whether it has any beneficial effects.

Who can participate?

People with PIMD who live in the participating twenty-four-hour residential facility (Royal Dutch Visio de Brink).

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group take part in the power-assisted exercise program. This involve three 30-minute sessions per week for 20 weeks. The program consists of exercises such as sit up, hip flexion (bending) and moving the arms and legs up and down with the assistance of six different powered exercise machines which support the participants in performing exercises. Participants in the second group continue to receive standard care for the duration of the study.

What are the possible benefits and risks of participating?

Participants who take part in the exercise program benefit from being able to exercise more, which could improve their general health. There are no notable risks involved with participating in this study.

Where is the study run from?
De Brink, Royal Dutch Visio (Netherlands)

When is the study starting and how long is it expected to run for?
June 2009 to October 2016

Who is funding the study?
University of Groningen (Netherlands)

Who is the main contact?
Miss Leontien Bossink
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessing the feasibility of evaluating a power-assisted exercise intervention in people with profound intellectual and multiple disabilities: a pilot randomised controlled trial

Study objectives
1. The power-assisted exercise intervention and trial design are feasible and acceptable to people with PIMD

2. The intervention effects the potential outcomes (e.g. functional abilities, alertness, body composition, muscle tone, oxygen saturation, cardiovascular fitness and quality of life) in people with PIMD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Participants were recruited form a large-scale twenty-four-hour residential facility which planned to implement the intervention. Approval for this research was granted by the institutional review board of this facility and all parents or legal representatives of the participants provided written informed consent.

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Physical inactivity in persons with profound intellectual and multiple disabilities

Interventions
Participants are randomised to one of two groups using a computer minimisation programme to create two similar groups with respect to gender, age (<18, 19-37, 38-57 and >58) and GMFCS level (IV or V).

Intervention group: Participants undertake power-assisted exercise program, which involves 30 minute sessions three times a week over a twenty week period. The intervention consists of power-assisted exercises such as sit-ups, hip flexion, spreading and closing of arms and legs and moving arms and legs up and down. All the exercises are carried out using six different powered-exercise machines which support the participants in performing exercises. The intervention is an adaptation of a power-assisted exercise programme for elderly without intellectual disabilities.

Control group: Participants receive usual care for the duration of the study.

Follow up for all participants involves repeated measurements at five-week intervals. Measurements take place at baseline, week 5, week 10, week 15, week 20.

Intervention Type
Other

Primary outcome measure
1. Overall trial feasibility is assessed using researcher and test assistant notes during the recruitment process
2. Intervention feasibility is assessed using programme compliance rates, measured by test assistant during every training session (three times a week over a twenty-week period)

Secondary outcome measures
1. Functional ability is measured using the Behavioural Appraisal Scales assessed by blinded test assistants at baseline and 20 weeks
2. Alertness is measured using the Alertness Observation List (observation list) assessed by blinded test assistants at baseline, 5 weeks, 10 weeks, 15 weeks and 20 weeks
3. Body composition is measured using the Body Mass Index assessed by carers at baseline, 5 weeks, 10 weeks, 15 weeks and 20 weeks
4. Muscle tone is measured using the Modified Ashworth Scale assessed by blinded test assistants at baseline, 5 weeks, 10 weeks, 15 weeks and 20 weeks
5. Oxygen saturation is weekly measured only in the intervention group using a finger pulse oximeter by test assistants at the first session of the week
6. Cardiovascular fitness is weekly measured only in the intervention group using a finger pulse oximeter by test assistants at the first session of the week
7. Quality of life is measured using the QOL-PMD (questionnaire) by carers at baseline and 20 weeks

Overall study start date
01/06/2009

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Profound intellectual disability (estimated intelligence quotient (IQ) below 20–25 points or a developmental age of up to 24 months)
2. Profound or severe motor disabilities (classified as Gross Motor Function Classification System level (GMFCS) IV or V)
3. Living in a large-scale twenty-four-hour residential facility (Royal Dutch Visio de Brink) which plans to implement the power-assisted exercise intervention

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
40

Total final enrolment
37

Key exclusion criteria
1. A medical condition which could not be resolved in the short term excluded participation
2. Parents or legal representative of the participants did not provide written informed consent

Date of first enrolment
01/10/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
De Brink
Royal Dutch Visio
Veenweg 20
Vries
Netherlands
9481 TJ

Sponsor information

Organisation
University of Groningen

Sponsor details
Grote Rozenstraat 38
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Sponsor type
University/education

ROR
https://ror.org/012p63287

Funder(s)

Funder type
University/education

Funder Name
University of Groningen

Results and Publications

Publication and dissemination plan
Planned publication of a scientific article.

Intention to publish date
01/11/2016

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study are available upon request from Leontien Bossink, Department of Special Needs Education and Youth Care, University of Groningen (l.w.m.bossink@rug.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/01/2017	07/12/2021	Yes	No