Development and evaluation of a bicycle test and training protocol for adults with cerebral palsy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON32024

Source
ToetsingOnline

Brief title
Cycle test and training protocol for CP

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
brain paralysis, cerebral palsy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Er zal een aanvraag worden gedaan bij de Phelps-Stichting voor spastici

Intervention

Keyword: cerebral palsy, cycling, physical capacity, training

Outcome measures

Primary outcome

The main outcome measure is the physical capacity, measured as the peak power output. The peak power output will be determined during a maximal exercise protocol on a cycle ergometer.

Secondary outcome

Submaximal parameters (oxygen uptake, heart rate, mechanical efficiency)

Sprint power

Muscle strength lower extremities

Walking ability

Mass and height

Skinfold thickness

Active lifestyle, measured by a questionnaire (PASIPD)

Participation, measured by a questionnaire (SIP68)

Study description

Background summary

An inactive lifestyle and secondary problem often play a central role in daily life of people with a disability. To prevent secondary complications and to improve the physical capacity, it is important that people with a disability participate in sport activities. However, it is difficult for them to join regular sport clubs because specific knowledge and equipment is often not available. For people with and without a disability, who participate in sport, it is important that their performance (i.e. fitness, strenght, speed) is tested regularly. With these test results the capacity of the persons can be

determined, which is necessay for developing a good individual training protocol.
Very little information is available about test and training protocols for adults with cerebral palsy. The purpose of this study is to develop knowledge about the most ideal test and training protocol for adults with cerebral palsy. With this knowledge we are better able to advise people with a cerebral palsy who want to participate in recreational or elite sports.

Study objective

The primary goal of this research project is to develop and evaluate the effect of a 6-weeks cycling training program for adults with cerebral parese on the physical capacity, walking function, participation, and active lifestyle (part 2).
An associated goal is to develop and evaluate a reliable and valid test protocol for aduls with cerebral palsy (part 1). The results of this test protocol will be used to develop and evaluate the training program.

Study design

A controlled-randomized trial (part 2).

Intervention

The intervention is a 6-weeks cycling training program, 3x/week for 45 minutes on 50% heart rate reserve on a cycle ergometer.

Study burden and risks

Part 1: Subjects will perform tests on 3 test days to determine the physical capacity, walking function, active lifestyle and participation and their relationship.

Part 2: Subjects will participate in a 18 weeks research project, executing a 6 week training program on a cycle ergometer, 3 days/week 45 min on 50% heart rate reserve. Measurements will be performed at 3 different time slots.

Subjects may experience some discomfort and/or muscle soreness after the peak exercise test or training. Furthermore, the risks during training and testing sessions are relatively low because of thorough screening prior to participation, use of skilled and licensed therapist and safety precautions throughout training and testing. The expected benificial training effects in combination with the limited risks would justify execution of the proposed study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosis of Cerebral Palsy;
Stable medication use;
They have to be cognitively able to understand and perform the tasks;

Exclusion criteria

Medication use that affects muscle performance negatively;
Cardiovascular contra-indications for testing according to the American College of Sports Medicine (ACSM) guidelines, or a resting diastolic blood pressure above 90 mm Hg or a resting systolic blood pressure above 180 mm Hg.
Musculoskeletal complaints of the lower extremities or back.

Plans to start another lifestyle (e.g. more physical active, diet) in the months that the experiment is going on.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL21815.029.08