The feasibility of Supramaximal Verification of peak oxygen uptake of a Graded Maximal Treadmill Test in adults with an Intellectual Disability

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42078

Source
ToetsingOnline

Brief title
Supramaximal test in adults with ID

Condition

- Other condition
- Neurological disorders congenital
- Cognitive and attention disorders and disturbances

Synonym
cardiorespiratory fitness, endurance

Health condition

verstandelijke beperking

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: via zorgorganisatie Abrona

Intervention

Keyword: adults, cardioresiratory fitness, intellectual disability, supramaximal verification

Outcome measures

Primary outcome

What is the completion rate of performing both the GXTT and the SET in adults

(18-50 years) with ID?

Secondary outcome

• What is the subjective experience of adults (18-50 years) with ID of

performing familiarization procedure, the GXTT and the SET?

• Does the VO2peak measured with the GXTT is likely to reflect the VO2max in

adults with ID?

• Which baseline characteristics have a possible influence on the feasibility

of the GXTT combined with the SET?

Study description

Background summary

Cardiorespiratory fitness is an important component of physical fitness and refers to the ability of the circulatory and respiratory systems to supply

oxygen to working muscles during physical activity and is measured by the maximum volume of oxygen (VO2max), that can be transported per minute. The gold standard for measuring cardiorespiratory fitness is a maximal cardiorespiratory exercise test, like the Graded Maximal Treadmill Test (GXTT). For people with an intellectual disability, it is unknown if the results of a maximal cardiorespiratory exercise test reflect their maximal capacity. The scores of a GXTT can be compared with a Supramaximal Exercise Test (SET) to determine whether the attained VO2 during the GXTT is indeed the true VO2max. It is unknown if the GXTT and the SET are feasible for adults with ID.

Study objective

The aim of this study is to test the feasibility of a GXTT, combined with a SET in adults with ID, through completion rate of the GXTT and the SET, the subjective experience of the participants and determining if the VO2peak of the SET is likely to reflect the VO2peak of the GXTT.

Study design

This is a study with a crosssectional observational design

Study burden and risks

The participants will perform a GXTT and a SET, with a heart rate and breath analyses. Due to the nature of the tests only participants who can sign their own informed consent will be included in this study. The safety of executing these two tests is screened on beforehand and checked with a physician in case of doubt. If safety is not sufficiently confirmed a participant will be excluded. To optimize maximal testing results, the participants will go through a three-step familiarization process before performing the treadmill tests, to ensure the participants are able to perform with maximal effort. Only when a participant is familiar with the current step will the next step be introduced. Additional familiarization sessions will be scheduled for each step for participants who need more practice sessions. For safety, the tests will be administered by a physical therapist, oxygen saturation and heart rate will constantly be monitored during testing and the participant can hold on a bar during testing. Since this study tests the feasibility of the GXTT and SET for adults with ID, this study could not be tested in other populations.

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

•Between 18-50 years old
•Diagnosed with an intellectual disability (ID)
•Able to follow instructions regarding testing
•Able to sign informed consent according to the participants* behavioral therapist
•Completed a Physical Readiness Questionnaire (PAR-Q). If one of the question is answered with *YES*, a medical doctor will be consulted for medical clearance to participate.

Exclusion criteria

•Significant ambulatory problems that would inhibit treadmill walking
•Taking medications that could affect normal physiological responses to exercise
•Medical contraindications to exercise
•Heart-rate-altering medications
•Congenital or atherosclerotic heart disease, metabolic disease,
•Respiratory disorders including asthma
•Not obtaining medical clearance

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-03-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51441.078.14

Study results

Date completed:	03-07-2015
Actual enrolment:	12