

# Physical fitness of children with a moderate to severe intellectual disability

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The objective is to examine the physical fitness of children with moderate to severe intellectual disability.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | Other condition            |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON38815

### Source

ToetsingOnline

### Brief title

Fitness children ID

### Condition

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

### Synonym

endurance, physical fitness

### 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 Reinaerde

## Intervention

**Keyword:** Children, Epidemiology, Intellectual disability, Physical fitness

## Outcome measures

### Primary outcome

The main parameter is physical fitness. This consists of four components: body composition (height, weight, waist circumference), muscle strength (standing long jump, throwing a bag), muscular endurance (stair climbing) and cardiorespiratory endurance (6-minute walk test).

### Secondary outcome

In addition, the motor and cognitive developmental age, lifestyle (nutrition and physical activity), functional independence and characteristics of the participants are assessed.

## Study description

### Background summary

Increasing physical fitness leads to health benefits. A limited number of studies, with small sample sizes and specific characteristics, shows that children with an intellectual disability (ID) seems to be less fit than their peers. Measuring physical fitness in these children with ID is more difficult than in children without disabilities and little research has been done with feasible and reliable methods.

### Study objective

The objective is to examine the physical fitness of children with moderate to

severe intellectual disability.

### **Study design**

This is a cross-sectional study with a pilot study to determine the feasibility and reliability of fitness tests to be used.

### **Study burden and risks**

The study population has specific characteristics. Therefore the objective can only be assessed by conducting the research in this population. Participation in this study brings along negligible risks. The fitness tests do not require maximum effort and are conducted and supervised by professionals who have experience with the study population and the tests.

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## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Children (2-11 years)

## Inclusion criteria

- age 2-18 year
- able to walk independantly (possible with walking aid like orthopedic shoes or walker)
- moderate to severe intellectual disbality
- completed physical activity readiness questionnaire (PARQ)
- informed consent of both parents or gardian

## Exclusion criteria

- behavioral problems that might worsen by participating in this study
- medical problems that might worsen by participating in this study

## 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): 24-02-2014

Enrollment: 204

Type: Actual

## Ethics review

Approved WMO

|                    |   |
|--------------------|---|
| Date:              | 13-12-2013  |
| Application type:  | First submission  |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO       |   |
| Date:              | 20-02-2015  |
| Application type:  | Amendment   |
| 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     | NL44974.078.13 |

## Study results

|                   |            |
|-------------------|------------|
| Date completed:   | 01-02-2016 |
| Actual enrolment: | 133        |