# Feasibility and reliability of Whistler pulmonary function testing in adults with an intellectual disability.

Published: 16-10-2015 Last updated: 16-04-2024

Is pulmonary function testing using the Whistler device a feasible method in adults with an intellectual disability? Is pulmonary function testing using the Whistler device a reliable method in adults with an intellectual disability? Does the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

# Summary

#### ID

NL-OMON41881

**Source** ToetsingOnline

Brief title WhistlerID

### Condition

• Bronchial disorders (excl neoplasms)

#### Synonym

funtion of the lungs, pulmonary function

#### **Research involving** Human

### **Sponsors and support**

Primary sponsor: Geneeskunde voor Verstandelijk Gehandicapten, afdeling
Huisartsgeneeskunde
Source(s) of monetary or material Support: salaris van de onderzoekers wordt betaald

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door de zorginstelling waar zij in dienst zijn (ASVZ;Lunet zorg;Daelzicht; S Heeren Loo Noordwijk). Het onderzoek maakt deel uit van de opleiding tot Arts voor Verstandelijk Gehandicapten.

#### Intervention

Keyword: feasibility, intellectual disability, reliability, Whistler

#### **Outcome measures**

#### **Primary outcome**

Primary Objective: Is pulmonary function testing using the Whistler device a

feasible method in adults with an intellectual disability?

#### Secondary outcome

Secondary Objective: Is pulmonary function testing using the Whistler device a

reliable method in adults with an intellectual disability?

Third Objective: Does the feasibility and reliability of pulmonary function

testing using the Whistler device differ between adults with a mild or moderate

intellectual disability?

# **Study description**

#### **Background summary**

Currently spirometry is used as the \*gold standard\* for the diagnosis of obstructive pulmonary diseases. Tidal breathing pulmonary function measurements are more feasible and practical in people with intellectual disability. Interrupter technique (Rint) is such a measurement which tests airway resistance during tidal breathing, and can be used as an alternative for spirometry. Rint measurements may be obtained by portable equipment (the Whistler) and is effort-independent, non-invasive and requires minimal subject co-operation.

#### **Study objective**

Is pulmonary function testing using the Whistler device a feasible method in

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adults with an intellectual disability? Is pulmonary function testing using the Whistler device a reliable method in adults with an intellectual disability? Does the feasibility and reliability of pulmonary function testing using the Whistler device differ between adults with a mild or moderate intellectual disability?

#### Study design

A multicenter observational study to determine the feasibility and the reliability of Whistler in people with an intellectual disability. There will be a single measuring moment.

#### Study burden and risks

Because of the absence of a suitable device to measure lung function in people with intellectual disability, this group may be at risk to under diagnosis and therefore under treatment. The test with the Whistler device is performed quickly and is not associated with any considerable risks or adverse events. The burden placed upon participants is considered minimal.

## Contacts

**Public** Selecteer

Wytemaweg 80 Rotterdam 3015 CN NL Scientific Selecteer

Wytemaweg 80 Rotterdam 3015 CN NL

### **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

#### **Inclusion criteria**

minimum age of 18 year mild or moderate intellectual disability receiving care by ASVZ, Lunet Zorg, \*S Heeren Loo Noordwijk, Daelzicht

### **Exclusion criteria**

no specific exclusion criteria

# Study design

### Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

#### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	131
Туре:	Anticipated

#### Medical products/devices used

Generic name:	pulmonary function measurement by Whistler (Rint)
Registration:	Yes - CE intended use

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# **Ethics review**

Approved WMO Date: Application type: Review commission:

16-10-2015 First submission 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 CCMO **ID** NL52482.078.15