Feasibility of pulmonary function testing in adults with intellectual disabilities: pilot study

Published: 25-03-2010
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Information on feasibility of spirometry, impulse oscillometry and body plethysmography in adults with mild and moderate intellectual disabilities.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34772

Source
ToetsingOnline

Brief title
Pulmonary function tests in intellectual disability

Condition

- Respiratory disorders NEC

Synonym
n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: feasibility, pulmonary function, test

Outcome measures

Primary outcome

Feasibility will be operationalised as:

1. cooperation (resistance, anxiety and nervousness, enthusiasm, premature

quitting)

2. technical feasibility (patterns of flow-volume curve and body

plethysmography curve)

3. reproducibility (variability of measured values)

Secondary outcome

not applicable

Study description

Background summary

In adults with intellectual disabilities, early diagnosis of chronic pulmonary disease and evaluation of treatment effects are hampered by difficulties with cooperation with standard pulmonary function testing by means of spirometry. Because of a rapidly increasing life expectancy in this population, an increase of chronic pulmonary disease is to be expected. Internationally, no epidemiological information is available on chronic pulmonary disease in this group.
At this moment, 4.5% of the adult client population of five large Dutch intellectual disability care providers are being treated with inhalation corticosteroids, without any objective information on pulmonary functions. Because usually, subjective symptoms are insufficiently communicated by these persons, it is to be expected that chronic pulmonary disease often will be diagnosed in an advanced stage. On the other hand, over-treatment is also to be expected.
Nowadays, methods of pulmonary function testing are available which do not

require active cooperation.

Study objective

Information on feasibility of spirometry, impulse oscillometry and body plethysmography in adults with mild and moderate intellectual disabilities.

Study design

Non-invasive observational feasibility pilot study.

Study burden and risks

This pilot concerns a non-invasive observational study. The studied methods are internationally accepted for clinical diagnosis.
The burden consists of time (1 hour), taking the afternoon off, travelling to the hospital, and the unknown situation, which can be felt as threatening. We know from earlier studies, that pulmonary function testing based on normal breathing is usually not experienced as threatening, if the situation is explained in a quiet way, whereas spriometry using an incentive was met with enthusiasm by most participants. Practicing with the mouthpiece at home will advance security and improve cooperation. There is no systematic information on the application of body plethysmography. Sitting in a closed glass cabin might be felt as threatening. The involved pulmonary function test assistant has applied this test as part of regular diagnostics in some persons with intellectual disabilities. Acceptation was varying.

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

age 40 years and over
mild or moderate intellectual disability

Exclusion criteria

no

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):	01-03-2010
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	25-03-2010
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	NL30159.078.09