

the feasibility and reproducibility of the MicroRint pulmonary function test in people with an intellectual disability, aged 50 years and older.

Published: 13-03-2008

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To determine feasibility and reproducibility of MicroRint pulmonary function testing in 50+ people with different levels of intellectual disability.

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

Summary

ID

NL-OMON31766

Source

ToetsingOnline

Brief title

MicroRint testing in older adults with intellectual disabilities

Condition

- Respiratory disorders NEC

Synonym

Chronic obstructive lungdisease, lungfunction

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: intellectual disabilities, pulmonary function testing

Outcome measures

Primary outcome

The feasibility as well as short-time (within one hour) and long-time (one to two weeks later) reproducibility of the MicroRint pulmonary function testing

Secondary outcome

NVT

Study description

Background summary

For early diagnosis, adequate treatment and follow-up of chronic obstructive pulmonary disease, pulmonary function testing is essential. However, routine pulmonary function testing (spirometry) is not feasible in many people with intellectual disability. An alternative method is the interrupter technique (MicroRint). Using this technique, airway resistance is measured during normal breathing. MicroRint is feasible in children with severe neurological impairment, but feasibility has not been evaluated in adults with intellectual disabilities.

Study objective

To determine feasibility and reproducibility of MicroRint pulmonary function testing in 50+ people with different levels of intellectual disability.

Study design

Residents aged 50 years and over will be recruited through three Dutch care providers for people with intellectual disabilities. Per level of intellectual disability, 30 persons will be included. Feasibility (willing to participate? accepting facemask? tolerating the measurement? interpretable results?) as well as short-time (within one hour) and long-time (one to two weeks later)

reproducibility will be assessed.

Study burden and risks

There will be minimal burden associated with participation. During the testing the client has to sit in a chair and can breath normally. There will be familiar person present to assure the burden is as small as possible. This person and the researcher decide together if or when the test is to much of a burden for the client. The testing then will be stopped and if possible restarted after a few minutes. If this is not possible the testing will be stopped.

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

intellectual disabilities
50 years and older

Exclusion criteria

age<50
no intellectual disability
Alzheimer disease

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 13-03-2008

Enrollment: 150

Type: Actual

Ethics review

Approved WMO

Date: 13-03-2008

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	NL21090.078.07