# Novel diagnostics in dysfunctional breathing using a wearable breathing trainer

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Primary study objective:To impartially identify the focus of breathing (thoracic or abdominal) using respiratory inductance plethysmography for children aged 8 to 18 with dysfunctional breathingSecondary objectives:• To investigate the effects of...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON56859

**Source**
ToetsingOnline

**Brief title**
Wearable Breathing Trainer

### Condition

- Other condition

**Synonym**
breathing pattern disorder, ineffective breathing

**Health condition**

Ademhalingsstelsel, adempatroonafwijkingen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente
**Source(s) of monetary or material Support:** Regieorgaan SIA

## Intervention

**Keyword:** Breathing, Dysfunctional breathing, Physical therapy, Respiratory inductance plethysmography (RIP)

## Outcome measures

### Primary outcome

The primary goal of this study is to determine the effects of breathing exercises given by the pediatric physiotherapist objectively using RIP. The current gold standard in treatment is solely based upon the expertise of the physical therapist. In our study, we aim to determine feasible objective parameters to assess the focus of breathing. The amount of stretch caused by breathing causes an increase in RIP signal. Exhalation reduces the amount of stretch and causes the RIP signal to decrease. These signal alterations allow for the following parameters to be measured:

• RIP amplitude

• RIP frequency

• RIP peak variation

All parameters are measured at both abdomen and thorax and the combined parameters provide an indication for the focus of breathing. A focus towards an abdominal breathing pattern is preferred.

### Secondary outcome

A secondary goal is determining the intention to use technology to support

breathing exercises at home. Intention to use and influencing factors will be evaluated in a qualitative way through semi-structured interviews. The topics of the semi-structured interviews will be based on technology acceptance models.

# Study description

### Background summary

Rationale: RIP bands are capable of accurately measuring breathing patterns in patients and is therefore capable of measuring dysfunctional breathing patterns in patients.
Objective: To study (the treatment of) dysfunctional breathing patterns using a wearable breathing trainer.
Study design: Prospective cross-over study
Study population: 25 children aged 8-17 with paediatrician diagnosed dysfunctional breathing
Intervention (if applicable): All children are treated by their physical therapist while the wearable breathing trainer measures their breathing pattern in the first visit. In the other study visit children are given feedback on their breathing through vibrations given by the wearable breathing trainer based upon their breathing pattern. Due to the cross over design of the study, half of the children participate in the second visit first.
Main study parameters/endpoints: The primary goal of this study is to determine the effects of breathing exercises given by the pediatric physiotherapist objectively using RIP
These signal alterations allow for the following parameters to be measured:
• RIP amplitude
• RIP frequency
• RIP peak variation

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are no risks associated with this study. Participation entails two sessions at the physical therapist, all measurements are conducted within regular care visits to the physical therapist and therefore take no extra time to complete.

### Study objective

Primary study objective:
To impartially identify the focus of breathing (thoracic or abdominal) using

respiratory inductance plethysmography for children aged 8 to 18 with dysfunctional breathing

Secondary objectives:
• To investigate the effects of vibrotactile feedback on breathing during breathing exercises at the physical therapist
• To compare the effects of vibrotactile feedback to verbal and tactile instructions given by the physical therapist
• To determine the performance of RIP measurements during breathing exercises
• To determine the experience of included patients (children) to use technology to support breathing exercises

**Study design**

The wearable breathing trainer is a vest equipped with RIP bands capable of measuring the focus of breathing in patients in individual breaths. Additionally, it is equipped with actuators which can be used to steer the focus of breathing towards the abdomen.

This study will be performed during regularly planned visits to the physical therapist and will have a cross-over design. Subjects will be selected from the Asthma Exercise and Research Centre of the Eastern Netherlands (AIRCON) at the paediatrics department of MST. All subjects will be referred as usual, to the physical therapist for their dysfunctional breathing pattern. Upon diagnosis they will be informed about this study and if they are interested, they will be provided with the PIFs for the appropriate age groups.

At the first visit, a treatment plan is set up in consultation with the physical therapist. At this first visit, subjects and their parents are also asked to bring the informed consent forms when making the appointment if they wish to participate. If they forget but do wish to participate, they are allowed to bring the informed consent forms to the second visit. No measurements will be conducted prior to obtaining informed consent.

During the second and third visit, subjects will wear the wearable breathing trainer. Half of the subjects will first perform the exercises with the physical therapist as usual, whilst the wearable breathing trainer only measures the breathing pattern (group A). At the next visit, subjects will perform the exercises with the physical therapist whilst not receiving feedback from their therapist, but from the vibrating motors in the wearable breathing trainer. The other half will perform the exercises with the wearable breathing trainer the other way around (group B). Participants will be divided into group A or B by the investigator alternately. It is not possible to blind the physiotherapist and patient after enrollment into the study.

A cross-over design makes it possible to compare the intervention with the control condition within each participant. The alternating assignment of the

starting condition allows for the evaluation of starting physical therapy with or without the intervention.

After the third visit an evaluation moment will be planned by the investigator with the subject to evaluate the use of technology (RIP bands and actuators) for applying haptic feedback. A semi-structured interview will take place with topics based on the technology acceptance model (TAM) and Unified Theory of Acceptance and Use of Technology (UTAUT).

We aim to include one subject every week after starting inclusion. At AIRCON we examine over 700 patients each year, of which roughly 25% are diagnosed with dysfunctional breathing. Earlier research has shown a large willingness to participate in research that does not take any additional time and is performed alongside regular care.

**Study burden and risks**

There are no risks associated with participation in this study. Furthermore, participation entails measurements performed alongside regular care and therefore do not provide an additional burden.

# Contacts

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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

Children with paediatrician diagnosed dysfunctional breathing
Ages 8 up to and including 17
Referred to a paediatric physical therapist for treatment

## Exclusion criteria

Children and/or parents that do not speak Dutch
Co-morbid diseases that may influence dysfunctional breathing
Poor asthma control
Psychomotor retardation

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-03-2024 |
| Enrollment: | 25 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | Science suit (Klasse I);Breathpal (Klasse IIa) |
| Registration: | No |

## Ethics review

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| Approved WMO Date: | 17-06-2024 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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 | NL86166.100.24 |