Home-based treatment of dysfunctional breathing

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To investigate the feasibility of treating pediatric patients with suspected dysfunctional breathing with the Glimp Pebbles.

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional research applied for the first time in human subjects

Summary

ID

NL-OMON57692

Source
Onderzoeksportaal

Brief title
Feasibility, acceptance and exploratory effectiveness of a home-based treatment of dysfunctional breathing.

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
dysfunctional breathing, hyperventilation dysorder

Research involving
Human

Sponsors and support

Primary sponsor: Hagaziekenhuis, Den Haag
Source(s) of monetary or material Support: Subsidie - Kansen voor West

Intervention

- Medical device

Explanation

N.a.

Outcome measures

Primary outcome

Primary endpoint: Adherence to study regimen

Secondary outcome

Secondary endpoints: Patient satisfaction
Heart rate variability pattern over time Exploratory endpoints: Difference in symptom scores and physiotherapeutic assessments. Comparison with historical cohort.

Study description

Background summary

Dysfunctional breathing refers to inefficient or uncoordinated breathing patterns that can interfere with effective respiratory function it has been observed addressing dysfunctional breathing through breathing retraining can be beneficial in asthmatic patients (10). Breathing retraining requires consists of multiple sessions with a physiotherapist and of breathing exercises to conduct at home. However, compliance to breathing exercises is variable, and it is difficult to ascertain whether they are conducted correctly. The hand-held breath device “Pebbles” from Glimp was developed to offer guided breathing exercises through vibrations and bio-feedback in a home-setting. The sensor synchronizes with the breath and provides vibration feedback to guide breathing towards a target respiratory rate within the exercise. Glimp has developed a breathing program for breathing retraining which can be beneficial in dysfunctional breathing, which has not been tested in (pediatric) patients. The aim of this study is to investigate the feasibility of using Pebbles in a pediatric cohort suspected of dysfunctional breathing.

Study objective

To investigate the feasibility of treating pediatric patients with suspected dysfunctional

breathing with the Glimp Pebbles.

Study design

Exploratory interventional study investigating the feasibility of using Pebbles in children with asthma and suspected dysfunctional breathing. Children will be enrolled and will subsequently use the Pebbles for a period of 28 days.

Intervention

A breathing program has been developed that supports the patient during breathing exercises. The retraining schedules consist of a 28-day programme that works towards a target breathing pattern based on inspiratory and expiratory breathing duration. The Pebbles provide guidance on breathing pattern via vibrations of the devices.

Study burden and risks

We believe that using the Glimp Pebbles in the way described in the protocol may lead to better treatment of dysfunctional breathing compared to standard of care. However, this has not been proven. On the other hand, the risks are negligible as well. The breathing exercises that children will conduct are extremely similar to those administered by a respiratory physiotherapist, and they are not considered to give rise to health risks.

The Glimp Pebbles have been widely used by adults as a consumer product, with internal company data (unpublished and non-placebo controlled) showing high satisfaction among adult users and positive feedback from care providers, who report that the device helps clients perform exercises more effectively. However, it remains uncertain whether the Pebbles actually improve the execution of breathing exercises in adults' home settings, as there is no observer present to assess this, and the presence of an observer (such as a physiotherapist) could influence the exercise's execution. Despite this, there are strong reasons to believe that the Pebbles could be beneficial, particularly for children. The value of the Pebbles in executing breathing exercises lies in the vibration of the devices, which removes the need for patients to count their breaths, thus facilitating better exercise adherence. This aspect may be more challenging for children than for adults. Therefore, it is crucial to consider the entire package (Pebbles, app, and specific breathing exercises) as a whole, not just the device itself.

Given this and the fact that the study involves group-related aspects (as discussed below) and a greater 'unmet need' for children compared to adults, we believe conducting the study in adults would not be beneficial. There are several reasons for the group-related nature of this study:

- The primary outcome measure is adherence (treatment compliance). The accompanying app is specifically designed for children to improve adherence, meaning that using the app and Pebbles with adults would likely have a different effect, potentially making it less appealing. This could lead to inaccurate conclusions if results from adults were applied to children.

- The 4-week program developed for this study is tailored to children, created in collaboration with pediatric physiotherapists. While a similar treatment might apply to adults, there are differences in difficulty levels, such as the duration of inhalation and exhalation. Using this program with adults would likely result in lower difficulty, impacting treatment compliance (either positively or negatively). As a result, conclusions drawn from adult use would not be valid for children.
- Breathing exercises are significantly harder for children to perform without guidance compared to adults, due to their higher tendency to get distracted and, depending on age, their less developed cognitive abilities. This affects both adherence and efficacy, and children are likely to benefit more therapeutically from the Pebbles. Therefore, lack of effectiveness in adults does not provide useful information for determining whether the study should be conducted in children.
- Finally, from a therapeutic perspective, dysfunctional breathing in children is less often of the hyperventilation type, while in adults, thoracic-dominant breathing is uncommon. This makes studying the treatment in adults irrelevant, as any effect on hyperventilation symptoms does not necessarily apply to children with mainly thoracic-dominant breathing.

Contacts

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Trial sites

Trial sites in the Netherlands

HagaZiekenhuis
Target size: 25

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

- Age 8 years to 18 years.

- Nijmegen questionnaire result > 18 points OR Breathing pattern assessments tool (BPAT) score > 3 OR evidence of thoracic-dominant breathing using the Manual Assessment of Respiratory Motion (MARM) test.

- Informed consent according to Law on research with Medical subjects.

- Access to mobile device with Android and/or iOS

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- Inability to use the device

- Insufficient proficiency in the Dutch language.

Study design

Design

Study phase: N/A

Study type:	Interventional research applied for the first time in human subjects
Intervention model:	Single
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	25
Duration:	1 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	Medical device
Generic name:	Pebbles
Registration:	Yes - CE outside intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	16-06-2025
Application type:	First submission
Review commission:	METC LDD

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
Research portal	NL-009296