SpiroPlay: a study to evaluate the performance, usability and userexperience of gamified spirometry in asthmatic children

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29175

Source Nationaal Trial Register

Brief title SpiroPlay

Health condition

Pediatric asthma

Sponsors and support

Primary sponsor: Medisch Spectrum Twente **Source(s) of monetary or material Support:** Pioneers in Healthcare fund (https://www.utwente.nl/nl/techmed/innovatie/fondsen/pioneers-in-healthcare/)

Intervention

Outcome measures

Primary outcome

• The amount and types of errors made during spirometry in children in gold standard inhospital spirometry as well as in SpiroPlay spirometry.

• Lung function outcome parameters (FEV1, FVC, Tiffeneau index, PEF, FEF2575) in gold standard in-hospital spirometry as well as in SpiroPlay spirometry.

• The provided feedback and feedforward to the patient, based on raw lung function data.

Secondary outcome

- The usability and user-experience of SpiroPlay spirometry in children.
- The preference of children for certain metaphors.
- The relation between specific metaphors and frequently made errors.
- The correlation between age and the amount and type of errors.

Study description

Background summary

Rationale:

Monitoring of paediatric asthma relies heavily on subjective information acquired during scheduled visits when children are usually asymptomatic as asthma is an episodic disease. This stresses the urge for complementary objective methods to monitor childhood asthma. Modern technology can facilitate home-monitoring with spirometry and the acquisition of relevant clinical data when symptoms appear. Spirometry measurements however require maximal effort and maximal patient cooperation to have an accurate outcome measure.

Objectives:

The primary objective of this study is to evaluate SpiroPlay spirometry in comparison to the gold standard: in-hospital spirometry with professional guidance. This evaluation incorporates investigating the amount and types of errors made during spirometry in children in gold standard in-hospital spirometry as well as in SpiroPlay spirometry, comparing lung function outcome parameters (FEV1, FVC, Tiffeneau index, PEF, FEF2575) between gold standard in-hospital spirometry and SpiroPlay spirometry, and investigating whether the SpiroPlay provided proper feedback and feedforward to the patient based on raw lung function data. The secondary objectives of this study are to explore the usability and user-experience of SpiroPlay spirometry in children, to investigate whether children have a preference for certain metaphors, to examine whether there is a relation between specific metaphors and frequently made errors and to investigate whether there is a correlation between age and the amount and type of errors.

Study design:

This study has a prospective, multi-centre, cross-over design. The children will be asked to perform two spirometry series of three reproducible blows; one series of gold standard inhospital spirometry with professional guidance and one series with the developed SpiroPlay game. With gold standard in-hospital spirometry, the child will receive the instruction and feedback from a professional healthcare provider. With SpiroPlay spirometry, the child will receive the instruction and feedback from the SpiroPlay game. Both spirometry series will be performed according to the closed circuit method as described in Miller et al. After performing both spirometry series, the child be interviewed in order to explore the usability and user-experience of SpiroPlay spirometry and to investigate whether children have a preference for certain metaphors.

Study population:

The study population will consist of 60 children with paediatrician diagnosed asthma in the age of 6 – 11. 30 children will be included in Medisch Spectrum Twente (MST) Enschede and the other 30 children will be included in Deventer Ziekenhuis (DZ).

Study objective

We hypothesize that providing an attractive game with appropriate metaphors and personalized feedback and feedforward will positively impact the quality of home spirometry in asthmatic children.

Study design

Single session (+-15min) during their regular outpatient visit.

Intervention

SpiroPlay game

The SpiroPlay game is an android app (figure 1) which is linked to a spirometer via a Bluetooth connection on a smartphone or tablet. The game consist of persuasive metaphors for the spirometry manoeuvre with the intention to increase quality and adherence of spirometry in children. The game consist of 3 phases: an instruction/feedforward phase, an encouragement phase and a feedback phase.

The instruction/feedforward phase:

During regular spirometry, children are instructed on how to perform the manoeuvre (i.e. sit straight, attach noseclip, breathe out slowly, full deep breath in, blow as hard and as long as you can out). The SpiroPlay incorporates this instruction in the storyline of the game to prepare the child for the blow. Moreover, personalized feedback from previous blows is used to remind and focus the child on certain aspects of the blow ("this time try to go on with exhaling till your completely empty").

The encouragement phase:

Appropriate game metaphors (e.g. letting an elephant empty its trunk full of water) will be used to positively influence effort and duration of the spirometry manoeuvre. These metaphors will include the inspiration- as well as the expiration technique.

The feedback phase:

Based on the measured spirometry data, SpiroPlay automatically recognizes incorrectly performed expiration techniques (e.g. coughing or glottic closure, early termination, non-

maximal effort). Based on the type of error, SpiroPlay provides personalized feedback to support the child in performing correct spirometry in a following attempt, based on behaviour change strategies and the persuasive systems design (PSD) model.

Contacts

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Eligibility criteria

Inclusion criteria

- Children with paediatrician diagnosed asthma.
- Children aged between 6 and 11 years.
- Children who have to perform spirometry at a regular outpatient visit in MST or DZ.
- Written informed consent of the parents or legal guardians.

Exclusion criteria

• Children with acute asthma symptoms.

• Children with comorbidities who could have difficulties with the instruction of lung function measurements / children with comorbidities that might influence the execution of lung function measurements (i.e. autism, developmental impairment, neuromuscular diseases).

• Children who are unable to understand or speak Dutch, or whose parents or legal guardians are unable to understand or speak Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

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Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	60
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

Deidentified IPD (characteristics (age, gender), processed lungfunction data, user experience data, and logdata of application) will be shared within the consortium of the Pioneers in Healthcare fund (Medisch Spectrum Twente, pediatric department, Deventer Ziekenhuis, pediatric department, University of Twente, human media interaction and Saxion university of applied sciences, Ambient Intelligence Research Group). All processed data is stored in the data management system with audit trail and used for analysis to identify primary and secondary outcome parameters.

Ethics review

Positive opinion Date: Application type:

27-09-2019 First submission

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
NTR-new	NL8048
Other	CCMO, METC Twente : KH19-17 (N-WMO waiver)

Study results

Summary results

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