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The impact of giving individual feedback about symptom perception to asthmatic children – results of a pilot study

MASTER THESIS OF HEALTH SCIENCES

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PREFACE

Before you lies the thesis “The impact of giving individual feedback about symptom perception to asthmatic children – results of a pilot study”. It has been written to fulfill the graduation requirements of the Master of Health Sciences at the University of Twente.

As a child, I dreamed of being owner of a day-care for children and when I grew older, I started dreaming of being pediatrician. Finishing my master program with a study concerning children is the result, where I switched between day-care manager, pediatrician and scientist. In the summer of 2015, I moved from Veldhoven to Enschede to start the bachelor of Technical Medicine and after receiving my bachelors degree and being half-way in the Master program, I decided to switch to the master of Health Sciences, the one I will be finishing with this thesis.

The research I have done took place in Enschede, in Medisch Spectrum Twente, at the pediatric department. The subject of my thesis has been formed after conversations with a pediatric pulmonologist, dr. Thio, where he described several problems practitioners face in the pediatric department. One of the main problems was the lack of knowledge about asthmatic symptom perception in children and from that view I started to develop the subject and research question of my thesis.

I would like to thank my supervisors Mattiènne van der Kamp, Job van der Palen and Anke Lenferink for their guidance and support during the process of my master thesis. I would also like to thank the five participants who were willing to be included in my pilot study; without their cooperation I would not have been able to complete this thesis.

Lastly I would like to thank my family and friends, in supporting me during this process, especially Esther for helping me to visualize my ideas about the Perception Rainbow and Tim, who helped me a lot on this thesis and kept me always motivated, even where some circumstances made that difficult.

I hope you will enjoy reading my thesis.

Ingrid de Bekker
Enschede, January 2022

ABSTRACT

BACKGROUND

Having a bad asthmatic symptom perception, e.g. mismatching perceived symptoms with objectified lung function, results in under- or overestimation of symptom severity. In children with asthma, overestimation might be associated with over-medication and accompanying side-effects, and on top of that, underestimation of symptoms is a major risk factor for hospitalization, emergency department visits and (near-) fatal asthma attacks. Therefore, the aim of this study is to investigate whether giving individual feedback to asthmatic children about their asthmatic symptom perception results in a better perception.

METHODS

In this prospective intervention pilot study, children whose perception possibly could be improved were included and received five sessions of feedback on their home-monitored perception measurements for at least six weeks. The Perception Rainbow was designed during this study as a tool to measure the perception, consisting of the FEV_1 and a Visual Analogue Scale (VAS), where different colors represent different asthmatic symptom perception scores (ranging from 1 to 16). The data was analyzed on change patterns in perception scores over time.

RESULTS

Five participants contributed in this study and in all five participants, at the and of the study, the asthmatic symptom perception was improved with a mean change in perception score of 3.54 (SD=2.32). The largest shift towards a better perception took place between week 1 and 2. The study population performed on average 5.2 measurements at home per week during this study, rising from an average of 3.6 measurements in week 1 to an average of 7.6 measurements in week 5.

CONCLUSION

Giving feedback on home-monitoring measurements for six weeks have led to an improvement in perception in all five participants, with the largest improvement between week 1 and 2. A recommendation is to perform a follow-up study with a larger study population.

Contents of this thesis

1. Introduction

1.1 Clinical background

Asthma has a prevalence of 5-10% in children up to 12 years old in the Netherlands and is therefore the most prevalent chronic childhood disease [1]. Despite the availability of effective asthma treatment, uncontrolled asthma is still highly prevalent [2]. Although controlled asthma has a minimal impact on everyday living, uncontrolled asthma is associated with quality of life by an increased risk of emergency department visits, hospitalization and absenteeism of school [3].

1.2 Perception

Perception is defined as the patient's sensation and is a series of processes: there is a pathophysiologic stimulus, from which the information is transmitted, processed and interpreted, leading to acknowledgment by the patient [4]. Having a bad perception, e.g. mismatching perceived symptoms with objectified lung function, results in under- or overestimation of symptom severity by patients. Asthmatic children and parents have been found to underestimate their asthma severity, leading to health care professionals often underestimating asthma symptom prevalence and lifestyle limitation. As a result, asthmatic children and parents overestimate asthma control, thereby perceiving significant levels of symptoms as good control. [5][6] Moreover, in children with asthma, underestimation of symptoms is a major risk factor for hospitalization, emergency department visits and (near-) fatal asthma attacks [7]. On the contrary, overestimation might be associated with over-medication and accompanying side-effects [4]. Costs associated with asthma are increasing and the most important direct cost drivers are hospitalization and medication, while the largest percentage of indirect costs is found in work and school absenteeism [8]. Caregivers managing a child with high-risk asthma indicate the need for asthma education and family-centered interventions [9]. By improving perception in children with asthma, hospitalization, unnecessary use of medication and school absenteeism might be averted.

1.3 Exercise and provocation testing

In the majority of asthmatic children, exercise induces airway constriction [10] and the fear of having an asthma attack is a main barrier for exercise in adolescents [11]. Exercise induced bronchospasm (EIB) is an increase in airway resistance, occurring after a period of physical exercise. EIB is especially problematic in children, since children have a high level of physical activity. [12] The airway responsiveness can be measured with a bronchoprovocation test using different tools, including cold air and exercise [13][14].

1.4 Spirometry

Spirometry is a method used to measure the change in lung volumes during forced breathing manoeuvres and is used for diagnosing, managing and monitoring patients with respiratory diseases [15]. Spirometry can also be performed with home-monitoring devices, giving parents the possibility to self-monitor the objectified lung function at home and determine their asthmatic symptom perception. The study of Van Der Kamp et al. [16] showed a correlation between the data of home-monitoring devices and the hospital-based spirometry assessment of asthma control.

For the diagnosis of asthma, obtaining evidence of expiratory lung function variability is necessary, particularly the drop in Forced Expiratory Volume in 1 second (FEV_1) ≥ 13% after exercise or its reversibility by administration of a bronchodilator. This reversibility is defined in children as an increase in FEV_1 > 12% compared to the FEV_1 results before administration of a bronchodilator. [17][18][19][20]

1.5 Problem, aim and research question

Since having a bad perception has a large impact on many aspects on daily life, there is need for a method to improve the asthmatic symptom perception. The aim of this pilot study is to determine

whether it is possible to improve the perception of symptoms in a home-setting in asthmatic children by giving feedback to those children and parent(s)/caregiver(s).
The research question of this pilot study is: *What is the impact of giving personal feedback to children on the perception of their asthma?*

2. Methods

2.1 Study design

This study is a (prospective) intervention pilot, set up to investigate the impact of feedback on asthmatic symptom perception in children in a home-monitored setting over a data collection period of at least six weeks incorporating five feedback sessions. To be able to perform this study, a *non-wmo* declaration of Medisch Spectrum Twente (MST) was obtained and this study is registered in the Dutch Trial Register (NTR number: NL9638). Therefore, a protocol and information letters have been written. These documents are attached in Appendix A.

2.2 Study population

Patients (asthmatic children) whose perception possibly could be improved, were recruited from the AIRCON lab in MST, where children underwent an exercise provocation test for regular care to assess their current asthma status. The exercise provocation test is used for the diagnosis and control of exercise-induced asthma in patients with a history of shortness of breath during or after physical activity. During this test, bronchospasms are additionally provoked through airway cooling and drying. [10]
Inclusion criteria were:

- Moderate to severe persistent and uncontrolled asthma (Asthma Control Test (ACT) score < 20 [20] or a drop in $FEV_1 \geq 13\%$ after exercise [17])
- Experience asthmatic symptoms at least twice a week, questioned at the AIRCON consult (to guarantee enough data could be collected during the study)
- Having a poor perception, based on the expert opinion of the pediatric pulmonologist

Patients were excluded if, based on the expert opinion of the pediatric pulmonologist, the spirometry technique was unlikely to be performed correctly in a home-monitoring setting.

2.3 The Perception Rainbow

To define the perception in relation to the measured lung function, a rainbow-graph (the Perception Rainbow) (Figure 1) was created as a tool to visualize the disparities of the objectified and subjective lung function. Different colors represent the grade of perception: the green area represents a good perception, while the red areas represent a poor perception. The Perception Rainbow consists of the objectified lung function on the y-axis, measured with spirometry and is expressed as the percentage FEV_1 compared to the baseline FEV_1 of the specific patient, set against the simultaneously measured subjective sensation of their asthmatic complaints on the x-axis, measured with a Visual Analogue Scale (VAS). During the consultation at the hospital, the baseline FEV_1 was determined by conducting a maximum effort spirometry. A decrease in FEV_1 after exercise ≥ 13% is regarded as diagnostic for asthma [17], which explains the transition from the green to the yellow line at 88%. The VAS has a range from 0 to 10. The VAS is a

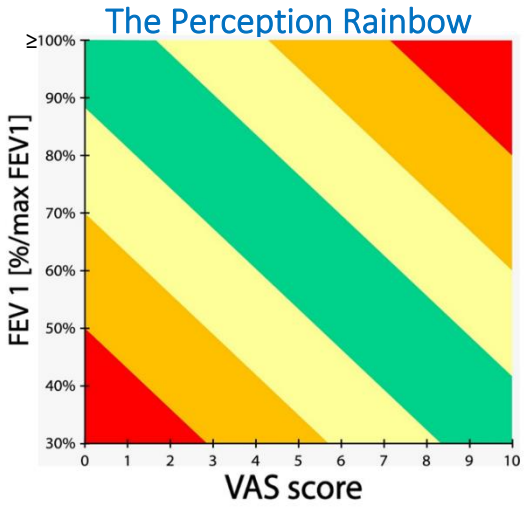

Figure 1: The Perception Rainbow, a tool to visualize the disparities between spirometry measurements on the y-axis (expressed as the percentage FEV_1 compared to the maximal FEV_1 of the specific patient) and the results of the Visual Analogue Scale score on the x-axis. Different colors represent the grade of perception. The green area represents a good perception, while the red areas represent a poor perception.

line with anchors at both ends, representing the extremes of dyspneic sensation, on which the subject is instructed to place a mark to quantify their dyspnea [21] and is a valid measure to predict current asthma control [22].

2.4 Measurements at home

A measurement at home can be done with or without the parent(s)/caregiver(s) of the participant and consists of filling in a few questions, followed by performing spirometry with a home-monitoring spirometer. The questions focused on the acute symptoms at the moment they occurred and these questions were drafted regarding the ecological momentary assessment (EMA) principle [23]. The goal of these questions was to gain insight in the setting in which the measurement was performed. One of those questions was a VAS to determine the experienced asthmatic severity, other questions regarded the asthmatic symptoms, the level of activity prior to the measurement (no activity (resting), low intensity activity (e.g. walking) or high intensity activity (e.g. sporting)) and possible interventions the participant would perform after completing the measurement (administering medication, resting or no intervention (continue activity)). Additionally, one question regarded the emotional status (with three optional answers: negative, neutral or positive) of the participant, since emotion can have a huge effect on perception of dyspnea [24]. Apart from the VAS, all questions were multiple-choice questions so they were easy to interpret and quick to complete.

To measure the lung function at home, participants received a spirometer device: the Air Next spirometer (NuvoAir, Stockholm, Sweden). This is a Bluetooth connected device with disposable mouthpieces, allowing people to connect the spirometer with their smartphone. The Air Next spirometer is compatible with both Android and Apple smartphones. Three consecutive measurements need to be performed and were graded on reproducibility and a sufficient form of the flow-volume curve to preserve validity. The measurement with the highest FEV_1 value was regarded as the current lung function, as it is possible to perform under possible maximum function, but not above. Whether the parent(s)/caregiver(s) or the participant was responsible for performing the spirometry at home was concluded in consultation with the parent(s)/caregiver(s) and participant together.

2.5 Feedback sessions

All participants had five ten-minute feedback sessions during the study, held via video-consultation using WhatsApp. A structured interview-frame (asking the same questions in the same order to all participants) was used during the sessions, to be sure the same things were discussed in all sessions. The results of the home-monitoring measurements were visualized in the Perception Rainbow and shown to the participant. The content of the feedback was determined by the discrepancy and agreement between the subjective and objectified lung function. Feedback sessions consisted of three topics: first, the asthmatic complaints and experienced difficulties in performing spirometry in the last week were discussed. Next, the Perception Rainbow was discussed, going over the circumstances and degree of perception of every measurement. Lastly, there was room for questions or remarks from the participant and/or parent/caregiver. During the last session, the success- and critical factors of this pilot-study were evaluated with the participants to benefit follow-up research. This was done with open questions on the duration, the method of measuring and receiving feedback, the contact with the researcher and there was room for some general remarks about this research.

2.6 Data analysis

To determine the impact of giving individual feedback about symptom perception to asthmatic children, all the results of the home-monitoring measurements were plotted in the Perception Rainbow. Next, to score the perception, areas in the Perception Rainbow were graded with a score ranging from 1 to 16, 1 meaning no perception and 16 meaning maximal perception. The Perception Rainbow with scores is displayed in Figure 2, with two results visualized (1 and 2). Measurement 1 receives a score of 6 perceptionpoints and measurement 2 receives a score of 8 perceptionpoints.

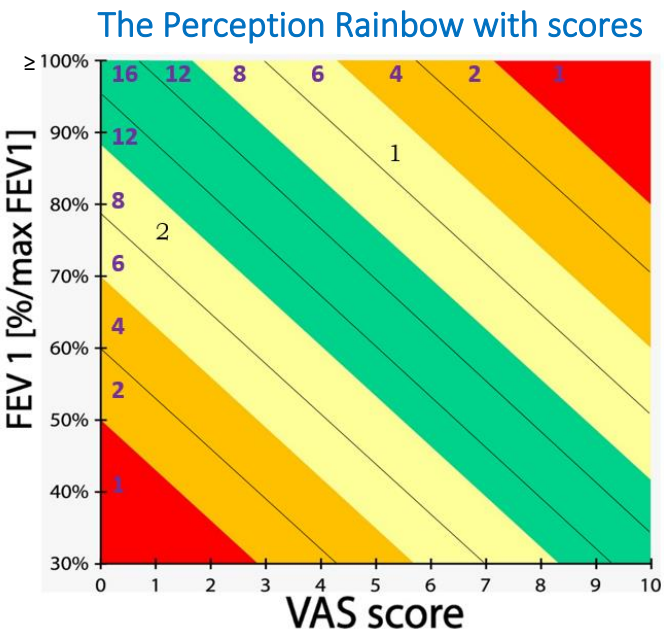

Figure 2: The Perception Rainbow with the perception scores. Measurement 1 consists of a FEV_1 of 88% and a VAS score of 5.3, while measurement 2 consists of a FEV_1 of 76% and a VAS score of 1.1. Measurement 1 receives a score of 6 points and measurement 2 receives a score of 8 points.

2.6.1 Changes in perception score over time

To determine the change in asthmatic symptom perception over the study period, the change in scores over the weeks was calculated by taking the mean perception score per week. The perception score at week 1 is compared to the perception score at week 5 and visualized in a graph for all participants. To investigate whether the improvement in perception was significant, a Wilcoxon signed rank test was performed by comparing the perception score of week 5 with week 1.
To investigate the trends and the speed of changes of the measurements of all participants, the measurements of all participants combined were visualized in one Perception Rainbow graph per week.

2.6.2 Impact of settings and emotional status on perception score

Also the results of all participants were combined and split up per defined setting, namely regular measurement, experiencing asthmatic symptoms, pre-exercise, post-exercise or after administering medication. The mean perception scores were calculated per week for all different settings to define the gradients in perception scores between week 5 and 1 in the different settings.
Lastly, the impact of the emotional status at the moment the measurement was done was investigated. On this topic, it was investigated whether a positive emotional status had a positive effect on perception scores compared to a negative or neutral emotional status.

3. Results

3.1 Study population

From July to September 2021, six patients were included in this study. One was lost to follow up, since this patient did not perform any measurement. The five participants were all boys and their characteristics are shown in Table 1.

Table 1: Characteristics of the participants

	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5
Age [years]	9	12	9	7	7
ACT score at inclusion	9	17	20	11	15
Baseline lung function [%predicted] & ([%drop]) at inclusion	81% * (-4%)	94% * (-9%)	102% (-6%)	51% (-16%)	69% (-57%)
Perception score at inclusion	8	7,5	7,5	14	6
Over/under-perceiver	Over	Over	Over	Under	Over
Medication used during the study	3DD1 Foster (100 µg), Ventolin	2DD1 Qvar (100 µg), Ventolin	Montelukast, Pulmicort 2DD1, Beconase 2DD1, Desloratadine 2,5 mg 1DD1, Ventolin	Qvar 2DD1, Ventolin	Qvar 2DD1, Ventolin
Diagnosed with asthma since	07-2021	08-2021	06-2021	07-2014	09-2021
	*Participant had taken medication right before the inclusion, possibly affecting the results in lung function				

3.2 Changes in perception score over time

All perception measurements performed at home were graded with an asthmatic symptom perception score. The mean perception score per week was calculated per participant, displayed in Figure 3. All five participants had a positive change in their mean perception score in week 5 compared to week 1, with the largest change in subject 1 (+6.67) and the smallest change in subject 5 (+0.33). The mean change in perception score of all subjects in week 5 compared to week 1 was 3.54 (SD=2.32).

A Wilcoxon signed rank test was performed by comparing the perception score of week 5 with week 1 and the result of the Wilcoxon signed rank test was a p-value of 0.043.

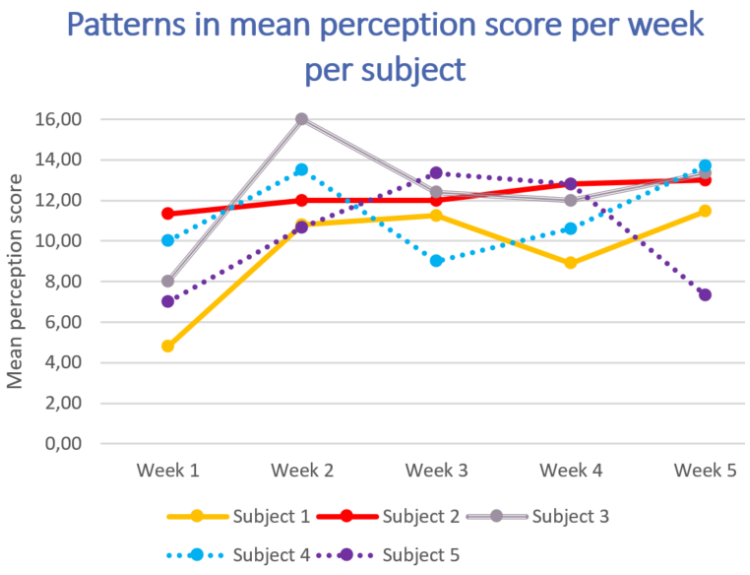

Figure 3: A graph of the patterns in the mean perception scores per week per subject

The trends of all the perception measurements of all participants combined in different colors in the Perception Rainbow graphs are shown in Figure 4. The largest shift from measurements to an area which represents a better perception (from orange to yellow or from yellow to green) took place between week 1 and 2. The percentage in a specific color represents the percentage of all the measurements in this color, including the measurements in the concurring color stroke on the other side of the green stroke.

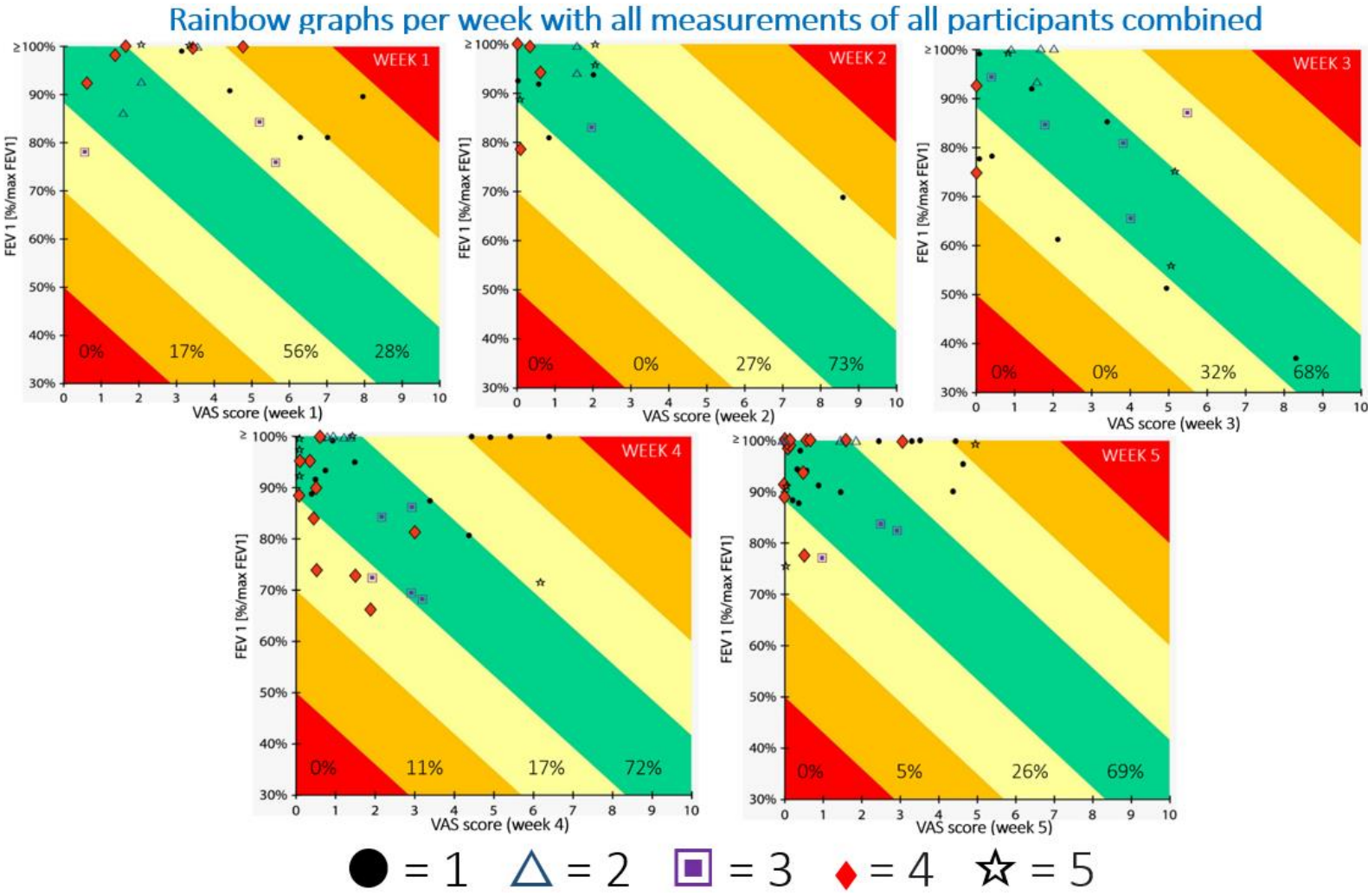

Figure 4: Five Perception Rainbow graphs, consisting of all the perception measurements performed per week. Each symbol represents a participant and each graph represents all the measurements of all five participants in one week. The symbols below the graphs describe what symbol represents what participant. The percentage in a specific color represents the percentage of all the measurements in this color, including the measurements in the concurring color stroke on the other side of the green stroke.

3.3 Impact of setting and emotional status on perception score

The changes of the mean perception scores have been grouped per defined setting and demonstrated differences between those settings, shown in Table 2. The largest difference between week 1 and 5 is found in the measurements after exercising, while the smallest difference is found in measurements done before exercising. The blanks were due to an absence of measurements concerning that specific setting that week.

Table 2: Changes in mean perception scores per week per setting

	Standard/regular measurement	Symptoms	Pre-exercise	Post-exercise	After salbutamol
Week 1	8.3 (n=6)	4.0 (n=1)	12.0 (n=3)	7.0 (n=8)	
Week 2	12.8 (n=5)	6.0 (n=1)	9.0 (n=2)	14.4 (n=5)	10.0 (n=2)
Week 3	11.3 (n=11)	13.3 (n=3)	13.3 (n=3)	8.7 (n=3)	14.0 (n=2)
Week 4	12.3 (n=16)	6.0 (n=3)	13.0 (n=8)	9.3 (n=8)	12.0 (n=1)
Week 5	12.0 (n=16)		13.8 (n=11)	10.9 (n=11)	

One question was about the emotional status of the patient at the moment the question was filled in and the measurement was done. The results of the relation between the perception score and the emotional status of the patients showed that the average perception score was 12.5 when the emotional status was positive (n=47) and the perception score was 10.6 when the emotional status was neutral or negative (n=82).

3.4 Feasibility and evaluation of the study

The participants performed on average 5.2 measurements at home per week during this study, rising from an average of 3.6 measurements in week 1 to an average of 7.6 measurements in week 5. At the end of the study, an evaluation was held. During these evaluations, positive aspects and recommendations for this study were given. Of the five participants, three mentioned the explanation of the study procedure was clear, four mentioned the contact and feedback sessions via WhatsApp using their personal smartphone was experienced as pleasant and easy and two participants mentioned the Air Next spirometer was easy to use, although one participant mentioned to have some trouble with the Air Next spirometer in the connection to the smartphone. Also, one participant mentioned a broader explanation about the Perception Rainbow was desirable and another participant recommended to make the questions more children-friendly and add an open box at the questions to give additional information about the situation the measurement was performed in.

4. Discussion

This study showed that all five participants had a positive gradient in their perception score, meaning they improved their perception during this study. The goal of this study was to investigate the impact of receiving feedback about asthmatic symptom perception in children and these results implicate that participation in this study improved perception by performing the measurements at home and gaining feedback on those measurements. In this study, all participants were boys. A majority of boys in the study population was expected, since the asthma incidence, prevalence, and hospitalization rate on pre-pubertal age is higher in boys compared to girls of the same age [25].

A few studies similar to this study have been done, however, the focus and method differs from this pilot study. In the study of Feldman et al. [26], results showed a decrease in under-perception in children who received feedback compared to children who received no feedback, which is in line with the results of this pilot study. The Childhood Asthma Perception Study (CAPS) [7] has a duration of 15 months and consists of two groups: one group receives feedback on their PEF and one receives feedback consisting of standardized messages and have 3 control feedback visits and asthma education. No results are posted for this study yet, however, it shows the relevance of this subject.

4.1 Interpretation of the results

Results showed that the trend of all the measurements of all five participants was moving to the central green area during the study and in addition to the improvement in the perception scores, all five participants also mentioned during and after the study they felt they improved their perception. Remarkable is the fact that all the measurements in the orange area in week 4 are from one subject. These measurements were four measurements at the same situation: directly after exercising, while salbutamol was taken after exercising. The largest improvement in perception was seen between week 1 and 2 and therefore it could be useful to shorten the study period in a follow-up study. This improvement in the first weeks could be explained by it was the first time these participants could measure their lung function in certain situations outside the hospital, giving them insight into their own perception.

When comparing the different defined measurement settings, the largest improvement in the perception score was seen in the measurements after exercising followed by a standard measurement. The large improvement in perception score after exercising can be explained by the difficulty to make the distinction between feeling like having shortness of breath due to asthma and shortness of breath, due to exertion. In the evaluations with patients, this was also mentioned by participants, who felt safer in taking more risks during the study, by taking less salbutamol and by measuring more often to identify whether it was shortness of breath, due to exertion or due to asthma. The smallest improvement when comparing the first and last measurement was seen in the measurements before exercising, followed by measurements performed when experiencing asthmatic symptoms and after taking salbutamol. The explanation for this small improvement could be that when participants took salbutamol, participants were aware of the rise in their objectified lung function, since the purpose of taking salbutamol is to reduce asthmatic symptoms.
It occurred in some weeks that not all settings were measured. E.g., measurements when experiencing asthmatic symptoms in week 5 are missing and less measurements were performed after the administration of salbutamol. This could possibly implicate better asthma control at the and of the study than in the previous weeks. However, research with a control group needs to be done to identify the circumstances leading to experiencing less asthmatic complaints and using less salbutamol.

It has been shown that emotion can have a huge effect on perception of dyspnea [27]. The results of this pilot study show a higher average perception score when the emotional status was positive, compared to a neutral or negative emotional status. This outcome suggests patients to be able to understand their asthmatic symptoms better when their emotional status was positive that moment.

The rise in the amount of measurements per week could be explained by the participants own internal motivation to increase their perception. As mentioned by participants, experiencing the benefits in the first few weeks drove them to test their lung function in more situations.

4.2 Strengths, limitations and recommendations

A great strength of this study design was its intensity. By performing a lot of measurements and having frequent contact with the researcher, a huge participation effort was asked to improve the perception. The increase in the amount of measurements per week results in outliers having less impact on the average perception scores in the later weeks.

Besides those strengths of this study, there were some limitations. Firstly, due to many unknown variables, no feasible power analysis could be performed and hence, this study was set-up as a pilot study. Next, the aim was to include 10 patients in this study, nevertheless, this goal was not reached because the perception of the AIRCON patients was not as bad as expected based on earlier literature and before measuring the perception. In the selection of the study population, no exclusions based on age were done, since a study of Eigen et al. [28] showed that 82.6% (n=214/259) of children aged between 3 and 6 was successful in generating technically acceptable flow-volume curves in their first try. However, in the inclusion period in this study, some children in this age category were excluded based on the criterion that they were unable to perform spirometry correctly. Lastly, the aim of this pilot study was to investigate whether giving feedback on home-monitoring measurements contributed to a better perception. However, no control-group participated in this study and therefore no research has been done on the impact of only performing measurements at home and therefore the impact of feedback can-not be defined in this study.

In a follow-up research, it could be useful to use a control-group with participants who will not receive feedback and only perform measurements at home. By comparing the control-group and feedback-receiving group, the impact of giving feedback can be defined. Another recommendation for follow-up research is to use a control-group and an intervention group, both receiving feedback for only 2 weeks, since the results showed the largest shift in perception score between week 1 and 2. Next,
it will be necessary to review the choices made in creating the Perception Rainbow graph, especially the definition and scaling of the x-axis and y-axis and besides the scores given to the colors and the colors used. Since the effects of under-perceiving seem to have larger effects on quality of life, over-perceiving is not as dangerous as under-perceiving [4][7]. Therefore, under-perceivers might need to be colored with red and over-perceivers with a more neutral color. Another recommendation is to review the questions used in this study to make them more clear and children-friendly. Additionally, in a follow-up research it will be interesting to determine how long the reached perception gained using this feedback model will endure and if it will be necessary to repeat (a part of) the intervention to maintain the asthmatic symptom perception.
Due to its intensity for the participants, it might be difficult and time-consuming to find enough willing participants to implement this study on a greater scale.
More recommendations for follow-up research are attached in Appendix C.

5. Conclusion

This pilot study was performed to improve the asthmatic symptom perception in a home-monitoring setting in children receiving feedback over a period of at least six weeks, incorporating five feedback sessions and using the Perception Rainbow. The results of this study demonstrate improvement in perception of asthmatic symptoms in a home-monitoring setting. The largest improvement in perception was seen between week 1 and 2 and in the post-exercise setting by comparing week 1 and 5. The participant contributed actively in this study, what was seen in the rise of home-monitoring perception measurements from 3.6 measurement per week to 7.6 measurements per week. In a follow-up research, the Perception Rainbow needs to be reviewed on the use of the colors and the definition of the axes. Also the use of a control group is recommended to investigate the impact of the feedback sessions and to define the time frame necessary for the desired improvement in perception.

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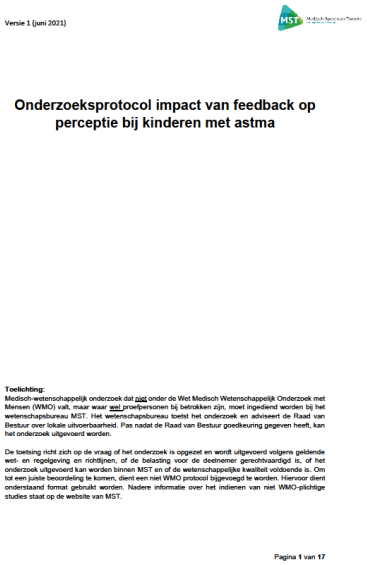
Appendix A: forms n-wmo application

Appendix A.1: Research protocol



Versie 1 (juni 2021)

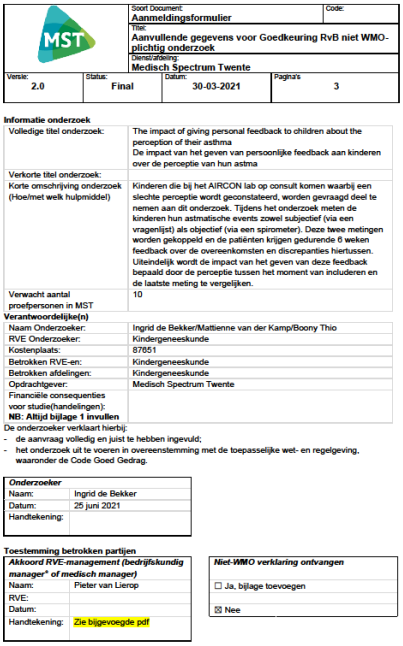
Onderzoeksprotocol impact van feedback op perceptie bij kinderen met astma

Toelichting:
Medisch-wetenschappelijk onderzoek dat niet onder de Wet Medisch Wetenschappelijk Onderzoek met Mensen (WMO) valt, maar waar wel proefpersonen bij betrokken zijn, moet ingediend worden bij het wetenschapsbureau MST. Het wetenschapsbureau toetst het onderzoek en adviseert de Raad van Bestuur over lokale uitvoerbaarheid. Pas nadat de Raad van Bestuur goedkeuring gegeven heeft, kan het onderzoek uitgevoerd worden.

De toetsing richt zich op de vraag of het onderzoek is opgezet en wordt uitgevoerd volgens geldende wet- en regelgeving en richtlijnen, of de belasting voor de deelnemer gerechtvaardigd is, of het onderzoek uitgevoerd kan worden binnen MST en of de wetenschappelijke kwaliteit voldoende is. Om tot een juiste beoordeling te komen, dient een niet WMO protocol bijgevoegd te worden. Hiervoor dient onderstaand format gebruikt worden. Nadere informatie over het indienen van niet WMO-plichtige studies staat op de website van MST.

Pagina 1 van 17

Appendix A.2: Aanmeldingsformulier MST



MST	Soort Document: **Aanmeldingsformulier**		Code:
	Titel: **Aanvullende gegevens voor Goedkeuring RvB niet WMO-plichtig onderzoek**		
	Dienst/afdeling: **Medisch Spectrum Twente**		
Versie: **2.0**	Status: **Final**	Datum: **30-03-2021**	Pagina's **3**

Informatie onderzoek

Volledige titel onderzoek:	The impact of giving personal feedback to children about the perception of their asthma De impact van het geven van persoonlijke feedback aan kinderen over de perceptie van hun astma
Verkorte titel onderzoek:	
Korte omschrijving onderzoek (Hoe/met welk hulpmiddel)	Kinderen die bij het AIRCON lab op consult komen waarbij een slechte perceptie wordt geconstateerd, worden gevraagd deel te nemen aan dit onderzoek. Tijdens het onderzoek meten de kinderen hun astmatische events zowel subjectief (via een vragenlijst) als objectief (via een spirometer). Deze twee metingen worden gekoppeld en de patiënten krijgen gedurende 6 weken feedback over de overeenkomsten en discrepanties hiertussen. Uiteindelijk wordt de impact van het geven van deze feedback bepaald door de perceptie tussen het moment van includeren en de laatste meting te vergelijken.
Verwacht aantal proefpersonen in MST	10

Verantwoordelijke(n)

Naam Onderzoeker:	Ingrid de Bekker/Mattienne van der Kamp/Boony Thio
RVE Onderzoeker:	Kindergeneeskunde
Kostenplaats:	87651
Betrokken RVE-en:	Kindergeneeskunde
Betrokken afdelingen:	Kindergeneeskunde
Opdrachtgever:	Medisch Spectrum Twente
Financiële consequenties voor studie(handelingen): **NB: Altijd bijlage 1 invullen**	

De onderzoeker verklaart hierbij:
- de aanvraag volledig en juist te hebben ingevuld;
- het onderzoek uit te voeren in overeenstemming met de toepasselijke wet- en regelgeving, waaronder de Code Goed Gedrag.

Onderzoeker	
Naam:	Ingrid de Bekker
Datum:	25 juni 2021
Handtekening:	

Toestemming betrokken partijen

Akkoord RVE-management (bedrijfskundig manager* of medisch manager)	
Naam:	Pieter van Lierop
RVE:	
Datum:	
Handtekening:	Zie bijgevoegde pdf

Niet-WMO verklaring ontvangen
☐ Ja, bijlage toevoegen
☒ Nee

Appendix A.3: Proefpersonen informatie formulieren

Regenboogonderzoek over mijn astma

Informatie over onderzoek voor kinderen tot 12 jaar

WAAR GAAT HET OVER?

WAT GAAT ER GEBEUREN?

Regenboogonderzoek over mijn astma

Informatie over onderzoek voor kinderen van 12 tot en met 15 jaar

Vragen en contact

Over het onderzoek

Perceptie-onderzoek

Informatie over onderzoek voor kinderen onder den 16 jaar

Perceptie-onderzoek

Informatie over onderzoek voor ouders

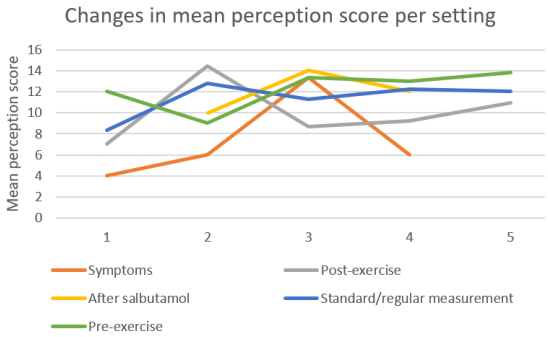
Appendix A.4: Vragenlijst in Qualtrics

Versie 1 (juni 2021)

Vragenlijst regenboogonderzoek

Appendix B: other results

Changes in mean perception scores per setting for all subjects



The results of the Wilcoxon signed rank test between the perception scores

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The median of differences between Start period and End period equals 0.	Related-Samples Wilcoxon Signed Rank Test	,043	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is ,05.

Ranks

		N	Mean Rank	Sum of Ranks
End period - Start period	Negative Ranks	0[a]	,00	,00
	Positive Ranks	5[b]	3,00	15,00
	Ties	0[c]		
	Total	5		

a. End period < Start period

b. End period > Start period

c. End period = Start period

Appendix C: practical recommendations for follow-up research

Aanbevelingsdocument perceptie-regenboogstudie

Het regenboogfiguur

Schaling y-as

In dit onderzoek wordt gedurende 6 weken de maximale longfunctie (100% op de y-as) gelijk gehouden. We houden deze dus ook gelijk als er een step-up wordt gedaan in de medicatie, terwijl er wordt verwacht dat de longfuncties dan zullen verbeteren. Daardoor is het mogelijk dat een patiënt vaak >100% blaast. Het is dan de vraag of patiënten nog slechte longfuncties kunnen blazen; als ze continu 120% blazen en dan eens 90%, is het wel een daling van 30% ten opzichte van de vorige meting. Het is goed om in het vervolg kritisch te kijken naar de schaling van de y-as en of het juist is om de maximale waarde (zonder salbutamol) in het MST geblazen te pakken hiervoor. In deze studie was er in het geval van één patiënt een step-up, waardoor in de eerste week deze patiënt alleen maar boven de 100% had geblazen. Daardoor is de y-as opnieuw geschaald naar de 100% waarde die gelijk stond aan de maximale waarde die de patiënt in de eerste week in thuissetting had geblazen.

Ook is de gevoeligheid van de metingen bij een slechte uitgangslongfunctie in twijfel te trekken. Als een patiënt een baseline longfunctie blaast van 50% voorspeld, zijn er dan wel fluctuaties waarvan je iets kan zeggen of is het altijd slecht?

Verdeling scores

Op dit moment zit er een groot verschil in scores tussen de punten in het groene en het gele deel, terwijl je eigenlijk vooral de rode en oranje slecht wil laten zijn. In dit onderzoek hebben we de scores wel zo gelaten, omdat het aannemelijk is dat de meeste patiënten zich daar zullen bevinden, maar over de verdeling van de scores kan worden nagedacht in vervolgonderzoek.

Vorm

We hebben aangenomen dat de ideale perceptie ligt rond de lijn y=-x. Kunnen we wel aannemen dat het in zo'n vorm correleert? Dat is iets wat in het vervolg onderzocht zou kunnen worden.

VAS

In dit onderzoek meten we de VAS, dus de ervaring van de klachten op dat moment, van het kind zelf. Bij kinderen hebben de ouders ook nog een grote rol in de behandeling van hun astma. Daarom zou het waardevol kunnen zijn om ook de VAS van de ouders mee te nemen in dit onderzoek. Daarbij kan de focus worden gelegd op 'hoe denkt u dat uw kind zich nu voelt' en 'wat zou de vervolgstap zijn op basis van hoe u uw kind nu ziet?'. De focus van het onderzoek wordt dan wel net anders en je krijgt meer en andere data.

De VAS op de x-as die we gebruiken in dit onderzoek is niet gekalibreerd, zoals we dat met de FEV1 op de y-as wel hebben gedaan. Daardoor liggen soms alle metingen te ver naar rechts, terwijl het gaat om de relatieve verandering van de perceptie tussen verschillende punten. Een delta-VAS as zou mogelijk de oplossing hiervoor kunnen zijn. We kunnen dan de VAS op t=0 gebruiken als 0% klachten. Het relatieve verschil is ook interessant: als iemand van 0,2 naar 1,6 gaat is dat een relatief groot verschil, terwijl in ons figuur 1,6 een lage score is. Maar ook weer niet, want het gaat nog steeds over een schaal van 1 tot 10. Het is een overweging die meegenomen kan worden.

Hierop aanhakend is het misschien niet nodig om de baseline meting in het regenboog figuur te plaatsen. Dit kan wel nuttig zijn, om de relatieve verandering te zien van de VAS gedurende het consult. Echter, als er in de toekomst wordt gewerkt met een delta-VAS, wordt eigenlijk hetzelfde effect bereikt als kijken naar de baseline VAS meting.