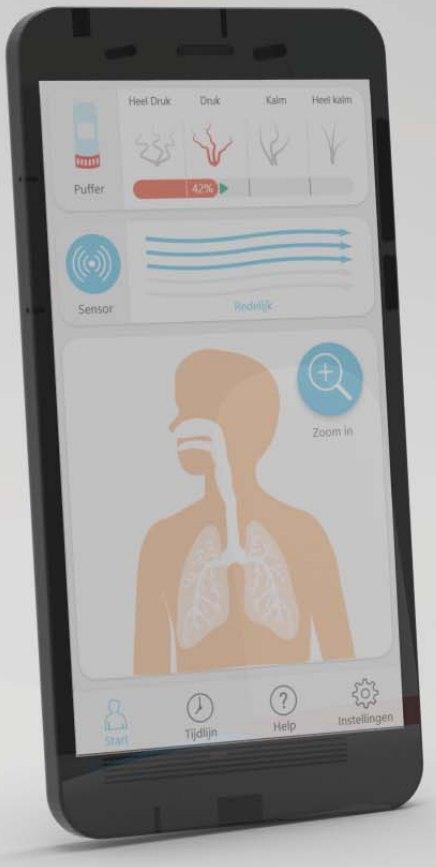
TURBUSCOPE

Designing an eHealth solution to improve medication adherence for asthma patients with low health literacy.



Turbuscope

Master Thesis Integrated Product Design by **Jasper Faber**

Monday the 1st of July 2019

Supervisory team

Dr. Ir. N. A. Romero Herrera - Chair
Industrial Design - Design contextualisation and communication

Msc. T. Dekkers - Mentor
Industrial Design - Applied Ergonomics and Design

Client

Msc. C. C. Poot - Client mentor
LUMC - Public Health en Eerstelijnsgeneeskunde

Executive Summary

Asthma is a chronic pulmonary disease. It results in sensitive airways that are continuously inflamed, causing symptoms such as breathlessness, coughing and wheezing. The Netherlands currently counts 641.000 asthma patients (PIAMA, 2019). 45% of these patients have partially controlled or uncontrolled asthma (NIVEL, 2007). Partially controlled or uncontrolled asthma may lead to a reduced quality of life caused by an increased risk of exacerbations, increased symptom perception and physical, social and environmental limitations. There are many safe and effective treatments available that help to manage and reduce asthma symptoms. The most common form of treatment is the provision of anti-inflammatory medication. Although the daily use of this medication can severely reduce the asthma symptoms, there is a wide range of factors that make it difficult for patients to adhere. Non-adherence is associated with decreased control over asthma and may cause patients to experience an unnecessary reduction in their quality of life.

The aim of this project is to design an eHealth intervention that will help asthma patients with low health literacy (LHL) to increase their medication adherence. Electronic health (eHealth) technologies are now widely used to support and deliver healthcare to patients. These technologies provide new opportunities for accessing health information and self-management of health conditions. With the increasing adoption of these services in clinical practice, individuals are increasingly expected to engage in appropriate self-care and self-management of their conditions through eHealth. (Fagnano et al. 2012). Examples of current eHealth trends in the field of asthma are Smart Inhalers, Wearables, and Mobile applications. This project will focus on the smart inhalers category. A smart inhaler can increase asthma control, improve quality of life, increase awareness and improve medication adherence. This project will specifically focus on a vulnerable target group within this topic: patients with a LHL. Health literacy can be defined as: "people's knowledge, motivation and competencies to access, understand, appraise and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention, and health promotion" (Sørensen et al. 2012). Individuals with limited health literacy experience disparities in their health and access to healthcare resources (Herndon et al. 2011). They tend to use fewer preventive services and have a poor adherence to treatment regimens, which is associated with poor health outcomes (Sudore et al. 2006) (Paasche-Orlow & Wolf, 2007). Although the introduction of eHealth can provide major benefits, especially for those who have trouble managing their health, it can be difficult for people with LHL to effectively utilize and interact with eHealth technologies (Jensen et al. 2010).

This project is funded by AstraZeneca. This pharmaceutical company is currently evaluating the effectiveness of the Turbu+. The Turbu+ can be categorized in the abovementioned "smart inhaler" category. It is a combination of their anti-inflammatory inhaler (Turbuhaler) with smart sensor technology developed by Adherium and a smartphone app. This technology makes it possible to measure medication usage, provide reminders, register symptoms and log and present the adherence data to patients and healthcare providers. Currently, a user-centered design research is executed at the LUMC in which the needs and wishes of asthma patients regarding this technology are revealed. This research should shed light on possible design directions that are important to take into account regarding the implementation of the Turbu+. As part of this overarching project, this graduation project will focus on a specific domain within this research: to tailor the intervention towards asthma patients with a LHL. The project starts off with a user-centered design research. The goal of this

research was to identify personal determinants of non-adherence behavior as well as the identification of possible barriers and opportunities regarding the acceptance of eHealth technologies. For this, informal talks have been conducted with general practitioners and practice nurses who work in disadvantaged neighborhoods. The obtained insights were organized and complemented with literature according to the intervention mapping (IM) approach (Bartholomew et al. 1998). The insights were synthesized into four different personas that were used in discussion with experts and healthcare providers to verify certain assumptions. The personas were thereafter converted to a research artifact in the form of scenarios (fictive stories). These artifacts enabled the verification of the non-adherence insights with the target group. A second artifact was devised in order to verify the barriers and opportunities regarding the acceptance of eHealth technologies. For this, the co-constructing stories (CS) methodology is utilized (Buskermolen & Terken, 2012). This synthesis into tangible artifacts helped both the researcher and participant, to get a picture of how the insights could be translated to a real life scenario. In the end, these two artifacts were integrated into interview sessions with two asthma patients with LHL.

The insights that emerged from these interview sessions, in combination with the insights that were identified from the expert talks and the literature insights, were analyzed and clustered into key determinants for non-adherence behavior. These determinants were thereafter, according the IM approach, plotted against performance objectives to create a matrix of change. A combination of coding and quantifying the insights together with an evaluative discussion with the practice nurse, led to the identification of the most important objectives to change. These change objectives were subsequently synthesized into three design opportunities: Provide capabilities, Create awareness and Support attitude. A critical selection process, in which the directions were considered regarding project requirements, led to the identification of a design vision. This vision states that the overall goal of the design is to create awareness about asthma and the effect of maintenance medication. This should be achieved by facilitating self-monitoring of asthma by gathering data about adherence and asthma state in way that is objective, effortless and engaging.

Subsequently, an ideation phase was initiated that was aimed at exploring how to provide an engaging self-monitoring experience, what data could be used to objectively track asthma state and how to present this data to create awareness. The vast number of ideas that were generated have been focused down to four preliminary concepts. These concepts have been exhibited through mock-ups and presented to three asthma patients with LHL. It was found that the combination of perceived usefulness and an effortless experienced should be used as an engaging element. In addition, it was found that the tracking of nocturnal asthma symptoms through a non-invasive sleep sensor was the optimal way of acquiring data about the state of asthma. Finally, it was found that a combination of a holistic, realistic and immersive interface was effective in presenting the data.

The final iteration within this project focused on conceptualizing and developing this new design vision. A functional prototype was made to find out how the nocturnal asthma data could be acquired. In addition, an interface was developed and prototyped with the goal to communicate the data and create awareness of asthma and the effect of the medication. This prototype was thereafter evaluated with fwour participants with LHL. The end product of this project is a finalized concept that embodies design guidelines and recommendations for future design within the field of promoting medication adherence for asthma patients with LHL.

Table of Contents

Report Structure

The structure of this design process (figure 1) was based on the five steps of design thinking by Hasso Plattner Institute of Design at Stanford. During this process, the way of thinking was structured according to the IM approach, where the path is mapped from recognition of a need or problem to the identification of a solution through a theoretical framework.

Background

At the start of this design project, the first essential step was to conduct a background research on the topics within the project scope. In this project, this was done by doing an extensive desktop literature review, conducting several informal talks with experts and patients and a field visit to a community in a disadvantaged neighborhood. This information helped to be able to frame the unknown areas, hence, to identify the research questions for the research phase.

Empathize

To aid formulation of the research questions, a logic model of the problem was created, as defined in the IM approach. The logic model of the problem resulted in two research questions: 1. What are the determinants of non-adherence behavior in asthma patients with low (health) literacy and 2. What is the acceptance of eHealth in asthma patients with low (health) literacy? In this section, the report describes the activities conducted in order to gather the answer to questions such as: why are the patients non-adherent and why should users engage in a new technology.

Define

In the define phase, all the insights were analyzed and brought together in order to create a proper focus and vision for the design process. The logic model of change was created based on the IM approach. This resulted in a 'matrix of change' that helped to identify design opportunities. These opportunities were used to synthesize a problem statement and design vision.

Iteration 1

This section of the report explains how different activities were performed to collect answers to certain design challenges. It will elaborate on the synthesis of these answers into concepts and prototypes. It concludes with a user evaluation, its results and the statement of a new design vision. The user evaluation showed that patients are particularly interested in useful technology that can be used without a lot of effort, which resulted in the following vision: To design an automatic nocturnal symptom tracker, to collect data about the asthma state that can be used to create awareness.

Iteration 2

This chapter elaborates on the conceptualization of the new concept direction. It discusses the development of two major sub-systems within this concept: The sleep sensor and the interface. The sleep sensor development has resulted in the creation of a functional prototype, that makes use of a digital stethoscope, integrated in a non-invasive neck-cuff. This development process eventually resulted in a final concept and future design recommendations that emerged from the development.

Conclusion

This chapter presents the final concept as a result the concept development phase. This concept consists of the Turbu+, a sleep sensor, a docking station and a smartphone. The chapter will also present an overview of the design principles and will suggest a roadmap for future implementation of the device, which consists of further concept development, verification & validation and bringing to the market.

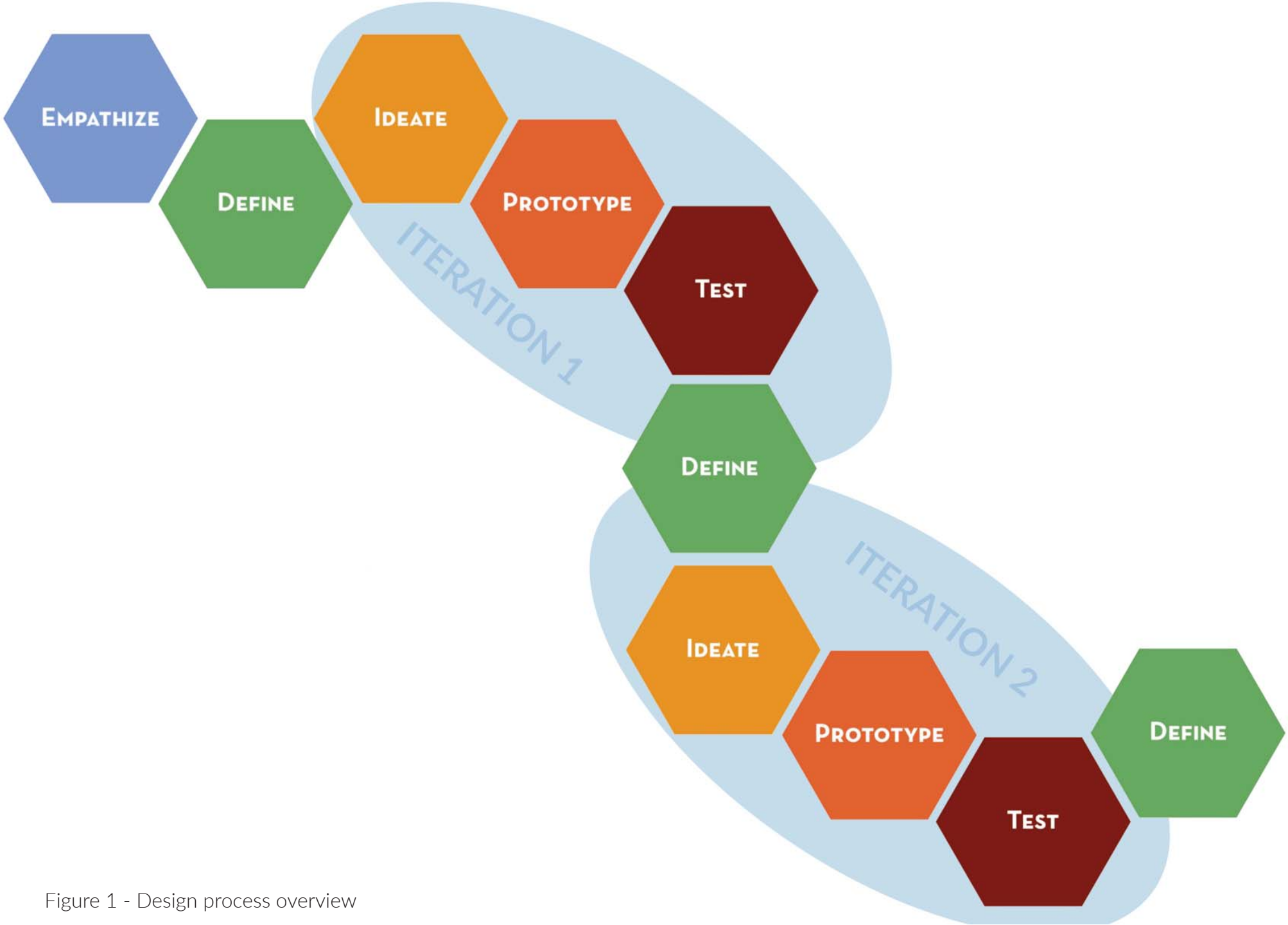


Figure 1 - Design process overview

Meeting Asthma Advice Panel

Brainstorm about experiences with asthma and the Turbu+ together with two patients from the Asthma Advice Panel

CHAPTER 1 | Background

During the background research, information gathered about the topics within the project scope. The goal of this research was to be able to identify possible research areas. Within this research, the topics asthma, health literacy, adherence and eHealth were investigated.

1.1 | Asthma

In this part of the research it was discovered what asthma is, what effect it has on the quality of life and what treatment currently exists to reduce these effects. To create this understanding, several talks were held with researchers, asthma experts and patients (Appendix A). In addition, a first feeling was created towards how people feel about having asthma. This was done by listening to audio recordings of interview sessions of the overarching project.

The Disease

Asthma is a chronic inflammatory disease of the airways and lungs. It is caused by a combination of genetic and environmental factors (Martinez, 2007). The inflammation results in swollen and sensitive airways, resulting in increased contractibility of the surrounding muscles (figure 2). This muscle contraction is typically reversible with or without treatment. The main difference between asthma and COPD (chronic pulmonary disease) is that in the case of COPD, the airways are irreversibly damaged.

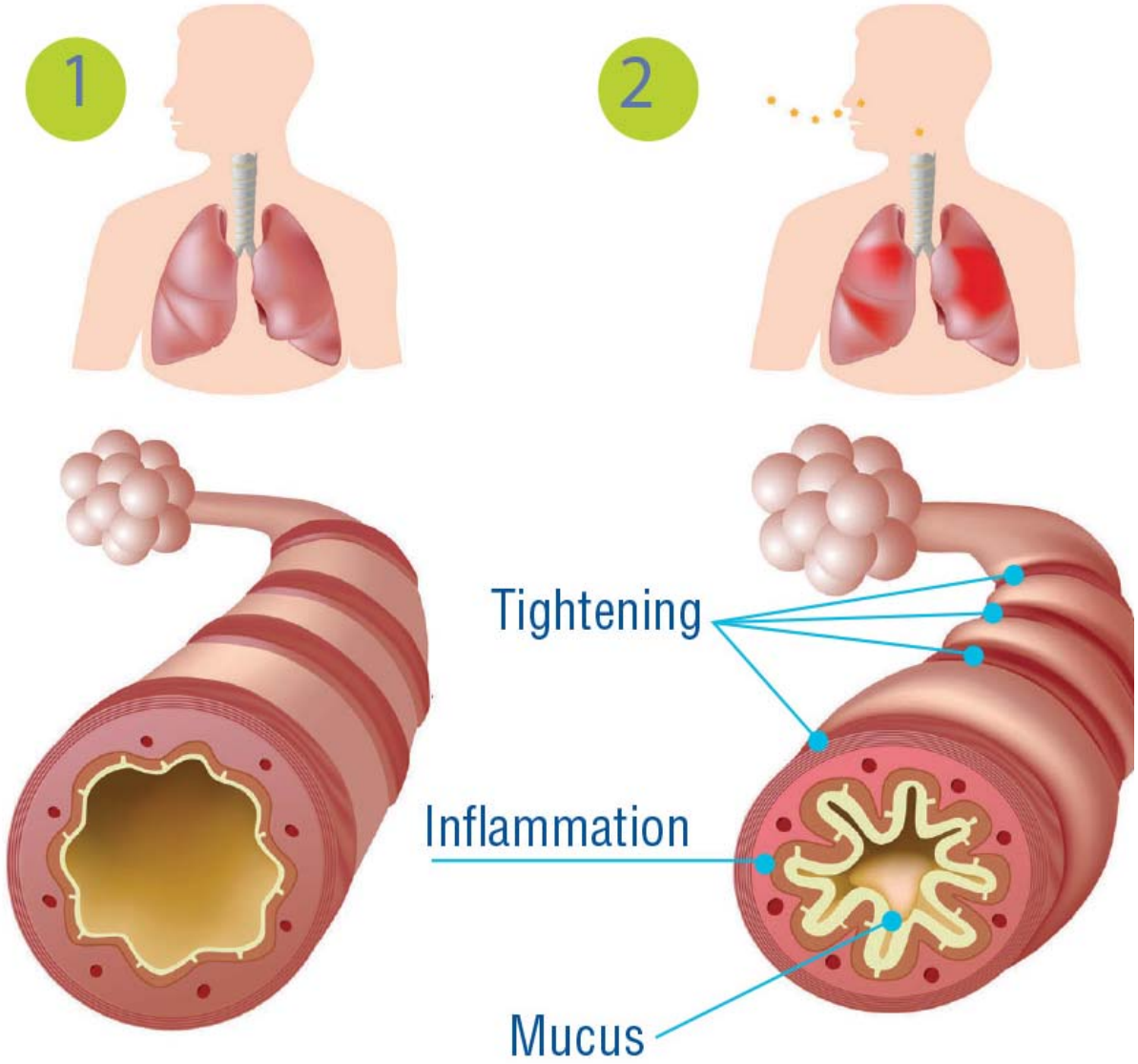


Figure 2 - 1. Normal Airways 2. Asthmatic Airways (Lung.ca)

Asthma Classification

Asthma can be classified into categories of severity and type. The severity of asthma can be classified into four general categories (Mayo Clinic Staff, 2018):

Mild intermittent

Mild symptoms up to two days a week and up to two nights a month.

Mild persistent

Symptoms more than twice a week, but no more than once in a single day

Moderate persistent

Symptoms once a day and more than one night a week.

Severe persistent

Symptoms throughout the day on most days and frequently at night.

In addition, a distinction can be made between the following common types of asthma:

Adult-Onset Asthma

This type of asthma only shows signs when people are turning adults.

Allergic Asthma

Allergic asthma often has an overlap between allergies and asthma. Frequently, allergens in the air such as pollen, dust, and pet substances are the cause of asthma attacks.

Exercise-Induced Bronchoconstriction (EIB)

In this type of asthma, airways narrow as a result of physical activity. Most of the asthmatic patients also have a form of EIB. It is caused by the loss of heat, water or both from the airways during exercise when quickly breathing in air that is drier than what is already in the body.

Nonallergic Asthma

This type of asthma isn't specifically caused by allergens or physical activity. Nonallergic asthma can be caused by viral respiratory infections, irritants in the air, stress, drugs and food additives or extreme weather conditions.

In conclusion it can be said that asthma as a disease is relatively broad. The different types of severity and cause, lead to a wide spectrum of illness perception, self-management and treatment strategies that help to keep asthma under control.

Asthma Control

There is an important difference between asthma severity and asthma control. As mentioned before, asthma severity is static and can not be changed by treatment. The amount of control is a variable and can be increased by proper treatment. Uncontrolled asthma can be defined as any moment that the person experiences limitations in daily activities based on symptoms as a result of asthma. Normally, when a person adheres to the treatment regime and takes the prescribed maintenance medication on a daily basis, there is a high chance that asthma will be under control. There are cases however, for example in severe persistent asthma, that the asthma is seldom under control, even when the patient is fully adherent to the treatment.
This project will focus on the group of patients that have a case of uncontrolled asthma, as a cause of improper adherence to the treatment regimen.

Societal Impact

Asthma affects people of all ages, but most often starts during childhood (NHLBI, 2018). In the Netherlands, 641.000 people are affected by asthma (PIAMA, 2019). On the list of diseases based on their disease burden, Asthma is ranked at the 25th place, based on disability-adjusted life years (DALY's) (PIAMA, 2019)

Personal Impact

Asthma can result in symptoms like recurring periods of wheezing, chest tightness, shortness of breath, and coughing. The experience of these symptoms can have a severe impact on the quality of life.
If symptoms get too extreme, it can result in an asthma attack or exacerbation. An exacerbation frequently results in a visit to the hospital and has a severe negative effect on the lungs (Halpin et al. 2017). In the worst case, an exacerbation results in death. In 2017, asthma has resulted in a total of 160 cases of death in the Netherlands (PIAMA, 2019).
Lack of control over the symptoms, may result in a large number of lifestyle limitations. One example is social limitations, where a patient might be allergic to certain pets and therefore is unable to visit certain friends or family. Often it seems that the environment isn't aware of the burden asthma can bring. Therefore patients are frequently discouraged or ashamed

to ask for specific measures, which can result in a feeling of loneliness or even depression. Patients do not want to feel like a patient and want to participate in everyday activities like everybody else.
Asthma can also result in physical limitations, which might be the inability to work for a full day.
Asthma is different for every person, meaning that the response to triggers, the severity of the symptoms and the resulting treatment are always varying. Although asthma is an incurable disease, the symptoms of asthma and the accompanying impact on the quality of life can severely be reduced by proper self-management in terms of symptom control, maintaining physical activity and medication adherence (Australian Asthma Handbook, nd).

Treatment

Prevention and long-term control are key to stop asthma attacks before they start. Usually, treatment involves learning to recognize your triggers, taking steps to avoid them and tracking your breathing to make sure your daily asthma medications keep the symptoms under control.

Medications play an important role in the management of asthma. There are a large number of different medications available on the market that range from quick-relief medication to preventive maintenance medication. What medication to choose depends on age, symptoms, triggers and personal preference.

The different medications can be categorized into three different categories: relievers, controllers, and preventers (figure 3).

Relievers

Salbutamol, Fenoterol, Anticholinergics, Ipratropium Bromide, and Tiotropium
These medications are based on short-acting-β-agonists. These substances work fast (display effect usually between 5 and 10 minutes) and help the muscles that are surrounding the airways to relax, resulting in instant widening of the airways.

Controllers

Formoterol, Salmeterol
These are based on long-acting-β-agonists The substances basically have the same effect as the relievers, however, their effects persist over a longer period of time (up to 24 hours) and therefore help to control and reduce asthma symptoms throughout the day.

Preventers (Maintenance)

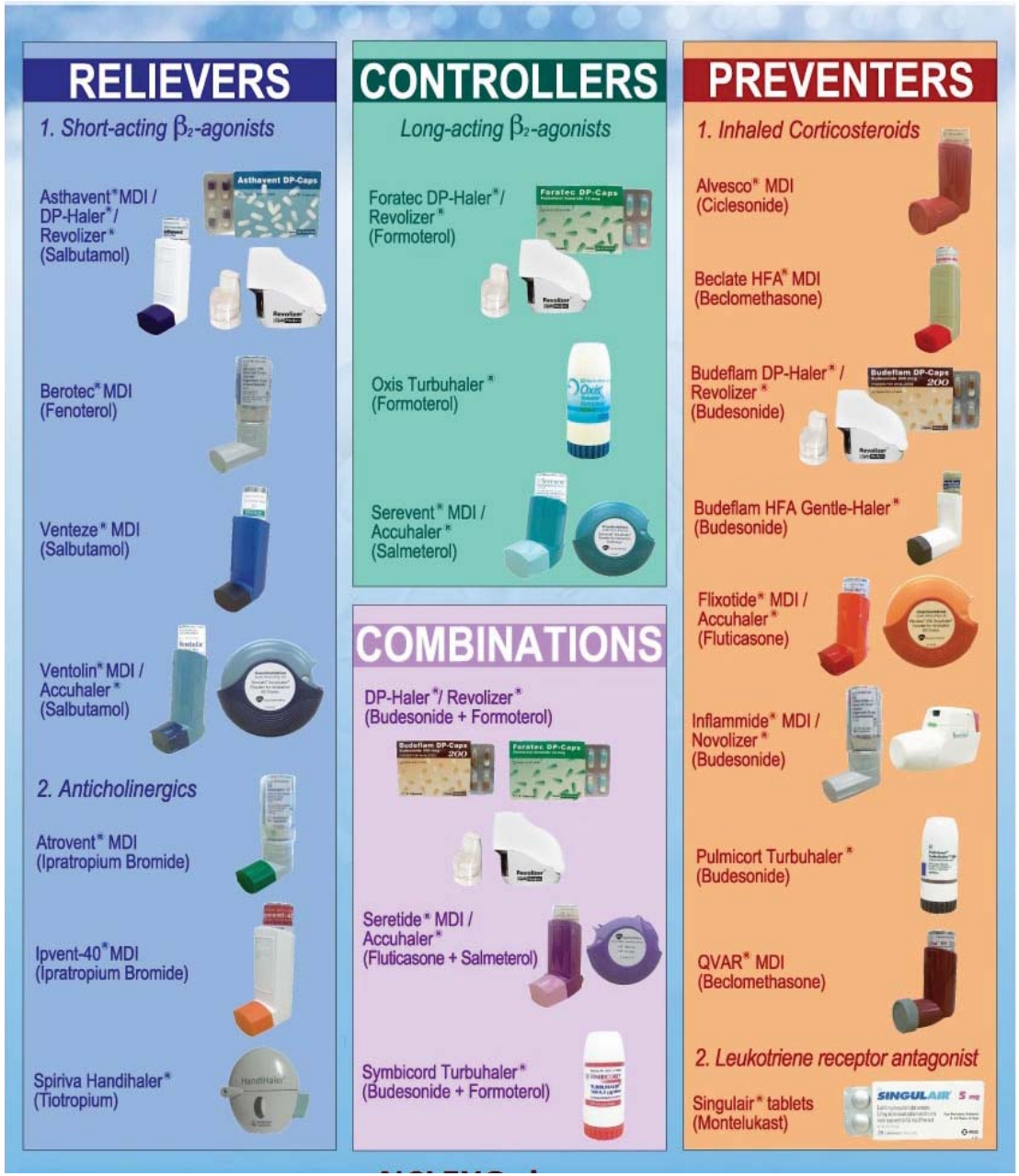
Ciclesonide, Beclomethasone, Budesonide, Fluticasone, Beclomethasone
These substances are based on inhaled corticosteroids, and therefore are also frequently referred to as ICS. ICS doesn't work on the respiratory muscles and therefore doesn't provide the quick relief provided by the β-agonists. It does, however, help to reduce the overall inflammation of the airways. Since the inflammation is the root cause of the asthma symptoms, including the tightening of the respiratory muscles, it is essential to diminish the inflammation with the use of the preventer medication. Since the effect is not directly noticeable, many asthma patients tend to be more keen to use their quick-relief medication more often instead of their maintenance medication. Consequently patients build a level of dependence on their quick-relief medication and overuse of the reliever is frequently reported. One example of this phenomenon is for example the cause of fear that arises regarding exacerbations.

A combination of the abovementioned medications is also possible, where long-acting-β-agonists are combined ICS. These combination medicines are specifically useful as they frequently eliminate the need for quick-relief medication and also frequently reduce the number of inhalers. The Turbuhaler, the inhaler used in the Turbu+ device, is an example of such a combination medication.

Inhaler use

Maintaining the proper inhalation technique is essential for the medication to be effective. However, it frequently appears that patients have trouble understanding and executing the proper technique. Giraud & Roche (2012), have found that inproper use is found in 14–90% (with an average of 50%) of the cases. This points out that a cause of inproper medication adherence could be related to unintential factors like inproper usage of the medication.

Figure 3 - Asthma Inhalers (NClexQuiz)



Insights

Personal Impact

/ Patients often do not want to feel like a patient or reminded that they are a patient
/ Asthma is personal, patients have different needs, motivations, and goals.
/ Having Asthma can be lonely, the social surrounding often doesn't understand.
/ Having asthma can lead to several limitations in life, therefore reducing the quality of life.

Treatment

/ Patients rely on their quick-relieve medication.
/ Fear for exacerbations is often a motivator to use of reliever medication.
/ Maintaining a proper inhalation technique is difficult for most patients.

1.2 | Health Literacy

In order to understand health literacy, what it is and who is involved, several literature sources were consulted. In addition, informal talks were held with experts on the topic of low literacy and low SES. Also a disadvantaged neighbourhood community was visited.

Health literacy can be defined as: "people's knowledge, motivation and competencies to access, understand, appraise and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention, and health promotion" (Sørensen et al. 2012).

Low health literacy (LHL) shows a clear relation with negative health outcomes. Low health literacy is associated with an increased chance of having asthma, COPD, diabetes, cancer, and vascular diseases (Nivel, 2014). In addition, low health literacy is associated with a shorter life span (Bostock & Steptoe, 2012). Furthermore, people with LHL use healthcare related services more often and they are overall less satisfied with these services. (Berkman et al. 2011) Medication use in people with LHL is seen to be twice as high as higher educated patients (CBS Statline, 2017). This is due to wrong interpretation of vocal explanation or the inability to understand written instructions.

In everyday life, patients with low health literacy experience many barriers that prevent them from acquiring the care they need. They have trouble navigating the healthcare system, searching for information online (digital skills), understanding written information, communicating with healthcare providers and put their explanations into practice and self-management. Figure 4 shows a picture taken at *de Weggeefwinkel* in Leiden. In this picture one of the shop volunteers is helping with the translation of a letter from the municipality, a live example of one the barriers.

In the Netherlands, 9,5% of the population with an age of 18 and above, has insufficient health literacy skills. 26,9% of the population has limited health literacy skills (NIVEL, 2018). This points out that the target group is relatively large and goes beyond the consideration of merely low literacy barriers. According to Nivel (2016), this population consists mainly of elderly, low-educated and non-western immigrants. LHL is acknowledged as an important health issue. Recently, The Dutch government has increased the budget to counteract low literacy with 35 million euros. Which will help this part of the population. (Ministerie van Onderwijs, Cultuur en Wetenschap, 2019).

Insights

/ LHL is related to negative health outcomes
/ Barriers associated with LHL are navigating the healthcare system, understanding and interpreting information, interpret body signals and general self-management skills.
/ The group of low health literates is large and is composed of different societal groups.
/ The problem is high on the political agenda, however, too few services have been inclusively developed to take this target group into account.

Figure 4 - Shop employee translating a letter for one of the visitors.

1.3 | Adherence

Medication adherence forms a large part of the project scope. Understanding the motivations behind non-adherence is complex but needed in order to create a full understanding of the problem. To gain more insight into this theme, literature sources were consulted as well as an informal talk with a researcher in non-adherence.

Regarding adherence, several terminologies are described in the literature. The most common terminologies used are compliance, adherence, and concordance (Horne et al. 2005).

Compliance
Compliance is the: "doctor says, the patient does model". In most of the cases, a patients situation is very personal of which the doctor is insufficiently aware.

Adherence
A process in which the patient and healthcare provider are coming to a decision together is called adherence. When we talk about adherence, we talk about a mutual agreement between patient and doctor on the treatment plan.

Concordance
Concordance is a fairly new approach in which the doctor becomes fully aware of the patients' situation and therefore helps to tailor the treatment to these variables.

Throughout the rest of the report, the term (non-)adherence will be followed. According to Horne et al (2005), non-adherence can be categorized into three different 'phenotypes' (figure 5).

Intelligent
The intelligent are conscious about their decisions and intentionally choose not to adhere to the treatment. This can be the result of personal beliefs about medication (it is poison, it is not natural, it causes side effects) or other reasons (too expensive, being ashamed). For this phenotype, interventions such as shared decision making, motivational interviewing, reimbursement or link to personal goals are effective strategies for an intervention.

Erratic
The erratic phenotype is mainly troubled by a busy lifestyle resulting in therefore forgetting to use the medication. An intervention regarding reminders, simplification or a link to a daily habit is therefore effective for this phenotype.

Unwitting
Unwitting non-adherence is caused by lack of knowledge regarding the treatment or medication. This causes an the patient to unintentionally be non-adherent to the treatment. Interventions that target inhaler technique, instruction, change of inhaler and a self-management plan are effective for this phenotype.

Interventions aimed at improving the adherence of patients target either practical barriers (reminders, self-management plans) or deal with the perception and beliefs of the patients (shared decision-making, reimbursement). There are also interventions that have a combination of both. Some of those interventions have been proven to be successful, while others have failed to do so. It is unfortunately not properly documented why and because of what factors these interventions reached that result. It is however known that targeting adherence is a complex development that needs careful consideration of personal motivations for being non-adherent. Interventions should base their design features on the origin of these motivations.
Several factors mentioned by Horne et al. (2005) related to non-adherence are:

Complexity
The amount of different medication, as well as the inability to fit in the daily routine, can be seen as complex.

Socio-Demographic
Elderly, low-educated and minorities might have personal and environmental barriers that constrain them from being adherent.

Knowledge
A certain level of interpretation capabilities is needed in order to understand and apply the medication regime. The link between medication and the effect might not be clear.

Memory and Recall
Forgetting the instructions or forgetting to take the medication.

Environmental constraints
Costs or inability to navigate the healthcare system might hold the patient back from filling their medication.

Social influence
Lack of social support or influenced by peers and the social environment can be an influence in the adherence process

Beliefs
Beliefs about the (side) effects, dependence, disruptive side effects, becoming immune, masking and the perception of the medication being unnatural.

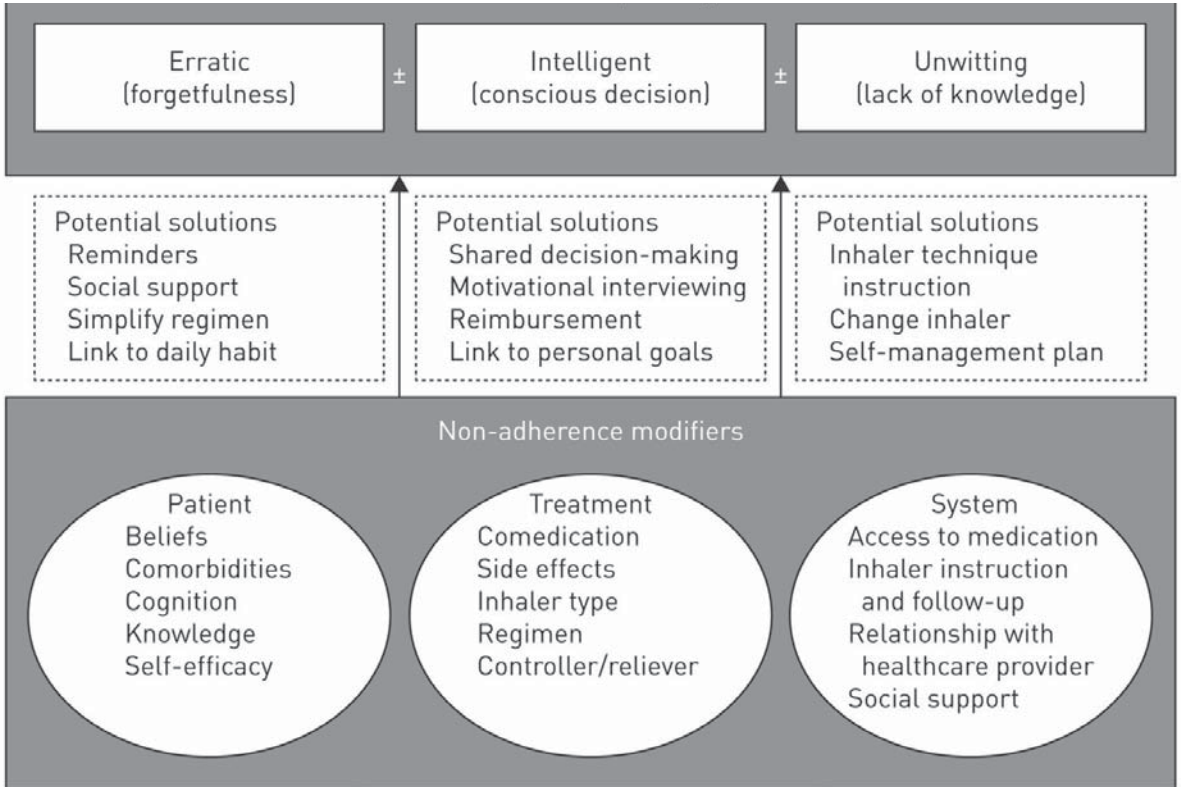


Figure 5 - Non-adherence theory (van Boven et al. 2017)

/ Intentional non-adherence is closely related to personal beliefs, active decision making, attitude, and expectations.
/ Unintentional non-adherence is frequently caused by practical barriers (time, money), individual constraints (memory and dexterity) and environmental constraints (access, competing demands)
/ Non-adherence interventions need to be designed taking into account the underlying phenotype-related factors.

1.4 | eHealth

In order to create a better understanding of eHealth, what its developments are in the field of asthma and what eHealth means for low health literacy, several sources were consulted. Literature about eHealth literacy as well as barriers for low health literates was read. In addition, a talk with the supervisor of the alliance between Longfonds and Pharos led to some first insights regarding eHealth use by people with low health literacy. Also the Turbu+ was thoroughly used and explored in order to create an understanding of the technology at hand.

Trends

Currently, there are some rapid eHealth developments in the field of asthma. Three of the main trends are smart inhalers, wearables and apps (Philips, 2019).

Smart Inhalers

Smart inhalers can include mouthpieces with integrated electronics, or coaches to teach how to inhale properly. This data is frequently used to provide the healthcare provider with real time data. They can also include digital sensors that determine frequency and accuracy of inhaler use, and sync wirelessly with smart devices through Bluetooth.

Wearables

Wearables can be seen in the form of wristbands and patches that help to predict and prevent asthma attacks. Motion, heart rate and oxygen can be monitored in the blood. Patches can be used to track respiratory rate, skin impedance and wheezing of the lungs.

Mobile Applications

Mobile applications can help to manage asthma and its symptoms. They can provide tips, remedies or help to log certain data, which eventually can lead to a database of valuable knowledge.

Figure 6 - eHealth in Asthma, (iMedicalApps)

Turbu+

The Turbu+ (Figure 7) is a combination of a smart inhaler with mobile application. The smart inhaler is able to register when the medication is used. This is sent through Bluetooth to a connected mobile device. In the app, a history can be seen of the medication use over time. If a dose is forgotten, the app can provide a reminder in order to stimulate the patient to take the dose anyway. Another functionality of the app is that provides a platform to log symptoms. The symptom history in combination with the medication history can provide insight into the disease progression over time and the effect of the medication.

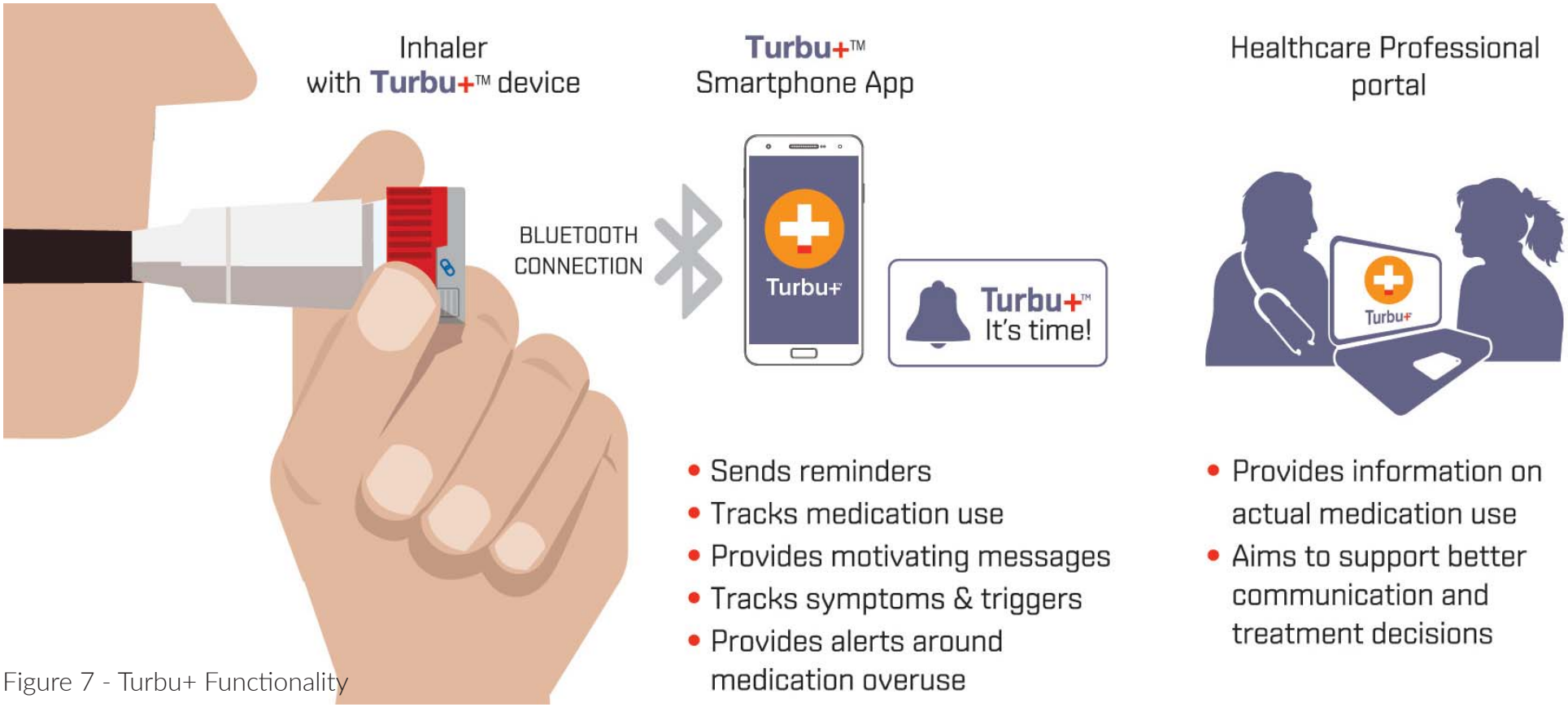


Figure 7 - Turbu+ Functionality

eHealth Literacy

Technologies that haven been developed in the aforementioned field of eHealth for asthma have proven to be effective in solving various problematic areas regarding asthma self-management. Although the potential of these technologies is vastly documented, there still remains the essence to handle the design of such technologies with care.

According to Chan & Kaufman (2011), the adoption of eHealth technologies is closely related with the level of eHealth literacy. There seems to be a relation between low health literacy and low **e**Health literacy (Jensen et al. 2010). Therefore, it is important to be aware of the barriers that come with a low eHealth literacy. These barriers can be categorized into three different levels: perception, understanding and reasoning (figure 8). A person can be affected through one of these layers, by a combination or by all of them.

Perception

The perception level involves the ability to perceive (read or hear) health-related information. A person with perceptive barriers might not speak the native language and therefore experiences trouble reading the information that is provided. In addition, becoming of age could play a role. When people get older, their eyesight and hearing capabilities decrease. This limitation in perceptive ability might result in difficulty reading small text or hearing a spoken explanation.

Understanding

The understanding level involves the ability to process the perceived information.
One might be able to read the text, but might lack the cognitive skills to process what it actually means. For instance, not having a wide

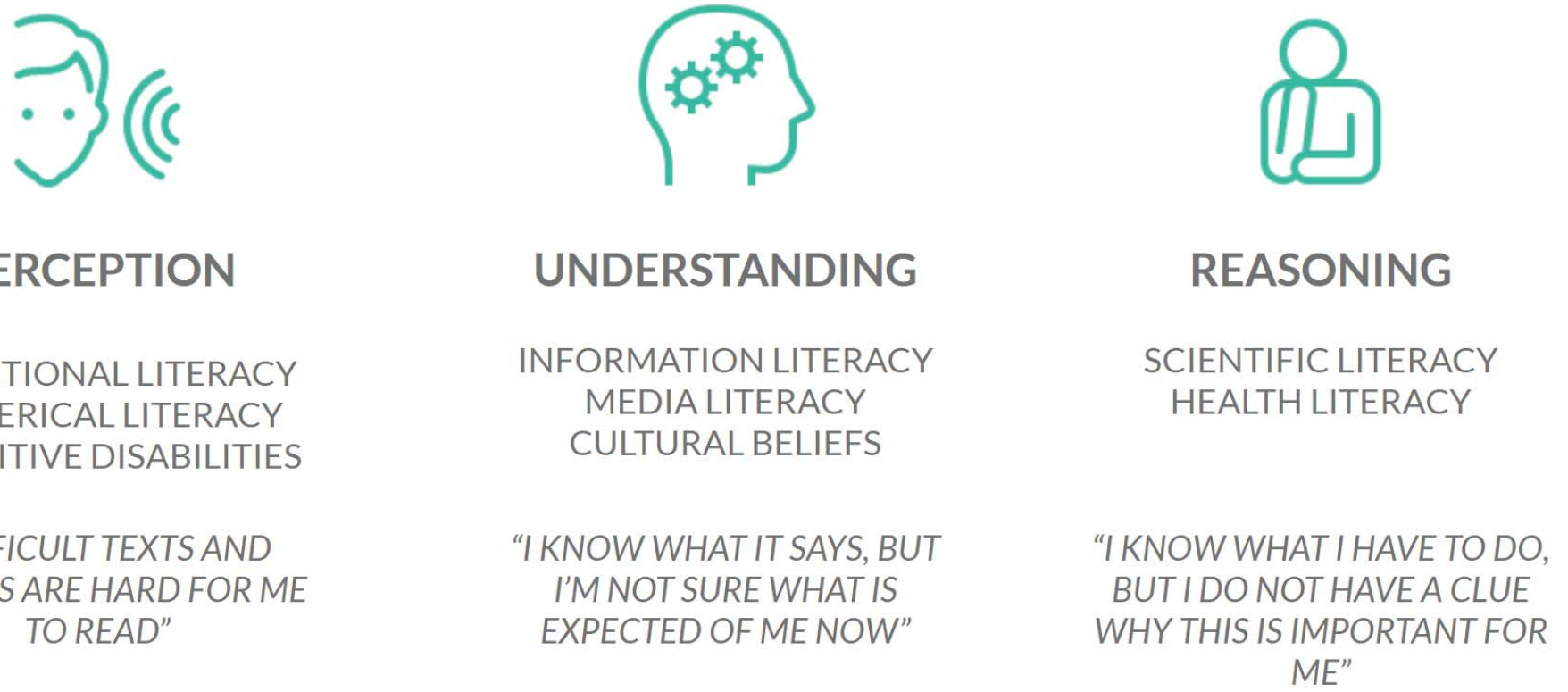


Figure 8 - eHealth Literacy Classification

vocabulary regarding medical jargon.
Or it can be the cause of a cultural barrier, which results in certain explanations being interpreted in a different way. Cognitive disabilities as a result of a disorder or being of age can also have a major impact on the interpretation abilities. Finally, another example of this category is that the person might lack the skills to know where to find health-related information on the internet, or to judge whether the information is trustworthy or not.

Reasoning

The third level is the reasoning level. What if the person is able to properly read the information, and also understands what is said. There still is a need to link the received information to your own body in order to give value to the information. One has to be in the possession of a basic level general biological and scientific knowledge in order to properly judge whether a statement is applicable to one's own situation.

Insights

/ eHealth technologies have great potential in dealing with various asthma related problems.
/ Smart inhalers, wearables and mobile applications are common developments in this area.
/ Despite these benefits, the design of eHealth technologies needs to be handled with thought and care.
/ Low health literacy is associated with low eHealth literacy.
/ Low eHealth literacy brings forth several barriers that can be categorized under a perception, interpretation and reasoning level.

User Interview

Performing a co-constructing stories session with one of the participants

CHAPTER 2 | Empathize

This chapter focusses on the identification of the research questions and the methodology that was carried out to answer those questions. The chapter will conclude with a discussion of the results.

2.1 | Logic Model of the Problem

The aforementioned background research phase made it possible to fulfil the first step of the IM approach: Creating the logic model of the problem. This chapter will explain what a logic model of the problem is and how it was used to identify the research questions.

In the logic model of the problem (figure 9), one starts with the health problem and its effect on the quality of life. Subsequently, one moves on to determining what behaviour causes this health problem and what personal determinants are responsible for this behaviour. The health problem in this project is uncontrolled asthma. The next step in the model is to determine the behavior that is responsible for this health phenom

The final step in the creation of this logic model, is to find out what personal determinants are responsible for this behavior. In chapter 1.2 it was discussed that there is a relation between LHL and non-adherence. The determinants behind non-adherence in asthma are already identified in literature, under which the afore-mentioned study by Horne et al. 2005. However, there is little evidence of non-adherence behavior regarding asthma patients with a LHL. This led to the identification of the first research question: What are the personal determinants for non-adherence amongst patients with LHL?

As discussed in chapter 1.4, eHealth technologies are aimed at reducing the non-adherence behavior. However, there is a second 'behavior' that counteracts this support. Which is the lack of adoption of these technologies by patients with a LHL. Although there is some evidence that points out several factors that relate to the rejection of eHealth technologies by the target group, there is little evidence of how these reflect in the current Turbu+ device. Since the design of the project will use the Turbu+ as starting point, it will be essential to learn what determinants are related to the rejection or acceptance of this technology. Hence, the second research question could be formulated: What is the current acceptance of the smart asthma inhaler?

Research Question 1

What are the determinants for non-adherence amongst asthma patients with LHL?

Sub-questions

What phenotype according to Horne et al. 2005, has the most in common with the non-adherence behavior of the patients?

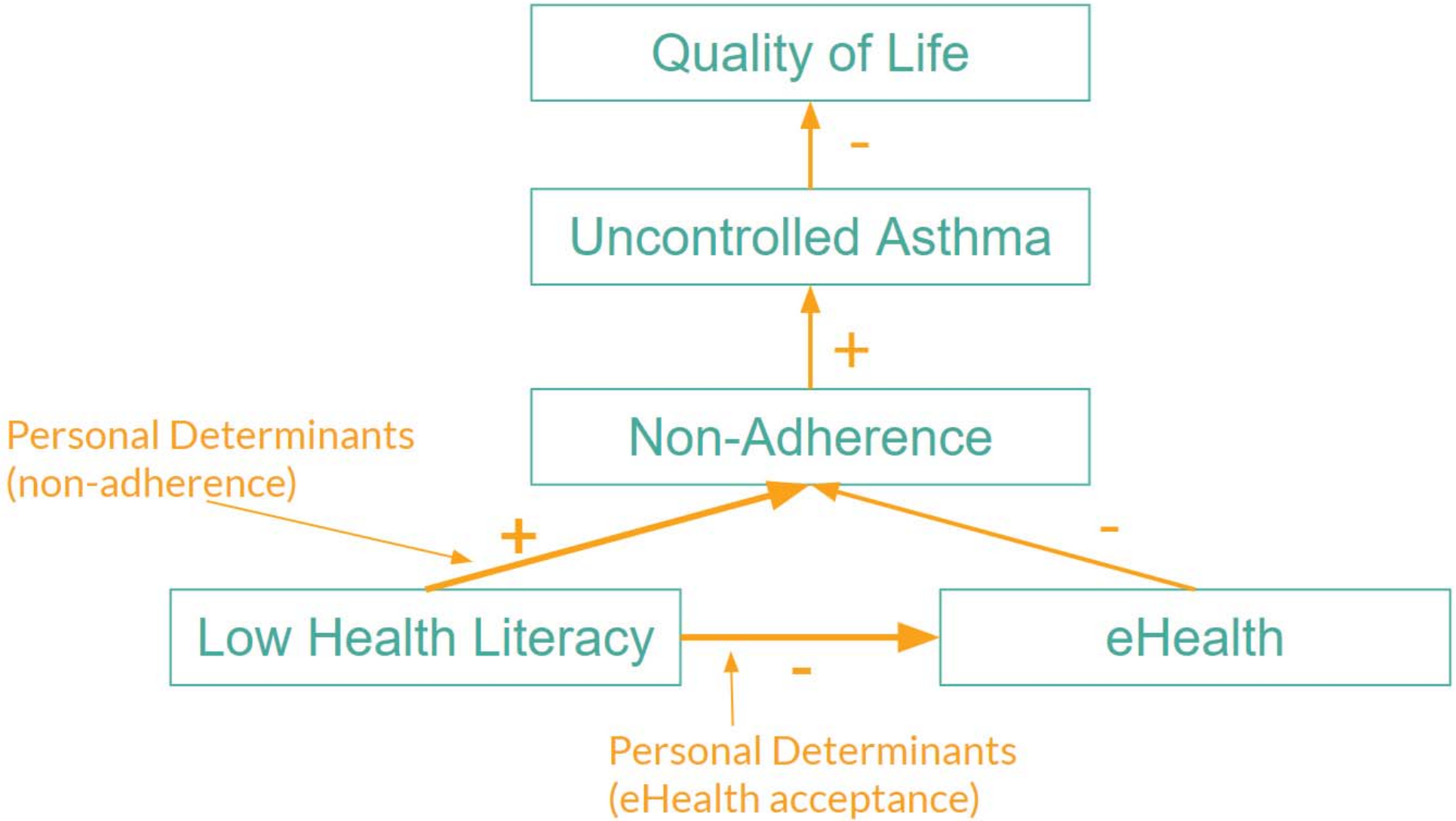
Research Question 2

What is the current acceptance of a smart asthma inhaler?

Sub-questions

What is the acceptance of the Turbu+?
What are its deficits?
What are eHealth related opportunities?

Figure 9 - Schematic of the logic model of the problem



2.2 | Research Question 1: Non-adherence

This chapter will elaborate on the process regarding the first research question. In this process, insights were collected by analysing the expert and literature sources of the background research phase. These insights were thereafter converted to personas, to aid the discussion with practice nurses. Finally, the personas were converted to fictional scenarios that were used in an interview with the target group in order to validate the insights.

Insights

The adherence research resulted in several interesting possible factors that result in non-adherence. The table in figure 10 highlights the factors as presented by Horne et al (2005). In order to find out which of these factors are related to the problem scope, the insights from the background research about asthma and LHL (Appendix B-E) were integrated using a mindmap (Appendix F). The mindmap was used to organise the insights gained regarding LHL against the non-adherence factors. Which resulted in a list of possible factors for non-adherence:

Figure 10 - Table of factors derrived from Horne et al. 2005

	Erratic	Intelligent	Unwitting
Internal	**Complexity** Amount Routine	**Percepton/Beliefs** Unnatural Adverse effects Dependance Immune	**Knowledge** Not understanding Not a direct link Incorrect technique
		Shame Not wanting to feel like a patient	**Information** Not being able to acquire
External	**Lack of social support** Family Neighbourhood	**Cultural Influences** Country of origin Neighbourhood	**Communication** Poor communication with HCP
	Stress Work Other health Family Irregular lifestyle	**Social Norms** Influence by social network	
		Media Advertisements	
		Resources Money	

Complexity
Patients find it difficult to remember the names of medication. Often the patients receive multiple sorts of medication which often leads to confusion, especially in case of comorbidity. Patients might find it difficult to navigate the Dutch healthcare system, therefore avoid tasks that are related to this as much as possible.

Communication
The first consult can be overwhelming, where the patients has to process a vast amount of information in a relatively short period of time. As a result, instructions might not be properly understood. Patients are ashamed of being low literate and therefore might be ashamed to ask for additional clarification. Patients are most of the time unable to read supplementary material that is provided by the healthcare provider.

Memory and Recall
Although low literacy patients are trained throughout the course of life to use their memory as a means to hide their disability, it frequently occurs that the provided information is forgotten.

Resources
Patients do not possess the capabilities to consult online resources as they lack the media, information or digital skills. In order to be able to manage and integrate medication into the daily regime, a certain set of organizational skills is needed. Most patients do not possess these skills in general. The medication is frequently seen as expensive. The low-cost inhalers frequently are harder to use, which provides an additional barrier. Usually a spacer is needed in order to simplify the technique, however the spacer is perceived as bulky and unpleasant.

Stress
It appears that people from disadvantaged neighbourhoods are frequently exposed to additional external stressors, therefore reducing their cognitive bandwidth. As a result, the patients might only be focussed on short term solutions rather than future benefits. The motivation to put effort in understanding and getting grip on their health situation is therefore also reduced.

Social Environment
Help is often requested and provided by family members, however, these have a life on their own and might not be able to provide the necessary support. In some cases the family and neighbourhood can provide a barrier as they haven't received the explanation and therefore might have the wrong beliefs and want to convince the patient against the advice of the healthcare provider.

Knowledge
Patients have trouble understanding what the medication is, what is does and what the effect is on their lungs and breathing ability.
Patients have trouble understanding the importance of daily use of the maintenance medication.

Attitude
Patients are not 'interested' in being healthy and might rather go for measures that makes them feel healthy. Since asthma is fluctuating disease, there are moments that symptoms are less. Absence of symptoms can work demotivating on taking the medication.

These non-adherence themes have only been acquired from indirect sources such as literature or experts. It seemed essential to validate the accuracy of these themes with the target group. Through talks with LHL experts, it was learned that a standard interviewing technique is likely to fail as the target group can be aloof towards the interviewer. Therefore it was decided to synthesize the insights into tangible instruments, that would help both the researcher and the target user, to get a picture of how these insights could be translated to a real life scenario. Therefore the insights were translated into persona's and scenarios.

Personas

In order to be able to create the personas, it was essential to map the insights and use them to characterise different personas. This characterisation can be found in Appendix H. As mentioned before, the goal of these personas was to get an idea on how the identified barriers could manifest themselves in a situation applicable to the project scope. Another reason for this conversion was to create an artefact of discussion to acquire feedback on the insights with the practice nurses (Appendix I & J).

In the end, four personas were created: Rita, Theo, Ayse and Boris. Figure 11 shows the end product of the Rita persona. The other personas can be found in Appendix K.

Within the persona's, Rita and Theo are more oriented towards encompassing personal determinants. In terms of adherence, these determinants can be mostly categorized under the unwitting phenotype. The main difference between Rita and Theo is that Rita doesn't remember the details (which medication, when, how many times) of her treatment. This is caused by her lack of self-efficacy on the area of communication. She is not interested in the underlying reasoning, and would already be helped if she was able to perceive and interpret the information.

Theo, on the other hand, knows the details of his treatment. However, because he is not understanding why and because he is a bit aversive towards medication, he sometimes forgets to use it. Providing Theo with the proper insight into the added benefit of his maintenance medication should help to increase his motivation.

Boris and Ayse are more focussed on interpersonal determinants. The non-adherence pattern of Ayse can be mostly seen back in the intelligent non-adherence phenotype. She chooses intentionally not to take the medicines, as they are perceived as very costly and unnecessary. For her, it is mostly a matter of beliefs. These beliefs are the result of the influence of her past cultural perceptions as well as beliefs by her neighbourhood, friends and family.

The pattern of non-adherence of Boris can be categorized under the erratic phenotype. Because of his low perceived control and external pressure.

The personas have been discussed with two practice nurses (Appendix I & J). During these discussions it was asked if the personas were recognised and if there were aspects that were still missing. Both nurses mentioned that all the four types were recognisable. One practice nurse, who has recently switched to a less disadvantaged neighbourhood, highlighted that Boris (forgetting because of a busy lifestyle) is more present in his current neighbourhood then it was in his previous neighbourhood. He indicated that Ayse is a very common character as he recognizes the influence of neighbourhood and family. He didn't agree with Rita as he frequently notices when a patients didn't understood and therefore actively provides the clarification. Theo was very recognisable as he mentioned that a lot of patients have trouble understanding the vastness of his explanations.

The other practice nurse mentioned that costs indeed are a barrier and also agreed that it is hard to explain all the necessary information the short amount of time that they have.

Figure 11 - Persona of Rita

Rita

Confused & Ashamed

Age	46 years
Nationality	Dutch
Occupation	Housewife
Education	Special school (LOM)
Family status	Married, 2 kids

Bio

When I was ten I moved to a LOM-school because I had trouble fitting in. This didn't help me. Instead of learning how to read, write and calculate, I learned how to iron and cook. After finishing, I got married and became housewife. Till the day of today I do not know to read and write. When I think back of the moment I got diagnosed with asthma, I can not remember a lot. For me it is a bit of a fuzzy moment. They explained me what kinds of medicines I had to use, all with confusing and long names. Then they taught me how to use it and when. It all was a bit much, but they ensured me that the flyers they gave me provided all the necessary information. Also if I needed something else to know, I would be able to find it online. Unfortunately I have a lot of trouble reading and interpreting the flyers, also I don't exactly know where to search online for information. I also feel ashamed to ask the doctors as my questions are probably very stupid and they don't want to bother their time with me. So actually what I do now is just take that one medicine that I should take when I feel stuffy. The other one doesn't really do anything and I think it doesn't work for me.

"I want to do what is best for me, only I do not know how and asking for help and telling people I can't read scares me"

Barriers

- Limited understanding of her medication and the effect of it
- Hard to actively search for information
- Ashamed to ask or take initiative for help

Facilitators

- Eager to learn and adopt new knowledge
- Support from family

Scenarios

The personas served as a proper way for the researcher to clearly understand how the different insights could be translated towards real life behaviour. However, personas are less functional in a way that they can help to provoke responses during an interview. Therefore it was decided to convert the persona's and their elements into scenarios. The writing behind the scenarios can be found in Appendix Q. In the scenarios we follow the four personas through a fictional journey from the point where they receive the asthma diagnosis, through several consults and thoughts and behaviour at home. Each story ends with a possible solution, as mentioned by the healthcare providers. Appendix G shows a mindmap of the collected strategies. In these stories, non-adherence behaviour is reflected with a relation to the underlying determinants. The scenarios were visualised using the storyboardthat tool (storyboardthat.com). Figure 12 shows one of the crafted scenarios. The annotations on the left indicate the different underlying determinants. The three other scenarios can be found in Appendix L.

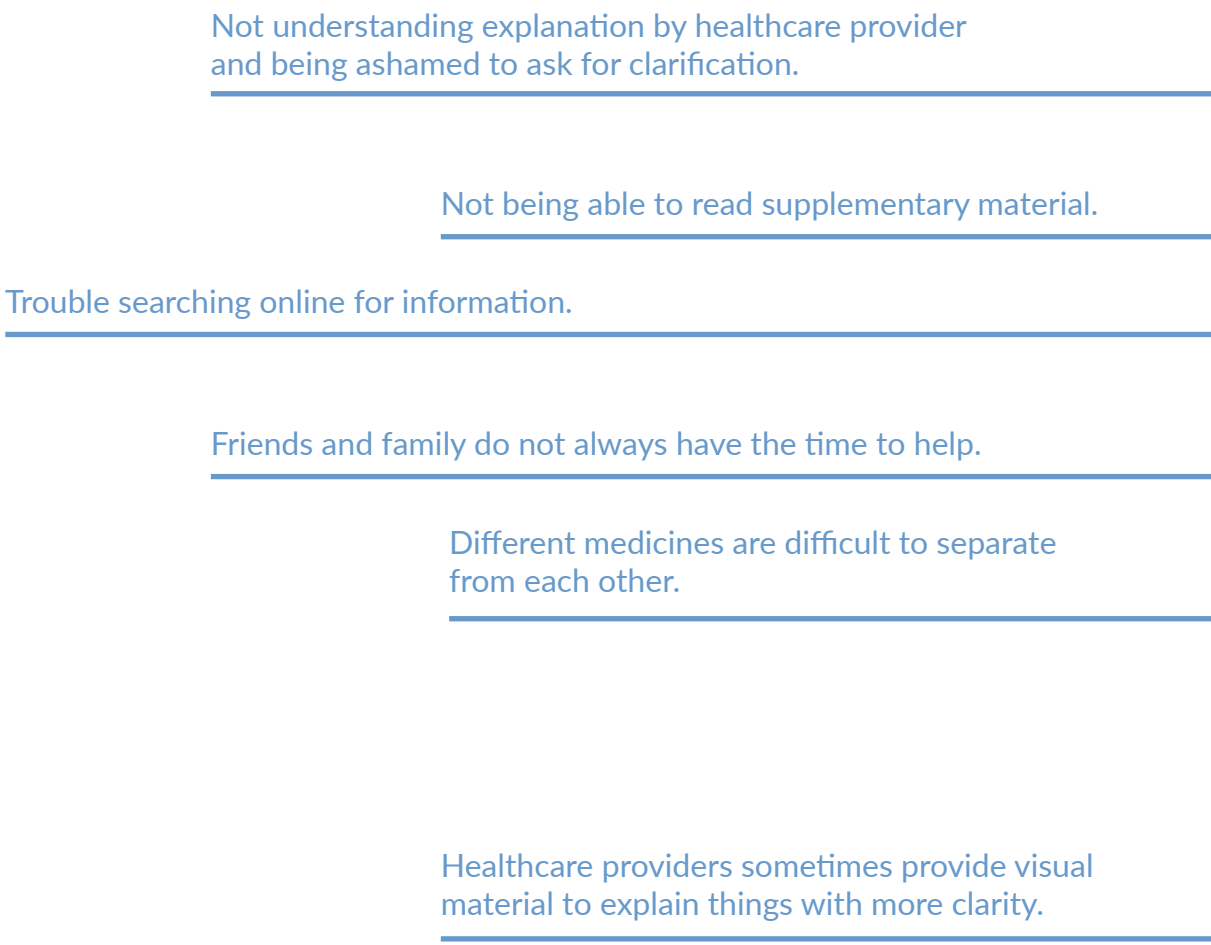


Figure 12 - Scenario of Rita

2.3 | Research Question 2: eHealth Acceptance

This chapter will elaborate on the second research question: What is the acceptance of a eHealth technologies regarding smart asthma inhalers.
In this chapter, several frameworks were consulted and possible barriers were extracted. A summary of these factors can be found in the table in figure 13. These findings were then synthesised into main insight themes. Finally, the chapter explains how these insights are integrated into a design-research methodology.

Chan (2011)

Several tasks were extracted from Chan (2011) that are common skill-related challenges to use of common eHealth tools. These tasks can be described as the following:

/ Entering personal information into medical record
/ Having computer skills to effectively use all the different features and tools
/ Being familiar with health concepts to enter and extract appropriate information in record.
/ Evaluating and weighing evidence to inform a decision: Understanding risk and uncertainty and obtaining evaluating evidence-based information.
/ Interpreting and using health information appropriately for self-care activities

Cashen (2004)

According to (Cashen, 2004), the following characteristics are common in posing barriers for vulnerable populations:

/ Not being able to read or understand communicated information.
/ Cultural aspects such as language proficiency, race, culture and other socio cultural differences are not addressed which are essential to inspire trust, foster adherence and support a persons care-seeking activities.
/ Lack of access to technology, in the form of not having internet connection, possession of smartphone or even not being able to use technology in case of sensory, mobility and cognitive losses.
/ Low education levels and therefore not having knowledge and information to address advance life skills. It can also lead to having a lower self-efficacy, sense of control and decreased enthusiasm for future planning and organisation.

Lezen en schrijven (2015)

According to stichting lezen en schrijven (2015), 80% of the people with low literacy have limited or insufficient digital skills. Limited skills is defined as the ability to perform simple click and navigation tasks, also called: knoppenkennis. This group lacks the strategic skills to reach a certain goal through more complex tasks such as: navigating through multiple pages, clever searching in large amounts of info (spreadsheets) or online information. Also comparing products, services or other values and judge these on relevance and trustworthiness is difficult

Rahimi (2018)

The Technology Acceptance Model (TAM), is often applied to help identify the acceptance of a certain technology through perceived usefulness and perceived usability. According to Rahimi et al. (2018), there have been a lot of applications of the TAM in medical domains in the past years to assess the acceptance of health informatics systems. In some of the cases the original TAM was used, while in other cases the model has been extended with factors beyond usability and usefulness. In the paper, a table is shown that addresses the different factors, categorized according application domain and

intended user group. For this research it was chosen to look further into the technology category: mobile applications. From this row it was chosen to look from patient perspective. This yielded a set of factors and variables that are summarized in figure 13.

Kayser (2015)

Concludingly, the eHealth literacy framework was consulted as developing effective eHealth products requires a complete understanding of the end-users' needs. The framework that has been developed by Kayser et al. (2015), was utilized in order to elicit these needs in the area of low eHealth literacy. This resulted in a set of themes that are added to the table.

Figure 13 - Summary of insight and insight themes

Insight Themes	Chan (2011)	Cashen (2014)	L&S (2015)	Rahimi (2018)	Kayser (2015)
Technological Anxiety	Computer Skills	Lack of access to technology	Digital Skills	Anxiety Privacy Self-efficacy Support	Acces to technologies Feel in control and secure
Unable to interpret information	Interpreting Using Evaluating Weighing	Interpreting Low education			Knowledge about ones own health
No perceived usefulness					Feel that using technology is beneficial
Lack of subjective norm		Cultural Aspects			
Lack of personalisation				Personalisation Person-centered communication	Access to technologies that suit individual needs
Low perceived usability				Prior Experience Information technology experience Compatibility	Ability to engage with technology

Insights

The abovementioned exploration has led to the synthesis of the following clusters of insight themes. These themes represent possible barriers for the adoption of eHealth technologies by the target group. Note that these insight themes were merely based on the synthesis of insights that emerged from indirect sources. Till this point, no actual involvement of the direct target user has taken place.

Technological anxiety

Most people with a LHL also have a low digital literacy, this means that they have trouble using (reading, writing, navigating) and being aware of (seek & assess information, privacy and safety). Although they might have grown accustomed to common apps and technologies, learning new apps or understanding new technology structures might be hard and even scary. Transparency regarding the data is also an important aspect that needs to be considered

Unable to interpret information

Although an essential aspect of the Turbu+ is to log and reflect on the input data, it might be hard for the user group to properly interpret what the app is communicating. This is due to a lack in information skills, which makes it hard to interpret abstract figures and graphs. In addition they have limited health- and scientific literacy which results in the inability to link the information that is presented on the screen to their own body.

No perceived usefulness
Why should users engage in a new technology? It should be clear what they can gain from using the app. Telling them that, eventually, it will contribute to better adherence and therefore better health, is suspected to be too farfetched. It is known that the patients often have a temporal horizon indicating that short-term direct benefits are considered more useful than far future benefits (Pampel et al. 2010).

Lack of subjective norm
It seems that the subjective norm plays an important role. Therefore it is important to include an element of communication. Communication with the care provider, to establish trust, feeling control and to provide advice and motivation. But also with relatives to help out to translate/ interpret certain information, provide motivation and provide more trust.

Lack of personalisation
The system should take into account the amount of functionality/complexity the user wants and the openness of their data. It should address a personalised treatment plan and be considerate about medication preferences and differences.
It is important to consider user preferences in the visualisation of the interface as well

Low perceived usability
According to McFarland and Hamilton (2006), computer efficacy has a strong influence on the perceived ease of use. It can be suspected that the target group has a relatively low computer efficacy and that therefore the user might see the technology as difficult to use. They have little experience with information and data interpretation.

Co-constructing Stories
The abovementioned insight themes are merely assumptions about possible barriers of the target group. In order to assure that these assumptions are in the correct direction, it was essential to convert the insights to artifacts that allow discussion and provocation with the target group. This was done through the Co-constructing stories (CS) methodology.

The CS methodology involves inviting the participant to tell their story about the subject to research. This method was found particularly useful, as it would provide discussion material based on real-life scenarios instead of theoretical themes. The design of these stories can be described as the following:

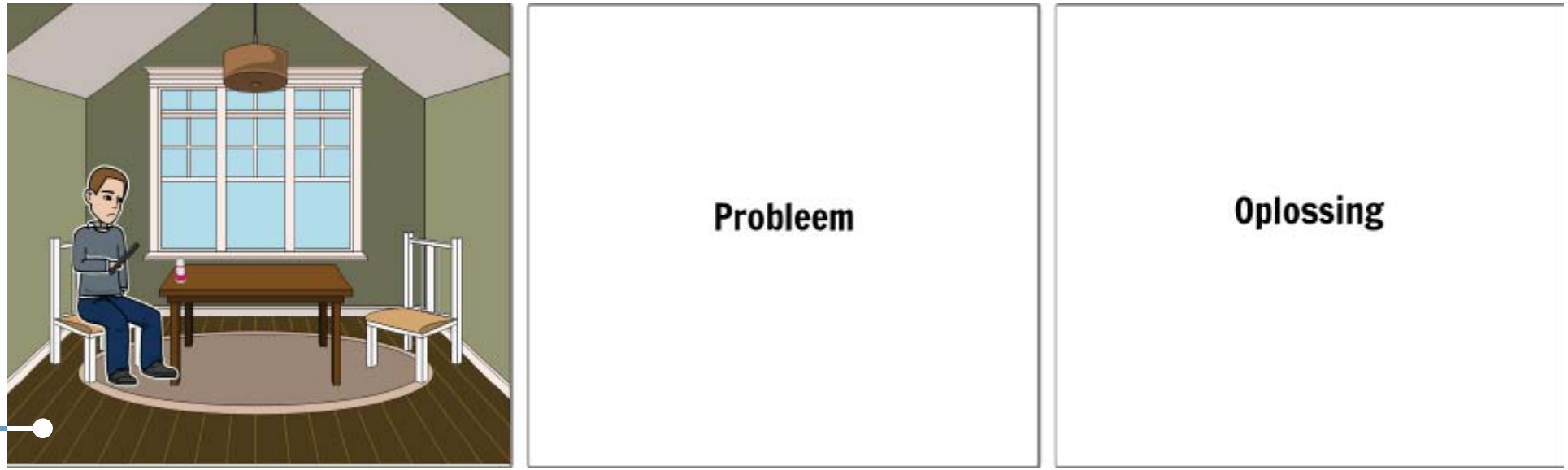
The story consists of three different frames. In the first frame of the story, a person is seen that has just received the Turbu+. However, this person is not happy with the device. The second and the third frame were left blank. For the second frame, story elements were created based on a combination of the aforementioned eHealth insight themes and a critical analysis of the Turbu+ (Appendix N). These elements could be used to guide the participant in telling the story about why they would not want to use the Turbu+. For the third frame, story elements were created targeted at solution areas. These areas were based on solution strategies that were collected throughout the research. A mind map of these strategies can be seen in Appendix G. Figure 14 shows an example of a combination of story elements. The other story elements can be found in Appendix M.

Story creation template

Problem area: Not having the time to engage with a new kind of technology

Solution strategy: Using familiar technology platforms

Figure 14 - CS examples



2.4 | User Study

This chapter will elaborate on how the scenarios and CS methodology have been applied into a user study. This user study consisted of a pilot, in which the setup was tested and improved and two interviews in which the aforementioned material was discussed.

Pilot

Before executing the interview session with the real participants, the session was first piloted with two students from Industrial Design Engineering (figure 15). This was done to help the researcher become familiar with the research flow and to identify possible improvements. The pilot resulted in the following changes in the study setup:

Going through a scenario took approximately 15 minutes. Hence, discussing all four scenarios would take too much time during the session. It was suggested by one of the participants to merge the four scenarios into two. In order to reduce the effort needed by both researcher and participants.

Figure 15 - Pilot Study

Most of the story elements were focussed on the Turbu+ and the app. In case additional insights were needed that go beyond the app, it was suggested to provide some elements that focus on provoking these kind of ideas.
There were blank cards about the app, and the context, but not for the inhaler itself. In order to provoke reactions that were also applicable to the inhaler, an extra blank card was made in which the Turbu+ is visible. It turned out that the amount of text in the images could be reduced. Since the participants would be guided through the interface by the researcher, most of the explanations could be delivered orally. The second part where the participants were asked to create stories themselves was seen as a nice and fun approach.
Based on this it was suspected that the participants would think the same, and therefore would be more engaged throughout the interview.

Execution

In total, two participants participated in the interview sessions (figure 16). One participant has had asthma complaints and has used medication as a treatment. This participant moved to the Netherlands a while ago and worked as a volunteer in 'de weggeefwinkel' in Leiden. The second participant used medication on a daily basis and was, because of a cognitive disability, considered to have a LHL.
The interviews took place at the facilities where the patients were recruited. Either because of residential or employment status. The interviews took approximately 1 hour. Both interviews were recorded.

The interview followed a topic-guide (Appendix P) and was structured in the following way: The interview started with a general part in which general information about the patient was acquired such as living situation and occupation. In the second part of the interview, information was gathered about the disease. What type of asthma, do they consider the asthma under control? What symptoms do they experience? What is their relation with the healthcare provider? etc. A full overview of the research setup can be found in Appendix O.

After this initial part, the sensitisation session began, in which the participant was asked to go through one of the scenarios. The researcher chose, based on the initial part, the scenario that felt the most in line with the participant. Based on response of the participant, a second story was used. After this session, the participant was told that there is a device currently aimed at supporting the problem described in the scenarios: The Turbu+. The researcher provided the participants with short explanation of the Turbu+ in which the five key tasks were discussed.
After this, the participant was asked to then create a own story following the previous described CS methodology.

Figure 16 - Discussing one of the scenarios with a patient

2.5 | Results

In this section the results of the interview sessions are presented. First the most striking results of the fictive scenarios regarding the non-adherence determinants are presented. Subsequently, the results of the CS are highlighted regarding the eHealth acceptance determinants. The notes of the interviews can be found in Appendix R.

RQ1 – Non adherence

Understanding

The first striking result from the interviews was that neither of the participants had a proper understanding of the maintenance medication and its effect. P2 mentioned that he used the medication because it was told so by the doctor and because he is reminded by his home-care support. When it was asked whether he could reproduce the instruction provided by the doctor, he stated that he had never totally understood the instructions. Also, when asking P1 about the instructions that were provided by the healthcare provider, he was unable to reproduce them.

P2: "According to the doctor, I just have to do it. That is what I know."

Quick-relief medication

P2 indicated that he has used his quick-relief medication (the blue one) in the past. He indicated that right now the amount of complaints is significantly less, and therefore he doesn't need to use it anymore. He did indicate that, when the help of the home support was absent, he would stop use the maintenance medication and prefer to use the quick-relief medication.

P2: "I can read comics if I want. But my mother helps me to read more difficult things."

Interpreting written material

As mentioned before, P2 receives help with the adherence of this maintenance medication. In addition, regarding the interpretation of written instructions, his mother helps him out by reading it to him and explaining. He indicated that he can read a little bit and does like to read comics. P1 is also able to read certain material, however he mentioned that people in his neighborhood are less capable of reading material and that the often has to help to translate certain written material.

Trusting the doctor

P1 mentioned that in the country of his origin, the doctor is of higher authority and everybody is used to listen to the doctor. In his country, the doctor is always right. P2 also mentioned that, although he doesn't actually remember the why of his treatment, he still believes its best for him.

Social Influence

According to P1, the neighborhood can have a significant influence on the perception of the patient regarding their medication. If the patients completely understanding the instructions of the doctor, he or she might be more perceptive towards the opinions of the people around them.

Attitude

P1 mentioned that health for him doesn't mean knowing that you are doing healthy things. For him it was more important to directly feel that you are healthy. Such as having a good life, lots of friends, no struggles with family etc. He mentioned health for him is more oriented towards feeling happy instead of knowing you are doing the good thing from scientific perspective. He mentioned that life can be hard and there can be moments with a lot of setbacks. In these times one might feel less healthy.

RQ2 – eHealth Acceptance

Problem

The main problems areas for P2 were the inability to share data with relatives and the interpretability of the information within the app. Especially textual information and graph-like representations of data were difficult for him to understand. In addition, the menu was perceived as not really clear as it contained a lot of text. He indicated that this could result in him not using the app. P2 did mentioned that the factors "new technology" and "time" were not of an issue for him. He indicated that he enjoyed exploring new technologies and that in the evening he has enough time to look at the app and check how he is doing.

P2: "If I have nothing else to do, for example before going to sleep, I would be interested to look at how my day was."

Solution

P2 particularly liked that he would be able to share the adherence data with his mother and caregivers (figure 17). It would mean that he would receive more self-authority but that his care providers could come to aid when they see in the app that he for example forgot his medication. Another suggestion P2 made was that it would be good to include the doctor as well. Because of this, he believed that he wouldn't need to go there that often and only when something is wrong.

P2: "If I forget, others can see it. They can use the app and I can use my medication."

Furthermore, he mentioned that he prefers to see a visual representation of the data, instead of text and numbers. Seeing an image of the lungs or a flower was preferred above graphs. He mentioned to have the preference for an abstract (flower) or realistic (lungs) image. Furthermore, he replied that it would be a cool feature to add fun things to the app such as a picture of your girlfriend in the background.

P2: "The more fun, the more interesting it is."

When presenting P2 with a story element of being able to compare with other asthma patients, he mentioned that he doesn't know other people with asthma but that it would be interesting to see how others are doing compared with yourself.

The possibility to visualize the feedback not in the app but on the inhaler itself, was seen as a good idea. As the medication is situated at home most of the time, he wouldn't be able to check it regularly. Therefore displaying the information in the app would be more beneficial as you always carry it with you.

Concludingly, P2 mentioned that it would be good to add some support to the app, for example when a certain subject is not clear. He indicated that having contact with the doctor is not preferred as they are often busy. As a way to solve this, he mentioned a Siri-like function that could explain the matters to you through spoken voice. He provided a demonstration of how he is able to retrieve the latest soccer-score through his Siri interface.

In the end session, where the participant was asked to create a story, he mentioned that the main problem would be that he isn't able to share the data with his care-providers (mother and homecare). As solution he mentioned that he wanted to see a collection of several solution strategies that would make the interface more interesting.

2.5 | Discussion

In this section, the results of the interview sessions are discussed and interpreted. In addition, the limitations of the study are acknowledged.

RQ1: Non-Adherence

The discussion of the scenarios helped to elicit several interesting insights regarding the determinants of medication non-adherence.

It was learned that P2 had significantly less complaints compared to the past. It can be argued that this was the cause of his proper adherence to the maintenance medication. I was learned however, that without help, he would probably not use it and use his maintenance medication instead. This, in combination with the fact that both participants were not able to reproduce the actual effect of the maintenance medication, suggests that there is limited awareness about the medication and its effects.

Both P1 and P2 were able to read written material. Although P2 mentioned to be only interested in comics. It could be argued that for him, the perception layer (chapter 1.4) was present, but that he was not able to interpret the subjects. Therefore it could be suspected that non-adherence caused by misinterpretation of written material is more related towards the interpretation and reasoning layer as presented in chapter 1.4.

A possible determinant of non-adherence was that patients could have distrust in the doctor, as stated in the scenario of Ayse. However it seemed that both patients were loyal to the treatment provided by their doctors and believed this was best for them.

P1 also mentioned that for him it was more important to feel healthy, instead of knowing that you are healthy from biological perspective. This suggests that the attitude can be a possible determinants of non-adherence. As stated in chapter 1.1, the effect of the maintenance medication can often be perceived as “invisible”. If someone has the attitude to judge their health based on noticeable factors, it could be suspected that this attitude has an effect on the adherence of the patient.

Ehealth acceptance

Both participants had a basic level of digital efficacy, which is comparable with the limited digital efficacy stated in stitching lezen en schrijven (2015). Although P2 mentioned that he doesn’t look for online information as it is not interesting enough, he does seem to have the skills to find the information. Whether he is able to judge and use the information, remains to be questioned. If the subject is of interest to him, for example in the form of a computer game, he is able to consult tutorial videos and other sources to assess if he wants to buy the game. This suggests that the level of engagement the content provides is factors that plays an important role. In the end session of the story creation session, it was learned that the most important aspects of the interface would be that he is able to share information, for example with family members, and that the interface should be made engaging.

Figure 17 - Story created by P2

Problem area: Not being able to share with mother

Solution strategy: Different options of sharing data

Solution strategy: Playful way of visualising data

Limitations

The goal of this research activity was to validate the insights that were gathered throughout this phase. Although the participants could be considered as asthma patients with LHL, their state of asthma was under control. Which made it difficult to relate to someone that has uncontrolled asthma because of non-adherence. In addition, one of the interviews was conducted prior to the pilot tests, which resulted in an elongated sensitisation phase. Because of this there was no time/effort left to go into the elaboration phase. Instead, a small discussion was held about the acceptance/usage of technology in daily life.
Because of the small sample group, the controlled asthma and the other limitations, it was difficult to draw any definitive conclusions on the accuracy of the insights. Nevertheless, the insights acquired during these interviews were taken along in the define process that is explained in the next chapter.

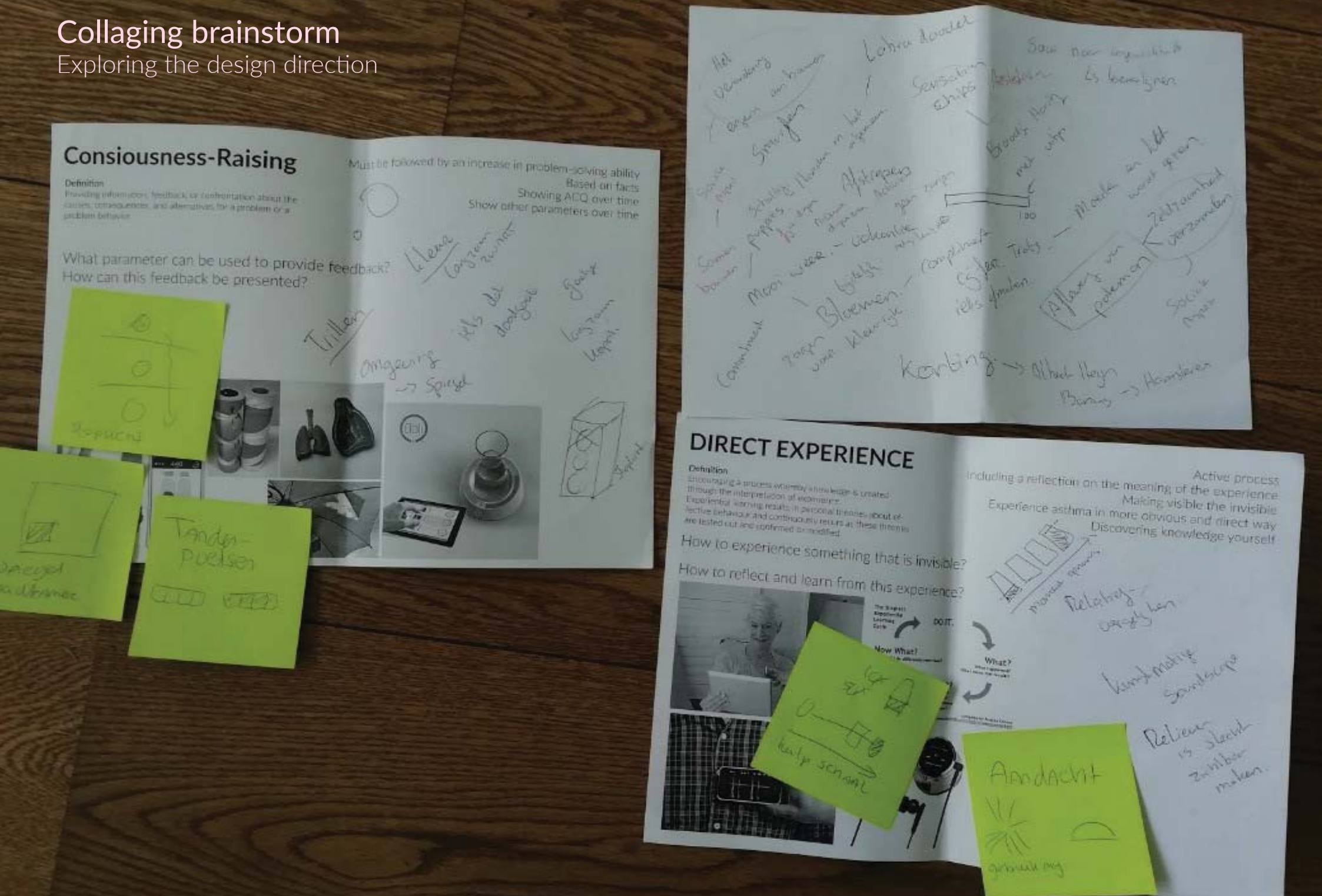
Key Findings

Non-adherence
/ Limited understanding of asthma and medication.
/ Social support plays a key role
/ Attitude towards being healthy is different

eHealth acceptance
/ Digital efficacy depends on motivation
/ Sharing information with relatives is an important feature

Collaging brainstorm

Exploring the design direction



CHAPTER 3 | Define

In this chapter, the results from the empathize phase were further interpreted. This was done through the creation of a matrix of change according the IM approach. From this matrix, three design directions were synthesized. The chapter concludes with the presentation of the resulting design vision.

3.1 | Determinants and Performance objectives

The first step in the creation of the matrix is change is to determine (1) high-level determinants and (2) performance objectives. This chapter will briefly explain their definition and how they have been acquired.

Determinants

The insights that have been explored and validated during the research phase, are not directly usable. In order to be able to work with them, it is essential to convert these low-level insights into high-level theory- and evidence-based determinants (figure 18). These determinants are utilized for example in the Reasoned Action Approach (Fischbein & Ajzen, 2010), Social Cognitive Theory (Bandura, 1991), the Health Action Process Approach (Schwarzer, 2008) and the theory of Implementation Intentions (Gollwitzer, 1999). For the purpose of this project, the determinants as categorized in the taxonomy of behaviour change (Kok et al. 2016), have been used to organise the insights. By interpreting the insights, it was chosen to focus on the determinants: 2. Awareness, 4. Attitude, 5. Social Influence and 6. Capability.

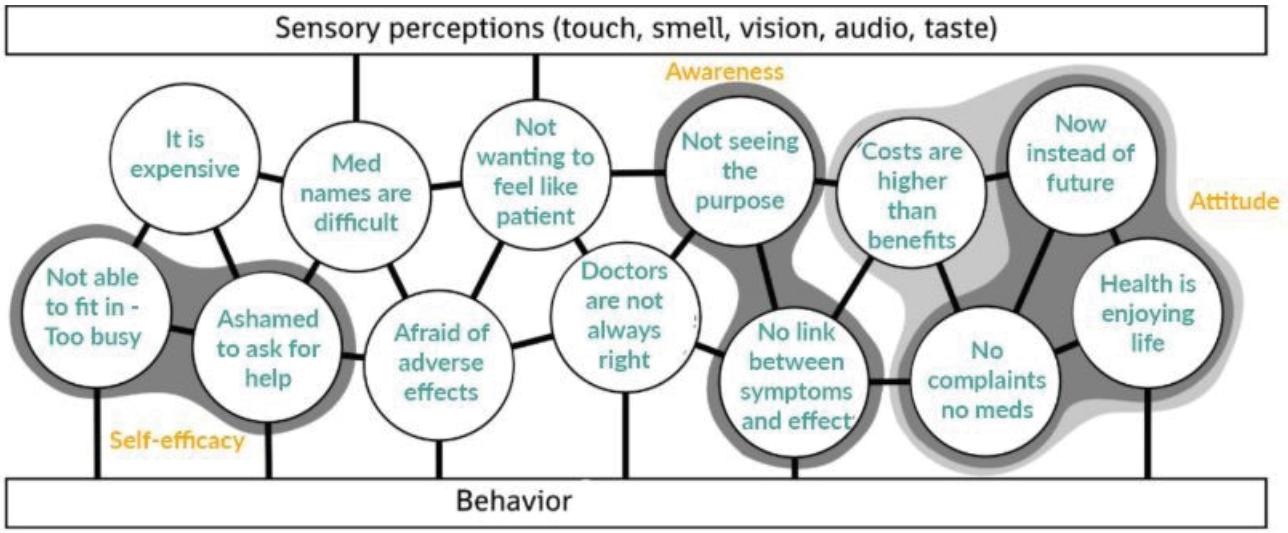


Figure 18 - Visualisation of low-level (green) and high-level (orange) determinatns

Performance Objectives

The second ingredient required for the creation of the matrix were performance objectives. Performance objectives were needed because the target behavior can be seen as too complex to be analysed by itself. Therefore the behavior could be substituted into sub-behaviors that were needed to fulfil the required target behavior. These sub-behaviors could also be defined as performance objectives. In order to help to identify these performance objectives, Bailey et al. (2013) has lined out a model of medication self-management which is literacy informed (figure 19). It presents a conceptual model that deconstructs the tasks associated with taking prescription drugs. This includes knowledge, skills and behaviors necessary for low literacy patients to correctly take medications and sustain use over time. It offers guidance to interventions promoting medication self-management, especially among patients with low literacy.

According to this source, the self-management of medication can be deconstructed in the following components:

Fill

The first step needed is to fill and pick up their prescription. Drug cost, poor understanding of why the drug is necessary and fear of side effects have been cited as potential root causes. Also poor provider-patient communication is likely to lead to misunderstandings (Bailey et al. 2013).

Understand

It is essential to learn the proper inhalation technique effectively and safely. Also the ability to identify the different inhalers and to understand what and why they are taking it, is an important aspect of medication self-management. Patients with limited health literacy skills have consistently shown to have greater difficulty understanding medication instructions (Bailey et al. 2013)

Organize

It is essential for patients to organize and plan medication use around their daily regime. Patients with limited literacy skills are more likely to overcomplicate the regimen. The possession of organization and planning skills are essential for a successful integration of medication in the daily regime. (Bailey et al. 2013)

Take

Forgetfulness, unclear instructions, side effects, lack of regimen familiarity, lack of symptoms and loss of interest are all factors that have been identified to potentially lead to failure to take medications correctly and consistently. (Bailey et al. 2013)

Monitor

An important aspect of safe and effective medication use is the ability to be vigilant when taking medicine and be aware of the side effects, risks and warnings connected to the medication. It turns out that patients with limited health literacy are 3.4 times more likely to misunderstand warning labels (Bailey et al. 2013).

Sustain

The final step of effective medication self-management is to sustain the medication use throughout a longer period of time. Evidence suggests that options often reduce or discontinue use of their medications over time. Busy lifestyles, unpleasant side effects, perceptions that the medication is ineffective or no longer necessary and being unaware of the need to refill and continue medication due to inadequate provider-patient counselling can all be identified as possible causes of reduced self-management ability.

Figure 19 - Visualisation of performance objectives

3.2 | Matrix of Change

The identification of both the determinants and the performance objectives made it possible to devise a matrix of change. In this matrix, the performance objectives were plotted against the determinants. Subsequently, the matrix was filled with the insights from the research.

To be able to fill in the matrix, all the evidence that was collected throughout the research (talks, literature, interview sessions) was gathered. This was done by devising a table, in which the insights were combined and clustered. This overview can be found in Appendix S. Subsequently, the formed clusters were transferred to the matrix, where they were converted to 'change objectives'; an objective need to met in order to change behavior.

Ideally, all the change objectives need to be met in order to be able to change the behavior. However, when considering the feasibility of this project, it seemed essential to select only the change objectives that are considered the most important and changeable. According the IM approach, importance of change objectives can be investigated through literature, while changeability has to be derived from common sense. In this project, the importance of change objectives was derived from a coding activity. This activity was an iterative process of re-clustering insights and going through the resources. This led to an approximation of the amount of sources that relate to a certain insight. This 'quantification' was used to provide a colour map to the initial matrix. The background coding activity can be found in Appendix S. The result of this initial matrix including the first colour map can be found in Appendix U.

Validation

Since the matrix was devised by the researcher alone, there was a high chance of being subject to a large number of biases. In order to counteract these biases, the matrix was discussed with one of the practice nurses. The goal of the discussion was to find out if there are still blank areas in the matrix that should be filled and to find out which of the cells can be seen as most important. The matrix therefore was discussed without the coding layer integrated.
The following aspects were mentioned by the practice nurse during the discussion:

Missing change objectives
/ **Capability to take:** Patient should be able to maintain the proper inhalation technique
/ **Awareness to fill:** Patient should be aware of the inhaler being empty and order a refill on time.
/ **Attitude to take:** Taking medication can be enjoyable, but more important is effortless with a direct vision on the benefits

Important change objectives
/ Capability to understand the medication
/ Aware of the effects of maintenance medication
/ Reducing the social influence of family and neighbourhood.

The missing change objectives were filled in and the important change objectives were taken into account in the quantification of importance. This yielded the final matrix of change which can be seen in figure 20. In this matrix the boxes with the most sources mentioning it and the boxes that were mentioned in the final discussion with the practice nurse were highlighted.

Figure 20 - Final version of matrix of change (including practice nurse comments)

DETERMINANTS	PERFORMANCE OBJECTIVES: Fill Fill medication at pharmacy	Understand Understand how, when and why to use	Organize Integrate into daily regime	Take Take the medication	Monitor Monitor (side) effects	Sustain Sustain use over longer period of time
Capabilities Is able to	Navigate the healthcare system Afford the medication	**Understand and interpret information** Ask for clarification	**Remember and apply treatment instructions** **Express confidence**	Use the proper inhalation technique	Interpret symptoms and severity Monitor dosage level left	
Awareness Sees	The importance of refilling in time	**The importance of prevention medication**		The importance of using the proper technique	**The effect of prevention medication**	Being healthy is more than feeling healthy
Attitude Believes that	Taking medication is acceptable		Future health is as important as health now	**Taking medication is enjoyable and effortless**		Taking medication is also important when there are no symptoms
Social Influence	**The patients family accepts the acquirement of medication**	The patient is aware of other patients' medication adherence		**The social environment accepts the taking of medication**		The patient has a trustworthy relationship with the care-provider

3.3 | Design Opportunities

After the matrix was validated, it was possible to derive the most promising change objectives (figure 21). This chapter elaborates on these objectives and how they are integrated.

The most important change objectives from the matrix were combined into three main design directions.

The first direction lies in the “capabilities“ determinant, where the patient will be empowered to understand and organise their medication and to gain confidence in the area of self-management.

The second direction focusses on the “awareness“ determinant. Within this direction it is deemed essential that the patient understands the medication and what its effect is on the body. The use of maintenance medication, its effect and its relation with symptom relief is an important link that needs to be made visible

The third direction aims at changing the “attitude“ determinant. Most patients do not like to take medication and if there is no visible effect, they are most likely to be less adherent to the treatment. It will be essential to make them realise that being healthy is more than only feeling healthy and that some healthy decisions might not be directly noticeable on the short term but will definitely show effect over a longer period of time.

Figure 21 - Design Directions

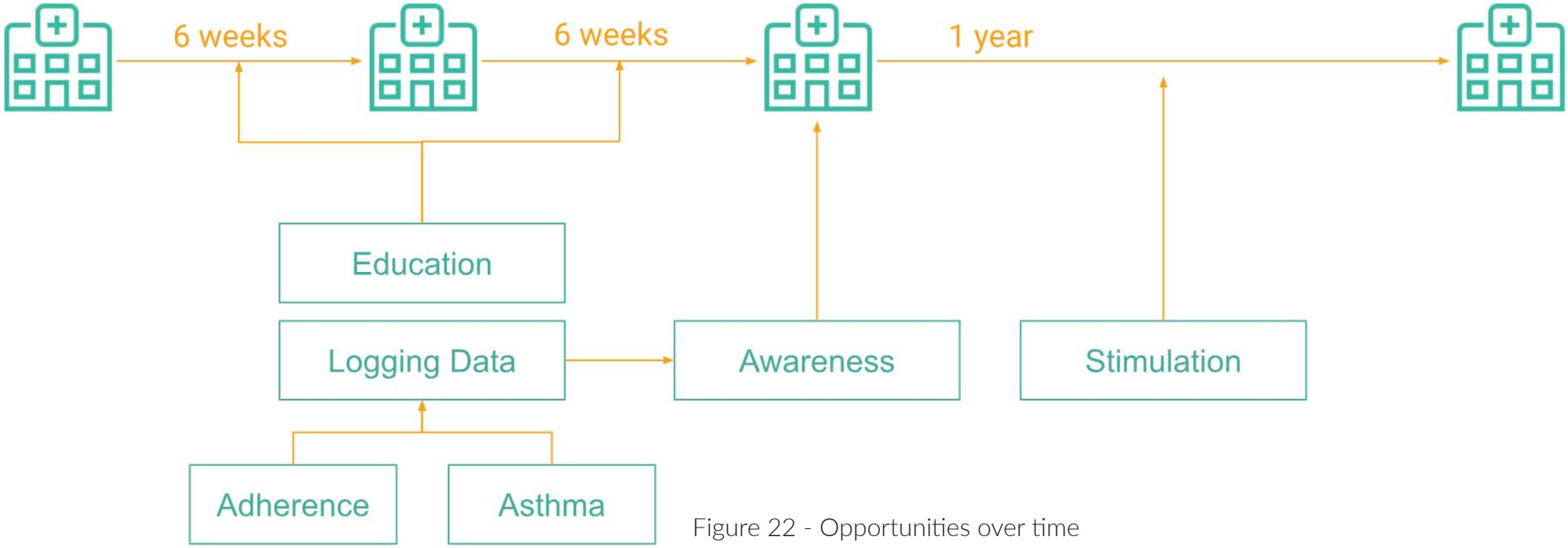


Figure 22 - Opportunities over time

These three directions can be integrated into a real life scenario as presented in figure 22).
The "capabilities" direction can be implemented during the different consults. In these periods the patient is empowered to self-educate and to learn and understand the treatment. This period could also serve to gather essential data about adherence and state of asthma. This data could thereafter be used for the "awareness" direction. This direction could be implemented during a consult with the practice nurse, where the patient is asked to reflect upon the data. By reflecting and seeing improvement, the patient could become aware of the effect of the maintenance medication.

After this period, the "attitude" direction can be implemented. The goal of this direction would be to stimulate the patient to maintain their attitude over a longer period of time.

After the identification of these directions, it was needed to explore the solution space. This would shed light on the possibilities that lie within the different directions.

3.4 | Exploring Solution Space

This chapter will highlight the different methods that were used in order to acquire a grasp on the solution space.

Taxonomy of Behaviour Change

The first method that was used to explore possible solutions was to further explore the taxonomy of behavior change methods (Kok et al. 2016). This source was initially used to identify the high-level determinants for the matrix of change. At this point, the contents of the according tables could be used to choose theory- and evidence-based methods that could potentially be used to be integrated into a design solution. The tables of capabilities, awareness and attitude were used for further investigation. It was needed to determine which of the methods provided in the tables, provided the most potential. For this, first, the methods were made familiar by skimming through the relevant literature. After getting a better idea of the contents of these methods, a collaging activity was performed. One of the collages can be seen in figure 23. The full set of collages can be found in Appendix V. The collaging activity helped to force the production of possible directions within the proposed method. While some methods quickly resulted in a vast set of different inspirational sources and solution strategies, others remained blank, suggesting that those were not the most fruitful methods to explore. Eventually, based on this activity, the following methods were chosen to further explore:

Awareness
Consciousness Raising
Scenario Based Risk Information

Attitude
Direct Experience
Conditioning

Capabilities
Guided Practice
Set Graded Tasks
Self-monitoring

Solution Insights

During the empathize phase, not only insights were gathered regarding the non-adherence and eHealth acceptance, but also about solution strategies. While talking to the different experts, they frequently mentioned different approaches that could be utilised in order to aid people within the target group. These strategies ranged from topics such as motivation and communication. An overview of these strategies can be found in Appendix T. These solution elements were taken into account in the decision of the design direction.

Figure 23 - Example of behaviour change collage

Consiousness-Raising

Definition
Providing information, feedback, or confrontation about the causes, consequences, and alternatives for a problem or a problem behavior.

Must be followed by an increase in problem-solving ability
Based on facts
Showing ACQ over time
Show other parameters over time

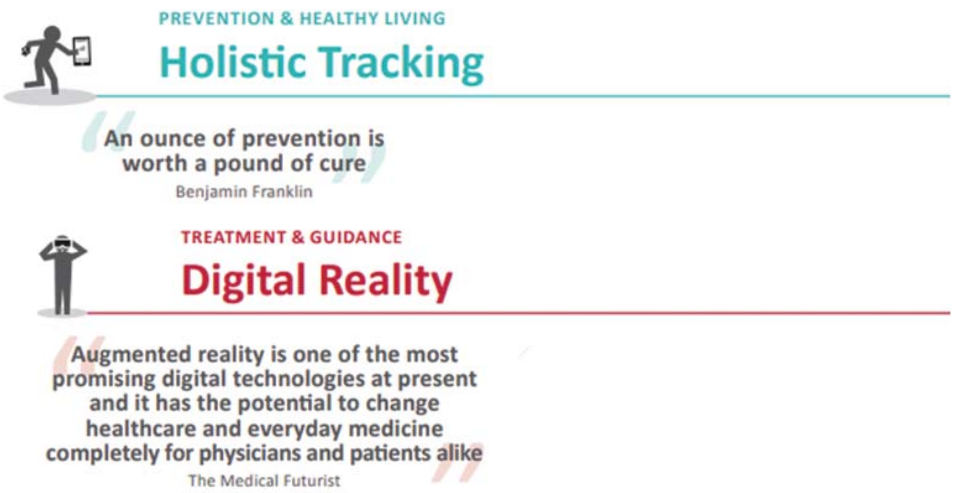
What parameter can be used to provide feedback?
How can this feedback be presented?

3.5 | Design Direction Selection

In this chapter, the different design directions are considered and evaluated against their potential for the project. It is suspected that all directions are beneficial in terms of the research goal. Therefore, the decision is based on more practical criteria such as personal learning goals, client interest and project practicalities.

It is desirable, to integrate all of the elements stated above into a design solution. For the sake of this project, it was decided to only focus on a specific part of this solution space. During a project meeting, it was decided to either focus on the education or on the awareness elements.
An exploration regarding current healthcare trends and technologies was conducted by consulting the Healthcare Enablers book (BeBright, 2019). From this book, several trends and technologies were retrieved that could be utilised for one of the two concept directions.

Awareness



Education

In the end the following technologies were selected:
In order to choose to proper direction, a set of project requirements was devised:

Personal Learning Goals
/ Hardware
/ Smart System
Client
/ Costs
/ Innovative
/ Turbu+ Integration
Project
/ Measurable
/ Time
/ Target group specific

With the requirements and the technologies in mind, it was decided to devise Harris profiles (figures 26 & 27) in order facilitate the decision. Based on these profiles it would be possible to get a better overview of the pro's and con's of the different directions. The personal learning goals boxes were filled in based on estimated possibilities within the direction. The client boxes were filled in based on a project meeting with Astrazeneca in which they provided future suggestions. The project boxes were filled in based on estimated possibilities and constraints.

		Awareness	
	Criteria	Holistic Tracking	Digital Reality
Personal Learning Goals	Hardware		
	Smart		
Client	Costs		
	Innovative		
	Turbu+		
Project	Measurable		
	Time		
	Target group specific		

Figure 26 - Harris Profile Awareness

		Education	
	Criteria	Serious Gaming	Robotic Care
Personal Learning Goals	Hardware		
	Smart		
Client	Costs		
	Innovative		
	Turbu+		
Project	Measurable		
	Time		
	Target group specific		

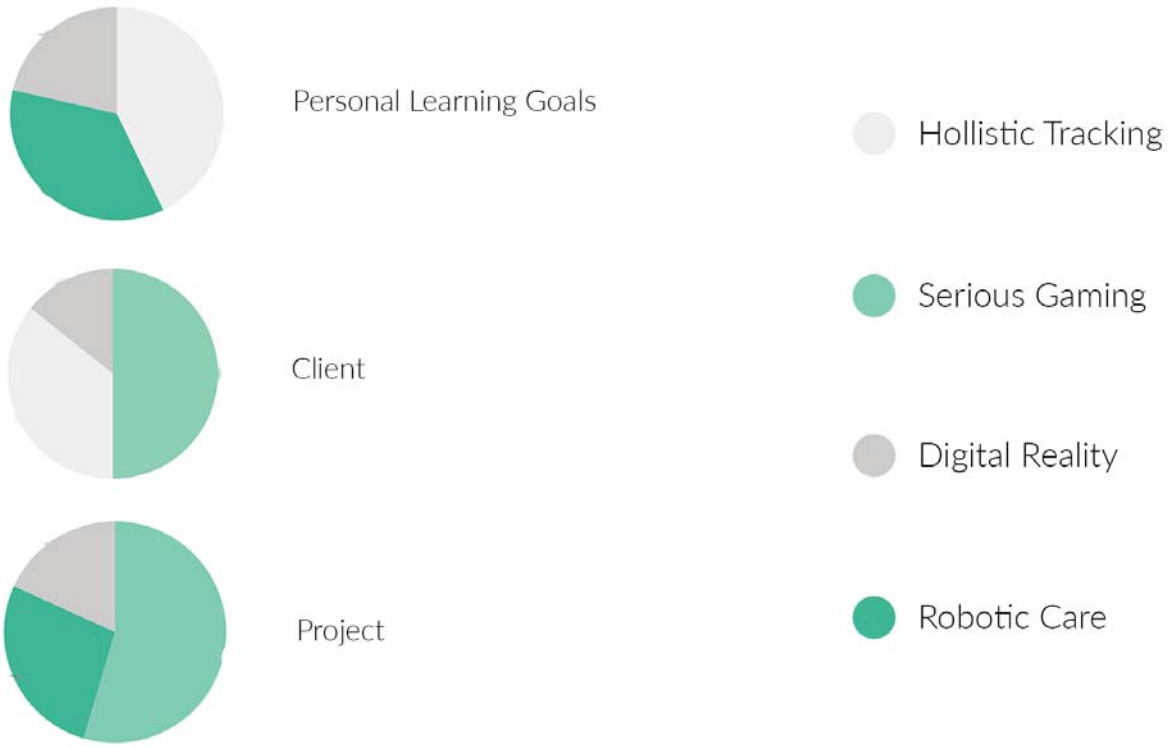
Figure 27 - Harris Profile Education

Top-3 selections (figure 28) were made based on these Harris profiles. In these selections, scores were given based on the amount of boxes each direction has (negative boxes count as -1).
From this top-3 selections it was decided that data comparison and serious gaming both have the most potential. Therefore it was decided that both could be chosen as direction to take on, while taking into account the weak points. Hence, the following directions were identified as a possible next step.

/ Creating awareness through data comparison while considering the engagement of the target group.

/ To educate through gamification with the involvement of a hardware design to enable the measurement of personal data.

Figure 28 - Top 3 Selections



	Criteria	Education					Logging					
Personal Learning Goals	Hardware		■	■						■	■	■
	Smart			■	■					■	■	■
Client	Costs			■	■				■	■		
	Innovative			■	■					■	■	
	Turbu+		■	■						■	■	■
Project	Measurable		■	■					■	■		
	Time			■						■		
	Target group specific			■						■		

Figure 29 - Harris Profile final direction

In order to choose a final direction, it was decided to make another matrix (figure 29). For this, the same matrix layout for the two directions was used. From the matrix it seems that overall, for the client, both directions are beneficial.
Despite this side note, the impactful self-monitoring seemed more beneficial for personal learning experiences. Therefore the final direction has been chosen as the following:
Creating awareness through data comparison while considering the engagement of the target group.

3.6 | Vision

As discussed in the previous chapter, impactful self-monitoring was chosen as a final design direction. This chapter will elaborate on this direction and will state the vision that evolved from it.

In short, the vision can be stated as the following:

"To engage the patient to objectively log and monitor the state of their asthma in a way that it creates awareness about the disease and the effect of the medication."

The following design criteria are defined to reach the desired design vision (figure 30):

Objective monitoring

According to Ignacio-Garcia & Gonzalez-Santos (1995), the personal use of an objective measure of lung function in association with a medication self-management plan leads to improvement in the patient's condition. The additional data can help the patient to judge and remember their state of asthma control. As this is usually quite difficult for people with LHL to do.

Engaging

The monitor experience should be engaging so that the patient will be motivated to use the monitoring device for the period between two consults. According to a practice nurse this is usually around 6 weeks. This is essential in order to acquire enough data for the final moment of awareness.

Provide Awareness

Not only should the data be stored so that it can be used for the final moment of reflection, it should also provide relatable feedback at the moment of interaction. With relatable it is meant that the data should relate to the respiratory function and already provide some awareness during the 6 week period. This is essential to stimulate the usage of the second data stream: the maintenance medication. The goal will be to teach them how to recognize and interpret inadequate respiratory function and to provide the insight that maintenance medication can help to improve this function.

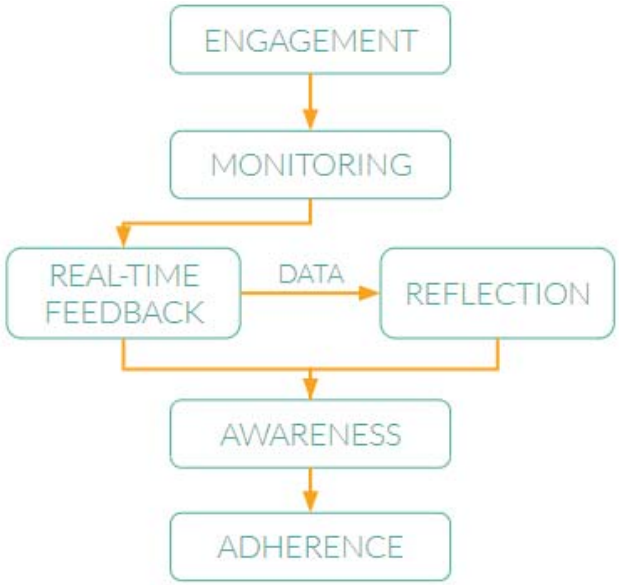


Figure 30 - Vision Schematic

User Evaluation

Testing one of the interaction prototypes with one of the participants.

CHAPTER 4 | Iteration 1

This chapter will elaborate on the exploration of the solution space within the design criteria, and how these solutions were synthesized into the first preliminary concepts. These concepts were prototyped and evaluated in a session with the target group.

4.1 | Ideation

Based on the design criteria, the following set of questions was identified that needed further research and exploration in the ideation phase:

/ How to capture data objectively?
/ How to provide awareness?
/ how to provide engagement?
/ How should it be embodied?
/ What should be the context of use?

This chapter will elaborate on the activities that were conducted in order to achieve answers to these questions. It concludes with a user evaluation in which a collection of possible solutions were evaluated.

Objective Measurement

The first objective within this research activity was to identify possible methods for measuring the level of asthma control. For this desktop research was performed.

Requirements

The requirements for identifying methods were stated as the following:

Capture progress

The method should be able to capture an increase in asthma control based on increased medication use. The essence is that a basic improvement has to be seen. Accurate measurement as might be needed for diagnosis is therefore not a main requirement.

Done by the patient

The measuring method should be easy to perform by the patient at his/her own home. Complex techniques that require monitoring by an expert therefore need to be excluded.

Effortless

Even though a method could be performed by the patient him/her self, it is of importance that this method is as effortless as possible. The more effort it will cost to perform a certain measurement, the more difficult it will become to motivate and engage the patient.
During the research, the amount of effort was determined and given the following scores: 0: High effort (time intensive, high cognitive effort or unpleasant experience), 1: Medium effort (small amount of time needed, low cognitive effort) 2: Low effort (automatic)

Referable

The data that is gathered should be easy for the patient to comprehend and to relate to the perceived respiratory symptoms. This is an important function that relates back to the overarching design criterium to create awareness during the monitoring process.
During the research, the ability to refer was determined and given the following scores: 0: Low ability to refer (Difficult concept, multiple steps needed to trace it to a symptom), 1: Medium ability to refer (a direct link with the respiratory symptoms, easy to trace) 2: Low effort (the symptoms themselves)

Methods

The following methods were identified as potential strategies for capturing asthma control data within the design requirements:

Peak Flow

Spirometry is the most widely employed objective measure of lung function (Larson et al. 2012).. During such a test, the patient has to forcefully exhale into a flow-monitoring device. One of the measures that can be derived from such a test is the Peak Expiratory Flow (PEF). This measures the maximum expiratory speed of the patient. Peak flow measurement at home allows for patients to more regularly monitor for trends and detect changes in lung function. Figure 31 displays the progression of peak flow over the course of 18 months. The solid line indicates the peak flow for a group that uses ICS. The other two are without use of ICS. It can be seen that during the first 3 months, a significant increase in Peak Expiratory Flow can be measured. It has to be noted that these participants were selected based on their low peak expiratory flow. Therefore it has to be stated that this method might not work on patients that do not experience effect on their peak flow.

There are several challenges for using spirometry at home, such as: costs, patient compliance and usability (Larson et al. 2012). The costs of such a device have significantly reduced over time. Low-cost peak flow meters exist with a range of 10 – 50 euro. They are pocket-size and use a mechanical design to measure the PEF.

The usability and patient compliance of the device are still one of the challenges of successful home-use. Forceful expiration is a not a commonly performed action and can be experienced as uncomfortable. Appendix Z elaborates on the performed benchmark between different peak flow meters currently on the market.

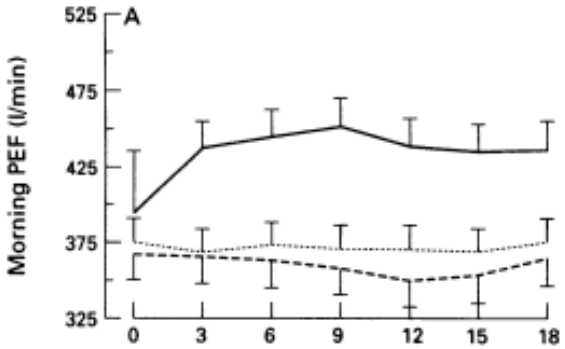


Figure 31 - Peak flow progression (Kerstjens et al. 1994)

Automatic Symptom Tracking

As can be seen in figure 32, both airway hyperresponsiveness and airway obstruction result in the experience of clinical symptoms. Although these symptoms are mostly heterogeneous across patients, there are some symptoms that are relatively common across all patients. According to Manfreda et al. (2001), wheeze and nocturnal cough are most common symptoms among adults with asthma. In the clinic, wheezing sound is usually considered as an indicator symptom to reflect the degree of airway obstruction. This is usually done through auscultation by the physician. However, several studies have already been performed on the area of automatic wheeze detection through algorithms (Li et al. 2017). In addition, Raherison et al. (2006) reports a 60% prevalence of nocturnal symptoms. In this study, it is also stated that 42,2% of the patients declared having no symptoms during the night, but these were detected by the GP during the visit. According to Bentur et al. (2003), night-time symptoms are often indicative of poorly controlled asthma. This suggests that an automatic nocturnal symptom tracker could be of benefit on the one hand to automatically log the state of asthma control and on the other hand provide extra insight into symptoms that would otherwise go unnoticed. Overall, automatic symptom tracking technology could be both beneficial in terms of clinical accuracy and usability. However, since it is a relatively new topic, not many technologies have been properly validated yet.

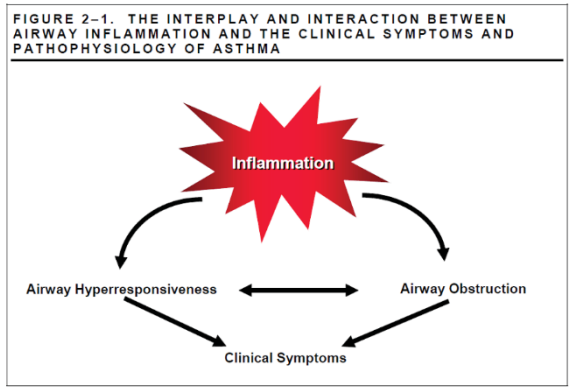


Figure 32 - Interplay between asthma systems

Nitric Oxide

The use of exhaled nitric oxide measurements (FeNO) in clinical practice is frequently used to diagnose and identify airway inflammation. It is used as a complementary method in conventional pulmonary function testing. Nitric oxide analysers are now available, making the testing of airway inflammation a practical possibility. One of the leading nitric oxide testers is the NIOX device (figure 33).

Where a peak flow meter might fail to accurately define asthma control, the nitric oxide meter can succeed as it directly measures the source of the respiratory function: the inflammation. The downside of these devices is that it might be hard for the patients within the target group to relate the level of nitric oxide to their own respiratory functioning. In addition, these devices are still relatively expensive, which makes them more difficult to implement on a large scale.

Automatic Reliever Tracking

Finally there is also the possibility to automatically track the usage of the quick-reliever medication. This can be done by using the same technology present in the Turbu+. Although this offers an effortless and low-cost way to track improvement in asthma control, it might not directly provide a relatable link between data and perceived symptoms.

Asthma Control Questionnaire (ACQ)

Another frequently applied method of measuring the state of asthma control is the ACQ. Frequently, the ACQ consists of six questions including the occurrence of symptoms and the usage of reliever medication. The ACQ is a widespread used instrument by general practitioners and respiratory physicians during consultation as it is easily applied, low-cost and can be used a predictor for exacerbation. The disadvantage of symptom based self-management is that a proportion of asthmatic patients perceive changes in airway diameter poorly, allowing significant airways obstruction to go unnoticed. In addition, for patients with a LHL, it is even more difficult to assess and judge their symptoms. Therefore a subjective assessment such as the ACQ is not preferred.

Figure 33 - NIOX device (niox.com)

The methods have been plotted against the design criteria, which resulted in the matrix in figure 34. This matrix has also been discussed with a general practitioner in order to validate the given scores. In the end it seemed that automatic symptom tracking, measuring the airway obstruction and automatically tracking the quick-reliever use can be seen as possible objective measuring methods.

	Peak flow	Automatic Symptom Tracking	NO	Quick-reliever use	ACQ
Effortless	0	1	1	2	1
Objective	2	2	2	2	0
Referable	1	2	0	1	2
Total	**3**	**5**	**3**	**5**	**3**

Figure 34 - Matrix of objective measurement comparison

Engaging Experience

The second requirement for the final concept was the ability to engage the user in the monitoring process on a daily basis for at least six weeks. In order to achieve answer to this question, a creative session with other design students was organised. Since the topic of providing engagement can be seen as a rather broad topic and is difficult to source out of literature alone, this was deemed like a proper approach.

For this session, three students of Integrated Product Design and one student of embedded systems were invited for a brainstorm session (figure 35). This session had the following structure:

/ First round: How to make it fun to monitor a plant?
/ Discussion and clustering
/ Explanation of project and target group
/ Second round: How to engage patients in monitoring their asthma?
/ Discussion and clustering
/ Third round: Creating concepts and present

Figure 35 - Ideative Session

During the first two rounds, ideas were generated for two minutes and written onto sticky notes. These sticky notes were discussed and clustered after each round. In the final round, the participants were asked to combine several of their favourite ideas and into concepts. Subsequently, they were asked to present and explain these concepts to each other.
The brainstorm session yielded several clusters. When looking at the conceptual framework for defining user engagement with technology (O'Brien & Toms, 2008), we can categorise the clusters within the identified categories of engagement strategies (Sensual, Emotional, Spatiotemporal). The clusters can be found back in the table in figure 35.

Sensual

Aesthetic Elements are pleasing or attention getting, novel presentation of information.

Aesthetically pleasing

Engage the user by providing an aesthetic experience such as a catchy song, intriguing physical feedback, colours, transparency, moving objects, visuals or a relaxing experience.

Emotional

Motivation to accomplish a task or to have an experience, Interest.

Fun

Provide a fun experience through talking objects, interacting, singing, dancing or making music

Direct rewards & punishments

Motivate the user through discount on medicine, receiving a massage, lose money when forgetting, not being able to unlock your phone or listen to a terrible song.

Gamification

Provide an element of competition or challenge. Also engagement could be evoked by beating high-scores or performing a bet.

Progression

Elucidate the progression of the user and make this explicit in an interface or through shape changing over time.

Spatiotemporal

Becoming situated in the 'story' of the application, ability to take ones time when using the application

Social

Motivate the user by involving the social environment. This could be done through giving the doctor an observatory role, involving others into a game or collaborative activity, share results on a blog or post results on Facebook or another online community.

Effortless

Engage through making the monitoring as effortless as possible. For example through automatic monitoring, decreasing the measurement interval or make the results easy to interpret.

Awareness

How to provide awareness about asthma and the effect of the medication? To answer this question, the collages that were made in the define phase were recalled. Specifically the collages that were aimed at changing behaviour through awareness. In addition, several strategies that were use by the practice nurses to provide them with awareness were also integrated. These activities provided inspiration for the formulation of the following themes:

Metaphor

To visualise the impact of taking the medication into a metaphorical presentation of the respiratory system. One of the practice nurses stated that working with metaphors helped her to explain several concepts to the target group.

Start simple and build up

According to two practice nurses it helps to bring the information in small chunks. Through this way you do not overwhelm the patient. Therefore it is advisable to start simple and slowly build up to the more complex picture. This strategy also refers to the guided practice approach derived from the social cognitive theory. Although it is officially not an awareness strategy, it can provide the patient with the capabilities to become aware.

Direct experience
Use technology to provide an experiential learning experience that is strong and leaves a long-lasting impression. This strategy is derived from Theories of Learning (Maibach & Cotton, 1995)

Self-reevaluation
Connect the experience of the respiratory information to the patient him/her self. In this way the link between what they see and how this relates to their own body is significantly stronger. This strategy was derived from the Trans-Theoretical Model (Prochaska et al. 2015).

The table in figure 36 shows the possible elements that were extracted from the ideation activities. For the objective measurement, momentary wheeze detection, nocturnal symptoms and peak flow have been selected as most promising methods. For the engagement category, the clusters from the brainstorm session were selected. Strategies to increase awareness were taken from the awareness exploration. For embodiment and context of use, several possible strategies were brainstormed and noted down. The next step was to integrate these elements into concepts.

Objective Measurement	Engagement	Awareness	Embodiment	Context
Wheeze (Moment)	Pleasant Experience	Metaphor	Measuring Device	Every morning bed/bath-room
Peak Flow	Involving social environment	Simple, building up	Physical Product	Weekly / home
Nocturnal Symptoms	Effortless	Experience	Wearable	During the night (continuous)
	Gamification	Self-reevaluation	Tablet Interface	During the day (continuous)
	Reward/Punishment		Smartphone Interface	
	Seeing progression			

Figure 36 - Summary of ideas

4.2 | Conceptualisation

The exploration activities mentioned in the previous chapter eventually resulted in several possible elements to embody into a concept. This chapter will elaborate on these different elements, how they have been integrated into preliminary concepts and how these concepts have been evaluated with the target group. The chapter will conclude with the results and the final design direction.

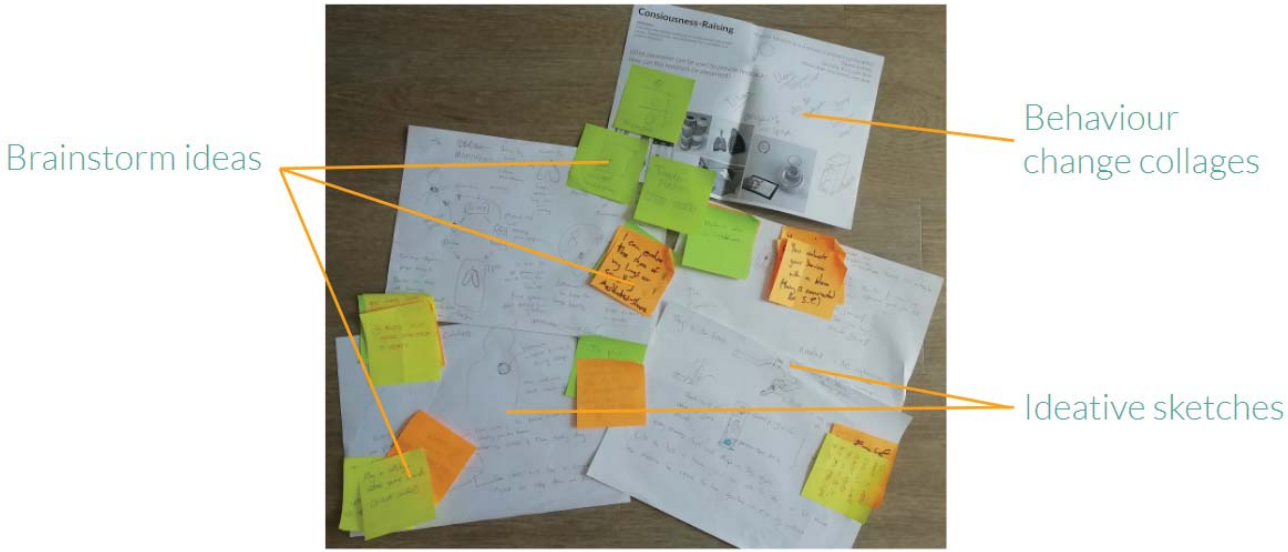


Figure 37 - Conceptualisation

By taking inspiration from the raw ideas of the brainstorm session and from the behaviour change collages, in combination with ideative sketching, four different preliminary concepts emerged (figure 37). The goal of these concepts was to cover as many different elements as possible and therefore representing the majority of the tabulised solution elements. It has to be stated that, although these concepts look as separate entities, their elements can be freely intertwined. For example, the objective measurement technique of the first concept could be combined with the engagement strategy of the third and the awareness strategy of the second. The main goal of these concepts was to evaluate the separate solution elements.

Concept 1 - Ballenblaas

Objective Measurement
/ Peakflow
Engagement
/ Seeing progression
/ Game-element
/ Involving others
Awareness
/ Metaphor
Embodiment & Context of use
/ Physical product

Objective measurement
In this concept (figure 38), the peak flow measurement was integrated as the objective measurement method. The goal of integrating the peak flow measurement was to find out whether patients would be willing to perform a peak flow measurement on daily basis.

Engagement & Awareness
In this concept, the patient will be asked to make the ball float by exhaling forcefully into the device. The ball will be calibrated by the general practitioner based on the patients base value and the expected increase in peak flow value. The goal of integrating this game element was to find out whether the integration of such an element would help to stimulate the patient to engage with the monitoring experience on a daily basis.
This concept also consists of a social element. Every morning the ball can be found on the ground. When the peak value is reached, the ball will stick at that position during the course of the day. Because it is a physical object, the other family members around the house will notify the height of the ball. This allows them to judge and comment on the relative daily performance. In case of a poor performance, family members could be triggered to stimulate the patient, for example in terms of medication use. In case of a good performance, family members can provide the patient with compliments and additional stimulation. The idea of this function was to find out whether making it a collaborative activity would help to engage the patient.

Embodiment & Context of use
This concept was embodied into a physical product. The goal was to find out what the response in a physical product would be and where and when the patients would want to use it.

Figure 38 - Visualisation of Ballenblaas

Concept 2 – Luisterend Oor

Objective Measurement
/ Wheeze detection
Engagement
/ Financial Reward
Awareness
/ Simple, Building up
Embodiment & Context of use
/ Measuring device
/ Momentary

Objective measurement

For this concept (figure 39), it was decided to integrate automatic wheeze detection. Evidence exists for devices that can capture the presence of a wheeze in the breathing cycle during a several minutes measurement (wheezo.com). The idea behind this device is that is must be held against the trachea, which is suggested to be the most optimal place for detection wheeze (Li et al. 2017).
The measurement will take place using a condenser microphone that records the respiratory sounds. These sounds are then analysed by an algorithm and converted to a wheeze score, that represents that percentage of wheeze that is measured.

Engagement

In this concept the idea of directly rewarding the patient was integrated. This will be done by providing a financial discount on medicine. This financial discount can be gathered by collecting sponsors and will be collected in a wallet. If the patient succeeds in achieving good wheeze scores during the 6 week period, a large part of the gathered money will be released. If the patient fails to take medication on a regular basis, only a small part of the money will be released. The money that is released can be used as a discount on a next batch of medicine. The integration of this function should identify whether patients would be engaged by direct rewards such as money. In addition, it should verify if the price of medication is indeed something that could hold a patient back from using medication. Finally it should identify whether sponsorship would be an acceptable method of acquiring this financial reward.

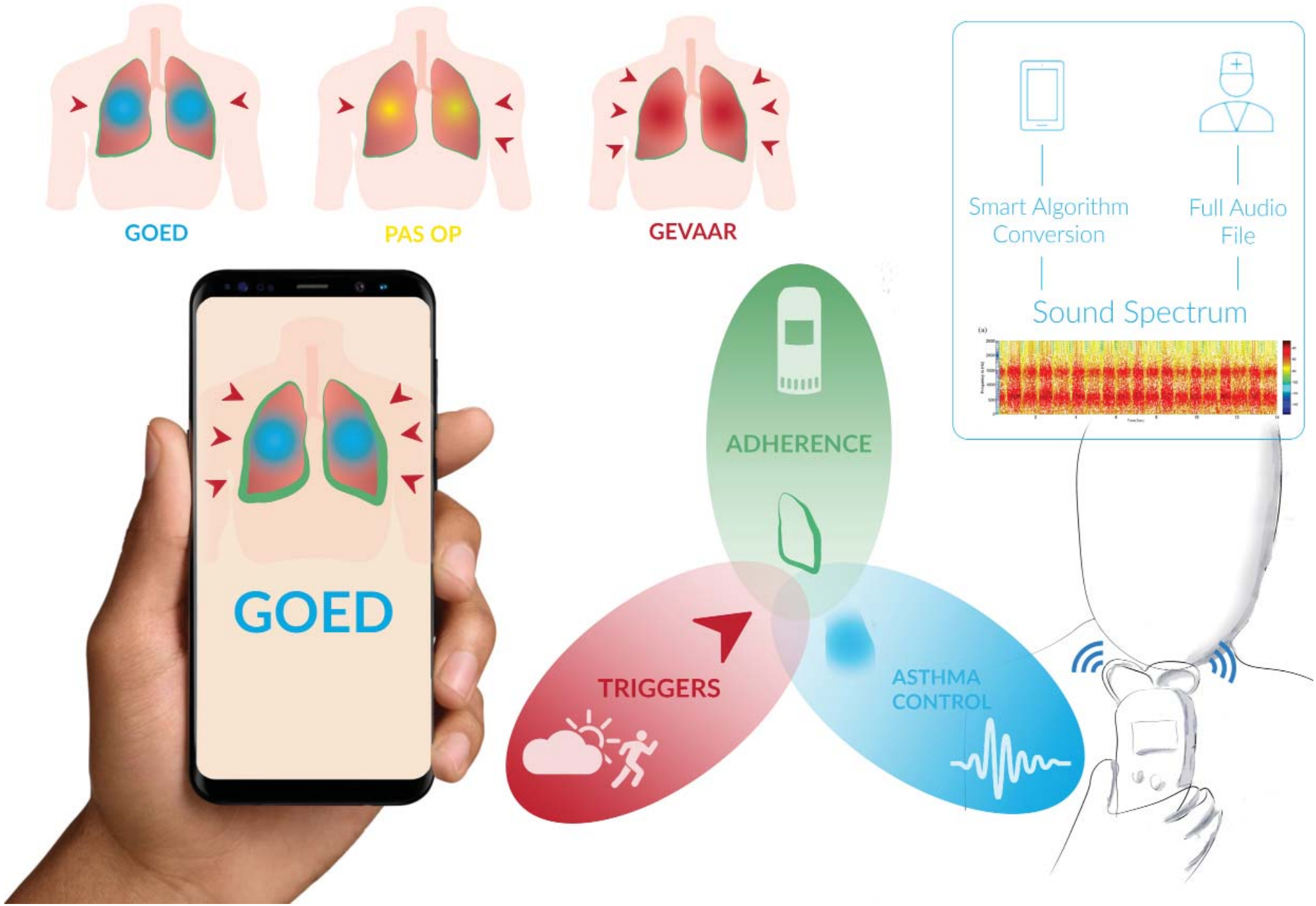
Awareness

In this concept, awareness is provided by beginning with a simple concept and slowly building up. This interface is presented in the smartphone application interface. It can start by picturing the lungs and displaying the measured wheeze score as a colorized overlay on this image. Where red means a high wheeze score and blue means a low wheeze score. Later on, medication adherence could be added by providing a green layer around the lungs. Also triggers could be implemented for example by indicating the presence of red arrows. In the end the patient should become aware of the interplay between those factors on a slowly increasing scale.
The idea behind this concept is to test whether this kind of abstract app interface could provide the necessary improvement of awareness.

Embodiment & Context of use

This concept exists in the form of a measurement device that has to be held at the trachea for several minutes a day. The idea was to find out what the users opinion was about this kind of use. Also the goal was to find out whether the app interface could be used as presentation format.

Figure 39- Visualisation of Luisterend Oor



Concept 3 – Geluidenvanger

Objective Measurement
/ Nocturnal Symptoms
Engagement
/ Effortless
/ Pleasant experience
Awareness
/ Direct experience
Embodiment & Context of use
/ Wearable
/ During sleep

Objective measurement
In this concept (figure 40) it was chosen to embody the detection of nocturnal symptoms. The device will measure nocturnal wheezing and coughing. This can be done by applying an adhesive patch to the body before going to bed. This patch will record respiratory sounds and detects whether there is a presence of wheeze or cough. In the morning this data can be presented to the patient.

Engagement
The main engagement strategy in this concept is that it requires little amount of effort. Instead of performing a measurement, the patient only has to apply the sleeping patch before going to bed and remove it when getting out. The analysis will be done automatically. In the morning, the data will be presented through a pleasant experience. For example by showing a nature landscape or by providing a soundscape of the sounds that have been detected at night. The goal of this integration was to find out whether the patients would prefer such an effortless yet pleasant experience.

Awareness
In this concept, awareness will be caused by providing a direct experience. The idea is that, when the patients level of asthma control improves, the soundscape also improves. The patient will notice that during the course of the medication usage, the soundscape will become more pleasant over time.

Embodiment & Context of use
The goal of this concept was to find out whether the patients would be keen on wearing a sleeping patch during the night, since there could be a change that it would be regarded as invasive and therefore not preferred.

Figure 40 - Visualisation of geluidenvanger

Concept 4 – De Ervaring

Objective Measurement
/ Wheeze
Engagement
/ Immersive experience
Awareness
/ Self-reflection
/ Immersive experience
Embodiment & Context of use
/ Tablet
/ Weekly use

Objective measurement
In this concept (figure 41), the same objective measurement detection method was applied as in concept 2. However, in this concept it was embodied into a necklace.

Engagement
The engagement strategy in this concept was not derived from one of the predetermined strategies. It has however embodied the strategy of providing an immersive experience with innovative technology. The immersive experience is offered through augmented reality, where the respiratory system is projected onto the patients body. The idea was that exposing them to a relatively innovative and immersive technology such as augmented reality could motivate them in the use of the medication.

Awareness
This concept makes use of projecting the respiratory system onto the body of the patient. By doing this, the patient should get an increased feeling of awareness since they see it as a self-reflection. In addition, the immersive experience could have an additional effect on the level of awareness. Next to the augmented reality experience, another idea was to present the user with a sound interface that could mimic the interaction of 'listening to your own lungs' and to hear the sounds that normally only a doctor could hear.

Embodiment & Context of use
This concept makes use of a tablet. Also this concept should identify whether patients would want to use a measurement device that might not be needed on a daily basis. Finally, the embodiment of this device would be in the form of a necklace. By doing this the patient has his/her hands free to interact with the app interface.

Figure 41 - Visualisation of de ervaring

4.3 | Prototype

A special kind of approach was selected to be able to communicate the concepts in an optimal way to the target group. For this it was decided to setup a design exhibition in which the concepts were explained by the researcher with help of a visual presenter. In addition, in each concept, the interactive aspect was integrated into a physical mock-up (figure 42). The full set of visual presenters can be found in Appendix W.

Prototypes

Ballenblaas

The visual presenter showcased a rendered look of the product in combination with a storyboard that showcases the scenario of use. The interaction of raising something by blowing into a tube was integrated into a mock-up that used a volumetric exerciser integrated into a cardboard box.

Luisterend Oor

The visual presenter showed the embodiment of the device and how the scores could be represented in a smartphone interface. It also explained the concept of earning starts over the course of several weeks and that better measurements lead to more stars. Subsequently it was explained that the more starts you earn, the more money you receive with the sponsorship. Since the sponsorship was suspected to be difficult to understand by the target group, a demonstrator was built that visualises the money flow with use of images and coins (Appendix X)

Geluidenvanger

The presenter showed the embodiment of the product and how it was integrated into the daily regime with help of a scenario of use. In order to visualise a possible embodiment of the sleeping patch, a conceptual circuitry was printed on transparent paper and subsequently glued onto a silicone bandage. In addition, the morning interface was prototyped using google presentations and was displayed on a phone. See Appendix Y for the full interface.

De Ervaring

The presenter showed a representation of the app interface and how this could be displayed onto a tablet. For the interaction prototypes, two aspects were worked out. For the visual augmented reality experience, the virtuali-tee by Curiscope was used. This t-shirt can be worn by the user and serves as an anchor in 3D space to allow the application to project anatomical information on the body. During the exhibition, the respiratory system was projected onto the user. The app also consisted of a 360 degree look 'inside' the lungs where the application took the user inside a lung cavity and showed how it looks like.

For the soundscape interface, a soundboard was prototyped and hooked up with a smartphone to a Bluetooth speaker. This soundboard consisted of five different sounds. A general body background sound, healthy inhale and exhale and unhealthy inhale and exhale. The user was asked to put a prototype necklace (acting as sensor) onto their neck. At that time, the background sounds started playing. Subsequently the user was asked to inhale and exhale. During these phases the healthy sounds were played. In the second round, the unhealthy sounds were played. Through this way, the user was informed about the different soundscapes that could be presented.

Figure 42 - The prototypes in exhibition setup

4.4 | Evaluate

This section will elaborate on the evaluation of the prototypes through a design exhibition. It will present the setup of the session, a description of the participants and the results that were found. The section concludes with a discussion of these results.

Session

The evaluation session (figure 44) took place at the a health facility in a disadvantaged neighbourhood. A separate room was booked in which the exposition was built up. Three participants were invited for a 45-minute session. Prior to the session, the participants were sent a short introduction video, in which the researcher, the project and the session were introduced (figure 43). The participants were selected by the practice nurse based on their LHL and uncontrolled asthma. The sessions were conducted with two of the three participants. The third participant was visited at this house the next day. The session consisted of a short introductory talk. The remaining time was dedicated to presenting and discussing the concepts. Appendix BB shows the research setup and the interview questions.

Participant description

P1 was a male that has finished secondary school on mavo level and subsequently directly went into the construction industry. He works there till the day of today. He has asthma complaints on a regular basis and indicated these moments mostly appear when work is stressful or when he is physically challenged.
In terms of non-adherence behavior, this patient was slightly non-adherent in an unintentional way. The non-adherence behavior seemed to come close to erratic behavior. The patient stated that he saw the importance and the need for the medication but sometimes forgets to take it as his lifestyle was irregular.

P2 (figure 45) was a 44-year-old male that has done a study in metal crafting. He didn't manage to receive his certificate and has had several jobs throughout his life. At this point, he is cleaning keyboards, mouses and computer screens. He has a wife and two kids. He indicated that his asthma complaints are worse at the end of the day and during the night. The patient indicated that he has trouble seeing the importance of the maintenance medication and that this makes it difficult for him to adhere to it. This non-adherence behavior has the most similarities with the unwitting phenotype.

P3 was a 64-year-old Turkish male that has moved to the Netherlands a while ago. In the Netherlands, he has had several management positions in the fishing and catering industry but is now on retirement. He lives at home with his wife, daughter, and granddaughters. He has had multiple surgical interventions in the past year concerning his vascular system. Also, he needs to take certain precautions regarding diabetes. He regularly experiences asthma complaints such as shortness of breath. It seemed that the severity of the complaints help this patient to be adherent to his maintenance medication (a combination of long-acting and ICS). He pointed out that forgetting the medication directly results in the experience of complaints.

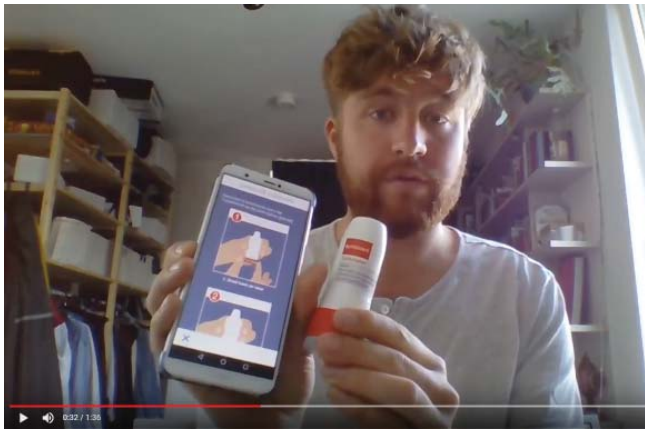


Figure 43 - Introduction Video

Results

The results can be categorized under several different themes as described below. The full set of results including their quotes can be found in Appendix CC.

Immersion/Innovativeness

P2 responded enthusiastic regarding the "De Ervaring" prototype. He mentioned that innovative technologies can be seen as more than technology. He achieved a moment of insight while using the technology and told that he already understood better why to use the medication. For him it was also interesting to realise that the lungs are on the same location for everybody. Finally, he mentioned that the immersive experience could also cause fear, which could work motivating in some cases.
P3 indicated that he did not like the immersive experience. He mentioned that the interface made him remember his recent experiences with surgery. Seeing the organs like that didn't provide him with a nice feeling. Also seeing the lungs and bad consequences added additional worries and stress and was therefore not preferred.

P2: "This wakes you up, you will know more. I didn't know any of this, but now I have a feeling for how it works"

P2: "It is not just a cool technology, it is even more than that. Just like robots."

Figure 44 - Overview of interview environment

Sponsorship

P2 noted that money is not an issue in terms of using medication, as it is funded by the insurance. Receiving a discount on other products then medication seemed to be good, but not overwhelmingly convincing. He couldn't estimate if people around him would sponsor him. P1 seemed to be indifferent regarding the sponsorship.

P2: "If you are insured, everything is paid for you and you don't notice anything."

Effortless

P1 indicated that something effortless, such as a sleeping patch, would be desirable. He mentioned that it is like a bandage. Something that you can simply stick on your skin and it makes you better automatically.
P2 stated that using it a few minutes a day is not a problem. However, wearing something continuously throughout the day was not preferred.

P1: "It is just like sticking a bandage on your wound. You feel nothing, and after a while, you just remove it."

Self-Monitoring

P2 was enthusiastic about being your own doctor. He indicated that it could help him to judge the state of his asthma as it was difficult to do it himself. P1 indicated that it might be interesting and fun to do once or twice as a game, but didn't seem to have the need for something to help him judge. He did indicate that the sleep sensor would be interesting as it provided an effortless solution to know more about his health. P3 indicated that this added an additional layer of stress and didn't want to be bothered by it. Also, his complaints were on a level of severity that he didn't need additional tools to help him judge when something was wrong. He did mention that the sleep sensor would be interesting as there was no possibility to judge his nocturnal symptoms.

Involving others

P1 indicated that he has trouble remembering to take his medication. When he was asked in what way others in his house could help him remember, he indicated that because of irregular lifestyles it might become difficult.
P1 and P2 both mentioned that relatives have a life on their own and are therefore limited in the amount of attention they can spare.
P2 indicated that the involvement of children is not preferred as they need to concentrate on their lives as much as possible and should not worry about their father's health. He stated that adults are a different case.
P1 mentioned that having a physical object could be of great benefit to aid the discussion around medication adherence.

P2: "If you child is worried at school, their focus will be less high, therefore I don't like it."

Daughter of P3: "I think it is good for him, as he has a lot of restless nights"

Embodiment

P1 pointed out that he didn't understand the use of an iPad. According to him, it has the same functionality as a phone. P2 pointed out that the first step would be to have it on your phone as you can bring your phone anywhere and therefore allow you to check it any time of the day.
On the other hand, P3 seemed to be frightened by the real-like display of the augmented reality app and therefore preferred the smartphone app interface.
P1 seemed to be indifferent towards the app, but mentioned that it would be good to have a reminding service if he has forgotten his medication. He liked the idea of a physical object that is on eye level and helps you remember every time you see it.
P1, P2 and P3 indicated that wearing something like a patch during sleep is no problem.

P1: "If I see it at table level, and see it inevitably, then I will remember it"

Figure 45 - P2 during the session

Discussion

Engagement

During the tests, a few results stood out. First, it seemed that regarding the engaging strategy, all participants preferred a self-monitoring method that provided useful information. All participants regarded the sleep tracking sensor as useful as it provided information about nocturnal symptoms, which seemed to be valuable to all participants.
According to Raherison (2006), 42,2% of asthma patients experiencing nocturnal symptoms declared having no symptoms during the night. This indicates that these symptoms often go unnoticed and therefore there lies value in capturing these. The nocturnal symptom tracking makes it possible, in contrary to for example peak flow measurement, to gather data over an extended period of time. On top of that, according to Manfreda et al. (2001), the measurement of nocturnal symptoms (wheezing and coughing) is regarded as the most accurate way of relating symptoms to asthma control.

While it was hypothesized that the patients could have an aversion towards new and unknown technology, it was embraced as useful, innovative and life-saving. The patients mentioned that innovative technologies like the sleep sensor and the augmented reality experience are of the highest level of technology and are therefore perceived as extremely useful. A possible explanation could be that this target group is less exposed to such technologies in daily life. Even though some technologies are already becoming part of everyday life for most people (like augmented reality). The combination of this perceived usefulness through the innovative aspect with the ease of implementation, could be a valuable direction in the design of products for this target group.

Two of the three participants mentioned that they are not eager to put a lot of effort into this monitoring experience. Even if it can bring other benefits in return such as fun or a direct reward. The patients had more preference for a stronger core value of the concept. That could explain the fact that they were not overwhelmingly positive about the sponsorship, gamification, involving others and seeing the progression.

Awareness

The augmented reality experience succeeded in providing the necessary insight and awareness. One of the participants indicated that he directly experienced a feeling of insight. Also, he mentioned now being able to properly see the lungs and where they are. In addition, the function of being able to take a look inside the lungs was seen as interesting. He indicated that it would make you awake, and that smoking people would have a strong urge to stop smoking if they would see bad things in there.
It could be argued that several aspects of the augmented reality interface were responsible for this experience. On the one hand, it could be the immersive aspect, which is causing a direct grip on the persons' attention, therefore being able to better communicate a message. On the other hand, there is also a holistic experience. Being able to see the lungs first, and thereafter being able to zoom into an airway was perceived as a good way to connect the two concepts. Finally, it seemed that the realistic appearance of the lungs made the participant aware of what was really happening.
All with all, it therefore is suggested that the future design should host an interface that provides realistic, holistic and immersive feedback in order to succeed in providing awareness.

Limitations

The participants that took part in the interviews seemed to all have a different non-adherence behavior. Therefore it seems necessary to look at the reasons why certain opinions have been formed on the selected elements. P2 seemed to be the best representative for the target group since his determinants behind the non-adherence relate with the ones identified in the previous research.

Regarding the awareness question, because of time constraints, one participant hadn't seen the prototype. The third participant had seen it but wasn't fond of it as it reminded him of past surgery. That means that the insight is based on the reaction of only one participant. However, the participant had the closest match with the target group, being unwittingly non-adherent. Therefore it was suspected that his reaction could occur on the majority of the target group.

It has to be noted that the quality of the prototypes could have had an influence on the result.

The ball-game for example only existed in the form of an image and rough interaction prototype, whether the sleep patch was worked out till a level closer to reality. This could have resulted in a reduced enthusiasm towards the ball-game concept.

Key Insights

Objective Data
/ Sleep data is considered valuable
/ Sleep data is an accurate source

Engagement
/ Innovative is perceived as useful
/ An effortless experience in combination with a high perceived usefulness works as an engaging strategy

Awareness
/ Holistic approach works in telling the story
/ Immersive aspect helps to capture attention and bring the point across
/ Realistic interface helps to avoid misconceptions

CHAPTER 5 | Iteration 2

This chapter will elaborate on the results that were found during the first iteration. In this iteration, a final concept is developed through several sub-iterations and prototypes. The chapter concludes with the evaluation and interpretation of one of these prototypes.

5.1 | New Design Vision

With the insights from the evaluation of the first iteration in mind, it was possible to derive the final concept direction. In this concept, the sleep patch was used as an innovative and effortless solution to provide engagement as well as objective measurement. This data, in combination with the Turbu+ adherence data will be processed and presented through an interface in a realistic, holistic and immersive way.

Figure 46 presents these identified sub-systems and how they interrelate with each other.

The following chapters will elaborate on the development of the interface and sensor subsystems.

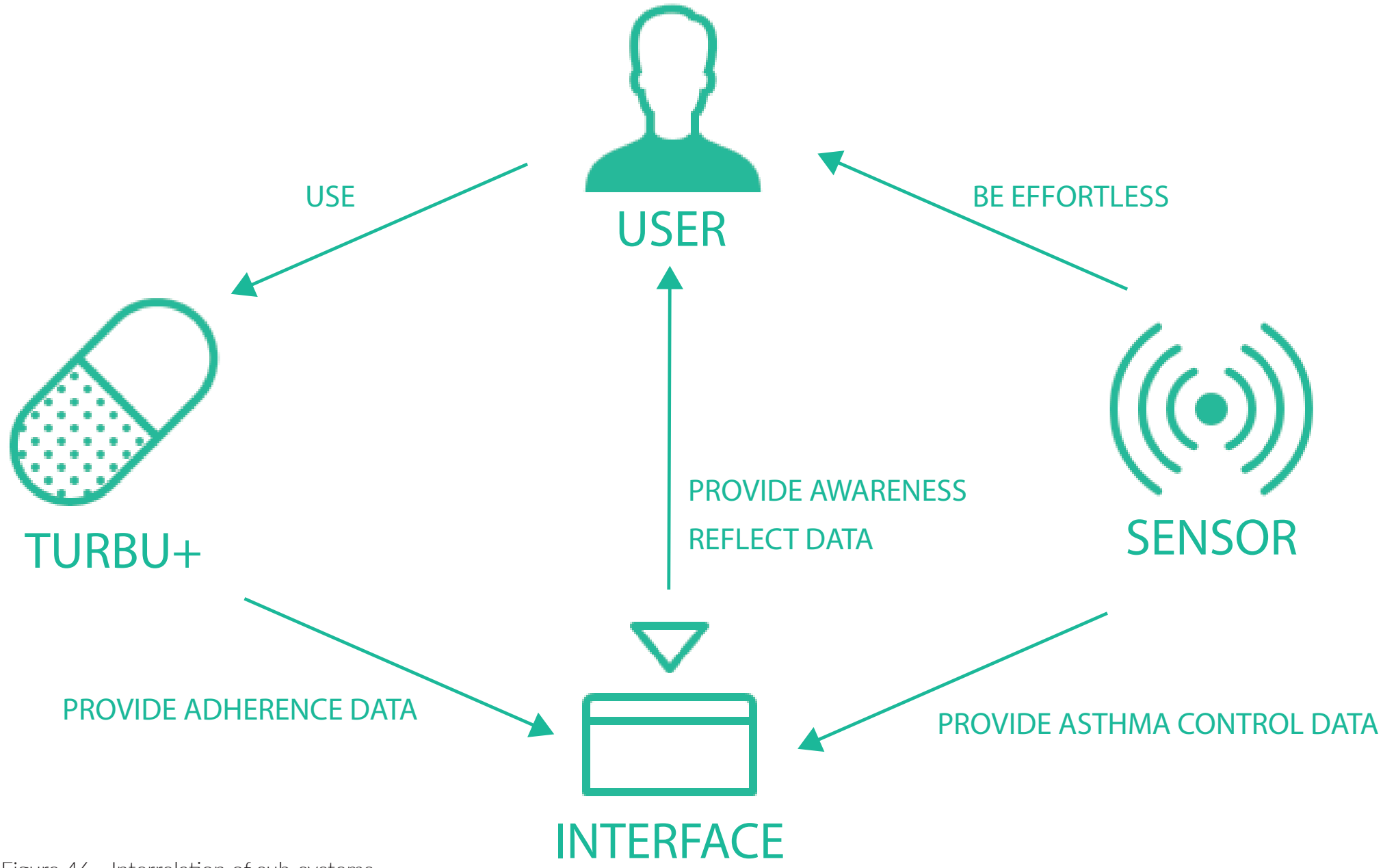


Figure 46 - Interrelation of sub-systems

5.2 | Sensor

This chapter will revolve around the design process of the first sub-system: the sleep sensor. It will highlight the process that entails the exploration of different solution strategies, the production of a functional prototype and the identification of future improvement areas.

Exploration

Requirements

There were several requirements that needed to be taken into account for the design of the sensor.
First, the sensor has to produce an accurate dataset. For this it was essential to have a proper quality audio recording as well as an algorithm that is able to process these sounds with the computational power of the phone. The algorithm has to be able to analyse the sound spectrum and determine the presence of a wheeze. Secondly, the sensor has to be comfortable enough to be worn throughout the night in order to complement the effortless experience of wearing the sensor.

Data acquisition

Generally, for detecting wheeze in a patient, a stethoscope is used. The sounds are interpreted (auscultation) by a doctor who can make a proper diagnosis based on these sounds. Although sometimes the wheezing sound can be heard by the naked ear, the majority of these sounds are soft and need a special device like a stethoscope to be heard. Interpreting the sounds is another difficulty, as only trained professionals are able to distinguish abnormalities in the breathing sound.
Hence, there is a need for an automated wheeze detection device that can acquire and analyse the breathing sounds and present the results to the patient without the involvement of an expert. A literature review was conducted in which several studies aimed at producing automated wheeze sensing systems were investigated. The goal of this review was to find out which of the proposed elements in these studies could be integrated in this concept. The necessary elements that needed to be identified are listed below.

Sound acquisition

According to Shaharum et al 2012, the simplest method to detect wheeze is using a microphone mounted on a stethoscope. It is mentioned that this method is non-invasive and not time-consuming, which properly fits the requirements of the sensor module.

Placement location

Shaharum et al. (2012), suggests the placement of the microphone over the trachea region (throat). It is claimed that this location is reliable because all air-propagated lung sound from the two lungs integrate in the trachea. In contrary to the chest wall, where high frequencies are filtered out, most of the frequency information is preserved.

Sound processing

Once the sounds are propagated from the stethoscope bell to the microphone, a few processing steps need to be carried out. First the sound needs to be amplified with an amplifier circuit. Li et al. (2017) suggests to use a gain of 500 times. Subsequently, the sounds need to be digitized. This can be done by an analog-to-digital converter.

Sound analysis

The sound of a wheeze is continuous and high-pitched, often described as a musical sound. It consists of specific characteristics in the duration and frequency domain. Normal breathing sounds can usually be found in the range

between 100HZ and 1000HZ. For a wheezing sound, the frequency is generally between 250Hz and 800Hz (Li et al. 2017). It usually is presented as a specific narrow line pattern, for a duration of approximately 250 milliseconds in the spectrogram of breathing sounds. See figure 47 for an example.

These characteristic sounds can be extracted from the incoming data using an algorithm. According to Li et al. (2017), a Fast Fourier Transform with Hanning window can be used to calculate the power spectrum of the frequency domain. The values in the domains 0Hz – 250Hz, 250Hz – 500Hz, 500Hz – 1000Hz and 0Hz – 1000Hz can be calculated. Based on this, the algorithm can determine whether the sound fits a set of predetermined wheeze criteria. If it fits and the duration is longer than 250ms, the sound can be identified as a wheeze.

Sound transmission

Regarding the perceived comfort of wearing the device, it seemed essential to maintain a wireless connection to the processing system. Two wireless transmission sources were considered: Radio wave transmission and Bluetooth. Radio wave transmission is often used to transmit sound signals over distances, however it seems that this kind of communication causes several noisy sounds and is therefore not desired. A Bluetooth signal, is therefore regarded the best option for transmitting the signal.

Comfort

Identifying the technical specs of the sound processing system was an essential step to identify the requirements for the design of the sensor. The goal of the sensor design would be to make it wearable and as comfortable as possible. This should be done while taking into account that the device should feature a stethoscope mechanism that has a tight fit around the trachea region.

Two possible wearable strategies were identified that could be used to apply the stethoscope with the abovementioned requirements. This could be done either in the form of an adhesive patch or in the form of a neck-cuff. Through prototyping and testing out (figure 48), it appeared that applying an adhesive patch of this size would not work as the trachea region has a highly irregular surface. The patch could work when applied on the chest, however this was identified as not an optimal location regarding sound quality. Therefore it was decided to continue with the neck-cuff design.

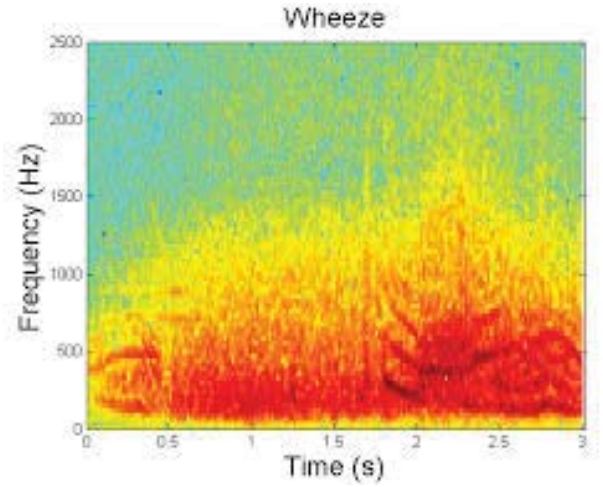


Figure 47 - Spectogram of a breathing cycle with wheeze (dark red lines in the bottom right corner) (Tocchetto et al. 2014)

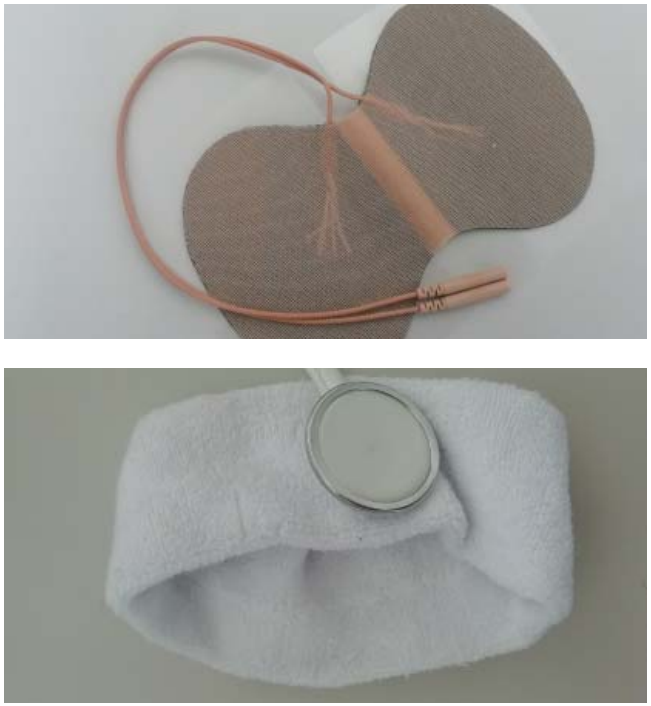


Figure 48 - Wearable options

Prototype

The abovementioned exploration enabled the synthesis of a first functional prototype. The goal of this prototype was to evaluate whether the chosen set of working principles (recording location, technique, design etc.) would produce a viable quality sound file in which wheeze could be recognized.

For this prototype (figure 49), the stethoscope diaphragm (1) is used to propagate the sound waves from the trachea to the a microphone. A stethoscope has two sides (bell and diaphragm) according to the guidelines, the bell is often used for lower frequency signals such as sounds originating from the heart. The diaphragm is often used for the higher frequency spectrum, under which breathing sounds.

The stethoscope piece is attached to an air tube that connects the piece to the microphone (2). The connection is made air-tight to ensure a proper transmission of the soundwaves towards the microphone.

For the microphone an electret microphone piece is used (HUACAM YYPJ-01-1). This microphone is connected to an audio recorder (3) (Sony ICD-BX140) to provide amplification and analog-to-digital conversion.
To transmit this audio to the processing unit, two Bluetooth transmitters (4) are paired (JTECH).

The stethoscope diaphragm was integrated into an elastic headband (5). During use, the electronics can be stored in the wearable sports-pouch (6).

Evaluation

The functional prototype was worn for a few minutes while recording breathing sounds. This was done to verify whether the chosen set of design elements would have the potential to properly analyse breathing sounds. When listening back the recorded sounds, the breathing sound was easily recognisable. Artificial wheezing sounds were made and although they were too soft to be heard by the naked ear, the functional prototype was able to record them. Although it was not within the scope of the project to test whether these sounds can be recognised by an algorithm, the vast availability of such algorithms make it assumable that this is possible. Chapter 6.2 and 6.3 will elaborate on the details of the algorithm as well as suggestions for future development.

The evaluation of the functional prototype was reasonably limited by the time constraints of the graduation project. However, the exploratory studies suggest that there is potential for further development of the device. The suggestions and future recommendations are discussed in chapter 6.

Figure 49 - Functional prototype of sleep sensor

5.3 | Interface

This section will elaborate on the design of the interface. First it is decided through what medium the feedback should be presented. Subsequently, it is researched how this should be tailored towards the target group. The sections ends describing the development and evaluation of the prototype.

Exploration

Requirements

One of the requirements of this interface was that it should reflect the health concept of asthma in a holistic, realistic and immersive way.
In addition, at this point, the viability of the device needs to be taken into account. As the client company mentioned during the preliminary concept presentation, the device should be as low-cost as possible to allow for scalability. The client company mentioned that a physical feedback device such as Ballenblaas is not wished for as it would result in a complicated manufacturing process.

The following challenges could be stated for the design process of the interface:

Embodiment
/ In what form should the feedback be presented?
/ How can the embodiment ensure cohesion between the different elements?
/ How can the embodiment provide a trigger for medication and sensor usage?

Presentation
/ How to present data streams in a holistic, realistic and immersive interface?

Embodiment

For this a small brain dump was held in which different possibilities of presenting this feedback were thought of. For instance the use of a soundscape, a physical reflection, abstract presentation or a visual experience through the phone. In the end it seemed that integrating the feedback in the phone was the most preferred option. The first reason for choosing the phone is because it is the most viable option in terms of cost. The phone was needed in any case to make use of the Turbu+ application. In addition, the phone already has most of the required technology on board. The second reason for choosing the phone as interface device is because the screen provides a significant amount of freedom in designing an interface to reflect the health concept of asthma. Finally, it was decided that the embodiment should also consist of a physical docking station, that would enable a cohesion between the different elements as well as to provide a trigger through its physical appearance. A conceptualisation of this docking station is presented in figure 50.

Figure 50 - Proposal of interface embodiment

Presentation

Since the presentation of the data streams can be seen as the core of the concept, it was decided to put extra emphasis on this design challenge. As appeared from the user evaluation, the presentation of the feedback should be as real as possible. There are two aspects that need to be taken into account when considering the realism of the interface.

First, the more real something is presented, the less educative and engaging impact it has. For example documentaries, which have the goal to inform and provide awareness, often contain certain elements of drama to ensure the audience is engaged. If a documentary would present the facts in a plain but accurate way, the audience would quickly disengage.

Second, when presenting the story as accurate as possible, it can quickly lead to a story which is too complex for laymen to understand. Therefore, it is necessary to add certain simplifications to the story.

On the other hand, adding drama and simplifications within a health model can pose certain struggles. It can easily happen that a dramatization is comprehended as reality. An example is the dramatization used by a commercial for heartburn medicine (figure 51). They visualise a stomach that is on fire which is subsequently extinguished by the medicine. Although it is not likely, there is a chance that a part of the audience misinterprets the message and thinks that their stomachs are actually on fire.

The only way to counteract this is to make sure that the presentation, although close to real, is easily separable from a real experience. A metaphor or analogy could be of benefit in explaining certain models with accuracy while not being interpreted as actually real.

Galesic (2012), compared the use of analogies for explaining simple and complex health concepts to people with a low and a high literacy. The study revealed that for difficult medical problems, analogies were helpful for people with a high literacy but less for people with a low literacy. For easy medical problems, the results were reversed.
Based on these results, it can be suspected that analogies only work if most of the background information is already present. This allows the person to give the analogy a place. In the case of people with a LHL, it might become difficult to create an effective analogy. The analogy would need to contain a significant amount of information and would therefore grow complex very quickly. The goal would be to present the health related information as real as possible where simplifications need to be made on several systems that do not embody ultimate necessary information. Finally the presentation should be presented in such a way that it is clear for the target group that it is a fictional presentation.

Based on this reasoning, it seemed that there are two different scales at play when we talk about the communication of a health concept.

The first scale is the level of **dramatization**. On the one end the concept is presented as close as possible to the reality, while on the other end the concept is presented as dramatized and engaging as possible with limited clinical accuracy.
The second scale is the level of **simplification**. On the one end the concept is presented extensively with all the possible sub-concepts that are attached, in order to match the reality as closely as possible. On the other end, only the essential concepts are presented in a simplified and abstract way.

Figure 51 - Reflux medicine commercial

Figure 52 presents a matrix of these two scales. A desktop research session has led to a collection of several different interfaces of communicating the health concept of asthma. These include medical games, tv shows and websites. These interfaces have been mapped into the matrix in order to get an idea of how these scales could reflect in a visual embodiment. In addition, some self-made explorations were made and discussed with a LHL expert. These can be found in Appendix DD. The red circles in the matrix point out the risky sections for communicating health concepts. They will be briefly summarized below:

1. Difficult to separate drama from reality due to the true to nature display
2. Complex and disengaging due to the lack of drama and simplification
3. Difficult to relate back to the original concept due to the highly figurative level
4. A lot of room for misinterpretation due to the abstract level

As can be seen in the matrix, there is a blue space that could provide a possible negotiation between the different scales and their downsides. These include the following possibilities:

5. A true to nature display with a significant amount of drama so that it becomes clear that it is most definitely not true.

6. The border between abstract presentation and true to nature where the amount of misconceptions is limited while the level of abstractness communicates that reasonable amount of drama isn't real. In this area it seems that the amount of drama added shouldn't influence perceptive quality.

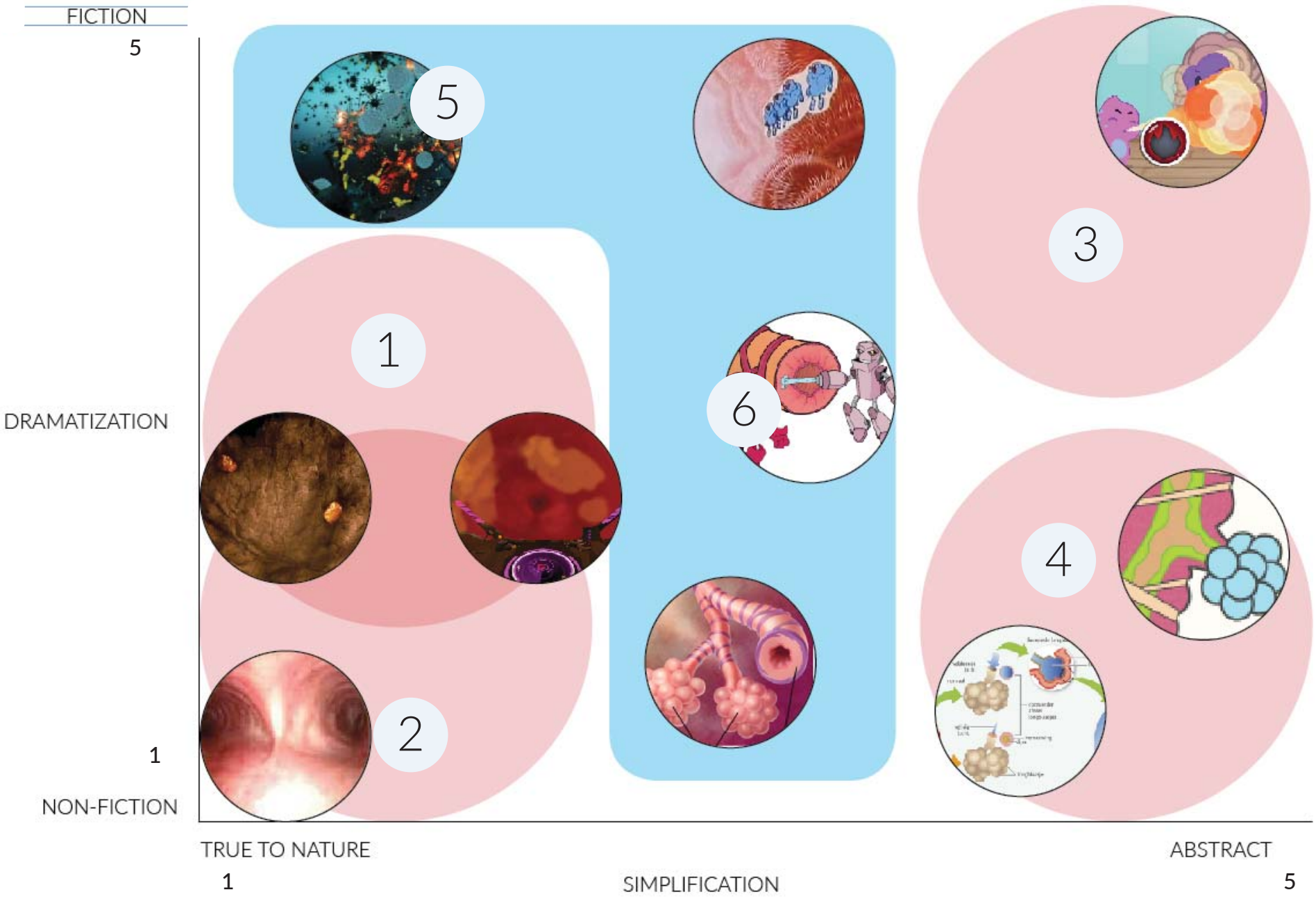
For the interface to successfully provide awareness, it is suggested that at least the following health concepts should be communicated.

Inflammation
Showing the progression one is making in terms of reducing the inflammation in the lungs. The inflammation is responsible for the symptoms but the inflammation itself is invisible for the patient. The goal of this element is that it should communicate that the medication reduces the inflammation and that this can take up to several weeks.

Adherence
The interface should show the adherence of the person. It should show that once a person has failed to adhere to the medication intake, the progression that was made on the inflammation side will be reduced. On the other hand, being adherent will show a progression in reducing the inflammation.

Asthma State
The data that is captured by the sensor should be visualised in a understandable way. It should be visualised in a way that the patient understands that the data relates to the symptoms and that the symptoms relate to a reaction of lungs that is caused by the inflammation.

Figure 52 - Visualisation style matrix



Prototype

Iteration 1

The next step in the development process was to prototype possible visualisation styles that could accommodate for communicating the abovementioned health concepts. This was done while taking into account the possible styles of the matrix. Figure 53 presents a visualisation of how these screens could be visualised and figure 54 presents how these screens could fit within the matrix.

Image 1 displays an airway that embodies the three health concepts. The airway is visualised with a balance of realism and simplicity. The tightness of the muscles displays the sensor data, the colour of the lung wall displays the adherence and the diameter of the airway displays the level of inflammation. Appendix EE shows a possible visualisation of this interface with different scenarios.

Image 2 displays a more close to real visualisation with the addition of a dramatic element. Here the airway is visualised as a 3D environment, in the same way as in the augmented reality experience. In this interface, a character is used to embody the concept of inflammation. The colour and diameter of the airway represent the asthma state data. Appendix EE presents the two different scenarios.

In image 3, three different screens can be seen. They indicate an abstract interface in which characters are used to display the inflammation. The asthma state is visualised through airway diameter and presence of mucus. The top bar shows the overall inflammation progression and the arrow within shows the adherence.

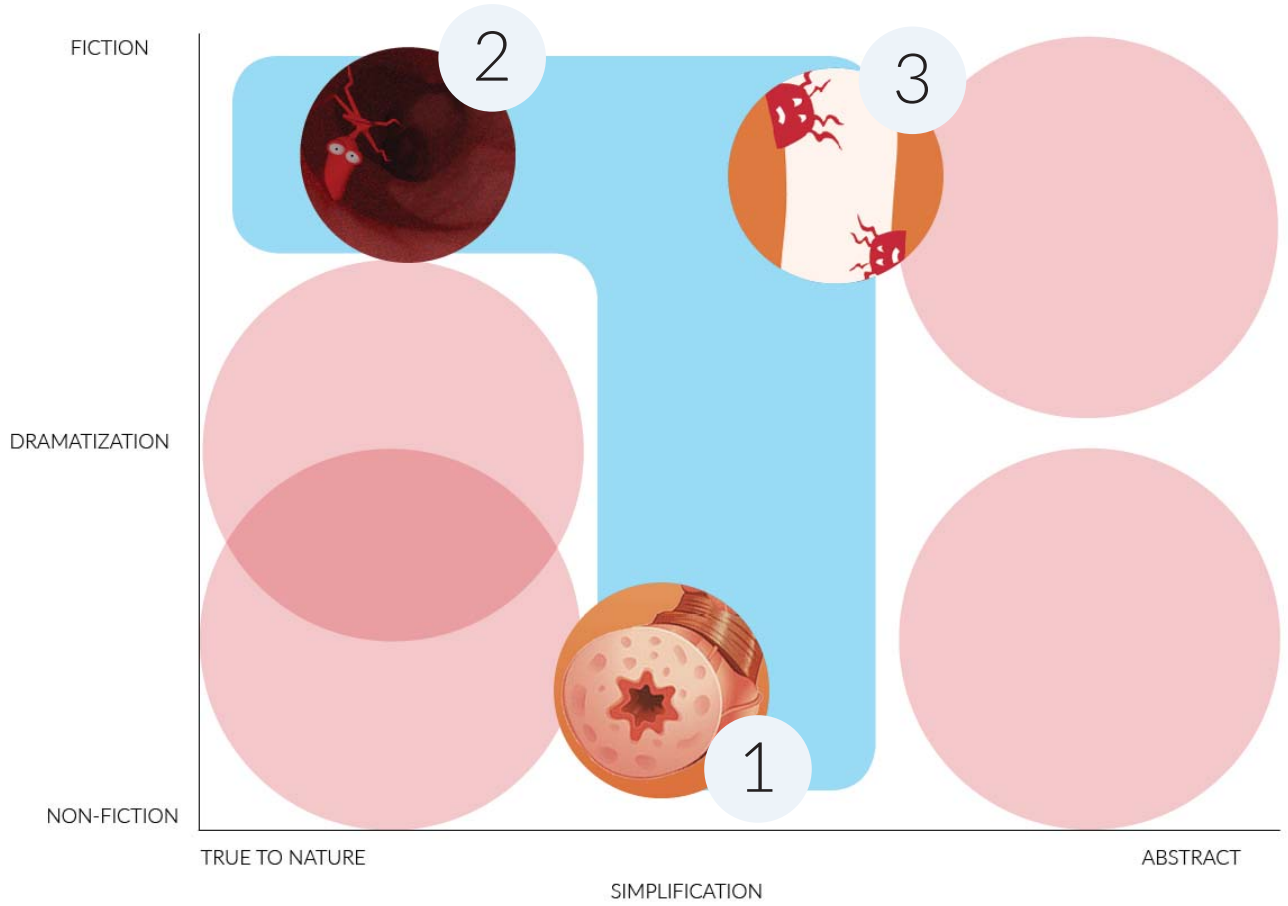


Figure 54 - Prototypes in matrix

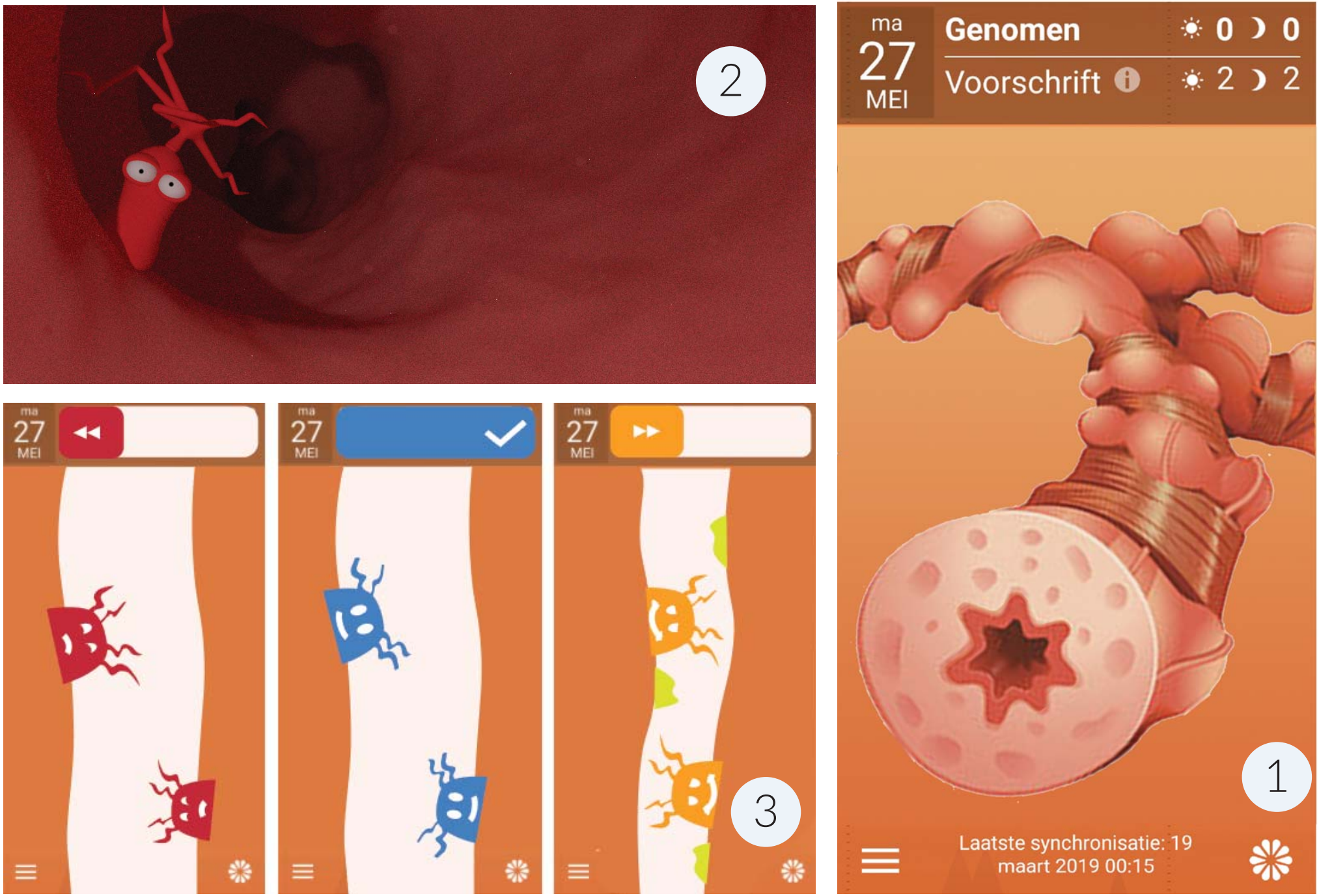


Figure 53 - Visualisation exploratory prototypes

Iteration 2

During the team meeting the following improvements for the interface were suggested:

/ Increase the functionality of the app. Instead of only being able to see the visualisation of the lungs, one must also be able to see history over time and have the possibility to troubleshoot.
/ Increase the shades in between. At this point, the interfaces contain only the extremes of the parameters. It should be investigated how many shades in between are needed on how these could be communicated clearly.

Eventually, the goal of the interface was that it should be tested with low literates to check whether the proposed interface would succeed in creating awareness. For this, Pharos, an expertise center for health differences, was approached to help with the execution of this test. The representative of Pharos made a few suggestions:

/ Provide an introduction to the participants. Since the participants of the user evaluation will not be familiar with the concept of asthma, it would be good to provide them with a brief introduction to the problem and concept.
/ Unnecessary details will catch attention and distract the user from the key information
/ A checklist was provided for accessible information for education material and eHealth applications. The points on this checklist were taken into account for the final design of the interface. This checklist can be found in Appendix GG.

The combination of the abovementioned points for improvement, in combination with the visualization style matrix, resulted in the final design of the interface. The interface consists of several different elements. These are described on the next page according the annotated picture in figure 55.

1. Adherence data
In this box, the adherence data is visualized. The image of the inhaler with the text underneath was designed to tell the patient that the data that is presented next to it has a connection with the inhaler. The green arrow displays if the patient has taken his or her medication. The green arrow displays proper adherence, while a red arrow would indicate that the person has forgotten to take medication. The goal of the arrow is to inform the patient about the progress they are making regarding the inflammation. If a patient succeeds in retaining a green arrow for a longer period of time, the overall progress bar will progress towards the end. The goal for the patient is to reach 100%, indicating that they have been sufficiently adherent for a longer period of time.

2. Sensor data
In this box, the sensor data is visualized. The image of the lungs was designed to tell the patient that the data that is presented next to it has a connection with the respiratory information that is measured by the sensor. The blue arrows indicate the state of lungs, where the number of blue arrows is related to the occurrence of symptoms at the night of measurement. The text underneath displays the date of the last measurement.

3. Holistic View
The holistic view (3.1) was added to provide the patient with the necessary background information regarding the data. The goal of this interface is to help the patient become more aware of the data and what it means within the concept of asthma. The view starts with an outside perspective on the torso including the respiratory system. Once the patient taps the “zoom in” button, they are taken to an “inside the lungs” perspective (3.2), where they can observe the blue arrows as being air going through the airways. One more tap on the “zoom in” button allows the patient to take even a closer look and observe the “detectors” (3.3). The design of these detectors was based on the matrix in figure 52. The goal of the design was to visualize the rather complex concept of inflammation in a way that it is understood by the target group. The “restlessness” of the detectors indicates the state of the inflammation. Through this visualization, the patient is enabled to put the progression data presented in (1) into the context of asthma.

4. Timeline
The timeline visualizes the progression of the patient over time. This is visualized as an airway that interacts based on the measured data by the sleep sensor. The wideness of the airway represents the number of symptoms measured during the night. The color of the airway wall represents to progression that was made regarding the inflammation. The goal of the timeline is that it can be used to reflect on the effect of the maintenance medication. After several weeks the patient can observe an overall increase in the airway wideness in combination with the progress made on the inflammation.

5. Help & Settings
In this prototype, these functions have deliberately been left blank, in order to ask the user what they would expect to find there.

Explanatory video
Accompanied by this app prototype, a video was made that explains the concepts of breathing, the respiratory defense mechanism, asthma, the medication, the problem, the solution and the application to the participant. Within this video, the same graphical representations are used as used in the prototype interface. Through this method, the participant can already get familiar with the concepts.

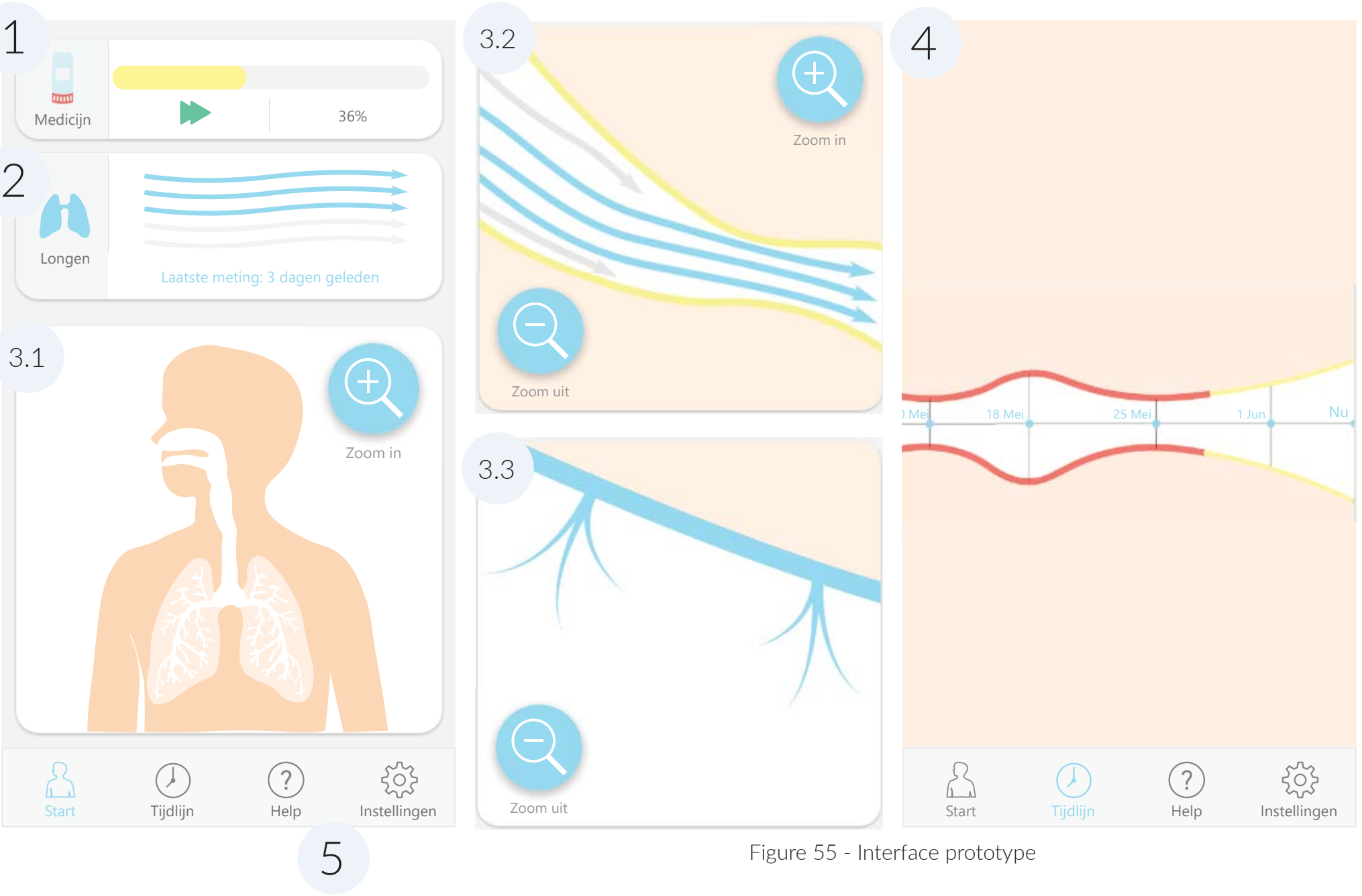


Figure 55 - Interface prototype

Evaluation

The evaluation took place at the facility of Pharos in Utrecht. The evaluation consisted of three sessions of 1,5-hour length spread across 2 days. The participants, being language ambassadors, were considered to have LHL. One of the sessions was attended by a couple.
The sessions were executed by a representative of Pharos, who is experienced in the evaluation of educative material for low literates. Beforehand, she was provided with the designers goal of the evaluation (Appendix HH), the interface screens to test (Appendix II) and the explanatory video. Based on this she developed a testing script, which can be found in Appendix JJ.
At the start of the session, the explanatory video was shown. Subsequently, the interface screens were presented and discussed on their comprehensibility. In case of an element being unclear, the participant was asked to provide suggestions for improvement.

Results

1. Adherence Data

One of the participants seemed to be needing more contrast between the yellow color and the background. All participants indicated that the location of the percentage was confusing, as it wasn't directly clear that the percentage belonged to the progress bar. Although all participants could understand that the green arrow represents something good and progression, the relation of the arrow to the progress bar was not clear. The yellow color of the progress bar was seen as confusing and didn't provide the proper information about the data being good or bad.

"The green arrow, I know it means something is good. But I'm not exactly sure what."

All participants indicated that the use of the medication symbol helped to provide information about what kind of data is shown. Almost all participants indicated that the percentage is a clear way to represent a progression, however, it should be integrated within the progress bar itself. Regarding the green arrow, some participants suggested adding extra explanatory text underneath. Other participants suggested placing the arrow inside the progress bar to make their relationship more clear.

2. Sensor Data

The picture of the lungs was received as confusing to almost all the participants. Some participants indicated that the blue color of the lungs was confusing, as this is not the natural color of the lungs.

Some patients suggested replacing the figure of the lungs with the actual picture of the sensor, to make it clear that they are related. The relation of the blue arrows with the state of the lungs was understood by all the participants.

"It could be improved by making the lungs the natural color, I believe it is reddish. Or even better, put a picture of the sensor"

3. Holistic View

3.1

Although all participants understood that the image displayed the asthma patient, most of them did suggest that it would add something to make it more personal. For example by adding a picture of yourself or your name. The "zoom in" button was understood by almost all the participants. One of the participants mistook the button for a search engine, however after reading the text underneath it was clear that the button was used to zoom in. All participants understood that zooming in would mean to take a closer look at the lungs.

"I think that button means that you search something. It must be some search engine."

3.2

All the participants understood that the image displayed an airway and that the blue arrows indicated the amount of air that was able to pass through. All participants were able to argue that a low number of arrows would mean that the person is not doing well, whether with a high number the person is doing well. Most of the participants understood that from this screen it was possible to zoom out to the body again or to zoom in even further.

3.3.

Some participants mentioned being confused by the blue color, as this is not a natural color for the airways. Almost none of the participants seemed to understand the relation of the detectors with the progress bar and the concept of inflammation. Most of the participants relat-

ed the state of the detectors back to 'how well you are doing'.

"It means that you are doing good, the detectors look calm and relaxed"

All participants understood the image as representing the detectors. All participants mentioned that is was clear that the detectors were in a 'calm' state. One of the participants suggested using the visual representation of these detectors as a way to indicate their state, instead of the color. The same participant also mentioned using their natural color.

4. Timeline

None of the participants seem to understand that the color of the depicted lung wall represented the progression of the inflammation. Some of the participants understood that red was worse than yellow, while others didn't understand this relationship. One of the participants mentioned that red is the color of the body so that it should be good.

All participants understood that an airway was depicted over time. They understood that the wideness of this airway represented how well someone was doing during that time.
Regarding the interpretation of the colors, some participants suggested adding a legend to the screen where the colors and their meaning are explained.
Overall, the timeline function was well received by the participants, as they saw great value in being able to look back at their asthma control. One of the participants mentioned that it would be good to add additional notes to measurement so that one can check why someone was having a poor score on a certain day.

5. Menu

The icon of the first button was perceived as clear by almost all participants. Most of them did mention that the word "start" was confusing as it could indicate the starting of a measurement or movie. Regarding the second icon, most participants mentioned being confused by the word: "timeline". Most of them expected to see a screen focused on specific times of medication intake.
One of the participants suggested replacing the word "timeline" by something within the area of "looking back" as this more explicitly indicates what one can expect on the screen.
The help and settings icons were understood by most of the participants as they mentioned that these are common icons they recognized from computer use. Under the help button, the participants expected to find information about the disease, medication and about the interface itself. Under the settings button, they expected to find options to manage the sensor and app preferences.

"Start, I think it means that you can start something, like a measurement or a video"

Discussion

Interface

An important goal of the interface was to be able to communicate the three concepts within asthma (adherence, inflammation, state) in a clear and effective way. It seemed that during the evaluation, these concepts were frequently mixed together. What stood out was that the participants often described the inflammation elements as asthma state elements. For example, they indicated that a restless detector would mean that someone is experiencing symptoms. Since the goal of the design was to separate asthma state from inflammation state, it seems that improvements are needed to make the distinction more clear.

Several aspects were suspected to be the cause of this misunderstanding. First, the relation between the blue arrows shown in the home interface and the asthma state data was clear for all the participants. It was suspected that the presentation of the blue arrows within the explanatory movie, helped the participants to form this relation. This direction relation was not present for the inflammation data. The inflammation data was connected to their representative (detectors) through a color map, which was not properly perceived.
Another possible cause for this misunderstanding could be attributed to the fact that the top bar (medication) displays two parameters: adherence and inflammation state. It could be assumed that the presentation of two parameters in the same visual could result in additional confusion.

A possible improvement of the interface could be to show the actual detectors in the home interface and create a direct relationship with the concepts presented in the movie. Instead of mapping the progression through color, the improvement could be mapped by changing the actual appearance of the detectors, as was suggested by one of the participants. In addition, the green arrow and the percentage could be placed within the progress bar itself to make their relationship more clear.

Movie

Initially, the movie was solely added to help the participants get into the subject of asthma and the concept, in order to be better able to provide valuable results. When the patients were asked to explain what they expected to find behind the help button, some of the patients suggested that they wanted to see (parts of) the video again. Initially, it was decided that the practice nurse would use the first consult to explain asthma and the workings of the app. However, after this insight, it was suspected that the movie could be used during the first consult to support the practice nurse in explaining asthma. This could be beneficial on multiple levels.
Firstly, it was learned that the time during the first consult is too short to properly explain all the necessary information to the patient. The explanation of the app would therefore only consume even more of this limited time. By using the movie during the first consult, a mutual cooperation could exist between the concept and the nurse. The movie could support the nurse in telling the story about asthma, and the nurse will subsequently use this moment to explain the interface.
The second benefit of showing the movie is that the concepts presented within are repeated within the interface, therefore significantly increasing their understandability. A famous saying by Confucius goes: I hear, I know. I see, I remember. A strategy to help the patients become aware, as mentioned by the practice nurses, was to repeat the content as often as possible. However, the time of a consult is short, and the time in between is long. Integrating the concepts in an interactive interface that enables the patient to be exposed to them on a daily basis, could therefore significantly improve their understandability.

These insights acquired within this evaluation, ranged from more prominent issues as described above, to smaller, more detail oriented insights. A downside of the evaluation was that the interfaces were printed out and shown separately to the participants. Therefore, certain aspects that would become clear through interaction were understood with more difficulty. For example the zoom and menu buttons.
It has to be mentioned that the evaluation was mostly oriented towards the comprehensibility of the visual elements of the interface. The understanding of the deeper layer, meaning, the interrelation between the three different asthma concepts, was not directly tested.

The design and evaluation of the interface has shed light on a new direction for the interface. During the user evaluation, the overall comprehensibility of the interface and movie were judged as good. Therefore it can be concluded that the proposed interface is in the right direction. Chapter 6 will present the final interface including the discussed recommendations.

Key Insights

/ The movie worked well to explain the different concepts and their relation with the application
/ The visual presentation style was overall clearly understood
/ The overall system was judged as useful and innovative

/ The interrelation between the different variables should be made more clear
/ Several details within the interface caused confusion and should be improved

CHAPTER 6 | Conclusion

In this chapter, the final concept is presented as a result of the concept development phase in the previous chapter. Subsequently, the according design recommendations and future steps are discussed.

6.1 | Final Concept

The Turbuscope (figure 56) consists of a cohesion of three different products and an app. These products are aimed at collecting data about asthma and presenting it in clear way so that it creates awareness and engages the patient in the process of asthma self-management.

The first product within this system is the Turbu+. Within this concept, the Turbu+ is connected to the smartphone and functions as a way to log and collect data of medication usage.
The second product is a smart sensor, that uses a 3D-printed stethoscope housing and a microphone to capture respiratory sounds. This sensor is embodied into a comfortable neck-cuff that can be non-invasively worn during the night. The sound signals are transmitted through Bluetooth to the smartphone.
The third product is the docking station, that functions as a way to provide cohesion between the different elements and provides quick feedback to help the patient stay on top of their asthma management.
Finally there is the app on the smartphone. The app functions as a central hub for all the incoming data. The incoming sound signals from the sensor are received by the phone and are thereafter analysed and converted to a score. This score in combination with medication adherence information is presented in the app in a way that is tailored towards people with a LHL. With simple and clear graphics the patient is informed about the current state of their asthma and medication adherence.

Value

The main aim of the Turbuscope is to improve maintenance medication adherence of asthma patients with a LHL by providing awareness to the patient about asthma and the effect of the medication. Once the patient is aware of the importance of adherence to the maintenance medication, he or she will be more motivated to take their medication as prescribed and therefore reducing the impact of asthma on the quality of life.

To create this awareness, the concept makes use of objective holistic data tracking. Since patients with a LHL have trouble interpreting and assessing their own health, they could significantly benefit from the solution that supports them in this process. By presenting the objective data of the state of asthma next to the use of the medication, the patient will become aware of its effect.

This concept is specifically tailored towards the needs of people with a LHL. The innovativeness of the concept fosters a feeling of usefulness and therefore triggering engagement. The feedback provided by the app was developed together with low literates and is presented in a clear and interpretable way.

The data that is gathered by the app does not only provide valuable insight for the patient but can also help the healthcare provider to make better judgements about treatment procedures. In addition it provides a platform for discussion and therefore resulting in a more effective and efficient way of communication during consults.

Figure 56 - Final concept

Timeline

Figure 57 presents how the product is used over time. The product is used over a period in between the first two consults. The product can be applied for patients that have a fresh diagnosis of asthma or for patients that are identified to have very poor adherence and are in need of a 'reset'. For the concept to show effect it is important that improvement over this period is seen. Therefore it is important that, at the start of the usage, the user has had no or very little maintenance medication.

The first consult

The patient is diagnosed with asthma by the general practitioner. The general practitioner will, during this 10 minutes consult, provide the result and the first instructions. Then, the patient is redirected to a practice nurse. This consult takes 40 minutes in which the practice nurse will explain the topics of asthma in more detail. During such a consult, the patient receives instructions about asthma treatment. During this consult, the Turbuscope will be introduced. Within the app of the Turbuscope, several movies are available that help to explain the concept of asthma (1). While watching the movies, the patient already introduced to the concepts present in the app, such as the respiratory system, asthma state and the medication. On the one hand the app supports the practice nurse in explaining asthma and on the other hand the practice nurse helps to explain the app. In the end the patient will take home the product and use it for the upcoming weeks until the next consultation.

At home

The patient is asked to install the product at home. The optimal location for the product is to place it somewhere where it is seen on a daily basis. Such as next to the bed, in the bathroom, in a hallway or living room. Throughout the weeks, the docking station will tell the patient what actions are required. The patients is triggered to perform several measurements throughout this period and to stay adherent to the maintenance medication. During this period, the docking station will gather data about the adherence (2) and the asthma state (3).

Second Consult

During the second consult, the data gathered by the Turbuscope, is used by the practice nurse and the patient to reflect upon the past period. The patient can use the timeline (4) as a tool to tell a story of how their asthma has been doing. If the patient has been properly adherent, an improvement in lung function can be observed over time. Together with the practice nurse they will reflect on the medication usage. The practice nurse can use the results to explain why it is important to use the maintenance medication.

At this point the patient can decide whether he or she wants to buy the Turbuscope or want to return it. If the patient returns the Turbuscope, they are allowed to keep the app. Although the app does not provide the tracking anymore, they are still able to check their past results and the view explanatory movies in the app.

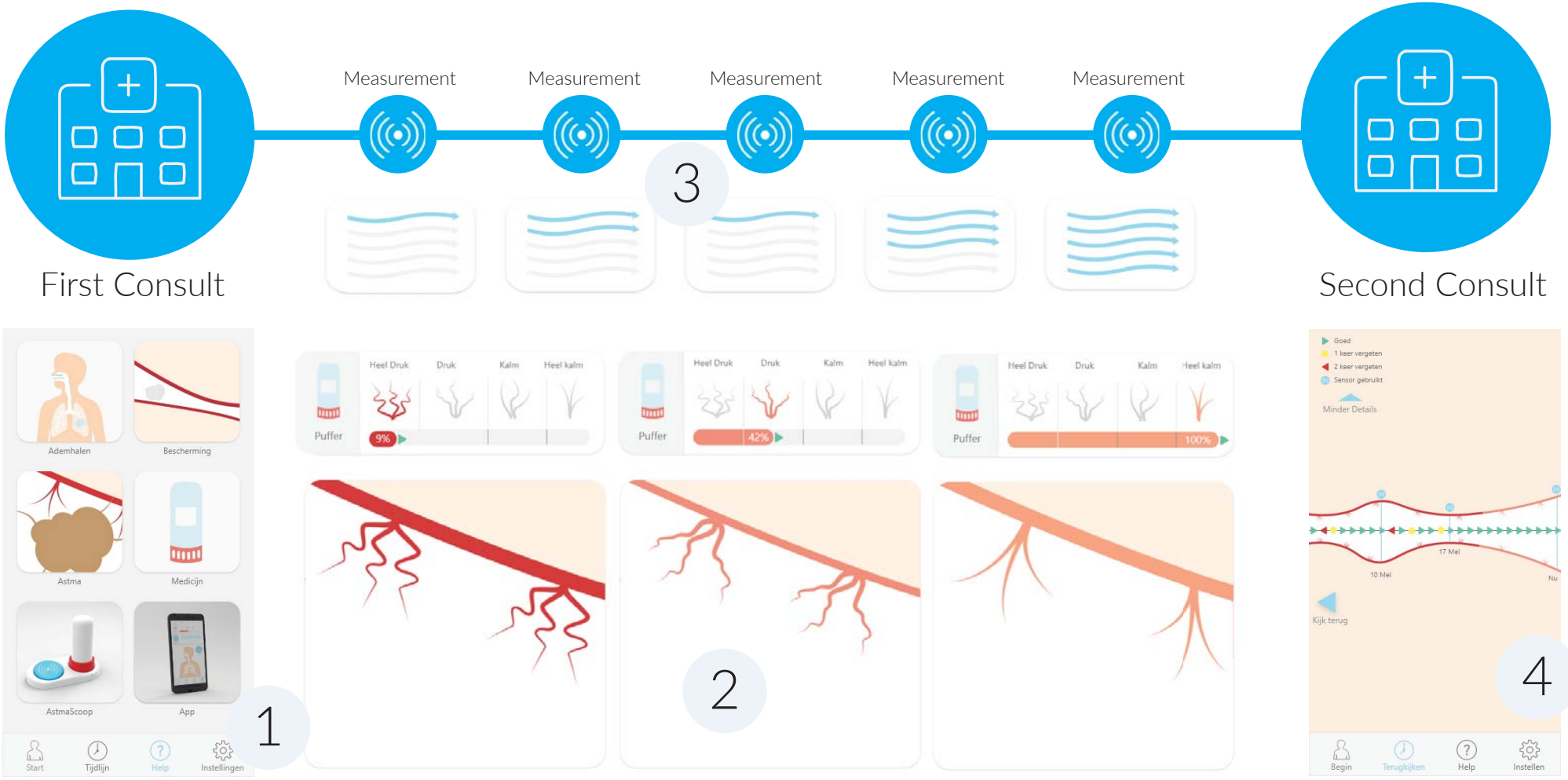


Figure 57 - Usage over time

Scenario of use

Figure 59 presents a typical scenario of use. The main functionality of the docking station is to provide a trigger for this usage throughout the period at home. It contains of two sets of light indicators: one to indicate sensor information and one to indicate medication information. When the lights below the sensor start to blink, it means that it is time to perform a measurement. For this, the patients wears the sensor-cuff during the night, to track coughing and wheezing sounds (figure 58). In the morning, when the sensor is placed back in the docking station, the indicator will show the score that was measured during the night. Based on this information, the patient can decide whether he or she wants to check out the app for further details. The patient can also decide to delay this interpretation to a later, more convenient, moment. The docking station will also highlight whether it is time to take the medication. The medication notification system will notify this by showing different colours of light. A green light means that everything is well and that the patient is making progress. A yellow light means that the patient has forgot his/her medication once and that the progress is on a hold until the medication is taken again. A red arrow means that the patient has forgotten to take the medication multiple times in a row and that the progress is decreasing. Once the medication is taken again, the light directly jumps to green, therefore preventing the patient from 'making up' for forgetting in the past.

.

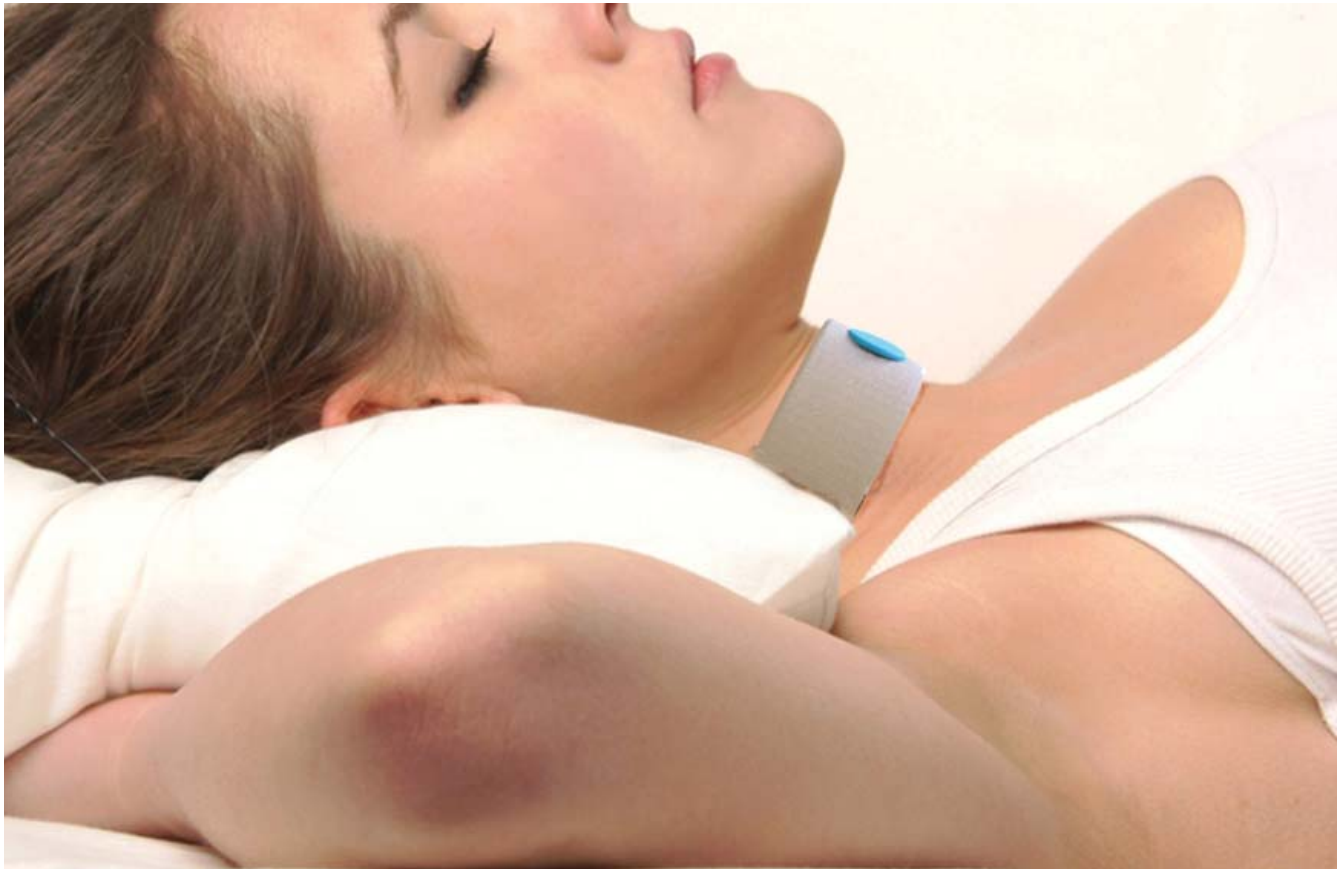
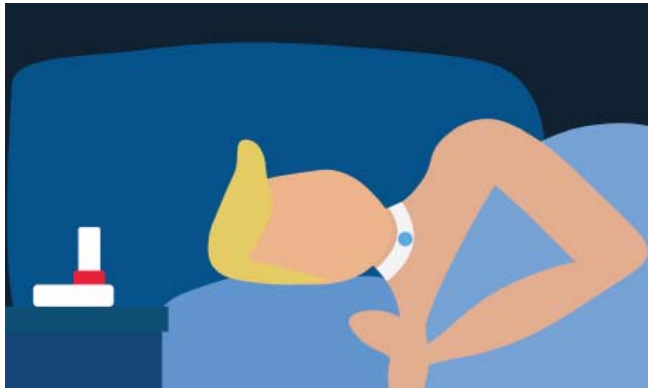


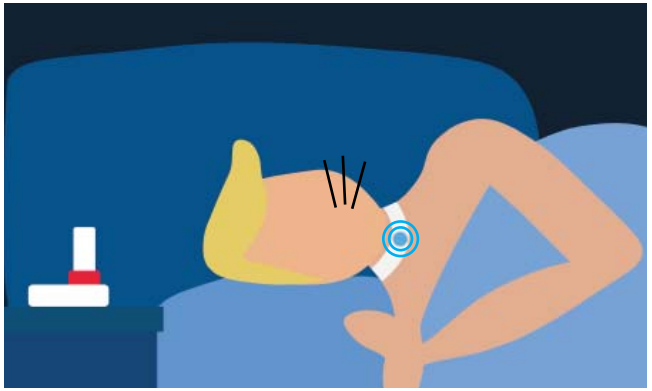
Figure 58 - Wearing the sensor

Figure 59 - Scenario of use

Blinking indicates it is time for a measurement

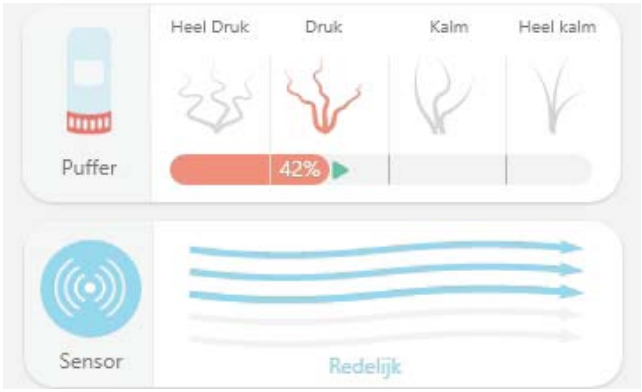


Patient wears the sensor during the night



Sensor captures coughing and wheezing sounds

In the morning, the result is displayed on the docking station



At any time, it is possible to check the results in more detail in the app.

When the medication light turns red, it means that the medication has been forgotten.

When the patients uses the Turbu+, the medicine light turns green again.

App

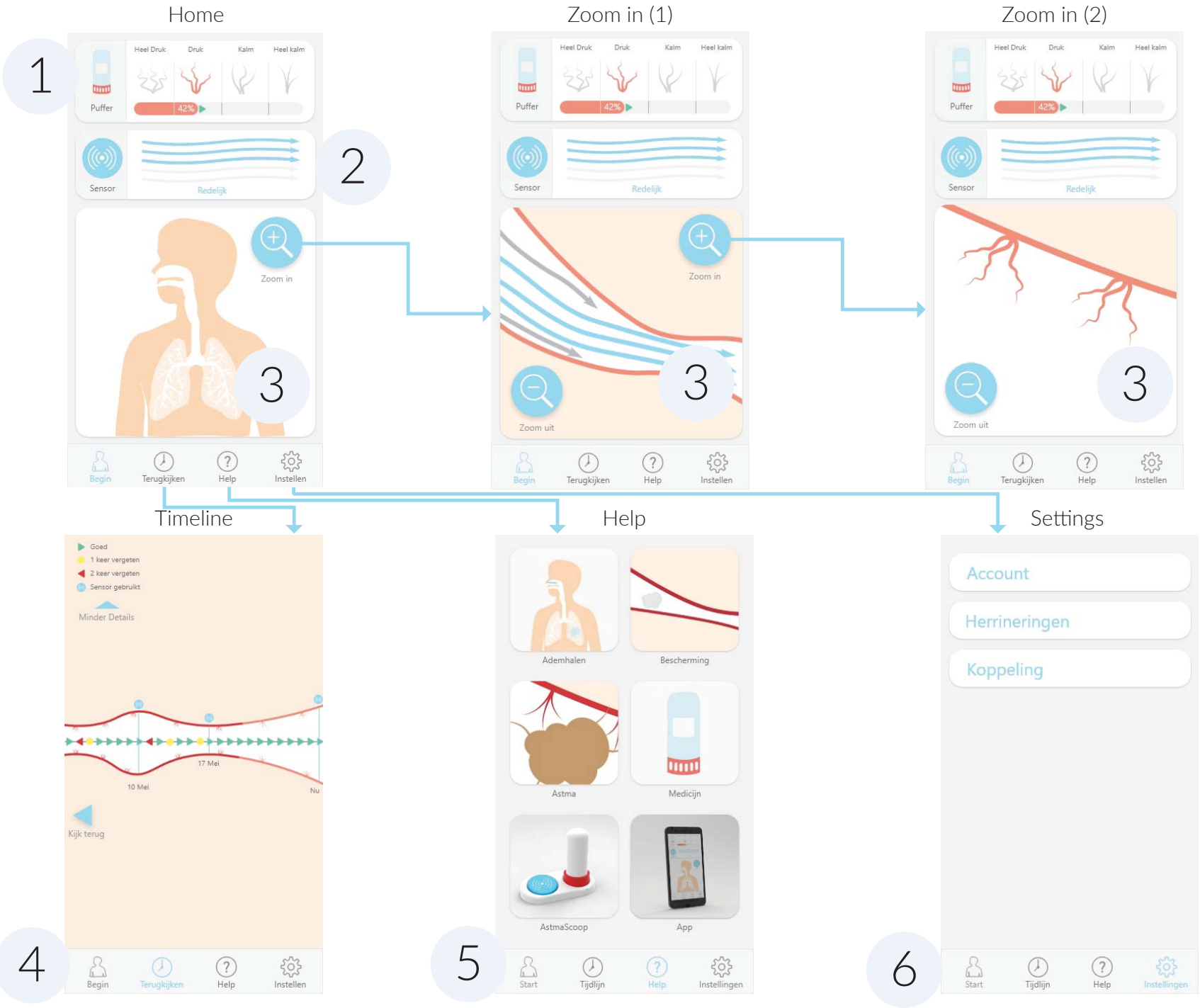
Figure 60 presents the app architecture. The top bar (1) presents the total progression the patient has made. This progression is linked to the process of building up a protection against the inflammation by use of the maintenance medication. When the patient succeeds in being adherent to the maintenance medication, the bar will slowly fill up. The arrow that is integrated within the bar represents the adherence information (the same information as presented on the docking station). The second bar (2) presents the measurement data as recorded by the sensor. This is presented in the form of five arrows. The more blue arrows are presented, the better the score of the latest measurement was. 3 presents the holistic view. This view will help the patients to explore the meaning of the data representations into the context of the concept of asthma. It will help the patients, in case they have forgotten the instructions and do now want to watch the movies back, to rehearse and understand the meaning. In this holistic view, two layers are present. One layer in which the meaning of the blue arrows (air travelling through the lungs) is displayed, and one layer where the detectors (severity of inflammation) is displayed.

The timeline (4) helps to show the patient the progression they have made over time. At the lung wall, the detectors are displayed, indicating the progression the patient has made over time regarding the inflammation. The diameter of the airway displays the asthma state. Through this interface, the patients could see how they have been doing over time and how this is related to the use of the maintenance medication. The arrows on the timeline provide information about the adherence. Through this way, the patients can see when and how often they have forgotten to take their medication.

The help (5) screen displays several sections of the introductory movie, that can be looked back on demand. They are categorized according the subjects: breathing, defense mechanism, asthma, medication, Turbuscope and the app.

The settings (6) page serves as a platform to adjust several functions within the app, such as reminders, account preferences and connectivity. Within this section it is also possible for the patient to determine whether the data should be shared with the healthcare practitioner.

Figure 60 - App Interface architecture



Specifications

Docking Station

The docking station (figure 61) consists of a plastic housing with integrated Bluetooth microcontroller. The Bluetooth module is connected to the smartphone of the patient and receives adherence and sensor data. This data is converted to visual output with the use LED lights. The mount socket of the sensor has a micro-USB port integrated in a way that the sensor can charge while it is inside its socket. The docking station has a USB 5V power connection that is used to power the microcontroller and Bluetooth module as well as the sensor when it is in charging position.

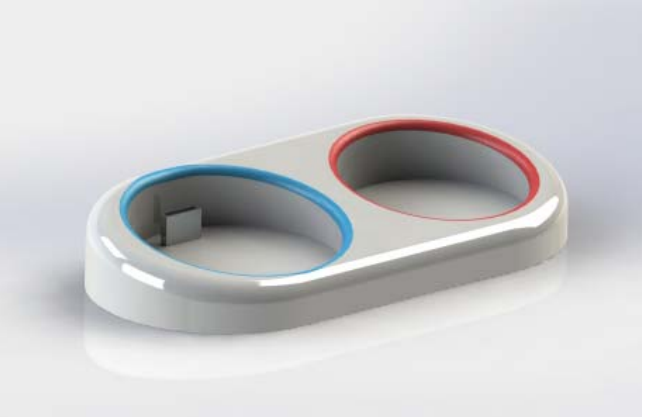


Figure 61 - Docking station

Sensor

The sensor (figure 62) consist of a 3D printed housing that embodies a stethoscope diaphragm. The sound waves that are captured by the **diaphragm (1)** are transmitted to the **hollow conical space (2)** at the other side of the diaphragm. The conical shape of this space helps to transmit the sound waves to the **electret microphone (3)** situated at the top of the cone. The microphone is connected to a **Silicon MEMS Microphone Breakout (SPW2430) (4)** where the sound signal is amplified. This amplified signal is subsequently sent to a **BLE BTM835 Bluetooth module (5)** where it is transmitted to the smartphone.
This digital sound is subsequently transmitted to a Bluetooth module that is able to transmit the sounds to the smartphone. The entire sensor system can made in a way that it fits the diameter of the stethoscope diaphragm. A **1000mAh Lipo battery (6)** is used to ensure enough power for one night of usage.
The sensor fits inside a comfortable fabric elastic neck-cuff which allows a tight placement of the diaphragm at the trachea region.

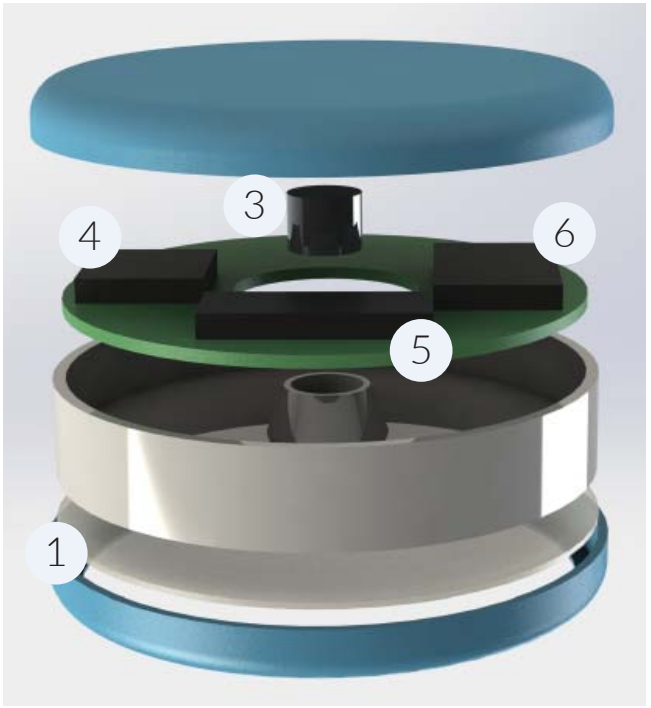


Figure 62 - Sensor Architecture

Algorithm

After the sound is transmitted to the smartphone, it will be processed by an algorithm (figure 63). The algorithm makes use of the analysis of power spectral density (PSD) features, as this is currently the most popular method. The first step is to pre-process the sound, to filter out redundant frequencies and other disturbances. Subsequently, this pre-processed sound is subdivided into small segments of approximately 200ms. The segmentation of the incoming audio allows the data to be properly analyzed. This analysis will be done with use of a Fourier transform method. Through this method it is possible to create a plot of spectral density of the sound segment. This data can also be seen as the sounds fingerprint. Analyzing this fingerprint and comparing it to that of abnormal breathing sounds, makes it possible to extract the wheeze and coughing features. When such a feature is detected, the segment can be marked. Over the course of the night, the system will be able to determine the percentage of wheeze in the respiratory sounds as well as the number of coughs that are detected.

It has to be stated that this description only highlights the basic functionality of the algorithm. In order to achieve a high accuracy, it is important to properly tweak the algorithm towards the data. Suggestions on how to proceed for the development of the algorithm can be read in chapter 6.3.

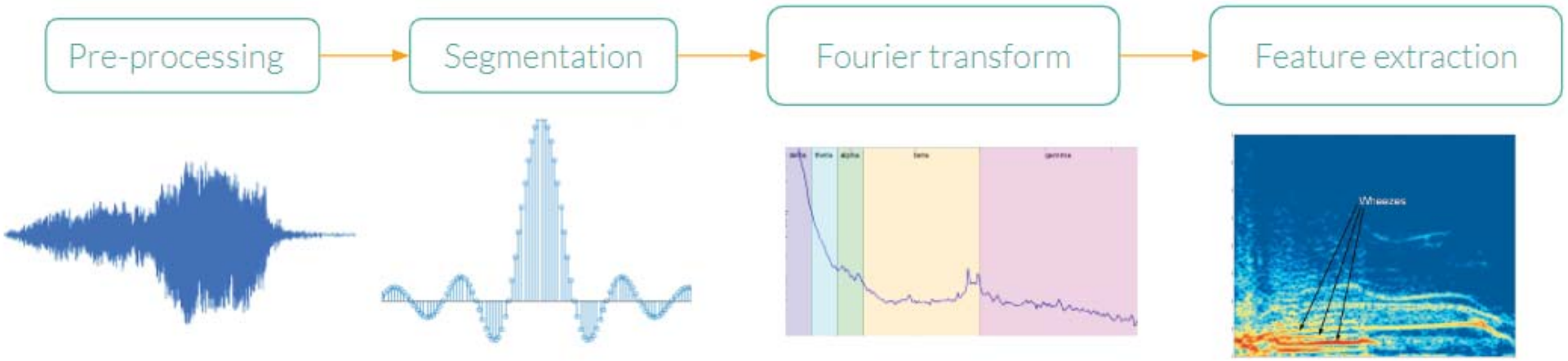


Figure 63 - Algorithm Process

Integration

Data

The data that is gathered should be transferred to a secure environment. This environment is needed to store the acquired data and to send it to the healthcare practitioner. This enables the healthcare practitioner to monitor the progress of the patient and to step in if it is needed. If the patient decides that the healthcare practitioner is allowed to look into the data, he or she can do this through the online portal (figure 64). Currently, the Turbu+ already hosts a system that securely stores this data and presents it in an online interface. Within this concept, the data source of the sensor will also be added to this online environment. This makes it possible for the doctor to not only monitor adherence but also if any progress is made.

Costs

The calculation of the total material costs can be found in Appendix KK. The total system price is based on the material costs of the sensor (€ 17,30) and the material costs for the docking station (€ 7,71). This brings it to a total of € 25,01. A rule of thumb can be taken into account when estimating the cost price, 10% of the material price can be assumed to be labour and overhead costs. This brings it to a total of € 27,01. The company that will produce this system is Astrazeneca. In order for the company to receive a profit out of the system, a 50% of the production price is added which comes down to a final retail price of approximately € 40. Including the Turbu+ in this price, as it is part of the system, will add € 20 to the price. This brings the total retail price of the product at approximately € 60.

In a final talk with a manager of a healthcare clinical, it was learned that for this order of magnitude, the clinical would be interested to use the devices. She indicated that it would be interesting to acquire a set of approximately 5 devices.

In a final talk with a manager of a healthcare clinical, it was learned that for this order of magnitude, the clinical would be interested to use the devices. She indicated that it would be interesting to acquire a set of approximately 5 devices and test whether they work. She did mention however, that it would be essential to use the acquired data for research purposes. She indicated that there are research networks available that would be interested in such datasets and would therefore also want to fund the further development of the system. Currently, the Turbu+ is already in use and provided for free to a few healthcare facilities, once a contract is singed that says that the facility will advise the certain medication from the pharmaceutical company. This same costs structure could be applied for the Turbuscope, after its safety and effectiveness are proven. Chapter 6.3 will provide a more elaborate explanation about this process.

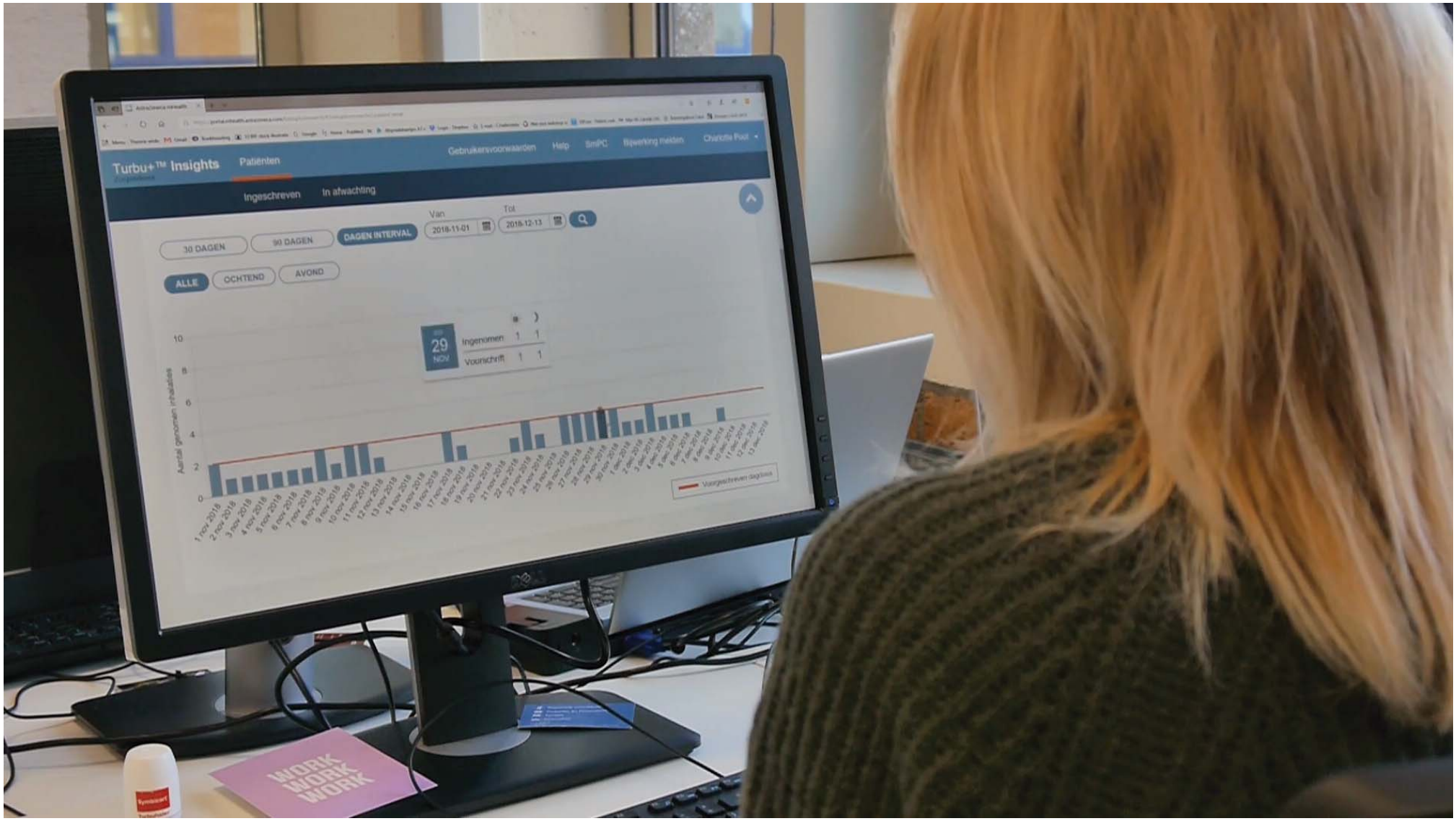


Figure 64 - Online environment for health practitioner

6.2 | Design Recommendations

This chapter will elaborate on the findings that have been identified throughout the project. It will outline the final design recommendations that should be considered when designing such a monitoring eHealth device to improve medication adherence for asthma patients with LHL.

Objective Measurement

Nocturnal Symptom Tracking

It was found that the tracking of nocturnal asthma symptoms has potential to objectively track asthma state in an effortless and non-invasive way. Currently, the field of research around the development of automatic wheeze detection systems is booming. A wide variety of setups have been developed and validated. From all the different systems the that was developed by Jin et al. (2008) was found to have the closest match with the proposed system. They tested a setup consisting of an electret microphone placed on the trachea region to automatically detect wheezes. With their setup they have managed to achieve an overall wheeze detection accuracy of 97,9% for wheezes during expirations and up to 85,3% for wheezes in inspirations. These values show that the usage of this setup has the potential to accurately detect wheezing sounds. On top of that, according to Manfreda et al. (2001), the measurement of nocturnal symptoms (wheezing and coughing) is regarded as the most accurate way of relating symptoms to asthma control.

Neck-cuff

The placement of the sensor has currently been focused around the trachea region with use of a soft and elastic neck-cuff. Shaharum et al. (2012), states that the trachea region is the most effective way for acquiring wheeze sounds. A comfortable neck-cuff system was found to currently be the most optimal trade-off between measurement accuracy and perceived comfort. Rofouei et al. (2011) have already demonstrated that a neck-cuff system can be utilized to successfully monitor real-time respiratory sleep data.

Awareness

Holistic

One of the barriers for people with a LHL that reduce capability to understand, is the limited awareness about the body in combination with a limited visual literacy. Therefore, showing a picture of an airway as they are frequently presented in medical images, is not an optimal way. It is important to show the context around the image. For an airway, it is important to holistically show the system. This can be done by starting with the body and the location of the lungs, and thereafter step-by-step zoom in to the airways and related concepts.

Balanced presentation

After the showing the context around the image, it is important that the image itself is also displayed in a comprehensible way. In a certain stage of this research, it was found that the image should present the concept as realistic as possible. Further in the development it was found that the presentation of realism should be balanced with simplification and dramatization aspects. The degree to which these elements should be balanced should be investigated through iterative testing with the end-user. The full reasoning behind this recommendation can be read in chapter 5.3.

Repetitive
One of the main identified problem areas, was that the practice nurses do not have enough time within the consultation to explain all the necessary concepts. It was found that is was difficult for the patients to remember all the information in such a short notice. This concept introduces the health concepts at the first stage of the treatment and thereafter repeats these aspects through interactive elements in the app. This way of introducing health concepts and making them familiar through repetition has been found to be a key mechanism in providing awareness.

Reflective
It was found that it takes several weeks before the maintenance medications displays its effects and shows progression. In addition, it was found that patients frequently lose track of the progression they have made, as it the period is relatively long. Therefore it is advised to design an intervention that can track this progression, so that it can later be used to support the reflection on the progression. In this system the patients will reflect on the adherence and asthma state data.

Engagement

Innovative & Effortless
During the user interviews it was found that the tracking of nocturnal symptoms was perceived as very useful. According to Raherison (2006), 42,2% of asthma patients experiencing nocturnal symptoms declared having no symptoms during the night. This indicated that these symptoms often go unnoticed and therefore there lies value in capturing these. The patients expressed their trust in innovative technologies, such as the sleep sensor, to be able to reach such results. It was also found that, when combining this perceived usefulness with a low effort experience, the patients are likely to be engaged with the technology.

Trigger
It is advised to integrate a trigger within the system. A physical representation of the device helps to serve as a reminder to help the patient stay salient towards the self-management intervention. The system should also be capable of providing targeted triggers such as to stimulate medication usage, sensor use and monitor progress.

Cohesion
The medication often comes in multiple forms. In addition, within this system, multiple aspects are included. The design should therefore enable the different aspects to be cohesively integrated. This would prevent the patient from loosing the overview and to help determine the different uses and relations.

6.3 | Future

This chapter will discuss a roadmap (figure 65), that presents the future vision of the implementation of this concept.

Concept Development

Invention, Prototyping & Pre-clinical testing

During this phase, the concept will be further developed. The end goal of this phase is to design a first working prototype. Figure 66 presents a maturity matrix of the concept, which shows the level of development of the sub-systems within the concept. The funding to further develop the concept could be acquired from Astrazeneca if they decide to further support the development. Otherwise, a research proposal could be written oriented towards the further development of this concept. For the further development of the prototype, the following future directions are suggested:

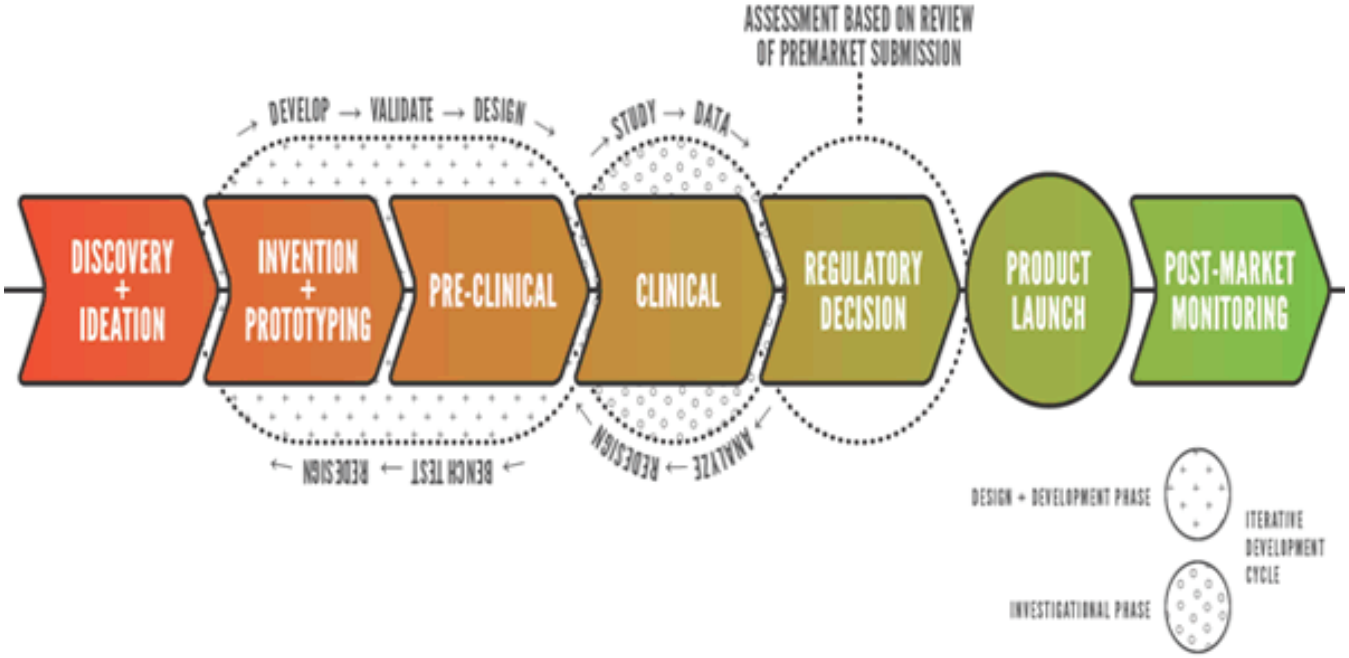


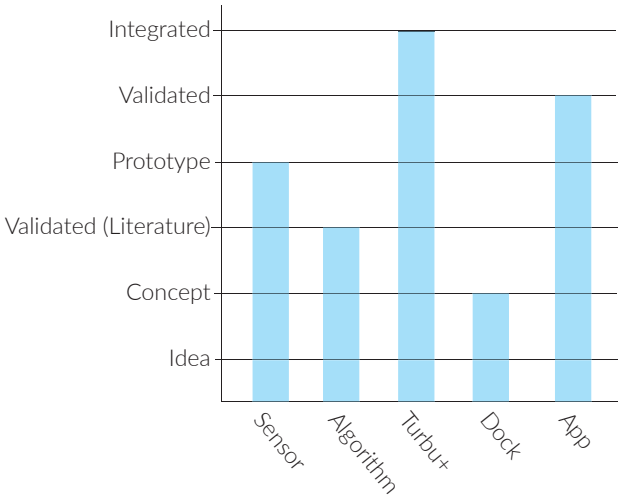
Figure 65 - Roadmap - Center for Devices and Radiological Health U.S. Food and Drug Administration (2011), Medical Device Innovation White Paper

Sensor

The next step for the sensor system, would be to perform a test with the functional prototype in order to test the accuracy of the wheeze detection. For this, first, a proper algorithm needs to be written and evaluated. Looking at the increasing number of articles on the topic of wheeze detecting algorithms, it can be seen that the research is gaining momentum. A main trend over the last 20 years is that the wheeze detection algorithms are shifting from the proposed logic-based identification, towards machine learning techniques (Nabi et al. 2019). Hence, it is recommended to consider machine learning based algorithms in the further development of the concept. After a proper algorithm is selected, the next step would be to test it with the audio recordings of the functional prototype. Several prototypes need to be worn by asthmatic patients that start with the use of maintenance medication. Several measurements throughout the course of at least 6 weeks should point out whether the proposed setup is able to measure a decrease in wheezing sounds.

A second aspect of the sensor system that could be improved is its perceived comfort. For this, several future directions could be taken. One possible improvement would be to reduce the overall size of sensor and therefore the size of the neck-cuff. Currently, the sensor size is based on the standard measurements of a stethoscope diaphragm. However, Jin et al. (2008) have done their experiments with a chamber diameter of 2cm. This suggests that it would be possible to reduce the overall height of the neck-cuff.
Another possible future direction could be to start with the focus on cough detection alone. The detection of cough can be performed by the microphone of the smartphone, therefore eliminating the need of wearing something on the body. Sterling et al. (2014) have researched a mobile platform to assess coughing in asthma patients continuously throughout the day. They mentioned that their initial intention was to design a device to monitor both coughing and wheezing. Eventually, they have decided to focus solely on cough detection. This because capturing wheeze during the day can bring a large set of additional challenges. In addition, cough is the most common symptom found in pediatric patients with uncontrolled asthma (Wildhaber et al. 2012) (Davis et al. 2011) and could, therefore, serve as a starting point for the further development of this system. Wheeze detecting abilities could be added later on in the further development of the system. The development of wearable acoustic measurement devices is constantly progressing. Kim & Shkel (2019) have patented an array

Figure 66 - Maturity Matrix



based respiratory monitoring wearable, capable of detecting wheeze that could significantly improve the comfort.

Awareness

It should be investigated whether the proposed setup (interface) indeed causes increased awareness. The user tests showed that the presented material was clear and understandable, even for non-asthmatic patients. Based on the research results and the results of the interviews, it could be assumed that this presentation could contribute to the awareness of the patients.
Nevertheless, further pre-clinical trials should provide evidence that the level of awareness indeed increases. For this it is suggested to perform an evaluation of the deployment of the app over the course of several weeks. To further develop the awareness providing aspects of the system, it is suggested to strengthen the core of the two separate design directions, as identified in chapter 3.3. In a final talk with a practice nurse, she indicated that some of the patients have extremely LHL. For these patients, it seems essential to provide an extensive educative period prior to the implementation of the proposed system. This is represented as the 'capabilities' design direction. In the proposed system, this education is provided through the explanatory movie. However, the effect of this educative elements can be further expanded through social robotics or gamification elements (chapter 3.5).

In the same final talk, the practice nurse also indicated that, for someone to become completely aware, it is necessary to create a moment to 'flip the switch'. This is represented as the 'awareness' design direction. In the proposed system, this moment is integrated during the second consult, where the practice nurse and patient use the timeline element to reflect on the progress the patient has made with the help of the medication. The effect of this element could be further expanded for example by strengthening the reflection moment through immersive technology (chapter 3.5).

Engagement

Future recommendations to extend the engagement of the patients could lie in the field of the development of a narrative. During this design project, the option to integrate the docking station, the sensors and the interface into one engaging and cohesive story, was

briefly explored. In this exploration, the patient was seen as the captain of a ship, that goes on a journey through the lungs. The different elements from the disease concept, such as taking medication, performing a measurement and detecting coughing or wheezing, could be mapped to elements of the story. Taking medication could for example be connected to persuasive game elements to boost engagement. The development of this game-like narrative could help to increase the engagement of the patient with the process of self-monitoring. Because of time constraints within the project, this direction was not further explored and it was assumed that the combination of usefulness with effortless provided enough engagement over the longer period of time.

Clinical Trial

After the creation of the first few working prototypes, it would be possible to implement the system on a small scale in healthcare facilities. The data that is gathered by the systems can be used by a research network such as the ELAN network. These networks could fund the deployment of the systems and in return achieve a valuable source of patient data. Through this funding, it would be possible to perform an (economic) evaluation. The process of this study goes through several steps (Tulder, 2018).

Identify and measure costs

First, the costs of the device are identified and measured. These are the costs required for the implementation of the medical device, as well as the costs that it can save. For example for medication, GP, medical specialist, and hospitalization. Also, direct non-medical costs need to be taken into account such as time traveled, waiting time, etc.

Identify and measure effects

Second, the effectiveness of the device needs to be measured. This has to be done through a randomized controlled trial (RCT). Within this RCT, the safety and the effectiveness of the device have to be demonstrated (figure 67)

Figure 69 - Device classification (CE Check, 2018)

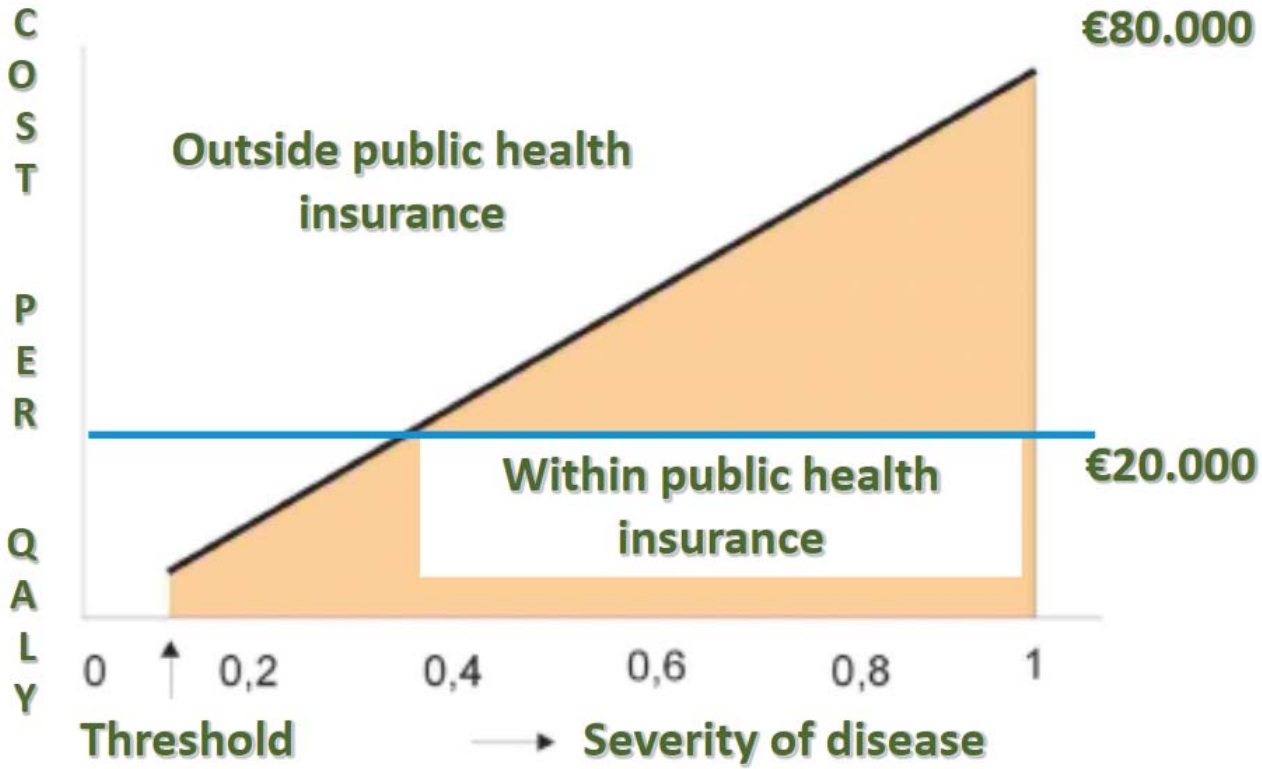


Figure 68 - Public health insurance threshold (RVZ, 2006)

Analyse cost - effectiveness

The cost-effectiveness will be analyzed with the use of the determination of the Incremental Cost-Effectiveness Ratio (ICER). The costs per quality-adjusted life year (QALY) gained will be determined through the following formula: Costs (intervention) - Costs (comparison) / effects (intervention) - effects (comparison)

Interpret and report results

The results will be interpreted and reported. This step is essential for creating evidence for the conformity with the CE mark. In addition, if the costs per QALY lie below the € 20.000 limit, the intervention can be adopted in the public health insurance (figure 68).

Regulatory Decision

The next step in the process is to deploy the first batch of products to perform a clinical trial and to achieve a CE mark. According to CE classification, the device can be seen as a class I medical device, as it is non-invasive and has only contact with intact skin (figure 69). According to CE Check (2019), the route towards CE marking is the following:

/ Prepare technical documentation to support the declaration of conformity
/ Notified body conformity assessment of the product with the metrological requirements
/ Compiling a declaration of conformity
/ Registration with the competent authority
/ Affixing the CE mark to the product, and storing the declaration of conformity and supporting evidence of the authority inspection.

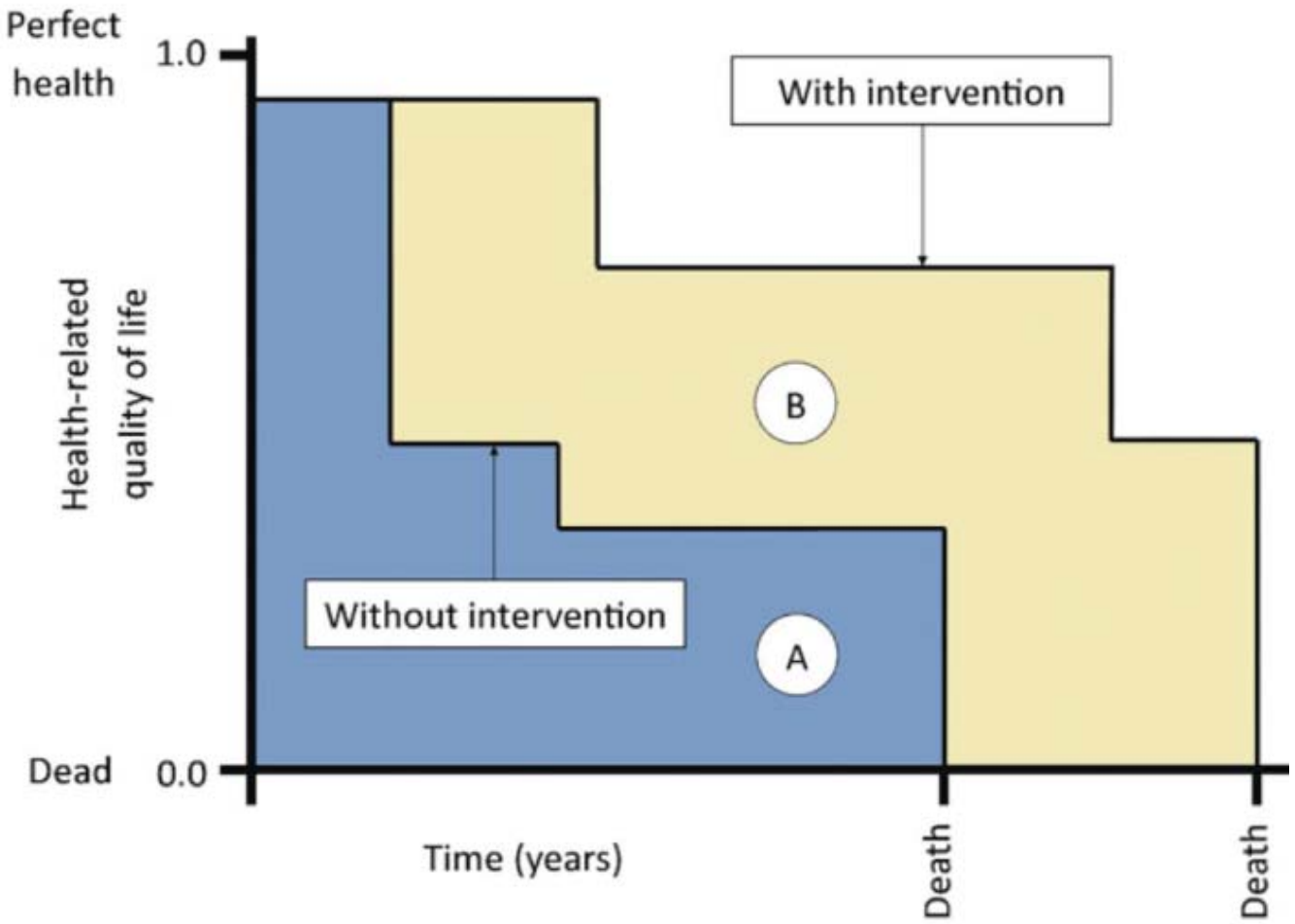


Figure 67 - QALY's gained with intervention (Sampson Rehab Articles, 2013)

Market Release

The final step is to implement the device and bring it to the market. Aftermarket release it is important to maintain good quality system requirements (QSR), begin medical device reporting and begin post-market surveillance. This should be done through the Corrective And Preventive Actions (CAPA) (Schrosch, 2018)

6.4 | Limitations

In this chapter, the limitations of the project will be acknowledged and reflected upon.

Designing something for a vulnerable target group can be very challenging. It requires constant validation with the target group since they are quite distant from the designer himself. Constant validation comes at a high price, as it can significantly slow down the design process. Since there was already limited time available in this graduation project, decisions about next steps were made without going too much into depth into other directions. The decisions that were made within this concept have led to the final result. However, this does not suggest that this is the optimal solution. The sidepaths that have been identified within this project could also have potential to be explored further. A brief elaboration on these sidepaths is discussin in Appendix LL.

The final decision of the design direction was made taking into account personal learning objectives and project outcomes. Realistically, these variables should not be taken into account when choosing a design direction in a professional setting. In this case, the client's wishes should have a stronger weight. Eventually, this could have resulted in a different design track, for example, an innovative persuasive game without a hardware element to reduce the costs.

During the final evaluation of the prototype with the practice nurse, it seemed that still questions were raised towards the understandability of the interface. It was mentioned that the participants of the second user evaluation were still considered to be of above average intelligence. In addition, the participants that participated in the final user evaluation were considered to be language ambassadors. It can be suspected that, even though their literacy skills are below average, they still have a reasonable amount of health literacy. Although a majority of the target group would be able to understand the interface, it still remains to be questioned whether the more extreme cases of LHL are able to understand it.

Overall, the project results would have benefitted from a larger sample of the target group during the evaluations. Within this project, the evaluations took place with a rather small user group, and within these user groups, it also seemed that in some cases, the users did not exactly match the predetermined profile. Within the project, additional validation was constantly integrated through the involvement of experts. Still, the overall quality would have had benefit from a larger sample during the user evaluations.

Acknowledgements

I would like to express my very great appreciation to everyone who has been involved in this project.

First of all, my TU Delft supervisors, Natalia and Tessa, thank you for all the valuable knowledge, advice and feedback.

I would like to offer my special thanks to Charlotte, my company mentor, who provided me with the opportunity to do this project, but also with an invaluable network of experts, patients, and knowledge.

I am particularly grateful for the services provided by Janneke. Thank you for your enthusiastic contributions, the sharing of experiences and the provision of connections to your patients. I want to thank Adri for making it possible to conduct the research at her facility and providing valuable suggestions about the implementation.

I wish to acknowledge the hospitality provided by Jeannette and Nienke.

Advice given by Persijn, Richi, Job, Haci, Manouk, Jorge, Valentijn and Naomi have been a great help in the project.

Thank you, Eline and Pharos for making it possible to perform an evaluation on such short notice.

Thanks to all the asthma patients, that shared their experiences and opinions.

Thank you mom and dad for the support all the way up to this point, thanks to my brother who made it possible to have an intern while being an intern, and thank you Robin for all the mental support.

And everyone else, thank you.

References

Australian Asthma Handbook. (n.d.). Providing information, skills and tools for asthma self-management for adults. Retrieved June 29, 2019, from https://www.asthmahandbook.org.au/management/adults/self-management/education

Bailey, S. C., Oramasionwu, C. U., & Wolf, M. S. (2013). Rethinking adherence: a health literacy–informed model of medication self-management. Journal of health communication, 18(sup1), 20-30.

Bandura, A. (2001). Social cognitive theory: An agentic perspective. Annual review of psychology, 52(1), 1-26.

Bartholomew, L. K., Parcel, G. S., & Kok, G. (1998). Intervention mapping: a process for developing theory and evidence-based health education programs. Health education & behavior, 25(5), 545-563.

BeBright. (2019). Healthcare Enablers. Retrieved from https://www.zorgenablers.nl/healthcare-enablers.html

Bentur, L., Beck, R., Shinawi, M., Naveh, T., & Gavriely, N. (2003). Wheeze monitoring in children for assessment of nocturnal asthma and response to therapy. European Respiratory Journal, 21(4), 621-626.

Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. Annals of Internal Medicine, 2011; 155(2):97-107.

Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: Longitudinal cohort study. BMJ, 2012; 344:e1602.

Buskermolen, D. O., & Terken, J. (2012, August). Co-constructing stories: a participatory design technique to elicit in-depth user feedback and suggestions about design concepts. In Proceedings of the 12th Participatory Design Conference: Exploratory Papers, Workshop Descriptions, Industry Cases-Volume 2 (pp. 33-36). ACM.

Cashen, M. S., Dykes, P., & Gerber, B. (2004). eHealth technology and Internet resources: barriers for vulnerable populations. Journal of Cardiovascular Nursing, 19(3), 209-214.

CBS Statline 2017: Voorgeschreven medicijngebruik in de afgelopen 14 dagen, naar onderwijsniveau.

Chan, C. V., & Kaufman, D. R. (2011). A framework for characterizing eHealth literacy demands and barriers. Journal of medical Internet research, 13(4).

CE Check. (2019, April 5). Medical Device Classification and Their Routes to CE Marking. Retrieved June 28, 2019, from https://ce-check.eu/medtech/medical-device-classification-routes-ce-marking/

Davis K. J., DiSantostefano R., Peden D. B. Is Johnny wheezing? Parent-child agreement in the Childhood Asthma in America survey. Pediatric Allergy and Immunology. 2011;22(1):31–35. doi: 10.1111/j.1399-3038.2010.01016.x.

Fagnano, M., Halterman, J. S., Conn, K. M., & Shone, L. P. (2012). Health literacy and sources of health information for caregivers of urban children with asthma. Clinical pediatrics, 51(3), 267-273.

Fishbein, M., & Ajzen, I. (2011). Predicting and changing behavior: The reasoned action approach. Psychology Press.

Galesic, M., & Garcia-Retamero, R. (2013). Using analogies to communicate information about health risks. Applied Cognitive Psychology, 27(1), 33-42.

Gillissen, A. (2007). Patients' adherence in asthma. Journal of physiology and pharmacology, 58(5), 205-222.

Giraud, V., & Roche, N. (2002). Misuse of corticosteroid metered-dose inhaler is associated with decreased asthma stability. European Respiratory Journal, 19(2), 246-251.

Gollwitzer, P. M. (1999). Implementation intentions: Strong effects of simple plans. American psychologist, 54(7), 493.

Halpin, D. M., Decramer, M., Celli, B. R., Mueller, A., Metzdorf, N., & Tashkin, D. P. (2017). Effect of a single exacerbation on decline in lung function in COPD. Respiratory medicine, 128, 85-91.

Heijmans M., Brabers A. & Rademakers J., Health Literacy in Nederland. Utrecht: Nivel, 2018

Herndon, J. B., Chaney, M., & Carden, D. (2011). Health literacy and emergency department outcomes: a systematic review. Annals of emergency medicine, 57(4), 334-345.

Horne, R., Weinman, J., Barber, N., Elliott, R., Morgan, M., Cribb, A., & Kellar, I. (2005). Concordance, adherence and compliance in medicine taking. London: NCCSDO, 2005, 40-6.

Ignacio-Garcia, J. M., & Gonzalez-Santos, P. (1995). Asthma self-management education program by home monitoring of peak expiratory flow. American journal of respiratory and critical care medicine, 151(2), 353-359.

Jensen, J. D., King, A. J., Davis, L. A., & Guntzviller, L. M. (2010). Utilization of internet technology by low-income adults: the role of health literacy, health numeracy, and computer assistance. Journal of aging and health, 22(6), 804-826.

Jin, F., Sattar, F., & Goh, D. Y. (2008, August). Automatic wheeze detection using histograms of sample entropy. In 2008 30th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (pp. 1890-1893). IEEE.

Kayser, L., Kushniruk, A., Osborne, R. H., Norgaard, O., & Turner, P. (2015). Enhancing the effectiveness of consumer-focused health information technology systems through eHealth literacy: a framework for understanding users' needs. JMIR human factors, 2(1).

Kerstjens, H. A., Brand, P. L., de Jong, P. M., Koeter, G. H., & Postma, D. S. (1994). Influence of treatment on peak expiratory flow and its relation to airway hyperresponsiveness and symptoms. The Dutch CNSLD Study Group. Thorax, 49(11), 1109-1115.

Kim, E. S., & Shkel, A. A. (2019). U.S. Patent Application No. 16/156,689.

Kok, G., Gottlieb, N. H., Peters, G. J. Y., Mullen, P. D., Parcel, G. S., Ruiter, R. A., ... & Bartholomew, L. K. (2016). A taxonomy of behaviour change methods: an Intervention Mapping approach. Health psychology review, 10(3), 297-312.

Larson, E. C., Goel, M., Boriello, G., Heltshe, S., Rosenfeld, M., & Patel, S. N. (2012, September). SpiroSmart: using a microphone to measure lung function on a mobile phone. In Proceedings of the 2012 ACM Conference on ubiquitous computing (pp. 280-289). ACM.

Li, S. H., Lin, B. S., Tsai, C. H., Yang, C. T., & Lin, B. S. (2017). Design of wearable breathing sound monitoring system for real-time wheeze detection. Sensors, 17(1), 171.

Maibach, E. W., & Cotton, D. (1995). Moving people to behavior change: a staged social cognitive approach to message design.

Manfreda, J., Becklake, M. R., Sears, M. R., Chan-Yeung, M., Dimich-Ward, H., Siersted, H. C., ... & Anthonisen, N. R. (2001). Prevalence of asthma symptoms among adults aged 20–44 years in Canada. Cmaj, 164(7), 995-1001.

Mayo Clinic Staff. (2018, September 13). Asthma - Diagnosis and treatment - Mayo Clinic. Retrieved April 6, 2019, from https://www.mayoclinic.org/diseases-conditions/asthma/diagnosis-treatment/drc-20369660

Martinez F. D. (2007). "Genes, environments, development and asthma: a reappraisal". European Respiratory Journal. 29 (1): 179–84

McFarland, D. J., & Hamilton, D. (2006). Adding contextual specificity to the technology acceptance model. Computers in human behavior, 22(3), 427-447.

Ministerie van Onderwijs, Cultuur en Wetenschap. (2019, March 18). Nieuwe ambities voor aanpak laaggeletterdheid. Retrieved April 9, 2019, from https://www.rijksoverheid.nl/actueel/nieuws/2019/03/18/nieuwe-ambities-voor-aanpak-laaggeletterdheid

Nabi, F. G., Sundaraj, K., Kiang, L. C., Palaniappan, R., & Sundaraj, S. (2019). Wheeze sound analysis using computer-based techniques: A systematic review. Biomedical Engineering/Biomedizinische Technik, 64(1), 1-28.

National Heart, Lung, and Blood Institute (NHLBI). (2018, May 2). Asthma. Retrieved April 6, 2019, from https://www.nhlbi.nih.gov/health-topics/asthma

NIVEL (2007), Factsheet Astma-/COPD-Monitor

Norgaard, O., Furstrand, D., Klokker, L., Karnoe, A., Batterham, R., Kayser, L., & Osborne, R. H. (2015). The e-health literacy framework: a conceptual framework for characterizing e-health users and their interaction with e-health systems. Knowledge Management & E-Learning: An International Journal, 7(4), 522-540.

O'Brien, H. L., & Toms, E. G. (2008). What is user engagement? A conceptual framework for defining user engagement with technology. Journal of the American society for Information Science and Technology, 59(6), 938-955.

Paasche-Orlow, M. K., & Wolf, M. S. (2007). The causal pathways linking health literacy to health outcomes. American journal of health behavior, 31(1), S19-S26.

Pampel, F. C., Krueger, P. M., & Denney, J. T. (2010). Socioeconomic disparities in health behaviors. Annual review of sociology, 36, 349-370.

Pavlosky, A., Glauche, J., Chambers, S., Al-Alawi, M., Yanev, K., & Loubani, T. (2018). Validation of an effective, low cost, Free/open access 3D-printed stethoscope. PloS one, 13(3), e0193087.

Peters, G.-J. Y. (2014). A practical guide to effective behavior change: How to identify what to change in the first place.
European Health Psychologist, 16(4), 142–155.

Philips. (2019, January 3). Three ways asthma treatment is getting connected. Retrieved April 9, 2019, from https://www.philips.com/a-w/about/news/archive/future-health-index/articles/20180430-three-ways-asthma-treatment-getting-connected.html

PIAMA, Preventie en Incidentie van Astma en Mijt Allergie geboortecohort.

Prochaska, J. O., Redding, C. A., & Evers, K. E. (2015). The transtheoretical model and stages of change. Health behavior: Theory, research, and practice, 125-148.

Puder, L. C., Wilitzki, S., Bührer, C., Fischer, H. S., & Schmalisch, G. (2016). Computerized wheeze detection in young infants: comparison of signals from tracheal and chest wall sensors. Physiological measurement, 37(12), 2170.

Rademakers J. (2014). Kennissynthese Gezondheidsvaardigheden. Niet voor iedereen vanzelfsprekend. NIVEL, Utrecht.

Raherison, C., Abouelfath, A., Gros, V. L., Taytard, A., & Molimard, M. (2006). Underdiagnosis of nocturnal symptoms in asthma in general practice. Journal of Asthma, 43(3), 199-202.

Rahimi, B., Nadri, H., Afshar, H. L., & Timpka, T. (2018). A systematic review of the technology acceptance model in health informatics. Applied clinical informatics, 9(03), 604-634.

Rofouei, M., Sinclair, M., Bittner, R., Blank, T., Saw, N., DeJean, G., & Heffron, J. (2011, May). A non-invasive wearable neck-cuff system for real-time sleep monitoring. In 2011 international conference on body sensor networks (pp. 156-161). IEEE.

Schorsch, J (2018). FDA Regulations [Powerpoint slides]. Retrieved from https://brightspace.tudelft.nl/d2l/le/content/125571/viewContent/1194121/View

Schwarzer, R., Lippke, S., & Ziegelmann, J. P. (2008). Health action process approach: A research agenda at the Freie Universität Berlin to examine and promote health behavior change. Zeitschrift für Gesundheitspsychologie, 16(3), 157-160.

Shaharum, S. M., Sundaraj, K., & Palaniappan, R. (2012). A survey on automated wheeze detection systems for asthmatic patients. Bosnian journal of basic medical sciences, 12(4), 249.

Short, C. E., DeSmet, A., Woods, C., Williams, S. L., Maher, C., Middelweerd, A., ... & Hingle, M. (2018). Measuring engagement in eHealth and mHealth behavior change interventions: methodological overview. JOURNAL OF MEDICAL INTERNET RESEARCH, 20(11).

Sørensen, K., Van den Broucke, S., Fullam, J., Doyle, G., Pelikan, J., Slonska, Z., & Brand, H. (2012). Health literacy and public health: a systematic review and integration of definitions and models. BMC public health, 12(1), 80.

Stanford, An introduction to design thinking, process guide. Retrieved at 29/06/19 from: dschool-old.stanford.edu/sandbox/groups/designresources/wiki/36873/attachments/74b3d/ModeGuideBOOTCAMP2010L.pdf

Sterling, M., Rhee, H., & Bocko, M. (2014). Automated cough assessment on a mobile platform. Journal of medical engineering, 2014.

Stichting lezen en Schrijven (2015). Laaggeletterden: achterblijvers in de digitale wereld? Retrieved from https://www.lezenenschrijven.nl/uploads/editor/ecbo.15-217-Laaggeletterden-achterblijvers-in-de-digitale-wereld-web.pdf at 09/04/2019

Sudore, R. L., Mehta, K. M., Simonsick, E. M., Harris, T. B., Newman, A. B., Satterfield, S., ... & Yaffe, K. (2006). Limited literacy in older people and disparities in health and healthcare access. Journal of the American Geriatrics Society, 54(5), 770-776.

Tocchetto, M. A., Bazanella, A. S., Guimaraes, L., Fragoso, J. L., & Parraga, A. (2014). An embedded classifier of lung sounds based on the wavelet packet transform and ANN. IFAC Proceedings Volumes, 47(3), 2975-2980.

Tulder, M (2018). Health Technology Asessment [Powerpoint slides]. Retrieved from brightspace.tudelft.nl/d2l/le/content/125571/viewContent/1195864/View

Wildhaber J., Carroll W. D., Brand P. L. P. Global impact of asthma on children and adolescents' daily lives: the room to breathe survey. Pediatric Pulmonology. 2012;47(4):346–357. doi: 10.1002/ppul.21557.

Ylitalo, K. R., Meyer, M. R. U., Lanning, B. A., During, C., Laschober, R., & Griggs, J. O. (2018). Simple screening tools to identify limited health literacy in a low-income patient population. Medicine, 97(10).