

### **MASTER**

Evaluation of an eHealth combination among cardiovascular disease patients, relatives and healthcare professionals in a clinical setting a qualitative study

Bluemink,	M.E.
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Evaluation of an eHealth combination among cardiovascular disease patients, relatives and healthcare professionals in a clinical setting: a qualitative study

M.E. Bluemink 0867531

in partial fulfilment of the requirements for the degree of

Master of Science in Human-Technology Interaction

### Supervisors:

Dr. Ir. F. Beute Prof. Dr. J.H.D.M. Westerink E. Broers, MSc

In cooperation with:

Dr. M. Habibović Prof. Dr. J.W.M.G Widdershoven Eindhoven University of Technology Eindhoven University of Technology Tilburg University / Elisabeth-TweeSteden Hospital

Tilburg University / Elisabeth-TweeSteden Hospital Elisabeth-TweeSteden-Hospital

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### Abstract

Cardiovascular disease is the number one cause of mortality in the society. Alternative technologies such as eHealth have potential to improve lifestyle and to change the traditional models of cardiovascular care. Even though commercial eHealth is widely implemented, qualitative research and scientific evidence in relation to cardiovascular disease and eHealth in a clinical setting is lacking behind. The current study is part of an international collaboration of the Netherlands, Spain, and Taiwan, known as 'Do CHANGE project'. This project focuses on developing a personalized disease management system (ecosystem) for patients with hypertension, cardiovascular disease, and heart failure.

The current study consists of three parts: Study One explored the barriers and opportunities of the Do CHANGE ecosystem among healthy elderly of the general population who have got in touch with the technology the first time. Study Two investigated the user experiences and adaptation of the ecosystem of cardiac disease patients and their relatives. Last, Study Three examined experiences, benefits and opportunities of the ecosystem among healthcare professionals. A qualitative approach with interviews with healthy elderly (Study One; N=10), two focus groups with cardiac patients and relatives (Study Two; N=16), and interviews with healthcare professionals (Study Three; N=3) were conducted.

Overall results of Study One showed that healthy elderly were doubtful about their willingness to use the ecosystem. The obtained themes for Study One were: informative and supportive expectations, personal relevance, and societal relevance. In study Two, patients and their relatives generally experienced the ecosystem as beneficial and useful. The revealed themes of patients and relatives were information, awareness and reassurance, concerns and challenges, and contact with others. In Study Three, the investigation of experiences among healthcare professionals existed in two main themes: healthcare professionals emphasized the consequences of using the ecosystem for their patients, and the changes that applied for themselves. Patients, relatives, and healthcare professionals assigned an increase of awareness and reassurance among patients. Moreover, improved lifestyle effects, better informed patients, a reduction of necessary hospital visits, and an increased level of communication between patients and professionals were other results of using the Do CHANGE ecosystem. Technical issues, lack of personalization, required efforts to use the system, and privacy issues were mentioned as concerns by patients, relatives, and healthcare professionals.

Overall, this study provided deeper insights into user experiences and concluded with recommendation for further developments of the ecosystem as part of the Do CHANGE project. The healthy elderly in Study One expected more barriers compared to one who experienced the Do CHANGE ecosystem in Study Two and Three. The Do CHANGE ecosystem had an overall positive impact on lifestyle change, but patients had different and complicated user needs dependent of personal preferences and their condition. Hence, more personalization in messages and devices was desired among all participants.

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### List of abbreviations

ACS Acute Coronary Syndrome

AP Angina Pectoris
BMI Body Mass Index

CAD Coronary Artery Disease
CHD Coronary Heart Disease

COPD Chronic Obstructive Pulmonary Disease

CVD Cardiovascular Disease

Do CHANGE Do Cardiac Health Advanced New Generation Ecosystem

ECG Electrocardiogram

ETZ Elisabeth-TweeSteden Hospital

GPS Global Positioning System

HF Heart Failure
HT Hypertension

ICD Implantable Cardioverter Defibrillator

ICT Information and Communication Technology

METC Medical Ethical Committee

MI Myocardial Infarction
MS Multiple Sclerosis

WHO World Health Organization

### 1 Introduction

Cardiovascular disease (CVD) is the number one mortality and morbidity cause in the world (WHO, 2017a). Alarmingly, mortality numbers increased in different countries over the past years while the age among patients decreased (Sanchis-Gomar, Perez-Quilis, Leischik, & Lucia, 2016). CVD is a disease in the heart vessels and might have a high impact on daily life. Lifestyle aspects such as alcohol intake, smoking, inactivity, and excessive intake of too salty, sugared and fat food, are of influence on the CVD risk (WHO, 2017a). Depending on the type of CVD disease, tracking patient's behavior and physiology is necessary in successful management of the disease, rehabilitation, and prevention of further heart incidences (Graham et al., 2007; Montalescot et al., 2013).

CVD patients who are first diagnosed with the disease receive treatment. Traditional models of cardiovascular care focus on treatment in a hospital, and patients might attend a rehabilitation program in a clinical setting or at home afterwards. So, patients participate in a predefined program whether or not personalized to the needs of the person. Cardiovascular care has evolved from simple monitoring to an integrated and personalized program with multiple components such as risk factor management, education, and psychosocial care (Mampuya, 2012). However, the current healthcare model for CVD patients might not be suitable for the future because of rising healthcare costs, (mobile) self-tracking possibilities and new (medical) insights about rehabilitation and prevention strategies. Therefore, a new model of cardiovascular care may be necessary to retain care accessible and effective.

A potential candidate for the renewed cardiovascular care is the development of eHealth. According to the World Health Organization (WHO; 2017b), eHealth is defined as follows: "eHealth is the use of information and communication technologies (ICT) for health". Literature in eHealth research argues that eHealth has a potential benefit as a health intervention and can change models of care (e.g. Burke et al., 2015; Free et al., 2013; Mampuya, 2012; Nguyen & Silva, 2016; Neubeck, 2015; Pfaeffli Dale, Dobson, Whittaker, & Maddison, 2016) because it might primarily reduce CVD risk factors (Widmer et al., 2014) and change lifestyle (van den Brekel-Dijkstra et al., 2016). Moreover, the technology might improve self-reliance and autonomy that might result in shorter treatment and less care demand (van Kammen, 2002).

Recently, eHealth and mHealth have been extensively developed and have become increasingly important for self-management in general. This increase has also a downside because commercial eHealth is widely implemented in existed healthcare programs, but scientific research is lacking behind. Scientific evidence about effectiveness of current existing cardiovascular mobile applications and investigation for both patient's and healthcare professional's utility is missing (Chow et al., 2016). Moreover, evidence for mobile phone CVD interventions on long term base is absent, and it is unknown which part of the mHealth intervention is the successful component of the treatment (Neubeck, Cartledge, Dawkes, & Gallagher, 2017). Other scholars argued that more research is required because eHealth is not investigated in relation to in the current cardiovascular health care

system (Nguyen, Carrieri-Kohlman, Rankin, Slaughter, & Stulbarg, 2004; Park, Beatty, Stafford, & Whooley, 2016) and that evaluation of current eHealth systems is absent (Burke et al., 2015; Wade & Stocks, 2017).

Another remark is that qualitative research in relation to cardiovascular disease and eHealth is limited and existing research is mainly quantitative (Park et al., 2016; Ly et al., 2015). For example, participants had not experienced any system or application before providing their opinion about a smartphone health intervention application during a focus group; however, only general perspectives on smartphone applications in health were investigated (Dennison et al., 2013). A process whereby qualitative research was deployed during the design process combined with pilot testing and interviews. The process was a more effective investigation of patient feedback for of a web-based CVD rehabilitation intervention (Pfaeffli et al., 2012). Beatty, Fukuoka and Whooley (2013) suggested that mobile applications should be tested in both qualitative and quantitative way to validate usability, efficacy, efficiency and user satisfaction because the optimal mobile intervention for cardiovascular rehabilitation is still unknown. So, qualitative research methods are desired to evaluate eHealth tools next to quantitative effects of the eHealth intervention, to increase effectiveness and user acceptance.

The current study is part of the Do CHANGE program that aimed to develop a personalized management system for patients with hypertension (HT), CVD, and heart failure (HF) (Do CHANGE, 2017; Habibović et al., 2018). Today, the questions are generally unanswered: first, which combination of (individual) risk management, exercise training components, and psychosocial support is effective. Second, what will be accepted by patients (Beatty et al., 2013). Third, how do patients experience those eHealth formats (Ly et al., 2015). Because previous research focused on independent trials, this eHealth evaluation was integrated in the existing healthcare. Hence, in order to expand the knowledge in the eHealth domain in combination with cardiology in a clinical setting, this study aimed to qualitatively explore the usage and benefits for patients, relatives and healthcare professionals of a cardiovascular eHealth intervention. Definitions of CVD, eHealth, and Do CHANGE will be discussed in the theoretical background chapter to provide underlying knowledge before the current research question will be presented.

## 2 Theoretical background

The theoretical background focuses on the definitions and explanations of CVD, existing literature about eHealth in relation to CVD and other diseases, the Do CHANGE study, and the research questions as well as aims of the current study.

### 2.1 Cardiovascular disease

This section describes the background of cardiovascular disease, risk factors, its rehabilitation, and (secondary) prevention.

### 2.1.1 Cardiovascular disease description

Cardiovascular disease (CVD) is the general term for a disease group of heart and vessels and it includes multiple diseases (WHO, 2017a). Moreover, many patients have comorbidities such as diabetes mellitus (25.8%), chronic obstructive pulmonary disease (COPD; 19.6%), and cancer (18.7%; Hartstichting, 2015). Providing an overview of all CVD types, its characteristics and symptoms is too extensive and out the scope of this report. Therefore, only the relevant disease types will be highlighted in Table 1.

Table 1: Relevant cardiovascular disease terminology

Cardiovascular disease	Abbreviation	Characteristics
type		
Cardiovascular Disease	CVD	General overall term for heart muscle and blood vessels
		diseases in the brain and heart (WHO, 2017a).
Coronary Heart Disease	CHD	General overall term for heart disease; blood vessels in
		the heart muscle (WHO, 2017a).
Coronary Artery Disease	CAD	Category of CVD and results to CHD (Sanchis-Gomar et
		al., 2016). CAD causes plaques narrow in the coronary
		arteries and lowers blood flow (Rimmerman, 2013).
Acute Coronary Syndrome	ACS	Subcategory of CAD (Sanchis-Gomar et al., 2016).
Myocardial Infarction	MI	Subcategory of ACS; better known as a heart attack
		(Rimmerman, 2013)
Heart Failure	HF	Insufficient heart pump function, e.g. the heart does not
		fill with enough blood and/or the heart has not enough
		strength pumping blood to the body. (National Heart,
		Lung, and Blood Institute, 2015)
Hypertension	HT	High blood pressure in the blood vessels. One has a
		hypertension if the blood pressure is higher than 140
		mmHg of systolic blood pressure (SBP) or ≥90 mmHg of
		diastolic blood pressure (DBP) (WHO, 2015)

#### 2.1.2 Risk factors of cardiovascular disease

CVD healthcare can be divided in different types of care; primary prevention, rehabilitation and secondary prevention. Understanding the patient's risk factors is necessary for rehabilitation, primary-and secondary prevention. Primary prevention focuses on prevention for a CVD diagnosis or incidence (Pearson et al., 2002), while secondary prevention focuses on repetition of an incidence among already diagnosed CVD patients (Leon et al., 2005; Piepoli et al., 2010). Those risk factors differ from person to person and cardiac rehabilitation might also be dependent of other diseases of the patient next to CVD (Appelman, van Rijn, ten Haaf, Boersma, & Peters, 2015; Neubeck et al., 2016; Prince, Reid, Pipe, & McDonnell, 2017).

Knowing the CVD risk factors is essential for reducing the CVD impact and possible disabilities (Piepoli et al., 2016). Cardiac rehabilitation is among others used to influence CVD risky behavior. The Dutch rehabilitation committee described that risk factors can be divided in two groups (Revalidatiecommissie NVVC/NHS, 2011). The first group assigns risk factors that could not be influenced by someone's behavior or a treatment (e.g. unmodifiable risk factors) and has four aspects. First, gender is a risk factor, because men have a higher risk for mortality within ten years compared to women (Piepoli et al., 2016). Second, a higher age implies also a higher risk (Piepoli et al., 2016). Third, family history regarding CVD at younger age is a risk factor. Fourth, personal history of cardiovascular diseases is the final factor. So, if one for example already experienced a cardiac incidence in the past repetition is plausible. The second risk group includes risk factors that could be affected by, for example someone's behavior (e.g. modifiable risk factors). Those factors are for example: overweight, smoking, excessive usage of alcohol, physical inactivity, increased cholesterol, increased blood pressure, and unhealthy food intake (Lloyd-Jones et al., 2009; Piepoli et al., 2016; Revalidatiecommissie NVVC/NHS, 2011). Besides the two group types, other overviews highlight also risks factors for CVD such as diabetes (Lloyd-Jones et al., 2011), and psychosocial factors like depression, anxiety, and distress (Montalescot et al., 2013).

### 2.1.3 Cardiac rehabilitation

According to the Dutch rehabilitation committee (Revalidatiecommissie NVVC/NHS, 2011), cardiac rehabilitation is a personalized program that evaluates the patient's medical program. It includes predefined exercises, psychological consults and advices aiming for risk factor change. The cardiac rehabilitation is a six to twelve-week program and contains certain physical, psychological, social, and behavioral goals managing the changeable risk factors. Specific goals are for example managing anxiety for physical exertion, recovering of emotional balance in social environment and work, stop smoking, regulate medicine intake, physical activity counseling, and development of a healthy diet (Leon et al., 2005; NICE, 2013; Revalidatiecommissie NVVC/NHS, 2011; Piepoli et al., 2010). Goals could be individually formulated; depending on the goals, healthcare professionals could offer the patient individual treatment, group sessions or no interventions at all (Revalidatiecommissie

NVVC/NHS, 2011). It is proven that rehabilitation improves the quality of life and decreases morbidity and mortality among cardiac patients (Revalidatiecommissie NVVC/NHS, 2011; Piepoli et al., 2010).

According to the Dutch guideline, the cardiac rehabilitation has to be accessible for everyone and should be offered as fast as possible after hospital discharge (two to maximum four weeks after discharge) (Revalidatiecommissie NVVC/NHS, 2011). However, the advice about when to offer the rehabilitation is different compared to the UK guidelines of National Institute for Health and Care Excellence (NICE; 2013). They advise to offer rehabilitation before hospital discharge to patients who experienced a Myocardial Infarction (MI).

Cardiac rehabilitation should be offered to patients at high risk for MI or experienced MI, and who are motivated to participate (Revalidatiecommissie NVVC/NHS, 2011). In the study of van Engen-Verheul et al. (2013), cardiac rehabilitation in the Netherlands was investigated based on insurance claims. They found that only a minority of the qualified patients for rehabilitation actually received this within a year; Only 28,5% of all the Acute Coronary Syndrome (ACS) patients and 3.0% of chronic Heart Failure (HF) participated in a rehabilitation program.

The National Institute for Health and Care Excellence (NICE) even argued that rehabilitation should be offered to all people who experienced a MI. However, only 44% of the patients attend rehabilitation after MI while the efficacy of rehabilitation is proven in literature and patients could benefit from it (NICE, 2013). Beside the NICE, Taylor and colleagues (2004) investigated rehabilitation in a meta-analysis and they found that exercise-based rehabilitation is beneficial for cardiac patients because it lowers mortality. However, they concluded that exercise-based rehabilitation did not influence risk factors of a further MI (Taylor et al., 2004).

#### 2.1.4 Prevention

Literature distinguishes rehabilitation and prevention. While rehabilitation is a short-personalized program after a cardiovascular incidence improving one's condition, primary prevention embraces an improved lifestyle behavior change on longer term aiming to avoid CVD in principal in the whole population (Graham et al., 2007). Secondary prevention has the same objective as general primary prevention, although this intervention type is to prevent iteration of a cardiovascular incidence such as a MI by in patients with already established CVD. Rehabilitation is a short-predefined program, while primary and secondary prevention encourages long-term lifestyle change which should be implemented in daily life. Both rehabilitation and prevention focuses on a better lifestyle and behavior change such as physical activity, stop smoking, medicine intake, and a balanced food intake. The goal is to make patients responsible for their own life and learn self-managing their risk factors.

Perk and colleagues (2012) described several reasons why prevention of CVD is desired. They argued that prevention functions, because of the improved treatments and the reduced mortality related risk-factors by CHD patients. Moreover, they mentioned that it is still possible to improve

prevention by managing risk factors. However, we do not know the long-term cost effectiveness of the cardiac prevention because this has been hardly investigated in literature and was mainly simulated. Cost effectiveness is depending on multiple complicated factors such as the country, population age and total cost of the interventions (Piepoli et al., 2016). Even though cost effectiveness evidence was limited, it is expected that governments, healthcare professionals, insurers, and policy makers will advocate for extension of cardiac prevention and rehabilitation in the future reducing CVD mortality and healthcare costs.

Today, the discussion focuses how we should develop cardiac rehabilitation and secondary prevention in the current changing healthcare domain. Whereas the first rehabilitation strategies only focuses on physical exercising is the current rehabilitation more complex and extended nowadays. Programs are more personalized in a home based or hospital setting (Mampuya, 2012). However, the question arises how we could implement lifetime achievement and increase rehabilitation participation among CVD patients in the future; eHealth might be a possible answer to this question.

### 2.2 eHealth

The expansion of eHealth over the past years resulted in a new field of research within healthcare and behavioral change. The developed eHealth interventions of five years ago might be already outdated due to fast developments. So, investigation of current eHealth interventions is necessary to improve the lifespan of those solutions. Studies with diseases such as depression, diabetes mellitus, and weight loss will also be considered because scientific research in the eHealth domain is rising, and the insights about eHealth with other diseases than CVD are valuable. This section first affords a definition of eHealth, followed by barriers and opportunities of initial usage of eHealth. Furthermore, the section provides in depth insights of existing research about eHealth, both in general, which is more qualitatively focused, and in relation to CVD, which is more quantitatively focused.

#### 2.2.1 eHealth definition

Different terms are used in relation to the concept of eHealth: telecommunication, telemedicine, telehealth, mHealth, mobile health, and digital health interventions are, for example, concepts that are regularly used in literature and related to care at a distance. A definition of eHealth was not clearly defined, and the other mentioned concepts were also interchangeably used instead of the concept eHealth while minimal differences occured between the concepts. Oh, Rizo, Enkin, and Jadad (2005) provided a systematic review about the definition of eHealth. They concluded that implicit understanding of the concept of eHealth occurs and that multiple definitions share terms such as "health", "internet", and "technology". Furthermore, the technology is used to support the human instead of replacing human (Oh et al., 2005). For the current study, the definition of Pagliari et al. (2005) that was adapted from Eysenbach (2001) is used:

"eHealth is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology" (Pagliari et al., 2005, p. 10).

### 2.2.2 Cardiovascular disease, healthcare and eHealth

Inspired on the model of Honeyman, Ding, Varnfield and Karunanithi (2014), Figure 1 presents an overview of possible types of healthcare during CVD and its goal. EHealth should adopt de goals of that certain CVD stage, providing optimal care to the patient. Up to now, literature demonstrated that eHealth focused mostly on one healthcare part or combined maximum two types. Klasnja and Pratt (2012) also distinguished five general intervention strategies for mHealth: tracking health behavior, involvement of the healthcare team, enable social influence of patients' environment, health information accessibility, and utilizing of entertainment. Those strategies are also present in current developed CVD eHealth interventions to a certain extent. There was no eHealth possibility found in literature that covered all types of CVD healthcare of Honeyman and colleagues (2014) or adapted all the five intervention strategies of Klasnja and Pratt (2012).

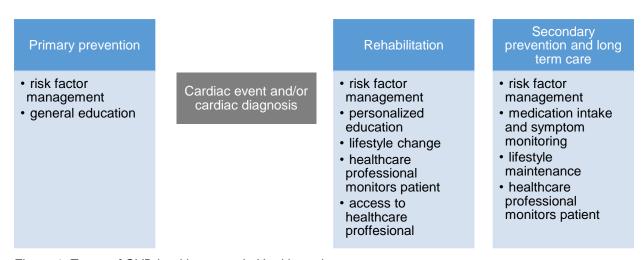


Figure 1: Types of CVD healthcare and eHealth goals

It should be noted that all the next described telemonitoring or eHealth interventions focused on one or more risk factors of CVD patients or other diagnoses (e.g. diabetes). Systems that provide an integrated solution are necessary for the future controlling prevention and rehabilitation of CVD. Those systems should be evaluated in both a quantitative and qualitative manner to prove efficiency and user acceptance.

### 2.2.3 Existing research of eHealth and other diseases

Three existing studies with other diseases than CVD will be illustrated, namely: depression, diabetes, and weight loss. Those studies are relevant for the current study because those diseases have

similarities in treatment approach and corresponding risk factors with CVD. Moreover, CVD patients might be diagnosed with comorbidities and, therefore, a broader perspective on qualitative research on other diseases than CVD is valuable.

First, Ly et al. (2015) investigated a qualitative review of the usage of a smartphone-based intervention as a depression treatment. The intervention included behavior activation using SMS messages such as: 'take a walk with a friend'. Users could weekly report their behavior and feelings to their therapist. The therapist could also reply to their patients (Ly et al., 2014). Participants were interviewed six months after finishing their eight-week treatment. Results addressed that participants generally experienced the behavior activation intervention as positive. Participants felt that they had better access to treatment in their daily life. They felt more awareness of their daily problems and how they could manage these. Remarks about the intervention were, for example, about the personalization and the lack of possibility to interact with their therapist. Some participants experienced the prescribed exercises as too general, irrelevant for themselves, and those were insufficiently varied (Ly et al., 2015). This study has relevance for the current study because of the comparable messages content and the intended behavior change. Although, differences should be noted. The study of Ly and colleagues focused more on education, symptoms were more extensively tracked, and the intervention was only one application instead of set of devices compared to the current study.

Second, experiences of a diabetes smartphone coaching intervention were qualitatively evaluated by Pludwinski, Ahmad, Wayne, and Ritvo (2016). Patients could communicate with a health coach, could track their blood levels, exercise data, taking pictures of food intake, and mood registration (Wayne, Perez, Kaplan, & Ritvo, 2015). Eleven participants who had used the intervention for six months were interviewed about their experiences and their health behavior change. Results showed that participants experienced more self-activation. They were more aware about their current health status and food intake due to the photo reporting. Next to that, participants indicated that the intervention was helpful and supported to focus on diet, medication, blood glucose monitoring, and exercising. Participants reported the coach component as supportive and felt more comfortable that someone was always available for help (Pludwinski et al., 2016). Barriers were limited reported, but it revealed that some individuals experienced that they were being followed in their progress.

Third, a meta-analysis of Lyzwinski, Caffery, Bambling, & Edirippulige (2017) compared twenty qualitative studies focusing on experiences of weight loss mHealth applications. Several themes appeared in the comparison; relevant themes related to the current study were, for example, the tone of messages (messages should have an education component but should also be supportive and sensitive), the simplicity of operating the application (the system should be easy to use), and frequency of messages (it is still unknown how many messages are ideal). Furthermore, the theme personalization resulted in the main theme of the meta-analysis. Participants preferred personalized messaged such as referrals to local sport possibilities, messages adjusted to personal schedules, and age-related instructions (Lyzwinski et al., 2017).

The three described studies demonstrated that qualitative participant feedback on eHealth is valuable. Those supported each other in the fact that eHealth could provide awareness about health and possibilities for contact. It is important to investigate user experiences next to quantitative results like blood pressure and weight control, because one could understand experiences and its rationale of users. However, one cannot generalize the obtained information in qualitative research due to low sample sizes and individual preferences and differences of the participants. More research is required to obtain in depth insights regarding to eHealth in general and in relation to CVD.

### 2.2.4 Existing research of eHealth and cardiovascular disease

Studies regarding to eHealth and CVD focuses mainly on rehabilitation programs. Prevention, both primary as secondary, is less investigated. This section presents several interesting results of existing programs with eHealth regarding to CVD.

#### 2.2.4.1 Prevention based on risk factors

Studies regarding to prevention (both primary and secondary) and CVD focused mostly on improvement of risk factors. A web-based program (both website and mobile phone) for primary prevention aimed to improve a healthy lifestyle and reduce cardiovascular risk factors (Widmer et al., 2014). Results showed a significant improvement in BMI (Body Mass Index), blood pressure, some cholesterol levels, and glucose. This might imply that a web-based program could be deployed as primary CVD prevention.

Several meta analyses concluded that digital health interventions influenced CVD patients by secondary prevention and risk factors such as weight reduction, improvement of BMI (Widmer, Collins, Collins, West, Lerman, & Lerman, 2015), physical activity, medicine intake (Pfaeffli et al., 2016), behavior change, and clinical improvement (Park et al., 2016). Evidence is still limited since few studies investigated this topic and variables used in the different studies were inconsistent. The scholars demonstrated the possible benefit of using mobile phone intervention during secondary prevention.

Looking at individual studies on secondary prevention, significant results on risk factors (physical activity, cholesterol levels, systolic blood pressure, and smoking) were found in the intervention group compared to the control group among CHD patients in a study of Chow et al. (2015). For six months, participants received on a weekly base four motivational and informative text messages on their mobile phone next to their usual care. The control group received only the usual care for their disease. Comparable results among ACS patients were found by Blasco and colleagues (2012); however, they did not find differences in smoking cessation between intervention and control group.

All those studies focused on evaluations of lifestyle change (e.g. be more physically active and healthy food intake) and medical improvement (e.g. lower blood pressure and less weight), beside the user experiences that were investigated. For example, the study of Athilingam et al. (2016) preliminary

evaluated the HearthMapp for HF patients with functions to motivate, change unhealthy behavior, provides information about the disease, and shows statistics. However, this evaluation was still a quantitative approach.

An example of a two-step evaluation was the investigation of Leon, Surender, Bobrow, Muller and Farmer (2015) and Bobrow et al. (2016). A clinical trial in South Africa with SMS messages for blood pressure control and medicine intake for Hypertension (HT) patients was evaluated with physical effects and user experiences. Participants were divided in three groups: one group received medical information with SMS messages, another interactive group received the same information as the information group, but those people could interact and respond to those messages. The third was the control group where participants received only usual care and non-medical SMS messages. Results showed a decrease in blood pressure in all groups after twelve months. No differences were found between the information and the interactive group. However, there were significant differences between the interaction respectively the information group compared with the usual care group (Bobrow et al., 2016). The user evaluation with two focus groups and fifteen interviews showed that participants were overall satisfied about the intervention. For example, participants had more awareness of their disease, had more feelings of responsibility regarding their disease and felt healthier. Subsequently, different participants indicated the medicine intake reminders as useful while other participants did not need those messages. Furthermore, positive results were also assigned to socialness and motivation. Hence, participants felt more connected to the healthcare professionals because they had feelings of being cared by others (Leon et al., 2015). One remark that should be noted is that negative experiences were hardly reported in the evaluation of Leon and colleagues.

Thus, prevention and CVD factors were investigated in several studies. The results were promising but more research is required since conclusions about eHealth were sometimes contradicted and effects on long term perspective were unknown.

### 2.2.4.2 Rehabilitation

The eHealth interventions were mostly investigated in relation to rehabilitation programs. Several scholars have shown beneficial results for home based programs; interventions were well received among patients who refuse regular rehabilitation enrolment for several reasons (Worringham, Rojek, & Stewart, 2011), it is an alternative for standardized rehabilitation (Varnfield et al., 2014), it might be a potential intervention in underdeveloped counties (Alsaleh, Windle, & Blake, 2016), and smartphone-based intervention during or after cardiac rehabilitation might imply a decrease of emergency department visits and rehospitalizations of patients (Widmer, Allison, Lerman & Lerman, 2015). Using the rehabilitation programs, significant results were found related to an increase in physical activity, number of steps, quality of life (Alsaleh, Windle, & Blake, 2016), and a decrease in weight (Widmer, Allison, et al., 2015), and blood pressure (Alsaleh, Windle, & Blake, 2016; Widmer, Allison, et al., 2015).

In contrast, other studies demonstrated less or no differences in outcomes between hospital rehabilitation versus home rehabilitation telemonitoring programs. Significant improvements such as a walking test, mental health, and dietary intake (Varnfield et al., 2014), work load, and exercise duration (Korzeniowska-Kubacka, Dobraszkiewicz-Wasilewska, Bilińska, Rydzewska, & Piotrowicz, 2011) were present in both intervention as control groups. Moreover, no results were found at the other dimensions such as blood pressure (Korzeniowska-Kubacka et al., 2011)

Those studies focused on physical outcomes of CVD, but it might also interesting to investigate the perceived usefulness and user acceptance of eHealth. Salvi et al. (2017) conducted a study with questionnaires and concluded that their home based mobile program for rehabilitation showed high levels of user acceptance and usefulness in the intervention group. However, high dropout numbers (13 out of 55 participants) existed due to technical problems and experiences of difficulty. So, the experiences of those participants were not included in the study of Savi and colleagues (2017), and the results might be distorted. In addition to this, it should be noted that high drop outs are a general problem in eHealth research (Eysenbach, 2005).

In contrast, a qualitative evaluation of rehabilitation program was conducted by Thorup and colleagues (2016). They interviewed twenty twelve cardiac participants who used a step counter during their rehabilitation program for three months. Moreover, they interviewed three healthcare professionals. However, this evaluation focused only on this separate device, the results might be valuable because both patients' and healthcare professionals' perspective was explored. Results demonstrated that participants felt more autonomy because of among others more awareness of their walking behavior, there was more competence because of a step goal possibility, and an improved relation between patient and healthcare professional due to supportive and observing aspects (Thorup et al., 2016).

Comparable results were found in a qualitative evaluation of a system among eighteen HF patients and five healthcare professionals (Fairbrother et al., 2014). The service was not focused on rehabilitation but aimed for self-management of the disease and increasing quality of life. Overall, the system was positively evaluated, and several themes were revealed. For example, patients were better informed about their own health, there was an increased level of communication between patients and healthcare professionals, and participants felt more reassured because they were monitored by professionals. In contrast, patients indicated that they had experienced technical problems, and felt less feelings of responsibility for their own health and self-management, because healthcare professionals were primary responsible for their patients' health. Healthcare professionals expressed that they consider the intervention as a short-term solution for their patients. They reported that they had a more extensive overview of the patient's health condition. Some healthcare professionals provided only beneficial aspects when patients were discharged from hospital; they aimed for a stable health. Controversy, they mentioned also the expected workload when using the intervention, they experienced technical problems (Fairbrother et al., 2014).

To summarize, different studies showed that cardiac rehabilitation with eHealth is promising in user acceptance and physical improvements. However, the physical outcomes were not straightforward, and more research is still required to verify outcomes of existing research in relation to CVD rehabilitation.

### 2.3 Do CHANGE

The current study is part of the larger project Do Cardiac Health Advanced New Generation Ecosystem (Do CHANGE). Do CHANGE is an eHealth program focusing on CVD patients and healthcare professionals by secondary prevention. It was a three years study program with funding of the Taiwanese government and European Union and is already accepted by the Medical Ethical Committee (METC). The study investigated eHealth among patients with HT, CVD, and HF in Taiwan, Spain and the Netherlands (Habibović et al., 2018).

The total Do CHANGE program included a development of a patient life management health ecosystem aiming at behavior change and managing CVD disease. Do CHANGE was a collaboration between ten partners such as universities, hospitals and (research) companies. It was an unique project because the eHealth was partly developed; the system consisted of a set of existing (mobile) devices (i.e. ecosystem). The overall goal of the Do CHANGE study was the development of a personalized disease management system for patients with Hypertension (HT), Heart Failure (HF), or Coronary Artery Disease (CAD). They intended to create a new healthcare service, in which all the stakeholders were involved such as patients, relatives, healthcare professionals, and policymakers.

During the whole program, there were two different trials whereby participants in the first trial received a part of the ecosystem and participants in the second trial received the total ecosystem. The current study focused on the evaluation during the second part of the trial in the Netherlands. Participants (N=75, the Netherlands) in the second trial used the ecosystem by themselves for six months. Participants were weekly called for three months about their process. After that time period, participants were no longer called but they could call voluntarily during the entire six-month period. A control group (receiving care as usual) was present and both the intervention as control group filled in questionnaires (among others: quality of life, depression, and lifestyle) at the beginning, halfway and after six months. The ecosystem would be used and evaluated in a clinical trial (Habibović et al., 2018). The results of this trial will be reported elsewhere for the Do CHANGE study (Do CHANGE, 2017).

CVD patients who were included into the intervention group of the Do CHANGE study, received a set of devices and mobile applications: the ecosystem. Figure 2 shows the Do CHANGE ecosystem that consists a medical and a lifestyle part.

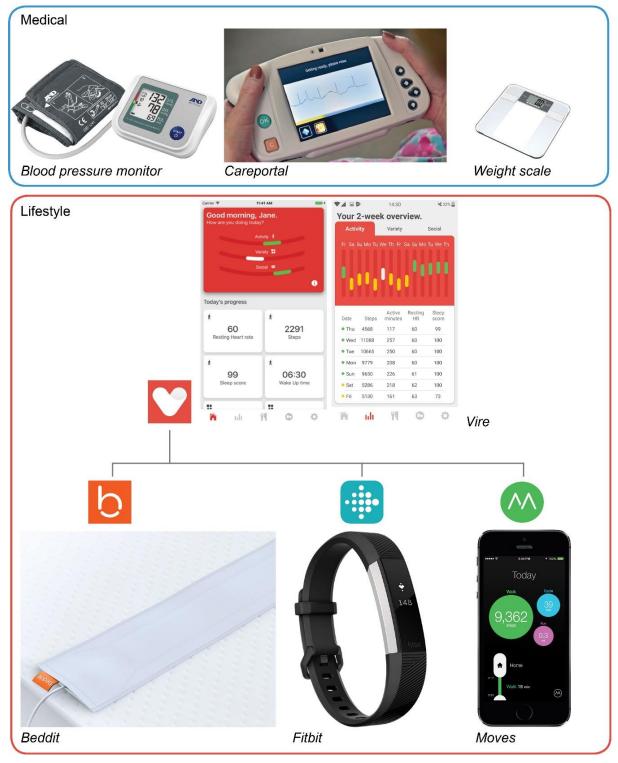


Figure 2: Do CHANGE ecosystem (Images adapted from: Direct2public, 2018; Docobo, 2015; Fitbit, 2018; Health-Care equipment, 2018; Moves, n.d.; Wetzels, 2017)

The first part of the Do CHANGE ecosystem in the medical part is the blood pressure monitor. Patients had to measure their blood pressure twice a day. Second, the Careportal consists of multiple components which patients filled in twice a day. They were asked about their symptoms, an ECG (Electrocardiogram) was made, patients filled in their weight and outcomes of the blood pressure monitor. Moreover, patients received motivational messages so called: 'To Do's'. This is a behavior coaching program whereby patients would be activated to change their habits and aimed for more flexibility. Patients receive messages such as: 'Try another vegetable than you are used to'. Third, only HF patients received also a weight scale because of disease specific reasons.

The lifestyle part of the ecosystem consisted four technologies. First, the Beddit which measured sleep patterns, sleep duration, heartrate. and breathing. It must be placed on the bed under the fitted sheet and the mobile application was installed on the smartphone. Second, the Fitbit is an activity device that measured number of steps, total number of active time, and calories. The Fitbit had a mobile application too and was installed on the smartphone. Third, Moves is an application that was installed on patient's smartphone and measured location and tracks displacement. Based on that, the extent of socialness was calculated and 'To Do's' were generated on this data. Fourth, the Vire application merged information about the Fitbit, Beddit, Moves together. This application was specially developed for the Do CHANGE program. Next to that, patients could make pictures of their food (at least three times a day), receive 'To Do's', and track their overall progress (Do CHANGE, 2017; Habibović et al., 2018).

### 2.4 Current study

Although several studies already demonstrated that eHealth has beneficial outcomes for rehabilitation, achieve behavior change, and influencing risk factors, more investigation and exploration of eHealth in relation to CVD is important because the question remains whether one would accept the intervention. Patients accept an eHealth system when they actually were diagnosed with CVD and if healthcare professionals were willing to use eHealth if they should work with it during their work (Dünnebeil et al., 2012; Gagnon et al., 2012). Moreover, eHealth might also influence relatives if their loved ones had to use an eHealth system for a longer period.

The current study focused on the evaluation of the ecosystem of the Do CHANGE study in the second trial. The aim of this study is threefold. First, it was an exploration of the expectations, barriers, and opportunities of the ecosystem among inexperienced and undiagnosed CVD healthy elderly of the general population. This was obtained since participants of the Do CHANGE study already accepted to participate in the program while the participants that had actual reasons to reject or had barriers to the study could refused participation. Second, experiences of the usage of the ecosystem by patients and relatives were investigated. Third, experiences of the ecosystem from a healthcare professionals' perspective were examined. Those evaluations were important to investigate the question why and how participants were (dis)satisfied about the ecosystem. This three-part study aimed to explore this

field with the higher objective to develop the ecosystem of the Do CHANGE project in the future and gained more information about how the different stakeholders dealt with eHealth and disease experience.

The research question is formulated as following:

What are the barriers and opportunities for patients, healthcare professionals, and relatives of using the ecosystem of the Do CHANGE project?

### The following sub-questions are derived:

- Part 1: What are the first impressions of healthy elderly with regards to potential barriers and opportunities of the ecosystem?
- Part 2: How do patients and relatives experience the use of the ecosystem and did it help them manage their/relatives' disease better?
- Part 3: How do healthcare professionals experience the ecosystem, and do they see benefits and barriers for themselves and their patients?

### 3 Method

This study explored potential barriers and opportunities about an eHealth system among healthy elderly and the user evaluation of the same system among patients, their relatives, and healthcare professionals. Therefore, this study was separated in three different parts. A pre-Study One with interviews with healthy elderly, a main Study Two with CVD patients and their relatives participating in a focus groups, and interviews with healthcare professionals in Study Three. The methods of those three parts will be explained in this chapter.

### 3.1 Part 1: pre-study

#### 3.1.1 Design

A pre-study with semi-structured interviews was developed to gain more insights in barriers and opportunities of initial using the Do CHANGE ecosystem among healthy elderly of the general population at a first impression. The interviews were conducted between November 16, 2017 and November 21, 2017 at the USE laboratory in the IPO-building of the Eindhoven University of Technology, the Netherlands.

#### 3.1.2 Participants

Ten participants (five males and five females) were recruited for the interviews, with mean age 68.4 ± 6.9 years (range 53-77). The participants were invited through the J. F. Schouten database of the Eindhoven University of Technology with an email invitation. The email invite had a general description without mentioning technology or eHealth. Participants were not informed in the invitation that the lifestyle intervention was based on an eHealth application, to not scare off those who experience barriers in using these types of technology. Participants had to meet the following selection criteria: Dutch speaking, older than 50 years old, and not participating in the Do CHANGE project. Participants received €7,50 for their participation and €2 extra if they were no student or employee and came outside of the Eindhoven University of Technology.

Participants were not selected on any disease before participating the interviews. So, they were questioned if they had been diagnosed for CVD or another (chronic) disease. Three male participants indicated that they had a type of CVD or have been recovered from heart problems. One participant was diagnosed (ten years ago) with a hypertrophic cardiomyopathy caused by hypertension, one participant was diagnosed (six years ago) with arrhythmia due to a valve regurgitation and one participant was diagnosed with arrhythmia in the past but he indicated that this diagnosis has no consequences at this moment. This same person was also diagnosed with COPD (15 years ago). Other participants were not indicated with CVD or other (chronic) diseases at all.

### 3.1.3 Settings and materials

A 45-minute semi-structured interview has been executed whereby one interviewer interviewed each participant individually in the USE lab of the IPO building. The interview was held at a table in the setting of a living room (Figure 3). Questions of the interview study were self-formulated based on literature research, first expectations, and experiences. The interview guide is attached in Appendix 1. No other people were present in the office during the interviews. The interviewer asked questions and took notes with pen and paper. The conversation was recorded with a Samsung A3 2016.



Figure 3: Setting of the interview in the USE lab of the IPO building

#### 3.1.4 Procedure

Before participants entered the room, the devices of the Do CHANGE ecosystem were hidden under a blanket so that the answers of the first questions were not affected by the presence of the ecosystem. First, the interviewer explained the procedure to the participant and the participant read and signed the informed consent form. Subsequently, the interviewer started the interview and asked the questions following to the interview script (Appendix 1). General questions about attitudes against technology were assigned in the first part. After that, participants were shown and explained the Do CHANGE ecosystem. The third part embraced questions about opinions and expectations of the ecosystem. After the interview, the participant filled in a questionnaire (Appendix 2) about age, gender, cardiovascular disease diagnosis and other diseases. Again, the questionnaire was at the end of the interview. So, the participants were not influenced by the questionnaire in advance. At the end, participants were debriefed about the formulation in the invitation; they were being told that it was intended to find participants with and without experience with eHealth applications. Participants were thanked and paid for their participation and it was emphasized that their contribution was highly valuable.

### 3.1.5 Analysis

The ten interview recordings were verbally transcribed, and a thematic analysis was conducted on the transcribed data aiming to discover initial opportunities and barriers of the ecosystem. The program QDA Miner Lite version 2.0.2. (Provalis Research, n.d.) was used for the data analysis. First, the described interviews were read in-depth and patterns across the dataset were examined. This

examination resulted in initial categories and themes. Second, refined themes and categories were defined and restructured after several iterations. The final themes were formalized after different comparisons and checks.

### 3.2 Part 2: patient and relative evaluation of Do CHANGE ecosystem

### 3.2.1 Design

A qualitative study with two focus groups was developed in order to investigate the usage experiences of the Do CHANGE ecosystem among cardiovascular disease patients and their relatives. The procedure of the focus group was part of the Do CHANGE study and approved by the METC. The current study focused only on the evaluation in the Netherlands. The focus groups were conducted on December 1, 2017 and December 7, 2017 at the boardroom in the Elisabeth-TweeSteden Hospital (ETZ) hospital, location TweeSteden in Tilburg, the Netherlands.

### 3.2.2 Participants

Participants (patients and their relatives) were involved in the Do CHANGE study. Inclusion criteria in this study had already been formalized by the Do CHANGE protocol .These criteria were: participants in this study had to be diagnosed with CVD, namely: patients with HF, patients with CAD (experienced a myocardial infarction, percutaneous coronary intervention, angina pectoris and coronary artery bypass graft surgery), and patients with HT (values of ≥140 mmHg of systolic blood pressure or ≥90 mmHg of diastolic blood pressure). HF patients should also have HF symptoms, for example: shortness of breath, chest pain or exhaustion. Moreover, participants had to be Dutch speaking and had a smartphone with internet access and had to be confidential with this device. Excluding criteria for the Do CHANGE project were: cognitive impairments, a life expectancy of one year or shorter, patients on a waiting list for a heart transplantation, life-treating comorbidities such as cancer and patients with psychiatric illnesses other than depression and anxiety (Habibović et al., 2018). If possible, patients had to bring a relative of them to the focus group, being a person who is close to the patient such as a partner, family member or neighbor.

The participants were recruited for two focus groups by phone. Furthermore, an information letter about the procedure of the focus groups was sent to their home address. After a week, participants were called again and were invited to participate in one of the focus groups with their partner or relative. Sixteen participants (nine males and seven females of which nine Do CHANGE patients and seven relatives) participated in two focus groups, with mean age 62.2 ± 8.0 years (range 51-77). Table 2 shows the participant demographics such as type and time of diagnosis, age and gender of the focus groups. Comorbidities such as diabetes or multiple sclerosis (MS) was present in both focus groups. However, other diseases than CVD were not specifically asked in a questionnaire, but participants mentioned this during the discussion by themselves. Every couple received a €10,00 voucher and a parking exit card as reward for their participation in the focus group.

Table 2: Participant demographics focus groups (N=16)

### Focus group 1

Participant	Gender	Age	Diagnose	Time of diagnose	Relation to patient
1	Women	63	-	-	partner
2	Male	63	HT	10 years	
3	Male	70	HF	8 months	
4	Male	50	CAD	4 months	
5	Women	53	-	-	partner
6	Male	68	CAD	13 years	
7	Women	76	CAD	17 years	
8	Male	51	-	-	son

### Focus group 2

Participant	Gender	Age	Diagnose	Time of diagnose	Relation to patient
9	Male	56	HF	9 years	
10	Women	51	-	-	partner
11	Male	62	HF	4 years	
12	Women	59	-	-	partner
13	Women	72	CAD	6 years	
14*	Male	72	CHD*	unknown*	partner
15**	Women	62	-	-	partner
16**	Male	67	CAD	15 years	

<sup>\*:</sup> Participant is not involved in Do CHANGE study but has an unknown CHD diagnosis and is patient in ETZ.

### 3.2.3 Settings and materials

A two-hour focus group has been executed whereby two researchers guided the group session in the boardroom (Figure 4). The first person was responsible for leading the group discussion and the second person had the responsibility to take notes and answer substantive questions related to the Do CHANGE study. Both researchers were not actively involved in the group discussion. Questions of the focus group were self-formulated based on the Do CHANGE protocol, literature research, and first expectations. The question guide is attached in Appendix 3. Besides the researches and the eight participants, no other people were present in the room during the focus groups. The conversation was recorded with a Zoom H6 handy recorder and a Samsung A3 2016 was used as a backup recording.

<sup>\*\*:</sup> Participant participated focus group only after the break.





Figure 4: Setting of the focus groups

### 3.2.4 Procedure

Participants confirmed their participation in a phone call and a conformation letter was sent to their home address afterwards. Participants were welcomed and were asked to read and sign the informed consent form. Moreover, participants who were involved in the Do CHANGE study filled in a questionnaire (Appendix 4a) about work status and diagnose history. Furthermore, relatives filled in a questionnaire (Appendix 4b) about working status and relation to the Do CHANGE participant. Next to this questionnaire, the RAND-36 questionnaire (36 items; Van der Zee & Sanderman, 1993) was also included for the relatives in the current study. However, the results of this questionnaire were not analyzed and reported. These will be reported elsewhere for the Do CHANGE study.

Before the focus group started, the procedure and guidelines were explained, and participants were asked if there were any uncertainties regarding the procedure of the focus group. Subsequently, the interviewer started the group discussion and asked the questions following to the interview script (Appendix 3). Halfway of the session, there was a short break of fifteen minutes. After the group session, participants were thanked for their participation, received the voucher and it was emphasized that their contribution was highly valuable.

### 3.2.5 Analysis

The two focus group recordings were verbally transcribed, and a thematic analysis was conducted on the transcribed data aiming to discover experiences of the Do CHANGE program. The program QDA Miner Lite version 2.0.2. (Provalis Research, n.d.) was used for the data analysis. First, the described sessions were read in-depth and patterns across the dataset were examined. This examination resulted in initial categories and themes. Second, refined themes and categories were defined and restructured after several iterations. The final themes were formalized after different comparisons and checks.

### 3.3 Part 3: healthcare professionals evaluation of Do CHANGE ecosystem

### 3.3.1 Design

A qualitative study with semi-structured interviews was executed investigating the usage experiences of the Do CHANGE ecosystem among healthcare professionals. The procedure of the healthcare professionals interviews was part of the Do CHANGE study and approved by the METC. The interviews were conducted between January 15, 2018 and January 23, 2018 at several offices in of the ETZ, location TweeSteden in Tilburg, the Netherlands.

### 3.3.2 Participants

Participants had to be employed at the cardiology department of the ETZ, location TweeSteden. Preferably, they should work with patients who are in the Do CHANGE program. The participants were personally requested or with an email invite for an interview. Three (two males and one female) participants were individually interviewed, with mean age 51.3 ± 13.8 years (range 32-63). Table 3 shows the participant demographics such as function, age and gender. Participants did not receive any (financial) compensation for their participation.

Table 3: Participant demographics healthcare professionals (N=3)

Participant	Gender	Age	Function	Work experience	Experience with eHealth
				(years)	(years)
1	Male	59	Cardiologist	25	5
2	Women	32	ICD nurse	12	0,5
3	Male	63	ICD nurse	45	4

ICD (Implantable Cardioverter Defibrillator)

Differences in experiences with the Do CHANGE study existed between the healthcare professionals. Participant one had extensive experience with the study and he treated multiple patients. The second participant had almost no own experience with the program because she had only contact with one Do CHANGE patient and knowledge was based on stories of colleagues. The last participant had some experience with Do CHANGE because he treated some patients of the study.

### 3.3.3 Settings and materials

A thirty-minute semi-structured interview has been executed whereby one interviewer interviewed each participant individually at the back office of the cardiology department or the personal office of the participant. Questions of the interviews were self-formulated based on the Do CHANGE protocol, literature research, and first expectations. The interview guide is attached in Appendix 5. No other people participated during the interviews. The interviewer asked questions and took notes with pen and paper. The conversation was recorded with a Samsung A3 2016.

#### 3.3.4 Procedure

First, the interviewer explained the procedure to the participant and asked to read and sign the informed consent form. In addition, participants filled in the in a questionnaire (Appendix 6) about their employment and personal characteristics. They also filled in the SUS questionnaire (10 items; Brooke,1996), and the CSQ - 3 (4 items; Larsen, Attkisson, Hargreaves, & Nguyen, 1979). However, the results of those two questionnaires were not analyzed and reported. These will be reported elsewhere for the Do CHANGE study. Subsequently, the interviewer started the interview and asked the questions following to the interview script (Appendix 5). Afterwards, participants were thanked for their participation and it was emphasized that their contribution was highly valuable.

### 3.3.5 Analysis

The three interview recordings were verbally transcribed, and a thematic analysis was conducted on the transcribed data aiming to discover experiences of the Do CHANGE program. The program QDA Miner Lite version 2.0.2. (Provalis Research, n.d.) was used for the data analysis. First, the described interviews were read in-depth and patterns across the dataset were examined. This examination resulted in initial categories and themes. Second, refined themes and categories were defined and restructured after several iterations. The final themes were formalized after different comparisons and checks.

### 4 Results

### 4.1 Part 1: interviews pre-study

This chapter shows the results of the pre-study whereby barriers and opportunities for initial using the ecosystem were explored. Although different themes appeared during the analysis, the described themes are mainly focused on the research question investigating the barriers and the opportunities. Three different themes were distinguished, namely: informative and supportive expectations, personal relevance, and societal relevance.

### 4.1.1 Informative and supportive expectations

Participants indicated that they had expectancies regarding to the data and that the results of the ecosystem might support in more awareness of their health and lifestyle change.

"(...) lifestyle and health are two things that are connected to each other. You have the possibility to objectively measure and you know your current status. And then you can change, preserve or cherish things if it is all right. Yes, I think it [ecosystem – ed.] is just fine, I think it is excellent and I am happy with progress." (P3)

"You are more aware of your behavior. At least some behavior aspects. It [ecosystem – ed.] could support you. However, I think you should have a trigger to control it. For example, the maximum weight should be this or my heart rate should be that. It helps you to stay in control." (P5)

The outcomes of the ecosystem might also help by diagnosing diseases and give medical insights.

"This [ecosystem – ed.] is progress because it did not exist before and it provided, especially in this case, opportunities in the medical field. So, I embrace the possibility to improve measurements, delivering objective measurements that could provide data, being a solid base for good diagnosis. Based on that, a diagnosis an action plan for healing can be made." (P10)

"There might be the effect that people see slumbering things, which I do not know at all. And maybe a doctor did not know too. So, it [ecosystem – ed.] might provide new insights." (P1)

Furthermore, three participants saw benefits from a healthcare professional perspective. For example:

"And in the meantime, you collect a big load of data that provides much better insights of someone who is nervous when he visits you only occasionally, forgetting vital things to tell, or reflecting on wrong question that had been asked. So, it [ecosystem – ed.] delivers broader insights." (P3)

"In case you feel something, they [healthcare professionals – ed.] can monitor you in a better way using smart technologies." (P7)

In contrast, most participants were doubtful whether they actually would use the ecosystem because they do not want to know the outcomes of the system, they do not know what to do with the data or they experienced the system as a burden.

"I do not need to know that all. I know how I feel by my own. I do not actually need that thing. (...) And the tool itself does not actually improve my health. I say: 'it is only registration, that is all'. My health is regularly registered at the doctor right now, but not constantly. But then again, I also do not constantly hold that thing to make a movie [ECG – ed.]." (P1)

"Yes, this requires too much commitment. Subsequently, I need to do all kinds of things every day. Oh, every day is too much. (...). Because I would not do this all every day." (P10)

Moreover, the faith in the ecosystem for changing your lifestyle was low because it might not be helpful, and three participants aimed for self-determination.

"I do not think that it [ecosystem – ed.] will change my lifestyle a lot. Because I want to have the supervision by my own. For me it is fine that essential medical data is forwarded if you have a disease. But beyond that, I just decide it myself." (P2)

"I know how the devices are working; can people verify if they have slept well or not and whether they have improved themselves? Because that is what I feel by my own when I wake up." (P1)

#### 4.1.2 Personal relevance

In general, all participants indicated the ecosystem as valuable; they saw the benefits. For example, a participant was convinced that the system was easy to use, and another participant considered the ecosystem as a helpful device if someone has a heart problem.

"If I were a heart patient than I should definitely use it. Why? Yes, it seems quite simple to me. You do not have to do much and there are a lot of results. The doctors are just able to better indicate what actually is the matter with you, especially that ECG." (P8)

"I assume that they [healthcare professionals – ed.] give it to you with a purpose. It is not just playing with it. In other words, in case of suffering a heart problem, I would like to be monitored [by healthcare professionals – ed.]. I would appreciate if I could have insights in my health condition myself as well. I do not have a negative attitude [towards the ecosystem – ed.]." (P7)

However, it is remarkable that all participants emphasized that they did not want to use the system right now since there was no medical reason or need for them. They only considered to use the ecosystem on recommendation of a doctor, after a consult, or a need in the future.

"First, I would ask why. I need some more reasons to convince me to use those things [ecosystem – ed.]. If the doctor says at one moment: 'sir, there is no need to visit the assistant for a blood pressure measurement four times a year. You can do it yourself', then I will do it myself and use that device. But all those devices together? I just think: 'why?'." (P9)

"This would be a reason for me to use it: if I am a heart patient and it is really important that I monitor my blood pressure. But overall, if they [healthcare professionals – ed.] say to me: 'you should more often go out for a walk', then I will do that. So, I do not need a step counter which verifies my activities." (P2)

"Only if it is necessary. I think everything that is not really necessary should be avoided. I do not go to the doctor if it is not necessary. Even no examination should be executed if it is not necessary. (...) Unless if you have really got sick, then it is fine that those kinds of systems are available." (P6)

Or three participants imagined that the ecosystem might be helpful for someone else but not for themselves.

"Well, I think, but I do not talk for myself, it can be difficult. I already said that I am convinced that I have a reasonably good lifestyle. Hence, there will only be little change. However, you sometimes see people, especially in my close circle or, for example, in these elderly homes who could benefit from it [ecosystem – ed.]. Provided that they become aware of certain risks related to their lifestyle." (P9)

"When you become older, you feel the need to check your condition. While looking back over the past years I can say: 'I felt fit, healthy, happy, and did nice things etcetera'. So, I do not consider using devices that measure my blood pressure. Over the years, it [health – ed.] becomes more important. Unless, not speaking for myself, people experienced health problems in an earlier stage." (P10)

Some participants were only interested in particular parts of the ecosystem because they indicated other parts of the system as patronizing or other parts were already known. Two participants emphasized that the components might differ from person to person.

"Yes, people tell you things that are common sense for you. But maybe that also differs from person to person. Some may have more need for it [ecosystem – ed.], may be less informed or are able to use the tips, while others do not care about it." (P2)

"But you [interviewer – ed.] talk about the system as one thing. I see different parts within the system, each with its own objective. So, I would say: 'What is your situation? I would discuss with him [a certain patient – ed.] about his situation, whether he can benefit of using modern technology. If yes, then we can discuss about it [ecosystem – ed.] together. You should never force him to use it (...). He will try it for a while but leaves it unused after a couple of months. This is not what you aimed for." (P9)

## 4.1.3 Societal relevance

The third theme focused more on concerns or opportunities for society in general. Privacy issues were one of the remarks. Four participants expressed that they were concerned about the privacy guarantees of the collected data and personal information.

"There should be clear privacy rules, regulating how to use your personal data. I think this is the most important thing. I allow you to measure everything; you can collect a lot of my personal data. Therefore, I would like to know what they are going to do with it. Other people can use it as well." (P7)

"I am wondering about the data. Where is it saved? Who has access to the data? Is my privacy at issue? (...). Is it possible that the data is made public domain or is sold to the health insurances? If so, they [health insurances – ed.] might discover that something is wrong with me and they could exclude me form insurance or raise the insurance fee. So, I would like guarantees that is not the case. (...). For me it is a very important aspect; my privacy should be guaranteed. (...). It must be clear and distinguished." (P6)

Three participants considered the accessibility and usefulness of the system for elderly. In general, they had doubts about the usability of different ecosystem devices by the target group of the ecosystem.

"I think that this [ecosystem – ed.] is for people who are getting older right now, those who are already accustomed to applications and digital tools. (...). So, I see a small threshold for people who have not gone along with the digital development, because you must press a lot of buttons and especially when you [interviewer – ed.] say everything assembles. That they do not panic or something else." (P3)

"It is also important that everything is logic and understandable, adapted to the older generations. Doing wrong things should be impossible because you can design a lot of buttons. It should not happen that you say: 'I do not know anymore'. I notice that by myself. (...). I think it is at least one of the conditions that it is incredibly friendly to operate." (P7)

Three participants emphasized also the opportunity of cost savings in the healthcare domain.

"Anyway, these tools can help to retain healthcare cost affordable. I think the healthcare cost in general tend to go completely out of control. We must draw a line somewhere when you see the costs of medicines and surgeries. We want that all of course, if it makes your life reasonable once again." (P7)

"It [ecosystem – ed.] is a huge potential cost saving for healthcare. (...). It saves a lot because people do not have to go to hospital for those expensive examinations every time." (P10)

In relation to this, four participants reported that patients will not be burden with hospital visits anymore since the ecosystem can be used easily at home. This cost reduction was seen as beneficial.

"You do not have to go to the hospital either. Although I live close to the hospital, you could subsequently do other things instead of visiting to the hospital. But most people that live on further distance of the hospital will lose half a day for a five minutes doctor visit". (P8)

"You do not want the burden for the people visiting the hospital every time, neither a raised stress level related to hospital visits. (...). I think it [ecosystem – ed.] is not very demanding for people." (P3)

### 4.1.4 Summary potential barriers and opportunities ecosystem

To summarize, the Do CHANGE ecosystem has both potential barriers as well as several opportunities. Participants indicated more awareness of their health and lifestyle, insights in their data, possibilities for diagnosing, and ease of using. They suggested a healthcare cost saving potential and expected less burden due to reduced hospital visits using the ecosystem. On the other hand, participants reported a potential burden of using the system, an (irrelevant) unhelpful system, unreliable data, patronizing feelings, privacy issues, and unacquainted technology as potential barriers for initial using the ecosystem.

# 4.2 Part 2: focus groups patients and relatives

The results of the two focus groups with patients and relatives will be presented. Different themes revealed during the sessions, namely: information, awareness and reassurance, concerns and challenges, and contact with others.

# 4.2.1 Information, awareness and reassurance among patients

## 4.2.1.1 Monitor myself and improve lifestyle

All participants, both patients and relatives, expressed that they had positively experienced the Do CHANGE program. They perceived the ecosystem as helpful because they could monitor their disease themselves.

"I especially value the self-monitoring feature, having the possibility to check your health status. I find this important." (P4)

"I can just keep an eye on my blood pressure and determine: 'oh my god, this goes out of control'. But yes, you [researchers – ed.] check it too, because I receive a phone call from you. I like that very much. But I cannot control it [high blood pressure – ed.]; it is just as it is." (P13)

Six patients indicated that the ecosystem was easy to use. Sometimes it was easier than they expected in advance.

"I am not so convenient with mobile phones. So, I was a bit reluctant to use it [ecosystem – ed.] in the beginning. But I have to say: 'it was not too bad'." (P2)

"And it [ecosystem – ed.] is just manageable for everyone. Everyone can handle it." (P9)

Furthermore, six participants reported that the Do CHANGE program was motivating to improve their lifestyle or their relatives' lifestyle.

"It [ecosystem – ed.] is a lifestyle improvement for us. Doing more physical activities like walking." (P5)

"It is positive that he also started to do more physical activities, aligning with his day rhythm. So, that is a positive effect of it [ecosystem – ed.]." (P12)

It was remarkable that the Fitbit was mentioned multiple times as a helpful device for lifestyle change during both focus groups, because other devices of the ecosystem were expressed less frequently or were even not mentioned at all.

"I think the Do CHANGE project is awesome. It really encourages you to take more steps than you were used to do before, because you regularly look at your wristband to check. Every week, you try to reach a higher number [of steps – ed.] than the week before." (P6)

"I think the Fitbit has the greatest impact on awareness and is the easiest to use and maintain. In that respect, I would consider to buy it myself." (P4)

However, monitoring yourself and participating in the Do CHANGE project has a drawback. Six participants or relatives expressed or confirmed that using the system required effort and discipline. Participants suggested to make the program less intensive and/or shorter so that the Do CHANGE program would become less demanding.

"I think that you can follow the program for a few months because it is pretty intensive. It requires a lot of discipline. Intensive might be a big word, but it [measurements – ed.] is the first thing you do in the morning (...) and it repeats in the evening. I think it is a good help to get you on the way. Maybe one should do it with intervals or something like that. (...). Right now, the program lasts three months or six months. Consider that you start with the program for three months, and after this period you try it yourself. After another three months, you continue the program again. Or you must make some changes [in the program – ed.]. (...). Encourage people to endure the program. It is just an idea to make a less intensive trajectory [for the patient – ed.]." (P3)

"Reduce the frequencies and quantities. It could be a relieve for many people if they could say: 'well, I only need to check my blood pressure only twice a week, once a day'." (P14)

### 4.2.1.2 Awareness and reassurance

The themes of awareness and reassurance were important aspects during both focus groups. Participants reported that they felt more reassured because they knew that they have been observed by professionals.

"It gives reassurance that you know that if something is wrong, someone remains standby; that you always can count on someone." (P10)

"She has become a lot more relaxed because the blood pressure, which is quite high at the moment, is being monitored. [People – ed.] from the hospital said: 'your medication has to be changed'. Well, it is very nice that you know that they immediately take measures based on actual results. By the way, that is daily practice during the whole period of six months. I did not expect this before. I think that is a good thing, a big relieve." (P14)

Subsequently, also the fact that there was the possibility to get in contact with the healthcare professionals by phone provided reassurance among patients and their relatives.

"This project really supports me that I get more trust in myself. I did not have that for a long time.

(...) And you can just call. Coincidentally, I also called yesterday because my heart was out of control. So, I was reassured and it went well again afterwards." (P9)

"I agree with that. The fact that she has a backup provides comfort for my wife. That is fine, nothing wrong with that." (P14)

Patients explained that there was more awareness of their health and possibility of improvement due to the ecosystem. Seven patients or relatives mentioned this during the focus groups.

"It is part of the awareness. (...). However, there are many things in life that someone else has to make you aware of, such as: pay attention to this or that. And I think we all generally know what is healthy and unhealthy but there is often a big temptation doing unhealthy things. And yes, to keep that under control. (...). Nevertheless, you are more often reminded to take a step back". (P2)

"Yes, it certainly stimulates change. Wearing a Fitbit, you are more actively in control regarding your lifestyle. 'How much steps did I make?'. It is even that bad that when I go to the gym and I forgot to wear it [Fitbit – ed.] that you think: 'It makes no sense to exercise, since it is not registered at all'. So, it definitely influences you. Also, the task of making pictures of your food is contributing to awareness. (...). So, it [Do CHANGE program – ed.] provided a change. However, without participating in the program, I would have examined for a change myself anyway." (P4)

The fact of awareness has two downsides. First, The Do CHANGE project forced patients to think more about their disease. It supported and encouraged them to change their behavior. One participant expressed that he was more undesirably aware of his disease in daily life.

"I have the feeling that I am lived by someone else. I believe what the other gentlemen says about a bit of reassurance, but I do not feel that reassurance so much myself. It feels like big brother is watching you. I am a bit uncomfortable with that. I am retired, and I want to do things that I like to do but that thing [Fitbit – ed.] pursues me. I would appreciate if it [program – ed.] has less impact for me. No ECG and blood pressure measuring twice a day. (...). Well, I am working on it. It should be a bit less for me. If I did not walk enough, then I would take another walk to achieve the goal at eleven o'clock in the evening." (P16)

Second, participants might have had troubles interpreting the data of outcomes of the ecosystem. They worried more instead of they felt reassured because participants sometimes explain data outcomes for themselves in a different way.

"Now and then, I am afraid of the Careportal. I do not know if I make a ECG. I sometimes see all kinds of results and think: 'I am sick as a dog' [laughs]. It confuses me, and it shocks me sometimes because it [ECG – ed.] goes all over the place. However, the next day it apparently goes well again. I guess it is just me because I sometimes call and then I verify my situation. They say everything is fine. So, I do not have a clue anymore, but it is always a bit of a shock." (P3)

"You [other participant of focus group – ed.] are talking about the peaks downwards. I had the same in the beginning. Fist I noted upward peaks and, at a certain moment, I saw upward peaks. Coincidentally, that occurred when I felt much more tired during a certain period. This really worried me. Finally, there was nothing wrong with me. I talked about those downward peaks with the cardiologist afterwards during one of my regular visits; those downward peaks actually do not matter. It is quite normal that it goes up and down, depending on how the sensor measures the heart. You do not know that in advance; that is a disadvantage of monitoring yourself. You start Google to find an answer to your question: 'what it means if the peaks go up and down', but you do not know as a layman. However, based on that you can talk with the professionals: 'is that right what I have seen? Is that okay?' It has both positive as negative effects." (P11)

"I discovered that the Beddit sometimes did not indicate well [sleep pattern – ed.] It is open. Was there apnea at that moment? I had to deal with apnea quite often in the past. If it does not continue for a moment, does that mean that: 'she does not breathe?'. Might that be possible?" (P13)

### 4.2.2 Concerns and challenges among patients

#### 4.2.2.1 Personalization

The Do CHANGE program consisted multiple devices and not every device or message appeared appropriate for every patient. Some questions could not be relevant for some patients while for others the question of the Careportal could be more relevant. Participants indicated this by themselves; however, they often did not explicitly mention the term personalization but questioned the relevance or personal utility of certain devices within the ecosystem.

"I do not think that the ECG influences me. It looks always the same. It shows the same thing [results – ed.] every time. My question is: 'is that useful?'." (P13)

"Well, regarding the blood pressure measurements, that is important for me anyway. And any of the other systems are fine. Well, you do not suffer from the Beddit either. (...). I often enter the same thing in the portable because it [the measurements – ed.] is the same." (P2)

"Are you short of breath? Sorry, I think that [question is not applicable for me – ed.]; it easily can be excluded for me. It might be important for someone else but for me it is a question that I do not want to answer. It is about short of breath. Could you omit that question? Because there is an entire row." (P7)

Moreover, it could occur that participants were not always able to reflect to or identify themselves with the messages they received.

"Those 'To Do's' that you receive. In the beginning I read those [messages - ed.] sometimes, but now I quickly push them away. It is not really person-oriented because when I get to read: 'you should use less salt and suchlike' while my blood pressure is already very low. Yes, there is no point. I think this approach, if I may say so, looks like an American sales system." (P11)

Or messages were indicated as helpful but were not relevant for themselves. One participant imagined that the messages were more intended for others.

"Yes, I think that those ['To Do's' – ed.] are meant for people who are almost 80 years old. Those who live alone and are more weakened. 'Think about your medicines and did you already do this or that?' (...). I would think: 'yes, I need to do that'. But we are all...". (P10)

Some messages content even might be patronizing. The example of meeting other people as a 'To Do' instruction was independently mentioned in both focus groups.

"But those 'To Do's' questions and suchlike. I think of several ones: 'yeah right'. It is common sense that you are doing this or doing that. I think I am already doing that. (...) Search for contacts... [laughing by others]." (P13)

"We just fulfilled our task: 'talk to a stranger' [laughing by others]." (P3)

#### 4.2.2.2 Technical issues

In general, participants experienced functioning problems with devices. However, the technical problems differed from person to person and the issues were not unambiguous. For example, where the Fitbit did not work for one person, for another person the Beddit or Vire application was more problematic.

"The Fitbit application does not work properly; this is known to you. Overall, it works." (P4)

"The Beddit functions sometimes and sometimes it does not work at all. This is frustrating". (P3)

Next to that, several comments about the Careportal were discussed. Participants indicated that they had difficulties to fill in the questions and ECG's before eleven o'clock in the evening. Some participants preferred an extension of this time slot or wanted to add or change information at another moment.

"In the morning when I wake up there is no problem. But just going to bed late in the evening I realize: 'it has been eleven o'clock PM, I cannot do it [fill in the data – ed.] anymore'." (P13)

"You can only pass them [questions – ed.] in the Careportal before eleven o'clock in the evening. Why is that? (...). I do not stay at home for that." (P6)

Another remark of the Careportal was about the indication of days off. One participant desired the possibility to clarify moments that participants were unable to fill in the questions and ECG's due to a holiday, a day out, or other unsuitable moments.

"That you indeed can notify when you are away for a day or on holiday. Or you can indicate that." (P10)

Other comments of the Careportal focused on the device producing too much light in stand by modus, the existence of a camera in the Careportal was not mentioned in the informed consent, and more variation in the questions to stay refreshed was desirable.

"You have standardized questions and questions for statistics in the Careportal. To excite interest [of the patient – ed.], you could, for example, ask another question once. Because you see the same repetition [of questions – ed.] every morning and evening. This question could be more personally related to the patient." (P4)

"I think the presence of a camera and microphone in the Careportal was not mentioned in the registration [information letter – ed.]. Although, they [researchers – ed.] say that both are not being used but are out of function. You should assume that but on the other hand it is technically possible. They should have mentioned this at the beginning, before signing the contract. I think it is important that you mention all the resources that can record." (P4)

Regarding the Vire application, taking food pictures was the biggest concern in both focus groups. All participants emphasized multiple times that this function did not work well. For example: they had to wait long, had to upload the photo multiple times, or the function did not work at all.

"Yes, making pictures takes too long. You take a photo and then, you have to wait for two minutes before it is in the application. First you think it just does not work, but suddenly you have captured five, six photos at once. So, that is a little problem. It might depend of the software or the telephone; I do not know." (P9)

"Yes, I captured, I believe, more than hundred photos; way too many. If I take a picture, then it [Vire app – ed.] says: 'okay' and shows a checkmark. When I press the check mark, then I suddenly have two pictures. Thus, I deleted all of those [photo's – ed.] yesterday. So, you may have seen the same thing [in the system – ed.]. However, I consider this as a one of my mistakes." (P16)

Furthermore, the use of the photo function might be a burden for the participants in general or in a social (public) context.

"Only the application of taking food pictures does not work well. Subsequently, he is grumbling during dinner and sometimes I do not like that. I normally start eating and in the meanwhile it does not work, [he still struggles with it – ed.], and it needs to be done over again." (P5)

"And you have to think about taking photos every time, being in a restaurant or having dinner with friends with (P10). Taking pictures can occasionally be annoying (P9). We do not mind at all to explain it [participating in the Do CHANGE study – ed.]. It [participating – ed.] contributes to the research project but after finishing we are [done – ed.]." (P10)

Comments to improve the photo function contained the option to add and delete photos on a later moment and the possibility for a comment next to the photo.

"Well, I actually stated this already, discussing those food pictures. It is a pity because I actually update at a different time. I take the photos but if you forgot it in the evening one time, then you cannot publish the photos again the next day." (P3)

"Maybe it is also important to be able to add a text. That people can say I have eaten this." (P9)

Overall, the Moves application provided the most complications among the users. There was no participant who indicated a well working application.

"The Moves application does not work at all. So, I contacted with one of the researchers to say that I uninstalled it [application – ed.]. It consumed batteries and I was in Paris while the application was in Berlin so to speak. So, yes that is not true. (...). I removed that Moves application". (P11)

"Yes, [I do not use – ed.] the Moves application because I have no internet subscription [of a telecom provider – ed.] and it does not work if I leave the WIFI environment. For example, going outside, visiting the woods. So, he eliminates that [registered walking distance – ed.]. For example, it registers that I have walked twelve kilometres, but I only have walked for seven minutes. I cannot walk that fast [laughs – ed.]." (P16)

The technical problems with the Beddit focused mostly on the connection of the application. Six participants reported or confirmed problems such as missing data during the nights.

"Regularly there is a break down. It is often five minutes but sometimes it happens that it indicates that I have been out of bed for an hour. But that is wrong." (P9)

"Yes, my husband's Beddit sometimes skips collecting data. Sometimes even during more than one hour." (P12)

#### 4.2.2.3 *Privacy*

The topic privacy was a brief part of the interview guide. Although, differences about privacy occurred between the two focus groups. One group came up with more concerns while in the other group some participants assumed everything was well organized and that they could trust the privacy organization of the Do CHANGE program. For example:

"Of course, the privacy and patient protection is important, but what can someone else do with my data? No, I am worry about it. I am sure it will all be all right." (P11)

"Well, I only wonder if I would participate if I was 25 years old because everything [personal data – ed.] is registered and might be used in a personal capacity. But even then; no, I do not think I would have done it. Although, what can happen to someone of my age? That will not be that much. However, one example: imagine you are selected by your insurance company and suppose that they have access to things [personal data - ed.] in the future. They might say: 'well, that person will not receive a life insurance or a mortgage or something like that'." (P2)

#### 4.2.3 Contact with others

#### 4.2.3.1 Contact with relatives

During the focus group, the influence of the ecosystem on the relation and personal contact with relatives, healthcare professionals, and others was investigated. Overall, patients pronounced that the ecosystem had almost no or a positive influence on their relation with their relatives.

"I also think it [ecosystem – ed.] is positive. It worked out in a positive way for us because we are both dealing with it. It is not something that he is doing alone; so, it is something you are doing together. I think that is positive." (P5)

"No, no influence at all." (P15)

On the other hand, one couple experienced this aspect differently. They explained that the ecosystem and participating in the current study had an influence on one their relatives.

"Yes, to the extent that we have the Careportal and the other things on the bedside table. Because he has a long medical history (...) and we experienced other medical incidences in our family. Our daughter is unhappy with that. (...). She just prefers to keep it out of her life and she understands that we are participating in this study and that she valuated as very important. However, after all the trouble we have gone through, we just want her to have a life as normal as possible. (...). Hence, we will install the devices out of sight; we do not install the devices in the living room. This is actually the only comment I have because overall we are fine with it." (P10)

#### 4.2.3.2 Contact with healthcare professionals

The ecosystem had also influence on the contact with the healthcare professional. This could be both on the cardiology department as for example with the general practitioner. Subsequently, one participant explicitly indicated that there was no change in contact with the healthcare professionals.

"In a certain way yes because my husband had a very low blood pressure and heart rate. So, he went to the general practitioner first and they discussed what has happened. He [general practitioner – ed.] advised to contact the cardiologist by phone, informing him that something has to be changed." (P12)

"Not for me. The general practitioner only said: 'It is fine. I think it is very good that you participate'." (P7)

Moreover, three participants indicated that they were more prepared for a consult with knowledge of themselves and data of Do CHANGE compared to regular treatment.

"An example, I always have had a very low blood pressure since an early age. At a certain moment, the cardiologist had decided to halve one pill. This caused an increased blood pressure. Based on Do CHANGE and the registered data, we saw that the actual blood pressure was very high. Thus, in consultation with the cardiologist, it was decided to prescribe one pill again, because that is more appropriate for me." (P11)

"Somewhat, because you know more about yourself and your own situation the moment you start exercising at the cardio physiotherapist. For example, I see my heartbeat at the beginning and after exercising. You see the differences afterwards; it gives you better insights. You know more about yourself and you can better explain your physical state to your physiotherapist. So, in that sense it enriched something [communication about my health condition – ed.]." (P4)

Part of the Do CHANGE program was the weekly telephone consultation up to three months. Some participants implied that they appreciated the possibility of getting in contact with a professional (this is already described by reassurance) and they even wanted to expand this with more confirmation. Moreover, one participant suggested to add a coach in, for example, the Careportal.

"I think that feedback on the data you provided would be nice once in a while. For example, the ECG's, well, they all seemed perfect in the past six months. It should not be a long report, rather not even. That you have really the feeling that all has been checked. I think this also stimulates participation. (P3). Medically supported (P4). Yes (P3)."

"In case you have a question that cannot wait on the next telephone conversation. For example, I have problems with my software or I have a question about my medical condition. Or maybe a question about food intake. Suppose that this type of healthcare is future established than you could also expect a connected dietician to whom you can address a question. It makes sense to install this. (...) The possibility for interaction." (P4)

Using the ecosystem could also reduce the burden of hospital visits. Four participants indicated this.

"It is also ideal that you do not have to go to the hospital every time." (P14)

"Besides the costs, I think it is nice for a person if there is less need going to the hospital." (P10)

## 4.2.4 Summary evaluation ecosystem patients and relatives

To summarize, the evaluation of the Do CHANGE ecosystem revealed in three main themes: (1) information, awareness and reassurance, (2) concerns and challenges, and (3) contact with others. The program has both benefits as barriers for patients and their relatives. Patients generally experienced the ecosystem as beneficial. Participants were more aware of their lifestyle and medical condition providing more motivation for improvement and reassurance. However, the patients and relatives were more conscious of their disease during daily life due to the system and the system demanded effort.

The lack of personalization, technical problems, and privacy issues were concerns during both focus groups. First, technical problems varied from person to person. Most issues were noted with the Moves application and the photo function of the Vire application. Second, some devices, questions, or 'To Do's could not be relevant for every individual patient. Third, privacy concerns existed among the participants. Some persons had more concerns than others.

The Do CHANGE project had influence on the contact with healthcare professionals. Participants assigned personal contact during the study as valuable. They were more prepared for a consult and were able to present their own data. The system had almost no effect on the relation and contact with relatives.

# 4.3 Part 3: interviews healthcare professionals

This section presents the exploration of experiences of the ecosystem among healthcare professionals. The analysis of the interviews resulted in two different themes: (1) the effects for patients and (2) changes in healthcare.

# 4.3.1 Effects for patients

This section embraces the changing aspects for patients according to the healthcare professionals. It was remarkable that healthcare professionals imaged themselves in the patient's situation instead of focusing on themselves because this was not primary asked by the interview guide.

# 4.3.1.1 Information, awareness and reassurance for patients

The increase of awareness among patients was an important aspect during the interviews. All healthcare professionals reported that patients were more conscious about their lifestyle and current condition.

"The people who participated those three months have more relaxed feelings anyway. They are perhaps more aware of their condition and their lifestyle too. That is really important." (P3)

"Well, I hear positive stories of my colleague. I think that it [Do CHANGE project – ed.] stimulates patients because they have to fill in everything. For example, taking pictures of your food motivates also to do your best." (P2)

One healthcare professional was not sure about the proven lifestyle effects. Controversy, another healthcare professional mentioned that patient monitoring had no guarantees for improved patient's health and thought that the ecosystem was only appropriate for a short time.

"They [patients – ed.] are more involved. And they are more serious about it and they like it. I have seen people who are saying: 'Yes, I am going to walk a bit more in the evening. I still want to achieve ten thousand [steps – ed.]'. Yes, I hear that. So, I do not know if they are more fit, but they do their best. Yes, they receive feedback and that has an effect on people. I do not know, and that is a disadvantage of the study, how sustainable it is. I would like to know [the effects – ed.] after six, twelve, and twenty-four months too" (P1)

"And you should not make them [patients – ed.] dependent on that stuff. You also offer a completely unfounded certainty. They can just die. Use it only the first three or four months for teaching lifestyle, set up and suchlike. Use it only in the beginning as education and monitoring, but after that you should not do it anymore." (P3)

Next to that, healthcare professionals indicated that participants of the Do CHANGE study were more informed comparing to patients who receive regular treatment. An increase of self-reliance instead of dependency of healthcare professionals was a result of this.

"So, I think it is very good for the patient. There is more self-management. (...). Patients start doing things more, but not because others say it needs to be done. They have more insights about their disease and about the rules in daily life. If they do this somewhat better, what is the effect on their weight? So, they are more aware by themselves, also related to medicines." (P2)

Two healthcare professionals suspected that there was more reassurance among Do CHANGE participants.

"I feel that the patient is more comfortable. They like it very much if somebody is carefully looking at them. That their complaints are taken seriously, that the data is seen, and that action is taken. They are more relaxed. I did not ever measure it with numbers, but I have that feeling. Yes, they come to me more relaxed because they already know that many things, which I normally check, are fine. So, this is again an argument for telemonitoring and not come back to me." (P1)

On the other hand, awareness might be experienced negatively by patients. Healthcare professional 3 expressed that patients might be undesirable confronted with their disease.

"I think the system might have a positive effect of being more aware of what people are doing. However, it is also true that you sometimes want to give people a favor of not bothering them with their ailments all the time." (P3)

"Some people do not want the home monitoring. They say: 'It is nice to come here twice a year'. Some people are saying: 'yes, I find this too much confronting with my illness if I see that box all the time'. I hear that frequently. So, that are actually the most important reasons why people do not want it. Accidentally, I had a talk with a patient who has been asked for Do CHANGE and eventually for a heart failure pilot project, but he said: 'it stresses me too much spending a lot of time with it'." (P2)

#### 4.3.1.2 Concerns and challenges for patients

The healthcare professionals had thoughts about concerns and challenges for patients of using the ecosystem. All participants indicated that the intervention might not be suitable for every patient.

"I notice that there is a certain category of patients that do not want it [intervention – ed.] or do not dare it. They become anxious about it or are too much worried about their illness and other aspects come along. It is not good for everyone, nothing is good for everyone. The 80/20 rule applies. You can design it very well for 80% [of the patients – ed.], but do not give it to the other 20%. (...). You can offer it, but they do not want it and they do not use it." (P1)

"Nowadays, everything goes digital of course. And you notice that this is still difficult for the older patients. They are not used to it yet." (P2)

Besides, the applicability of the intervention for certain patients was considered. One participant commented on the personalization of the overall intervention. He expressed that some parts of the intervention were not relevant for every participant.

"You have to personalize it [the ecosystem – ed.] well. You should not give a blood pressure monitor to someone who does not have a high blood pressure. You should not give a scale to someone with a normal BMI. You really have to focus on the patient's problem. (...). You collect false positive results. And otherwise you [patients – ed.] cannot preserve it. If the cholesterol is your problem than you have to measure cholesterol, move, lose weight, and diet. You [healthcare professionals – ed.] should give advice and you should not nag about other things. You should only focus on one thing." (P1)

The technical problems and privacy during the Do CHANGE program were only briefly mentioned. Only one participant discussed those experienced issues of the intervention.

"It [Do CHANGE – ed.] should be easier integrated. Some people are very carefully checking their data and they say: 'my step counter indicated that I had walked a certain number of steps while the other devices indicated a different number. The discrepancy between the different sensors is a bit annoying. They [patients – ed.] do not understand that. That is difficult for me. I cannot explain that properly. People realize that it is under development, but it is important for me that we have reliable data. (...). Passwords and messages about your email address are incorrect and such things are present in the current world but what is difficult for a certain generation." (P1)

"I doubt about the security. I do not know that. I would like to have more guarantees. (...). I think it is important that you know who has access to the data. If you start working with eHealth, the patients also go to the internist who wants to know the blood pressure and weight etcetera. So, you have to give permission to several professionals." (P1)

# 4.3.2 Changes in healthcare

This section describes the changed aspects for the healthcare professions themselves. The Do CHANGE program or eHealth in general changed modified the existing healthcare contact and treatments.

#### 4.3.2.1 Contact with patients

The three interviewed healthcare professionals experienced the patient contact differently. One healthcare professional indicated that no changes in patient contact occurred with the Do CHANGE project; nevertheless, he also more reserved using eHealth and reported that eHealth changed patient contact in general.

"No, not yet for me. Not in this pilot, because patients visit me here. (...). You can never examine people so well. That is not possible. People can do everything with those things at home, while I cannot notice it. I think that is also fine, but I am more reserved. (...). Internet of things is simply not good. (...). Loneliness increases. It sounds a bit strange, but people do not want to come to the hospital in general. That applies to everyone of course. But it [consult – ed.] is still some contact for a lot of people and that will be completely left out [with eHealth – ed.]". (P3)

The other healthcare professionals expressed that patient contact has changed. Phone calls, the discussed topics during consults, and the frequency of contact using the DO CHANGE program or eHealth in general differed comparing to regular healthcare.

"You talk more about the parameters; so, I am better informed about to the patients. They [patients – ed.] show you graphs and they explain problems that already have been solved. They say: 'my blood pressure was too high, but I had a message of one of the researchers that I should double a pill or something like that'. Or: 'I was dizzy, and they checked my blood pressure and heart rate, but everything was still good. So, that is solved'. Therefore, they are more prepared. I have the idea that they are better informed. (...). That is nice, and I think if they are even a bit more informed than you do not have to come anymore and you can do it remotely. So, it is a rehearsal of steps and we are talking about things that have already been solved. They [patients – ed.] share it with me again. I think: 'Yes, they also know that they should tell me something'." (P1)

"As a ICD nurse you have more contact with them [patients – ed.]. Because, they only came to the ICD technician first. If problems with the home monitor occurred, they [patients – ed.] have complaints, or they want to know if the system works, then they often call the ICD nurse first. So, you speak some people more often than others. Some patient just like to call more often because they have questions about that home monitor. Thus, the contract is different. Yes, you have more telephone contact about the pacemaker technique. Some ICD [patients – ed.] only come once a year instead of twice, because the home monitor takes over once." (P2)

One participant expressed that the change in patient contact with eHealth needed habituation. The procedure changed and required more patient trust and self-management instead of the professional's responsibility.

'You allow the patient to do self-management and alert us when something is wrong. (...). It is also a refreshing working style if you do it in a different way. If you receive all the data via internet instead of seeing the patient in front of you. (...). I like it, but you have to get used to it. I cannot completely release it [responsibility – ed.] and give it to the patients. How do you say that, that you only see the numbers? Yes, that is something that I have to get used to it. That I think: 'How are you going to do that?'." (P2)

### 4.3.2.2 Improve treatment quality

One healthcare professional expressed that the consult procedure itself changed by patients who participated in the Do CHANGE project.

"I do not even measure a blood pressure by the Do CHANGE patients, that is nonsense. It is measured throughout the year and it does not make sense if they measured again when they come to me. Furthermore, I have no need to check if the devices are properly calibrated. I assume that the blood pressure measures well. We only make a twelve channel ECG because Do CHANGE includes only one channel ECG. (...). You already have a lot of data." (P1)

The healthcare professionals reported that the intervention could improve the patient's treatment. The intervention supported, for example, in medication regulation and cardiovascular information for the patient.

"I like that you are able to change something in a patient's policy if you see that the blood pressure is too high or there are too many complaints. That you do not have to wait for the next consult in three, six, or twelve months. I think the patients are more reassured. You provide them more certainty and hopefully a better prognosis if you give a better treatment." (P1)

"I have had a few patients of the Do CHANGE project whereby I could better adjust the blood pressure and heart rate remotely. I see value for that, but it is also quite limited. (...). So, for example, if you increase the beta blocker, you could check if the frequency or the blood pressure decreases and those kinds of things. Whether your therapy is successful." (P3)

In addition to this, one participant emphasized that the intervention provided beneficial effects; however, he also implicated that the intervention could be too much.

"I think it is a good idea to help patients if you want to teach your patients first, and to set medicines. There is also less need for seeing them and you can regulate [e.g. medicines and/or settings – ed.] them more strictly. You can explain them more if there is an education system behind [the ecosystem – ed.]. But you also take pictures of potatoes and stuff like that. Then I think: 'Whatever! That is something too much'." (P3)

Another part of treatment quality is the reduction of hospital visits. Two healthcare professionals indicated that it was less necessary for patients to visit the hospital and this caused less burden.

"Right now, we see a lot of patients at the outpatient clinic once, twice, or three times a year. During those short visits, weight and blood pressure is measured, an ECG is made, and patients are asked about their complaints. That can all be done remotely. It is nonsense that people come to this expensive location while you are collecting information that you already could receive by eHealth. They [patients - ed.] should park their car and their family should bring them or not, etcetera. Moreover, you could daily receive data 24/7 while it [regular consult - ed.] is once or twice a year now. And if everything is fine you tell them [patients - ed.]: 'you can come back next year'. Completely useless. It is more financially driven than patient driven." (P1)

In contrast, remote healthcare resulted in a different employee demand in the future. One participant did not had thoughts about that. Another participant had ideas for managing this change in healthcare while the third participant expected problems in the staffing.

"There should be a case manager or something like that, someone who is in between [patient and professional – ed.]. I should not receive all the information. (...). Someone who calls the patients and asks: 'did you take your medicines?'. I do not have to know that. It is not that I am not good for that, but I am too high educated for asking such questions. (...). The case manager can talk about that. WE have HF nurses, atrial fibrillation nurses and many other types of nurses and we might probably have an eHealth nurse." (P1)

"We have to check the home monitoring. We do not have that many [patients – ed.] yet. But you always need someone if you have 1200 or 1300 patients. So, this might result in staffing problems since we should check it in the weekend as well? Do CHANGE is not being tracked during the weekend either. There has been a lady who said: 'what would you think if patients were being followed day and night by the internet?'. I call that crazy. You cannot arrange that." (P3)

#### 4.3.3 Summary evaluation ecosystem healthcare professionals

To summarize, the evaluation of the Do CHANGE ecosystem among healthcare professionals existed in two main themes: (1) where healthcare professionals emphasized the consequences of using the ecosystem for their patients and (2) the changes in healthcare that applied to themselves.

Healthcare professionals assigned the increase of awareness, reassurance, improved lifestyle effects, and better informed patients as results of using the Do CHANGE ecosystem. However, privacy, technical issues, and the question whether the devices were suitable for every patient were discussed concerns for the healthcare professionals' patients.

Next to that, the use of the ecosystem sometimes changed the procedure of consults comparing to regular healthcare. The contact between patients and healthcare professionals differed because patients were better informed due to self-reliance. Healthcare professionals also indicated that the treatment quality would be improved, and the program would give opportunities for hospital visit reduction. Suggested worries existed about the requested effort for the patients and the employee demand in the future.

# 5 Discussion

The aim of this study was the evaluation of an eHealth ecosystem in a clinical trial, namely the Do CHANGE project. The study consisted of three parts. In Study One, ten interviews with healthy elderly of the general population were conducted in order to establish potential barriers and opportunities of the ecosystem for people from the general population in. As participants in the Do CHANGE project may be biased towards using the ecosystem as they have voluntarily enrolled, the aim was also to try and capture first impressions of the system among people who may not have chosen to participate in the study. The interviews provided understanding about expectations of using the system among healthy elderly people who saw the ecosystem for the first time. In Study Two, two focus groups with actual CVD patients, who were enrolled in the Do CHANGE program, and their relatives were conducted. Those group sessions gained insights about user experiences and adaptation of the ecosystem. In Study Three, three interviews with healthcare professionals were performed to understand their view on using the ecosystem for their patients and themselves. Overall, this qualitative analysis of the interviews and focus groups resulted in general themes such as (1) awareness of lifestyle and disease, (2) reassurance and (3) changes in contact with healthcare professionals as well as concerns about (4) privacy, (5) personalization, and (6) technical issues of the Do CHANGE ecosystem. This section will discuss these overarching themes that emerged. Furthermore, limitations of the study will be discussed and suggestions for future research will be proposed. Last, recommendations for the Do CHANGE project and practical implications will be suggested.

# 5.1 Findings of the current research

# 5.1.1 Awareness, reassurance, and self-responsibility

Findings suggest that the Do CHANGE ecosystem was accepted by patients, their relatives, and healthcare professionals and they were generally comfortable with using it. All participants, including healthy elderly, indicated that the Do CHANGE ecosystem increased the awareness of patients' health condition and lifestyle. Previous studies that evaluated eHealth interventions suggested the same assumption (Leon et al., 2015; Ly et al., 2015; Pludwinski et al., 2016; Thorup et al., 2016). However, it should be noted that these studies do not all evaluate eHealth applications specifically aimed for CVD.

The presence of awareness resulted also in reassurance. Patients, relatives, and healthcare professionals indicated that patients were more relaxed during the program because they knew they were under surveillance. Moreover, patients could see the data by themselves, and patients were better prepared and informed for consults. Patients also mentioned that they had appreciated the possibility of contact with the researchers because this provided a backup and reassurance. This finding was in accordance with existing research whereby patients felt more connected with healthcare professionals (Leon et al., 2015) and were more comfortable that someone was always available for help (Pludwinski et al., 2016).

Moreover, healthcare professionals mentioned that patients had taken their own responsibility for their disease; for example, patients were more involved with their own data and did self-management. Patients partly took over the monitoring from the healthcare professional compared to regular care. Leon et al. (2015) reported similar feelings among patients about self-responsibility. In contrast, patients did not discuss the increased self-responsibility in Study Two. They mentioned the self-monitoring part but did not express that they felt more or less responsible for themselves. They neither experienced less responsibility of the healthcare professionals. However, this finding contradicted with results of Fairbrother et al. (2014); they found that patients felt less self-responsibility for their own because healthcare professionals were primary responsible for the patients. All those aspects corresponded with the aim of the Do CHANGE program: realization of lifestyle change. In addition to this, the current study gained more insights about drawbacks that other research did not mention before.

One drawback that was found in the current study was the increase of disease awareness. Results showed that patients were reminded more of their disease in daily life when they had to use the ecosystem. This reminder was not always appreciated among patients. Healthcare professionals also reported this issue in Study Three.

Furthermore, problems with interpreting the data (e.g. ECG's and Beddit data) were a new drawback that revealed among patients. Patients worried more and experienced no reassurance because participants explain data in a wrong way. This finding was not reported during Study One or Three, neither found in existed research. So, awareness and reassurance were important themes for the current study and those were also related to the degree of contact between patient and healthcare professional.

### 5.1.2 Contact with healthcare professionals

The change in contact between patient and healthcare professional was an important aspect during treatment and disease management because patient and healthcare professional collaboration is needed in order to achieve the most optimal results in lifestyle, medicine regulations, and improvement of disease. Several aspects were mentioned. First, patients, relatives, and healthcare professionals reported that the contact has changed compared to regular care because extensive data (e.g. blood pressure and ECG's) during consults were available. Second, the possibility of contact with the researchers next to the regular consultations by phone was valuable. Third, adjustments in treatment (e.g. medications prescription) could be made faster which resulted in an increase in treatment quality. Other scholars confirmed that contact was appreciated among patients (Ly et al., 2015; Pludwinski et al., 2016). The patient – healthcare profession relation has been improved due to eHealth (Thorup et al., 2016) and reassurance increased because patients felt being cared of by others (Fairbrother et al., 2014). The healthy elderly did not discuss the communication and relationship between patient and healthcare professional in Study One, but only indicated that the reduction of hospital visits could reduce patient burden and healthcare costs. This benefit was also briefly mentioned during Study Two

and Three among patients, relatives, and healthcare professionals, but was not found in existing research. Next to the contact with others, personalization was discussed in all partial studies.

#### 5.1.3 Personalization

Overall, participants over the different studies indicated the need for personalization. The healthy elderly participating in Study One, as they did not have a diagnosis of heart disease, indicated that they did not or partially need the Do CHANGE ecosystem even though the system could also contribute to a healthier lifestyle in general. They saw benefits of using the system only for someone else, but the ecosystem use was not applicable for themselves. These findings among the healthy elderly implied a desire for customized services.

This outcome was also emphasized during Study Two and by one healthcare professional of Study Three. Participants indicated that the use of relevant devices of the ecosystem could differ from person to person because there was no medical need for using all the technologies. Patients noted the same with the received messages: they felt that those messages were sometimes intended for others, patronizing, or irrelevant for them. Similar results were found in other studies where instructions were reported as irrelevant or too standardized (Ly et al., 2015) and messages should be adjusted to the person (Leon et al., 2015) in frequencies, tone, and content (Lyzwinski et al., 2017). So, findings of the current study and other scholars suggested that personalization of both messages and devices of the ecosystem might be desirable in an eHealth solution for daily hospital practice.

In addition to this, all healthcare professionals wondered if the intervention was suitable for every patient because healthy elderly might not be capable of using it or patients might even not want the ecosystem. Those two points were also mentioned during Study One. The healthy elderly considered the usability of the ecosystem among the target group. Suggesting that implementation of the system among CVD patients should be applied carefully and it might occur that the system would not be accepted by everyone. The healthy elderly could also reject the ecosystem in case the ecosystem was, for example, judged as unhelpful device or participants aimed for self-determination. Those reasons were also part of barriers among the healthy elderly.

#### 5.1.4 Other barriers

More barriers for using the ecosystem were mentioned among healthy elderly compared to people who actually used it. The healthy elderly indicated that they were doubtful about the willingness to use the ecosystem. Several reasons were given: first, they did not need the ecosystem for themselves because of absence of a cardiac diagnosis. Second, healthy elderly mentioned that they did not want to know the data, or did not know what they should do with the outcomes of the data. Third, the ecosystem would require effort and would be a burden. Fourth, the system would decrease self-determination because the technology might instruct what one should do instead of being supervised

about themselves. Fifth, the healthy elderly worried about their privacy. Sixth, the system was not even helpful at all.

Those concerns, except privacy, were not reported among patients, relatives, and healthcare professionals implying that there might be prejudices, fears and thresholds if people maybe should have to use the ecosystem. Moreover, this effect could also be explained by the fact that there was a difference between Study One and Two. Participants of Study One might not have chosen to use the ecosystem while participants of Study Two accepted the use accepted to use the system in advance. Whereas the healthy elderly indicated expectations as the most relevant problems, results of Study Two assigned technical problems as most frequented concerns.

# 5.1.5 Technical problems

Technical issues were extensively discussed among patients and relatives and also might have caused frustration among patients and their relatives. Previous studies have also reported technical problems with eHealth interventions (Fairbrother et al., 2014; Salvi et al., 2017). This insight about technical issues was supported by one healthcare professional in Study Three. Patients were motivated for executing the correct procedures for the Do CHANGE study, but errors were assigned sometimes for themselves instead of technical problems of the system. For example, making food photos did not work well and was not always appreciated by patients and their relatives. However, Pludwinski et al. (2016) demonstrated that making photos of your food increased awareness about health status and food intake. This finding was only partly confirmed in the current study. Privacy and security problems were briefly mentioned by all participants during all three studies. The mentioned problems suggested that the ecosystem needs more development before implementation in the regular care.

# 5.2 Limitations and implications future research

Limitations existed in every part of the current threefold study. In Study One, healthy elderly were invited for an interview without mentioning terms such as technology of eHealth in the invitation. This could be affected the results, because the healthy elderly were open-minded before the interviews. Participants who had initially no affinity with technology, might sign up more easily for the interview when technology concepts were not mentioned. However, those healthy elderly were invited by email and it seemed that all participants signed up for the interview within four hours. So, it could be assumed that participants were acquainted with technology because they had an email address and they relatively signed up fast for the interview. Moreover, two participants indicated by themselves that they had worked at Philips and another participant also had a technical job back in the days. It turned out afterwards that the participants were more familiar with technology than intended and expected beforehand. It is suggested to request previous working experiences and function to verify someone's interests and experiences. Furthermore, one should recruit participants more face to face and with other platforms as well for future research. It is expected that a more varied group of participants might

result in other aspects. For example, other scholars reported concepts such as anxiety (Huygens et al., 2016) and self-conviction of less capacities to use technology (Sanders et al., 2012).

Another limitation of the pre-study was the difficulty of the concept of 'lifestyle'. It was remarkable that multiple participants could not identify themselves with 'lifestyle' because they were talking about life events such as having kids, change of job, or retirement. Explanation of the concept by the interviewer sometimes resulted in biased answers afterwards (e.g. one immediately talked about walking if the interviewer explained the concept with a walking explanation). For future research, one might use another concept such as 'health' or should explain the concept before the interview starts.

In relation to this, the fact that not all participants were not diagnosed with CVD or another disease was also difficult. An interview with only presenting the devices could be not enough time to consider the devices of the system sufficiently and imagine themselves to use the ecosystem. The demand to imagine that they would use it was maybe too complicated and difficult for them to investigate the intended barriers and opportunities. For future research, it is proposed to implement a short try-out period of devices, for example, one week solving the prior ignorance of participants. It is also suggested to interview CVD patients who declined participating in the Do CHANGE project for more extensive barriers.

As regards to Study Two, more in-depth evaluations about the separated devices within the ecosystem might be needed because this study was a more overall evaluation of the Do CHANGE ecosystem. A bias could occur in Study Two because participants would participate because of themselves while participants in Study One had no intentions to use the ecosystem by themselves beforehand. Moreover, the ecosystem was extensive, and details of separate devices could be missed during the focus groups because of the interview script and time restrictions. For example, other functions besides taking pictures of the Vire application were hardly discussed, while there might also be unused functions or issues in this application. This additional in-depth evaluation is valuable because the Vire application was a specially developed application for Do CHANGE, while the other devices were already existing technologies of third parties. User experience verification of specific functions of the different devices is suggested for future investigation to improve the ecosystem.

A part of the Do CHANGE study protocol was that researchers called participants weekly for three months. Technical issues, uncertainties and even the patient's health condition were discussed during this phone call. After three months this weekly phone consultation stopped. Participants reported the weekly phone consultation as appreciated and the fact that there was the possibility to get in contact provided reassurance among patients and their relatives. However, the Do CHANGE program is a study and the weekly telephone consultations of the researchers were only three months part of the official intervention. It is not feasible to call patients weekly if the ecosystem will be implemented in the future. Although, participants could possibly experience the phone consultations as more important than intended in advance. So, the weekly phone calls could affect the reassurance to a large extent.

This given should be considered when the Do CHANGE intervention will be implemented in the current clinical setting. The question how the patient – healthcare professionals contact could be practically organized, should be discussed.

Two focus groups with sixteen patients and relatives were executed. A strength of this study was the fact that it was possible to organize those group sessions with this number of CVD patients and their relatives. However, it is desired to execute one or two more focus groups verifying the results and control for biases in group decision making (Liamputtong & Ezzy, 2005).

In Study Three, the protocol of the Do CHANGE project regarding healthcare professionals was a limitation because they were less involved with the patients compared to the researchers. The researchers executed the intervention and did the weekly calls with patients while healthcare professionals came only in contact with Do CHANGE patients during the regular consults. Thus, two healthcare professionals had to provide their experiences about the intervention in the interviews while they were only indirectly involved with the project. One healthcare professional

This protocol of the Do CHANGE study also caused the final small sample size of the interviews with healthcare professionals in Study Three. There were hardly healthcare professionals who implemented the intervention in their working routine, because they were indirectly involved in the project. Moreover, one healthcare professional was involved as one of the Do CHANGE program headers and might have contributed experiences and interests from this point of view. Implementation and evaluation of the intervention among healthcare professionals is desired in the future to gain more realistic insights of their experiences.

# 5.3 Recommendations Do CHANGE project and practical implications

To summarize, findings of the current study gained insights about experiences of healthy elderly, patients, relatives, and healthcare professionals of a cardiovascular eHealth intervention. This has implications for both the Do CHANGE project, which will continue for another four months after completion of this master thesis, and implementation of eHealth applications in general.

Recommendations for the Do CHANGE project will be discussed. First, it is recommended to investigate the reasoning why people did reject participation in the Do CHANGE program next to the included Do CHANGE participants. This group of people was already diagnosed with CVD and had been invited for participation. Therefore, it is expected that more extensive barriers will reveal in contrast to interviews with healthy elderly of Study One. Second, it is suggested to obtain more indepth evaluations about the added value of the separated devices of the Do CHANGE project. Those insights could be used for future development of the ecosystem. It should at least be executed for the Vire application because this technology was specially developed for the Do CHANGE program and the other devices were already developed by third parties. Third, it is recommended that the usage of

the Do CHANGE program among healthcare professionals will be extended and more evaluated. They should be able to experience and criticize the program in their function themselves.

Besides the recommendations for the Do CHANGE project, practical implications of the current study will be considered. First, eHealth interventions could change the models of the regular healthcare. One of the aims of the Do CHANGE project is to reduce costs in the healthcare domain and change the treatment set up. It is expected that patients will be more responsible for their disease management and that they will visit the hospital less often, reducing the care demand. However, findings of the current study implied that contact with researchers was appreciated. The weekly phone consultations were not considered as part of the Do CHANGE protocol, but reassurance increased among patients and their relatives due to, among others, the possibility of contact. This implication might be contradicted with the overall goal of eHealth, because patient consultation by phone might require more effort and time of the healthcare professionals instead of a decrease in care demand.

Second, personalization was considered during all three parts of the current study. However, it was not discussed how personalization could be realized and how this practically for with the Do CHANGE project in the future. It was implied that the healthcare professionals should carefully consider the condition of the patient. The ecosystem should be adapted to the personal situation of the patient dependent of CVD diagnosis, symptoms, complaints, comorbidities of other diseases, and other contexts. It is complicated to provide fixed instructions on how to do this. However, a discussion between healthcare professional and patient might provide insights about personal preferences and desires of the patient. Or patients will just use the devices, so that most optimal combination of devices will be experienced.

Third, barriers to use the ecosystem among certain targets groups could always exists among potential users. However, if the ecosystem could be implemented on a bigger scale, than more people might be persuaded to participate in the Do CHANGE program. Therefore, understanding of barriers is essential. The system and its benefits should be explained to people who initially rejected the ecosystem. One should carefully empathize with the patients about his doubts to take away the concerns.

Fourth, the relevance of using the ecosystem for society should be considered. The overall goal of the Do CHANGE project was to develop of a personalized disease management system for CVD patients aiming to improve lifestyle and manage CVD disease. It should change the regular models of care. It could improve treatment quality for the patient, reduce workload for healthcare professionals, and decrease healthcare costs in general. The current study has contributed in this development because it showed valuable insights about experiences of the Do CHANGE ecosystem use.

### 5.4 Conclusion

This study explored the barriers and opportunities of the Do CHANGE ecosystem among patients, relatives, and healthcare professionals. A pre-study investigated possible barriers and opportunities among healthy elderly at a first impression. Overall, healthy elderly were doubtful to use the ecosystem. In contract, the cardiac patients, their relatives, and healthcare professionals assigned the Do CHANGE ecosystem as beneficial. The themes awareness, reassurance, self-responsibility, personalization, technical problems, and the contact between patient and healthcare were the most important discussed subjects during the evaluations. Despite the limitations, results has contributed to interesting insights in eHealth domain with cardiac patients. Outcomes of the current study can be used in the further development of the Do CHANGE ecosystem increasing treatment quality in hospital practice. The Do CHANGE program was integrated in a clinical setting and was evaluated among different stakeholders, and therefore, those were two strong points of this study. More research is needed; however the current study supported in the understanding of eHealth and the application in daily life among cardiac patients. This study was a contribution to hopefully reduce the number one cause, namely cardiovascular disease, for mortality and morbidity in the world.

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### Appendix 1: interview guide part 1 – pre-study

Question	Translated question	
Part 1: questions about current lifestyle		
Bent u tevreden over uw levensstijl?	Are you satisfied with your current lifestyle?)	
Heeft u ooit in het verleden of bent u op dit	Have you ever changed your lifestyle or are you	
moment bezig uw levensstijl te veranderen?	changing your lifestyle right now?	
- Waarom wel? / Waarom niet?	- Why? / Why not?	
- Welke aspecten?	- Which aspects of your lifestyle do/did	
- Hoe doet u dat? / Welke hulpmiddelen	you change?	
gebruikt u daarvoor?	- How are you changing your lifestyle? /	
	Which tools did / do you use?	
Hoe staat u er tegenover om uw levensstijl te	What is your opinion about changing your	
veranderen door middel van mobile applicaties?	lifestyle with mobile applications?	
- Waarom vindt u dat?	- Why do you think this?	
Heeft u ervaringen met het gebruik van mobile	Do you have experience with mobile	
telefoons in relatie tot gezondheidzorg?	applications in relation to healthcare?	
- Waarom niet?	- Why not?	
- Welke ervaring heeft u dan?	- Which experience do you have?	
Part 2: explanation of the ecosystem		
- Ik ga u nu het hulpmiddel presenteren. Dit is	- I am going to present the intervention right	
een hulpmiddel voor het veranderen van	now. This is a tool for lifestyle change and it	
iemands levensstijl en omvat verschillende	includes different parts.	
onderdelen.	- The first part is a blood pressure monitor	
- Het eerste onderdeel is een bloeddruk meter.	where you can measure your own blood	
Hiermee kun je thuis zelf je bloedruk opmeten.	pressure at home.	
- Het tweede onderdeel is de Careportal. Dit is	- The second part is the Careportal. This is a	
een kastje met een aantal onderdelen. Hier	device with several parts whereby you receive	
ontvangen mensen motiverende berichten op	motivational messages (show example).	
(laat voorbeeld zien). Daarnaast kun je hier	Moreover, you can fill in daily questions about	
dagelijkse vragen invullen om de voortang en	your progress and symptoms. Finally, you can	
lichamelijk symptomen in te vullen. En als	make a ECG with this device.	
laatste kun je met dit apparaat een hartfilmpje		
maken.		
- Het derde onderdeel is een klassieke	- The third part is a normal scale. I do not have	
weegschaal om je gewicht op te meten. Deze	this device right now but I hope you know what I	
heb ik hier nu niet. Maar u kan zich vast wel een	mean.	
voorstelling bij maken.		

- Het vierde apparaat is de Beddit. Hiermee - The Beddit is the fourth device that measures worden slaappatronen 's nachts geregistreerd. sleep patterns during the night. For example, the Bijvoorbeeld de hartslag, slaaptijden en ook of u heartbeat, sleeping times and light or deep sleeping statistics. The Beddit has a separate een diepe of licht heeft geslapen. De Beddit heeft een aparte app op de mobiele telefoon. application on the mobile phone. - The Fitbit is the fifth device. This is a bracelet - Het vijfde apparaat is de Fitbit. Dit is een armbandje die je om je pols doet en deze that measures daily activity such as heart beat, registreert je dagelijkse activiteit zoals je number of active minutes, and the number of hartslag, aantal actieve minuten en de steps. hoeveelheid stappen op een dag. - Het zesde apparaat is de Moves applicatie. - The sixth device is the Moves application Deze registreert de locaties waar je bent which registers the location that you have visited and based on that it determines the social factor geweest en op basis daarvan bepaald hij hoe of the user. sociaal de gebruiker wel of niet is geweest. - Als laatste is er de Vire applicatie. Dat is een - Finally, the Vire application is a mobile mobile applicatie waarbij de data van de application which combines the prescribed three applications. Moreover, users are able to make voorgaande drie applicaties wordt gecombineerd. Daarbij kunnen mensen ook pictures of their food intake and upload these foto's maken van hun eten en deze uploaden. pictures. - Zijn er nog onduidelijkheden of dingen die u - Are there some uncertainties or questions wilt weten over het hulpmiddel? about the intervention? Part 3: questions about the system Wat is uw eerste indruk van het systeem? What is your first impression about the system? - Waarom vindt u dat? - Why? Are you willing to use this system in your daily Zou u dit systeem willen gebruiken in uw dagelijkse leven? life? - Waarom niet? / Waarom wel? - Why not? / Why? - (indien ja:) Zou u kunnen uitleggen hoe - (if yes:) Could you explain how you u dit systeem zou willen gebruiken? want to use this system? - (indien ja:) Zou u kunnen uitleggen - (if yes:) Could you explain when do wanneer u dit systeem zou willen you want to use the system? gebruiken? Wat zijn uw verwachtingen van dit hulpmiddel in What are your expectations in relation to het kader van het verbeteren van uw levensstijl? improving your lifestyle? - (indien nee) Waarom heeft u geen - (if no:) Why do you not have verwachtingen? expectations? Wat zijn redenen voor u om dit hulpmiddel te What are reasons for you to use this system? - Why? gebruiken? - Waarom?

Wat zijn redenen voor u om dit hulpmiddel niet	What are reasons for you for not using the
te gebruiken?	system?
- Waarom?	- Why?
Als uw dokter aangeeft dat u dit systeem zou	If your doctor indicates that you should use the
moeten gebruiken, zou u dat dan doen?	system, would you do this?
- Waarom wel of waarom niet?	- Why yes or why not?
Welke dingen missen er volgens u in het	What things are missing in the system?
hulpmiddel?	- Why?
- Waarom?	- Could you explain this?
- Kunt u uitleg geven?	
Zou u dit systeem aanbevelen aan een vriend of	Could you recommend this system to a friend or
familielid die hulp nodig heeft?	a family member who needs help?
- Waarom?	- Why?
Zijn er nog dingen die u kwijt wilt over het	Do you want tell something extra that we not
systeem of over dit interview die wij nog niet	have discussed yet?
hebben besproken?	

#### Appendix 2: questionnaire pre-study

Vragenlijst: Verander je levensstijl 1. Wat is uw leeftijd? \_\_\_\_\_ jaar 2. Wat is uw geslacht? ☐ Man ☐ Vrouw 3. Bent u gediagnostiseerd met hart en vaatziekten? ☐ Nee (ga door naar vraag 5) ☐ Ja, namelijk: \_\_\_\_\_ 4. Hoe lang heeft u al hart en vaatziekte? 5. Bent u gediagnostiseerd met een andere (chronische) ziekte? ☐ Nee (einde vragenlijst) ☐ Ja, namelijk: \_\_\_\_\_ 6. Hoe lang heeft u deze (chronische) ziekte? \_\_\_\_\_ jaar

Hartelijk dank voor het invullen!

# Appendix 3: interview guide part 2 – patient and relative evaluation

Question	Translated question	
Effectiveness		
Zijn de verwachtingen van het ecosysteem	Were the expectations of the ecosystem been	
waargemaakt?	realized?	
- Waarom wel of niet?	- Why or why not?	
Hebt u verandering in uw gedrag gemerkt, heeft	Have you noted a behavior change and helped	
het systeem hierbij geholpen?	the system with this?	
Partner/naaste vraag: heeft u verandering in het	Partner / relative question: have you noted a	
gedrag van uw partner/naaste gemerkt?	behavior change at your partner / relative?	
Wat zijn redenen om het ecosysteem te	What are reasons to use the ecosystem?	
gebruiken?		
Wat zijn redenen om het ecosysteem niet te	What are reasons for not using the ecosystem?	
gebruiken?		
Zijn er redenen geweest gedurende de	Are there reasons to consider stopping during	
interventie waardoor jullie overwogen om te	the intervention?	
stoppen?		
Social, legal and ethical issues		
Hebt u het informed consent ingevuld voordat u	Did you have to sign the informed consent	
begon aan de studie?	before participating the research study?	
Hebt u de uitleg in het informed consent volledig	Did you fully understand the informed consent?	
begrepen?		
Heeft het systeem invloed gehad op het contact	Did the system affect the contact between	
met partners of naasten?	partner or relatives?	
- Kunt u dat uitleggen?	- Could you explain your answer?	
Partner/naaste vraag: hoe heeft u dat als	Partner/relative question: How did you	
partner/naaste ervaren?	experience this as a partner/relative?	
Heeft het systeem invloed gehad op het contact	Did the system affect the contact with your	
met zorgprofessionals?	healthcare professional?	
- Kunt u dat uitleggen?	- Could you explain your answer?	
Technical aspects		
Werkte het systeem zoals het zou moeten? Was	Did the technological solution work as it was	
het stabiel?	intended to? Was it stable?	
Welke elementen van het systeem vindt u	Which elements of the system do you think are	
waardevol?	valuable?	
- Waarom?	- Why?	
Welke elementen hebt u vaak gebruikt?	Which elements of the system have you use	
- Waarom?	often?	

of nauwelijks gebruik? - Waarom?  Welke elementen zou u weg willen laten? - Waarom?  Zijn er elementen die missen in het systeem?  Hoe ervaart u het gebruiksgemak van het systeem?  Data privacy and patient security  Omdat een gedeelte van het systeem online wordt aangeboden door middel van een technologie zoals de Careportal, heeft u het gevoel dat uw data veilig is? - Waarom wel of niet?  De data van de Careportal wordt gedeeld met ons door middel van PDS (Personal Data Store). Vertrouwd u erop dat deze data hierin veilig is? - Waarom wel of niet?  Economical aspects  Zou u door willen gaan met het systeem na de studie? - Indien ja, wat vindt u een redelijke prijs? - Indien nee, waarom niet?  Which elements of the system have you not or hardly used? - Why?  Which elements of the system have you not or hardly used? - Why?  Which elements of the system have you not or hardly used? - Why?  Which elements of the system have you not or hardly used? - Why?  Which elements of the system have you not or hardly used? - Why?  Which elements of the system have you not or hardly used? - Why?  Which elements of the system?  Which elements of the system?  Which elements of the system?  Which elements or used iminate? - Why?  Which elements or usedility of the system?  Why?  Which elements or used iminate? - Why?  Which elements or used iminate? - Why?  Which elements or usedility of the system?  The data of the Careportal safe?  - Why or why not?  Would you like to continue?  Wat da v	Welke elementen van het systeem heeft u niet	- Why?	
- Waarom?  Welke elementen zou u weg willen laten? - Waarom?  Zijn er elementen die missen in het systeem?  Hoe ervaart u het gebruiksgemak van het systeem?  Data privacy and patient security  Omdat een gedeelte van het systeem online wordt aangeboden door middel van een technologie zoals de Careportal, heeft u het gevoel dat uw data veilig is? - Waarom wel of niet?  De data van de Careportal wordt gedeeld met ons door middel van PDS (Personal Data Store).  Vertrouwd u erop dat deze data hierin veilig is? - Waarom wel of niet?  Economical aspects  Zou u door willen gaan met het systeem na de studie? - Indien ja, wat vindt u een redelijke prijs? - Indien nee, waarom niet?  Naarom wel of centrological platform, do you feel through a technological pla		•	
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Heeft u nog iets anders toe te voegen wat nog  Would you like to add something else that is not	Wat is het meest relevante onderdeel met	What do you think is the most relevant thing	
	betrekking tot uw ervaringen met Do CHANGE?	regarding your experience with Do CHANGE?	
niet is besproken tot nu toe? discussed yet?	Heeft u nog iets anders toe te voegen wat nog	Would you like to add something else that is not	
	niet is besproken tot nu toe?	discussed yet?	

#### Appendix 4: questionnaires patient and relative evaluation

#### A: Do CHANGE gebruiker

1.	vvat is uw geboortedatum?	
2.	Wat is uw geslacht?  ☐ Man  ☐ Vrouw	
3.	Bent u momenteel werkzaam?    Ja  Nee  Pensioen  Anders:	
4.	Hoe lang bent u al gediagnostiseerd met uw hartziekte?	
	jaar	
B: Part	ner/naaste	
1.	Wat is uw geboortedatum?	
2.	Wat is uw geslacht?  ☐ Man  ☐ Vrouw	
3.	Bent u momenteel werkzaam?	
4.	Wat is uw relatie tot de persoon die de interventie heeft doorlopen?  Man/vrouw  Zoon/dochter  Broer/zus  Ander familielid  Vriend  Partner	

## Appendix 5: interview guide part 3 – healthcare professional evaluation

Question	Translated question
General questions	
Heeft u ervaringen met eHealth? Zo, ja kunt u	Do you have experiences with eHealth? If yes,
een voorbeeld geven?	could you give an example?
Hoe staat u er tegenover om eHealth	What is your attitude regarding the use of
toepassingen te gebruiken in uw functie	eHealth in your job?
Do CHANGE questions	
Wat zijn uw ervaringen met het Do CHANGE	What is your experience with the Do CHANGE
project?	project?
Hoeveel patiënten ziet u die meedoen aan het	How much of your patients are participating in
Do CHANGE project?	the Do CHANGE project?
Wat zijn de negatieve ervaringen?	What are your negative experiences?
Wat zijn de positieve ervaringen?	What are your positive experiences?
In hoeverre heeft u Do CHANGE geïntegreerd in	To what extend did you integrated Do CHANGE
uw behandelingen of bent u bezig met Do	in your consults or are you using Do CHANGE?
CHANGE?	
Heeft het systeem invloed gehad op het contact	Had the system influence on the contact with
met patiënten? Kunt u dat uitleggen?	patients? Could you explain that?
Heeft u inzicht in de data van Do CHANGE op	Do you have insight in the Do CHANGE data
dit moment en hoe zou u dit graag inrichten in de	right now and how do you prefer to organize this
toekomst?	in the future?
Wat zijn redenen om het ecosysteem te	What are reasons for using the ecosystem as a
gebruiken voor u als zorgverlener?	healthcare professional?
Wat zijn redenen om het ecosysteem niet te	What are reasons for not using the ecosystem
gebruiken voor u als zorgverlener?	as a healthcare professional?
Zou u de interventie willen inzetten na afloop van	Would you use the intervention after the end of
het Do CHANGE project tijdens behandelingen?	the Do CHANGE project? Why or why not?
Waarom wel of niet?	
Heeft u gedragsveranderingen gemerkt bij uw	Have you noted a behavior change by patients
patiënten die meededen met het Do CHANGE	who participated in the Do CHANGE project? If
project? Indien ja, kunt u een voorbeeld geven?	yes, could you give an example?
Welke dingen missen er volgens u nog aan de	Which parts are missing in the intervention in
interventie?	your opinion?
Conclusion/ resume	
Wat is het meest relevante onderdeel met	What do you think is the most relevant thing
betrekking tot uw ervaringen met Do CHANGE?	regarding your experience with Do CHANGE?

Heeft u nog iets anders toe te voegen wat nog	Would you like to add something else that is not
niet is besproken tot nu toe?	discussed yet?

### Appendix 6: questionnaires healthcare professional evaluation

1.	Datum invullen vragenlijsten:
2.	Wat is uw geslacht?  □ Man □ Vrouw
3.	Wat is uw geboortedatum?
4.	In welke functie bent u werkzaam?
5.	Hoeveel jaar werkervaring heeft u?
6.	Hoeveel jaar werkervaring heeft u met eHealth?
7.	Hoeveel patiënten ziet u gemiddeld per week? patiënten
8.	Hoe is uw huidige beroepssituatie?  ☐ Voltijd werkend  ☐ Deeltijd werkend
9.	Indien deeltijd werkend, hoeveel uren per week heeft u de aanstelling?
	uur per week.
10.	Hoeveel procent van uwe werk omvat taken die niet direct gerelateerd zijn aan behandeling van patiënten? (bijvoorbeeld administratie en casemanagement)
	% van mijn werk.