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e-Rehabilitation

Design and effectiveness of a tailored Internet- and mobile-based intervention to support maintenance of physical activity after cardiac rehabilitation

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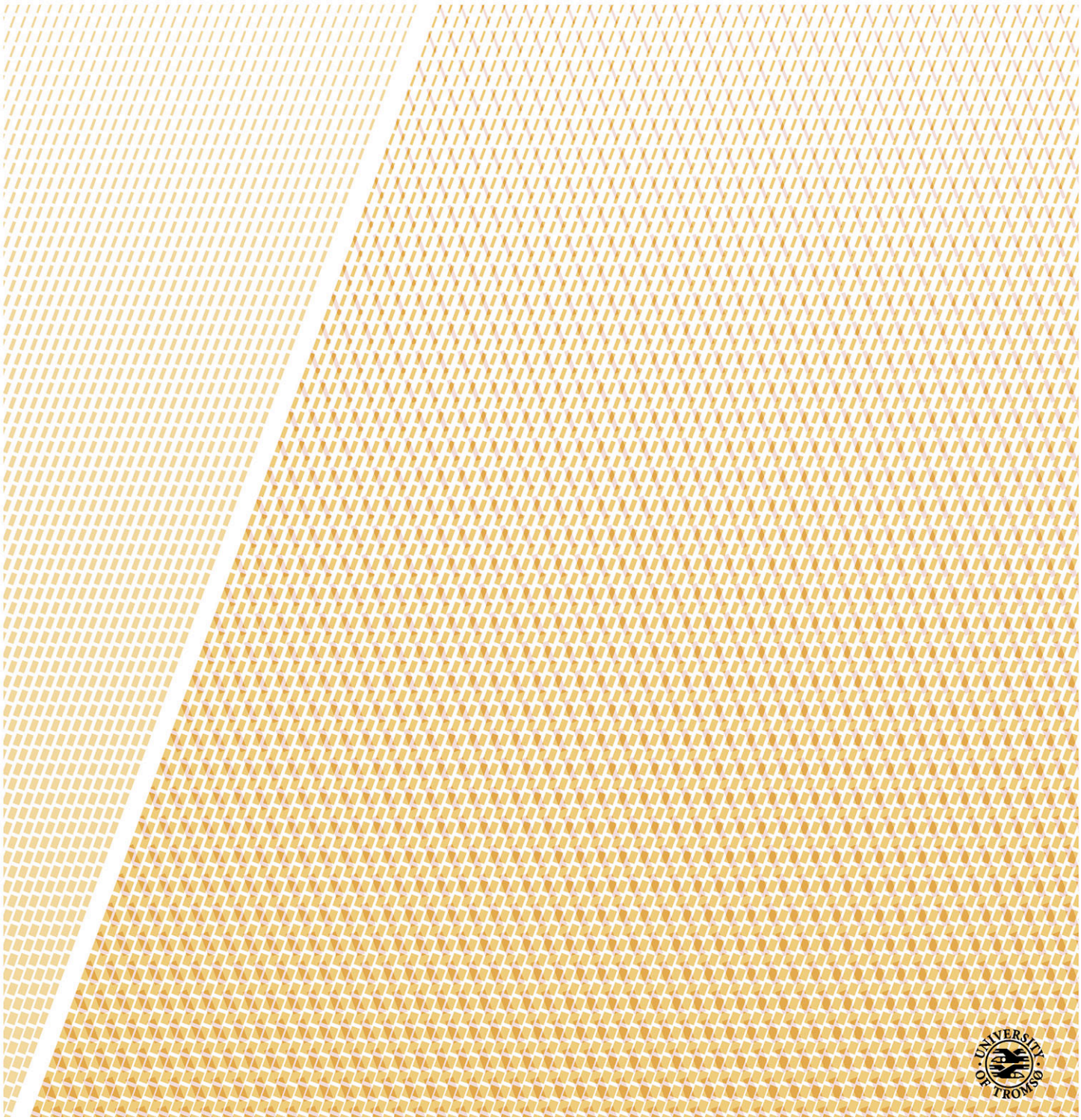

e-Rehabilitation: Design and Effectiveness of a Tailored Internet- and Mobile-based Intervention to Support Maintenance of Physical Activity after Cardiac Rehabilitation

Scientific environment

The candidate was employed by and the research was conducted at the Norwegian Centre for Integrated Care and Telemedicine, University Hospital of North Norway, Tromsø, Norway.

The candidate was a PhD student at the Telemedicine and E-health Research Group, Department of Clinical Medicine, UiT The Arctic University of Norway.

The candidate was supervised by Associate Professor Silje C. Wangberg.

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Summary

Objectives

The main objective of this PhD project was to offer an effective Internet- and mobile-based intervention to support patients in maintaining physical activity after a cardiac rehabilitation stay. The work presented in three papers describes the process from the design of the intervention to the final results. Paper I describes the process of designing an intervention based on components that are known to be effective, theory, and user input. In Paper II, the objective was to design a randomized controlled trial, as an assessment tool for the effectiveness of the tailored intervention. Finally, the objective of Paper III was to present and analyse the results of the trial, and discuss the effectiveness of our intervention.

Methods

There are several available methodologies for designing information and communication technology (ICT)-based health interventions but most of them do not properly address simultaneously both of the factors we identified as important for effective interventions, namely user input and a strong theoretical framework. In Paper I, we describe the methodology we employed to combine users' needs and health behaviour models in the design of our intervention. We used a narrative overview of the literature on health behaviour theories to construct the theoretical framework. For the user input, we conducted a focus group with 11 patients from the cardiac rehabilitation centre where we later ran the trial in order to understand their needs, thoughts, and ideas regarding physical activity after the cardiac rehabilitation stay, and how technology could support them. We used thematic analysis to identify and analyse patterns of meaning in the transcribed data.

In Paper II, we describe the protocol of a randomized controlled trial to evaluate the effectiveness of our intervention. We used parallel group cluster randomization with participants of each monthly group of the cardiac rehabilitation program at Skibotn Rehabilitation Centre. Each cluster was given either the tailored intervention or the non-tailored intervention (control group).

The participants of the non-tailored group had access to a website with generic information regarding cardiac rehabilitation, a discussion forum, and an online physical activity calendar. The participants of the tailored group had access to the same functionality as the non-tailored group. In addition, they also received reminders and tailored content based on models of health behaviour through the website and mobile text messages.

The self-reported level of physical activity measured in Metabolic Equivalent of Task (MET)-minutes per week was obtained online using the international physical activity questionnaire at baseline, at discharge, at one month, and at three months after discharge from the cardiac rehabilitation program. Secondary outcome measures were self-efficacy, social support, anxiety, and depression. Process measures were the stage of change, perceived tailoring, use of the intervention, and user evaluation of the intervention.

In paper III, we present the data of the randomized controlled trial from 69 participants at baseline, 24 participants at one month after discharge, and 19 participants at three months after discharge. Because of the small sample size and the types of measures we used, we analysed the data with non-parametric measures. For the same reasons and because of the large variance in the size of the clusters, we did not account for the clusters in our comparisons. For the main outcome, and for other continuous variables, we used the Kolmogorov-Smirnov Z to compare the tailored group with the non-tailored group. For the analysis of the categorical data, we used a chi-square test. To maximize the use of our data, we included all the cases with valid data per time-point and per variable. For the analysis of the adherence to the website, we used Kaplan-Meier survival curves, and compared the adherence curves of the tailored and non-tailored groups with the generalized Wilcoxon test of Breslow.

Results

From the thematic analysis of the focus group data presented in Paper I, we identified seven themes regarding the needs, thoughts and ideas of the users: social, motivation, integration into everyday life, information, planning, monitoring and feedback, and concerns and potential problems.

The results of the randomized trial presented in Paper III showed that the tailored group had a higher median in overall physical activity than the non-tailored group at three months after discharge, and the difference was statistically significant. We did not find statistically significant differences between the groups in stage of change, self-efficacy, social support, perceived tailoring, anxiety or depression. Both groups had low adherence and there was no statistically significant difference between the two groups. The majority of the users in both groups evaluated the intervention positively and most of the functionality was considered to be useful.

Conclusions

The combination of health behavioural theory and user input that we propose for designing interventions is a feasible approach that combines the high efficacy of theory-based interventions with the sometimes-higher perceived usefulness of interventions designed according to user input. The information that is gathered from the user input can also be very useful in the interpretation of the results.

The assessment of the intervention in a randomized controlled trial revealed that the users of both groups had positive feelings towards the intervention, but the adherence rate was generally low. The small sample size limited our ability to make firm conclusions regarding the effectiveness of our intervention, but there is an indication that the tailored approach might have contributed to a longer maintenance of physical activity after the cardiac rehabilitation stay.

List of publications

I. Antypas K, Wangberg SC. Combining users' needs with health behaviour models in designing an Internet- and mobile-based intervention for physical activity in cardiac rehabilitation. JMIR Research Protocols. (forthcoming) 2013.

II. Antypas K, Wangberg SC. E-Rehabilitation - an Internet and mobile phone based tailored intervention to enhance self-management of Cardiovascular Disease: study protocol for a randomized controlled trial. BMC Cardiovascular Disorders. 2012;12:50.

III. Antypas K, Wangberg SC. An Internet- and mobile-based tailored intervention to enhance maintenance of physical activity after cardiac rehabilitation: short-term results of a randomized controlled trial. JMIR (under review) 2013.

Contents

Introduction

According to the Global Burden of Disease 2010 study (Lim et al., 2012), cardiovascular and circulatory diseases have a major impact on the Disability Adjusted Life Years (DALY[1]) in various age groups. For Norway, the burden of cardiovascular and circulatory diseases accounts for 14.5% of the total DALYs. Rehabilitation and secondary prevention for these diseases can decrease mortality risk and increase quality of life (I. Graham et al., 2007; Ipser, Dewing, & Stein, 2007). A major focus of such programs is health behaviour change targeting, among other factors, physical activity. However, the changes in health behaviour do not tend to last long after the end of the rehabilitation program (Moore, Ruland, Pashkow, & Blackburn, 1998). A user-centric approach that combines technology and health behaviour theory has great potential in increasing the effectiveness of cardiac rehabilitation programs and prolonging their positive impact.

Science has always tried to answer questions about life, from the biggest ones—about the universe, for example—to the smallest ones, such as why didn't I go to the gym today. This continuous search for answers and truth has unquestionably led to the evolution of human societies and has improved many aspects of our lives, but it becomes more and more obvious that we are far from finding all the answers or the truth. The world is not as simple as we thought in the big-scale, nor in the small-scale. If it is not the answers that are driving this evolution, what it is, then, that science has contributed? And if we don't have the answers, how can we help others, and ourselves, fulfil our social roles, or our roles as human beings and as health professionals?

Socrates (469 BC–399 BC), the classical philosopher, would try to solve a problem by breaking the problem down into smaller questions. He then would try to distil the answers out of another person—and he would be a bit ironic, too.

[1] One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability. DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the health condition or its consequences. (WHO definition)

This approach, the dialectic method—aside from the obvious implications it has in the scientific hypothetico-deductive method with the hypothesis forming and its subsequent elimination or acceptance—might offer a solution to our dilemma, too. My interpretation of this in health care is that every person is able to find the answers to better health if they are asked the right questions. Actually, quite a few scholars defend this sometimes-radical notion within health care that only the person himself can find the right answers to improve own health. Our models and theories are not perfect enough to completely describe each person's health behaviour. Even if they were, there are at least two remaining issues: Is the person willing and able to share with a health professional all the dimensions of his health behaviour? Is it effective enough to just give the answers to a person if the person has not been through the search for them?

Socrates was also famous for stating that he knew only one thing: that he did not know anything[2]. As health professionals, of course it is not true that we don't know anything, but we cannot behave as if we know everything, either. Health science has long suffered from a paternalistic approach (Coulter, 1999), an overconfidence that the professional always knows better than the patient. It is very positive that we are on the right track of adopting a more Socratic approach. User involvement is the key for this new-old understanding. The patients, the users, know better what they need because only they have complete access to their view of their life-world (Todres, Galvin, & Dahlberg, 2007). Let's look at the example of the ICT-based health interventions. Until the day that the majority of users will design their interventions themselves (a trend that is already visible, e.g., patientslikeme.com), they should be involved in their design through interviews or focus groups. Health professionals will play the role of Socrates, asking the right questions (and developers will take on the role of Plato, to make the user's answers into interventions that will survive in the centuries to come). The result of an intervention based on users' input will be grounded in the context of the users and will be closer to their real needs, but a major effect is expected to come just from being part of this answer-seeking process.

[2] This makes more sense in the pre-Internet era.

Unlike face-to-face interaction with health professionals, which is usually subject to time restrictions, ICT-based interventions have the technical ability to constantly put users through an answer-seeking quest. In contrast to the static approach that provides generic "one-size-fits-all" information through ICT, tailoring utilizes technology to offer dynamic and personally relevant interventions to the user. The process of tailoring an intervention is described as creating an individualized pathway based on answers that the user gives to certain questions. The choice of questions to be asked can be further tailored based on the answers to previous questions. Usually the individualized pathway is providing predefined feedback, messages that have been created by health professionals to correspond to each answer. It is possible, though, to use a more Socratic approach, just to remind people of their own answers to the questions, like in the face-to-face health behaviour change method of motivational interviewing (Miller & Rollnick, 2012). Again, the process of looking for the answers might be more important than the answers themselves, by helping the users gain insight and awareness of their own situation and needs.

A legitimate question related to this approach could be: Is everybody able to find the answers to the health behaviour questions by himself? Health disparities are closely related to socioeconomic inequality, and some might argue that people with low-level or no education might not be able to do it. In his dialogue with Meno, Socrates managed to distil the solution of a geometrical problem from one of Meno's slaves, who had no education or previous geometry experience. Without going into the philosophical debate regarding inborn knowledge, especially in health issues, Socrates' example has important implications for healthcare. If our interventions are not effective for people with a low educational level, its not their educational level that is to blame, but our interventions. People are more likely to perform a health behaviour if they have concluded themselves that it is better for them than if they are dictated to. They are also much less likely to do what they are dictated to do, if what they are dictated to do is decided by someone who has very little understanding of the patients' understanding. Health professionals still play an important role, even in cases where they have little understanding of their patients' understanding due

to differences in educational level. They can facilitate the answer-finding process by posing the right questions.

A universal observation that applies to all kinds of natural structures that must adapt and change to survive is the existence and the importance of feedback loops. In a similar way, human beings have their own autoregulation mechanisms that through complex processes help them maintain physical, psychological and social balance in order to survive. This homeostatic balance is mostly based on automatic processes. When a person faces a situation that is threatening his life or his quality of life, a disease for example, we observe an active and conscious response from the person. This response has many manifestations and among those manifestations it is possible to see the initiation of health behaviour change. The success of this effort depends on personal and social factors and the disease itself, for example severity, prognosis and complications. Despite their good will, most people face challenges in maintaining this health behaviour change; they are drawn to their previous homeostatic condition and go back to old habits and lifestyle. Nevertheless, this window of opportunity for behaviour change exists, and health care professionals can seize the opportunity to help the person establish new homeostasis incorporating the desired health behaviour. Technology can play an important role in assisting health professionals to intervene in the feedback loop in a timely manner, creating early and effective awareness about the problematic behaviours. It can extend the effect of the behaviour changes over a longer period by using the right media of delivery, intervening at the right time and for the right duration, with the right content. As I will discuss later in more detail, today's technology is capable of reaching more people and can become more ubiquitous than many conventional health interventions. Prior to that discussion, I will now give an overview of more traditional approaches to cardiac rehabilitation.

Cardiac rehabilitation

Cardiac rehabilitation is used to describe coordinated, multifaceted interventions that aim to optimize the physical, psychological and social

functioning of cardiac patients, and in parallel aim to stabilize, slow and, if possible, reverse the progression of the underlying atherosclerotic processes (Leon et al., 2005). Cardiac rehabilitation and secondary preventive strategies based on the adoption of healthy behaviours such as quitting tobacco use, healthy diet and increasing physical activity can decrease mortality risks and increase quality of life (I. Graham et al., 2007; Ipser et al., 2007; Leon et al., 2005). Involvement in physical activity is a lifestyle modification that is crucial, as it is associated with several cardio-protective mechanisms (Leon et al., 2005). Exercise interventions can cause a 27% reduction in total mortality and a 31% reduction in cardiac mortality in patients with coronary heart disease (Jolliffe et al., 2001).

Cardiac rehabilitation is recommended for patients with coronary artery disease, recent cardiovascular surgery and intervention, cardiac transplantation, chronic heart failure, peripheral arterial disease and surgery/intervention of the great vessels, diabetes mellitus and metabolic syndrome, and recipients of ventricular assistance devices, pacemakers, implantable cardioverter defibrillators and cardiac resynchronisation therapy (Leon et al., 2005; Piepoli et al., 2012). In the United States, the cardiac rehabilitation enrolment rate was reported to be 10 to 35% of the eligible patients depending on the condition (Leon et al., 2005; Pack et al., 2013; Suaya et al., 2007).

Core components of cardiac rehabilitation

There are several guidelines and position statements that describe the necessary content and the objectives of cardiac rehabilitation (Leon et al., 2005; Piepoli et al., 2012). The core elements of cardiac rehabilitation are:

- Patient assessment with medical control,
- Physical activity counselling,
- Prescription of exercise training,
- Diet/nutritional counselling,
- Weight control management,
- Lipid management,

- Blood pressure monitoring and management,
- Smoking cessation,
- Vocational support,
- Psychosocial management.

These elements aim towards improving clinical stability, controlling symptoms, reducing cardiovascular disease (CVD) related risk, increasing the adherence to medications, and supporting health behaviour changes to improve quality of life, social integration and prognosis. Some of the components normally will need medical supervision, but it becomes obvious that a multidisciplinary approach is preferred, if not required.

Different approaches in cardiac rehabilitation

Conventional approaches

Conventional cardiac rehabilitation programs are usually divided as follows (Piepoli et al., 2012):

Phase I: Refers to the early intervention during the acute phase of the hospitalization, and includes early mobilization and measures to prevent complications secondary to immobilization.

Phase II: Refers to the promotion and provision of preventive and rehabilitation services to patients after a CVD event. It includes stabilization, risk stratification and promotion of long-term prevention. Phase II cardiac rehabilitation can be offered by specialized centres as an inpatient (residential) program, mainly targeting high-risk patients. These types of programs appear to be much more common in Europe than in North America (Jobin, 2005). An alternative to the inpatient cardiac rehabilitation is the early outpatient cardiac rehabilitation, which usually starts three to six months after the CVD event, and lasts for at least eight to 12 weeks and preferably up to one year. Finally, we have the home-based program that is delivered at the patient's home under the supervision of a cardiac rehabilitation team. The home-based and centre-based cardiac rehabilitation programs appear to have equal effect, with no difference in costs

(Jolly, Taylor, Lip, & Stevens, 2006; Taylor, Dalal, Jolly, Moxham, & Zawada, 2010).

Phase III: Refers to long-term outpatient cardiac rehabilitation that delivers preventive and rehabilitative services in the outpatient setting or in the community.

The cardiac rehabilitation interventions at every phase should aim towards empowering the patient to play an active role in the management of his own condition. Self-management is a very important and effective aspect of cardiac rehabilitation. There are several definitions of self-management, with the following as one of the more prominent and inclusive definitions (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002):

> Self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to affect the cognitive, behavioural, and emotional responses necessary to maintain a satisfactory quality of life. Thus, a dynamic and continuous process of self-regulation is established (178).

The importance of self-management has been shown in different studies demonstrating its role in cases like diabetes management, smoking cessation, weight loss and medication adherence (Glanz, Rimer, & Viswanath, 2008; Williams, McGregor, King, Nelson, & Glasgow, 2005). Self-management interventions have beneficial short-term effects on the well-being of the participant and are successful in increasing participants' knowledge, self-efficacy, and use of self-management behaviours (Barlow et al., 2002).

ICT-based approaches

ICT-based cardiac rehabilitation interventions correspond of course to the main categorization of cardiac rehabilitation programs, but can also be separated into several other categories, based on whether they are standalone interventions, the media of delivery, the techniques they utilize or the core element they focus on. A first rough categorization can divide them into two categories. The first category includes interventions that replace the traditional cardiac rehabilitation programs. The second category includes interventions that are complementary to the traditional cardiac rehabilitation programs and aim to impede the decline in the different health behaviours related to cardiac rehabilitation.

Based on the media of delivery, we can identify several categories, with many interventions utilizing more than one. The most prominent are telephone-based (Neubeck et al., 2009), Internet-based (Munro, Angus, & Leslie, 2013), and mobile technology-based (Beatty, Fukuoka, & Whooley, 2013).

Categorization based on the techniques that are utilized can lead to an extensive list. Some of the categories can include remote monitoring, persuasive design, and social web (web 2.0). Remote monitoring includes the transfer of data from an electrocardiogram (ECG), blood pressure sensor or physical activity sensor to a different location. The use of persuasive technologies includes many subcategories referring to techniques that aim to increase adherence to the interventions (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). Interventions belonging to this category indicate a more advanced use of ICT than simply an information transfer channel. Persuasive design includes tailoring, personalization and self-monitoring, which are all particularly relevant for our intervention. Finally, social web is also used in cardiac rehabilitation interventions, with the aim of affecting the social interaction between the users and the levels of peer-support (Neubeck et al., 2009). Again, it is very common for interventions to use more than one technique in order to combine the potential benefits of each approach.

Finally, we can also categorize an intervention based on which core element of cardiac rehabilitation it is targeting. Many interventions target more than one core element, and most of the core elements of cardiac rehabilitation have already been addressed by different ICT-based interventions.

Cardiac rehabilitation in Northern Norway

Northern Norway is the north part of mainland of Norway, with a population of about 463,000 people. Northern Norway's population represents roughly 10% of the total population of Norway, but in terms of area, it comprises about 35% of the Norwegian mainland. Specialist health care in Northern Norway is offered by the Helse Nord RHF (Northern Norway Regional Health Authority), one of the four Regional Health Authorities under the administration of the Ministry of Health and Care Services. The healthcare system in Norway is funded by the national budget.

In the area under the responsibility of Helse Nord RHF, there were 5190 registered cases of ischemic heart disease during the first eight months of 2012 (Folkehelseinstituttet, n.d.). During the same period, Helse Nord RHF had agreements with private rehabilitation institutions for only 235 heart patients per year (110 patients per year at Skibotn Rehabilitation Centre and 125 patients per year at Valnesfjord Health Centre). Patients were also offered a two-day self-management course organized by two hospitals in Northern Norway, Helse Finnmark HF or UNN HF. The municipality contribution in the same area seems to vary, with the Municipality of Tromsø, which has the biggest population, not having a specific program to offer. Despite the fact that we cannot render a precise image of the situation, since the number of cases might include re-hospitalisations of the same patient, not all the patients are eligible for cardiac rehabilitation, and some patients might be referred to rehabilitation centres in the rest of Norway, the number of available places for cardiac rehabilitation in Northern Norway seems to be low.

Another problem for cardiac rehabilitation in Northern Norway seems to be the long time interval between discharge from the hospital and recruitment in a

cardiac rehabilitation program. It is generally recommended for a patient to start rehabilitation four to six weeks after discharge, or even as short as one week for uncomplicated cases (Carrel & Mohacsi, 1998; Dafoe, Arthur, Stokes, Morrin, & Beaton, 2006; Dubach, Myers, & Wagner, 1998). The main reasons for this are that early cardiac rehabilitation is not more dangerous than late (Macchi et al., 2007), and because earlier appointments for rehabilitation increase the chance of attendance at cardiac rehabilitation (Pack et al., 2013). Some preliminary studies suggest that for every day of delay between the hospital discharge and the cardiac rehabilitation, there is a 1% decrease in participation (Russell et al., 2011). This delay seems to be long in Northern Norway. Skibotn Rehabilitation Centre accepts patients eight weeks after surgery or a heart incident and has an additional average of 4 weeks waiting time, while Valnesfjord Health Centre has an average of 20 weeks waiting time. In practice, the situation appears to be even worse since an exercise capacity test is often required, which also has a long wait time. Other reasons might be that family doctors are not informed about the rehabilitation offer, and that the patients either lose interest or get complications. It is estimated from patient reports that the time interval between discharge from the hospital and enrolment in cardiac rehabilitation is up to six months long.

Physical activity in cardiac rehabilitation

Physical activity and exercise training are core components of cardiac rehabilitation. They have well-documented effects in reducing mortality and in reducing hospital readmissions by 25% in patients with myocardial infarctions (Heran et al., 2011). The recommended physical activity for patients in cardiac rehabilitation varies according to their risk profile, their exercise capacity, and whether the exercise training is supervised or not (Fletcher et al., 2013). The general recommendation is a minimum of 2.5 hours per week of moderate aerobic activity, in multiple bouts lasting more than 10 minutes, and evenly spread throughout the week. This should be combined with the suggestion of sub-maximal endurance training and weight/resistance training twice a week (Piepoli et al., 2012). There is evidence that aerobic interval training in short

high intensity bouts is beneficial for patients with CVD (Moholdt et al., 2009) and is also safe (Aamot et al., 2013; Rognmo et al., 2012). Home-based unsupervised high intensity training was as effective and safe as supervised hospital-based training (Aamot et al., 2013), but it had lower adherence rates. Interval training has not yet been included in guidelines for cardiac rehabilitation (Fletcher et al., 2013).

Conventional cardiac rehabilitation programs have been quite successful in increasing physical activity in the short term (Heran et al., 2011), but their long-term performance is debatable. It seems that after the completion of a cardiac rehabilitation program, the level of physical activity and exercise adherence in most of the studies decreases significantly, with only 30%–60% of those that complete a rehabilitation program still being physically active after three to six months (Moore et al., 1998). Nevertheless, there is a published study where the benefits of the inpatient cardiac rehabilitation program seemed to be maintained two years after the rehabilitation stay (Boesch et al., 2005). This cardiac rehabilitation program had duration of one month, had relatively high training stimulus and emphasized on education for maintenance of physical activity after discharge. There are a few interventions that have tried to support the maintenance of the benefits of the rehabilitation stay, with mixed results (Brubaker et al., 2000; S. Lear, 2003).

In a randomized controlled trial (RCT) that evaluated the effectiveness of an intervention in preventing deterioration following the completion of a cardiac rehabilitation program, at one year there were no significant differences between the intervention and the usual care group (N=49, S. Lear, 2003). The intervention consisted of six cardiac rehabilitation sessions over the first three months, and over the first year six telephone follow-ups and three risk factor and lifestyle counselling sessions. The intervention used the Transtheoretical Model of Behaviour Change (TTM) and Social Cognitive Theory for assessment and counselling at each contact with the participants. The control group (usual care) only received care from their family physician and was only contacted for outcome assessment once a year. Physical activity was measured with the

Minnesota Leisure Time Physical Activity questionnaire and at 12 months the intervention group (n=17) had a mean of 2440±1698 kcal/week while the control group (n=19) had 2288±1554 kcal/week.

Another RCT compared a nine-month home-based intervention for post rehabilitation support versus centre-based continuation of the cardiac rehabilitation program and versus a control group (Brubaker et al., 2000). The home-based group (n=16) received one home visit to instruct the patient on exercise and monitoring of exercise, phone follow-up calls every other week with a physiologist, and required completion of weekly self-report exercise logs by the patient. The centre-based group (n=17) continued the supervised three-times-per-week program at the rehabilitation centre for 12 weeks, while the control group (n=15) only received basic instructions and recommendations at discharge from rehabilitation. By the end of the intervention, all of the groups had increased their exercise capacity, but there was no statistically significant difference between the groups.

Engagement in physical activity is a health behaviour, and as such has been the subject of many health behaviour change interventions. In comparison to other health behaviours, it seems that physical activity is more challenging to support, and it takes more time and effort (Shumaker, Ockene, & Riekert, 2008). An additional challenge is that unlike other health behaviours, it does not have a binary outcome (in contrast to smoking, for example). The complexity of the task, though, is compensated by the great potential it has in improving health.

Health behaviour change

Gochman (Gochman, 1997) defines health behaviour as follows:

> Those personal attributes such as beliefs, expectations, motives, values, perceptions and other cognitive elements; personality characteristics, including affective and emotional states and traits; overt behaviour patterns actions and habits that relate to health maintenance, to health restoration and to health improvement (3).

He further explains that behaviour denotes something that people do or refrain from doing, consciously or unconsciously, both voluntarily and not voluntarily. Behaviour is not something that is done to them, thus treatment is not considered a health behaviour (Gochman, 1997). Combining this definition with the definition of health[3], which includes physical, mental and social well-being, it is clear that the health behaviour of each individual is a very complex construct, with many—sometimes contradicting—manifestations.

Health behaviour change is usually a public health goal and aims for the adoption and maintenance of health behaviour either in an individual or a community or group level. It encompasses a wide variety of social, emotional, and cognitive—often interrelated—factors, which, in order to be understood and studied, have been organized into theories and models (Schwarzer, 2008).

Models of health behavioural change

Models for health behaviour can be roughly divided into continuum models and stage-based models (Schwarzer, 2008). Velicer and Prochaska (Velicer & Prochaska, 2008) argue that Schwarzer's (Schwarzer, 2008) distinction between continuum and stage-based models is in fact a distinction between theories of behaviour and theories of behaviour change. The theories of behaviour are based on correlation studies of predictors of on-going behaviour, while the theories of behaviour change are based on studies of predictors of transitional processes into a greater readiness for change. We will present some of these theories following Schwarzer's dichotomy.

Continuum models assume that a person's behaviour is the outcome of conscious intention, so by placing the person in a range according to their likelihood of action and by influencing specific predictors, the intervention can move the person towards action. They model behaviour change as a linear process without accounting for qualitative changes over the course of time, and as a result the

[3] The World Health Organization defines health as the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (WHO, 1946).

sequence of the processes of an intervention is not important. Another characteristic of the continuum models is that the period between intentions and behaviour is not accounted for in the model and consequently creates what has been characterized as the "intervention-behaviour gap" or "black box" (Schwarzer, 2008).

The theory of reasoned action by Ajzen and Fishbein, one of the most well-known continuum models, focuses on intentions as predicted by the individual's attitude towards the behaviour and the subjective norm associated with the behaviour (Clark & Houle, 2008). The proportion of the influence of the person's attitude to the behaviour and of the subjective norms depends on the targeted behaviour. Socioeconomic status, cultural and other demographic factors are also included in the model as influencing behaviour through the determinants of behavioural intention.

Another continuum model is the theory of planned behaviour. It is an extension of the theory of reasoned action that includes both volitional and non-volitional behaviours (Clark & Houle, 2008). The model adds the idea that behaviour is also influenced by the perceived behavioural control, which includes personal and external factors. So, the attempt to perform a behaviour is affected by the intention and the opinion of significant others, and the success of the behaviour depends on the control that the individual feels he has over internal and external factors that influence his behaviour.

The most popular stage-based model is the Transtheoretical Model of Behaviour Change (TTM). According to this model, health behaviour change has five stages defined by the person's past behaviour and future goals, and each stage requires a different intervention in order to promote the health behaviour. The five stages are pre-contemplation, contemplation, preparation, action and maintenance. There are also ten processes of change, perceived pros and cons of changing, perceived self-efficacy, and temptation that complete the model. Despite its popularity, the model has been criticized for lack of definition of the stages, that the stages lack qualitative properties, and that they are arbitrary subdivisions of a continuous process (Schwarzer, 2008).

Finally, the newest stage-based model is the health action process approach (HAPA) by Schwarzer (2008). In this model, there are two stages: pre-intentional motivation that leads to behavioural intention and post-intentional volition that leads to the actual health behaviour (Schwarzer, 2008). In each stage, there are certain socio-cognitive determinants that influence behaviour. In the first stage these include risk perception, outcome expectancies and action self-efficacy. In the second stage, when the person's intention to engage in the behaviour has been formed, these determinants include action and coping planning and maintenance self-efficacy.

Models vary as to whether and which variables are necessary and sufficient for behavioural change to happen. For instance, several models agree that having an intention to perform a behaviour is necessary (but not sufficient) for the actual behaviour to occur.

Researchers within both kinds of models agree that there is a "gap" between intention and behaviour (Sheeran, 2002), but a discussion that has important implications for interventions is whether, for instance, intention is a static (indicator) or a dynamic (and changeable) variable (Velicer & Prochaska, 2008). Before and after forming an intention is a common chasm across several stage models (Schwarzer, 2008) and is also seen as an important distinction demanding different strategies in non-theoretical methods such as Motivational Interviewing (Miller & Rollnick, 2012), which has been successful in supporting people in changing a host of health behaviours (Lundahl, Kunz, Brownell, Tollefson, & Burke, 2010; Martins & McNeil, 2009) including those relevant to CVD risk (S. Hardcastle, Blake, & Hagger, 2012; S. Hardcastle, Taylor, Bailey, & Castle, 2008; S. Hardcastle & Hagger, 2011; S. J. Hardcastle, Taylor, Bailey, Harley, & Hagger, 2013).

Internet- and mobile-based technology to support behaviour change

In the last two decades the world has experienced the explosive development of the Internet. Nowadays, use of the Internet is so widespread in many countries that it has become a popular means of delivering interventions to assist in the

diagnosis, treatment and prevention of illness and the promotion of health. Health-related websites were estimated in 2000 to be more than 100,000, while today that number has increased so greatly that it is not even possible to find an accurate estimate (Illman, 2000). A recent report found that 72% of the Internet users in the United States (US) has looked online for health information in 2012 (Fox & Duggan, 2013). In 2008, 67% of Norwegians reported having used the Internet for health purposes (Wangberg, Andreassen, Kummervold, Wynn, & Sørensen, 2009).In 2008, 67% of Norwegians reported having used the Internet for health purposes (Wangberg et al., 2009). It would be risky to estimate the general impact of Internet use on health, but research has shown that under certain conditions it can be a very useful tool in supporting health (Fanning, Mullen, & McAuley, 2012; C. L. Jackson, Bolen, Brancati, Batts-Turner, & Gary, 2006; Lau, Lau, Wong, & Ransdell, 2011; McLean et al., 2012; E Murray, Burns, See, Lai, & Nazareth, 2005; Omboni, Gazzola, Carabelli, & Parati, 2013; Samoocha, Bruinvels, Elbers, Anema, & van der Beek, 2010).

Internet- and mobile-based cardiac rehabilitation interventions

One of the first randomized controlled trials of an Internet-based intervention for cardiac rehabilitation was conducted in the US and included 104 participants with CVD (Southard, Southard, & Nuckolls, 2003). From these, 53 were randomized to use the special intervention and 51 received usual care. The special intervention included logging on to the website for a minimum of 30 minutes once a week, communicating with the case manager through a secure direct messaging function of the website, following education modules assigned by the case manager, and entering data regarding the number of minutes of exercise and blood pressure measurements into progress graphs. There were also an online discussion forum and access to a dietician through the integrated direct messaging function. The education modules included self-tests with related feedback on a later screen and the participants received small rewards for completing these modules or for being active in other ways on the website. The duration of the intervention was six months and data were collected at baseline and at the end for both groups. Pre-post comparisons for self-reported

physical activity did not show a statistically significant difference between the two groups, but the special intervention group had a higher increase in minutes of weekly aerobic exercise (baseline minutes were 150.2 and at six months 208.4) than the usual care group (baseline minutes were 142.4 and at six months 165.0). There was a statistically significant difference (*p=0.003*) in the reduction of BMI with the special intervention group having a small reduction (BMI at baseline was 30.9 and at six months 30.3) and the control group having a slight increase (BMI at baseline was 29.2 and at six months 29.3). The success in weight reduction was attributed to the personal goals set by the subjects since it was the most frequently chosen goal (75% of the special intervention users), but the result has little clinical relevance because the reduction was around 1.7%, lower than the 5–10% that is considered modest but effective weight loss (Haslam, Sattar, & Lean, 2006). The acceptance of the intervention by the users and the physicians was good, and the authors also reported on the cost of the intervention that was estimated at $413 per person (net savings were calculated at $1418-453=$965 per person). The estimated return on the investment was 213%. As limitations of the study were reported, including the lack of blindness of the case manager at the exit visit and the inadequate definition of aerobic exercise in the physical activity measure, they affected the validity of the results. If a standardized and well-studied physical activity measurement was used, it would increase the validity of the results and would make it comparable to other studies.

The second study was a pilot study from Canada that included 15 patients referred to a hospital-based cardiac rehabilitation program (Zutz, Ignaszewski, Bates, & Lear, 2007). The participants did not have prior experience with cardiac rehabilitation and entry to a cardiac rehabilitation program was delayed until the completion of the study. They were randomized to either an Internet-based cardiac rehabilitation program (n=8) that lasted for 12 weeks, or to an observational control group (n=7). The intervention was designed to simulate the hospital cardiac rehabilitation program, with intake forms, one-on-one chat sessions with the rehabilitation team lasting approximately one hour, weekly educational sessions with presentations and multiple choice tests, data

collection, and monthly ask-an-expert group chat sessions. The participants were using heart monitors while exercising and had to upload their exercise data and other data to the website at least twice a week. All the participants underwent an assessment at baseline and at 12 weeks that included an exercise capacity test that estimated the maximal METs using the Bruce protocol, physical activity measured in kcal/week with the Minnesota Leisure Time Physical Activity Questionnaire, fasting serum lipids, blood pressure, BMI, waist circumference, and general and exercise-specific self-efficacy. There were within-group statistically significant improvements only in the intervention group for exercise capacity (baseline 11.7 ± 3.4 MET, 12 weeks 13.2 ± 3.3 MET), weekly physical activity (baseline 982 ± 399 kcal/week, 12 weeks 6018 ± 5104 kcal/week), exercise-specific self-efficacy (baseline 68.5 ± 6.2, 12 weeks 73.1 ± 5.2), and blood values (triglycerides and HDL-C). There was no statistically significant difference between the two groups at 12 weeks. The sample of the intervention group was also matched with 16 historical controls before and after a standard 16-week hospital-based cardiac rehabilitation program and the historical controls had, among others, significantly better exercise capacity. The main limitation of this study was the small sample size. The conclusion of the authors was that as a pilot study, the results indicated that the Internet is a safe and feasible medium for the delivery of cardiac rehabilitation at home.

An observational study of a six-week mobile-based intervention for cardiac rehabilitation from Australia helped the participants to improve their exercise capacity measured with the six-minute walk test (Worringham, Rojek, & Stewart, 2011). The study utilized telephone contact with the providers, as well as use of a smartphone application, single-lead ECG, and global positioning system (GPS). The smartphone was only used to transfer the ECG and GPS data to the providers. The effect on exercise capacity can be compared to conventional cardiac rehabilitation programs, but the study had a small sample size (N=6) and there were no data on the long-term effects of intervention.

A trial in Poland compared a five-week mobile-based intervention to guide and monitor exercise (n=30) with supervised exercise sessions

(n=32)(Korzeniowska-Kubacka, Dobraszkiewicz-Wasilewska, Bilińska, Rydzewska, & Piotrowicz, 2011). The intervention followed an almost three-week period of supervised exercise sessions for both groups, after which the control group continued the same procedure, while the other group received the mobile-based intervention. The results at the end of the study showed that there was no statistically significant difference between the two groups in exercise capacity or other risk factors. The study did not include women, participants were not randomized into the different groups, and no long-term results were reported.

In an RCT from Spain, the control group (n=101) received usual care, while the intervention group (n=102) monitored blood pressure, heart rate, weight, glucose, and lipids, and then sent those values by Short Message Service (SMS) to the cardiologist, who responded with recommendations, also by SMS (Blasco et al., 2012). The duration of the study was 12 months. It did not report statistically significant differences in physical activity, but the physical activity measurement tool was not well described.

Tailored interventions

Many successful eHealth interventions are utilizing tailored content (Foster, Richards, Thorogood, & Hillsdon, 2013; Kelders et al., 2012; Lustria et al., 2013). Tailoring is a process of personalization similar to face-to-face patient counselling. The answers that a patient gives to questionnaires creates an individualized path through the intervention, including feedback and follow-up questions based on predefined algorithms. Different answers to the same questions over time generate changes in the treatment or the behaviour change plan that reflect the changes in a patient's characteristics or change process. One approach to how this works suggests that the messages that are generated through this process have increased personal relevance. By perceiving the message to be more relevant, the motivation of the users to act on the message also increases, and makes them more sensitive to the strength of the argument presented (Petty & Cacioppo, 1986). Another approach relates the perceived

personal relevance with persuasion, given that the perceived argument strength is increased (Lustria et al., 2013).

Tailored health information is generally perceived as being more interesting and personally relevant, better liked, more thoroughly read and discussed, and better remembered than non-tailored educational material (Brug, Campbell, & van Assema, 1999; Campbell et al., 1994; de Nooijer, Lechner, & de Vries, 2002; Lustria et al., 2013; Neville, O'Hara, & Milat, 2009; Oenema, Brug, & Lechner, 2001). A meta-analysis of web-based tailored health behaviour change interventions showed that they are connected with greater improvement in health outcomes in comparison to control conditions, and this difference was stronger when the comparison was made with non-tailored web-based versions than with usual care control (Lustria et al., 2013). To the best of my knowledge, there is no publication of results of an Internet- or mobile-based tailored intervention for cardiac rehabilitation.

Challenges of Internet- and mobile-based health behaviour change interventions

Internet- and mobile-based interventions have a large potential for reaching people, but many interventions have been quickly developed and implemented to many users. During their development, only a few interventions adhere to proven approaches despite the existence of a variety of models and methodologies. These interventions thus often prove ineffective. When interventions happen to succeed, it is difficult both to identify the effective components and to replicate their success, for in their haste to develop they have disregarded methodology. The effectiveness of Internet-based health interventions has been connected with the adoption of the appropriate theoretical framework (Elizabeth Murray, 2012; Neville et al., 2009; Revere & Dunbar, 2001; Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009), while their viability has been associated with strong user involvement in the design of the intervention (Kelders et al., 2012).

Attrition and high drop-out levels are, in any case, a major issue in health behaviour change and self-help interventions (Farvolden, Denisoff, Selby, Bagby, & Rudy, 2005; Gould & Clum, 1993; Marcus et al., 1998). In ICT-mediated interventions the problem is even bigger and characterized as the law of attrition. It predicts that in any eHealth application a substantial proportion (higher than in other traditional treatments and higher than expected) of users will drop out before completion (Eysenbach, 2005). Persuasive technology is one of the suggested approaches that are effective in increasing adherence to web-based interventions. Tailoring is an important element of persuasive technology and at the same time a very important feature of effective health communication (Kelders et al., 2012; Wangberg, Bergmo, & Johnsen, 2008).

Design of effective interventions

Though several approaches to designing Internet-based health interventions have been published, they have received limited dissemination. Reasons for this limitation may include their being rooted in the traditions of one of the disciplines involved and their being disseminated only through discipline-specific channels. Furthermore, their field-specific jargon often complicates their ability to be understandable and accessible to specialists from different backgrounds.

Designing effective Internet-based interventions, including those unrelated to health services, has drawn much attention from the field of human-computer interaction (HCI) and the technological world in general. To a large extent, HCI approaches focus on user involvement to improve the design of user-computer interface and functionality. At the same time, approaches presented by health care researchers largely focus on theory- and evidence-based designs and largely ignore the factor of user involvement.

Our approach to the design of Internet- and mobile-based health interventions pays specific focus to issues that are often ignored in ineffective interventions. For example, many researchers state in their reviews that the persuasive part of the intervention deserves more focus than the technology itself. As mentioned in

a systematic review from 2012, technology should not be introduced into the intervention process only for its own sake or its potential to spawn even more technology. Instead, technology should always be developed to address the needs of target users and operators and always with the clear goal of creating viable eHealth technology (Kelders et al., 2012). At the same time, another review emphasizes the importance of implementing theory in web-based interventions (Neville et al., 2009). By combining users' input as well as theory, the approach we have used tries to fulfil conditions that render other Internet-based health interventions effective. Our approach was to first review relevant models of health behaviour and construct a theoretical framework for the intervention and then assemble focus groups of end-users at an early stage of the intervention design. Their feedback was qualitatively analysed in order to gather user input regarding both their general needs during interventions and the specific elements of the theoretical framework developed.

Whatever method we use to design an Internet- and mobile-based health intervention, it is important to measure the proposed outcomes and mediators to ensure that the intervention actually intervenes according to the proposed theoretical framework (Baranowski, Anderson, & Carmack, 1998). By gathering data on the relevant processes predicted, we may further develop our interventions and theories alike (Rothman, 2004). Since randomized controlled trials are accepted as the "gold standard" for the evaluation of the effectiveness of an intervention (Eysenbach, 2002), Internet- and mobile-based health interventions based on user needs and theoretical evidence must undergo trials, preferably randomized controlled ones. Trial design should thus not only determine the effectiveness of the intervention but should be performed in order to help us understand what works and why.

Aims and research questions

The overall aim of our approach is to offer an effective Internet- and mobile-based intervention to help patients maintain physical activity after a cardiac rehabilitation stay. Our secondary aims were to discover the appropriate design method for the intervention and identify what users need from such an

intervention. Thirdly, we aimed at designing and implementing a study that would evaluate the effect of the intervention on the maintenance of physical activity and, secondarily, on self-efficacy, social support, anxiety, depression and adherence.

The specific research questions were:

1. How can we combine users' needs with health behaviour models in the design of an Internet- and mobile-based intervention for physical activity in cardiac rehabilitation? (Methodology issue, Paper I)
2. What are the needs, thoughts and ideas of the users regarding support to maintain physical activity and what role does technology play in these? (Paper I)
3. How can we evaluate the effectiveness of an Internet- and mobile-based intervention for physical activity in cardiac rehabilitation? (Methodology issue, Paper II)
4. What is the effectiveness of the tailoring of our Internet- and mobile-based intervention on physical activity? (Paper III)
   Hypothesis: The users of the tailored intervention will maintain their level of physical activity better than the users of the non-tailored intervention (control group).
5. What is the effectiveness of the tailoring of our Internet- and mobile-based intervention on self-efficacy, social support, anxiety, depression and adherence? (Paper III)
   Hypothesis: The users of the tailored intervention will better maintain their level of self-efficacy, social support, anxiety, and depression, and will have better adherence to the intervention in comparison to the users of the non-tailored intervention (control group).

In order to fulfil our aims, we had to combine different approaches from the literature, elaborate on each step of our efforts and sometimes revisit established practices. Taking it from the beginning, we questioned ourselves regarding the best approach to design an intervention, and specifically how to combine what the users say they need with what we already know is helpful for

them. To find out what the users need we conducted a focus group with potential users. In parallel, we utilized bibliographic evidence and previous experiences of our team in implementing a tailoring functionality, an element that has been known to boost effectiveness. Even if those actions seem reasonable to maximize the effectiveness of an intervention, only a rigorous assessment can demonstrate its effectiveness. Randomized controlled trials are considered to be the most robust method for the assessment of health interventions, and their design constitutes a methodologically as well as theoretically challenging task on its own. Finally, the results of the RCT would determine the verdict regarding the effectiveness of our intervention: whether it works, how it works and for whom.

These research questions were addressed in three papers that present our comprehensive approach to the design of effective health behaviour change interventions. The approach includes all the phases from the design of the intervention combining theory with users' needs, to the choice of the evaluation method of the intervention, to the implementation of the intervention, and eventually to the presentation of the results of the evaluation. Finally, this beginning-to-end aspect of the project offers a complete view of the ethical, theoretical and practical issues pertaining to conducting real-world research with humans.

Methods

Combining users' needs and theory

In our approach we tried to combine user involvement and a strong theoretical framework. Because of an identified lack of design approaches that can effectively combine these two elements, we decided on a distinct approach that simply suggests the merging of the two processes. Our suggested approach can be described as two parallel processes from which design requirements emerge, as well as, in time, the implemented intervention.

One process begins by selecting theories to implement into the intervention; the selection processes could possibly include a systematic review of the literature, a narrative review, and/or a review of the extensive experience of health professionals. A research team, alternatively, might choose a theoretical foundation based on the research questions that need answers. The aim of adding theory as a distinct step in the process of designing interventions is not to force the design team to make the right choice so much as to remind the team to consider both empirical knowledge and previous studies while designing. In the current entrepreneurial spirit of health technology, it might seem innovative to "reinvent the wheel"; however, if the goal is effectiveness and improved usability, a well-grounded rationale must support the intervention. When published with results, this rationale would direct future reviews and possibly applications, as would reporting the theoretical background behind each functionality of the intervention, especially in cases where different theories have been combined. Theory selection could precede the second phase so that its outcomes may be considered during the focus group discussion.

The second but parallel process of our suggested approach focuses on user involvement during the intervention design process. Although several ways to involve users in the design process exist, an effective and systematic method implements focus groups. Group processes both help participants to explore and clarify consensus more effectively than individual interviews and encourage the participation of users who resist individual interviews, feel that they have

nothing to say, and/or are regarded as "unresponsive patients" (Kitzinger, 1995). This last advantage can also be very useful in gathering useful feedback on how to involve underrepresented groups in interventions. Recommending focus groups does not suggest that individual interviews cannot produce useful outcomes or provoke feedback that users would be embarrassed to discuss in groups. The selection of one method over the other should derive mostly from the specific type of intervention, the time available, and project resources. If researchers choose to implement focus groups, these same factors figure importantly in determining group size (the recommended size is 6 to 10 participants) (Kvale & Brinkmann, 2009), the number of groups, and session duration. Above all, focus group discussions should use open-ended questions and encourage participants to reveal in their own words what is important for them during Internet-based interventions.

To design Internet-based health interventions, researchers may loosely direct discussions based on a predefined outline aimed at learning users' needs in as many areas of the intervention as possible. Our suggested predefined outline includes a section in which the participants who have not yet been exposed to the ideas of the design team are asked to discuss how technology can help them to achieve the specific behaviour called for by the intervention. In this way, participants become engaged in discussions to the point where they will reveal their true and unbiased thoughts, which may even contradict the ideas initially considered by the design team. During focus group discussions the design team will also gain useful insights regarding the preferred technology of users.

Another useful component of our suggested outline involves asking participants to comment on the design team's initial ideas. For this component, the role of the selected theory figures significantly. Together, theory and the existing expertise of the design team will very likely produce concepts that the design team is willing to implement. After having gathered unbiased input from focus-group participants, it is very useful to invite participants' opinions regarding those concepts and their implementation. In this more specific feedback part, the design team can also collect valuable data regarding the interface, the timing of communication, and the content and type of the intervention.

Analysing the verbatim transcription of the focus group discussions requires a systematic approach in order to describe the design requirements of the intervention and their future implementation. For this stage, we suggest using a well-known qualitative tool: thematic analysis. Thematic analysis identifies and analyses patterns of meaning in the dataset. One possible approach to thematic analysis commences with two researchers who, after examining the full dataset, each create a coding framework. These two researchers can thus examine the inconsistencies of their frameworks, determine an agreeable framework, and recode the material. At this point, codes can be grouped by themes. A theme refers to a specific pattern of meaning found in data, either by direct observation in the transcript or by indirect references. Both inductive and deductive sets of themes can be used during thematic analysis, meaning that themes can be based on either the raw data, which helps generate new knowledge, or on the existing theoretical ideas, which helps inspire themes and thus examine how those ideas are reflected in the coding frameworks and raw data (Harper & Thompson, 2012). In our suggested approach for designing Internet-based health interventions, this step can also be used to juxtapose the theoretical concepts initially chosen while gathering users' input. Ultimately, the selected theory can be evaluated for its relevance to the needs of the specific group and, if found to be irrelevant, it can be replaced with a different theoretical framework.

In sum, our suggested approach aims to create a dialogue between theories and the analysed user input data to specify and document requirements according to user needs that will factor into intervention design. Instead of unilaterally replacing other approaches, our suggested approach aims to emphasize essential principles that all design approaches should consider. If time and resources are available, it is possible to combine our suggested approach with one or more other approaches to enhance the benefits of either or both.

Randomized controlled trial

Design

We designed a two parallel group, cluster randomized controlled trial to assess the effect of an Internet- and mobile-based tailored cardiac rehabilitation

intervention. The clusters were randomly assigned to either the control group, which had access to a generic version of the website and the online discussion forum, or to the tailored group, which had access to a tailored version of the intervention in addition to the generic content and the discussion forum. The intervention was offered as an extension of the face-to-face rehabilitation stay at the Skibotn Rehabilitation Centre. The initial aim was to have a blind experiment, where the researchers and outcome assessors would be blinded, too. However, due to a technical problem that could compromise the quality of the data, the randomization was un-blinded early in the statistical analysis.

The main aim of the trial was to isolate and assess the specific effect of the tailoring, rather than the more generic effect of using Internet- and mobile-based technology for supporting the maintenance of physical activity as part of cardiac rehabilitation. Recent reviews have concluded that both Internet-based (Foster et al., 2013) and mobile-based (Fanning et al., 2012) interventions can be effective in increasing physical activity and the role of these interventions is already discussed as part of guidelines for physical activity (Garber et al., 2011). Our intervention was designed to support participants in a face-to-face rehabilitation program after their discharge from that program. The option of having a control group that would receive "usual care" would mean almost no cardiac rehabilitation-related care until a new incident. Our assumption was that a "usual care" control group would make almost any intervention look effective and would not add much to the existing—already strong—evidence. The limited value of such an approach would weaken the justification of conducting an RCT on human subjects. On the other hand, despite the evidence that tailoring is an effective element of such interventions (Foster et al., 2013), there are still many unanswered questions, such as what type of tailoring is more engaging and which theoretical framework is more effective. In addition, the exact mechanism of the effect of tailoring has not yet been fully described. To answer these kinds of questions, a more active tailored group is needed. In our case, and because the applied tailoring algorithm was used for the first time, we chose a non-tailored intervention control group in order to isolate the effect of tailoring. This practice has been used in at least nine other (out of 23) tailored interventions targeting

physical activity (Lustria et al., 2013), but to the best of our knowledge has not been used before in cardiac rehabilitation or with the same combination of theories.

The main hypothesis was that the tailored group would have higher adherence to the intervention and would be more physically active in comparison to the non-tailored group (control).

Inclusion criteria were participation in the rehabilitation at the Skibotn Rehabilitation Centre, access to Internet at home and possession of a personal mobile phone. The trial was registered in the registry of clinical trials at clinicaltrials.gov (NCT01223170).

Cluster randomization

The participants were randomized in clusters. The randomization of the clusters was conducted with the help of an online random number service and each cluster consisted of the participants that attended the cardiac rehabilitation program together in a given month. The cluster randomization had a two-fold purpose: to account for differences in the face-to-face rehabilitation program of the monthly groups, and to protect from "contamination" across participants who belonged to the same monthly group but who would receive different versions of the intervention.

In cluster randomized trials the subjects are not allocated to the different treatments independently, but at the group level (Bland, 2004). One of the reasons for doing this is that the members of the cluster are expected to be more similar to each other than to members of other clusters. In our trial, the participants of the cardiac rehabilitation program in the same month would receive the same treatment from the same personnel, would have the same level of social interaction and would share similarities in several other factors we cannot always predict. Despite the efforts of the rehabilitation centre to offer a steadily high quality of care, it is also reasonable to assume that there will be differences between the monthly groups due to changes in the workforce, seasonal variation of the outdoor activities offered and adaptation to the needs

of each monthly group. Cluster randomized trials can take into account these similarities that will lead to correlations in the observations derived from the participants of the same group (D. M. Murray, Varnell, & Blitstein, 2004).

Another reason to randomize at the cluster level is that participants belonging to the same monthly group would have daily contact with each other at the rehabilitation centre and would continue contacting each other afterwards (also as a result of using the intervention and the discussion forum). If those individuals were receiving the two different versions of the intervention, it would be more likely that they would understand which is the enhanced version, resulting in "contamination" of the control group (S. J. L. J. L. Edwards, Braunholtz, Lilford, & Stevens, 1999). This possibility is not completely eliminated, since the users can still contact each other even outside of the monthly clusters, but the possibility is reduced with cluster randomization.

The statistical analysis of clustered randomized trials requires the use of specific approaches, such as mixed-model analysis of variance (ANOVA), analysis of covariance (ANCOVA) or random coefficient models (D. M. Murray et al., 2004). In the statistical analysis of our trial, despite the fact that it was designed as clustered, and the sample size was calculated with that in mind, we did not use the clusters in the analyses. The reasons for this are the very small size of the clusters, the large variations in cluster size, and the non-normal distribution of our observations. This is a limitation in terms of not taking into account the within-cluster correlations, but it seems to be common and sometimes justified (Bland, 2004). This does not cancel the benefit of clusters in protecting from between-group contamination.

Intervention

The intervention lasted for one year from the discharge of each cluster, and offered tailored content based on models of health behaviour. The main concepts to tailor, based on the existing bibliography, were self-efficacy, stage of change, planning and regulatory focus. Aside from the tailored content, the intervention

also provided general information about CVD and self-management, including diet, physical activity, smoking and medication, a discussion forum and behavioural monitoring.

Control group

All of the participants were given access to the basic Internet-based intervention, "ikkegideg.no" (Norwegian for "Don't give up"), which contained general information about CVD and self-management, including information about diet, physical activity, smoking, and medication, as well as access to an online discussion forum. In the discussion forum, there were two levels of access. The closed group level allowed the users to create and take part in discussions that could only be accessed by those who were members of the same monthly group. In the second, open level of access, all of the users were able to create, read and take part in discussions that were visible by all of the registered users of the website. The participants of the control group were also able to plan training activities but were not prompted or reminded to do so and did not receive any feedback on the website or by SMS.

Tailored intervention

The participants of the tailored group had access to the same functionality as the control group, and in addition, had access to tailored content. The participants in the tailored group were required to answer more online questions than the control group, usually every two weeks, and received tailored messages via the website and Short Message Service (SMS). Depending on their stage of change, the participants were asked to plan training activities or set weekly goals. They then received feedback in the form of a simple graph on the website regarding the achievement of their goals. If the participants planned an activity, they received an SMS reminder shortly before the start of the planned activity. At the end of the planned activity, they received another SMS asking them to confirm that the activity was completed.

Measures

The data were collected from January 2012 until October 2013. The study measurements were made using questionnaires delivered online when the participants logged on to the Internet site while at the rehabilitation centre (baseline), a short time after the planned discharge from the rehabilitation centre (1-3 days), one month after discharge, and three months after discharge. One more study point was planned for one year after discharge. E-mail and SMS reminders were sent to the participants for three days each time they had to fill in the online questionnaire. All the questionnaires were in Norwegian. The main outcome measure was self-reported physical activity. The secondary outcome measures were self-efficacy, social support, anxiety and depression, and the process measures were the stage of change, perceived tailoring, use of the intervention, and user evaluation of the intervention.

The background information we collected for the baseline included age, gender, highest level of education, weight and height. According to the protocol we also collected level of yearly income, employment situation, alcohol use, co-morbidities, and chest pain using WHO's ROSE questionnaire (Lampe et al., 1998).

Physical activity was measured using Norwegian validated version (Kurtze, Rangul, & Hustvedt, 2008) of the seven-item International Physical Activity Questionnaire IPAQ (Hagströmer, Oja, & Sjöström, 2006; Kurtze et al., 2008). IPAQ is mainly designed for population surveillance in adults between 15-69 years old and has been used relatively often as an outcome measure (Hagströmer et al., 2006). Like other self-reported user recall measures for physical activity, IPAQ is not as accurate as real-time reporting of physical activity by accelerometers (Beatty et al., 2013), but because of the high cost of reliable accelerometers in comparison to the benefits received, and the technological and administrative complexity they would add, IPAQ was deemed to be an adequate and cost-effective solution. Other measures can also be more objective in evaluating the effectiveness of the intervention, like measurements of exercise capacity at specific time points, but we did not include them in the

protocol because of ethical implications. It would considerably increase the cost of the study, increase the workload of the available resources that offer the service and possibly increase the waiting time for patients, and would require the participants to travel long distances just to do the test, something that would be in direct opposition to our initial reasons for offering an Internet-based solution. Any misclassification because of recall bias of the self-reported measure was non-differential (happening in both groups) without considerably affecting the between-groups comparisons.

Self-efficacy was measured using one item of the Norwegian translation (Wangberg, 2008) of the perceived competence for regular physical exercise (PC-EX) scale (Williams & Deci, 2005). The responses were reported using a scale from 0 (not at all) to 6 (to a great extent). Tailoring on self-efficacy has consistent effects (Noar, Benac, & Harris, 2007) and we measured it to see to what extent the tailored intervention targeting self-efficacy actually affected it. An important reason for having one-item was to reduce the number of questions the users had to answer, making it not monotonous and less time consuming for the responders (Kwon & Trail, 2005). Another reason was to avoid asking many times the participants of the tailored group the same or similar questions, since self-efficacy was a central concept of the tailoring algorithm. This could affect their responses in the two questionnaires –research and tailoring– in a similar way the common methods variance affect the responses in the same questionnaire (Podsakoff, MacKenzie, Lee, & Podsakoff, 2003). Also, asking about self-efficacy has an effect itself by making the participants think about it and even improve it, would diminish the differences between the two groups due to contamination of the control group (dilution bias). A study that compared five measures of self-efficacy found that the single-item measure was highly correlated with multiple-item scales, but it suggested the use of multiple-item over single-item measures (C. Lee & Bobko, 1994).

Social support was assessed using a 12-item adaptation of the scale from Barrera et al. (2002). The original version was adapted from diabetes care to physical activity and then translated to Norwegian by a professional translator. Two researchers that are native Norwegian speakers reviewed the translation. Since

the scale was both altered and translated, we assessed its reliability and validity, but ideally, we should have pilot tested the questionnaire prior to its use (Hambleton & Patsula, 1998; Tanzer & Sim, 1999).

Reliability refers to the consistency of the results obtained from a measure (Domino & Domino, 2006, pp. 42–66). For social support scale we found that the test-retest reliability coefficient between baseline and discharge is r_{27}=0.60 (*p=0.001*), and between baseline and one month after discharge r_{17}=0.81 (*p<0.001*). Similar coefficients are demonstrated between the other time points too. We also found very similar Cronbach's α (0.93) to the previously reported value (Cronbach's α=0.92, Barrera Jr, Glasgow, McKay, Boles, & Feil, 2002). The mean at baseline of our version was 4.2 and the standard deviation 1.13, while in the original version it was 4.0 with standard deviation 1.3.

Validity is the property of a test to measure what it is intended to measure. It has been theorized to have many categories, but should be rather seen as a unitary process (Domino & Domino, 2006, pp. 42–66). The original measure has been developed with the rational-theoretical approach with emphasis on face and content validity relative to three social support domains, emotional support, advice and information, with four sub-items for each domain (Barrera Jr et al., 2002). Half of the items were for general support and half for peer support and the measure focused on both computer-mediation interaction and face-to-face interactions. We further assessed the convergent aspect of validity of our version and we found significant negative correlation with levels of anxiety (r_{66}=-0.44, *p<0.001*) and depression (r_{66}=-0.38, *p=0.002*) at baseline, and significant positive correlation with physical activity at three months after discharge (r_{18}=0.59, *p=0.010*). We also found some evidence of discriminant validity. The measure was not significantly correlated with living with others (r_{66}=0.04, *p=0.743*), or socioeconomic factors like years of education (r_{65}=0.06, *p=0.614*), and gross household income (r_{65}=0.07, *p=0.552*).

Anxiety and depression were assessed using the 14-item Norwegian version of Hospital Anxiety and Depression Scale (HADS) (Bjelland, Dahl, Haug, & Neckelmann, 2002; Mykletun, Stordal, & Dahl, 2001), which is widely and

successfully used for the post-discharge period and demonstrates satisfying diagnostic usefulness for screening depression symptoms and measuring anxiety in CVD patients (Thombs et al., 2007). There are seven items associated with anxiety with Cronbach's α ranging between 0.68 and 0.93 and seven items for depression with Cronbach's α ranging between 0.67 and 0.92 (Bjelland et al., 2002). In our study Cronbach's α for anxiety was 0.88 and for depression 0.81.

In addition to the primary and secondary outcomes, we also collected some process measures. These tools were measuring constructs that were targeted by the intervention in order to change the main and secondary outcomes, and they were important for understanding the mechanisms of how the intervention, and specifically the tailoring, worked.

The stage of change was assessed using the 24-item Norwegian version of URICA-E2 scale (Lerdal et al., 2009), a scale that has been designed specifically to address the complexity of applying the stage of change theory in physical activity. The scale gives a more comprehensive assessment of the stage than simply time before or after initiation of an action. The reported Cronbach's α varied from 0.72 to 0.92 for each subscale and in our study it varied from 0.66 to 0.84. Stage of change forms the core of the tailoring algorithm we have used and measuring it is important in order to understand the value of the tailoring algorithm.

To understand to what extent the tailoring algorithm succeeded in making the users of the tailored version of the intervention feel that the intervention experience was more relevant, we measured the perceived tailoring. Perceived tailoring has been found to be a mediator of the effect in other types of Internet-based health interventions (Dijkstra, 2005; Strecher, Shiffman, & West, 2006). The perceived tailoring was assessed using four items from the Norwegian translation (Wangberg, Nilsen, Antypas, & Gram, 2011) of Dijkstra (2005). Cronbach's α for the scale was 0.86.(Dijkstra, 2005).

The data used were gathered through web logging. Our intent was to measure the number of logins, time spent logged in, and what elements were used most by each participant. Usage statistics can help us understand how the participants

use the intervention, how often, which elements they prefer, and if tailoring affects the duration of use (time from first to last visit) and the total time spent using the website. This type of information is also a useful contribution to the attrition discussion, which is a major issue in ICT-based behaviour change interventions (Eysenbach, 2005). Due to a technical issue, the "time spent logged in" data that we collected was not reliable. Instead, we used the time between the first and last login as the duration of the website use. We suspect there may have been issues with the number of logins per user as well, but in this case, the problem affected only a small portion of the users for a limited period of time.

Sample size estimation

An *a priori* sample size estimation was performed with an equivalence test for two-proportions in a cluster-randomized design. Based on previous research with chronic disease self-management it was reasonable to expect that a relatively low proportion of users would achieve the goals for self-management behaviours at their one-year follow-up. To discover the differences in proportions of the size of 15% vs. 5% between the two groups at a 0.05 alpha level and with 0.80 power, we needed a total sample of 16 clusters with 15 participants each. We suggested that the recruitment of a total of 17 clusters would provide a sufficient sample.

Statistical Analyses

We tested the normality of the distribution with the Shapiro-Wilk test because after the baseline adjustment the sample size was reduced to less than 50 (Razali & Wah, 2011). We found that we could not assume a normal distribution for the majority of the variables at most of the time points. Therefore, we reported the median and the interquartile range (IQR) for the variables in each group, and we have used non-parametric methods to compare the two groups. Also, because of the small sample size, for the main outcome and for other continuous variables we used the Kolmogorov-Smirnov Z with an exact calculation of the significance to compare the intervention with the control group. As an indicator of the effect size of the Kolmogorov-Smirnov Z comparisons, we calculated the strength of association, r. For the analysis of the categorical data, we used a chi-square test

with an exact calculation of the significance and presented the effect of the size with the phi coefficient (φ). We used analysis of variance (ANOVA) for the scale variables at baseline that were found to be normally distributed, since parametric tests have higher power and we did not want to miss statistically significant differences that would indicate that the two groups are not equal at baseline. For the effect size of the ANOVA comparisons, we used eta squared (η^2). To maximize the use of our data, we included all the cases with valid data per time-point and per variable.

We report Cochrane's α for comparison and completeness reasons rather than as reliability measure, since it has been heavily criticized. Cochrane himself suggests that α fits within a much larger system of reliability analysis and α by itself is not enough to express reliability (Cronbach & Shavelson, 2004). Sijtsma (2009a) concludes that Cochrane's α should be reported because it is required by top journals, but for better reliability estimation the greatest lower bound (glb) should be reported too. A problem with glb is that it can be positively biased for lower reliability values, samples lower than 1000 cases and for tests with more than ten items (Sijtsma, 2009b). In our study, we had less than 1000, so we expect glb to be biased. As response to Sijtsma's paper, Revelle & Zinbarg (2008), suggest the use of McDonald's ω_t, which seems to be biased too (Sijtsma, 2009b). Confirmatory factor analysis and structural equation modeling, seems to produce reliable estimators, but we could not apply them to our sample because of its size (Cronbach & Shavelson, 2004; Revelle & Zinbarg, 2008; Sijtsma, 2009a, 2009b).

For the analysis of the adherence to the website, we used Kaplan-Meier survival curves. We used the days between the first and the last login, and we defined "quit event" as not having used the website for the last month before the data retrieval. A Kaplan-Meier analysis can calculate the time-to-event in the presence of censored cases, such as users who are still using the website or recently recruited users. We compared the adherence curves of the tailored and control groups with the generalized Wilcoxon test of Breslow because we expected and experienced considerably higher dropout rates at the beginning as compared to the rest of the period, and the censoring patterns were similar between the

groups. In contrast, when comparing the difference in adherence for gender, we used the log-rank test because we only had censored cases for the male participants.

The statistical analyses were conducted using IBM SPSS Statistics for Mac, Version 21.0, Armonk, NY, USA, by IBM Corp.

Ethical aspects

The regional research ethics committee (REK Nord) approved the study protocol, its updates and all the questionnaires. The participants in the study were volunteers and signed a paper giving informed consent prior to their participation. Given the small participation rate, we can safely assume that those who took part did it without any pressure (peer-related or from health personnel). The participants were also informed about their right to withdraw without any consequences (as at least one participant did) ("WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects," 2013).

We have selected the appropriate control group according to the ethical principles for medical research ("WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects," 2013). The use of placebo or no intervention is used in special circumstances where no proven intervention exists. Since there is strong evidence that ICT-based interventions have a positive effect on physical activity, our control group received the same intervention as the study group, with the exception of the tailored functionality we intended to test. No additional risks of serious or irreversible harm were anticipated from not receiving the tailored version.

The users, through the consent form and the personnel of the Skibotn Rehabilitation Centre, were informed about the processes and the two randomization conditions of the study. Specifically, they were informed that there was a control group that would receive access to a generic version of the website and an intervention group that would receive access to a version of the website that was tailored to the user. In addition, the intervention group would

have access to a mobile functionality. They were also informed that all the users would be asked to answer five questionnaires during the one-year period of the study and instructed as to how their data would be protected and how it would be used for research. Finally, as mentioned above, they were informed about the possibility to withdraw from the study.

Use of the intervention was free of charge. All participants received a present of symbolic value if they filled out the questionnaire at one month after discharge. The regional research ethics committee approved the practice and information about the present was included in the informed consent. The present was offered as an incentive to use the intervention and participate in the study, but also as a token of appreciation for being part of the study. There are ethical concerns related to payment of participants in clinical trials, because they can unduly influence the participants, leading them to stay in a study despite risks that otherwise would have made them quit (Grady, 2005). However, the value of the gift was so low (NOK 50-60) that the risk of affecting the judgment of the participants was minimal.

Since our research involved human subjects, we carefully assessed the potential benefits of the intervention both for the individuals and for society, in comparison to the potential burdens and risks for the participants in our trial. The effectiveness of ICT-based interventions to increase physical activity (Foster et al., 2013) outweighs the burden of being part of the study. The risk from using the intervention was also predicted to be very low, since is not expected to exceed the risk of being part of a cardiac rehabilitation program. The estimated risk of cardiac rehabilitation programs is one cardiac arrest for every 115,000 patient-hours of cardiac rehabilitation and one death for every 750,000 patient-hours (Fletcher et al., 2013).

To further minimize the risks, we conducted a Risk Assessment Report to identify any potential risks, mainly related to the use of Internet and ICT in general. Appropriate practices have been adopted to minimize the identified risks; for example, all data were gathered and stored in de-identified form, user-related data were secured through necessary encryption and authentication, and

a backup of the data was regularly stored in a different physical location than the intervention server, to prevent data loss.

Another ethical aspect we have to consider in ICT-based health interventions is the possibility of magnifying the already existing inequalities in health. Low socioeconomic status is strongly related not only to higher incidence of CVD, but also to lower use of the Internet (Hawkins, Jhund, McMurray, & Capewell, 2012; Wangberg, Andreassen, et al., 2008), making Internet-based interventions for CVD less accessible to those that need it more. The same applies for mobile technology (Stephens & Allen, 2013). Similar trends have been observed for older individuals who might be less familiar with the Internet or new technologies than younger individuals would be. Among older individuals, there is also a difference between men and women, with women of older age tending to be less familiar with the Internet than men of the same age (Kummervold et al., 2008). Illiteracy, technological illiteracy and e-health illiteracy are all closely related to low socioeconomic status and factors that increase health inequalities (Pampel, Krueger, & Denney, 2010; Wangberg, Andreassen, et al., 2008).

Our study only partially addressed these inequalities. On the one hand, it required as inclusion criteria the existence of an Internet connection at home and the possession of a mobile phone, making it impossible for participants that did not have those requirements to be part of the study. On the other hand, we offered training on the use of the intervention, so participants that met the requirements, but who were not familiar with using them, could take part; for example, the participant had an Internet connection at their home, but it was used principally by another member of the household (such as a spouse or a child), while the participant did not regularly use it.

Results

This section summarizes, and to some extent repeats, the results of Papers II and III. Please find more details in the attached papers.

Results from the focus group

Designing an effective Internet- and mobile-based intervention for health behaviour change is a challenging task. The effectiveness of these interventions is connected to the adoption of the appropriate theoretical framework, while their viability is associated with strong user involvement in their design. For the development of our intervention, we used a methodological approach that combined the user input and health behavioural theory to develop an Internet- and mobile-based physical activity intervention for cardiac rehabilitation. The theoretical framework is presented in detail in Paper II, and in the Methods section of this thesis.

To identify the user needs, we conducted a focus group in February 2010 at the Skibotn Rehabilitation Centre. We included three women (mean age=64.3), and eight men (mean age=59.4) that were attending the cardiac rehabilitation program at the centre. The focus group lasted for one hour and was a two-part semi-structured discussion with the participants. For the first part the participants were asked to express their needs, thoughts, and ideas regarding support for increasing physical activity and the corresponding role of physical activity. In the second part, the interviewers presented some initial ideas about the intervention and asked for more concrete feedback from the participants. We used thematic analysis to extract patterns of meaning from the transcribed material.

We identified seven main themes: 1. Social, 2. Motivation, 3. Integration to everyday life, 4. Information, 5. Planning, 6. Monitoring and feedback, and 7. Concerns/Potential problems.

Figure 1. Thematic map of the focus group themes

The social theme was the most prevalent one. It included ideas, thoughts, and needs expressed by users referring to companionship, belonging to a group or communicating with others.

The theme of motivation refers to ideas and methods believed to influence or be able to influence the behaviour of the participants. The participants strongly believed that the responsibility for change of behaviour is personal, especially after they leave the rehabilitation centre.

Integration to everyday life was related to thoughts and things to do that are helpful to the participants in integrating a desirable behaviour into their everyday lives, like small changes and the creation of habits. Technology is relevant if it is assists them in maintaining the desired behaviour.

The information theme refers to the participants' need for tools that would help them get the right information after the rehabilitation stay. The need for correct answers was repeatedly mentioned, and the possible technology-related solutions were a discussion forum and an online "knowledge bank".

In planning, the participants expressed the necessity of planning their physical activity in advance and having realistic goals in order to actually do it.

Monitoring and feedback appeared in the second part of the focus group and refer to the necessity and the requirements related to keeping a record of the

participant's physical activity and how to give meaningful feedback based on that record.

Finally, in concerns and potential problems, we have included those parts that revealed scepticism on the side of the users, both related to the health behaviour change and the involvement of technology in it.

In order to gain an understanding of the relevance of the theoretical framework we developed, we tried to juxtapose the theoretical concepts with the themes created from the focus group, and we found several encouraging examples.

The final design of the intervention, including the functionality of the website, and the algorithm, was a combination of the theoretical framework and the users' needs assessment as expressed through the focus group. The functionality that was included in the intervention consisted of a microblog for communication among users and personnel, an activity calendar for planning physical activity, a discussion forum, the development of reliable content about CVD and behaviour change and a weekly activity goal functionality (described in Paper II).

Results of the RCT

There were 69 participants included in the study. 29 (7 women) of them were allocated to the tailored group and 40 (8 women) to the non-tailored group. The mean age of participants in the tailored group was 59.5 (56.3 – 62.8), and in the non-tailored group the mean age was 58.8 (55.8 – 61.7). At baseline the two groups were quite similar since we did not find any statistically significant differences in age, body mass index (BMI), years of education, social support, self-efficacy, level of anxiety, level of depression or stage of change.

At baseline the tailored group had higher total physical activity scores (IPAQ continuous score) than the non-tailored group but the difference was not significant. At discharge, the tailored group decreased compared to baseline, while the non-tailored group increased the total physical activity. One month after discharge, the overall physical activity score of the tailored group had

increased compared with that at discharge, and the total physical activity of the control group had decreased compared with discharge. This trend continued at three months after discharge, with the tailored group having a significantly higher median physical activity than the control group at this time point.

In intensity-specific physical activity score, we find similar patterns. The non-tailored group showed a decrease in all forms of activity at three months after discharge compared with the baseline value, whereas the participants in the tailored group showed an initial drop in physical activity before returning to approximately baseline levels at three months post-discharge. Three months after discharge, the tailored group had a significantly higher level of walking than the control group, whereas the differences between the two groups for moderate and vigorous activity were not statistically significant.

Self-efficacy at baseline was slightly higher for the tailored group than for the control group. At discharge, self-efficacy for the tailored group decreased, reaching the same level as the non-tailored group, which showed no change since baseline, and remained the same until one month after discharge. Finally, at three months post-discharge, self-efficacy remained the same for the tailored group and increased slightly for the non-tailored group. The differences between the two groups were not significant at any time point.

The baseline social support scores for the tailored and the non-tailored groups were similar. At discharge, social support increased in the tailored group, at one month it decreased, and at three months after discharge it increased again. Social support remained more or less the same for the non-tailored group from baseline until one month after discharge, and decreased slightly at three months. The difference between the groups was not significant at any time point.

The level of anxiety at baseline was higher for the non-tailored group than for the tailored group. At discharge, it was reduced in the tailored group and remained the same in the non-tailored group. The level of anxiety further decreased for both groups one month after discharge, but the non-tailored group experienced higher levels of anxiety than the tailored group. Three months after

discharge, the level of anxiety increased for both groups, but was still higher in the non-tailored group. No statistically significant differences were observed.

The level of depression at baseline was higher in the non-tailored group than in the tailored group. The level of depression at discharge declined for both groups, and at one month after discharge, depression for the non-tailored group reached the same level as for the tailored group, which remained stable since discharge. Three months after discharge, the level of depression increased in both groups, but showed a greater increase in the tailored group. The differences between the groups were not statistically significant.

At baseline, almost half of the participants of both groups were in the contemplation stage of change. The stage of change was not determined at discharge, but at one month after discharge almost half of the participants of both groups were in the action stage. Three months after discharge, approximately half of the participants of the non-tailored group were in the action stage and one fourth of them were in the maintenance stage, whereas half of the members of the tailored group were in the action stage and the other half were in maintenance. Overall, the participants in both groups progressed forward through the stages of change over the course of the study and there were no significant differences between the two groups.

Perceived tailoring was measured at one month after discharge and was the same in the tailored and the non-tailored group. At three months after discharge, the level of perceived tailoring had increased in the tailored group and remained the same for the non-tailored group. We did not find the difference between the two groups to be statistically significant at any time point.

The mean adherence time for the tailored group was 176.3 (100.3–252.4) days and 177.9 (119.1-236.6) days for the non-tailored group; these findings were not significantly different. The mean adherence time for men was 207.9 (132.2–228.2) days and 92.5 (56.4–128.6) days for women; these values were significantly different.

At one month and three months after discharge, the tailored group seemed to have visited the website more often than the non-tailored group, but without a statistically significant difference. Also, 66.7% of the tailored group participants would recommend the website to a friend, while 75.0% of the non-tailored group would do so. Regarding the utility of the different functionalities of the intervention, the most popular general functionality was goal setting, followed by the activity calendar.

Discussion

The PhD project addressed the issue of designing an effective Internet- and mobile-based intervention for maintenance of physical activity after cardiac rehabilitation stay in a comprehensive approach. By comprehensive I mean a beginning-to-the-end approach where we tried to identify and employ techniques and practices that would maximize the effect of the intervention. Because of this comprehensive approach, this project has the potential to demonstrate results in two levels. The first level refers to the effect of the overall approach. The second level refers to the results of each of the components of the presented approach. Even if the overall approach does not manage to demonstrate significant effect, the results of the individual components can be useful for future research.

The first of the secondary aims was to identify a method for combining users' needs with health behaviour models in the design of the intervention, and we addressed that by describing a process of juxtaposing theory and focus group input in a feasible methodology. The second secondary aim was to extract these user's needs from a focus group, along with the thoughts and ideas of the users regarding the maintenance of physical activity in cardiac rehabilitation, which we did with thematic analysis and present them in seven themes. The third secondary aim was to design an approach to assess the effect of the intervention on maintenance of physical activity and the other secondary and process outcomes; therefore we designed a clustered randomized controlled trial. Finally, we aimed to study the results of the trial in order to conclude regarding the effect of the tailored and the non-tailored version of the intervention. Despite the small sample size we found significant differences between the two groups in physical activity at three months after discharge and not in any other secondary or process measure.

Design of Internet- and mobile-based interventions

User involvement in design of Internet- and mobile-based interventions is very important. It allows the users to express their needs and gets them involved in

the design of health interventions. The necessity of such an approach might have benefits for different outcomes, but it is essential on ethical and moral grounds. The participation can increase the sense of empowerment and control by the patients and promote health (Wallerstein, 1992). Because of the nature of automated Internet- and mobile-based interventions, user involvement should take place prior to or in tandem with the design process. These needs can be expressed in focus group discussions, after which a systematic qualitative analysis can identify a series of themes to be used to formulate intervention requirements. Other similar approaches exist in the literature (Arsand, Tatara, Østengen, & Hartvigsen, 2010; Proudfoot et al., 2010), which suggest user involvement is an essential step during every ICT-based intervention design. At the same time, while designing interventions based solely upon either an assessment of what users report needing or on what technology is available may lead to higher usage rates for the intervention, as neither element on its own ensures changes to health behaviour.

Theory-based and user-input-based approaches can complement one another and offer more holistic approaches to user-centric designs. Our approach combines the traditions of health and behavioural sciences, calling for strong theoretical as well as empirical backgrounds to design interventions with the methodologies of human-computer interaction (HCI) that recommend incorporating user involvement in design. Our approach also brings the decision of theoretical framework a step closer to the users. In this sense, our approach involves users in the theoretical debate by considering their personal experiences and needs, in terms of both technology and health behaviour change for the intervention's success. Bias toward a specific theory may emerge due to users' previous exposure to a specific model of behavioural change. During cardiac rehabilitation, for example, all participants of the focus group of Paper I had been exposed to the stages of change model, and possibly to other theories, during their stays at rehabilitation facilities. In some cases, bias is not necessarily a disadvantage, as choosing a model familiar to a specific group implies an additional step of tailoring to make the intervention more relevant for its users.

An interesting and thorough approach to improving the uptake and impact of eHealth technologies has been used to construct the holistic framework of CeHRes (van Gemert-Pijnen et al., 2011). This framework emerged out of a review of existing frameworks and empirical research and suggests six working principles: participatory development approach, continuous evaluation cycles, development intertwined with implementation, persuasive design techniques, business modelling, and advanced assessment methods. Our approach can be seen as an elaboration on some of the framework's components regarding practical implications. Meanwhile, the user involvement element and focus group interviews that we suggest are clearly part of the participatory development and contextual inquiries approaches. Requiring a sound theoretical framework to base the intervention design on is also reflected in various elements of the CeHRes model, though we have mainly focused on both the principle of involving persuasive design techniques and the value specification process. Our approach is distinguished by its emphasis on producing a bibliographical rationale of the theoretical foundations for all elements of an intervention. Finally, the concept of meshing elements of theory with user input is completely compatible with the principles and requirements of this holistic framework.

Theoretical implications of focus group

Ideally the existence of each component in interventions should be grounded in both user input and theoretical constructs. Since models of health behaviour are developed based on observations of humans, we expect that they will be reproducible and that to some extent will appear in the focus group. The main theme that appeared in the data was the social needs of the users, which was in accordance with the initial incentive of creating such an intervention. The idea came from the users and the personnel of the Skibotn Rehabilitation Centre, who were asking for a tool that would help them to stay in touch with each other after the rehabilitation stay. The social needs were also an obvious reflection of the theoretical framework for health behaviour change (J O Prochaska & Velicer, 1997) and the needs of the users.

More specifically, the participants of the focus group expressed the wish to prolong the social effect of the face-to-face experience, to talk to someone, to brag about achievements, and to make commitments. Also, previous research shows that social support can influence health behaviour and health status (Barrera, 1986). It has been associated with more physical activity-related indicators like time spent in physical activity, frequency, and aerobic capacity, and it was even found to have a dose-response relationship with physical activity (Kahn et al., 2002). This suggests that social variables should clearly play a part in the theoretical foundation for the intervention.

The participants of the focus group were already engaging in physical activity as part of their daily routine in the cardiac rehabilitation. Indeed, most of the discussion topics reflected ideas, thoughts and needs that are characteristic of the stages of action and maintenance of TTM (James O. Prochaska, Redding, & Evers, 2008) and the volitional phase of HAPA (Schwarzer, 2008). For example, the users did not talk much about risk perception, outcome expectancies or action self-efficacy. They talked mainly about coping/maintenance self-efficacy and recovery self-efficacy, action planning and coping planning. The baseline data of Paper III showed a different situation. The majority of the participants were in the contemplation stage of TTM, and the reasons for this discrepancy can be many. The participants of the focus group were on their third week of rehabilitation, while this time frame differed from the participants of the RCT, who were usually in the first two weeks of the rehabilitation. This could imply a very quick transition, taking place during the rehabilitation stay. Another plausible explanation could be the nature of the questions for measuring stage of change and the questions given to the focus group. The focus group questions were general and mostly concentrated on the future, while the URICA-E2 questionnaire that we used (Marcus, Selby, Niaura, & Rossi, 1992) took into account the past, present and future.

Looking at some other themes, we also find useful theoretical references. The planning theme was similar to the action planning process of the HAPA model (Schwarzer, 2008; Sniehotta, Scholz, & Schwarzer, 2006). Action planning is defined as the process that links actions to cues by defining when, where and

how to act. Also, the themes of motivation and integration into everyday life consist of elements that assimilate the coping planning process of HAPA, which is the process that prepares the individual for successfully coping with challenging situations that make it difficult to achieve the intended action (Schwarzer, 2008; Sniehotta et al., 2006).

Another useful implication of the interplay between theory and user input was the relapse prevention. As a concept, it is mainly present in the bibliography of substance abuse interventions (Irvin, Bowers, Dunn, & Wang, 1999), but there is evidence that it can be a useful element of physical activity interventions as well (Kahn et al., 2002). The focus group participants were concerned that a health problem, like back pain, could make them cease physical activity for long periods of time and they were afraid that it could be difficult to start exercising again. For this reason, they wanted to get support in dealing with feelings such as disappointment, sadness, and being a loser, in order to recover. In addition, the relationship of the social support with the relapse prevention, as seen in the focus group, is coherent to the previous findings, which indicated that social support is related to the resistance of relapse into physical inactivity in men (Kahn et al., 2002).

Whereas the stage-based models that we applied may carry some merit for creating tailoring algorithms, they are not sufficient in accounting for all the determinants of physical activity (Adams & White, 2005). Within health promotion, more ecological models (Sallis, Owen, & Fisher, 2008) are used, including factors from within the individual, via the closest network, community to societal regulations and resources. Although more inclusive, these kinds of models raise a number of methodological and logistical challenges (Sallis et al., 2008). A somewhat more limited ecological model that would fit well with our existing variables while including more of the social ones is the social cognitive theory (SCT, Bandura, 1998). Whereas self-efficacy is the most important variable in the SCT, social variables play several important roles. They influence our expectations about outcomes and self-efficacy, and they constitute direct facilitators of as well as impediments to behaviour. Thus, in a temporal

perspective, social variables are important throughout the stages of behavioural change.

Effect of the intervention

Looking at the results of the RCT, we see progress in stage of change after the rehabilitation stay. At baseline, about half of the participants are in the contemplation stage, and at three months half of the participants are in the action stage. The results seemed to be independent of the randomization condition, since we did not find any statistically significant difference in stage of change between the two groups. However, we found that at three months after discharge, the tailored group maintained a higher level of total physical activity than the non-tailored group, and the difference was statistically significant and clinically meaningful. Since the progress in stage of change was similar for both groups but the actual behaviour was not, we believe that the intervention did not work in the way it was hypothesized. A similar observation was made in an RCT testing an Internet-based tailored intervention targeting fat intake, physical activity and smoking cessation (Oenema, Brug, Dijkstra, de Weerdt, & de Vries, 2008). The intervention significantly improved behaviour in fat intake and the likelihood of meeting physical activity guidelines in high-risk participants, but this was not reflected in the intention to change, since both groups had similar fluctuations.

The statistically significant difference in total physical activity at three months after discharge is most probably related to the statistically significant difference in walking. The tailored group had higher walking activity as measured by IPAQ, while moderate and vigorous activity were also higher at the same time point but without statistical significance. The walking-specific difference can be partially attributed to the tailored messages that promoted small everyday life changes, a strategy that was also expressed during the focus group of Paper I. Also, because of the high age of our study population it is easier to maintain physical activity by continuing or even increasing walking (King, 2001), not to mention the role of Scandinavian cultural norms which promote hiking (Gelter, 2000).

The recommended levels of physical activity in cardiac rehabilitation depend on the risk profile of the patient (Fletcher et al., 2013). For apparently healthy individuals the recommended minimum energy expenditure is 500.0–1000.0 MET-min/week (Garber et al., 2011), with an emphasis on moderate and vigorous activity and the note that some activity is better than no activity at all. The total activity of our sample is above these recommendations; the lowest group median of MET-minutes/week of overall activity was observed for the tailored group at discharge (875.2) and the second lowest was observed for the non-tailored group three months after discharge (1356.0). At three months after discharge, when we observed a significant difference between the two groups, the median of the total activity of the tailored group was 5613.0 MET-min/week and for the control group it was 1356.0 MET-min/week. Both values are well above the recommended levels, but it is suggested that there is a dose-response between physical activity and health outcomes, and more is better (Garber et al., 2011). Statistically significant differences in moderate and vigorous activity energy expenditure would of course be of even higher clinical value for cardiac rehabilitation (Fletcher et al., 2013; Piepoli et al., 2012).

The results of the RCT did not show statistically significant differences in adherence either. Despite the non-significant difference, for the first 146 days of the intervention, the attrition was higher for the tailored group. One possible explanation is the increased workload of answering more questions that was expected from the participants of the tailored group. The fact that the difference is not so big as to be significant might be a positive sign, since other studies have reported significantly higher attrition for the intervention group (Oenema et al., 2008). The dropout rate of both groups was higher in the beginning of the intervention, leading to an L-shaped adherence curve that indicates that the intervention did not manage to address the needs of many of the users (Eysenbach, 2005). The lack of a “curiosity plateau” in the beginning, the period where the users stay in a trial out of curiosity, might be explained by the timing of the recruitment and by the characteristics of the study population. Most of the participants of the study, especially during the beginning of their rehabilitation stay, might be very eager to employ as many methods as they can to change and

maintain behaviour, an attitude that might have eased after discharge. Also, women that were interested in participating dropped out very early, significantly earlier than men. After all, there is a known problem caused by the failure of cardiac rehabilitation interventions to address women's specific needs (Bjarnason-Wehrens, Grande, Loewel, Völler, & Mittag, 2007; L. Jackson, Leclerc, Erskine, & Linden, 2005; Neubeck et al., 2009).

To the best of our knowledge, Paper III is the first report of an Internet- or mobile-based tailored intervention targeting physical activity in cardiac rehabilitation patients. A recent review demonstrated evidence that Internet- and mobile-based interventions are effective in increasing physical activity in apparently healthy adults (Foster et al., 2013), but there is a fundamental difference between interventions for a healthy population and an intervention targeting individuals after a cardiac rehabilitation stay. In the first case, physical activity is expected to increase from baseline, while in the second case, physical activity is high at baseline and the intervention is aimed at supporting the individual in maintaining this level of physical activity over time. There are two reviews of mobile-based interventions in cardiac rehabilitation that concluded that more research is needed, since they identified only a few studies (Beatty et al., 2013; Stephens & Allen, 2013). Two RCTs of interventions after cardiac rehabilitation did not show statistically significant differences at their end (Brubaker et al., 2000; S. A. Lear, Ignaszewski, Laquer, Pritchard, & Frohlich, 2003).

Strengths and limitations

A general limitation of the whole approach was that it only focused on the maintenance of physical activity and ignored most of the other core elements of cardiac rehabilitation. Targeting more health behaviours might have increased the complexity of the intervention, the costs and the administrative workload, but according to existing evidence, it would not have affected the effect size of the intervention (Lustria et al., 2013). We chose to prioritize physical activity but an overall approach definitely should be considered in the future.

Strengths and limitations of Paper I

Paper I elaborated on the combination of theory and user input in the design of Internet- and mobile-based behaviour change interventions. For the construction of the theoretical framework we presented a narrative overview of the existing literature on health behaviour change theories, rather than a systematic review. A systematic review of the literature would employ a more comprehensive strategy to identify all available theories and models, and would reduce bias in the selection of theories to be considered for inclusion in the theoretical framework. We did, however, choose to start our construction of the theoretical framework for the intervention from the empirical knowledge and experience of the research team based on their experience with other tailored interventions (Wangberg et al., 2011; Wangberg, 2008) as well as from the theory of existing tailored health interventions from other research groups (Lustria et al., 2013).

To collect user input we conducted a focus group with participants from the collaborating rehabilitation centre. A major issue within cardiac rehabilitation is that low proportions of cardiac patients in general, and especially among women, actually participate in such programs (Leon et al., 2005; Pack et al., 2013; Suaya et al., 2007). Our focus group offers very limited knowledge regarding the reasons for the low participation rates in cardiac rehabilitation and even so could not be generalized to the CVD patient population due to sampling bias. The target group of our intervention was, however, the participants of this specific collaborating rehabilitation centre; therefore recruiting patients from this centre for the focus group was the ideal sample to maximize the likelihood of real-world effectiveness in our intervention trial.

One limitation of the study might be that the duration of the focus group (one hour) was too short for all the participants to express their opinions and allow for adequate amounts of discussion. For example, during the analysis of the data it emerged that a gender-related issue that was expressed by a female participant of the focus group was not properly discussed during the focus group. Later, during the statistical analysis of the results (Paper III), we did in

fact discover higher attrition amongst women in comparison to men. Hence, we went back to the focus group data to see if it could cast some light on the differential use of the intervention. We were not able to find an explanation, though, as there was no elaboration on the gender issue. This fact indicates the importance of allowing more time for and encouraging further elaboration on expressed concerns that are even briefly touched upon by individual members of a focus group. On the other hand, longer focus group duration might have been more exhausting for the participants. However, it could also be possible to organize two focus group sessions to address this issue.

The focus group took place at the beginning of the intervention design process. During the second part of the discussion, the participants were presented with some initial ideas for the functionality of the intervention. The feedback they provided was useful for refining these ideas, but it would have been even more useful if we could have planned more meetings with the same participants in order to collect feedback as we developed the prototype (Arsand & Demiris, 2008). This method would more actively involve the users in the design of the intervention, and would help to develop a service even more closely related to their needs. Such an approach has been applied successfully in the design of a type 2 diabetes system (Tatara, Arsand, Skrøvseth, & Hartvigsen, 2013), but it is a time- and resource-demanding method that also has to be incorporated into the routines of externally hired developers, as it was in our case. In addition, the participants of a typical monthly cardiac rehabilitation group at Skibotn Rehabilitation Centre come from a huge geographical area, and depending on the place, this might require a trip that would take multiple hours, combining boat, bus and plane rides.

Strengths and limitations of Paper II

As discussed in the Methods chapter, the tool we used for measuring physical activity is not as accurate as measuring physical activity with accelerometers (Beatty et al., 2013). The international physical activity questionnaire is self-reported and it introduces a recall bias, which should be considered in comparing the results of our studies with other studies. This is not expected to

have an important effect on our between-group comparisons since we use the same measure and the same frequency in both groups. Related to this issue is also the fact that we allowed the users of the non-tailored group (control group) to use the physical activity calendar functionality. If the use of the calendar functionality has an effect on recall ability, our results will not be biased because both groups had access to it. On the other hand, the activity calendar could have given a certain personalized functionality that attenuates some of the differences between the intervention conditions.

Attrition is a known problem in eHealth trials and can be separated into dropout attrition and non-usage attrition (Eysenbach, 2005). Dropout attrition is the situation where the participants are lost to follow-up; they stop answering the online research questionnaires. Non-usage attrition is when the participants stop using the intervention. The two types of attrition are related and can co-exist but they might be connected to different factors. Also, one typically finds a very skewed distribution in the amount of use of Internet-based interventions, with the majority of participants exploring the website for up to an hour on their first visit and spending minimal time with the intervention thereafter, and with a few of the participants spending a substantial amount of time with the intervention over a longer time period.

In our study we used only one item for assessing the level of self-efficacy. A study that compared five measures of self-efficacy, including a single-item scale, found that the measures with multiple performance levels had higher convergent and predictive validity than the single-item one (C. Lee & Bobko, 1994). Nevertheless, the single-item scale values were highly correlated with the results of the other scales. Single-item scales for self-efficacy have been also criticized for being perceived by responders as assessment of their confidence in outcome expectancies rather than efficacy expectations, the judgement of capability to achieve a performance level (Moritz, Feltz, Fahrbach, & Mack, 2000). Outcome expectancies are not as predictive of performance, as efficacy expectations. However, multiple-item scales are not necessarily empirically better than single-item scales (Gardner, Cummings, Dunham, & Pierce, 1998). Also single-item measures are preferred if we are interested in a general measure of a construct

(Kwon & Trail, 2005), and there references in the literature suggesting the construct of general self-efficacy (Schwarzer, Bäßler, Kwiatek, Schröder, & Zhang, 1997). Several other studies advocate the use of single-item measures as more appropriate under certain circumstances (Bergkvist & Rossiter, 2007; Fuchs & Diamantopoulos, 2009; Zimmerman et al., 2005), and as it is repeatedly quoted, "the use of single-item measures should not be considered fatal flaws in the review process" (Wanous, Reichers, & Hudy, 1997, p. 250).

Despite the effort to shorten some measures, the number and length of research questionnaires was very extensive. This increases the amount of effort and the time that the users need to invest in the intervention and it is possible that this contributed to the high study dropout and increased the amount of missing data (Cook, Heath, & Thompson, 2000; P. Edwards et al., 2002). On the other hand, the purpose of our study was not only to measure the effect of the intervention but also to understand how the intervention works and for whom, so process measures were important to collect, thus necessitating an increase in the length of the questionnaires.

The way the tailoring works in our intervention and in most tailored interventions is by using the answers from extensive questionnaires. This places an additional burden on the participants belonging to the tailored group, with the possibility of increasing the non-usage attrition. In Paper III, we did not find any statistically significant differences between the two groups in adherence. A possible explanation could be the counteraction of the positive effect of tailoring, such as being perceived as more interesting, with the negative effect of the burden presented by the increased workload (Wangberg, Bergmo, et al., 2008). Asking questions is a necessary part of making the intervention relevant for the user, and it might have a positive effect on its own by helping the user to understand himself or herself. Nevertheless, the length of the questionnaires takes its toll on adherence.

One of the strengths of the study is that it included five data collection time points in a period of a bit over one year. The existence of data from both the time the participants were attending the rehabilitation program (baseline) and the

first days after discharge can help us separate the effect of the intervention from the effect of the cardiac rehabilitation stay. A limitation is that the baseline data were not collected prior to the rehabilitation stay. In that case, the baseline and discharge data would have more clearly indicated the effects of the rehabilitation stay and we would have had more reliable information regarding the pre-rehabilitation level of activity. The rest of the collection time points at one, three and 12 months after discharge help us to compare our results with other studies with different durations and detect fluctuations in behaviour. For example, the findings of Paper III showed that the progress of the level of physical activity after discharge is not a monotonic decrease or increase. Also, the existence of intermediate time points between baseline and 12 months after discharge allowed us to present interesting results, even if the recruitment rates and the adherence are lower than expected.

In conventional clinical trials, dropout and non-usage attrition is often addressed with follow-up routines. In cases that are lost to follow-up, a routine is activated to find the reasons for dropping out, and in some cases to bring the subject back to the trial. In Internet- and mobile-based trials like ours, this can, to a certain extent, be addressed through reminders sent by email and SMS. In our trial we were only sending an SMS and a daily email for three days, but we did not have any additional follow-up phone calls or actions after a dropout. This comes at a cost to the integrity of the data, but in my opinion it better resembles a real-world sustainable scenario for such an intervention. Most of the functionalities of the intervention were automated, requiring little contribution from health personnel after the registration. In this way, the non-usage attrition rate of our study is an accurate estimate of the non-usage attrition rate the intervention is going to have if it is implemented as a routine service.

The design of the trial had several methodological elements that contributed to its strength, but there were two elements we planned that we did not manage to implement. We used cluster randomization to protect from between-group "contamination" and to account for similarities within the monthly groups (more details in Methods). The large variance in the number of participants in each cluster, the small sample size, and the use of non-parametric methods made the

use of clusters redundant. The second element was blindness. Our intention was to have the assessors blinded, but this was not possible because we had to perform a quality assurance procedure regarding the randomization early in the data analysis phase. Those two elements are now limitations of the study.

The participants or the recruiting health professional could not predict the treatment allocation prior to the enrolment and this prevents selection bias (Zhao, 2013). The participants of the study were not told their intervention condition allocation, and the study was designed in a way that the participants belonging to the tailored intervention group would have limited contact with the participants belonging to the non-tailored group. However, the consent form informed them that only the intervention group would have access to the mobile functionality, so it was possible to deduce into which intervention condition they were allocated. In addition, there is a possibility that participants could exchange information about the type and the amount of information they were getting and realize which group was receiving the tailored conditions. This is a known limitation of online trials (Elizabeth Murray et al., 2009) and its impact is not expected to be higher than in other trials.

Some studies of ICT-supported cardiac rehabilitation interventions apply very restrictive eligibility criteria, such as specific heart condition, age group, distance from the hospital and absence of co-morbidities (Neubeck et al., 2009; Zutz et al., 2007). Such an approach increases the internal validity, and can produce valuable knowledge concerning the specific group, but has limited external validity (Ho, Peterson, & Masoudi, 2008). Our study design employs wide inclusion criteria in an effort to demonstrate results with high external validity, which are relevant for clinicians in deciding whether they want to implement the intervention as a routine service for their typical patient population. Real-world RCTs might be more challenging to implement, have higher drop-out rates and be more difficult to demonstrate efficacy, but their value is recognized as being more relevant for evidence-based decision-making (Ho et al., 2008; Tunis, Stryer, & Clancy, 2003).

Several RCTs of physical activity interventions have used "usual care" as a control group (Foster et al., 2013; Neville et al., 2009). Moreover, a recent review of ICT-based physical activity interventions concludes that there is a need for more studies using appropriate control groups than comparison studies between different variants of technological interventions (Foster et al., 2013). Under this light, our choice not to use usual care as control group, but rather to use a non-tailored version of the intervention, can be considered a limitation. This choice is expected to come at a cost to statistical power. Theoretically, it is more difficult to detect statistically significant differences between two groups that receive an intervention with different characteristics, than between an intervention group and a usual care group. In practice, a review of web-based tailored health interventions showed that studies with a non-tailored comparison group had significantly smaller weighted mean effect sizes than studies with a no-treatment comparison group (Lustria et al., 2013). The same review suggests that the result is counter-intuitive and characterizes it as a methodological artefact related to the low quality of tailoring in studies with no treatment comparison group.

The choice of the control group also has an ethical dimension (Beatty et al., 2013). Reviews of Internet- and mobile-based interventions for physical activity present evidence of positive results, so we can already consider them as best practices, especially when they are compared only to "usual care." To offer best-practice treatment to the control group and compare it against an intervention that is aimed at further improving the best practice is an ethically reasoned choice, supported by multiple calls for such choices. No-treatment and usual-care control studies have been criticised for lacking relevance to real-world decisions (Ho et al., 2008; Neville et al., 2009), making it difficult for decision makers to implement the interventions and the findings in clinical practice (Tunis et al., 2003).

Strengths and limitations of Paper III

The size of the sample presented in Paper III was smaller than the one required by the sample size calculations of Paper II. This is a limitation of the study due to an incorrect estimation of the interest in the study. A possible reason could be

that the age of the participants was higher than expected, resulting in increased skepticism for new technologies. The problem increased with the high attrition rate for the study, which resulted in an even smaller sample during the follow-up time points. High dropout attrition is nevertheless a known problem in online trials (Eysenbach, 2005). The data analysis was performed with non-parametric methods that are criticized for having lower statistical power than parametric methods. One reason for this choice is the small sample size. The other reason is the measurement tools we have used; for example, IPAQ's scoring manual suggests the use of non-parametric methods. Indeed, the data in most variables were not normally distributed. This makes the argument of lower statistical power of non-parametric methods redundant in our case. In fact, it is impossible to calculate the statistical power of a parametric method when the normal distribution assumption is not fulfilled, therefore it is impossible to compare the two methods (Field, 2005).

Underrepresentation of women is a serious limitation of our study that has been extensively discussed in the ethical implications of methods. We did not manage to include enough women, a fact that is related to the general low participation of women in cardiac rehabilitation and appeared to be a problem in the focus group as well. In addition, we did not manage to address the needs of these women, as we can see from the higher and earlier attrition among women in comparison to men. On the other hand, we included participants of higher age, a population that is often excluded in other studies (Stephens & Allen, 2013).

In addition to the missing data due to loss to follow up, we also had a certain amount of data missing because of technical issues or because the participants did not respond to all the questions. Amongst the responders, even if correlations showed that the data were missing at random, the small sample size and the non-normal distribution of our data create some problems for applying missing data methods (Schafer & Graham, 2002). Multiple imputation seems to be able to work well with non-normal data, and with sample size as low as 50, so it will be considered once more data are collected (J. W. Graham, 2009).

A related issue is the strategy regarding the inclusion of non-responders in the study. It is generally suggested that the optimal approach for unbiased randomized controlled trial statistical analysis is the intention to treat (ITT) strategy (Montori & Guyatt, 2001). ITT means that during the analysis, the patients are included in the groups to which they were originally randomly assigned even if later it is found that they did not satisfy the entry criteria, or that they received a different than the intended treatment, or that they subsequently withdrew from the study or deviated from the protocol (Hollis & Campbell, 1999). It has also been suggested to apply the ITT strategy to eHealth research (Eysenbach, 2005). To include the dropouts in the ITT analysis, which is our main problem, it is assumed that they have negative or neutral outcomes. Such an approach though, would greatly diminish the power to detect differences between the two groups (Eysenbach, 2005). In addition, my impression is that this is an overly conservative approach given the fact that users that drop out in eHealth research do not necessarily have negative or neutral outcomes. For example, in smoking cessation, non-responders were more likely to quit than responders (Tomson, Björnström, Gilljam, & Helgason, 2005) and in an online weight management intervention, those doing light exercise were more likely to respond at 12 months than those doing moderate or vigorous exercise (Couper, Peytchev, Strecher, Rothert, & Anderson, 2007). The use of a more advanced missing data strategy might offer a more realistic estimate for the outcome, but we still have the obstacles of small sample size and non-normality to apply these techniques (Schafer & Graham, 2002). Recent guidelines for reporting trials has also changed the request for ITT analysis, in favour of a more accurate description of the analysis used (Schulz, Altman, & Moher, 2010). In our statistical analysis we included the existing data at each time-point in order to maximize the use of the data, in an effort to offer a pragmatic estimation of the behaviour and outcomes of the participants that used the intervention.

One of the results of the study that troubled us was the absence of any statistically significant differences in behavioural determinants, despite the significant difference in physical activity. In another RCT of a tailored lifestyle intervention targeting saturated fat intake, smoking cessation and physical

activity, the behaviour was also improved but this was not reflected in the behaviour measures intention to change (Oenema et al., 2008).such as intention to change (Oenema et al., 2008). In that case, this discrepancy was attributed either to poor choice of behaviour measures or to the possible pre-existing positive intention of those that changed their behaviour. Regarding the perceived tailoring, which was found to be similar in both groups, a possible explanation might be related to the quality of the generic information on the website and some contact with the personnel through the discussion forum. The target group of the intervention is very specific, and the information on the website was developed mostly by the personnel of the rehabilitation centre for the same target group, so the relevance was high. Also, the non-tailored group had access to the activity calendar functionality, thus potentially making the perceived personal relevance of the intervention high in both conditions, blurring out the potential additional effect of the tailoring.

Use of technology in health interventions can always include a certain degree of unpredictability. Despite the rigorous testing of the technical solution prior to the launch, a certain number of technical issues—bugs—made their way into the final product. The existence of bugs is certainly a limitation, but their severity varies. A bug that affected the quality of the results was related to the module that would calculate the time each user spent on each webpage. Unfortunately, after a security update, the module stopped recording. To overcome this limitation, we took the time of the first login and the time of the last login and calculated the duration between them. The result is not indicative of the amount of website use, but rather is an indication of the overall length of use.

Aside from the bugs, another factor related to the design can be considered a limitation. Even though we developed the intervention based on stated user needs, some elements of the intervention did not satisfy some of the users. One example is the feedback we received from some users that they would like to be able to stop receiving SMS messages for a defined period of time, such as if they are on holiday or sick. This of course negatively affects the user acceptance level and might lead to higher attrition rates. A combination of methodological, economical and technical reasons did not allow these changes to happen. I

believe that it was more methodologically consistent to not change an important functionality of the intervention while the trial was still running.

The online discussion forum was one of the initial requests from the personnel and the patients of the collaborating rehabilitation centre and was also requested during the focus group. We also included the discussion forum in the tailoring algorithm as a social support resource. However, it seems as if it did not manage to fulfil the expectations of the users. There was some use, typically between baseline registration and discharge, but the activity appeared to decline after discharge. A possible explanation is that due to the small number of participants, the website did not have the necessary critical mass to take off.

Suggestions for future research

Long-term effect

The design of the RCT included a follow-up one year after discharge from the rehabilitation program. When all the users have completed the one-year follow-up, we will analyse and publish the results of the long-term effects of the intervention.

Recruitment of more participants in the RCT would help us increase the sample size. With a larger sample we might be able to fulfil the normality assumption, at least for some of the data. Then we can apply parametric methods and account for the clusters in the analysis. We can also use even more advanced statistical methods, like Structural Equation Modelling (SEM). With SEM we can develop a model of how we think behavioural variables relate to the behavioural outcome and assess it to see if it fits with the data. An advantage to this is that we can analyze the behavioural constructs without measurement error, but again, it is a very big challenge to recruit the necessary sample size for such an analysis (Nachtigall, Kroehne, Funke, & Steyer, 2003).

Further improvement

One of the limitations of the study was that it only included one focus group prior to the design of the intervention. The addition of at least one more focus

group of users that have used the intervention would be interesting and would complement the study. Such an approach would offer a qualitative insight in several quantitative findings, but also would refer back to the first focus group to determine if the needs of the users remained the same and if they were properly addressed by the intervention. With this mixed methods approach, we would be able to develop a more complete understanding of how the intervention works and how the users perceive it, and we would be able to improve it further.

The intervention should be developed further to include and address the needs of women and other underrepresented groups. Since women are already underrepresented at the face-to-face rehabilitation program, a different approach should be used for this facet of the project. In this case a focus group should be organized for CVD patients after their discharge from the hospital and without having participation in a cardiac rehabilitation program as a precondition to eligibility.

One of the major issues identified in the intervention is the high attrition rate. Our future research should focus even more on studying attrition and should include different elements that can reduce it. Even more advanced persuasive design might be a possible approach (Kelders et al., 2012).

Earlier cardiac rehabilitation

An interesting direction for future research would be to study the effect of such an intervention before an individual's participation in a cardiac rehabilitation program. Specifically in the case of North Norway, where there is a long interval between discharge from the hospital and entering cardiac rehabilitation, an intervention like this could be offered during this interval. This has the added potential to increase recruitment to the cardiac rehabilitation program (Pack et al., 2013).

Adherence and engagement

As the field of health behaviour change evolves, the use of neuroimaging methods to understand behaviour change seems promising (Falk, Berkman, &

Lieberman, 2012; Falk, Berkman, Whalen, & Lieberman, 2011). Neural activity is used to index unconscious processes, or at least processes not captured by current self-report methods. Neuroimaging (functional magnetic resonance imaging—fMRI) has the potential to improve our understanding of theory, to assist in the development of new self-report methods, and to make health behaviour change interventions more effective. As fMRI is becoming more accessible and affordable to researchers, we might be able to include it as the third element of an approach for designing effective interventions, alongside user input and the strong theoretical framework.

Serious games and gamification receive a lot of attention, partly due to their popularity but mainly due to their potential in improving health and physical activity (Papastergiou, 2009). Using games for engaging cardiac rehabilitation patients in physical activity might be a way to increase the effectiveness of Internet- and mobile-based interventions. An important characteristic of computer games is their ability to help the user experience flow (Chou & Ting, 2003). Flow is an emotional state of concentration and enjoyment that appears when people are absorbed in an activity because the difficulty of the task matches their skills. Flow has also been described in the context of sports, experienced by elite athletes (S. A. Jackson, 1996). Research on serious games in combination with tailored interventions has the potential to make physical activity an interesting experience for cardiac rehabilitation patients. In the same context, future research on combining tailored health behaviour change interventions with social media has also the potential to improve adherence, and increase recruitment (Bradshaw, Hughes, & Day, 2013; J. Lee, Lee, & Choi, 2012; Neiger et al., 2012; Neiger, Thackeray, Burton, Giraud-Carrier, & Fagen, 2013). Experience with a tailored smoking cessation intervention shows that utilization of social media functionality to built a community of users might have positive impact on health behaviour and adherence to the intervention (Vambheim, Wangberg, Johnsen, & Wynn, 2013; Wangberg et al., 2011).

A side effect of extensive and longitudinal tailoring is the use of copious and repetitive questionnaires that might negatively affect the users' satisfaction and adherence levels. The use of accelerometers, location data, cameras and other

sensors has the ability to provide a large amount of information that we need, which could drastically reduce the length of the questionnaires. As technology evolves, sensors are becoming more affordable and more portable and the data transfer automatic and seamless. Future research should make use of these capabilities in order to improve the effectiveness of tailoring and of the interventions in general. This does not mean that the process of asking the users questions will stop being useful. The process can be enhanced with speech recognition techniques and natural language processing to make the technological interface more intuitive, but it should not be completely replaced by sensors. What technology can do is to help reduce the number of questions, so the user will have more time, energy and interest to focus on the important ones.

Conclusions

Health behaviour theories offer a solid foundation for creating an effective Internet- and mobile-based intervention for cardiac rehabilitation, especially if the theory is incorporated in a tailoring algorithm. User input, on the other hand, has the potential to increase the perceived relevance and usefulness of the intervention and thus increase its utilization, but is also strongly advised on ethical grounds. In addition, the user input proved useful in the interpretation of the quantitative results. A focus group seemed to be an appropriate method for involving users, but multiple sessions spread throughout the design process are expected to be more useful than a single session. The combination of strong theoretical framework with user input is feasible and strongly recommended.

Randomized controlled trial is the best method to evaluate the effect of the intervention. Randomization in clusters has the potential to protect the participants from "contamination" and to account for within-group similarities, but adds even more complexity to the challenging task of running a trial. Possible risks are the low interest of the target population in taking part in the trial, and the high attrition rate, which is quite a common phenomenon in online trials. Recruiting women and managing to keep them interested in the intervention is also a great challenge, endemic in the field of cardiac rehabilitation. Another risk, inherent in technological solutions, is technical issues, or bugs, that can jeopardize the quality of the provided intervention and of the research data.

Our study faced all of the above-mentioned challenges, with the most important being the small sample size. Despite this limitation, most users were positive in their attitudes towards the intervention and would suggest it to a friend. The secondary and process measurements did not reveal statistically significant differences between the tailored and non-tailored groups. However, we did find a statistically significant difference in physical activity at three months after discharge, indicating that the tailored group might have managed to maintain physical activity for a longer time than the non-tailored group. The discrepancy between the secondary and process measures and physical activity shows that

the intervention might have worked, but not in the way it was hypothesized it would work, thus creating some more questions for us to answer.

Research on humans and in eHealth is a complicated and strenuous process, with many pitfalls that can lead to failures, and not so successful efforts. Researchers should not be discouraged to report their efforts even if the results are not the desired ones, a common phenomenon reported as publication bias. Of course, a long-lasting effort that only presents moderate results, strict reviews, or failed funding applications are painful and discouraging, a feeling predicted even by Socrates. Socrates that learned his method from his mother, who was a midwife[4], resembles the process of finding answers with the process of giving birth. As persistence and patience are innate parts of giving birth, they are also innate parts of the knowledge seeking process[5]. Even if the effort leads to a failure to find all the answers, it is just a small deviation of the collective effort of humanity to find answers, and every experience if collected in an ethical way, is a valuable contribution to this effort.

[4] The Socratic method in ancient greek is reffered as child-delivering method (μαιευτική). This might set the origin of the Socratic method in Health Sciences and specifically in Nursing.

[5] These arguments should be seen under the light that Socrates most probably did not experience giving birth himself.

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Paper I

Paper II

Paper III