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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.

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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

Original Paper

Combining Users' Needs With Health Behavior Models in Designing an Internet- and Mobile-Based Intervention for Physical Activity in Cardiac Rehabilitation

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Abstract

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KEYWORDS
focus group; design methodology; user involvement; user needs; health behavior models; tailoring; SMS; Internet; cardiac rehabilitation; smoking cessation; physical activity

Acknowledgments
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See manuscript file.

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Original paper

Combining users' needs with health behaviour models in designing an Internet- and mobile-based intervention for physical activity in cardiac rehabilitation.

Abstract

Background: Internet-based physical activity interventions have great potential in supporting patients in cardiac rehabilitation. Health behaviour change theories and user input are identified as important contributors in the effectiveness of the interventions but they are rarely combined in a systematic way in the design of the interventions.
Objective: The aim of this study is to identify the appropriate theoretical framework, along with the needs of the users of a physical activity intervention for cardiac rehabilitation, and to combine them into an effective Internet- and mobile-based intervention.
Methods: We explain the theoretical framework of the intervention in a narrative overview of the existing health behaviour change literature as it applies to physical activity. We also conducted a focus group with 11 participants of a cardiac rehabilitation programme and used thematic analysis to identify and analyse patterns of meaning in the transcribed data.
Results: We chose stage-based approaches, specifically the Trans-theoretical model and the Health action process approach as our main framework for tailoring, supplemented with other theoretical concepts such as Regulatory focus within the appropriate stages. From the thematic analysis of the focus group data, we identified seven themes: social, motivation, integration into everyday life, information, planning, monitoring and feedback, and concerns and potential problems. The final design of the intervention was based on both the theoretical review and the user input, and it is explained in detail.
Conclusions: We applied a combination of health behavioural theory and user input in designing our intervention. We think this is a promising design approach with the potential to combine the high efficacy of theory-based interventions with the higher perceived usefulness of interventions designed according to user input.

Introduction

Burden of Cardiovascular Diseases

The contribution of noncommunicable diseases to the burden of disease has increased over the last decades, especially in Western Europe. Cardiovascular diseases clearly have an important impact in this, ranked at the top of the causes of death with an increasing share in the burden of disease from 1990 to 2010 [1].

The Internet and Health Care Interventions

In the same period the world 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 diagnosis, treatment, prevention of illness, and the promotion of health. The number of health-related websites was estimated in the year 2000 to be more than 100,000, while today there are so many that it is not even possible to find an accurate estimate [2]. It would also be risky to estimate the general impact of Internet use on the burden of disease, but research shows that under certain conditions it can be a very useful tool in supporting self-management [3-9]. More specifically, there is the potential to influence physical activity that is very important for the prevention and the rehabilitation of cardiovascular diseases [7,10].

The effectiveness of Internet-based health interventions is connected with the adoption of the appropriate theoretical framework [11-14], while the viability of these interventions is associated with strong user involvement in their design [15]. For that reason, we are using a methodological approach that is combining the user-input and health behavioral theory to develop an Internet- and mobile-based physical activity intervention for cardiac rehabilitation [16].

Following our suggested process, we first review relevant models of health behavior and discuss our choice of the theoretical background for the intervention. We next present results from a user needs focus group, and finally, we describe the resulting design of the intervention.

Methods

Theoretical Framework Choice

The choice of a theoretical framework is explained through a narrative overview and discussion of models of health behaviors in light of applicability to longitudinal tailoring. Then, theoretical concepts fitting well within different stages of behavioral change are reviewed.

User Needs Focus Group

The user needs focus group took place in February 2010 at the Skibotn Rehabilitation Center in Norway. There were three women with mean age 64.3 years and eight men with mean age 59.4 years, all attending the center's cardiac rehabilitation program that month. The focus group was conducted at the center during the fourth and last week of the program's duration and lasted one hour.

The discussion was based on an interview guide, but it was stressed that the goal would be an open discussion. The first part of the focus group was about needs, thoughts, and ideas of the users regarding support to increase physical activity and the corresponding role of technology. During this first part, the interviewers didn't present any of the ideas for the intervention. The second part started with a very short presentation of some of the researchers' ideas regarding the proposed intervention. The discussion that started in parallel with the presentation, and continued afterwards, focused on the opinions and reflections of the participants on the proposed concepts and intervention features. There were two interviewers that led the discussion.

The focus group discussion was audio recorded, verbatim transcribed, and analyzed with thematic analysis. Of the two researchers that analyzed the data, the first is a nurse with work experience in cardiovascular diseases. By the time of the focus group, the cardiovascular nurse had already developed some ideas regarding the intervention based on discussions with personnel at the rehabilitation center and on previous experiences with heart patients. The second researcher is a health psychologist with previous experience in developing Internet-based as well as tailored, health behavior change interventions, thus interpreting the data through glasses tinted by health behavior theories.

Results

Theoretical Framework Rationale

Tailoring and Models of Health Behavioral Change

In this section, we present the rationale behind the choice of the theoretical framework we chose for the Internet- and mobile-based intervention for physical activity. At first we explain why we use tailoring, an effective element of persuasive technology [15]. Then we present the different models of health behaviors, and how we combined them to comprise the core of the tailoring algorithm.

Tailoring

Bibliographic evidence is pointing toward the effectiveness and usefulness of tailoring. For example, perceived program relevance and amount of the materials read are found to be mediators of the effect of a Internet-based smoking cessation program [17]. A tailored intervention is one that is adapted to the characteristics of the individual, typically based on responses to a questionnaire [18]. Tailoring relies on three main methods: (1) personalization, (2) adaptation, and (3) feedback [19]. Personalization involves referring to the recipient in the text on the basis of details such as first name, age, gender, or hometown. Adaptation concerns the content of the text itself, which can be tailored according to a variety of theories. Feedback is a widely used feature in which the recipient is informed about scores on a scale, and how to interpret the results. In newer, more complex tailoring, these features are often combined, and the components of the Internet-based intervention may also be tailored.

Tailored health messages are in general perceived as more interesting and personally relevant, liked better, read more thoroughly, discussed more, and remembered better compared to nontailored educational material [20-23]. Personalization shows the most consistent effects of being tailored to [24,25] and involves referring to the recipient in the text on the basis of details such as first name, age, gender, or hometown. This is consistent with self-referent encoding, that all information that we associate with ourselves, is more easily noticed, stored, and retrieved [26].

Models of Health Behavioral Change

Tailoring on Variables

Models for health behavior can be roughly divided into two categories: (1) continuum models, and (2) stage-based models [27]. Velicer and Prochaska [28] argue that Schwarzer's [27] division between continuum versus stage-based models can be conceptualized as theories of behavior versus theories of behavior change, as the first ones, to a great extent, are based on correlational studies of predictors of an on-going behavior, whereas the latter, to a greater extent, have studied predictors of transitional processes into a greater readiness for change. For the purpose of clarifying different implications for tailoring, we will continue our discussion with Schwarzer's dichotomy.

Continuum models describe antecedents of behavioral change with the implicit assumptions that the sum of these antecedents needs to be above a certain threshold for a behavior to occur. Models vary as to whether and which variables are necessary and sufficient for behavioral change to happen. For instance, several models agree that having an intention to perform a behavior is necessary (but not sufficient) for the actual behavior to occur. Stage-based models, on the other hand, assume that there are distinct stages characterized by specific cognitive processes and motivational needs that the individual should pass through in sequence to get to behavioral change.

Researchers within both kinds of models agree that there is a "gap" between intention and behavior [29], but a discussion with important implications for interventions is whether (for instance) intention is a static (indicator) or a dynamic (and changeable) variable [28]. Before and after forming an intention is a common chasm across several stage-based models [27], and is also seen as an important distinction demanding different strategies in nontheoretical methods such as motivational interviewing [30], which has been successful in supporting people in changing a host of health behaviors [31,32], including those relevant to cardiovascular disease risk [33-36]. Tailoring based on the continuum kind of models would imply that one determines which variables are "low" and then aims the intervention at increasing these, while tailoring based on stage-based models will identify the stages and deliver an intervention directed at the described processes within the particular stage.

Noar et al [37] found in their meta-analysis of tailored interventions that those based on the Transtheoretical model (TTM) [38] had the greatest effect. They further found that the number and type of theoretical concepts tailored on, including stage of change and processes of change, were associated with behavior change [37]. In general, physical activity interventions based on the TTM have not been very effective. Adams and White [39] point out potential reasons why this may be–that physical activity is complex, and that several of the reviewed interventions might not have optimally operationalized the TTM concepts. In other words, how we tailor to the relevant needs and processes within each stage is at least as important as the overarching framework (ie, the stages). The stages of the TTM with relevant variables in each stage can be seen in Table 1.

As the first step in our tailoring, the participants' stage of change is assessed using the University of Rhode Island Change Assessment – Exercise 2 (URICA-E2)[44]. In the next step, they follow different paths depending on the stage, starting with feedback on the current stage. As can be seen in Table 1, in addition to the variables described in the TTM [38], we have added some specific constructs from other theories according to what we see to be a good fit to the relevant processes in each stage. These are described in more detail below, along with our operationalization of these constructs in the tailoring of our physical activity intervention.

Table 1. The five TTM stages enriched with well fitting constructs from several theories.

	Stages from the TTM				
	Precontemplation	Contemplation	Preparation	Action	Maintenance
Relevant psychological constructs in different stages	Consciousness raising [38], Regulatory focus [40,41], Values [30], Environmental reevaluation [38], Outcome expectancies [42], and Supporting autonomy [30]	Decisional balance [38] and Self-reevaluation [38]	Action planning [27], Coping planning [27], Implementation intentions [43], and Self-efficacy for action [27]	Contingency monitoring [38], Counterconditi-oning [38], Stimulus control [38], Helping relationships (TTM) [38], Social support, Self-monitoring rewards, and Self-efficacy for maintenance [27]	Self-efficacy for recovery [27] and Relapse prevention

Regulatory Focus

A variable that we tailor on when we deliver health information to those who are concerned with the pros and cons of behavior change (ie, those in the first two stages) is the individuals' promotion- or prevention-goal orientation (regulatory focus). Regulatory focus theory [40,41] separates those who are primarily motivated by achievement and gaining rewards (promotion) from those who are more concerned about avoiding loss and risk of such (prevention). This has implications for the kind of health information the individual is most affected by, and consequently, how we frame health information. Latimer et al showed that tailoring to regulatory focus (ie, matching it to the individuals' regulatory focus), can increase both physical activity [45] as well as fruit and vegetable intake [46]. Our participants are presented with a regulatory focus assessment (RFQ)[41]. Depending on classification, the participants are sent either prevention- or promotion-framed SMS text messaging (short message service, SMS) messages concerning physical activity over the next two weeks.

Decisional Balance

The balance between the pros and cons of behavior change has been shown to predict readiness to change across a host of health behaviors [47]. Our contemplators are presented with a decisional balance questionnaire [48]. The participant is then presented with immediate feedback according to whether they perceive more pros or cons with regard to regular physical activity. Next, the participant is presented with a list of potential reasons for becoming more physically active, and asked to tick off the relevant ones, before being asked to add some more in free text. This list is displayed on "My Page." "My Page" is the profile page of the intervention where the most important information, the activities and the interaction of the user, and of their friends, are presented as a feed. A more detailed description of the functionality, as developed in combination with the user input, can be found in the section "Functionality" of the website.

Planning

In the planning phase of another stage-based model, the Health Action Process Approach (HAPA)[27,49], one separates action planning from coping planning [50,51]. Action planning refers to the planning of where, when, and how to perform the target behavior, and is thus similar to Gollwitzer's concept implementation intentions [43]. Coping planning, on the other hand, concerns strategies for dealing with anticipated barriers, and is thus strongly connected to self-efficacy. From the preparation stage and onwards, the participant is asked to plan their physical activity in the "Exercise Agenda." There, they can add several entries by planning what kind of activity, when, and where for each entry, thus forming an implementation intention. After completing planning, they are assessed for self-efficacy for this action plan. If it is very low, the user is asked to revise the action plan to make it more realistic.

Self-Efficacy

The concept self-efficacy refers to the degree to which an individual perceives that he or she can perform a particular behavior. The concept of self-efficacy stems from the social cognitive theory [42], but since self-efficacy is so closely related to behavior change, several researchers have assimilated it into other theories [27,30,52,53]. In the context of the two-stage HAPA [27], self-efficacy is important throughout behavior initiation, action, and maintenance, but HAPA distinguishes three kinds of self-efficacies: (1) action self-efficacy, you can perform the target behavior; (2) maintenance self-efficacy, you can maintain the target behavior despite barriers; and (3) recovery self-efficacy, you believe that you can succeed after a setback. While action self-efficacy in the HAPA model is directly related to intention, it is only indirectly related to behavior mediated via intention. Maintenance and recovery self-efficacy are on the other hand not related to intention, but directly related to behavior [27]. All these self-efficacies are assessed in the preceding stage. If the self-efficacy is low or moderate, the participant receives SMSs concerning self-efficacy for the relevant stage over the next two weeks and also is asked to identify potential barriers (selecting from a list and in free text), and to generate strategies to address them. Strategies are then listed on "My Page."

Social Support

Social support is important both directly for health status and via its influence on health behaviors [54]. In the TTM, social support is referred to as helping relationships and is seen as relevant to the action stage [38]. Social support is also found to increase throughout the stages [55]. We assess and give immediate feedback on social support in the preparation stage.

Relapse Prevention

Relapse prevention is trying to identify, prevent, or prepare to deal with high-risk situations. Additionally, preparing for continuing with the new health behavior in the event of a lapse, rather than giving in, perceiving the situation as all gains are lost, and all effort wasted, thus turning the lapse into a relapse [56]. Relapse prevention is mostly considered in relation to giving up substance use (eg, smoking cessation) [57], but we consider it relevant for other health behaviors too, and send SMSs about relapse prevention to those of our participants in the maintenance stage that have indicated low to moderate self-efficacy for maintenance.

The Focus Group

The Seven Themes

There are seven main themes that were identified in the focus group: (1) Social, (2) Motivation, (3) Integration to everyday life, (4) Information, (5) Planning, (6) Monitoring and feedback, and (7) Concerns/Potential problems. Figure 1 shows the themes presented in a thematic map (see Multimedia Appendix 1). The results and the thematic map presented in this paper are a slightly more revised version than the one used for the development of the intervention, in the direction of improved synthesis of the data.

Social

The largest pattern of meaning that appeared in the focus group was the social theme. In addition to its high level of frequency, this theme is the one that included the most subthemes and codes. Under this theme we have included ideas, thoughts, and needs, expressed by the users referring to companionship, belonging to a group, or communication with others.

One of the dimensions of this theme repeatedly expressed by the participants was the importance of not being alone in the behavior change endeavour. This was an important factor that helped them during their stay in the rehabilitation center, and it was something that they wished to maintain after they were discharged. In some cases, they were referring to the importance of staying connected with the very same people with whom they shared the rehabilitation program.

> Man: …I am like this, that I need a bit of this motivation from the others also, to try alone, this is…This is the problem…so...this here with the local

> team, this can be a reasonable angle of this also, or approach eeh…attach yourself to the local team, also continue this you have started with them now…for example.

The importance and the benefits of belonging to a group were further explained. Peer support is the main benefit the participants seemed to enjoy at the rehabilitation center, and is one of the mechanisms through which they can help each other.

> Man 1: A forum of course is also something to talk about, a brilliant thing… talk with each other in a forum and ask things … put out eeh…
>
> Man 2: … you should have a forum only between … peers…

As expected, the peer support appears to be connected with the functionality of the forum. In the next extract, we also see the concept of the social obligation that the participants recognize as a possible mechanism to maintain or increase physical activity. The participants feel the obligation to do something that their peers are doing or ask them to do.

> Woman: I am saying that if we have it fixed, one time per week, that we send a message to each other and then, then you feel committed to say yes, for as long as you like…Yes, then you must have something else that really, you have something else that you have to do, or else… you just do it.

In another instance, the social obligation is connected with a request for a training diary combined with the forum.

> Man: Training diary on the Internet… And also have a group where someone can subscribe to a forum, or have a… to brag… yesterday I walked for an hour and today I have been to the training… and tomorrow I have thought, yes… So, it is like this that someone gets to, a bit, a bit like a competition, internally between each of us. We will train, as much as possible we will commit to ourselves a bit more also.

Commitment is also related to a healthy competition with each other. Through the forum, the participants suggested that they would succeed simply to encourage each other, an important mechanism related to the social theme.

> Man: Yes, yes I think that for many… if you take as basis the situation we are in now and you want to prolong it as long as possible, all of us want to stay here four weeks more, isn't it? And four weeks after that, life is great here… But to stay in touch with the "gang," so, so I think that the most of us would think that, yes, the Internet, the approach that is best, I don't have any faith in SMS, but eeh, Internet, a forum yes. To keep up, keep the spirit of the team up, the mood, the good flow.

The participants also had specific suggestions regarding the functionality of the forum. For example, they were positive about having two levels of access, one reserved only for the members of the same monthly group. In this level, they would like to share photos with the other members, maintaining their bonds after the rehabilitation stay. The social dimension of the forum was not only mentioned in relation to the other participants, but also included the personnel of the center. The participants mentioned that they would like to know that at the forum there are health professionals they can trust to answer their questions.

> Man: Yes, there should be someone that can answer, that has a clue and that can answer.
>
> Woman: There should be professionals too…yes.

The fact that Facebook is the largest and most popular social network, and one of the most popular websites in Norway, can explain that users were often inspired by Facebook functionality, and sometimes even explained a desired functionality as "like Facebook." In the same context, the concept of a training buddy was also popular. That is a person that would be paired with that participant, and they would support each other possibly with their physical presence, but mainly through the interaction the Internet tool would provide.

> Man: Almost like Facebook that… A forum is a living thing, like you come here and just are…new things pop up all the time and…between users…it's alive. (…) Do you want to be my workout friend?
> (Laughter from the rest of the group)

Regarding the choice of technology that would support the social functions of the intervention, participants mentioned the Internet and SMS in both parts of the focus group (in the general discussion and the discussion after the initial ideas were presented). One participant was sceptical to the usefulness of the SMS, but this didn't reflect the opinion of the rest of the group.

Motivation

The theme Motivation includes ideas and methods believed to influence or capable of influencing the participants' behavior. The theme includes the strong belief that the responsibility for change of behavior is personal. The participants mentioned it mainly in relation to what is going to happen after they leave the rehabilitation center.

> Man 1: I believe actually, I believe that someone gets used to it, if we make a system, habits. That it doesn't get too much, that we know that … we go online… and we get our own responsibility of our own training.

> Man 2: It is not, it is not that anyone says that you have to cycle. Also, it is made that each does what himself/herself feels.

> Man 3: So, so, it requires self-discipline.

Making a decision to prioritize themselves and the behavioral change was also very central. Prioritization was discussed in several instances as a method to maintain physical activity and generally continue the changes in behavior after the discharge.

> Woman: That we chose to prioritize the demands others have of us.
>
> Man 1: Down-prioritize ourselves all the time.
>
> Man 2: Got to be better at saying–"No thanks, today I can't." But on Tuesday it doesn't work either, for I'm exercising"

Integration into Everyday Life

Another theme that emerged from the focus group was Integration into everyday life. The participants often referred to thoughts and things to do that are helping them to integrate a desirable behavior into their everyday life. In the same way, the participants wanted technology that would assist them in maintaining the desired behavior in a way that also integrates it into their everyday life. Special emphasis was placed on simple changes in the activities of their everyday life that can increase physical activity.

> Man: I think that someone should not have high expectations of himself, that would make him strive to get there. I believe that you get tired of it, I think you should have only simple changes in your life.

The participants also discussed that creating new habits is helpful in changing behavior by integrating the desired behavior into everyday life, mainly by replacing old bad habits. The reverse order also seemed to be possible. By integrating an activity or even a technology into everyday life, an old habit could be replaced with a new good one that would assist in changing behavior.

> Man: I believe in small simple things like in everyday life, that if someone manages to walk to the store or walk to work maybe…things like that can also be important, instead of taking the elevator, if you are working in a building that you can take the stairs instead of the elevator, if you do it often, it is not bad either… instead of sit in the car and drive a few meters, to walk to the shop instead, so can someone ride a bicycle when it is becomes summer, or go with the chair-sledge…that someone can do things like that, it gets possible. Someone becomes so lazy that doesn't bother, sits in the car, the old habit, instead of just walking.

A technology that would help to integrate the desired behavior into everyday life should also be integrated into everyday life. Ubiquitous technology can support behavior change in the challenging situations of everyday life, or remind users of their own commitments.

> Man 1: If you could get a message every day, there and then?
>
> Man 2: Have you been good today? No, now you have to go out, time for exercise.
>
> Man 1: Get out you lazy bastard!
>
> Man 2: And it should come on a specific time you have decided to walk today, or go out…
>
> Man 1: Or even better, a couple of hours before… so you won't change your mind.

Information

Despite being in a rehabilitation program where they could have access to all the information they needed, or maybe because they were there and were experiencing good access to information, the participants of the focus group expressed their need for tools that would help them access the right information for a long time after their discharge. They referred repeatedly to the need to find the right answers, either through a forum or a kind of knowledge bank. They also wanted the health professionals to take an active part in the forum, and specifically for physical activity, provide suggestions for training plans.

> Man 1: It should be a forum where you have the opportunity to get… eeh… get the right answers, […] access to a resource, this is what I believe it becomes. It has an effect.

> Man 2: What is good with a forum is that everything that is asked and discussed and answered…it stays there, you don't even have to ask, if… if it [the forum] is used a lot, you can just with a simple search find what you need… The hope is that it will become a kind of knowledge bank. And the problems you have experienced like pain and things that you can go in and have a look and talks to others about them.

Planning

This theme covers a very effective part of the behavior change process. The participants expressed the necessity to plan in advance their physical activity in order to actually do it. First of all, the plans have to be realistic in order to make it possible to achieve them.

> Man: […] if we were sportsmen, we would have to climb extremely high. As you say, leave the car, to walk a bit, we have made a lot.
>
> Woman: Maybe it is a bit of [your] responsibility, a time schedule with realistic goals.

The technical dimension of this theme was expressed with a clear request for a training diary that would help the users plan activity, preferably on a weekly basis so they would avoid being drawn to their old way of behaving, where physical activity was constantly neglected.

> Man: […] I believe that what is important with the schedule is that you set it off, you prioritize a bit, you see that okay, that and that day it passes better maybe. So you say at those two days or three days a week, they are mine, then I should train. If you don't make it to a system, it gets difficult, easy to neglect, if you don't put aside time for it, because then it is so many other things that comes in front all the time. Then it becomes neglected, this is anyway my experience. But if you, like what I did before Christmas, before I came here, then I decided that in the evenings I should be going on walking tours. When the children go to lie down, I am going for a tour. And I did it. […] It should come first… or we die, this is how I am thinking…

Monitoring and Feedback

The theme of Monitoring and feedback appears in the second part of the focus group, during the discussion and after the presentation of some specific ideas for the intervention. It refers to the necessity and the requirements related to keeping a record of the physical activity of the users, and how to present it in a meaningful way to them. The discussion was dominated by the previous experiences of some of the participants with monitoring sensors, feedback statistics, and graphs, mainly from commercial products and services. The rest of the group was also interested even if they had no personal experience with the sensors, and generally were positive to the idea.

> Man: After what I have seen, there is a whole program, and shows graphically also how the climb has been, also the mountains, everything is there. There is also the pulse there. I have been many times in on the Internet and seen how the whole training of the day has been. […] And there you can see them, there is graphic representation, how it has been, up the hill, down the hill and …

Concerns and Potential Problems

Despite the positive reception to the idea of an intervention, several concerns and fears for potential problems were expressed during the focus group. Regarding the process of changing behavior, the participants of the focus group were concerned about the obstacles they have to overcome in their effort to maintain or increase physical activity. Lack of training facilities, lack of time, or just going back to their everyday life are possible obstacles that make them question their ability to maintain the desired behavior.

> Man 1: We have developed some habits while here. This, this I believe we cannot manage outside. And then we maybe cannot maintain, keep enough habits. We haven't… […] I live far from people and fatherland, to say it like this. […] Yes, my place is far [from a city]… we have no swimming pool or any big activities. We should just organize our own activities…when we live far, far in a village.

> Man 2: For example, 52 weeks that I can use them as I want, but I should try to use them right. [Me] and someone else that has to go to work, we cannot do it equally.

Along with the concerns about the obstacles in changing behavior were the concerns about relapsing from the desired behavior. For various reasons individuals might stop being physically active for short or long periods of time, and for that case, the participants expressed a need for support to get them back on track.

> Man: And when you come home and you get back pain, you don't manage to keep up, so you become disappointed and sad, and you feel that, no, I am a loser.

The major concerns though, were expressed for the technology. When it came to the usability of the website, the participants suggested that we should consider e-literacy issues and offer training to the users. They also recommended that the website be maintained in such a way that it is constantly updated, with the content remaining politically and religiously neutral and independent. A few participants were sceptical of the SMS technology, believing it was not answering the needs for behavior change. This view was balanced by the request of many other participants to send them reminders and motivational messages to trigger behavior change. The potential risk of high dropout rate from the forum was also discussed.

As in many Internet-based interventions, participants shared another important concern–privacy. They asked to have the choice on what to share with whom.

> Man: You can choose, if you want it… to make it public… Make it accessible for the others, so… it should be a keystroke or a choice you do […] In periods it might be like that, that you don't want to show it…

A female participant also expressed a concern regarding the ability of an intervention to cover the needs of women too. This shows the need for a gender-sensitive approach, mainly by offering additional training where it is needed. Finally, tailoring, a concept very central to the suggested intervention caused scepticism in a few participants. They questioned the ability of technology to provide a satisfying degree of personalization.

> Man: But it is not possible that you [have] many different [categories], because someone is not so individual that cannot fit in maybe four different …I am thinking like this…I want to believe that to make conclusions from the questionnaire there, that has maybe four different categories…do you know what I mean? … I answer in this way, I belong to category four, Ola answered that, he belongs in category three, in this way, a bit slack it is, …If it is tailored to 12 different [categories], then it becomes, it becomes very ambitious, I think…

The Design of the Intervention

The researchers translated the combination of the theoretical framework and the user input into the technical requirements documentation that was later used by an external collaborator to develop the actual intervention. In Table 2, we list the contribution of the theoretical constructs and the relevant focus group themes in each functionality element of the intervention. The intervention is based on the popular open source content management framework Drupal. The main phase development that produced a functional prototype lasted one year. It was followed by a second phase of six months that included bug fixing by the external collaborator, the implementation of the tailoring algorithm into Drupal, testing, and content development by personnel of the Norwegian Center of Integrated Care and Telemedicine and the Skibotn Rehabilitation Center.

Table 2. Contribution of theory and user input in the functionality included in each element of the intervention.

Elements of the intervention	Relevant theoretical constructs	Relevant focus group themes
Levels of access	-	Social, Concern/Potential problems
Microblog functionality of "My Page"	Social support, Consciousness raising, and Helping relationships (TTM)	Social and Motivation
Activity calendar	Preparation (TTM), Action planning, Contingency monitoring, and Self-monitoring	Planning, Monitoring and feedback, Social, Information, Motivation, and Integration into everyday life
Discussion forum	Social support and Helping relationships (TTM)	Social and Information
General information	Consciousness raising and Self-efficacy for action	Information
Contact with physiotherapist and technical support	Social support	Social, Information, Concerns/Potential problems
Weekly activity goal on "My Page"	Outcome expectancies, Self-efficacy for action, Action planning, Implementation intentions, and Supporting autonomy	Motivation, Planning, and Monitoring and feedback
Simple feedback graph on "My Page"	Outcome expectancies, Self-reevaluation, and Consciousness raising	Monitoring and feedback, Information, and Planning
My reasons for physical activity, my strategies to increase physical activity, and overcome barriers on "My Page"	Self-efficacy for maintenance and recovery, Values, Coping planning, Relapse prevention, and Decisional balance	Motivation, Integration into everyday life, Information, and Concerns/Potential problems
Tailoring algorithm	Mainly based on theoretical constructs (see detailed explanation under Theoretical framework and Table 1)	Motivation, Planning, Social, Information, Integration into everyday life, and Concerns/Potential problems

Functionality of the Website

The Graphic Design

The graphical design of the website was based on the graphic profile of the patient organization that owns the collaborating rehabilitation center. Since the offer of the intervention is an extension of the services offered by the face-to-face rehabilitation, it is important to use the visual elements and a palette familiar to the users and identical to the website of the rehabilitation center, the patient organization that owns the center, and all the printed materials that are used by the organization and all its services. Since the patient organization is one of the biggest and most active in Norway, we expect that the level of trust toward our intervention will be positively affected. The main colors of the website are blue and light blue, which, according to the graphic profile of the organization, have been chosen because they symbolize clean air and breath. For the typography, modern, but simple fonts have been selected to make the information easy to read.

Three Levels of Access

There are three levels of access for most of the components of the website. The first one is information accessible by all the registered users of the website. The second level is accessible only by a specific group of users that are called friends. Friends are by default the participants of the same rehabilitation monthly group, for example, participants that have been to the rehabilitation center in January 2012. A user can add or delete friends from her profile page. A third level of access is reserved for the user and the information that is private. Users with administrative roles can have access to information of all levels.

My Page

For the user, the starting point is the profile page, called "My Page" (Figure 2 shows this page). The profile page includes a wall functionality that could also be described as a microblog functionality, where the planned and completed activities from the calendar appear. The user can write how they feel in general or about the activities they have planned, and can see other users' posts. To avoid lengthy posts, a limit of 340 characters is applied. For each post on the profile, there is the possibility for the friends of the user or the center's personnel to comment. From the profile page, the user can access the friends' list and the personal information page. The most recently planned physical activities appear also on the side of the profile page. There is also a link to the group page. The group page is similar to the profile page, but only shows the latest activities of the members of the monthly group to which the user belongs.

Activity Calendar

The activity calendar is a planning and reminder tool. The main view is the weekly calendar (Figure 3 shows this weekly view), since the users are encouraged to plan activities on a weekly basis, but daily, monthly, and yearly views are also available. The completed activities appear on the calendar with a different color, and the user can edit both the completed and planned activities. To plan an activity, the user can choose from a preselected list with common activities (Figure 4 shows this page). The user has to set the start date and time, duration in hours and minutes, and planned intensity according to Borg's scale [58]. In addition, the user can choose to make the activity public or private, to write the place of the activity, and to provide an additional description. An important functionality is that there is the possibility to challenge some or all of their friends to take part in the activity by inviting them through the same page. The invited friends will see an invitation on their profile page and will also get an email and an SMS invitation. For each planned activity, the user will receive an SMS reminder 15 minutes before the planned beginning of the activity, and an SMS at the planned end asking about the completion of the activity (Figure 5 shows this reminder). The last SMS contains a URL link that users with smartphones can use to confirm their activity as completed and state the actual duration of the activity, the actual intensity, and write a comment if they want (Figure 6 show this page). Users without a smartphone can update the information the next time they log in on the website. The information about the completed activity is published on the profile of the user and can also be seen by their friends on their page.

Discussion Forum

The discussion forum is a standard discussion forum with three levels of access (Figure 7 shows the forum). The first one is only accessible to all the registered users of the website. The second level is for discussions that are only accessible by users that belong to the same monthly group. The third level of access is reserved for the administrators and the health professionals that can access all the discussions to moderate and give professional advice and motivation.

General Information

The health professionals involved in the project have developed and posted on the site general information regarding physical activity and training, cardiovascular disease, diabetes, lung problems, cholesterol, smoking cessation, and other topics that are relevant for the users. There is also information regarding motivation, self-management, and lifestyle change that are closely related to the concepts the intervention is built upon. The information is accessible to all the visitors of the website, reflecting requests from participants of the rehabilitation program. It is a reliable and verified resource.

The users can seek assistance in navigating the website by calling a physiotherapist responsible for it, during working hours. For technical issues, they can complete an Internet-based form and submit their comment or problem. When possible, they receive a response within three working days.

Additional Functionality for Intervention Group

Some additional functionality is available only for the members of the intervention group of the randomized controlled trial [59]. On the profile page, those users can see their weekly activity goals. The users set the weekly goals on a new page as minutes of activity in two categories: (1) high intensity, and (2) moderate intensity. The users receive feedback regarding the level of activity in comparison to the suggestions by the American College of Sports Medicine that are much in line with the suggestions from the Norwegian Directorate of Health [60]. The feedback is offered as advice and the user can proceed even without complying with the suggestions, this is to reflect the individual needs and exercise capacity of the user and the focus on self-management. The goals appear on the side of the profile page and are accompanied by feedback related to the planned activity and how it compares to the set weekly goals. Related to the achievement of the goals, is the graph that appears on the profile page. In a simple feedback graph, the user appears as a figure on a ladder with 5 steps and, according to completed activities, the figure is on one of the 5 steps (Figure 2). The figure on the top of the ladder represents the successful completion of the weekly goals, and it appears to be in a more cheerful position than when on the base of the ladder. The figure is different for male and female users. On the side of the profile the user can find certain strategies to increase physical activity or overcome barriers (depending on the stage of change of the user), and their most important reasons to be more physically active, again chosen by the user. The strategies and the reasons appear only for users in specific stages and the users have either chosen them from a list of suggestions or written them by themselves.

Tailoring Algorithm

Stages of Change

As the first step in tailoring, the participants' stage of change is assessed using the URICA-E2 [44]. In the next step, they follow different paths depending on stage.

Precontemplation

The participant is given immediate feedback on the current stage, and is then asked whether they would like to test their knowledge about physical activity. If yes, a quiz on benefits of physical activity is given, followed by the results. Then the participant is presented with a RFQ [41]. Depending on classification, the participant will be sent either prevention- or promotion-framed SMS messages concerning physical activity over the next two weeks (see Multimedia Appendix 2). After two weeks the participant is reassessed for stage of change.

Contemplation

The participant is given immediate feedback on the current stage, and is then presented with a decisional balance questionnaire [48]. Afterwards, the participant is presented with immediate feedback according to whether they perceive more pros or cons regarding regular physical activity. Next, the participant is presented with a list of potential reasons for becoming more physically active, and asked to tick off the relevant ones, before being asked to add some more in free text. This list is displayed on "My Page." The participant is then asked if they want to plan their physical activity. If yes, they are presented with the "Exercise Agenda." There, they can add several entries by planning what kind of activity, when, and where for each entry, thus forming an implementation intention. After completing planning, they will be assessed for self-efficacy for this action plan. If it is very low, the user will be asked to revise the action plan to make it more realistic, while if it is moderately low, they will receive SMSs concerning self-efficacy for action over the next two weeks. If the participant declines planning, they will be led to "My Page." All participants will be reassessed for stage again in two weeks.

Preparation

The participant is given immediate feedback on the current stage, and then self-efficacy for their action is assessed. The participant is asked to identify potential barriers and to generate strategies to address them. These strategies are then listed on "My Page." Next, social support is assessed and immediate feedback is given. Then, the participant is asked to plan physical activity in the activity calendar. Over the next two weeks the participant will receive SMSs about self-efficacy and/or social support, depending on the above assessment, before stage is reassessed (see Multimedia Appendix 2).

Action

The participant is given immediate feedback on the current stage, and then self-efficacy for maintenance is assessed. The participant is asked to identify potential barriers and to generate strategies to meet them. The strategies are then listed on "My Page." The participant is also asked if they want to update their activity calendar. After planning activities, they are asked about self-efficacy for this plan. Over the next two weeks SMSs about maintenance are sent to those who were low on self-efficacy for this, and then stage is reassessed.

Maintenance

The participant is given immediate feedback on the current stage, and then self-efficacy for relapse is assessed. The participant is asked to identify potential barriers and to generate strategies to meet them. The strategies are then listed on "My Page." The participant is then asked if they want to update their activity calendar. After planning activities, they are asked about self-efficacy for this plan. Over the next month SMSs about relapse prevention are sent to those who were low on self-efficacy for this, and then stage is reassessed.

Discussion

Communication Design

The communication design of a website is an essential component of the intervention. There are several factors that have to be considered in relation to the target group and the communication channel that is going to be used, such as font style and size, balanced use of graphics and text, and intuitive structure and navigation menus [61,62]. Building credibility also has great potential; since it seems that it affects the confidence in one's thoughts, health behavior, and cognition [63]. This can be effectively done with visual and design cues [64], and for our intervention this was applied with the right choice of communication design elements like template, colors, fonts, and of course the logos of the organizations.

Theoretical Implications

In this paper, we describe how we developed an intervention in which the existence of each of its functionality elements is grounded on both user input and theoretical constructs. Of course, the health behavior models that we used to create the theoretical framework were developed based on research of human behavior, which to a certain extent qualifies for user input. It was expected that those concepts about human behavior would be reproducible and would reappear in our focus group.

An example of the reflection of theory in the focus group appears in the themes of Planning and Motivation. According to the HAPA, there is a distinction between action planning and coping planning [50,51]. The participants of the focus group were clearly concerned in a different way about planning an activity, compared to preparing to cope with the barriers of physical activity once they completed their rehabilitation stay. It seemed that both are necessary, but prioritization and motivation are needed to make sure each participant will be ready to overcome any difficulties.

Another example of integration is concerning relapse prevention [65,66]. The focus group confirmed its relevance for the case of physical activity. The participants mentioned that after a health problem, like back pain, they might backslide and find it difficult to start physical activity again. For that reason, they would like to get support in dealing with such feelings as disappointment, sadness, and being a loser, in order to recover. Also, the relationship of the social support with the relapse prevention, as seen in the focus group, is coherent to the previous findings that indicated that social support is related to the resistance of relapse into physical inactivity in men [66].

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 [39]. Within health promotion, more ecological models [67] 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 [67]. Some, such as the purely Internet-based, might be even more difficult to tackle, while others might benefit from the improved trackability of an Internet-based intervention. A somewhat more limited ecological model that would fit well to our existing variables, while including more of the social ones, is the social cognitive theory [68]. Whereas self-efficacy is the most important variable in the SCT, social variables play several important roles–they influence our expectations about outcomes, self-efficacy, and they constitute direct facilitators as well as impediments for behavior. Thus, in a temporal perspective, social variables are important throughout the stages of behavioral change.

Nevertheless, as we add more variables to our models, we should be careful to measure our proposed mediators to make sure that we are actually intervening according to our proposed theoretical framework [69]. By gathering data on the relevant processes hypothesized to take place, not only can we further develop our interventions, but our theories as well [70]. We therefore aimed to design the randomized controlled trial of the current intervention [59] so that in addition to being able to conclude whether the intervention was effective or not, we will know something about what works and why. Ideally, we believe, the design of the intervention and the design of the trial should go hand in hand.

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Author Contributions

KA and SCW participated in the design of the intervention as well as the study, analysis of data, and drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

The authors have participated in the design of the interventions mentioned in the manuscript.

Abbreviations

HAPA: Health Action Process Approach
RFQ: regulatory focus assessment
TTM: Transtheoretical model

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Paper II

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STUDY PROTOCOL Open Access

E-Rehabilitation – an Internet and mobile phone based tailored intervention to enhance self-management of Cardiovascular Disease: study protocol for a randomized controlled trial

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Abstract

Background: Cardiac rehabilitation is very important for the recovery and the secondary prevention of cardiovascular disease, and one of its main strategies is to increase the level of physical activity. Internet and mobile phone based interventions have been successfully used to help people to achieve this. One of the components that are related to the efficacy of these interventions is tailoring of content to the individual. This trial is studying the effect of a longitudinally tailored Internet and mobile phone based intervention that is based on models of health behaviour, on the level of physical activity and the adherence to the intervention, as an extension of a face-to-face cardiac rehabilitation stay.

Methods/Design: A parallel group, cluster randomized controlled trial. The study population is adult participants of a cardiac rehabilitation programme in Norway with home Internet access and mobile phone, who in monthly clusters are randomized to the control or the intervention condition. Participants have access to a website with information regarding cardiac rehabilitation, an online discussion forum and an online activity calendar. Those randomized to the intervention condition, receive in addition tailored content based on models of health behaviour, through the website and mobile text messages. The objective is to assess the effect of the intervention on maintenance of self-management behaviours after the rehabilitation stay. Main outcome is the level of physical activity one month, three months and one year after the end of the cardiac rehabilitation programme. The randomization of clusters is based on a true random number online service, and participants, investigators and outcome assessor are blinded to the condition of the clusters.

Discussion: The study suggests a theory-based intervention that combines models of health behaviour in an innovative way, in order to tailor the delivered content. The users have been actively involved in its design, and because of the use of Open-Source software, the intervention can easily and at low-cost be reproduced and expanded by others. Challenges are the recruitment in the elderly population and the possible underrepresentation of women in the study sample. Funding by Northern Norway Regional Health Authority.

Trial registration: Trial registry www.clinicaltrials.gov: NCT01223170.

Keywords: Tailoring, Cardiac rehabilitation, Cardiovascular disease, EHealth, Internet-based, Mobile-based, Self-management, Physical activity

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Background

Cardiovascular diseases (CVD) according to the World Health Organization (WHO) are leading causes of death and represent 30% of all global deaths and 48% of the deaths in Europe [1,2]. Moreover, the current trends predict increase in deaths caused by CVD over the next years. Secondary preventive efforts can decrease mortality risk as well as increase health among CVD patients. This study suggests a new approach in supporting the self-management of CVD patients after rehabilitation. The experimental research model that is implied investigates the effectiveness of tailoring an Internet- and mobile-based intervention according to concepts derived from models of health behaviour, and will contribute to develop these further. If successful, concepts from this project can potentially be extended to primary prevention of CVD among high-risk groups.

The prevention policy for CVD is based on strong scientific evidence and is focusing on three major health behaviours: smoking cessation, healthy diet, and increase of physical activity [3-5]. A rehabilitation and secondary preventive strategy based on the adoption of the same health behaviours after the diagnosis and/or symptoms can decrease mortality risk and increase quality of life [4,5]. Involvement in physical activity is a lifestyle modification that is crucial for the post-discharge period. Exercise interventions can cause a 27% reduction in total mortality and a 31% in cardiac mortality in patients with Coronary Heart Disease [6]. Post-discharge physical activity programmes can take place in hospital setting or at home with no significant differences in physiological and psychological outcomes [7]. The achieved lifestyle changes, however, often prove difficult to maintain [8].

Social support might be one way of increasing long-term adherence to exercise. One likely mechanism through which peer support is important in lifestyle change, is by providing modelling of overcoming barriers towards successful behaviour, thus increasing the belief of the individual that he can succeed in changing his own behaviour (self-efficacy) [9]. However, not everyone has the opportunity to participate in face-to-face groups, so the Internet might provide a good alternative *e.g.* [10].

Internet-based interventions have a large potential for reaching people. In 2008, 67% of Norwegians reported having used the Internet for health purposes [11]. In general, reviews of Internet-based interventions might present a rather confusing picture, as the only common ground is the delivery medium. The interventions include online publish of pamphlets, combinations of text-based information and communicative features such as forums, "ask an expert" services, individually computer tailored content, and multimedia iterations. Nevertheless, a review of six Internet-based interventions for supporting diabetes self-management found that five of the six studies reported improvements in health behaviours [12]. A more general review of Interactive Health Communication Applications (IHCA) for people with chronic diseases concluded that these applications improved users' knowledge, social support, health behaviours and clinical outcomes [13].

Many of the most successful Internet-based interventions for supporting change in health behaviours utilise tailored content. A tailored intervention is an intervention that is adapted to the characteristics of the individual, typically based on responses to a questionnaire [14]. Tailored interventions have generally proven more effective than standardized self-help materials for smoking cessation [15,16]. Previous research has shown that tailored health messages are in general perceived as more interesting and personally relevant, are better liked, read more thoroughly, discussed more, and remembered better compared to non-tailored educational material [17-20].

Although the tailoring component in Internet-based interventions has received some attention, to the best of our knowledge, no studies have yet compared two versions of an Internet-based intervention for supporting CVD self-management with and without tailoring. A system that additionally can monitor physical activity can give feedback to the patient about the efficacy of the exercise, indicating the exercise capacity of the patient [21]. A review of eHealth interventions for increasing physical activity indicated that these could increase the number of steps, walking minutes and level of activity. Physiological indicators validated the indicated increase of physical activity, *i.e.* increase of heart rate and VO_2 max and decrease of percentage of body fat [22]. From the same review it is suggested that higher utilization and dose of intervention have better results in health behaviour change, that peer support modules increase log-on rates and that most users read the information they received electronically.

In addition to the bibliographic evidence, we conducted a focus group with 11 CVD patients of the Rehabilitation Centre where the study is going to take place. During a semi-structured discussion with them, the potential users of our service expressed the need for continuing support after they are discharged from the rehabilitation centre. They said that, when they go back home, they need help to remain active, to remain in contact with other participants they met at the rehabilitation centre, to set realistic goals, to plan according to those goals and to receive feedback on their effort to remain physically active. One participant suggested: "What if we could get an email every day at a specific time? Time for exercise!" and when the discussion was about the usability of an exercise diary another participant said: "…a diary where you can show others what you have done…maybe it could create some sort of competitive drive between some of the users. It could make it feel more like an obligation". Generally participants were positive to the idea of a system that could support them in extending the positive impact the rehabilitation programme had on them. To meet that need, we have to find a way to bring the intervention next to the participants in the same way their peers and the personnel is at the Rehabilitation Centre. Mobile technology seems to be the most appropriate tool since it can be portable and be carried by the participant everywhere.

Aims and hypotheses

Our aim is to assess the effects of a tailored Internet- and mobile-based intervention on maintenance of self-management behaviours after a cardiac rehabilitation stay. Our hypothesis is that the intervention group (tailored) will have higher adherence to the Internet-based intervention, and be more physically active.

Methods

Tailoring

Models of health behaviour often form the core of adaptive tailored interventions. It is therefore important to have adequate process measures in these kinds of interventions in order to identify which variables one should tailor to, for whom, and when. Self-efficacy is one of the theoretical constructs thus far having shown the most consistent effects of being tailored to [23]. Studies have indicated that the stage of change for the cardiac rehabilitation patient when entering an exercise programme is related to outcome, and is therefore another relevant variable to tailor interventions to [24]. We propose to combine and extend this research in line with the Health Action Process Approach HAPA [25], through tailoring to different self-efficacies according to where the individual are in their process of change. A third variable that we will tailor on is the individuals' promotion- or prevention-goal orientation (regulatory focus). Latimer and colleagues have shown that tailoring to regulatory focus can increase both physical activity [26] as well as fruit and vegetable intake [27].

Study population

Participants

The population of the study is recruited among the participants of the Skibotn Rehabilitation Centre's cardiac rehabilitation programme. Participants to that programme are people with cardiovascular diseases that usually have been discharged from the region's main hospital, the University Hospital of North Norway, during a period of 6 months before the programme's start. They are referred to the Centre by their family doctor and a recent cardiac stress test is required. The cost of the four-weeks programme is partially covered by the participants and the Norwegian Health Scheme covers the rest.

Inclusion criteria

The study is open to all the participants of the cardiac rehabilitation programme of the Skibotn Rehabilitation Centre that have access to Internet after their stay at Skibotn, have a personal mobile phone, are willing to participate and have signed the informed consent form.

Sample size estimation

Power analysis for *a priori* sample size estimation was performed with equivalence test for two-proportions in a cluster-randomized design by the computer program PASS [28]. The participants that attend the cardiac rehabilitation programme together a given month, consist a cluster. Based on previous research with chronic disease self-management [29] it is reasonable to expect that the proportions meeting goals for all self-management behaviours at one-year follow-up will be relatively low *e.g.*, 15% *vs.* 5%. To discover differences of this size between two groups at a 0.05 alpha level and with 0.80 power, we need a total sample of 16 clusters with 15 participants each. We will recruit a total of 17 clusters, equalling continuous recruitment of all the participants of the cardiac rehabilitation programme of Skibotn Centre over 18 months.

Ethical aspects

The study protocol, its updates and all the questionnaires have been submitted for approval by the Regional Ethics Committee. The study uses a convenience sample, *i.e.*, the participants have volunteered. Participation in the study is based on informed consent. In addition, an extensive Risk Assessment Report has been produced to identify potential risks and appropriate practices have been adopted to minimize the identified risks. For example all data will be gathered and stored in de-identified form and user-related data will be secured through necessary encryption and authentication.

Design

Skibotn Rehabilitation Centre receives each month (except from July) a group of 10–20 CVD patients that are admitted in the rehabilitation programme. Since these people are hosted in the same environment for all of this period and social interaction related to the rehabilitation is encouraged, a randomisation among the members of the same group would make it very likely for patients to realize whether they belong to the control or intervention branch. In order to minimize this risk of contamination of the control group, the participants will be blinded to condition by randomizing the monthly clusters of participants to one of two conditions:

(1) A control condition involving a basic Internet-based self-management intervention

(2) An experimental condition where the participants get access to a tailored and enhanced version of the Internet-based intervention

The researchers are also blinded for the condition of each monthly group, so we will avoid introducing any bias in the analysis of the data. To ensure true randomness of the groups, we used random.org to allocate the groups to the two conditions. Random.org is a true random number online service that is based on the atmospheric noise. The duration of the study is one year after the discharge from the cardiac rehabilitation programme.

Control internet-based intervention

All participants will be given access to a basic Internet-based intervention, "ikkegideg.no" (Norwegian for "Don't give up"), consisting of general information about CVD and self-management, including diet, physical activity, smoking and medication, and a discussion forum. In the discussion forum we have two levels of accessibility. There is the closed groups level, where the users are able to create and take part in discussions that are only accessible by those that are members in the same monthly group. Users that belong to the same monthly group have met physically during the rehabilitation programme and it is expected that the level of trust among them will be higher. At the same time, all the users will be able to create, read and take part in discussions that will be visible by all the registered users of the website. This helps the discussion forum to become more active, since more users will be contributing to the discussions.

Enhanced internet-based intervention

In the intervention group, the participants will in addition to general information and the discussion forum have access to the following: (1) content tailored to stage of change, regulatory focus and self-efficacy; (2) behavioural monitoring (self-reported physical activity).

The tailoring process is in some ways emulating face-to-face patient counselling. The answers that patient gives to the 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 the time generate changes in the treatment or behaviour change plan that reflect the changes in a patient's characteristics or change process [14]. The adaptive tailoring in this intervention is based on integrative models that combine socio-cognitive determinants of health behaviour with a process view, such as the Integrated Model for explaining motivational and behavioural change I-Change [30] and the Health Action Process Approach HAPA [25]. Thus, we tailor to stage of change [24], which determine when the other concepts are tailored on; for instance, self-efficacies [25,29,31], and regulatory focus [26,32].

Procedure

During the first days of the stay of each monthly group at the Centre, a physiotherapist, who is member of the staff there and administrator of the site, presents the website and the study, answers questions and distributes the consent form to the participants that are interested. Then another session is scheduled for those participants that decide to sign the consent form and take part in the study. In this additional session, the participants are registering to the website, fill-in online the baseline questionnaire and they receive training on how to use the website. During these two meetings the potential participants are generally informed of the features of the site and of the two study conditions, but not in such detail that it will be possible for them to understand in which group they belong.

At the end of the rehabilitation stay, participants are offered a repetition Internet-training session, and are being asked to log-on to fill out the Post-rehab questionnaire. The participants are being encouraged to keep visiting the intervention website after they return home, and are given prompts by email and SMS (Short message service) to fill out follow-up questionnaires at 1, 3, and 12 months after leaving the centre.

Measures

For an overview of all measures over the different measurement time points, please see Table 1.

The main outcome for this study is maintenance of physical activity, measured through self-report. Secondary outcomes are self-efficacy, perceived social support and user evaluation of the intervention. In order to link outcomes to use of the intervention we will assess perceived tailoring, and use of the intervention through web logging.

The background variables that are assessed include age, gender, education, income, alcohol use, and co-morbidity. Disease related symptoms like chest pain is assessed through WHO's ROSE questionnaire [33]. Physical Activity is measured with the International Physical Activity Questionnaire IPAQ [34,35]. Stage of change is assessed with the scale URICA-E2 [36], which gives a more comprehensive assessment of stage than simply time before or after initiation of action. Self-efficacy is measured with modified versions of The perceived competence for regular physical exercise (PC-EX) scale [37]. Responses are given according to a scale from 0 (not at all) to 6 (to a great extent). We have previously used this scale with diabetes patients, and it performed satisfactorily with regards to both construct and predictive validity [29]. Regulatory focus is assessed with a short form of the Regulatory Focus Questionnaire [38]. This scale has been used successfully in the context of heart disease previously [39]. Social support is assessed with an adaptation of the scale from Barrera et al. [10]. Anxiety and Depression is assessed with Hospital Anxiety

Table 1 Overview of measures over the different time points of the study

	Baseline	Post-rehab	1 month	3 months	12 months
Socio-economic status	Y				
Co-morbidity	Y				Y
Alcohol use	Y				Y
Health-related Internet use	Y				Y
Disease related symptoms	Y	Y	Y	Y	Y
iPAQ	Y	Y	Y	Y	Y
Social support	Y	Y	Y	Y	Y
Self-efficacies	Y	Y	Y	Y	Y
HADS	Y	Y	Y	Y	Y
Perceived Tailoring			Y	Y	Y
Stage of change	Y	Y	Y	Y	Y
Decisional balance	Y	Y	Y	Y	Y
Regulatory focus	Y				
7-day smoking abstinence	Y	Y	Y	Y	Y
Quality of life	Y	Y	Y	Y	Y
Usage logging	Y	Y	Y	Y	Y
User evaluation			Y		Y
Return to work	Y		Y	Y	Y

and Depression Scale (HADS) that is widely and successfully used for the post-discharge period that demonstrates satisfying diagnostic usefulness for screening depression symptoms and measuring anxiety of CVD patients [40]. We use the EQ-5D to measure health-related quality of life [41]. Perceived tailoring will be assessed *via* four items from Dijkstra [42]. eHealth literacy is assessed by the eHealth Literacy Scale [43].

Data on use of both interventions will be gathered through web logging. Number of log-ins, time logged in, what elements have been used most per user will be registered.

Statistical analysis

As participants are randomized at group level, a multilevel analysis will be performed to check for clustering effects. If the intraclass correlation coefficients for our primary outcome variables are different from zero this will be taken into account in the following analyses, in order to reduce p-value bias. Potential confounders will be added as covariates. Data analysis will be performed using IBM SPSS and MLWiN. Group differences after intervention will be analysed with baseline data as a covariate in ANCOVA. Should clustering effects be found, multilevel mixed regression will be used.

Discussion

The intervention suggested in this protocol is utilizing longitudinal tailoring based on models of health behaviour combined in a way that, to the best of our knowledge, have not been tested before. At the same time, the intervention provides the users with tools of online social interaction, but in a secure setting controlled by health professionals that commercial social interaction platforms cannot offer. In addition, the use of the randomized controlled trial methodology will help us understand if our approach succeeds in its objectives.

Study strengths

The duration of the follow-up is one year after the discharge from the rehabilitation centre, so we will be able to investigate the long-term effects of the intervention. We are proposing the use of simple and wide spread technology in order to not challenge our users that we will be mostly middle-aged and senior citizens. The intervention has strong theoretical foundations in behavioural change models responding to the calls asking for more theory-based interventions [44], and its complexity will result in an extensively tailored system underneath the hood of a more simple user interface. The intervention is based on models of health behaviour that to a large extent have been tested independently in other eHealth interventions but – to our knowledge – it is the first time they are combined. Another strength of our study is the level of the user-involvement in the design of the intervention. As the intervention aim to fulfil the demand from the rehabilitation centre professionals and their participants, it is by definition user-initiated and we managed to maintain the high level of user-involvement by having an open dialog with them.

The study results are also expected to have high external validity, since it can be categorized as an effectiveness trial. The inclusion criteria are very broad, and in this way the results will be more relevant in the implementation of the intervention in a real-world setting, outside of strictly controlled clinical trials.

Cluster randomization will protect the blindness of the sample to the study condition. The data will be analysed in a way that will not reveal the study condition of each group, ensuring the blindness of the researchers.

The platform we are using is the Content Management System Drupal. It is an Open Source platform and this has offered many benefits to the intervention. The development costs of the study remained low, since the use of Drupal is free, making sure that funding that come from public sources was spend in the most effective and ethical way. Using an Open Source platform facilitates the reproducibility of the study with greater accuracy and at very low-cost. In addition, the continuation and the maintenance of the project don't rely on individuals, single research institutes and software companies, but rather to a big community of contributors.

Methodological considerations

Many of the methodological considerations of this study are related to its online nature. First of all, the population that we target, individuals with CVD history, is not in a large extent –because of their age– familiar with the Internet and the mobile technology. That makes recruitment challenging and it might introduce a bias related to the socioeconomic status of those that have access to the Internet and can take part in the study. In the same age group, we expect that women are even less familiar with new technologies and this might lead to underrepresentation of women in the sample.

Expected outcomes, contribution and future studies

This project addresses one of the major health issues in the world, CVD, and aims to contribute to the empirical as well as theoretical basis for developing effective Internet and mobile phone based primary and secondary preventive interventions with high reach. The proposed methodology can also be applied to other health problems that can benefit from lifestyle interventions. Should the intervention prove successful, the Internet-based cardiac rehabilitation follow-up will be offered to patients at other cardiac rehabilitation facilities. It will enable the users to bring an extension of the rehabilitation services with them home, thus potentially increasing the chances of maintaining Physical Activity, which again likely will reduce rehospitalisation rates. Finally, concepts from this study can potentially be extended to primary prevention of CVD among high-risk groups.

Trial status

The trial is open for participant recruitment and is registered in ClinicalTrials.gov (identifier NCT01223170).

Abbreviations

ANCOVA: Analysis of covariance; CVD: Cardiovascular disease; HADS: Hospital anxiety and depression scale; HAPA: Health action process approach; IHCA: Interactive health communication applications; IPAQ: International physical activity questionnaire; PC-EX: Perceived competence for regular physical exercise; SMS: Short message service; WHO: World health organization.

Competing interests

Both authors declare that they have no competing interests.

Authors' contributions

KA and SCW participated in the design of the study and drafted the manuscript. All authors read and approved the final manuscript.

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Paper III

Original Paper

An Internet- and mobile-based tailored intervention to enhance maintenance of physical activity after cardiac rehabilitation: short-term results of a randomized controlled trial

Abstract

Background: An increase of physical activity in secondary prevention of cardiovascular disease and cardiac rehabilitation has been shown to have multiple therapeutic benefits, including decreased mortality. Internet- and mobile-based interventions for physical activity have shown promising results in helping users increase or maintain their level of physical activity in general and specifically in secondary prevention of cardiovascular diseases and cardiac rehabilitation. One of the components related to the efficacy of these interventions is tailoring of the content to the individual.

Objective: Our trial assessed the effect of a longitudinally tailored Internet- and mobile-based intervention on physical activity as an extension of a face-to-face cardiac rehabilitation stay. The main hypothesis was that the users of the tailored intervention would maintain their physical activity level better than the users of the non-tailored version of the intervention.

Methods: The study population included adult participants of a cardiac rehabilitation program in Norway with home Internet access and a mobile phone. The participants were randomized in monthly clusters to a tailored or non-tailored (control) intervention group. All of the participants had access to a website with information regarding cardiac rehabilitation, an online discussion forum and an online activity calendar. In addition, those randomized to the tailored intervention received tailored content based on models of health behavior via the website and mobile fully automated text messages. The intervention was built on the free and open-source content management framework Drupal. The main outcome was the self-reported level of physical activity measured in MET-minutes per week, which was obtained using an online international physical activity questionnaire at baseline, at discharge, at one month and three months after discharge from the cardiac rehabilitation program. The randomization of clusters was based on a true random number online service.

Results: Included in the study were 69 participants. At one month after discharge, we analyzed 10 users in the tailored intervention group and 14 in the control group, and at three months after discharge, we analyzed 7 users in the tailored and 12 in the control group. One month after discharge, the tailored intervention group had a higher median level of overall physical activity ($Mdn_{tailored}$=2737.5, $IQR_{tailored}$=4200.2) than the control group ($Mdn_{control}$=1650.0, $IQR_{control}$=2443.5), but the difference was not significant (K-S Z=0.823, *p=0.385,* r=0.17). At three months after discharge, the tailored intervention group had a significantly higher median level of overall physical activity than the control group ($Mdn_{tailored}$=5613.0, $IQR_{tailored}$=2828.0, $Mdn_{control}$=1356.0, $IQR_{control}$=2937.0, K-S Z=1.397, *p=0.024*, r=0.33). The median adherence was 45.0 (95% CI: 0.0–169.8) days for the tailored group and 111.0 (95% CI 45.1-176.9) for the control group; however, the difference was not significant (Breslow χ^2=0.725, *p=0.395*). There were no statistically significant differences between the two groups in stage of change, self-efficacy, social support, perceived tailoring, anxiety or depression.

Conclusions: Due to the small sample size and the high attrition rate at the follow-up visits, we cannot safely make conclusions regarding the efficacy of our approach, but the results indicate that the tailored version of the intervention may have contributed to the long term higher physical activity maintained after cardiac rehabilitation by participants receiving tailored intervention compared with those receiving non-tailored intervention.

Trial Registration: www.clinicaltrials.gov: NCT01223170.

Keywords: Tailoring, Cardiac rehabilitation, Cardiovascular disease, EHealth, Internet-based, Mobile-based, Self-management, Physical activity

Introduction

The burden of disease due to cardiovascular diseases (CVDs) has increased over the last several decades, currently ranking as the most common cause of death in Western Europe [1]. There is solid evidence that secondary prevention and cardiac rehabilitation programs can decrease the mortality risk and increase health among patients with CVD [2,3], and an important element of such interventions is engagement in physical activity [4,5]. There are different models for the delivery of secondary prevention and cardiac rehabilitation interventions, but Internet- and mobile-based platforms are very promising [6].

Internet- and mobile-based health interventions are easily accessible to many people and have the potential to influence the physical activity level of those people [7–9]. Reviews in the literature have indicated that under certain conditions, such interventions can be useful tools in supporting self-management [7,10–15] and health behavior [16,17]. The effectiveness of these health interventions depends on the adoption of the appropriate theoretical framework [7,18–21], whereas the viability of these interventions is associated with strong user involvement in their design [22]. In addition, many successful interventions have utilized tailored content [9,16,22]. A tailored intervention is an intervention that is adapted to the characteristics of an individual, typically based on an individual's responses to a questionnaire [23]. Tailored health information is generally perceived as more interesting and personally relevant, better liked, more thoroughly read and discussed, and better remembered than non-tailored educational material [16,20,24–27].

We can roughly separate the technology-based cardiac rehabilitation interventions for physical activity into two categories. The first category aims to replace the traditional cardiac rehabilitation programs and increase the physical activity of the participants in comparison with the baseline physical activity. The second category is complementary to the traditional cardiac rehabilitation program and aims to help the users maintain their baseline level of physical activity for a longer period of time. In two studies that have tested the effects of such interventions utilizing telephone follow-up, the results have been inconsistent [28,29].

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 [2]. The general recommendation is a minimum of two and a half hours per week of moderate aerobic activity, in multiple bouts lasting more than ten minutes, and evenly spread throughout the week. This should be combined with the suggestion for sub-maximal endurance training and weight/resistance training twice a week [4]. There is evidence that aerobic interval training in short high intensity bouts is beneficial for patients with CVD [30] and safe [31,32]. Home-based unsupervised high intensity training was as effective and safe as supervised hospital-based [32], but it had lower adherence. After leaving cardiac rehabilitation, patients are expected to maintain at least the recommended level of physical activity. In Northern Norway, after discharge the patients are only followed-up by their family doctor and there is no formal follow-up procedure by the rehabilitation centre or other specialist care structure. An intervention that would support patients in maintaining the level of physical activity after the rehabilitation stay, and also would assist the contact and follow-up by the specialists from the rehabilitation centre has the potential to facilitate the compliance with the current guidelines for cardiac rehabilitation.

The aim of our study was to assess the effect of a tailored Internet- and mobile-based intervention on the maintenance of physical activity levels after a cardiac rehabilitation stay. Our main hypothesis was that the users of the tailored intervention would maintain their level of physical activity better than the users of the non-tailored intervention (control group). In our cluster randomized controlled trial, we compared a tailored version of the intervention with a non-tailored version. The study design, described previously [33], allowed us to isolate the effect of tailoring and understand how and for whom the intervention worked in a real-world setting. We developed the intervention using a methodological approach that combines user input from a focus group and health behavioral theory that we have described previously in detail [34].

Methods

Design

The study used a two-group cluster randomized control trial design. The clusters were randomly assigned to either the control group, which was given access to a generic version of the website and an online forum, or the tailored group, which received the tailored intervention in addition to access to the generic content and the online forum. We used parallel groups cluster randomization based on a true random number online service. The investigators and outcome assessors were blinded to the group assignments; however, for quality assurance related to technical issues, they had to uncover the assignments early during the statistical analysis process. The participants were instructed by the personnel of the rehabilitation center to use a specific number (code) that would automatically allocate them to their monthly cluster and they were not informed of their assignment condition.

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 center (baseline), a short time after the planned discharge (1-3 days) from the rehabilitation center, one month after discharge, and three months 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, but no further retention efforts were made. The first time the users would visit the website, after having received reminders about a questionnaire, they were re-directed to the questionnaire. Any inconsistencies due to this were corrected to the closer follow-up time. More specifically, we analyzed at a later time point one response from baseline, seven from discharge, and four from one month. Three responses from three months were excluded because they were closer to one year after discharge.

The main outcome measure was self-reported overall physical activity measured with the International Physical Activity Questionnaire (IPAQ) at one month and three months after discharge. 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.

Participants

The participants included 69 Norwegians between the ages of 33 and 75 recruited from Skibotn Rehabilitation Center. The inclusion criteria were (1) older than 18, (2) history of cardiovascular disease, (3) admission to Skibotn Rehabilitation Center, (4) access to the Internet after their stay at the rehabilitation center, and (5) possession of a personal mobile phone. The study protocol was approved by the Regional Ethics Committee for health region NORD (REK-NORD), and all the participants signed a consent form before being included in the study. All participants received a present of symbolic value (a water bottle with web address of the intervention, NOK 50-60) if they filled the questionnaire at one month after discharge. 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. The majority of the participants were referred to the cardiac rehabilitation program by their general practitioner approximately six months after a hospitalization for CVD, usually after myocardial infarction.

The intervention

All the participants of the cardiac rehabilitation program were informed in a meeting about the study during their four-week rehabilitation stay. Those who were interested met later to receive additional information, complete the consent form in paper and receive training in the use of the intervention. During the training, the users registered and answered the baseline questionnaire online. The time of registration varied for the clusters. Then, the participants completed the normal rehabilitation stay, receiving no differential treatment while at the rehabilitation center. There were computers at the rehabilitation center, where the participants could start using the intervention ahead of their discharge. However, the usage was not prompted by the intervention, and the tailored component of the intervention for the tailored group was activated after discharge. Detailed description of the intervention, the tailoring algorithm, and the functionality of the intervention have been published in previous papers [33,34].

We used the free, open-source content management framework Drupal to implement all of the necessary functionalities of the intervention. The intervention was provided free-of-charge to the users. The content of the website was created by the personnel of the rehabilitation center and the authors. The website was administered by one member of staff of the rehabilitation center but most of the functionality, including the tailoring, was fully automated. We had minor changes and bug fixes on the intervention, and some of the website content was updated, but since both groups were using the same website, the changes affected both groups in the same way.

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 (Figure 1). 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 (Figure 2) but were not prompted or reminded to do it and received no feedback.

Tailored group

The participants of the tailored group had access to the same functionality as the control group as well as 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 they were reminded to log in through email and Short Message Service (SMS) messages and answer the questionnaires. Based on the tailoring questionnaires they received tailored messages via the website and SMS

(Figure 3). 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 (Figure 4). 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 (Figure 3). The adaptive tailoring of this intervention was based on integrative models that combined socio-cognitive determinants of health behavior with a process view, such as the Health Action Process Approach HAPA (Multimedia Appendix 1)[35]. As we have described previously [34], we tailored first to the stage of change [36], which then determined if and when the other concepts were used for further tailoring (e.g., self-efficacies [35,37,38] and regulatory focus [39,40]).

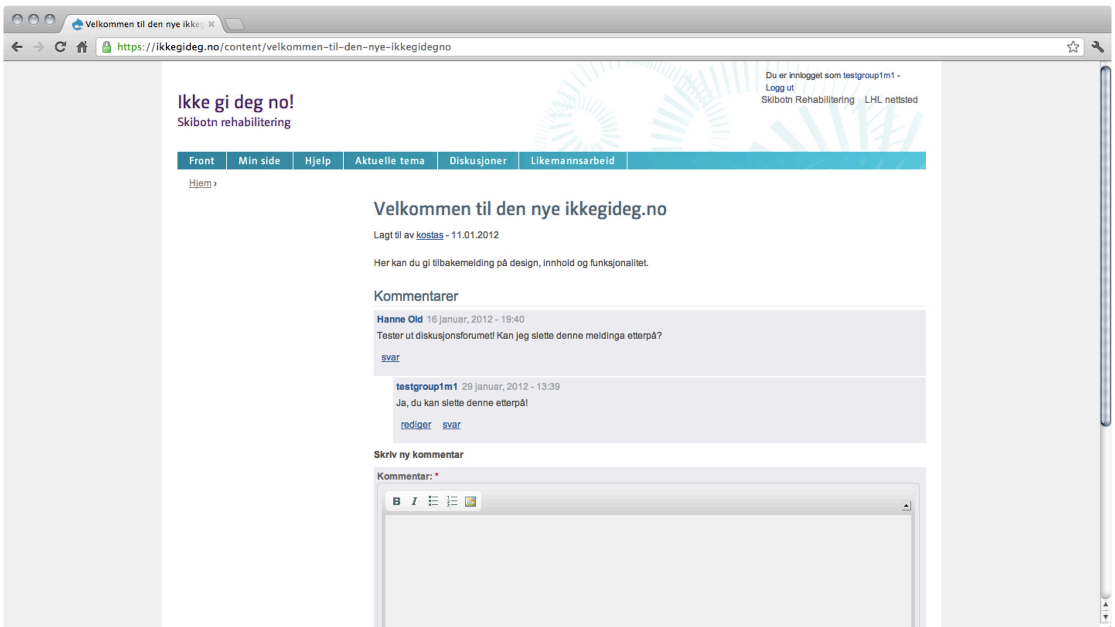

Figure 1. The discussion forum.

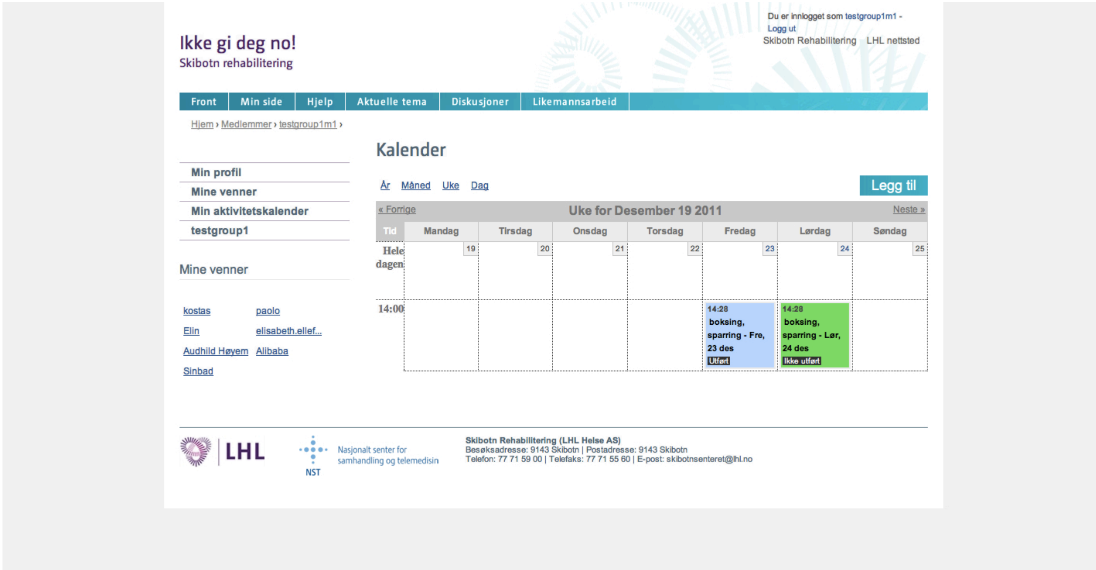

Figure 2. Weekly overview of the planned activities of the Activity Calendar.

Figure 3. Translations of Sample SMS. Motivational SMS (top): Don't give up! Both young and old benefit from physical activity. Therefore it is never too late to start. SMS before planned activity (middle): Remember Ball game, football/handball at 17:50. SMS after planned activity (bottom): Did you do the activity Ball game, football/handball? If so, you can confirm it by following the link [unique URL].

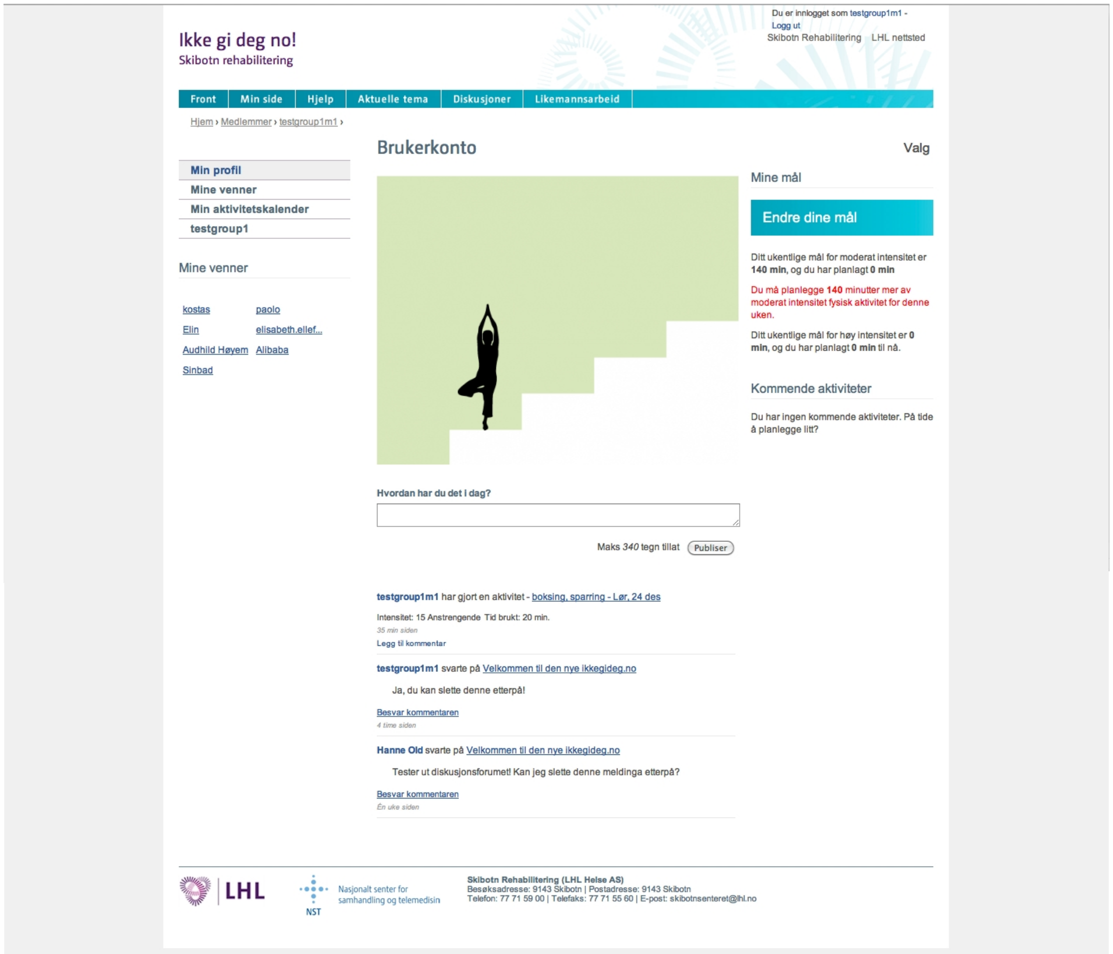

Figure 4. The profile page (My Page) with a graph representing the level of achievement of the weekly physical activity goals of the user.

Measures

The background information collected included age, gender, highest level of education, weight and height. Physical activity was measured using the IPAQ [41,42]. Adverse events and cardiovascular outcomes were not measured. The data on use were gathered through web logging. Our intent was to measure the number of logins, time spent logged in, and what elements were used most for each participant. 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.

The stage of change was assessed using the URICA-E2 scale [43], which gives a more comprehensive assessment of the stage than simply time before or after initiation of an action. Cronbach's α of the four items that represent each stage, varied from 0.66 to 0.84. Self-efficacy was measured using the perceived competence for regular physical exercise (PC-EX) scale [44]. The responses were reported using a scale from 0 (not at all) to 6 (to a great extent). Social support was assessed using an adaptation of the scale from Barrera et al. (Cronbach's α=0.93) [45].

Anxiety and Depression was assessed using the Hospital Anxiety and Depression Scale (HADS), 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 [46]. There are seven items associated with anxiety that had Cronbach's α=0.88 and seven items for depression with Cronbach's α=0.81. The perceived tailoring was assessed using four items from Dijkstra (Cronbach's α=0.86) [47].

The user evaluation was assessed based on whether they would recommend the site to a friend and whether they found each of the components useful. The participants were also asked to choose from the list of the components, the one that they found most useful and the one the found least useful.

Statistical Analyses

We calculated the *a priori* sample size estimation with an equivalence test for two proportions in a cluster-randomized design to detect 15% vs. 5% differences in the proportion of meeting self-management behavior goals. For a 0.05 alpha level and a 0.80 power, the required sample size was 16 clusters with 15 participants in each [33]. This sample size would be able to detect differences of 2608.1 MET-min/week in total IPAQ continuous score, a difference that according to recent recommendations can result in up to 8% higher reduction in all-cause death or hospitalizations [2]. We used standard deviation of 6095.9 MET-min/week [48], 0.015 intracluster correlation coefficient [49], and the program PASS, Version 12, Kaysville, Utah, USA, by NCSS. In practice, we recruited 18 clusters, but the interest of the participants within the groups was much lower than the expected, resulting in an average recruitment of 3.8 participants per cluster. Because of the small size of the clusters and the variance in their size, in the following analyses we did not take into account the clusters but analyzed the population in two groups (tailored and control).

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. 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.

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 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.

Results

The characteristics of the study participants are described in Table 1. There were no significant baseline differences between the two groups with respect to age, body mass index (BMI), years of education, overall physical activity (IPAQ continuous score), social support, self-efficacy, anxiety, depression or stage of change. The flow of the participants through the study is presented in Figure 5.

Table 1. Baseline characteristics and comparisons of the participants in the tailored and control groups.

	Tailored group, n=29	Control group, n=38	Test for difference
Mean age (95%CI)	59.5 (56.3 – 62.8)	58.8 (55.8 – 61.7)	F (1, 65)= 0.138, p= 0.712, η^2=0.02
Women	7 (24%)	8 (21%)	χ^2 (1, N=67)= 0.090, p= 0.776, φ=0.04
Mean BMI (95%CI)	30.4 (28.8 – 32.0)	29.0 (27.3 – 30.4)	F (1, 60)= 1.917, p= 0.171, η^2=0.03
Mean educational attainment (95%CI)	13.4 (11.9 – 14.9)	12.4 (11.4 – 13.4)	F (1, 65)= 1.300, p= 0.258, η^2=0.02
Median baseline IPAQ continuous score for walking (MET-minutes per week)(IQR)	1386.0 (742.5)	792.00 (841.5)	K-S Z=1.039 , $p=0.126$, r=0.14
Median baseline IPAQ continuous score for moderate activity	1440.0 (2400.0)	930.0 (1320.0)	K-S Z=1.067 , $p=0.103$, r=0.14

(MET-minutes per week)(IQR)			
Median baseline IPAQ continuous score for vigorous activity (MET-minutes per week)(IQR)	3240.0 (4260.0)	2400.0 (2802.0)	K-S Z=1.003 , *p=0.187,* r=0.14
Median baseline IPAQ continuous score for overall activity (MET-minutes per week)(IQR)	4266.0 (6999.0)	3810.0 (3649.1)	K-S Z=0.960 , *p=0.257,* r=0.12
Mean social support scale (95%CI)	4.2 (3.8 – 4.6)	4.2 (3,8 – 4.6)	F (1, 65)= 0.004, p= 0.949, η^2<0.01
Median self-efficacy (IQR)	6.0 (2.0)	5.0 (2.0)	K-S Z=0.737, *p=0.649,* r=0.09
Median anxiety (IQR)	4.0 (4.0)	5.0 (5.0)	K-S Z=0.579, *p=0.656,* r=0.07
Median depression (IQR)	2.0 (3.5)	3.0 (4.0)	K-S Z=0.289, *p=0.956,* r=0.03
Stage of change			χ^2 (4, N=67)= 0.170, p= 0.990, φ=0.05
Precontemplation	2 (7%)	3 (8%)	
Contemplation	14(48%)	17 (45%)	
Preparation	1 (3%)	1 (3%)	
Action	6 (21%)	8 (21%)	
Maintenance	6 (21%)	9 (24%)	

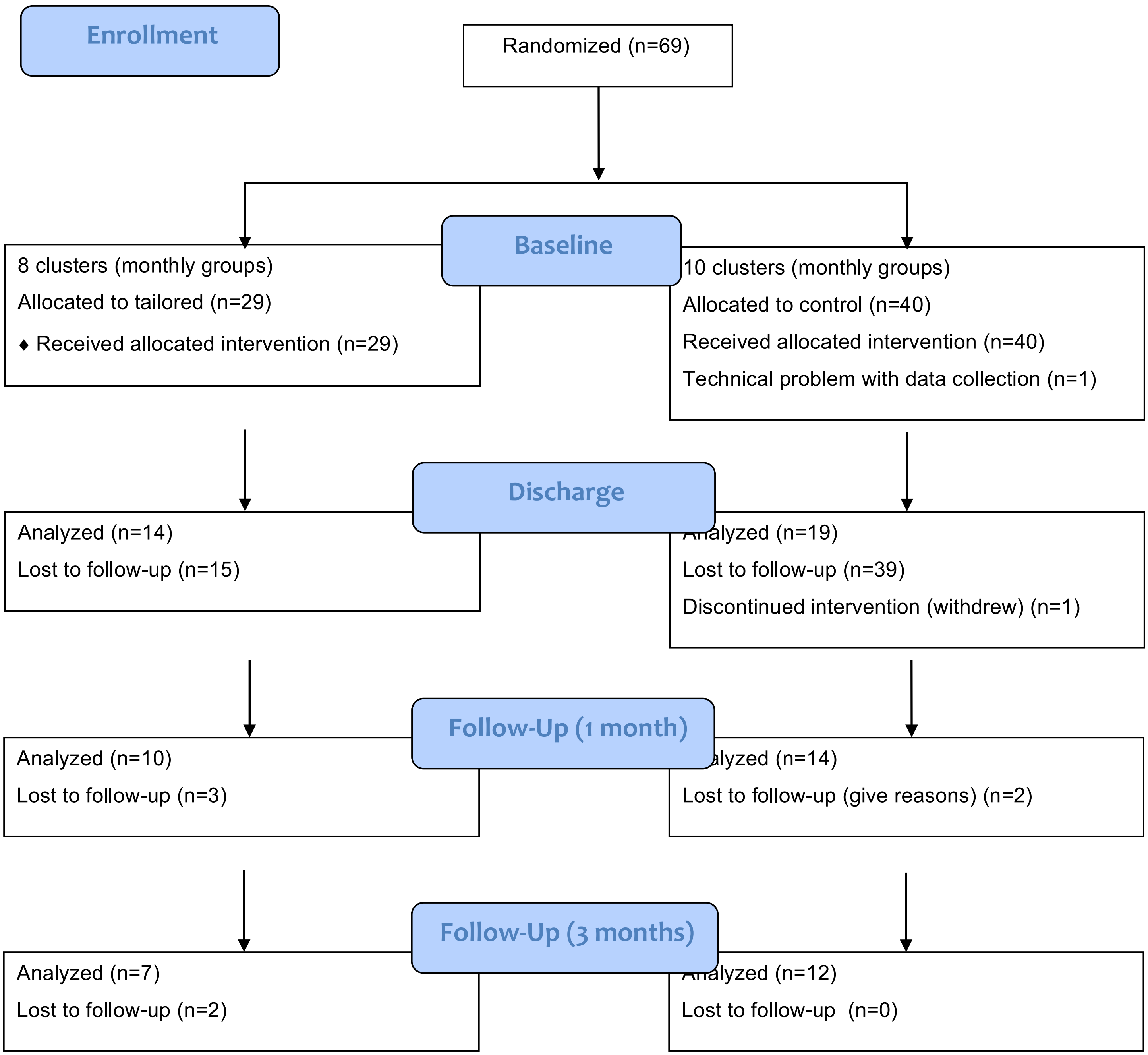

Figure 5 Flow diagram of the study.

Physical activity

The changes in total physical activity as well as per type of physical activity for each group are shown in Figure 6, and the medians and comparisons for total physical activity at each time point after baseline are shown in

Table 2. One month after discharge, the overall physical activity score of the tailored group ($Mdn_{tailored}$=2737.5, $IQR_{tailored}$=4200.2) was higher than the overall physical activity of the control group ($Mdn_{control}$=1650.0, $IQR_{control}$=2443.5). 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 ($Mdn_{tailored}$=5613.0, $IQR_{tailored}$=2828.0; $Mdn_{control}$=1356.0, $IQR_{control}$=2937.0).

If we look at the physical activity at different intensities, we find similar patterns. Typically, the control 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 (Figure 6). Three months after discharge, the tailored group had significantly higher level of walking than the control group ($Mdn_{tailored}$=940.5, $IQR_{tailored}$=891.0, $Mdn_{control}$=486.7, $IQR_{control}$=742.5), whereas the differences between the two groups for moderate ($Mdn_{tailored}$=1440.0, $IQR_{tailored}$=2000.0, $Mdn_{control}$=480.0, $IQR_{control}$=1080.0) and vigorous activity ($Mdn_{tailored}$=2300.0, $IQR_{tailored}$=1824.0, $Mdn_{control}$=0, $IQR_{control}$=1920.0) were not statistically significant.

For the minutes per day spent sitting, we found that at one month after discharge, the sitting time was higher for the control group ($Mdn_{control}$=300.0, $IQR_{control}$=300.0) than the tailored group ($Mdn_{tailored}$=150.0, $IQR_{tailored}$=315.0) but the difference was not significant (K-S Z=0.572, *p=0.611*, r=0.14). At three months after discharge, the tailored group showed a greater increase in sitting time than the control group, reducing the difference between the sitting times of the two groups ($Mdn_{tailored}$=280.0, $IQR_{tailored}$=155.0, $Mdn_{control}$=360.0, $IQR_{control}$=180.0, K-S Z=0.816, *p=0.430*, r=0.23).

Total physical activity Walking

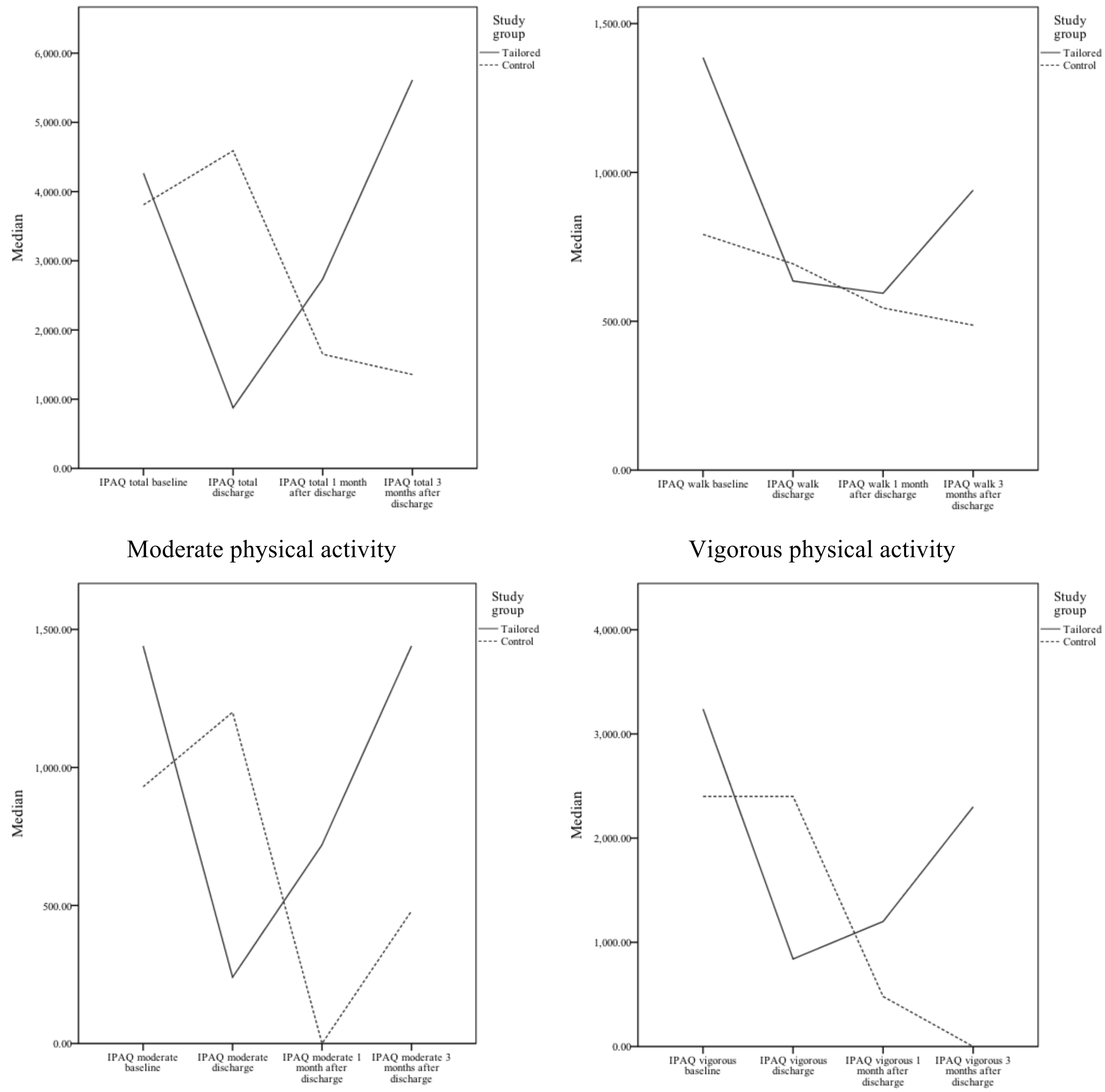

Figure 6 Changes in total physical activity, walking, moderate activity, and vigorous activity for each group over time.

Table 2. IPAQ score of total activity for the tailored and control group.

	Study group						
	Tailored			Control			
	n	Median	IQR	n	Median	IQR	Comparison test

IPAQ total at discharge	14	875.2	5959.5	19	4590.0	3978.0	K-S Z=1.473, *p=0.017,* r=0.26
IPAQ total at 1 month after discharge	10	2737.5	4200.2	13	1650.0	2443.5	K-S Z=0.823, *p=0.385,* r=0.17
IPAQ total at 3 months after discharge	7	5613.0	2828.0	11	1356.0	2937.0	K-S Z=1.397, *p=0.024,* r=0.33

Secondary outcomes

Self-efficacy at one month after discharge was the same for the tailored and the control group (Mdn=5.0, $IQR_{tailored}$=2.0, $IQR_{control}$=1.0). At three months post discharge, the tailored group self-efficacy remained unchanged ($Mdn_{tailored}$=5.0, $IQR_{tailored=}$2.0), but the self-efficacy of the control group increased slightly ($Mdn_{control}$=5.5, $IQR_{control}$=2.0). The differences between the two groups were not statistically significant at one month (K-S Z=0.709, *p=0.273*, r=0.16) or three months after discharge (K-S Z=0.667, *p=0.365*, r=0.15).

Social support scores at one month post-discharge, was the same for the tailored group ($Mdn_{tailored}$=4.2, $IQR_{tailored}$=1.8) as for the control group ($Mdn_{control}$=4.2, $IQR_{control}$=2.7). Three months after discharge, the social support of the tailored group increased ($Mdn_{tailored}$=4.8, $IQR_{tailored}$=2.3) but decreased in the control group ($Mdn_{control}$=3.9, $IQR_{control}$=1.8). The difference between the groups was not significant at one month (K-S Z=0.522, *p=0.879*, r=0.12) or three months after discharge (K-S Z=0.775, *p=0.460*, r=0.19).

At one month after discharge the control group experienced more anxiety than the tailored group ($Mdn_{control}$=3.0, $IQR_{control}$=3.5 versus $Mdn_{tailored}$=2.5, $IQR_{tailored}$=4.2). Three months after discharge, anxiety had increased for both groups, but was still higher in the control group ($Mdn_{control}$=4.5, $IQR_{control}$=4.7, $Mdn_{tailored}$=4.0, $IQR_{tailored}$=4.0). The difference in the anxiety level between the groups was not statistically significant at one month (K-S Z=0.276, *p=0.983*, r=0.06) or three months after discharge (K-S Z=0.701, *p=0.443*, r=0.16).

At one month after discharge, depression in the control group was the same as in the tailored group ($Mdn_{control}$=1.0, $IQR_{control}$=3.2 $Mdn_{tailored}$=1.0, $IQR_{tailored}$=4.0). Three months after discharge, depression increased in both groups ($Mdn_{control}$=1.5, $IQR_{control}$=2.0, $Mdn_{tailored}$=2.0, $IQR_{tailored}$=2.0). The difference in the level of depression between the groups was not statistically significant at one month (K-S Z=0.311, *p=0.983*, r=0.06) and three months after discharge (K-S Z=0.576, *p=0.581*, r=0.13).

Process measures

At one-month after discharge, 3 out of 7(43%) of the tailored group and 4 out of 8 (50.0%) of the control group were in the action stage. Three months after discharge, 5 out of 11(45%) of the control group participants were in the action stage and 3 out of 11 (27.3%) were in the maintenance stage, whereas 3 out of 6 (50.0%) of the members of the tailored group were in the action stage and the other 3 (50.0%) were in maintenance. Overall, the participants in both groups progressed forward through the stages of change over the course of the study. There were no significant differences between the two groups at one month ($\chi^2_{4, N=15}$= 2.085, p>0.999, φ=0.37) or three months after discharge ($\chi^2_{3, N=17}$= 2.222, p=0.774, φ=0.36).

Perceived tailoring measured at one month after discharge and was the same in the tailored and the control group ($n_{tailored}$=6, $n_{control}$=8, Mdn=3.2, $IQR_{tailored}$=1.4 and $IQR_{control}$=1.6). At three months after discharge, the level of perceived tailoring had increased in the tailored group ($n_{tailored}$=6, $Mdn_{tailored=}$3.6, $IQR_{tailored=}$1.4) and remained the same for the control group ($n_{control}$=11, $Mdn_{control}$=3.2, $IQR_{control}$=1.7). We did not find the difference between the two groups statistically significant at one month (K-S Z=0.694, *p=0.598*, r=0.19) or three months after discharge (K-S Z=0.716, *p=0.394*, r=0.17).

The adherence curve is L-shaped reaching a stable use plateau at around 30% (Figure 7). At one year from baseline, the adherence rate was 25.6% for the tailored group and 24.0% for the controls. The median for adherence time for the tailored group was 45.0 (95% CI: 0.0–169.8) days and 111.0 (95% CI 45.1-176.9) days for the control group; these findings were not significantly different (Breslow χ^2=0.725, *p=0.395*). The median adherence time for men was 122.0 (95% CI 14.8–229.2) days and 75.0 (95% CI 0.0–153.3) days for women; these values were significantly different (Log Rank χ^2=4.206, *p=0.040*).

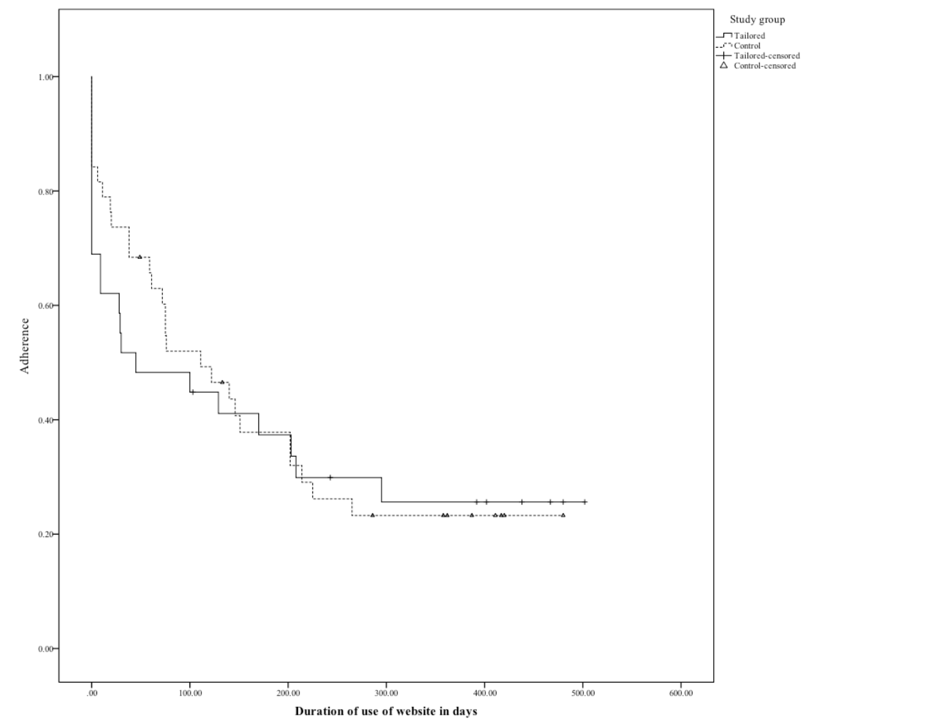

Figure 7. Adherence to the website.

In terms of total page views, one month after discharge, the tailored group had visited the website more often ($Mdn_{tailored}$=733.0, $IQR_{tailored}$=606.0) than the control group ($Mdn_{control}$=392.5, $IQR_{control}$=464.0). However, the difference was not statistically significant (K-S Z=1.249, *p=0.056*, r=0.27). By three months after discharge, the tailored group had still visited the website more often than the control group ($Mdn_{tailored}$=1312.0, $IQR_{tailored}$=1171.0, $Mdn_{control}$=712.0, $IQR_{control}$=669.0), but difference between the two groups was not significant (K-S Z=0.851, *p=0.382*, r=0.19).

The user evaluation was measured at one month after discharge. Of the tailored group, 66.7% of the participants would recommend the website to a friend and 75.0% of the control group would do likewise. This difference was not significant ($\chi 2_{1, N=21}$= 0.175, p > 0.999). We also asked whether the participants found the different functionality elements useful. The percentages of the participants in each group that found the various functionalities useful are presented in Table 3. The most popular general functionality was goal setting (approved by 100% of the participants in both groups), followed by the activity calendar (approved by 100% of the tailored group and 90% of the control group), general information (approved by 83.3% of the tailored group and 80% of the control group) and the discussion forum (approved by 85.7% of the tailored and 72.7% of the control group). None of these differences between groups was statistically significant.

For tailored group considered the email and SMS reminders and messages (28.6%) and the questionnaire's functionality (14.3%), i.e. the core of the tailoring, to be the least useful functionality elements (approved by 28.6% and 14.3% of the participants, respectively). The control group considered the SMS reminders and messages to be the least useful (approved by only 20% of the control group participants); for the control group, these were only the reminders to complete the study questionnaires. The activity calendar chosen as the most useful functionality by the highest proportion of users in both the tailored group (10.3%) and the control group (18.4%). For both the least and the most useful functionality of the intervention, the users were presented with the same list functionalities listed in Table 3.

Table 3. Usefulness of intervention elements.

		Study group			
		Tailored		Control	
		Count	%	Count	%
General information	Yes	5	83.3%	8	80.0%
	No	1	16.7%	2	20.0%
Discussion forum	Yes	6	85.7%	8	72.7%
	No	1	14.3%	3	27.3%
Activity calendar	Yes	6	100.0%	9	90.0%
	No	0	0.0%	1	10.0%
SMS messages and reminders	Yes	4	66.7%	5	50.0%
	No	2	33.3%	5	50.0%
E-mail messages and reminders	Yes	4	66.7%	7	70.0%
	No	2	33.3%	3	30.0%
Challenge others	Yes	5	83.3%	7	70.0%
	No	1	16.7%	3	30.0%
Challenged by others	Yes	5	83.3%	7	77.8%
	No	1	16.7%	2	22.2%
My page	Yes	5	100.0%	9	100.0%
	No	0	0.0%	0	0.0%
Visit other profiles	Yes	3	60.0%	5	55.6%
	No	2	40.0%	4	44.4%

Group page	Yes	3	60.0%	5	55.6%
	No	2	40.0%	4	44.4%
Questionnaires	Yes	4	80.0%	7	77.8%
	No	1	20.0%	2	22.2%
My goals	Yes	3	100.0%	8	100.0%
	No	0	0.0%	0	0.0%

Discussion

The intervention had high attrition rates, and in the beginning of the intervention, there was a higher drop-out rate in the tailored group than in the control group, although the difference in average time until drop-out for the two groups was not statistically significant. Overall, the remaining participants in our intervention moved forward through the stages of change following their rehabilitation stay; at discharge, about half of the participants were in the contemplation stage whereas three months after discharge, half of the participants were in the action stage. Despite the fact that half of the participants received a version of the intervention that was tailored to the stage of change, there were no differences between the groups with respect to their stage progressions. There was, however, a clinically meaningful as well as statistically significant difference between the groups in how well they were able to maintain their total physical activity. After discharge, the tailored group began increasing their physical activity after an initial drop, whereas the control group's physical activity decreased. This trend continued at three months after discharge; the physical activity of the tailored group continued to increase, whereas the physical activity of the control group continued to decline.

As the stage of change results suggest, this intervention might not have worked through the hypothesized mechanisms. The participants in the tailored group did not perceive their intervention as more personally relevant than the participants in the control group perceived theirs, and they did not consider the tailored messages received by email and SMS or the tailored questionnaires as particularly useful. Furthermore, the participants in the tailored group reported slightly lower self-efficacy than the control group and about the same level of perceived social support as the control group.

The number of responders at three months was 19 out of the 69 recruited at baseline (27.5%). This participation rate is low but it is an expected rate for an eHealth [50], Internet-based [51] physical activity [52] intervention. There were no statistically significant differences between the two groups. Despite the non-significant difference, in the beginning of the intervention, the attrition was higher for the tailored group. A possible explanation is the increased workload of answering more questions that is required by the participants of the tailored group. The fact that the difference is not so high to be significant might be a positive sign, since other studies have reported significantly higher attrition for the intervention group [53]. 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 [50]. 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, something that might have eased after discharge. Also, women that were interested to participate, 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 needs [54–56].

Another reason for the users to stop using the intervention is that they might have achieved a satisfactory, for them, level of activity, therefore not needing the help of the intervention. A similar effect has been reported in smoking cessation, where nonresponders were more likely to quit than responders [57]. 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 [58]. For the tailored group of our intervention, the algorithm would detect that the user is in the stage of maintenance, making the intervention less intensive, but anyhow for stage-detection the user would have to answer some questions. If the user has already achieved a behavior, given the least effort principle, might not see the point in spending time answering the questions. In addition, it has been found that frequency of interaction with the system might have negative impact on adherence [22]. For the non-tailored group, a reason might be exactly the lack of tailoring that makes it less appealing. We can assume that because the intervention was starting immediately after the discharge from the cardiac rehabilitation program, some users would be already falling in the category of having an adequate level of physical activity.

A member of staff from the collaborating rehabilitation center was administrating the website, but there were no regular planned interactions by protocol. A Delphi-type study that tried to identify issues relevant to the development of an Internet-based cardiac rehabilitation intervention among specialists, found that one of the issues that scored high in relevance and consensus was the role of cardiac case manager [59]. The frequency of interaction with a counselor was found to be a significant predictor of adherence in web-based interventions [22]. Also, “push” factors related to researchers practices to keep participants in the study have also the potential to decrease dropout attrition [50], and this might be the reason that RCTs have been found to have higher adherence than large real-life studies [22]. In our trial, for the research questionnaires we were only sending an SMS and an email reminder daily for three days, but we did not have any additional follow-up phone calls or actions after a dropout. Since most of the functionalities of the intervention were automated, they required little contribution from health personnel after the registration, resembling more a real-world sustainable scenario for such an intervention. 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. Nevertheless, it is expected that increased intervention-related interaction with health professionals will improve adherence.

Problems related to user experience might have been a reason for low adherence too [50]. Even if we developed the intervention based on user needs, some elements of the intervention did not satisfy some of the users. An 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, if they are on holiday or sick. This of course affects negatively the user acceptance and might lead to higher attrition. A combination of methodological, economical and technical reasons did not allow for these changes to happen. It can also be considered as more methodologically consistent to not change an important functionality of the intervention while the trial was running. However, we found that the participants were in general satisfied with the intervention.

The higher level of physical activity observed in the tailored group at three months can be mainly attributed to the increase in walking (MET-minutes/week). This difference may be due to several factors. The motivational messages that were sent to the users based on the tailoring algorithm promoted the implementation of small everyday life changes to increase physical activity, using the strategy that the participants expressed preference for in a formative focus group [34]. In addition, it may be easier for older individuals to increase their walking rather than moderate and vigorous activity [60], and individuals in Norway might prefer walking tours over other activities either on their own or in a group, due to the open-air activity culture of Scandinavia [61].

Regarding the clinical relevance of our findings, 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 control group three months after discharge (1356.0). Thus, all of the measured activity levels in our study were close to or above the recommended minimum limits of energy expenditure of 500-1000 MET-min/week [62]. The same guidelines, however, emphasize the importance of moderate and vigorous activity. Walking is typically categorized as a low-to-moderate activity [2,63], although its intensity can be perceived differently for different age groups [63]. Ideally, we would like to see differences in moderate and vigorous activity too, to achieve levels that can predict improvements in cardiorespiratory fitness [2,4], but this does not mean that we cannot expect a benefit from the observed improvement.

To the best of our knowledge, this is the first report of an Internet- or mobile-based computer-tailored intervention targeting physical activity in cardiac rehabilitation patients. There are, however, many relevant studies of Internet-based physical activity interventions in other populations. A review of general Internet- and/or –mobile-based interventions for physical activity has found consistent evidence that such programs are effective in increasing physical activity, and the most effective interventions provided tailored guidance and ongoing support [9]. Another review of Internet-based tailored health behavioral interventions that included 23 studies targeting physical activity also suggested that there is evidence for the overall efficacy of such interventions [16]. Mobile phone-based interventions to increase physical activity have been demonstrated to have a beneficial impact on influence physical activity behavior as well, especially if they are theoretically grounded [7,64].

Strengths and limitations

Our sample was small, so we believe that our comparisons did not have enough power to confidently detect the effect of the intervention. Despite our efforts, the recruitment of participants was not at the desired levels, mainly because of the age of the participants of the cardiac rehabilitation program we were recruiting from. The mean age of the participants at the rehabilitation center was higher than expected, and therefore their interest was lower since they were less familiar with the technology we used. In addition to the small sample size, our study was characterized by high attrition. Our study protocol did not include additional contact with the participants other than automated SMS and email reminders in the event of a dropout or nonusage, reflecting our choice to conduct a real-world trial of an automated system.

Furthermore, our control group received a non-tailored version of the intervention, whereas the control group in other studies received the usual care. This makes a difference between the groups even more difficult to detect, adding to the low statistical power problem. Although the design of our study might have decreased the statistical power, it helps us estimate if the tailored program is helpful and if so, how it work and for whom. Our design was an effectiveness study design with the goal of isolating the effect of the tailoring rather than determining the effect of an intervention compared with a no-treatment control group.

Our approach, like that of many others [54–56], was not successful in addressing the needs of women, therefore our results cannot be generalized to both genders. There were only a small number of women that were interested in the study and alas among women we had higher attrition rates, contributing to the high attrition problem. Reasons that may contribute to the low adherence of women to rehabilitation programs include the tendency to minimize or play down the impact of their health situation to avoid burdening their social contacts, lower functional capacity after ischemic heart disease, and a lack of time due to family or social commitments [54]. Comorbidities such as arthritis, osteoporosis, and urinary incontinence can also make it harder for women to exercise [54]. At the focus group during the design phase of the intervention, women expressed their need for a service that would appeal to them too [34], but we did not receive enough information to determine what that meant and we assumed that the tailoring algorithm would address the individual needs. To increase the participation and adherence of women, we should have investigated more thoroughly any gender-specific barriers and needs.

The inclusion criteria of our study were very broad, allowing for the recruitment of participants within a wide age range with a variety of comorbidities. This makes it more difficult to demonstrate the effect of the intervention since it is more difficult to affect the health behavior of patients with more complicated cases or older people and more difficult to isolate the effect of the intervention in a carefully selected population. However, this makes our study a real-world trial that will help us understand if and how the intervention is helping the population that needs it.

Future research

One of the major issues identified in the intervention is the high attrition. Our future research should focus even more on studying attrition, and include different elements that can reduce it. A cardiac case manager that would have often interaction with the participants seems to have great potential in improving adherence [22,59].

The addition of at least one 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 into several of the quantitative findings, especially the problem of high attrition. The intervention should be developed further to include and address the needs of women, and since women are already underrepresented at the face-to-face rehabilitation program, a different approach should be used. In this case a focus group should be organized for CVD patients after their discharge from the hospital and without having the participation to cardiac rehabilitation program as a precondition.

An interesting direction for future research would be to study the effect of such intervention before the participation in a cardiac rehabilitation program. Specifically in the case of North Norway, that there is a long interval between discharge from the hospital and cardiac rehabilitation, an intervention like this can be offered during this interval. This has the potential to increase the recruitment to the cardiac rehabilitation program [65], since this seems to be more problematic than long-term maintenance of physical activity [66].

Conclusion

Our main hypothesis was that participants who receiving a tailored intervention would maintain higher levels of physical activity over time compared with the control group. We also expected the tailored group to have better adherence to the intervention and to achieve a better self-efficacy for maintenance of physical activity than the control group. The small sample size and the high attrition rate at the follow-up visits did not allow us to draw clear conclusions; however, the trends from our findings indicated that tailored intervention holds promise for supporting the maintenance of long-term physical activity after cardiac rehabilitation.

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Conflicts of Interest

The authors have participated in the design of the interventions described in the manuscript.

Multimedia Appendix 1

Video presenting an example of the tailoring algorithm.

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Supplementary tables

	Study group						
	Tailored			Control			
	n	Median	IQR	n	Median	IQR	Comparison test
IPAQ walk at discharge	12	635.2	1212.7	15	693.0	511.5	K-S Z=0.732, *p=0,494*, r=0.14
IPAQ walk at 1 month after discharge	10	594.0	726.0	12	544.5	730.1	K-S Z=0.272, *p=0.995*, r=0.06
IPAQ walk at 3 months after discharge	6	940.5	891.0	10	486.7	742.5	K-S Z=1.226, *p=0.050*, r=0.31
IPAQ moderate at discharge	12	240.0	1620.0	17	1200.0	2700.0	K-S Z=1.014, *p=0.181*, r=0.19
IPAQ moderate at 1 month after discharge	9	720.0	1070.0	12	0	1860.0	K-S Z=0.756, *p=0.431*, r=0.16
IPAQ moderate at 3 months after discharge	7	1440.0	2000.0	9	480.0	1080.0	K-S Z=0.976, *p=0.209*, r=0.24
IPAQ vigorous at discharge	12	840.0	3600.0	18	2400.0	2120.0	K-S Z=1.043, *p=0.169*, r=0.19
IPAQ vigorous at 1 month after discharge	10	1200.0	2340.0	11	480.0	1416.0	K-S Z=0.728, *p=0.446*, r=0.16
IPAQ vigorous at 3 months after discharge	6	2300.0	1824.0	11	0	1920.0	K-S Z=1.134, *p=0.075*, r=0.27

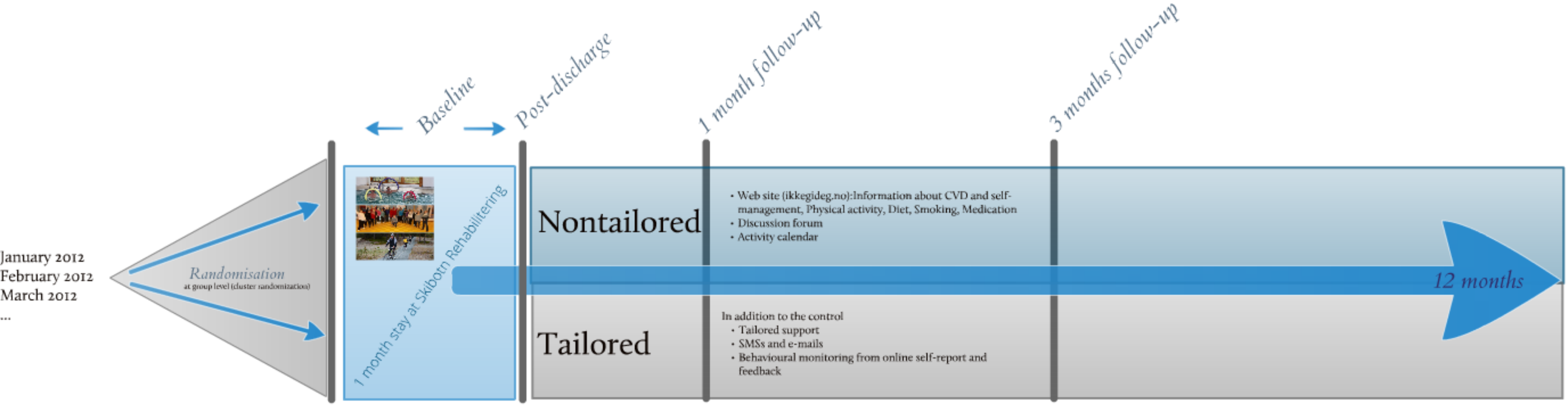
	Study group				
	Tailored		Control		
	Median	IQR	Median	IQR	Comparison test
Self-efficacy at discharge	5.0	2.0	5.0	2.0	K-S Z=0.505, *p=0.521*, r=0.09
Self-efficacy at 1 month after discharge	5.0	2.0	5.0	1.0	K-S Z=0.709, *p=0.273*, r=0.16
Self-efficacy at 3 months after discharge	5.0	2.0	5.5	2.0	K-S Z=0.667, *p=0.365*, r=0.15

	Study group				
	Tailored		Control		
	Median	IQR	Median	IQR	Comparison tests
Social support scale at discharge	4.7	2.0	4.2	1.8	K-S Z=0.477, *p=0.871*, r=0.09
Social support scale at 1 month after discharge	4.2	1.8	4.2	2.7	K-S Z=0.522, *p=0.879*, r=0.12
Social support scale at 3 months after discharge	4.8	2.3	3.9	1.8	K-S Z=0.775, *p=0.460*, r=0.19

	Study group				
	Tailored		Control		
	Median	IQR	Median	IQR	Comparison tests
Anxiety at discharge	3.0	5.2	5.0	5.0	K-S Z=0.640, *p=0.453*, r=0.11
Anxiety at 1 month after discharge	2.5	4.2	3.0	3.5	K-S Z=0.276, *p=0.983*, r=0.06
Anxiety at 3 months after discharge	4.0	4.0	4.5	4.7	K-S Z=0.701, *p=0.443*, r=0.16

	Study group				
	Tailored		Control		
	Median	IQR	Median	IQR	Comparison tests
Depression at discharge	1.0	5.2	2.0	4.0	K-S Z=0.918, *p=0.205*, r=0.15
Depression at 1 month after discharge	1.0	4.0	1.0	3.2	K-S Z=0.311, *p=0.983*, r=0.06
Depression at 3 months after discharge	2.0	2.0	1.5	2.0	K-S Z=0.576, *p=0.581*, r=0.13

		Study group				
		Tailored		Control		
		Count	Column N %	Count	Column N %	Comparison tests
Stage of change at 1 month after discharge	Precontemplation	1	14.3%	0	0.0%	χ^2 (4, N=15)= 2.085, *p*>0.999, φ=0.37
	Contemplation	1	14.3%	1	12.5%	
	Preparation	0	0.0%	1	12.5%	
	Action	3	42.9%	4	50.0%	
	Maintenance	2	28.6%	2	25.0%	
Stage of change at 3 months after discharge	Precontemplation	0	0.0%	1	9.1%	χ^2 (3, N=17)= 2.222, *p*=0.774, φ=0.36
	Contemplation	0	0.0%	2	18.2%	
	Preparation	0	0.0%	0	0.0%	
	Action	3	50.0%	5	45.5%	
	Maintenance	3	50.0%	3	27.3%	


January 2012
February 2012
March 2012
...
Randomisation
at group level (cluster randomization)
Baseline
Post-discharge
1 month follow-up
3 months follow-up
1 month stay at Skibotn Rehabilitering
Nontailored
• Web site (ikkegideg.no):Information about CVD and self-management, Physical activity, Diet, Smoking, Medication
• Discussion forum
• Activity calendar
12 months
Tailored
In addition to the control
• Tailored support
• SMSs and e-mails
• Behavioural monitoring from online self-report and feedback