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]).

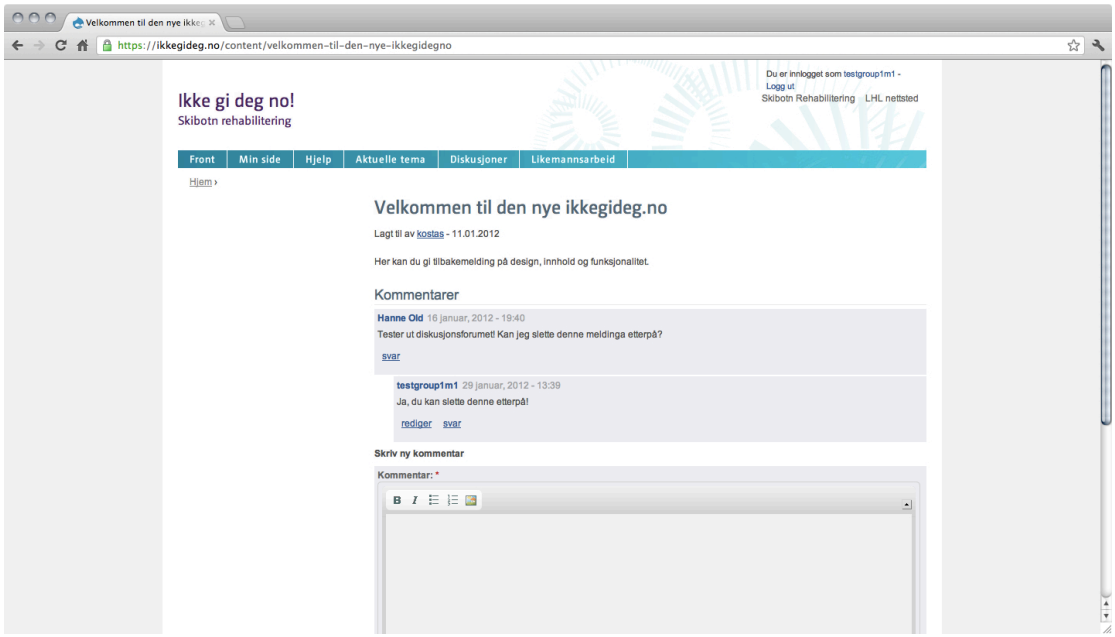

Figure 1. The discussion forum.

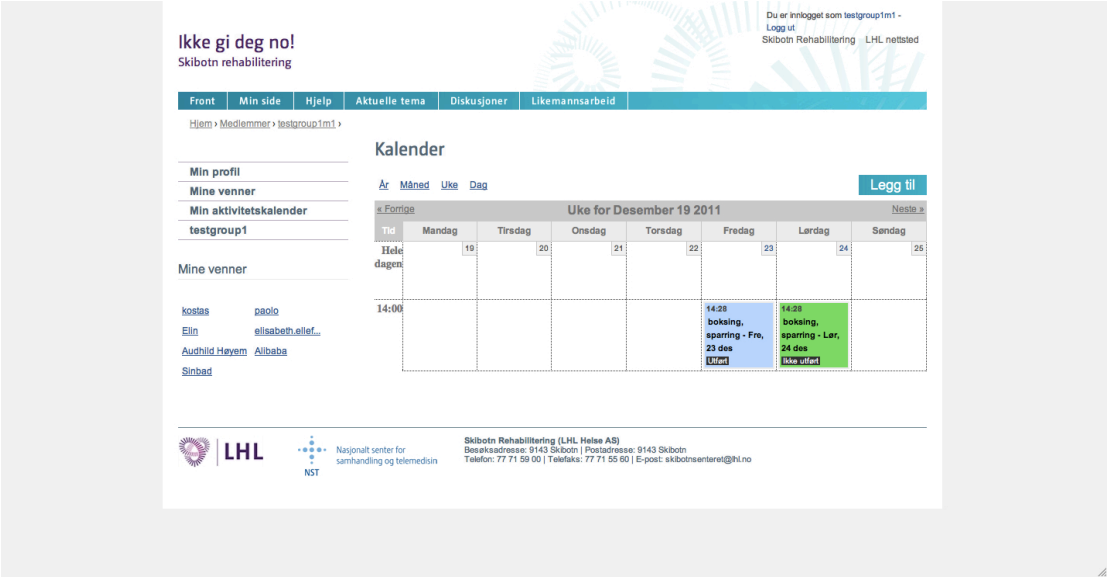

Figure 2. Weekly overview of the planned activities of the Activity Calendar.

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].

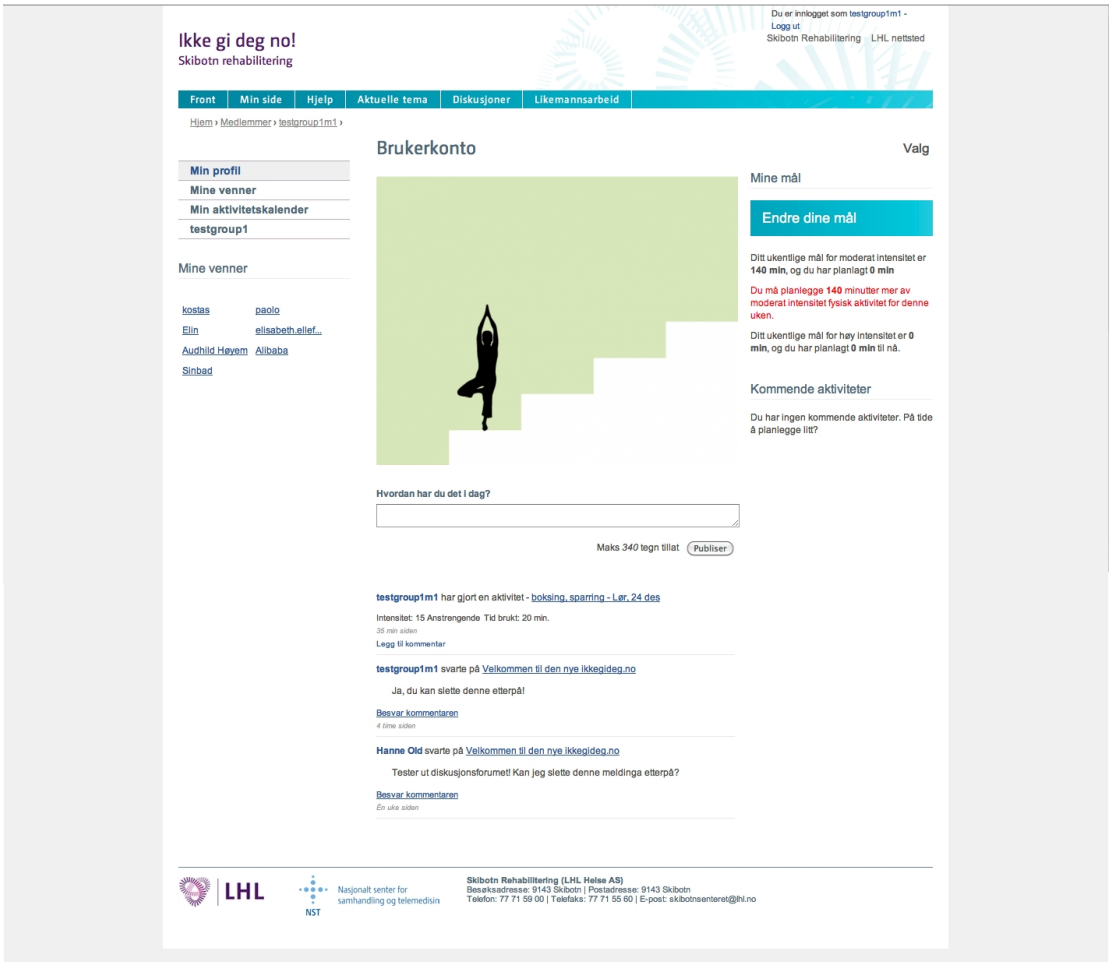

Figure 4. The profile page (My Page) with a graph representing the level of achievement of the weekly physical activity goals of the user.

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%)	

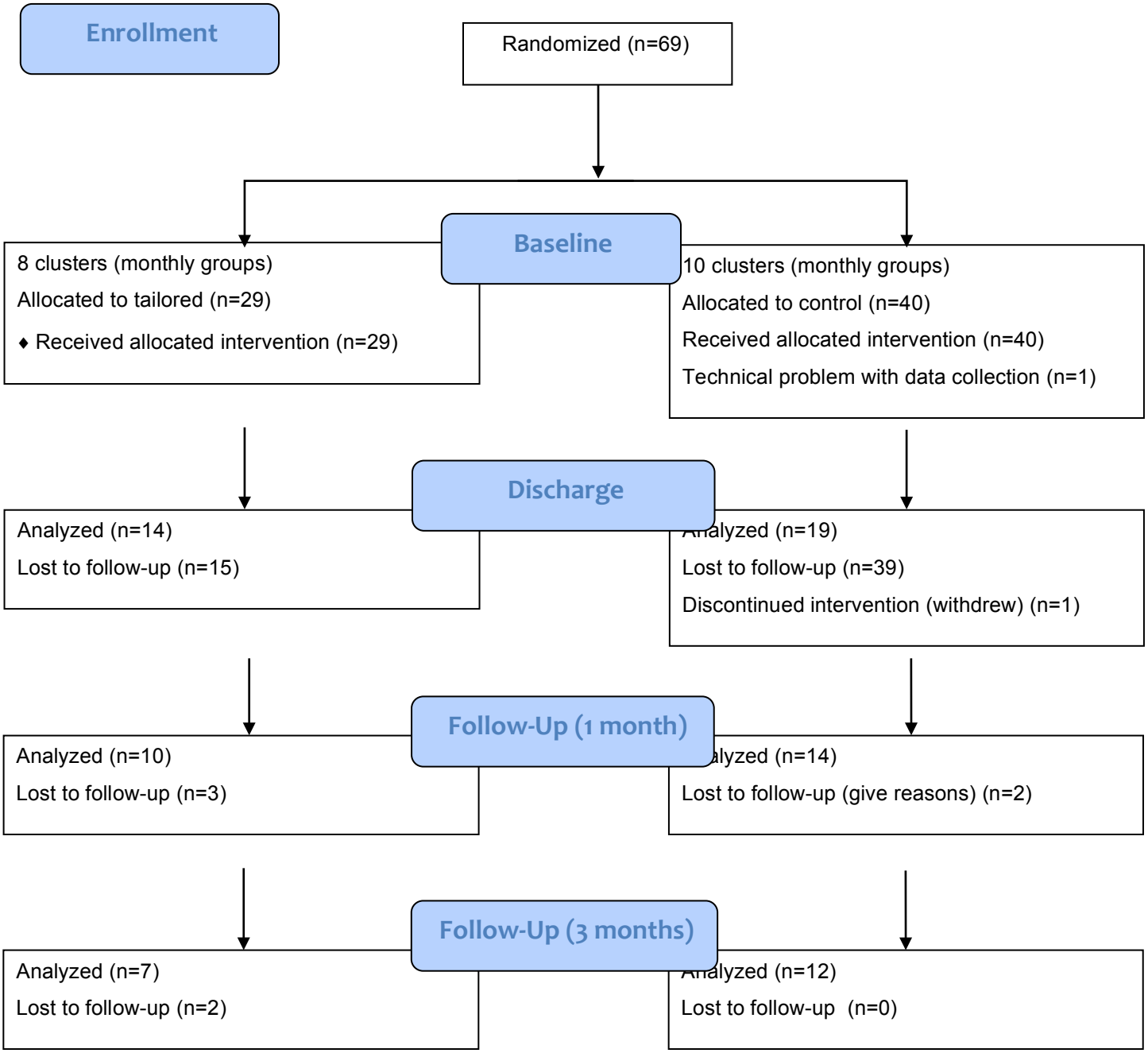

Figure 5 Flow diagram of the study.

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

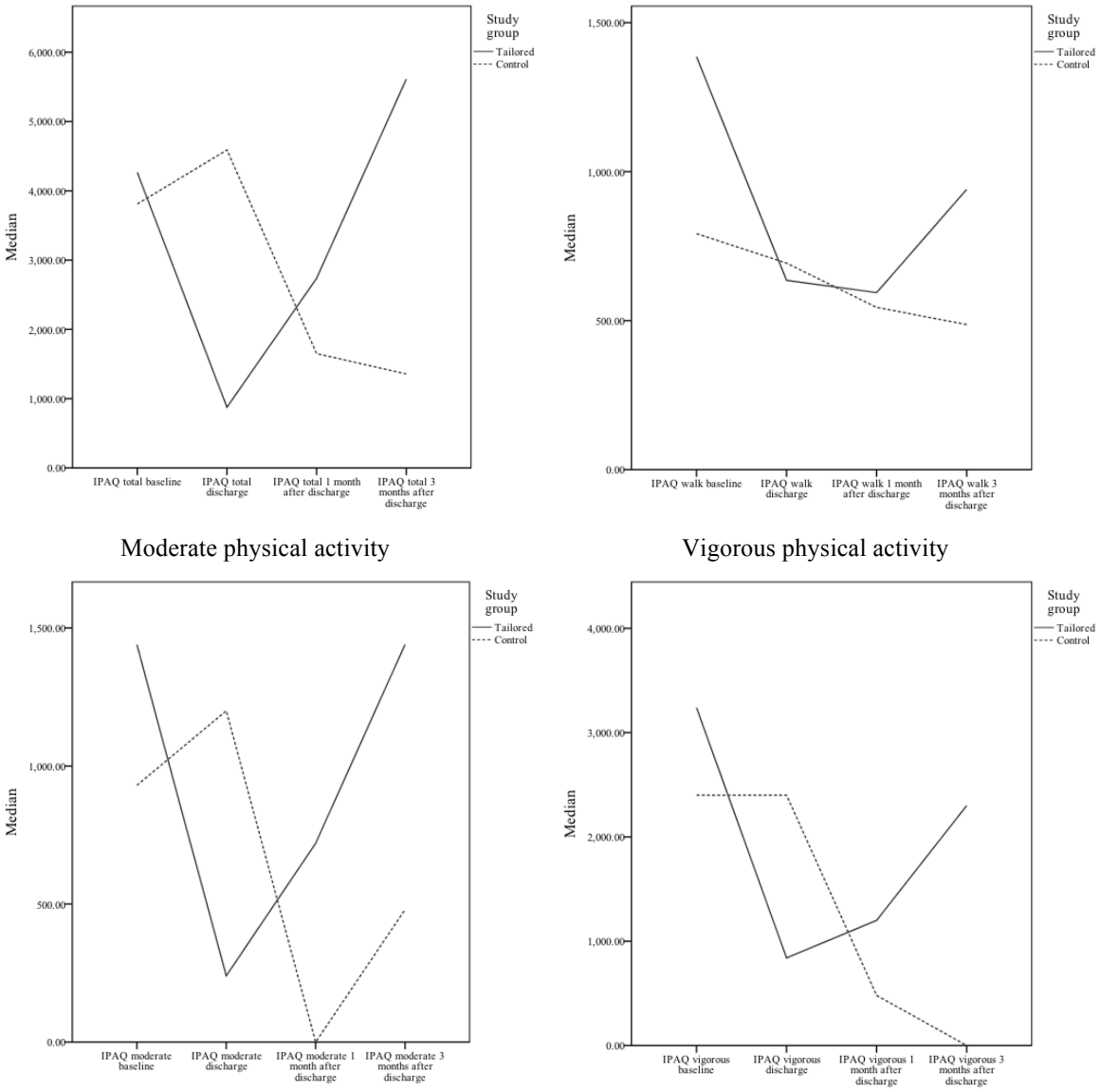

Figure 6 Changes in total physical activity, walking, moderate activity, and vigorous activity for each group over time.

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*).

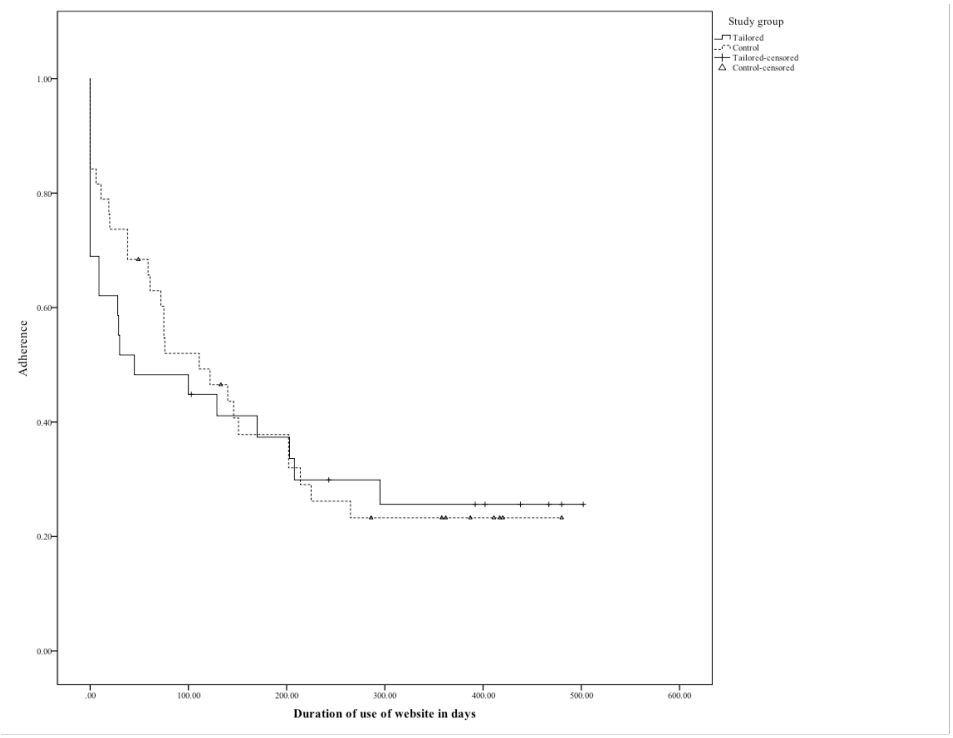

Figure 7. Adherence to the website.

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

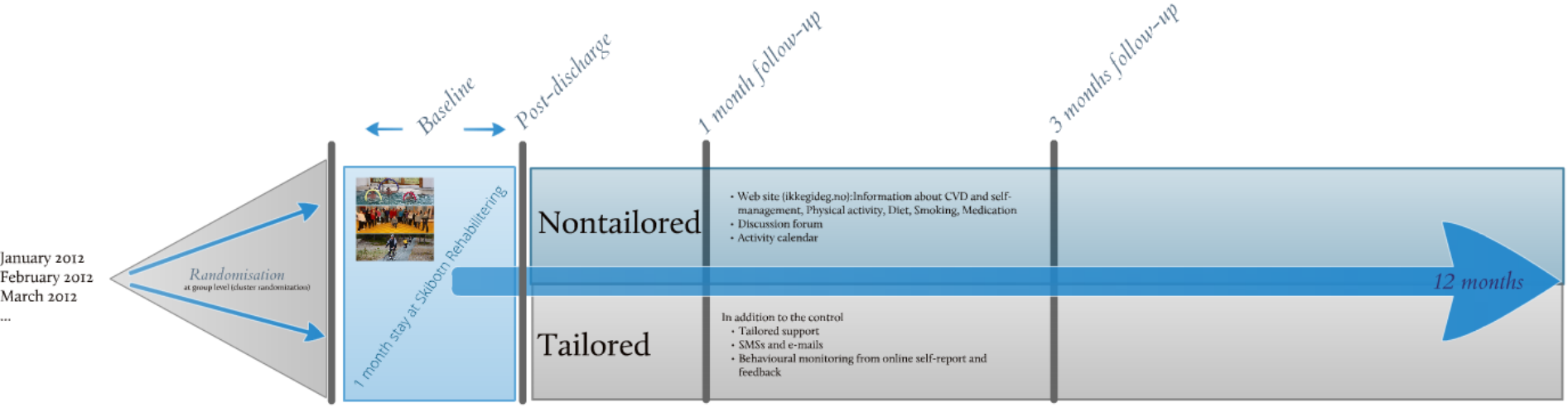
	Study group				
	Tailored		Control		
	Median	IQR	Median	IQR	Comparison test
Self-efficacy at discharge	5.0	2.0	5.0	2.0	K-S Z=0.505, *p=0.521*, r=0.09
Self-efficacy at 1 month after discharge	5.0	2.0	5.0	1.0	K-S Z=0.709, *p=0.273*, r=0.16
Self-efficacy at 3 months after discharge	5.0	2.0	5.5	2.0	K-S Z=0.667,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


Baseline
Post-discharge
1 month follow-up
3 months follow-up
January 2012
February 2012
March 2012
...
Randomisation
at group level (cluster randomization)
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
Tailored
In addition to the control
• Tailored support
• SMSs and e-mails
• Behavioural monitoring from online self-report and feedback
12 months