A Behavioral Change-Based Mobile Intervention for Promoting Regular Physical Activity in Medical Rehabilitation Maintenance of Patients With Coronary Artery Disease: a Controlled Trial

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Abstract

Background: Cardiac rehabilitation is known to reduce coronary artery disease (CAD) severity and symptoms, whereas adoption of a healthy post-rehabilitation lifestyle remains challenging. Innovative eHealth solutions could help, but behavioral change-based eHealth maintenance programs for CAD patients are scarce. RehaPlus+ aims to improve post- rehabilitation outcomes with a personalized eHealth intervention built on behavioral change concepts emphasizing healthy lifestyle changes, especially regular physical activity (PA).

Objective: To evaluate the effectiveness of the personalized eHealth program RehaPlus+ for promoting regular PA against usual care.

Methods: 169 patients with CAD after stent implantation or bypass surgery were divided unblinded into a case manager-assisted 24-week eHealth group (RehaPlus+, n=84) or conventional physician-assisted outpatient program (usual care, n=85) recruited after center-based phase II rehabilitation using a quasi-experimental approach. The study was designed as a non-inferiority trial. RehaPlus+ participants received customized motivational messages twice weekly for six months, while the usual care group engaged in a six-month outpatient program involving 24 sessions of 90-minute strength and endurance training. The primary outcomes, evaluated using the self-assessed BSA questionnaire, were regular PA (? 150 minutes per week) and weekly activities of daily living (ADL) six months post-rehabilitation. Secondary outcomes involved PA during work and floors climbed weekly (BSA), psychological well-being (WHO-5), cardiac self-efficacy (CSE), health-related quality of life (SF-36), and work ability (WAI) via questionnaire.

Results: Data of 105 patients (RehaPlus+: 44, usual care: 61; 80 males, 25 females; mean age 56.0 ± 7.3 years) were available at 6-months follow-up. At 6 months after discharge from phase II CR, the RehaPlus+ group exhibited 182 ± 208 min/week of PA and the usual care group 119 ± 175 min/week (P=.15), with no interaction effect (P=.12). The RehaPlus+ group showed an ADL level of 443 ± 538 min/week compared to the usual care group with 308 ± 412 min/week at 6 months follow-up with no interaction effect (P=.84). The differences observed in PA and ADL levels between the RehaPlus+ and usual care groups were within the predefined non-inferiority margin, indicating that the RehaPlus+ intervention is not inferior to usual care based on these outcomes. There were no differences between the groups for all secondary outcomes (P >.05).

Conclusions: RehaPlus+ is not inferior to the usual care program since both groups improved PA and ADL to a similar extent. These findings emphasize the potential of eHealth interventions to assist in maintaining healthy lifestyles post-rehabilitation. Clinical Trial: ClinicalTrials.gov NCT06162793

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Short title: RehaPlus+ for promoting physical activity

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ABSTRACT

Background: Cardiac rehabilitation is known to reduce coronary artery disease (CAD) severity and symptoms, whereas adoption of a healthy post-rehabilitation lifestyle remains challenging. Innovative eHealth solutions could help, but behavioral change-based eHealth maintenance programs for CAD patients are scarce. RehaPlus+ aims to improve post- rehabilitation outcomes with a personalized eHealth intervention built on behavioral change concepts emphasizing healthy lifestyle changes, especially regular physical activity (PA).

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Conclusions: RehaPlus+ is not inferior to the usual care program since both groups improved PA and ADL to a similar extent. These findings emphasize the potential of eHealth interventions to assist in maintaining healthy lifestyles post-rehabilitation.

Trial Registration: ClinicalTrials.gov NCT06162793

Keywords: rehabilitation; eHealth; mHealth; telemedicine; cardiovascular disease; behavioral change

INTRODUCTION

Coronary artery disease (CAD) is a chronic disease without definitive cure, however, its consequences in terms of restricted physical performance, health-related quality of life, and perceived wellbeing can be minimized. Cardiac rehabilitation (CR) is an evidence-based and class IA recommended therapy [1] provided to minimize the physiological and psychological impact of CAD, decrease morbidity and mortality rates, and to enhance physical performance. CR constitutes a complex approach with a strong focus on physical exercise [2] and cardiovascular risk factor reduction which have been shown to exert the most significant influence on the effectiveness and success of CR [3, 4].

CR can be categorized into three distinct stages (Figure 1) [5]. The initial stage, Phase I CR, is located to acute clinics often following a coronary intervention or surgery. Patients receive education about their health condition and risk factors, with an emphasis on early mobilization and moderate physical activity (PA) [6]. Phase II CR, the reconditioning phase, takes place in inpatient or outpatient CR centers [7], focusing on patient education, supervised exercise training, diet, smoking cessation, and psychological support [8] to reduce cardiovascular risk, enhance exercise capacity, and support personal health management. Successful completion of phase II CR reduces mortality and morbidity risks [9] and restores the ability to work and engage in social activities [10]. Phase III CR, the maintenance phase, emphasizes lifelong self-care, risk factor management, and regular (self-organized) PA [6]. The successful transition from phase II to phase III CR including the implementation of healthy life-style habits are of paramount significance for the long-term health of CAD patients [5].

However, and despite the general effectiveness of Phase II CR [11], cardiovascular risk profiles often deteriorate significantly thereafter [12]. This effect has been attributed to the fact that maintaining a healthy lifestyle including regular PA is challenging for most patients and adequate support is often not available [13]. Existing maintenance programs are largely affected by high monetary expenses for lifelong support if provided by general practitioners and local cardiologists [14, 15]. On the patient’s side, time constraints and travel limitations, impeding participation due to work and family commitments, and general lack of individualization may reduce adherence to center-based care. Additionally, during the COVID-19 pandemic, on-site maintenance programs were largely unavailable [16].

Current eHealth solutions for CR maintenance are spurred by innovative technologies and the growing prevalence of mobile devices among patients. The general momentum toward digitalization including the expansion of mobile data transfer infrastructure aligns with the concept of mobile healthcare. This evolution presents significant prospects for enhanced patient health maintenance, as eHealth applications possess the capacity to amplify rehabilitation effectiveness and to sustain patient support post-discharge [17, 18]. Prior studies have already provided evidence that electronic communication and health information technology in form of eHealth may represents an effective alternative to Phase II CR [19-21] and a recent meta-analysis on the use of eHealth in phase III CR maintenance suggested that eHealth based on behavioral change techniques (BCTs) may assist patients with CAD to achieve improved health outcomes [22]. Most previous eHealth studies in the recent meta-analysis have predominantly utilized text messages and have not explicitly focused on incorporating BCTs. Hence, the present study represents a novelty in this regard, as it is based on behavioral change theories and BCTs, emphasizing the use of individualized messages tailored to the patient's life situation. Another recent study has found that a telehealth program may effectively contribute to behavioral and also emotional recovery following a cardiac event [23].

Objective

Since increasing PA is one of the major goals in phase III CR that has been associated with a 27-35%

decrease in cardiovascular mortality [24], this study aimed to evaluate the effectiveness of an individualized, message-based, eHealth maintenance concept (“RehaPlus+”) for the motivation of CAD patients towards increased PA. Our hypothesis was that RehaPlus+ would be equally effective as the German usual care in form of a center-based maintenance program (Individualized Rehabilitation Aftercare in Post-Acute Treatment, “IRENA”) in terms of supporting regular PA and Activity of Daily Living (ADL), as well as in improvement of psychological well-being, cardiac self-efficacy (CSE), health-related quality of life (QoL), and work ability assessed 6 months after discharge from phase II CR.

METHODS

Study Design and Participants

To compare the effects of the eHealth maintenance program RehaPlus+ to the German usual care in form of a centre-based maintenance program (IRENA, provided by the German pension fund), a quasi-experimental study with a comparison at six-month follow-up (post phase II CR) was performed (Clinical Trials NCT06162793) in accordance with the eHealth CONSORT guidelines (Supplemental document 1). RehaPlus+ has been developed by the Clinic Königsfeld to provide a multimodal eHealth-based aftercare program to CAD patients as alternative to the standard rehabilitation aftercare concept. Main outcomes assessed were PA and ADL. Data for both groups were collected at two timepoints: at the beginning of in-patient CR (baseline; defined as T_0) and at follow-up (24 weeks after discharge; defined as T_1). Both groups transitioned to phase III CR within one or two weeks after discharge from inpatient CR.

Eligibility criteria

The study enrolled patients with documented CAD during in-patient CR (Figure 2). The patients were recruited on-site at Clinic Königsfeld during phase II CR. Enrollment window was within six weeks of a cardiac event or intervention, including post-ST-Elevation Myocardial Infarction (STEMI) and Non-STEMI, and/or stent implantation, and/or bypass surgery. Patients had to declare readiness for behavioral change during phase II CR (see below for details). The patients were required to have the necessary computer and internet skills (assessed in an one-on-one interview) as well as possess a smartphone. Patients with significant language barriers were not eligible to participate.

Ethical considerations

The study complied with the Helsinki Declaration “Ethical Principles for Medical Research Involving Human Subjects” and received approval by the ethics committee of University Witten/Herdecke (#91/2018) and was performed at the medical rehabilitation center Clinic Königsfeld, Germany. Prior to enrollment, all participants provided written informed consent. The patients had the option to withdraw from participation at any time. The data were de-identified, with patients being assigned numerical identifiers. No compensation for participation was provided to the patients.

Group allocation

A quasi-experimental design was chosen as described [25] driven by practical and ethical considerations (IRENA is considered as an effective aftercare concept). This approach enables the examination within the constraints of a real-world setting, where full random allocation is not viable.

Both groups (RehaPlus+ and usual care) participated in two group seminars during Phase II CR (Figure 2). The patients were invited to the initial group seminars based on the Transtheoretical Model of Behavioral Change (TTM),[26-28] where intentional health-relevant behavior change is categorized into different (subsequent) stages (precontemplation, contemplation, preparation, action, maintenance, termination). Since action-oriented programs are unsuitable for individuals in stage 1 or 2,[28] only patients in at least stage 3 were included. Since RehaPlus+ was an experimental program that could not be actively requested by patients, CAD patients eligible to participate were screened between September 2021 and May 2023 using a questionnaire based on the TTM to determine their readiness for behavioral change [29]. Readiness for behavioral change was congruently accepted by participation in the usual care program since patients needed to actively request participation by making an appointment with an assistant and connecting with the providing center.

For the individual counseling sessions, both patient groups registered voluntarily. Patients were then assigned to either usual care or RehaPlus+ program based on the availability of the program in their residential area (30 km radius). Patients with no access to a local center or those who were unable to

participate in the program due occupational reasons were assigned to the RehaPlus+ program. The key difference between the groups was that RehaPlus+ participants received additional support through an application and phone calls in Phase III CR, which included personalized messages and action planning, while usual care took part in the usual care program. Patients of both groups

Intervention (RehaPlus+)

The group seminars were rooted in various psychological theories of health behavior change [27, 30, 31], and concepts of self-efficacy for promoting healthy habits [32]. The initial 60-minute seminar (≤ 15 participants) focused on a health psychological intervention and aimed at elevating participant's self-efficacy expectation through action planning including setting of goals and creating strategies to achieve them. The importance of health-promoting lifestyle changes, including regular PA and ADL, was explained. Participants outlined their health goals and motivations for altering their lifestyle into a structured action plan. During a subsequent 30-minute seminar, coping strategies tailored to distinct circumstances of each participant were discussed. The health psychology group seminars aimed to empower patients to take independent action and enable them to autonomously pursue and achieve their health-related goals. During the individual face-to-face counseling session, participants received their individual access to the application and were guided through the process of installing the messenger application on their smartphone and a comprehensive overview of the associated procedures was provided. For individualization of prompts and messages, habits, identified problems/challenges, work commitments, shift schedules, and aspirations were documented and aligned with the patient's action plan, emphasizing on its feasibility and practicality.

At the end of Phase II CR, the eHealth intervention started for a period of 6 months. The RehaPlus+ participants began receiving motivational and informational messages (3 per week using a mobile phone app; described below), tailored to their individual objectives, training schedule, and working commitments. Participants were contacted by their designated case manager at two and five months via telephone to address any technical challenges as well as barriers encountered in incorporating physical exercise into their daily routine.

Application and messaging

An application was developed for the unidirectional delivery of informative, educational, and motivational messages (Figure 3). The messages were sent using end-to-end encryption technology and patients used a pseudonym to register. No personal data was exchanged via the app. Messages were delivered three times per week with a total of 72 messages within 24 weeks.

The creation process of the messages followed a Delphi approach, involving iterative feedback loops with patients (n=56). Initially, the case manager developed message templates based on common activities. Subsequently, through rounds of anonymous feedback from a panel of patients (n=5), adjustments were made to ensure the messages resonated with their preferences and needs.

Building upon insights gained through the Delphi method, it was identified where individualization would be most beneficial. Messages were then customized accordingly, tailoring them to each patient's specific needs, defined activities, scheduled timing, and considerations such as working hours. Each message was crafted to focus on specific rehabilitation objectives and suitable PAs. This personalized approach ensured that messages were delivered at optimal times to align with the patient's schedule, providing continuous encouragement and guidance throughout the rehabilitation process. Messages were intended to provide continuous encouragement and guidance throughout, delivering nudges and support. As an example, a message reads: "Hello [pseudonym], for today, you have planned to pedal for 30 minutes. Put on your sports shoes and let's get started! Remember, cycling is a great way to improve your cardiovascular fitness and strengthen your leg muscles. Keep up the fantastic work!" The back-end of the system offered a multi-messaging functionality, allowing CMs to prepare predefined messaging queues which were then triggered automatically.

Usual care (IRENA)

In Germany, the phase II CR center assists the individual patient in finding suitable post-rehabilitation facilities offering the usual care program. It is essential that these recommended post-

rehabilitation services are located in a convenient distance to patient's residence (< 30 km) .[33] The usual care program "IRENA" is a multimodal post-rehabilitation program which comprises 24 sessions conducted in small groups with a maximum of 10 participants and begins the end of Phase II CR for a period of 6 months. Each session includes a 90-minute combination of strength and endurance training as well as information, motivation and education as described.[34] The program includes both an initial assessment and a concluding discussion.

Blinding

Due to the nature of the intervention, blinding was not possible.

Outcomes

Primary study outcomes were defined as self-reported PA and ADL at 24 weeks (6 months) after discharge, assessed by questionnaire at 4 weeks prior to rehabilitation (baseline) and 6 months follow-up (see below). Secondary study outcomes included PA at work and floors climbed per week at 6 months follow-up as well as change in psychological well-being, cardiac self-efficacy, health-related QoL and work ability from 4 weeks prior to rehabilitation to 6 months follow-up, all assessed by questionnaire.

Questionnaires

PA and ADL (including PA at work and climbed floors per week) were assessed by the validated German Bewegungs- und Sportaktivität (BSA) questionnaire [35]. Health-related QoL was assessed through the validated German version of the Short Form (36) Health Survey (SF-36; 4-week version, Cronbach α: 0.87 - 0.89) following the guidelines of the RAND Corporation. The SF-36 physical and mental component subscores (PCS/MCS) were calculated according to Ware et al [36]. Subjective psychological well-being was assessed using the validated 5-item World Health Organization Well-Being Index (WHO-5(Cronbach α: 0.92)) [37]. Work ability was evaluated using the validated [38] Work Ability Index (WAI(Cronbach α: 0.58 – 0.77)) [39]. Cardiac self-efficacy was measured using the validated CSE Scale (Cronbach α: 0.87 – 0.90) [40]. All outcomes were self-assessed through online questionnaires.

Statistical analyses

Statistical analyses were performed using SPSSv28 software (IBM, Armonk, NY, USA) and GraphPad Prism V10 (GraphPad Software, Boston, USA). Constant variables are expressed as mean ± standard deviation (SD), median (range), or 95% CI as indicated. Categorical variables are presented as n (%). The normal distribution was statistically and graphically tested via Kolmogorov-Smirnov Test. Differences between groups over time (RehaPlus+ vs usual care) were analyzed using two-way ANOVA. MANOVA with two measurement time points, with gender and group as between-subject factors, was conducted to assess the difference between women and men. Categorical variables (gender, education, occupation, and marital status) were analyzed using Chi-square test. Data was analyzed for outliers using the ROUT option under GraphPad Prism. Data points falling outside the 1% threshold were considered outliers and potentially excluded from the analysis. Cohen *d* was used to express effect sizes (ES). Power calculation was performed using G*Power (G*Power, V3.1.9, Germany). Sample size was calculated based on unpublished data on PA in CAD patients assessed by BSA with an ES of d=0.4 and a non-inferiority limit of half the SD, suggesting that a sample size of 100 participants (50 per group) would result in a statistical power of 1-beta = 0.80 at alpha = 0.05. A non-inferiority comparison between the RehaPlus+ group and the usual care group was conducted using a pre-defined margin, assessed by calculating the 95% CI around the primary endpoint. The non-inferiority margin was set at half the SD of 87.5 of the primary endpoint, to represent a clinically acceptable difference between the new intervention and the established standard therapy. According to this approach, a difference less than this non-inferiority limit between the groups is considered irrelevant (not meaningful).[41] The one-sided interpretation of results was based on the meaningful differences. Responder analysis was performed for PA, ADL, PA at work and floors climbed per week as described using the typical error (TE) method and the following equation: $TE = SD_{diff} / \sqrt{2}$, where SD_{diff} is calculated as the difference between the variance (SD) of

two repeated measures [42]. Responders were defined as participants who demonstrated an increase greater than 2×TE away from zero. Statistical significance was accepted at $p < .05$.

RESULTS

A total of 1,258 eligible patients with CAD were screened and 169 were included (see flowchart, Figure 4). Participants' baseline characteristics are presented in Table 1. Following a three-week period of inpatient CR, patients transitioned to the long-term follow-up phase. After six months, 31/75 (41.3%) of the RehaPlus+ group and 22/83 (26.5%) of the usual care group were lost to follow-up (*P*=.07), respectively, mainly due to contacting problems for follow-up examinations. The final analysis included 105 patients with assessments at both time points (RehaPlus+, n=44, usual care, n= 61). During the study, a total of 72 individual messages was sent to each patient in the RehaPlus+ group as planned (100%). In general, patients indicated that the messages were motivating and that they served as helpful reminders for performing regular PA. Additionally, the handling of the messaging system was found to be straightforward and user-friendly by the CMs, further contributing to its efficiency in supporting patient engagement.

Primary outcome

Physical activity

At 6 months after discharge from phase II CR, the RehaPlus+ group exhibited 182 ± 208 min of PA per week, while the usual care group exhibited 119 ± 175 min/week (*P*=.12). To ensure statistical robustness and impartiality, outliers were removed (n=2), without any effect on the observed results (*P*=0.10). Over time (T_0 to T_1) both groups combined showed a significant increase in PA per week with an average increase of 92 ± 211 min per week from pre-rehabilitation to 6-months follow-up (Figure 5A; *P*=.001). There were no significant effects of gender over time in terms of change in PA levels (*P*=.10). Notably, a responder analysis for PA revealed that 31/44 (70%) of RehaPlus+ participants were responders compared to 29/61 (48%) in the usual care group.

Activity of daily living

The RehaPlus+ group showed an ADL level of 443 ± 538 min/week compared to the usual care group with 308 ± 412 min/week at 6 months follow-up without significance (Table 2; *P*=.84). Of note, ADL levels were already higher in the RehaPlus+ group at baseline assessment. Removal of outliers (n=7) had no effect on the observed results (*P*=.37). Over time (T_0 to T_1), both groups combined showed a significant increase in ADL per week from pre-rehabilitation to 6-months follow-up compared to T_0 (Figure 5B, 131 ± 472 min; *P*=.006) without significant gender effects (*P*=.38). A responder analysis for ADL revealed that 20/44 (45%) of RehaPlus+ participants were responders compared to 20/61 (33%) in the usual care group.

Secondary outcomes

Physical activity during work

At 6-months follow-up (T_1), the RehaPlus+ group and usual care group both reported an average level of PA at work of 6 (6) (Table 2; *P*=.96), with no significant time × group interaction effect (+1 (11), *P*=.07). Compared to pre-rehabilitation (T_0), an overall change in the level of PA during work (+ 1 (2); *P*=.028) was observed at 6-months (Figure 5C).

Floors climbed weekly

At T_1, the RehaPlus+ group showed an average of 28.5 ± 32.0 climbed floors per week, while the usual care group had an average of 23.1 ± 29.8 climbed floors per week (Table 2; *P*=.82). Overall, (both groups combined), there was a significant change in floors climbed weekly at 6-months follow-up compared to T_0 with an average increase of 8.6 ± 36.4 floors per week (Figure 5D; *P*=.02).

Psychological well-being

The pre-intervention scores for the RehaPlus+ and the usual care group showed an increase in psychological well-being, with RehaPlus+ group changing from 9.6 ± 8.1 to 12.7 ± 7.0 post-intervention and the usual care group changing from 10.9 ± 6.4 to 12.9 ± 7.2, without a significant time by group interaction (Table 3; *P*=.53). Compared to T_0, an overall change in well-being (+ 2.5 ± 7.6; *P*=.001) was observed at 6-months (Figure 5E).

Cardiac self-efficacy (CSE)

The baseline values of CSE were significantly different, with the RehaPlus+ group starting with a significantly higher value (*P*=.001). The pre-intervention scores for the RehaPlus+ and the usual care group showed an increase in CSE, with the RehaPlus+ group changing from 29.5 ± 9.8 to 31.8 ± 9.2 post-intervention and the usual care group changing from 20.9 ± 15.6 to 30.2 ± 12.0, with a significant time by group interaction (Table 3; *P*=.03). Over all patients at 6-months follow-up, there was a significant change in CSE, compared to T_0 with an average increase of 6.3 ± 16.3 (Figure 5F; *P*=.001).

Work ability

At T_0, the RehaPlus+ group had an average WAI score of 23.0 ± 10.6 at baseline and an average score of 23.0 ± 11.0 at T_1, while the usual care group decreased from 23.6 ± 10.2 to 22.6 ± 10.8, however without a significant difference between the groups (Table 3; *P*=.66).

Health-related QoL

The SF-36 scores were comparable between both groups at T_0, however the usual care group started with a higher MCS score (*P*=.03). Over time (T_0 to T_1) health-related QoL changed significantly during phase III CR over both groups combined (RehaPlus+, MCS + 14%, PCS + 18%; usual care, MCS + 12%, PCS + 17%, *P*=.05) with no difference between the groups (*P*=.36) (Figure 6).

DISCUSSION

The aim of the present study was to evaluate the efficacy of the multimodal, behavioral change-based maintenance program RehaPlus+ and to determine its non-inferiority to the German usual care. In brief, the main findings of the study are that 1) the RehaPlus+ program, which utilizes behavioral change techniques and theories delivered partly via eHealth, was found to be non-inferior to the usual care program, 2) both interventions induced a comparable and significant increase in PA during work, floors climbed weekly, psychological well-being, CSE, work ability and health-related QoL, 3) the implementation of the RehaPlus+ messaging system was perceived as user-friendly by the involved case-managers. The analysis revealed that there were no significant differences between the RehaPlus+ and usual care group across outcome measures.

RehaPlus+ uses a range of established BCTs such as goal-setting, action-planning, motivational and coping strategies to empower cardiac patients to make positive lifestyle changes. BCTs are designed to target and modify a specific behavior that plays a role in overall health and well-being. Goal-setting as one central component likely empowered participants to establish clear and attainable objectives related to their desired outcomes, as research highlights the effectiveness of these techniques in promoting PA in cardiology patients [43]. Action planning is crucial in the initial phases of rehabilitation, while coping strategies are hypothesized to facilitate the long-term maintenance of behavior change [44]. Coping strategies may have helped RehaPlus+ participants to identify and address barriers, enabling them to develop strategies for overcoming challenges and sustain their progress. This is supported by the observation that individuals with higher levels of coping planning post-discharge are more likely to engage in increased levels of exercise [45]. Coping

planning is a self-regulation strategy designed to anticipate and counteract personal risk situations that threaten intended behavior. It creates a mental connection between potential risks and appropriate coping responses [45]. It has been demonstrated that people who effectively plan for high-risk situations, like exercise relapse, are less likely to give in to these challenges [46]. This approach is aligned with techniques used in cognitive behavioral therapy, where anticipating and preparing for potential challenges helps manage unwanted behaviors. While action planning facilitates task execution, coping planning focuses on avoiding distractions. The effectiveness of coping planning increases over time with experience, as it relies on an individuals' understanding of their personal risk situations and responses. This strategy is crucial for maintaining focus on long-term goals and preventing unwanted behaviors [45]. Coping planning interventions are found to be effective, especially when participants receive support in developing their coping plans [47]. This approach is similar to the one employed in the RehaPlus+ program, where guided assistance in coping plan formulation is a key component.

In RehaPlus+, the implementation of BCTs may have contributed to the development of healthy exercise habits and enhanced self-efficacy for lifestyle changes. However, it is crucial to assess the respective contributions of the technology-driven message delivery system and the support provided by the case managers to the overall success of the intervention. The case manager met the patient in a face-to-face session and helped to create an action plan and set goals, considering potential barriers. The case manager then developed a tailored message chain for the patient, taking into account the discussed goals and planned actions. Additionally, the case manager contacted the patients during two phone calls to adjusted the timing or content of the messages as needed based on changes in activities or work schedules. This aspect represents a common challenge in studies of this nature, and the individual impact of each component on the outcomes cannot be differentiated.

According to HAPA,[31] the maintenance of health behavior requires specific input, including: a) action planning, to specify situation parameters ("when", "where") and a sequence of action ("how") to implement intended behavior, b) action control, to help sustaining the behavioral change and c) coping planning as a self-regulatory strategy or alternative behavior to overcome barriers. Therefore, RehaPlus+ case managers suggested practical solutions to everyday barriers motivating participants to incorporate "what-if" sentences to their individual action plans. These sentences focus potential obstacles and simultaneously identified solutions, such as "If it's raining during my scheduled outdoor workout, I will move indoors and complete my exercise routine." RehaPlus+ aimed to motivate CAD patients towards increased, self-organized PA as well as increased ADL through targeted lifestyle adjustments and health-promoting behavior in everyday life. In contrast, the usual care program, focuses on promoting PA through regular appointments for guided group-based exercise sessions. However, despite its targeted focus on PA, usual care did not demonstrate superiority over RehaPlus+. Both programs were effective in promoting PA, suggesting that different methodologies in rehabilitation can be equally successful in achieving similar outcomes in PA enhancement.

With regard to ADL, a recent meta-analysis reported significant effects of different e-Health interventions in increasing walking steps in elderly [48], suggesting that e-Health has the potential to effectively enhance everyday activities with minimal barriers and versatility in practice. Our data support these findings in that the RehaPlus+ group showed an increase in ADL, likely caused by the fact that RehaPlus+ was designed to stimulate a broader range of daily activities. This observation is consistent with previous research [49] emphasizing the significant impact of BCTs on habit formation, which play a crucial role in maintaining regular exercise routines for cardiovascular health promotion. The effects of RehaPlus+ may also relate to the personalized approach, which considered individual barriers. Tailoring the intervention to individual characteristics and preferences is a crucial aspect of ensuring the success of the rehabilitation program. By focusing also on implementation, RehaPlus+ seeked to maximize the effectiveness of the BCTs, aligning them with the unique needs of each patient. This approach is in line with the principle that the success of

behavior change interventions is significantly influenced by how well they are adapted to individual patient profiles [50], ensuring that the strategies employed are not only theoretically sound but also practically relevant and effective in the specific context of each patients' rehabilitation journey. However, it is possible that the combination of human intervention and personal contact during the maintenance period together with the use of technology may have contributed to the observed treatment effect synergistically. RehaPlus+ integrates a personalized eHealth intervention with behavioral change concepts, emphasizing healthy lifestyle changes also supported by case managers. It is likely that the personal contact enhances the value and trustworthiness of the messages, further enhancing the effectiveness of the intervention. In addition, technology enhances accessibility, convenience, and scalability, allowing for continuous engagement at home beyond traditional center visits. Further studies are warranted to delineate the relative contributions of human interaction and technology in driving treatment outcomes. For instance, future investigations could explore the impact of reducing the duration of personal contact or modifying the intensity of the message component.

Based on the assumption that the effectiveness of BCTs relies on an appropriate implementation, which takes into account individual characteristics and preferences. The improvements in health-related QoL, CSE and overall well-being may have likely played a role in adherence to the respective programs.

With respect to the participants' baseline characteristics is seems important to note that approximately 99/105 (94%) of participants did not have qualifications extending beyond high school level. Of note, the RehaPlus+ group had a higher percentage of participants (15/44, 33%) with an educational level exceeding high school. While it is unlikely that these differences may have influenced the outcomes, the finding underscores that eHealth interventions should be adaptable to the individual participant and potential hurdles for patients with lower literacy should be reduced. In general, it is crucial that eHealth solutions, such as mobile applications, should be easily understandable and accessible to all patients, regardless of their educational background. In the context of gender-sensitive care, caregiving can exert distinct mental and physical health effects depending on gender roles and societal expectations. A gender-sensitive approach allows for tailored interventions and support systems, acknowledging and mitigating these unique health impacts experienced by caregivers of different genders.

The use of eHealth programs such as RehaPlus+ offers several advantages, also in terms of cost-effectiveness [51]. In this case, the outpatient usual care program IRENA generates costs of approximately €770 per patient for 24 weeks. In contrast, the costs for RehaPlus+ as eHealth program are calculated with approximately 540€ per patient for 24 weeks [52]. However, RehaPlus+ is scalable, and the costs in other countries will depend on local conditions and circumstances.

Additionally, similar outcomes can be achieved with lower costs, reduced resource utilization, and less staff burden.

Recent systematic reviews have highlighted the cost-effectiveness of cardiac telerehabilitation in a broader context, showing that eHealth interventions hold the capacity to reach a broader and more diverse audience at lower cost [53, 54]. Such programs can overcome geographical barriers, enhancing accessibility for individuals situated in remote or underserved areas. Furthermore, eHealth programs can be structured for self-administration, reducing the demand for extensive human resources, and subsequently lowering operational expenses. However, for a comprehensive assessment, a detailed cost-effectiveness analysis of RehaPlus+ would be required to compare the expenses associated with implementing eHealth programs against the benefits in terms of health outcomes and reduced healthcare utilization.

Limitations

The self-reported nature of PA is one of the major limitations of this study. This method relies on subjective assessments and memory recall, which could lead to biases in reporting participants' actual activity levels, even if likely comparable between both groups. The study experienced considerable loss to follow-up rates, primarily due to difficulties in obtaining questionnaire-based outcome data six months after the intervention. Even though the observed rates were comparable between both groups and equal to previous eHealth, and non-technology-based interventions for behavior maintenance [55-57], it is crucial to thoroughly examine that motivation is a relevant aspect in eHealth approaches, and there is a risk that eHealth interventions may ultimately leave only highly compliant patients. Patients who drop out of eHealth interventions may require different incentives and motivations to stay engaged and achieve their health goals in the long term. To effectively support individuals in earlier stages of change, it may be essential to first implement other interventions aimed at promoting intrinsic motivation for change. These interventions may include motivational interviewing, psychoeducation about the risks and benefits of behavior change, and building self-efficacy through goal-setting and reinforcement. By addressing these factors, individuals in stage 1 or 2 (according to the TTM) can be supported in developing the internal drive necessary for sustained behavior change [28]. Additionally, it is important to acknowledge that baseline data from 11 participants were unavailable for analysis. These participants were prematurely discharged from their rehabilitation due to COVID-19 infections, hindering the completion of baseline assessments. Further, outcomes were measured by questionnaires, and no objective measurements were employed.

Conclusion

The present study demonstrates that the behavioral change-based eHealth maintenance program RehaPlus+ was equally effective as the standard German usual care in promoting regular ADL and PA in patients with CAD. This achievement can be attributed, in part, to the successful utilization of BCTs within the RehaPlus+ program. This study underscores the importance of evidence-based BCTs in eHealth interventions and highlights the need for personalized eHealth intervention strategies. Future research should refine BCT implementation in eHealth programs to improve health behaviors across diverse populations.

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No generative artificial intelligence (AI) was utilized in this manuscript.

Data availability statement

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Author contributions

MW, FM, and BS designed the study. MW coordinated the study. MW and MT enrolled participants. MW supervised group seminars and individual counseling. MW, BS, RG and MK analyzed data and interpreted results. MW and BS drafted the manuscript. All authors read and approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors report no conflicts of interest in this work.

REFERENCES

1. Knuuti J, Wijns W, Saraste A, Capodanno D, Barbato E, Funck-Brentano C, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J. 2020 Jan 14;41(3):407-77. PMID: 31504439. doi: 10.1093/eurheartj/ehz425.
2. Goel K, Lennon RJ, Tilbury RT, Squires RW, Thomas RJ. Impact of cardiac rehabilitation on mortality and cardiovascular events after percutaneous coronary intervention in the community. Circulation. 2011 May 31;123(21):2344-52. PMID: 21576654. doi: 10.1161/CIRCULATIONAHA.110.983536.
3. Balady GJ, Williams MA, Ades PA, Bittner V, Comoss P, Foody JM, et al. Core components of cardiac rehabilitation/secondary prevention programs: 2007 update: a scientific statement from the American Heart Association Exercise, Cardiac Rehabilitation, and Prevention Committee, the Council on Clinical Cardiology; the Councils on Cardiovascular Nursing, Epidemiology and Prevention, and Nutrition, Physical Activity, and Metabolism; and the American Association of Cardiovascular and Pulmonary Rehabilitation. Circulation. 2007 May 22;115(20):2675-82. PMID: 17513578. doi: 10.1161/CIRCULATIONAHA.106.180945.
4. Heran BS, Chen JM, Ebrahim S, Moxham T, Oldridge N, Rees K, et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2011 Jul 6(7):CD001800. PMID: 21735386. doi: 10.1002/14651858.CD001800.pub2.
5. Giuliano C, Parmenter BJ, Baker MK, Mitchell BL, Williams AD, Lyndon K, et al. Cardiac Rehabilitation for Patients With Coronary Artery Disease: A Practical Guide to Enhance Patient Outcomes Through Continuity of Care. Clin Med Insights Cardiol. 2017;11:1179546817710028. PMID: 28638244. doi: 10.1177/1179546817710028.
6. Simon M, Korn K, Cho L, Blackburn GG, Raymond C. Cardiac rehabilitation: A class 1 recommendation. Cleve Clin J Med. 2018 Jul;85(7):551-8. PMID: 30004380. doi: 10.3949/ccjm.85a.17037.
7. Bjarnason-Wehrens B, McGee H, Zwisler AD, Piepoli MF, Benzer W, Schmid JP, et al. Cardiac rehabilitation in Europe: results from the European Cardiac Rehabilitation Inventory Survey. Eur J Cardiovasc Prev Rehabil. 2010 Aug;17(4):410-8. PMID: 20300001. doi: 10.1097/HJR.0b013e328334f42d.
8. Walsh DMJ, Moran K, Cornelissen V, Buys R, Claes J, Zampognaro P, et al. The development and codesign of the PATHway intervention: a theory-driven eHealth platform for the self-management of cardiovascular disease. Transl Behav Med. 2019 Jan 1;9(1):76-98. PMID: 29554380. doi: 10.1093/tbm/iby017.
9. Dalal HM, Doherty P, Taylor RS. Cardiac rehabilitation. BMJ. 2015 Sep 29;351:h5000. PMID: 26419744. doi: 10.1136/bmj.h5000.
10. American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs. Kinetics H.
11. Janssen V, De Gucht V, van Exel H, Maes S. A self-regulation lifestyle program for post-cardiac rehabilitation patients has long-term effects on exercise adherence. J Behav Med. 2014 Apr;37(2):308-21. PMID: 23334387. doi: 10.1007/s10865-012-9489-y.
12. Hansen D, Dendale P, Raskin A, Schoonis A, Berger J, Vlassak I, et al. Long-term effect of rehabilitation in coronary artery disease patients: randomized clinical trial of the impact of exercise volume. Clin Rehabil. 2010 Apr;24(4):319-27. PMID: 20176771. doi: 10.1177/0269215509353262.
13. Bjarnason-Wehrens B, Grande G, Loewel H, Voller H, Mittag O. Gender-specific issues in cardiac rehabilitation: do women with ischaemic heart disease need specially tailored programmes? Eur J Cardiovasc Prev Rehabil. 2007 Apr;14(2):163-71. PMID: 17446793. doi: 10.1097/HJR.0b013e3280128bce.
14. Russell MW, Huse DM, Drowns S, Hamel EC, Hartz SC. Direct medical costs of coronary

artery disease in the United States. Am J Cardiol. 1998 May 1;81(9):1110-5. PMID: 9605051. doi: 10.1016/s0002-9149(98)00136-2.
15. Tarride JE, Lim M, DesMeules M, Luo W, Burke N, O'Reilly D, et al. A review of the cost of cardiovascular disease. Can J Cardiol. 2009 Jun;25(6):e195-202. PMID: 19536390. doi: 10.1016/s0828-282x(09)70098-4.
16. Drwal KR, Forman DE, Wakefield BJ, El Accaoui RN. Cardiac Rehabilitation During COVID-19 Pandemic: Highlighting the Value of Home-Based Programs. Telemed J E Health. 2020 Nov;26(11):1322-4. PMID: 32552412. doi: 10.1089/tmj.2020.0213.
17. Silva-Cardoso J, Juanatey JRG, Comin-Colet J, Sousa JM, Cavalheiro A, Moreira E. The Future of Telemedicine in the Management of Heart Failure Patients. Card Fail Rev. 2021 Mar;7:e11. PMID: 34136277. doi: 10.15420/cfr.2020.32.
18. Schmitz B GD, Peña-Gil C, et al. Patient-centered cardiac rehabilitation by AI-powered lifestyle intervention – the timely approach. Atherosclerosis. 2022 (355):251. doi: 10.1016/j.atherosclerosis.2022.06.959.
19. Chen J, Sun D, Zhang S, Shi Y, Qiao F, Zhou Y, et al. Effects of home-based telerehabilitation in patients with stroke: A randomized controlled trial. Neurology. 2020 Oct 27;95(17):e2318-e30. PMID: 32999058. doi: 10.1212/WNL.0000000000010821.
20. Pakrad F, Ahmadi F, Grace SL, Oshvandi K, Kazemnejad A. Traditional vs Extended Hybrid Cardiac Rehabilitation Based on the Continuous Care Model for Patients Who Have Undergone Coronary Artery Bypass Surgery in a Middle-Income Country: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2021 Nov;102(11):2091-101 e3. PMID: 34175270. doi: 10.1016/j.apmr.2021.04.026.
21. Rawstorn JC, Gant N, Direito A, Beckmann C, Maddison R. Telehealth exercise-based cardiac rehabilitation: a systematic review and meta-analysis. Heart. 2016 Aug 1;102(15):1183-92. PMID: 26936337. doi: 10.1136/heartjnl-2015-308966.
22. Heimer M, Schmitz S, Teschler M, Schafer H, Douma ER, Habibovic M, et al. eHealth for maintenance cardiovascular rehabilitation: a systematic review and meta-analysis. Eur J Prev Cardiol. 2023 May 8. PMID: 37154363. doi: 10.1093/eurjpc/zwad145.
23. Rogerson MC, Jackson AC, Navaratnam HS, Le Grande MR, Higgins RO, Clarke J, et al. Behavioural and psychological telehealth support for people with cardiac conditions: Randomised trial of the 'Back on Track' self-management program. Eur J Cardiovasc Nurs. 2023 Mar 29. PMID: 36989400. doi: 10.1093/eurjcn/zvad034.
24. Lollgen H, Lollgen D. [Risk reduction in cardiovascular diseases by physical activity]. Internist (Berl). 2012 Jan;53(1):20-9. PMID: 22086105. doi: 10.1007/s00108-011-2889-1.
25. Axelrod DA, Hayward, R. Nonrandomized Interventional Study Designs (Quasi-Experimental Designs). In: Penson, D.F., Wei, J.T. (eds) Clinical Research Methods for Surgeons. Humana Press. 2006. doi: 10.1007/978-1-59745-230-4_4.
26. Prochaska J.O, DiClemente C.C.. Toward a comprehensive model of change. In W R Miller & N Heather, Applied clinical psychology Treating addictive behaviors: Processes of change. 1986:3-27.
27. Prochaska J.O, DiClemente C.C. The transtheoretical approach. In J C Norcross & M R Goldfried (Eds), Handbook of psychotherapy integration 1992:300-34.
28. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot. 1997 Sep-Oct;12(1):38-48. PMID: 10170434. doi: 10.4278/0890-1171-12.1.38.
29. Marshall SJ, Biddle SJ. The transtheoretical model of behavior change: a meta-analysis of applications to physical activity and exercise. Ann Behav Med. 2001 Fall;23(4):229-46. PMID: 11761340. doi: 10.1207/S15324796ABM2304_2.
30. Schwarzer R. Modeling health behavior change: How to predict and modify the adoption and maintenance of health behaviors. Applied Psychology: An International Review. 2008;57 (1):1-29. doi: 10.1111/j.1464-0597.2007.00325.x.

31. Schwarzer R. Self-efficacy in the adoption and maintenance of health behaviors: Theoretical approaches and a new model. R S, editor1992. 217-43 p.
32. Bandura A. Self-efficacy: the exercise of control. New York: Freeman. 1997.
33. Deutsche Rentenversicherung. Rahmenkonzept zur Nachsorge für medizinische Rehabilitation nach § 15 SGB VI. 2015.
34. Deutsche Rentenversicherung. Fachkonzept "IRENA®". 2021.
35. Fuchs R KS, Gerber M, Seelig H. Messung der Bewegungs- und Sportaktivitaet mit dem BSA-Fragebogen. Zeitschrift für Gesundheitspsychologie. 2015;23(2):60-76.
36. Ware JE KM, Keller S. SF-36 physical and mental health summary scales. A user's manual. Boston: Health Institute, New England Medical Center.1994.
37. Topp CW, Ostergaard SD, Sondergaard S, Bech P. The WHO-5 Well-Being Index: a systematic review of the literature. Psychother Psychosom. 2015;84(3):167-76. PMID: 25831962. doi: 10.1159/000376585.
38. Martus P, Jakob O, Rose U, Seibt R, Freude G. A comparative analysis of the Work Ability Index. Occup Med (Lond). 2010 Oct;60(7):517-24. PMID: 20573840. doi: 10.1093/occmed/kqq093.
39. Ilmarinen J, Tempel, J. Erhaltung, Förderung und Entwicklung der Arbeitsfähigkeit — Konzepte und Forschungsergebnisse aus Finnland. In: Badura, B., Schellschmidt, H., Vetter, C. (eds) Demographischer Wandel: Herausforderung für die betriebliche Personal- und Gesundheitspolitik. Fehlzeiten-Report: Springer, Berlin, Heidelberg. 2003.
40. Sullivan MD, LaCroix AZ, Russo J, Katon WJ. Self-efficacy and self-reported functional status in coronary heart disease: a six-month prospective study. Psychosom Med. 1998 Jul-Aug;60(4):473-8. PMID: 9710293. doi: 10.1097/00006842-199807000-00014.
41. Kishore K, Mahajan R. Understanding Superiority, Noninferiority, and Equivalence for Clinical Trials. Indian Dermatol Online J. 2020 Nov-Dec;11(6):890-4. PMID: 33344335. doi: 10.4103/idoj.IDOJ_130_20.
42. Schmitz B, Niehues H, Thorwesten L, Klose A, Kruger M, Brand SM. Sex Differences in High-Intensity Interval Training-Are HIIT Protocols Interchangeable Between Females and Males? Front Physiol. 2020;11:38. PMID: 32063866. doi: 10.3389/fphys.2020.00038.
43. Luszczynska A, Scholz U, Schwarzer R. The general self-efficacy scale: multicultural validation studies. J Psychol. 2005 Sep;139(5):439-57. PMID: 16285214. doi: 10.3200/JRLP.139.5.439-457.
44. Baker A, Cornwell P, Gustafsson L, Stewart C, Lannin NA. Developing tailored theoretically informed goal-setting interventions for rehabilitation services: a co-design approach. BMC Health Serv Res. 2022 Jun 22;22(1):811. PMID: 35733190. doi: 10.1186/s12913-022-08047-6.
45. Sniehotta FF SR, Scholz U, Schüz B. Action planning and coping planning for long-term lifestyle change: theory and assessment. European Journal of Social Psychology. 2005;35(4):565-76.
46. Simkin LR, Gross AM. Assessment of coping with high-risk situations for exercise relapse among healthy women. Health Psychol. 1994 May;13(3):274-7. PMID: 8055862. doi: 10.1037//0278-6133.13.3.274.
47. Dominika Kwasnicka JP, Martin White & Falko F. Sniehotta. Does planning how to cope with anticipated barriers facilitate health-related behaviour change? A systematic review. Health Psychology Review. 2013;7(2):129-45. doi: 10.1080/17437199.2013.766832.
48. Kwan RYC, Salihu D, Lee PH, Tse M, Cheung DSK, Roopsawang I, et al. The effect of e-health interventions promoting physical activity in older people: a systematic review and meta-analysis. Eur Rev Aging Phys Act. 2020;17:7. PMID: 32336996. doi: 10.1186/s11556-020-00239-5.
49. Moore SM, Charvat JM, Gordon NH, Pashkow F, Ribisl P, Roberts BL, et al. Effects of a CHANGE intervention to increase exercise maintenance following cardiac events. Ann Behav Med. 2006 Feb;31(1):53-62. PMID: 16472039. doi: 10.1207/s15324796abm3101_9.
50. Hardcastle SJ, Hagger MS. Psychographic Profiling for Effective Health Behavior Change Interventions. Front Psychol. 2015;6:1988. PMID: 26779094. doi: 10.3389/fpsyg.2015.01988.

51. Frederix I, Solmi F, Piepoli MF, Dendale P. Cardiac telerehabilitation: A novel cost-efficient care delivery strategy that can induce long-term health benefits. Eur J Prev Cardiol. 2017 Nov;24(16):1708-17. PMID: 28925749. doi: 10.1177/2047487317732274.
52. Deutsche Rentenversicherung. Kernangebote der Reha-Nachsorge. Anlage 1 zum Rahmenkonzept zu Nachsorge nach medizinischer Rehabilitation. 2024.
53. Shields GE, Wells A, Doherty P, Heagerty A, Buck D, Davies LM. Cost-effectiveness of cardiac rehabilitation: a systematic review. Heart. 2018 Sep;104(17):1403-10. PMID: 29654096. doi: 10.1136/heartjnl-2017-312809.
54. Scherrenberg M FM, Dendale P. Cost-effectiveness of cardiac telerehabilitation in coronary artery disease and heart failure patients: systematic review of randomized controlled trials. European Heart Journal - Digital Health. 2020;1(1):20-9. doi: 10.1093/ehjdh/ztaa005.
55. Eysenbach G. The law of attrition. J Med Internet Res. 2005 Mar 31;7(1):e11. PMID: 15829473. doi: 10.2196/jmir.7.1.e11.
56. Wangberg SC, Bergmo TS, Johnsen JA. Adherence in Internet-based interventions. Patient Prefer Adherence. 2008 Feb 2;2:57-65. PMID: 19920945.
57. Fjeldsoe B, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior change following physical activity and dietary interventions. Health Psychol. 2011 Jan;30(1):99-109. PMID: 21299298. doi: 10.1037/a0021974.

Figure legends

Figure 1: Stages of cardiac rehabilitation (CR). In phase III CR, the usual care program can be prescribed as an outpatient program to patients in Germany. Nearby (< 30 km) usual care centers are not always available, leading to many individuals without post-rehabilitation program alternatives. EHealth programs such as RehaPlus+ may bridge this gap by providing a readily available alternative for patients with coronary artery disease (CAD).

Figure 2: Study design. Patients were recruited at the beginning of the three-week inpatient cardiac rehabilitation (baseline, T_0) and participated in the RehaPlus+ or usual care program, depending on local availability after discharge (24-weeks maintenance phase). Only patients indicating willingness to change were included. The RehaPlus+ and usual care group attended two group seminars and one face-to-face individual counseling session in Phase II CR. In Phase III CR RehaPlus+ recipients received three customized motivational text messages weekly for six months, while the usual care group engaged in a six-month outpatient program involving 24 sessions of 90-minute strength and endurance training.
Follow-up examinations, were conducted 24 weeks after discharge (T_1). CAD, coronary artery disease; CR, cardiac rehabilitation.

Figure 3: Sample message. Each RehaPlus+ patient received a total of 72 messages over a period of 24 weeks.

Figure 4: CONSORT-Flowchart. One hundred and sixty-nine patients referred to either a 24-week e-Health group (RehaPlus+, n=84) or a conventional center-based program (usual care, n=85). Eleven patients (RehaPlus+, n=9; usual care, n=2) did not complete the baseline assessment due to premature discharge. Thirty-one and twenty-two patients were lost to follow up due to contacting problems for RehaPlus+ and for usual care, respectively. The final analysis included 105 patients (RehaPlus+, n=44; usual care, n=61).

Figure 5: Changes in primary and secondary outcome measures over 6 months. All variables were assessed by questionnaire at T_0 (start of phase II CR) and after 24 weeks. Overall, a significant increase at 6-months follow-up compared to baseline was detected in physical activity (P=0.001), activity of daily living (P=0.006), physical activity during work (P=0.028), floors climbed weekly (P=0.018), well-being (P=0.001) and CSE (P=0.001) with no significant difference between groups. Data is presented as mean ± SD. Differences between groups over time (RehaPlus+ vs usual care) were analyzed using two-way ANOVA.

Figure 6: Health-related quality of life assessed by SF-36 questionnaire. At baseline, SF-36 scores were comparable between both groups, although the usual care group had a higher MCS score (P=0.033). Both groups increased their pre-intervention score with no difference observed between the two groups ($p \geq 0.362$). Data is presented as 95% CI; changes over time between groups (time x group interaction) were calculated using general linear model. SF-36 score range 0 – 100 (higher = greater wellbeing). PF, physical functioning; RP, role physical; RE, role emotional; Vit, vitality; MH, mental health; SF, social functioning; BP, bodily pain; GH, general health; PCS, physical component summary; MCS, mental component summary.

Tables

Table 1: Patients' characteristics

	Overall (n=105)	RehaPlus+ (n=44)	Usual care (n=61)	*P*-value
Demographic data				
Age, years	54.9 ± 7.2	53.6 ± 8.1	56.2 ± 6.2	.06
Sex, n (%)				
female	25 (24)	12 (27)	13 (21)	.47
male	80 (76)	32 (73)	48 (79)	
Height, cm	177.5 ± 9.1	179.3 ± 9.1	176.0 ± 8.9	.06
Weight, kg	94.1 ± 18.2	98.2 ± 16.6	90.7 ± 18.9	**.03**
BMI, kg*m^{-2}	29.8 ± 5.3	30.6 ± 5.2	29.2 ± 5.4	.14
Education[#] (%)				
< High School	73 (94)	22 (67)	51 (94)	**.002**
≥ High School	13 (6)	10 (33)	3 (6)	
Occupation[€] (%)				
Worker	22 (22)	8 (19)	14 (25)	.53
Employee	71 (71)	33 (77)	38 (67)	.27
Self-employed	5 (5)	1 (2)	4 (7)	.15
Retiree	2 (2)	1 (2)	1 (1)	.84
Unemployed	0 (0)	0 (0)	0 (0)	
Marital Status[£] (%)				
Single	24 (24)	9 (21)	15 (26)	.52
Married	63 (62)	27 (61)	36 (63)	.37
Divorced	12 (12)	7 (16)	5 (9)	.08
Widowed	2 (2)	1 (2)	1 (2)	.85
Clinical data				
Diseases of the circulatory system				
Coronary artery disease, n (%)				
one vessel disease	31 (30)	13 (30)	18 (30)	.84
two vessel disease	39 (37)	18 (41)	21 (34)	.81
three vessel disease	35 (33)	13 (30)	22 (36)	.62
STEMI/N-STEMI, n (%)	59 (56)	26 (59)	33 (54)	.63
Cardiac arrhythmia, n (%)	6 (6)	4 (9)	2 (3)	.29
Arterial hypertension, n (%)	78 (74)	32 (72)	46 (75)	.55
Pulmonary embolism, n (%)	6 (5)	3 (7)	3 (5)	.53
Endocrine, nutritional or metabolic diseases, n (%)				
Obesity	28 (24)	13 (25)	15 (24)	.94
Type 2 diabetes mellitus	16 (15)	4 (9)	12 (19)	.18
Other	75 (71)	33 (75)	42 (68)	.59

(Hypo/hyper)tyroidism, n (%)	10 (9)	6 (11)	4 (6)	.36
Diseases of the musculoskeletal system/ connective tissue, n (%)	20 (19)	9 (20)	11 (18)	.98
Depressive/ adjustment disorders, n (%)	18 (17)	8 (18)	10 (16)	.99
Medication				
ACE inhibitor	54 (47)	22 (42)	32 (51)	.32
Statin	102 (97)	42 (95)	60 (98)	.15
Beta blocker	94 (89)	36 (82)	56 (91)	.36
AT-II receptor blocker	37 (32)	18 (34)	19 (30)	.67
Calcium channel blocker	22 (19)	8 (15)	14 (22)	.33
Anticoagulant	103 (98)	42 (95)	61 (100)	.45
Antiarrhythmic	1 (1)	1 (2)	0 (0)	.27
Diuretic	41 (39)	22 (50)	19 (31)	**.03**
Analgesic	13 (11)	6 (11)	7 (11)	.97
Antidepressant	5 (5)	2 (5)	3 (5)	.53
Diabetes medication	18 (17)	5 (11)	13 (21)	.12

Data is presented as mean ± SD or n (%). Between-group comparison was performed using unpaired two-sided t-test or Chi-square test. [#]Nineteen participants did not provide their educational level (RehaPlus+ = 12, usual care = 7). BMI, Body Mass Index. [€]Five participants did not provide their occupation level (RehaPlus+ = 1, usual care = 4). [£]Four participants did not provide their marital status (RehaPlus+ = 0, usual care = 4).

Table 2: Physical activity at 6-months follow-up by group

	Overall (N=105)	***P*-value time**	**RehaPlus+ (n=44)**	**Usual care (n=61)**	***P* -value group**	**95% CI Interaction**
Physical activity (PA)						
T0	53.8 ± 164.8		52.4 ± 127.1	54.7 ± 188.3	.99	
T1	145.5 ± 191.0		181.85 ± 207.84	119.20 ± 174.89	.15	
Δ	91.7 ± 210.8	**.001**	129.5 ± 220.6	64.5 ± 200.9	.12	
95% CI	-132.5 to -50.9		-196.5 to -62.4	-115.9 to -13.0		-127.2 to 11.2
Activity of daily living (ADL)						
T0	233.7 ± 365.9		300.5 ± 469.1	185.43 ± 262.2	.31	
T1	364.6 ± 471.0		442.79 ± 537.93	308.27 ± 411.52	.20	
Δ	131.0 ± 472.0	**.006**	142.3 ± 574.6	122.8 ± 386.5	.84	
95% CI	-210.2 to -30.6		-317.0 to 32.4	-197.8 to -11.0		-200.3 to 75.9
Levels of physical activity at work						
T0	5 (9)		4 (9)	5 (9)	.08	
T1	6 (6)		6 (6)	6 (6)	.96	
Δ	1 (2)	**.03**	1 (11)	0 (12)	.07	
95% CI	-1.0 to -0.1		-1.8 to -0.2	-0.7 to 0.4		-1.8 to 0.1
Floors climbed per week (n)						
T0	16.8 ± 24.5		18.9 ± 23.7	15.3 ± 25.2	.76	
T1	25.4 ± 30.7		28.5 ± 32.0	23.1 ± 29.8	.56	
Δ	8.6 ± 36.4	**.02**	9.6 ± 36.4	7.9 ± 36.8	.82	
95% CI	-15.6 to -1.5		-20.6 to 1.5	-17.3 to 1.6		-16.1 to 12.7

Variables were assessed by BSA questionnaire after 24 weeks. Data is presented as mean ± SD and 95% CI. Differences between groups over time (RehaPlus+ vs usual care) were analyzed using two-way ANOVA. Levels of physical activity at work: range 0 – 9 (higher = greater activity).

Table 3: Change in wellbeing, cardiac self-efficacy and work ability

	Overall (N=105)	***P*-value time**	**RehaPlus+ (n=44)**	**Usual care (n=61)**	***P*-value group**	**95% CI Interaction**
Wellbeing						
T0	10.3 ± 7.1		9.6 ± 8.1	10.9 ± 6.4	.61	
T1	12.9 ± 7.1		12.7 ± 7.0	12.9 ± 7.2	.97	
Δ	2.5 ± 7.6	**.001**	3.1 ± 8.7	2.1 ± 6.7	.53	
95% CI	-4.0 to -1.0		-5.7 to -0.4	-3.8 to -0.4		-3.9 to 2.0
Cardiac self-efficacy						

T0	24.5 ± 14.1		29.5 ± 9.8	20.9 ± 15.6	**.001**	
T1	30.8 ± 10.9		31.8 ± 9.2	30.0 ± 12.0	.71	
Δ	6.3 ± 16.3	**.001**	2.3 ± 9.6	9.1 ± 19.3	**.03**	
95% CI	-9.4 to -3.1		-5.2 to 0.6	-14.1 to -4.2		-0.5 to 13.1
Work ability						
T0	23.3 ± 10.3		23.0 ± 10.6	23.6 ± 10.2	.97	
T1	22.8 ± 10.8		23.0 ± 11.0	22.6 ± 10.8	.98	
Δ	-1.0 ± 9.5	.66	0.0 ± 7.7	-1.0 ± 10.6	.66	
95% CI	-1.5 to 2.6		-2.7 to 2.7	-2.1 to 4.0		-5.2 to 3.3

WHO-5, CSE and WAI were assessed by questionnaire at baseline (start of phase II CR, T0) and after 24 weeks (T1). Data is presented as mean ± SD and 95% CI. Δ indicates the mean individual difference between T0 and T1. Differences between groups over time (RehaPlus+ vs usual care) were analyzed using two-way ANOVA.WHO-5: range 0 – 25 (higher = greater wellbeing); WAI: range 7 – 49 (higher = improved work ability); CSE: range 0 – 100 (higher = greater wellbeing).

Appendices

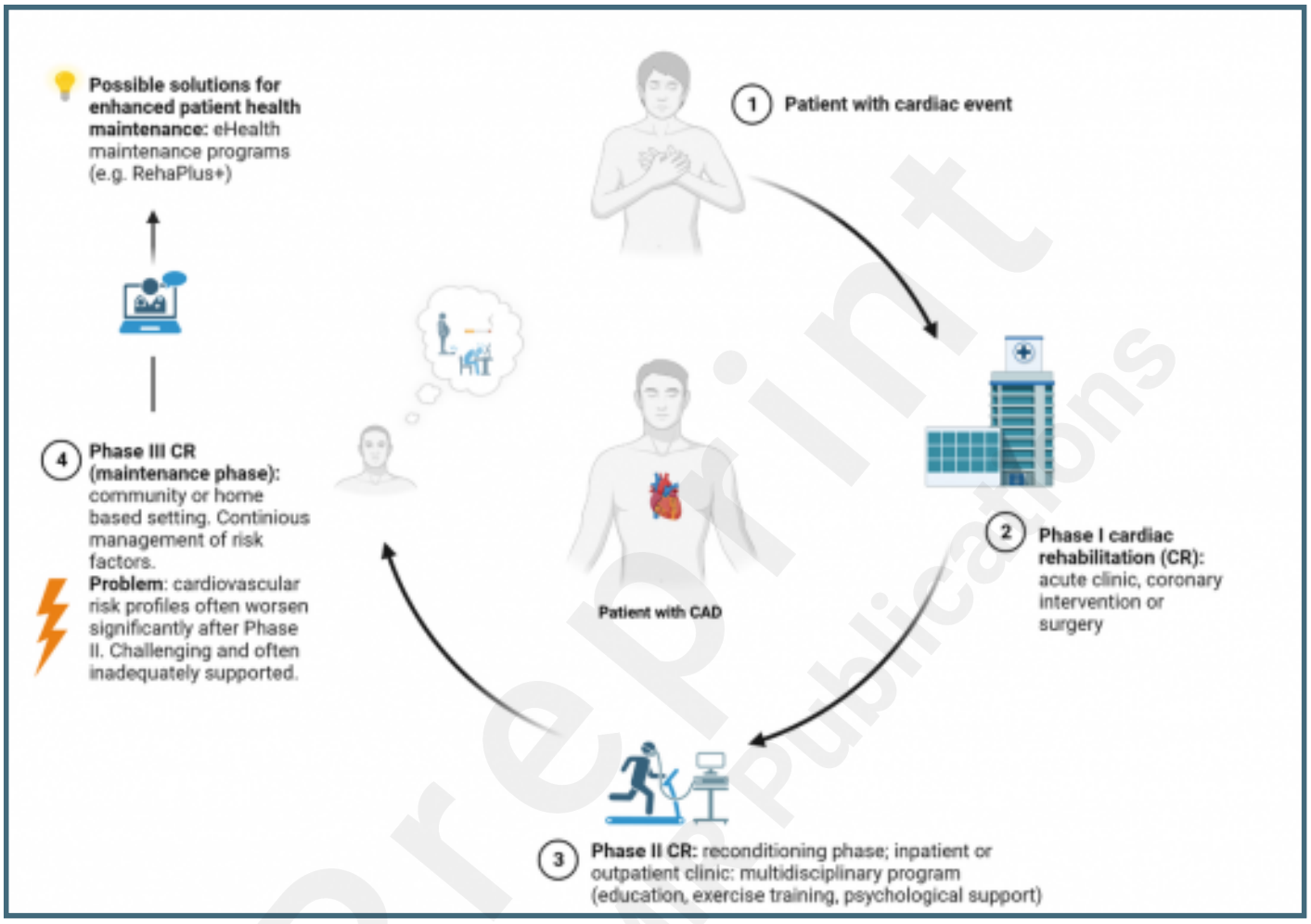
Supplemental document 1: CONSORT-EHEALTH V1.6.

Supplementary Files

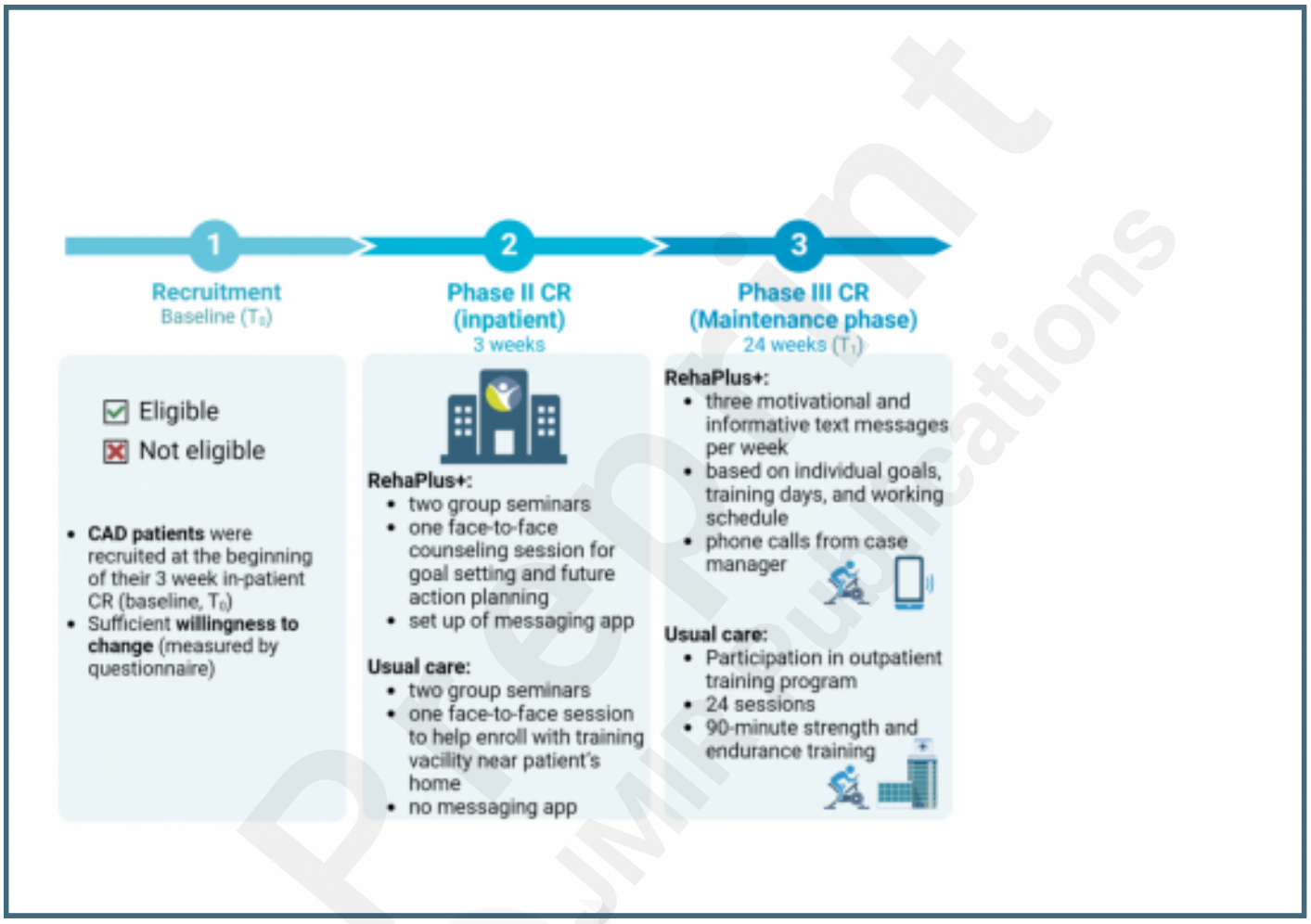
Untitled.
URL: http://asset.jmir.pub/assets/4bc794e6fb1eb5f599ff43c166b81517.pdf

Figures

Stages of cardiac rehabilitation (CR). In phase III CR, the IRENA program can be prescribed as an outpatient program to patients in Germany. Nearby (< 30 km) IRENA centers are not always available, leading to many individuals without post-rehabilitation program alternatives. E-health programs such as RehaPlus+ may bridge this gap by providing a readily available alternative for patients with coronary artery disease (CAD).



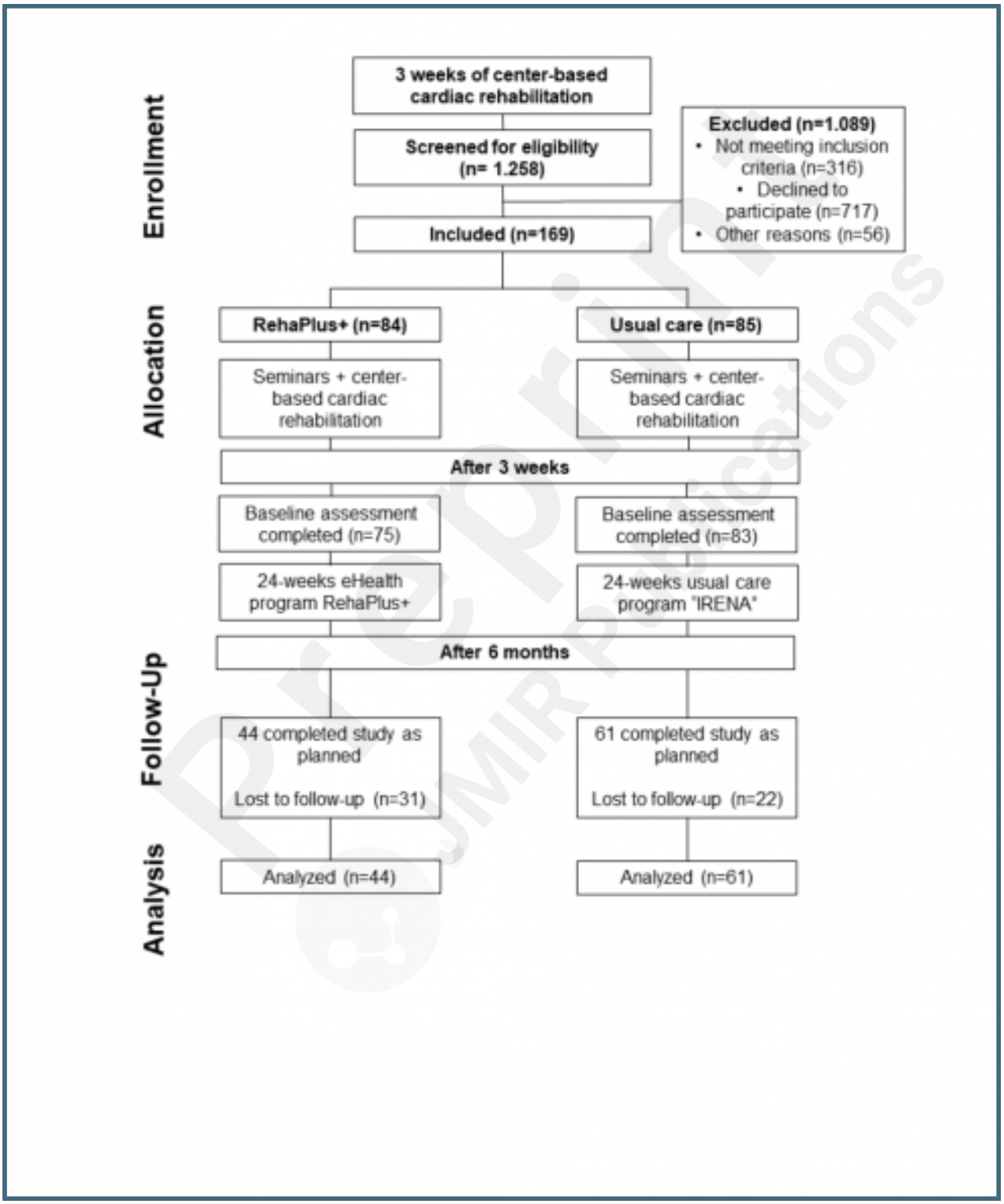
Study design. Patients were recruited at the beginning of the three-week inpatient cardiac rehabilitation (baseline, T0) and participated in the RehaPlus+ or usual care program, depending on local availability after discharge (24-weeks maintenance phase). Only patients indicating willingness to change were included. The RehaPlus+ and usual care group attended two group seminars and one face-to-face individual counseling session in Phase II CR. In Phase III CR RehaPlus+ recipients received three customized motivational text messages weekly for six months, while the usual care group engaged in a six-month outpatient program involving 24 sessions of 90-minute strength and endurance training. Follow-up examinations, were conducted 24 weeks after discharge (T1). CAD, coronary artery disease; CR, cardiac rehabilitation.



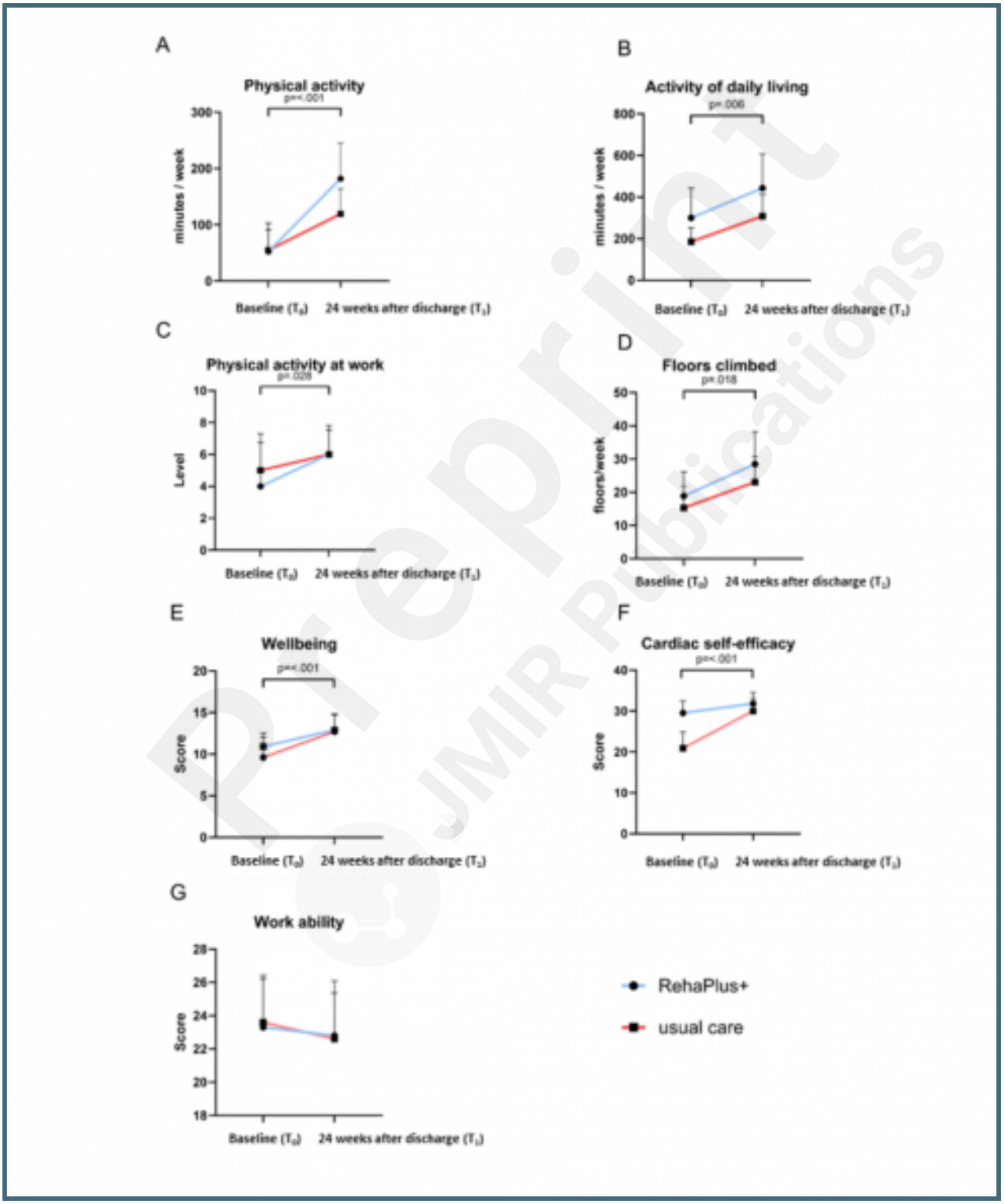
Sample message. Each RehaPlus+ patient received a total of 72 messages over a period of 24 weeks.

Application (24 weeks utilization)	
Content	Informative, educational, motivational
Frequency	3 x/week
Message tailoring	Tailored to the patient based on their profile, rehabilitation goals, and predetermined activities.
Message timing	Timing was customized to align with the patient's work schedule.
Purpose	Ongoing support and guidance during the rehabilitation journey.

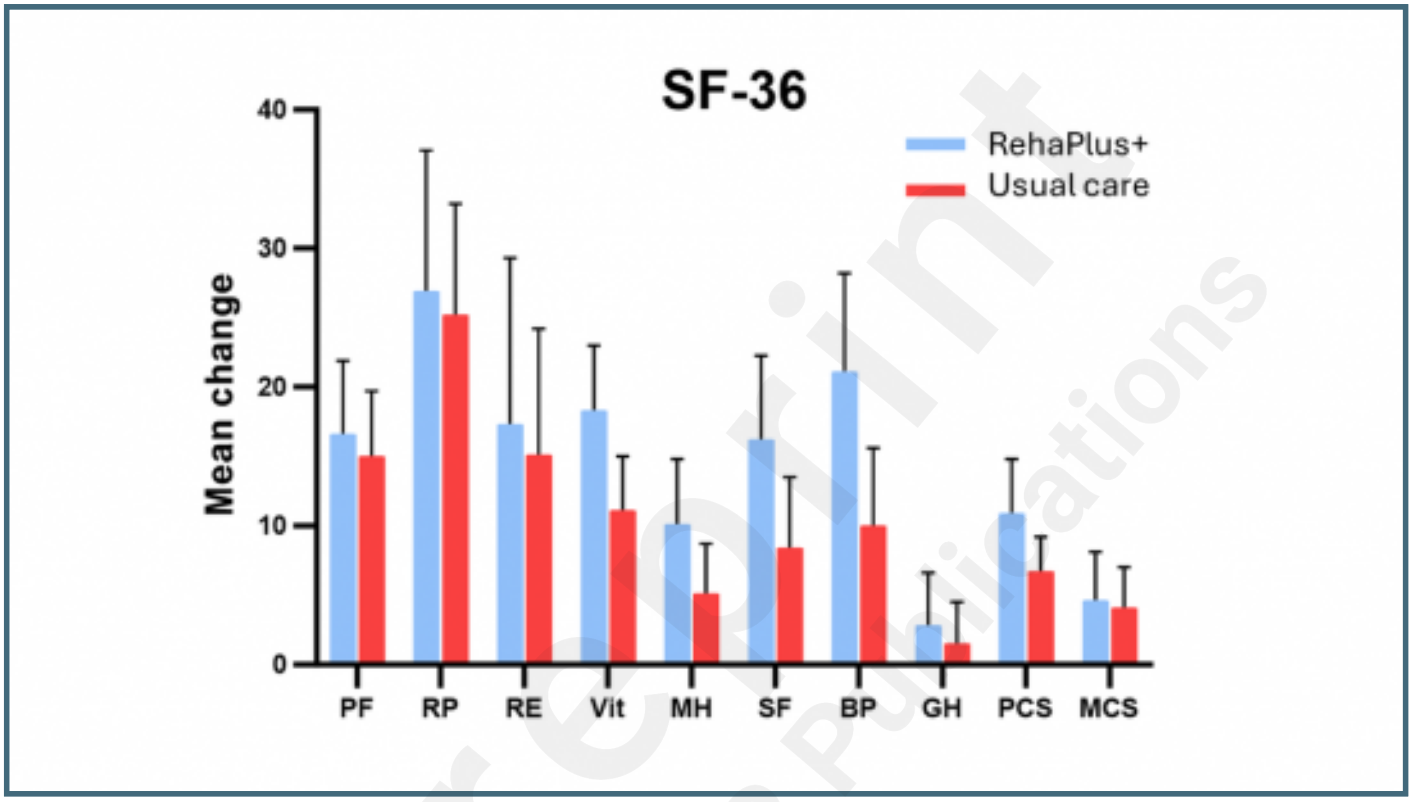
CONSORT-Flowchart. One hundred and sixty-nine patients referred to either a 24-week e-Health group (RehaPlus+, n=84) or a conventional center-based program (usual care, n=85). Eleven patients (RehaPlus+, n=9; usual care, n=2) did not complete the baseline assessment due to premature discharge. Thirty-one and twenty-two patients were lost to follow up due to contacting problems for RehaPlus+ and for usual care, respectively. The final analysis included 105 patients (RehaPlus+, n=44; usual care, n=61).



Changes in primary and secondary outcome measures over 6 months. All variables were assessed by questionnaire at T0 (start of phase II CR) and after 24 weeks. Overall, a significant increase at 6-months follow-up compared to baseline was detected in physical activity (P=0.001), activity of daily living (P=0.006), physical activity during work (P=0.028), floors climbed weekly (P=0.018), well-being (P=0.001) and CSE (P=0.001) with no significant difference between groups. Data is presented as mean ± SD. Differences between groups over time (RehaPlus+ vs usual care) were analyzed using two-way ANOVA.



Health-related quality of life assessed by SF-36 questionnaire. At baseline, SF-36 scores were comparable between both groups, although the usual care group had a higher MCS score (P=0.033). Both groups increased their pre-intervention score with no difference observed between the two groups (p?0.362). Data is presented as 95% CI; changes over time between groups (time x group interaction) were calculated using general linear model. SF-36 score range 0 – 100 (higher = greater wellbeing). PF, physical functioning; RP, role physical; RE, role emotional; Vit, vitality; MH, mental health; SF, social functioning; BP, bodily pain; GH, general health; PCS, physical component summary; MCS, mental component summary.



CONSORT (or other) checklists

CONSORT-EHEALTH (V 1.6.1). Supplemental document 1.
URL: http://asset.jmir.pub/assets/3bfc52ac3a1dc88ffb1a87cf8aa6f5b2.pdf