Effectiveness of the aktivplan digital intervention for supporting regular heart-healthy levels of physical activity following completion of a phase II rehabilitation programme (ACTIVE- CaRe Pilot): protocol for a randomised controlled pilot study

Dirk Leysen, Bernhard Reich, Anna Eleonora Carrozzo, Rik Crutzen, Vincent Grote, Devender Kumar, Barbara Mayr, Josef Niebauer, Franziska Pfannerstill, Eva Maria Propst, Daniela Wurhofer, Mahdi Sareban, Jan David Smeddinck, Gunnar Treff, Stefan Tino Kulnik

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Dirk Leysen[1, 2] MSc; Bernhard Reich[3, 4, 5] PhD; Anna Eleonora Carrozzo[2] PhD; Rik Crutzen[2, 6] Prof Dr; Vincent Grote[7] PhD; Devender Kumar[2] PhD; Barbara Mayr[4, 5] PhD; Josef Niebauer[3, 4, 5, 2] Prof Dr Med; Franziska Pfannerstill[2] PhD; Eva Maria Propst[2] MSc; Daniela Wurhofer[2] PhD; Mahdi Sareban[4, 2] Dr med; Jan David Smeddinck[2] PhD; Gunnar Treff[5, 2] Prof Dr Med; Stefan Tino Kulnik[2] PhD

[1] Department of Health Promotion, Care and Public Health Research Institute, Maastricht University Maastricht AT
[2] Ludwig Boltzmann Institute for Digital Health and Prevention Salzburg AT
[3] REHA Zentrum Salzburg Salzburg AT
[4] University Institute of Sports Medicine, Prevention and Rehabilitation Salzburg AT
[5] Institute of Molecular Sports and Rehabilitation Medicine, Paracelsus Medical University Salzburg AT
[6] Department of Health Promotion, Care and Public Health Research Institute, Maastricht University Maastricht NL
[7] Ludwig Boltzmann Institute for Rehabilitation Research Vienna AT

Corresponding Author:
Dirk Leysen MSc

Ludwig Boltzmann Institute for Digital Health and Prevention
Lindhofstraße 22
Salzburg
AT

Abstract

Background: Patients with cardiovascular disease (CVD) often encounter challenges in establishing and maintaining heart-healthy physical activity habits, even after successfully completing a cardiac rehabilitation programme. Digital health technologies hold promise to support long-term habit formation in the secondary prevention of CVD. The aktivplan digital health intervention has been developed to support patients with CVD in establishing long-term heart-healthy physical activity habits.

Objective: The primary study objective is to pilot and assess the feasibility of a randomised controlled trial design to investigate the effectiveness of the aktivplan intervention; and to assess the usability, user experience and acceptance of the intervention. The secondary objective is to collect clinical and safety outcomes.

Methods: This multi-centre, randomised controlled pilot study aims to recruit 40 patients with an established diagnosis of CVD or with increased risk of CVD (physically inactive plus one further CVD risk factor) who are undergoing phase II rehabilitation at two rehabilitation centres in Austria.

Participants will be allocated to the intervention or standard care control group by stratified randomisation and will be monitored for 10 weeks after discharge from phase II rehabilitation. Participants, healthcare professionals, and outcome assessors are not masked (blinded) to group allocation.

Data collection includes recruitment and drop-out rate; data completeness; adherence to the intervention; usability, user experience, and user acceptance questionnaires; technical reliability of the intervention; clinical assessments (exercise capacity, physical activity behaviour, CVD risk factors); adverse events; self-reported outcome measures (health-related quality of life, exercise self-efficacy, depression and anxiety, kinesiophobia); as well as patient interviews and focus groups with healthcare professionals.

Quantitative data will be analysed descriptively, and 95% confidence intervals will be calculated for recruitment and drop-out

rates and for data completeness. No confirmatory inferential statistical analysis or hypothesis testing will be conducted. Qualitative data will be analysed thematically by framework analysis.

Results: A total of 34 participants were recruited between October 2023 and May 2024. Data collection was completed in August 2024. Currently, the data is being analysed and prepared for publication. The first publication of feasibility results is expected for summer 2025.

Conclusions: This pilot study is expected to generate valuable and comprehensive insights to inform the study design of a future definitive effectiveness trial of the aktivplan intervention, guide the need for further iteration of aktivplan prior to entering a definitive trial, and inform future implementation strategies for the intervention. Clinical Trial: ClinicalTrials.gov: NCT06025526. Registered 29 August 2023
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Authors

Dirk Leysen[1,2]
Bernhard Reich[3,4,5]
Eleonora Carrozzo[1]
Rik Crutzen[1,2]
Vincent Grote[6]
Devender Kumar[1]
Barbara Mayr[4,5]
Josef Niebauer[1,3,4,5]
Franziska Pfannerstill[1]
Eva Propst[1]
Daniela Wurhofer[1]
Mahdi Sareban[1,4]
Jan David Smeddinck[1]
Gunnar Treff[1,5]
Stefan Tino Kulnik[1]

Affiliations

[1] Ludwig Boltzmann Institute for Digital Health and Prevention, Salzburg, Austria
[2] Department of Health Promotion, Care and Public Health Research Institute, Maastricht University, Maastricht, Netherlands
[3] REHA Zentrum Salzburg, Salzburg, Austria
[4] University Institute of Sports Medicine, Prevention and Rehabilitation, Salzburg, Austria
[5] Institute of Molecular Sports and Rehabilitation Medicine, Paracelsus Medical University, Salzburg, Austria
[6] Ludwig Boltzmann Institute for Rehabilitation Research, Wien, Austria

Corresponding author

Dirk Leysen
Ludwig Boltzmann Institute für Digital Health and Prevention
Lindhofstrasse 22, 5020 Salzburg, Austria
Tel.: +43 (0) 57 255 82701
Email: dirk.leysen@lbg.ac.at

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strategies for the intervention.

Trial registration
ClinicalTrials.gov: NCT06025526. Registered 29 August 2023
https://www.clinicaltrials.gov/search?cond=NCT06025526

Keywords

App, behaviour change, cardiac rehabilitation, cardiovascular disease, digital technology, eHealth, exercise, habit formation, mHealth, secondary prevention

Introduction

Cardiovascular disease (CVD) remains the most common cause of death worldwide, with 18.6 million deaths attributed to CVD in 2019 (1). In Austria, CVD was the most common cause of death in 2022 (34.3% of all deaths) and the most frequent discharge diagnosis for all acute hospital admissions (11.6%) (2). Cardiac rehabilitation constitutes an important care pathway for the secondary prevention of CVD (3,4). Cardiac rehabilitation programmes aim to support patients in implementing a lifelong heart-healthy lifestyle, including regular physical activity, e.g., through joining cardiac exercise groups or through self-directed training at home (3). As a general recommendation, patients should carry out aerobic physical activity at a moderate or moderate-to-high intensity at least three times per week, and ideally six to seven times per week. Aerobic physical activity should amount to at least 150 minutes per week at moderate intensity, or 75 minutes per week at vigorous intensity, or an equivalent combination thereof. In addition, patients should perform muscle-strengthening exercises for the large muscle groups twice per week with 8 to 15 repetitions per set. The overall training volume should amount to an energy expenditure of 1,000 to 2,000 kcal per week (5–7).

High-level scientific evidence demonstrates the effects of cardiac rehabilitation programmes on reducing long-term morbidity and mortality. Cardiac rehabilitation has therefore received the highest class of recommendation in clinical guidelines for patients with chronic heart failure, chronic cardiovascular risk, after myocardial infarction with ST-elevation, after myocardial revascularization, and for cardiovascular prevention in clinical practice (6). The cardiac rehabilitation pathway is organised according to phases, whereby phase I describes the period of acute hospital admission. Phase II describes a structured and supervised programme, delivered in an inpatient or outpatient setting and lasting several weeks, which aims to provide patients with the knowledge and awareness of the health-promoting effects of regular physical activity and other heart-healthy lifestyle choices, and to impart the skills to effectively plan and implement these CVD preventive behaviours (5,6).

However, it is a well-documented problem that many CVD patients struggle to establish regular physical activity habits. In the EUROASPIRE V survey of 8,261 coronary patients in 27 European countries, only 34% of respondents reported performing regular physical activity (i.e. ≥30 minutes on average five times a week), only 16% reported performing high-intensity physical activity for ≥20 minutes at least three times a week, only 35% reported performing planned physical activity to increase their physical performance, 42% of patients did not perform regular physical activity and had no intention of starting in the next six months, and 46% of patients could not recall ever having received a personal recommendation or advice on physical activity (8).

The same is true for people with an increased risk of CVD who have not yet developed the disease (i.e., primary prevention of CVD) (9). According to the Austrian Health Interview Survey, only 48.1% of men and 45.1% of women aged 18 to 64 years meet the World Health Organization (WHO) recommendation to carry out at least 150 minutes per week of endurance-type physical activity at moderate intensity, and only 26.0% of men and 21.1% of women meet the WHO recommendations for both endurance-type physical activity and muscle-strengthening exercises (10).

Moreover, successful completion of a phase II cardiac rehabilitation programme does not necessarily lead to establishing long-term heart-healthy physical activity habits. The systematic review by ter Hoeve et al. included 26 randomized controlled trials (RCTs) and reported limited and conflicting evidence that cardiac rehabilitation programmes improved long-term (≥6 months) maintenance of physical activity recommendations compared to groups who did not attend cardiac rehabilitation

(11). These findings are corroborated in the systematic review by Dibben et al. who included 40 randomised controlled trials and found that ≤12 months and >12 months after a CR program, only 26% of physical activity outcome comparisons showed statistically significant differences in favour of the cardiac rehabilitation groups (12).

This urgent and challenging problem has also been highlighted in statements and position papers from medical and scientific societies. For instance, the European Research Area Network for Cardiovascular Diseases has defined this problem as a priority topic for scientific research in 2019 (13):

> *"Maintaining a healthy lifestyle appears to be difficult for an increasing majority of the population despite the general acknowledgement of the benefit of keeping risk factors for cardiovascular disease as low as possible. This not only applies to young people – for whom cardiovascular disease will often not develop for some time – but also to patients who, after a period of intensive rehabilitation have difficulties maintaining the healthy lifestyle by themselves. So far research has not delivered any effective strategy to improve healthy lifestyle maintenance. Research in this area will have to explore whether optimal use of new technologies like intelligent wearables will offer personalised innovative and effective solutions to this problem."* (13)

The current European Society of Cardiology guideline on CVD prevention mirrors this statement, describing a specific evidence gap concerning physical activity *"Implementation of strategies to achieve long-term adherence to PA [physical activity]"* and a further evidence gap that suggests a possible solution through digital technologies: *"Evaluation of the effects of eHealth tools in promoting PA [physical activity]"* (14).

Digital technologies offer potential innovative solutions for long-term and sustainable habit formation for independent regular heart-healthy exercise. A recent review of nine randomised controlled trials has shown that services which supported physical activity through digital technologies following a cardiac rehabilitation programme achieved higher physical performance outcomes compared to standard care (without digital technology support following a cardiac rehabilitation programme) (15). Accordingly, the present study will investigate a novel digital health intervention (16) (**aktiv**plan) that has been developed specifically to support patients in establishing regular heart-healthy physical activity habits following completion of a phase II rehabilitation programme in the Austrian healthcare context. Because the structure and organisation of cardiac rehabilitation pathways and healthcare systems differ from country to country, it is important to generate such evidence specifically for the Austrian national context.

Methods

Aim

The primary aim of this study is to pilot and assess the feasibility of a randomised controlled trial design to investigate the effectiveness of the **aktiv**plan digital intervention; and to evaluate the usability, user experience and acceptance of the **aktiv**plan digital intervention.
The secondary aim of this study is to collect clinical outcomes to inform definitive effectiveness trial design and to demonstrate patient safety of the intervention.

Study design

This is a multi-centre randomised controlled pilot study. Forty patients undergoing phase II rehabilitation will be recruited from two study sites (20 patients per site). Study participants will be individually randomised to the intervention group (**aktiv**plan digital health intervention) or control (standard care, i.e., not including any routinely provided digital technologies) and will be followed-up for ten weeks after discharge from phase II rehabilitation.

The reporting of this study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (17), the Consolidated Standards of Reporting Trials (CONSORT) statement extension to randomised pilot and feasibility trials (18), and the Template for Intervention Description and Replication (TIDieR) checklist (19). The SPIRIT, CONSORT, and TIDieR checklists are attached in online supplements 1-3.

Ethics and informed consent

This study protocol was reviewed and received favourable ethical opinion from the research ethics committees of the Austrian federal states of Salzburg (reference 1065/2023) and Vorarlberg (reference EK-2-14/2023). Participation in this study is voluntary and all participants give written informed consent to take part in the study. Participants retain the right to withdraw from the study at any time and without giving a reason. In accordance with applicable medical device and product regulations in Austria, the study was registered with the Austrian Federal Office for Safety in Health Care (reference 102214904). For general transparency and disclosure, the study was prospectively registered on ClinicalTrials.gov (NCT06025526).

Regulatory considerations

This study protocol is in accord with national and international ethical and regulatory standards, including the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) (20), the European Union (EU) Medical Device Regulation (MDR) (21), and the EU General Data Protection Regulation (GDPR) (22).

Indemnity insurance and monitoring visits
Study participants, site principal investigators and other clinical personnel at the study sites are covered by indemnity through a study insurance. Data monitoring is performed by the study steering committee in periodic meetings and by independent monitoring visits at the study sites.

Setting

The study is set in two rehabilitation centres in Austria, one outpatient rehabilitation centre in the city of Salzburg (study site 1), and one inpatient rehabilitation clinic in the rural Montafon valley (study site 2). The outpatient rehabilitation centre offers phase II rehabilitation of 4-6 weeks duration for adults with cardiac, pulmonary (including long-COVID), metabolic, oncological, and orthopaedic conditions. The inpatient rehabilitation centre provides phase II rehabilitation stays of 3-4 weeks duration for adults with cardiac, neurologic, orthopaedic and psychiatric conditions.

Participants
All patients admitted to phase II rehabilitation at study site 1 and all patients admitted to phase II cardiac rehabilitation at study site 2 will be screened against pre-defined eligibility criteria.

Inclusion criteria

Included are adult patients who are enrolled either in a phase II cardiac rehabilitation programme, or who are enrolled in phase II rehabilitation due to a non-cardiac indication but who present with increased cardiovascular risk (i.e., physical inactivity plus at least one of the following CVD risk factors: smoking, hyperlipidaemia, arterial hypertension, diabetes, obesity). Additionally, eligible patients must possess and use a smartphone compatible with the **aktiv**plan digital intervention (operating system versions Android 4.4 / Apple iOS 11.0 or above and internet access).

Exclusion criteria

- Existent use of a digital intervention to support regular heart-healthy physical activity by the patient already established in standard care at the time of recruitment.
- Medical contraindications to: symptom-limited incremental cycle ergometry, regular heart-healthy physical activity, exercise and sports, or the use of a smartphone.
- Insufficient cardiovascular exercise capacity (e.g. due to severe impairment of the musculoskeletal system).
- Participation of the patient in another clinical trial within the last 6 months.
- Addiction or other illnesses that do not allow the person to assess the nature, scope and possible consequences of participation in the study.
- Pregnancy in the third trimester, or pregnancy in the in the first and second trimester with a medical contraindication to physical activity, exercise and sports.
- Breastfeeding women with a medical contraindication to physical activity, exercise and sports.
- Indications that the patient is unlikely to comply with the protocol (e.g., unwillingness to cooperate).

Sample size

The sample size of 40 patients (20 patients per site) reflects the typical sample size for a clinical pilot study (23) and allows the detection of problems (e.g., participant withdrawals) with a prevalence of 7.5% with 95% confidence (24).

Recruitment

All patients admitted to phase II rehabilitation at study site 1 and all patients admitted to phase II cardiac rehabilitation at study site 2 will be screened against the in- and exclusion criteria by the site

principal investigators. Eligibility of each individual patient will be documented in a screening log, including reasons for exclusion.
All patients who meet the eligibility criteria will be invited to take part in the study by the site principal investigators. The site principal investigators explain the study, provide the study information sheet and answer any questions about the study. Patients are given at least 48 hours to consider participation in the study. Patients who express interest in participating in the study are asked to provide written informed consent, which is required before study initiation.

Randomisation

Participants will be individually randomised to the intervention or control group. Randomisation will be stratified by study site, participant sex, and participant exercise capacity (P_{peak} <1.3 W/kg, 1.3-1.8 W/kg, and >1.8 W/kg in incremental cycle ergometry). The randomisation schedule will be prepared in advance and stored securely at the study sponsor's office (Ludwig Boltzmann Institute for Digital Health and Prevention) which is at a different location to the study sites. Random allocation is concealed, as personnel at the study sites have no access to the randomisation schedule. After a new study participant has been recruited, the site principal investigator informs the study sponsor of the patient's sex and exercise capacity, and the randomisation result is then returned to the site principal investigator.

Description of the intervention

The **aktiv**plan digital health intervention was developed at the Ludwig Boltzmann Institute for Digital Health and Prevention, Austria, in a human-centred process with both co-design and iterative participatory design elements, involving healthcare professionals and cardiac patients between 2020 and 2022 (25). The core feature of **aktiv**plan is a digital calendar for planning regular heart-healthy physical activity. Healthcare professionals access this calendar via a website/webapp (view for healthcare professionals), and patients access the calendar via an app on their smartphone, tablet, or – if required – via a website on a smartphone, tablet or computer (view for patients). Prior to discharge from the phase II rehabilitation programme, **aktiv**plan is introduced to the patient in a 1:1 consultation with a healthcare professional experienced in exercise prescription (e.g., physiotherapist, sports scientist, exercise physiologist, etc.). This consultation is conducted according to the principles of shared decision-making (26). A personalised heart-healthy physical activity plan is agreed upon, which the patient should carry out independently following discharge from the phase II rehabilitation programme. The healthcare professional enters this training plan into the **aktiv**plan calendar. Using the **aktiv**plan app, the patient can view their planned physical activity sessions, mark sessions as completed, or enter additional unplanned physical activities (e.g., spontaneous activities that are self-initiated by the patient). The healthcare professional can view the calendars and assess adherence with personal physical activity plans for all patients under their care.
In addition to this core functionality, **aktiv**plan includes further distinct features such as automated messages to the patient with motivational content or reminders of planned physical activity sessions, personalised goal setting, and the option for the healthcare professional to give the patient feedback and contact them via an in-app message. Further details on the **aktiv**plan digital health intervention are given in the TIDieR checklist in online supplement 3. Details of the logic model and psychological / behaviour change theory underpinning the **aktiv**plan digital intervention have been published previously (27).

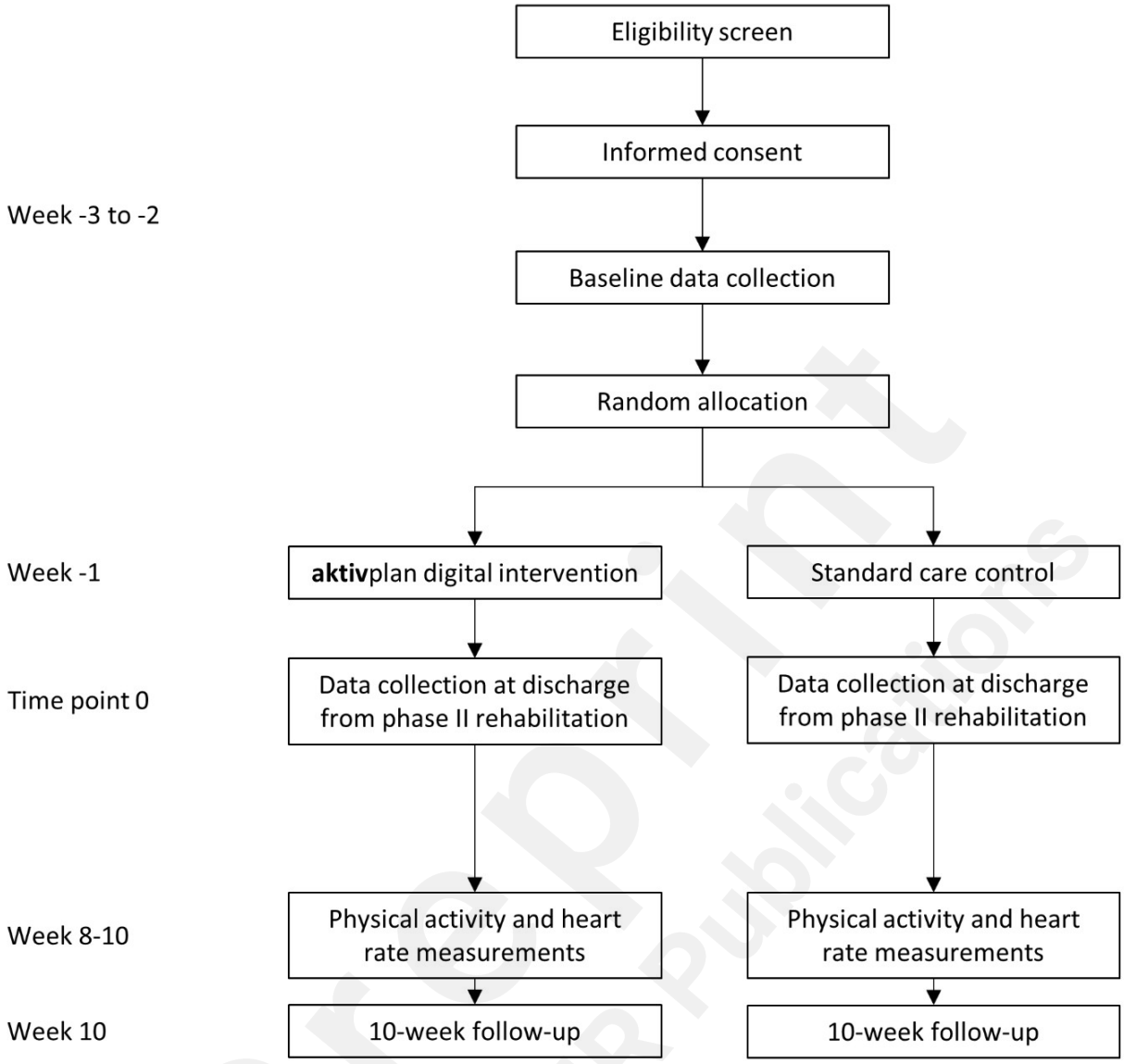
Description of the comparator

The control group receives usual care according to Austrian national standards, which does not include any digital interventions or digital technology provision during or following phase II rehabilitation. No placebo or comparative treatment is offered. In addition to standard care, patients in both study groups may take individual action to support their adherence to physical activity recommendations (e.g., join an exercise class or gym, hire a personal trainer, download a freely available physical activity app, etc.), and any such activities are documented by self-report.
After completing their participation in the study, participants who are randomised to the control group are offered to receive the **aktiv**plan physical activity planning session and use **aktiv**plan for a period of 2 weeks. This offer is made for ethical reasons and to counteract possible premature withdrawal from the control group.

Procedure

The CONSORT flow diagram is given in figure 1. The SPIRIT figure is given in figure 2. Study procedures are as follows:

1. *Screening for eligibility*: All patients admitted to phase II cardiac rehabilitation programmes at the study sites are screened against study eligibility criteria.
2. *Recruitment*: All eligible patients are invited to take part in the study. Those expressing interest to take part are consented.
3. *Baseline data collection (weeks -3 to -2)*: Baseline data are collected. A detailed description of measures is provided below and in figure 2.
4. *Randomisation*: Patients are randomly allocated to intervention or control group. Random allocation is concealed and stratified according to study site, patient sex, and patient exercise capacity.
5. ***aktiv****plan physical activity planning session (week -1)*: Participants allocated to the intervention group receive the **aktiv**plan physical activity planning session prior to discharge from the phase II rehabilitation programme.
6. *Data collection at discharge from phase II rehabilitation (time point 0)*: Data are collected at discharge from phase II rehabilitation. A detailed description of measures is provided below and in figure 2.
7. *Follow-up period*: Patients in both study groups are followed-up for 10 weeks after discharge from phase II rehabilitation. Patients in the intervention group use the **aktiv**plan digital intervention.
8. *Physical activity and heart rate measurements (week 8 to 10)*: Patients in both study groups receive wearable sensor devices (accelerometer and heart-rate sensor) for continuous measurement during waking hours for 3 weeks (weeks 8 to 10 of the follow-up period). A detailed description of measurements is provided below.
9. *10-week follow-up (week 10)*: Data are collected in the concluding study visit. A detailed description of measures is provided below and in figure 2.
10. ***aktiv****plan digital intervention for control group patients*: Following completion of the study, patients in the control group are offered to receive the **aktiv**plan physical activity planning session and use **aktiv**plan for 2 weeks.



	STUDY PERIOD												
	Enrolment		Discharge from phase II rehabilitation	Follow-up period									Close-out
TIMEPOINT	*Week -3 to -2*	*Week -1*	*Time point 0*	*Week 1*	*Week 2*	*Week 3*	*Week 4*	*Week 5*	*Week 6*	*Week 7*	*Week 8*	*Week 9*	*Week 10*
ENROLMENT:													
Eligibility screen	X												
Informed consent	X												
Baseline data collection	X												
Random allocation	X												
INTERVENTION:													
aktivplan physical activity planning session		X											
aktivplan use for self-directed physical activity				←	—	—	—	—	—	—	—	→	
ASSESSMENTS:													
Demographic data	X												
Medical history	X												X
Medication	X		X										X
Height	X												
Weight	X		X										X
Vital parameters	X		X										X
Incremental cycle ergometry	X*		X*										X
Blood cholesterol and HbA1c	X*		X*										X
Physical activity and heart rate											←	→	
Adverse event reporting													X
BFI-10, ATI	X												
RAPA	X												X
PHQ-4, EQ-5D-5L, kinesiophobia, ESES	X		X										X
IPAQ, wearable comfort rating													X
UTAUT-2, MAUQ, AttrakDiff mini, MARS													X^
Qualitative interview													X

At the time of discharge from phase II rehabilitation (time point 0), data from routinely conducted assessments and clinical records are collected: medication, body mass, vital parameters, incremental cycle ergometry, and blood tests (cholesterol, HbA1c). Self-reported questionnaires are completed (kinesiophobia, ESES, PHQ-4, and EQ-5D-5L).

During the 10-week follow-up period, usage of the **aktiv**plan application by participants in the intervention group is automatically logged, including planned physical activity sessions that participants mark as completed and additional physical activity sessions that participants enter to the

app.

In weeks 8-10, continuous measurements of physical activity and heart rate are conducted in both study groups using two wearable sensor devices (wearables). Study participants are instructed to wear the devices daily for three weeks during waking hours, and to return the wearables at the final study visit (10-week follow-up). Physical activity is measured with the ActiGraph GT9X Link accelerometer (ActiGraph LLC, Pensacola, FL), worn on the non-dominant wrist. Heart rate is measured with the Polar Verity Sense device (Polar Electro Oy, Kempele, Finland), worn on the non-dominant upper arm or forearm. Study participants receive both devices by post, together with written instructions and a link to an online instructional video on how to operate the wearables. Telephone support is provided by the study team if needed.

The final study visit takes place at the study sites. A venous blood sample is taken for blood cholesterol and HbA1c analysis. The medical history is taken and any adverse events during the previous 10 weeks are recorded. Vital parameters and body mass are measured and a resting electrocardiogram recorded. These examinations serve to rule out possible contraindications to incremental cycle ergometry. If there are no contraindications, incremental cycle ergometry is then performed according to a standard operating procedure (36). Self-reported questionnaires are completed: RAPA, International Physical Activity Questionnaire (IPAQ) (37), kinesiophobia, ESES, PHQ-4, EQ-5D-5L, and (wearable) Comfort Rating Scale (CRS) (38). Then an audio-recorded semi-structured qualitative interview is conducted to inquire about participants' experiences of participating in the study, any self-initiated support for physical activity during the study period, and experiences of using the **aktiv**plan application (in the intervention group only). The interview schedule is provided in online supplement 4.
Lastly, study participants in the intervention group complete questionnaires on the usability and user experience of the **aktiv**plan application, including: mHealth App Usability Questionnaire (MAUQ) (39), Unified Theory of Acceptance and Use of Technology 2 questionnaire (UTAUT-2) (40), Mobile App Rating Scale (MARS-G) (41), and AttrakDiff mini questionnaire (42). For some of these questionnaires, only relevant sections are used.

Study participants who discontinue or deviate from the intervention protocol will be encouraged to complete all outcome assessments regardless.

Data collection from healthcare professionals

To assess usability, user experience and acceptance of the **aktiv**plan digital health intervention from the perspective of healthcare professionals as well, data will also be collected from those members of staff at the study sites who implement the **aktiv**plan digital intervention with patients. These members of staff are physiotherapists or sports scientists who have provided written informed consent to have their data collected and who have received a full day of training on the **aktiv**plan digital intervention before the start of the study. At the beginning of the study, the healthcare professionals complete the ATI and BFI-10 questionnaires and rate their self-efficacy with regard to implementing the **aktiv**plan intervention. During the running of the study, they keep concurrent reflective notes on the use of the intervention, document any technical difficulties, and log their time requirements for implementing the intervention. After each **aktiv**plan physical activity planning session, the 9-item Shared Decision Making Questionnaire (SDM-Q-Doc) (43) and items from the Nasa-Task Load Index (NASA-TLX) (44) are completed. At the end of the study, the healthcare professionals again rate their self-efficacy for implementing the **aktiv**plan intervention, complete the MAUQ, MARS-G, UTAUT-2, AttrakDiff mini, and the Normalisation Measure Development

(NoMAD) (45) questionnaires, and take part in an audio- and video-recorded focus group. The focus group discussion will elicit the healthcare professionals' views on implementing the **aktiv**plan intervention in routine clinical practice at the study sites, facilitating and hindering factors for the implementation of **aktiv**plan, any problems experienced with the application, suggestions for improvement and new desired features of the application, and any problems and other observations regarding the conduct of the study that would need to be considered in the design of a larger definitive trial. The focus group topic guide is given in online supplement 5.

Outcomes

The primary outcomes address the primary study aim, i.e., to pilot and assess the feasibility of a randomised controlled trial design to investigate the effectiveness of the **aktiv**plan digital health intervention; and to assess the usability, user experience and acceptance of the **aktiv**plan digital health intervention. The primary outcomes are:

- Recruitment rate (number of recruits per week, percentage of screened patients who were recruited, percentage of eligible patients who were recruited)
- Drop-out rate (number of drop-outs at the 10-week follow-up, percentage of recruited patients who dropped out)
- Data completeness (percentage of missing data fields in study database)
- Adherence to the **aktiv**plan digital intervention (automated usage logging of the **aktiv**plan application, video recording of the **aktiv**plan physical activity planning session)
- Usability of the **aktiv**plan digital intervention (MAUQ)
- User experience of the **aktiv**plan digital intervention (AttrakDiff mini questionnaire)
- User acceptance of the **aktiv**plan digital intervention (MARS-G, UTAUT-2)
- Technical reliability of the **aktiv**plan digital intervention (number and types of technical problems, qualitative data)
- Use of alternative and additional strategies for supporting physical activity (number and types of additional strategies, qualitative data)
- Experiences and perspectives of rehabilitation professionals regarding the intervention and study procedures (qualitative data from focus groups)

The secondary outcomes address the secondary study aim, i.e., the collection of clinical outcomes to inform the sample size calculation for a definitive effectiveness trial and to provide evidence towards demonstrating patient safety of the intervention. The secondary outcomes are:

- Exercise capacity (highest mechanical power output achieved during incremental cycle ergometry, P_{peak})
- Physical activity behaviour (accelerometry, daily minutes of moderate to vigorous physical activity)
- Body mass
- Arterial blood pressure
- Blood cholesterol levels
- HbA1c levels
- Smoking (number and type of smoking products per week)
- Health-related quality of life (EQ-5D-5L questionnaire)
- Exercise self-efficacy (ESES)
- Depression and anxiety (PHQ-4)
- Kinesiophobia (TKS items)
- Patient safety (adverse events reporting according to regulatory standards: number, type and severity of adverse events, CRS)

Data management

At the study sites, data are recorded on paper-based case report forms (CRFs). Following completion of data collection, the CRFs and electronic data collection devices (wearables, dictaphones, video cameras) will be collated and securely stored at the study sponsor site. Data from CRFs will be entered onto a Microsoft Excel file. Quality of data entry will be assessed by independently cross-checking the accuracy of 10% of data cells. After completion of the analysis, study data will be securely archived by the sponsor for 10 years.

Analyses

The statistical data analysis will be carried out using statistical analysis software. The analytical code will be documented and stored to ensure that the statistical analyses can be reproduced at a later date. For descriptive data analysis, the appropriate summary measures will be calculated according to data type, including measures of central tendency and spread for continuous data (arithmetic mean, standard deviation, median, interquartile range, minimum, maximum, range) and frequency, proportions or percentages for categorical data. 95% confidence intervals will be calculated for recruitment and drop-out rates and for data completeness. Since this is a pilot study, no confirmatory inferential statistical analysis or hypothesis testing will be conducted.
An exploratory group comparison (descriptive analysis and 95% confidence intervals) will be described for the secondary (clinical) outcome measures for both intention-to-treat and per-protocol approaches.
The qualitative data analysis will be conducted according to the framework analysis method (46) and using qualitative data analysis software. Recordings of the patient interviews and the focus groups with healthcare professionals will be transcribed verbatim by a professional transcription agency. The transcripts will be checked for accuracy against the original recordings. In the reporting of qualitative findings, care will be taken to preserve the anonymity of patients and healthcare professionals.

Dissemination

The results of this study will be published in peer reviewed scientific journals. Authorship will follow the International Committee of Medical Journal Editors (ICMJE) authorship criteria for manuscripts submitted for publication. Professional medical writers will not be employed. It is not planned to make the participant-level dataset publicly available.

Results

Recruitment commenced on 02 October 2023. A total of 34 participants were recruited by May 2024 and all data of the participants was collected by August 2024. Currently, the data of the study is being analysed and prepared for publication. The first publication of results is expected for summer 2025.

Discussion

This pilot study will generate valuable and comprehensive insights to inform the study design of a future definitive effectiveness trial of the **aktiv**plan digital intervention. Additionally, data on the usability, user experience and acceptance of **aktiv**plan will guide the need for further iteration of the

aktivplan application prior to entering a definitive trial; and findings regarding the implementation in practice of **aktiv**plan will inform future implementation strategies, including training for healthcare professionals, background technical support for healthcare professionals and patients, reimbursement strategies, and considerations to minimise barriers to implementation.

Abbreviations

ATI	Affinity for Technology Interaction questionnaire
BFI-10	Big Five Inventory
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case report form
CVD	Cardiovascular disease
EQ-5D-5L	EuroQol health-related quality of life measure
ESES	Exercise Self-Efficacy Scale
EU	European Union
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMJE	International Committee of Medical Journal Editors
IPAQ	International Physical Activity Questionnaire
MARS-G	Mobile App Rating Scale
MAUQ	mHealth App Usability Questionnaire
MDR	Medical Device Regulation
PHQ-4	Patient Health Questionnaire 4
RAPA	Rapid Assessment of Physical Activity questionnaire
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
TIDieR	Template for Intervention Description and Replication
TSK	Tampa Scale for Kinesiophobia
UTAUT-2	Unified Theory of Acceptance and Use of Technology 2 questionnaire
WHO	World Health Organisation

Declarations

Ethics approval and consent to participate

This study protocol was reviewed and received favourable ethical opinion from the research ethics committees of the Austrian federal states of Salzburg (reference 1065/2023) and Vorarlberg (reference EK-2-14/2023). Participation in this study is voluntary and all participants give written informed consent to take part in the study.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

STK conceived and designed the study with contributions from BR, EC, RC, VG, DK, BM, JN, FP, EP, DW, MS, JDS and GT. In particular, DW and JDS contributed technical considerations and procedures for the **aktiv**plan digital intervention; MS drafted standard operating procedures for clinical assessments; DK and DL contributed considerations and drafted standard operating procedures for home-based physical activity assessment; DL, FP, EP, DW and JDS contributed considerations and procedures for usability and acceptability assessment; FP developed the focus group topic guide; and DL and EP developed training materials for therapists and patients.
EC prepared the randomisation schedule and advised on sample size requirements and statistical analyses. STK is the sponsor representative for this study. DL drafted this manuscript with contributions from STK. All authors read and approved the final manuscript.

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Figure titles

Figure 1. CONSORT flow diagram
Figure 2. Schedule of enrolment, interventions, and assessments according to the SPIRIT statement. *collected from routine clinical data, ^for participants in the intervention group only

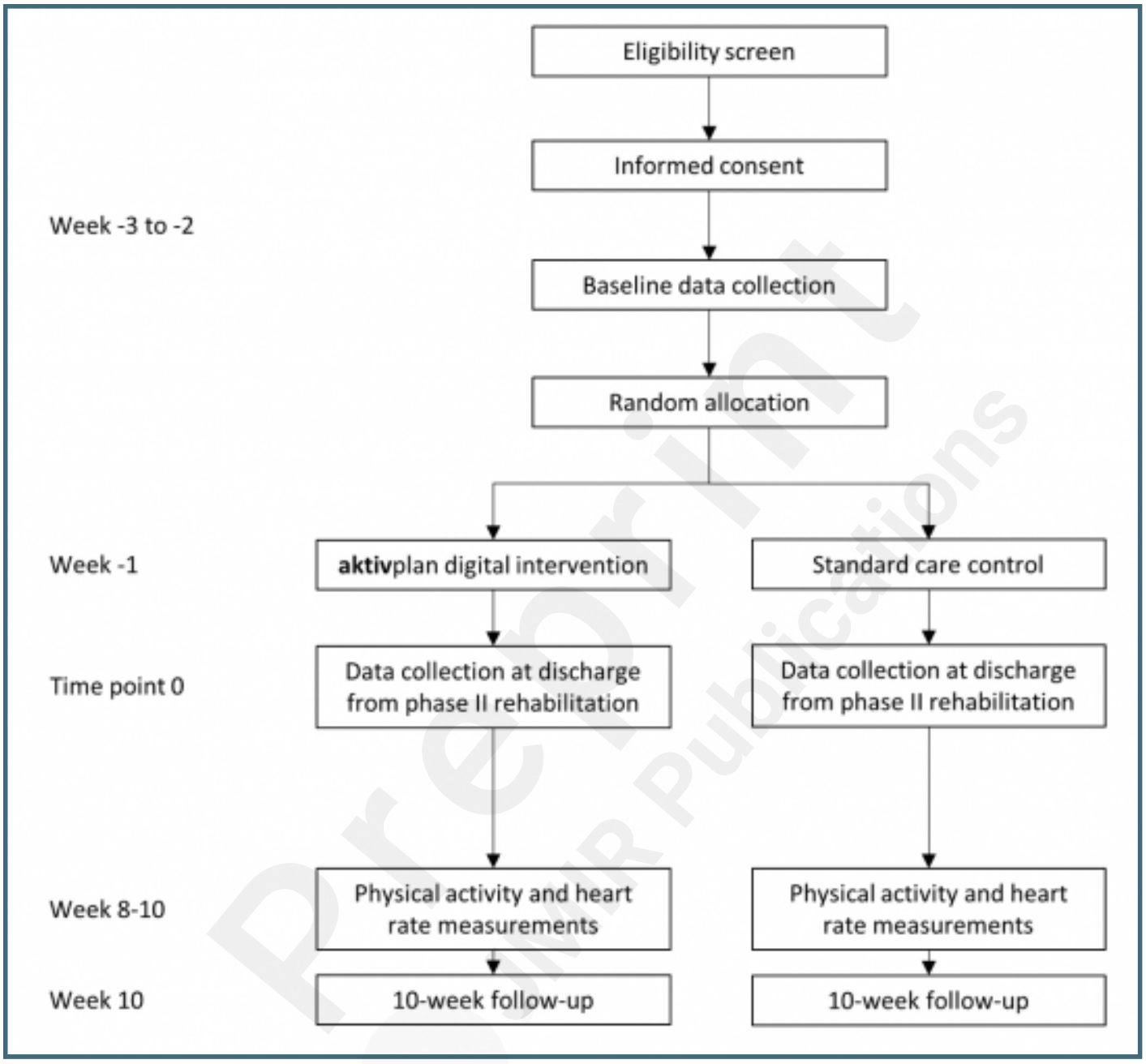
Online Supplements

Online supplement 1. SPIRIT checklist
Online supplement 2. CONSORT checklist
Online supplement 3. TIDieR checklist
Online supplement 4. Qualitative interview schedule
Online supplement 5. Focus group topic guide

Supplementary Files

Figures

Consort flow diagram.



Spirit.

	STUDY PERIOD												
	Enrolment		Discharge from phase II rehabilitation	Follow-up period									Close-out
TIMEPOINT	Week -3 to -2	Week -1	Time point 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
ENROLMENT:													
Eligibility screen	X												
Informed consent	X												
Baseline data collection	X												
Random allocation	X												
INTERVENTION:													
aktivplan physical activity planning session		X											
aktivplan use for self-directed physical activity				←	—	—	—	—	—	—	—	—	→
ASSESSMENTS:													
Demographic data	X												
Medical history	X												X
Medication	X		X										X
Height	X												
Weight	X		X										X
Vital parameters	X		X										X
Incremental cycle ergometry	X*		X*										X
Blood cholesterol and HbA1c	X*		X*										X
Physical activity and heart rate											←	—	→
Adverse event reporting													X
BFI-10, ATI	X												
RAPA	X												X
PHQ-4, EQ-5D-5L, kinesiophobia, ESES	X		X										X
IPAQ, wearable comfort rating													X
UTAUT-2, MAUQ, AttrakDiff mini, MARS													X^A
Qualitative interview													X

CONSORT (or other) checklists

CONSORT checklist.
URL: http://asset.jmir.pub/assets/7adb64efca7338e399fa99471350889f.pdf

SPIRIT checklist.
URL: http://asset.jmir.pub/assets/6bfc9fe53b25c9e142d4c0dd231b682e.pdf

TIDieR checklist.
URL: http://asset.jmir.pub/assets/0c5afa026e994d2145c303efb73b678e.pdf