Study Protocol

Title: Prehab2Rehab: Digitally Supported Short-Term Prehabilitation Before Total Knee Replacement. A Randomized Controlled Feasibility Trial

Short title: Prehab2Rehab-KneeTEP

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Abstract

Introduction: Osteoarthritis is the most prevalent joint disease worldwide and a leading cause of disability in older adults, with the knee being the most affected joint. Total knee replacement (TKR) is the standard treatment for advanced disease, but post-surgery outcomes often remain heterogeneous, with delayed functional recovery in many patients. Prehabilitation has the potential to optimize patients' physical and psychological condition before surgery, and digital technologies may support structured exercise delivery within the limited preoperative time frame. This study will aim to evaluate the feasibility of implementing a short-term, digitally supported prehabilitation program for patients undergoing TKR and to explore its potential effects on perioperative recovery compared with usual care. **Methods:** The Prehab2Rehab-KneeTEP is a single-center, two-arm, feasibility randomized controlled trial that will recruit patients with advanced knee OA scheduled for elective TKR at Medizinisches Zentrum Bad Vigaun, Austria. Patients will be randomized (1:1) to either i) a multimodal video-supported prehabilitation program or ii) usual care (control group). The prehabilitation program will last 10 to 14 days before surgery and will include endurance, resistance, and coordination exercises, including practicing gait with crutches. In addition, digital support will be extended into the early post-discharge period (transition phase) to bridge the time between hospital discharge and the start of formal inpatient rehabilitation. During this period, participants will continue app-based exercises and educational content tailored to their postoperative functional level, reflecting the exercises already learned during the in-hospital phase. This component aims to help patients safely maintain mobility, adherence, and self-efficacy while preparing optimally for subsequent inpatient rehabilitation. Activity scheduling, adherence fostering, and reporting will be supported by the digital aktivplan application and a single teleconsultation via CAATS. The institution will provide inpatient and follow-up rehabilitation to ensure continuity of care. **Outcomes:** The primary outcomes will be feasibility, assessed through recruitment, retention, adherence, fidelity, and safety. The secondary outcomes will include standardized clinical and functional outcomes, as well as acceptance. Clinical outcomes will include recovery indicators and patient-reported outcomes. Functional outcomes will include anthropometry and body composition, functional exercise capacity, and muscle strength. Outcomes will be assessed at baseline (start of prehabilitation, PRE1), at the end of prehabilitation (PRE2), at hospital stay (discharge), at the beginning of rehabilitation (REH1), and at the end of rehabilitation (REH2). **Ethics and dissemination:** The study protocol will be submitted to the responsible ethics committee for approval. Written informed consent will be obtained from all participants. Findings will be disseminated through peer-reviewed publications and conference presentations to inform the design of future large-scale trials.

Trial registration number: To be completed prior to enrollment.

Keywords: Osteoarthritis; Digital health; Rehabilitation pathway; Functional recovery

Introduction

Osteoarthritis (OA) is the most prevalent joint disease worldwide and represents a leading cause of disability in older adults [1]. It is ranked among the ten most disabling conditions in developing countries [2]. Global estimates indicate that approximately 10% of men and 18% of women aged 60 years and older experience symptomatic OA [3]. Higher age and female sex remain the strongest predictors of disease onset [4], while obesity and previous joint injuries represent additional risk [5]. OA is characterized by progressive structural changes that affect the whole joint, causing pain, stiffness, functional impairments, and a decline in quality of life (QoL). The knee is the most frequently affected joint in the lower extremities, and patients with knee OA commonly report difficulties with mobility and participation in daily activities [1, 3].

Total knee replacement (TKR) is considered the standard and most effective treatment for relieving pain and restoring function in advanced OA [6]. Although surgical techniques and perioperative care have improved substantially, outcomes remain heterogeneous, and a substantial proportion of patients experience persistent pain, impaired mobility, or delayed functional recovery following TKR [7]. These variations highlight the importance of optimizing patients' preoperative condition to improve both surgical and functional trajectories.

In 2022, Austria faced a considerable burden of TKR, with 212.9 procedures performed per 100,000 inhabitants [8]. This number is projected to increase by 23% to 262 per 100,000 inhabitants by 2075 [9], reflecting both demographic trends and the rising prevalence of OA. The growing demand pressures healthcare systems and underscores the importance of developing cost-effective perioperative strategies to improve outcomes and reduce postoperative care needs [10].

Prehabilitation has emerged as a proactive approach to enhance both physical and psychological readiness before surgery. It integrates structured exercise training, physiotherapy, lifestyle modification, and patient education [11-13]. Evidence from cancer [11], cardiopulmonary [12], and cardiovascular patients [13] indicates that prehabilitation enhances the tolerance to surgical stress and accelerates postsurgical recovery. In the context of knee OA, preoperative modifiable factors such as functional capacity, pain levels, body mass index (BMI), and psychological well-being are associated with postsurgical outcomes [14]. Exercise-based programs before TKR have shown benefits related to pain reduction, strength, and, consequently, functional

performance [15, 16]. A systematic review of 48 trials including 3,570 patients demonstrates that prehabilitation improves presurgical physical function, muscle strength, and health-related QoL, while conferring sustainable functional benefits in both short- and medium-term post-surgery [17]. Several clinical studies indicate that pre-surgical exercise enhances balance, range of motion, muscle strength, and health-related QoL, while reducing stiffness and length of hospital stay (LOS) [18-21]. Short-term interventions of four to eight weeks have been particularly effective in improving functional performance in patients with severe OA [12]. Konnyu et al. [22] exemplify that prehabilitation is usually delivered in outpatient or inpatient rehabilitation sites. Currently, there are no guidelines published for prehabilitation programs preceding TKR, but typical prehabilitation programs are multimodal interventions, including strength, endurance, flexibility, balance, and task-specific training, such as stair climbing or sit-to-stand exercise, complemented by patient education. Evidence shows heterogeneity, and reported outcomes across trials remain inconsistent, limiting the ability to conclude [23].

Digital technologies (DTs), such as mobile applications and telemedicine platforms, hold potential to support such programs by reducing barriers related to travel, enhancing and adjusting patient adherence, and facilitating continuity of care throughout [24]. In specific contexts, the prehabilitation period is limited due to severe physical pain or organizational structures in the public healthcare sector. In Austria, patients treated in private clinics or with supplementary private insurance experience markedly shorter waiting periods for joint replacement [25], thereby limiting the time for prehabilitation and leading to the implementation of short-term interventions within the perioperative phase. In such cases, efficient methods are required to deliver prehabilitation within limited time periods, offering an opportunity to evaluate the effectiveness and cost-efficiency of short-term interventions, promising relevant insights for the public health sector.

Moreover, after surgical discharges, patients typically spend a short period at home before entering inpatient rehabilitation. During this time, limited information on how much they should move, what activities are safe, and how to manage early post-surgery discomfort [26] often leads to reduced mobility and perceived lack of guidance [27]. Evidence indicates that simple passive and active-assisted movements, such as gentle knee flexion and extension, ankle mobility, and light isometric exercises, are safe and beneficial during the immediate post-surgery phase [27, 28]. Digital tools can

help to empower patients' health literacy during this transition phase by providing clear instructions, reducing uncertainty of patient care pathways while maintaining continuity within [29, 30]. Studies [29, 30] have shown that, despite the physical and functional improvements, digital tools can also strengthen adherence and structured engagement in a rehabilitation context.

Given the rising number of TKRs in Austria and associated pressure on healthcare resources, there is a need for cost-effective strategies for optimizing outcomes and reducing postoperative care demands. Structured prehabilitation has the potential to address this gap by preparing patients physically and psychologically for surgery. Digital tools potentially enhance accessibility, adherence, and continuity of care, consequently supporting the transition from prehabilitation to rehabilitation.

Thus, the primary objective of this study is to design and assess the feasibility, acceptability, and safety of a short-term, digitally supported prehabilitation program for patients scheduled for total knee replacement (TKR). The intervention is intended to prepare patients physically and mentally for surgery through structured exercise, education, and digital guidance.

As a secondary, exploratory objective, the study aims to examine how prehabilitation may be associated with the overall recovery trajectory and whether an additional digitally supported transition phase may influence post-surgery outcomes. Specifically, the study will explore whether digital prehabilitation and the subsequent transitional digital support, respectively, influence clinical and functional outcomes during post-surgery rehabilitation Phase I (in-hospital recovery) and the following inpatient rehabilitation Phase II (Anschlussheilbehandlung), by comparing patients receiving both interventions with those receiving usual medical care without prehabilitation and digital accompaniment.

Methods

Study design

Prehab2Rehab-KneeTEP is a 1:1 randomized controlled feasibility trial designed to test the practicality and acceptability of a multimodal digitally supported prehabilitation intervention for patients scheduled to undergo a TKR. The study protocol follows guidance from Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [31]. A SPIRIT schedule of enrolment, interventions, and assessments is provided in Table 1, and a SPIRIT checklist is provided in

Supplementary File S1. A schematic overview of the study structure, including screening, randomization, prehabilitation, surgery, rehabilitation, and follow-up, is illustrated in Figure 1.

Ethics and Regulatory Approvals

The study will be conducted in accordance with the Declaration of Helsinki [32] and the principles of Good Clinical Practice (GCP) [33]. Ethical approval will be obtained from the Ethics Committee of the state of Salzburg before the study initiation and patient acquisition. Any substantial amendments to the protocol will be submitted for review and approval by the Ethics Committee before implementation. All procedures related to data collection, storage, and analysis will comply with the European General Data Protection Regulation (GDPR/DSGVO). Personal data will be pseudonymized and handled confidentially in accordance with the applicable data protection laws. The study will be registered on ClinicalTrials.gov or an appropriate European alternative before including the first patient. Study findings will be disseminated through peer-reviewed scientific publications, conference presentations, and stakeholder meetings. Summaries of aggregated results will be made available to participants upon request. No individual-level data will be publicly disclosed to ensure participant confidentiality. Authorship will follow the recommendations of the International Committee of Medical Journal Editors (ICMJE), and the investigators will retain full independence in data analysis, interpretation, and publication. The funder will have no authority over the decision to publish or the content of the resulting manuscripts.

Trial setting

Patients will be recruited in the *Medizinisches Zentrum Bad Vigaun, Bad Vigaun, Austria*. Recruitment will start after trial registration and receipt of positive ethical approval. The recruitment period is expected to continue until approximately 8 weeks before the end of the project's funding period, which is currently anticipated for April 30, 2027. Any extensions of the recruitment period within the funded project duration will be communicated to the ethics committee if applicable. Each participant will be involved in the study for approximately 47 to 61 days, covering the prehabilitation, hospital stays, and inpatient rehabilitation.

Eligibility criteria:

Eligibility will be determined during the outpatient consultations at the Medical Center in Bad Vigaun. Patients will be screened against the following criteria:

- Age ≥18 years at the time of enrolment.
- Clinically diagnosed with advanced osteoarthritis and with a medical indication for elective TKR.
- Either a scheduled surgery or a documented intention to undergo TKR within the recruitment period.
- Elective surgery is scheduled for at least 14 days after enrolment to allow completion of the 10 to 14-day prehabilitation intervention.
- Physical ability to safely perform the prescribed exercise program, as confirmed by the treating physician.
- Willingness to participate in a digitally supported training intervention at either the center or home-based.
- Sufficient digital literacy and access to internet-enabled devices (smartphone, tablet, or computer).
- Adequate German language proficiency to follow exercise instructions and study procedures.

Exclusion criteria:

Patients will be excluded if any of the following apply:

- Pregnancy at the time of enrolment.
- Emergency, revisional, or non-elective surgery.
- Surgery scheduled less than 14 days after enrolment.
- Severe physical impairment or medical contraindication to exercise training (e.g., unstable cardiovascular disease, uncontrolled hypertension, acute musculoskeletal injury).
- Patients with contraindications outlined in the Medizinisches Leistungsprofil (MLP) 2.0 that preclude rehabilitation and/or surgery.
- Participation in another clinical study that could interfere with the intervention or study outcomes.

Participant Recruitment and Informed Consent

Potentially eligible patients will be identified among those scheduled for elective TKR with one of the study members at the Medical Center Bad Vigaun. During the initial telephone contact, patients will only be contacted to arrange the date for their preoperative consultation, and no information regarding the study will be provided at this stage. Once a surgical consultation has been scheduled, patients will meet the orthopedic surgeon to discuss the indication, procedure, and potential risks and benefits of the planned TKR. After a positive decision has been made, the investigator will provide the first information about the study. Patients who meet the eligibility criteria will receive comprehensive verbal and written information, including the purpose, procedures, potential risks and benefits, confidentiality safeguards, and the voluntary nature of participation. They will be given sufficient time to consider participation and may take up to two days to decide, allowing them to discuss the study with family members or healthcare professionals if desired. A member of the research team will be available to answer any questions, confirm eligibility, and obtain written informed consent before any study-related procedures are initiated. Following the signing of the informed consent, patients will undergo baseline assessments (PRE1) and will be randomized to either the intervention or the control group. Before any study involvement or assessment, the informed consent will be signed and dated by both the patient and a member of the research team, with a copy provided to the patient and the original securely stored in accordance with institutional policy. All study-related procedures will be conducted in compliance with the Declaration of Helsinki, Good Clinical Practice (GCP), and national regulations.

Randomization

Patients will be randomized after the completion of baseline assessments (PRE1) by a member of the local research team using the package “blockrand” for R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Randomization will be generated using a computer-generated permuted block with a 1:1 allocation ratio to either the multimodal video-supported prehabilitation intervention or usual care (control group). Allocation will be stratified according to the following baseline characteristics: (i) sex (male, female) and (ii) functional status assessed by the 6-minute walk test (6MWT). For the 6MWT, the following cut-off

values will be applied: ≤ 314 m (indicative of poorer postoperative performance) [34] and ≥ 315 m (indicative of better postoperative performance) [35]. These stratification factors are used to support balanced group allocation in this feasibility trial. Afterwards, patients will be informed of their treatment allocation.

Usual care (Control Group)

All patients allocated to the usual care group arm will follow the regular treatment provided by the *Medizinisches Zentrum Bad Vigaun* after TKR surgery. Briefly, patients attend a pre-surgery consultation with the orthopedic surgeon and the anesthesia team. Hospital admission generally occurs one day before surgery for routine diagnostics and preparation. Surgical procedures are performed according to institutional standards, in some cases supported by robotic assistance (ROSA® system, Zimmer Biomet). The average post-surgery hospital stays range from 6 to 12 days, depending on medical recovery and wound status. Following TKR and a transition phase of 10 to 14 days at home, patients will undergo regular standardized 3-week inpatient rehabilitation (Phase II) at the site in accordance with the *Medizinisches Leistungsprofil für die stationäre Rehabilitation* [36]. During this period (REH1 and REH2), patients will receive the regular interdisciplinary rehabilitation, including medical care, physiotherapy, occupational therapy, nursing, psychological support, social work, and health education according to the *PVA Leistungskatalog* [36].

Multimodal video-supported prehabilitation intervention (Intervention Group)

Patients allocated to the intervention group will undertake prehabilitation over a period of 10 to 14 days before surgery and receive digital support during the transition phase (i.e., between discharge from hospital and the beginning of the inpatient rehabilitation (REH1). The prehabilitation intervention will include exercise training as well as general health literacy information delivered through a digital application (aktivplan). Patients of the intervention group will have access to aktivplan throughout the whole study period. In addition, patients will receive an in-person introduction to the rehabilitation center and will be familiarized with exercises to be taken up during postoperative rehabilitation, thereby supporting continuity of care.

The primary aim of the prehabilitation intervention is to optimize physical and functional capacity before surgery to enhance postoperative recovery and establish a solid foundation for rehabilitation, as well as to inform and psychologically prepare

patients with improved self-efficacy towards positive outcomes and experience, as well as their own ability to adhere to the required protocols and activities. The primary physical component of the prehabilitation program will focus on:

- Practicing and training gait with crutches,
- Strengthening the quadriceps and hip musculature,
- Improving knee mobility,
- Enhancing balance and coordination.

The secondary psychological component includes:

- Information mediated through digital health application materials as well as during remote video consultation,
- Engagement with prehabilitation activities having a general potential to improve psychological stance towards surgery, expected outcomes, experience, and one's own ability to adhere to procedures and activities as planned.

Six training sessions will be planned for each week, lasting approximately 20 to 30 minutes. At the beginning of the program, patients will attend an introductory session at the Medizinisches Zentrum Bad Vigaun, during which exercise techniques will be demonstrated and practiced, safety aspects explained, and individual adaptations made if necessary. Subsequently, the program will be carried out at home with pre-recorded video support using the aktivplan application (Ludwig Boltzmann Institute for Digital Health and Prevention), which will provide structured exercise instructions. aktivplan will also allow documentation of training adherence. Teleconsultation via the CAATS software (Loidl Consulting, Wien, Austria) will be scheduled within the first 3 to 5 days to provide feedback, ensure exercise safety, and support progression. In addition, stAPPone research sensor insoles (Stappone, Wien, Austria) will be used during standardized tests in clinical settings as well as during home-based training assessments and sessions. The sensor insoles will enable the objective recording of training data, such as plantar pressure distribution and regular gait parameters, such as number of steps, step length, and cadence, thereby supporting training documentation and progress monitoring during the preoperative phase.

Training volume (number of sets and repetitions) will be individualized by an experienced and accredited exercise therapist based on each participant's functional capacity and exercise tolerance. If required, the training program will be adjusted during the prehabilitation phase according to participant progress and tolerance. Adjustments will primarily be made during the scheduled teleconsultation (after 3 to 5 days of training), where participants receive feedback, and modifications are discussed and documented. All training will be documented via the aktivplan application. Safety is emphasized: patients are instructed to avoid pain beyond mild discomfort, to interrupt training in case of swelling, dizziness, or other warning signs, and to promptly report any adverse events to the study team. Adverse events occurring during home-based sessions will primarily be captured through direct contact with a member of the research team, who is reachable by phone throughout the intervention period.

An important feature of the intervention is continuity with inpatient rehabilitation. Many of the exercises introduced during the prehabilitation phase (PRE1 and PRE2) are seamlessly integrated into the standard rehabilitation (REH1 and REH2) routine at Bad Vigaun. This familiarization before surgery is expected to shorten the learning curve, improve adherence, and accelerate functional recovery after surgery. Integrated into the standard rehabilitation routine at Bad Vigaun. This familiarization before surgery is expected to shorten the learning curve, improve adherence, and accelerate functional recovery after surgery.

A detailed exercise catalogue specifying training components, repetitions, sets, and rest periods is presented in Table 2. The prehabilitation intervention follows guidance from "The Template for Intervention Description and Replication (TIDieR)" [37]. The TIDieR checklist is provided in the Supplemental file S2.

Digitally supported transition

In addition to the multimodal video-supported prehabilitation intervention, digital support will be extended into the early post-discharge period (transition phase). This phase covers the time between hospital discharge and the start of Rehabilitation Phase II (REH1 and REH2). During this period, participants in the intervention group will continue to receive low-threshold digital guidance through the aktivplan application.

The content will include simple, safe movements and educational materials reflecting the exercises taught during the postoperative hospital stay at the Medizinisches Zentrum Bad Vigaun. These typically include gentle knee flexion and extension within the pain limits, ankle mobility exercises, light isometric contractions of the quadriceps, and gluteal muscles. These activities will require roughly 5 to 10 minutes daily and are designed to help patients maintain mobility, support early functional recovery, and promote confidence in using the healing limb while at home.

By providing structured yet flexible guidance, the digital support aims to empower patients to take an active role in their recovery, fostering self-efficacy, motivation, and continuity of care between the inpatient surgical phase and the upcoming rehabilitation program. It encourages patients to remain active within safe limits, reinforces exercises introduced by physiotherapists, and supports gradual preparation for the structured Rehabilitation Phase II.

Rehabilitation

After surgery, all patients will undergo the standard rehabilitation program (REH1 and REH2) at the Medizinisches Zentrum Bad Vigaun according to the Medizinisches Leistungsprofil für die stationäre Rehabilitation [36].

Description and data protection of the digital tools

The study employs both digital software applications and sensor-based systems that support the implementation, monitoring, and documentation of the prehabilitation intervention. All components comply with the European General Data Protection Regulation (GDPR/DSGVO) and are operated on secure, ~~ISO 27001-~~ certified servers located within the European Union.

Among the digital tools used, aktivplan and CAATS are not classified as medical devices, whereas the MOTUM inertial measurement unit (IMU) system and the stAPPone insole system are CE marked and classified as medical devices under the European Medical Device Regulation (MDR, Regulation (EU) 2017/745) or the former Medical Device Directive (MDD). Within this study, all digital tools and devices used, regardless of their regulatory status, are used solely for educational, organizational, and documentation purposes. None of the systems are intended or used for diagnostic, therapeutic, or clinical decision-making functions.

aktivplan is used as a digital training diary and exercise planner. It provides structured exercise instructions, allows real-time documentation of training adherence, and facilitates feedback between participants and the research team. The application is DSGVO-compliant and hosted by Alphaport OG (Peuerbach, Austria), ensuring encrypted and pseudonymized data handling, with sensitive data stored on servers within the European Union. It does not collect physiological or sensor-derived data. In addition, aktivplan has been used in previous studies [38, 39] with approval of the Landesethikkommission Salzburg**.**

The CAATS teleconsultation software enables secure, video-based supervision and communication between patients and the study team. It is CE-marked, DSGVO-compliant, and hosted on ISO 27001-certified servers within the European Union. CAATS is used solely for one teleconsultation session with a qualified health care professional from the study center to provide feedback, increase exercise safety, and support motivation. CAATS is not used for diagnostic or therapeutic decision-making and operates solely as a communication interface.

The MOTUM IMU system is a sensor that is CE-certified and MDR-classified. It will be used to capture biomechanical motion data for scientific purposes at pre- and post-testing (PRE1, PRE2, and REH2, respectively) only. All data are stored on institutional servers in the European Union and used exclusively for research purposes without any diagnostic or therapeutic function.

The stAPPone insoles, used by the patients at home during training, are class I medical devices (MDD) equipped with 12 pressure sensors, an accelerometer, a gyroscope, and a magnetometer. They enable the objective recording of plantar pressure distribution and gait parameters such as step count, length, and cadence during testing and training sessions. All data is DSGVO-compliant, encrypted, and stored on secure servers within the European Union.

Sample size

The sample size calculation is determined a priori, and variance is based on the baseline 6-minute walk test (6MWT) using the reported value of Hsieh et al., 2020 RCT study [40]. The pooled baseline standard deviation (SD) of ≈ 95 m will be considered. Based on this variability, a between-group difference of 50-60 m corresponds to a standardized mean difference in the range of d ≈ 0.53-0.63, which

provides a plausible magnitude of change for contextualizing exploratory between-group differences in this feasibility study.

Given the feasibility-oriented nature of the trial, the sample size is not chosen to formally test hypotheses or to demonstrate clinical effectiveness. Instead, the sample size is selected to support the evaluation of feasibility outcomes (including recruitment, retention, adherence, and data completeness) and to allow estimation of outcome variability and effect sizes required for the planning of a future adequately powered randomized controlled trial.

To account for potential dropouts (≈ 10%), the recruitment target will be set at a minimum of 60 participants (30 per group). If recruitment permits, the sample size may be expanded to 80 participants (40 per group) to improve the precision of feasibility estimates and exploratory effect size estimates, without modifying the feasibility focus of the study.

Outcomes

Primary outcomes

The primary outcome focuses on evaluating the feasibility of implementing a multimodal, digitally supported intervention encompassing both a short-term prehabilitation phase before surgery and an early transitional digital support phase after hospital discharge. Feasibility will be assessed in terms of recruitment, adherence, safety, and patient acceptability across both components. Feasibility is operationalized into four domains: Process, Resource, Management, and Participant engagement, following the structure presented in Table 3.

The process outcomes will include the recruitment rate, defined as the proportion of eligible patients who are approached and provide informed consent; refusal rates, assessed through frequency and reasons for non-participation; and the retention rate, defined as the proportion of enrolled patients who complete the study. These indicators will evaluate the ability to identify, enroll, and retain participants throughout the perioperative pathway.

Resource outcomes will assess the communication with participants, including the schedule, duration, and modality of contact between study staff and participants, to identify potential logistical or organizational challenges, and will further evaluate data collection and entry procedures to determine their practicality and reliability.

Management outcomes will focus on digital tool usability, including data on the use of aktivplan and CAATS teleconsultation, such as completion rates of digital questionnaires, training documentation, and potential technical issues encountered. Participant engagement outcomes will include acceptance, usability, user experience, fidelity, adherence, and safety. Acceptability will be measured through post-session participant surveys and engagement logging. Fidelity will be assessed using a standardized checklist documenting whether each session was delivered as planned; adherence will be measured by attendance rates and digital training diary entries; and safety will be monitored by recording the number and type of serious and non-serious adverse events related or possibly related to the intervention or study procedures.

Additionally, user acceptance, usability and user experience of the digital tools as well as user experience will be assessed using validated instruments, including the Unified Theory of Acceptance and Use of Technology (UTAUT-2) [41], the mHealth App Usability Questionnaire (MAUQ) [42], the Mobile App Rating Scale (MARS) [43]; the Perceived Hedonic and Pragmatic Quality Questionnaire (AttrakDiff) [44], and the Affinity for Technology Interaction (ATI) [45].

Secondary outcomes

Clinical outcomes

The clinical outcomes will be assessed in this feasibility study to provide preliminary data on the effectiveness and safety of the multimodal video-supported prehabilitation intervention and digitally supported transition phase. The outcomes will include: i) clinical recovery indicators, ii) patient-reported outcomes. The selection of outcomes follows the recommendations of the Performance Catalogue of the Austrian Pension Insurance (PVA) [36]. The complete schedule of assessments is summarized in Table 4.

i) Clinical recovery indicators

Clinical recovery will be assessed using routinely collected hospital data. The length of hospital stays (LOS), defined as the number of days from the date of surgery to the date of hospital discharge. LOS is widely used in total knee replacement research as a robust and objective measure of postoperative recovery, reflecting the overall efficiency of perioperative care and early functional restoration. In addition, it

will also include the occurrence of postoperative complication rate and hospital readmission rate.

ii) Patient-reported outcomes

The Health Assessment Questionnaire (HAQ) is a validated, patient-reported instrument widely used to evaluate physical functioning and disability in individuals with musculoskeletal conditions such as osteoarthritis and rheumatoid arthritis [46]. It assesses eight domains of daily living: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities. Domain scores are averaged to derive the HAQ Disability Index (HAQ-DI), with higher values indicating greater disability.

The Barthel-index (BI) is a validated, 10-item ordinal scale used to measure functional independence in activities of daily living, including feeding, bathing, dressing, continence, and mobility [47, 48]. Scores range from 0 to 100, with higher scores indicating greater independence.

The Oxford Knee Score (OKS) is a validated, disease-specific patient-reported outcome measure designed to assess pain and physical function in individuals undergoing total knee replacement [49]. It comprises 12 items scored on a five-point Likert scale (0-4), covering activities such as walking, stair climbing, and rising from a chair. Total scores range from 0 to 48, with lower scores indicating greater pain and disability, and higher scores representing better knee function.

The Patient Health Questionnaire-4 (PHQ-4) is an ultra-brief screening instrument designed to assess symptoms of anxiety and depression, comprising the two-item Generalized Anxiety Disorder scale (GAD-2) and the two-item Patient Health Questionnaire depression scale (PHQ-2). Each item is scored from 0 (“not at all”) to 3 (“nearly every day”), producing a total score from 0 to 12, with higher scores indicating greater psychological distress [50].

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) will be applied to assess pain, stiffness, and physical function specific to osteoarthritis. It consists of 24 items divided into three subscales: pain (5 items), stiffness (2 items), and physical function (17 items). Each item will be scored on a 5-point Likert scale (0 = none, 4 = extreme), and subscale scores will be summed, with higher scores indicating worse symptoms or function [51].

The EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) is a standardized, generic measure of health-related quality of life that evaluates five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on five levels of severity, from “no problems” to “extreme problems,” and the instrument also includes a visual analogue scale (VAS) for self-rated health [52].

The Rapid Assessment of Physical Activity (RAPA) is a brief, validated questionnaire designed to assess the physical activity levels among adults [53]. It includes items covering “aerobic” physical activity, strength, and flexibility, providing a quick categorization of participants’ activity levels.

The Exercise Self-Efficacy Scale (ESES) is a validated instrument developed to measure confidence in performing regular exercise under various circumstances [54]. It includes 10 items rated on a 4-point scale, where higher scores reflect greater perceived self-efficacy for exercise.

Functional outcomes

The functional outcomes will be assessed as part of this feasibility study to evaluate the potential impact of the prehabilitation intervention and the digitally supported transition phase on patients' physical capabilities and mobility. These outcomes will provide preliminary data on the effectiveness and effect size of the proposed interventions in improving functional status. The specific outcomes to be measured are: i) anthropometrics and body composition, ii) 6-Minute Walk Test (6MWT); iii) Timed Up and Go (TUG) Test; iv) Single-Leg Stance (SLS); v) Ten-meter gait analysis with crutches (10-mGA^{+}); vi) Ten-meter Walk Test without crutches (10-mWT); vi) Knee Range of Motion (ROM); vii) Handgrip strength (HG).

Biomechanical outcomes will be measured with MOTUM. A wireless inertial sensor measurement unit (IMU) system (Ultium Motion, Noraxon, Scottsdale, AZ, USA) will be used to capture 3D joint kinematics and spatiotemporal parameters using a lower body model complemented by trunk, consistent with the literature [55]. A wireless inertial sensor measurement unit (IMU) system (Ultium Motion, Noraxon, Scottsdale, AZ, USA) will be used to capture 3D joint kinematics and spatiotemporal parameters using a lower body model complemented by trunk, consistent with the literature [55].

Furthermore, stAPPone sensor soles will be used for 6MWT, TUG, and 15-mGA^{+} with crutches in clinical settings as well as for training at home. stAPPone is

a medical-class I-certified smart insole system that combines textile pressure sensors and motion sensors, enabling location-independent mobile gait assessments as well as real-time live biofeedback rehabilitation therapy. The system includes 12 textile pressure sensors as well as 2 accelerometers, 1 gyroscope, 1 magnetometer, and 128mb internal memory in each insole.

i) Anthropometric and body composition

Body mass and height will be measured using a medically approved digital scale and a stadiometer. Subsequently, the body mass index (BMI) will be calculated. Body composition will be assessed using bioelectrical impedance analysis (BIA), a non-invasive, rapid, and reliable method for estimating fat mass, fat-free mass, and total body water. Measurements will be performed using a validated multifrequency BIA device BIACORPUS RX4004M (MEDI CAL HealthCare GmbH, Karlsruhe, Germany), following the manufacturer's guidelines and standard pre-test conditions, including abstention from food, drink, and vigorous physical activity for a specified period before assessment. The obtained data will be used to characterize the patient's body composition, namely fat mass and lean mass, to monitor potential changes over time.

ii) Six-Minute Walk Test (6MWT)

The 6MWT is widely used to assess functional exercise capacity, making it a valuable tool for baseline measurement in patients undergoing knee joint replacement surgery [56]. During the test, patients will be instructed to walk at a comfortable pace along a flat, straight 30-meter indoor corridor for a total duration of six minutes. The primary objective is for the participant to cover the greatest possible distance within the allotted time. Standardized encouragement and instructions will be provided throughout the test to ensure safety, consistency, and motivation. The total distance walked, measured in meters, will be recorded as a key indicator of functional capacity.

iii) Timed Up and Go (TUG)

The TUG test is designed to assess functional mobility and balance, both of which are crucial factors for patients undergoing knee joint replacement surgery. During the test, the patient will be instructed to rise from a standard armchair, walk three meters at a comfortable and safe pace, turn around, return to the chair, and sit

down. The time taken to complete the task, measured in seconds, will be recorded [57]. To obtain the spatiotemporal data, the test will be instrumented with three IMUs placed on the feet and on the trunk to collect additional spatiotemporal data for a more detailed analysis (e.g., time, step frequency, steps required for the turn, and rotation speed at the turn).

iv) Single-Leg Stance (SLS)

In the SLS test, participants will be asked to stand on their dominant leg with their non-dominant leg held in 90° knee flexion. They must keep their non-dominant leg from touching the floor or the other leg while maintaining their balance on the dominant leg. The test will start once the non-dominant leg is lifted from the floor, and it will stop if the non-dominant leg touches the floor, the other leg, or if the participant uses their arms to help maintain balance. At least one practice trial will be conducted before the actual test to familiarize participants with the procedure [58]. The SLS will be performed on a Zebris pressure distribution platform (Zebris Medical GmbH, Isny, Germany), which records objective balance parameters such as center-of-pressure movement and sway characteristics during the stance. The total time a participant can maintain balance will be recorded. The test will be recorded on each leg to assess potential side-to-side asymmetries.

v) Ten-meter Gait Analysis with crutches (10-mGA^{+})

In the 10-mGA^{+}, patients will be asked to walk a 10 meters distance with assistive walking device (e.g., using crutches). The test serves as a functional outcome measure to evaluate the effectiveness of the prehabilitation intervention in improving patients' ability to perform assisted gait safely and independently before surgery. The time taken to perform the test and the number of steps taken will be recorded [59]. The gait will be analyzed using MOTUM's validated biomechanical assessment system, allowing for to capture and monitoring of potential changes of spatiotemporal parameters (e.g., walking speed, step length, cadence, stance, and swing phase duration) and 3D joint kinematics (e.g., knee flexion and extension, knee adduction and abduction, and shank orientation during the stance phase of the gait.

vi) Ten-meter Walk Test without crutches (10-mWT)

In the 10-mWT, patients will be asked to walk 10 meters without crutches. The time taken to perform the test and the number of steps taken are recorded [59]. Gait will be analyzed using MOTUM's validated biomechanical assessment system, allowing for to capture and monitoring of potential changes of spatiotemporal parameters (e.g., walking speed, step length, cadence, stance, and swing phase duration) and 3D joint kinematics (e.g., knee flexion and extension, knee adduction and abduction, and shank orientation during the stance phase of the gait).

vii) Knee range of motion (ROM)

The ROM will be assessed using a standard goniometer, following established measurement protocols [60]. Patients will be positioned in supine lying with the hip in neutral alignment. Passive knee flexion and extension will be measured by aligning the goniometer's fulcrum over the lateral femoral epicondyle, the stationary arm along the lateral midline of the femur directed toward the greater trochanter, and the movable arm along the lateral midline of the fibula pointing toward the lateral malleolus. Measurements will be recorded in degrees, with higher values indicating greater joint mobility. Both active and passive ROM will be assessed bilaterally to detect asymmetries.

vii) Handgrip strength (HG)

The HG strength will be measured using a validated hand-held digital dynamometer (Activbody Activforce 2; Activbody Inc., San Diego, USA), following standardized testing procedures [61]. Patients will be seated in an armless chair with the trunk upright and both feet flat on the floor. The arm will be positioned with the shoulder adducted and neutrally rotated, the elbow flexed at 90°, the forearm in a neutral position, and the wrist maintained in slight extension (up to 30°). After a familiarization trial, patients will perform three maximal voluntary contractions, each for five seconds, with each hand. The highest value obtained, expressed in kilograms of force (kgf), will be recorded for analysis.

Routine rehabilitation outcomes

Routine rehabilitation outcomes will be assessed during the inpatient rehabilitation phase in accordance with the *PVA Leistungskatalog* [36]. Standardized assessments will include HAQ, BI, PHQ-4, WOMAC, EQ-5D-5L, RAPA, and ESES,

which are routinely conducted at admission and discharge to monitor functional independence, psychosocial well-being, and quality of life. Functional measures during rehabilitation will include 6MWT, TUG, SLS, 10-mWT, Knee ROM, LLS, and HG following the schedule defined in Table 4. This data will provide complementary information on lower-limb function and mobility recovery throughout the rehabilitation phases.

Timing and procedures of outcome data collection

Outcome data will be collected at predefined time points across the prehabilitation and rehabilitation pathway to observe the changes from baseline through post-surgery recovery Table 4. During the prehabilitation (PRE1 and PRE2), data will be obtained at PRE1 and again at PRE2 after the completion of the prehabilitation program, but before the surgery. At these two time points, patients will undergo the standardized assessments defined under secondary outcomes and functional outcomes. This procedure will allow the characterization of the initial status and short-term effects of prehabilitation.

In the subsequent rehabilitation phase II (REH1 and REH2), a reduced set of measurements and tests will be repeated as part of the assessment schedule covering the entire treatment pathway (see tables 1 and 4 for details). This approach will allow continuous monitoring of the patients' recovery trajectories and enable direct comparison of rehabilitation outcomes between patients receiving prehabilitation and those receiving usual care. Additionally, semi-structured interviews will be conducted to explore the participants' experiences with prehabilitation and digital support along the patient pathway. These interviews will be scheduled at the end of the digital support phase, either at REH2 (online interviews) or during follow-up (in-person interviews). Timing will be individually coordinated with participants to ensure flexibility. The qualitative findings will complement quantitative outcomes by providing insights into user perception, feasibility, and overall satisfaction with the digitally supported prehabilitation program. These interviews will be conducted by randomly selected sampling, “to saturation” or approximately 10 participants [62].

Patient data will be pseudonymized at source. A separate patient identification Log will link personal identifiers to study IDs and will be stored under restricted access at the study site. The log will contain study ID, family name, given name, date of birth, sex, contact information, consent date, enrolling site, randomization code, and notes.

To complement study findings, aggregated Austrian reference data on total knee replacement (ICD-10: M17, T93, M23) from the Ludwig Boltzmann Institutes' Rehabilitation Research database will be used for contextual comparison of outcomes. The dataset comprises 3,150 anonymized rehabilitation cases collected over the past two years (mean age 68.8 ± 11.6 years; 61.7 % female). This data provides national reference values for key outcomes (6MWT, TUG, ROM, BI, PHQ-4, WOMAC, EQ-5D-5L, HAQ). A coarsened exact matching (CEM) procedure [63] will be applied to compare trial data with the reference dataset and contextualize rehabilitation outcomes within Austrian standard care.

Harms and safety monitoring

All adverse events will be systematically monitored from enrolment until the end of follow-up. An adverse event is defined as any unfavourable and unintended medical occurrence in a participant during the study, regardless of its causal association with the intervention. Serious adverse events are defined as events resulting in death, life-threatening conditions, hospitalization or its prolongation, persistent or significant disability, or any event that the research investigators consider relevant. All events will be documented in standardized case report forms and reviewed by the investigator at the site Bad Vigaun. Each event will be assessed for severity, expectedness, and potential causal association with the intervention. Participants will receive detailed instructions to ensure safe exercise execution and to report any signs of discomfort, pain, or other unexpected symptoms immediately to the study team. Contact for reporting adverse events will also be made readily accessible within the aktivplan to facilitate timely communication with the study team.

Statistical analysis

Statistical analyses will follow the intention-to-treat principle, with an additional per-protocol analysis including patients with at least 70% adherence. All randomized participants will be included in the intention-to-treat analysis according to their allocated group, while the per-protocol analysis will include only those meeting the adherence criteria. Feasibility outcomes such as recruitment, retention, adherence, fidelity, and safety will be summarized descriptively using appropriate measures of central tendency and dispersion (e.g., means, medians, proportions).

Continuous outcomes, including clinical and functional measures, will be described using descriptive group trajectories and graphical representations. Changes over time and between groups will be summarized as descriptive trends. As this is a feasibility study, no inferential statistical models or hypothesis tests will be applied.

Categorical outcomes such as adverse events and patient experience will be summarized descriptively by group and assessment time point. Harms and adverse events will be analyzed descriptively, with rates summarized as frequencies and proportions. No inferential hypothesis tests will be applied to categorical outcomes.

Exploratory subgroup analyses will consider baseline factors such as sex, age, BMI, comorbidities, and functional status. These subgroup analyses are descriptive and hypothesis-generating only and will not be used for confirmatory inference. Missing data will be reported descriptively in terms of amount and pattern, without imputation or assumptions regarding the missing data mechanism.

Given the feasibility-oriented design of the study and its exploratory, hypothesis-generating analytical framework, the emphasis will be on feasibility outcomes and descriptive estimation of possible effect sizes rather than on confirmatory hypothesis testing. No p-values or statistical significance thresholds will be used, and no confirmatory statistical inference will be performed. Analyses will be conducted using R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Qualitative data from participant interviews and open-ended feedback will be analyzed using an established content-analytic approach. A structured qualitative content analysis will be applied as the primary analytical framework to identify themes related to feasibility, acceptability, and perceived usefulness of the intervention [64]. Depending on the depth and variability of the data, thematic analysis may additionally be conducted to capture broader patterns and relationships within the material [65]. All interviews will be audio-recorded with participants' consent and transcribed verbatim. Transcription will be performed locally using Whisper, followed by manual verification by members of the research team to ensure accuracy. To protect participants' privacy, any identifying information (e.g., names of individuals, institutions, or places) will be systematically replaced or removed before transcripts are stored in the study record. Participants will be reminded during the interview to avoid mentioning personal or sensitive data.

Transcripts will be stored in pseudonymized form on secure institutional servers. Audio files may be deleted after transcription accuracy has been verified to enhance anonymity or retained under pseudonymized identifiers until study completion if deemed necessary for quality control. Only authorized members of the study team will have access to the qualitative data.

Publication Strategy

The results of this clinical trial will be published in peer-reviewed scientific journals and may also be presented at scientific conferences. Any publication or presentation of study results requires prior review and approval by the Sponsor. Data protection and confidentiality of all participant information will be strictly maintained; only pseudonymized or aggregated data will be reported. The reporting of the protocol and primary outcomes will follow the recommendations of the CONSORT Statement, including the extension for randomized pilot and feasibility trials (www.consort-statement.org).

At least two scientific publications in international peer-reviewed journals are planned:

1. Publication of the study protocol.
2. Publication of the main trial results (primary and secondary outcomes may be published separately).

Any additional or subsequent publications (e.g., subgroup analyses or complementary investigations) must be discussed with and approved by the Sponsor before submission. The publication of interim results is not intended. Authorship will be based on the recommendations of the International Committee of Medical Journal Editors (ICMJE, https://www.icmje.org). The Principal Investigator will ensure adherence to these guidelines and coordinate the publication strategy in collaboration with the Sponsor and project partners. Detailed provisions on authorship, publication rights, and related responsibilities are defined in the consortium agreement and the internal governance procedures agreed upon within the consortium board of the Prehab2Rehab Project (www.prehab2rehab.at).

Author Contributions

Giorjines Boppre and Gunnar Treff contributed to the conceptualization and design of the study, drafted the initial protocol, and coordinated its revision. Thomas Hofstädter, Hildebert Hutt, and Josef Sturm contributed clinical expertise and reviewed the protocol for medical and procedural accuracy. Daniela Wurhofer, Jan Smeddinck, and Vincent Grote provided methodological input and supported the design and outcome assessments. Andrea Planatscher contributed to the coordination of study materials, documentation, and revisions across multiple sections. Jan Smeddinck provided the original research concept for the overarching project, critically reviewed and contributed to the refinement of the final protocol manuscript. All authors read and approved the final version of the study protocol.

References

1. Hunter, D.J. and S. Bierma-Zeinstra, *Osteoarthritis.* Lancet, 2019. **393**(10182): p. 1745-1759.
2. Murray, C.J., et al., *Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010.* Lancet, 2012. **380**(9859): p. 2197-223.
3. Zhang, Y. and J.M. Jordan, *Epidemiology of osteoarthritis.* Clin Geriatr Med, 2010. **26**(3): p. 355-69.
4. Litwic, A., et al., *Epidemiology and burden of osteoarthritis.* Br Med Bull, 2013. **105**: p. 185-99.
5. Cross, M., et al., *The global burden of hip and knee osteoarthritis: estimates from the global burden of disease 2010 study.* Ann Rheum Dis, 2014. **73**(7): p. 1323-30.
6. Carr, A.J., et al., *Knee replacement.* Lancet, 2012. **379**(9823): p. 1331-40.
7. Sreckovic, S., et al., *Chronic post-surgical pain after knee arthroplasty: a role of peripheral nerve blocks.* Frontiers in Medicine, 2024. **Volume 10 - 2023**.
8. Eurostat. *Surgical operations and procedures statistics*. 2025 18 August 2025; Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Surgical_operations_and_procedures_statistics.
9. Hitzl, W., et al., *Projected numbers of primary total knee replacement in Austria from 2015–2075.* Der Orthopäde, 2019. **48**(2): p. 144-149.
10. Pabinger, C., et al., *Projections of hip arthroplasty in OECD countries up to 2050.* Hip Int, 2018. **28**(5): p. 498-506.
11. Minnella, E.M. and F. Carli, *Prehabilitation and functional recovery for colorectal cancer patients.* Eur J Surg Oncol, 2018. **44**(7): p. 919-926.
12. Hulzebos, E.H., et al., *Preoperative intensive inspiratory muscle training to prevent postoperative pulmonary complications in high-risk patients undergoing CABG surgery: a randomized clinical trial.* Jama, 2006. **296**(15): p. 1851-7.
13. Santa Mina, D., et al., *Effect of total-body prehabilitation on postoperative outcomes: a systematic review and meta-analysis.* Physiotherapy, 2014. **100**(3): p. 196-207.
14. Riddle, D.L., et al., *Using surgical appropriateness criteria to examine outcomes of total knee arthroplasty in a United States sample.* Arthritis Care Res (Hoboken), 2015. **67**(3): p. 349-57.
15. Calatayud, J., et al., *High-intensity preoperative training improves physical and functional recovery in the early post-operative periods after total knee arthroplasty: a randomized controlled trial.* Knee Surg Sports Traumatol Arthrosc, 2017. **25**(9): p. 2864-2872.
16. Skoffer, B., et al., *Efficacy of preoperative progressive resistance training in patients undergoing total knee arthroplasty: 12-month follow-up data from a randomized controlled trial.* Clin Rehabil, 2020. **34**(1): p. 82-90.
17. Wang, L., et al., *Does preoperative rehabilitation for patients planning to undergo joint replacement surgery improve outcomes? A systematic review and meta-analysis of randomised controlled trials.* BMJ Open, 2016. **6**(2): p. e009857.
18. Domínguez-Navarro, F., et al., *A randomized controlled trial assessing the effects of preoperative strengthening plus balance training on balance and functional outcome up to 1 year following total knee replacement.* Knee Surg Sports Traumatol Arthrosc, 2021. **29**(3): p. 838-848.
19. Mat Eil Ismail, M.S., et al., *Preoperative physiotherapy and short-term functional outcomes of primary total knee arthroplasty.* Singapore Med J, 2016. **57**(3): p. 138-43.

20. Nguyen, C., et al., *Effect of Prehabilitation Before Total Knee Replacement for Knee Osteoarthritis on Functional Outcomes: A Randomized Clinical Trial.* JAMA Network Open, 2022. **5**(3): p. e221462-e221462.
21. Skoffer, B., et al., *Efficacy of Preoperative Progressive Resistance Training on Postoperative Outcomes in Patients Undergoing Total Knee Arthroplasty.* Arthritis Care Res (Hoboken), 2016. **68**(9): p. 1239-51.
22. Konnyu, K.J., et al., *Prehabilitation for Total Knee or Total Hip Arthroplasty: A Systematic Review.* Am J Phys Med Rehabil, 2023. **102**(1): p. 1-10.
23. Adebero, T., et al., *Effectiveness of prehabilitation on outcomes following total knee and hip arthroplasty for osteoarthritis: a systematic review and meta-analysis of randomized controlled trials.* Disabil Rehabil, 2024. **46**(24): p. 5771-5790.
24. Jiang, S., et al., *The comparison of telerehabilitation and face-to-face rehabilitation after total knee arthroplasty: A systematic review and meta-analysis.* J Telemed Telecare, 2018. **24**(4): p. 257-262.
25. Kraus, M., et al., *Equal waiting times for all? Empirical evidence for elective surgeries in the Austrian public healthcare system.* Public Health, 2024. **236**: p. 216-223.
26. Artz, N., et al., *Physiotherapy provision following discharge after total hip and total knee replacement: a survey of current practice at high-volume NHS hospitals in England and wales.* Musculoskeletal Care, 2013. **11**(1): p. 31-8.
27. Han, A.S.Y., et al., *Early Rehabilitation After Total Knee Replacement Surgery: A Multicenter, Noninferiority, Randomized Clinical Trial Comparing a Home Exercise Program With Usual Outpatient Care.* Arthritis Care & Research, 2015. **67**(2): p. 196-202.
28. Lisi, C., et al., *Early rehabilitation after elective total knee arthroplasty.* Acta Biomed, 2017. **88**(4s): p. 56-61.
29. Lang, S., et al., *Do digital interventions increase adherence to home exercise rehabilitation? A systematic review of randomised controlled trials.* Archives of Physiotherapy, 2022. **12**(1): p. 24.
30. Lebleu, J., et al., *Digital Rehabilitation after Knee Arthroplasty: A Multi-Center Prospective Longitudinal Cohort Study.* J Pers Med, 2023. **13**(5).
31. Hróbjartsson, A., et al., *SPIRIT 2025 explanation and elaboration: updated guideline for protocols of randomised trials.* BMJ, 2025. **389**: p. e081660.
32. Association, W.M., *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.* JAMA, 2013. **310**(20): p. 2191-2194.
33. (ICH), I.C.f.H.o.T.R.f.P.f.H.U., *ICH Harmonised Guideline: Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E&(R2)*. 2016: Geneva.
34. Bade, M.J., et al., *Predicting poor physical performance after total knee arthroplasty.* Journal of Orthopaedic Research, 2012. **30**(11): p. 1805-1810.
35. Ferreira, A.M., et al., *The Value of a Standardized Knee Functional Assessment in Predicting the Outcomes of Total Knee Arthroplasty.* J Knee Surg, 2021. **35**(10): p. 1126-1131.
36. Pensionsversicherungsanstalt, *Medizinisches Leistungsprofil für die stationäre Rehabilitation (MLP STAT)*, in *MLP STAT*. 2025, Pensionsversicherungsanstalt (PVA): Wien.
37. Hoffmann, T.C., et al., *Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide.* Bmj, 2014. **348**: p. g1687.
38. Leysen, D., et al., *Feasibility of the aktivplan Digital Health Intervention for Regular Physical Activity Following Phase II Rehabilitation: Protocol for a Mixed Method*

Randomized Controlled Pilot Study (ACTIVE-CaRe Pilot). JMIR Res Protoc, 2025. **14**: p. e73704.
39. Mayr, B., et al., *Effects of structured exercise training on miRNA expression in previously sedentary individuals.* PLoS One, 2024. **19**(12): p. e0314281.
40. Hsieh, C.J., et al., *Effect of Outpatient Rehabilitation on Functional Mobility After Single Total Knee Arthroplasty: A Randomized Clinical Trial.* JAMA Netw Open, 2020. **3**(9): p. e2016571.
41. Harborth, D. and S. Pape, *German Translation of the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) Questionnaire.* SSRN Electronic Journal, 2018.
42. Meryk, A., et al., *Use of Daily Patient-Reported Outcome Measurements in Pediatric Cancer Care.* JAMA Network Open, 2022. **5**(7): p. e2223701-e2223701.
43. Messner, E.-M., et al., *The German Version of the Mobile App Rating Scale (MARS-G): Development and Validation Study.* JMIR Mhealth Uhealth, 2020. **8**(3): p. e14479.
44. Hassenzahl, M., M. Burmester, and F. Koller, *AttrakDiff: Ein Fragebogen zur Messung wahrgenommener hedonischer und pragmatischer Qualität*, in *Mensch & computer 2003: interaktion in bewegung*. 2003, Springer. p. 187-196.
45. Franke, T., C. Attig, and D. Wessel, *A Personal Resource for Technology Interaction: Development and Validation of the Affinity for Technology Interaction (ATI) Scale.* International Journal of Human–Computer Interaction, 2019. **35**(6): p. 456-467.
46. Bruce, B. and J.F. Fries, *The Health Assessment Questionnaire (HAQ).* Clin Exp Rheumatol, 2005. **23**(5 Suppl 39): p. S14-8.
47. Mahoney, F.I. and D.W. Barthel, *FUNCTIONAL EVALUATION: THE BARTHEL INDEX.* Md State Med J, 1965. **14**: p. 61-5.
48. Quinn, T.J., P. Langhorne, and D.J. Stott, *Barthel Index for Stroke Trials.* Stroke, 2011. **42**(4): p. 1146-1151.
49. Dawson, J., et al., *Questionnaire on the perceptions of patients about total knee replacement.* J Bone Joint Surg Br, 1998. **80**(1): p. 63-9.
50. Kazlauskas, E., et al., *Psychometric properties of the Patient Health Questionnaire-4 (PHQ-4) in 9230 adults across seven European countries: Findings from the ESTSS ADJUST study.* Journal of Affective Disorders, 2023. **335**: p. 18-23.
51. Bellamy, N., et al., *Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee.* J Rheumatol, 1988. **15**(12): p. 1833-40.
52. Bilbao, A., et al., *Psychometric properties of the EQ-5D-5L in patients with hip or knee osteoarthritis: reliability, validity and responsiveness.* Quality of Life Research, 2018. **27**(11): p. 2897-2908.
53. Kulnik, S.T., et al., *Translation to German and linguistic validation of the Rapid Assessment of Physical Activity (RAPA) questionnaire.* J Patient Rep Outcomes, 2023. **7**(1): p. 109.
54. Kroll, T., et al., *The SCI Exercise Self-Efficacy Scale (ESES): development and psychometric properties.* Int J Behav Nutr Phys Act, 2007. **4**: p. 34.
55. Liu, W. and J. Bai, *The correlation of gait and muscle activation characteristics with locomotion dysfunction grade in elderly individuals.* Frontiers in Bioengineering and Biotechnology, 2024. **Volume 12 - 2024**.
56. Jakobsen, T.L., H. Kehlet, and T. Bandholm, *Reliability of the 6-min walk test after total knee arthroplasty.* Knee Surg Sports Traumatol Arthrosc, 2013. **21**(11): p. 2625-8.
57. Podsiadlo, D. and S. Richardson, *The timed "Up & Go": a test of basic functional mobility for frail elderly persons.* J Am Geriatr Soc, 1991. **39**(2): p. 142-8.

58. Goldberg, A., A. Casby, and M. Wasielewski, *Minimum detectable change for single-leg-stance-time in older adults.* Gait & Posture, 2011. **33**(4): p. 737-739.
59. Lozano-Meca, J., J. Montilla-Herrador, and M. Gacto-Sánchez, *Gait speed in knee osteoarthritis: A simple 10-meter walk test predicts the distance covered in the 6-minute walk test.* Musculoskeletal Science and Practice, 2024. **72**: p. 102983.
60. Norkin, C.C. and D.J. White, *Measurement of joint motion: a guide to goniometry*. 2016: FA Davis.
61. Roberts, H.C., et al., *A review of the measurement of grip strength in clinical and epidemiological studies: towards a standardised approach.* Age and Ageing, 2011. **40**(4): p. 423-429.
62. Hennink, M. and B.N. Kaiser, *Sample sizes for saturation in qualitative research: A systematic review of empirical tests.* Social Science & Medicine, 2022. **292**: p. 114523.
63. Blackwell, M., et al., *Cem: Coarsened Exact Matching in Stata.* The Stata Journal, 2009. **9**(4): p. 524-546.
64. Mayring, P., *Qualitative content analysis: theoretical foundation, basic procedures and software solution.* 2014.
65. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative research in psychology, 2006. **3**(2): p. 77-101.

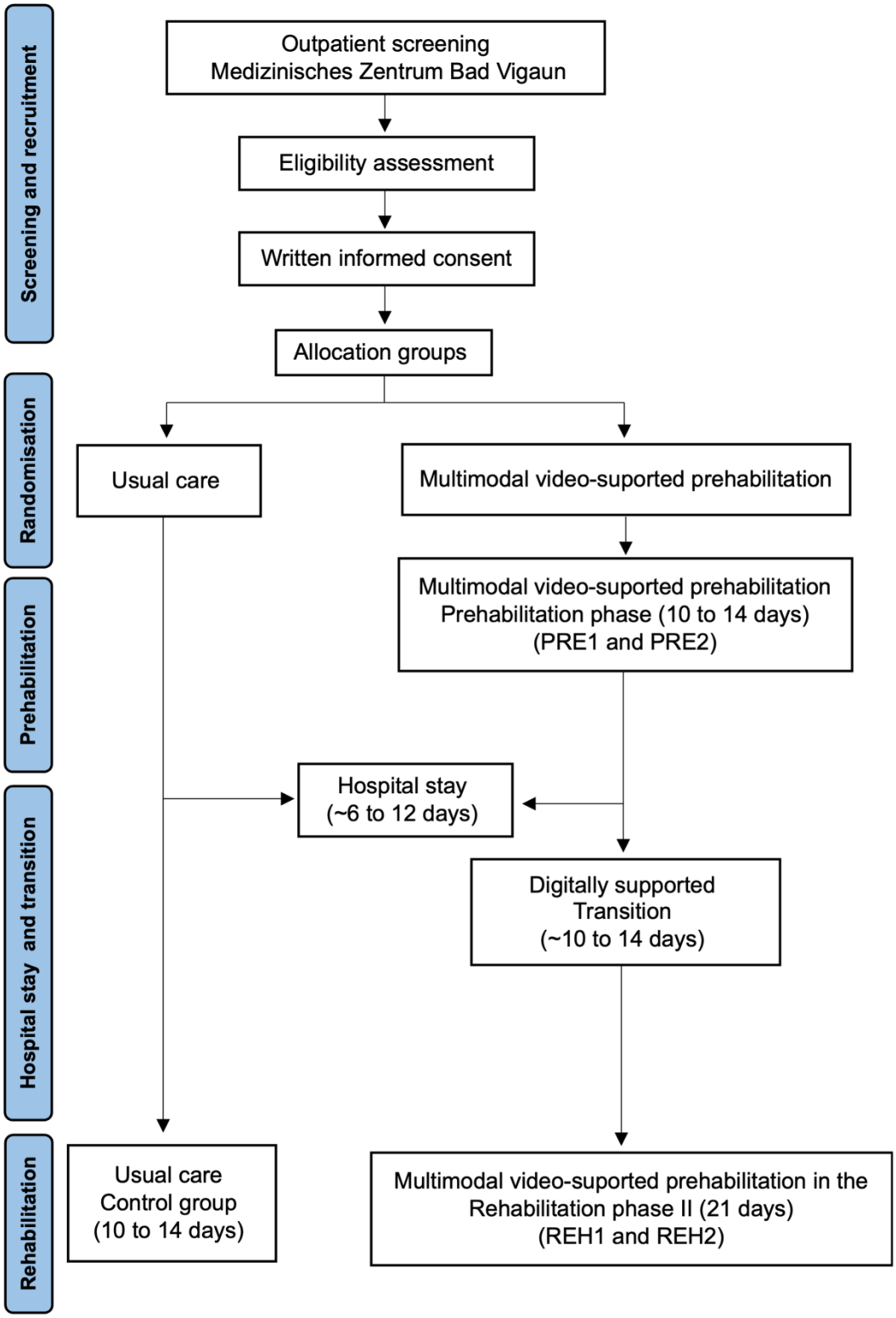

Figure 1: Flow chart of the Prehab2Rehab-Knee Trial
Abbreviations: Start of prehabilitation (PRE1); end of prehabilitation (PRE2); start of rehabilitation (REH1); end of rehabilitation (REH2).

Table 1: SPIRIT schedule of enrolment, intervention, and assessments

Timepoint	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				
	Screening	0	PRE1	PRE2	Discharge	REH1	REH2
Enrolment							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
Interventions							
Prehabilitation group		X	X				
Control group		X	X				
Assessments							
Demographics			X				X
Unified Theory of Acceptance and Use of Technology (UTAUT-2)							X
mHealth App Usability Questionnaire (MAUQ)							X
Mobile App Rating Scale (MARS)							X
Perceived hedonic and pragmatic quality questionnaire (AttrakDiff)							X
Affinity for Technology Interaction (ATI)							X
Structured interviews							X
Health Assessment Questionnaire (HAQ)			X	X		X	X
Barthel-Index (BI)			X			X	(X)
Oxford Knee Score (OKS)			X				X
Patient Health Questionnaire-4 (PHQ-4)			X	X		X	X
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)			X			X	X
EuroQol-5 Dimensions-5 Levels (EQ-5D-5L)			X	X	X	X	X
Rapid Assessment of Physical Activity (RAPA)			X				X
Exercise Self-Efficacy Scale (ESES)			X	X			X
Anthropometrics and Bioelectrical impedance analysis (BIA)			X				X
6-Minute Walk Test (6MWT)			X			X	X
Timed Up and Go Test (TUG)			X	X		X	X
Single-Leg Stance (SLS)	X	X				X	X

Ten-meter Gait Analysis with crutches (10-mGA+)			X	X		X	(X)
Ten-meter Walk Test without crutches (10-mWT)			X	X			X
Knee Range of Motion (ROM)			X	X	X	X	X
Handgrip (HG) strength			X				X
Abbreviations: Start of Prehabilitation (PRE1); end of Prehabilitation (PRE2); start of Rehabilitation (REH1); end of Rehabilitation (REH2); Follow-up (FU). (X): Optional							

Table 2: Video-based exercise program prehabilitation

Periodization	Component	Exercise	Sets	Repetitions / Time	Rest
Week 1	Gait training with walking aids (wearing shoes with sensor insoles)	Normal walking (NW); Stork walking (SW);	NW 2 SW 1	NW 1 to 2 min SW 1 min NW 1 to 2 min	-
	Mobilization and strengthening in supine (without shoes)	Bilateral ankle pumps	1	15 to 20 reps each side	-
		Bilateral heel slides	1	15 to 20 reps each side	-
		Isometric quadriceps contraction with towel roll (knee extension), bilateral	1-2	15 to 20 reps each side	30 s
		Bridging	1-2	10 to15 reps	30 s
	Optional	Single-leg bridge hold (advanced)	1-3	5 to10 s	30 s
		Clamshell	1-2	15 to 20 reps each side	30 s
	Coordination and strengthening in standing (with shoes and sensor insoles)	Sit-to-stand	1-3	10 to 20 reps	30 s
		Single-leg stance with slight knee flexion, with support if needed (optional without support)	1-2	15 to 30 s each side	30 s
	Optional	Step-ups (advanced)	1-3	5 to 10 reps each side	30 s
		Split squat (advanced)	1-2	5 to 10 reps each side	30 s
Week 2	Gait training with walking aids (wearing shoes with sensor insoles)	NW SW	NW 2 SW 1	NW 2 min SW 1 min NW 2 min	-
	Mobilization and strengthening in supine (without shoes)	Bilateral ankle pumps	1	20 reps each side	-
		Bilateral heel slides	1	20 reps each side	-
		Isometric quadriceps contraction with towel roll (knee extension), bilateral	1-2	20 reps each side	30 s
		Bridging	1-2	15 repetitions	30 s
	Optional	Single-leg bridge hold (advanced)	1-3	10 s	30 s
		Clamshell	1-2	20 reps each side	30 s
	Coordination and strengthening in standing (with shoes and sensor insoles)	Sit-to-stand	1-3	20 reps	30 s
		Single-leg stance with slight knee flexion, with support if needed (optional without support)	1-2	30 s each side	30 s
	Optional	Step-ups (advanced)	1-3	10 reps each side	30 s
		Split-squat (advanced)	2	10 reps each side	30 s
Notes: Repetitions (reps); Normal walking (NW); Stork walking (SW)					

Table 3: Outcomes for the Prehab2Rehab-KneeTEP

Outcomes		Measure
Primary outcomes		
Feasibility	i) Recruitment rate	A proportion of eligible patients who are recruited and give informed consent to participate in the study.
	ii) Retention rate	The proportion of patients who consent to take part in the study.
	iii) Communication with participants	Schedule and duration of communication between team members and study staff to address operational issues.
	iv) Data collection and entry	Time and system assessment.
	v) Adherence	Average proportion of the prehabilitation sessions attended by the patients.
	vi) Fidelity	Extent to which the intervention is implemented as intended, in adherence to the protocol and with consistency of delivery.
	vii) Safety	The number and type of serious and non-serious adverse events that are related or possibly related to the intervention or study procedures
	viii) Acceptability	Acceptability of digital components assessed via: Unified Theory of Acceptance and Use of Technology 2 (UTAUT-2); Usability: mHealth App Usability Questionnaire (MAUQ); User experience: Mobile Application Rating Scale (MARS); Perceived Hedonic and Pragmatic Quality Questionnaire (AttrakDiff); and Affinity for Technology Interaction (ATI).
Secondary outcomes		
Clinical and functional	i) Clinical recovery indicators	Post-surgery complication rate; hospital readmission rate.
	ii) Patient reported outcomes	Health Assessment Questionnaire (HAQ); Barthel-index (BI); Oxford Knee Score (OKS); Patient Health Questionnaire-4 (PHQ-4); Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC); EuroQol-5 Dimensions-5 Levels (EQ-5D-5L); Rapid Assessment of Physical Activity (RAPA); Exercise Self-Efficacy Scale (ESES).
	iii) Anthropometric and body composition	Body mass (kg); body height (cm); body mass index (kg/m^2); Phase angle; body fat and lean mass (kg).

	iv) Functional exercise capacity	6-Minute Walk Test (6MWT); Timed Up and Go Test (TUG); Single-Leg Stance (SLS); Ten-meter Gait Analysis (10-mGA^{+}); Ten-meter Walk Test without crutches (10-mWT); and Knee Range of Motion (ROM).
	v) Muscle strength.	Handgrip (HG).

Table 4: Schedule and timing of outcome assessments

Outcomes	Prehabilitation		Hospital Stay			Transition	Rehabilitation Phase II	
	PRE1	***PRE2***	***Surgery***	***Rehabilitation Phase I***	***Discharge***		***REH1***	***REH2***
Duration	**10 to 14 days**		**~ 6 to 12 days**			**~10 to 14 days**	**21 days**	
Clinical Outcomes								
Health Assessment Questionnaire (HAQ)	X	X					X	X
Barthel-index (BI)	X						**X**	(X)
Oxford Knee Score (OKS)	X							X
Patient Health Questionnaire-4 (PHQ-4)	X	X					**X**	**X**
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)	X						X	X
EuroQol-5 Dimensions-5 Levels (EQ-5D-5L)	X	X			X		**X**	X
Rapid Assessment of Physical Activity (RAPA)	X							X
Exercise Self-Efficacy Scale (ESES)	X	X						X
Anthropometrics and Bioelectrical impedance analysis (BIA)	X							X
Functional Outcomes								
6-Minute Walk Test (6MWT)	X						**X**	X
Timed Up and Go Test (TUG)	X	X					X	X
Single-Leg Stance (SLS)	X	X					X	X
Ten-meter Gait Analysis with crutches (10-mGA^{+})	X	X					X	(X)
Ten-meter Walk Test without crutches (10-mWT)	X	X						X
Knee Range of Motion (ROM)	X	X			X		X	X
Handgrip strength (HG)	X							X