

Improving Physical Activity Through Adjunct Telerehabilitation Following Total Knee Arthroplasty: Randomized Controlled Trial Protocol

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Background. Physical activity remains low and nearly unchanged from preoperative levels following total knee arthroplasty (TKA), and this is thought to underlie long-term functional limitations, secondary health problems, and higher health care costs after TKA.

Objective. Our objective is to determine whether a telehealth-based intervention could improve physical activity and functional outcomes after TKA.

Design. The design is a 2-arm, parallel, assessor-blinded, randomized controlled trial with baseline, midintervention, postintervention, and 6-month follow-up assessments.

Setting. The setting is one academic medical center and one Veterans Affairs health care system.

Participants. One hundred US military veterans (aged 50–85 years) scheduled for unilateral TKA will participate in this study.

Intervention. The telehealth-based intervention to change physical activity behavior will be delivered through 10 sessions each of 30 minutes over a 12-week period. Participants will be provided with a wearable physical activity monitor to receive feedback on step count and guide goal-setting. Control participants will receive telehealth-based education on nonbehavioral aspects of health for the same frequency and duration as the intervention group. For both groups, telehealth sessions will occur concurrently with standardized outpatient rehabilitation.

Measurements. The primary outcome will be change in physical activity, assessed as daily step counts measured using an accelerometer-based sensor. Secondary outcomes will be measured using the Life-Space Assessment questionnaire and change in physical function (30-Second Chair-Stand Test, Timed “Up & Go” Test, Six-Minute Walk Test, Western Ontario and McMaster Universities Osteoarthritis Index, and Veterans RAND 12-Item Health Survey).

Limitations. Participant and interventionist blinding is not possible.

Conclusions. This trial will assess the efficacy of a novel behavior-change intervention to improve physical activity and physical function in patients after TKA. Effective physical activity behavior change could provide clinicians with a technique to augment current practice and resolve poor physical activity outcomes, long-term health problems, and high costs following TKA.

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More than 700,000 total knee arthroplasties (TKAs) are performed annually in the United States to alleviate pain and disability associated with knee osteoarthritis (OA).¹ Although TKA reduces pain and improves self-reported function, physical activity remains low and nearly unchanged compared with preoperative levels.²⁻⁵ Such low physical activity has negative health consequences including higher mortality and higher prevalence of cardiovascular and metabolic disease.⁶⁻⁸ This evidence suggests that current rehabilitation strategies, primarily directed toward acute postoperative impairments and function, do not address persistent physical activity patterns after TKA.

Chronically low physical activity is a likely mechanism underlying long-term functional limitations, secondary health problems, and higher health care utilization and cost after TKA.^{2,4,8} Behavior-change interventions, based upon principles of social-cognitive and control theories, effectively improve physical activity when administered either in person or via telehealth.⁹⁻¹⁷ With expanding internet access and increasing TKA use, interest in telehealth as a delivery method for rehabilitation following TKA has grown.¹⁸ For example, randomized trials comparing clinic- with telehealth-delivered rehabilitation following TKA resulted in similar patient-reported and functional outcomes.¹⁹⁻²² Additionally, telehealth is well accepted by patients,^{20,23,24} minimizes time and travel burdens for patients in rural or underserved areas,^{25,26} and is less expensive than in-clinic sessions.^{24,27,28} Our previous pilot study used a telehealth-delivered behavior-change intervention in patients who had completed rehabilitation following TKA and found the intervention increased daily step count and was acceptable to the participants.¹³ It remains unknown if a telehealth-based behavior-change intervention improves physical activity when delivered concurrently with conventional outpatient TKA rehabilitation.

We will conduct an assessor-blinded randomized controlled trial (RCT) to determine if a telehealth-based physical activity behavior-change intervention: (1) improves physical activity, and (2) improves physical function. Lastly, to explore the effect of physical activity on health outcomes, we will document health care utilization during the 18 months following TKA. We hypothesize that postoperatively the intervention group will have greater increases in physical activity and physical function than a control group, and the group differences will persist for 6 months following the intervention.

Methods

Study Setting

The study will be conducted at an academic medical center and a Veterans Affairs Medical Center.

Trial Design

This is an assessor-blinded RCT (NCT03226106) with 100 participants randomized into 2 groups (behavior-change intervention [INT] and attention control [CTL]) using computer-generated randomization codes with a 1:1 allocation ratio, stratified by decade of age and presurgical physical activity (≥ 5000 or < 5000 steps/day) (Fig. 1). Randomization will occur after participants undergo TKA but before they begin outpatient rehabilitation; it will be done by an investigator not involved in testing, intervention delivery, or data analysis concealing group allocation.

Participants

Eligible individuals will be US military veterans who are 50 to 85 years of age and scheduled for primary TKA at participating medical centers. A standardized questionnaire will be used to assess exclusion criteria including: severe nonsurgical limb pain ($> 5/10$) with walking, unstable orthopedic, neurological, or cardiopulmonary conditions that limit physical function, uncontrolled hypertension, uncontrolled diabetes, acute systemic infection, active cancer treatment, or stroke within 2 years.

Behavior-Change Intervention

The INT will begin concurrently with outpatient rehabilitation, consisting of 10 mobile-health tablet-based sessions each of 30 minutes. Each of the 10 behavior-change sessions is specifically prescribed to allow for personalized intervention for each participant's circumstance. Frequency of the INT sessions will be tapered down over 12 weeks (Fig. 2). One week before the first telehealth session, a trained clinician will visit the INT participant's home to perform a home-safety check and provide a wearable activity sensor (Fitbit Alta HR, San Francisco, California, USA) and a smart device with installed application. This week will serve as an equipment accommodation period for the participant and establish baseline self-monitored daily step count.

The intervention, delivered using Motivational Interviewing strategies, will systematically address 7 components of successful behavior change (Tab. 1). Motivational Interviewing is a patient-centered communication approach in which participants are encouraged to set their own goals and elaborate on their own reasons for behavior change.²⁹ To standardize intervention dose, all intervention elements are included in each of the 10 sessions (Tab. 2). The participants will self-monitor their daily step counts by using the sensor and software, recording step counts in a participant's log or within the software, and reviewing step counts at each session (approximately 5 minutes). Tailored feedback from the sensor and the interventionist will detail progress over time (approximately 5 minutes). Barriers and facilitators of progress toward walking goals will be discussed (approximately 5 minutes) with emphasis on problem

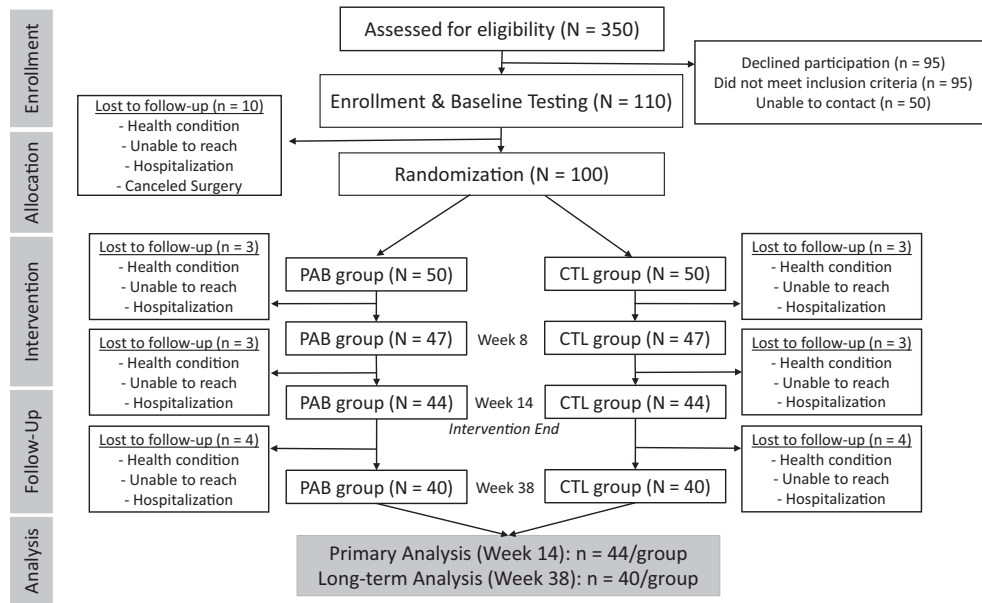


Figure 1. Anticipated Consolidated Standards of Reporting Trials (CONSORT) flow diagram. PAB = physical activity behavior change.

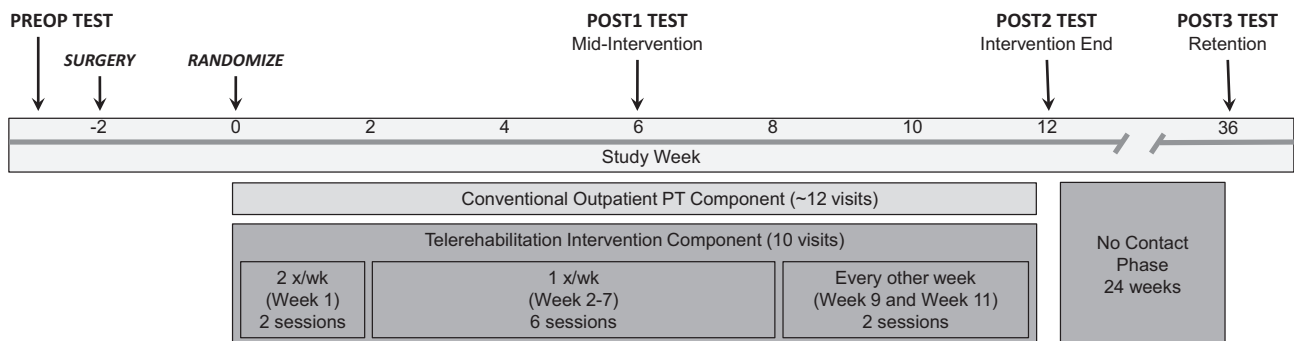


Figure 2. Study design.

solving to take advantage of facilitators and minimize barriers unique to each participant (approximately 5 minutes). Action planning will be based on step count goals set collaboratively by the participant and interventionist, based on data from the wearable sensor (approximately 5 minutes). Finally, encouragement will be provided by the interventionist putting progress or lack of progress in perspective according to the participant's efforts (approximately 5 minutes). During each session, the interventionist will document step-count goal status, participant-identified barriers and facilitators, and problem-solving strategies to be used before the next session. Finally, the sessions will transition from the interventionist leading the discussion to having the participant self-manage the process and lead the sessions, promoting long-term retention of behavior change (Tab. 2).

Attention Control

The CTL sessions will be semiscripted with the same duration and frequency as the INT group to control for attention and volume of telehealth interaction and will use the same mobile-health tablets as described previously. The CTL sessions, delivered by a trained clinician, will focus on health-related education topics including: pain management, home safety, diet, medication management, and falls and fractures.

Outpatient TKA Rehabilitation

Both groups (INT and CTL) will participate in controlled outpatient rehabilitation after TKA. The protocol will consist of exercise, functional training, manual therapy, and modality interventions designed to be delivered in 12 sessions over a 12-week period. All outpatient therapists will be blinded to group assignment. During each

Table 1.
Physical Activity Behavior-Change Components

Intervention Characteristic	Theoretical Framework
Education	Social-cognitive theory
Action plan (collaborative)	Social-cognitive theory
Self-monitoring	Control theory
Tailored feedback	Control theory
Barrier/facilitator identification	Social-cognitive theory
Promotion of problem solving	Social-cognitive theory
Encouragement	Social-cognitive theory

Table 2.
Intervention Overview

Intervention Technique	Progression From Interventionist Coaching to Participant Self-Management	
Education	Interventionist delivers education topic ^a (eg, self-monitoring, problem solving, identifying barrier/facilitators, action plans)	Participant reports most important information learned
Self-monitoring	Interventionist guides participant in tracking daily step-count patterns since last visit	Participant tracks daily step-count trends weekly and over the course of intervention
Tailored feedback	Interventionist leads collaborative review of step-count data for action plan goal setting	Participant leads review of step count and other physical activity goals
Barrier/facilitator identification	Interventionist guides participant to identify barriers/facilitators of goal attainment	Participant self-identifies barriers and facilitators for goal attainment
Promotion of problem solving	Collaborative generation of solutions to overcome barriers to goal attainment	Participant generates solutions to identified barriers to goal attainment
Action planning	Collaborative activity goal generation; interventionist guides, using 3% increase in daily steps from previous week's target	Participant-led weekly goal generation; interventionist ensures independence in action planning
Encouragement	Interventionist reviews plan for the next week, while encouraging participant on successes attained toward improved physical health	Participant leads the review of the plan for upcoming week

^aEach week will have a specific “take-home” message linking physical activity and movement behavior to health. Messages will be brief and based on research evidence.

outpatient session, the therapist will complete a standardized checklist, controlling for time spent on exercise, functional training, and joint range-of-motion activities. Use of subacute and home health services will be documented.

Data Collection and Outcomes

Outcomes will be measured during in-house tests 2 to 4 weeks before the surgical procedure (Fig. 2; PREOP) and postoperatively at intervention midpoint (Fig. 2; POST1), within 1 week of the final telehealth session (Fig. 2; POST2), and 6 months after the telehealth intervention ends (Fig. 2; POST3).

Primary outcome. The primary outcome at all time points will be physical activity, measured as daily step count averaged over a 10-day period. Participants will wear an activPAL micro3 sensor (PAL Technologies,

Glasgow, UK) mounted on their nonsurgical thigh at all times (including sleep). The activPAL sensor uses accelerometer-derived data (20 Hz) to estimate daily step count with >98% accuracy and has been validated for assessing step counts in older adult populations.³⁰

Secondary outcomes. The Life-Space Mobility Assessment (LSA), a secondary measure of physical activity, is a participant-reported measure based on home and community activity.³¹ The LSA composite and subscale scores are highly correlated with measures of function and health for older adults, have excellent test-retest reliability, and are responsive to change in older adults.³¹

The 30-Second Chair-Stand test (30SCS) assesses the number of times in 30 seconds a person can stand and return to sitting from a 46-cm-high chair without using

their upper extremities for assistance.^{32,33} The 30SCS has excellent reliability, established validity, and is responsive to change with intervention.^{34,35}

The Timed “Up & Go” Test (TUG) is a measure of participants’ basic physical function and fall risk. Participants will be instructed to rise from a chair (seat height 46 cm), walk 3 minutes, turn, and return safely to sitting as quickly as possible.³⁶ The TUG has established cutoff scores to indicate fall risk, has high levels of test-retest reliability, and is responsive to changes in mobility status over time.^{37,38}

The Six-Minute Walk Test (6MWT) is a test of walking endurance and long-distance walking ability.³⁹ Participants will be instructed to cover as much ground as possible on a 15-m, straight, level surface in 6 minutes.⁴⁰ Total distance traveled and total number of turns will be documented. The 6MWT has established test-retest reliability and is responsive to change during TKA rehabilitation.^{41,42}

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) measures participant-reported impact of OA on pain, stiffness, and disability.⁴³ The WOMAC is a valid, reliable, and responsive self-report assessment that is recommended for use in patients with lower limb OA.⁴³

The Veterans Rand 12-Item Health Survey (VR-12) is a self-report survey measuring health-related quality of life and has well-established reliability and validity when used with older adult populations.^{44,45}

Other measures. Baseline descriptive measures will include demographics (age, sex, education), anthropometrics (height, weight), comorbidities (Functional Comorbidity Assessment),⁴⁶ depression (Geriatric Depression Scale SF),⁴⁷ cognition (Folstein Mini-Mental State Exam),⁴⁸ exercise self-efficacy (Self-Efficacy for Exercise Scale),⁴⁹ exercise readiness to change (Exercise Stages of Change),⁵⁰ social support (Multidimensional Scale of Perceived Social Support),⁵¹ and fear of falling (Falls Efficacy Scale-International).⁵²

For both groups health care utilization will be observed over an 18-month period after TKA. The length of stay for inpatient use, number of visits for outpatient use, and reason for interactions will be extracted from participants’ medical charts and documented.

Data Management

Protocols for informed consents, screening scripts, checklists for INT and CTL telehealth sessions, and data forms will be kept in a manual of procedures. Study data will be collected and managed by blinded study personnel using double data entry and quarterly reconciliation in the Research Electronic Data Capture platform. Data analysis

will be conducted with SAS software (SAS Institute Inc., Cary, North Carolina, USA).

Data Analysis Plan

The primary analysis will be group comparison of change in average daily step count (primary outcome) from PREOP to POST2 (Fig. 2; primary end point). Statistical inference will be based on a 2-sided *t* test for the GROUP variable from an analysis of covariance-style regression model. Covariates include the stratification variables (PREOP daily step count and age). Conclusions about group differences will be made based on this single statistical test, controlling the type I error rate at 0.05. Secondary analyses will assess differences between study groups in physical function, from PREOP to POST2 as described above for the primary analysis. Daily step count and physical function will also be analyzed at POST3 to evaluate sustainability of the behavior-change intervention. Number of health care visits and length of inpatient stays will be compared between groups to explore the potential impact of increased daily step count on health care utilization.

All participants with outcome measurements will be included in the intent-to-treat analysis. No participant will be dropped from follow-up measurements for lack of compliance with assigned intervention. Patterns of missing data will be examined to provide insight into the mechanism of missingness and guide analysis in an appropriate manner. If data are missing completely at random, analyses of complete cases will provide unbiased parameter estimates. Lastly, missing data due to dropout are accounted for in the sample size estimation.

Monitoring and Auditing

Procedural reliability. Two investigators will be responsible for participant data collection. Reliability of the physical function tests (30SCS, TUG, 6MWT) will be evaluated within and between testers to ensure consistency at the start of the study, after 4 months, and then every 6 months. If the reliability of outcomes is below 90%, as measured by the intraclass correlation coefficient, additional training sessions will be scheduled.

Protocol fidelity. Clinicians providing the telehealth-based INT and CTL interventions will be licensed health care professionals (eg, physical therapist, prosthetist), receive 10 hours of intervention training from the principal investigator (PI), have Motivational Interviewing training (8 hours), and use a standardized semiscripted protocol document that has been created for each of the INT and CTL group sessions. Training for INT will focus on Motivational Interviewing techniques to use during sessions and aid the participants in self-management. The PI will meet with interventionists monthly throughout the course of the study. Additionally, 5% of telehealth sessions for both the INT and CTL groups

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will have in-person fidelity observations by an unblinded assessor. Fidelity outcomes will include delivery of the 7 key components of the behavior-change intervention (INT) or the nonbehavioral educational topic (CTL).

Manuals with protocol details, clinic and home exercise plans, documentation forms, and lab contact information will be provided to all therapists involved in delivering the controlled outpatient protocol to both groups. The manual will be reviewed during 1 to 2 initial training sessions led by a study coordinator. The first participant for each therapist will have 1 to 2 sessions observed for fidelity to the protocol. Following the initial participant, outpatient rehabilitation fidelity will be assessed in 20% of all participants. Additionally, treatment notes for all participants will be reviewed, documenting the number of sessions, session frequency, and time spent on exercise, functional training, and joint range-of-motion activities.

If fidelity in any aspect of the telehealth protocols or outpatient rehabilitation falls below 90%, as assessed by completion of all required aspects, additional training will be scheduled for the outpatient therapist or telehealth interventionist.

Participant compliance. Participant compliance with the telehealth intervention will be tracked in the INT group using data from the Fitbit sensor. When sensors are not being worn, no accelerometer signal is recorded. When reviewing sensor data, a research assistant will look for any unusual or missing data and confirm days of use. We will report participant compliance with sensor use as the percent of days (out of total possible) that the sensor was worn over the intervention period.

Trial monitoring and safety. The PI will have primary responsibility for the overall conduct of the study. The study team will meet quarterly to review study progress, procedures, data quality, and safety. A designated safety officer will be provided with quarterly updates and meet the PI and study coordinators annually. Anticipated adverse events include medical complications of the older adult population and the surgical procedure. Fall risk will be monitored using the TUG and Falls Efficacy Scale-International at all test points.⁵³ Also, occurrence of falls will be recorded at each telehealth session for participants in both groups. If the total number of injurious falls for the intervention group exceeds that of the control group by 5 (5% of enrollment) at any time, the study will be suspended until an evaluation of study relatedness is performed by the safety officer.

Sample Size Estimate

Statistical power has been estimated using variability estimates from pilot data.¹³ The observed standard deviation (SD) of percent change after 3 months of intervention for the pilot sample was 42%, with an effect size of $d = 0.64$. This effect size equates to a detectable

difference of 1611 steps/d between groups. Based on this expected group difference, a 2-sample, 2-sided t test at the 5% level with 80 patients (40 per group) would have 80.7% power to detect a group difference. We will randomize 100 participants (50 per group) to allow for an approximately 20% loss to follow-up.

Role of the Funding Source

The funding sources have had no role in the design of this study, its execution, analyses, interpretation of the data, or decision to submit the results for publication.

Ethics and Confidentiality

The study has received approval from the University of Colorado institutional review board. All participants will provide informed consent and HIPAA authorization before enrollment. Participants' understanding of study expectations, procedures, risks, and benefits will be assessed verbally before they are asked for their informed consent. Deidentified data will be stored in a secure database with daily backup, and hard copies of data will be kept in an approved, secure storage facility. Any protocol modifications will be approved by our institutional review board, reported at 6-month intervals to the trial registry, and detailed when the final results are published. We aim to publish the results of this study in an internationally recognized journal, make the deidentified database publicly available through the trial registry, and inform all participants of the study findings at the conclusion of the study.

Discussion

Reduced physical activity is a long-standing behavioral issue for people with knee OA that is not improved by TKA.^{3,54–56} The lack of increase in physical activity after TKA is particularly troubling considering that the amount of presurgical physical activity is significantly less for people with knee OA compared with healthy individuals of a similar age.⁵⁷ In a previous study from our lab, patients with end-stage knee OA considered to be “high-functioning” took 5886 steps/d on average.¹³ Daily step counts in that range are considered “low active” and are indicative of functional limitation.⁵⁸ Traditional TKA rehabilitation focuses on physical impairments and functional limitations but fails to address chronic low physical activity.⁵⁴ As a result, current rehabilitation does not optimize recovery of physical function or reduce long-term health consequences of low physical activity after TKA.^{2–4}

This study intervention is an innovative combination of behavior-change methods and telehealth technology to address a gap in conventional TKA rehabilitation shortfalls. By using a physical activity behavior-change intervention during TKA rehabilitation, we will address poor physical activity behaviors when these individuals are electing to make a health change (ie, TKA elective surgery), capitalizing on an opportune time for

implementing behavior change. Furthermore, the ability to access rehabilitation providers through telehealth platforms is pertinent to many patients. Although in-clinic supervised behavior-change intervention could be delivered, such programs have a high patient burden (eg, transportation and time), which is of particular concern for individuals living in remote or rural areas.^{59–61}

Our study will be limited to recruiting only Veterans of the US military. For this reason, our study is likely to have a higher percentage of male participants than is represented in the general TKA population.⁶² Another limitation is the inability to blind participants and interventionists due to the nature of the intervention. However, study personnel responsible for collecting and assessing participants' outcomes will be blinded to group assignment. Finally, although initial evidence is promising for the potential of telehealth to reduce rehabilitation costs after TKA, this study is not designed to analyze cost-effectiveness.^{27,28,63} Such an analysis will be warranted if the intervention proves efficacious.

This study is an important step in advancing conventional TKA rehabilitation. Effective physical-activity behavior change, embedded within conventional rehabilitation, could be critical to resolving the chronic poor physical activity outcomes, long-term health problems, and high costs following TKA.

Author Contributions and Acknowledgments

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 Consultation (including review of manuscript before submitting): W.J. Sullivan, P.J. Blatchford, M.J. Miller, J.E. Stevens-Lapsley

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Ethics Approval

The study has received approval from the University of Colorado institutional review board. All participants will provide informed consent and HIPAA authorization prior to enrollment.

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Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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