Optimizing Physical Activity Outcomes After Total Knee Arthroplasty
NCT ID (NCT03226106)
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Study Protocol

I. Hypotheses and Specific Aims:

The primary objective of this randomized controlled trial is to determine efficacy of physical activity behavior-change telerehabilitation on improving physical activity after total knee arthroplasty (TKA).

Aim 1: To determine if PAB (Physical Activity Behavior-Change) intervention results in improved physical activity after TKA compared to the control group (CTL). Physical activity will be measured using accelerometer-based wearable sensors and self-reported daily activity (Life-Space Assessment)[1,23].

Hypothesis 1.1: The PAB group will have greater increases in accelerometer-assessed daily step count (primary outcome) and percent time engaged in standing & walking activity than the CTL group from PREOP to POST2 (primary endpoint), and group differences will persist at POST3.

Hypothesis 1.2: The PAB group will have greater improvements in Life-Space Assessment scores than the CTL group from PREOP to POST2 (primary endpoint), and group differences will persist at POST3.

Aim 2: To determine if PAB intervention results in better physical function after TKA compared to the CTL group. Physical function will be measured with standardized performance-based (30-Second Chair-Stand Test, Timed Up-and-Go, Six-Minute Walk Test) and self-report (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] and Veterans RAND 12-Item Health Survey [VR-12]) measures.

Hypothesis 2: The PAB group will have greater improvements in all functional outcomes compared to the CTL group at POST2 and POST3 test points, with outcomes meeting clinically meaningful thresholds.

Exploratory Aim: To identify predictors underlying responsiveness to PAB rehabilitation (i.e., change in average daily step count) from PREOP to POST2 in the PAB group.

Hypothesis 3: We expect preoperative daily step count and physical activity-related psychosocial factors (self-efficacy, stage of change, social support, fear of falling) will be significant determinants of intervention responsiveness, in addition to key demographic, anthropometric, and comorbidity determinants.

II. Background and Significance:

This study is significant for Veterans with total knee arthroplasty (TKA) based on: 1) high utilization of TKA, 2) persistent physical activity deficits, 3) high rates of secondary health problems and costs following TKA, and 4) lack of guidelines for improving physical activity behavior.

High Utilization of TKA Surgery

The number of Veterans undergoing TKA is increasing. The primary indication for TKA is knee osteoarthritis (OA), a chronic, degenerative joint disease that disables approximately 10% of people over the age of 60 and compromises the quality of life of more than 20 million Americans.[4] The prevalence of OA increases with age, with an estimated 52% of Veterans over the age of 65 having knee OA.[5] As a result, more than 700,000 TKAs are performed each year in the United States, and this number is expected to increase to nearly 3.5 million per year in less than 20 years.[6]

Persistent Deficits in Physical Activity after TKA

While it is clear that TKA intervention is effective for reduction of knee pain, TKA and subsequent rehabilitation do not typically result in significantly increased physical activity.[7] Energy expenditure and daily physical activity after TKA remain similar to pre-surgical levels.[8] This lack of increase in physical activity is particularly troubling when considering that the amount of pre-surgical physical activity is significantly less for people with knee OA than those achieved by healthy individuals of similar age.[9] For example, in our pilot research, we found “high functioning” patients with end-stage unilateral knee OA had 5,886 steps/day on average (see Section D.3) classifying these individuals as “low active”, which is indicative of functional limitation.[10] The issue of low physical activity is particularly important for the VA health-care system, as Veteran VA users are less physically active than Veterans who obtain health care outside the VA.[11]

The same pattern of persistent physical activity limitations after TKA is also seen when examining physical function.[12,13] Even after completion of rehabilitation, walking performance outcomes remain 20-30% lower than healthy, age-matched older adults,[12,14] and more physically demanding tasks, such as stair climb times, are nearly 50% slower.[12] Moreover, 75% of patients report difficulty negotiating stairs

>1 year after TKA.[13] In fact, 52% of TKA patients report some degree of limitation in performing functional tasks, compared to only 22% of age-matched subjects without knee disorders.[13] Physical function continues to worsen over time, with patients two to three years after TKA showing accelerated rates of functional decline relative to expected changes.[15]

Individuals with end-stage knee OA, requiring TKA, exhibit long-standing physical inactivity and poor physical function, which require targeted and tailored intervention. Despite the presence of these long-standing behaviors, current rehabilitation efforts are directed towards acute post-operative impairments following TKA, such as strength and range of motion exercises. While it is clear that progressive strengthening and impairment-based rehabilitation are critical to recovery after TKA,[16] there is also a clear need to address persistent physical activity behaviors with a focused intervention.

High Rates of Secondary Health Problems and Costs

There are severe negative health consequences of chronic low physical activity after TKA.[8,12,17] For example, inactive older adults have higher mortality rates,[18] higher prevalence of cardiovascular disease,[19] and higher prevalence of metabolic syndrome than active people of similar age.[20] The relationship between TKA and risk for negative health consequences is compounded by the underlying issue of OA being linked to metabolic disease. The relationship between metabolic disease and TKA is illustrated in the Veteran population. For example, Veterans with diabetes aged 56-65 years demonstrate rates of TKA that are 2.6 times higher than Veterans without diabetes.[21] Importantly, a key thread common to chronic metabolic disease and OA is underlying sedentary lifestyles.
For patients with knee OA, moving from sedentary to light intensity physical activity can greatly diminish the odds of acquiring the metabolic syndrome (OR = 0.45).[20] However, the typical sedentary behaviors adopted by patients with lower limb OA persist after TKA and conventional rehabilitation. The interaction between physical activity, metabolic disease, and TKA is of foundational significance for our proposed study, which is designed to address the downward spiral of health by targeting improved physical activity behaviors.

The problem of inactivity after TKA also has health cost implications. The associated medical cost for chronic conditions attributed to physical inactivity has been estimated at $35.3 million annually.[22] The cost of physical inactivity likely accounts, in part, for the high costs related to TKA. The pursuit of strategies to reduce the cost of TKA is important, as overall costs are significant. For example, total Medicare expenditures for TKA procedures in 2011 exceeded $3.5 billion.[23]

Increasing physical activity intensity is linked to improved health and quality of life outcomes for patients with chronic disease, such as OA, diabetes and vascular disease.[24-27] For example, individuals with diabetes and peripheral artery disease can significantly improve gait speed and mental health scores with home-based walking interventions, compared to standard of care.[27] Similarly, moderate- compared to low-intensity physical activity is linked to better cardiovascular health, blood glucose control, and quality of life in patients with DM.[28] Furthermore, increased activity is associated with improved physical function, pain, and joint stiffness scores on the Western Ontario and McMasters University Osteoarthritis index (WOMAC) for older adults with OA.[26]

Lack of Guidelines for Improving Physical Activity Behavior after TKA

Conventional rehabilitation guidelines do not address chronic poor physical activity behavior after TKA. As a result, current rehabilitation does not 1) optimize recovery of physical function or 2) reduce long-term health consequences of low physical activity after TKA - two major remaining challenges in rehabilitation. An NIH consensus statement on Total Knee Replacement stated “the use of rehabilitation services is perhaps the most understudied aspect of the perioperative management of TKA patients.”[29] Furthermore, “there is no evidence supporting the generalized use of any specific pre-operative or post-operative rehabilitation intervention.”[29] While evidence has emerged in the past decade for addressing acute impairments after surgery, substantial room remains for improving strategies targeting long-term outcomes following TKA. Specifically, poor physical activity after TKA could be targeted using physical activity behavior-change strategies.

Rehabilitation strategies to improve physical activity after TKA are neither well-defined nor well-studied, despite objective physical activity being well below recommended levels for patients with TKA.[30] Physical activity behavior-change interventions are not included in current rehabilitation guidelines following TKA.[16] Yet physical activity behavior-change interventions are known to benefit older adults with chronic diseases, including hip and knee OA.[25,26] For example, older adults with lower limb OA improved in exercise self-efficacy and exercise minutes per week after behavior-change intervention, with changes persisting 12 months after intervention (effect sizes >0.67 at all time points).[26] In addition,

older adults in Medicare-sponsored physical activity programs have lower fall risk than similarly aged peers.[31] Our pilot study data have also shown that physical activity behavior training can be effective at increasing physical activity and functional outcomes (See Section D.3). This proposed study seeks to determine the efficacy and persistence of a behavior-change effect when incorporating physical activity behavior training into conventional rehabilitation for Veterans after TKA.

III. Preliminary Studies:

We have conducted pilot studies to: 1) examine the current levels of physical activity for patient with TKA and 2) determine the initial effectiveness of the PAB intervention, which are detailed in the next sections.

Physical Activity Description for Patients with TKA after Progressive Rehabilitation

The idea for the PAB intervention was supported by our initial sub-analysis of participants from a recently completed randomized controlled trial (NIH R01-D065900). The intervention of the parent trial involved progressive resistance strengthening exercise to improve functional outcomes. The progressive group was compared to a group of patients receiving traditional rehabilitation after TKA. We hypothesized that the progressive strengthening group would demonstrate superior outcomes in terms of strength, functional performance, and mobility when compared to traditional rehabilitation. Within that study, we performed a sub-analysis to examine physical activity before and after rehabilitation in a subset of participants from both groups using accelerometry (ActiGraph GT3X, ActiGraph Corporation, Pensacola, Florida). We measured physical activity in terms of average steps per day over a one-week period at five time points: before (2 weeks) and after (1, 3, 6, and 12 months) surgery.

This preliminary study showed no significant change in steps/day for the entire cohort, the traditional group, or the progressive strengthening group (Table 2). In other words, mode of rehabilitation

Table 1. Daily Step Count Before and After Total Knee Arthroplasty

Time Point	Traditional Control Group	Progressive Strengthening Group	Total
Pre-Operative	5047 ± 2105	6071 ± 2341	5623 ± 2230
Month 1 Post-Operative	3201 ± 2269 ; p = 0.146	3994 ± 2518; p = 0.257	3598 ± 2323; p = 0.046
Month 3 Post-Operative	3625 ± 1170 ; p = 0.963	5942 ± 3518; p = 0.295	5512 ± 2633; p = 0.563
Month 6 Post-Operative	5704 ± 2966 ; p = 0.004	6299 ± 2976; p = 0.857	6001 ± 2870; p = 0.210
Month 12 Post-Operative	5895 ± 3150 ; p = 0.075	6450 ± 3923; p = 0.381	6151 ± 3385; p = 0.092

Note: Data are presented as mean ± SD; p-values are comparisons to Pre-Operative visit.

(progressive strengthening vs. traditional) had no effect on physical activity. In fact, even with progressive rehabilitation, the participants with TKS only gained and average of 379 steps per day from the pre-operative to 12 months post-operative time points. The lack of change in physical activity (steps/day) is an interesting finding, considering that the focus of the progressive strengthening was designed to improve strength and function outcomes. These results suggest that physical activity after TKA must be an intentional focus of intervention beyond targeted progressive strengthening. From these findings, we inferred that an innovative intervention was necessary to target the persistent physical activity behaviors after TKA.

PAB Pilot Study

We have recently completed a pilot study to test the feasibility and initial efficacy of the PAB intervention for people undergoing unilateral TKA. In this pilot study, the first version of our PAB intervention (including the behavior-change techniques of education, self-monitoring, tailored feedback, barrier identification, problem solving, action planning, and encouragement) was compared to an attention control group in which patients reported their self-assessed recovery by telephone. Each participant began the pilot study as they were ending conventional outpatient physical therapy. Researchers worked collaboratively with the PAB group participants to create physical activity action plans and promote problem solving for overcoming the individually identified barriers to physical activity. Each PAB participant was given a Fitbit wearable sensor and tablet with a Fitbit application for home use similar to the proposed study (see details Section D.4.5). Intervention duration was 12 weeks with remote sessions conducted once weekly between the participant and researcher. The attention control group had the same frequency and duration of contacts with the researcher over the 12 week period.

Results of the pilot study (n=14 per group) demonstrate the feasibility of the intervention as well as the potential for such an intervention to improve physical activity levels. In terms of feasibility, all participants in the PAB intervention group found the devices and periodic interactions to be acceptable, as measured by a compliance rate of 91% (days of Fitbit use) over the 12 week intervention. No adverse events were reported by any participant in either group.

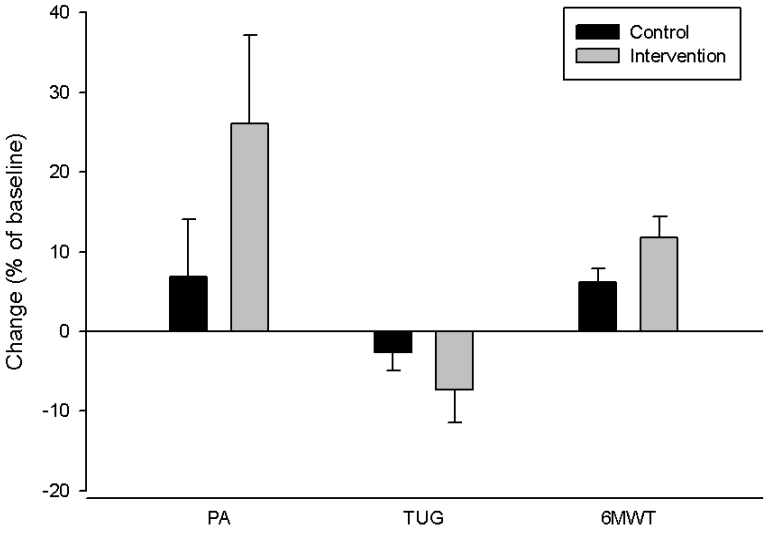

Figure 2. PAB pilot study outcomes. Abbreviations: PA, physical activity; TUG, Timed Up-and-Go test; 6MWT, 6-Minute Walk test.

At the end of the 12-week intervention, the PAB pilot group had an increased step count of 1611 steps/day (PRE: 5456 ± 3003, POST: 7067 ± 3677 steps/day; mean ± SD) compared to 363 steps/day in the control group (PRE: 5250 ± 1544, POST: 5613 ± 2388 steps/day) (Figure 2). The PAB pilot group had a nearly 2 second improvement in the Timed Up-and-Go test (PRE: 9.6 ± 3.1, POST: 7.9 ± 1.9 s) compared to 0.6 second improvement in the control group (PRE: 8.9 ± 1.0, POST: 8.3 ± 1.1 s). The PAB pilot group also increased walking distance by 16.2 m for the 6-Minute Walk Test (PRE: 136.2 ± 37.5, POST: 152.4 ± 26.5 m) compared to 8.5 m in the control group (PRE: 143.9 ± 22.3, POST: 152.4 ± 25.3 m). Although under-powered for between-group statistical comparisons, the PAB pilot group improvements represent medium effect sizes (Steps per day, *d*=0.57; TUG, *d*=0.43; 6MWT, *d*=0.70).

The PAB pilot investigation provides initial evidence that daily step count can be improved through a physical activity behavior-change intervention, and these changes are associated with functional improvements. However, a larger scale intervention is necessary to more definitively demonstrate benefits of such an intervention.

Based on the pilot study experiences, the proposed PAB intervention includes two key alterations. First, the PAB intervention will be initiated two weeks after surgery to better integrate the intervention into conventional rehabilitation. Second, the proposed PAB intervention sessions will taper down in frequency from bi-weekly to once monthly across the 12-week intervention period. This approach provides patients opportunity to frequently interact with the therapist during the initial acquisition of the new behavior and promotes participant self-efficacy as they gradually assume more control of managing their behavior with intervention progression.

IV. Research Methods

A. Outcome Measure(s):

Descriptive Variables. Baseline descriptive measures will include demographics (age, sex, education level), anthropometrics (height, weight, BMI), comorbidities (Functional Comorbidity Assessment[32]), depression (Geriatric Depression Scale SF[33]), cognition (Folstein Mini-Mental State Exam[34]), exercise self-efficacy (Self-Efficacy for Exercise Scale[35]), exercise readiness to change (Exercise Stages of Change[36]), social support (Multidimensional Scale of Perceived Social Support[37]), and fear of falling (Falls Efficacy Scale-International[38]). These descriptive variables will be used as candidate predictor variables for change in accelerometer-based physical activity.

Accelerometer-based Activity Monitoring. The primary outcome for this study will be accelerometer-based physical activity (average daily step count) objectively monitored for all participants over a 7-day period, at all four test points. Participants will wear an activPAL micro accelerometer-based sensor (PAL Technologies, Glasgow, UK) to measure physical activity. The activPAL sensor is a small (23.5x43x5 mm) and lightweight (10 g) device that uses accelerometer-derived information about thigh position to estimate daily step count and time spent in different body positions (e.g. sitting/lying, standing and stepping) with high level of accuracy (99-100%).[39] The sensor will be placed in a small nitrile sleeve and wrapped with a non-allergenic water-proof dressing on the midline of the thigh, approximately 1/3 distance between the hip and knee. Because the activPAL is wrapped in a waterproof dressing, participants will be instructed to wear it at all times (including sleep) except when swimming. The event data file from the activPAL software will be used to determine time spent sitting/lying, standing, and

stepping per day. A customized program will convert data to a file to estimate additional metrics of sedentary behavior (e.g., breaks in sedentary time, average duration of sedentary bouts). Daily step count and time spent in sedentary positions (lying or sitting), standing, and walking (as defined by orientation of the activPAL sensor) will be recorded; daily averages will be taken for the total period, weekdays, and weekend days. The activPAL monitor has been validated in older adult populations for assessing daily step count and types of postures/activities in older populations.[39]

Life-Space Assessment (LSA). The LSA is a participant-reported measure of movement within the home and outside community, extending to movement beyond the geographic region of the participant's home.[40] The LSA asks the participant to report the number of times in the previous 4 weeks that he/she has travelled outside of the bedroom (or room that they sleep in), and life space is evaluated in a series of levels radiating from that room: other rooms in the home, outside the home, within neighborhood (~1/2 mile), within town/city (5 mile), and outside town/city. For each level, participants are asked whether they needed assistance from another person or an assistive device. An LSA score is obtained for each level by multiplying the level number (1-5) by a value for independence (2=no assistance, 1.5=assistive device only, 1=another person) multiplied by frequency of travel in that area (1=<1/wk, 2=1-3x/wk, 3=4-6x/wk, 4=daily). A composite measure of life space is obtained by summing the LSA for each level, with scores ranging from 0 (totally bed-bound) to 120 (travelled out of town every day without assistance). We will also obtain simple scores of life space attained without considering frequency of movement. These measures will include maximal life space (range 1-5); independent life space (range 1-5), the highest life space attained without help from another person or assistive device; life space using assistance, the highest life space attained with help from another person or assistive device; and restricted life space, a dichotomous measure of independent life space defining individuals having restricted (e.g. confined to neighborhood) or unrestricted independent life space. Baker et al.[41] have shown that life space composite, independent life space, and life space using assistance measures are highly correlated with measures of function and health, and thus, are most likely to be sensitive to change in the proposed intervention. The LSA has established validity compared with physical function, health and disability measures.[42] The LSA has excellent test-rest-reliability (ICC=0.96) and is responsive to change in community-dwelling older adults.[40]

The Late Life Function and Disability Instrument (LLFDI). The LLFDI is a measure of self-perceived function and participation in everyday life will be measured using the Late Life Function and Disability Instrument (LLFDI).[1,2] The function component contains 32 questions surrounding the participant's perceived difficulty level on certain functional tasks.[1] The disability component consists of 16 items and participants each rate how often they do that item, and how limited they feel doing the activity.[2] The limitation questions in the disability component are referred to as the Late Life Disability Instrument-Instrumental Limitation Scale (LLDI-IL) and measure the participant's perceived limitations in a variety of instrumental activities of daily living (IADLs).[2] Higher scores on the LLDI-IL indicate improved participation in home and community activities. The LLDI-IL was used to measure participation in 218 individuals before and 12-months following a TKA, and participants showed significant improvements in participation 12-months post TKA.[43] Although the LLDI was developed for elderly individuals, participants post-TKA <65 years old showed significant improvements on the LLDI-IL. However, one third of all participants still scored <67/100 on the LLDI-IL which indicated that they had participation restrictions 1-year and 2-years post TKA.[43,44]

The Barriers to Being Active Quiz (BBAQ). Barriers to physical activity will be quantitively measured using the BBAQ, a 21 question self-report measure of barriers to physical activity published by the Centers for Disease Control and Prevention (CDC).[3] Within the BBAQ, barriers to physical activity are classified into 7 subscales: lack of time; social influence; lack of energy; lack of willpower; fear of injury; lack of skill; and lack of resources. In a sample of older adults, the BBAQ has shown moderate to strong internal consistency on all 7 subscales, and high overall reliability.[45] A score of >5 on any subscale indicates a specific barrier to physical activity.

30-Second Chair Stand Test (30SCS). The 30SCS is a measure of functional ability and lower extremity strength.[46,47] Participants will be instructed to stand from a seated position and return to sitting as quickly as possible, safely in the 30-second time frame. The chair will be a standardized height of 46 cm. Participants will be encouraged to not use their upper extremities for pushing, but if they are unable, hand placement on thighs will be allowed and documented as an adapted test result.[46] The 30SCS test has excellent reliability when used with patients with lower limb OA, has established validity compared to other standardized measures, and is responsive to change with intervention.[48,49]

Timed Up-and-Go (TUG). The TUG will be performed by participants at all test points, as a measure of basic mobility skill and indicator of fall risk. Participants will be instructed to rise from a chair (seat height of 46 cm), walk

three meters, turn and return to sitting in the same chair as quickly as possible, safely.[50] The TUG test has established cut-off scores to indicate fall risk in community dwelling older adult populations.[51] In addition, the TUG has high levels of test-retest reliability,[52] and is responsive to changes in mobility status over time.[53]

Six-Minute Walk (6MW). The 6MW is a test of walking endurance and long-distance walking ability and is a commonly used measure for quantifying functional performance following TKA.[54,55] Participants will be instructed to cover as much ground as possible during the six-minute time with rest allowed as needed, although the timer will continually run. Total distance traveled and total number of turns will be documented at each test. The 6MW has established test-retest reliability in populations with lower limb OA[56] and is responsive to change during rehabilitation following TKA.[57]

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The WOMAC assesses participant reported impact of OA on pain, stiffness, and disability.[58] The WOMAC consists of 24 items and takes approximately 10 minutes for the participant to complete. The WOMAC is a valid, reliable, and responsive self-report assessment that is recommended for use in assessing functional outcomes related to lower limb OA.[58,59]

Veterans RAND 12-Item Health Survey (VR-12). The VR-12 is a self-report survey that takes approximately five minutes for participants to complete. The survey measures health-related quality of life, is commonly used as an outcome measure for patients with OA, and has well-established reliability and validity when used with older adult populations.[60,61]

Semi-structured interviews and field notes. Semi-structured interviews will be used to discover participants' perceived changes in barriers and facilitators to physical activity, as well as life participation following the PAB intervention. We will select up to 20 participants from the PAB group who agree to participate in semi-structured interviews. Selected participants will then be interviewed following randomization and at the end of the intervention (POST2). Interviews will occur either in person, over the phone, or through an audio-visual application. All interviews will be audio-recorded and transcribed verbatim. Additionally, the facilitator will take field notes during the interview. Field notes will be used to capture elements of the interview such as the facilitator's overall impressions, facilitator's immediate reflections, interview context, and potential nonverbal behaviors.

COVID-Related Changes to Physical Activity. Self-report questionnaire describing changes to physical activity and describing mask usage due to COVID 19.

B. Description of Population to be Enrolled:

100 Veterans (50 per group) will be enrolled from Denver VAMC and the University of Colorado Hospital (UCH). Potential participants scheduled for TKA surgery will be identified by a VAMC or UCH surgeon who will refer candidates for study screening. Flyers will also be provided to orthopedic surgeons and health-care providers in the greater Denver metro area. Upon referral and prior to surgery, Veterans will be screened by a research team member, provide informed consent and participate in a pre-operative (PREOP) test session. Consent will be obtained face to face, or with an e-consent. The e-consent will be available to the participant prior to the consent discussion. A qualified study team member will Zoom phone/video call the potential participant. The potential participant will verify their identity. The study team member will explain the consent process and that the participant can navigate forward and backward through the consent form pages and that they may return to the form if later if they want time to think about their participation. The study team member will read the consent form with the participant and will answer all questions that the participant has. The participant and the study team member will both sign and date the consent form and the participant will be able to download or email themselves a copy of the signed form.

Physical activity at PREOP will be quantified as average daily step count (accelerometer-based monitors; see *Accelerometer-based Activity Monitoring* below).[62] To ensure representative physical activity levels between groups, randomization will be stratified using two levels of PREOP step count: <5000 and ≥5000 steps/day. Randomization will also be stratified by decade of age. A research assistant, who is not involved in participant testing/intervention, will manage randomization and maintenance of intervention codes. The study will adhere to the CONSORT statement recommendations for reporting randomized trials (Figure 3).

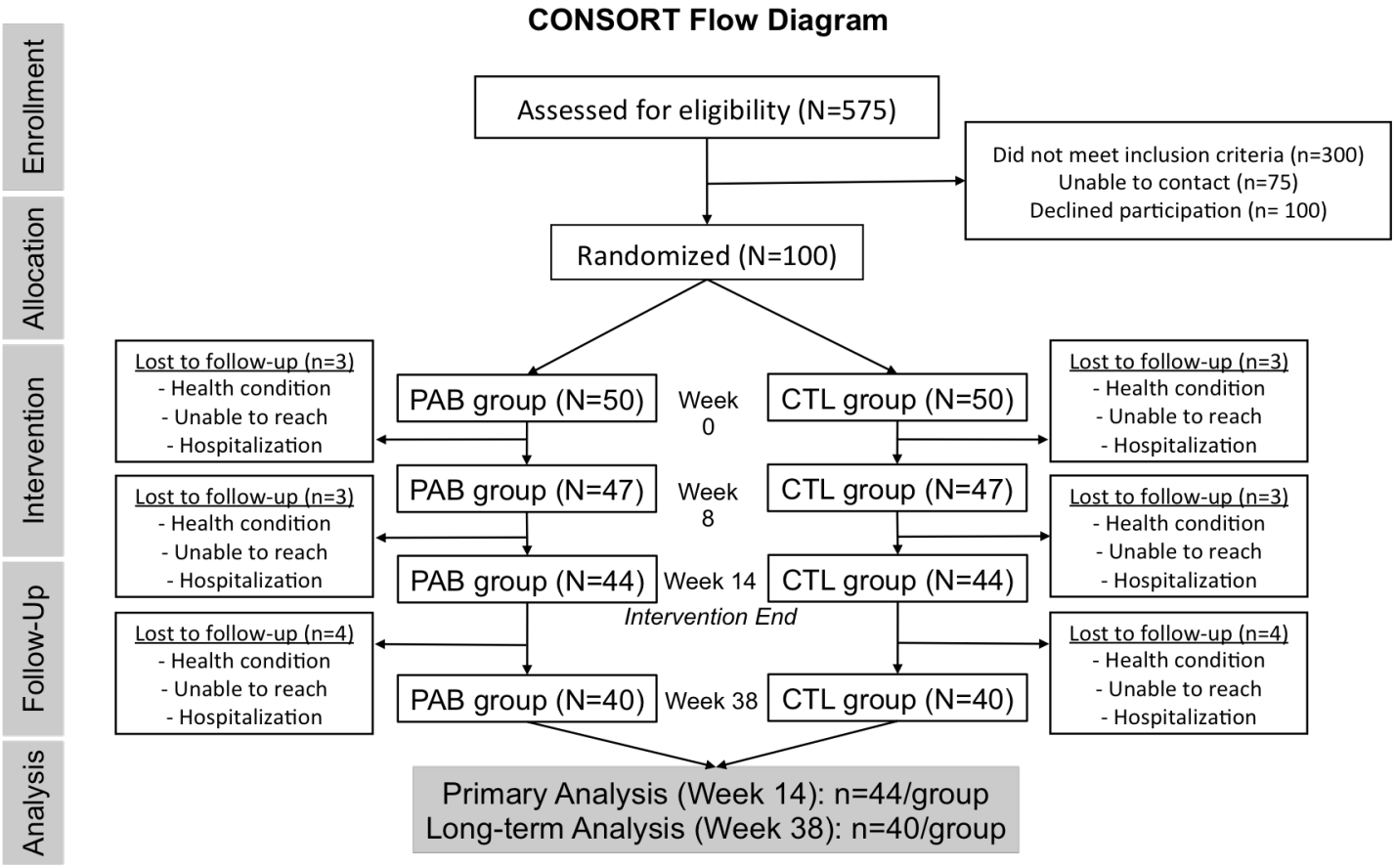

Figure 3. Anticipated CONSORT Flow Diagram

Inclusion criteria: 50-85 years of age at enrollment, Veteran, and planned unilateral primary TKA.

Exclusion criteria: severe non-surgical limb pain (pain >5/10 on non-surgical limb with walking); unstable orthopedic, neurologic, or pulmonary conditions that limit physical function; unstable cardiac condition; uncontrolled hypertension; uncontrolled diabetes; acute systemic infection; active cancer treatment; or recent stroke (within 2 years).

Statistical power was estimated using variability estimates from our pilot data collection, where the change in physical activity (steps/day) was assessed in 42 participants (21 receiving intervention, 21 attention control) following TKA. The observed 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 1,611 steps per day 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 enroll 100 participants (50 per group) to allow for a ~20% loss to follow-up. Previous clinical trials in our laboratory, for patients with TKA, have resulted in dropout rates of 4.9% and 6.5% at 3 months post-op and 8.2% and 15.2% at 12 months. Therefore, we are conservatively estimating a dropout rate of 20% at 9 months.

C. Study Design and Research Methods

This is a single-blind, randomized controlled trial with 100 Veterans scheduled to have unilateral primary TKA at the Denver VAMC or UCH. The two study arms will be physical activity behavior-change (PAB) and attention control (CTL). Researchers collecting data will be blinded to group assignment.

Conventional TKA rehabilitation at the Denver VAMC and at the University of Colorado Hospital consists of a total of 20-24 combined inpatient and outpatient visits. To ensure the total number of rehabilitation interactions in the proposed study is comparable to conventional rehabilitation, a total of 14 conventional rehabilitation visits (inpatient and outpatient) will be combined with 10 telerehabilitation sessions for 24 total rehabilitation interactions in both groups.

Physical Activity Behavior-Change (PAB) Intervention

The PAB intervention will be integrated into the current evidence-based conventional rehabilitation following TKA (Figure 4 and Appendix 6). The PAB intervention will begin at the start of Week 3 Post-TKA and consist of a total of 10 participant/therapist telerehabilitation sessions (30 minutes each). The telerehabilitation sessions will occur using video-based interactions with computer tablets provided by the VA, to ensure Veteran confidentiality standards are met. One week prior to the first PAB session, a VA WOC physical therapist who specializes in behavior-change intervention will perform a home visit to provide each PAB participant with a Fitbit wearable sensor and feedback tablet for the Fitbit, along with the telerehabilitation tablet. The therapist will also perform a home-safety check (Appendix 7). The Fitbit wearable sensor is designed specifically to provide user visual physical activity feedback through an application on the feedback tablet. Fitbit use instructions will be provided verbally and in written form (Appendix 8). The Fitbit application will provide the participant feedback on the number of steps he/she has taken during daily living activity and progress toward physical activity goals.

The first week of using the Fitbit activity sensor will be an accommodation period for the participant to interact with the equipment and establish his/her baseline for self-monitoring daily step count. The telerehabilitation tablets will provide the means for remote video interactions between the participant and therapist. The participant will then work with the therapist in the 30-minute video-based telerehabilitation sessions on participant-tailored functional action plans. Each plan will be based on the tailored physical activity feedback provided by the Fitbit sensor. The 10 PAB sessions will be tapered between Week 3 and Week 14 Post-TKA: Week 3 twice weekly (2 sessions), Weeks 4-9 once weekly (6 sessions), and Weeks 10-14 once every other week (2 sessions). The therapist will systematically address the seven components of PAB intervention: education, self-monitoring, feedback, barrier and facilitator identification, problem solving, action planning, and encouragement (Table 3 and Appendix 6) with varying levels of time focused on each of these components as the intervention progresses. The therapist will also document health visits, falls, knee pain, and medication changes at each telerehabilitation session.

Table 2. PAB Intervention Overview

Intervention Technique	Progression from Therapist Coaching to Participant Self-Management	
Education	Therapist delivers education topic* (e.g., Self Monitoring, Problems Solving, Identifying Barrier/Facilitators, Action Plans)	Participant reports most important information learned.
Self Monitoring	Therapist 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	Therapist 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	Therapist 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.Therapist guides, using 3% increase from daily steps from previous week target.	Participant-led weekly goal generation. Therapist ensures independence in action planning.
Encouragement	Therapist 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.

* Each 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.

Control (CTL) Intervention

The CTL group will perform all of the conventional inpatient and outpatient visits following TKA, just as the PAB group (Appendix 8). Some conventional outpatient visits will occur at the Colorado Springs VA Clinic. CTL group telerehabilitation sessions will match the frequency and duration of PAB group. The CTL group sessions will focus on education related to non-behavioral aspects of health. Education will be systematically delivered by the

therapist using the telerehabilitation tablets with the following topics: Sessions 1-2) Pain Management; Sessions 3-4) Home Safety; Sessions 5-6) Diet; Sessions 7-8) Medication Management; Sessions 9-10) Falls & Fractures (Appendix 8). In addition, the therapist will document health visits, falls, knee pain, and medication changes at each telerehabilitation session. The participant/therapist video-based telerehabilitation sessions will be semi-scripted with the same duration (30 min.) and same tapered schedule as the PAB group. In this manner, the study design controls for attention and volume of rehabilitation intervention. Telerehabilitation sessions will be conducted by therapists who may be physically present on the Anschutz Medical Campus. Some telerehabilitation sessions from both the PAB group and the CTL group may be audio recorded for interventionist fidelity checks.

Data Collection and Outcomes
Preoperative testing will occur 2 weeks prior to TKA (PREOP). Postoperative testing will occur midway through the PAB intervention (POST1), at the end of PAB intervention (POST2), and 24 weeks after PAB intervention (approximately 9-months after TKA) (POST3). The POST1 test will assess early between-group responses to intervention, while the POST2 test will assess group differences at intervention end (Primary End Point). The POST3 test is critical, as a key component to assessing success of behavior change is the long-term persistence of behavior change. Each test session will include the standardized procedures described in the next sections. Importantly, all test sessions occur at participant homes, to eliminate time and travel burdens for the participants and minimize barriers for rural participants. The 30-Second Chair Stand Test andTimed-up-and Go may be conducted remotely via video call and surveys may be conducted via phone/video call or through REDCap. Semi-structured interviews will occur following randomization, and again following the POST2 assessment period. Up to 20 participants will be randomly selected from the PAB group to have at least 10 paticipants participate in semi-structured interviews at both time points. An interview guide will be used with questions regarding the PAB program, perceptions of barriers and facilitators to physical activity, and perceptions of participation in everyday life. Depending on participant preference the interview can occur in-person, over the phone, or via an audio-visual application. All interviews will be audiorecorded and transcribed verbatim by a research team member or an approved transcription service.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Anticipated adverse events include medical complications due to the complex medical conditions of the older Veteran population and the surgical procedure prior to the intervention. Although no increase rate of falls was seen in the pilot study, we also anticipate increased exposure to fall risk due to increased exposure to physical activity. As such, a Safety Officer, Dr. Susan Ladley, experienced in clinical trial safety outcome measures will meet with the PI quarterly to review study progress and adverse events. Fall risk will be monitored using the TUG test and Falls Efficacy Scale-International (FES-I)[63] at all test points (PREOP, POST1, POST2, POST3). Also, occurrence of falls will be recorded at each weekly visit for both the PAB and CTL groups. Fall occurrences (injurious and non-injurious) and other adverse events will be reported on a quarterly basis to the Safety Officer. The incidence of falls, defined as “inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position,”[64] will be of particular focus. All study-related falls (possibly, probably, or definitely) will be tracked. If the total number of falls reaches 5, the Safety Officer will review incidence by group. If the 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 for each incidence is performed by the Safety Officer. Also, some questions may make subjects feel uncomfortable. There is a rare but significant risk of loss of confidentiality. There are also risks that are unknown at this time.

E. Potential Scientific Problems:

Potential for dosing of intervention to be specific to participant. Standardizing the number of visits for all participants allows us to control the intervention dose for the PAB intervention. We acknowledge that not all patients will necessarily require the same number and frequency of visits to achieve an optimal response to the intervention. However, our pilot study data and previous literature in other populations support the 10 visits that will be used in the current intervention.[65] We expect our exploratory analysis will identify key determinants of responsiveness, which then can be used to help better dose the PAB intervention to individual patients in future studies of clinical implementation.

Missing data. All participants with outcome measurements will be included in the intent-to-treat analysis. Although the protocol encourages participants to be fully compliant with the assigned intervention and testing sessions, no one will be dropped from follow-up measurements for lack of compliance. We will make every effort to prevent missed intervention sessions and test visits. Figures examining the pattern of missing data will be created to provide insight into the mechanism of the missingness and guide the analysis in an appropriate manner. If the

data are missing completely at random, analyses of complete cases will provide unbiased parameter estimates; provision for missing data due to dropout has been accounted for in the sample size justification. If the data are missing at random, valid analyses may still be performed using a likelihood-based analysis of all available data, still generating unbiased parameter estimates.

F. Data Analysis Plan:

The primary outcome for this study is average number of steps taken per day, as measured by accelerometer-based wearable sensors (activPAL) over a 7-day period at the end of the intervention. This time point is chosen for clinical relevance to establish efficacy of the intervention. Sustainability will be tested as a secondary outcome, by assessing steps taken per day six months after conclusion of the intervention period. Other secondary outcomes include time spent in standing/walking activities and physical function measures. Preliminary descriptive and graphical analyses (including boxplots, scatterplots, profile plots of change over time) will be used for data cleaning, data visualization, and assessing statistical assumptions.

Primary Analysis (Aim 1): The primary analysis will be an intent-to-treat comparison of the differences between the study groups (PAB and CTL) in the change average daily step count from PREOP to POST2 (primary endpoint). Statistical inference will be based on the estimated coefficient for the group variable using an analysis of covariance (ANCOVA) model with change in average daily step count from PREOP to POST2 as the response variable. Additional covariates include the stratification variables (PREOP physical activity and age) to improve the precision of the estimate. The conclusion about group differences will be made based on this single statistical test to control the type I error rate at 0.05. A similar between-group analysis will be performed on the change in daily step count from PREOP to POST3 (6-month effect post-intervention). A sensitivity analysis will be done to evaluate whether conclusions would differ when other covariates are added to the model (e.g., demographics, anthropometrics, comorbidities, psychosocial factors).

Secondary Analyses (Aims 1 & 2): Differences between study groups in the secondary outcomes of 1) time spent in standing/walking activity (activPAL) and 2) physical function (performance-based and self-reported outcomes), from PREOP to POST2 will be analyzed as described above for the primary analysis. All outcomes will also be analyzed at POST3 to evaluate the long-term sustainability of the PAB intervention. We anticipate that the secondary outcomes will be correlated with the primary outcome, and would interpret the results from the secondary analysis as reinforcing the findings in the primary outcome. Failure to observe consistency between primary and secondary outcomes will be interpreted as evidence that the effects of the PAB intervention are not clear, and that further study is necessary to resolve inconsistencies. This approach reduces the risk of false-positive conclusions resulting from multiple statistical tests.

Exploratory Analysis (Exploratory Aim): The exploratory analysis will delineate the mechanisms underlying responsiveness to the PAB intervention by using multiple linear regression to identify key predictors of average daily step count from PREOP to POST2 in the PAB group. We will use the approach of fitting all possible models to identify the most parsimonious model predictive of the primary outcome of changes in steps per day across the intervention period. Candidate predictor variables will be those with theoretical evidence of predicting physical activity, including: PREOP steps per day, demographics (age, sex, education level), anthropometrics (height, weight, BMI), and comorbidities (Functional Comorbidity Assessment). In addition, we will focus specifically on physical activity–related psychosocial factors (depression, exercise self-efficacy, exercise readiness to change, social support, and fear of falling). The set of candidate predictor variables will be assessed for collinearity (and any collinearity reduced to the extent possible) before beginning model selection procedures. With k predictor variables, there are 2^k possible regression models. Each of the 2^k models will be fit and both 1) the adjusted R2 and 2) Mallows' C_p statistic will be generated for each model. A plot of Mallows' C_p vs p+1 (where p = the number of model parameters) will be used to identify parsimonious candidate models according to Hocking's criterion. The best candidate models will be compared using their statistical properties as well as subject knowledge expertise and practical considerations (e.g. an objective variable may be preferred over a subjective variable). A final model will be selected from the candidate models. We hypothesize that baseline average steps per day at PREOP and all included psychosocial factors will be significant determinants of intervention responsiveness. The results of this exploratory aim will provide evidence for clinicians in determining the prognosis of patients in terms of likely physical activity improvement from the PAB intervention. We hypothesize that the PAB intervention will effectively increase physical activity, as measured in average steps per day. Whether that hypothesis is proven or not, the exploratory aim will add to the current body of rehabilitation knowledge by identifying key predictors of future activity based on baseline variables.

Qualitative Analysis (Exploratory Aim). Pragmatic qualitative analysis will be used to analyze data from the semi-structured interviews. Savin-Baden[66] outlined three steps to pragmatic qualitative research: (1) visually familiarize yourself with the data by reading the transcripts, then identify primary categories, (2) generate conclusions, and

(3) check the results. The 14 domains of the Theoretical Domains Framework (TDF) will be used as a priori codes to classify the barriers and facilitators discussed by participants. The 14 domains in the TDF are: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention, and decisions processes; environmental context and resources; social influences; emotion; and behavioral regulation.[67] The TDF domains will be used to as "primary categories" (i.e. a priori codes) to capture participants' responses to barriers and facilitators of physical activity (step 1 in pragmatic qualitative analysis). The researcher will then read through the coded data as well as the data that was not coded to generate conclusions and construct themes related to perceived barriers and facilitators to physical activity and changes throughout the PAB program (step 2). Finally, the themes and raw data supporting each theme will be reviewed by the researcher with attention to accurate representation of participants' perception of barriers and facilitators (step 3). To enhance rigor we will consider procedures to promote credibility, consistency, and transferability.[68] First, to ensure credibility we will *triangulate* between data sources (interviewers notes, transcripts, and interdisciplinary discussion). Second, to enhance consistency, the researcher who is coding will keep an *audit trail* of all decisions related to coding, interpretation, and constructed themes. Third, we will randomly select up to 20 participants from the PAB group to ensure *maximal variation* in PAB group experience, and the experience of potential barriers and facilitators to physical activity.

Data analysis will be conducted with de-identified data on the Anschutz Medical Campus.

G. Summarize Knowledge to be Gained:

This study is an essential step for providing foundational evidence to support the effectiveness of a telerehabilitation approach aimed to increase physical activity in patients with TKA. The ultimate goal of this research line is to 1) develop and refine methods for implementing findings of the current study into clinical rehabilitation practice and 2) effectively disseminate these intervention methods to clinical institutions, both nationally and internationally. We will work with the Denver GRECC to develop strategies for operational partnerships both locally and nationally through Home Based Primary Care programs and through connections with other GRECC Associate Directors for Clinical Programs. In addition, Dr. Stevens-Lapsley has developed strong working collaborations with the Center for Research in Implementation Science and Prevention (CRISP) at the University of Colorado Denver to facilitate additional strategies for rapid transition to implementation strategies immediately upon conclusion of the proposed investigation.

Personalized Rehabilitation to Optimize Utilization. Current rehabilitation guidelines after TKA are generalized based on population expectations.[69] However, there is high individual variability within the population of Veterans undergoing TKA and thus, we expect variable responses to rehabilitation. By identifying the key predictors of responsiveness to intervention, we expect the results of our study to lead to methods for individually tailored approaches to personalize rehabilitation practices, which will optimize Veteran outcomes and lower overall costs.

Application of Findings to Other VA Populations. Future investigations could apply the proposed PAB rehabilitation to other populations with chronic physical activity deficits. We expect our findings to be generalizable to a variety of populations of Veterans who are routinely seen for orthopedic surgeries and other medical conditions. We chose to initially focus on TKA because of the high utilization of TKA, the great need to improve physical activity in these Veterans, and the ability to capitalize on the "teachable moment" of elective TKA surgery.

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Statistical Analysis Plan

An intention-to-treat approach was used for the primary data analysis. The two treatment arms were compared by demographics and baseline clinical characteristics using standardized mean difference and confidence intervals. Observed means of the primary and secondary outcomes were calculated. To assess group differences in the primary outcome (average daily step count), a linear mixed model (LMM) was used. The LMM accounted for the within-subject correlation associated with repeated measures through the inclusion of a random intercept for subject. Decade of participant age was included in the LMM as a continuous fixed effect. The model also included as fixed effects time and an interaction between intervention arm and time. Between-group difference at baseline was set at zero, so estimated baseline scores were equal between groups.

The primary analysis was conducted using the first 3 time points (pre-surgery, 8 weeks post-surgery, 14 weeks post-surgery), and the test of intervention effect on daily step count was tested using a Likelihood Ratio Test (LRT). P-values for the effect of intervention were derived from a LRT comparing the model with interaction of intervention arm and time versus the reduced model without the interaction. Contrasts were used to estimate group means and confidence intervals.

Secondary and exploratory analyses used the same methods as the primary outcome (pre-surgery, 8 weeks post-surgery, 14 weeks post-surgery, and 38 weeks post-surgery), and week 38). A secondary LMM analysis with the four time points was also conducted to test for group difference in daily step count at Week 38. All analyses were performed using R statistical software version 4.3.0.