Title

Biobehavioral Intervention Targeting Physical Activity Behavior Change for Older Veterans after Nontraumatic Amputation: A Randomized Controlled Trial.

Journal

PM&R, 12(10)

Authors

Christiansen, Cory
Christiansen, Cory
Miller, Matthew
et al.

Publication Date

2020-10-01

DOI

10.1002/pmrj.12374

Peer reviewed

HHS Public Access

Author manuscript

PM R. Author manuscript; available in PMC 2021 October 01.

Published in final edited form as:

PM R. 2020 October ; 12(10): 957–966. doi:10.1002/pmrj.12374.

Biobehavioral Intervention Targeting Physical Activity Behavior Change for Older Veterans after Nontraumatic Amputation: A Randomized Controlled Trial

Cory L. Christiansen, PT, PhD,

Department of Physical Medicine and Rehabilitation, University of Colorado, Aurora, CO; and VA Eastern Colorado Geriatric Research, Education, and Clinical Center, Rocky Mountain Regional VA Medical Center, Aurora, CO

Matthew J. Miller, PT, DPT, NCS,

Department of Physical Therapy and Rehabilitation Science, University of California, San Francisco, San Francisco, CA; and Division of Geriatrics, University of California, San Francisco, San Francisco, CA

Paul W. Kline, PT, DPT, PhD,

Department of Physical Medicine and Rehabilitation, University of Colorado, Aurora, CO; and VA Eastern Colorado Geriatric Research, Education, and Clinical Center, Rocky Mountain Regional VA Medical Center, Aurora, CO

Thomas T. Fields, PT,

Department of Physical Medicine and Rehabilitation, Rocky Mountain Regional Medical Center, Aurora, CO

William J. Sullivan, MD,

Department of Physical Medicine & Rehabilitation, Vanderbilt University Medical Center, Nashville, TN

Patrick J. Blatchford, PhD,

VA Eastern Colorado Geriatric Research, Education, and Clinical Center, Rocky Mountain Regional VA Medical Center, Aurora, CO; and Department of Biostatistics and Informatics, University of Colorado, Aurora, CO

Jennifer E. Stevens-Lapsley, PT, PhD

Address correspondence to: C.L.C.; cory.christiansen@ucdenver.edu.

Disclosure Statement: Contents are the authors' sole responsibility and do not necessarily represent official National Institutes of Health views. The contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government. No previous presentation of the results of this research in any manuscript, abstract, or conference presentation.

ClinicalTrials.gov Identifier: NCT02738086

Disclosure

Dr. Christiansen reports grants from VA and from the National Institutes of Health (NIH) during the conduct of the study.
Dr. Miller reports grants from Department of Veterans Affairs, during the conduct of the study.
Dr. Kline reports grants from NIH/NCATS Colorado CTSA, during the conduct of the study.
Dr. Sullivan reports personal fees from North American Spine Society (NASS), outside the submitted work.

This material has been presented as an abstract at the American Physical Therapy Association 2020 Combined Sections Meeting.

All financial disclosures and CME information related to this article can be found on the mē® site (http://me.aapmr.org/) prior to accessing the activity.

Department of Physical Medicine and Rehabilitation, University of Colorado, Aurora, CO; and VA Eastern Colorado Geriatric Research, Education, and Clinical Center, Rocky Mountain Regional VA Medical Center, Aurora, CO

Abstract

Background: Lower-limb amputation (LLA) due to non-traumatic vascular etiology is linked to extremely low physical activity and high disability.

Objective: To test the feasibility of a biobehavioral intervention designed to promote physical activity.

Design: A randomized, single-blind feasibility trial with a crossover design.

Setting: Veterans Administration Medical Center.

Participants: Military veterans (age: 65.7 [7.8] years; mean [standard deviation]) with nontraumatic lower-limb amputation (LLA), randomized to two groups: GROUP1 (n = 16) and GROUP2 (n = 15). Both groups had similar baseline amputation characteristics (level of amputation and time since amputation).

Interventions: Twelve weekly, 30-minute telehealth sessions of physical activity behavior-change intervention, with GROUP1 participating in weeks 1–12 and GROUP2 in weeks 13–24. GROUP1 noncontact phase in weeks 13–24 and GROUP2 attention control telehealth phase in weeks 1–12.

Main Outcome Measures: Feasibility (participant retention, dose goal attainment, intervention acceptability [Intrinsic Motivation Inventory [IMI] Interest and Enjoyment scale], safety) and signal of efficacy (free-living physical activity [accelerometer-based average daily step count], Late Life Function and Disability Index - Disability Scale [LLFDI-DS]).

Results: Participant retention rate was high (90%), with three participants lost to follow-up during the intervention period. Dose goal attainment was low, with only 10% of participants achieving an a priori walking dose goal. Intervention was rated as acceptable, with mean IMI Interest and Enjoyment score (5.8) statistically higher than the null value of 5.0 ($P = .002$). There were no between-group differences in adverse event rates (falls: $P = .19$, lower extremity wounds: $P = .60$). There was no signal of efficacy for change in average daily step count ($d = -0.15$) or LLFDI-DS ($d = -0.22$ and 0.17 for frequency and limitations scales, respectively).

Conclusions: Telehealth delivered biobehavioral intervention resulted in acceptable participant retention, low dose goal attainment, high participant acceptability, and low safety risk, while having no signal of efficacy (physical activity, disability) for people with nontraumatic LLA.

Introduction

The increasing U.S. population of patients with lower-limb amputation (LLA) is attributed largely to an aging population with chronic vascular conditions, such as diabetes mellitus (DM) and peripheral artery disease (PAD). Such vascular-related, nontraumatic amputations in older adults account for the majority of LLA (>80%).[1–3] Worldwide, the number of people diagnosed with DM has steadily increased over the past several decades;[4] therefore,

despite current declines in amputation rate for the general population, the incidence of amputation due to complications of DM and/or PAD is not declining.[5–8] For U.S. military veterans, relative amputation rate decreased 34% from 2000 to 2004. However, due to an increase in number of veterans with DM during the same period, the population of veterans with DM and initial amputation increased by 23%.[7]

The loss of lower limb due to vascular-related etiologies is characterized by extremely low levels of physical activity[9] and high disability.[10] It is possible that such low physical activity and high disability are associated with chronic behaviors that predate the need for amputation.[11] Current clinical practice guidelines for rehabilitation describe a comprehensive approach, including mobility training and community reintegration after LLA.[12] Conventional LLA rehabilitation guidelines encourage increasing free-living physical activity through resistance exercise, mobility training, cardiovascular exercise, and other specific functional exercises.[13] However, the poor physical activity outcomes indicate the need to target the habitual sedentary behaviors associated with DM[14] and PAD[15] that become compounded after nontraumatic LLA.

The use of theory-based biobehavioral intervention founded in chronic disease self-management theories is a promising approach to helping people become more physically active. Biobehavioral interventions can reduce fall risk and improve quality of life for people with chronic diseases, including DM and PAD.[16–18] Home-based behavior change intervention to promote exercise, walking activity, and disease self-management has been piloted in people recovering from nontraumatic transtibial amputation, resulting in increased daily step count.[19] However, the intervention did not focus solely on physical activity. In addition, the previous trial was implemented within the first 6 months after amputation and physical activity progression was potentially limited due to the need for some participants to resolve wound and incision healing issues from the amputation.

Thus, the purpose of this trial was to test the feasibility of using a biobehavioral intervention focused on changing physical activity behavior for people with nontraumatic LLA, who were 1–5 years removed from the amputation surgery. Feasibility of the intervention (Aim 1) was assessed using measures of participant retention, dose goal attainment, participant acceptability, and safety. In addition, an efficacy signal (Aim 2) was assessed using physical activity and disability outcomes.

Methods

The study was a randomized (1:1 allocation), single-blind (outcome assessors blinded) feasibility trial with a crossover design (Figure 1). After a 12-week telehealth biobehavioral intervention period, participants in GROUP1 participated in a no-contact 12-week phase. GROUP2 participated in a telehealth attention control period for 12 weeks, crossing over to the telehealth biobehavioral intervention for the final 12 weeks. Details of the clinical trial methods have been previously published.[20] The study protocol was approved by the Colorado Multiple Institutional Review Board and Rocky Mountain Veterans Affairs Review Board and written informed consent obtained from all participants.

Participants

U.S. military veterans with nontraumatic LLA were recruited for trial participation. Veteran volunteers were included if they were ≥50 years of age, had major LLA (above ankle) 1–5 years prior, had type 2 DM and/or PAD, and were ambulatory using a prosthesis. Participants were excluded if their LLA was a trauma or cancer-related etiology or if they had an unstable heart condition, uncontrolled hypertension, acute systemic infection, recent stroke (within 2 years), active cancer treatment, or lower extremity wound or ulcer that limited ambulation. Participants were also required to live within 50 miles of the medical center for feasible home-based testing. Descriptive measures included age, height, weight, time since amputation, amputation level, the Geriatric Depression Scale-Short Form,[21] the Mini-Mental Status Examination,[22] the Chakrabarty Residual Limb Score,[23] and the Functional Comorbidity Index.[24] In addition, individual prosthetic componentry was identified and categorized for each participant.

Physical Activity Behavior-Change Intervention

Both groups participated in 12 individual sessions of the physical activity behavior-change intervention (GROUP1: weeks 1–12; GROUP2: weeks 13–24). The initial home-based session presented the intervention concepts, provided the participant with equipment (FitBit wearable sensor, FitBit Inc., Boston, MA), provided mobile-health computer tablet training, and guided the participant on long-term (12 weeks) and short-term (weekly) physical activity goals. After the initial home visit, 12 weekly video-based interactions between participant and therapist occurred through the mobile health tablet.

Details of the behavior-change intervention are previously published.[20] The weekly video-based interactions (12 sessions, ~30 minutes each) included systematic biobehavioral intervention that consisted of participant education (~5 minutes), self-monitoring (~3 minutes), tailored feedback (~3 minutes), barrier and facilitator identification (~5 minutes), promotion of problem solving (~5 minutes), action planning (~5 minutes), and encouragement (~2 minutes). Finally, participants reported on fall occurrence, research activity difficulties, their residual limb issues, healthcare visits, and health issues (~2 minutes).

The 12 intervention sessions were conducted by the therapist following a semistructured script. The intervention required daily participant interaction with the FitBit wearable sensor coupled to a tablet application. The commercially available tablet application (FitBit) provided feedback on daily steps and progress toward physical activity goals. Participant activity feedback and personal motivations guided the weekly goals and barriers to reaching goals were identified. The therapist used the participant-identified barriers to guide the participant in reasoning solutions.

Attention Control Sessions

Veterans in GROUP2 participated in an attention control, telehealth delivered education program for weeks 1–12. In these sessions, the therapist provided specific health and safety education on nonexercise topics pertaining to aging (~10 minutes). In addition, through the video interface, the therapist led the patient through a brief period of light upper and lower

extremity range of motion tasks with participants seated in a chair (~15 minutes). At the end of each session, participants completed a similar safety and healthcare utilization report as in the intervention sessions (~5 minutes).

Intervention Fidelity

Intervention and control sessions were delivered by a single trained physical therapist, who completed a self-checklist for each session to optimize intervention fidelity. Additionally, intervention fidelity was assessed by an in-person reviewer for at least one session per participant, which was randomly allocated for various times throughout the 12-week periods.

Outcome Measures

Participants were tested at their homes prior to intervention start (baseline), at the end of intervention (12 weeks), and 24 weeks postintervention (Figure 1). Feasibility outcomes (participant retention, dose goal attainment, intervention acceptability, safety), free-living physical activity (average daily step count), self-report questionnaires (Late Life Function and Disability Index - Disability Scale [LLFDI-DS], Prosthesis Evaluation Questionnaire - Mobility Section [PEQ-MS], Falls Efficacy Scale International [FES-I], Multidimensional Scale of Perceived Social Support [MSPSS], Self-Efficacy of Exercise Scale [SEE], Exercise Stages of Change Scale [ESC]), and performance-based functional measures (Timed Up-and-Go [TUG], 5-Meter Walk Test [gait speed], and Two-Minute Walk [2 MW]) were measured at each time point.

Feasibility Outcomes—Participant retention rate was assessed by tracking the number of participants lost to follow-up during the intervention period (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2). Dose goal attainment was assessed by the proportion of participants achieving 3% average weekly increase in steps, a value based on data for physical activity gains in other intervention studies.[25–27] Intervention acceptability was measured with the Intrinsic Motivation Inventory (IMI) Interest and Enjoyment subscale, with a mean score of <5/7 considered a negative acceptability result.[28] Adverse and serious adverse events, including falls, were used to measure safety at all weekly telehealth sessions and test sessions.

Free-Living Physical Activity—Average daily step count was measured for assessing free-living physical activity, using an accelerometer-based activity monitor (ActiGraph GT3X-BT, ActiGraph, Pensacola, FL). Participants wore the monitor on a waist-belt for a 10-day period, with instruction to wear at all times except during bathing. The ActiGraph monitor was used only for outcome data and provided no feedback to participants. During the 10-day wear period, participants completed an Activity and Exercise Diary, which was used to verify wear times of the ActiGraph. Acceleration data were sampled at 60 Hz during the 10-day period. Days with >10 hours of monitor wear were used for analysis,[29] with the requirement of collecting a minimum of 3 week-days and 1 weekend day of physical activity from each participant at each test point. All valid days were used for calculating average daily step count for the 10-day period (mean number of steps/d).

Self-Report Questionnaires

Participation—The LLFDI-DS measures life participation in two scales: Frequency and Limitation. Participants report frequency (very often [5] to never [1]) and to what extent they feel limited (not at all [5] to completely [1]) across the 16 different tasks, where higher scores indicate greater frequency of task performance and less limitation in tasks.[30,31] The LLFDI-DS is internally consistent (Cronbach alpha, frequency = 0.75 and limitation = 0.94) and reliable (interclass correlation coefficient [ICC], frequency = 0.68 and limitation = 0.82) for adults living with chronic conditions.[32,33]

Physical Function—An average PEQ-MS score was used to rate the amount of difficulty completing locomotion tasks. The PEQ-MS is a reliable (ICC: 0.0.73–0.90) and internally consistent (Cronbach alpha = 0.96) measure with people who have LLA, where 0 indicates inability to complete a task to 4, which indicates no difficulty.[34,35]

Self-Efficacy—The FES-I was used to measure the amount of concern about the possibility of falling while completing 16 different tasks. Participants report “not at all concerned” (score of 1) to “very concerned” (score of 4).[36,37]The FES-I has been validated for use with community dwelling older adults and other specific complex health populations.[36] The FES-I is internally consistent (Cronbach alpha = 0.96), reliable (ICC = 0.92–0.96), and has been used with people who have LLA.[36–38] The SEE scale measured the amount of confidence one has to participate in exercise three times a week if specific conditions were present, on a 0 (no confidence) to 10 (total confidence) scale.[39] The SEE has demonstrated reliability with an alpha coefficient of 0.92.[39] Using the ESC questionnaire, participants indicated readiness for physical activity behavior change with four questions about participation in physical activity, intention to be more active, and participation in regular activity for the past 6 months.[40] The ESC was adapted from a measure of contemplation of smoking cessation and has been validated for use in physical activity.[40,41]

Social Support—The MSPSS is a 12-item questionnaire that quantifies the amount of social support participants feel they have on a scale of 1 to 7. Lower scores indicate lower perceived social support.[42,43] The MSPSS has demonstrated internal consistency (Cronbach alpha = 0.88) and reliability (r = 0.85).[42–45]

Performance-Based Functional Measures

The TUG was measured as the time (handheld stopwatch) required for the participant to rise from a chair (46 cm seat height), walk 3 m, return to the chair, and sit back down, as quickly and safely as possible.[46,47] Original TUG protocol instructions asked participants to walk at a comfortable pace.[46] The instructions to perform the test quickly were included in this study, to allow comparison to other data from community-dwelling adults[47] and people with LLA.[19] The TUG performed as “quickly and as safely as possible” has high interrater reliability (ICC = 0.98) in community dwelling adults at high risk for falls.[47] The TUG has established cutoff scores to indicate fall risk.[47,48] In addition, the TUG is responsive to changes in mobility status over time.[49] Gait speed, assessed with the 5-Meter Walk Test, was used to measure the time (handheld stopwatch) required for the participant to walk 5 m (with a 2 m acceleration and deceleration zone at both ends) at their typical, freely chosen pace.

Gait speed is a widely used measure of functional capacity and is predictive of multiple health outcomes, for example <0.8 m/s is an indicator of low life expectancy and poor ability for community ambulation.[50,51] The 2 MW was performed on a level walkway, with walkway length differing between some participants based on their home environment (7–15 m) but remaining consistent for each participant at each test session. Both the 2 MW and gait speed are reliable across time and tester and are valid measures for patients with LLA and non-disabled adults.[52–54] Blood pressure and heart rate were assessed prior to performance-based functional testing in accordance with the American College of Sports Medicine Exercise Testing and Prescription Guidelines.[55]

Statistical Methods

Aim 1 (feasibility) was assessed as participant retention, dose goal attainment, participant acceptability, and safety. To assess participant retention rate, an a priori cutoff of 85% retention (ie, loss of >6 participants) was deemed as a negative outcome, based on previous activity change programs for patients with DM or PAD.[18,56] Mean retention rate was compared to the null value of 85% using a one-sample *t*-test ($\alpha = .05$). The ability to attain a 3% average weekly step increase for >75% of participants (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2) was the a priori determination of a positive result for dose goal attainment. The proportion of participants attaining a 3% average weekly step increase was calculated (95% CI) and compared to the null value of 75% using a one-sample binomial proportions test ($\alpha = .05$). Mean IMI Interest and Enjoyment score at end of intervention (12-week test) was compared to the null value of 5.0 using a one-sample *t*-test ($\alpha = .05$) to assess intervention acceptability. Adverse and serious adverse event (AE/SAE) rates (events/participant) were compared using a chi-square test of proportions for Weeks 1–12 (Intervention for GROUP1, attention control for GROUP2). Similar AE/SAE rates between groups would indicate no negative safety issues with intervention.

Aim 2 was assessed by calculating the effect size of the intervention with Cohen's d, using mean and SD for change in average daily step counts and LLFDI-DS scores (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2). Statistical inference of group differences during the first 12-week period was based on linear models with average daily step count and LLFDI-DS frequency and limitation scores as outcome variables ($\alpha = .05$). Explanatory variables in each model included primary medical diagnosis (PAD, DM, or both), group, and baseline average daily step count or LLFDI-DS (frequency and limitation) scores.[57,58] Similarly, group differences were also assessed for the secondary outcomes (self-report questionnaires and performance-based functional measures) during the first 12-week period.

Results

Participants

Sixty-six veterans were assessed for eligibility, with 31 veteran men enrolled (Figure 2). Thirty-five veterans screened as ineligible, due to time since amputation (n = 7), amputation etiology (n = 6), nonambulatory status (n = 5), distance from medical center (n = 2), unstable health condition (n = 1), and age (n = 1). Participant characteristics were similar between groups (Table 1). Most participants (84%) had transtibial amputation, with 2 participants in

GROUP1 and 3 participants in GROUP2 having transfemoral amputation. Interventionist fidelity to the protocol was 97%, including at least one session with 75% of participants during the intervention period (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2). Adherence to the telehealth sessions was high, with only 9% of total sessions missed (49/552 possible sessions missed).

Feasibility Outcomes

Participant retention was 90% (95% CI [74.4, 96.5]), with 3 participants lost to follow-up during the intervention period (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2). Total participant retention for the study (including nonintervention periods) was 87.9% (4 total participants lost to follow-up). Three participants (2 in GROUP1, 1 in GROUP2) were lost to follow-up during the first 12-week intervention period, leaving 28 participants who completed the 12-week test. One additional participant was lost to follow-up in GROUP2 between the 12- and 24-week tests, leaving 14 GROUP1 and 13 GROUP2 participants who completed the 24-week test.

Ten percent of participants achieved the dose goal attainment of 3% average weekly step increase. The mean IMI Interest and Enjoyment score was 5.8 at the 12-week test for GROUP1, statistically higher than the a priori value of 5.0 ($P = .002$). Adherence to the use of the FitBit sensor for tracking physical activity was high, with participants interacting with the device an average of 6.8 days per week during the 12-week intervention period.

There were no between group differences in total AE/SAE rates between groups during the first 12-week time period (falls: $P = .19$, wounds: $P = .60$), with no AE/SAEs occurring during research activities. A total of 10 (GROUP1 = 3, GROUP2 = 7) falls occurred during the first 12-week period. Only four other events (eg, vascular procedure, hospitalization) occurred within the first 12-week period and were related to progression of comorbid conditions and not related to the study protocol.

Preliminary Efficacy

Outcome data were normally distributed, based on Kolmogorov-Smirnov analysis. There was no signal of efficacy identified for the physical activity behavior-change intervention, with a calculated effect size (Cohen's d) of −0.15 for change in average daily step count during the intervention period (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2). There was no between-group difference in average daily step count change for the first 12-week period ($P = .09$) (Table 2).

The effect sizes for within-group change in LLFDI-DS during the intervention period (Weeks 1–12 GROUP1, Weeks 13–24 GROUP2) were −0.22 and 0.17 for the frequency and limitations scales, respectively. There were no between-group differences in LLFDI-DS frequency ($P = .09$) and limitations ($P = .56$) scales for the first 12-week period. Secondary outcomes had the following effect sizes during the intervention period (GROUP1 and GROUP2): TUG (−0.10), gait speed (−0.05), 2 MW (−0.15), PEQ-MS (−0.05), FES-I (−0.10), MSPSS (0.17), SEE (0.05), and ESC (0.39), with no between-group differences for change in the first 12-week period.

Discussion

Biobehavioral intervention targeting physical activity change was feasible in terms of participant retention, intervention acceptability, and safety for veteran participants with nontraumatic LLA. Participant retention rate (90%) was above the a priori cutoff of 85%, although the 95%CI included 85%, indicating a reasonable level of retention for this small trial. In addition, participants reported interest and enjoyment with the intervention, and both groups had similar adverse event rates, which were characteristic of the complex, multi-comorbid condition of nontraumatic amputation. However, participants did not achieve the dose goal of an average of 3% weekly increase in average daily step counts, and the biobehavioral intervention did not result in average daily step count increases. In addition, the biobehavioral intervention did not change participants' reports of life participation.

The small effect sizes indicate no clinically meaningful change in efficacy outcomes. Step counts in both groups were low compared to minimum physical activity recommendations,[59] with no mean daily step count difference between groups, and the trend of change being negative (ie, slightly fewer average steps per day after intervention) during the intervention period. Clinically significant changes in step count have not been established for people with LLA, although clinically meaningful changes in step count range from 600 to 1200 steps/d in populations with similarly low levels of physical activity (eg, diabetes mellitus type 2, older age).[59,60] The <600 steps/d change in the current study does not suggest a clinically significant change. The findings of this study are in contrast to a previous biobehavioral intervention trial for people with nontraumatic transtibial amputation, who were provided a similar intervention to the current trial, but starting within the first 6 months following amputation.[19] In this previous pilot trial, people with nontraumatic transtibial amputation increased their average daily step count by 1135 steps. Two primary differences between the current and previous trial were (1) a singular focus on physical activity goals in the current trial and (2) the time since amputation. In the previous pilot trial, participants had a transtibial amputation within 6 months prior to study enrollment (mean 18 weeks from amputation). In the current trial, the mean time since amputation was 36.4 months. Thus, there is indication that the timing of biobehavioral intervention could be a key factor. It is possible that people are more able or willing to change walking behaviors early after LLA compared to more than a year after LLA (as in the current trial). Indeed, there is evidence that pivotal experiences (such as LLA) may provide time windows of opportunity when people are open to health behavior changes.[61]

Little is known regarding the influence of time since amputation on physical activity. A study of 72 people with LLA from various etiologies (35% nontraumatic, dysvascular) found lower self-reported physical activity to be weakly associated with shorter time since amputation.[62] It is also known that people with nontraumatic amputation typically report lower levels of physical activity than those with traumatic amputation.[62,63] The time course of physical activity recovery for patients with nontraumatic LLA is unique, as they require extended recovery times compared to patients with LLA from other etiologies, due to vascular and medical comorbidity.[64] Previous studies in nontraumatic LLA have found accelerometer-based average daily step counts to be very low,[9,11] equating to less than one-third of the recommended daily steps for people with disabilities.[59] For example, average

daily steps for people within the first 6 months after LLA have been measured at 1721 (1524) steps/d [mean(SD)].[9] The combined average daily step count of both groups in this current study, 1743 steps/d, is comparable to previous data. Further investigation regarding the effect of time since amputation on responsiveness to physical activity behavior change intervention is needed to better understand the combined influence of time and motivation for change.

Numerous barriers to physical activity have been identified for people with nontraumatic LLA. For example, a qualitative metasynthesis identified patient education, motivation, social support, self-efficacy, and prosthesis factors as overarching categories influencing physical activity for people with LLA.[65] In addition, higher age, less experience with the prosthesis, more comorbidities, and lower functional capacity are associated with lower levels of physical activity after LLA.[63,66] Also, U.S. military veterans have slightly higher physical activity than nonveterans, although veterans who use the Veterans Health Administration for health care may have slightly less physical activity than other veterans.[67] All participants in this current study were veterans who obtained at least some of their care from the Veterans Health Administration.

Although multiple mechanisms underlie low levels of physical activity after LLA, the approach of increasing physical activity through behavior change intervention has been shown to improve physical activity in people recovering from nontraumatic transtibial amputation.[19] In the current trial, the biobehavioral intervention focused on physical activity, with the primary target for participant self-monitoring being daily steps. In the previous trial with similar intervention, participants targeted goals in (1) home exercise, (2) disease self-management, and (3) physical activity.[19] It is possible that efforts in home exercise and/or disease self-management may have indirectly influenced physical activity in the previous trial. Although there is no definitive conclusion regarding the effect of goal specificity on physical activity outcomes, it is has been suggested that less specificity (eg, being generally more active) might be advantageous for people in the early stages of learning how to be active.[68] In addition, people with nontraumatic LLA may not be motivated to focus solely on physical activity behavior change. The influence of goal specificity on physical activity outcomes following LLA should be further investigated.

There are limitations of our study. First, only men were successfully recruited. Based on the small number of veteran women living with amputation (approximately 2% of the veteran amputee population in 2016),[69] fewer women than men were expected. However, based on evidence of gender differences in physical activity,[70] future research on gender differences in response to biobehavioral physical activity intervention are necessary. Second, the behavior-change intervention employed specific methods based largely on social cognitive theory. However, other behavior-change methods may prove effective in helping people improve physical activity after the 1-year post-amputation time point. Third, the biobehavioral intervention was delivered using telehealth video sessions. Despite previous studies demonstrating efficacy of telehealth biobehavioral intervention, it is possible that other modes of intervention delivery (eg, in-person or group sessions) may result in physical activity improvements for people who are more than a year removed from LLA. Finally, the study sample size was small. Despite being appropriately powered for the primary analysis,

as a feasibility study it was not powered to allow for other demographic comparisons (eg, level of amputation, assistive device use).

Conclusion

Telehealth delivered biobehavioral intervention resulted in acceptable participant retention, low dose goal attainment, high participant acceptability, and low safety risk, while having no signal of efficacy (physical activity, disability) for people with nontraumatic LLA. Time since amputation and participant selection of functional goals may be important factors in determining intervention efficacy for this population.

Funding Sources:

VA RR&D I21RX002054, NIH K12 HD055931; NIH/NCATS UL1-TR001082.

References

1. Dillingham TR, Pezzin LE, MacKenzie EJ. Limb amputation and limb deficiency: epidemiology and recent trends in the United States. South Med J. 2002;95(8):875–883. [PubMed: 12190225]
2. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med Rehabil. 2008;89(3):422–429. [PubMed: 18295618]
3. Margolis DJ, Hoffstad O, Nafash J, et al. Location, location, location: geographic clustering of lower-extremity amputation among medicare beneficiaries with diabetes. Diabetes Care. 2011;34(11): 2363–2367. [PubMed: 21933906]
4. Menke A, Casagrande S, Geiss L, Cowie CC. Prevalence of and trends in diabetes among adults in the United States, 1988–2012. JAMA. 2015;314(10):1021–1029. [PubMed: 26348752]
5. Dillon MP, Quigley M, Fatone S. A systematic review describing incidence rate and prevalence of dysvascular partial foot amputation; how both have changed over time and compare to transtibial amputation. Syst Rev. 2017;6(1):230. [PubMed: 29162147]
6. Shin JY, Roh SG, Sharaf B, Lee NH. Risk of major limb amputation in diabetic foot ulcer and accompanying disease: a meta-analysis. J Plast Reconstr Aesthet Surg. 2017;70(12):1681–1688. [PubMed: 28865989]
7. Tseng CL, Rajan M, Miller DR, Lafrance JP, Pogach L. Trends in initial lower extremity amputation rates among Veterans Health Administration health care System users from 2000 to 2004. Diabetes Care. 2011;34(5):1157–1163. [PubMed: 21411510]
8. Hussain MA, Al-Omran M, Salata K, et al. Population-based secular trends in lower-extremity amputation for diabetes and peripheral artery disease. CMAJ. 2019;191(35):E955–E961. [PubMed: 31481423]
9. Paxton RJ, Murray AM, Stevens-Lapsley JE, Sherk KA, Christiansen CL. Physical activity, ambulation, and comorbidities in people with diabetes and lower-limb amputation. J Rehabil Res Dev. 2016;53(6):1069–1078. [PubMed: 28355032]
10. Coffey L, Gallagher P, Desmond D. Goal pursuit and goal adjustment as predictors of disability and quality of life among individuals with a lower limb amputation: a prospective study. Arch Phys Med Rehabil. 2014;95(2):244–252. [PubMed: 23994250]
11. Miller MJ, Cook PF, Kline PW, Anderson CB, Stevens-Lapsley JE, Christiansen CL. Physical function and pre-amputation characteristics explain daily step count after dysvascular amputation. PM R. 2019;11(10):1050–1058. [PubMed: 30729727]
12. VA/DoD Clinical Practice Guideline for Rehabilitation of Lower Limb Amputation. Department of Veterans Affairs & Department of Defense; 2008.
13. VA/DoD Clinical Practice Guideline for Rehabilitation of Lower Limb Amputation. Department of Veterans Affairs & Department of Defense; 2017.

14. de Rekeneire N, Volpato S. Physical function and disability in older adults with diabetes. Clin Geriatr Med. 2015;31(1):51–65, viii. [PubMed: 25453301]
15. McDermott MM, Liu K, O'Brien E, et al. Measuring physical activity in peripheral arterial disease: a comparison of two physical activity questionnaires with an accelerometer. Angiology. 2000;51(2):91–100. [PubMed: 10701716]
16. Greenwood-Hickman MA, Rosenberg DE, Phelan EA, Fitzpatrick AL. Participation in older adult physical activity programs and risk for falls requiring medical care, Washington state, 2005–2011. Prev Chronic Dis. 2015;12:E90. [PubMed: 26068411]
17. Collins TC, Lunos S, Carlson T, et al. Effects of a home-based walking intervention on mobility and quality of life in people with diabetes and peripheral arterial disease: a randomized controlled trial. Diabetes Care. 2011;34(10):2174–2179. [PubMed: 21873560]
18. McDermott MM, Liu K, Guralnik JM, et al. Home-based walking exercise intervention in peripheral artery disease: a randomized clinical trial. JAMA. 2013;310(1):57–65. [PubMed: 23821089]
19. Christiansen CL, Miller MJ, Murray AM, et al. Behavior-change intervention targeting physical function, walking, and disability after dysvascular amputation: a randomized controlled pilot trial. Arch Phys Med Rehabil. 2018;99(11):2160–2167. [PubMed: 29746823]
20. Miller MJ, Stevens-Lapsley J, Fields TT, et al. Physical activity behavior change for older veterans after dysvascular amputation. Contemp Clin Trials. 2017;55:10–15. [PubMed: 28153768]
21. Yesavage JA. Geriatric depression scale. Psychopharmacol Bull. 1988;24(4):709–711. [PubMed: 3249773]
22. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975;12(3):189–198. [PubMed: 1202204]
23. Chakrabarty BK. An audit of the quality of the stump and its relation to rehabilitation in lower limb amputees. Prosthet Orthot Int. 1998; 22(2):136–146. [PubMed: 9747998]
24. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. J Clin Epidemiol. 2005;58(6):595–602. [PubMed: 15878473]
25. Mays RJ, Rogers RK, Hiatt WR, Regensteiner JG. Community walking programs for treatment of peripheral artery disease. J Vasc Surg. 2013;58(6):1678–1687. [PubMed: 24103409]
26. Gardner AW, Parker DE, Montgomery PS, Scott KJ, Blevins SM. Efficacy of quantified home-based exercise and supervised exercise in patients with intermittent claudication: a randomized controlled trial. Circulation. 2011;123(5):491–498. [PubMed: 21262997]
27. De Greef K, Deforche B, Tudor-Locke C, De Bourdeaudhuij I. A cognitive-behavioural pedometer-based group intervention on physical activity and sedentary behaviour in individuals with type 2 diabetes. Health Educ Res. 2010;25(5):724–736. [PubMed: 20338978]
28. McAuley E, Duncan T, Tammen VV. Psychometric properties of the Intrinsic Motivation Inventory in a competitive sport setting: a confirmatory factor analysis. Res Q Exerc Sport. 1989;60(1):48–58. [PubMed: 2489825]
29. Tudor-Locke C, Camhi SM, Troiano RP. A catalog of rules, variables, and definitions applied to accelerometer data in the National Health and Nutrition Examination Survey, 2003–2006. Prev Chronic Dis. 2012;9:E113. [PubMed: 22698174]
30. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. development and evaluation of the disability component. J Gerontol A Biol Sci Med Sci. 2002;57(4):M209–M216. [PubMed: 11909885]
31. Sayers SP, Jette AM, Haley SM, Heeren TC, Guralnik JM, Fielding RA. Validation of the late-life function and disability instrument. J Am Geriatr Soc. 2004;52(9):1554–1559. [PubMed: 15341561]
32. Hand C, Richardson J, Letts L, Stratford P. Construct validity of the late life function and disability instrument for adults with chronic conditions. Disabil Rehabil. 2010;32(1):50–56. [PubMed: 19925276]
33. Beauchamp MK, Schmidt CT, Pedersen MM, Bean JF, Jette AM. Psychometric properties of the late-life function and disability instrument: a systematic review. BMC Geriatr. 2014;14:12. [PubMed: 24476510]

34. Franchignoni F, Giordano A, Ferriero G, Orlandini D, Amoresano A, Perucca L. Measuring mobility in people with lower limb amputation: Rasch analysis of the mobility section of the prosthesis evaluation questionnaire. J Rehabil Med. 2007;39(2):138–144. [PubMed: 17351696]
35. Legro MW, Reiber GD, Smith DG, del Aguila M, Larsen J, Boone D. Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. Arch Phys Med Rehabil. 1998;79(8):931–938. [PubMed: 9710165]
36. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the falls efficacy scale-international (FES-I). Age Ageing. 2005;34(6):614–619. [PubMed: 16267188]
37. Delbaere K, Close JC, Mikolaizak AS, Sachdev PS, Brodaty H, Lord SR. The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. Age Ageing. 2010;39(2):210–216. [PubMed: 20061508]
38. Barnett CT, Vanicek N, Rusaw DF. Do predictive relationships exist between postural control and falls efficacy in unilateral transtibial prosthesis users? Arch Phys Med Rehabil. 2018;99(11): 2271–2278. [PubMed: 29920230]
39. Resnick B, Jenkins LS. Testing the reliability and validity of the self-efficacy for exercise scale. Nurs Res. 2000;49(3):154–159. [PubMed: 10882320]
40. Dannecker EA, Hausenblas HA, Connaughton DP, Lovins TR. Validation of a stages of exercise change questionnaire. Res Q Exerc Sport. 2003;74(3):236–247. [PubMed: 14510288]
41. Herzog TA, Blagg CO. Are most precontemplators contemplating smoking cessation? Assessing the validity of the stages of change. Health Psychol. 2007;26(2):222–231. [PubMed: 17385974]
42. Dahlem NW, Zimet GD, Walker RR. The multidimensional scale of perceived social support: a confirmation study. J Clin Psychol. 1991;47(6):756–761. [PubMed: 1757578]
43. Zimet GD, Powell SS, Farley GK, Werkman S, Berkoff KA. Psychometric characteristics of the multidimensional scale of perceived social support. J Pers Assess. 1990;55(3–4):610–617. [PubMed: 2280326]
44. Unwin J, Kacperek L, Clarke C. A prospective study of positive adjustment to lower limb amputation. Clin Rehabil. 2009;23(11):1044–1050. [PubMed: 19717504]
45. Williams RM, Ehde DM, Smith DG, Czerniecki JM, Hoffman AJ, Robinson LR. A two-year longitudinal study of social support following amputation. Disabil Rehabil. 2004;26(14–15):862–874. [PubMed: 15497915]
46. Podsiadlo D, Richardson S. The timed “Up & Go”: a test of basic functional mobility for frail elderly persons. J Am Geriatr Soc. 1991;39(2):142–148. [PubMed: 1991946]
47. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. Phys Ther. 2000;80(9):896–903. [PubMed: 10960937]
48. Dite W, Connor HJ, Curtis HC. Clinical identification of multiple fall risk early after unilateral transtibial amputation. Arch Phys Med Rehabil. 2007;88(1):109–114. [PubMed: 17207685]
49. van Iersel MB, Munneke M, Esselink RA, Benraad CE, Olde Rikkert MG. Gait velocity and the Timed-Up-and-Go test were sensitive to changes in mobility in frail elderly patients. J Clin Epidemiol. 2008;61(2):186–191. [PubMed: 18177792]
50. Studenski S, Perera S, Patel K, et al. Gait speed and survival in older adults. JAMA. 2011;305(1):50–58. [PubMed: 21205966]
51. Abellan van Kan G, Rolland Y, Andrieu S, et al. Gait speed at usual pace as a predictor of adverse outcomes in community-dwelling older people an International Academy on Nutrition and Aging (IANA) task force. J Nutr Health Aging. 2009;13(10):881–889. [PubMed: 19924348]
52. Boonstra AM, Fidler V, Eisma WH. Walking speed of normal subjects and amputees: aspects of validity of gait analysis. Prosthet Orthot Int. 1993;17(2):78–82. [PubMed: 8233772]
53. Brooks D, Parsons J, Hunter JP, Devlin M, Walker J. The 2-minute walk test as a measure of functional improvement in persons with lower limb amputation. Arch Phys Med Rehabil. 2001;82(10):1478–1483. [PubMed: 11588757]
54. Brooks D, Hunter JP, Parsons J, Livsey E, Quirt J, Devlin M. Reliability of the two-minute walk test in individuals with transtibial amputation. Arch Phys Med Rehabil. 2002;83(11):1562–1565. [PubMed: 12422326]

55. American College of Sports Medicine, Riebe D, Ehrman JK, Liguori G, Magal M. ACSM's Guidelines for Exercise Testing and Prescription. 10th ed. Philadelphia, PA: Wolters Kluwer Health; 2018.
56. De Greef KP, Deforche BI, Ruige JB, et al. The effects of a pedometer-based behavioral modification program with telephone support on physical activity and sedentary behavior in type 2 diabetes patients. Patient Educ Couns. 2011;84(2):275–279. [PubMed: 20732776]
57. Cavalcante BR, Farah BQ, dos A Barosa JP, et al. Are the barriers for physical activity practice equal for all peripheral artery disease patients? Arch Phys Med Rehabil. 2015;96(2):248–252. [PubMed: 25281872]
58. Loprinzi PD, Abbott K. Association of diabetic peripheral arterial disease and objectively-measured physical activity: NHANES 2003–2004. J Diabetes Metab Disord. 2014;13:63. [PubMed: 24967220]
59. Tudor-Locke C, Craig CL, Aoyagi Y, et al. How many steps/day are enough? For older adults and special populations. Int J Behav Nutr Phys Act. 2011;8:80. [PubMed: 21798044]
60. Demeyer H, Burtin C, Hornikx M, et al. The minimal important difference in physical activity in patients with COPD. PloS one. 2016; 11(4):e0154587. [PubMed: 27124297]
61. Bhattacharya A, Kolovson S, Sung YC, et al. Understanding pivotal experiences in behavior change for the design of technologies for personal wellbeing. J Biomed Inform. 2018;79:129–142. [PubMed: 29337132]
62. Langford J, Dillon MP, Granger CL, Barr C. Physical activity participation amongst individuals with lower limb amputation. Disabil Rehabil. 2019;41(9):1063–1070. [PubMed: 29303002]
63. Jayakaran P, Perry M, Hale L. Comparison of self-reported physical activity levels and quality of life between individuals with dysvascular and non-dysvascular below-knee amputation: a cross-sectional study. Disabil Health J. 2019;12(2):235–241. [PubMed: 30389342]
64. Kelly DA, Pedersen S, Tosenovsky P, Sieunarine K. Major lower limb amputation: outcomes are improving. Ann Vasc Surg. 2017;45:29–34. [PubMed: 28602903]
65. Miller MJ, Jones J, Anderson CB, Christiansen CL. Factors influencing participation in physical activity after dysvascular amputation: a qualitative meta-synthesis. Disabil Rehabil. 2019;41(26):3141–3150. [PubMed: 30261758]
66. Sions JM, Arch ES, Horne JR. Self-reported functional mobility, balance confidence, and prosthetic use are associated with daily step counts among individuals with a unilateral transtibial amputation. J Phys Act Health. 2018;15(6):423–429. [PubMed: 29771620]
67. Littman AJ, Forsberg CW, Koepsell TD. Physical activity in a national sample of veterans. Med Sci Sports Exerc. 2009;41(5):1006–1013. [PubMed: 19346987]
68. McEwan D, Harden SM, Zumbo BD, et al. The effectiveness of multi-component goal setting interventions for changing physical activity behaviour: a systematic review and meta-analysis. Health Psychol Rev. 2016;10(1):67–88. [PubMed: 26445201]
69. Randolph BJ, Nelson LM, Highsmith MJ. A review of unique considerations for female veterans with amputation. Mil Med. 2016;181(S4):66–68. [PubMed: 27849464]
70. Rosenfeld CS. Sex-dependent differences in voluntary physical activity. J Neurosci Res. 2017;95(1–2):279–290. [PubMed: 27870424]

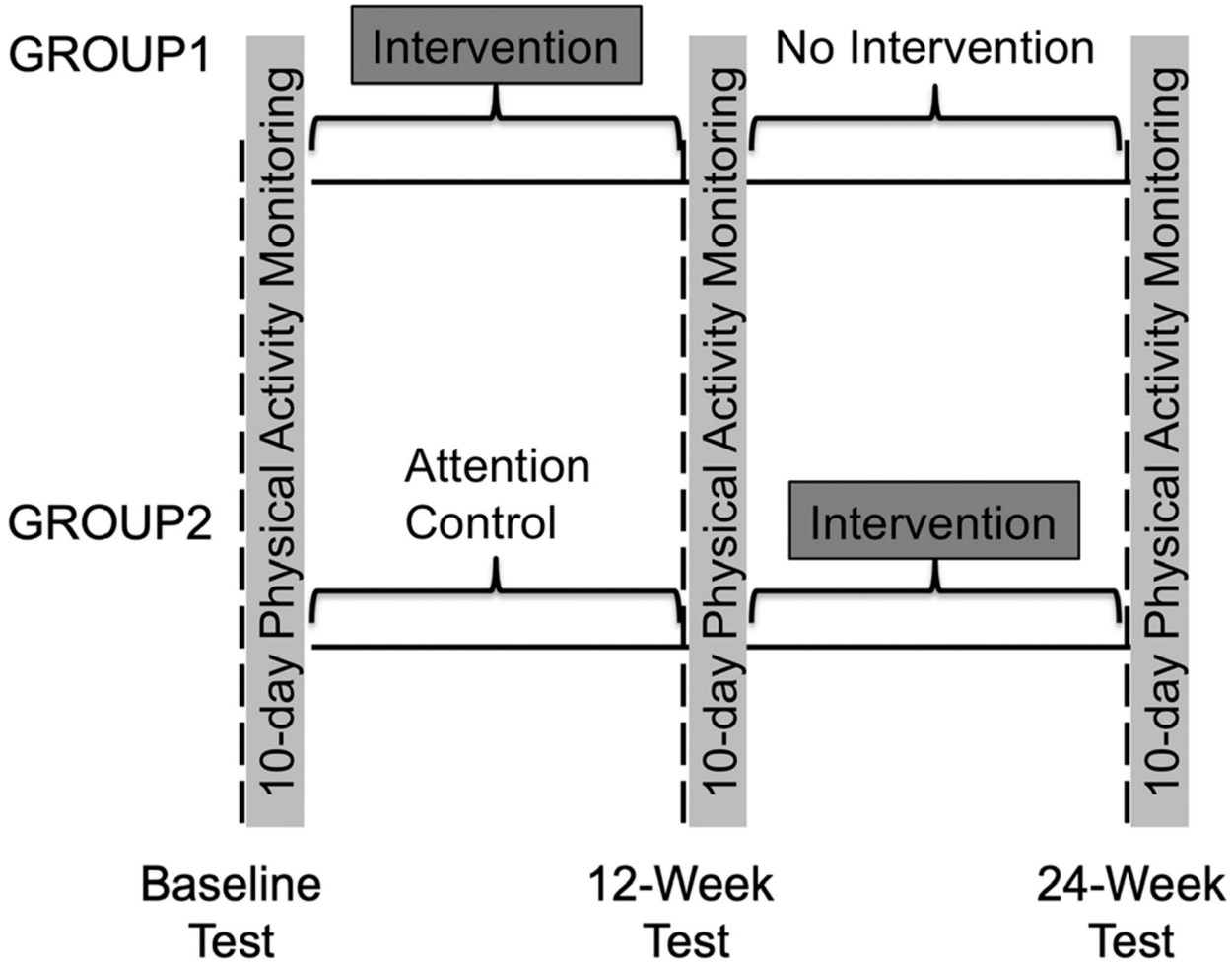

Figure 1.
Study design overview.

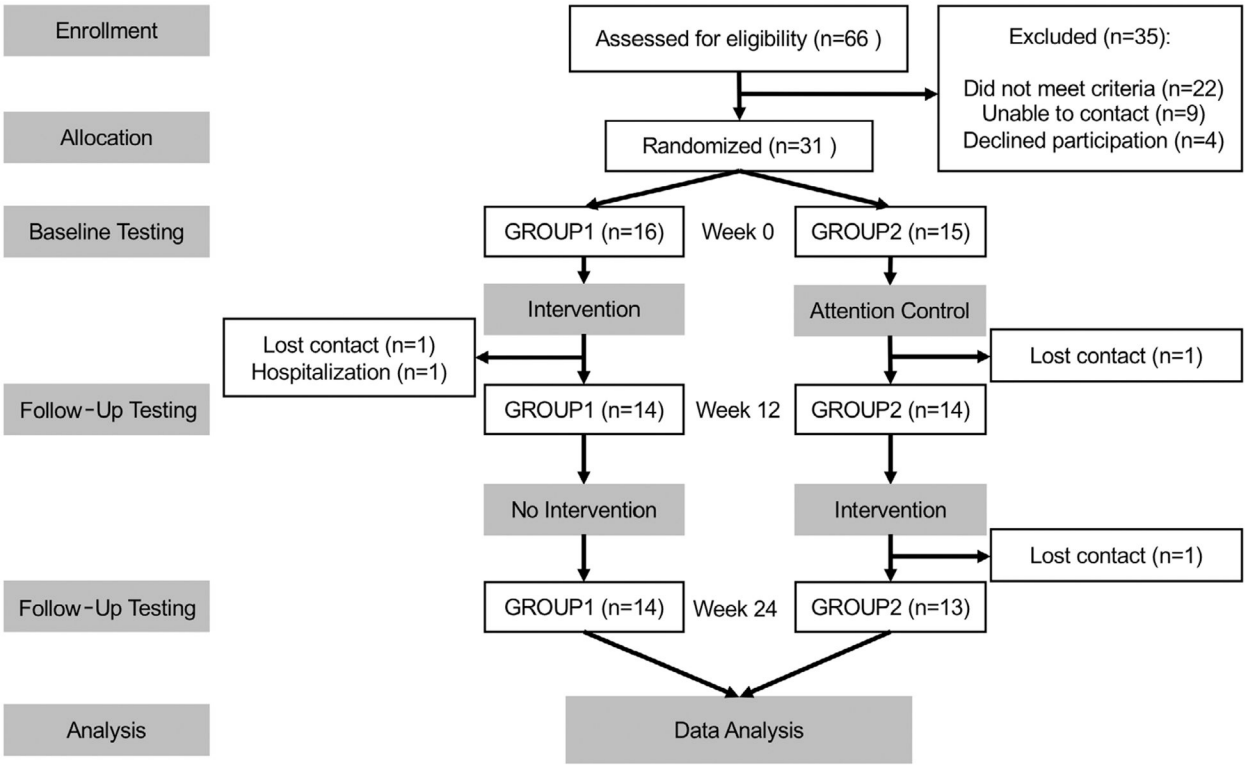

Figure 2.
Enrollment CONSORT diagram.

Table 1

Baseline participant characteristics by group *

Variable	GROUP1 (n = 16)	GROUP2 (n = 15)
Age, y	67.9 (6.2)	63.4 (8.9)
Gender, n (%) male	16 (100%)	15 (100%)
BMI, kg/m^2	26.9 (4.9)	30.9 (6.1)
Time since amputation, months	36.5 (40.8)	36.2 (16.0)
Amputation level, n (%) transtibial	14 (88%)	12 (80%)
GDS, score out of 15	4.1 (4.0)	3.7 (3.8)
MMSE, score out of 30	28.4 (4.5)	29.0 (1.6)
Chakrabarty Grade, score out of 100	84.8 (18.4)	85.7 (12.4)
Functional Comorbidity Index, score out of 20	6.8 (3.3)	6.0 (3.2)

BMI = body mass index; GDS = Geriatric Depression Scale; MMSE = Mini-Mental Status Examination.

* Data shown are means (SD) or n (%), unless otherwise stated.

Table 2

Daily step count, performance-based function, and self-report outcomes by group *

	GROUP1			GROUP2		
Variable	**Baseline**	**12 W**	**24 W**	**Baseline**	**12 W**	**24 W**
Free-living physical activity						
Daily step count, steps/d	1862 (1117, 2606)	1609 (826, 2393)	1716 (948, 2483)	1869 (1114, 2625)	1897 (1242, 2551)	1773 (1189, 2357)
Self-report questionnaires						
LLFDI-Frequency, scaled to 100	49.7 (45.8, 45.7)	49.3 (46.2, 52.4)	52.5 (48.6, 56.3)	51.5 (47.3, 55.6)	54.5 (48.5, 60.6)	51.3 (48.4, 54.3)
LLFDI-Limitation, scaled to 100	66.3 (58.2, 74.5)	71.4 (63.2, 79.7)	74.3 (65.3, 83.3)	69.2 (61.3, 77.1)	68.1 (55.3, 80.9)	68.6 (60.7, 76.4)
PEQ-MS, score out of 12	2.5 (1.9, 3.1)	2.4 (1.8, 3.0)	2.7 (2.2, 3.2)	2.7 (2.4, 3.0)	2.6 (2.2, 3.0)	2.7 (2.3, 3.0)
FES-I, score out of 64	28.9 (24.4, 33.4)	30.3 (25.0, 35.6)	27.5 (23.7, 31.4)	28.0 (23.6, 32.4)	32.5 (27.5, 37.4)	29.1 (24.6, 33.7)
MSPSS, score out of 84	64.3 (57.4, 71.2)	70.8 (64.0, 77.7)	67.8 (58.0, 77.6)	68.1 (57.5, 78.7)	70.2 (60.2, 80.2)	68.6 (58.9, 78.3)
SEE, score out of 10	7.2 (6.1, 8.3)	6.7 (5.6, 7.8)	7.1 (6.0, 8.2)	7.5 (6.6, 8.4)	7.0 (6.0, 7.9)	7.7 (6.5, 8.9)
ESC, score out of 5	3.3 (2.6, 3.9)	3.6 (2.9, 4.3)	3.8 (3.0, 4.6)	3.7 (3.0, 4.5)	3.7 (2.8, 4.5)	4.3 (3.7, 5.0)
Performance-based functional measures						
TUG, s	19.4 (10.5, 28.4)	18.0 (13.8, 22.3)	15.3 (10.3, 20.2)	14.9 (11.8, 18.0)	14.8 (10.4, 19.2)	14.5 (11.5, 17.4)
Gait speed, m/s	0.92 (0.74, 1.10)	0.79 (0.62, 0.95)	0.93 (0.73, 1.12)	0.96 (0.83, 1.08)	0.94 (0.81, 1.06)	1.03 (0.90, 1.15)
2 MW, m	97.7 (77.2, 118.3)	85.5 (65.8, 105.2)	103.4 (83.4, 125.4)	101.8 (88.3, 115.2)	101.3 (85.07, 117.5)	103.3 (88.0, 118.6)

LLFDI = Late Life Function and Disability Index; TUG = Timed Up-and-Go test; 2 MW = Two-Minute Walk test; PEQ-MS = Prosthesis Evaluation Questionnaire - Mobility Scale; FES-I = Falls Efficacy Scale - International; MSPSS = Multidimensional Scale of Perceived Social Support; SEE = Self-Efficacy of Exercise Scale; ESC = Exercise Stages of Change Scale.

* Data are estimated means (95% confidence interval [CI] Bounds). No between-group differences in change scores for any variable ($P < .05$).