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Physical activity behavior change for older veterans after dysvascular amputation

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ABSTRACT

Objective: Determine the feasibility of using a physical-activity behavior-change (PABC) intervention for increasing physical activity and reducing disability in Veterans 1–5 years following dysvascular lower-limb amputation (LLA).
Design: Cross-over, feasibility trial
Setting: VA Geriatric Research Education and Clinical Center and Veterans Homes
Participants: 32 Veterans with dysvascular LLA (1–5 years after major LLA)
Intervention: The home-based study, using telerehabilitation technology, is intended to reduce participant burden by removing transportation and time barriers. Participants will be randomized into two participation periods of three months (Months 1–3 and 4–6). PABC intervention will occur Months 1–3 for GROUP1 and Months 4–6 for GROUP2. During PABC Intervention, participants engage in weekly video interaction with a physical therapist, who uses a collaborative approach to develop self-monitoring, barrier identification, problem solving and action planning skills to improve physical activity. GROUP2 will participate in a no physical activity intervention, attention control in Months 1–3. GROUP1 will have a no contact, intervention "wash-out" period in Months 4–6.
Main outcome measures: Feasibility will be determined using measures of 1) participant retention, 2) dose goal attainment, 3) participant acceptability, 4) safety, and 5) initial effect size. Effect size will be based on accelerometer-based physical activity and self-report disability using the Late-Life Function and Disability Index.
Conclusions: This study focuses on a prevalent and understudied population with low physical activity and high levels of disability due to dysvascular LLA. The results of this study will guide future development of targeted rehabilitation research to improve long term physical activity and disability outcomes.

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1. Introduction

The number of Americans with dysvascular lower limb amputation (LLA) is expected to grow from 1 million in 2010 to 2.3 million by 2050 due to the rising incidence of Diabetes Mellitus (DM) and Peripheral Artery Disease (PAD) in an aging United States population [1]. Patients with dysvascular LLA, referring to amputation caused by complications related to DM and/or PAD, participate in dynamic walking activities half as much as healthy people of similar age [2] and only 33% of Veterans with major LLA achieve pre-amputation mobility one year after LLA [3]. Importantly, patients with PAD and DM have lower physical activity and greater disability than healthy peers [4,5]. In addition, LLA of any etiology leads to lower physical activity and disability [2,3,6].

Despite the well documented physical limitations following dysvascular LLA [7,8], rehabilitation strategies to improve physical activity after dysvascular LLA are neither well-defined nor well-studied [9]. Current VA/DoD Clinical Practice Rehabilitation Guidelines describe a comprehensive approach, including community reintegration after LLA [10], yet no intervention strategies have been investigated to improve the chronic physical inactivity that falls well below recommended levels [11]. While the majority of LLAs (>80%) are dysvascular [12], available functional outcomes research is largely based on relatively younger populations with traumatic, congenital, or cancer-related LLAs, limiting the knowledge needed to develop rehabilitation strategies following dysvascular LLA [9,13]. Additionally, supervised exercise programs for patients with chronic health conditions can create short-

Abbreviations: LLA, Lower Limb Amputation; DM, Diabetes Mellitus; PAD, Peripheral Artery Disease; PABC, Physical Activity Behavior Change; VAMC, Veterans Administration Medical Center; GRECC, Geriatric Research Education & Clinical Center.

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term improvements in physical activity [14–17], but such programs have high patient burden (e.g., transportation and time). This burden is especially relevant to Veterans living in remote or rural areas [18]. Physical activity interventions for older adults with chronic diseases, including DM and PAD, have known benefits including decreased fall risk and improved health outcomes [14,19–21]. However, activity interventions using telerehabilitation for patients with chronic vascular disease in addition to LLA have not been established. Supervised exercise programs for patients with telerehabilitation interventions are a promising alternative to traditional direct supervised intervention to decrease patient burden and improve long-term activity behavior [14,21–25].

The primary objective of this pilot study is to determine the feasibility a physical-activity behavior-change (PABC) intervention targeting improved physical activity and reduced disability in Veterans 1–5 years following dysvascular LLA by assessing 1) practicality, 2) implementation feasibility, 3) participant acceptability, and 4) safety. Establishing initial effect size estimates of the PABC intervention is a secondary objective of this study.

2. Methods/design

The proposed pilot study is a randomized, tester-blinded design assessing PABC intervention feasibility (Aim 1) and effect size (Aim 2). We plan to randomize 32 participants to one of two groups (GROUP1 or GROUP2) using computer-generated random blocks of 2 and 4, stratified by amputation level (transtibial and transfemoral). Fig. 1 presents the *anticipated* number of Veterans to be screened, randomized, and complete the study. An investigator not involved with testing or intervention will conceal group allocation. A crossover design is used to simultaneously accomplish the aims and optimize recruitment. The PABC Intervention will be delivered to both groups (GROUP1 during Months 1–3 and GROUP2 during Months 4–6). The crossover design provides $n = 32$ for assessing Aims 1 and 2. Intervention effect retention will be tested at six months for GROUP1 ($n = 16$). The study was approved by the Colorado Multiple Institutional Review Board and Denver VA Research & Development Committee.

2.1. Setting

The study will occur at the Denver Veterans Administration Medical Center (VAMC) Geriatric Research Education and Clinical Center (GRECC). Intervention delivery will occur with the participant at home and therapist at the Denver VAMC, using VA-supplied and approved mobile-health tablets and wearable activity sensors (FitBit).

2.2. Participants

Thirty-two participants will be recruited from the Denver VAMC. The target sample is older Veterans diagnosed with PAD and/or DM, who have major LLA. We expect <15% attrition, based on previous studies in our lab group enrolling Veterans with similar diagnoses, with a goal of 26 participants completing.

2.3. Eligibility criteria

Inclusion criteria: ≥50 years of age, LLA 1–5 years prior, Type II DM and/or PAD, and ambulatory using a prosthesis. Exclusion criteria: trauma or cancer-related etiology of the LLA, unstable heart condition, uncontrolled hypertension, acute systemic infection, cancer, recent stroke (within 2 years), lower extremity wound or ulcer that limits ambulation.

2.4. Recruitment and screening

Participants will be recruited through the Denver VAMC. Potential participants will be pre-screened via standardized phone screen. We will increase the recruitment pool for this study from our previous studies, by allowing participants with both transfemoral and transtibial amputation.

2.5. D.5. Intervention

The home-based study design is intended to reduce participant burden by removing transportation and time barriers. There will be two participation periods of three months (Months 1–3 and 4–6). PABC intervention will occur Months 1–3 for GROUP1 and Months 4–6 for GROUP2 (Fig. 1). GROUP2 will participate in a no physical activity intervention, attention control in Months 1–3. GROUP1 will have a no contact, intervention "wash-out" period in Months 4–6. The 3-month intervention period was determined by evidence of physical activity behavioral interventions for people with chronic conditions. There is a high heterogeneity of session number and length of intervention reported for such behavioral interventions, ranging from one session, to multiple sessions over a two-and-a-half-year period [26]. More specifically, the largest portion of studies provided multiple sessions (>80%) over a 1 to 5-month period (34%) [26]. To maximize dosage, we selected weekly intervention over 3 months.

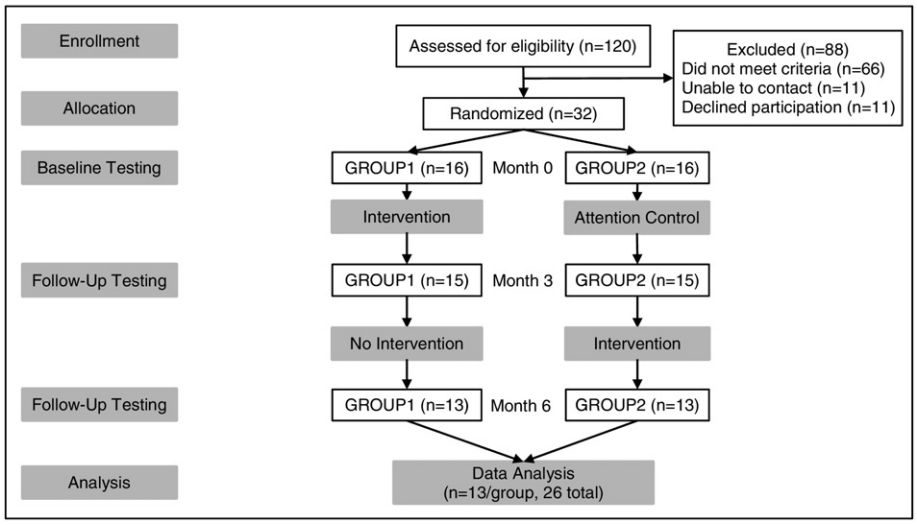

Fig. 1. Anticipated CONSORT flow diagram.