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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.

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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.

Keywords

Dysvascular Amputation; Physical Activity; Behavior Change; Veteran; Telerehabilitation; Feasibility

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 age² 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-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). Figure 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.

2.5.1. Study Initiation—A physical therapist will initially meet with each participant at his/her home to: 1) obtain informed consent and authorization, 2) deliver and orient the participant to wearing an activity monitor (ActiGraph Inc. Pensacola FL), 3) assess the prosthetic fit and function (Prosthetic Evaluation Questionnaire), and 4) perform a home evaluation. If prosthetic fit and function concerns are identified, the participant will be given recommendations for seeing his/her prosthetist, which must be met before beginning the intervention. Results of the home evaluation will guide recommendations to minimize risk for falls. The participant will wear the ActiGraph monitor for 10 days after the initial visit. The ActiGraph monitor will be used only for outcome data (not intervention) and provides no feedback to participants. Following the initial visit, participants will be randomized to GROUP1 or GROUP2.

2.5.2. Physical-Activity Behavior-Change (PABC) Intervention—The intervention begins with a home visit in which the therapist delivers and outlines the PABC intervention and use of equipment (FitBit wearable sensor (FitBit Inc., Boston MA) and FitBit application on the tablet). The FitBit wearable sensor is designed specifically to provide user feedback through an application on the home-based tablet. The first intervention week will be an accommodation period for the participant to interact with the equipment and establish baseline activity feedback. After the first week, an individualized participant action plan will be developed and the therapist will deliver the intervention following a semi-structured script (Tab. 1). Weekly video-based interactions between participant and therapist (30 minutes) will occur during the 3-month intervention (12 visits) using the mobile-health tablets. The PABC intervention will require daily participant interaction with the tablet application. The tablet application is commercially available through FitBit and will provide feedback on number of steps taken and progress toward activity goals. Participants’ activity will guide the goals for each week and barriers to reaching goals will be identified. The therapist will guide the participant in reasoning how to address any identified barriers to activity progression. Each week will include scripted education delivered by the therapist during the video interaction, on a relevant intervention topic (e.g., fall prevention, monitoring blood sugar and diet relative to increasing activity, etc.) (10 minutes), and

identifying and recording any adverse or serious event occurrence. The initial education topic will be fall prevention, to minimize fall risk during the study period.

2.5.3. No Physical Activity Intervention, Attention Control Period—During Months 1–3, GROUP2 will weekly have weekly video interactions with a therapist using the mobile-health tablets, in a no physical activity intervention control period. These meetings will provide health and safety education on non-physical activity topics pertaining to older Veterans (e.g., fall prevention, diet, medication management, retirement issues, etc.). Physical activity recommendations will not be discussed. Each week will include scripted education on one topic (10 minutes), a brief period of light upper and lower extremity range of motion tasks led by the therapist with the video interface and participants seated in a chair (20 minutes), and identifying and recording any adverse or serious event occurrence. As in the PABC intervention period, the initial education topic for the control period will be fall prevention, to minimize fall risk during the study period. The rationale for the no physical activity intervention, attention control period is to determine the natural change in physical activity and disability without PABC intervention, while accounting for any potential benefit from contact with the physical therapist (i.e., attention control).

2.5.4. Outcomes—Outcomes will be measured during in-home visits (Baseline, 3M, and 6M), to promote safety and reduce fall risk during the test session (Table 2).

2.5.4.1. Feasibility (Aim 1): The primary aim of this study is to determine feasibility of using the PABC intervention with older Veterans who have dysvascular LLA by assessing: 1) practicality, 2) implementation feasibility, 3) participant acceptability, and 4) safety.^{27, 28} Practicality will be assessed by measuring participant retention through the duration of the research protocol. Implementation feasibility, measured by dose goal attainment, will be the proportion of participants achieving an average of 3% improvement per week during the intervention phase. Participant acceptability will be assessed with the Intrinsic Motivation Inventory–Interest / Enjoyment Subscale²⁹, a commonly used scale to assess participant acceptability in feasibility trials. Safety will be assessed by comparing frequency of Adverse and Serious Adverse events between GROUP1 and GROUP2.

2.5.4.2. Effect Size (Aim 2): The secondary aim of this study is to establish effect size estimates of the PABC intervention using physical activity and self-report disability outcomes. Physical activity effect size estimates will be established from average 10-day physical activity counts using research grade physical activity monitors (ActiGraph monitors^{22,30}). The Late-Life Function and Disability Index (LLFDI^{31, 32}) will be used to establish effect size estimates for self-reported disability.

2.5.4.3. Descriptive Measures: In addition, descriptive measures will be collected including demographics, medications, cognition (Folstein Mini-Mental State Exam³³), depression (Geriatric Depression Scale SF^{34, 35}), comorbidities (Functional Comorbidity Index³⁶), residual limb quality (Chakrabarty Scale³⁷), sensory testing (Michigan Neuropathy Screen^{38, 39}), prosthesis description, perceived social support (Multidimensional Scale of Perceived Social Support⁴⁰), exercise readiness to change (Exercise Stages of Change^{41, 42}), self-efficacy (Falls Efficacy Scale–International (FES-I)^{43, 44}, Self-Efficacy for Exercise

Scale⁴⁵), self-report physical performance (Prosthesis Evaluation Questionnaire–Mobility Subscale^{46, 47}), and physical performance (Timed Up and Go (TUG)⁴⁸, 5-Meter Walk Test⁴⁹, 2-Minute Walk Test^{50, 51}, and Single Leg Standing Balance).

2.6. Data Management

The FitBit sensor will be used to guide the intervention and data from the sensors will not include personal health information; with generic accounts will be created for each user without participant-identifiable information. FitBit data will not be used as outcomes, but rather, only to guide the PABC intervention. Outcome data will be managed using the REDCap (Research Electronic Data Capture) platform. REDCap is a secure, web-based application designed to support research data capture, providing user-friendly case report forms, real-time data entry validation (e.g., data type and range checks), audit trails, transaction logs, and a de-identified data export to common statistical packages.

2.7. Sample Size Estimate

The sample size estimate was based on evidence for activity change in patients with DM and PAD, which indicates a reasonable expected increase of 3% walking activity per week (e.g., steps, distance, time) over 3 months.^{14, 31, 52, 53} A baseline mean (SD) of 2000 (900) steps/day was estimated based on data from our ongoing dysvascular LLA randomized controlled trial (RCT) and published LLA data.^{54–56} A 3% weekly increase in steps during intervention, assuming no order effect, would provide an effect size of 0.8 (Cohen's d). Based on those assumptions, a sample size of 13 per group with a crossover design (total n=26) provides >95% power to detect an intervention effect (effect size=0.8, $\alpha=0.05$, two-tailed paired t test). The study is generously powered intentionally, because the assumption of 'no order effect' will not likely hold. We will recruit 32 participants, and expect at least 26 to complete. This 15% attrition estimate is conservative, based on an historical attrition rate <15% in our intervention studies with other older adult populations^{57, 58} and our current dysvascular LLA RCT.

2.8. D.9. Data Analysis Plan

2.8.1. Feasibility (Aim 1)—The analyses for Aim 1 are based on four hypotheses: 1) participant retention, 2) dose goal attainment, 3) intervention acceptability, and 4) safety.

Retention rate will be assessed using a cut off of 15% attrition (i.e., loss of >6 participants). Mean attrition rate will be compared to the null value of 15% using a one-sample t-test ($\alpha=0.05$). This attrition rate is considered feasible based on previous activity change programs for patients with DM or PAD.^{25, 59}

Dose goal attainment will be assessed by the proportion of participants achieving the goal of 3% average weekly increase in steps, based on activity gains in other intervention studies.^{14, 31, 53} The ability to attain a 3% average weekly step increase for <75% of the participants will be considered a negative result. The proportion of participants attaining a 3% average weekly step increase will be reported (95% CI) and compared to the null value of 75% using a one-sample binomial proportions test ($\alpha=0.05$).

Acceptability of the intervention will be measured with the IMI Interest and Enjoyment subscale, with a mean score of $<5/7$ considered a negative acceptability result.²⁹ Mean IMI Interest and Enjoyment score will be compared to the null value of 5.0 using a one-sample t-test ($\alpha=0.05$).

Adverse and serious adverse event (AE/SAE) rates (events/participant) will be compared between groups for Months 1–3 (PABC intervention for GROUP1, attention control for GROUP2). We expect similar AE/SAE rates between groups.

2.8.2. Effect Size and Preliminary Efficacy of PABC Intervention (Aim 2)—Effect size of the PABC intervention will be calculated with Cohen's d using mean and standard deviation for change in activity counts and LLFDI scores. Statistical inference of group differences for calculation of sample size estimates will be based on linear models with activity counts and LLFDI scores as outcome variables. Explanatory variables in each model will include primary medical diagnosis (PAD, DM, or both), group, and baseline activity count or LLFDI score.

2.9. Expected Outcomes and Interpretation

Determining feasibility of the PABC intervention will set the stage for implementing a larger efficacy study. The expected result is that Veterans with LLA can be enrolled and retained in the PABC intervention with adherence to a 3% weekly increase in physical activity dose. In addition, the effect size is expected to be 0.80. While similar interventions have been feasible and successful for other chronic disease populations, this trial will be the first to target chronic physical inactivity behavior for Veterans living with dysvascular LLA.

2.10. Participant Safety

Anticipated adverse events include falls and medical complications due to DM and PAD. A Safety Officer for the study 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) at all test points (baseline, 3M, 6M). Also, occurrence of falls and adverse events will be recorded at each of weekly visit in both the intervention and control periods. Fall occurrences 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”,⁶⁰ will be of particular focus. All study-related falls (possibly, probably, or definitely) will be tracked weekly. If the total number of falls reaches 4, the Safety Officer will review incidence by group. If the number of falls for the intervention group exceeds that of the control group by 3 (10% 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.

3. Discussion

This pilot study is significant for Veterans with dysvascular LLA based primarily on poor long-term rehabilitation outcomes, limited evidence-based physical activity rehabilitation strategies and barriers for Veterans accessing rehabilitation clinicians. Patients with

dysvascular LLA participate in dynamic walking activities half as much as healthy people of similar age², yet rehabilitation strategies to improve physical activity after dysvascular LLA are neither well-defined nor well-studied.⁹ Additionally, the access to supervised exercise clinicians is especially relevant to Veterans living in remote or rural areas.¹⁸ This trial will assess the feasibility of an innovative intervention to improve physical activity in an underserved and understudied population.

Traditional rehabilitation focuses on physical impairments, neglecting physical activity behaviors that often exist prior to dysvascular LLA. Chronic inactivity behavior compounds the insult of LLA, resulting in dangerously low activity levels after LLA.^{2, 54, 61} However, health benefits of being physically active are well established, with higher levels of physical activity linked to improved health and quality of life in patients with chronic disease.^{11, 62} This study will implement behavior change techniques, proven successful for other chronic disease populations,^{14, 21, 24, 25} to target physical inactivity following dysvascular LLA.

This study advances current physical rehabilitation by using home-based intervention to build on inpatient and outpatient rehabilitation success. While physical function improves across the course of rehabilitation,^{63, 64} long-term functional outcomes after LLA are poor.^{3, 8, 65, 66} Traditional physical rehabilitation focuses narrowly on care immediately following LLA, emphasizing prosthetic function, mobility/gait training, and targeted remediation of physical impairments.^{9, 67} Once Veterans complete traditional outpatient rehabilitation, continued physical activity intervention is often not practical, especially for Veterans living in rural areas with unique barriers to healthcare access.¹⁸ Improved long-term physical activity outcomes may result from practical behavior changes through home-based intervention to supplement clinic-based rehabilitation.

This study adds value to emerging mobile health technology currently used for Veteran populations with various other complex health conditions. The proposed mobile-health technology in this pilot study is currently used in the VA system to promote psychological health,⁶⁸ diabetes monitoring,⁶⁹ and pharmacological management of cardiovascular disease.⁷⁰ This study will provide added value to the VA mobile-health technology by using the technology for promoting physical activity behavior change in a population of Veterans at high risk for physical inactivity and high disability.

This pilot study is an important stepping-stone for a larger research line focused on optimizing physical activity and minimizing disability for Veterans with dysvascular LLA. Data from this pilot study will inform a larger intervention trial targeting mobile-health physical activity change.

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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

References

1. 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.* Mar; 2008 89(3):422–429. [PubMed: 18295618]
2. Bussmann JB, Grootcholten EA, Stam HJ. Daily physical activity and heart rate response in people with a unilateral transtibial amputation for vascular disease. *Arch Phys Med Rehabil.* Feb; 2004 85(2):240–244. [PubMed: 14966708]
3. Czerniecki JM, Turner AP, Williams RM, Hakimi KN, Norvell DC. Mobility changes in individuals with dysvascular amputation from the presurgical period to 12 months postamputation. *Arch Phys Med Rehabil.* Oct; 2012 93(10):1766–1773. [PubMed: 22543258]
4. Egan AM, Mahmood WA, Fenton R, et al. Barriers to exercise in obese patients with type 2 diabetes. *QJM : monthly journal of the Association of Physicians.* Jul; 2013 106(7):635–638. [PubMed: 23525164]
5. McDermott MM, Domanchuk K, Liu K, et al. The Group Oriented Arterial Leg Study (GOALS) to improve walking performance in patients with peripheral arterial disease. *Contemp Clin Trials.* Nov; 2012 33(6):1311–1320. [PubMed: 23158112]
6. Bussmann JB, Schrauwen HJ, Stam HJ. Daily physical activity and heart rate response in people with a unilateral traumatic transtibial amputation. *Arch Phys Med Rehabil.* Mar; 2008 89(3):430–434. [PubMed: 18295619]
7. Davies B, Datta D. Mobility outcome following unilateral lower limb amputation. *Prosthetics and orthotics international.* Dec; 2003 27(3):186–190. [PubMed: 14727699]
8. van Velzen JM, van Bennekom CA, Polonski W, Sloopman JR, van der Woude LH, Houdijk H. Physical capacity and walking ability after lower limb amputation: a systematic review. *Clin Rehabil.* Nov; 2006 20(11):999–1016. [PubMed: 17065543]
9. Cumming JC, Barr S, Howe TE. Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. *Cochrane Database Syst Rev.* 2006; (4):CD005260. [PubMed: 17054250]
10. VA/DoD Clinical Practice Guideline for Rehabilitation of Lower Limb Amputation. Department of Veterans Affairs & Department of Defense; 2008.
11. American College of Sports Medicine Position Stand. Exercise and physical activity for older adults. *Medicine and science in sports and exercise.* Jun; 1998 30(6):992–1008. [PubMed: 9624662]
12. Margolis DJ, Hoffstad O, Nafash J, et al. Location, location, location: geographic clustering of lower-extremity amputation among Medicare beneficiaries with diabetes. *Diabetes care.* Nov; 2011 34(11):2363–2367. [PubMed: 21933906]
13. Fortington LV, Geertzen JH, Bosmans JC, Dijkstra PU. Bias in amputation research; impact of subjects missed from a prospective study. *PLoS One.* 2012; 7(8):e43629. [PubMed: 22916286]

14. 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*. Feb 8; 2011 123(5):491–498. [PubMed: 21262997]
15. Lane R, Ellis B, Watson L, Leng GC. Exercise for intermittent claudication. *Cochrane Database Syst Rev*. Jul 18; 2014 7:CD000990.
16. Heiwe S, Jacobson SH. Exercise Training in Adults With CKD: A Systematic Review and Meta-analysis. *American journal of kidney diseases : the official journal of the National Kidney Foundation*. Jun 6; 2014
17. Zafrir B. Exercise training and rehabilitation in pulmonary arterial hypertension: rationale and current data evaluation. *Journal of cardiopulmonary rehabilitation and prevention*. Sep-Oct; 2013 33(5):263–273. [PubMed: 23962982]
18. Luptak M, Dailey N, Juretic M, et al. The Care Coordination Home Telehealth (CCHT) rural demonstration project: a symptom-based approach for serving older veterans in remote geographical settings. *Rural and remote health*. Apr-Jun; 2010 10(2):1375. [PubMed: 20518592]
19. 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]
20. 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*. Oct; 2011 34(10):2174–2179. [PubMed: 21873560]
21. McDermott MM, Liu K, Guralnik JM, et al. Home-based walking exercise intervention in peripheral artery disease: a randomized clinical trial. *JAMA*. Jul 3; 2013 310(1):57–65. [PubMed: 23821089]
22. Geraedts H, Zijlstra A, Bulstra SK, Stevens M, Zijlstra W. Effects of remote feedback in home-based physical activity interventions for older adults: a systematic review. *Patient education and counseling*. Apr; 2013 91(1):14–24. [PubMed: 23194823]
23. Liebreich T, Plotnikoff RC, Courneya KS, Boule N. Diabetes NetPLAY: A physical activity website and linked email counselling randomized intervention for individuals with type 2 diabetes. *Int J Behav Nutr Phys Act*. 2009; 6:18. [PubMed: 19327141]
24. Plotnikoff RC, Pickering MA, Glenn N, et al. The effects of a supplemental, theory-based physical activity counseling intervention for adults with type 2 diabetes. *Journal of physical activity & health*. Sep; 2011 8(7):944–954. [PubMed: 21885885]
25. 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 education and counseling*. Aug; 2011 84(2):275–279. [PubMed: 20732776]
26. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychol*. Nov; 2009 28(6):690–701. [PubMed: 19916637]
27. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*. May; 2009 36(5):452–457. [PubMed: 19362699]
28. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. Jan 06; 2010 10:1. [PubMed: 20053272]
29. McAuley E, Duncan T, Tammien VV. Psychometric properties of the Intrinsic Motivation Inventory in a competitive sport setting: a confirmatory factor analysis. *Research quarterly for exercise and sport*. Mar; 1989 60(1):48–58. [PubMed: 2489825]
30. Yates T, Davies M, Gorely T, Bull F, Khunti K. Effectiveness of a pragmatic education program designed to promote walking activity in individuals with impaired glucose tolerance: a randomized controlled trial. *Diabetes Care*. Aug; 2009 32(8):1404–1410. [PubMed: 19602539]
31. Mays RJ, Rogers RK, Hiatt WR, Regensteiner JG. Community walking programs for treatment of peripheral artery disease. *Journal of vascular surgery*. Dec; 2013 58(6):1678–1687. [PubMed: 24103409]

32. Conn VS, Hafdahl AR, Minor MA, Nielsen PJ. Physical activity interventions among adults with arthritis: meta-analysis of outcomes. *Seminars in arthritis and rheumatism*. Apr; 2008 37(5):307–316. [PubMed: 17888500]
33. Folstein MF, Folstein SE, McHugh PR. “Mini-mental state”. A practical method for grading the cognitive state of patients for the clinician. *Journal of psychiatric research*. Nov; 1975 12(3):189–198. [PubMed: 1202204]
34. Hoyl MT, Alessi CA, Harker JO, et al. Development and testing of a five-item version of the Geriatric Depression Scale. *Journal of the American Geriatrics Society*. Jul; 1999 47(7):873–878. [PubMed: 10404935]
35. Rinaldi P, Mecocci P, Benedetti C, et al. Validation of the five-item geriatric depression scale in elderly subjects in three different settings. *J Am Geriatr Soc*. May; 2003 51(5):694–698. [PubMed: 12752847]
36. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. *J Clin Epidemiol*. Jun; 2005 58(6):595–602. [PubMed: 15878473]
37. Chakrabarty BK. An audit of the quality of the stump and its relation to rehabilitation in lower limb amputees. *Prosthetics and orthotics international*. Aug; 1998 22(2):136–146. [PubMed: 9747998]
38. Furber S, Monger C, Franco L, et al. The effectiveness of a brief intervention using a pedometer and step-recording diary in promoting physical activity in people diagnosed with type 2 diabetes or impaired glucose tolerance. *Health promotion journal of Australia : official journal of Australian Association of Health Promotion Professionals*. Dec; 2008 19(3):189–195. [PubMed: 19053935]
39. Patterson RB, Pinto B, Marcus B, Colucci A, Braun T, Roberts M. Value of a supervised exercise program for the therapy of arterial claudication. *J Vasc Surg*. Feb; 1997 25(2):312–318. discussion 318–319. [PubMed: 9052565]
40. Zimet GD, Powell SS, Farley GK, Werkman S, Berkoff KA. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *Journal of personality assessment*. Winter; 1990 55(3–4):610–617. [PubMed: 2280326]
41. Savage P, Ricci MA, Lynn M, et al. Effects of home versus supervised exercise for patients with intermittent claudication. *Journal of cardiopulmonary rehabilitation*. May-Jun; 2001 21(3):152–157. [PubMed: 11409225]
42. Degischer S, Labs KH, Hochstrasser J, Aschwanden M, Tschoepel M, Jaeger KA. Physical training for intermittent claudication: a comparison of structured rehabilitation versus home-based training. *Vasc Med*. May; 2002 7(2):109–115. [PubMed: 12402991]
43. 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 and ageing*. Nov; 2005 34(6):614–619. [PubMed: 16267188]
44. 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 and ageing*. Mar; 2010 39(2):210–216. [PubMed: 20061508]
45. Resnick B, Jenkins LS. Testing the reliability and validity of the Self-Efficacy for Exercise scale. *Nursing research*. May-Jun; 2000 49(3):154–159. [PubMed: 10882320]
46. 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*. Aug; 1998 79(8):931–938. [PubMed: 9710165]
47. 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*. Mar; 2007 39(2):138–144. [PubMed: 17351696]
48. Dite W, Connor HJ, Curtis HC. Clinical identification of multiple fall risk early after unilateral transtibial amputation. *Arch Phys Med Rehabil*. Jan; 2007 88(1):109–114. [PubMed: 17207685]
49. Studenski S, Perera S, Patel K, et al. Gait speed and survival in older adults. *Jama*. Jan 5; 2011 305(1):50–58. [PubMed: 21205966]
50. 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*. Nov; 2002 83(11):1562–1565. [PubMed: 12422326]

51. 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.* Oct; 2001 82(10):1478–1483. [PubMed: 11588757]
52. Diedrich A, Munroe DJ, Romano M. Promoting physical activity for persons with diabetes. *The Diabetes educator.* Jan-Feb;2010 36(1):132–140. [PubMed: 20019197]
53. 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 education research.* Oct; 2010 25(5):724–736. [PubMed: 20338978]
54. Parker K, Kirby RL, Adderson J, Thompson K. Ambulation of people with lower-limb amputations: relationship between capacity and performance measures. *Arch Phys Med Rehabil.* Apr; 2010 91(4):543–549. [PubMed: 20382285]
55. Halsne EG, Waddingham MG, Hafner BJ. Long-term activity in and among persons with transfemoral amputation. *J Rehabil Res Dev.* 2013; 50(4):515–530. [PubMed: 23934872]
56. Berge JS, Czerniecki JM, Klute GK. Efficacy of shock-absorbing versus rigid pylons for impact reduction in transtibial amputees based on laboratory, field, and outcome metrics. *J Rehabil Res Dev.* Nov-Dec;2005 42(6):795–808. [PubMed: 16680617]
57. Stevens-Lapsley JE, Bade MJ, Shulman BC, Kohrt WM, Dayton MR. Minimally invasive total knee arthroplasty improves early knee strength but not functional performance: a randomized controlled trial. *J Arthroplasty.* Dec; 2012 27(10):1812–1819. e1812. [PubMed: 22459124]
58. Stevens-Lapsley JE, Balter JE, Wolfe P, Eckhoff DG, Kohrt WM. Early neuromuscular electrical stimulation to improve quadriceps muscle strength after total knee arthroplasty: a randomized controlled trial. *Phys Ther.* Feb; 2012 92(2):210–226. [PubMed: 22095207]
59. McDermott MM, Guralnik JM, Criqui MH, et al. Home-based walking exercise in peripheral artery disease: 12-month follow-up of the GOALS randomized trial. *Journal of the American Heart Association.* Jun.2014 3(3):e000711. [PubMed: 24850615]
60. Organization WH. WHO Global Report on Falls Prevention in Older Age. Geneva, Switzerland: World Health Organization; 2007.
61. Lin SJ, Winston KD, Mitchell J, Girlinghouse J, Crochet K. Physical activity, functional capacity, and step variability during walking in people with lower-limb amputation. *Gait Posture.* 2014; 40(1):140–144. [PubMed: 24731451]
62. Colberg SR, Sigal RJ, Fernhall B, et al. Exercise and type 2 diabetes: the American College of Sports Medicine and the American Diabetes Association: joint position statement executive summary. *Diabetes care.* Dec; 2010 33(12):2692–2696. [PubMed: 21115771]
63. Munin MC, Espejo-De Guzman MC, Boninger ML, Fitzgerald SG, Penrod LE, Singh J. Predictive factors for successful early prosthetic ambulation among lower-limb amputees. *J Rehabil Res Dev.* Jul-Aug;2001 38(4):379–384. [PubMed: 11563490]
64. Christiansen C, Fields T, Lev G, Stephenson RO, Stevens-Lapsley JE. Functional Outcomes After the Prosthetic Training Phase of Rehabilitation After Dysvascular Lower Extremity Amputation. *PM & R : the journal of injury, function, and rehabilitation.* May 12.2015
65. Raya MA, Gailey RS, Fiebert IM, Roach KE. Impairment variables predicting activity limitation in individuals with lower limb amputation. *Prosthetics and orthotics international.* Mar; 2010 34(1): 73–84. [PubMed: 20196689]
66. Deans SA, McFadyen AK, Rowe PJ. Physical activity and quality of life: A study of a lower-limb amputee population. *Prosthetics and orthotics international.* Jun; 2008 32(2):186–200. [PubMed: 18569887]
67. Gailey, RS., Clark, CR. Physical therapy management of adult lower limb amputees. In: Bowker, JH., Michael, JW., editors. *Atlas of limb prosthetics: surgical, prosthetic and rehabilitation principles.* St. Louis, Baltimore: Mosby Yearbook; 1992. p. 569-597.
68. Fortney JC, Pyne JM, Kimbrell TA, et al. Telemedicine-based collaborative care for posttraumatic stress disorder: a randomized clinical trial. *JAMA psychiatry.* Jan 1; 2015 72(1):58–67. [PubMed: 25409287]
69. Kirkizlar E, Serban N, Sisson JA, Swann JL, Barnes CS, Williams MD. Evaluation of telemedicine for screening of diabetic retinopathy in the Veterans Health Administration. *Ophthalmology.* Dec; 2013 120(12):2604–2610. [PubMed: 24084501]

70. Melnyk SD, Zullig LL, McCant F, et al. Telemedicine cardiovascular risk reduction in veterans. *American heart journal*. Apr; 2013 165(4):501–508. [PubMed: 23537965]

Figure 1.
Anticipated CONSORT Flow Diagram

Table 1**PABC Intervention Overview**

Technique	General Content of Weekly Visit*
Education	<ol style="list-style-type: none"> 1 Specific weekly educational message 2 Participant feedback on message 3 Therapist clarification as needed
Self-Monitoring	<ol style="list-style-type: none"> 1 Promote self-monitoring using FitBit 2 Self-monitoring goal creation
Tailored Feedback	<ol style="list-style-type: none"> 1 Direct feedback from FitBit application
Barrier Identification	<ol style="list-style-type: none"> 1 Participant input on barriers 2 Therapist assists identification 3 Falls & adverse events recorded
Promotion of Problem Solving	<ol style="list-style-type: none"> 1 Ideas for addressing barriers 2 Participant and therapist provide input
Action Planning	<ol style="list-style-type: none"> 1 Collaborative weekly action plan 2 Guideline: Increase 3% in weekly steps 3 Goals based on individual needs
Encouragement	<p>Therapist ends session by:</p> <ol style="list-style-type: none"> 1 Reviewing the “take home” message 2 Reviewing action plan for next week 3 Acknowledging achievements

Table 2

Data collection summary by visit.

Month of assessment	0	3	6
Informed Consent	X		
Feasibility (AIM 1)			
Participant retention	X	X	X
Dose Goal Attainment	X	X	X
Acceptability	X	X	X
Safety	X	X	X
Effect Size (AIM 2)			
Physical Activity Monitoring	X	X	X
Self-Report Disability LLFDI	X	X	X
Descriptive Measures			
Demographics	X		
Medications	X		
Cognition	X		
Depression	X		
Comorbidity	X		
Residual limb quality	X		
Sensory Testing	X		
Prosthesis Description	X		
Perceived social support	X	X	X
Exercise readiness to change	X	X	X
Self-efficacy	X	X	X
Self-report physical performance	X	X	X
Physical performance	X	X	X