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PRINCIPAL INVESTIGATOR: NOAH J. ROSENBLATT

CONTRACTING ORGANIZATION: ROSALIND FRANKLIN UNIVERSITY OF MEDICINE AND SCIENCE

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14. ABSTRACT The purpose of this project is to test whether a novel, multicomponent intervention that addresses both the physical and psychological factors underlying low balance confidence, can increase community participation in persons who use lower limb prostheses. To date we have recruited a total of 17 participants (including 2 who failed initial screening) that have been randomized to either a sham-control group (home-based seated exercises) or an intervention group, which includes eight on-site sessions with a physical therapist and psychologist. The primary study outcome of balance confidence, i.e., Activity Specific Balance Confidence(ABC)scale, as well as other measures of community participation are captured at baseline (week 0) and again at week 8 (post-intervention), week 16 and week 24. To date we have recruited 22 participants, of whom 19 have been randomized (10 intervention). Mixed model analysis indicates a significant group x time interaction on gait self-efficacy, but not ABC score.					
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Accomplishments	1-26
4. Impact	26
5. Changes/Problems	26
6. Products	27-28
7. Participants & Other Collaborating Organizations	28-30
8. Special Reporting Requirements	30
9. Appendices	31-100

1. INTRODUCTION

A majority of individuals with lower limb amputation report low balance confidence, i.e., overwhelming concern regarding their ability to maintain balance and prevent falls during activities of daily living. This is not trivial as low balance confidence predicts reduced community participation, independent of functional mobility; improvements in gait and balance do not necessarily manifest as improved confidence or reduced avoidance behavior. Despite its importance, no intervention that targets low balance confidence exists for users of lower limb prostheses. The purpose of this project is to test whether a novel, multicomponent, subject-specific intervention that simultaneously addresses both the physical and psychological factors underlying low balance confidence, can improve confidence and in turn increase community participation in persons who use lower limb prostheses. Specifically, the experimental intervention combines physical therapy (PT) exercises (in the form of virtual reality games that address balance and functional gait) with techniques from cognitive behavioral therapy (CBT; e.g., cognitive restructuring to alter maladaptive cognitions related to avoidance behaviors). In this proposed study we plan to conduct a randomized clinical trial on 60 total participants, in order to demonstrate feasibility and efficacy of the intervention. This represents the first step in a line of research, the long-term goal of which is to integrate this multicomponent intervention into acute care rehabilitation settings to maximize prosthetic use and community participation from the time of initial prosthesis prescription.

2. KEYWORDS

transtibial amputation, rehabilitation, active video gaming, community integration, cognitive behavioral therapy, fear of falling, self-efficacy, gait, balance, prosthesis

3. ACCOMPLISHMENTS

3.1. Major goals of the project

The major goals of the project and proposed timeline as stated on the SOW include:

1. Developing Training Material (month 1-2)
 - a. finalizing PT and CBT exercise
 - b. run protocol with sample subject
2. Train clinicians to administer the intervention (month 1-2)
3. Baseline assessments for all participants (months 2-27)
 - a. obtain local IRB and HRPO approval
 - b. recruit and screen participants
 - c. perform baseline assessments (Berg Balance Test, L-Test of walking, ABC scale and outcome surveys)
 - d. monitor activity for 1 week
4. Administer interventions (months 2-28)
 - a. complete eight 1.5-hour intervention session (intervention group only)
 - b. repeat baseline assessments and activity monitoring after 8 weeks
5. Collection of outcomes measures in the community (months 2-30)
 - a. repeat baseline assessments at 8 weeks following completion of control or experimental intervention
 - b. repeat baseline assessments at 16 weeks following completion of control or experimental intervention
6. Data Analysis (month 30-36)
7. Identify opportunities to improve intervention (months 6-36)
 - a. conduct key informant interviews
 - b. generate initial and final coding lists
 - c. teach coding structure to graduate student
 - d. analyze final coding list

3.2 Activities accomplished under the major goals Pages 3-25 contain a working draft of a manuscript (discussion to be written), expected to be submitted for publication by April 1, 2023. The work summarizes the overall findings from the project, thus addressing all activities accomplished under the major goals. Publication information will be shared with scientific and grant officers after project closure.

INTRODUCTION

Low balance confidence, defined as low self-perception in ones' ability to maintain balance while performing specific activities, is a prevalent yet overlooked issue among lower limb prostheses users (LLPUs) that can significantly affect community participation [1] and quality of life. In a cohort of 435 community-dwelling individuals who had been living with lower limb amputation for at least six months, 65% reported levels of balance confidence below the threshold at which intervention is advocated for able-bodied adults [2, 3]. In the same cohort, low balance confidence was a significant predictor of participation in social activities, even after accounting for mobility capability and other prosthesis-related characteristics [4], which is critical as low social participation significantly limits quality of life [5, 6]. Low balance confidence is also a strong predictor of whether a LLPU can attain a level of walking consistent with a community-ambulator [7], and may be a precursor to increased disability. People may avoid engaging in activities in which they lack confidence, and activity avoidance can promote a more sedentary lifestyle and associated adverse health outcomes through disuse syndrome [8]. Indeed, A review on intact older adults suggested that "Interventions to maintain appropriate levels of balance confidence must...be viewed as preventative...on the pathway leading to disability" [9]. Nonetheless, "balance confidence is not directly addressed during prosthetic rehabilitation." [10]

Although it is logical to assume that low balance confidence manifests as a result of poor functional abilities, the former need not depend on the latter. In part this reflects the fact that balance confidence is a measure of self-efficacy and therefore depends on one's beliefs in their abilities to engage in activities, which need not reflect their true abilities. Indeed, in LLPUs, measure of balance confidence and performance-based measures of balance are only moderately correlated [11]. Similarly, following discharge from rehabilitation, persons with a lower limb amputation continue to improve walking ability, while balance confidence does not continue to improve, suggesting the two may be independent [10]. Even in intact older adult, incongruence between perceived and actual abilities is common. One-third of community-dwelling older adults report balance confidence that either over- or under-estimates their physiological fall risk [12] .

Interventions targeting low balance confidence, and associated limitations in community participation and activity, may require approaches that simultaneously address both the physical and

behavioral underpinnings of the low confidence. A review of 8 studies that included balance confidence as a primary intervention outcome in older adults, reported that there was more robust evidence of benefits from multifactorial interventions, i.e., those which included a physical and behavioral component, compared to a single component [9]. A more recent review specifically evaluated interventions that included a cognitive behavioral therapy (CBT)-based psychotherapeutic strategy in conjunction with prescribed exercise/rehabilitation, although the outcomes of interest was fear of falling, (a construct closely associated with balance confidence and often quantified using both balance and falls self-efficacy scales). The authors reported significant immediate effects of these multicomponent interventions on fear of falling in intact older adults, with a combined standard mean difference of 0.28 in favor of the interventions [13]. Two of the included studies considered balance confidence, specifically the Activities-specific Balance Confidence (ABC) scale, as the primary outcome to quantify fear of falling. One reported a strong significant effect of the multicomponent intervention compared to exercise alone, at least in those with low baseline ABC scores [14]. However, the other one reported no greater improvements in ABC scale between a control group (strength and balance only) and those in the multicomponent intervention [15]. Thus, the evidence to support the efficacy of multicomponent interventions (CBT in conjunction with exercise) for improving balance confidence, at least in older adults, is not completely clear. Still, even if adding CBT to an exercise program does not enhance the effects of the intervention on measures of self-efficacy, the inclusion of CBT components has the potential to impact other related constructs. For example, Liu et al reported that Thai Chi both with and without CBT had a similar effect of on fear of falling but that self-reported well-being improved to a greater extent in those receiving the CBT component [16].

Despite the potential for multicomponent interventions to target balance confidence and activity in LLPUs, such interventions have received limited attention in this population. We previously reported on a protocol to targets balance confidence to increases community integration in LLPU [17]. The intervention consisted of eight sessions that integrated physical therapy (PT) exercises, primarily virtual reality (VR) active gaming, with CBT strategies that increase balance confidence by addressing subject-specific avoidance behaviors and maladaptive cognitions (published protocol can be found in Appendix K). We demonstrated initial feasibility by testing the intervention (termed CBPT intervention for cognitive

behavioral and physical therapy intervention) on a case subjects in whom balance confidence, as assessed by the ABC scale, more than doubled from the start of the intervention to a one-month follow-up [18] (published manuscript is included as Appendix L). The purpose of this study was to conduct a randomized controlled trial to evaluate the effects of the same intervention on balance confidence as well as on balance, functional mobility, community participation and quality of life. We hypothesized the following: H1: LLPUs receiving CBPT would demonstrate improvements in balance confidence compared to those in a sham control group; H2: LLPUs receiving CBPT would demonstrate improvements in community participation over time compared to those in a sham control group; H3: LLPUs receiving CBPT would demonstrate improvements in quality of life over time compared to those in a sham control group. H4: LLPUs receiving CBPT would demonstrate improvements balance and functional mobility compared to those in a sham control group. In addition to testing the initial effectiveness of the CBPT intervention we were interested in identifying residual barriers to social activity and mobility that exist despite the CBPT protocol, as well as the CBPT strategies that were deemed most effective and additional strategies to address social activity and mobility barriers (e.g., behavioral activation, different PT strategies).

METHODS

Participants

Participants were recruited using several different methods. First, local amputee support groups and veteran groups (e.g. local Veterans of Foreign War posts) were sent information about the study and study team members visited groups to provide short recruitment presentations. Participants that contacted investigators were encouraged to share study information with their peers. Study sites also contacted individuals with unilateral transtibial amputation that were included in existing subject data bases. Finally, after receiving proper approvals, we searched medical records from four regional VA facilities for persons having a unilateral transtibial amputation and prescribed prosthesis at least 6 months prior. We sent these individuals a form letter indicating that they may qualify for a study and included initial screening material (ABC scale and balance-concern question mentioned below) that was to be returned if they were interested in receiving additional information. We then followed up with those

individuals whose screeners met our inclusion criteria. Inclusion criteria were: >18 years of age, unilateral transtibial amputation, at least 6 months experience with using a prosthetic device, ABC score ≤ 80 (low balance confidence), affirmative response to: “Do you have balance concerns that prevent you from engaging in activities that you would otherwise like to do”. Subjects were excluded for: neurodegenerative diseases, currently being in physical therapy for any reason, and inability to independently stand for 2 minutes (occasional light touch of an assistive walker was permitted). For all other participants these screening criteria were addressed during initial phone contact. The last criteria ensured that the participant would be able to perform the PT exercises without an assistive device, which would interfere with the equipment being used.

Study Protocol

Screening and baseline assessments

After providing informed consent for this IRB-approved study, a certified prosthetist (CP) evaluated the LLPU to ensure a proper prosthetic fit and functioning of components and to ensure a healthy residual limb. The CP recorded information about the individuals prosthetic history and current componentry (Table 1). A study physician then performed a basic physical screening that to ensure that it would be safe for the participant to engage in low-to-moderate levels of exercise as dictated by the study protocol. A mini mental status exam (MMSE) was then performed to ensure a score of at least 25 (out of 30). It was not always possible to coordinate participant availability with that of both the study CP and the study physician. In the case where only one screener could attend the session, a sign-off form was sent to the participants CP or physician. In the event that the form was not returned in a timely manner attempts were made to facilitate an onsite screening session with the outstanding clinician. In one case this process led to a recruited participant receiving sign off from one clinician but never being randomized to a group due to loss to follow-up (i.e., inability to complete screening process; see Figure 1).

After passing screening all participants completed a written version of the ABC scale., the main outcome for the study. The scale has individuals rate their level of confidence (0-100%) in completing 16 complex functional tasks without losing balance [19], and the average of all items is reported. The ABC scale has strong reliability (ICC=0.91), internal consistency (Cronbach α =0.95), and good construct validity [20].

The scale was immediately scored and, as in the initial phone screening, participants needed to score ≤ 80 to be further included in the study. One participant who passed phone and clinical screening reported ABC scores outside of this range (Figure 1).

While the ABC scale is intended to quantify balance self-efficacy across a variety of tasks, in light of the focus of many of the physical therapy exercises on gait, participants also completed the modified Gait Self Efficacy (mGES) scale as an exploratory measure that was outside of the initially proposed work. The scale, which was previously modified from the original version to remove items that do not relate to daily walking (e.g., escalators), includes ten items that ask individuals to rate their confidence in their ability to safely complete a task (e.g., walk on uneven surfaces or walk up stairs) [21]. Items are rated from 0-10 and the total score is taken, with higher scores indicating greater gait self-efficacy. The scale has good psychometric properties [21-23]. A second exploratory measure, the Fear of Falling Avoidance Behavior Questionnaire (FFABQ), was also collected. The FFABQ was developed to streamline the quantification of fear avoidance in older adults, which is a downstream outcome of low balance confidence that is directly relevant to the larger goal of the CBPT intervention - to increase community participation. The scale uses a 5-anchor rating to evaluate the extent of agreement with the statement: "Due to my fear of falling I avoid (activity)..." [24]. The scale includes 14 items, each worded to be consistent with The World Health Organization's International Classification of Functioning and Health model of activity limitation and participation restriction [25]. Sample items in the final FFABQ include: stair ambulation; walking on uneven surface; walking in dimly lit unfamiliar places; and recreational and leisure activities (e.g. plays, sports). The psychometric properties in older adults with a variety of balance impairment are good-to-excellent [24]. Total scores range from 0 to 56 with higher score indicating greater avoidance.

In addition to assessing balance self-efficacy, two self-reported measures, The Short-Form Health Survey (SF36) and Frenchay Activity Index (FAI), were completed at baseline and included as primary outcomes to measure community participation. The SF36 consists of 36 questions that measure eight dimensions of health-related quality of life. The dimensions of role limitation due to physical health problems, social functioning and role limitation due to emotional problems have been recommended for quantifying community participation [26]. Only these subscales were analyzed. The FAI is a behavioral

scale that primarily measures social participation, as well as daily activities. It includes 15 items spanning three dimensions - domestic/chores, work/leisure and outdoor activities. Frequency of participation in activities over the last 3-6 months is rated on a four-point scale, with items summed to provide a total score of 15-60 (higher scores indicate greater participation). For the purposes of this study we modified the scale to address periods of two months (the intended time period between assessments). The FAI is a valid and reliable measure among LLPU (ICC=0.79) [27].

In addition to completing assessments related to the main and primary outcomes of self-efficacy and community participation, during the baseline visit participants also completed measures to assess the secondary outcomes of quality of life and of functional mobility. For the former we used the Well-being scale of the Prosthetic Evaluation Scale (PEQ). The PEQ was developed to quantify function and prosthesis-related quality of life for persons with lower limb amputation. This Well-being scale (WB-PEQ) has good consistency (Cronbach α = 0.83) and reliability (ICC=0.89) [28]. It includes only two scored items that ask participants to rate their satisfaction and their quality of life over the last four weeks using a 10 cm visual analog scale. Although it is a simplified assessment of quality of life, it allows participants to easily provide a summary of experiences by considering the construct as unidimensional. Each item is scored from 0-100 (based on millimeters along the scale) and the average is taken, with high numbers indicating greater well-being.

After completing surveys, participants performed the Berg Balance Scale (BBS) and the L-test of walking to measure aspects of functional mobility expected to be impacted by the physical therapy exercises. The BBS requires participants to complete 14 tasks of increasing difficulty beginning with sit-to-stand and progressing to unipedal stance. It is a well-established outcome measure initially designed to assess balance in older adults [29] and has been validated for persons with lower limb amputation [11]. For the L-test of walking, participants rise from a chair without armrests, walk 3m, turn right, walk 7m, turn around and trace their path back to the start. The time to complete the task is recorded. The test has strong reliability (ICC=0.98) and validity ($r=0.93$ for timed-up-and-go) [30]. We choose the L-test because it is better than timed-up-and-go at distinguishing changes in walking ability of fit, younger LLPU [10]. Functional tests were performed by an investigator blinded to the study purpose or participant grouping (for post-intervention assessments).

After completing self-reported and performance-based baseline assessments, participants were fitted with an activity monitor (Step Watch 4; Modus Health LLC: Seattle WA) that recorded steps counts and reported on cumulative counts in 10 s bins. The monitor was to be worn on the pylon of the prosthesis (attached via Velcro straps) for one week during which time it was unnecessary to charge the monitor. A GPS receiver (Qstarz BT-Q11000XT) was also attached to the pylon and was set to record position data every 10 s. Participants were informed that the monitors provided information about the activities they were performing and where they were being performed, and that we were specifically interested in quantifying the extent of activity performed outside of the home and not the specific locations visited. Participants were instructed in how to turn the GPS monitor on and off, if desired, and that the monitors required daily charging. Monitors were returned to the study members at the first treatment session, which was intended to occur 1-2 weeks after baseline assessments.

During the week of monitoring following the baseline laboratory screening visit, a study team member contacted the participant to administer the Community Reintegration of Servicemembers (CRIS). The CRIS includes three subscales to address the nine chapters of the International Classification of Functioning and Disability Health that dealing with activity and participation [31]. We considered the Extent of Participation scale and the Perceived Limitation scales, as these have been recommended for evaluating community participation. The former asks individuals to rate on a 7-point frequency scale how often they engage in certain activities – e.g. “In the past two weeks on average, how often did you engage in recreational activities, not including watching TV?”. The latter uses a 7-point agreement scale to evaluate self-perceived limitations in participation-e.g., “I avoided going to crowded places such as the mall or community gatherings”. While there is some overlap of scales from CRIS and the SF-36, the items addressed in the SF36 are broader. The CRIS was administered over the phone due to its length and the fact that it was initially designed to be conducted through interview.

Randomization

Prior to the start of the study a randomization plan was created by a study team member that did not interact with participants. Block randomization was used with block size of N=4 stratified by cause of amputation (dysvascular vs all other causes). The investigator placed group assignments in sealed

envelopes which were opened by a member of the study team following baseline screening and prior to treatment visit 1. The logistics of the study necessitate that the group assignment be disclosed to study team members prior to the first treatment visit in order to coordinate the participants schedule with that of the study team members that needed to be present for the session. For participants assigned to the control group (at home exercise treatment arm) the study physical therapist needed to be present, whereas the physical therapist and behavioral counselor were needed for all sessions in the intervention group (CBPT/intervention treatment) . The group assignment was not disclosed to the study participant until they arrived at the laboratory for the first session. In the event that participants failed to attend their first session, even after repeated rescheduling, the randomization plan did not include replacement of the group allocation; the plan continued as if the group assignment was disclosed to the participant in order to avoid any future bias by study team members during recruitment and screening.

Control group (at-home exercise treatment)

Specific details regarding the control and intervention have been previously reported [17]. Here we briefly review the major components of each. During the first treatment visit, participants assigned to the control condition were provided a manual that described a series of seated exercises and the schedule for performing the exercises. We intentionally chose seated exercise to minimize any impact on gait and balance. The exercises were adapted from online sources available through the National Institute of Aging and the Center for Disease Control and were to be performed a minimum of 3 times per week for a total of 8 weeks although different exercises were introduced or dropped throughout the 8 weeks. The physical therapist demonstrated all exercises to the participant and adapted them to the participant as needed. The last page of the manual included a worksheet for participants to mark of the days that they performed exercises. Participants were contacted by phone every 2-3 weeks during the 8-week intervention period to maintain engagement.

Intervention group

The intervention was designed to consist of eight, 90-105 minute, weekly sessions that integrated CBT and PT components. Each session began with a brief initial interaction between the CBT

practitioner and participant to check in and review weekly home assignments (sessions 2-8). Key components of the homework assignments (and other session activities) are outlined in Table 2, with one of the most important elements being completion of a structured behavioral recording form (see supplementary information in [17]). The check in was followed by a 45-60 minute session of virtual reality (VR) gaming using the C-Mill balance suite (Hocmoa, Switzerland). Six games targeting the domains of balance (postural responses to self-induced destabilizations or shifts in the center of mass) and gait adaptability (the ability to adjust gait to unpredictable environments) were included in training. A detailed description of the VR exergames can be found elsewhere [17]. During the gaming session the participant wore an overhead harness to prevent a fall to the treadmill surface and the session was designed to consist of eight, 5-minute gaming blocks. The progression of gaming between blocks was guided by a preset progression that was modified based on session-to-session fluctuations in the participants energy, mood and pain. In addition after each block participants reported on their “current level of distress” on a scale of 0 (“no distress”) to 100 (“extreme distress”), as well as their level of stability (assuming the harness was not present) on a scale of 1 (“completely stable as if you were standing or sitting undisturbed on solid ground”) to 10 (“about to fall – extremely challenging, have to stop and/or grab supports to keep balance”) and responses guided the physical therapists choice to progress gaming; too little distress or instability suggested a need to increase the level of difficulty and too much indicated a need to reduce the level. The CBT clinician was present thought out the gaming to facilitate integration of PT and CBT techniques. For example, having the CBT clinician present during the gaming allowed them to encourage learned relaxation techniques if signs of stress were identified.

Following the gaming portion of the intervention (for session 2-8 only) the participant completed a short exposure therapy procedure. Based on review of behavioral data from homework assignments, the physical therapist and behavioral counselor structured a low-level exposure exercise to approximate a task involved in an avoided community activity (or involved in an activity that was completed, but with significant anxiety) that was also congruent with the participants functional abilities. For example, one participant who avoided hunting due to concerns related to walking on uneven terrain was exposed to walking on the uneven grassy surfaces surrounding the university (while wearing a gait belt for safety). A second participant, who described avoiding activities due to concerns related to an inability to rise from

the floor in the event of a fall, was tasked with practicing that task (starting first with getting up from a kneeling position using a nearby chair and progressing to rising from a laying position with no objects nearby). Throughout the exposure exercise the participant reported on distress using the same scale as during gaming. The goal was to observe a reduction in distress with continued exposure, in response to which the extent of exposure would progress. Throughout the exercise the CBT clinician reinforced the connection between the specific exposure exercise and the avoided activity. At the end of each session, the CBT clinician and physical therapist discussed their emerging understanding of the participant's fear hierarchy relating to prosthetic use of and their progress in physical training in order to identify a progression of the existing exposure exercises or to better identify a better exercise for future sessions. Following the exposure therapy the CBT clinician further reviewed homework assignments, taught new or reinforced previously learned coping skills (e.g., relaxation strategies) and discussed upcoming assignments.

Follow up assessments

Following completion of the treatment (CBPT intervention or at-home exercise), participants were asked to return to the laboratory to repeat all baseline (pre-treatment assessment) assessment and to receive activity and GPS monitors, which were to be returned one week later using a prepaid envelope (post-treatment assessment). During the week of monitor wear a researcher called participants to complete the CRIS. Participants who completed the CBPT intervention also took part in a semi-structured interview to address their experience with the intervention (likes, dislikes, feedback on assignments, etc.) and to understand what barriers to community participation were not addressed by the intervention. Eight and 16 following post-treatment assessment, participants were mailed a set of all self-reported outcome measures, monitors and a self-paid envelope to return the surveys and monitors after one-week of use. Again, during the week of wear time a researcher called participants to review the CRIS. Although our primary interest was on the immediate effects of the innervation (pre- vs post-treatment), the last two time points were added to better capture the full extent to which training-induced changes in behavior were incorporated into daily living. Moreover, given that most studies that have evaluated the effect of multicomponent interventions on balance and falls-self efficacy report only on the

immediate effects of the training [13], at least in older adults, we thought it was important to capture and report on this data.

Analysis Plan

To test H1-3 we planned to perform a mixed model with group as the between-subject factor, with time (4 samples) as the within subject factor, and with random factor subject-specific slope and intercept terms. A significant time x group interaction would demonstrate support of the hypotheses. For H4 only 2 data points were collected (pre- and post-treatment). Therefore, we planned to conduct a two-way repeated measures ANOVA with a significant interaction again supporting our hypothesis.

To test H1, scores from the ABC scale were entered into the statistical model. For H2 scores from self-reported primary outcomes were entered into models as was data derived from the GPS and activity monitors. In particular, to determine the location of activity data from the two monitors, the data was time synced and custom algorithms were then used to determine if activity was performed inside or outside of the home [32]. From this we extracted the following for each day of data collection: number of steps taken outside the home and total time spent outside the home. However, because it was not always possible to identify location from GPS data, e.g., due to signal drop or uncertainty as to whether the location was inside or outside of the home due to proximity to the home location, we calculated these variables based on the number of hours-of-GPS-data-with-known-location, and then scaled this to a 24-hour period. Finally, we averaged these across collection days to obtain two metrics of community participation: steps per day taken outside the home and hours per day spent outside the home. To test H3, scores from WB-PEQ were entered into the statistical model; for H4, BBS score and L-test time. were entered

With regard to goal of identifying residual barriers to social activity and mobility and CBPT strategies that were effective or that should be added, a standard approach was used to identify themes in key informant interviews. Specifically, interviews transcripts were reviewed by a study investigator to develop an initial codebook. Two coders reviewed the codebook with the investigator prior to coding transcripts. One transcript was coded independently by the investigator and coders, who then met to review the transcripts and resolve discrepancies. Changes to the codebook were made. This process

occurred two more times; the coders then independently coded the remaining transcripts and reviewed their coding with the investigator to resolve discrepancies. From the coding structure themes were identified.

RESULTS

Sample size and final analysis plan

A priori, we expected to recruit 60 eligible participants (30 intervention and 30 control participants) and used G*Power 3.1 to conduct a sensitivity analysis (with regard to Hypothesis 1), specifying a power of .80, an alpha of .05, and an average correlation of observations of 0.50. According to the analysis, with 30 participants in each group we would be able to detect a small to medium effect ($f = .152$) of intervention on ABC score over time, which is consistent with the size of effect observed for older adults [9, 33]. However, restrictions due to COVID-19 presented significant recruitment challenges, and as a result of these challenges and other resource limitations, we recruited 22 participants (See Figure 1), of which 19 were randomized (two failed screening and one was withdrawn for medical reasons; Figure 1). As a result, the final analysis differs from that which was planned.

It is well established that detection of a significant interaction requires considerably larger sample size than is needed to detect a main effect. Indeed, “the sample size needed to detect a 2×2 interaction in a mixed-effects linear regression model is fourfold that to detect a main effect of the same magnitude.” [34]. Therefore, rather than directly testing for an interaction in a single model that included all time points, we limited analysis to evaluate several simple effects that, collectively we would interpret as evidence of an interaction. Specifically, we first considered only pre- and post-treatment data, as this included the largest number of samples, and conducted 2 (group) $\times$ 2 (time) repeated measures ANOVAs with outcomes from H1, 2 and 3 as the dependent variables. Support of our hypotheses would be demonstrated if all of the following criteria were met based on post-hoc analyses using LSD corrections: 1) no significant differences between groups at baseline; 2) no significant pre- vs. post-treatment improvement for the control group; and 3) a significant pre- vs post-treatment improvement (baseline for the intervention group. In the event that groups differed at baseline, e.g. the intervention group scored significantly lower, then criteria 1 would be altered to “no significant differences between

groups post-intervention”; higher baseline scores in the intervention group would not allow for the type of analysis suggested.

For those variables that demonstrated a pre- vs post-treatment effect of the CBPT intervention, we tested whether the effect persisted at the final time point by repeating the analysis on the post-treatment data and the final time point data, focusing on the post-hoc comparison between time points for the intervention group only. No significant difference in an outcome for the intervention group would provide support of a longer-term effect of the intervention on that outcome measure.

For most measures there was a total of 9 intervention and 4 control group participants who had data pre- and post-treatment data. Of those with post-treatment data, six CBPT participants and three control group participants also had data at 16 weeks following the post-treatment assessment. For the PEQ-WB scale only, baseline data was missing for one CBPT participant. For one intervention subject who completed 7 sessions and then suffered a stroke, we carried forward data that was collected after session 4 (as part of an exploratory analysis we collected self-reported data for intervention subjects only at week 4) for his post-treatment data. As the CRIS was not collected after session 4, this participant is not included in the CRIS analysis (which includes 8 intervention group subjects). The CRIS data sets also include data from one control participant who failed to complete his post-treatment assessments at the laboratory but was contacted for the CRIS and excludes data from a separate control group participant who completed post-treatment assessments but was unable to be contacted for the CRIS (for a total of 4 control participants). For functional mobility data, which required a post-treatment visit to the laboratory, data is available for six intervention participants and three control group participants (two CBT participants that scored 56/56 on BBS at baseline were not tested post-treatment and one control group participant agreed to continue surveys but did not want to return to the lab for testing). Finally, due to numerous technical difficulties with GPS data, e.g. incorrect time stamps or participant failure to wear the monitors, data is analyzed for only 6 CBPT participants and 2 control group participants.

Deviations from designed intervention

While the intervention was designed to include eight sessions spanning eight weeks, in practice a number of unexpected challenges regarding scheduling resulted in alterations to this scheduling. For

example, one participant who was enrolled during the summer had a month-long scheduled vacation with her children and it was decided that we would complete her intervention after 6 sessions rather than 8 sessions in order to avoid a one-month delay. In another case a participant had ongoing challenges in managing blood pressure with his medication, which often resulted in several weeks delay between sessions. On average, participation in the CBPT intervention lasted 13.4 ± 5.1 , with an average of 7.4 ± 0.9 sessions per participant.

Another deviation from anticipated protocol related to the number of games played within a session. Whereas the study was designed to include 8 blocks of gaming per session, many participants required considerably longer rest periods than anticipated. In addition, the check-in period (prior to the gaming) often lasted longer than anticipated, despite concerted efforts to minimize its length, requiring that the gaming session be shortened to ensure that the total session length aligned with clinicians time constraints. On average participants engaged in 3.9 ± 0.5 gaming blocks per session.

Effect of intervention on outcomes of interest

Main Outcome – Balance Confidence (H1)

Although, on average, there was a 12.1% increase in balance confidence scores in the control group following the at-home exercise program (equivalent to a 6.4-point increase), the change in the intervention group was nearly double - 23.0% (13.0 points). Overall, statical results point to an effect of the intervention (Figure 2). In particular, whereas there was no difference between groups at baseline (61.4 ± 13.6 control vs. 61.2 ± 11.8 intervention; $p=0.974$), there was a significant pre-post treatment increase in ABC scale for the intervention group (61.2 ± 11.8 baseline vs. 74.2 ± 16.5 post intervention; $p=0.018$) but not for the control group (61.4 ± 13.6 baseline vs. 67.8 ± 13.2 ; $p=0.318$). The effects of the intervention on balance confidence persisted with time. Among the participants in the intervention group with ABC scores both post-treatment and at 16 weeks later, there was no significant change in ABC score between time points (74.2 ± 16.5 post intervention vs 67.8 ± 27.0 16 weeks later; $p=0.140$).

Primary Outcome – Community Participation (H2)

Among the eight measures used to assess community participation (2 subscales from the CRIS, 3 subscales from the SF36, FAI and 2 measures derived from the monitor data), two - the CRIS Extent of participation scale and the SF-36 role limitations due to physical health scale - met the criteria to suggest an intervention effect. Following the intervention the CRIS - Extent of participation scale increased by an average of 3.55 points, which represents 5% of the entire scale range. Overall, whereas CRIS – Extent of Participation was not different between groups at baseline (53.2 ± 3.2 control vs. 53.2 ± 5.6 intervention; $p=0.874$), there was a significant pre-post increase in the scale for the intervention group (53.2 ± 5.6 baseline vs. 56.8 ± 4.2 post intervention; $p=0.034$) but not for the control group (53.2 ± 3.2 baseline vs. 50.2 ± 6.6 ; $p=0.161$) (Figure 2). With regard to the SF-36 role limitation due to physical health, participants in the intervention group had significantly lower scores than those in the control group at baseline (62.5 ± 43.3 for control group at baseline vs 13.9 ± 28.3 for intervention group, $p=0.032$). However, at post-treatment the between-group difference was no longer significant (31.25 ± 37.5 for control vs 63.9 ± 43.5 for intervention group, $p=0.222$) and the improvements in the score for the control group were significant ($p=0.023$) (Figure 2).

There was no effect of intervention on CRIS Limitation subscale (54.7 ± 5.4 vs 57.6 ± 7.9 pre- vs. post treatment for intervention group, $p=0.072$), SF-36 social functioning (68.1 ± 25.9 vs 80.6 ± 15.5 ; $p=0.691$), SF-36 role limitation due to emotional problems (70.4 ± 45.5 vs 81.5 ± 29.4 ; $p=0.771$); FAI (29.2 ± 10.9 vs 28.8 ± 10.6 ; $p=0.800$), hours per day out of home (8.8 ± 5.7 hours vs 6.0 ± 6.2 hours; $p=0.291$), or in steps per day outside of the home (3566.1 ± 32549.4 steps vs 2066.5 ± 2057.4 steps; $p=0.311$).

Secondary Outcome – Quality of Life (H3), Balance (H4) and functional mobility (H4)

None of the secondary outcomes demonstrated significant improvements with the CBPT intervention – PEQ-WB (58.3 ± 28.0 vs 70.5 ± 19.1 , pre- vs. post treatment for intervention group; $p=0.672$), BBS (45.3 ± 11.9 vs 48.0 ± 8.3 ; $p=0.314$), L-test (45.5 ± 30.4 s vs 41.9 ± 27.0 s; $p=$

Additional Outcomes – Gait Self-efficacy and fear-of-falling avoidance behavior

In addition to the main, primary, and secondary outcomes that were proposed, we also explored the effects of CBPT on gait-self efficacy (mGES) and on fear-of-falling avoidance behavior, intervention effects observed in the former but not the latter. On average, the mGES scores increased by 32% with the CBPT intervention. Whereas mGES scores were not different between groups at baseline (64.0 ± 20.5 for control group at baseline vs 59.2 ± 15.8 for control group, $p=0.653$), there was a significant pre-post improvement in scores for the intervention group (59.2 ± 15.8 at baseline vs. 75.9 ± 14.4 post-treatment, $p=0.004$) and there was no significant pre-post change in mGES scores for the control group ($p=0.887$). CBPT-induced changes in mGES persisted after 16 weeks ($p=0.180$ for post-treatment mGES. Vs mGES 16 weeks later for the intervention group). Changes in FFABQ scores mirrored those of the mGES but failed to reach significance. FFABQ scores were not significantly different between groups at baseline ($p=0.786$), with a pre-post reduction in the CBPT of, on average, 8.8 ± 14.8 points on the 56-point scale ($p=0.063$) and with smaller, non-significant reductions in the control group (reduction of 3.3 ± 3.2 points, $p=0.620$).

Exit interviews to identify opportunities to improve intervention efficacy.

Of those assigned to the intervention, 7 participants completed key informant interviews. Analysis of themes is ongoing and we anticipate completion in the upcoming months with a manuscript submission by Spring 2023. Here we present preliminary results. Participant benefits from the intervention were highlighted in several key themes. Psychological strategies that were identified most commonly by participants included: 1) learning the connection between their thinking and movement; and 2) stress reduction breathing techniques. Physical therapy benefits that were identified most commonly by participants included: 1) Learning new exercises; and 2) treadmill games to work on balance and movement.

Key themes were identified that provide insight into intervention modifications that might improve intervention efficacy, acceptance, and completion, and could be incorporated into a future study. Participants desired improvements in some of the homework forms to improve usability and comprehension and in the treadmill game to reduce technical difficulties. Participants also suggested increasing the amount of sessions to enable greater time for achieving goals and to address challenges

beyond avoidance and fear of falling. However some participants desired differences in the frequency of visits (multiple visits per week vs one visit per week) and noted challenges in attending in person sessions. Telehealth could be useful for increasing session amount while minimizing participant burden.

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Table 1. Characteristics for recruited participants (those that provided informed consent to participate)

GROUP	AGE	SEX	BMI (kg/m ²)	RACE	VETERAN	CAUSE OF AMPUTATION; YRS SINCE AMPUTATION	ASSISTIVE DEVICE; # OF FALLS	PROSTHETIC SET-UP (SOCKET COMFORT SCORE - SCS)	RELEVANT MEDICAL HISTORY
C	75	M	29.02	--	Y	Synovial sarcoma; 11.1 yrs	N; 0 falls	Bionx, empower foot; total contact socket; vacuum suspension with harmony; (SCS=9)	vertigo; severe stenosis; contralateral knee OA
I	72	M	25.25	W	Y	Trauma; 28.1 yrs	N; 0 falls	Flexfoot; total contact w/polyethylene inner socket; mechanical pump (vacuum) with gel suspension sleeve (SCS=10)	type II diabetes; ipsilateral hip replaced
C	54	M	30.12	H	Y	Infection; 1.2 yrs	N; 3 falls	Alpha silicone liner; suspension sleeve (SCS=9)	ipsilateral meniscal tear
I	77	M	31.49	W	N	Diabetes; 2.8 yrs	Y; 1 fall	RUSH foot; TSB socket with suction vacuum (SCS=10)	diabetes; contralateral partial foot amputation and prosthesis
C	60	M	28.48	W	N	septic shock; 1.3 yrs	Y; 2 falls	Dynamic Response foot, TSB socket with pink lock suspension; 1 ply sock with silver sheath inner against skin (SCS=9)	contralateral trans metatarsal amputation
I	65	M	24.03	W	N	bacterial infection; 2.5 yrs	Y; 0 falls	College Park foot multiaxial; total contact socket; flexible plastic inner medium plus gel liner; sleeve suspension; 6 mm sock (SCS=8)	lower lumbar spinal fusion failed due to fall; knee replacements on both sides
I	52	F	25.06	W	N	Trauma; 6.2 yrs	Y; 0 falls	dynamic response foot; currently in temporary socket; suction seal in suspension (iceross seal-in); light weight soft sock (SCS=4)	phantom pain very often
I	42	F	19.26	W	N	Trauma; 15.5 yrs	N; 1 fall	Elation foot; Ossur gel liner; pin suspension (SCS=7)	reported 2mm aneurysm and former TBI; vertigo; daily phantom pain
DNQ	56	M	34.99	W	Y	Trauma; 3.0 yrs	N; 0 falls	Dynamic Response Renegade AT foot; 38 alpha duo liner w/ fabric overlay (socket not noted) (SCS=9)	nothing noted
C	51	M	29.45	W	N	osteomyelitis/MR SA; 5.8 yrs	N; 2 falls	Ossur running leg for daily use; TSB socket; sleeve suspension with expulsion valve on socket (SCS=8)	nothing noted
C	67	F	27.46	W	N	Congenital; 54.8 yrs	N; 0 falls	total contact socket with gel liner; pin lock suspension; 5 ply socks with and distal cup (SCS=9)	fell and broke right femur several years ago; vertigo; daily lower back pain (L3-5 discs trimmed)

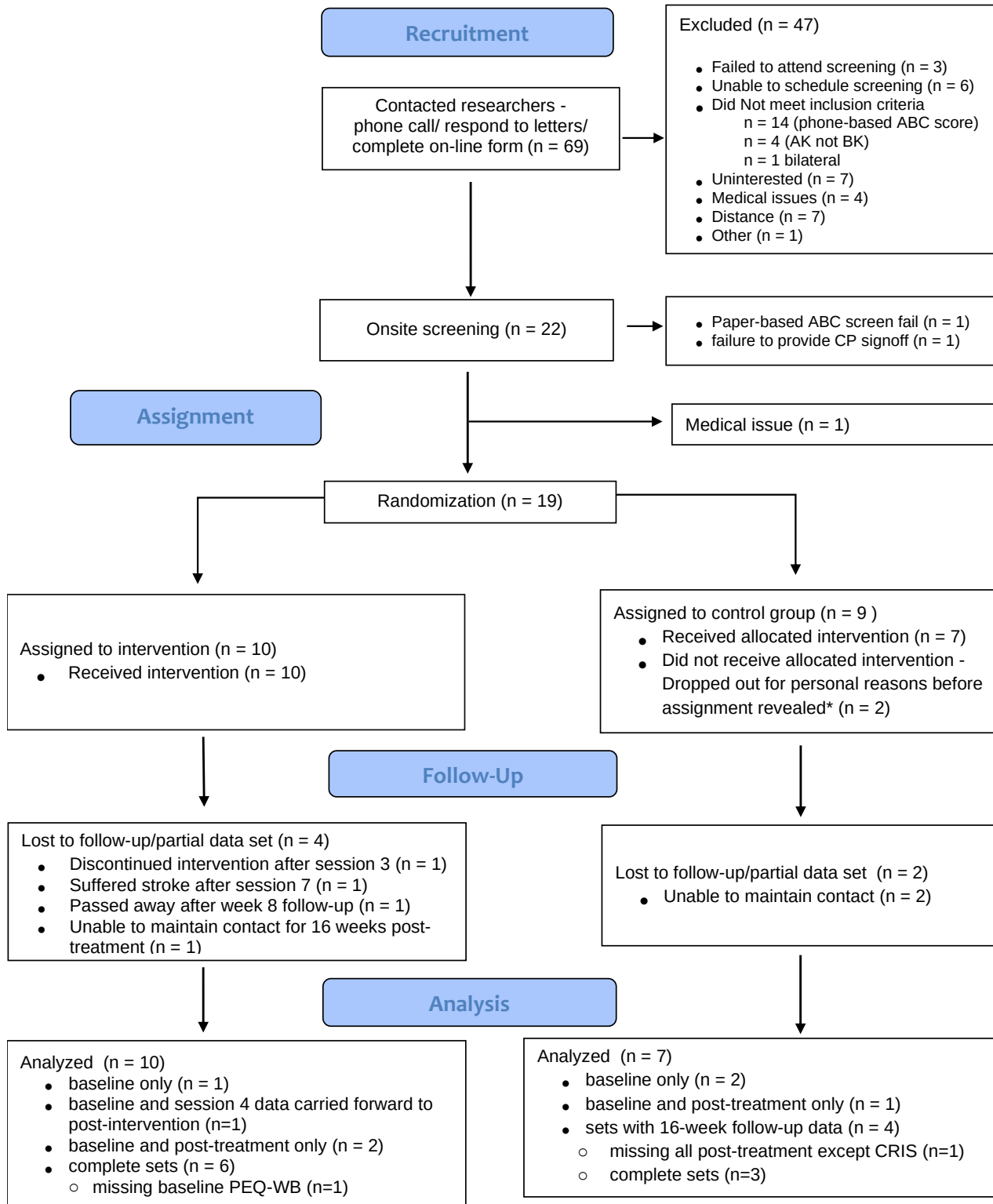
GROUP	AGE	SEX	BMI (kg/m ²)	RACE	VETERAN	CAUSE OF AMPUTATION; YRS SINCE AMPUTATION	ASSISTIVE DEVICE; # OF FALLS	PROSTHETIC SET-UP (SOCKET COMFORT SCORE - SCS)	RELEVANT MEDICAL HISTORY
I	79	M	28.23	W	Y	trauma; 6.3 yrs	Y; 1 fall	Dynamic Response Low Profile foot; TSB socket; vacuum suspension with sleeve (Harmony P4); 3mm gel liner (SCS=8)	vertigo; arthritis in lower back
I	38	M	30.66	W	N	Trauma; 4.8 yrs	N; 0 fall	Ossur low profile Dynamic Response Split Toe foot; TSB socket; vacuum heel pump system with silicone gel liner silicone (SCS=8)	daily phantom pain
DNQ	41	M	48.78	AA	N	Charcot Foot; 10.0 yrs	Y; 4 falls	sleeve suspension (socket and foot not noted)	on hemodialysis
C	71	M	25.60	W	Y	Diabetes; 21.0 yrs	Y; 3 falls	Ossur Dynamic Response foot; suction with sleeve suspension; Silver 1ply sock against skin (gel liner) (SCS=7)	diabetes; quadruple bypass 10 years prior; contralateral foot 1st three toes amputated; herniated disc
C	72	F	46.68	W	N	Trauma; 17.0 yrs	N; 0 falls	Ossurs Dynamic Response/UNITY foot; total contact socket with gel liner system; suction with suspension sleeve (SCS=9)	diabetes; lower back and hip pain when walking; vertigo; contralateral knee replacement
C	49	F	42.05	W	N	infection; 1.2 yrs	N; 3 falls	--	--
I	55	M	29.29	W	N	Trauma; 33.3 yrs	N; 0 falls	Ossur Pro-flex XC, category 7 foot (socket not noted) (SCS=10)	targeted muscle reinnervation surgery several months ago for neuromas, no limb sensation; vertigo
DNQ	57	M	26.31	AA	N	Diabetes	N; 0 falls	--	nothing reported
I	82	M	31.93	W	Y	diabetic infection; 2.8 yrs	Y; 1 fall	non articulating, carbon graphite foot; plastic inner socket; sleeve suspension	diabetes; vertigo; back pain; ipsilateral knee replacement; contralateral knee bone-on-bone OA
I	54	M	24.63	H	Y	Diabetes; 4.1 yrs	N; 1 fall	Kinterra DF/PF motion carbon fiber foot; carbon fiber socket with soft silicone plastic inner liner and alpha silicone liner; sleeve suspension with supra condular clip (SCS=9)	diabetes; lower back is extremely stiff upon walking; phantom pain most days; pain in both hips
C	53	M	32.49	AA	Y	PVD; 1 1.8 yrs	N; 0 falls	carbon graphite foot; silicone liner with pin suspension (SCS=9)	vertigo; back pain with long walking

Note: order of participants in table corresponds to order of recruitment; Group: C- Control, I – Intervention, DNQ – Did not qualify; Race: W- White, H – Hispanic, AA – African American; Y – yes and N- No; Falls are defined as number of self-reported falls in the prior year while wearing the prosthesis

Table 2 – Overview of key activities during the 8-session CBPT intervention

Session	Key Activities	Homework
1	• Introduction to some VR games • Program overview • Introduction to behavioral recording form	• Complete behavioral recording form
2	• Introduction to additional VR games • Review of homework • Develop behavioral goals • Introduction of diaphragmatic breathing	• Complete behavioral recording form • Review diaphragmatic breathing information
3 -7	• VR gaming • Homework review and practice of diaphragmatic breathing • Introduce systematic exposure in the context of reducing fear and changing behavior • Exposure exercise	• Complete behavioral recording form • Practice diaphragmatic breathing • At home exposure exercises
8	• Summarize progression made toward behavioral change goals and in balance and gait • Present Strategies for preventing relapse	

Figure 1. Participant Flow Chart



* for administrative reasons, i.e., scheduling a time for the physical therapist and/or psychologist that aligned with the participants schedule, it was necessary to assign the participant to a group and make study team aware of the assignment before it was disclosed to the participant

Figure 2 . Proposed outcome measures demonstrating a significant, immediate intervention effect. (Top) The main study outcomes, balance confidence, as assessed with the Activities-Specific Balance Confidence scale increased with the intervention. All plots in the figure include pre- and post-treatment means (light gray and dark grey bars, respectively) and standard error bars (to account for differences in sample size) for the control group and intervention group as well as subject specific data shown as individual lines. Following a 2-way repeated measures ANOVA, significant intervention effects were demonstrated by significant pre-post effects in the CBPT group with no simultaneous effect in the control group, as per post-hoc tests. (Middle) Community Reintegration of Service Members (CRIS) – Extent of Participation scale. (Bottom) 36-item Short Form (SF-36) - Role Limitations due to Physical Health.

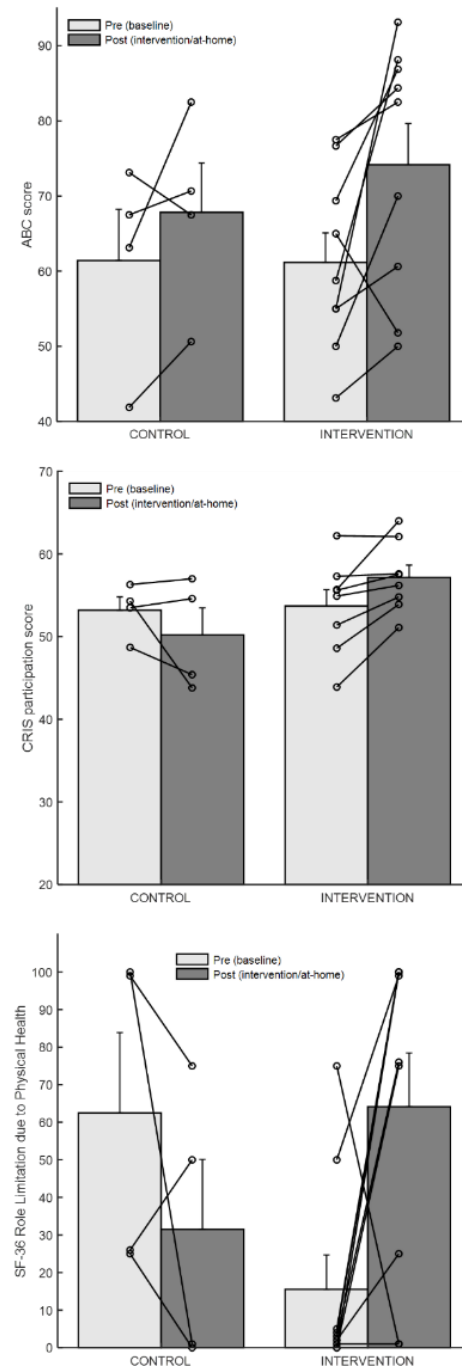
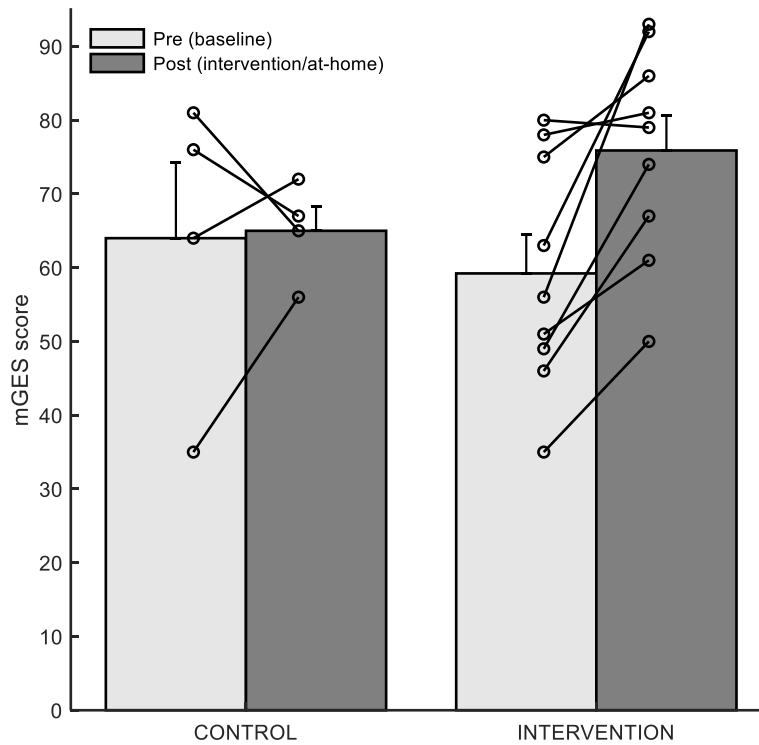


Figure 3 . Exploratory outcome measure demonstrating a significant, immediate intervention effect. Gait self-efficacy, as assessed with the modified Gait Self-efficacy scale (mGES) increased with the intervention. Pre- and post-treatment means (light gray and dark grey bars, respectively) and standard error bars (to account for differences in sample size) for the control group and intervention group are shown, as well as subject specific data as individual lines. Following a 2-way repeated measures ANOVA, significant intervention effects were demonstrated by significant pre-post effects in the CBPT group with no simultaneous effect in the control group, as per post-hoc tests.



3.3 Opportunities for training and professional development provide by the project

Nothing to report

3.4 Dissemination of results to communities of interest

See section 6.1

3.5 Plans for the next reporting period to accomplish goals

N/A

4. IMPACT

4.1 Impact on the development of the principal discipline(s) of the project

Through the work, we have successfully broadened knowledge of stakeholders (prosthetists, physical therapist and psychologists) regarding the importance of managing balance confidence and fear of falling to maximize rehabilitation of the lower limb prosthesis user. We have brought to light the need to address both physical and psychological factors related to low balance confidence when trying to increase community participation. While some military and rehabilitation hospitals make use of sophisticated and sizable virtual reality environments as a means to challenge the balance and improve walking ability in lower limb prosthetic patients, our therapeutic intervention is of greater clinical applicability as it involves simpler techniques, requires less space, and is more economical. The successful completion of this project provides a strong rationale for continued research that explores methods of clinical integration of this approach in both the acute and long-term rehabilitation phases to support wounded servicemembers and veterans alike.

4.2 Impact on other disciplines

Nothing to report

4.3 Impact on technology transfer

Nothing to report

4.4 Impact on society beyond science and technology

Nothing to report

5. CHANGES/PROBLEMS

5.1 Changes in approach and reasons for change

No major changes to the approach have occurred over the course of the project

5.2. Problems or delays and actions to resolve them

The primary problem faced throughout the length of the project related to recruitment. One major hurdle was understating the process for obtaining contact information for VA patients meeting inclusion criteria, which involved submitting a Data Access Request Tracker (DART) application in August of 2020 (nearly two years into the grant). When we finally received approval, we received an uptick in responses with many screenings scheduled. However, as we were also contending with COVID-related research delays the recruitment effort was considerably less fruitful than anticipated. Nonetheless, we now have the knowledge need to utilize this method for future projects. In addition, despite lower than anticipated recruitment rates, the results presented in section 3 are extremely promising and collectively demonstrate the feasibility of implementing the proposed intervention and identify areas for improvement in future iterations of the program. Moreover, we are currently leveraging these findings when applying for new funding. During the past year worked with Hanger Clinic on an FY23 OPORP proposal that was scored in the Excellent range, which was focused on acquiring stakeholders feedback (e.g., prosthetists, therapists, patients, owners) related to potential barriers to translating the work into clinical practice (another aspect of feasibility). We are also submitting the work to NIDLIRR and possibly to TBIPHRP.

5.3 Problems or other factors that significantly impacted expenditures

N/A

5.4 Significant changes in use of human subjects

Nothing to report

6. PRODUCTS

6.1 Publications, conference papers, and presentations

All publications, conference papers and presentations from this project are included in the Appendix material. The following is a bibliography of all publications and meeting abstracts related to this material. The posters and orals included in the bibliography cover presentation of work that directly addresses study hypotheses as well as exploratory analyses of data collected under the project. Included manuscript include a presentation of the study protocol and two case studies - one related to initial testing of the protocol and one related to the deleterious effects of prosthesis disuse on balance confidence.

1. K.Schneider, J. Heck, N.J. Rosenblatt (presenters), M.Major, J. Calamari, S. Kraut, C. Reddin,R. Walker (authors) Integrated Physical Therapy Intervention & Cognitive-Behavioral Training To Enhance Prosthesis Users' Balance Confidence. Society of Behavioral Medicine Annual Meeting, Washington DC, March 2019 (symposium).
2. N.J. Rosenblatt, M. Major, J.C. Duncan, K. Schneider, J. Calamari, R. Henderson, C. Reddin, A. Stachowiak. Integrated PT & CBT To Enhance Prosthesis Users' Balance Confidence. 15th Annual Lewis Landsberg Research Day. Northwestern University. April 14, 2019 (poster)
3. R. Hendersen R, N. Rosenblatt, K. Schneider, J. Calamari, C. Reddin, M. Major. Active Virtual Reality Training and Cognitive Behavioral Therapy; An Interprofessional Approach to Promote Balance Confidence, Balance, Functional Mobility, Community Participation and Quality of Life in Trans-Tibial Prosthesis Users. American Physical Therapy Association Combined Sections Meeting (APTA-CSM), January 2019 (oral)
4. N.J. Rosenblatt , J.C. Duncan, J.A. Kent, K. Schneider, J.E. Calamari, R. Henderson, C. Reddin, A. Stachowiak, M.J. Major. Cognitive Behavioral Therapy With Physical Therapy To Address Balance Confidence Following Transtibial Amputation. 46th Annual Meeting and Scientific Symposium (American Academy of Orthotists and Prosthetists), Chicago, March 2020. (oral)
5. N. J. Rosenblatt, S. Yalla, J.A Kent, M. Major. The Association Between Physical Activity Parameters, Self-Efficacy, Quality Of Life and Community Participation in Users of Unilateral Transtibial Prostheses. American Orthotic and Prosthetic Association Annual Meeting, virtual. September 2020 (oral).
6. N. J. Rosenblatt, S. Yalla, J.A Kent, M. Major. The Association Between Physical Activity Parameters, Self-Efficacy, Quality Of Life and Community Participation In Users Of Unilateral Transtibial Prostheses. Virtual American Society of Biomechanics Annual Meeting, August, 2020 (poster)
7. N.J. Rosenblatt. Step length asymmetry is associated with fear of falling activity avoidance in persons with unilateral transtibial amputation. Virtual meeting of the XXVIII Congress of the International Society of Biomechanics, July 2021 (poster)
8. N.J. Rosenblatt Step Length Asymmetry Is Associated With Fear Of Falling Activity Avoidance In Persons With Unilateral Transtibial Amputation. Virtual meeting of the International Society of Prosthetics and Orthotics (ISPO), November 2021 (oral)
9. M. Bourque, K.L Schneider, J.E. Calamari, M.J Major, C. Duncan, C. Reddin, A. Stachowiak, R. Muthukrishnan, N.J. Rosenblatt. Combining physical therapy and cognitive behavioral therapy techniques to improve balance confidence and community participation in people with unilateral transtibial amputation who use lower limb prostheses: a study protocol for a randomized sham-control clinical trial. *Trials* 20, 812 (2019)
10. N.J. Rosenblatt , C. Reddin, A. Stachowiak. Prosthetic Disuse Leads to Lower Balance Confidence in a Long-term User of a Transtibial Prosthesis *Advances in Wound Care*, 2019.
11. Rosenblatt, Noah J., Aaron Stachowiak, and Christopher Reddin. "rosthetic disuse leads to lower balance confidence in a long-term user of a transtibial prosthesis." *Advances in Wound Care* 10:9, 529-533 (2021)

12. R. Churchill, K. L Schneider, J.E. Calamari, R. Henderson, S. Hwang, M.J. Major, C. Duncan, A. Stachowiak, C. Reddin, N.J. Rosenblatt. Feasibility of an Interdisciplinary Intervention to Promote Balance Confidence in Lower Limb Prosthesis Users: A Case Study. Journal of Prosthetics and Orthotics. July 30, 2021, doi: 10.1097/JPO.0000000000000325

6.2 Other Products

We have developed an intervention manual for clinicians and patient manuals (included as Appendices in the first-year annual report). Although the proposed transition plan did not discuss these knowledge products, we plan to initiate discussion with the Office of Technology Transfer regarding if and how to best protect this knowledge product (it may not be possible given the public disclosure), which could include copyright protection and/or housing material on a university website to help ensure authenticity. Any changes to protection of the product following closure of the grant will still be made known to the grants officer.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

7.1 Individuals who have worked on the project

Name:	Noah Rosenblatt
Project Role:	PI
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	Obtain local IRB and HRPO documentation, overseeing: development of training material; training of graduate students and PT hire; subject recruitment; communications
Funding Support:	grant

Name:	Kristin Schneider
Project Role:	Co-I
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	development of training material; conducting case study; training graduate psychology students
Funding Support:	grant

Name:	John Calamari
Project Role:	Co-I
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	development of training material; training graduate psychology students; conducting initial intervention sessions
Funding Support:	grant

Name:	Sara Haag
Project Role:	Research PT (Rosalind Franklin University faculty)
Researcher Identifier	
Nearest person month worked:	

Contribution to Project:	<i>Clinician responsible for conducting the PT exercises within the experimental intervention and teaching the seated chair exercise to the control group</i>
Funding Support:	grant

Name:	<i>Kav Hagopian</i>
Project Role:	<i>Research PT (Rosalind Franklin University faculty)</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>Clinician responsible for conducting the PT exercises within the experimental intervention and teaching the seated chair exercise to the control group</i>
Funding Support:	grant

Name:	<i>Elaine Schultz</i>
Project Role:	<i>Research coordinator responsible for recruitment efforts</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>Recruiting</i>
Funding Support:	grant

Name:	<i>Rachel Walker</i>
Project Role:	<i>Graduate psychology student</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>Trained in administering CBT aspects of intervention, will be responsible for conducting interventions</i>
Funding Support:	grant

Name:	<i>Aaron Stachowiak</i>
Project Role:	<i>Research MD</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>Screening participants and referring participants from FHCC amputee clinic</i>
Funding Support:	(time in kind)

Name:	<i>Sri Ranjin Muthukrishnan</i>
-------	---------------------------------

Project Role:	<i>Research MD</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>referring participants from Hines VA amputee clinic, intellectual contributions</i>
Funding Support:	(in-kind)

Name:	<i>Matthew Major</i>
Project Role:	<i>Site PI</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>recruitment; overseeing graduate student; protocol development</i>
Funding Support:	grant

Name:	<i>Chad Duncacn</i>
Project Role:	<i>Research prosthetist</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>recruitment; screening; clinical insight</i>
Funding Support:	Grant

Name:	<i>CAPT Chritopher Reddin</i>
Project Role:	<i>Co-I</i>
Researcher Identifier	
Nearest person month worked:	
Contribution to Project:	<i>recruitment; screening; clinical insight</i>
Funding Support:	Time in kind

7.2. Changes in PI support

N/A

7.3. Changes in the senior/key personnel since the last reporting period

N/A

7.4. Other organizations involved as partners

None to report

8. SPECIAL REPORTING REQUIREMENTS

A final updated Quad Chart has been submitted with this report.

A bibliography of all publications and meeting abstracts is included in section 6.

A list of personnel (not salaries) receiving pay from the research effort is found in section 7.1

9. APPENDICIES

- Appendix A - Abstract of symposium at annual meeting of the Society of Behavioral Medicine (2019)
- Appendix B - Poster from Lewis Landsberg Day (2019)
- Appendix C - Accepted abstract from 2019 APTA Combined Sections Meeting (2019)
- Appendix D - Abstract of oral at the annual meeting of the American Academy of Orthotists & Prosthetists (2020)
- Appendix E - Abstract of oral at the annual meeting of the American Orthotics and Prosthetics Association (2020)
- Appendix F - Poster presented at the annual meeting of the American Society of Biomechanics (2020)
- Appendix G - Poster presented at the XVII Congress of the International Society of Biomechanics (2021)
- Appendix H - Abstract for oral presented at the Congress of the International Society of Prosthetics and Orthotics (2021)
- Appendix I - Original (unrevised) submission Manuscript currently in revision in PM&R
- Appendix J - Manuscript published in Advances in Wound Care
- Appendix K – Manuscript published in Trials
- Appendix L - Manuscript published in Journal of

**APPENDIX A. ABSTRACT FOR SYMPOSIUM PRESENTATION AT THE ANNUAL MEETING OF THE SOCIETY OF
BEHAVIORAL MEDICINE (2019)**

Integrating Virtual Reality Gaming, Physical Therapy and Psychotherapy Strategies into Physical Activity Interventions

Presenters: Kristin Schneider (chair), Noah Rosenblatt, Justin Heck
Discussant: Alyson Littman, Ph.D.

Virtual reality active games are increasingly being used in physical therapy settings to enhance patient motivation and enjoyment, and facilitate physical activity. For some patients though, gaming interventions might not be sufficient to address psychological barriers to physical activity such as fear of falling and low balance confidence, which could limit the treatment effect. This symposium will provide three unique perspectives on how to develop and implement physical activity interventions for populations that struggle with physical activity due to physical and psychological barriers. Presenters will use examples from a clinical trial that tests the efficacy of a multicomponent, interdisciplinary physical activity intervention to illustrate how to integrate virtual reality gaming and psychotherapy strategies into physical therapy. The intervention was developed for adults with a lower limb amputation who use a prosthesis. While low balance confidence is often associated with older adults, low balance confidence impacts a variety of populations with chronic health conditions and, in particular, is a prevalent, overlooked issue among adults who use a prosthesis. The intervention consists of 8 sessions co-led by a physical therapist and psychologist that integrate physical therapy exercises, delivered primarily by virtual reality active gaming, with cognitive behavioral strategies that increase balance confidence by addressing avoidance behaviors and maladaptive cognitions. [Removed for blinded review] the PI, will discuss the development of the intervention and study results. [Removed for blinded review], a clinical psychologist, will discuss her experience with integrating the cognitive-behavioral strategies into the physical therapy content, and provide the physical therapist's perspective. Benefits of and challenges with co-leading sessions will be highlighted. [Removed for blinded review], a prosthetist who has a lower limb prosthesis, will discuss the value of incorporating patient and provider feedback during intervention development, from the perspective of both a prosthetist and a person who uses a prosthesis. Our discussant, [removed for blinded review], an epidemiologist and leading expert on promoting physical activity among individuals with a lower limb amputation, will provide her thoughts on this intervention approach and ideas for improving physical activity in adults who have unique physical and psychological activity barriers.

Learning objective 1: Identify strategies for integrating two disciplines into physical activity interventions for adults with unique physical activity barriers.

Learning objective 2

Learning objective 3: Understand the value of including patient and provider input into multidisciplinary interventions.

Title: The value of adding patient and provider perspectives to the development of multidisciplinary physical activity interventions

Authors: Justin Heck

Low balance confidence, defined as low self-perception in ones' ability to maintain balance while performing specific activities, is a prevalent, yet overlooked issue among adults with a lower limb prosthesis. Sixty-five percent of community-dwelling individuals with a lower limb amputation reported poor balance confidence at a level requiring intervention. Adults with a lower limb prosthesis and low balance confidence are less likely to engage in physical activity compared to adults who have not had an amputation. In adults who use a lower limb prosthesis lower levels of physical activity are associated with lower quality of life, less engagement in social relationships and increased disability. This presentation will focus on the presenter's personal and professional experience as a prosthetist with a lower limb amputation and the value of including patients and

providers in intervention development. The presenter will discuss the expertise he lent to the development of the multicomponent intervention, and strategies for encouraging adults with unique barriers to participate in physical activity research. The lack of sufficient support for adults newly fitted with a prosthetic device, the ramifications of the insufficient support provided, and the opportunities for novel interventions will be highlighted. The presentation will include a discussion of the common issues that adults with low balance confidence encounter (e.g., avoidance behavior, falls), and the issues that are unique to adults with a lower limb prosthetic device (e.g., including hidden disability, trauma, and adjustment to the prosthetic device), and how all of these issues contribute to less physical activity and community engagement. The presenter will also discuss how challenges can evolve and change over time for individuals with low balance confidence and those with a lower limb prosthesis.

Learning objective 1: Describe the benefits of having individuals with personal and professional expertise in working with the patient population participate in intervention development.

Learning objective 2: Identify barriers to physical activity among adults with a lower limb prosthesis who report low balance confidence

Title: Integration of Virtual Reality Gaming into Physical Therapy: Initial Evidence on Adults who Use a Prosthesis

Author: Noah Rosenblatt¹, Ph.D., Matthew Major, Ph.D.

Whereas a growing body of scientific literature objectively demonstrates a relationship between balance confidence and community participation in adults who use lower limb prostheses, to date no intervention exists that specifically targets balance confidence and related activity avoidance behavior in this population. Given that <40% of variance in balance confidence can be explained by physical performance, such an intervention must address both functional abilities (i.e. balance and gait), as well as the underlying cognitions that contribute or lead to low confidence. A Matter of Balance (MOB) is an evidenced-based, national program that helps older adults without amputation increase balance confidence and includes balance exercises and cognitive therapy techniques that teach participants to think about fear of falling (low balance confidence) as controllable. However, this program may not be ideal for prosthesis users - e.g., the group-based approach is not practicable for the small, heterogenous population; the program fails to consider prosthesis-specific factors such as residual limb pain or a having a fixed ankle, which can affect behavior. This presentation will provide the scientific rationale for the development of the integrated intervention and its specific components, as it relates to prosthesis users, including the use of novel VR games to target specific aspects of ambulation that are not easily addressed with standard physical therapy practice. The presenter will demonstrate these games with video footage from program participants. During the process, he will introduce the audience to validated clinical tools to quantify balance confidence and fear of falling and discuss the challenges of developing a simple, self-report measure to quantify how fear impacts an individual's behavior, highlighting a newer self-reported scale for this purpose. The presenter will conclude the overall presentation by presenting qualitative and quantitative results from participants who completed the intervention, including data from a case participant whose balance confidence scores increased from a 51 (on a 100 point scale) at baseline to a 92 at one-month follow-up and whose physical activity (steps/day) increased by 53% over that time. He will then discuss our future directions.

Learning objective 1: Describe the rationale for inclusion of physical therapy and cognitive behavioral therapy to address low balance confidence and activity avoidance in adults who use lower limb prostheses.

Learning objective 2: : Identify ways to include virtual reality gaming into physical activity interventions

Title: Integrating mental health professionals into physical therapy sessions to address balance confidence in individuals who use a prosthesis: rationale, challenges and lessons learned

Authors: Kristin L. Schneider, Ph.D., John Calamari, Ph.D. Sara Kraut, PT, Christopher Reddin, Ph.D. Rachel Walker Churchill, Noah Rosenblatt, Ph.D.

Since mental health and physical health issues often co-occur, integrated care is becoming more common in clinical settings. While psychologists often collaborate with physical therapists in clinical settings to address issues like pain or anxiety during physical therapy sessions, few studies include interventions in which psychologists and physical therapists co-treat patients. Interventions that typically integrate psychotherapy strategies into physical therapy often teach physical therapists modified versions of the strategies, or have mental health professionals meet separately with participants, rather than having psychologists or other mental health professionals co-lead treatment sessions. The presenter will discuss the challenges and advantages of interventions in which mental health professionals and physical therapists co-lead treatment sessions, and the rationale for why this approach was selected for the current intervention, which addresses balance confidence in adults who use a lower limb prosthesis. Using examples from the case study and the ongoing clinical trial, the presenter will highlight the advantages of a co-led approach to addressing balance confidence. Specific topics covered include identifying and discussing feared situations, selecting and conducting exposure in collaboration with the physical therapist, tempering participant expectations when identifying goals, and homework assignments to ensure that participants remain safe and are not discouraged by slower progress. Provider characteristics and settings critical to the success of a co-treatment approach will be described. The presenter will conclude with a discussion of lessons learned and opportunities for future co-treatment approaches.

Learning objective 1: Identify opportunities for physical therapists and mental health professionals to co-lead treatment sessions

Learning objective 2: Identify strategies to facilitate successful treatment partnerships between physical therapists and mental health professionals.

**APPENDIX B. POSTER PRESENTED AT THE ANNUAL LEWIS LANDSBERG RESEARCH DAY AT
NORTHWESTERN UNIVERSITY (2019)**

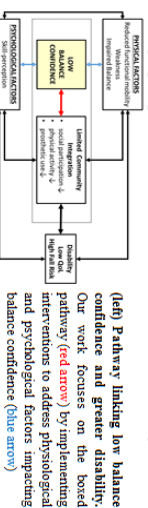
Case Study: Integrated PT & Cognitive Behavior Therapy To Enhance Prosthesis Users' Balance Confidence

Rosenblatt, N.¹, Major, M.^{2,3}, Duncan, J.^{2,3}, Schneider, K.¹, Calamari, J.¹, Henderson, R.¹, Reddin, C.⁴, Stachowiak, A.⁴

¹Roseland Franklin University Medical School, ²Northwestern University Prosthetic & Orthotic Center, ³Department of Physical Medicine and Rehabilitation, ⁴Captain James A. Lovell Federal Health Care Center,

Background

Low balance confidence, i.e., low self-perception in one's ability to maintain balance while performing specific activities, is a prevalent issue among adults using lower limb prostheses. Sixty-five percent of individuals with a lower limb amputation report balance confidence at a level requiring intervention. Importantly, low balance confidence is a predictor of reduced social and physical activity; we avoid activities we feel we cannot successfully accomplish. Thus, interventions addressing low balance confidence may limit increased future disability. Given that balance confidence and physical function are only moderately associated, such interventions must address balance and gait deficits as well as any underlying cognitions that contribute to low balance self-efficacy.



Methods

We are currently conducting a randomized control trial (RCT) to evaluate the effectiveness of an intervention to improve balance confidence by integrating physical therapy in the form of active video games (Figure 1-top) with cognitive behavioral therapy techniques (Figure 1 bottom). The intervention includes 8 weekly sessions, each 1.5-2 hours in duration, with a licensed physical therapist and clinical psychologist working side-by-side (Figure 2). Here we present data from a case subject recruited to assess feasibility of the intervention prior to initiating the RCT.

Inclusion/Exclusion for case subject (and all persons in the RCT):

- Activity-specific Balance Confidence scale (ABC) score of <80%
- No open wounds on weight-bearing surfaces
- Well-fitting and functioning prosthesis - determined by research prosthetist
- Clearance to engage in low-intensity exercise - determined by the research physician

Northwestern Medicine
Fennberg School of Medicine

Methods (continued)

Study Outcomes

Twice at baseline, then again 4, 8 and 12 weeks (month follow-up) Later

Primary outcome - ABC score

Secondary outcomes

- Average steps per day using a StepWatch activity monitor
- Fear of Falling Avoidance Behavior Questionnaire (FFABQ)
- Quality of life via the Well-being scale of the Prosthetic Evaluation Questionnaire (PEQ)
- Social participation via the French Activity Index (FAI)
- Berg Balance scale (BBS) - (0 and 8 weeks only)
- L-test of walking - (0 and 8 weeks only)

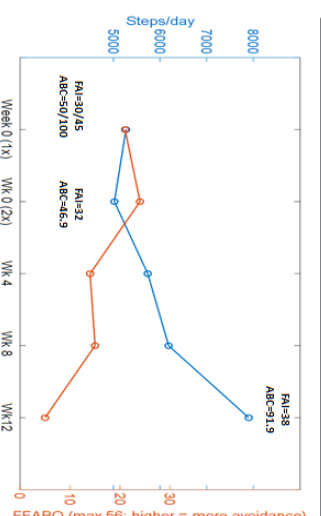


Figure 1. Pictures taken during the PT (top, A) and the CBT portion (bottom) of the intervention, as well as screenshots of several active video games used in the PT portion (top, A-C). Note that the participants shown are not the case subject discussed herein. (top A-B) The active video games are played on a calibrated treadmill and focus on involve weight-shifting. Difficulty can be scaled by changing the speed of objects or length of the paddle. (top, C) Games that focus on functional gait by projecting objects onto the treadmill surface are also used. (top, C). (bottom) During the CBT portion the participant works with a behavioral counselor while the PT is present.

Case Subject

A 57 year old African American male (68.6 kg, 170.1 cm), who suffered a unilateral transfibular amputation 9 years prior as a result of osteomyelitis secondary to a non-healing diabetic ulcer. The subject had a Medicare Functional Classification K-Level of 3. He used a total surface bearing socket with sleeve suspension and a customized Otobock Uno Unique gel liner. He had a very prominent fibula head and reported a socket comfort score of 6/10. The subject was prescribed but rarely used a cane. He reported often stumbling and having a fall inside the home 2 months prior. The subject had peripheral neuropathy on the contralateral limb with drop foot but did not use a brace. His baseline ABC was 48.5.

Results



Results from case subject Activity data (blue line) represents average values from 1 week of monitoring. Fear-avoidance, behavior i.e. FFABQ, is shown in red. Balance confidence continuously increased throughout the intervention, increasing by 90% from base line to 1 month follow-up (ABC: 48.5 vs. 91.9; maximum score: 100). Increased confidence was mirrored by a 47% increase in physical activity (5362.8 steps/day vs. 7900.9) and a large reduction in fear avoidance behavior (FFABQ scores). BBS increased by 9 points from 44 to 53 (out of 56) and FAI increased from 32 to 38 but L-test and PEQ were unaffected. Taken together results provide strong initial evidence of efficacy for the intervention.

**APPENDIX C. ABSTARCT FOR PRESENTATION AT AMERICAN PHYSCIAL THERAOY ASSOICATION (APTA)
COMBINED SECTIONS MEETING (2019)**

CONTROL ID: 3041299

TITLE: ACTIVE VIRTUAL REALITY TRAINING AND COGNITIVE BEHAVIORAL THERAPY; AN INTERPROFESSIONAL APPROACH TO PROMOTE BALANCE CONFIDENCE, BALANCE, FUNCTIONAL MOBILITY, COMMUNITY PARTICIPATION AND QUALITY OF LIFE IN TRANS-TIBIAL PROTHESIS USERS

PRESENTATION TYPE: Platform

CURRENT SECTION: Federal Physical Therapy

Author Details

AUTHORS (LAST NAME, FIRST NAME): Henderson, Roberta J.¹; Rosenblatt, Noah²; Schneider, Kristen³; Calamari, John³; Reddin, Christopher⁴; Major, Matthew

INSTITUTIONS (ALL):

1. Physical Therapy, Rosalind Franklin University of Medicine & Science, North Chicago, IL, United States.
2. CLEAR, SCPM, Rosalind Franklin University of Medicine & Science, North Chicago, IL, United States.
3. Psychology, Rosalind Franklin University of Medicine & Science, North Chicago, IL, United States.
4. Mental Health, Captain James A Lovell Federal Health Care Center, North Chicago, IL, United States.
5. Feinberg School of Medicine, Northwestern University, Chicago, IL, United States.

SPONSOR NAME: None

Presenter Bio (case studies): (none)

Abstract

ABSTRACT BODY:

Background & Purpose : The focus of rehabilitation for persons with amputation is on promoting function and mobility, not balance confidence (BC). Low BC (low self-perception in ones' ability to maintain balance while performing specific activities) can limit community participation and quality of life (QoL). Confidence may be as important as skill level in determining participation in activities, thus there is need to develop integrated rehabilitation strategies to simultaneously promote skills and BC. Active Virtual Reality Training (AVRT) may promote skill. Cognitive Behavioral Therapy (CBT) may promote BC by addressing avoidance behaviors and maladaptive cognitions. The purpose of this study was to design and evaluate a novel program to promote BC, balance, functional mobility, community participation and QoL in lower limb prosthesis users.

Case Description : PARTICIPANT: The volunteer participant was a 58 year old African American man with unilateral trans-tibial amputation. He expressed concerns about falling that prevented participation. METHODS: Assessments were prior to eight 90 minute intervention sessions (IS), following 4th and 8th IS, and one month following the last IS. A physical therapist (PT) and CBT practitioner collaborated in all IS. The format for IS included interaction between the participant and the CBT practitioner, and review of homework, followed by a 45 minute AVRT session designed and supervised by a PT. Brief exposure therapy was implemented, designed to address participant-specific fear avoidance behavior. Finally coping skills and homework were discussed. OUTCOME MEASURES: BC was assessed with the Activity Specific Balance Confidence Scale (ABC), Fear of Falling Avoidance-Behavior Questionnaire (FFABQ) and Modified Gait Efficacy Scale (mGES). Balance was assessed with the Berg Balance Scale (BBS) and Functional Mobility was assessed with the L-Test. Community Participation was assessed with the Community Reintegration of Injured Service Members scale (CRIS), the Frenchay Activity Index (FAI), and GPS recording of actual steps taken in the community. Quality of Life was measured with the SF-36 and the Prosthetic Evaluation Questionnaire (PEQ).

Outcomes : Increased BC (ABC; pre=48.5, post=91.9) and self-efficacy (mGES; pre=43, post=95), and decreased fear-avoidance behavior (FFABQ; pre=22.5, post=5) were evident. Balance increased (BBS; pre=43, post=51), as did Community Participation (FAI; pre=30, post=38)(GPS Steps/Day; pre=5271, post=6185). QoL increased (SF-36, Emotional; pre=33.4, post=66.7)(SF-36, Physical Functioning; pre=35, post=80). There was little change in Functional Mobility (L-Test; pre=29.3 sec., post=31.4 sec).

Discussion : The positive results of this innovative, interprofessional program demonstrate its efficacy and potential to benefit prosthetic users with trans-tibial amputation, including the disproportionately large number of aging Veterans with amputation.

KEYWORDS: Virtual Reality, Cognitive Behavioural Therapy, Amputee.

References: Limit to only those materials that ensure that the content is evidence-based; minimum 5 references, no more than 10 years old (2009 and forward): 1. Bradford DW, Jette AM, Hernandez CJ. Issues in defining and measuring veteran community reintegration: Proceedings of the working group on community reintegration, VA rehabilitation outcomes conference, Miami, FL. *Journal of rehabilitation research and development*. 2012;49(1):87.

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**APPENDIX D. ABSTRACT FOR ORAL PRESENTATION AT THE 46th ANNUAL MEETING OF THE AMERICAN
ACADEMY OF ORTHOTISTS & PROSTHETISTS (AAOP) (2020)**



COGNITIVE BEHAVIORAL THERAPY WITH PHYSICAL THERAPY TO ADDRESS BALANCE CONFIDENCE FOLLOWING TRANSTIBIAL AMPUTATION

Rosenblatt, N.J.¹, Duncan, J.C.², Kent, J.A.^{2,3}, Schneider, K.¹, Calamari, J.E.¹, Henderson, R.¹, Reddin, C.⁴, Stachowiak, A.⁴, Major, M.J.^{2,3}

Rosalind Franklin University of Medicine and Science 1, Northwestern University Prosthetic & Orthotic Center 2, Jesse Brown VA Medical Center 3, Captain James A. Lovell Federal Health Care Center 4

INTRODUCTION

Low balance confidence, i.e., low self-perception of ones' ability to maintain balance while performing specific activities, is a prevalent issue among adults using lower limb prostheses (Miller et al., 2002). Sixty-five percent of individuals with a lower limb amputation report balance confidence at a level requiring intervention (Miller et al., 2002). Importantly, low balance confidence is a predictor of reduced social and physical activity; we avoid activities we feel we cannot successfully accomplish. Thus, interventions that address low balance confidence may limit future disability. Given that balance confidence and physical function are moderately associated (Major et al., 2013), such interventions should address any underlying thought patterns that contribute to low balance self-efficacy, in addition to balance and gait deficits.

The overarching aim of this study is to evaluate the effectiveness of an intervention to improve balance confidence that integrates physical therapy (PT) in the form of active video games with cognitive behavioral therapy (CBT) techniques. In the current work we present results from a case subject recruited at initiation of an ongoing randomized controlled trial.

METHOD

Case subject: A 57-year-old African American male (68.6 kg, 170.1 cm), who acquired a unilateral transtibial amputation 9 years prior as a result of osteomyelitis secondary to a non-healing diabetic ulcer. The subject was a K-Level 3 ambulator and used a total surface bearing socket with sleeve suspension. He had a very prominent fibula head and reported a Socket Comfort Score of 6/10. The subject was prescribed but rarely used a cane. He reported often stumbling and having had a fall inside the home 2 months prior. The subject had peripheral neuropathy on the contralateral limb with drop foot but did not use an orthosis. His baseline Activities Balance Confidence (ABC) Scale score was 48.5.

Intervention: Video gaming and CBT in 8 weekly sessions, each 1.5-2 hours in duration, with a licensed physical therapist and clinical psychologist.

Assessment: Evaluations were performed twice at baseline, and repeated 4, 8 and 12 wks later (mid-and post-intervention, and 1-month follow-up). The primary outcome was ABC score. Secondary outcomes included: average steps per day during a one-week period, using a StepWatch monitor; Fear of

Falling Avoidance Behavior Questionnaire (FFABQ); quality of life via the Well-being scale of the Prosthetic Evaluation Questionnaire (PEQ); and social participation via the Frenchay Activity Index (FAI). The Berg Balance scale (BBS) and L-test were assessed pre- and post-intervention (0 and 8 wks).

RESULTS

Balance confidence continuously increased throughout the intervention; by 90% from baseline to 1-month follow-up (ABC: 48.5 vs. 91.9; maximum score: 100). Increased confidence was mirrored by a 47% increase in physical activity and a large reduction in fear avoidance behavior (Fig.1). BBS increased from 44 to 53 (max 56) and FAI increased from 32 to 38 (range 15-45). The L-test and Well-being section of the PEQ were unchanged.

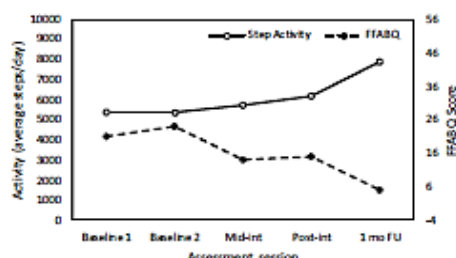


Figure 1. Longitudinal activity data (average values from 1 week) and FFABQ results.

DISCUSSION

Improvements were seen in all measures except for the L-test and PEQ. Improvements continued 1-month post-intervention suggesting that the intervention may have been successful in modifying cognitive patterns in this single case subject. The ongoing RCT aims to comprehensively test this paradigm, and also includes biomechanical measures of gait and balance.

CONCLUSION

These results provide strong initial evidence of efficacy for the integrated PT & CBT intervention.

CLINICAL APPLICATIONS

Combining CBT with PT may lead to lasting improvements in participation and quality of life through increased balance confidence.

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- Major, M. J. et al. Arch. Phys. Med. Rehabil. 94(11), 2194-2202, 2013.

American Academy of Orthotists & Prosthetists
46th Academy Annual Meeting
& Scientific Symposium
March 4-7, 2020

**APPENDIX E. ABSTRACT FOR ORAL PRESENTATION AT AMERICAN ORTHOTOC AND PROSTHETIC
ASSOICATION (AOPA) ANNUAL MEETING (2020)**

THE ASSOCIATION BETWEEN PHYSICAL ACTIVITY PARAMETERS, SELF-EFFICACY, QUALITY OF LIFE AND COMMUNITY PARTICIPATION IN USERS OF UNILATERAL TRANSTIBIAL PROSTHESES

Noah J Rosenblatt^{1*}, Sai Yalla¹, Jenny A Kent², and Matthew Major²

¹Center for Lower Extremity Ambulatory Research, Rosalind Franklin University of Medicine and Science, North Chicago, IL USA

²Northwestern University Prosthetics Orthotics Center, Chicago, IL USA

Email: *noah.rosenblatt@rosalindfranklin.edu

INTRODUCTION

Prosthesis users face unique barriers to physical activity (PA), e.g., socket discomfort, components that poorly accommodate to inclines or uneven surfaces. However, interventions to address these barriers do not always promote PA. For example, changing socket suspension from pin to vacuum, which should increase comfort and mobility¹, reduces steps per day². In addition, while evidence supports the use of microprocessor-controlled knees to increase self-reported mobility, step counts and duration of activity may be unaffected by the type of knee³. To some extent these findings may reflect the fact that traditional measures of PA such as step count do not closely relate to changes in community participation or well-being, which may be expected with increase mobility⁴, and therefore may not well capture the impact of these interventions. Moreover, traditional measure of PA may not well capture the complexity of PA patterns that may also be impacted. Recent studies using detrend fluctuation analysis (DFA) suggest that daily fluctuations in PA are not random, but rather demonstrate scale invariance (appear similar at short and long time scales). This property is thought to reflect overall motor health, is insensitive to total level of activity and is impacted by disease states such as chronic fatigue that alter the temporal nature of the PA⁵. The purpose of this study was to evaluate the relationship between a number of PA measures derived from activity monitors and self-reported outcome measures associated with well-being, community participation and PA patterns in order to provide insight to guide assessments in future intervention studies.

METHODS

We present data from the first 17 persons with unilateral transtibial amputation recruited into a larger randomized control trial to reduce fear of falling and increase community participation in prosthesis users. To participate, individuals: reported an Activity-specific Balance Confidence (ABC) score <80 and had at least 6 months experience with a definitive prosthesis; they were excluded for: active wounds on weight-bearing surfaces. All participants meeting inclusion were screened by a prosthetist to ensure a well-fitting prosthesis and by a physiatrist to ensure they were safe to engage in low-to-moderate levels of exercise. Participants then completed 6 self-reported measures: ABC; the Fear of Falling Avoidance Behavior Questionnaire (FFABQ) which asks individuals to rate how much fear of falling leads to avoidance of 14 different activities; modified Gait self-efficacy scale (mGES) which asks level of confidence in completing 10 different gait-related tasks; the well-being scale of the Prosthesis Evaluation Questionnaire (PEQ); the Short-form 36 Healthy Survey (SF-36) - we present data from the physical functioning scale only; and the Frenchay Activity Index (FAI) to quantify social participation. Participants wore a Step Watch 3 activity monitor (Modus Health) on their pylon for 1 week, which recorded steps taken in 10 s epochs. From the raw data we calculated 6 PA measures: steps/day (average across all days); median and maximum walking-bout length and number of walking bouts/day, where a bout was defined as ≥ 5 consecutive steps; the DFA scaling exponent;

and the “decay” exponent. For DFA, we followed standard procedures⁶: integrate the time series; plot the average size of the fluctuations (variations about the local trend) of data within windows of increasing size n as a function of n ; calculate the slope of the best fit line (α) on a log-log scale. To calculate the “decay exponent” we fit a histogram of the bout data with an exponential decay function and report the exponent; larger values indicate data is skewed toward more short walking bouts. Independent correlations were run to determine the strength of association between the 6 PA measures and 6 self-reported measures. Due to missing data, the number of points differs across correlations.

ACTIVITY PARAMETERS		SELF-REPORTED MEASURES					
		Self-efficacy and participation				Quality of life	
		ABC	FFABQ	mGES	FAI	PEQ	SF-36
Amount	Steps/day	0.18	0.22	0.22	0.68 ($p=0.004$)	0.50 ($p=0.085$)	0.28
	Bouts/day	0.01	-0.07	0.05	0.58 ($p=0.063$)	0.23	0.18
	Median bout length	0.02	-0.08	0.18	0.47 ($p=0.064$)	0.54 ($p=0.058$)	0.20
	Maximum bout length	0.22	-0.45 ($p=0.096$)	0.24	0.45 ($p=0.082$)	0.64 ($p=0.019$)	0.55 ($p=0.040$)
	DFA exponent	0.31	-0.43	0.22	0.58 ($p=0.018$)	0.66 ($p=0.014$)	0.51 ($p=0.061$)
Pattern	Decay exponent	0.40	-0.14	0.10	0.23 ($p=0.068$)	0.52 ($p=0.089$)	0.47

Table 1: Correlations between self-reported and PA measures. Grey values correspond to $p>0.10$; bold values correspond to $p<0.05$

RESULTS

In general, measures of self-efficacy (ABC and mGES) and related activity avoidance (FFABQ), which, theoretically, should directly relate to PA show nearly no associations with PA measures (Table 1). On the other hand, FAI, a direct measure of participation, as well as quality of life (PEQ) are significantly associated with many PA measure of activity including the DFA scaling exponent. The strongest correlation among all measures was between FAI and the traditional PA measure of steps/day.

CONCLUSION

If activity is an outcome of interest within a prosthetic intervention it may be important to include self-report measures related to activity and quality of life as well as objective measures to assess both amount of activity and pattern of activity to fully understand the impact of the intervention. Additional work is needed to determine the extent to which changes in self-reported measures correspond to changes in PA measures, and vice versa.

SIGNIFICANCE

Prosthetic interventions should include a wide variety of measures to fully understand their impact on the patient.

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ACKNOWLEDGMENTS

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**APPENDIX F. POSTER PRESENTED AT THE AMERICAN SOCIETY OF BIOMECHANICS (ASB) ANNUAL MEETING
(2020)**



UNIVERSITY OF ILLINOIS
AT CHICAGO
COLLEGE OF PODIATRY MEDICINE

The Association between Physical Activity Parameters, Self-Efficacy, Quality of Life and Community Participation in Users of Unilateral Transfemoral Prostheses

Noah J Rosenblatt^{1*}, Sai Yalla¹, Jenny A Kent², and Matthew Major²

¹Center for Lower Extremity Amputation Research (CLEAR),

²Department of Medicine at Rosalind Franklin University of Medicine and Sciences, North Chicago, IL, USA
³Northwestern University Prosthetics Orthotics Center, Chicago, IL, USA



CDMRP

Introduction

- Prosthetic users face unique barriers to physical activity (PA), e.g., socket discomfort, components that poorly accommodate to inclines or uneven surfaces.
- Interventions to address these barriers do not always promote PA. For example, changing socket suspension from pin to vacuum, which should increase comfort and mobility, reduces steps per day¹.
- In addition, while evidence supports the use of microprocessor-controlled knees to increase self-reported mobility, step counts and duration of activity may be unaffected by the type of knee².
- To some extent these findings may reflect the fact that traditional measures of PA, such as step count do not closely relate to changes in community participation or well-being, which may be expected with increase mobility³.
- Moreover, traditional measure of PA may not well capture the complexity of PA patterns that may also be impacted.
- Recent studies using detailed fluctuation analysis (DFA) suggest that daily fluctuations in PA are not random, but rather demonstrate scale invariance.
- Scale invariance is thought to reflect overall motor health, is insensitive to total level of activity, and is impacted by disease states such as chronic fatigue that alter the temporal nature of the PA⁴.

Purpose

- To evaluate the relationship between a number of PA measures derived from activity monitors and self-reported outcomes measures associated with well-being, community participation and PA patterns in order to provide insight to guide assessments in future intervention studies

Methods

- We present data from the first 17 persons with unilateral transfemoral amputation recruited into a larger randomized control trial to reduce fear of falling and increase community participation in prosthetic users
- To participate, individuals reported an Activity specific Balance Confidence (ABC) score <80 and had at least 5 months experience with a definitive prosthesis. Exclusion criteria was any active wounds on weight-bearing surfaces
- All participants meeting inclusion were screened by a prosthetist to ensure a well-fitting prosthesis and by a physiatrist to ensure they were safe to engage in low-to-moderate levels of exercise.

Methods continued

- Participants then completed 6 self-reported measures: ABC scale; the Fear of Falling Avoidance Behavior Questionnaire (FFABQ) which asks individuals to rate how much fear of falling leads to avoidance of 14 different activities;
- modified gait self-efficacy scale (mGES) which asks level of confidence in completing 10 different gait related tasks;
- the well-being scale of the Prosthesis Evaluation Questionnaire (PEQ);
- the Short-Form 36 Healthy Survey (SF-36) - we present data from the physical functioning scale only;
- the Frenchay Activity Index (FAI) to quantify social participation.
- Participants wore a Step Watch 3, activity monitor (Modus Health) on their girth for 1 week, which recorded steps taken in 10 s epochs.
- From the raw data we calculated 6 PA measures: step/day (average across all days); median and maximum walking- bout length and number of walking bouts/day, where a bout was defined as 25 consecutive steps; the DFA scaling exponent;

Results and Discussion

Table 1: Correlation between self-reported and PA measures. Step values correspond to p=0.10; bout values correspond to p=0.25

ACTIVITY PARAMETER	SELF-REPORTED MEASURES					
	ABC	FFABQ	mGES	PEQ	SF36	FAI
Step/day	0.18	0.22	0.23	0.20	0.26	0.68
DFA exponent	0.31	-0.43	0.22	0.46	0.51	0.58
# of bouts/day	0.03	-0.49	0.06	0.21	0.18	0.47
Median bout length	0.02	-0.48	0.18	0.24	0.20	0.50
Max bout length	0.22	-0.45	0.34	0.64	0.55	0.45
Exponential decay	0.40	-0.14	-0.10	0.22	0.47	0.23

- measures of self-efficacy (ABC and mGES) and related activity avoidance (FFABQ), which, theoretically, should directly relate to PA, show nearly no associations with PA measures (Table 1).
- On the other hand, FAI, a direct measure of participation, as well as quality of life (PEQ) are significantly associated with many PA measure of activity including the DFA scaling exponent.
- The strongest correlation among all measures was between FAI and the traditional PA measure of step/day

Conclusion

- If activity is an outcome of interest within a prosthetic intervention it may be important to include self-report measures related to activity and quality of life as well as objective measures to assess both amount of activity and pattern of activity to fully understand the impact of the intervention.
- Additional work is needed to determine the extent to which changes in self-reported measures correspond to changes in PA measures, and vice versa.

Significance

- Prosthetic interventions should include a wide variety of measures to fully understand their impact on the patient

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Acknowledgements

- This work was funded by DoD W81XWH-17-1-06

**APPENDIX G. POSTER PRESENTED AT THE XVII CONGRESS OF THE INTERNATIONAL SOCIETY OF
BIOMECHNCIS (2021)**

Step length asymmetry is associated with fear of falling activity avoidance in persons with unilateral transfibular amputation

Introduction

- Low balance confidence and fear of falling are common among prostheses users [1] and can significantly limit activity.
- People with transfibular amputation often display asymmetry in step length (SL) with greater prosthetic-side SL due to increased intact push off.
- While asymmetry is commonly viewed as a negative consequence of amputation, SL asymmetry may represent a functional adaptation to maintain stability and prevent a backward fall [2]
- Leveraging SL asymmetry to ensure stability may facilitate balance confidence and reduced fear of falling; SL asymmetry may serve as a marker of self-efficacy.

Purpose

The purpose of this study was to evaluate the association between step length asymmetry and measures of: i) balance confidence; ii) gait self-efficacy; and iii) fear of falling related activity avoidance.

We also evaluated the associations between symmetry indices for other gait characteristics associated with FoF in intact older adults and the latter outcomes.

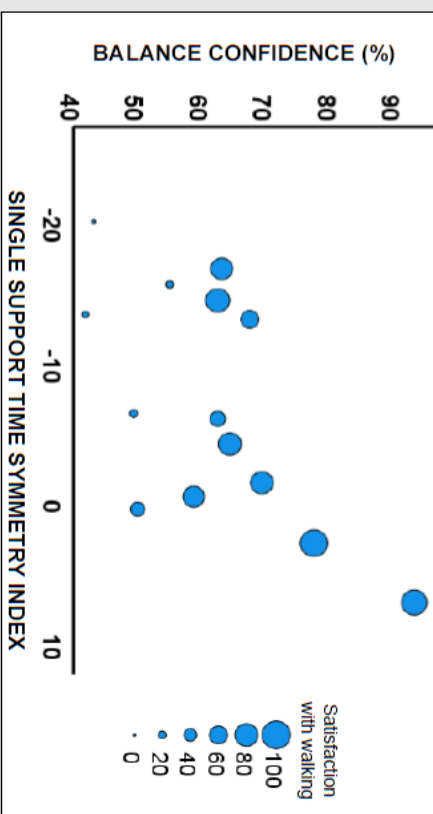
Methods

- Participants: 17 with unilateral TTA (5 F/12 M, 58.8±12.6 yrs); 4 vascular-related amputations primarily
- Walked across a 10m laboratory walkway 10-20 times at a self-selected pace.
- For each limb, the following were averaged across steps: SL: step width (SW); step time (ST); percent single support (%SS); single support time (SST); percent double support (%DS) and double support time (DST) for the DS phase following heel strike of a given limb.
- Symmetry indices (SI) calculated as: (prosthetic –intact)/0.5*(prosthetic+intact)
- The following surveys were completed and correlated with gait variables:
 Activity-Specific Balance Confidence (ABC) scale
 Modified Gait Self Efficacy Scale (MGES)
 Fear of Falling Avoidance Behavior Questionnaire (FFABQ)
 One item from the Prosthetic Evaluation Questionnaire (PEQ) that states "Over the past 4 weeks, rate how satisfied you have been with how you are walking".

Acknowledgements

This work was funded by US Department of Defense award W81XWH-17-1-06

Results and Discussion



	PROSTHETIC STEP LENGTH	INTACT STEP LENGTH	STEP LENGTH SYMMETRY INDEX
Balance confidence (ABC) (higher = more confidence)	0.608 (0.010)	0.378 (0.135)	0.341 (0.180)
Gait self efficacy (MGES) (higher = greater efficacy)	0.570 (0.027)	0.290 (0.295)	0.422 (0.117)
Fear of Falling activity avoidance (FFABQ) (higher = more avoidance)	-0.729 (0.002)	-0.371 (0.173)	-0.572 (0.026)
Walking satisfaction (PEQ) (higher = more satisfaction)	0.539 (0.047)	0.421 (0.134)	0.212 (0.466)

Prosthetic SL but not intact SL was significantly associated with all survey measures. However, only FFABQ, was associated with SL SI (table). Neither limb-specific measures nor SI measures for SW, ST, % SS, %DS or DST were significantly associated with any survey measures. However, SST SI was significantly associated with ABC and walking satisfaction (top), greater prosthetic SST relative to intact SST was associated with greater confidence and gait satisfaction. Longer prosthetic side steps (which rely on intact push off) and longer relative prosthetic SST (reliant on prosthetic side balance) may promote self-efficacy and limit FoF-related activity avoidance. Fostering symmetry in rehabilitation may not be desirable.

**APPENDIX H. ABSTRACT FOR ORAL PRESENTED AT THE 18th WORLD CONGRESS OF THE
INTERNATIONAL SOCIETY OF PROSTHETICS AND ORTHOTICS (ISPS)**

2.6.3.c

Step Length Asymmetry is Associated with Fear of Falling Activity Avoidance in Persons with Unilateral Transtibial AmputationNoah Rosenblatt

Rosalind Franklin University of Medicine and Science, North Chicago, USA

BACKGROUND

Low balance confidence and fear of falling (FoF) are prevalent issues among prostheses users [1] that can significantly limit activity. To our knowledge no studies have evaluated gait characteristics specific to persons with transtibial amputation (pTTA). Common gait asymmetries in pTTA, e.g., greater prosthetic step length (SL), may represent a functional adaptation to maintain stability [2], and not a negative consequence of amputation.

AIM

The study aimed to evaluate the association between i) step length asymmetry (as well as other symmetry indices) and ii) measures of balance and gait self-efficacy as well as FoF-related activity avoidance.

METHOD

Seventeen pTTA participated. Participants walked across a 10m walkway at a self-selected pace. For each limb, motion capture quantified: SL; step width (SW); step time (ST); percent single support (%SS); single support time (SST); percent double support (%DS) and double support time (DST). Symmetry indices (SI) were calculated based on across-step averages. Participants also completed: i) Activity-specific Balance Confidence (ABC); ii) Modified Gait Self Efficacy Scale (mGES); iii) Fear of Falling Avoidance Behaviour Questionnaire (FFABQ); iv) One item from the PEQ - "Over the past 4 weeks, rate how satisfied you have been with how you are walking". Correlational analyses were conducted.

RESULTS

Prosthetic-side SL was significantly associated with all survey measures (Table 1). However, only FFABQ, was associated with SL SI. Neither limb-specific measures nor SI measures for SW, ST, %SS, %DS or DST were significantly associated with any survey measures. However, SST SI was significantly associated with ABC and the PEQ walk item (Figure 1); greater prosthetic relative to intact (positive SI) was associated with greater confidence and gait satisfaction.

DISCUSSION AND CONCLUSION

Longer prosthetic side steps (reliant on intact push off) and longer relative prosthetic SST (reliant on prosthetic-side balance) may promote self-efficacy and limit FoF-related activity avoidance. Fostering symmetry in rehabilitation may not be desirable outcome.

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ACKNOWLEDGEMENTS: This work was funded by DoD award W81XWH-17-1-06.

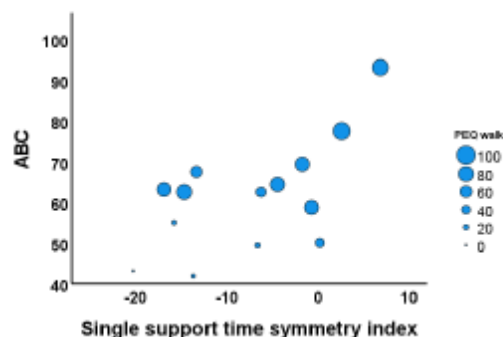


Figure 1. ABC vs. SST SI; bubble size relative to PEQ question.

APPENDIX I – ORIGINAL (UNREVISED) SUBMISSION MANUSCRIPT CURRENTLY IN REVISION IN PM&R

Title: Validating a fear-of-falling-related activity avoidance scale in lower limb prosthesis users
ABSTRACT

Introduction: Fear of falling is a common among lower limb prosthesis users and associated with multiple negative rehabilitation outcomes. The impact of fear of falling on these outcomes may be exacerbated when the fear leads to self-imposed declines in activity. There is a need to identify the reliability of fear of falling activity avoidance scales in lower limb prosthesis users.

Objective: To evaluate the convergent, discriminant and criterion validity of the modified Survey of Activities and Fear of Falling in the Elderly for lower limb prosthesis users. Secondly, we sought to determine if the scale could be reduced without losing information regarding construct validity.

Setting: This is a cross-sectional study consisting of on-line survey completion

Participants: Fifty-nine persons with unilateral or bilateral amputation at the transtibial or transfemoral level, with ≥ 6 months experience using a definitive prosthesis for activities other than transfers completed the survey.

Intervention: Not applicable

Main outcome measures: Correlational analyses and independent samples t-tests were performed to assess validity; hierarchal regression modeling was performed to compare the full and shortened scale.

Results: Significant correlation coefficients of $|0.440-0.825|$ were found for convergent validity with evidence of criterion validity ($p < 0.021$ for all comparisons). There was evidence for discriminant validity, with non-significant associations for two-of-three correlations, although leisure time boredom was, surprisingly, associated with fear-of-falling-related activity avoidance ($r = 0.43$, $p < 0.001$). A shortened six-item modified Survey of Activities and Fear of Falling in the Elderly scale fit the nomological network similar to the entire 17-item scale, with regressions suggesting information regarding validity was maintained with scale reduction.

Conclusion: The modified Survey of Activities and Fear of Falling in the Elderly is a valid scale to assess fear-of-falling-related activity avoidance in lower limb prosthesis users. A 6-item scale may be appropriate if completing the full scale would be taxing or time consuming.

Key words: accidental falls, amputees, artificial limbs, prostheses and implants

INTRODUCTION

Fear of falling (FoF), a persistent and overwhelming concern about falling during daily activities, affects nearly 50% of lower limb prosthesis users (LLPUs) [1, 2]. While FoF is associated with reduced functional mobility, increased fall risk and diminished quality of life [3-5], these effects may be exacerbated when it leads to self-imposed declines in activity. Indeed, FoF-related activity restriction may be a critical mediator between FoF and future disability [6]. For example, older adults with FoF-related activity restriction report greater difficulty in performing activities of daily living [7], compared to those with FoF alone. FoF-related activity avoidance is not uncommon in LLPUs, with 17% of older LLPUs reporting FoF as a major barrier to engaging in physical activity [8]. Accurately assessing FoF-related activity avoidance may be critical to maximizing activity participation and long-term rehabilitation outcomes for LLPUs.

Whereas scales to assess constructs related to FoF in LLPUs, e.g., balance and falls self-efficacy [9, 10], have received attention in the literature, they are insufficient to fully explain FoF-related activity restriction. Only 46 % of the variance in FoF-related avoidance behaviors in intact older adults can be explained by balance self-efficacy [11]. Moreover, a content analysis linking FoF scales to categories within the International Classification of Functioning, Disability and Health (ICF) framework suggests that balance and falls self-efficacy scales do not link with the category of “activity and participation” [12]; only one evaluated scale did link to this category - the modified version of the Survey of Activities and Fear of Falling in the Elderly (mSAFE).

The mSAFE is one-of-two published scales to quantify self-reported FoF-related activity avoidance - the other being the Falling Avoidance Behavior Questionnaire. While the validity of each has been demonstrated in intact older adults [11, 13], only the mSAFE has demonstrated some psychometric support with LLPUs . Nugent et al reported excellent relative reliability for the mSAFE in LLPUs [14]. Nonetheless, reliability is only one aspect of scale validation, which must be rigorously established before advocating wider scale acceptance.

Building upon the work of Nugent et al, the purpose of this study was to evaluate the strength of evidence for the construct validity of the mSAFE for use with LLPUs. In particular, we considered: convergent validity with scales that capture constructs which are expected to differ between those with high and low FoF-related activity avoidance; discriminant (or divergent) validity with scales that capture constructs presumed to be unrelated to FoF-related activity

avoidance; and criterion validity with regards to mobility and falls. Secondly we sought to determine if it was possible to reduce the number of items on the 17-item scale and still maintain similar levels of construct validity. The rationale relates to the long-term goal of wider scale use. While certified prosthetists generally see value in clinical assessment tools, a minority report routinely using such tools [15-17], with 30-79% of prosthetists and orthotists reporting time as an obstacle to using assessments in clinical practice [15, 18]. Most CPs are unwilling to spend >10 minutes on administering self-reported surveys [17]. Thus, an equally valid shortened version of the mSAFE is more likely to be implemented in a clinical setting.

METHODS

Participants

We recruited participants using online advertisements including a posted on national foundation website and messages on listservs, as well as emails to leaders of amputee support groups. Advertisement material led interested LLPUs to an online survey, hosted in Qualtrics, that asked only for the individual's email address and captured the IP address of the individual. If both addresses were not previously entered, then a unique link was sent to the email address. A total of 110 unique links to the complete online survey were circulated. If the survey was not completed within one month, a reminder email was automatically generated. If a response was not received within two months, the link became inactive. One month thereafter, the individual was sent a new unique link that was again active for two more months.

Individuals who clicked on the link were directed to the full survey. The first question was for internal validity and asked participants to enter the two-letter abbreviation of the state they were currently in. If the entered state did not match exactly (case-sensitive) with that associated with the IP address, as determined directly from the survey software, then the survey ended. If the respondent incorrectly entered the state (i.e., "nc" instead of "NC") or if the software placed the IP address in a neighboring state (e.g., the participant entered "NJ", but the software associated the IP address with "NY") then a new link was sent to the respondent. After entering state information, screening questions were presented related to inclusion/exclusion criteria. Inclusion criteria were: having a unilateral or bilateral amputation

at the transtibial or transfemoral level; having ≥ 6 months experience using a definitive prosthesis; and being at least a typical community ambulator who uses the prosthesis for activities other than transfers (i.e., K2-level). Those passing screening were taken to a short consent form, which explained this Institutional Review Board approved study. Following consent, participants completed the study survey.

Survey

The study survey consisted of several sections that were collectively used to assess aspects of construct validity of the mSAFE. The first section assessed the following patient demographics: age; sex; race; number of comorbidities according to the Functional Comorbidities Index [19]; the number of amputations and level(s) of amputation; time since most recent major amputation; experience using a prosthesis (years); use of a cane or walker for daily ambulation; number of falls in the last 12 months. In addition, participants completed three questions to ascertain the presence of FoF and FoF-related activity avoidance: 1) How afraid are you that you will fall and hurt yourself in the next year (4-point scale: 1=very afraid to 4=not at all afraid); 2) Are there things you don't do because you might fall? (yes/no); and 3) Are there things you have stopped doing because you are worried that you might fall (yes,no)? A response of 1, 2 or 3 on the first question was used to indicate the presence of FoF and a “Yes” response on at least one of the remaining questions was used to indicate FoF-related activity avoidance. These questions were originally developed by Howland et al [20] and used in the original development and validation study of the Survey of Activities and Fear of Falling in the Elderly (SAFE) by Lachman et al. [13]

The next section of the survey consisted of the mSAFE itself. The mSAFE is a modified version the SAFE that was developed to assess the role of FoF in activity restriction [13]. Whereas the SAFE was intended for face-to-face interview and included 22 items with subscales related to whether an individual does an activity (e.g., going up and down stairs, going for a walk), the level of “worry about falling” during the activity and how much worry about falls prevents activity participation, the mSAFE is intended to be self-administered and focuses only on avoidance of activities. The mSAFE includes 17 of the original SAFE items. For each item, individuals use a 3-point scale to answer if they would avoid

activities because of a fear of falling, with higher total scores indicating greater avoidance [21]. The sum of all items indicates the mSAFE score.

The final sections of the survey included previously validated scales that were used to assess convergent and discriminant validity (Table 1).

[INSERT TABLE 1 HERE]

The entire survey was expected to take 20-40 minutes to complete, and participants were compensated for completing the survey. To ensure internal validity, if a participant completed the survey in under 20 minutes, their data was flagged for internal validation. As an additional check for internal validity, there were nine attention check questions throughout the survey (e.g., “Enter choice three here”) and participants would be immediately withdrawn from the study if they incorrectly answered three attention check questions; no respondents were excluded for this reason. Of the 110 unique links sent out, data from 59 participants is included in the analysis (see Figure 1)

[INSERT FIGURE 1 HERE]

Analysis

To assess convergent and discriminant validity of the full 17-item mSAFE, we conducted Pearson’s or Spearman’s correlations (for the International Physical Activity Questionnaire Short Form only since the final scoring was not continuous but categorical) between scores from the scales shown in Table 1 and the mSAFE score. Validity was suggested according to expected significant correlations ($p < 0.05$) between mSAFE and those scales used for testing convergent validity and non-significant correlations for those testing discriminant validity. For example, there should be a non-significant association between mSAFE and leisure boredom (Leisure Boredom Index) as the latter is intrinsically linked to a lack of motivation [22], not FoF. We considered the following cutoffs to define the strength of correlations [23]: < 0.30 - negligible; $0.30-0.50$ - low; $0.50-0.70$ moderate; $0.70-0.90$ strong; $0.90-1.0$ very strong.

For criterion validity, four separate independent samples-t-tests were used to compare the mSAFE score between groups of individuals who did and did not self-identify as: 1) using an assistive device for daily locomotion; 2) experiencing at least two or more falls during the prior year; 3) having a FoF; and 4) avoiding activities due to a FoF. We expected that FOF-related avoidance would be higher in those with a FoF, as has been reported for intact older adults

[11, 13, 21] and that mSAFE would be higher in fallers [24]. We chose to group fallers based on report of two or more falls as this magnifies the difference between fallers and non-fallers and reflects LLPUs with inherently worse balance ability [25]. We also expected that mSAFE would be higher in those with impaired mobility as evidenced by use of an assistive device and in those who endorsed FoF-related activity avoidance. Criterion validity was suggested if the expected differences were significant ($p < 0.05$).

To determine if it was possible to reduce the number of items on the mSAFE without reducing construct validity, several steps were taken. First, we conducted a redundancy analysis and continuously eliminated the item that would lead to the smallest change in Cronbach's α , until it was no longer possible for Cronbach's α to remain above 0.90. We then reran the validity analyses described above with the cumulative score from the remaining items (smaller set) to determine whether the smaller set fit into the nomological network the same way as the entire set of 17-items. We also performed a series of hierarchical regression analyses to determine whether the information about validity contained in the small set could be increased by including the removed items (remaining set), i.e., whether the entire set of 17-items provides information not captured in the 6-items. To do this, the score from each scale used for convergent or criterion validity (Table 1) were entered as the dependent variable into two separate regressions (linear or logistic), each consisting of two blocks. In one regression (case 1), the scores from the smaller set were entered as the independent variable on block 1 and those of the remaining set were entered in block 2. In the other regression (case 2), the order of entering sets was reversed. If for case 1 the addition of the remaining set did not explain significantly greater variance above the smaller set, and, if for case 2 the smaller set added significantly to the remaining set, then this would provide evidence that information regarding validity was not lost by shortening the scale. A total of twenty hierarchical regressions were run for 10 dependent variables - six used for convergent validity (Table 3a) and four for criterion validity (Table 3b).

RESULTS

Eighty-seven percent of study participants were individuals with unilateral amputation, approximately three quarters of whom had transtibial amputations (Table 2). The mean time of prosthesis use for the cohort was just over 11

years, with no single causes of amputation representing the majority of the participants. The majority (55.9%) of the 59 participants considered in the analysis reported falling three or more times and an even higher proportion (76.3%) reported FoF-related activity avoidance.

Validity of 17-item mSAFE

There was moderate to strong evidence of the convergent validity of the full mSAFE with the absolute value of all correlation coefficients ranging from 0.440-0.825 (Table 3a). mSAFE scores were not associated with two-of-three scales used to assess discriminant validity (Table 3b), which was expected, although the correlation coefficients were just below the threshold for detecting significance with the given sample size ($p=0.056$ and $p=0.060$). Surprisingly, the mSAFE scores were significantly associated with leisure time boredom ($r=0.432$, $p<0.001$). The full mSAFE showed evidence for criterion validity with significantly higher values (greater avoidance) in LLPUs with a history of falls, LLPUs who use assistive devices, LLPUs who report FoF and LLPUs who report FoF-related activity avoidance (Table 3b).

[INSERT TABLE 3a AND TABLE3b HERE]

To further explore the strength of criterion evidence with regard to those who do and do not endorse FoF-related activity avoidance, we considered whether LLPUs with multiple endorsements, i.e., those that responded yes to both FoF-related activity avoidance questions, had higher mSAFE scores and also greater FoF. In doing so it was observed that 39-of-45 LLPUs that endorsed some level of FoF-related activity avoidance, reported multiple endorsements. A one-way ANOVA revealed no significant differences in mSAFE scores between those that endorsed no FoF-related activity avoidance and those reporting a single endorsement (mSAFE; 21.4 ± 5.1 vs 22.2 ± 3.7 , respectively, $p=.809$), but significant differences between both groups and those reporting multiple endorsements (mSAFE= 31.7 ± 7.8 , $p<0.001$ for both comparisons). When the number of endorsements was plotted relative to level of FoF (Figure 2) it was observed that all individuals in the two highest FoF levels reported multiple endorsement of FoF-related avoidance behaviors, despite a wide range of mSAFE scores (22-45). In those with a little FoF, there was considerable overlap in mSAFE scores between those who did and did not endorse FoF-related activity avoidance, with 3-of-7 of the highest mSAFE scores being in those who did not endorse avoidance behaviors.

[INSERT FIGUR 2 HERE]

Evaluating a shortened version of the mSAFE

Cronbach's alpha for the 17-item mSAFE was 0.935. After systematically removing items to minimally impact alpha and ensure that it remained at or above a value of 0.90, six items remained (Table 4), which corresponded to Cronbach's alpha of 0.907. The six remaining items fit into the nomological network the same way as the entire set. Specifically, construct validity was demonstrated by correlations coefficient with absolute values ranging from 0.391-0.831. In addition, divergent validity was demonstrated with two-of-three non-significant correlations, although LBI was again significantly associated with the mSAFE score derived from the 6 items. The associations for the three measures to test divergent analysis were all weaker for the six items than for the entire mSAFE.

[INSERT TABLE 4 HERE]

Of the ten variables entered into hierarchical regression models, three provided strong evidence in support of using the six-item scale (Tables 5a and 5b). For four of the variables, there was evidence to support the use of the shortened scale (i.e., the 6 items explained additional variance above and beyond the 11 remaining items, and the 11 items did not explain a meaningful amount of added variance above that of the 6-item scale). For another four variables there was evidence to support the sue of the full scale. in support of the full scale for only three variables. For the two remaining variables, the addition of the 11 items to the 6 items explained no additional variance over the 6 items but, at the same time, the addition of the 6 items to the 11 items also did not explain any additional variance above the 11 items. In these cases, we argue that evidence points to using a more parsimonious option (6-item scale). Accordingly, for 5-of-10 variables considered there is evidence that validity (convergent and criterion) is not lost by using the 6-item scale over the full scale.

[INSERT TABLE 5a and TABLE 5b HERE]

DISCUSSION

The purpose of this study was to evaluate the strength of evidence for the validity of the mSAFE for use with LLPUs. We found moderate-to-strong evidence for convergent validity, demonstrated criterion validity, and moderate evidence for discriminant validity (Tables 3a and 3b). Collectively, this suggest that the mSAFE is a valid instrument to

assess FoF-related activity restriction in LLUPs. A secondary purpose of this study was to determine if it was possible to reduce the number of items on the 17-item scale without losing convergent or criterion validity, in order to reduce administration time and burden. We identified 6 items (Table 4) that appear to meet this goal. These 6 items fit the nomological structures of the full scale (Tables 3a and 3b). In addition, given that half of the hierarchical regression models suggest information regarding validity is not lost by using the shortened scale, this scale could be appropriate for initial screening purposes in which time is critical or in cases where mSAFE is included as part of a larger battery of tests, given that it should require one-third of the time to complete. In addition. Including fewer items for online administration may promoted less distracting aesthetics. However, additional work is needed to further validate a shortened scale.

When testing discriminant validity, we found a significant association between mSAFE and leisure time boredom, which was unanticipated. Leisure time boredom can be defined as “the subjective perception that leisure experiences are not sufficient to instrumentally satisfy needs for optimal arousal” [26]. At face value (apriori), this definition seems to be independent of FoF. On the other hand, FoF can lead to a reduced pursuit of previously valued leisure activities [13], such that available leisure activities (i.e., those viewed as safe to pursue, or unlikely to lead to a fall) may be less pleasurable. Given that leisure boredom is associated with negative affect and lower quality of life [26, 27], for the LLPU who endorses a high-degree of FoF-related activity avoidance (high mSAFE score), identifying and encouraging participation in rewarding (arousing) activities that the LLPU still perceives as available (safe), may promote well-being.

The six items included in the shortened scale appear to capture a range of important activities that may be impacted by FoF including: stair ambulation, exercise (walking a half mile), socialization, and community participation (going to shops). Many of the excluded items addressed basic activities of daily living (ADLs): hygiene (taking a bath and taking a shower), cleaning the house, preparing simple meals, walking around indoors. It seems reasonable that avoiding ADLs due to fear of falling would be indicative of the highest possible degree of avoidance, which was rarely attained in our cohort (minimum of K2-level functional user), e.g., only four participants indicated that they would “always avoid” taking a bath or preparing simple meals if they were to fall. Thus, responses to items relating to these tasks were very

dissimilar to others such that the items could be removed without minimum impact on internal consistency. On the other hand, those who endorse always avoiding these basic activities due to FoF may be the same individuals who would most benefit from targeted interventions. Future examination of the shortened 6-item scale should be conducted with a cohort of LLPUs with a wide range of functioning.

Screening for and addressing FoF-related activity avoidance behavior may be important for ensuring successful rehabilitation progress of the LPU. For example, in a study of 57 stroke survivors, community integration was predicted from scores on the SAFE avoidance subscale (which, forms the basis of the mSAFE), but not from scores on a balance self-efficacy scale [28]; in older adults with chronic musculoskeletal pain, sedentary behavior was explained by mSAFE, but not pain interference nor fall history [29]. While lower limb prosthetics practice in the United States is reasonably focused on performance outcomes and their relationship with functional mobility, psychological factors such as FoF that can meaningfully contribute to long-term rehabilitation outcomes are often overlooked. Information on FoF-related avoidance behavior may address the holistic needs of the prosthetics patient by informing targeted cognitive and physical therapies to minimize these behaviors and increase prosthesis use and overall activity levels [30, 31]. Given the potential for FoF-related avoidance behaviors to impact prosthesis use, knowledge of these behavior may be a relevant metric when assigning rehabilitation potential through Medicare Functional Classification (K-)Level System, as it speaks to motivation and desired activity level [18].

Although LLPUs who endorse FoF-related avoidance, i.e. respond “yes” to at least one-of-two yes/no questions on the topic, have significantly higher mSAFE scores than those who do not endorse these behaviors, such questions appear to be insufficient for distinguishing the degree of avoidance. For example, all LLPUs with higher (top two) levels of FoF responded “yes” to both questions despite the fact that mSAFE scores ranged from 22-45 (on the 51 point scale) (Figure 2). Similarly, even in some individuals with low levels of FoF, mSAFE scores remained relatively high in those who did not endorse FoF-related avoidance (mSAFE scores of 29-32 in three individuals). Thus, these dichotomous questions do not appear to capture the same information as the mSAFE, supporting its need. It is also interesting to note that 2-of-10 LLPUs that reported no FoF did endorse avoiding activities due to FoF (Figure 2). This could reflect the fact that the question used to assess FoF focused only on a single basis for this fear, i.e., injuring oneself. However, FoF need not be

limited to ones' perceptions of physical harm from falling and could include, e.g., a fear of reduced functional abilities and independence following a fall [32] or a fear of social embarrassment following a fall [33]. The two individuals who endorsed FoF-related avoidance without FoF may still have a FoF but one that originates from concerns other than fall-related injuries. Future validation should include a more general FoF definition.

LIMITATIONS

The primary limitation of the current study relates to the extent to which the level of validity observed in the sample generalizes to all LLPUs. Certain attributes of the cohort appear dissimilar to those of the general population. Whereas other studies report nearly 60% of persons with major lower limb amputation having etiologies related to dysvascular disease with comorbidity of diabetes [34], here only 10% of participants reported diabetes complications as the cause for amputation. Similarly, other studies have reported lower rates (18-43%) of LLPUs with two or more falls [35, 36]. In addition, we screened out K1-level persons, i.e., those using a prostheses for transfers only, as many items on the mSAFE relate to weight-bearing activities. Finally, the racial make-up of our cohort was overwhelmingly white, with only 6.5% identifying as Black or African American, which is far below the prevalence in persons receiving Medicare benefits for amputations [37]. Future work should consider more targeted recruitment, and larger sample sizes, to ensure representative cohort.

CONCLUSION

In conclusion, we provided initial support for the mSAFE as a valid measure of FoF-related activity avoidance in LLPUs. A shorter 6-item version of the 17-item scale, may have similar validity and could be useful for situations where completion of the full scale would be taxing or time consuming. Overall, identifying LLPUs who avoid activities as a result of FoF may be necessary to improve long-term rehabilitation outcomes for LLPUs.

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Table 1. Summary of scales used to assess construct validity

Scale	Description	Type of validity assessed
The Activity Specific Balance Confidence scale (ABC scale)	- measures balance self-efficacy - individuals report confidence in their ability to perform 16 different tasks without losing balance. - valid and reliable for LLPUs (38)	Convergent validity
The Activity Restriction subscale of the Trinity Amputee Prosthetic Evaluate Survey - Revised (TAPES-R)	- addresses prosthesis-related limitations 10 items each answered on a three-point scale: "Does having a prosthesis limit you in (activity)?" - excellent internal consistency (39)	
Short Form 12 – General Health Status Survey (SF-12)	- generic measure of quality of life across a variety of health domains 12 items representing a shortened version of the SF-36. - includes two summative scores related to physical health and mental health - validated for persons with major lower extremity amputation (40)	
The Frenchay Activity Index (FAI)	- quantifies the extent to which a person engaged in a social activity, e.g., hobbies, volunteer work, over last 3 months 14 items answered on a 4-point scale - validity and reliability established for LLPUs (41)	
International Physical Activity Questionnaire – Short Form (IPAQ - SF)	- asks about frequency and duration over the prior week of - walking, moderate-intensity activities, and vigorous-intensity activities. Activity can take place as part of leisure time physical activity (PA), domestic activities, work-related PA or transport-related PA. - level of PA defined as low, moderate or high based on scoring guidelines that consider frequency of activity and METs (42)	
The Leisure Boredom Inventory (LBI)	- assess the "perception of low or inadequate stimulation or motivation towards present leisure time experience" (26) - uses a 5-point Likert scale to rate level of agreement/disagreement to 16 items (e.g., "Leisure experience are an important part of my quality of life") - internally consistent with adequate construct validity (26)	Discriminant validity
The Arnett Inventory of Sensations Seeking (AISS)	- sensation seeking is operationalized as the need for varied, novel and intense sensations (43) 20 items adapted from an original 40 items scale after removing high-risk items, e.g., those related to drug use and activities such as skiing 4-point scale used to rate the extent to which each item describes a person (e.g., "I would like to travel to places that are strange and far away"). - Items summed for two subscale scores – intensity subscale and novelty in sensory experiences subscale (43)	
Descriptor questions	- Use of an assistive device (Yes/No) - History of multiple falls (Yes/No)	Criterion validity

	• FoF (Yes/No) • 2 questions on FoF-related activity avoidance (Yes/No)	
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Table 2. Participant descriptors

Number (percent) or mean(SD); (N=59)	
DEMOGRAPHICS/GENERAL DESCRIPTORS	
Age (years)	53.2±14.6
Mass (kg)	88.6±22.9
Gender	
Male	34 (57.6)
Female	24 (40.7)
Prefer not to answer	1 (1.7)
Race	
White	52 (83.9)
Black or African American	4 (6.5)
Asian	1 (1.7)
Hawaiian/Pacific Islander	1 (1.7)
“Other”	1 (1.7)
Assistive Device Use	21 (35.6)
Falls history	
0 in prior year	12 (20.3)
1 in prior year	5 (8.5)
2 in prior year	6 (10.2)
3 or more in prior year	33 (55.9)
no response	2 (3.4)
Number of Functional Comorbidities	
0	11 (18.6)
1	10 (16.9)
2	11 (18.6)
3	9 (15.3)
4 or more	18 (30.5)
Fear of falling	
None	10 (16.9)
A little	25 (42.4)
Somewhat	16 (27.1)
Very	8 (13.6)
Fear-of-falling-related activity avoidance	45 (76.3)
PROSTHESIS/AMPUTATION SPECIFIC DESCRIPTORS	
Time since amputation (years)	12.1±15.2
Prosthesis use (years)	11.4±15.3
Level and laterality	
unilateral transtibial	38 (62.7)
unilateral transfemoral	13 (22.0)
bilateral transtibial	5 (8.5)
transtibial and transfemoral	2 (3.4)
bilateral transfemoral	1 (1.7)
transtibial and partial foot	1 (1.7)
Etiology (number of limbs)	
trauma	26 (38.2)

diabetes	7 (10.3)
vascular disease (non-diabetes)	7 (10.3)
infection (non-diabetes)	11 (16.2)
other	17 (25.0)

Table 3a. Results from convergent and discriminant validity analysis

Reference scale		correlation coefficient (p-value)	
		17 items	6 items
Convergent	ABC scale	-0.825 (<0.001)	-0.826 (<0.001)
	FAI	-0.681 (<0.001)	-0.638 (<0.001)
	SF-12 mental component	-0.563 (<0.001)	-0.530 (<0.001)
	SF-12 physical component	-0.604 (<0.001)	-0.549 (<0.001)
	TAPES-R	0.800 (<0.001)	0.831 (<0.001)
	IPAQ level	-0.444 (<0.001)	-0.391 (0.005)
Discriminant	AISS Novelty	-0.252 (0.056)	-0.184 (0.167)
	AISS Intensity	-0.248 (0.060)	-0.166 (0.214)
	LBI	0.432 (<0.001)	0.335 (0.010)

Table 3b. Comparison of 17-item and 6-item SAFE scores by group status for establishing criterion validity

	17-item mSAFE	6-item mSAFE
<i>History of multiple (≥ 2) falls</i>		
Yes	29.9 $\pm$ 7.4	11.6 $\pm$ 3.2
No	24.8 $\pm$ 7.5	8.4 $\pm$ 3.1
p-value	0.021	<0.001
<i>Uses Assistive Device</i>		
Yes	31.8 $\pm$ 7.0	12.4 $\pm$ 2.8
No	24.8 $\pm$ 7.5	9.7 $\pm$ 3.4
p-value	0.009	0.002
<i>Fear of Falling</i>		
Yes	30.2 $\pm$ 7.1	11.4 $\pm$ 3.2
No	18.9 $\pm$ 1.9	6.6 $\pm$ 0.8
p-value	<0.001	<0.001
<i>FoF-related Activity Avoidance</i>		
Yes	30.5 $\pm$ 7.2	11.5 $\pm$ 3.2
No	21.4 $\pm$ 5.1	7.7 $\pm$ 2.4
p-value	<0.001	<0.001

Table 4. Six items included and 11 excluded from the shortened mSAFE

Included	Excluded
going to the shops	preparing simple meals
walking a half mile	going to doctor or dentist
visiting a friend or relative	taking a bath
going to a place with crowds	taking a shower
going up and down stairs	going for a walk
going out to a social event	going out when it is slippery
	walking around indoors
	cleaning my house
	bending down to get something
	traveling by public transport
	reaching for something above your head

from

Scale	Block	Entry	Change in R ² (p-value)	Interpretation
ABC scale	1	6 items	0.683 (<0.001)	favor using 6-item scale
	2	11 items	0.021 (0.050)	
	1	11 items	0.576 (<0.001)	
	2	6 items	0.128 (<0.001)	
FAI	1	6 items	0.407 (<0.001)	favor using 17-item scale
	2	11 items	0.056 (0.020)	
	1	11 items	0.436 (<0.001)	
	2	6 items	0.027 (0.099)	
SF-12 Mental	1	6 items	0.280 (<0.001)	mixed
	2	11 items	0.036 (0.094)	
	1	11 items	0.296 (<0.001)	
	2	6 items	0.021 (0.203)	
SF-12 Physical	1	6 items	0.301(<0.001)	favor using 17-item scale
	2	11 items	0.067 (0.019)	
	1	11 items	0.358 (<0.001)	
	2	6 items	0.010 (0.367)	
TAPES-R	1	6 items	0.691 (<0.001)	favor using 6-item scale
	2	11 items	0.003 (0.463)	
	1	11 items	0.513 (<0.001)	
	2	6 items	0.181 (<0.001)	

Table 5a. Results hierarchical linear regression analysis

Note: data in light grey represents non-significant findings, $p \geq 0.05$

Table 5b. Results from hierarchical logistic (binary or ordinal) regression analysis

Scale	Block	Entry	Change in χ^2 (p-value)	Interpretation
<i>IPAQ-SF</i>	1	6 items	102.71 (<0.001)	favor using 17-item scale
	2	11 items	3.97 (0.046)	
	1	11 items	98.763 (<.001)	
	2	6 items	0.023 (0.0878)	
<i>Fall history (≥ 2 falls)</i>	1	6 items	11.110 (<0.001)	favor using 6-item scale
	2	11 items	5.665 (0.017)	
	1	11 items	2.156 (0.142)	
	2	6 items	14.619 (<0.001)	
<i>Fear of falling</i>	1	6 items	21.825 (<0.001)	favor using 17-item scale
	2	11 items	6.249 (0.012)	
	1	11 items	26.878 (<0.001)	
	2	6 items	1.195 (0.274)	
<i>FoF- related avoidance</i>	1	6 items	14.716 (<0.001)	mixed
	2	11 items	3.243 (0.072)	
	1	11 items	17.208 (<0.001)	
	2	6 items	0.751 (0.386)	
<i>Assistive device use</i>	1	6 items	9.785 (0.002)	favor using 6-item scale
	2	11 items	0.654 (0.419)	
	1	11 items	4.182 (0.041)	
	2	6 items	6.257 (0.012)	

FIGURE CAPTIONS

Figure 1. Flow of participants from 110 initial invites to 59 included data sets

Figure 2. Distribution of mSAFE scores based on level of fear of falling and endorsement of avoidance behaviors.

LLPUs who endorse FoF-related avoidance behaviors, either with a positive response to one-of-two (filled star) or two-of-two (filled square) questions, have significantly higher mSAFE scores than those who do not endorse these behaviors (open circle). However, these questions appear to be insufficient for distinguishing the degree of avoidance, particularly in those with higher levels of FoF, as all individuals in these categories reported multiple endorsements. Similarly, in those with low levels of FoF, mSAFE scores were high both in those who did not endorse FoF-related avoidance behaviors and those that reported multiple endorsements. Collectively, this demonstrates the need for measures such as the mSAFE that can quantify the level of avoidance behavior.

APPENDIX J - MANUSCRIPT PUBLISHED IN ADVANCES IN WOUND CARE

Prosthetic Disuse Leads to Lower Balance Confidence in a Long-Term User of a Transtibial Prosthesis

Noah J. Rosenblatt,^{1,*} Aaron Stachowiak,² and Christopher Reddin²

¹Dr. William M. Scholl College of Podiatric Medicine's Center for Lower Extremity Ambulatory Research (CLEAR), Rosalind Franklin University of Medicine and Science, North Chicago, Illinois.

²Captain James A. Lovell Federal Health Care Center, North Chicago, Illinois.

Residual limb wounds or ulcers are one of the most frequent skin problems reported by lower extremity prosthesis users. Healing often requires prosthesis disuse, which can logically impair physical functioning. However, there are limited data available to support this idea. We report the impact of prosthesis disuse by presenting assessments of balance, gait, physical activity, and balance confidence obtained on a case subject before experiencing a wound and following reintroduction to a well-fit prosthesis after wound-related prosthesis disuse. The case subject was a 76-year-old male who suffered a unilateral, transtibial amputation due to synovial sarcoma 13 years before. After presenting with a history of pain in the area of a chronic skin plaque, he received a punch biopsy, which resulted in 4 weeks of prosthesis disuse followed by 12 weeks of limited use before a final well-fitting socket was received. The following data were collected 24 weeks before the biopsy and 4 weeks after receiving the final well-fitting socket: Berg Balance Scale, L-test of walking, quantitative gait analysis, Activity-specific Balance Confidence Scale, and 1 week of community-based activity. Balance confidence decreased nearly 19%, walking speed decreased by 12%, and steps/day decreased by 19% following ~4 months of prosthesis disuse/limited use; functional measures were not impacted. Lower balance confidence is not trivial as it can lead to activity avoidance and increased fall risk. Interventions to target balance confidence changes following prosthesis disuses may be important to minimize the impact of disuse on physical and mental well-being.



Noah J. Rosenblatt, PhD

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*Correspondence: Dr. William M. Scholl
College of Podiatric Medicine's Center for Lower
Extremity Ambulatory Research (CLEAR), Rosa-
lind Franklin University of Medicine and Science,
3333 Greenbay Road, North Chicago, IL 60064
(e-mail: noah.rosenblatt@rosalindfranklin.edu).

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INTRODUCTION

SKIN PROBLEMS ON the residual limb of the lower limb amputee are common, affecting up to 63% of prosthetic users.¹ Despite the broad etiology of skin problems for lower limb prosthetic users (LLPU), wounds/ulcers are consistently one of the most commonly reported. A 6-year retrospective chart review of cases presenting to an amputee clinic reported pressure ulcers were the most fre-

quent cause of skin problems, accounting for 27% of cases.² In another study, 57% of surveyed individuals reported experiencing a pressure ulcer >1 month before completing a survey.¹

A systematic review on interventions to manage residual limb ulcers due to prosthetic use concluded that prosthetic discontinuance is a viable method to promote healing in severe acute ulcers, particularly in patients

with specific comorbidities that can impact healing such as advanced dysvascular disease or a history of chronic ulceration.³ Indeed 53% of individuals with a history of skin problems self-report a reduction in prosthetic wear time as a result of skin problems.⁴ Logically, prosthetic discontinuance, or significant reduction in wear time, may compromise physical and mental functioning and lead to diminished community participation. In one study, 28% of persons with skin problems reported these problems negatively influenced their ability to perform household activities and 21% reported these problem negatively influenced their ability to engage in social activities.⁴ In a second study, dysvascular, transtibial amputees suffering from ulcers engaged in a 12-week rehabilitation program either after receiving a prosthesis that could be used while the ulcer healed, or after being assigned to prosthesis fitting only after healing.⁵ At the end of the rehabilitation program, a greater proportion of the former group could independently ambulate. However, these are the only studies we are aware of that have considered the impact of prosthesis disuse on functional outcome and activity.

CLINICAL PROBLEM ADRESSED

In this study, we report on the impact of prosthesis disuse on balance, gait, physical activity (PA), and balance confidence of a single transtibial amputee, by presenting assessments obtained before disuse and following reintroduction to his prosthesis.

METHODS

Participant

The case subject was a 76-year-old male (185.4 cm, 100 kg) who suffered a unilateral, transtibial amputation due to synovial sarcoma 13 years before. Information regarding his prosthetic setup and medical history is summarized in Table 1.

Table 1. Prosthetic set-up and medical history

Variable	Description
Prosthetic socket	Total contact
Prosthetic suspension	Harmony vacuum suspension (Otto Bock) Proflex suspension sleeve (Otto Bock)
Liner	3 mm alpha gel
Prosthetic ankle	Empower Ankle (Otto Bock)
Prior medical conditions	History of vertigo (no recent bouts) Severe spinal stenosis (cervical, thoracic, and lumbar) Arthritic knee pain (contralateral limb) Phantom pain Neuropathy (contralateral limb)
History of falls in previous year	None

On July 26, 2018, the participant enrolled in our on-going 24-week randomized control trial (RCT) to evaluate the effects of different exercises on balance confidence. Twenty-three weeks later (on January 4, 2019), he presented to his dermatologist reporting a 6-month history of increased pain just posterior to the fibular head of the residual limb, in the area of a chronic (4 years) skin plaque. As a result of his medical history, a 4 mm punch biopsy of the lesion of the residual limb was taken and the patient was instructed to stop wearing his prosthesis. Approximately 4 weeks later (February 8, 2019), the wound healed enough that the dermatologist cleared the patient to be fit for a new prosthesis, intended to limit irritation posterior to the fibular head. Due to fit issues of the new socket, prosthesis use was limited for the next 9 weeks, at which point (April 11, 2019), the patient returned to the amputee clinic for an appointment and a new socket was ordered to address excess space between the residual limb and current socket. A well-fitting definitive socket was received 3 weeks later.

Protocol

The participant provided written informed consent to participate in the RCT and separate written consent to participate in the follow-up assessment, which fell outside of the time frame of the RCT. The Rosalind Franklin University IRB approved protocols for both the RCT and follow-up study. Only details of the RCT relevant to this case study are presented.

Upon enrolling in the RCT (baseline), the subject completed two performance-based measures of function: the Berg Balance scale (BBS) and L-test of walking. The BBS involves completing 14 balance tasks, graded on a scale of 0–4 (maximum score of 56). The L-test involves getting up from a chair, walking an 8-m path in the shape of an L, and then returning to the seat along the same path⁶ with the time to completion recorded. A quantitative gait analysis was also performed at baseline using standard motion capture methods from which the following gait parameters were calculated for each limb: step time, stride time, step length, and step width; walking speed was calculated for each pass across the walkway. The subject also completed the Activities-specific Balance confidence (ABC) scale, the primary outcome measure of the RCT. The ABC scale is a widely used survey, originally developed by Powell and Myers,⁷ which measures one's perceived ability to maintain balance, while performing 16 activities of daily living on a scale of 0–100%. The scale has previously been validated for lower limb amputees.⁸

After completing baseline measures, the participant was provided a StepWatch 3 activity monitor (modus health, Edmonds WA), which was worn around his prosthesis for 7 days to measure steps/day. He then returned to the laboratory and was randomized to engage in 8 weeks of at-home, seated exercises, not expected to improve balance or balance confidence. Sixteen weeks later (late December 2018), the participant was mailed an ABC scale and activity monitors to use. An additional 6 weeks later, we received the mailed materials with a note that said “As of 1-18-2019 Lost use of prosthetic, walker, crutches, wheelchair only.” Thereafter, we maintained contact until prosthesis use resumed, at which point, we invited him to the laboratory (follow-up) to complete the same tests performed at baseline. Follow-up occurred ~4 weeks after receiving the final well-fit definitive socket (May 29, 2019).

For all gait measures and step counts, which included multiple steps or days of recording, average values and effect sizes (Cohen's *d*) were calculated.

RESULTS

Performance-based measures of function were not meaningfully affected by prosthesis disuse. BBS at baseline was 55/56 and 54/56 at follow-up; L-test of walking required 20.2 s to complete at baseline and 20.7 s at follow-up. Although objective balance measures were unaffected by prosthesis disuse, the subjects' balance confidence score dropped from 79.4 at baseline to 60.9 at follow-up. In addition, several changes in gait were noted (Table 2). Finally, there was a medium-to-large effect of prosthesis disuse on PA with steps/day decreasing from 8258.8 ± 2092.8 to 6698.0 ± 2296.1 ($d = 0.90$).

DISCUSSION

Perhaps the most important change with disuses was the 19-point reduction in balance confidence. This change exceeds the minimum detectable

change of 13 points established for patients with Parkinson's disease.⁹ Although a score of 60.9 at follow-up is consistent with the average of 63.8 reported for amputees,¹⁰ it may also indicate increased fall risk. For example, in a group of older adults, a score of <67 accurately classified fallers 84% of the time.¹¹ The lower level of confidence is concerning in light of the impact that low balance confidence can have on activity. An LLPU may avoid an activity if they lack balance confidence, regardless of whether or not they have the skill to safely complete the activity. Indeed, low balance confidence is a significant predictor of participation in social activities, even after accounting for mobility capability¹²; it is a strong predictor of whether an LLPU can attain a level of walking consistent with a community ambulator¹³; and it is significantly correlated with steps/day in patients with transtibial amputation.¹⁴

The fact that balance confidence and PA decreased, but not functional performance, is not entirely surprising. Balance confidence and BBS are only moderately correlated¹⁵ and the case subjects' baseline abilities were high (his BBS was nearly perfect and L-test time was considerably faster than the average of 32.6 ± 14.9 s reported for LLPU⁶). In addition, baseline PA was considerably higher than the average of 3,000 steps/day reported for LLPU,¹⁶ which may limit the impact of prosthesis disuse. Highly active amputees are able to perform activities without prostheses, although with reduced functional ability,¹⁷ and limiting sedentary behavior may promote better outcomes following reintroduction to the prosthesis.

Although functional measures were not impacted, several gait parameters appear to have changed. Specifically, we observed a reduction of 0.14 m/s in walking speed, which is not trivial. In older adults, the chances of mortality decrease by 12% for every 0.1 m/s increase in self-selected walking speed.¹⁸ Slower walking speed may also increase the amount of time required to complete

Table 2. Summary of gait measures

	Prosthetic Side			Intact Side		
	Baseline	Follow-Up	Cohens' d	Baseline	Follow-Up	Cohens' d
Walking speed (m/s) ^a	1.19 ± 0.04	1.05 ± 0.04	3.5	—	—	—
Stride length (mm)	1389.2 ± 38.2	1310.5 ± 46.5	1.9	1379.4 ± 39.9	1315.7 ± 48.7	1.5
Step length (mm)	704.2 ± 29.4	666.8 ± 25.9	1.3	676.2 ± 25.2	645.8 ± 30.6	1.1
Stride time (s)	1.14 ± 0.03	1.23 ± 0.03	3.0	1.14 ± 0.02	1.22 ± 0.03	3.5
Step time (s)	0.56 ± 0.02	0.60 ± 0.02	2.7	0.58 ± 0.02	0.63 ± 0.02	2.2
Double support time (s)	0.20 ± 0.03	0.23 ± 0.03	1.1	0.17 ± 0.02	0.18 ± 0.02	1.0
Single support time (s)	0.75 ± 0.03	0.81 ± 0.03	2.4	0.75 ± 0.06	0.83 ± 0.04	1.2
Step width (mm)	168.1 ± 33.7	184.9 ± 41.2	0.5	164.2 ± 47.5	184.1 ± 54.6	0.4

^aSpeed is listed under prosthetic side only, but is calculated independent of side.

daily activities, which may in turn limit the number of activities that are performed. Accordingly, a reduction in walking speed may reinforce any negative effect of lower balance confidence on PA.

The extent to which changes in balance confidence, gait, and/or PA would persist over time is unclear. At follow-up testing, the participant reported “getting tired quickly” (fatigue), which is a known barrier to activity.¹⁹ Presumably, through continued prosthesis use, this barrier would reduce and PA would increase. Nonetheless, any activity restriction for this participant could significantly impact his mental health and quality of life. At the start of the study the subject took pride in hobbies such as independently sailing across Lake Michigan (despite having to walk long ramps to get to the dock). It is hard to imagine that the process of being confined to a wheelchair and then having reduced confidence to safely engage in such hobbies would not promote feelings of depression and diminished quality of life. Future work should evaluate the impact of disuse on mental health. Even if mental health were not impacted, changes in PA are still concerning, given that inactivity may be the mediating factor between low balance confidence and increased fall risk.²⁰

Views on limiting and/or addressing impact of prosthesis disuse

Reducing the risk of wounds or ulcers can clearly prevent disuse, and reducing the time of prosthetic disuse, should wounds occur, can minimize its impact. More directly, therapies to address low balance confidence and activity avoidance may be prudent.

Prosthetic technologies allowing users to accommodate to diurnal fluctuations in residual limb volume that contribute to poor fit and abnormal intrasocket pressures may reduce the risk of ulceration. Elevated vacuum suspension (EVS) uses negative pressure to tightly anchor the prosthesis to the limb and has been shown to limit fluctuations in limb volume,²¹ reduce peak socket pressures,²² and improve socket fit and comfort.²³ However, not everyone responds well to EVS²⁴ and, despite using a socket with EVS, our case subject still faced issues. Commercially available adjustable prosthetic sockets offer another solution to address fit issues, allowing the user to directly tighten or loosen the socket as needed and may help reduce the risk of wounds. However, these devices have been studied considerably less than EVS.

In the event that wounds do occur, the negative pressure used in EVS may promote healing. In-

deed, certain users with active wounds can continue prosthesis use and maintain activity levels even during healing,^{5,25} minimizing time of disuse. The effects of disuse may also be minimized by reducing the time required to fabricate a well-fitting socket. The case subject waited 3 weeks to receive a socket that corrected for the fit issues, which contributed to his wound (after using an ill-fitting socket for 9 weeks). 3D printing is a technology with promise to provide rapid, inexpensive production of multiple sockets that can be easily and quickly adjusted throughout the fitting process. While initial safety of 3D printed sockets has been reported,²⁶ additional work is needed to understand its long-term usability.

With regard to rehabilitation methods to address balance confidence, it has been stated that, “Balance confidence is not directly addressed during prosthetic rehabilitation despite evidence that [it] is low. ...Improvements in balance confidence may require [a more] specialized or targeted intervention.”¹² Based on studies from intact older adults (see review by Rand *et al.*²⁷), such interventions should be multifaceted and include exercises to target balance and gait, as well as components of balance self-efficacy (confidence) training. Indeed, this is the basis of the experimental intervention that is being tested in our RCT (see Bourque *et al.*²⁸ for details). We believe such an intervention (and variants thereof) may be particularly important, immediately following (and during) prosthetic disuse.

SUMMARY

In conclusion, balance confidence decreased nearly 19%, walking speed decreased by 12%, and steps/day decreased by 19% for our case subject following ~3 months of prosthesis disuse/limited use; functional measures were not impacted.

TAKE HOME MESSAGE

Interventions to target balance confidence changes following prosthesis disuses may be important to minimize the impact of disuse on physical and mental well-being.

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AUTHOR DISCLOSURE AND GHOSTWRITING

No competing financial interests exist.

ABOUT THE AUTHORS

Noah J. Rosenblatt, PhD, earned his PhD in biomedical engineering and has been an Assistant Professor with the Center for Lower Extremity Ambulatory Research since 2015. He is the principle investigator for the RCT to improve balance confidence in LLPU and is focused on research to improve outcomes in this population. **Aaron Stachowiak, MD**, Physiatrist at the Captain James. A. Lovell

Federal Health Care Center (FHCC), where he runs the weekly amputee clinic within the Department of Physical Medicine and Rehabilitation. **Christopher Reddin, PhD**, registered nurse as well as a recently retired Captain of the US Navy. His most recent appointment with the Navy was as a Staff Psychiatric Nurse Practitioner within the Department of Outpatient Mental Health at the FHCC. He is currently in private practice in the Chicago area.

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ABBREVIATIONS AND ACRONYMS

ABC = activity-specific balance confidence
 BBS = Berg Balance Scale
 EVS = elevated vacuum suspension
 LLPU = lower limb prosthesis user
 PA = physical activity
 RCT = randomized control trial

APPENDIX K – MANUSCRIPT PUBLISHED IN TRIALS

STUDY PROTOCOL

Open Access



Combining physical therapy and cognitive behavioral therapy techniques to improve balance confidence and community participation in people with unilateral transtibial amputation who use lower limb prostheses: a study protocol for a randomized sham-control clinical trial

McKenzie O. Bourque¹, Kristin L. Schneider¹, John E. Calamari¹, Christopher Reddin², Aaron Stachowiak², Matthew J. Major^{3,4}, Chad Duncan³, Ranjini Muthukrishnan⁵ and Noah J. Rosenblatt^{6*} 

Abstract

Background: Low balance confidence is a prevalent yet overlooked issue among people who use lower limb prostheses (LLP) that can diminish community integration and quality of life. There is a critical need to develop rehabilitation programs that specifically target balance confidence in people who use LLP. Previous research has shown that multicomponent interventions including cognitive-behavioral therapy (CBT) techniques and exercise are feasible and effective for improving balance confidence in older adults.

Therefore, a cognitive behavioral–physical therapy (CBPT) intervention was developed to target balance confidence and increase community integration in people who use LLP.

Methods/design: This randomized control trial will recruit 60 people who use LLP with low balance confidence. Participants will be randomized to the CBPT intervention condition or control condition.

Discussion: The trial is designed to test the effects of the CBPT intervention on balance confidence and functional mobility in lower limb prosthesis users by examining self-reported and objective measures of community integration and quality of life. The trial will also examine the relationship between changes in balance confidence and changes in community integration following participation in CBPT intervention. Additionally, through participant feedback, researchers will identify opportunities to improve intervention efficacy.

Trial registration: ClinicalTrials.gov, [NCT03411148](https://clinicaltrials.gov/ct2/show/study/NCT03411148). Registration date: January 26, 2018.

Keywords: Amputee, Community integration, Activity, Fear avoidance, Virtual reality, Gaming

* Correspondence: noah.rosenblatt@rosalindfranklin.edu

⁶Dr. William M. Scholl College of Podiatric Medicines' Center for Lower Extremity Ambulatory Research (CLEAR), Rosalind Franklin University of Medicine and Science, 3333 Green Bay Road, North Chicago, IL 60064, USA
Full list of author information is available at the end of the article



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Background

Low balance confidence, defined as low self-perception in one's ability to maintain balance while performing specific activities, is a prevalent, yet overlooked issue among people who use lower limb prostheses (LLP). In a cohort of 435 community-dwelling individuals with lower limb amputation who had been living with LLP for at least 6 months, 65% reported levels of balance confidence below the threshold at which intervention is advocated for able-bodied adults [1, 2]. Low balance confidence can negatively impact community participation. In a cross-sectional study, low balance confidence was a significant predictor of social participation, even after accounting for mobility capability and other prosthesis-related characteristics [3]. Moreover, balance confidence at discharge from rehabilitation following a first amputation is a predictor of social participation 3 months after discharge [4], with low social participation significantly limiting quality of life [5, 6]. Low balance confidence is also associated with lower levels of physical activity [7].

Among people who use LLP, low balance confidence may be, in part, independent of functional ability; balance confidence and performance-based measures of balance are only moderately correlated [8] and, following discharge from rehabilitation, persons with a lower limb prosthesis continue to improve walking ability, while balance confidence does not continue to improve [4], suggesting the two may be independent. Accordingly, rehabilitation efforts that only target function may not necessarily improve balance confidence or increase community integration. In a 2014 study comparing two treadmill-based gait-training protocols for people who use LLP, participants demonstrated improved walking ability one month post-intervention (with no effect of intervention type) but reported no improvement in balance confidence [9]. Interventions that aim to improve community integration by alleviating restrictions due to low balance confidence may require multicomponent interventions that simultaneously address both physical ability and balance confidence.

A systematic review of 46 randomized control trials (RCTs) [10] and a separate meta-analysis of 24 RCTs [11] to improve balance confidence concluded that implementation of multicomponent interventions is feasible and effective in intact populations, particularly for persons with poor balance confidence. In most multicomponent interventions, physical abilities were addressed using physical therapy to target balance, gait, or strength; efficacy training (e.g., mastery experiences) increased the effects of physical therapy [11]. A major advantage of supplementing physical therapy exercises with cognitive behavioral therapy (CBT) strategies is that avoidance of activities can be directly targeted while

addressing balance confidence. Previous interventions that have supplemented exercises with CBT demonstrated improvements in self-efficacy and increased activity up to 6 months post-intervention [11–13]. Supplementing exercises that specifically address balance ability with CBT strategies to address balance confidence may produce similar improvements in activity and self-efficacy in people who use LLP.

There is a critical need to develop and implement rehabilitation programs that specifically target balance confidence in order to increase community integration for people who use LLP. There are no current interventions to address balance confidence in this population. Therefore, we have developed a combined cognitive behavior and physical therapy (CBPT) intervention in which a behavioral therapist works in conjunction with a physical therapist to address underlying cognitions and physical skills that promote low balance confidence. Of particular note, the physical therapist will implement exercise in the intervention through the use of virtual reality (VR) games in the C-Mill Balance Suite (Motek; Netherlands). The games are displayed to the player on a 65-inch high-definition television screen at the front of the C-Mill, which is a 4 × 1 m (length × width) instrumented treadmill. Virtual reality games, in contrast to more traditional modalities, are used for several reasons. VR games provide a means to standardize progression based on performance and the ability to target multiple domains in few tasks while including a cognitive component, they can be adjusted for difficulty depending on the participants' skill level, they encourage repetition of tasks and provide direct feedback in the form of a score, all of which promote motor learning [14, 15]. VR games are at least as effective as traditional physical therapy at improving balance and balance confidence in intact populations [16–18] and, moreover, are fun and motivating [14, 19, 20].

Specific aims

Aim 1 (primary analyses)

Compare the effects of the combined cognitive behavior and physical therapy (CBPT) intervention condition versus a sham control condition on balance confidence and performance-based measures of balance and functional mobility in lower limb prosthesis users.

Hypothesis 1a: Participants receiving CBPT intervention will demonstrate improvements in balance confidence over time compared to participants in the control condition.

Hypothesis 1b: Performance-based measures of balance will improve after CBPT intervention.

Hypothesis 1c: Performance-based measures of functional ability will improve after CBPT.

Aim 2 (secondary analyses)

Compare the effects of CBPT intervention versus a sham control on self-reported and objective measures of community integration and on quality of life.

Hypothesis 2a: Participants receiving CBPT intervention will self-report and objectively demonstrate increased community integration over time compared to participants in the control condition.

Hypothesis 2b: Participants receiving CBPT intervention will demonstrate improvements in quality of life compared to participants in the control condition.

Aim 3 (secondary analyses)

Examine the relationship between changes in balance confidence and changes in community integration following participation in CBPT intervention.

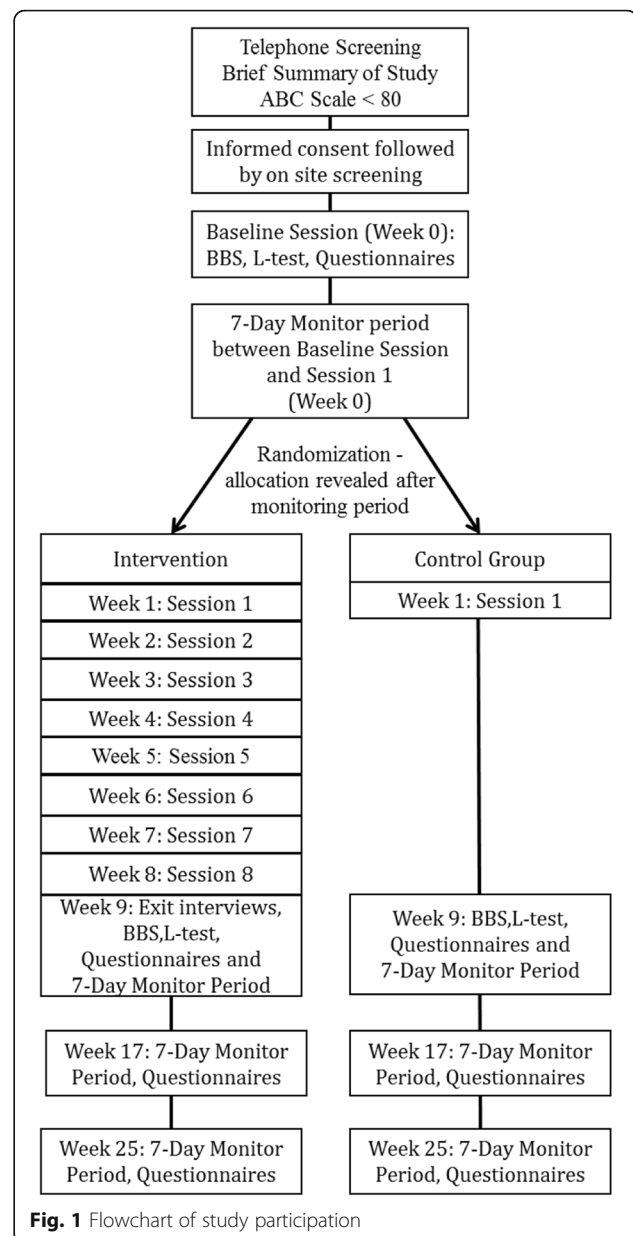
Hypothesis 3: For participants in the intervention condition, change in balance confidence from 0 to 25 weeks will be directly correlated with changes in community participation (0 to 25 weeks).

Aim 4 (exploratory analyses)

Identify opportunities to improve intervention efficacy. This exploratory aim involves key informant interviews to identify themes related to residual barriers to social activity and mobility, the CBPT strategies that were deemed most effective, and additional strategies to address social participation and mobility barriers (e.g., behavioral activation, different physical therapy strategies).

Methods/design**Study design**

Sixty people who use LLP with low balance confidence will be randomized to the CBPT intervention condition or control condition (Fig. 1). Participants will be assigned to one of two randomization plans based on etymology of amputation: vascular causes (e.g., diabetes, peripheral vascular disease) or non-vascular causes (e.g., trauma, osteomyelitis). For each plan, a block randomization will be used with a block size of 4 to ensure balance among the exercise groups throughout the study. The randomization plan will be developed by a researcher uninvolved with the project using www.randomization.com and sealed envelopes will be used to conceal the randomization schedule until enrolled participants are assigned to a group. For scheduling purposes, to ensure that the necessary clinicians are on site at the time that group assignment is revealed to the participant (at visit occurring ~1 week following enrollment), envelopes will be opened after the participant leaves the university after completing the enrollment visit.



Participants in the intervention condition will complete eight weekly training sessions that include a virtual reality active gaming component (i.e., PT component), with CBT strategies that increase balance confidence by addressing subject-specific avoidance behaviors and maladaptive cognitions. Each session will last approximately 1.5 h. Participants in the control condition will complete a series of at-home upper-body seated exercises during this 8-week period after being taught by a physical therapist how to perform the exercises. The intention of the sham control is to blind participants to the study group. At the start of the study and at 8 (post-intervention), 16, and 24 weeks following group allocation, participants will complete survey-based outcome

measures and activity monitoring. At baseline and post-intervention, participants will complete performance-based assessments of balance and of functional mobility. Outcomes measures are described below.

To minimize loss to dropout between baseline and final follow-up, research coordinators will routinely contact participants by telephone and email to maintain engagement in order to maximize participant adherence. Adherence will be quantified based on number of study visits attended and frequency of attendance. If a participant wishes to drop out of the study, they will be queried as to their reasons for doing so and every attempt will be made to address their concerns and to obtain the minimum amount of data necessary to address hypotheses related to the primary outcome (i.e., self-reported measures at 0 and 25 weeks).

Setting and ethics approval

The study will be performed at the Human Performance Laboratory at Rosalind Franklin University of Medicine and Science, North Chicago, IL, in conjunction with investigators at the Captain James A. Lovell Federal Health Care Center, North Chicago, IL, Edward Hines Jr. Veterans Administration Hospital, Hines, IL, and Northwestern University, Chicago, IL. The protocol described herein has already received institutional review board (IRB) approval from all study sites. Any modifications to the approved protocol or reporting of adverse events will be submitted to the IRB by the study PI according to published IRB policies.

Participants

Participants will be veterans recruited directly from local VA Medical Centers or civilians/veterans recruited from the community. Recruitment at local VA hospital centers will take place through a two-step process. In step 1, medical records will be reviewed for persons having a unilateral transtibial amputation and prescribed prosthesis at least 6 months prior. Veterans found through medical record search will be sent a form letter indicating they may qualify for a study and should respond to the letter only if interested in additional information. The letter will ask them to complete and return a copy of the Activities-specific Balance Confidence (ABC) scale. In step 2, participants with ABC scores less than 80% will be called by research coordinators to determine eligibility through the use of an IRB-approved script. Recruitment of civilians/veterans from the community will primarily take place through flyers posted at local prosthetic clinics, support groups, and physical therapy offices.

All participants must meet the following criteria: at least 18 years of age, unilateral transtibial amputation, at least 6 months experience with using a definitive

prosthesis, an ABC score less than 80. Participants will be excluded for open wounds on weight-bearing surfaces, inability to stand unassisted and weight-shift for 2.5 min (i.e., inability to perform the CBPT intervention), ill-fitting or ill-functioning prosthesis as determined during a screening with the study prosthetist, prohibited by primary care physician or research physician to engage in mild exercise, history of neurodegenerative diseases and stroke, or currently receiving physical therapy. No other concomitant therapies or interventions are excluded from the study and all other standards of care are permitted. Screening and all other study-related activities will occur only after the participant provides written informed consent, which will be taken by a study team member.

It is expected that 70 participants will be recruited in order to obtain a total of 60 eligible participants (30 intervention and 30 control participants), assuming a 15% drop-out rate. Using G*Power 3.1, a sensitivity analysis (with regard to Hypothesis 1a) was conducted, specifying a power of 0.80, an alpha of 0.05, and an average correlation of observations of 0.50. According to the analysis, with 30 participants in each group we will be able to detect a small to medium effect ($f = 0.152$) of intervention on ABC score over time with this design, which is consistent with the size of effect observed for older adults [10, 11]. We will have similar power for all hypotheses in Aim 2, which use the same analysis as Hypothesis 1a; we will have power to detect a medium effect size ($d = 0.46$) for Hypothesis 1b and a correlation of $r \geq 0.42$ for Hypothesis 3.

CBPT intervention

Below is a summary of the primary tasks undertaken during each of the eight sessions.

Session 1: The initial goal of session 1 is to introduce the participant to the eight-session CBPT intervention and develop rapport. The behavioral therapist will deliver psychoeducation on how the use of the video games can improve balance as well as how balance confidence can impact behavior. Participants' baseline physical skills on active video games will be assessed using two games (Trash Bin and Italian Alps; see Table 1 for a full description of the games) and the behavioral therapist will introduce the importance of goal setting in behavioral change. The behavioral therapist will introduce the *Behavior Recording Form for Prosthesis Use*, which is a standard behavior record with modifications to assess activity avoidance due to prosthesis concerns. Between-session assignment includes completion of the *Behavior Recording Form for Prosthesis Use* (Additional file 1).

Table 1 Description of virtual reality games

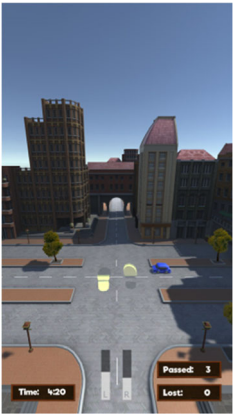
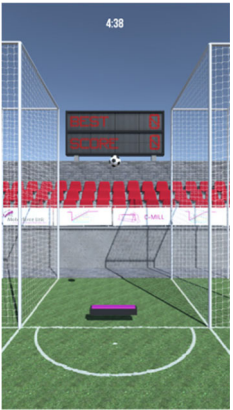
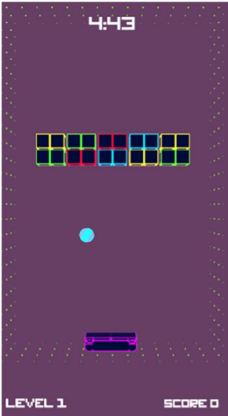
Name of game	Description
Trash Bin Game	The player must shift their center of pressure (COP) left or right to move a trash bin to catch falling waste, which only falls vertically. The difficulty of the game can be increased by increasing the rate at which paper falls. The game can be played while shifting COP with feet in place, while side-stepping or while walking by adjusting spatiotemporal gait parameters. A screen capture is shown below 
Traffic Jam	The goal of Traffic Jam is to allow cars, moving in two directions, to pass through an intersection, which is blocked when standing on both legs. The intersection clears by unloading one limb and shifting weight over the other limb; if cars are in the right lane then weight must be shifted to the left limb (<i>left yellow foot print</i> will disappear) and vice versa to clear the intersection. Traffic Jam focuses on limb loading and unloading and is only played while keeping both flat on the ground. A screen capture is shown below 
Playing Soccer	Playing Soccer is initially played while shifting weight side to side and standing in place. Like the Trash Bin Game it can also be played shifting weight by side-stepping or by altering stepping parameters (step length, step width, and stance time) while walking. However, the side-stepping and walking options are not presented until later in the intervention. In all modes of the game, balls are dropped from the sky and fall downwards on the screen and the goal is to continuously bounce the ball off of a paddle, which can be moved by side-to-side shifting of the COP. The ball can ricochet off of side nets. For every ten bounces in a row an additional ball falls. Each gaming mode (standing, side-stepping, or walking) has three levels of difficulty defined by the length of the paddle (decreasing the length of the paddle increases difficulty). A screen capture is shown below 

Table 1 Description of virtual reality games (*Continued*)

Name of game	Description
Playing Arkanoid	Playing Arkanoid is first played while standing in place. It can also be played in side-stepping mode or walking mode, but these modes are not shown until later in the intervention. In Playing Arkanoid, a ball is dropped from the sky and falls downwards on the screen; the goal is to continuously bounce the ball off of a paddle so that the ball hits and breaks a series of bricks at the top of the screen; after hitting the bricks the ball again falls down to the paddle. The paddle can be moved by shifting the COP. The ball can bounce off of side walls. A screen capture is shown below 
Forest Walk	Forest Walk is played only in walking mode. A forest scene is projected on the treadmill surface and animals and other objects appear and travel with the speed of the treadmill belt; the goal is to make on-line adjustments to the gait pattern in order to avoid stepping on the animals or other objects while intentionally stepping on projected stars and soccer balls; points are awarded for stepping on the proper objects and points are subtracted for stepping on all other objects. The game targets gait adaptability. An overhead view of the treadmill is shown below 
Italian Alps	The Italian Alps game is only played in walking mode. In Italian Alps, the player “pushes” a cart through a street and must collect ingredients to make a pizza (see bar across the bottom horizontal bar) to make a pizza while avoiding crashing into other objects such as flower boxes. The motion of the cart tracks the center of pressure (COP) and the flow of the scene is dictated by walking speed. A screen capture is shown below 

Session 2: Session 2 will begin with a brief participant check-in regarding health and any falls during the prior week to ensure that the participant is safe to continue physical therapy. Next, the participant will be introduced to the four new video games not used during

session 1 which will be played during the course of the intervention (Table 1). After completing the video games, the behavioral therapist will review the completed *Behavior Recording Form for Prosthesis Use* with the participant to gain an understanding of the

participant's activity restriction and avoidance behavior. Specific behavioral goals will be developed with the participant. The behavioral therapist will review the *Breathe to Relax* form with the participant, which teaches diaphragmatic breathing for relaxation (Additional file 2)

Between-session assignments will include completion of the *Behavior Recording Form for Prosthesis Use*, reviewing the *Breathe to Relax* form, as well as practice the breathing skill.

Session 3: After a brief check in to ensure the participant is well, the participant will play all four video games from Session 2. The behavioral therapist will then conduct an in-depth review of between-session assignments to continue skill building in behavior recording and goal setting. Additionally, the behavioral therapist will review and practice diaphragmatic breathing with the participant as well as refine initial behavioral goals. The behavioral therapist will then introduce systematic exposure to the participant in the context of reducing fear and changing behavior. This will be followed by an exposure exercise. The exposure exercise will be developed through a collaborative process between the behavioral therapist and the physical therapist based on an emerging understanding of the participant's fear exposure hierarchy and physical ability. A fear exposure hierarchy is composed of a series of graded tasks based on level of provoked fearfulness. An example of an exposure exercise is asking a participant that avoids reaching for an object above their head to practice reaching up high. Exposures will be conducted in the lab under the guidance of the behavioral therapist as well as at home in between sessions.

Between-session assignments will include completion of the *Behavior Recording Form for Prosthesis Use*, practicing *Breathe to Relax*, and an at-home exposure exercise.

Sessions 4 through 7: The physical therapist will continue to work on games with the participant. The behavioral therapist will continue to use and review previously introduced procedures, including physical skill acquisition, during physical therapy intervention, behavior recording, diaphragmatic breathing, and community-based exposure exercises.

Between-session assignments continue to include completion of the *Behavior Recording Form for*

Prosthesis Use, using the *Breathe to Relax* form, and performing an at-home exposure.

Session 8: The final session will focus on summarizing the participant's behavior change goals and progress made towards completing goals, as well as physical progress in the component and any learned behavioral strategies. The behavioral therapist will discuss strategies to continue to further gains as well as strategies for preventing relapse.

Key informant interview

At the end of the CBPT intervention (or at drop-out), participants who received the intervention will complete a 30–60 min, recorded, individual interview with investigators to discuss their experience with the intervention. A semi-structured interview will be used to assess the following areas.

Intervention experience

Participants will be asked to discuss what they liked and disliked about the intervention, their preference for the length of the intervention and the length of the individual sessions, the reasons they attended or missed sessions, their thoughts on combining the CBT and PT strategies, and the role of the CBT and gaming exercises in addressing their balance confidence and activity restriction. We will also obtain feedback on the CBT forms and assignments, including information on comprehension, burden, and usefulness for addressing balance confidence and activity restriction.

Barriers to participation

Participants will be asked about barriers to integration that they felt were not addressed during the intervention, as well as what the intervention could include to address those barriers.

Opinions on recruitment

Participants will be asked about advertising messages and recruitment venues that would increase the appeal of participating in similar future studies.

Training and oversight of behavioral therapist and physical therapist

Two advanced, clinical psychology doctoral students will be trained by two licensed clinical psychologists to deliver the CBT portion of the intervention. The behavioral therapists will review the treatment manual, which will be followed by four 2-h training sessions covering balance confidence, CBT, the integration of CBT into a PT setting, and understanding the psychological and physical health sequelae of a leg amputation. Two training sessions will focus on the delivery of the CBT strategies.

This will include a review of CBT theory and specific CBT strategies used to address balance confidence and activity restriction. In addition, behavioral therapists will role-play the delivery of the CBT strategies to ensure intervention fidelity and to provide feedback on adherence of the intervention protocol. Potential problems with the delivery of the CBT content will be discussed (e.g., participant fails to routinely complete assignments).

Once the intervention begins, behavioral therapists will receive supervision by licensed clinical psychologists. Supervisors will listen to audio recordings of the first eight sessions for each behavioral therapist and provide corrective feedback; thereafter, 10% of sessions will be reviewed. The behavioral therapists will also attend weekly supervision meetings to discuss their participant's progress and ensure fidelity to the intervention. Behavioral therapist and auditor checklists for each session will be used to ensure that treatment objectives for each CBPT session are met. The behavioral therapist will complete the behavioral therapist checklist after each session. A random selection of audio-recorded sessions for each participant will be audited by supervisors to monitor treatment fidelity. They will complete the appropriate auditor checklist. When a session is reviewed with less than 85% of treatment-specific objectives met, supervisors will remediate training as needed. This process will continue through all treatment waves so that drift can be swiftly corrected.

The research teams' senior licensed physical therapist will train a physical therapist to complete the PT components of the intervention. After reviewing the training manual, the sessions will include training on the operation system used for administering physical therapy exercises and all safety features in the laboratories. The physical therapist will also learn how to recognize adverse events, including excessive exertion, and be taught to monitor and assess vital signs throughout the intervention to avoid excessive exertion. Most importantly, the physical therapist will be instructed on how to regress and progress the level of difficulty for each game following the protocol.

Sham-control condition

Participants assigned to the control condition will be introduced to three exercise modules (Modules A–C) that include seated exercises to improve core and arm strength and flexibility. All of the exercises are demonstrated to the participant by a physical therapist at the initial session. Participants will be provided a manual with thorough descriptions and visual aids of the seated exercises. Some of the exercises include use of a resistive (plastic air-filled) ball, which will also be provided to the participant. Participants will be instructed to start with

Module A and continue for weeks 1–3, followed by Module B for weeks 4–6, and to finish with Module C for weeks 6–8. Participants will be told to follow the modules at their own pace. Each module includes approximately eight exercises that take 15–20 min to complete and participants will be told to work on the exercises three days per week. Participants will be provided a worksheet to record exercise days. Participants will be contacted by phone every 2–3 weeks during the 8-week intervention period to maintain engagement and encourage completion of the follow-up assessments.

The control is intended to account for a potential placebo effect and is considered a sham-control in that none of the exercises target lower extremity strength or flexibility, which is more likely to induce functional improvements and promote balance confidence during weight-bearing activities.

Outcome measures

Outcomes will be collected before the start of the intervention (baseline) and again at 8 weeks (post-intervention), 16 weeks, and 24 weeks following group allocation.

Balance confidence (primary outcome measure)

Balance confidence will be measured through the Activities-specific Balance Confidence (ABC) scale. The scale asks participants to rate their level of confidence in completing 16 complex functional tasks without losing balance [21]. It has strong reliability (ICC = 0.91), internal consistency (Cronbach α = 0.95), and good construct validity in samples of older adults with fear of falling [22]. The ABC scale has also been validated to assess balance confidence in individuals with lower limb amputations [1].

Community integration

The following measures will be used to quantify community integration (secondary outcomes).

Activity monitoring

Participants will receive a SmartWatch3 Activity Monitor (SAM; Modus Health, WA, USA), which records stride count data for every minute of use, and a QStarz BT-Q1000XT (Qstarz International, Taipei) GPS travel recorder, which records a participant's longitude, latitude, local time and date, and position every 10 s. The SAM and GPS will be worn for one week on the prosthetic pylon and then returned in a pre-paid envelope. Community integration will be assessed as the average number of steps/day, average number of steps/day taken outside the home, and total time spent outside the home per day. The individual who will link the GPS and activity monitor data to calculate steps/day as well as steps/day taken outside the home and total time spent outside

the home per day will only be sent coded data so as to be blinded to the group inclusion.

Community Reintegration of Service members

Community Reintegration of Service members (CRIS) measures activity and participation with three subscales, extent of participation, perceived limitation, and participation satisfaction. The first two of the three scales are included in this study. The extent of participation scale evaluates the frequency of engaging in specific activities using seven-point scales (e.g., “In the past two weeks on average, how often did you engage in recreational activities, not including watching TV?”). The perceived limitation scale uses seven-point scales to evaluate self-perceived limitations in participation (e.g., “I avoided going to crowded places such as the mall of community gatherings”). The CRIS has been validated in a sample of injured veterans [23].

Short-Form Health Survey (SF36)

The SF36 consists of 36 questions that measure eight dimensions of health-related quality of life [24]. Three subscales, role limitation due to physical health problems, social functioning, and role limitations due to emotional problems, will be separately examined as secondary outcomes to assess community integration.

Frenchay Activity Index

The Frenchay Activity Index (FAI) is a 15-item behavioral scale that primarily measures social participation and daily activities (i.e., domestic/chores, work/leisure, and outdoor activities) [25]. Frequency of participation in activities over the last 3–6 months is rated on a four-point scale resulting in a single summary score, ranging from 0 (inactive) to 45 (highly active). The FAI is a valid and reliable measure among users of a LLP (ICC = 0.79) [26]. We will include the measure based on its association with the ABC scale in users with a LLP [4].

Additional secondary outcomes include quality of life and functional ability as described below.

Quality of life

The Well-being scale of the Prosthetic Evaluation Questionnaire (PEQ) will be used to assess quality of life (QoL) [27]. The PEQ is a survey that was developed to quantify function and prosthesis-related QoL for persons with lower limb amputation. The user marks a visual analog scale with two anchor points to respond to the following: “Over the past four weeks rate”...1) “How satisfied have you been with how things have worked out since your amputation” (anchors “extremely dissatisfied” and “extremely satisfied”)? and 2) “Your quality of life” (anchors “worst possible life” and “best possible life”). The simplified assessment allows participants to easily

provide a summary of experiences by essentially considering QoL as unidimensional. This particular scale has good consistency (Cronbach $\alpha = 0.83$) and reliability (ICC = 0.89) [28].

Functional abilities

The Berg Balance Scale (BBS) and L-test of walking will be used to measure functional abilities. Blinded assessors with prior training in administering these measures will assess performance.

Berg Balance Scale: This test requires participants to complete 14 tasks of increasing difficulty beginning with sit-to-stand and progressing to unipedal stance. It is a well-established outcome measure initially designed to assess balance in older adults [29] and has been validated for persons with lower limb amputation [8]. A blinded assessor who is unfamiliar with the study protocol will perform the assessments at baseline and follow-up.

L-test: Participants rise from a chair without armrests, walk 3 m, turn right, walk 7 m, turn around and trace their path back to the start. The time to complete the task is recorded. The test has strong reliability (ICC = 0.98) and convergent validity ($r = 0.93$ with the Timed-up-and-Go test (TUG) [30]). The L-test is better than TUG at distinguishing changes in walking ability of fit, younger LLP users and it is as strong a predictor of social participation as is balance confidence [4]. The same blinded assessor who conducts the Berg Balance Scale will conduct the L-test.

Data management and sharing

Data collection methods include the use of: 1) commercially available step count monitors and GPS trackers; 2) completion of pen-and-paper versions of validated clinical surveys; 3) scores on validated performance-based functional tests of balance. The methods for managing each type of data are nearly identical. Specifically, when a potential participant arrives at a study site to obtain informed consent, they will be assigned a study ID number that contains no identifiable information. Should that participant enroll in the study, then all data will be labeled and referenced only with the study ID number. For example, data from the monitors will be downloaded onto password-protected computers, assigned the appropriate ID, and then analyzed offline. All pen-and-paper data will only have ID numbers listed on them and no identifiable information (e.g., participant name) to ensure confidentiality. A single list linking names and codes will be kept on a password-protected computer locked in the PIs laboratory. All performance based data and pen-and-paper based outcomes data will be entered into an IRB-approved secure on-line data collection tool,

Qualtrics, using the appropriate subject ID. Summative scores from Qualtrics will then be entered into electronic files on password-protected computers to further ensure confidentiality. De-identified data on Qualtrics can be shared among all research team members.

The study PI will periodically check the data values to ensure they are within range and will verify entries based on the original pen-and-paper versions, which will be stored in locked cabinets in the PI's laboratory to further ensure confidentiality. All data will be stored for no less than 3 years following submission of the final financial report. A separate data monitoring committee is not required by the IRB or funding source for this study. However, the Human Research Protection Office (HRPO) of the US Army Medical Research and Development Command can perform an on-site audit at any time. To ensure confidentiality, information about an enrolled participant will only be shared with team members unless instructed otherwise by the HRPO.

While the final dataset will be stripped of identifiers prior to release for sharing, there remains the possibility of deductive disclosure of subjects given the somewhat small number of persons with transtibial amputation in the Chicago-land VHA system meeting the inclusion criteria of the study. Thus, we will make the final research data (both the raw and processed data) and any relevant documentation available to users only under a data-sharing agreement requiring investigators to commit to: 1) using the data only for research purposes and not for purposes of identifying participants; 2) properly securing the data; 3) destroying or returning the data after analyses are completed; 4) an agreement to share any new data sets resulting from the initial sharing agreement. The research and clinical community will be made aware of the data when the study results are presented at scientific meetings and in final publication form.

Study administration

This trial will not include a coordinating center nor a Trial Steering Committee and there is no Stakeholder and Public Involvement Group involved. The study PI will undertake all administrative oversight, aside from that provided by the local IRB. He will have regular meetings with all investigators to discuss problems as they arise as well as progress of the study. The study PI will work with a study coordinator to identify potential recruits and consent will take place by any of the listed investigators on the study.

Analysis plan

To test Hypothesis 1a we plan to use a 2 (group) $\times$ 4 (time point) mixed ANOVA to examine if there are significant differences in changes in ABC scores between the groups (i.e., an interaction effect), accounting for any

missing data. In the event of a significant interaction, a post-hoc paired *t*-test will be used to compare ABC scale in the intervention group at 0 and 25 weeks and independent samples *t*-test to compare ABC scale between groups at 25 weeks.

To test Hypotheses 1b and 1c we will use a paired *t*-test to compare BBS scores and L-test times pre- and post-intervention. H1b and c do not compare time-related changes in performance between groups as they are only intended to assess the immediate effects of intervention.

The same analyses from Hypothesis 1a will be used to test all hypotheses in Aim 2. For Hypothesis 2a, a group $\times$ time interaction on self-reported community participation measures (CRIS, FAI, SF36 scales) and objective measures from the activity monitors will be tested. A false-discovery rate correction method will be used to minimize the likelihood of type I errors. For Hypothesis 2b, an interaction on the QoL score will be tested. In the event that H2a is not supported, alternative measures to assess integration will be considered.

To test Hypothesis 3 changes in ABC scores (0 weeks to 25 weeks) will be correlated with changes in self-reported and objective measures of community participation. A false-discovery rate correction method will be administered to minimize the likelihood of type I errors. In the unlikely event that Hypotheses 1a and 2a are not supported, this would not exclude the possibility of an association between subject-specific changes in confidence and participation. In such a case, a significant correlation would suggest that improving balance confidence can increase participation, but for optimum effectiveness of the intervention, one should only train individuals who are most likely to respond to the intervention (show large increase in ABC scores). As an initial step to identify commonality among "responders" we would employ a suite of supervised learning techniques (e.g., cluster and canonical correlation analysis) to explore multidimensional relationships among responses to individual items on the ABC, BBS, CRIS, and SF36.

To analyze intervention efficacy, the interviews will first be transcribed verbatim. After 15 interviews, all investigators will review the transcripts to generate an initial list of codes. After five additional interviews, they will again re-view transcripts to assess whether new codes emerged. If saturation is not reached after 20 interviews, another five participants will be interviewed and saturation will be reassessed. Once saturation is reached, lead investigators will review all transcripts to generate an initial list of codes using a content coding framework. The creation of the coding framework will begin by the identification of anything that participant's mention related to the CBT strategies, the gaming exercises, activity restriction, or fear of falling/balance

confidence. From this broad coding framework, responses will be sorted according to the themes. Brief descriptions of final codes will be created. A lead investigator will then meet with research assistants to discuss the coding structure. Research assistants will code three transcripts, meet to review discrepancies, and revise the codes, if necessary. Remaining transcripts will be coded individually; research assistants will then meet to resolve discrepancies. Final codes will be entered into NVivo, version 9 for analysis.

Discussion

This paper describes a randomized clinical trial comparing the effect of a novel CBPT intervention with that of a sham control condition on balance confidence and community integration for persons using LLPs. If successful, the proposed work has the potential to advance the field of prosthetic rehabilitation by integrating CBT and PT strategies into an intervention that will improve balance confidence, limit associated activity avoidance, and ultimately promote community integration. Integrating CBT and PT strategies within the rehabilitation of persons using LLPs is a fairly novel approach, but one that has demonstrated feasibility and effectiveness in the clinical setting among community-dwelling older adults, as well as elderly residents in assisted living centers [17, 31, 32]. Including a CBPT intervention early in rehabilitation may be critical as balance confidence is unlikely to change thereafter [4, 9].

Medical comorbidity is common in older individuals with LLP [33]. Issues related to complicated medical comorbidities may cause challenges in recruitment, such as scheduling difficulties due to unique physical health concerns. For example, participants with medical comorbidities may already have to manage many weekly medical appointments, which can pose a greater difficulty in scheduling intervention sessions. The research coordinator will work closely with participants to manage appointments and schedules. Additionally, the research team will have multiple trained behavioral therapists and physical therapists with varied availability to accommodate participant schedules. Unique physical concerns will be addressed by contacting participant's providers to gain further medical clearance. If necessary, and with the participants permission, research team members (e.g., physical therapist, research prosthetist) will communicate directly with the participant's providers. In order to accommodate participant schedules, it may be necessary to modify the number of intervention sessions. Although modifications may impact fidelity to the study protocol, including a representative sample with a variety of medical comorbidities will enhance generalizability.

The results of this trial will be submitted for publication in peer-reviewed journals and presented at local and national meetings regardless of outcome.

Limitations

Several factors may limit the impact of the work. The results may not generalize to persons using LLPs due to transfemoral and/or bilateral amputation. We will exclude these groups to avoid between-subject variability due to differences in components and residual length, which are exacerbated in these excluded groups. However, based on prior work demonstrating no effect of level of amputation on ABC score, [23] if successful, a similar intervention could improve balance confidence in these groups as well. However, future work would be needed to test the efficacy of CBPT intervention with these groups. In addition, the use of a multicomponent intervention precludes us from quantifying the extent to which CBT or PT components alone act to improve balance confidence, or if (and how) the combined effects interact. A future disentanglement study would be needed to determine whether, for example, CBT or active video games alone provide similar results. In addition, future studies will also need to demonstrate clinical feasibility by utilizing standard of care PT rather than a sham control condition as a comparator (Additional file 3).

Conclusions

The results of this study will provide information on the initial efficacy, feasibility, and impact of a combined CBT and PT intervention on balance confidence and community integration in adults with a LLP. If efficacious, increased support for novel care approaches in which behavioral therapists are integrated into other outpatient clinic settings will be necessary for further dissemination and implementation.

Trial status

Current protocol is SCPM 17–023, version 2.3, which was last updated on June 3, 2019. Recruitment began on April 5, 2018 with an anticipated recruitment completion date of December 31, 2020.

Supplementary information

Supplementary information accompanies this paper at <https://doi.org/10.1186/s13063-019-3929-8>.

Additional file 1. Behavior Recording Form for Prosthesis Use.

Additional file 2. Breath To Relax Description.

Additional file 3. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Abbreviations

ABC scale: Activities-specific Balance Confidence scale; BBS: Berg Balance Scale; CBPT: Cognitive behavioral–physical therapy; CBT: Cognitive–behavioral therapy; CRIS: Community Reintegration of Service members; FAI: Frenchay Activity Index; HRPO: Human Research Protection Office; IRB: Institutional review board; LLP: Lower limb prosthesis; PEQ: Prosthetic Evaluation Questionnaire (PEQ); QoL: Quality of life; RCT: Randomized control trials; SF36: 36 question Short-Form Health Survey; TUG: Timed-up-and-Go test; VR: Virtual reality

Acknowledgements

None.

Authors' contributions

NJR secured funding for the project and is protocol principle investigator. MM, KLS, JC, and MM assisted with securing funding and developing the protocol and are protocol co-investigators. MOB wrote the initial version of manuscript and is protocol research assistant. NJR and KLS critically edited the initial versions of the manuscript. AM and RM are research physicians on protocol. CD is a research prosthetist on protocol. All authors approved the final version of the manuscript and provided intellectual contribution to protocol development.

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This trial is supported by the Department of Defense award W81XWH-17-1-0697. The funding source had no role in designing the study, nor will they be involved in any aspects of conducting the study. Contact information for the trial sponsor can be obtained directly from the corresponding author.

Availability of data and materials

The protocol manual is available upon request.

Ethics approval and consent to participate

Ethics approval for this trial has been granted by the Institutional Review Boards of Rosalind Franklin University (approval number SCPM 17-023) and Lovell Federal Health Care Center/Hines VA (approval number 1089641-1). Any adjustments to the protocol can only be carried out if the Ethics Committee approve after thorough communication. Written informed consent is required for all participants. The findings of the trial will be published in peer-reviewed journals.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

¹Department of Psychology, Rosalind Franklin University of Medicine and Science, 3333 Green Bay Road, North Chicago, IL 60064, USA. ²Captain James A Lovell Federal Health Care Center, 2450 Buckley Rd, North Chicago, IL 60064, USA. ³Department of Physical Medicine and Rehabilitation, Northwestern University, Prosthetics and Orthotics Center, 680 North Lake Shore Drive, Chicago, IL 60611, USA. ⁴Jesse Brown VA Medical Center, 820 S Damen Ave, Chicago, IL 60612, USA. ⁵Edward Hines, Jr. VA Hospital, 5000 5th Ave, Hines, IL 60141, USA. ⁶Dr. William M. Scholl College of Podiatric Medicines' Center for Lower Extremity Ambulatory Research (CLEAR), Rosalind Franklin University of Medicine and Science, 3333 Green Bay Road, North Chicago, IL 60064, USA.

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APPENDIX L - MANUSCRIPT PUBLISHED IN JOURNAL OF PROSTHETICS AND ORTHOTICS

Feasibility of an Interdisciplinary Intervention to Promote Balance Confidence in Lower-Limb Prosthesis Users: A Case Study

Rachel Churchill, MSc, Kristin L. Schneider, PhD, John E. Calamari, PhD, Roberta Henderson, PhD, Sungsoo Hwang, PhD, Mathew J. Major, PhD, Chad Duncan, PhD, Aaron Stachowiak, MD, Christopher Reddin, PhD, Noah J. Rosenblatt, PhD

ABSTRACT

Introduction: Low confidence in one's ability to maintain balance during daily activities is a prevalent issue for lower-limb prosthesis users (LLPUs) that negatively impacts psychosocial function but is not currently addressed in rehabilitation. The purpose of this case study was to demonstrate feasibility of an intervention that combines cognitive behavioral therapy techniques with physical therapy to increase balance confidence, reduce avoidance behaviors, and increase community participation in LLPU.

Materials and Methods: A 58-year-old man with a unilateral transtibial amputation completed eight 120-minute intervention sessions, which included physical therapy in the form of virtual reality active gaming targeting balance and gait adaptability, followed by psychoeducation, cognitive restructuring, and a brief exposure exercise. The intervention was intended to improve balance and gait while addressing beliefs regarding physical abilities and their impact on behavior. All exercises were individually tailored to address real-world, subject-specific distress-inducing situations, identified jointly by a licensed physical therapist and behavioral counselor that were present throughout all intervention sessions. The primary outcome, balance confidence, was quantified before, during, immediately after, and 1 month after completion of the intervention. Additional measures of physical function and community participation were also assessed.

Results: Objective balance measures (Berg Balance Scale) improved by 9 points from baseline to follow-up, and balance confidence improved from 48.5% at baseline to 91.9% at 1-month follow-up. Gains in gait self-efficacy and reductions in fear-avoidance behavior mirrored this change.

Conclusions: This case study demonstrates that a multicomponent intervention is feasible and may provide a positive and helpful experience for LLPU to meaningfully improve balance confidence and reduce avoidance behavior. (*J Prosthet Orthot.* 2020;00:00–00)

KEY INDEXING TERMS: quality of life, balance, gait, cognitive behavioral therapy, virtual reality

An estimated 2 million Americans live with limb loss.¹ Lower-limb amputation (LLA) can lead to lifelong physical and psychological challenges.^{2,3} Physical limitations after an LLA, the most common of which are walking long distances and standing for an extended time, can negatively impact

participation in sports, recreational, and cultural activities.⁴ In addition, lower-limb prosthesis users (LLPUs) are more likely to encounter psychological and social barriers to physical activity and overall health, such as traumatic stress or mood disorders.^{5–7} Such barriers can increase difficulty in adjusting after an

RACHEL CHURCHILL, MS; KRISTIN L. SCHNEIDER, PhD; and JOHN E. CALAMARI, PhD are affiliated with the Department of Psychology, Rosalind Franklin University of Medicine and Science, North Chicago, Illinois.

ROBERTA HENDERSON, PhD is affiliated with the Department of Physical Therapy, Rosalind Franklin University of Medicine and Science, North Chicago, Illinois.

SUNGSOON HWANG, PhD is affiliated with the Department of Geography, DePaul University, Chicago, Illinois.

MATTHEW J. MAJOR, PhD and CHAD DUNCAN, PhD are affiliated with the Department of Physical Medicine & Rehabilitation, Northwestern University, Evanston, Illinois.

MATTHEW J. MAJOR, PhD is affiliated with the Jesse Brown VA Medical Center, Chicago, Illinois.

AARON STACHOWIAK, MD is affiliated with the Department of Physical Medicine and Rehabilitative Services, Captain James A. Lovell Federal Health Care Center, North Chicago, Illinois.

CHRISTOPHER REDDIN, PhD is affiliated with the Department of Fleet Mental Health, Captain James A. Lovell Federal Health Care Center, North Chicago, Illinois.

NOAH J. ROSENBLATT, PhD is affiliated with the Center for Lower Extremity Ambulatory Research, Dr. William M. Scholl College of Podiatric Medicine, Rosalind Franklin University of Medicine and Science, North Chicago, Illinois.

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Correspondence to: Noah J. Rosenblatt, PhD, Center for Lower Extremity Ambulatory Research, Dr. William M. Scholl College of Podiatric Medicine, Rosalind Franklin University of Medicine and Science, 3333 Green Bay Rd, North Chicago, IL 60064; email: noah.rosenblatt@rosalindfranklin.edu

amputation, which can promote feelings of helplessness.^{8,9} Accordingly, rehabilitation after an LLA should target physical, social, and psychological function.

Low balance confidence, defined here as low self-perception in one's ability to maintain balance while performing certain activities, is prevalent after LLA and may be important to target for encouraging mobility and continued social integration.¹⁰ In one study that looked at balance confidence in community-dwelling individuals living with LLA for at least 6 months, 65% of individuals reported balance confidence levels¹¹ below the threshold at which intervention is advocated for intact older adults.¹² Low balance confidence often translates to reduced community integration^{13,14} and is a significant predictor of social participation, even after accounting for mobility capability.¹³ Moreover, balance confidence is highly indicative of the level of physical activity achieved by LLPUs.¹⁵ Given that decreased physical activity and social participation may impede quality of life (QoL),^{16,17} it is critical to develop interventions that promote confidence and self-efficacy to increase engagement in physical and/or social activities for LLPUs.

Addressing low balance confidence may require interventions that specifically promote self-efficacy while improving physical function. Indeed, improving function alone may not necessarily improve confidence.^{18–20} Interventions integrating cognitive behavioral techniques such as addressing maladaptive thoughts while restructuring physical activity goals and expectations may help cultivate self-efficacy while improving physical function. Such interventions have been successfully implemented in older adults to improve balance confidence.^{21–23} However, similar interventions do not exist for LLPUs.

Here we present results from a single LPU who completed an 8-week interdisciplinary intervention that combined cognitive behavioral training (CBT) techniques with balance and gait exercises to improve balance confidence, address avoidance of activities, and in turn promote community integration.

METHODS

SUBJECT

The subject was a 58-year-old African American man (body mass index, 23.7 kg/m²) with a unilateral, left, transtibial amputation occurring 9 years prior as a result of osteomyelitis secondary to diabetes. A medical history revealed that the subject's most recent blood glucose A1C reading was 8.0 and that he had received a kidney transplant ~5 years prior. The subject wore a total contact socket with sleeve suspension. He used an Ottobock Uneo Unique custom-made liner, with a sheath and a 5-ply gel sock as well as a distal gel pad and a dynamic response Otto Bock Triton foot. The subject rated his socket comfort as 6 using the Socket Comfort Fit Scale. He was employed part-time during the academic year as a security guard. He had self-reported neuropathy on the contralateral limb and an observable drop foot, but he did not wear an orthosis. The subject reported lack of confidence when using his prosthesis for weight support. He did not use a cane or a walker for gait assistance. However, use of crutches for specific

activities was reported. The subject reported falling once in the prior year as a result of catching his intact limb on the carpet and reported often stumbling for similar reasons.

SCREENING AND BASELINE ASSESSMENTS

Before beginning the intervention, the subject was screened by a prosthetist to ensure prosthetic fit and function and by a study physician to ensure he was safe to engage in low-to-moderate levels of exercise. After screening, measures related to self-efficacy, functional ability, well-being, and community participation were assessed.

The primary outcome measure was balance confidence, quantified with the Activity-Specific Balance Confidence (ABC) scale, a scale that has been validated for LLPUs,²⁴ which asks individuals to rate how confident they are in their ability to maintain balance while performing 16 different activities.²⁵ The subject also completed the Modified Gait Efficacy Scale (mGES), which asks individuals to rate their level of confidence in their ability to safely complete 10 different walking tasks.²⁶ Although the scale has only been validated on intact older adults,²⁶ it was chosen here due to its focus on gait. As neither the ABC scale nor mGES directly quantify avoidance behavior, the Fear of Falling Avoidance Behavior Questionnaire (FFABQ) was also administered. The FFABQ asks individuals to rate how much fear of falling causes them to avoid 14 different activities.²⁷ The psychometric properties of the FFABQ were established in a population that included 25 healthy adults and 38 adults with pathologies known to impact balance²⁷; it has good overall test-retest reliability; it is significantly affected by fall history and is correlated with numerous self-reported and performance-based measures. However, the FFABQ has not been used previously on LLPUs.

The Berg Balance Scale (BBS) and L-test of walking were used to measure functional ability. The BBS scores subjects in their ability to perform 14 balance tasks. It is a well-established outcome measure initially designed to assess balance in older adults²⁸ and has been validated for persons with LLA.²⁹ The L-test of walking is a modified version of the timed up and go (TUG) test that includes two transfers, four turns (in both directions), and a walking distance of 20 m.³⁰ It was designed to better distinguish changes in walking ability of fit and younger LLPUs compared with the TUG, and it has excellent psychometric properties.³⁰ Self-reported physical functioning was assessed with the physical functioning subscale of the 36-item Short Form Health Survey (SF-36), which has been validated for LLPUs.^{16,31} Two other subscales were considered: role limitation due to emotional functioning and limitations due to physical health. Finally, QoL was quantified with the validated well-being subscale of the Prosthetic Evaluation Questionnaire (PEQ).^{32,33}

To quantify community integration, we used the validated Frenchay Activity Index (FAI) and measured physical activity. For the FAI, individuals report the frequency with which they engage in 15 domestic chores, leisure/work activities, and outdoor activities.³⁴ To measure physical activity, the subject wore a StepWatch 3 activity monitor (Modus Health LLC, Edmonds, WA, USA) around the pylon of his prosthesis for 1 week, a duration which is standard for capturing fluctuations that may occur between weekdays and weekends. The activity monitor recorded

the number of steps taken daily, from which the average number of steps per day is reported. To determine the location of activity, data from the activity monitor were time-synced with a Q1000XT GPS tracker (QStarz International, Taipei, Taiwan) also worn on the pylon. Custom algorithms³⁵ were used to code GPS data as inside or outside the home. However, because it was not always possible to identify location, we calculated the number of steps outside the home per hours of GPS data with known location, and then scaled this to a 24-hr period to obtain outside of home steps within a day. Values were then averaged across all days.

INTERVENTION

PROGRAM OVERVIEW

Our intervention applied physical therapy and CBT components to enhance the subject's balance confidence and promote community integration. We chose to simultaneously introduce both components (rather than serially introduce them) to be consistent with prior work on older adults.^{21–23} Eight sessions were intended to take place weekly and typically lasted 120 minutes, beginning with virtual reality active video gaming followed by psychoeducation, cognitive restructuring, and a brief exposure therapy. Both a physical therapist (PT) and behavioral counselor were present throughout all sessions. The protocol was approved by the Institutional Review Board at Rosalind Franklin University. Written informed consent was reviewed and obtained before baseline assessments.

VIRTUAL REALITY ACTIVE GAMING

Six different active video games were played on an instrumented treadmill (C-Mill by Motek, Amsterdam, the Netherlands), while wearing a safety harness and gait belt. The games collectively focused on balance and gait adaptability. In general, the games involved a combination of the following: 1) shifting weight while standing or walking in order to manipulate an object projected on a front-end screen, the movement of which coincided with the motion of the person's center of pressure; and 2) altering spatiotemporal gait kinematics (step length, time, and width) to avoid virtual objects projected on the front-end screen or directly on the treadmill surface. The difficulty of all games could be manipulated by the software based on recommendations from the PT. A more detailed description of the games and general progression for use in designing a randomized trial can be found elsewhere.³⁶ Throughout game play, the PT provided feedback to ensure safe and efficient movements. Holding the safety rails during game play was discouraged.

COGNITIVE BEHAVIORAL TECHNIQUES

The purpose of the CBT techniques was to identify unhelpful thoughts and behaviors that negatively influenced physical activity and develop new thoughts, behaviors, and skills to encourage activity. The CBT techniques included the following: behavioral recording to facilitate an understanding of the interconnectedness of thoughts and behaviors; goal setting to encourage attainable milestones connected to the subject's values; and exposure therapy to reduce distress by habituating to feared/avoided/

distressing activities. Additional tools, such as mindfulness and diaphragmatic breathing, were taught. Specific details regarding the CBT techniques can be found elsewhere.³⁶

SESSION PROGRESSION

The first session began with rapport building and a discussion of the relationship between balance confidence and avoidance behaviors. The subject then briefly walked on the treadmill to warm up before playing six gaming blocks of 2.5 minutes. Between blocks, education was provided to connect gaming skills to physical function and confidence during community-based activities. After game play, the behavioral counselor provided an overview of the CBT techniques to be used in the remaining sessions and introduced behavior recording. The subject was asked to complete behavioral recording forms as part of his home assignment (see Appendix in Bourque et al.³⁶ for a copy of the form).

At the start of session 2, and each session thereafter, the subject was asked if he experienced any falls during the previous week. Four new games were then introduced. Where possible, the skills targeted in each new game were connected to concerns reported on behavioral recording forms. After gaming, the behavioral counselor continued to address the interconnectedness of thoughts, feelings, and behaviors. Diaphragmatic breathing was introduced as a new coping skill. The subject was given homework to complete, which included writing down short, medium, and long-term goals, which were continuously reevaluated to ensure they were measurable and attainable.

Session 3 proceeded similarly to session 2, with questions regarding falls, followed by gaming, and then behavioral counseling guided by the behavioral recording forms. Thereafter, a belief rating scale was introduced to allow the subject to assess the accuracy of his thoughts and to consider more accurate or helpful appraisal of his ability. This skill of thought restructuring was referenced throughout subsequent sessions. At the end of session 3, an "exposure therapy" was introduced. This involved practicing a skill that well approximated a distressing activity, as reported on the behavioral recording form. During the exercise, the PT provided strategies to better perform the task while the behavioral counselor worked to generate accurate appraisals and reduce maladaptive cognitions. After the exposure exercise, the subject was assigned at home activities and developed with input from the PT and behavioral counselor to build strength and reduce distress surrounding activities identified as being important. Sessions 4 to 8 were generally similar to session 3. However, at the end of session 8, the PT provided suggestions to maintain the gains achieved, including seeking out group classes at community centers/gyms, and the behavioral counselor provided strategies to avoid relapse by continuing to practice cognitive strategies and relaxation techniques. The week after session 8, the subject returned to the laboratory and completed a 30-minute semistructured exit interview to discuss his experiences with the program.

ADDITIONAL ASSESSMENTS

All baseline assessments were repeated after intervention session 4, after the exit interview, and again 1 month later.

RESULTS

SUBJECT-SPECIFIC PROGRESSION

Supplementary Table 1 (<http://links.lww.com/JPO/A44>) summarizes the order of game progression. In addition, Supplementary Table 2 (<http://links.lww.com/JPO/A45>) summarizes the subject's responses on behavioral recording forms, and Supplementary Table 3 (<http://links.lww.com/JPO/A46>) summarizes the at-home exercises assigned. The following additional aspects of the subject's progression are noteworthy:

- After session 2, the following goals were identified: short-term—"increase comfort and confidence approaching obstacles, walking longer distances, and carrying or picking up heavier items"; medium-term—"overcome doubts and frustration associated with difficulties experienced in everyday life and reduce hesitation"; and long-term—"improve activities of daily living and engage in more social activities with friends and family."
- At the start of session 3, the subject reported falling the prior week while going up a single, high stair with no railings outside of his friends' home. The behavioral counselor identified this location/stair as a trigger for negative cognitions. Therefore, exposure exercises during sessions 3 to 6 targeted stair ambulation. For initial exposure, the subject was asked to walk up and down a single flight of stairs while holding the banister. As he used a step-over-step strategy rather than the more conservative step-by-step approach,³⁷ the PT taught him the latter, in response to which distress levels immediately declined. In ensuing sessions, exposure exercises focused on ambulating steps without a handrail and negotiating nonstandard step heights.
- At 1-month follow-up, the subject reported regularly working out at the gym and taking a part-time summer job (two 8-hr weekly shifts) in a factory, which involved standing for extended periods, lifting light-weight objects, and navigating complex environments. However, after several weeks, he reported quitting, noting that the rapid increase in activity caused residual limb soreness.

OUTCOME MEASURES

Table 1 summarizes changes in each of the outcomes and, where possible, provides information to help guide interpretation, for example, minimal clinically important difference (MCID) and/or minimum detectable change (MDC) for LLPUs or other populations. The participant's balance confidence improved immediately after the intervention and at follow-up. At the 1 month follow-up, the participant's balance confidence was 91.9, representing a 43.4-point increase, which is greater than the MCID of 11.2 to 13 points reported for patients with Parkinson diseases.^{38,39} Gains in gait self-efficacy and reductions in fear-avoidance behavior are mirroring these changes. The mGES improvement surpassed the MDC of 14.7 points reported for adults aged 60 years or older,⁴⁰ and improvements in FFABQ were greater than the MCID of 13 points reported for adults with

low back pain.^{41,42} Objective and self-reported measures of activity and participation (steps per day and FAI) also demonstrated continued improvements throughout the intervention and follow-up. The 7-point improvement in FAI from baseline was within the MDC for other populations; 6.7 points for patients with chronic stroke⁴³ and 8.6 points for Chinese older adults (mean age of 79 years).⁴⁴ BBS steadily increased from 43 at baseline, a value indicative of higher fall risk at²⁹ to a score of 53 at follow-up. Although there is no established MCID for the BBS for LLPUs, MDCs of 4.6 and 8 have been reported for chronic stroke patients and community-dwelling older adults, respectively.^{47,48} The 2.1-second improvement in the L-test (from 30.5 seconds at baseline to 28.4 seconds at follow-up) was smaller than the MCID for LLPUs (4.5 seconds).⁴⁹ The PEQ showed the greatest improvement after session 4 but returned to baseline at follow-up.

EXIT INTERVIEW

The subject noted the following initial concerns before the intervention: "Navigating terrain and moving around comfortably; type of prosthetic does not allow for the type of mobility needed for certain terrain." The subject reported no concerns regarding the intervention, and his overall experience "was very enjoyable, and [I] learned a lot." He described the virtual reality active gaming as "fun and therapeutic." In addition, the subject was less anxious with functional strategies to overcome instability ascending stairs/inclines or approaching uneven terrain. The subject developed a sense of acceptance and confidence in his ability to safely ambulate at his own pace. The exposure exercises "were really good because it simulated how I felt when I approached those things outside." Homework was perceived as a helpful tool to facilitate a way "to go forward and then just apply what I learned." This was an integral part of the program for the subject as it "...made me think outside of class that I could do with what I learned and also think of things that I might want to try. You say you might want to do something, but it's like you do not have the mindset or experience or even the confidence either to try it because nobody wants to actually fall." Overall, the intervention increased the subject's confidence in his mobility and balance. After the intervention, the subject described his outlook as "...different as far as the things that I can do better with the prosthetic and the mobility with it."

DISCUSSION

Our interdisciplinary intervention incorporated physical therapy and CBT techniques to increase balance confidence and reduce avoidance behaviors in an LLPU. Increasing balance confidence in LLPUs is critical as low balance confidence may be a precursor to increased disability.²¹ The intervention improved the subject's perception of his ability to perform daily activities, which resulted in less avoidance behavior and increased social participation and overall physical activity at 1-month follow-up. We posit that the maintenance of effects at 1-month follow-up reflects, in part, the reinforcement of problem-solving and coping within the intervention. For example, as a result of addressing the physical and associated cognitive components

Table 1. Summary of outcome measures cross time points

Outcome	Max Value; Interpretation	Time Point				MCID, MDC, and/or Average Value for LLPU or Other Populations
		Baseline*	During Intervention	End of Intervention	1-Month Follow-up	
ABC	100; higher = more confidence	48.45	83.8	85	91.9	MCID: 11.2–13 points reported for patients with Parkinson disease ^{38,39} MDC: 14.7 points reported for adults ≥60 years ⁴⁰
mGES	100; higher = greater self-efficacy	43	92	85	95	
FFABQ	56; lower = less fear-avoidance behavior	22.5	14	15	5	MCID: 13 points for adults with low back pain ^{41,42} ; 95% confidence interval for adults ≥60 years with fall history: 11.2–23.8 ²⁷
FAI	45; higher = greater social participation	31	34	30	38	MDC: 6.7 points for patients with chronic stroke ⁴³ ; 8.6 points for Chinese older adults ⁴⁴
SF-36: Physical Functioning	100; higher = higher function	32.5	70	75	80	MDC with a 90% confidence interval on version adapted for Veterans: 34.2 ⁴⁵
SF-36 Emotional Limitation	100; higher = less limitation	0	50	60	25	
SF-36 Physical Health Limitation	100; higher = less limitation	68	48	64	60	MDC with a 90% confidence interval on version adapted for Veterans: 26.3 ⁴⁵
PEQ	100; higher = greater QoL	32.25	59.5	42.5	31.5	
Total steps per day, mean ± SE	More steps = greater activity	5,362.8 ± 505.3	5,736.7 ± 541.7	6,201.1 ± 339.7	7,900.9 ± 1,924.5	Average value for persons with transistibial amputations with standard (nonshock absorbing) pylon: 2,976 ± 1,767 ⁴⁶
Steps per day outside the home, mean ± SE	More steps = greater community participation	3,359.8 ± 479.3	3,800.2 ± 430.4	2,497.7 ± 605.1	6,481.8 ± 1,737.3	
BBS	56; higher = better balance	44	47	51	53	MDC: 4.6 and 8 for chronic stroke patients and community-dwelling older adults, respectively ^{47,48}
L-test, s	Less time = better walking ability	30.5	31.6	31.4	28.4	MCID: 4.5 s for LLPU ⁴⁹ ; average for LLPU: 32.6 ± 14.9 s ³⁰

*Baseline represents the average of 2 measures taken 2 weeks apart; during the intervention represents data after session 4 except for activity data where the participant fell ill after session 4 so activity data were recollected after session 5; end of intervention is after exit interview, and 1-month follow-up is 1 month after this point.

associated with stair ascent, the subject developed a set of skills that could be applied outside of the therapeutic setting to other activities, for example, limiting stress when approaching a challenging situation and evaluating the safest biomechanical strategy to accomplish the task. We also argue that the effectiveness was driven by the inclusion of an interdisciplinary team, which is optimally equipped to identify true physical limitations versus self-imposed ones due to low balance confidence. Such a team is also well-suited to tailor the intervention to focus on activities connected to low balance confidence that simultaneously address individual goals.

The subject's willingness to practice outside of the laboratory, a necessary step to behavioral change and skill acquisition, may contribute to the large increase in self-efficacy. Indeed, he viewed the homework as a necessary step to help him integrate and master his skills, and reported weekly engagement in most of the techniques presented throughout the intervention. The subject's adherence to completing homework assignments reflects a general openness to engage in our intervention.

Using active video gaming provides a means to learn skills within a fun environment. The gaming was reported as enjoyable, and the subject was able to identify real-world applications of the gaming (e.g., improving the speed of weight-shifting can help to maneuver crowds). To some extent, the gaming aspect may have allowed the subject to engage in feared activities without focusing on fear, thereby better promoting motor learning and habituation. To our knowledge, this is the first study to use gaming as means of improving balance confidence in LLPUs. Although another case study demonstrated improve balance confidence in an LLPU with game play, that study was intended to target gait endurance.⁵⁰

Although most outcomes were improved at 1-month follow-up, QoL and physical health limitations were similar to baseline. This is surprising given the strong association between QoL and mobility in LLPUs.⁵¹ To some extent, this may reflect the subject's unstable and poor physical health (uncontrolled diabetes). Generally, poorer physical health and comorbidities can negatively impact QoL.^{18,52} It may be that balance confidence is a more robust outcome measure than QoL to quantify the impact of the intervention on LLPUs with comorbid health concerns.

Additional work is needed to determine the extent to which an individual would benefit from combining versus individually introducing the intervention components. For the case subject, equal focus on physical therapy and CBT techniques seemed warranted. Although he had average walking ability (L-test) and was relatively active at baseline, taking considerably more steps per day than the average person with transtibial amputation (3,000 steps/day),⁴⁶ he still reported low balance confidence, which, to some extent, was warranted by low balance ability (BBS = 44) and physical functioning (SF-36). However, it is also common for adults to demonstrate disparities between their perceived and physiological abilities.⁵³ In cases where risk is overestimated, emphasizing CBT techniques may be more beneficial at improving balance confidence than emphasizing PT exercises. It may be appropriate to utilize a stepped-care approach with this intervention whereby the "most effective"

component is first provided alone with the other component introduced later based on the individual's need.⁵⁴ Within this stepped-care model, demographics and initial screening measures could provide insight into which component would be most pertinent for individuals.

LIMITATIONS

There are several limitations of the current study. First, results may not generalize to all LLPUs, for example, persons with transfemoral amputation or new prosthesis users. The ability to target balance confidence in the latter is critical as gains in balance confidence that occur in rehabilitation after a first-time amputation may not persist after discharge.⁵⁵ Second, self-report measures can lend themselves to response bias. The subject may have had some social desire to please the research team, leading to a higher report of improvements. Third, a general limitation to practicing this intervention is that it requires two clinicians, which may present scheduling and billing challenges. In addition, the time requirements (120-minute sessions) may present challenges to clinical implementation. However, the extent to which this length and/or number of sessions is needed to attain the observed effects is unclear. It may be possible to attain similar results with more sessions that are shorter in length, such that total contact time is consistent, or even fewer shorter sessions. Although the protocol could be amended for either scenario, additional work is needed to understand the optimal session number and duration. Nonetheless, basic CBT techniques have been integrated into physical therapy to improve function and social participation in patients with chronic back pain.⁵⁶⁻⁵⁸

CONCLUSIONS

This case study demonstrated that an eight-session, multi-component intervention is feasible and can meaningfully improve balance confidence and avoidance behavior. The intervention was seen as a positive and helpful experience. Novelty lies in the fact that exercises are individually tailored to address real-world, distress-inducing situations, identified by an interdisciplinary team.

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