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TITLE: Targeting Balance Confidence as a Strategy to Increase Integration and Improve Outcomes in Users of Lower-Limb Prostheses

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14. ABSTRACT
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 balance confidence and in turn increase community participation in persons who use lower limb prostheses. To date the majority of effort has been dedicated to finalizing the intervention protocol and engaging in participant recruitment. As part of protocol development, we conducted the 8-week intervention on a case subject, and observed a marked increase in the primary study outcome of balance confidence quantified using the Activity Specific Balance Confidence(ABC)scale. The ABC score increased from 48.5/100 prior to the start of the intervention to 91.9 at one-month following the completion of the intervention, and there was a concomitant increase in community participation. The number of steps outside of the home per hour increased from 150.7±87.6 outdoor-steps/hour at baseline to 294.2±73.5 outdoor-steps/hour at one-month follow-up.

15. SUBJECT TERMS

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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 necessary 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

The following have been accomplished under the stated goals (the numbering aligns with the numbering in section 3.1):

1. All training materials have been developed and are included as appendices with this report (see section 4). The training material was used in the initial testing of a sample subject. The participant was a 54 year old, Africa American male who sustained an amputation as a result of osteomyelitis secondary to a non-healing diabetic ulcer. We collected all measures

at the following time points: i) following screening but before starting the intervention; ii) 3 weeks later but still prior to starting the intervention; iii) following session 3 of the intervention; iv) following session 6 of the intervention (activity data only as the participant was bedridden for some time following session 3); v) after session 8 was completed; vi) one-month after session 8 was completed. At each time point we measured the following:

- Activity-Specific Balance Confidence Scale (ABC): self-reported level of confidence in completing 16 complex functional tasks without losing balance (study primary outcome)
- Extent of Participation scale and Perceived Limitation scale from the Community Reintegration of Servicemembers (CRIS): self-report of frequency of engagement in certain activities and self-perceived limitations in participation.
- Role Limitation due to Physical Health and Role Limitation due to Emotional Health from the 36 item Short Form 36 (SF-36): self-reported measures of health-related quality of life
- Frenchay Activity Index (FAI): self-reported measure of social participation,
- Objective measure of physical activity: individuals wear a GPS monitor and activity monitor around the ankle of the prosthesis. Custom software is used to process the time-synced signal and derive the following - steps per day, number of steps per hour while outside the home (an indicator of how active the person is when outside), and average number of steps per trip outside.
- Berg Balance Scale (BBS): individuals are scored on performance of 14 functional tasks
- L-test of walking: the time to rise from a chair without armrests, walk 3m, turn right, walk 7m, turn around and trace their path back to the start is recorded.
- Fear of Falling Avoidance-Behavior Questionnaire (FFABQ): self-report of how fear leads to avoiding 14 different daily activities.
- Modified Gait Efficacy Scale (mGES): self-report of confidence during walking under 10 different conditions

Results from all measures are summarized in Table 1. Of note is the fact that the ABC scale (the primary study outcome) nearly doubled from an average of 48.5/100 at baseline (higher scores indicate more confidence) to a score of 91.9/100 at one month-follow up. These results are currently being written into a manuscript for submission (see section 6). Although the case study is indicated on the SOW, any related fees were not budgeted within the project being reported; all study fees were paid from a separate account. In addition, the case subject was not specifically described in HRPO documents and the participant was consented under a separate protocol. Nonetheless, as the effort of the PI and co-Is was, in part, salaried through the reported project, any such publication will acknowledge the project on which we are reporting (as noted in our prior quarterly report).

Table 1. Results from sample subject

			Time 1	Time 2	after session 3	after session 6	after sesion 8	1 month later
			Pre intervention		During	During	Post	Follow-up
Outcome	Score Range	interprtation						
ABC	0-100	higher=more confident	50	46.9	83.8		85	91.9
CRIS: Extent of Participation scale	0-70	higher=greater participation	50.8	48	50.8			49.1
CRIS: Participation Limitation sclae	0-70	higher=less limitation	46.8	45.7	46.4			47.9
SF-36: Physical Health Limtation sclae	0-100	higher=less limtation (higher related QoL	0	0	66.7		50	25
SF-36: Emotional Limitation	0-100	higher=less limtation (higher related QoL	33.4	0	50		66.67	66.67
SF-36: Physical Functioning Limitation	0-100	higher=less limtation (higher related QoL	35	30	70		75	80
FAI	0-45	higher=greater social particpation	30	32	34		30	38
outside-home-steps/hour of GPS data ± SE	N/A	higher=greater community particpation	126.9±50.7	161.6±25.3	102.6±25.4	154.7±14.0	117.6±21.9	294.2±73.5
outside-home-steps/hour outside-home ± SE	N/A	higher=higher activiy WHEN outside hom	302.6±112.1	417.6±63.6	270.4±32.1	376.4±106.8	396.0±76.3	550.0±120.1
outside-home-steps/trip ± SE	N/A	higher=higher activiy WHEN outside hom	496.4±126.6	633.6±87.9	768.3±312.2	724.3±161.7	572.5±51.3	1393.8±318.4
total steps/day ± SE	N/A	higher=greater activity	5270.7±709.9	5021.3±756.9	4311.4±570.2	5763.7±541.6	6185±401.4	7900±1924.4
BBS	0-56	higher=better balance	43	45	47		51	53
L-Test	timed	less time=better walking ability	29.3	31.7	31.6 s		31.4 s	28.4 s
Well-being scale of PEQ	0-100	higher=greater quality of life	25.5	39	59.5		42.5	31.5
FFABQ	0-56	lower=less fear-avoidance behavior	21	24	14		15	5
mGES	0-100	higher=greater self efficacy	44	42	92		85	95

ABC: Activity Specific Balance Confidence Scale (primary study outcome) CRIS: Community Reintegration of Service Members; SF-36: 36 Item Short form; FAI: Frenchay Activity Index; BBS: Berg Balance Scale; PEQ: Prosthetic Evaluation Questionnaire; FFABQ: Fear-of-Falling Avoidance Behavior Questionnaire; mGES: modified Gait Efficacy Scale

2. Two psychology graduate students have been hired and trained to perform the role of the behavioral counselor. As a result of unexpected changes to study personnel (see section 7) we have only recently completed training of the university physical therapist (Dr. Sara Kraut), whose role it is to train the part-time PT hire (Fe Ritz) responsible for running the majority of intervention session. As part of this training, Dr. Fe Ritz has been shadowing Dr. Kraut while conducting the intervention on our first two participants. Training will commence once these participants complete their eight intervention sessions.
3. The recruitment of subjects is a prerequisite to the collection of baseline data and administering of interventions. As outlined in our quarterly reports there have been a considerable number of activities undertaken to advertise the study and assist with recruitment. These include:

    - Sending informational mailings to 8 patients from the Federal Health Care Center (FHCC) identified as potential candidates (with follow-up for non-responsive individuals), as described in IRB approved documents
    - Sending informational mailings to an additional 2 patients from the Edward Hines VA identified by Dr. Muthukrishnan during amputee clinic (note that adding HInes as a recruitment site did not necessitate HRPO approval as Hines and FHCC share one IRB and Hines is not an engaged site)
    - Calling 3 addition Hines VA patients identified by Dr. Muthukrishnann
    - Contacting 2 local amputee support groups identified on National Amputee Coalition website (On This Leg and the Chicago Area Amputees Group)
    - Contacting leaders of two additional support groups affiliated with local hospitals - Dr. Bluzarik, a DPT at Marianjoy Northwestern, and Dr. Breshnahan, the Inpatient Physical Therapy Resource Clinician at Loyola Medicine. Both were responsive when contacted during the summer and indicated they would share study information at meeting in October after the summer break.
    - Contacting local amputee organizations including Dare2tri and Great Lakes Adaptive Sports Association (GLASA) to request that study information be shared through social media. GLASA was also contacted by a Rosalind Franklin faculty member with direct connections at the group.
    - Presenting study information at local and district VFW meetings (CAPT Reddin) and sending emails with study information to VFW members
    - Sending flyers and informational letters to 8 local prosthetic clinics and several physical therapy facilities
    - Speaking directly to prosthetist at 3 different prosthetic clinics, including one within 5 miles of the university, to explain the study. The PI worked with two of these practitioners in the past.
    - Posting flyers throughout the entire FHCC campus
    - Searching Rosalind Franklin Health Clinics records for possible participants. Two patients were identified and approached at a clinic visit.
    - Emailing 4 participants from prior studies (after receiving IRB approval to do so)
    - Contacting researcher and clinicians at the Milwaukee VA to participate in the study. One individual involved directly involved with the amputee clinic (Dr. Yacub Martin) indicated that at that time, the clinic was too busy to participate. The chair of the Physical Medicine and Rehabilitation Department at FHCC also contacted 2 MDs at Milwaukee VA, one of whom r (Dr. Keneth Lee) shared study information with Wisconsin Adaptive Sports Association (WASA)

    As of September 29, 2018, we have enrolled 5 participants, all of whom have completed baseline assessments, with four-of -five randomly assigned to groups (one participant withdrew during the week of activity monitoring prior to randomization). Two subjects have been randomized to the control group and 2 to the experimental group. One of the control participants has competed 8 weeks in the control group and the other is still waiting to begin the 8 week sham intervention. One of the intervention subjects has completed 3 intervention sessions and the other has completed 4 sessions. In addition to these participants, based on the efforts described above we have potential leads on at la east half dozen more individuals who, for various reason could not yet enroll (e.g., active wounds, or currently completing physical therapy).

4. (see 3 above)
5. This task has not yet begun as only 1 participant (a control subject) has completed 8 weeks in the study.
6. This task is not scheduled to be undertaken until month 30.
7. This task has not yet begun as we are still waiting for our first experimental group participant to complete 8 intervention sessions.

3.3 Opportunities for training and professional development provide by the project

Nothing to report

3.4 Dissemination of results to communities of interest

Nothing to report

3.5 Plans for the next reporting period to accomplish goals

The primary activities to be undertaken during year 2 include ongoing recruitment efforts and continued collection of data. In an effort to reach recruitment goals stated in the SOW we plan to undertake the following additional recruitment efforts in year 2:

- CAPT Reddin will work with contacts at the VFW to begin a recruitment campaign with Disability American Veterans (DAV)
- Mathew Major will submit IRB documents to the Jessie Brown VA (where he has a dual appointment) to obtain approval to post flyers at their amputee clinics
- The PI will consider giving presentations at meetings of the 4 amputee support groups that have already been involved in recruitment efforts
- The PI will work with faculty and podiatric providers at Rosalind Franklin University to assist in an advertisement campaign that targets external podiatric clinics with connections to the university (i.e., those that offer Clerkships to students). Although podiatrist rarely see patients with transtibial amputations, by targeting many clinics at the same time we would hope to capture at least a few potential participants.
- Initiating a Facebook ad targeting persons with amputation in a 25 mile radius
- Pay for advertisement on the Amputee Coalition website (this is low on the priority list in light of the fact that the website targets a national, rather than regional, audience)

We currently have a data base keeping track of the numerous efforts that have already been undertaken with regard to recruitment (see section 3.1); it includes point-of-contact information, date of past contact and responsiveness. In year 2 we plan to use this data base and periodically repeat prior efforts to maintain ongoing visibility. Should the team still be unable to reach recruitment goals with these large scale efforts, we would need to rely on the experiences of the funding organization to provide insight into additional possible opportunities with which we are unfamiliar.

4. IMPACT

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

Nothing to report

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

In an email sent to the scientific officer on June 9, 2018 (prior to the grant start date) we were approved for two changes that were not included in the original proposal. In particular we were approved to open the study to participants that scored ≥80 (rather than ≥75), on the ABC scale and to include activities such as phone calls and non-balance related exercises for the control group (see appendices of this report).

We would also like to draw attention to one of the approved exclusion criteria: "inability to perform the protocol without an assistive device (does not exclude use of a device)". Given that the physical exercises of the intervention target balance and functional gait, this criterion was initially

intended to exclude individuals who could not walk on a treadmill without their assistive device and therefore could not play active video games that addressed functional gait. However, by design, the intervention progression is subject-specific, and it is not mandated that a participants advance to playing games that target functional gait (the "more advanced" games). Accordingly, the minimum functional ability necessary to "perform the protocol without an assistive device" is the ability to weight-shift while standing without an assistive device for 2.5 minutes (the length of each gaming block). While we are still primarily interested in recruiting individuals who qualify under the initial interpretation of the exclusion criteria (e.g., K3-level) in an effort to maximize recruitment rates the study is officially open to any individual who meets the "minimum ability" criteria (e.g., K2 level); the study PT will screen participants to ensure the latter is met, if needed. Importantly, including the latter group of individuals does not change the scope of the study nor the goals, nor did it require altering the approved inclusion/exclusion, nor did it alter risk. As such it was unnecessary to request approval to change the protocol.

5.2. Problems or delays and actions to resolve them

The primary problem faced during the past year, which significantly delayed progress, was related to recruitment. In general, we did not begin to focus on recruitment until we knew we were ready to enroll participants – i.e. the protocol was completely developed (and approved by IRB and HRPO) and any unforeseen problems with the protocol were discovered and corrected during the case study. Whereas the original recruitment plan indicated we would being enrolling participant as early as month 2, given the length of the case study (1 moth baseline followed by 2 month intervention and 1 month follow-up) we should have anticipated enrollment beginning no earlier than month 6. In addition, due to scheduling conflicts, the case subject was not completed until month 8 (May 2018), at which point we began to focus on recruitment. However several unexpected factors led to further delay in recruitment (theses have also been described in our quarterly reports). In particular:

- As of June 2018 the PT on the project, Dr. Henderson, unexpectedly retired. As a result it was necessary to find and train a replacement (see section 7.3) before enrollment could begin. This process required 1-1.5 months.
- At the same time, there was a change to the original phone number assigned for study recruitment (and listed on the initial rounds of flyers distributed using methods described in section 3.2), which occurred when the university changed phone providers. Pursuant to these changes, we submitted IRB documentation to change flyers and final approval at Rosalind Franklin and FHCC was received June 24, 2108. Thereafter all recruitment efforts were repeated with new flyers.
- When we began to receive calls at the new number, the original study coordinator (Mr. Morris) was not reliably returning calls or actively assisting with recruitment; his time under the project was paid hourly, as a part-time position outside of his full-tie employment at the FHCC, where his responsibilities had increased. As a result the PI hired a second coordinator (McKenzie Bourque) to be the primary coordinator on the study. Mr. Morris will take on future responsibilities as needed, if his schedule allows.

As discussed, these problems have been addressed and there are a number of on-going recruitments efforts and planned future efforts (see sections 3.2 and 3.5) that have been or will be undertaken to minimize delays moving forward. In addition to recruitment issues, the following unanticipated delays related to progressing enrolled participants through the study have occurred:

- DoD001A - completed 8 weeks of training but failed to show up for follow-up testing; coordinator has left messages but participant has yet to respond
- DoD002B - participant was scheduled to begin training in late August but had a leak in his vacuum suspension that took over 1 months to resolve; the participant has since completed 3 intervention session, but in absence of the vacuum issue would have already completed the intervention
- DoD005A - participant was randomized to the control group (non-yet informed of randomization) and was scheduled to visit the lab for intervention session 1 but had a family emergency the night before; coordinator has left messages but participant has yet to respond

The study coordinator will continue to contact participants to avoid dropout/withdrawal. In addition, given that the primary time point of interest to the analysis is 16 weeks following the

conclusion of the intervention, all efforts will be made to ensure that data at this point is collected as close to this time as possible. We will record the date of all data collections relative to start date and co-vary for this as needed.

5.3 Problems or other factors that significantly impacted expenditures

As a result of delayed recruitment, expenditure has been significantly impacted. In particular the following have been impacted:

- The PT hire (Fe Ritz) and the psychology graduate students have not yet performed any interventions and have only billed for training hours
- The research coordinator has billed for fewer hours than budgeted due to reduced workload
- Few patient fees (up to $650 per intervention subjects) have been billed
- The prosthetist and GPS consultant have yet to invoice for their time

5.4 Significant changes in use of human subjects

Nothing to report

6. PRODUCTS

6.1 Publications, conference papers, and presentations

The following two abstracts have been submitted for presentation at the noted national conferences:

- *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;* Henderson, RJ; Rosenblatt N; Schnedier, K; Calamari, J; Reddin, C; Major, M. Abstract accepted for podium presentation within the Federal Physical Therapy Section of the Combined Sections Meeting of the American Physical Therapy Association, to be held January 23-26, 2019 in Washington, DC.

- *Integrating Physical Therapy and Cognitive-Behavior Strategies to Enhance Prosthesis User's Balance Confidence;* presenters*:* Schneider, K (chair); Rosenblatt N.J.; Heck J; Discussant: Littman, A.; non-presenting authors: Calamari, J; Walker, R; Kraut, S; Major, M; Abstract submitted for consideration as a symposium presentation at the 40th Annual Meeting of the Society of Behavioral Medicine to be held March 6-19, 2019. Awaiting decision

The PI presented an invited talk entitled: "The Effects of Fear of Falling on Neuromechanics of Gait and Balance: Lessons from Intact Adults and Implications for Prosthetic Design and Rehabilitation." presented at the Neuromechanics of Rehabilitation of Lower Limb Amputees Symposium held at the Northwestern University Prosthetics and Orthotics Center on June 11, 2018. At the talk, the PI discussed the study rationale, design and results from the case subject.

6.2 Other manuscripts

The following two manuscripts are currently in preparation and expected to be submitted to the listed journals during FY18 Q1:

- *Targeting Balance confidence as a Strategy to Increase Integration and Improve Outcome in Users of Lower Limb Prosthesis: a study protocol for a randomized clinical trial*. Bourque, M.; Reddin, C; Stachowiak A; Schneider, K; Calamari, J; Henderson R; Kraut S; Major, M; Duncacn, C; Rosenblatt, NJ; To be submitted as a Study Protocol toTrials

- *Targeting Balance confidence as a Strategy to Increase Integration and Improve Outcome in Users of Lower Limb Prosthesis: a case study*. Walker, R.; Reddin, C; Stachowiak A; Schneider, K; Calamari, J; Henderson R; Kraut S; Major, M; Duncan, C; Rosenblatt, NJ; To be submitted to the Veterans disability & Rehabilitation Research Channel of PLOS ONE.

6.3 Other Products

As part of protocol preparation, the team has created a detailed Clinician's Manual (see section 3), the intention of which is to guide other clinicians in administering the intervention. In the future this manual can be distributed when teaching courses on how to administer the intervention or it can be made available upon request by practitioners or researchers. The manual is a working document

that is continuously updated based on new knowledge gained from participants. The appendix of the manual includes all study forms that are completed by the participant during intervention sessions or as part of homework assignments; these forms are provided to the participant at the start of the intervention in a bound Participant Handbook. Both the handbook and manual are included as appendices with this report. In addition we include a copy of a second Participant Handbook which is provided to individuals assigned to the control group. This handbook describes a series of seated exercises to be practiced. The exercises and handbook have been adapted from other sources (see cover page of handbook) and the seated-exercises, when practiced with the excluded weight-bearing exercises, have been shown to improve function and mobility in intact, older adults. While we do not expect control subject to demonstrate improvements in our primary outcome measures, there is the possibility that this may occur. If improvements are seen then it may also be worthwhile to share the control participant handbook with practitioners.

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:	*3*
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:	

Name:	*Kristin Schneider*
Project Role:	*Co-I*
Researcher Identifier	
Nearest person month worked:	*2*
Contribution to Project:	*development of training material; conducting case study; training graduate psychology students*
Funding Support:	

Name:	*John Calamari*
Project Role:	*Co-I*
Researcher Identifier	
Nearest person month worked:	*2*
Contribution to Project:	*development of training material; training graduate psychology students; conducting initial intervention sessions*
Funding Support:	

Name:	*Roberta Henderson*
Project Role:	*Co-I (retired as of July 2018)*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*development of training material; conducting case study*
Funding Support:	

Name:	*Sara Kraut*
Project Role:	*Research PT (Rosalind Franklin University faculty)*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*Conducting intervention for initial participants to learn the protocol and train the part-time PT hire*
Funding Support:	

Name:	*Fe Ritz*
Project Role:	*Research PT (Part-time)*
Researcher Identifier	
Nearest person month worked:	*0*
Contribution to Project:	*Will be the primary clinician responsible for conducting the PT exercises within the experimental intervention and teaching the seated chair exercise to the control group*
Funding Support:	

Name:	*Arthur Morris*
Project Role:	*Research coordinator*
Researcher Identifier	
Nearest person month worked:	*0*
Contribution to Project:	*Recruiting, phone screenings, patient scheduling,*
Funding Support:	

Name:	*McKenzie Bourque*
Project Role:	*Research coordinator*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*Recruiting, phone screenings, patient scheduling,*
Funding Support:	

Name:	*Rachel Walker*
Project Role:	*Graduate psychology student*
Researcher Identifier	
Nearest person month worked:	*0*
Contribution to Project:	*Trained in administering CBT aspects of intervention, will be responsible for conducting interventions*
Funding Support:	

Name:	*Gregory Dams*
Project Role:	*Graduate psychology student*
Researcher Identifier	
Nearest person month worked:	*0*
Contribution to Project:	*Trained in administering CBT aspects of intervention, will be responsible for conducting interventions*
Funding Support:	

Name:	*Christopher Reddin*
Project Role:	*FHCC site PI*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*development of training material; recruitment, completion and submission of FHCC regulatory documents*
Funding Support:	(time in kind)

Name:	*Aaron Stachowiak*
Project Role:	*Research MD*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*Screening participants and referring participants from FHCC amputee clinic*
Funding Support:	(time in kind)

Name:	*Ranjin Muthukrishnan*
Project Role:	*Research MD*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*referring participants from Hines VA amputee clinic*
Funding Support:	

Name:	*Matthew Major*
Project Role:	*Site PI*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*recruitment; overseeing graduate student; protocol development*
Funding Support:	

Name:	*Chad Duncacn*
Project Role:	*Research prosthetist*
Researcher Identifier	
Nearest person month worked:	*1*
Contribution to Project:	*recruitment; screening; clinical insight*
Funding Support:	

7.2. Changes in PI support

As of September 2018, the project PI was listed as the Site PI (1.0 calendar months) on the following DoD funded project: *A Comparative assessment of conventional and adjustable transfemoral sockets* (grant number: W81XWH-18-1-0656). This project was not previously listed as pending on Other Support documentation. The PIs effort on this new project will not significantly impact his efforts on the project that is the subject of this report.

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

In an email dated July 26, 2018, the PI informed the Scientific Officer and Grant Specialist that an investigator on the project (Dr. Roberta Henderson) retired and that there was a new to add a new investigator to the project to fulfill her role. As a follow-up to this email on Aug 24, 2018 the PI emailed the same individuals to inform her that Dr. Sara Kraut would be added to the project in Dr. Henderson's stead, but listed as a university-affiliated Research Physical Therapist whose primary responsibility would be to learn the manual and then train and provide oversight to the part-time hired Research PT (Dr. Fe Ritz). Dr. Kraut has since helped to run the intervention for our first two participants, with Dr. Fe Ritz shadowing her. It is anticipated that moving forward Dr. Fe Ritz will be the primary therapist conducting the intervention with Dr. Kraut filling in as needed.

Other organizations involved as partners

Mr. Justin Heck, a certified prosthetist with Hangar Prosthetics, as well as a user of a lower-limb prosthesis, assisted the team in pilot testing the intervention. In particular, he worked with the psychologist and PT to test the games and the behavioral components and to provide his personal and professional knowledge to improve the protocol. His time was not compensated under the study being reported. Given his unique viewpoint regarding the protocol, he was asked to be a presenter on our symposium abstract (see section 6), where his affiliation was listed as Hangar prosthetics. Neither Justin Heck nor Hangar Prosthetics will be named on any future publications.

8. SPECIAL REPORTING REQUIREMENTS

An updated Quad Chart has been submitted as an attachment with this report

9. APPENDICIES

The following four appendices are included with this report:

I. Clinicians Manual
II. Participant Handbook (Control Group)
III. Seated Exercises Manual (Control Group)
IV. Participant Handbook (Experimental group)

APPENDIX I. CLINIALAN MANUAL

PROCEDURE MANUAL

Integrated Physical Therapy Intervention (PTI) & Cognitive-Behavioral Training (CBT) To Enhance Prosthesis Users' Balance Confidence

This manual describes the specific aspects of an eight-session multicomponent Physical Therapy Intervention (PTI) and Cognitive-Behavioral Training (CBT) program that is intended to enhance prosthesis users' balance confidence. Throughout the manual the therapist providing the PTI will be referenced as the *physical therapist* (PT) and the therapist providing the CBT will be referenced as the *behavioral counselor*. The term clinicians is used when both the PT and behavioral counselor are acting together. The terms behavioral counselor and behavioral therapy should be used with the participant rather than the terms psychologist or CBT, respectively, to minimize any stigma associated with psychological treatment.

The multicomponent program will be carefully integrated, with the PT and behavioral counselor concurrently present throughout the eight intervention sessions. The duration of the PTI is approximately 45 minutes and the CBT intervention component is approximately 30-45 minutes. The PTI (Gaming) and CBT sessions are described in detail below for each of the program's eight sessions. Note that there will be a pretreatment assessment visit prior to Intervention Session 1 and a posttreatment assessment visit with an exit interview following Intervention Session 8. Posttreatment assessments will also be completed at three months and six months.

Pretreatment Assessment (Visit 1); Total Time: 110 minutes

A. Anxiety, depression, and PTSD assessment

Prior to session 1, the participant will be asked to complete the *Depression Anxiety Stress Scales (DASS 21)*, a measure of depression, anxiety, and stress; and the *PTSD Checklist for DSM-5 (PCL-5)*, a measure of trauma related symptoms. The measures will be completed by participants at their first meeting with the experimenters, and these measures will be scored and reviewed together by the PT and the behavioral counselor prior to Session 1 (Visit 2). The assessment information is important because elevations in any of the symptoms assessed can affect the administration of both the PTI and the CBT treatment. For example, elevations of anxiety symptoms could affect the intensity of the participant's fear or distress during exposure exercises or affect the individual's willingness to complete the exercises. In such a situation, smaller steps on the individual's exposure hierarchy (described below) may be necessary. Similarly, identification and restructuring of anxiety-related catastrophic thoughts from the pre-treatment assessments may be necessary to facilitate completion of the exposure exercise.

DASS expected completion time: 3 minutes
PCL-5 expected completion time: 4 minutes

B. Balance Concerns and Other Assessment

The clinicians can also review several other assessments that the participant will complete at the beginning of the program which may provide additional information on the participant's fears and concerns around prosthesis use and related activity avoidance. These measures include: *The Activities-specific Balance Confidence Scale (ABC Scale*), *Berg Balance Scale, modified Gait Efficacy Scale (mGES), Fear of Falling Avoidance Behavior Questionnaire (FFABQ), Community Reintegration of Service members Survey (CRIS)*, *The Short Form (36) Health Survey (SF-36)*. To minimize mental fatigue during visit 1, the CRIS (which takes 20-30 minutes to administer) will be administered over phone (it has been validated for administration over the phone) following the session.

ABC expected completion time: 3 minutes
mGES expected completion time: 3 minutes
FFABQ expected completion time: 3 minutes
BBS expected completion time: 17 minutes
L-test for functional abilities: 5 minutes

(Other tests completed at home: Frenchay Activity Index - 4 minutes; PEQ well-being scale - 2 minutes; SF-36 - 8 minutes; CRIS – 30 minutes. These are not prerequisite for visit 2)

Total time for assessments: 38 minutes (additional 44 minutes at home)
Additional Time for Visit 1: 72 minutes (includes:10 minutes for informed consent, 22 minutes for screenings by medical doctor and research prosthetist, 5 minutes post-assessment discussion regarding follow-up monitoring, 35 minutes for gait analysis)

A copy of all of the pretreatment measures and scoring instructions are provided in Appendix A.

Intervention Session 1 (Visit 2); Total time: 85 minutes

Goals:

1) Develop rapport with the participant
2) Secure participant support for using the PTI and CBT to address low balance confidence
3) Psychoeducation on the use of gaming to improve balance and on how balance confidence can affect behavior
4) Determine baseline physical skills on active video games
5) Provide an overview of the eight session program
6) Discuss the importance of behavior change goals
7) Introduce the *Behavior Recording Form for Prosthesis Use* and discuss the importance of careful behavioral recording to making changes in one's behavior

Session 1 – Task A (S1.A): Initial interactions and Understanding the participants needs (20 minutes)

S1.A1) Introductions (3 minutes)

The clinicians will introduce themselves (e.g., student behavior counselor supervised by a licensed clinical psychologist), briefly provide an overview of the treatment (one sentence max) and then discuss confidentiality in the treatment process and the limitations of confidentiality (e.g., concerns about harming self or others; information to be shared with physical therapist because of the joint sessions and the two clinicians working together throughout the program).

S1.A2) Rapport building (5 minutes)

Clinicians will ask the participant to discuss their experience with their prosthesis. Participants may focus on:

- discomfort or pain associated with their prosthesis including phantom limb pain or residual limb pain
- depressive symptoms related to social isolation, disability and/or job loss, or guilt
- post-traumatic stress disorder symptoms if their amputation resulted from a traumatic event.
- social anxiety about using their prosthesis outside of the home
- appearance-related distress
- lack of trust in their prosthesis.

Questions should help to **develop an understanding of the individual's actual prosthesis use** with respect to activities of daily living and recreation, as well as their **prosthesis use concerns** with respect to falling fears and other related fears/anxieties that might limit prosthesis use and activity.

Build rapport with the participant by **normalizing their fears** (e.g., not unusual for people with a new prosthesis to be nervous about using it; be concerned about how others might react) and normalizing any physical limitation associated with prosthesis non-use (e.g., not unusual for people with a prosthesis to have difficulty walking on uneven sidewalks since it requires a lot of strength and balance, a lot of older adults lack the strength to walk up hills).

Use **active listening** skills to communicate your intense interest in understanding the participant's situation and related thoughts and feelings (e.g., reflect, clarify, and

empathize). Your goal is to attempt to understand the individual's experiences with the use of their prosthesis, and their related concerns including falling fears and/or other related fears.

S1.A3) Psychoeducation (12 minutes)

- *Overview*

The psychoeducation will provide initial examples of how balance confidence can affect behavior, thinking, and feeling as well as how ones functional abilities can affect balance confidence. Among the **objectives** are to illustrate how:

- low balance confidence can increase avoidance behavior
- low balance confidence can limit physical activity
- low balance confidence can increase inaccurate self-talk about fall risks.
- improving balance is one way to improve certain aspects of balance confidence
- changing thought is a complimentary way to improve certain aspects of balance confidence

In general, balance-confidence-related behavior and thinking are presented as processes that might inadvertently increase fall risk and limit quality of life. Changing balance confidence thinking and engaging in balance-related physical training are presented as the best approach for being better able to pursue activities of interest, manage activities of daily living, and use their prosthesis most effectively.

Psychoeducation begins with the behavioral counselor followed by the PT which will lead into the PTI

- *Role of the behavioral counselor*

- Provide an overview to the participant. You might begin with the following statement:

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> *"Our work will focus on directly addressing any feelings of low confidence or fears you have that are related to ambulating and/or using your prosthesis. We will do that by identifying the range and types of situations that impact your confidence and/or increase your fear, teaching you physical and mental strategies for addressing low confidence and fear and having you complete those activities or similar activities during your physical therapy training and homework assignments so that you can practice using those strategies.."*

- Define balance confidence - Balance confidence will be broadly defined as:

> *"the participant's perceived ability to successfully complete activities of daily living* ***without losing balance or falling*** *while wearing their prosthesis. Balance confidence can affect behavior."*

- If not already discussed **ask the participant about how their prosthesis use concerns or balance confidence influences their behavior**. During this discussion, clinicians should use the participant's words and experiences as much as possible to make the case for why it is important to address low balance confidence and/or related fears. For example:

If the participant describes feeling unsteady when using the prosthesis, ask about how "feeling unsteady" impacts the participant and discuss how those kinds of feelings can impede their ability to use their prosthesis effectively.

- Provide additional **examples of the effects of balance confidence and the importance of CBT** to address low confidence. Then proceed with language such as:

  "When an individual has low confidence for effectively using their prosthesis (e.g., fear they often might fall; believe the activity is too difficult), these beliefs can result in negative effects (e.g., try to do few things; get down or discouraged). The behavioral training component of the program that I will be leading is intended to help people take a look at aspects of their thinking and behavior that might affect their independent functioning and the reaching of their goals."

  "This part of the program will help you slow down and take a look at aspects of your thinking that might not be helpful or accurate. With practice, you will get better at noticing this type of thinking or 'self-talk', looking at how accurate it is, and changing your thinking if that is needed or helpful."

- Work with the participant **to identify one helpful and one not so helpful way of thinking** about prosthesis use. Then proceed with the following:

  "The program also focuses on what you do (i.e., your behavior) and how to make changes in behavior that you might decide you want to change. In particular, you will learn an approach for using your behavior to change feelings or concerns you might have about using your prosthesis and doing the things you want to do. By breaking these types of behaviors into a series of small steps, and then practicing behaving differently, you will be able to change related worries or concerns and comfortably do these things."

  (if relevant consider that pain can impact quality of life and that physical activity can be an important way to address pain.)

- Work with the participant to **identify one activity avoided or done with fear or concern** and explain how exposure therapy will be used to limit avoidance. Make sure to **normalize concerns/fears**. You might consider discussing an example that is entirely separate from fears of falling by discussing other common fears.

  If the individual is **fairly new to using a prosthesis** consider making an analogy to something the participant can relate to like the first time they learned to ride or ski (best to focus on a new skill attempted as an adult since their memory of that experience is clearer). For example:

  "What was it like the first few times you tried skiing?... During those initial attempts you might have noticed your heart racing, sweaty palms, tight grip…As you became more comfortable, those physiological sensations faded away, you felt more confident, and your ability improved."

If the individual has **used a prosthesis for a long time** consider making an analogy to something that could causes fear in general such as applying for a new job or getting promoted

"What was it like when you first started in the military/at your first job? ... During the first few weeks you might have had butterflies in your stomach or been on edge…As you become more and more comfortable, those physiological sensations faded and you feel more confident."

- You can also have the participant discuss someone else's experience if they have trouble coming up with a personal example

"Have you ever known anyone with little to no confidence in their ability to perform some task such as speaking in front of a large group of strangers? How did that person attempt to deal with that situation?" [if necessary prompt for responses related to avoidance, continued fear/low confidence, negative talk/feelings about self…]"

- Review how specific aspects of the CBT program can improve balance confidence and help the individual make changes they desire. Discuss the effects of thinking on behavior (e.g., the amount of out of home ambulation) and of behaviors on the participant's thinking and feeling (e.g., staying home and social withdrawal decreasing mood and lowering balance confidence).

- Address any questions or concerns the participant has about this approach. Ensure that they have an accurate understanding of how you will work with the physical therapist and the participant to address their low balance confidence / fear.

- *Role of the PT:*

The role of the physical therapist is to address how:

- the video games are intended to act as therapy
- how safety is ensured throughout the intervention
- improving balance is one way to improve certain aspects of balance confidence

The following script may be used to guide this process:

"In addition to what the behavior counselor has said about changing thought to improve balance confidence, exercise and practicing functional activities are also thought to improve balance and balance confidence. When we increase balance and balance confidence we believe that this will decrease risk of falls and increase your ability to do activities that you would like to do in your life"

'"When people think of physical therapy and exercise, what often comes to mind is something like lifting weights or participating in a group exercise class."

"The type of exercise that we are using in this research is different. It is called *gaming*. The *games* are specially designed to improve your balance and your walking. They will be played with you standing or walking on this special treadmill with the game projected onto this screen."

"I will be here with you at all times and you will wear this safety harness so even if you lose your balance, you will not fall. There are also handrails for you to hold on to if needed."

"Later in each of our eight sessions together, we will practice activities together in situations that negatively impact your confidence and/or increase your fear."

"In a few minutes you will watch a video that explain the how the *gaming* works and how to play the games. Do you have any questions for me now?"

S1.B. PTI (gaming session) (45 minutes)

The primary roles of the PT are to implement and supervise all aspects of the PTI. This includes:

- following all safety procedures described below as well as in the treadmill user manual
- providing instructions and guidance regarding playing of the games (in addition to that provided by instructional videos describe below)
- assessing the participants gaming skill level and when it is appropriate to increase difficulty based on performance milestones and self-rated stability
- asking participants to report perceived exertion using the Rating of Perceived Exertion (RPE), perceived stability using the Rating of Perceived Stability (RPS) scale, and level of distress using the distress scale as described below (see Appendix B for scales)

During Session 1 the following steps should be followed during the PTI:

1. (Prior to gaming if needed) Perform some initial simple exercises or physical evaluations to better understand the participants' capabilities – e.g., impairments, pain, balance, and ambulation

2. Complete the Safety Checklist (needs to be added) (see Appendix A)

3. Perform Participant Check-up

   The PT will ask the participant to report on:
   - any recent changes in physical or mental health
   - any recent changes in prosthesis components and functional abilities
   - any recent changes in operation and/or comfort of the prosthesis
   - any falls since their last visit

4. Take a baseline measure of blood pressure (BP) and hear rate (HR). Values should be consistent with those reported on the medical check list. If not, then work with the behavioral counselor to help relax the patient before continuing.

5. Show the participant Instructional *Video #1: Introduction and Demonstration of the Treadmill System*. The video makes salient to the participant the following aspects of the treadmill:
   - Handrails that can be adjusted to the patients height, but which are only to be used in the case of loss of balance
   - Harness/Ceiling Track

- Video Screen
- Computer
- Safety Stops

The video also includes a prosthesis user wearing the safety harness and walking on the treadmill and mentions the use of the RPE, RPS and distress scale

Following video viewing, don the harness and Gait Belt and assist participant onto the treadmill

6. Instruct the participant on the use of the RPE, RPS and distress scale informing them at the scales will be periodically assessed throughout the training. The RPE will be assessed after ever two gaming blocks (5 minutes of game play) during the mandatory 3 minute rest period. In the event that RPE is ever greater than 17/20 the rest period will be increased to 5 minutes and the gaming level may be decreased.

7. Begin warm-up. The warm-up consists of walking at a self-selected velocity (SSV) for 2.5 minutes. Inform the participant that the treadmill will slowly start up and that the speed will be slowly increased only until the point where the participant feels comfortable. After 2.5 minutes press the stop button on the software to allow the treadmill come to a gradual stop. Once stopped, administer the RPE and measure HR and BP. These measures should be elevated from baseline. In the event of excessive elevation (i.e. >169 SBP) BP and HR will be monitored every minute and the participant will not continue the PTI until BP and HR have returned to baseline. In addition, if excessive elevation occurs then BP and HR will be continuously monitored during all ensuing rest periods. In absence of elevation in these measures only RPE will be taken at the start of rest periods as described in 7 above.

8. During the first rest period following the warm-up show the participant *Video #2: Playing Catch Game.* In addition you should show *Video #3: Playing Italian Alps Game* during a future rest period prior to a block that includes this game. It is not recommended to show this video to everyone at the start as not everyone may advance to playing this game. I may be necessary to show this video at a future session if the game is used in future retention testing but not baseline assessment.

   Video #2 describes/demonstrates the following aspects of the Catch (Trash Bin) game (referred to as game A1 in Appendix C)
   - the game is projected on the front display screen
   - the game is played in static mode (standing in place. While the game can also be played in stepping mode or dynamic mode (while walking), this is only introduced as needed.
   - paper wads fall downwards on the screen and the goal is to catch the wads with a waste-basket projected on the screen – the basket can be moved by medial-lateral (side-to-side) shifting of the center of pressure (CoP);

   Additional information about the game not included in the video:
   - each playing mode has three levels of difficulty
   - difficulty is increased by increasing the number of and the falling speed of the wads as well as the range of the CoP needed to catch the wads.

- for static mode, the participant stands on footprints projected on the treadmill using whole body weight shifts – i.e. rotations abut the ankles- to shift the weight completely onto one foot or the other to move the CoP; improper movements include, but are not limited to: later trunk flexion, excessive use of the arms; improper and proper movements will be demonstrated by a prosthesis user in the video
- for side stepping mode a lighted box is projected on the treadmill and the participant moves the CoP by taking side steps while staying within the lighted area; again the participant should not rely on excessive trunk or arm motion
- for dynamic mode the participant will walk at 80% of SSV and alter cadence, step length, step width and step time as needed to appropriately shift the CoP; again the participant should not rely on excessive trunk or arm motion
- depending on the participants abilities and progression they may not play the game in all of these modes; they will only play the modes and level of difficulty that they are capable of performing

Video #3 describes/demonstrates the following aspects of the Catch (Trash Bin) game (referred to as game A2 in Appendix C)

- the game is projected on the frontal display screen
- the game is only played in dynamic mode (while walking)
- the participant walks at 80% of SSV and alters cadence, step length, step width and step time as needed to appropriately shift the CoP in order to maneuver a shopping cart forward. The goal of the game is to pick up 5 different pizza ingredients by shifting the CoP whilst avoiding obstacles.

Additional information about the game not included in the video:

- difficulty is increased by increasing the number of obstacles, decreasing the distances between obstacles, and placing obstacles more central to the center of the road.

9. (After viewing both videos) Ask the participant if there are any questions

10. Assist the participant onto the treadmill

11. Begin the process of determining the participants gaming skill level by playing 12 gaming blocks of 2.5 minutes each as outlined in Step 1 Appendix C

12. At the conclusion of the gaming session the PT will:
    - Summarize Gaming Skill Assessment (Session 1)
    - Reiterate connection of Gaming and enhancement of balance/balance confidence
    - Answer participant questions
    - Transition to clinical counselor for psychoeducation

- *Role of the behavioral counselor:*

- Unobtrusively observe the PT treatment in order to better understand the participant's use of their prosthesis. The goal is to gain understanding of the participant's abilities and limitations and prosthesis use concerns (e.g., extreme reluctance when the participant was asked to do a particular game activity).

- Observe the participant for any signs of distress including tensed facial expressions or heavy shallow breathing. Noting the game during which this occurred. When appropriate use this information to guide conversations during activities that occur after the PTI. For example, you may try to relate the skills in the game that cause distress to feared activities or specific thoughts identified in rapport building.

- Record the reported levels of RPE, RPS and distress on the data collection sheets. If any particular game or game level was associated with a high self-reported distress level, use this to guide ensuing conversations.

S1.C. Program review (5 minutes)

The behavioral counselor will briefly review:

- The structure of the 8-session program by referring to the page in the CBT Program participant handbook that includes the *Program Overview* (See *Appendix B*). Make sure to discuss that the program involves **"homework" assignments** between sessions. The program is framed to participants as analogous to taking a class to learn a new skill and that homework completion or practice is a very important component of learning new skills

- Pretreatment assessment findings based on the participant's completion of the *DASS 21* and *PCL-5* (Appendix A). Briefly discuss whether reported symptoms are within the nonclinical range or are elevated. Provide examples of how elevations of specific symptoms might affect thinking and behavior (e.g., depression related negative perceptions and low energy).

- If the participant's amputation resulted from a traumatic injury, the participant might have significant trauma from their injury; you will have some sense of this based on their completion of the *PCL-5*. Relatedly, trauma could result from a fall that occurred with the prosthesis. If the *PCL-5* is elevated (i.e., ~ $\geq$ 33pts), consider gathering the following information to assist with conducting exposure treatment related to the traumatic event.

  Amputation history: Gather details of the traumatic event that led to their amputation. When and where did the injury occur? What does the patient believe was the cause of the injury? Details of acute treatment received also help the practitioner to understand the patient's needs: How soon did help arrive? Were there any complications in the hospital course (some patients may have additional trauma in this regard)? What rehabilitation services has the patient received?

  Fall history: Falls, especially those that resulted in an injury, could also prompt a trauma response. Some of this information will be available on the medical intake form that was obtained prior to session 1, although the form only asks about falls in the last year. Gather details about the fall(s) to have a more complete picture of the participant's fear/anxiety.

  Remember to normalize the participant's response to the trauma and mention that aspects of the traumatic event might be integrated into the exposure training to address this aspect of the participant's anxiety.

S1.D. Assignment of Homework (10 minutes)

S1.D1) Assignment #1: Behavior recording (7 minutes)

Participants will be asked to monitor whether they avoid any activities or limit their activity during the upcoming week due to prosthesis concerns, and what thoughts occurred when this happened. Participants are asked to list specific occurrences of these behaviors including the date, time, context in which it occurred and their related thoughts using the *Behavior Recording Form for Prosthesis Use* that is provided for in the participant handbook (also see Appendix B of this manual). The behavioral counselor should:

- Review the *Behavior Recording Form for Prosthesis Use* with the participant,
- Provide the rationale for using this form

> *"Though you have already told me about some of the situations that you avoid and/or make you nervous, it is helpful to track the situations that come up over the course of the next week, what you think about them, and how they impact you. Some of these situations may be ones that you have already identified, but others may be new. By tracking these situations, we will increase your awareness of how any anxiety or nervousness you have about different situations impacts you, which we can then address in our work together."*

- Use one of the examples the participant provided earlier about prosthesis use concern to complete the behavioral form with the participant, including recording the date and time. You may also provide another example of a situation they might have experienced focusing on related thinking that might have occurred at the time..

S1.D2) Assignment #2: Goal setting (3 minutes)

The participant is asked to review the *Making Goals for Change* handout in the participant handbook (see Appendix B of this manual) before the next session. The participant should think about least 1 short, medium and long term goals relevant to balance confidence and/or physical/social activity. The goals will be collectively identified and written down during the next 2 sessions. The behavioral counselor should:

- Point out in the handbook and review the *Making Goals for Change page*
- Describes the importance of goal setting to making behavior change
- Provides examples of the process.

S1.E. End of session summary (5 minutes)

- Provide a brief summary of the session for the participant.
- Attempt to identify any possible obstacles to the completion of the assignments and problem solve with the participant possible solutions to such problems (e.g., always having the form with them, completing it before bed, taking notes on smartphone, asking someone to help remind them to complete the form…) Acknowledge that it is hard to remember to do a new behavior and discuss potential concerns about proposed solutions.
- Discuss any additional logistical barriers (e.g., meeting frequency)

- Remind participant of the time/date of their next session by writing it on the calendar in their handbook.

S1.F. Post-Session clinicians' review/discussion of participant's progress

To accomplish the regular integration of PT training with CBT, clinicians will work in close collaboration. At the end of each session, the PT and CBT clinicians will review and discuss the emerging understanding of the participant's fears and concerns, physical limitation, and overall progress in both components of the intervention program.

The clinicians will discuss the emerging understanding of the participant's fears and comfort with use of their prosthesis and their PT training progress. These discussions and reviews of patient progress will help to better integrate the two training program components. Thoughts regarding potentials exposure exercises for session 2 will be discussed by following the PT exercise hierarchy and a list of likely feared situations and potential exposure exercise that have been developed (**still needs to be added**)

Intervention Session 2 (Visit 3); Total time: 92 minutes

Session Goals:

1) Initial Review of behavioral recording to understand specific difficulties during week
2) Expose participant to all games that will be played throughout training and attempt to link at least one game to a difficulty identified in homework
3) Review Behavior recording in greater depth to increase understanding of participant's avoidance behaviors and activity restrictions
4) Work with the participant to develop specific behavioral goals
5) Introduce systematic exposure to feared activity (referred to as Exposure Therapy [ET] in the document) as a process for reducing fear, changing unhelpful thinking, and changing behavior
6) Review with the participant the *Breath to Relax* page in the participant handbook (see Appendix B of this manual) and guide them through the practice of diaphragmatic breathing

S2.A. Pre PTI Check in (no more than 5 minutes)

The PT will perform an initial check-in as described in S1.B (step 3). This should take place while donning the safety harness to maximize time. If time allows, the PT will ask about any movements that caused problems in terms of homework completion and try to connect them to upcoming games. For example, if lateral weight shifts are mentioned as problematic then the PT might say "I can see why that was a challenge. By playing the Trash Bin game today it should help you improve that movement". During game play the PT should return to this idea and make salient to the participant how the Trash Bin game is targeting lateral weight shifting. The behavioral counselor will actively listen to the check in and if avoided situations/emotions are mentioned during this period, will address this during later in the session**.**

S2.B. PTI (45 minutes)

During this session the participant will be exposed to four new games which are the four games involved in the treatment. The initial level of difficulty that is experienced for each game will be dictated by the gaming skill level determined at session 1. During gaming the PT should try to remind the participants about how their movements relate to activities identified at the Pre-PTI Check –in.

During Session 2 the following steps should be followed during the PTI:
(see section S1.B for additional details of those steps which are identical to steps from Session 1)

1. Complete the Safety Checklist

2. Take a baseline measure of blood pressure (BP) and heart rate (HR).

3. Don safety harness and assist participant onto treadmill.

4. Warm-up for 2.5 minutes followed be BP, HR and RPE measures taken during rest period

5. Conduct retention testing block

Instruct the participant that they will be playing a single 2.5 minute a game played during the last session to make sure that their gaming skill level hasn't changed. Before beginning make sure that hey recall how to play the games they experienced during session. The PT will follow Step 2 in Appendix C to determine whether game A1 or A2 will be played during retention testing and what level of that game will be played based on the level of gaming skill level determined at the end of session 1. After the retention block the RPS should be taken and a rest period inserted. Based on performance on the retention block, use Step 3 in Appendix C to determine the level at which each game should begin at during the ensuing game play. Follow up the 2.5 minute retention block with rest

6. (During the first rest period) Show the participant *Video #3: Playing Traffic Jam Game*;

   Video #3 demonstrates the following aspects of the Traffic Jam Game
   - the game is projected on the front display screen
   - the game is only played in static mode
   - the goal of the game 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 limb; if cars are in the right lane then weight must be shifted to the left limb and vice versa to clear the intersection.
   - the video will demonstrate that weight shifting can occur while keeping both flat on the ground. While weight shifting can occur by lifting the heel of the unloaded limb or by standing in single support by lifting the unloaded limb off the ground these motions are not initially appropriate. While this will not be told directly to the participant the PT should alert them during game play if inappropriate motions are used and help them to modify their motions.

   While the video is being shown the PT will describe theses aspects to the participant.

Note that for this game, difficulty is increased by increasing the rate at which cars approach the intersection

7. (After viewing all videos) Ask the participant if there are any questions

8. Assist the participant onto the treadmill

9. Begin gaming block 1 as described in Step 4 of Appendix C. After each block if a milestone is reached (see list of milestones in Step 4 of Appendix C) assess RPS. If based on RPS and observations the PT deems that progression is warranted for that game, then the difficulty may be increased according to Appendix C. After 5 minute (1 blocks) insert rest. Always take RPE and distress rating before rest and take BP/HR as needed

10. During the second rest period show the participant *Video #4 Playing Soccer Game;*

    Video #4 demonstrates the following aspects of the associated game, which are to be described by the PT while watching the video:
    - the games is projected on the front display screen

- the game is played in static mode (standing in place). While it can be played in stepping mode or dynamic mode (while walking) this is not shown at first.
- For Soccer Game: in all modes 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 medial-lateral (side-to-side) shifting of the center of pressure (CoP); after bouncing off the paddle the balls may ricochet off of side walls; each mode has three levels of difficulty; difficulty is increased by decreasing the length of the paddle..
- the general play in each mode is similar to that described in Video #2

As in all games each mode has three levels of difficulty; difficulty is increased by decreasing the length of the paddle.

11. Play block 2 and insert 3 minutes rest after blocks; always take RPE and distress rating before rest and take BP/HR as needed. While resting after block 4 (before block 5) show Video #5 – Playing Arkanoid. Similarly after block 5 (before block 6) show Video #6: Playing Forest Walk.

    Video #5 demonstrates the following aspects of the associated game, which are to be described by the PT while watching the video:
    - the games is projected on the front display screen
    - the game is played in static mode (standing in place). While it can be played in stepping mode or dynamic mode (while walking) this is not shown at first.
    - For Arkanoid Game: a ball is dropped from the sky and fall downwards on the screen and the goal is to continuously bounce the ball off of a paddle so that the ball hits and breaks a series of bricks; after hitting the bricks the balls again falls down to the paddle; the paddle can be moved by medial-lateral (side-to-side) shifting of the center of pressure (CoP);

      (additional information that may be left out)
      after breaking the bricks the balls may ricochet in different directions and the ball can also ricochet off of side walls; when all bricks on the screen are broken a screen with a new brick pattern appears; there are a total of 5 brick patterns;

    As in all games each mode has three levels of difficulty; difficulty is increased by decreasing the length of the paddle.

    Video #6 demonstrates the following aspects of the Forest Walk Game
    - the games is projected directly onto the treadmill surface
    - the game is played only in the dynamic mode (while walking)
    - 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 everything else

12. After completing block 6 note the highest level of difficulty attained for each game. The highest level attained will inform the level of game play for the retention block in the next session as described in Step 5 in Appendix C

13. At the conclusion of the gaming session the PT will:
    - Summarize Gaming Skill Assessment (Session 1)
    - Reiterate connection of Gaming and enhancement of balance/balance confidence
    - Answer participant questions
    - Transition to clinical counselor for psychoeducation

- *Role of behavioral counselor*

For all session the role of the behavioral counselor during gamin is the same as the role describe for Session 1 (see section S1.B – Role of the behavioral counselor for a description of the role)

S2.C. In depth-review of behavioral recording homework (12 minutes)

- Role of the counselor

The behavioral counselor will review the data entered on the *Behavior Recording Form for Prosthesis Use*. During the review the primary **goal of the counselor** is to:

- increase the participant's understanding of the connections between behavior and behavior avoidance
- increase the participant's understanding of their appraisal of and thinking about feared situations

The review should follow these general steps:

1. Ask the participant what they noticed during completion of their behavioral recording
2. Help the participant examine potential patterns in situations and avoidance behaviors
3. Specifically review the thoughts that prevented the participant from doing/completing an activity due to fears and concerns (e.g., "I almost fell once when reaching up high, so I am at high risk for losing my balance if I try to do that when I use my prosthesis")
4. Introduce thought restructuring in relation to the identified avoidance and fear related thoughts

   thought restructuring - the process of carefully examining specific thoughts and the accuracy of these thoughts, and the generation of more accurate reappraisals of situations
5. Provide the participant with the *Belief Rating Scale* (*Appendix B*) and have the participant rate their belief in the accuracy of the related thoughts
6. Help to generate a more accurate appraisal if the initial appraisal is found to be inaccurate.

The activity associated with the thoughts that are being appraised (steps 3-6) is the same activity that will later be approximated in exposure therapy (see below)

During review of recording forms the counselor should also:

- Reinforce the participant's completion of the form, acknowledging their effort
- Discuss any concerns about/obstacle to completing the behavioral recording form

If the participant did not complete any behavioral recording, collaboratively work on identifying issues that got in the way, and work with them to use problem solving to address the issues.

- Role of the PT

During the review the PT will attempt to connect thoughts to skills used during the gaming and to current functional abilities to help generate more accurate appraisals. In addition the PT will actively listen to determine if the potential exposure therapy exercise discusses at the end of session 1 will be appropriate for the next part of the session or if not, the PT will consider a new exercise to be used.

S2.D. Exposure therapy jointly undertaken by clinicians (14 minutes)

Based on review of the participant's behavioral data (as described above) and working with the participant, the clinicians should structure an initial low to moderate level exposure exercise - one that falls in the 30-60 range of the distress scale (Appendix B) - that approximates an activity avoided or completed with significant balance-confidence-related anxiety during the past week (e.g., reaching for an object on a shelf that is chest high or higher). A general idea should have emerged as to potential exercises that can be employed to accomplish this task following discussion after session 1. However, since we will only have limited insight into the participant's behaviors and fears by session 2, for simplicity and expediency, the **exposure therapy (ET) in this session should be limited to exercises on the treadmill – walking at increasing speed, narrow base of support walking, curved path walking around cones, perturbation training, obstacle avoidance (Forest Walk game).** In future sessions, ET exercises should ideally be limited to the PTI games only if it becomes apparent that anxiety during game play is limiting skill acquisition.

Example –a participant reported in their behavioral data avoiding crowded places because they feared they could not maneuver around people or would lose their balance if bumped into by someone. The PT also noticed that in this session the participant struggled with the game which focused on this skill (i.e. Forest Walk – see Appendix 3). In such a situation, the Forest Walk game could be used as a context for structuring an ET exercise. As the sessions progress, if the ET continues to focus on this same fear then the exercises should transition from the treadmill to over ground more realistic scenarios – e.g. walking in the university hall after classes let out.

The ET procedure will follow these steps:

1. Identify the activity to be addresses in the exposure therapy, which should emerge during in depth
review of behavioral recording as described in the steps 3-6 in section S2.C

2. Describe the ET exercise to the participant. The connection between the exercise and the avoidance behavior and feared situations from step 1 should be made salient to the participant by the clinicians.
3. Have the person rate their "discomfort" in having to engage in the task (e.g., fear, anxiety, other distress) using the *Distress Rating Scale* (*Appendix B*). If the rating is outside of the range of 30-60 then the difficulty should be increased/decreased appropriately and discomfort reevaluated.
4. Engage in the exercise and ask the participant to periodically re-rate their distress level to determine if discomfort has decreased (e.g., every 2-5 minutes)
5. Repeat/continue the activity and the distress ratings to promote the occurrence of an ET precipitated reduction in fear or distress (ideally 20 or more points on the distress rating).
6. At the completion of the ET activity, have the participant complete a final discomfort rating and a re-rating of their belief accuracy of the thoughts form step 1.
7. Ask about the irrational thought again and help the participant to generate a more accurate appraisal based on their experience during the exposure therapy.

- *Role of the PT during ET*

  In addition to determining the exercise to be used during the ET the PT will:
  - ensure that the ET exercises are properly and safely performed
  - scale the difficulty of the exercise based on skill level and performance

- *Role of the behavioral counselor during ET*

  The primary role of the behavioral counselor is to monitor the participants' beliefs and discomfort levels, as described above, making salient to the participant any changes in these metrics and the importance of these changes.

S2.E. Post Exposure Psychoeducation (15 minutes)

This task will primarily be performed by the behavioral counselor. Specific roles for the PT are noted

S2.E1) Goal setting (10 minutes)

This process is intended to guide the participant in the identification of one short term behavior change goal relating to the use of their prosthesis and their balance confidence, and allow the participant to continue the process as homework. The steps include:

1. Re-reviewing the *Making Goals for Change* handout.
2. Working collaboratively with the participant to identify one goal and the time line for the goal, and recording the goal on the goals sheet included in the participant handbook (see Appendix B in this manual)

   The goal should be:

   - Reasonable and realistic (e.g., won't require extreme effort on the part of the participant); the goal might be based on something that is already being done but could be improved

- Consistent with behavior change that the participant desires
- Sufficiently specific and objective so that its achievement can be reliably evaluated (i.e., think of SMART goals: Specific, Measurable, Achievable, Relevant, and Time-based)
- Chosen by the participant and not the behavioral counselor

3. Inform the participant that their experience with the goal will be discussed in the next session and that whether or not they achieve the goal, you both will learn something from their goal experience

Sometimes participants are enthusiastic and want to set unrealistic goals or that involve very rapid behavior change. If the participant wants to set goals that involve steps that are too big or occur too quickly, praise the participant's enthusiasm and desire to aim high, but work with him/her to make the goal more realistic. Let him/her know that she can always achieve more, but we want to ensure that the goal is attainable since sometimes things come up that make it more challenging than we anticipate when we set a goal. Remind them that the resultant goals can be modified as needed during the course of the program. Depending on how physically active the participant is, decreasing sedentary activity (i.e., watching television, surfing the internet…) might be an appropriate starting goal. Ultimately go with the goal(s) the participant chooses, understanding that their experiences might make them more receptive to goal refinement as the program progresses.

- *Role of PT*

Ensure that the goals being set are realistic in light of the current and anticipated functional abilities of the participant. If needed, assist the participant to set more reasonable goals by helping them understand their abilities and where they are expected to proceed by the end of the program. Ensure that this is further discussed with the behavioral counselor in step during the post-session clinical review of progress.

S2.E2) Relaxation training: introduction (5 minutes)

Learning to relax is presented as a skill that can be mastered with practice like other skills, and diaphragmatic breathing framed as an easy to learn and useful relaxation skill.

To achieve this goal the following steps should be included:

1. Review with the participant the *Breath to Relax* handout in the participant handbook (see *Appendix B*) in detail answering questions in the process.

2. Guide the participant through the practice of diaphragmatic breathing during the session (can be referred to as deep breathing; see Appendix B).

3. Remind participants to use the handout to guide their home practice.

S2.F. Assignment of Homework

S2.F1) Assignment #1: Behavioral recording (1 minute)

Participants are asked to continue behavioral recording using the *Behavior Recording Form for Prosthesis Use* form. Provide the following rationale for continuing this assignment:

- new situations may come up as the participant changes their behavior (e.g., attempts more out of the home travel) which will be important information to have
- new thoughts may arise regarding prosthesis use, which will be important information to have

Again address any concerns the participant has about completing this form and problem solving as needed.

S2.F2) Assignment #2: At-home exposure therapy (3 minute)

Based on the in-lab ET activity worked on during the session and the initial behavior change goal, the clinicians will work with the participant to identify a prosthesis use activity for practice at home before the next session. The activity is to be written down in the handbook where the participant will marks its' completion. The activity should be:

- achievable (e.g., won't require too much effort on the part of the participant; might be based on something he/she is already doing or has begun to practice)
- in-line with the participant's desired goals and activities.
- in-line with current functional abilities
- minimally/not at all risky to complete

The behavioral counselor will write down the activity on the proper page of the participant handbook (see Appendix B- At-home Assignments Completion Sheet). Participants are encouraged to complete the page whey have engaged in the ET activity. The page may be reviewed at the next Check-in and is used to remind the participant to complete the task and feel accomplishment after having done so.

S2.F3) Homework Assignment #3: Breathe to Relax (1 minute)

The participant is asked to review the *Breath to Relax* handout again before the next session and practice the procedure at least once. They will not down the completion in their handbook. Let the participant know that relaxation training will be reviewed, discussed further, and practiced again at the next session.

S2.F4) Homework Assignment #4: Goal setting (1 minute)

The participant is asked to identify additional short, medium and long term goals by completing the goal setting sheet in the handbook, following the criteria discussed above. Let the participant know that the goals will be reviewed and discussed further during the next session.

S2.G. End of session summary

- Provide a brief summary of the session for the participant.
- Attempt to identify any possible obstacles to the completion of the assignments (e.g., too much to do this week; not interested in setting goals), and problem solve with the participant possible solutions to such problems. Acknowledge that it is hard to remember to do a new behavior and discuss potential concerns about proposed solutions.
- Discuss directly whether what you are asking them to do as homework is realistic to complete before the next session and, if necessary, modify homework based on their feedback

- Remind participant of the time/date of their next session by writing it on the calendar in their handbook.

S2. H. Post-Session clinicians' review of progress

The process followed after Session 1 will be repeated making sure to incorporate additional information that the clinicians gathered during the current session to update their understanding of the participant's fears and concerns, physical limitation, and overall progress. The clinicians should make sure to discuss a potential ET exercise for the upcoming session that could approximate the activity assigned in F2 above. In general, the goal of these discussions is to integrate the two training program components seamlessly. Therefore any suggestions for future participants or future sessions with the current participant should be discussed at this time as well

Intervention Session 3 (Visit 4); Total time: 92 minutes

Session Goal:
1) Continue use of previously introduced procedures and skills
2) Review and practice diaphragmatic breathing as a useful coping skill in session
3) Refine initial goals for behavior change

S3.A. Brief check-in (4 minutes)

The check-in process is identical to that from session 2 (See section A from Session 2). In addition, it is important to briefly touch on the at home ET exercise.

S3.B. PTI (45 minutes)

See section B from Session 2

S3.C. In depth-review of homework assignments (25 minutes)

S3.C1) Review of At-home ET (6 minutes)

The results of the related homework assignment (Assignment #2) from the previous session are discussed and reviewed in detail. The clinician will:

- positively reinforce effort and approximations of success in the completion of this assignment
- discuss and problem solve any assignment related difficulties

If the assignment proved difficulty, inquire about the specific challenges for that particular goal and identify a similar in-session ET exercise for this session to approximate the activity assigned in the homework. This may require having the PT probe the specific movement patterns that led to the challenges.

S3.C2) Review of Relaxation training (4 minutes)

Follow the following steps:

1. Re-review the *Breath to Relax* handout
2. Discuss participants at home practice attempts

3. Practice diaphragmatic with the guidance of the clinician in session for approximately 5 minutes. The clinician should assist the participant during the practice in addressing any issues that came up during in home practice the prior week (e.g., frequent distracting thoughts) or questions about the procedures.

S3.C3) Review of Goal setting (5 minutes)

The behavioral counselor will review the new goals that were set by the participant after the prior session, using the approach laid out in Section E1 - Session 2. If goals still require additional thought then consider asking the participant to continue the goal-setting process as part of their home work assignment.

S3.C4) Review of Behavioral recording (10 minutes)

The process of reviewing this assignment is identical to that from Session2 (see section C) with one additional emphasis. The behavioral counselor should use the recordings to **identify progress** by making salient:

- any activities the participants is now beginning to try since session 1
- any activities the participant is now doing more frequently since session 1

S3.D. Exposure training (10 minutes)

The general process described in Section D - Session 2 will again be followed. In the current session however there is additional information provided by the prior completion of the At-home ET exercise and the discussion this assignment. The clinicians will work together to prioritize whether the ET exercise should be:

- related to activity from end of session 2 (e.g., if the participant was successful in completing the ET then increase the level of challenge and better approximate real-world situation – move from avoiding virtual obstacle on treadmill to physical obstacles while walking overground; repeat the level of challenge if it was still very difficult at the end of session 2)
- related to a specific challenge identified when discussing the ET homework assignment

If it is possible to have the exercise encompass both, and have this be made salient to the participant, then this would be ideal

S3.E. Assignment of Homework (4minutes)

Homework assignments are nearly identical to those from session 2 (see section S2.F for information on assignments) and include continuing to formulate individual goals. The one difference is that the Breath to Relax handout need not be re-reviewed (Assignment #3 from Session 2).

F. Session review (4 minutes)

The process of session review is identical to that following session 2 (see section S2.G for details on the process).

G. Post-Session clinicians' review of discussion

The process of the post-session review is identical to that following session 2 (see section S2.H for details on the process). By this point a more complete understanding of fears and skill levels will have been developed such that more specific potential future ET exercises can be discussed.

Intervention Session 4 (Visit 5); Total time: 88 minutes

Session goals:
To continue use and review previously introduced procedures including physical skill acquisition during PTI, behavioral recordings and community-based exposure exercises.

S4.A. Brief check-in (4 minutes)

The check in process is identical to that from Sessions 2 and 3 (see section S2.A for details)

S4. B. PTI (45 minutes)

The check in process is identical to that from Sessions 3 (see section S3.B for details)

S4.C. In depth-review of homework assignments (21 minutes)

The homework assigned after session 3 was similar to that assigned after Session 2 and discussed during session 3. Therefore the homework review process from session 3 (see Sections S3.C1, S3.C3 and S3.C4) should be followed. While the participant will not have specifically identified new goals since the prior sessions, goals will still be re-evaluated and updated at this point. While Breath to Relax will not specifically be practiced or reviewed the participant should be encouraged to continue to practice the skill at home and the assignment sheets for at-home ET ask the participant to note the amount of days breathing was practiced as a reminder. Positive reinforcement should be provided if the handbook indicates that the skill was practiced.

If the participant reports/demonstrates substantial improvements in anxiety and fear of falling and other, more traditional barriers to physical activity are present (e.g., lack of motivation) that limit their mobility, ***additional physical activity related content could be discussed during this session or in subsequent sessions***.

Potential topics include:

- Social support-instrumental and emotional

  Appendix D provides websites and contact information for support networks that are specific to prosthesis users and may be sought out. You may consider asking the participant to seek out information on similar organizations on their own as an at-home assignment that could be discussed at a future session, during which you may provide them with the complete listing in Appendix D.

- Setting physical activity goals and tracking physical activity (i.e., minutes, steps, specific activities)
- Finding ways to make physical activity enjoyable
- Identifying rewards for physical activity goal completion
- Identifying safe places for physical activity

  Appendix D provides websites and contact information for prosthesis-specific physical activity opportunities – although some may be relevant only to higher functioning individuals. You may consider asking the participant to seek out similar information on similar organizations on their

own as an at-home assignment that could be discussed at a future session, during which you may provide them with the complete listing in Appendix D.

- Planning and scheduling physical activity
- Identifying strategies for addressing pain related to prosthesis use

Finding activities that may reduce pain (e.g., bicycling). Remember that while we ideally want to increase physical activity, we are also interested in increasing community integration (participation), which need not be defined by increased physical activity. For example, you could recommend calling a friend and going to a coffee shop as well. By increasing social activity physical activity should also increase

Understanding the "sweet spot"- the amount of time spent engaged in physical activity before pain occurs

Maintaining more consistent levels of physical activity rather than engaging in high amounts of activity one day and then low amounts the next day

Identifying factors that increase pain related to prosthesis.

S4.D. Exposure training (12 minutes)

The general process for ET is identical to that used in session 3 (See section S3.D for details on the process)

For participants who reported traumatic events, exposure training could incorporate the trauma either via imaginal or in vivo exposure.

Imaginal exposure**:** Participants tell the story of their traumatic event. The telling of the story should last 10 – 20 minutes and can involve what happened prior to the trauma, as well as after the trauma. If the participant is asked to tell the story repeatedly, the behavioral counselor should structure the retelling by encouraging the participant to close their eyes, be more vivid in their description (e.g., what sounds, smells, sights were present? What sensations did you notice?…) and to close their eyes. Just as with the exposure that occurs during the treadmill session, distress ratings should be completed regularly. These retellings could be recorded for the participant to listen to in between sessions. If a participant's distress levels remain high at the end of the retelling, relaxation strategies should be used to help the participant feel better before h/she leaves. Be aware that negative cognitions about the accident could come up during the telling and retelling and should be restructured.

In vivo exposure: In vivo exposure related to the trauma will likely only be possible as a homework assignment. Imagining the completion of in vivo exposure may be an important step prior to assigning a homework assignment related to in vivo exposure of the trauma.

S4.E. Assignment of Homework (4minutes)

Homework assignments are nearly identical to those from session 2 with the exception of providing the See section S2.F1-3 (no Goal-setting assignment).

F. Session review (4 minutes)

The process of session review is identical to that following session 2 (see section S2.G for details on the process).

G. Post-Session clinicians' review of discussion

The process of the post-session review is identical to that following session 2 (see section S2.H for details on the process). By this point a more complete understanding of fears and skill levels will have been developed such that more specific potential future ET exercises can be discussed.

Sessions 5, 6 and 7 will follow the protocol outlined in Session 4. Remind participant that their last session is next week and that you will be discussing strategies for maintaining progress

Intervention Session 8 (Visit 9); Total time: 88 minutes

Goals:
1) Summarize progress made in PTI; Review of all strategies learned and used
1) Summarize the participant's behavior change goal(s) and their progress in reaching these goals changes
2) Review of all strategies learned and used
3) Discussion of strategies to make any necessary further gains
4) Discussion of strategies and prevent relapse.

S8.A. Brief check-in (4 minutes)

The check in is identical to all previous sessions.

S8.B.PTI (45 minutes)

The PTI is identical all other session. However after the final gaming block an additional 2.5 minute block is added. During this block they will play the level of game A1 or A2 corresponding to one level higher than they were able to complete during Session 1. It should be brought to the players' attention that they were unable to complete this level when they started as a means to reinforce skill acquisition.

S8.C. Further review of homework & CBT skill practice

S8.C1) Review of Behavioral recording (10 minutes)

The process of reviewing this assignment is identical to that from previous sessions with several important additions. The counselor should:

- Highlight the progress the participant has made by referring back to their first few forms and the problematic situations he/she identified any activities the participant is now doing more frequently since
- Ask the participant about what he/she thinks helped her make this progress
- Inquire about any changes in thoughts and behavior that may have contributed to the improvements noticed
- Identify any remaining issues from recording forms

S8.C2) Review of At-home ET exercise

This process is identical to all previous sessions (see Section S3.C4 for details of the process)

S8.C3) Identify any areas in need of additional efforts not covered above

S8.D. Exposure training (10 minutes)

The same process used in previous sessions will be used (see section S3.D for a description of process). In addition, if during the homework review areas requiring additional efforts are identified (section S8.C2) then additional ET exercise specific to these areas should be considered.

S8.E. Post Exposure training

S8.E1) Behavior change goal(s) review and progress summary

The participant's behavior change goal(s) and their progress in reaching their objectives is reviewed. The clinicians will focus on making progress salient to the participant by:

- Having the participant identify what progress they have noticed over the course of the program with respect to the At-home and in-lab ET task

    Both PT-related skill gains (e.g., balance shifting; ambulating around obstacles) and CBT-program gains (e.g., reductions in avoidance behavior) are discussed. If the participant does not directly bring these up they can be brought up through use of Socratic questioning

- Identifying related skills and strategies (e.g., deep breathing) that have been learned

S8.E2) Relapse prevention

Relapse prevent will broadly follow the procedures outlined by Marlatt and colleagues (e.g., Marlatt & Gordon, 1985; see summary by Parks & Marlatt, 2000) and more recently applied to a broad range of problems. Relapse, the loss of part or all of the desired behavior change, will be presented to the participant as an understandable and preventable process. Relapse will be framed as resulting from the occurrence stress increasing, high risk situations (e.g., prosthesis related lesion) and a failure to recognize and cope with challenging situations effectively (e.g., quickly see one's prosthetist for evaluation and intervention). Together the clinicians will follow the general steps below when discussing relapse:

1) Work with the participant to **identify at least three high-risk for relapse situations** that have a high probability of occurring sometime in the future. The discussion should include:

- Asking the participant about what kinds of things would potentially interfere with the progress made
- Encouraging the participant to think broadly about any kind of situation that could limit their balance confidence or restrict their activity.
- Discuss what signs/symptoms the participant would notice in themselves if their balance confidence decreased or they restricted their activity.

2) Provide the rationale that it is **easier to address** lapses in behavior change **when you catch them earlier.**

> An analogy can be made to stopping a snowball at the top of a hill rather than closer to the bottom of the hill. As the snowball goes down the hill, it gathers momentum and becomes larger and larger. Thus, it is much easier to stop it higher up on the hill rather than closer to the bottom of the hill.

3) Work with the participant to **identify maladaptive and adaptive coping strategies for each situation** from step 1. Coping strategies could include, but are not limited to:

- completing the *Behavior Recording Form*
- identifying goals
- deep breathing
- reaching out to friends/family who can provide support and help them work through their fear or restricted activities. Consider sharing the information from Appendix D regarding opportunities for support networks

4) Ask the participant to **discuss any related changes they have noticed**.

> *"Have any of the changes you made with respect to low balance confidence and feared situations impacted other areas of your life (e.g., social relationships, job related tasks or relationships, thoughts about the future, body image issues…)"*
>
> Try to connect some of these changes to the original rationale that was presented for addressing their fear and low balance: to address any restrictions in activity/behavior that result from the fear/low balance confidence and improve their quality of life.

References for relapse Prevention

Marlatt, G. A., & Gordon, J.R. (Ed.). (1985). *Relapse Prevention: Maintenance strategies in the treatment of addictive behaviors.* New York: Guilford Press.

Parks, G. A., & Marlatt, G. A. (2000). Relapse Prevention Therapy: A Cognitive-Behavioral Approach. *The National Psychologist, September 1, 2000*

Appendix A
Pretreatment Assessments

(Appendix A of the Clinicians Manual has been omitted from this report to save space; it includes all surveys that were included with IRB and HRPO approved protocols as well as administration instructions and scoring rubrics)

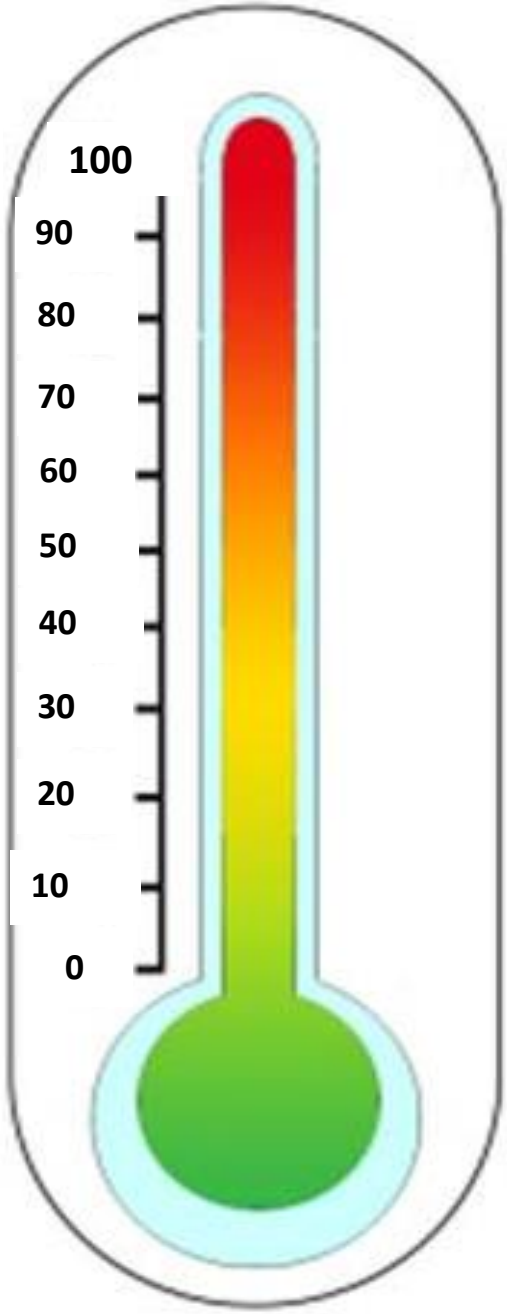
Appendix B

(Most of Appendix B of the Clinicians Manual has been omitted from this report to save space. In particular the appendix includes copy of all forms and materials contained in the Participant Handbook, which is included as a separate Appendix of this report. The Appendix also includes scales used during psychoeducation and exposure therapy exercises as described in the manual. These scales are still presents in this Apprndicx of the report)

Distress Rating Scale

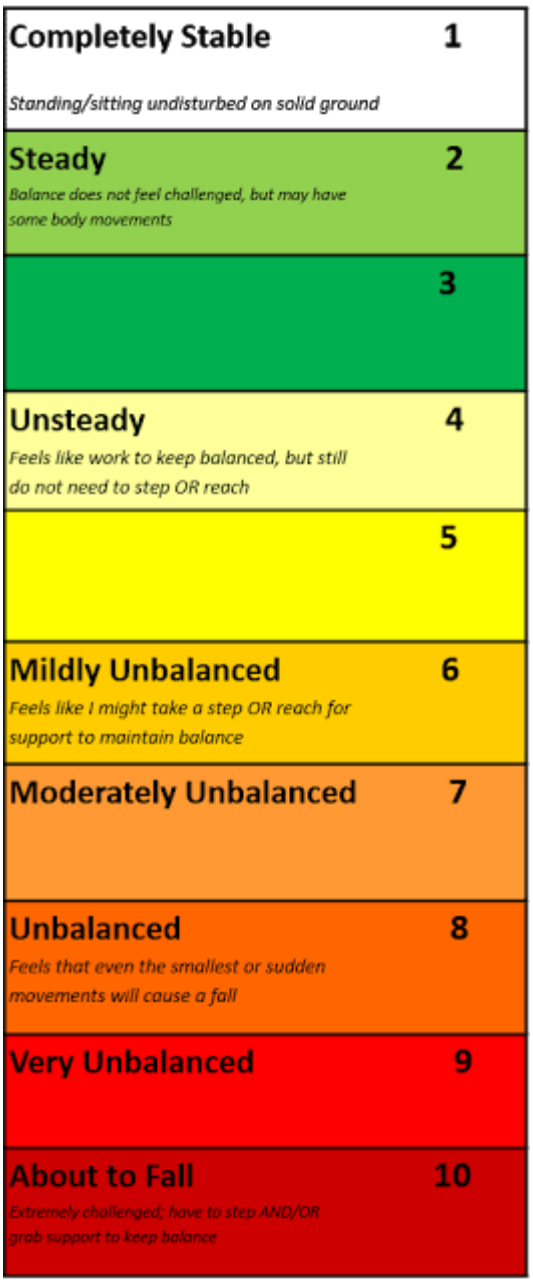
My current level of distress is….

Extreme distress



No distress

Rating of Perceived Stability (RPS) – taken from http://csumotionanalysislab.blogspot.com/p/rate-of-perceived-stability.html



Rating of Perceived Exertion (RPE)

We want you to rate your perception of exertion. This feeling should reflect how heavy and strenuous the exercise feels to you, combining all sensations and feelings of physical stress, effort, and fatigue. Do not concern yourself with any one factor such as leg pain or shortness of breath, but try to focus on your total feeling of exertion.

Look at the rating scale below while you are engaging in an activity; it ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Choose the number from below that best describes your level of exertion

Rating	Perceived Exertion
6	No exertion
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

Appendix C

This Appendix includes a step by step description of the progression of Game play both during the initial evaluation session and during ensuing training session. First, important general information about game play is presented followed by the specific steps that should be followed when determining game difficulty.

General Information on Game playing

- All but two games can be played while in the following posture or doing the following activities:

  1) Standing in place 2) stepping 3) walking

- All gams can be played under three challenge levels: Easy, Medium and Hard. Difficulty levels are adjusted in the software

- Within all but two games the overall **difficulty hierarchy** is:

  - Posture/Activity 1 at Easy challenge
  - Posture/Activity 1 at Medium challenge
  - Posture/Activity 1 at Hard challenge
  - Posture/Activity 2 at Easy challenge
  - Posture/Activity 2 at Medium challenge
  - Posture/Activity 2 at Hard challenge
  - Posture/Activity 3 at Easy challenge
  - Posture/Activity 3 at Medium challenge
  - Posture/Activity 3 at Hard challenge

- For games that can only be played while standing (Traffic Jam) or walking (Forest Walk) the order of difficulty is based only on the level of challenge

Step 1: Baseline Assessment at Session 1

The description of the assessment process as described in the manual and in the appendix below (as well as the process of increasing game challenge) is intended to be used a guideline that can be amended by the PT based on their perception of the players ability and rate of skill acquisition. For example if the progression is too slow, the PT can choose to skip a level of difficulty and as described in the manual. In addition meeting a milestone for a game at a given difficulty level does not necessarily mean the player is ready to advance to the next level if they still feel unstable or employ incorrect movement strategies.

Baseline assessment uses two games: Catch (game A1) and Italian Aps (game A2)

1. At the start of session 2 all players should begin with Catch game at the easiest difficulty level – i.e., Posture/Activity 1 at Easy challenge. Play game for 2.5 minutes.

2. If **LESS THAN 2 MISSES (milestone for Catch Game)** then increment the game play according to Table 1. Otherwise continue to play the same level of challenge. The **milestone for Italian Alps game is LESS THAN 2 MISSES AND 1 CRASH**

TABLE 1. PROGRESSION OF GAMES DURING BASELINE ASSESSMENT

"INCREMENT" (*i*)	**GAME**	**POSTURE/ACTIVITY**	**CHALLENGE LEVEL**
1	A1	1	Easy
2	A1	1	Medium
3	A1	2	Easy
4	A1	1	Hard
5	A1	2	Medium
6	A2	3	Easy
7	A1	2	Hard
8	A2	3	Medium
9	A1	3	Easy
10	A1	3	Medium
11	A2	3	Hard
12	A1	3	Hard

Notice that in this table we suggest playing Game A1 with Posture/Activity 2 and Easy challenge before playing Posture/Activity 1 and Hard challenge, which differs from the difficulty hierarchy established above. The thought was to maintain interest and be able to see early on if the patient has the ability to perform side-stepping. The PT can opt to order the Table according to order of difficulties listed above if desired

3. Remember to rest after every 5 minutes of game play

4. Repeat 12 times

5. At the end of the day note the final INCREMENT that was played.

Step 2: Retention testing at the start of Session 2

At the start of Sessions 2-8 you will use games A1 and A2 to determine if skills practiced during the prior sessions were "retained". For session 2 this retention process is a direct reflection of the skills acquired during session1 when only games A1 and A2 were played, but in ensuing session it may be less direct – as described below. In all cases, performance on the retention test informs the starting difficulty level for a given game. Games A1 and A2 will not be played during the remainder of eth PTI.

Use Table 2. Retention testing for Session 2 to determine the game to be played. If milestone was reached then the participant passes the retention testing.

TABLE 2. RETENTION TESTING FOR SESSION 2

This will be referred to as Retention Testing Increment in Table 3

HIGHEST "INCREMENT" PLAYED SESSION 1	GAME	POSTURE/ACTIVITY	CHALLENGE LEVEL
1	A1	1	Easy
2	A1	1	Easy
3	A1	1	Easy
4	A1	1	Medium
5	A1	2	Easy
6	A1	1	Hard
7	A1	2	Medium
8	A2	3	Easy
9	A1	2	Hard
10	A2	3	Medium
11	A1	3	Easy
12	A2	3	Medium

For example if Session 1 ended while playing "Increment" 6 – Game A2 with Position/Activity 3 and Easy Challenge - then based on Table 2 you would test retention using Game A1 with Position/Activity 1 and Hard Challenge. If you look at Table 4, this combination was played in "Increment 4" such that the participant should definitely be able to complete it again at the start of Session 2 if skills were retained.

Step 3. Determine the difficulty levels to start each Game during Session 2 based on Retention testing

During Session 2 there are 4 games that are introduced – Traffic Jam (called Game 1), Soccer (Called Game 2), Arkanoid (Called Game 3) and Forest Walk (Called Game 4).

- For Game 1 – Always begin Session 2 at the Easy level of difficulty.
- For Games 2 and 3 - use Table 3 below – Determining initial difficulty level of Games 2 and 3 for Session 2 - to determine the starting level of difficulty
- For Game 4 – Always begin Session 2 at the Easy level of difficulty.

TABLE 3. DETERMINING INITIAL DIFFULTY FOR GAMES 2 AND 3 FOR SESSION 2

RETENTION TESTING INCREMENT	PASSED RETENTION	START GAME 2 POSTURE/ACTIVITY LEVEL X; CHALLENGE LEVEL Y	START GAME 3 POSTURE/ACTIVITY LEVEL X; CHALLENGE LEVEL Y
1	Y	1; EASY	1; EASY
	N	1; EASY	1; EASY
2	Y	1; EASY	1; EASY
	N	1; EASY	1; EASY
3	Y	1; EASY	1; EASY
	N	1; EASY	1; EASY
4	Y	1; MEDIUM	1; EASY
	N	1; EASY	1; EASY
5	Y	1; MEDIUM	1; MEDIUM
	N	1; MEDIUM	1; EASY
6	Y	1; HARD	1; MEDIUM
	N	1; MEDIUM	1; MEDIUM
7	Y	1; HARD	1; HARD
	N	1; HARD	1; MEDIUM
8	Y	2; EASY	1; HARD
	N	2; EASY	1; MEDIUM
9	Y	2; MEDIUM	2; EASY
	N	2; EASY	1; HARD
10	Y	2; MEDIUM	2; MEDIUM
	N	2; MEDIUM	2; EASY
11	Y	2; HARD	2; MEDIUM
	N	2; MEDIUM	2; MEDIUM
12	Y	2; HARD	2; HARD
	N	2; HARD	2; MEDIUM

For example, if the player passes the retention increment 6 - Game A1, with posture/activity 1 at the Hard Level then Game 2 would start with posture/activity 1 at the Hard Level and Game 3 would start at posture/activity 1 at the Hard Level as Game 3 is generally more difficult than Game 2. If the initial Block of Game 2 is too challenging (e.g., the Hard level of Game 2 involves quite different skills then the hard level of Game A1)

then judgement should be used to change the level on the next block. If this is done then the starting level for Game 3 should also be adjusted

Step 4. Begin Game Play in Session 2

The progression of games for Session 2 as well as all ensuing session is shown in Table 4.

Based on Table 4, Session 2 will start with 1 block (5 minutes) of Game 1 at the Easy difficulty.

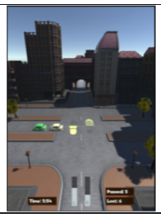
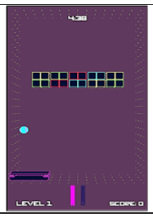
For session 2 Block 2 will start with Game 2 played at the level of difficulty determined in Step3. If the milestone is reached (more than 5 consecutive hits on at least 2 occasions), then the level of difficulty for Game 2 in Block 3 will be increased based on the difficulty hierarchy assuming that the PT believes it is warned based on RPE and perceived stability responses

For session 2, Block 5 will start with Game 3played at the level of difficulty determined in Step3. If the milestone is reached at the end of the block (passing at least 3 boards within the game)

For Session 2, Block 6 will start with one block of Game 4 at the Easy difficulty. Depending on the walking speed one block may not take a full five minutes. If not than the walk should be repeated.

TABLE 4. GAMING PROGRESSION AND MILESTONES FOR GAMES FOR ALL SESSIONS

		SESSION							
GOAL		1	2	3	4	5	6	7	8
	BASELINE ASSESSMENT		Exposure to all games; reinforce baseline skills		Begin to master balance, start gait adaptability		Continue to emphasize challenging balance games and master gait adaptability		
WARM-UP			2.5 MINUTES AT SSV						
RETENTION ASSESSMENT			2.5 MINUTES						
BLOCK 1			GAME 1						
BLOCK 2			GAME 2						
BLOCK 3									
BLOCK 4									
BLOCK 5			GAME 3						
BLOCK 6			GAME 4						
			END GAMING SESSION						

			
MILESTONE TO PROGRESS DIFFICULTY			
>85% passed	>5 consecutive hits at least two times in block	Complete 3 boards in a single block	≥4800 points (≈85% accuracy)

Note: ½ blocks means 2.5 minutes of one game followed by 2.5 minutes of another. The milestones remain the same.

Step 5. At end of Session determine level of difficulty for Retention testing at the start of next session

The level of retention testing is based only on progress on Games 2 and 3.

1. Recall the "highest" level of Game 2 and 3 played. In the event that the last (or only block) for a game was passed then assume that the "highest" level played is one higher on the difficulty hierarchy. For example if in Block 5 we played Game 3 at Posture/Activity 1 Medium Challenge and passed the milestone, then the "highest" level for this game is actually Posture/Activity 1 with Hard challenge. The reason for this is that retention is based on Games A1 and A2 which are generally simpler than games 2 and 3. By doing this we will ensure that a slightly higher level of Games A1 and A2 is used for retention testing, which may be more representative of the current skill level. The reason for thois adjustment is based on the fact that is challenging to use Games A1 and A2 to assess retention of skills from more challenging games (as mentioned in Step 2).

2. Use Table 5 to determine the level for retention testing. To do this, first look to see if the combination of "highest" levels is listed in a single row. If so then then the final column tells you the retention testing increment for the next session. If the combination is absent (e.g., GAME 2 "highest" level corresponds to Posture/Activity 1 at the Hard Challenge level and Game 3 "highest" level corresponds to Posture/Activity 1 at the Easy Challenge) then look in each column separately for the largest increment corresponding to the "highest" level for a given game and average the two numbers, rounding up if needed. So in the example, the highest retention increment for GAME 2 Posture/Activity 1 at the Hard Challenge is 7; the highest retention increment for GAME 3 Posture/Activity 1 at the Easy Challenge is 4; The average is 5.5, which we will round up to 6 as the retention testing increment for the next session. Note that Table 5 is essentially identical to Table 2 with columns reversed.

TABLE 5. DETERMINING LEVEL OF PLAY FOR RETNTON TESTING SESSION 3-8

"HIGHEST" LEVEL OF GAME 2 POSTURE/ACTIVITY LEVEL X; CHALLENGE LEVEL Y	"HIGHEST" LEVEL OF GAME 3 POSTURE/ACTIVITY LEVEL X; CHALLENGE LEVEL Y	RETENTION TESTING INCREMENT FOR NEXT SESSION
1; EASY	1; EASY	1
1; EASY	1; EASY	2
1; EASY	1; EASY	3
1; MEDIUM	1; EASY	4
1; MEDIUM	1; MEDIUM	5
1; HARD	1; MEDIUM	6
1; HARD	1; HARD	7
2; EASY	1; HARD	8
2; MEDIUM	2; EASY	9
2; MEDIUM	2; MEDIUM	10

2; HARD	2; MEDIUM	11
2; HARD	2; HARD	12

Note: If a plyer ever plays a game2 or 3 at Posture 3 then retention increment = 13

4. Use Table 6 to determine the level of the retention game to be played at the beginning of the next session. Note that this Table is identical to Table 1 with the addition of one row.

TABLE 6. DETERMINE LEVEL OF RENTION GAME BASED ON TABLE 5

RETENTION TESTING INCREMENT	GAME	POSTURE/ACTIVITY	CHALLENGE LEVEL
1	A1	1	Easy
2	A1	1	Easy
3	A1	1	Easy
4	A1	1	Medium
5	A1	2	Easy
6	A1	1	Hard
7	A1	2	Medium
8	A2	3	Easy
9	A1	2	Hard
10	A2	3	Medium
11	A1	3	Easy
12	A2	3	Medium
13	A2	3	Hard

Returning to the example, if retention increment is 6 then the retention block in the next session would involve Game A1 played at Posture/Activity 1 and Hard Challenge level.

As another example, assume that a player begins Game 2 and Game 3 both at Posture/Activity 1 easy Challenge (i.e., they passed retention increment 3 - see Table 3). Assume that the participant passes Block 2 (difficulty for Game 2 increases to Posture/Activity 1 Medium Challenge) does not pass Block 3 at this level and then passes Block 4 at this level. Also assume that they pass Block 5 for Game 3. Thus the “highest” level for Game 2 would be Posture/Activity 1 Hard Challenge and the “highest” level for Game 3 would be Posture/Activity 1 Medium Challenge. This corresponds to retention increment 6 in Table 5, which corresponds to using Game A1 Posture/Activity 1 Hard Challenge in the next session for retention testing. This is several levels greater than retention increment three at which they started, which makes sense given that they passed two new games. However, if we used the true highest levels played (Game 2 – Posture/Activity 1 Medium Challenge and Game 3 – Posture/Activity 1 Easy Challenge) then retention increment would be 4, which is only slightly higher than the level that was able to be achieved before playing the games.

Step 6. Complete retention testing for session 3-8 to determine starting levels for Games 2 and 3

After plying the retention game dictated by Step 5:

- If the player meets the milestone then begin gaming blocks (Step 6) at the level corresponding to the “highest” level achieved in Step6.

- If the player does not meet the milestone then start play for Games 2 and 3 at a level corresponding to one lower on the difficulty hierarchy than the “highest” level achieved in Step6.

Step 7. Begin Game Play in Session 3-8

(refer to Table 4 in Step 5)

If Block 1 includes Game 1, then this game should be played either at the level of difficulty from the last session, if the participant did not meet the milestone or if the participant met the milestone then play at one level of difficulty higher. So if in the previous session the easy difficulty level was completed then you should begin at the medium difficulty. If the participant passes the medium and hard difficulty levels the game can be made more difficult by requiring single limb support or adding “police cars” using the software.

Blocks including Games 2 and 3 will start at a level defined by Step 6

If Block 6 includes Game 4 then this game should be played either at the level of difficulty from the last session, if the participant did not meet the milestone, or if the participant met the milestone then play at one level of difficulty higher. So if in the previous session the easy difficulty level was completed then you should begin at the medium difficulty. If the participant passes the medium and hard difficulty levels the game can be made more difficult by increasing speed to more than 80% of self-selected speed.

Step 8.

Repeat steps 5-7

Appendix D

Sources for social support or activities specific to prosthesis users

Organizations that have programming of some sorts, for all levels (no experience needed) year round:

Dare2tri.org

GLASA.org

AdaptiveAdventures.org

These organizations also offer social support. Additional sources for social support include:

Amputee Coalition (Online,Nationwide)

AmPower (Online,Nationwide)

Chicago Area Amputee Support Group
(Meet in Arlington Heights once a month with a possible other group meeting in Paddock Lake, WI)

Exercise Group A
Participant handbook

Participant code: _____

If any of the following occur while involved in the study:

- **Scheduling conflict**
- **Inability to use prosthetic device for any reason**
- **Injury**
- **Major Illness**
- **Technical issue with monitors**
- **Changes in contact information (email, phone or home address)**
- **Other event you think we should know about**

Please contact the study Research Coordinator:

McKenzie Bourque
Email: mckenzie.bourque@my.rfums.org

Program Calendar (to be completed after Session 1)

Sun	Mon	Tues	Wed	Thurs	Fri	Sat

Sun	Mon	Tues	Wed	Thurs	Fri	Sat

8 week follow up (receive mailing):_____ 16 week follow up (receive mailing):_____

Exercise Log

You are encouraged to complete the exercises described in this handbook 3 days a week, ideally with one day of rest between exercise days, for the next 8 weeks. You should start with Module A and advance as described below. If you do not feel ready to advance to a new module you should take things at your own pace. Each week you should enter the letter of the module completed on the day you complete the module.

Week 1 (recommended: Exercise Module A for 3 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module completed							

Week 2 (recommended: Exercise Module A for 3 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module completed							

Week 3 (recommended: Exercise Module A for 2 days followed by Exercise Module B for 1 day)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module Acompleted							

Week 4 (recommended: Exercise Module B for 3 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module completed							

Week 5 (recommended: Exercise Module B 3 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module completed							

Week 6 (recommended: Exercise Module B for 1 day followed by Module C for 2 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module completed							

Week 7 (recommended: Exercise Module C for 3 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module completed							

Week 8 (recommended: Exercise Module C for 3 days)

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Module Acompleted							

Procedures for Study Follow-up

8 weeks and 16 weeks following completion of session 8 (see Calendar on page 3) you will receive a package in the mail that contains the following:

- a GPS monitor (Qstarz) in a carry case with strap attached
- 2 power cord for the GPS monitor – one for the car and one for indoors
- an activity monitor (StepWatch) with a strap attached
- a set of surveys
- a package of response scales for answering the CRIS survey (which will be given over the phone)
- a pre-paid return envelope (addressed to Dr. Matthew Major)

You should do the following with the contents of the package:

1) Attach the GPS monitor to the back of the pylon (metal pipe) of your prostheses using the strap. It should look similar to the red circled part of the picture above

2) Attach the StepWatch around the outside or inside of the pylon (metal pipe) just above where the ankle of the foot is, as in the picture below. Most people prefer to place it on the outside of the pylon. Be sure the StepWatch is properly oriented: with the **product name facing outward and the curved side up.** (see figure below). It will not record data when it is upside-down.

3) Use the instructions on pages 24-26 to turn the two monitors on and make sure that they are being used properly.

4) Art Morris will give you a call to make sure you received the package and to make sure that you are wearing the monitors. At this point he will also go through the CRIS scale. He will ask you to refer to response scales that were included in the box when going over that survey.

5) You should wear both monitors from the day you receive them until eight days later. At some point during those 8 days you should also complete the package of surveys that was included in the box.

6) After the eight days, wrap the monitors in the package material that was originally set to you and place them in the pre-paid return envelope with all of the surveys that you completed. You can call your local FedEx for free pickup or bring the box to a FedEx pick-up location,

GPS Use Instructions

A GPS unit will be used to track your location and movement for 8 consecutive days. A picture of the GPS Unit being used in this study and an explanation of its features are presented below.

Buttons on the GPS:

(1) Power Jack
(2) Mode Switch: OFF/NAV/LOG
(3) Battery Status LED
(4) IGNORE
(5) GPS Status LED
(6) IGNORE
(7) IGNORE
(8) IGNORE

Using the GPS Unit:

(1) To turn the GPS Unit on/off:

- GENTLY move the Mode Switch [Item (2) in figure above)] to **LOG**
- Check the status of the GPS (see); GPS LED should turn orange indicating that satellites position are being acquired
- **If you do not want us to know your locations** you can gently turn Mode Switch [Item (2) in figure above)] to OFF and then follow first three steps to turn it back on

(2) To Check the Status of GPS Position (Item 5 in Above Figure):

- An orange GPS status LED will be constant when the GPS unit is detecting satellites.
- There will be no GPS Status LED when the GPS is not powered on.

(3) To Check Battery Status (Item 3 in Above Figure):

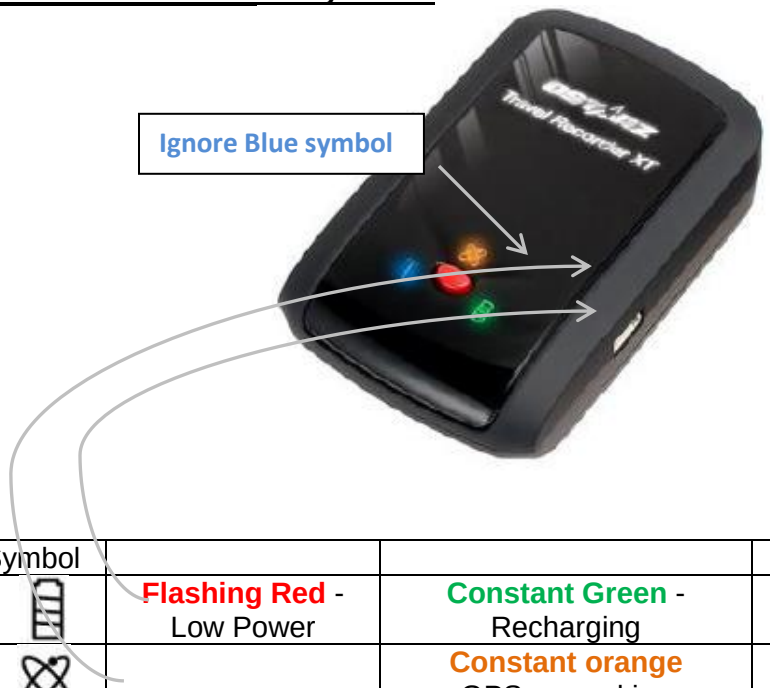
- A red battery status LED indicates a **low battery level**
- A green battery status LED indicates the **battery is charging**
- There will be no battery status LED when the battery is fully charged.
- A fully charged battery can last up to 42 hours, but we recommend charging nightly

(4) To Recharge the Battery

- Connect the mini USB power cable to the power jack on the GPS unit [Item (1) on figure above]. It should look like the picture at the right
- Connect the opposite end of the USB cable to a travel charger or car charger adaptor.
- Note: Charging time will take approximately 3 hours.

REMEMBER TO CHARGE NIGHTLY

LED Indicators and what they mean:



Symbol			
	Flashing Red - Low Power	**Constant Green** - Recharging	**No color** - Fully charged
		Constant orange GPS us working	**No color -** GPS is not powered

The GPS is not waterproof. If the prosthesis is worn in the shower, the GPS should be removed.

Stepwatch Use Instructions

The StepWatch does not need to be turned on or off and does not need to be charged.

After you first put on the Step Watch you should verify that it is working properly by doing the following:

1) swing your prosthetic leg back and forth while looking in a mirror or having a friend look at the watch
2) the monitor should flash once with each swing; if there is a problem you should call Art (see page 2)

StepWatch does not require any additional special attention once you place it on your prosthesis.

Other information:

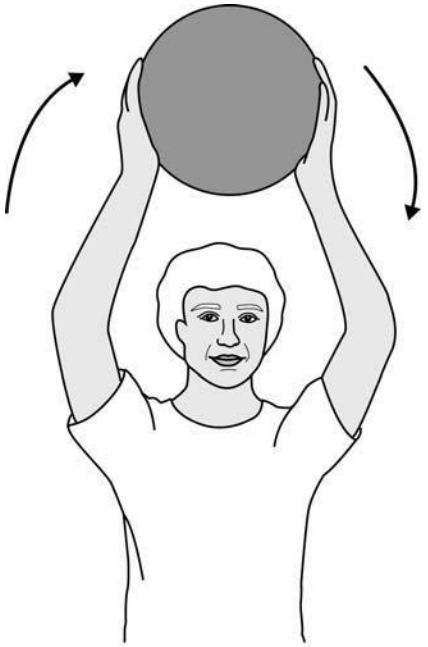
There are no battery indicators for the step watch

You should not apply any covering or write on the front cover of the StepWatch

Do not keep the StepWatch in hot places, such as the dashboard of a car.

StepWatch is not waterproof. If you wear your prosthesis in the shower, the StepWatch should be removed before showering.

Seated Exercises to Improve Strength and Flexibility of Lower Limb Prosthesis Users



Exercises were adapted from these sources:
National Institute on Aging: http://www.nia.nih.gov/HealthInformation/Publications/ExerciseGuide/.
Centers for Disease Control and Prevention: http://www.cdc.gov/nccdphp/dnpa/physical/growing_stronger/growing_stronger.pdf.

The wording and images in the manual taken from: www.livewellagewell.info/study/2007/12-ChairExercisesUGA113006.pdf

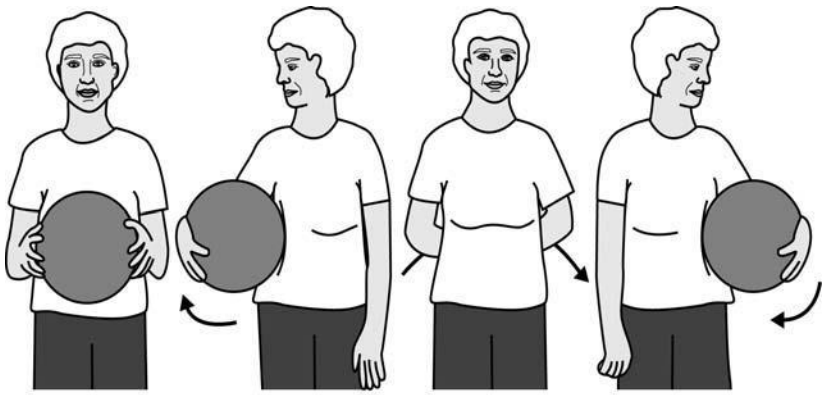
How to Use this Manual

The exercises in this manual are adapted from the National Institute of Aging and the Centers for Disease Control and Prevention. They are **designed to improve strength, flexibility and balance**. All of the exercises can be done while sitting in chair.

Many of the exercises incorporate a ball to add fun and interest, as well as to help improve coordination. We will provide you with plastic air-filled ball. If you lose it you can look to purchase one at discount stores. Using the ball provides resistance and the resistance is better with a plastic ball rather than a foam ball.

Before you begin exercising, read pages 3 and 4.

There are 3 exercise modules. When you are ready to start the exercises, start with Module A and do the warmup. You will do module A for 2-3 weeks then graduate to Module B for 2-3 weeks then finish with Module C for 2-3 weeks. If you do not feel ready to advance to a new module you should take things at your own pace.



WHEN YOU EXERCISE REMEMBER…

Wear loose fitting, comfortable clothing, and proper shoes that offer safety and support.

Drink water before, during, and after exercise.

Make sure to stretch after you exercise.

If you have questions, just ask!

If you have questions about the exercises in this booklet, please contact:

McKenzie Bourque, study coordinator
mckenzie.bourque@my.rfums.org

SPECIAL NEEDS

If you have diabetes…

Check your blood sugar 30-45 minutes before exercising.

If your blood sugar is…

F. **<u>LOWER</u> than 200 mg/dL, eat a low-fat snack with 15-20 g of carbohydrate, 30-45 minutes before exercise.**

G. **<u>BETWEEN</u> 200-300 mg/dL, exercise without a snack.**

H. **<u>GREATER</u> than 300 mg/dL, do not exercise and do drink water.**

If you have high blood pressure…

Take your medication the way your doctor prescribed. If possible, take your blood pressure before exercise. If your systolic reading is 140 or higher AND/OR your diastolic reading is 100 or higher, and this is outside your normal range, then relax a bit and retake your blood pressure. Begin exercises only when the numbers fall below these ranges

Exercise Module A

Module A is the first of three groups of exercises that contains several fun and easy movements designed to help you feel comfortable with chair exercises, and with using a ball as an exercise tool. You will do these exercises 3x a week during weeks 1, 2 and 2x during week 3.

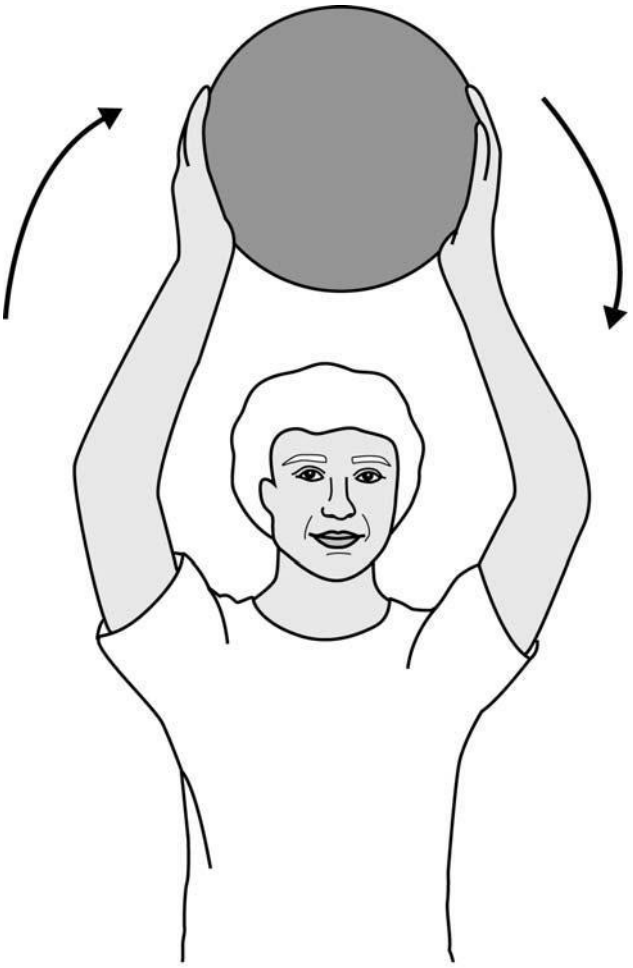
The exercises in **this module benefit our bodies** in many ways:

1. Sunshine arm circles: open torso and ribcage
2. Tummy twists: strengthen sides of the waist (oblique abdominals)
3. Hand squeeze: improves grip strength and strengthens the chest muscles (pectorals)
4. Back massage: promotes back and shoulder relaxation
5. Neck stretch: helps relieve neck tension

Begin with a light warm-up, about 3-5 minutes in length, to prepare the muscles and joints, and to help focus your attention. Only perform a warmup movements that you feel safe doing. Suggested warm-up movements include:

Marches in place with shoulder rolls
(hold onto something if needed)
Walking in a circle around the room
Tapping the toes to warm up the lower legs
Seated knee lifts to warm up the hips and upper legs

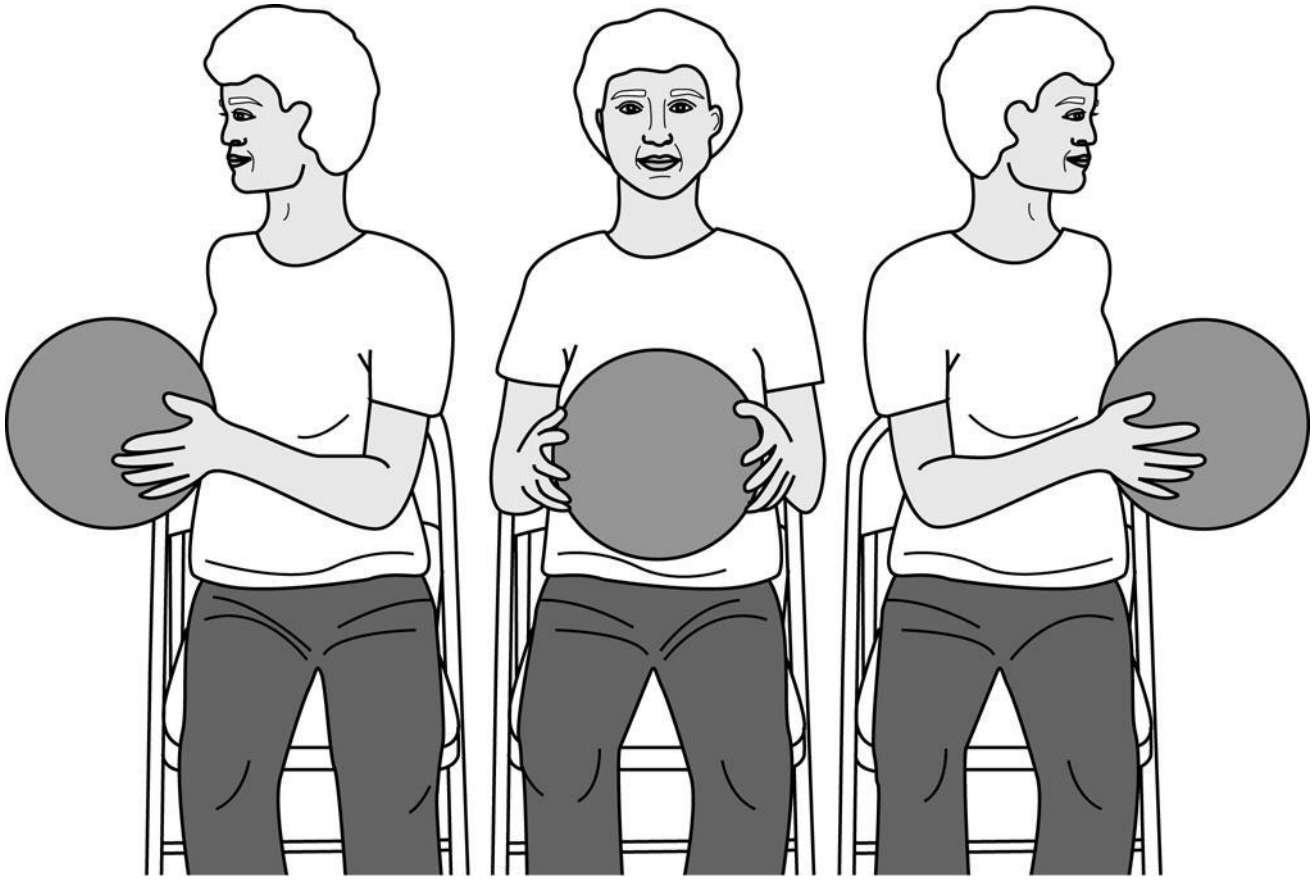
Sunshine Arm Circles



Seated in a chair with good posture, hold a ball in both hands with arms extended above your head and/or in front of you, keeping elbows slightly bent. Visualizing the face of a clock out in front of you, begin by holding arms up overhead at 12 o'clock. Circle the ball around to go all the way around the clock in a controlled, fluid motion.

When you've reached 12 o'clock again, reverse directions and circle the opposite way. Keep alternating circle directions. **Do 8 repetitions, rest then do another set of 8 repetitions.**

Tummy Twists

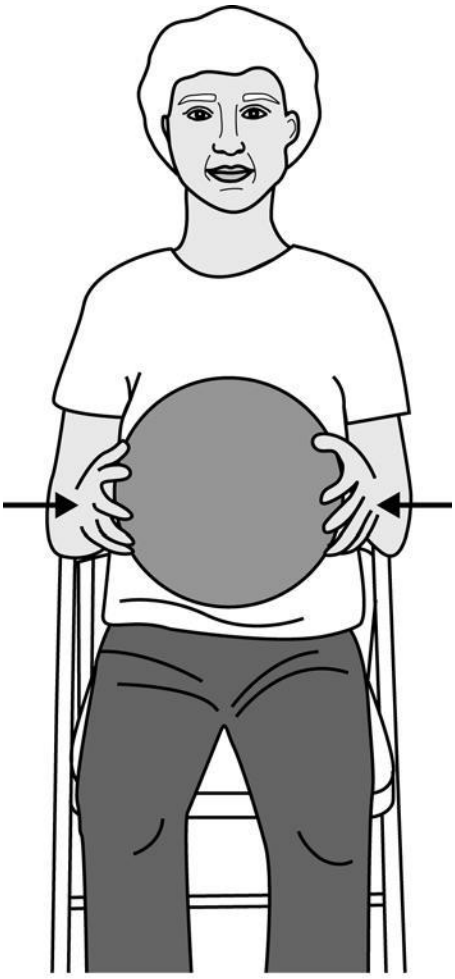


Seated in a chair with good posture, hold a ball with both hands close to the body, with elbows bent and pulled in close to the ribcage.

Slowly rotate your torso to the right as far as you comfortably can, being sure to keep the rest of your body still and stable. Rotate back to the center and repeat in the opposite direction.

Do 8 sets, where a set includes twists to each side. Rest. Do another 8 sets (two twists each).

Hand Squeeze



Seated in a chair with good posture, hold a ball with both hands slightly in front of your body. Squeeze the ball to activate the finger joints, then slowly press the ball with both hands, as if trying to deflate the ball. Hold for 4 seconds and slowly release.

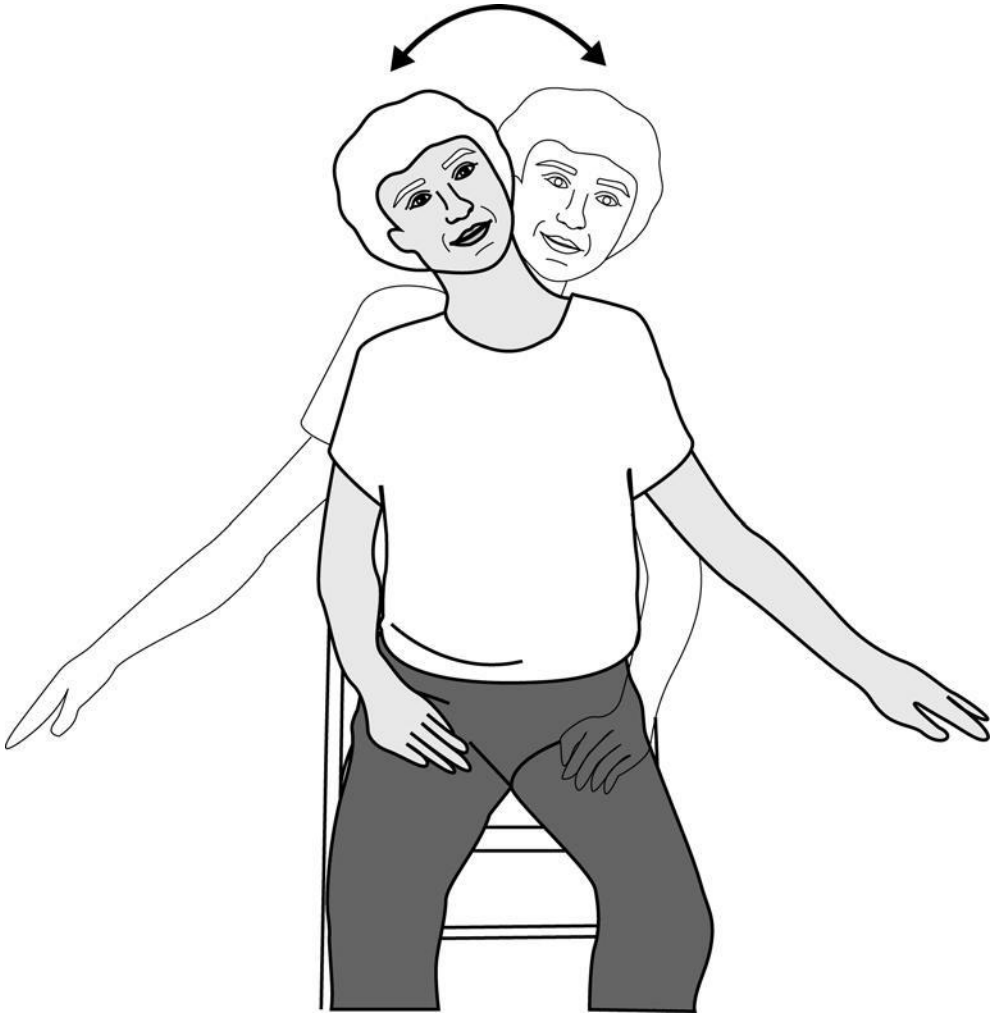
Repeat the exercise 8 times, rest, then do another set of 8 repetitions.

Back Massage

Seated in a chair with good posture, place a ball behind you and lean against it with your upper back to hold the ball up between you and the chair.

Rotate you torso side to side and bend up and down to give yourself a relaxing massage. There is no prescribed time or repetitions for this.

Neck Stretch



Seated in a chair with good posture, slowly tilt your head toward your right shoulder. Hold the head in this position, and extend your left arm out to the side and slightly downward so that your hand is at waist level. Release and repeat on the left side. **Do 2 times for each side.**

Modification: For a deeper stretch, gently pull the extended arm behind your back.

Exercise Module B

Module B is the second of three groups of exercises that is slightly more challenging than module A. It includes fun exercises that use a ball to strengthen a variety of muscles groups. You should start this module at the end of week 3 – perform 1x during week three. You will then repeat this 3x during weeks 4 and 5 and 1x at the start of week 6.

The exercises in **this module benefit our bodies** in many ways:

1. Ball chest press: strengthens the chest muscles (pectorals)
2. Front arm raises: strengthen the shoulders (deltoids)
3. Inner thigh squeeze: strengthens the inner part of the thighs (adductors)
4. Duck wing squeeze: strengthens the chest muscles (pectorals) and arms
5. Chest and upper back stretches: promote flexibility and relaxation through the chest and upper back

Begin with a light warm-up, about 3-5 minutes in length, to prepare the muscles and joints, and to help focus your attention. Only perform a warmup movements that you feel safe doing. Suggested warm-up movements include:

Marches in place with shoulder rolls
Walking in a circle around the room
Tapping the toes to warm up the lower legs
Seated knee lifts to warm up the hips and upper legs

Ball Chest Press

Seated in a chair with good posture, hold a ball with both hands at chest level, palms facing toward each other and elbows bent. Avoid bending forward by keeping your shoulders back at all times. Squeeze the ball slightly as you push the ball away from you in a fluid motion, taking about 2 seconds to extend the arms. Squeeze your shoulder blades together as you pull the ball back toward your chest.

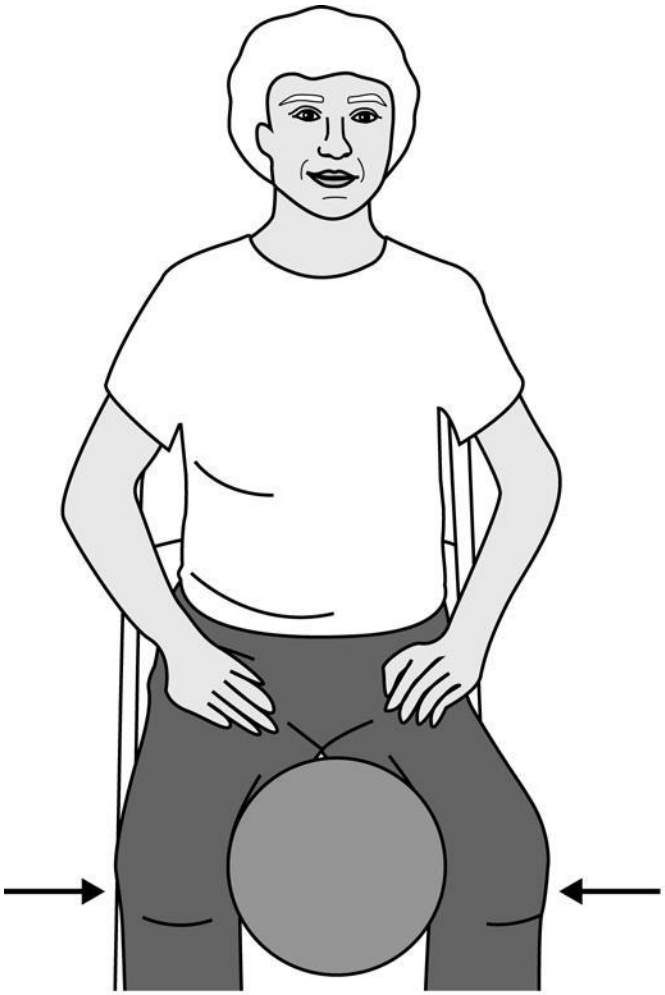
Repeat the push and pull motion 10 to 15 times. Rest. Do another set of 10 to 15 repetitions.

Front Arm Raises

In a seated position with good posture, hold a ball in both hands with palms facing each other. Extend the arms out in front of your body, keeping your elbows slightly bent. Starting with the ball lowered toward the knees, slowly raise your arms to lift the ball up to shoulder level (no higher), then lower the ball back to the starting position, taking about 2 to 3 seconds to lift and lower.

Repeat 10 to 15 times. Rest. Do another set of 10 to 15 repetitions.

Inner Thigh Squeezes



Sitting toward the edge of a chair with good posture and knees bent, place a ball in between your knees; press the knees together to squeeze the ball, taking about 1 to 2 seconds to squeeze. You should feel the resistance in your inner thighs. Slowly release, keeping slight tension on the ball so that it does not fall.

Repeat 8 to 10 times. Rest. Do another set of 8 to 10 repetitions.

Modification: For a greater challenge, change the count of the squeezes by squeezing the ball and holding for 5 seconds, then releasing again. Or, do short, quick pulsing squeezes.

Duck Wing Squeeze

In a seated position with good posture, place a ball underneath your right arm in the armpit region so that it does not fall. Squeeze the upper arm and elbow onto the ball like a duck folding its wing, feeling the chest and arm muscles tighten as you squeeze. Do not bend at the waist.

Do 8-10 repetitions then switch to the opposite side and perform 8 to 10 repetitions. Rest. Do another set of 8 to 10 repetitions on each side.

.

Chest and Upper Back Stretch

In a seated position with good posture and shoulders back and down away from the ears, extend your arms out in front of you at shoulder height. Interlace the fingers or grasp one hand with the other, and press out as you round the upper back and shoulders forward, feeling the upper back fan out. Hold for 10 seconds and release.

For the shoulders, pull extended arms back behind you and interlace the fingers or grasp one hand with the other, keeping your hands down toward the buttocks. Feel the chest and shoulders open up as you pull your shoulders back. Hold for 10 seconds and release.

Hold each stretch for 10 seconds. Rest. Repeat the upper back and chest stretches.

Exercise Module C

Module C is the third of three groups of exercises. The exercises can be modified as needed to accommodate different ability levels. You will complete this module 2x during week 6 and 3x during each of weeks 7 and 8

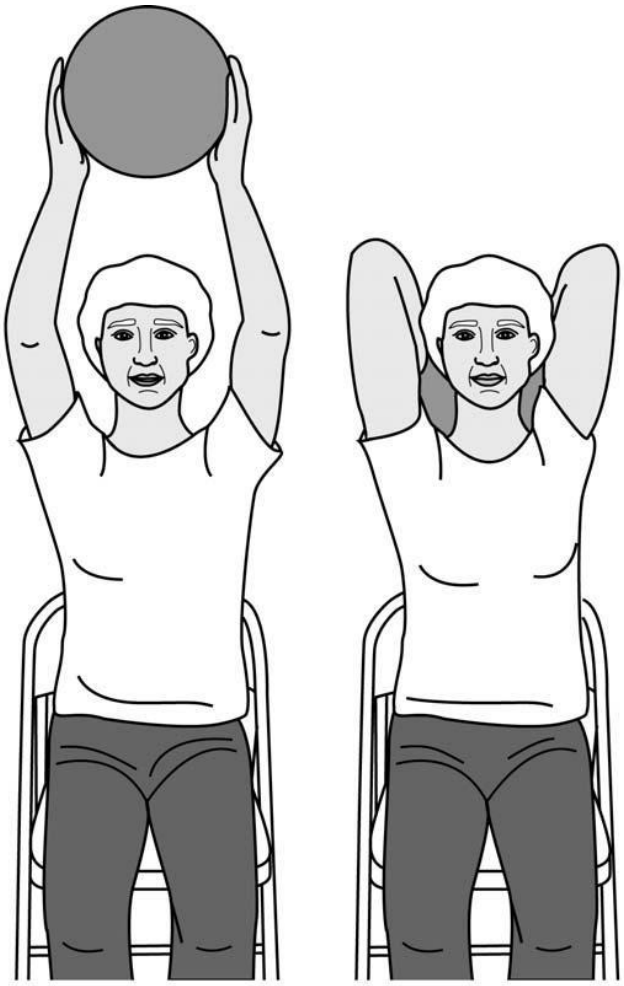
The exercises in this module benefit our bodies in many ways:

1. Overhead arm extensions: strengthen the back of the arms (triceps)
2. Elbow to knee: strengthens muscles around the waistline (oblique abdominals)
3. Balancing toe taps: improves balance by strengthening stabilizer muscles and stomach (abdominals) and improving body awareness
4. Overhead reach with side bends: opens torso and ribcage to improve flexibility and promote relaxation
5. Around the Big Wide world: helps to build core strength and coordination

Begin with a light warm-up, about 3-5 minutes in length, to prepare the muscles and joints, and to help focus your attention. Only perform a warmup movements that you feel safe doing. Suggested warm-up movements include:

Marches in place with shoulder rolls
Walking in a circle around the room
Tapping the toes to warm up the lower legs
Seated knee lifts to warm up the hips and upper legs

Overhead Arm Extensions

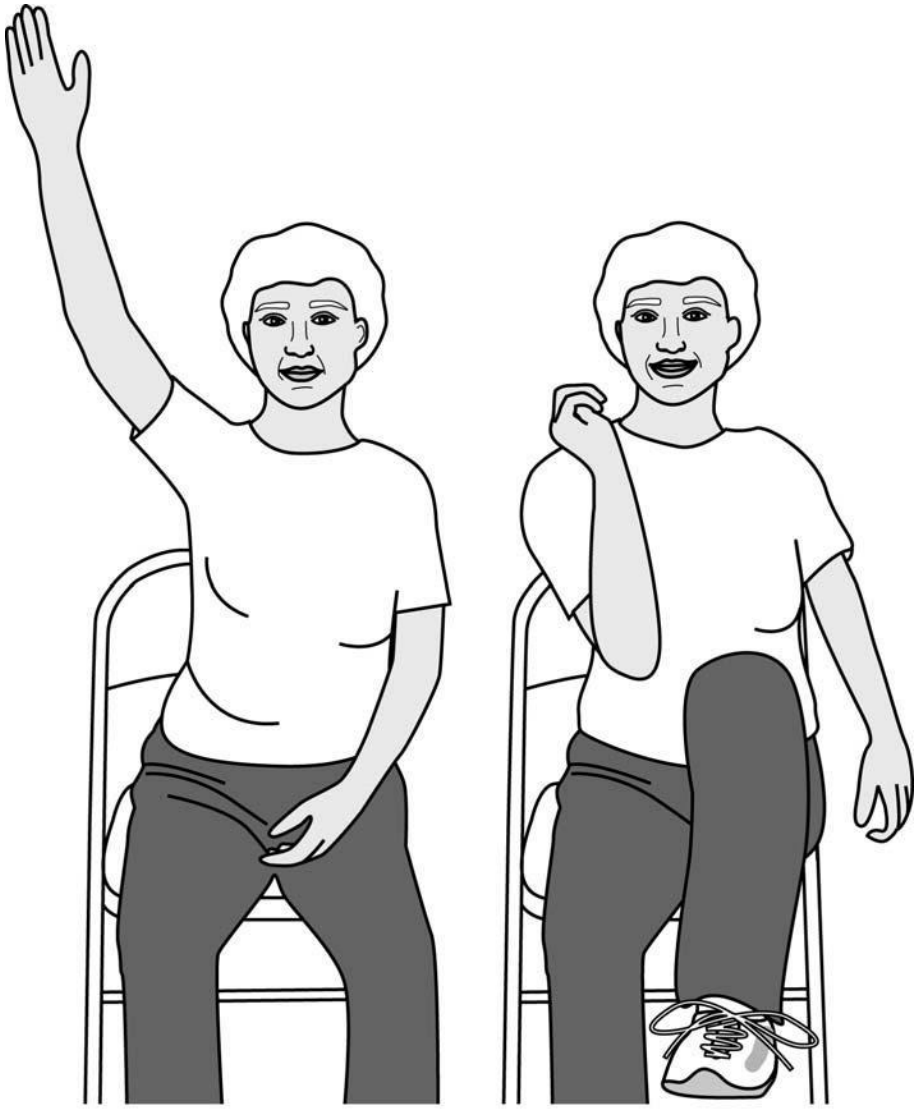


Seated in a chair with good posture, hold a ball with both hands and raise it up over your head, with arms extended without locking the elbows. Keeping the elbows pulled in toward the head, slowly bend the elbows to lower the ball down along the back of the neck, using about 2 seconds to go down, and then 2 seconds to push the ball back up over your head.

Repeat 8 to 10 times. Rest. Do another set of 8 to 10 repetitions.

Modification: Try seated triceps extensions (ball not required for this modification). Bending slightly forward with elbows tucked into your sides, slowly extend the elbows so that your forearms go back behind you, keeping the elbows pulled up and in for the entire movement. Return to the starting position and repeat. Hold soup cans or small weights for added resistance.

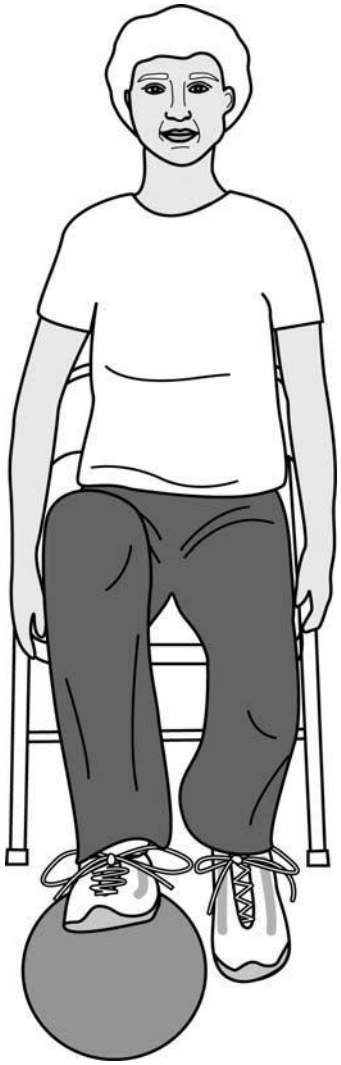
Elbow to Knee



Seated toward the edge of a chair with good posture and knees bent, start with your right arm extended up overhead. Slowly lift the left knee up as you lower your right elbow down toward your left knee, taking about 2 seconds to lower down. Try not to bend over at the waist. Release and go back to the starting position.

Repeat 8 to 10 times. Switch sides and do 8 to 10 repetitions. Rest. Do another set of 8 to 10 repetitions on each side.

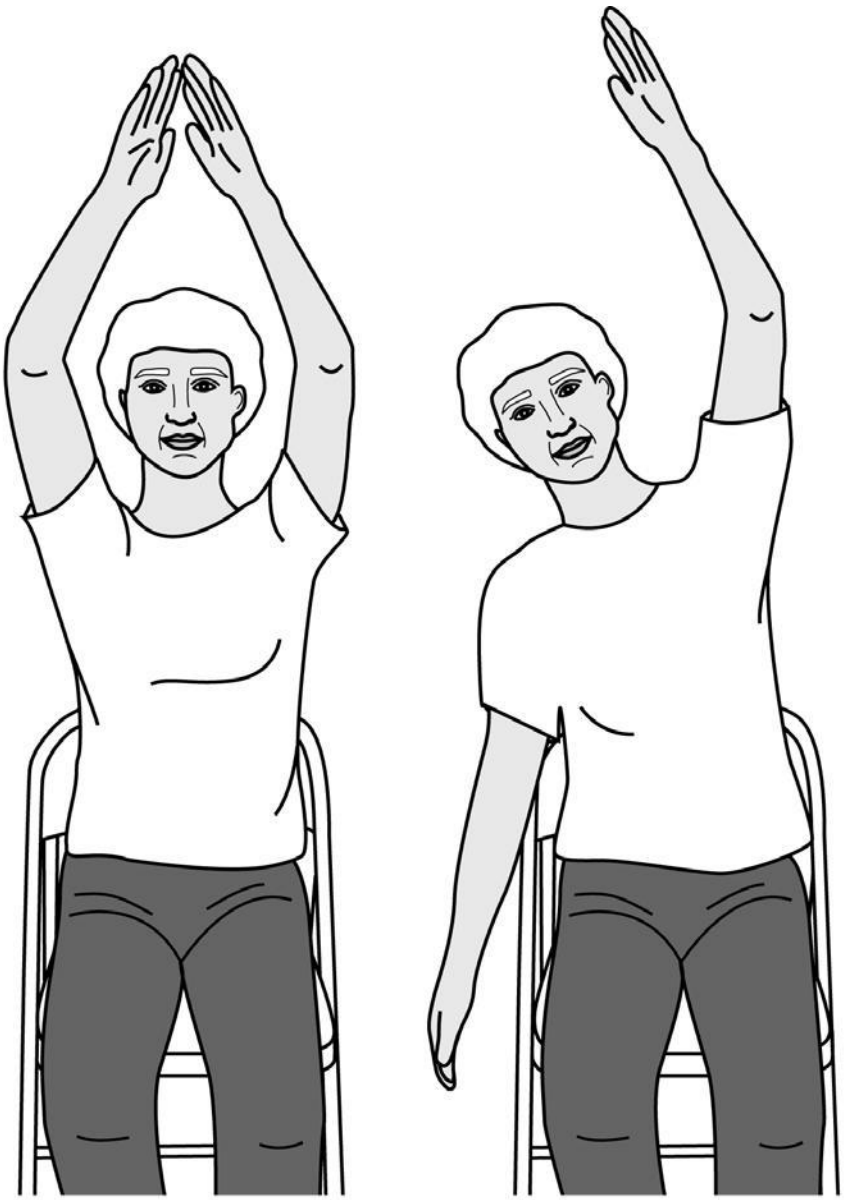
Balancing Toe Taps



In a seated position with good posture and knees bent, take a ball and place it on the floor near your feet. Holding onto the chair for balance as needed, place your right foot on top of the ball, trying to balance your weight as you do this. The left foot that is not on the ball can remain on the floor or can be lifted up off the floor if you feel stable enough. Hold for 3 to 4 seconds. Switch feet and repeat with the opposite foot.

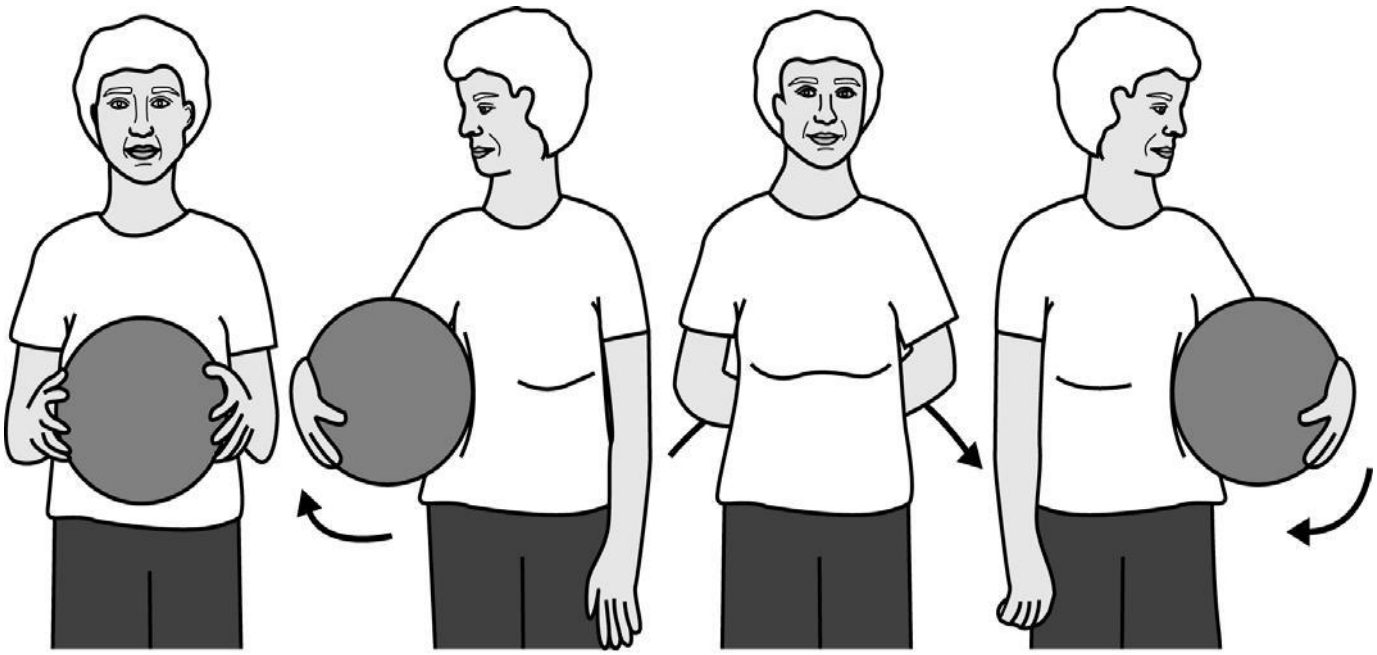
Keep alternating feet on the ball for 8 to 10 repetitions. Rest. Do another set of 8 to 10 repetitions.

Overhead Reach with Side Bends



Seated in a chair with good posture, reach your arms up overhead. Hold for 10 seconds. Allow your right arm to relax down by your side (can rest hand on chair seat) while your left arm stays up overhead. Slowly lean to the right and reach your left arm over your head to the right. **Hold for 8 to 10** seconds then come back up to the center position, pulling both arms overhead again. **Repeat by bending to the opposite side and holding for 8-10 s. Rest. Repeat another set**.

Around the Big Wide World



Starting in a seated or standing position with good posture, hold a ball with both hands at your stomach. Keeping the ball in contact with your body the entire time, move the ball around your waist, over your abdominals and lower back. Try to hold in your stomach without holding your breath as you do this exercise. **Repeat 8 to 10 times. Switch directions, circling the ball around your waist 8 to 10 times**

Exercise Group B
Participant handbook

Participant code: _____

If any of the following occur while involved in the study:

- **Scheduling conflict**
- **Inability to use prosthetic device for any reason**
- **Injury**
- **Major Illness (hospitalization, new medical condition)**
- **Technical issue with monitors**
- **Changes in contact information (email, phone or home address)**
- **Other event you think we should know about**

Please contact the study Research Coordinator:

McKenzie Bourque
Email: mckenzie.bourque@my.rfums.org

Program Overview

Balance confidence, your *perceived ability* to successfully do things while wearing your prosthetic, is affected by many things. Balance confidence significantly impacts behavior, and when it is low, it can cause you to limit or avoid physical activity and leave you feeling down or discouraged. Low confidence in your ability to use your prosthesis effectively (for example: fear you may often fall or believing an activity is too difficult) may be related to the fact that you do not currently have the skills needed to safely perform a task. Low balance confidence can also be related to negative and often inaccurate thoughts about your balance and fall risk. This program integrates a physical therapy intervention and a behavioral intervention to help increase your balance confidence. The physical therapy intervention (active video gaming) is intended to improve certain skills that are needed to safely engage in daily activities, such as shifting your weight side-to-side, or maneuvering around obstacles. The behavioral training component of the program is designed to complement your physical therapy intervention. This is accomplished by asking you to take a careful look at your thinking and behavior and how it affects how you function and your ability to reach your activity goals. Learning how to safely engage in activities and to pay attention to your thoughts can have a powerful effect on your life. Over the eight session of the program you will do the following:

Session 1

- Learn how to engage in active video game play with direct feedback from a physical therapist to ensure safer game play and use of proper movement strategies
- Lean how to use behavioral recording to better understand your concerns and worries about using your prosthesis
- Begin to learn the importance of *Making Goals for Change* as an important method for making the changes you want to occur.

Session 2

- Continue to gain confidence in the skills used in the active video games and progress in game difficulty as you begin to master certain levels
- Learn how to systematically work through your fears and reduce these fears
- Continue using behavioral recording to increase your understand of fears or concerns
- Learn how evaluate your thoughts and ignore thoughts that are not accurate views or are poor reflections of your skills
- Begin learning breathing methods to help you stay more relaxed
- Work with the therapists in the lab to safely complete tasks that connect to specific community activities you fear. You will be encouraged to expose yourself to these activities in during the week

Session 3

- Review and learn additional relaxation techniques with the help of the CBT clinician.
- Learn to examine behavioral recording forms for patterns and/or improvements.
- Continue to work on safely completing tasks that connect to fears and exposing yourself to related activities during the week.
- Begin to engage in activities outside of the laboratory that you may find challenging while practicing the techniques learned in the laboratory

Sessions 4 - 7

- Practice makes better - you will continue to use and practice using all the tools learned so far to move forward toward your goals.

Session 8

- Identify the important changes you made to your behavior and thinking, which have allowed you to increase your balance confidence
- Learn some additional strategies for maintaining these gains and what to do if you fall back into old patterns

Program Calendar (to be completed after Session 1)

Sun	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**

Sun	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**

8 week follow up (receive mailing):_____ 16 week follow up (receive mailing):_____

Making Goals for Change

Goals are an important part of making changes. In session 3, we will ask you to set goals that are structured appropriately to facilitate and mark progress. We use the acronym **SMART** to provide guidance for goal setting.

S = Specific. Goals should be specific such that it will be clear what you need to do to accomplish the goal. Specific goals give you something to work towards rather than vague goals like 'I will feel better.' If you come up with a vague goal, think about what specific steps it would take for you to achieve that vague goal and make one of those steps the goal. For example, if getting out and seeing friends more would help someone 'feel better,' then a specific goal could be to 'schedule and go to activities with friends at least 2 times per week.'

M = Measurable. Goals should be measureable such that it should be clear to you and to anyone else whether or not you accomplished the goal. Having measureable goals helps to promote awareness of the progress you are making and whether goals might need to be altered because they are too easy or too hard to accomplish.

A = Achievable. Goals should be achievable, meaning that you can reasonably accomplish the goal in a specified amount of time. When setting goals, consider starting with easier to achieve goals, (e.g., increasing a behavior that you are already doing), rather than setting challenging goals that will take a substantial amount of time and effort. Ensure that your goals do not depend entirely on another individual, since their might be impediments to the goal that do not reflect your effort towards the goal.

R = Relevant. Goals should be relevant to the area of your life in which you want to make change. In our work together, you'll want to focus on goals that are relevant to using your prosthetic device, engaging in physically activity, interacting with other people and any other areas that you feel limit your mobility.

T= Time sensitive. Goals should be specific such that the time frame for accomplishing the goal is clear (e.g., 'By the end of next week I will…'). You can create short term and long term goals, but it is most important to have short term goals to guide your behavior. The time frame can be adjusted if necessary, though if it needs to be adjusted, consider reassessing whether the goal was achievable.

Behavior Recording Form for Prosthesis Use – COMPLETE AFTER SESSION 1

The purpose of this form is to gather information about activities you might avoid or do less often because of concerns you have around the use of you prosthesis. The intent is to ***make note of situations during the next week where you might have limited or avoided something because of prosthesis use concerns****. You are asked to indicate the date, time, and situation you were in when concerns about using your prosthesis came up. You are also asked to note what you were thinking at the time. By carefully tracking these situations, you may become more aware of how anxiety or nervousness you have about different situations impacts you.*

Date/Day of week	*Time*	*What were you doing?*	*What were your thought or concerns?*	*What behavior was affected?*	*How did you feel afterward?*

Breathe to Relax (Introduced during Session 2)

Overview:

When people become nervous, anxious, or distressed it affects how they think and act. When these reactions go unchecked, they can result in even more anxiety. The purpose of the *Breathe to Relax* is to counter this reaction so that you feel less distressed and can continue to pursue the activities of life you choose to do. While *Breathe to Relax* will not to make all anxiety go away, it will allow you to manage it more effectively.

The *Breathe to Relax* procedure involves two skills:

1) Learning to notice your breathing and how to slow it down by breathing deeply into your lungs
2) Learning to remove your focus from negative thoughts that cause distress and focusing your attention in the present moment.

At home practice exercises:

You should practice relaxation skills in a quiet place in your home for approximately10 minutes each day

Step 1:
Sit in a comfortable chair. Place one hand on your upper chest and the other hand on your diaphragm muscle (i.e., right under your ribs). Notice your hand movements and how fast you are breathing. Deeper, more relaxed breathing will result in your hands being mostly still. Take in normal amounts of air and breathe smoothly.

Now practice slower, deeper breathing and see if your hands start to move less. After you become more practiced at slower, deeper breathing, practice with your hands simply resting at your side.

Step 2:
Focus your attention on your breathing. Notice the feeling of air coming in, and after a brief pause, air being exhaled. Notice these feelings and let your attention focus there as best you can.

If you find yourself feeling more relaxed, as you exhale think the word "relax".

Use your skill when needed:

If you experience a situation where you feel more anxiety or distress, use this relaxation skill as best you can. Possibly pause or slow down, notice your breathing and slow it down and breathe deeper into you're your lungs (breathe diaphragmatically). Focus your attention on your breathing for a moment and think "relax" as you feel yourself exhale.

Behavior Recording Form for Prosthesis Use - COMPLETE AFTER SESSION 2

The purpose of this form is to gather information about activities you might avoid or do less often because of concerns you have around the use of you prosthesis. The intent is to ***make note of situations during the next week where you might have limited or avoided something because of prosthesis use concerns****. You are asked to indicate the date, time, and situation you were in when concerns about using your prosthesis came up. You are also asked to note what you were thinking at the time. By carefully tracking these situations, you may become more aware of how anxiety or nervousness you have about different situations impacts you.*

Date/Day of week	*Time*	*What were you doing?*	*What were your thought or concerns?*	*What behavior was affected?*	*How did you feel afterward?*

This week I practiced Breath to relax for _____ days

Making Goals for Change

Begin to complete at-home after Session 2
TO BE FURTHER COMPLETED WITH BEHAVIORAL COUNSELOR DURING SESSION 3
(Refer to Page 5 when completing)

My short-term goals (within the next few session) are:

My medium-term goals (by the end of the program) are:

My long-term goals (after the program and beyond) are:

At-home Activity (post-Session 2)

We would like you to try the following activity sometime between today and session 3

(therapist will fill this out during session 2)

_____

_____

_____

_____

_____

_____

Answer these 3 questions after completing the activity:

1) I completed the activity on: _____ (fill in date)

2) While I was doing the activity I had the following thoughts:

_____

_____

_____

_____

3) While I was doing the activity I used some of the skills I learned in the program: ☐ Yes ☐ No

If Yes, what skills did you use:

_____

_____

_____

Answer the following whether or not you complete the activity:

This week I practiced "Breath to relax" for _____ days.

Behavior Recording Form for Prosthesis Use - COMPLETE AFTER SESSION 3

The purpose of this form is to gather information about activities you might avoid or do less often because of concerns you have around the use of you prosthesis. The intent is to ***make note of situations during the next week where you might have limited or avoided something because of prosthesis use concerns****. You are asked to indicate the date, time, and situation you were in when concerns about using your prosthesis came up. You are also asked to note what you were thinking at the time. By carefully tracking these situations, you may become more aware of how anxiety or nervousness you have about different situations impacts you.*

Date/Day of week	*Time*	*What were you doing?*	*What were your thought or concerns?*	*What behavior was affected?*	*How did you feel afterward?*

Previous 2 pages are repeated 5x more for session 3-7; these pages of the manual have been omitted to save space. These pages are then followed by a copy of the last four pages of the control manual which describe procedures for study follow-up including GPS and activity monitoring,

Belief Rating Scale (to be used by therapists as needed during sessions)

List a specific thought you have that relates to a concern about using your prosthesis (e.g., “I think that if I try to put something away on the top shelf I will fall”)

Specific Thought 1:

_____

_____

Now, rate how accurate you believe that thought is right now. Place an X on the rating scale.

Belief Rating 1

|----------|

0	*50*	*100*
I believe the thought is ***completely inaccurate***	*I believe the thought is* ***somewhat accurate***	*I believe the thought is* ***completely accurate***

Specific Thought 2:

_____

_____

Now, rate how accurate you believe that thought is right now. Place an X on the rating scale.

Belief Rating 1

|----------|

0	*50*	*100*
I believe the thought is ***completely inaccurate***	*I believe the thought is* ***somewhat accurate***	*I believe the thought is* ***completely accurate***

Extra Behavior Recording Form for Prosthesis Use

The purpose of this form is to gather information about activities you might avoid or do less often because of concerns you have around the use of you prosthesis. The intent is to ***make note of situations during the next week where you might have limited or avoided something because of prosthesis use concerns****. You are asked to indicate the date, time, and situation you were in when concerns about using your prosthesis came up. You are also asked to note what you were thinking at the time. By carefully tracking these situations, you may become more aware of how anxiety or nervousness you have about different situations impacts you.*

Date/Day of week	*Time*	*What were you doing?*	*What were your thought or concerns?*	*What behavior was affected?*	*How did you feel afterward?*

Targeting Balance Confidence as a Strategy to Increase Integration and Improve Outcomes in Users of Lower-limb Prostheses

OP160044
W81XWH-16-OPORP-PORA

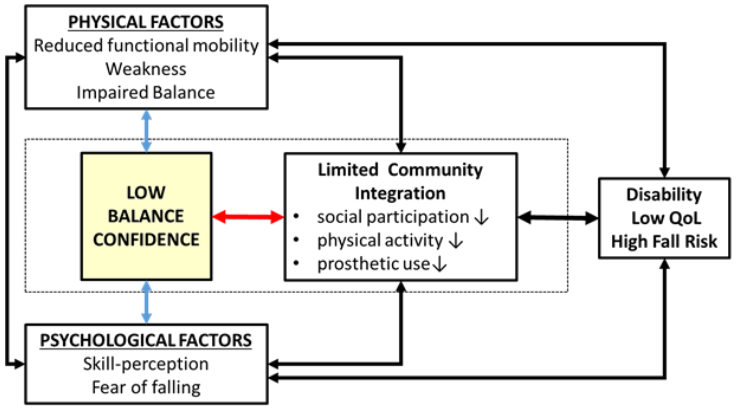
PI: Noah J Rosenblatt, PhD **Org:** Rosalind Franklin University of Medicine and Science **Award Amount:** $499,596

Study/Product Aim(s)

Quantify the effects an intervention that supplements physical therapy (PT) and cognitive behavioral therapy (CBT) strategies (termed CBPT intervention) on balance confidence and in turn community integration in individuals with lower limb amputation 0 and 2 and 4-months post-intervention

Approach

60 lower limb prosthesis users with self-reported low balance confidence and related activity restriction will be randomized to a control or intervention group (CBPT). Interventions will take place during eight, one-hour sessions. PT exercises will include active video games that address the domains of balance and functional gait. CBT strategies will include learning to evaluate the accuracy of appraisal of balance-confidence-related thoughts and include exposure therapy to reduce fear-related activity avoidance. In the latter, the PT and CBT clinician will work together to develop individualized exercises that approximate tasks within a subject-specific fear hierarchy, identified through discussion of weekly behavioral recordings. Measures of balance ability and self-reported scales of balance confidence, social activity and integration as well as objective measure of integration including activity data linked to GPS positional data, will be compared between groups at all points.



Pathway linking low balance confidence and greater disability. The proposed work focuses on the boxed pathway (red arrow) by implementing interventions to address physiological and psychological factors impacting balance confidence (blue arrow)

Timeline and Cost (start date: 9/30/17)

Activities	9/17-9/18	9/18-9/19	9/19-9/20
IRB/HRPO approval (all institutions)			
Intervention Development			
Training of clinicians			
Participant recruitment			
Aim 1 & 2 : Effect of CBPT on outcomes			
Aim 3: Relationship among outcomes			
Aim4 : Key informant interviews			
Analysis for H1 and H2			
Manuscript preparation			
Estimated Budget ($K)	**$227K**	**$188K**	**$83K**

Updated: October 26, 2018

Goals/Milestones

17/18 Goal - Enroll and begin data collection
- ☐ Obtain all institutional approvals
- ☐ Complete training manuals
- ☐Train researchers on conducting exercise and CBT protocols
- ☐ Begin testing and meet recruitment goals of Q2

18/19 Goal - Complete data sets on 45 participants
- ☐ On-going recruitment
- ☐ Continued running of the intervention and collection of follow-up data

19/20 Goal - Complete enrollment and data collection
- ☐ Complete lab-based protocol on remaining participant
- ☐ Complete follow-up on all participants
- ☐ Report results in multiple journals
- ☐ Finalize and distribute training material
- ☐ Seek out next funding source

Comments/Challenges/Issues/Concerns: Recruitment has been delayed due to investigators on summer vacations, changes in study phone line numbers and delayed flyer approval; concerted recruitment efforts began April 2018; expect to enroll first participant at end of July 2018.

Budget Expenditure to Date: Projected: $227 K (Year 1 budget); Actual: $100 K