Original Research

Effectiveness of an Evidence-Based Amputee Rehabilitation Program: A Pilot Randomized Controlled Trial

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Background. Despite the prevalence of lower limb amputation (LLA), only a small percentage of people with LLA actually receive physical therapy post amputation and are rehabilitated to their full potential level of function. There is a need for the development of a rehabilitation program that targets impairments and limitations specific to people with LLA.

Objective. The objective of this study was to determine whether the Evidence-Based Amputee Rehabilitation program would improve functional mobility of people with unilateral transtibial amputation (TTA) who have already completed physical therapy and prosthetic training.

Design. This study was a randomized, wait-list control, single-blinded pilot clinical trial.

Setting. This study researched participants who had received postamputation rehabilitation to varying degrees, either in an inpatient and/or outpatient settings.

Participants. The participants in this study included veterans and nonveterans with unilateral TTA due to dysvascular disease and trauma.

Intervention. This study included a prescription-based rehabilitation program for people with amputations.

Measurements. Results were measured with The Amputee Mobility Predictor with (AMPPro) and without a prosthesis (AMPnoPro) and 6-Minute Walk Test (6MWT) at baseline and at the end of the 8-week intervention.

Results. The intervention group improved on the AMPPro scores (36.4 to 41.7), AMPnoro scores (23.2 to 27.1), and 6MWT distance (313.6 to 387.7 m). The effect size for the intervention was very large (1.32). In contrast, the wait-list control group demonstrated no change in AMPPro scores (35.3 to 35.6), AMPnoPro scores (24.7 to 25.0), and 6MWT distance (262.6 m to 268.8 m).

Limitations. The sample size was small. A total 326 potential candidates were screened with 306 unable to meet inclusion criteria or unwilling to participate.

Conclusion. People with unilateral TTA who received Evidence-Based Amputee Rehabilitation program demonstrated significant improvement in functional mobility, with most participants (66.7%) improved at least 1 K-level (58.3%) and greater than the minimal detectable change (66.7%).

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Physical therapist services after lower limb amputation (LLA) can have a meaningful impact on physical function and quality of life. People with LLA receiving physical therapy are more likely to have better prosthetic weight-bearing and mobility, musculoskeletal endurance, walking speed, and prosthetic fit, as well as an increased 1-year survival rate, compared with those who do not receive physical therapy.[1-4] Unfortunately, physical therapist services are only received by a few people after amputation.[5,6] A review of 12,599 veterans with LLA found that only 55% received rehabilitation services postoperatively, with physical therapy being the most common service.[7] Furthermore, there is a concern that many people receiving postamputation physical therapy are not rehabilitated to their full potential level of function. In a cohort of 42 people with unilateral LLA who received physical therapy, the majority remained at a high risk for falls at discharge.[3] Miller et al reported on a cohort of men with dysvascular disease and transtibial amputation (TTA) that impairments and limitations persisted even after completing rehabilitation.[8] The impairments and activity limitations that persist can manifest into asymmetrical lower limb use when performing everyday activities such as rising from a chair, standing, walking, and negotiating environmental obstacles such as inclines, declines, or stairs.[9-11] These mobility limitations may place the person at risk for increased secondary health effects such as osteoarthritis, low back pain, cardiovascular disease, obesity, and risk for future amputation.[12,13] A physical therapy rehabilitation program for people with LLA where exercise prescription is determined by performance-based functional assessment does not exist. Because of the importance of postamputation physical therapy, there is a need for the development of a rehabilitation program that targets impairments and limitations specific to people with LLA.

The Amputee Mobility Predictor (AMP) is a reliable performance-based outcome measure (PBOM) that has been validated for use in people with LLA as a measure of functional capabilities and mobility without a prosthesis (AMPnoPro) or with a prosthesis (AMPPro).[14] The AMPPro score has been used as an activity limitations outcome measure and has a minimal detectable change (MDC) value of 3.4 points.[15,16] The AMPnoPro and AMPPro scores can differentiate between the Medicare Functional Classification Level (MFCL) or K-Levels as defined by Centers for Medicare/Medicaid Services (CMS).[14,17,18] The AMP was developed as a measure for people with LLA that could discriminate the functional capabilities between the MFCLs, assist with identifying limitations in functional capabilities, and assess prosthetic mobility.[14] The AMP has demonstrated the ability to discriminate functional capabilities and mobility in higher functioning[19-21] and lower functioning[22-24] people with LLA as well as people with bilateral amputations.[19,25] The Comparative Effectiveness Review committee for the Agency for Healthcare and Research Quality identified the AMP as 1 of 12 outcome measures for people with LLA that are generalizable to the Medicare population.[26,27] The AMP has been found to correlate with other measures such as walking speed[14,16,28-30] and Time-up and Go, as well as self-report measures of prosthetic mobility.[17] It has also been found to have good outcome prediction capabilities.[14,22,28] The AMP does have better discrimination between levels of amputation than other performance-based measures[24] and is also easily administered by a variety of clinicians.[31,32] The AMP also has the ability to quantify change over time after rehabilitation.[16,29,33]

The AMP can also be used to guide exercise prescription for limb loss and prosthetic rehabilitation. Each AMP task is designed to assess a person's ability to perform specific physical skills at the activity level (general tasks/demands and mobility); in addition, each AMP task is also comprised of a number of components (neuromusculoskeletal and movement-related functions) within the body function domain as defined by the International Classification of Functioning.[15,34] To successfully complete the task at the activity level, the components at the body function level must be performed correctly. For example, AMP task number 4 assesses the activity of rising from a chair. This task involves several body function components, including organizational skills, postural control, momentum strategies, and dynamic postural stability. The neuromusculoskeletal and movement-related functions can be further itemized to specific body function impairments for each component of the task where limitations in strength, power, coordination, balance, and speed can be defined. Once the limitations at the impairment level are identified, specific exercises can be prescribed to address the possible deficits associated with each AMP task. If the exercises are effective in improving the components at the body function level, then the activity level performance will be enhanced, thus improving the quality of the sit-to-stand task and producing a higher score on the AMP task and AMP test. By using the AMP, the physical therapist can quantify at the activity level the specific task limitations for the person with LLA and prescribe specific exercises at the body function component level that will address those impairments that limit functional capabilities.

The concept of Evidenced-Based Amputee Rehabilitation (EBAR) is relatively consistent with traditional physical therapist practice models where the physical therapist assesses the patient, prescribes treatment, treats the patient, and reassesses. What may differ with this program is that, after the patient completes the AMP, the tasks that received a less than a satisfactory score are identified and exercises designed to address the impairment or limitation are prescribed. The rehabilitation principles and exercises for people with amputation chosen for EBAR have gained widespread acceptance in the clinical community worldwide.[35-47] After a predetermined period of time, the patient is reassessed to determine the change in function and if any modification to the exercise program is necessary. An EBAR program that uses PBOM like the AMP to assist with clinical decision-making and the prescription of effective rehabilitation interventions in people with LLAs has not been previously described in the literature.

The primary purpose of this study was to determine if an EBAR program will improve the functional mobility of people with unilateral TTA who have previously completed a traditional prosthetic rehabilitation program. We hypothesized that the mobility of people with TTA receiving the EBAR intervention would improve over an 8-week period of time, while the wait list control participants would remain unchanged. The secondary purposes of this study were to determine the trajectory of mobility change over the course of the 8-week intervention and to document pre-post intervention changes in individual AMPPro tasks.

Methods

Study Design

This randomized, wait-list control, single blinded pilot clinical trial was conducted at the Miami Veterans Affairs Healthcare System (Miami VAHS), Miami, Florida, in cooperation with the University of Miami Miller School of Medicine, Department of Physical Therapy. Participants were recruited from clinician referral and clinics by the research and clinical teams from Miami VAHS, Jackson Memorial Hospital, and local South Florida prosthetic and physical therapy clinics. Every candidate contact was logged and screened by the lead research physical therapist to explain the study commitment and determine eligibility based on predetermined inclusion criteria and subsequently enrolled with the Miami VAHS institutional review board-approved consent form.

Appendix 1 illustrates the study design. Participants were male and female between 55 and 80 years of age with unilateral TTA due to traumatic or dysvascular etiology, at least 1 year postamputation, fitted with their current prosthesis for at least 6 months, and had completed traditional postamputation rehabilitation and prosthetic training. All participants had received postamputation rehabilitation to varying degrees either in an inpatient and/or outpatient setting. Participants were excluded if they presented with severe cardiac or pulmonary disease, poorly controlled metabolic disease, nonhealing wounds, limiting musculoskeletal diagnoses, neurological disorders, or prosthetic fit issues. Participants were excluded if they scored a 43 or higher on the AMPPro, indicating that they were functioning at the MFCL K4-level (43–47pts) and not requiring the EBAR program, which focused on basic mobility skills. Estimated AMP score ranges were used to classify participants to the respective MFCLs: K1 (15–26 points), K2 (27–36 points), and K3 (37–42 points).

Study Procedures

Each participant received a physical examination for medical clearance by the study physician. The study prosthetist evaluated the prosthesis for fit, comfort, and alignment. All necessary adjustments to the prosthesis were made prior to the start of the intervention. Two research physical therapists assumed different roles and were blinded from each other throughout the study. One physical therapist who administered the AMPPro, AMPnoPro, and 6MWT at baseline and at the end of the 8-week intervention was blinded to group assignment (intervention vs wait-list control) and all intervention data.

At the conclusion of baseline testing, participants were randomly assigned to either the 8-week intervention or wait-list control for 8 weeks. The other physical therapist implemented the EBAR program for all participants. The EBAR program was administered for 60 minutes, 3 times per week for 8 weeks. The AMP and 6-MWT were also administered at the conclusion of weeks 2, 4, and 6 to assess change in function and modify the exercise prescription as outlined in the EBAR program. After repeating baseline testing, participants assigned to the wait-list control group were eligible to begin the EBAR program.

EBAR Program

The EBAR program consisted of 5 primary components: (1) cardiopulmonary endurance and flexibility, (2) trunk and lower limb strengthening, (3) balance and coordination, (4) weight-bearing and stance control, and (5) prosthetic gait training.

A combination of cardiopulmonary aerobic and warm-up exercises was performed for a maximum of 15 minutes at the onset of each treatment session. To avoid any residual limb issues, regular skin checks were conducted before and after warm-up as participants progressed from non-weight–bearing to partial and then full weight-bearing with the prosthesis using the following sequence over the 8 weeks: upper limb ergometry for weeks 1–2, progressing from sitting to standing; Nu-Step (TRS 4000 Nu-Step Recumbent Cross Trainer) for weeks 3–4, which incorporates both upper and lower limb movement and trunk rotation; elliptical machine for weeks 5–6; and treadmill walking for weeks 7–8, progressing from self-selected to moderate walking speed or as tolerated for 15 minutes. The participant's heart rate and perceived exertion were monitored by the physical therapist. Flexibility exercises were performed for the lower limbs, pelvis, and trunk. Participants received from the physical therapist a manual stretching program for weeks 1–2 and then progressed to a 10-minute self-stretching program.

The remaining 35 minutes of the physical therapist session followed the exercise program outlined in the EBAR program (trunk and lower limb strengthening, balance and coordination, weight-bearing and stance control, and prosthetic gait training), which were guided by the performance on each AMP task. If the participant scored either a 0 (inability to perform the task) or 1 point (minimal level of achievement or with some assistance) out of 2 points (independence or mastery of task) on an AMP task, specific exercises that address the impairment were prescribed.[18] Exercises corresponding to tasks with scores of 0 points would take priority over scores of 1 point during exercise selection; however, the treating physical therapist could select the exercises from the task menu that in their professional judgement would best serve the participant (Appendix 2).

For example, if at baseline testing a participant scored 0 points (unable to vary walking cadence in a controlled manner) or 1 (asymmetrical increase in cadence in a controlled manner) on AMP Task #18 (Variable Cadence), they present with impairments related to single limb balance, prosthetic gait control (transverse pelvic rotation), and dynamic postural stability. The treating physical therapist would choose from the exercises that corresponded with AMP Task #18 that are designed to address and improve those impairments: stool stepping, trunk rotation, resisted walking, and speed training to increase step frequency.[18] Stool stepping promotes stability within the stump socket interface and weight-bearing through the prosthesis, controlled displacement of center of mass over the base of support, and speed of contraction for hip and knee musculature. Trunk rotation in opposition to pelvic rotation promotes balance and momentum during gait. Resisted walking promotes power and balance over the prosthetic foot to facilitate equal stride length. Speed training focused on equal step length between limbs with improved single limb balance helps promote the ability for increased cadence and, as a result, fast walking speed or the ability for variable cadence.

All exercises designed to address impairments identified at baseline testing were prescribed during weeks 1 and 2. The exercises were progressed by increasing the repetitions or changing the surface (noncompliant to compliant to dynamic), direction of movement (uni-planar to bi-planar to multi-planar), speed (slow to fast), position (supine to sitting to standing), and/or resistance (no resistance to manual resistance to weighted resistance or resistance bands). Participants were retested on the AMPPro and AMPnoPro after the conclusion of week 2. If their scores improved but did not achieve a maximal score on an AMP task, those exercises were continued and progressed for the next 2 weeks. If they demonstrated a maximum score on the AMP task, then those exercises were discontinued and alternate exercises were prescribed based on their performance with other AMP tasks. Several AMP tasks assess related components within a body function domain; as a result, 1 exercise could be prescribed to address impairments related to 2 or more AMP tasks. The previously described exercise program enables the clinician to address multiple AMP tasks with similar exercises and facilitated the progression of exercises as function improved without overwhelming the participants with too many different exercises.

Outcome Measures

AMP. AMP is a measure of functional capability of a person with amputation to ambulate with (AMPPro) or without a prosthesis (AMPnoPro).[14] As previously described, the AMP can be easily administered (10–15 minutes) and requires standard equipment typically found in a clinical setting.

The 6MWT is considered a measure of overall mobility, endurance, and physical functioning in the adult and geriatric population as well as for people with LLA.[33,48] Administration of the 6MWT was consistent with recommendations by the American Thoracic Society.[49] The rectangular course dimensions were 60 feet (18.28 m) by 30 feet (9.14 m) for a total distance of 180 feet. At the completion of the 6MWT, the distance walked was recorded in meters. The MDC for the 6MWT for those with LLA is 45 m.[16]

Statistical Analysis

Descriptive statistics were calculated to describe the intervention and wait-list control groups. Student's *t* tests and chi-square statistics were calculated to compare the baseline characteristics between the 2 groups. A 2-group repeated-measures analysis of variance was used to compare the change in AMPPro and AMPnoPro scores and 6MWT distance of the intervention and wait-list control groups. Effect sizes were calculated for change in AMPPro, AMPnoPro, and 6MWT separately for the intervention group and wait-list control groups.

The secondary analyses used data from the 9 intervention group participants and 3 wait-list control group participants who had successfully completed the entire 8-week intervention. In addition to the blinded information collected at baseline and 8 weeks, the AMPPRO, AMPnoPro, and 6MWT data collected at weeks 2, 4, and 6 to guide exercise prescription were analyzed. Single-group repeated-measures ANOVAs were calculated to examine intervention-related changes across the 5 time periods in AMPPRO, AMPnoPro, and 6MWT performance. Where the ANOVAs were significant, paired *t* tests were used to examine change between 2 relevant time periods. A frequency table was generated to examine pre-post intervention change at the item level.

Role of the Funding Source

This study was supported by the Department of Veterans Affairs and Rehabilitation Research and Development Services, which played no role in the design, conduct, or reporting of the study.

Results

Eighteen people with TTA were enrolled in the study, with 2 participants in the wait-list control group withdrawing for medical conditions unrelated to the study. Nine of the 18 participants completed the EBAR intervention and 7 completed the wait-list period. Two participants randomized to the wait-list control group voluntarily withdrew from the study. The mean age was 63.25 years, mean time since amputation was 8.1 years, 81.2% were male, and 75% lost their limb because of peripheral vascular disease or diabetes mellitus. Participants in the intervention and wait-list control groups did not differ in their demographic characteristics or PBOM baseline measures (Tab. 1). The mean number of PT treatments per week was 2.5 sessions.

Table 2 presents the repeated-measures ANOVA group × time interaction between the intervention group and the waitlist-control group at baseline and 8 weeks. The intervention group's mean AMPPro score increased from 36.4 to 41.7 while the wait-list control group's score remained unchanged from 35.3 to 35.6 ($P = .004$) (Tab. 2). The mean change in AMPPro of 5.3 points for the intervention group exceeds the AMPPro MDC (3.4 points).[16] Similarly, the AMPnoPro mean score of the intervention group improved from 23.2 to 27.1, while the wait-list control group score also remained unchanged (24.7 to 25.0; $P = .04$). The 6MWT distance of the intervention group improved from a mean of 313.6 m to 387.7 m ($P = .04$), while the wait-list control group again demonstrated virtually no change (262.6 m to 268.8 m). The mean change in 6MWT distance of 74.1 m exceeds the 6MWT MDC (45 m).[16] The effect size of the EBAR program for the intervention group was very large (1.32) for change in AMPPro scores. The AMPnoPro score and 6MWT distance had a moderate to large effect size (0.68 and 0.53, respectively).

Seven participants (58.33%) improved at least 1 MFCL K-level, with 2 of those participants improving 2 MFCL K-levels (K2-level to K4-level). Seventy-five percent of the participants who completed the EBAR program demonstrated improvement in AMPPro greater than the MDC (3.4 pts).[16]

Only 3 of the 7 participants who were randomized to the wait-list period completed the 8-week EBAR program. Two were lost to follow-up and 2 could not complete the intervention due to medical complications not related to the EBAR program participation (Fig. 1). The 9 participants in the intervention group and the 3 participants in the wait-list group who crossed over and completed the intervention were part of a secondary analysis examining the effects of the EBAR intervention over time. Table 3 describes the significant improvement in AMPPro and AMPnoPro scores (P .0001, respectively) and 6MWT distance ($P = .0006$) across the 5 intervention time periods (Tab. 3; Fig. 1). Table 4 describes the pairwise comparison of the AMPPro, AMPnoPro, and 6MWT distance across the 5 intervention time periods. No change occurred within the first 2 weeks. After 4 weeks, significant change occurred with the AMPPro score. Both significant statistical and clinical change in AMPPro and AMPnoPro scores, and 6MWT distance occurred between baseline and weeks 6 and 8 (Tab. 4), where mean change exceeded MDC for the measures.[16] Missing data from Tables 3 and 4 were the result of participants' noncompliance and not completing all testing intervals.

The item level analysis (Fig. 2) revealed participants demonstrated deficits in 21 of the 25 total tasks. A large proportion of the participants initially demonstrated deficits in the more challenging AMP tasks. Post intervention, participants improved in performance in up to 9 tasks with the mean improvement of 5 tasks. For the entire cohort (n = 12), there was an improvement of 58 points and only a 5-point decline.

Discussion

Even though the participants enrolled in this study were many years postamputation and post rehabilitation, those who received the 8-week EBAR program demonstrated clinically significant improvement in mobility as measured by the AMPPro, AMPnoPro, and 6MWT. The wait-list control group participants remained unchanged during the wait period and those who completed the EBAR intervention also demonstrated significant improvement. The intervention group pre-post intervention effect size for the AMPPro (1.32) was twice that for the AMPnoPro. This suggests that the physical therapy exercises focused on prosthetic training are effective for improving prosthetic mobility and function. The AMPPro tasks with greatest improvement were step length prosthetic limb (3 points/25%), step length sound limb (5 points/42%), foot clearance sound limb (3 points/25%), variable cadence (7 points/58%), stepping over an obstacle (6 points/50%), ascending stairs (6 points/50%), and descending stairs (4 pts/33%). Because the majority of participants in this study had moderate to high functional capabilities, the targeted exercises were designed to improve strength, muscular endurance, balance, and coordination with both lower limbs that would improve prosthetic control and function. These findings suggest that people with LLA have the potential to benefit from an EBAR program with a more targeted exercise approach after they have recovered from surgery and completed postamputation rehabilitation. The absence of change in the wait-list control participants indicates that simply walking with the prosthesis is not sufficient for continued improvement of functional mobility and that skilled physical therapy is required to facilitate prosthetic mobility skills.

The secondary analysis of the cohort who completed the EBAR intervention suggests that significant improvement

Table 1.
Participant Baseline Characteristics and Self-Report and Performance-Based Outcome Measures for Those Randomized to the Intervention and Wait-List Control Group[a]

Characteristics	Intervention Group (n = 9)	Wait-list Control Group (n = 7)	*P*
Sex, no. (%)			
Men	6 (67)	7 (100)	
Women	3 (33)	0 (0)	
Race, no. (%)			
Caucasian	1 (11)	4 (57)	.10
African American	8 (89)	3 (43)	
Cause of amputation, no. (%)			
DM	4 (44)	1 (14)	
PVD	0 (0)	3 (43)	
DM and PVD	1 (11)	3 (43)	
Trauma	3 (33)	0	
Tumor	1 (11)	0	
Age, y			
Mean (SD)	63.4 (11.5)	63.00 (7.1)	.93
Range	(44–78)	(54–75)	
Time since Amputation, y			
Mean (SD)	11.6 (11.4)	4.22 (4.3)	.13
Range	(1.7–19.0)	(1–8.2)	
Height, cm			
Mean (SD)	177.0 (8.4)	173.2 (8.4)	.39
Range	(166.4–188.0)	(158.8–188.0)	
Weight, kg			
Mean (SD)	100.6 (25.5)	95.8 (29.8)	.73
Range	(63.5–140.6)	(70.3–142.9)	
ABC, points			
Mean (SD)	65.0 (18.72)	68.4 (25.2)	.76
Range	(21–90)	(47–88)	
AMPPro, points			
Mean (SD)	36.4 (4.0)	35.3 (2.4)	.51
Range	(29–42)	(33–40)	
AMPnoPro, points			
Mean (SD)	23.2 (5.7)	24.7 (5.3)	.60
Range	(15–32)	(17–31)	
6MWT, m			
Mean (SD)	313.6 (138.9)	262.6 (132.4)	.47
Range	(97.4–505.8)	(89.8–432.1)	

[a]ABC = Activities Balance Confidence Scale; AMPnoPro = Amputee Mobility Predictor without a prosthesis; AMPPro = Amputee Mobility Predictor with a prosthesis; DM = diabetes mellitus; 6MWT = 6-Minute Walk Test; PVD = peripheral vascular disease.

Table 2.
Comparison Between Intervention and Wait-list Control Groups on Pre-post Intervention Change[a]

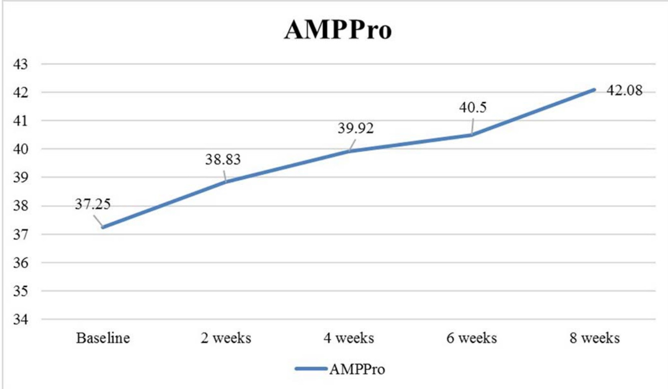
PBOM	Intervention Group (n = 9)				Wait-list Control Group (n = 7)				Group x Time Interaction (P)
	Pre Mean (SD) Range	Post Mean (SD) Range	Change Mean (SD) Range	[c]Effect Size	Pre Mean (SD) Range	Post Mean (SD) Range	Change Mean (SD) Range	[c]Effect Size	
AMPPro, points	36.4 (4.0)	41.7 (4.0)	5.3 (1.92)	1.32	35.3 (2.4)	35.6 (5.4)	0.3 (3.7)	0.12	.004[b]
Range	(29–42)	(35–45)	(3–9)		(33–40)	(28–43)	(−6–5)		
AMPnoPro, points	23.2 (5.7)	27.1 (5.7)	3.9 (3.4)	0.68	24.7 (5.3)	25.0 (6.2)	0.3 (2.8)	0.006	.04[b]
Range	(15–32)	(15–35)	(0–9)		(17–31)	(18–35)	(−5–4)		
6MWT, m	313.6 (138.9)	387.7 (130.6)	74.1 (63.0)	0.53	262.6 (132.4)	268.8 (157.4)	6.2 (52.2)	0.05	.04[b]
Range	(97.4–505.8)	(143.3–571.1)	(−30.2–164.2)		(89.8–432.1)	(55.7–435.8)	(−88.5–68)		

[a]AMPPro = Amputee Mobility Predictor with a prosthesis; AMPnoPro = Amputee Mobility Predictor without a prosthesis; 6MWT = Six-Minute Walk Test.
[b]Repeated-measures ANOVA group × time interaction.
[c]Individual group pre-post intervention effect size.

in prosthetic mobility as measured by the AMPPro occurred by week 4 with the greatest change occurring by week 6 and significant improvement found in both AMP tests. By week 8, all 3 measures demonstrated significant improvement. As expected, the 6MWT distance increased steadily over the course of treatment as strength, muscular endurance, and aerobic capacity improved, as did the distance walked, reaching a statistically significant improvement of 16% at week 8 (332 m progressing to 396 m). The change in walking speed and distance is consistent with other randomized controlled trial studies that used a specific exercise program in people with LLA.[50] Interestingly, previous work suggests that the estimated mean 6MWT distance for the K2-level is 190 m, 300 m for K3-level, and 400 m for K4-level.[14] This small cohort did have some participants with greater than expected mean distances for the 6MWT; however, the median distance for the entire group was 274 m at baseline progressing to 419 m at week 8.

There were 5 participants who were K2-level and 7 K3-level participants at baseline, with 7 of the 12 (58%) progressing 1 or 2 K-level(s) with a mean AMPPro increase of 6.3 points by week 8 and an average increase in 6MWT distance of 48.9 m. One K2-level and 3 K3-level participants remained within their MFCL; however, all participants improved with their AMPPro scores and 6MWT distance an average of 3 points and 104.3 m, respectively. The EBAR program identifies physical impairments related to lower body strength, muscular endurance, coordination, balance, postural control, and speed of movement that are assessed at the activity level with sitting and standing balance activities, transfers, walking, and ascending and descending stairs. Target exercises at the impairment level can help to improve many different functional activities beyond just walking.

The participants in this study were able to perform sitting activities and transfers and could ambulate with adequate foot clearance, step length, and step continuity. If a cohort of people with LLA who had lower level functional capabilities (K1-level and K2-level) had enrolled in this study, it would be interesting to see where the improvement in function occurred and how much improvement would take place over time. The AMPPro tasks that presented the greatest difficulty were single limb balance, variable cadence, stepping over an obstacle, and stairs. These tasks have been found by previous investigators to be predictors of function in people with LLAs.[23,51] Although some participants did improve with these tasks, for example 58% improved cadence variance, single limb balance on either limb was not improved. It was not possible to determine if participants had reached their maximal potential or if alternative treatment strategies would have yielded greater improvements. Postamputation rehabilitation is inconsistent across the various treatment settings with many clinicians using standard treatment protocols focused on discharge criteria



AMPPro = Amputee Mobility Predictor with a Prosthesis

Figure 1.
Mean change in AMPPro scores across the intervention intervals.

Table 3.
Change Across the Intervention Intervals in the Combined Intervention and Wait-List Groups[a]

	0	Interval 1	Interval 2	Interval 3	Interval 4	*P*
	Baseline	2 wk	4 wk	6 wk	8 wk	
AMPPro, points [Mean (SD)]	35.2 (4.2)	37.83 (3.9)	39.9 (3.0)	40.5 (3.7)	42.1 (3.6)	<.0001
Range	29–43	28–42	33–42	32–45	35–45	
n	n = 12	n = 12	n = 12	n = 12	n = 12	n = 12
AMPnoPro, points [Mean (SD)]	25.0 (6.3)	24.83 (5.5)	27.1 (5.0)	30.3 (4.1)	28.2 (5.4)	<.0001
Range	15–35	14–34	16–33	22–36	15–35	
n	n = 12	n = 12	n = 12	n = 10	n = 12	n = 10
6MWT	332.4 (130.3)	336.85 (113.9)	356.0 (131.0)	348.4 (131.3)	395.9 (113.8)	.0006
Test distance	97.4–505.8	110.35–495.5	118.6–531.3	101.5–556.3	143.3–571.1	
(m)	n = 12	n = 11	n = 11	n = 10	n = 12	n = 10

[a]AMPnoPro = Amputee Mobility Predictor without a prosthesis; AMPPro = Amputee Mobility Predictor with a prosthesis; 6MWT = 6-Minute Walk Test.

rather than using information based in evidence, such as using PBOM to determine physical impairments and limitations. Prosthetic gait training, typically administered a few weeks after surgery, is often insufficient for proficiency with a prosthesis. Many factors contribute to the person not reaching their prosthetic potential during the first bout of physical therapy, including, residual limb healing, pain, physical deconditioning, psychosocial adjustment to the loss of the limb, and simply the need for time to heal.[52–54] In addition, the rehabilitation goals and expectations can be low, resulting in the prescription of basic prosthetic componentry and limited access to the appropriate physical therapy. Evidence also suggests most people with amputations do not progress beyond the level of function achieved at discharge from acute rehabilitation.[55]

For these reasons, the investigators believed that the majority of secondary issues would be resolved, allowing participants to focus on improved prosthetic mobility, if they were given additional physical therapy 1 year postamputation. Approximately one-half of participants enrolled in this study were people with K2-level function defined as household ambulators/limited community ambulators; however, the EBAR program progressed the majority of participants to K3-level community ambulators. Rehabilitating people to an activity level that permits community participation is the long-term goal of most rehabilitation programs because it can positively influence a person's quality of life. This study demonstrates that a targeted rehabilitation program posttraditional rehabilitation period can significantly improve prosthetic mobility.

Table 4.
Pairwise Comparison of Change in AMPPro, AMPnoPro, and 6MWT by Intervention Intervals[a]

Time Intervals	AMPnoPro Change Mean (SD) Min-Max Participants	*P*	AMPPro Change Mean (SD) Min-Max Participants	*P*	6MinWalk Change Mean (SD) Min-Max Participants	*P*
Week 0–2	−0.2		0.6		13.8	
	(3.1)	.86	(3.8)	.61	(39.1)	.27
	−5–6		−4–10		−60.0–65.3	
	n = 12		n = 12		n = 11	
Week 0–4	2.1		2.7		32.95	
	(4.1)	.10	(3.3)	.02[b]	(60.8)	.10
	−5–9		−2–8		−54.6–147.2	
	n = 12		n = 12		n = 11	
Week 0–6	4.1		3.2		43.7	
	(3.8)	.008[b]	(2.7)	.001[b]	(81.9)	.13
	−1–12		−2–7		−90.7–147.9	
	n = 10		n = 12		n = 10	
Week 0–8	3.2		4.8		63.5	
	(3.7)	.01[b]	(2.6)	<.0001[b]	(61.2)	.004[b]
	−2–9		0–9		−30.2–164.2	
	n = 12		n = 12		n = 12	
Week 4–6	2.0		0.5		7.3	
	(2.0)	.01[b]	(2.5)	.44	(43.23)	.61
	−2–5		−5–4		−76.0–75.7	
	n = 10		n = 12		n = 10	
Week 6–8	−0.3		1.6		33.48	
	(1.8)	.62	(1.9)	.02	(36.7)	.02
	−3–3		−2–5		−2.6–103.5	
	n = 10		n = 12		n = 10	

[a]6MWT = 6-Minute Walk Test; AMPnoPro = Amputee Mobility Predictor without a prosthesis; AMPPro = Amputee Mobility Predictor with a Prosthesis; n = number of participants.
[b]Statistically significant difference.

Limitations and Future Studies

The sample size for this study was small. The investigators approached 326 potential candidates for this intervention study, offering a comprehensive preenrollment medical evaluation, an 8-week PT intervention program, financial compensation for transportation to and from the study site, and any required therapies at the conclusion of the study. A total of 306 people were unable or declined to participate in the study. Because those who were asked to enroll chose to decline, no informed consent was signed, data concerning reasons for nonparticipation were not obtained, and participants who enrolled introduced self-selection bias to the study. Wong's (2016) systematic review of 8 randomized controlled trial studies using exercise interventions in people with LLA found all other studies had similar enrollment with a range of 4 to 58 participants, illustrating the relatively low participation in these types of studies and the need for intervention research with larger populations.[50] As described in the introduction, the issue of low research rehabilitation participation by people with LLA is consistent with the literature and requires further understanding and investigation with respect to the motivation and reasons for participation or nonparticipation in physical therapy rehabilitation. Although the primary analyses achieved statistical significance, some aspects of the secondary analyses did not. This may be attributed to low statistical power. Sample size was affected by the inability of 2 of the wait-list control group participants to complete the EBAR program due to decline in medical status and 2 participants who withdrew for unknown reasons.

This pilot intervention study produced questions by investigators for future work. For instance: when is the

Item #	Task (maximum score)	IA		IB		IC		CA		ID		IE		IF		CB		IG		IH		CC		II		H	L
		B	F	B	F	B	F	B	F	B	F	B	F	B	F	B	F	B	F	B	F	B	F	B	F		
1	Sitting Balance (1)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
2	Sitting Reach (2)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0
3	Chair to Chair Transfer (2)	2	2	2	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0
4	Arise from Chair (2)	2	2	1	1	1	2	2	2	1	1	1	1	2	2	2	2	2	2	2	2	1	2	2	2	2	0
5	Attempts to Arise from Chair (2)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	1	2	2	0
6	Immediate Standing Balance (2)	2	2	1	0	2	2	2	2	2	2	1	2	2	2	2	2	2	2	1	1	1	2	1	2	3	1
7	Standing Balance (2)	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0
8S	Single leg standing balance: sound limb (2)	1	1	1	1	1	1	2	2	1	1	1	1	1	1	2	2	2	2	1	1	1	1	1	2	1	0
8P	Single leg standing balance: prosthetic (2)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	0
9	Standing reach(2)	1	1	1	1	1	2	2	2	2	2	1	1	2	2	2	2	2	2	2	2	2	2	1	2	2	0
10	Nudged (2)	2	2	1	0	2	1	2	2	1	1	1	1	1	2	2	2	2	2	1	2	2	2	1	1	2	2
11	Eyes Closed (1)	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	3	0
12	Picking up Object from floor (2)	1	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0
13	Sitting Down (2)	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0
14	Initiation of Gait (1)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
15P	Step length prosthetic limb(1)	0	1	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	0
15S	Step length sound limb (1)	0	1	0	1	0	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	5	0
15CP	Foot Clearance prosthetic limb (1)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0
15CS	Foot Clearance sound limb (1)	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	3	0
16	Step continuity (1)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
17	Turning (2)	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0
18	Variable Cadence (2)	1	1	0	1	1	2	1	1	1	2	1	2	2	2	1	2	1	1	1	2	1	1	1	2	7	0
19	Stepping over obstacle (2)	1	2	2	2	2	2	2	1	2	2	2	1	1	2	1	2	2	2	1	2	1	2	1	2	6	2
20a	Ascending Stairs (2)	1	1	1	1	1	1	1	1	1	2	1	1	1	2	2	2	1	2	1	2	1	2	1	2	6	0
20d	Descending stairs (2)	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	2	1	1	1	2	1	1	1	2	4	0
21	Assistive device	4	5	4	4	5	5	4	5	5	5	2	2	5	5	5	5	4	5	5	5	5	5	5	5		
	Total AMPPro Score	35	41	29	35	38	42	41	42	38	42	33	36	41	45	43	46	42	45	38	44	36	43	36	45		
	MFCL K-Level	2	3	2	3	3	3	3	3	3	3	2	3	3	4	3	4	3	4	3	4	2	4	2	4		
	# Better #Worse	5	0	8	2	5	1	1	1	4	0	4	1	4	0	3	0	2	0	6	0	7	0	9	0	58	5

Maximum Possible Score | Sub-maximal Score | Higher Score Post EBAR | Lower Score Post EBAR

a = ascending; AMPPro = Amputee Mobility Predictor with a Prosthesis; B = baseline testing; C = Control group participant; C = wait-list control group; d = descending; F = final testing; H = the total number of participants with higher scores; I = intervention group; I = Intervention group participant; L = the total number of participants with lower scores; P = prosthetic limb; S = Sound limb.

Figure 2.
Pre-post intervention by AMPPro task.

best time after amputation surgery to administer specific exercises, what is the appropriate duration for physical therapy, how do we know when a patient has reached their maximum potential, and should alternate exercises be added to the EBAR program? Moreover, the impact of the EBAR program during the acute phase of rehabilitation—when sitting balance, transfers, and standing with or without a prosthesis is the focus of physical therapy—is not known. Because there was so much improvement with this cohort, people with LLA should return to physical therapy regularly to receive EBAR over a lifetime for each new replacement prosthesis to maintain function or to reduce the risk of secondary health effects associated with age and long-term prosthetic use.

The EBAR program and targeted exercise prescription can significantly improve the efficacy of PT rehabilitation for people with TTA with the potential application for other patient populations. Future EBAR research should include a multi-site study at Veteran Affairs facilities and private sector hospitals that care for people with LLA. This study demonstrated that people with unilateral TTA can improve their prosthetic mobility after participating in an EBAR program when targeted exercises are prescribed based on the objective findings of the AMP. Physical therapy rehabilitation designed to address impairment level limitations can improve activity level tasks and mobility over 8 weeks of physical therapy administered 2 to 3 sessions per week. Most people who completed the EBAR program improved their AMP score, 6MWT distance, and functional K-level.

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Ethics Approval

This study was approved by the Human Studies Subcommittee and Institutional Review Board at the Miami Veterans Affairs Healthcare System.

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Clinical Trial Registration

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Disclosures

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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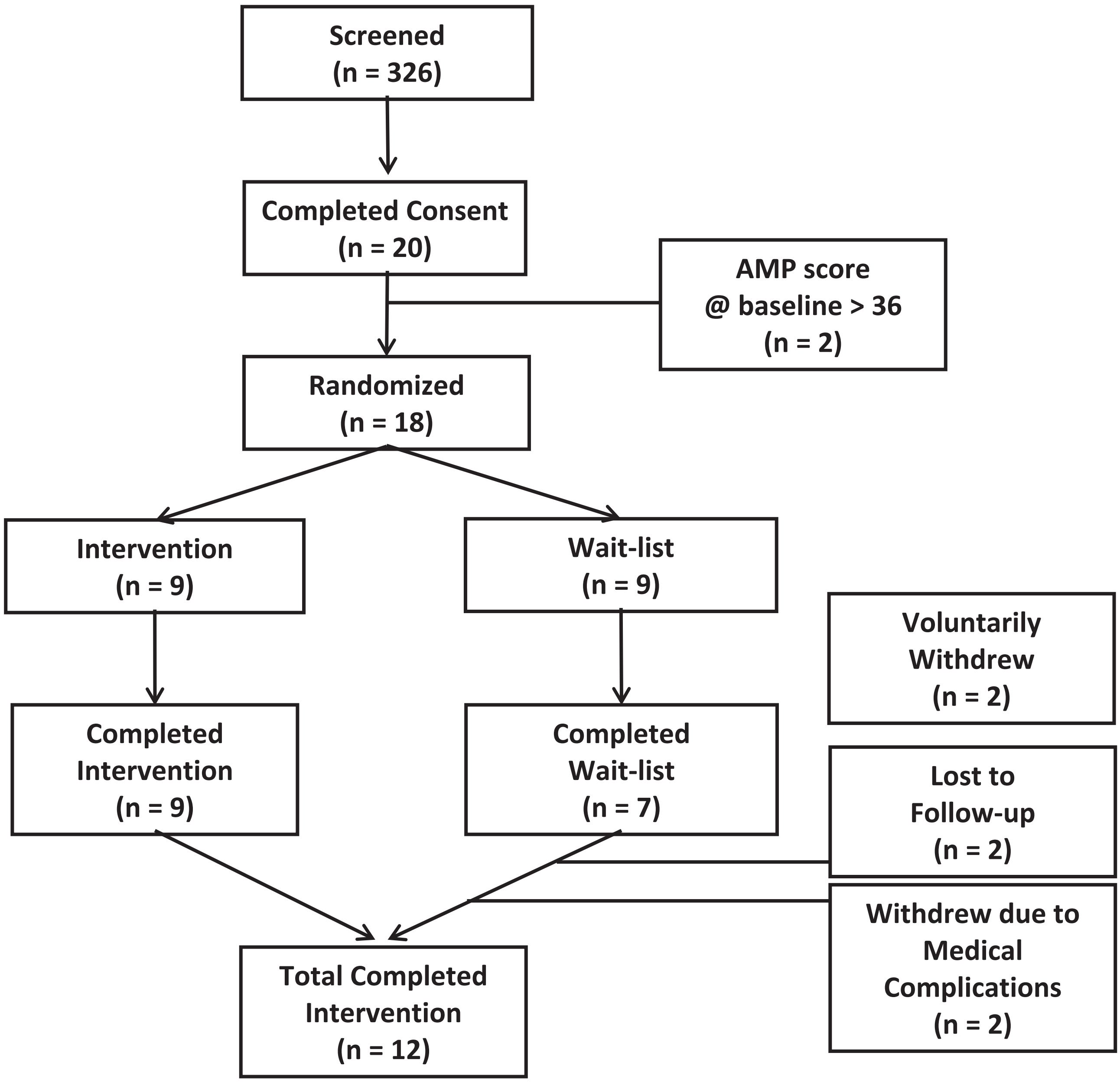
Appendix 1.

Evidence-Based Amputee Rehabilitation Program Study Design



Appendix 2.

Constructs/Systems Being Assessed for Each Amputee Mobility Predictor Task and Exercises Choice

Amputee Mobility Predictor Evidence-Based Amputee Rehabilitation Exercise Guide[a]

AMP Task	Primary Construct/System	Exercises
Task 1: Sitting balance	Sitting balance, trunk stability, sitting endurance	☐Trunk rhythmic rotation ☐Resisted trunk flexion & extension ☐Dynamic surface sitting exercise ☐Sitting endurance progression
Task 2: Sitting reach	Sitting balance, trunk/hip extensor strength	☐Trunk rotations with cane ☐Trunk rotations with heavy ball ☐Dynamic surface trunk flexion & extension ☐Heavy ball catch and throw
Task 3: Chair to chair transfer	Dynamic balance, upper/lower limb strength	☐Organizational planning transfers ☐Seated prosthetic weight-bearing ☐Seated dips ☐Partial chair squats
Task 4: Arise from a chair	Dynamic balance, trunk/lower limb strength	☐Organizational planning standing ☐Seated forward weight shifts ☐Sit-to-stand progression ☐Partial to full wall squats
Task 5: Attempts to arise from chair	Dynamic balance, Trunk/lower limb strength	☐Dynamic stump exercises ☐Organizational planning standing ☐Dynamic surface trunk rotations with cane ☐Dynamic surface trunk flexion & extension
Task 6: Immediate standing balance	Dynamic standing balance, postural stability	☐Rhythmic stabilization in standing pelvis-trunk ☐Perturbation in standing: thighs-pelvis–trunk ☐Dynamic surface standing ☐Dynamic surface trunk rotations with cane
Task 7: Standing balance	Standing balance, postural stability, muscular endurance	☐Postural positioning and feedback with mirror ☐Frontal plane weight shift ☐Sagittal plane weight shifts ☐Diagonal weight shifts
Task 8: Single limb balance	Single limb balance, strength, endurance, postural stability	☐Bridging ☐Stool stepping ☐Single limb trunk rotations with cane ☐Ball rolls on prosthetic limb
Task 9: Standing reach	Standing balance, COM over BoS displacement, trunk extensor strength	☐Perturbation in standing: rapid flexion/extension ☐Sagittal plane weight shifts with arm swing ☐Standing heavy ball swings ☐Standing heavy ball throws
Task 10: Nudged	Ankle, hip, step strategies	☐Standing resisted trunk flexion ☐Rhythmic stabilization in standing ☐Standing rapid trunk perturbation ☐Standing heavy ball chest pass
Task 11: Eyes closed	Possible vestibular/balance impairment	Refer to vestibular specialist
Task 12: Picking up object off floor	Dynamic balance, postural extensor strength	☐Bridging ☐Squats ☐Lunges ☐Weighted ball lunges
Task 13: Sitting down	Dynamic balance, eccentric trunk, lower limb strength	☐Organizational planning standing ☐Seated forward weight shifts ☐Sit-to-stand progression ☐Partial to full wall squats

(Continued)

Appendix 2.
Continued

AMP Task	Primary Construct/System	Exercises
Task 14: Initiation of gait	COM displacement over BoS, prosthetic gait control	☐Level walking ☐Multi-directional stepping ☐Stop and go walking ☐Ramp decline walking
Task 15: Step length & height	Single limb balance, range of motion, prosthetic weight-bearing, prosthetic gait control	☐Stool stepping ☐Restoration of pelvic transverse rotation ☐Resisted gait training ☐Ball rolls
Task 16: Step continuity	Single limb balance, double support time, prosthetic gait control	☐Resisted gait training ☐Lateral walking ☐Braiding ☐Stop and go walking
Task 17: Turning	Dynamic single limb balance, lower limb strength	☐Restoration of pelvic transverse rotation ☐Prosthetic turning progression ☐Braiding ☐Forward/lateral cup-walking[c]
Task 18: Variable cadence	Dynamic single limb balance, prosthetic gait control, dynamic postural stability	☐Stool stepping ☐Restoration trunk rotation ☐Resisted walking, prosthetic foot late stance ☐Speed training: increased step frequency
Task 19: Stepping over an obstacle	Dynamic single limb balance, prosthetic gait control, dynamic postural stability	☐Stool stepping ☐Forward cup-walking ☐Obstacle course performance ☐Resisted elastic kicks
Task 20: Ascending and descending stairs	Dynamic single limb balance, lower limb strength, prosthetic control	☐Prosthetic stair ascent progression ☐Prosthetic stair decent progression ☐Wall squats ☐Lunges

[a]Courtesy Advanced Rehabilitation Therapy, Inc. Miami, Florida Copyright © 2016. AMP = Amputee Mobility Predictor, BoS = base of support; COM = center of mass.