Effects of Task-Specific Locomotor and Strength Training in Adults Who Were Ambulatory After Stroke: Results of the STEPS Randomized Clinical Trial

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Background and Purpose

A phase II, single-blinded, randomized clinical trial was conducted to determine the effects of combined task-specific and lower-extremity (LE) strength training to improve walking ability after stroke.

Subjects

The participants were 80 adults who were ambulatory 4 months to 5 years after a unilateral stroke.

Method

The exercise interventions consisted of body-weight–supported treadmill training (BWSTT), limb-loaded resistive leg cycling (CYCLE), LE muscle-specific progressive-resistive exercise (LE-EX), and upper-extremity ergometry (UE-EX). After baseline assessments, participants were randomly assigned to a combined exercise program that included an exercise pair. The exercise pairs were: BWSTT/UE-EX, CYCLE/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX. Exercise sessions were 4 times per week for 6 weeks (total of 24 sessions), with exercise type completed on alternate days. Outcomes were self-selected walking speed, fast walking speed, and 6-minute walk distance measured before and after intervention and at a 6-month follow-up.

Results

The BWSTT/UE-EX group had significantly greater walking speed increases compared with the CYCLE/UE-EX group; both groups improved in distance walked. All BWSTT groups increased walking speed and distance whether BWSTT was combined with LE strength training or not.

Discussion and Conclusion

After chronic stroke, task-specific training during treadmill walking with body-weight support is more effective in improving walking speed and maintaining these gains at 6 months than resisted leg cycling alone. Consistent with the overtraining literature, LE strength training alternated daily with BWSTT walking did not provide an added benefit to walking outcomes.

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Impaired walking ability is a hallmark residual deficit following stroke. Although approximately 70% to 80% of adults who have survived a stroke will recover the ability to walk short distances on flat surfaces, only 50% achieve even limited community ambulation[1] and fewer than 20% have unlimited ambulation in the community.[2] In the early period following a stroke, lower-extremity (LE) paresis from impaired muscle activation limits the ability to advance the limb for swing and to support body weight during stance.[3,4] As time from stroke increases in the early poststroke period, motor control, muscle strength (force-generating capacity), and walking ability begin to improve.[5] Incomplete recovery and development of secondary impairments, however, may contribute to continued gait dysfunction.[4,6,7] In addition to paresis, stroke disrupts selective voluntary control and can leave the patient with primitive patterns of muscle action and spasticity.[8] Disuse muscular atrophy compounds the initial neurological injury, and muscle weakness remains prevalent despite some functional recovery during the acute phase.[9] The net effect of these impairments on walking is reduced speed and endurance, with impaired stability and asymmetry, during gait. Consequently, self-selected walking speed is a strong overall indicator of both stroke severity[10,11] and community ambulation status.[2]

Impairment in muscle strength is thought to be an important limiting factor in determining walking speed after stroke. There is a positive correlation between muscle strength and maximum gait speed.[7,11–14] Specific muscle groups that demonstrate the strongest relationship with walking speed vary greatly among studies, depending on the number of muscles investigated, the parameter used to quantify strength (ie, hand dynamometer force, isometric or isokinetic torques), and the method of documenting gait speed (eg, self-selected or fast speeds, distance walked, with or without assistive devices or orthoses).[7,11–14] Studies that have compared multiple muscle groups most frequently have identified strength in the hip flexors[15] and ankle plantar flexors[7,12] as the strongest predictor of walking speed after stroke, although strength in the knee extensors,[14,16,17] hip extensors,[13] and ankle dorsiflexors[18] was identified as being significantly related to gait speed. The contribution of the hip flexors and ankle plantar flexors to maximizing walking speed has been related to their large bursts of power generation late in the stance phase of the gait cycle.[7,15,19,20]

Muscle strength training may lead to improvement in both lower-limb strength and gait speed, although controlled studies that isolate this intervention are lacking. Programs that combined muscle strength training with stretching, balance training, and aerobic conditioning have demonstrated significant improvements in walking function.[21–23] However, because the protocols were multifaceted, it is not possible to determine the precise role that the strength training component may have played in improving walking function. Interventions of muscle strengthening for a single muscle group after stroke have demonstrated increased muscle strength, but little or no improvement in walking speed.[24] Several studies[21,25–27] demonstrated that strength training of multiple LE muscle groups produced significant increases in strength, resulting in modest functional changes in walking distance or improved balance or sit-to-stand ability, but did not increase walking speed. In a study of individuals with mild stroke severity (ie, baseline walking speeds of approximately 0.80 m/s), a program of progressive LE strengthening using functional weight-bearing activities such as step climbing and single-limb heel raises for exercise produced moderate increases in walking speed that were significantly correlated with increased strength in the paretic hip flexors, knee extensors, and ankle plantar flexors.[28] None of these studies compared effects of muscle-specific strengthening protocols or interventions that used resisted locomotor-like activities such as a loaded cycling task. In addition, no studies have combined task-specific locomotor training with various types of LE strength training such as these.

Task-specific training is the repetitive practice of a task that is specific to the intended outcome. Repetitive stepping on a treadmill is an example of task-specific gait training that appears to be critical to the achievement of improved walking speeds.[23,25,29,30] Visintin et al[31] demonstrated that treadmill training with 40% body-weight support (BWS) provided in early training that was progressively decreased over training sessions resulted in better walking outcomes after stroke than treadmill training without BWS.

A recent Cochrane meta-analysis[32] and an evidence-based systematic review conducted by Foley et al[33] of the Canadian Stroke Network both concluded that there is conflicting (level 4) evidence that treadmill training with or without BWS improves walking activity after stroke. Across these 2 reviews, 9 randomized clinical trials (RCTs) specifically investigated treadmill training with BWS. There were large disparities among the trials in terms of the exercise parameters specified in the intervention protocols (ie, frequency, intensity, and duration). Frequency (the number of sessions in a week) varied from 3 times per week[34,35] to 4 times per week[31] to 5 times per week.[36–40] Training intensity can be quantified by measuring within-session attributes such as walking time and treadmill speed. Actual walking time was reported in only 5 of the 9 RCTs and varied from 14 to 30 minutes of total walking time, with or without rest breaks.[31,32,35,38,40] Treadmill walking speed varied from 0.22 to 1.1 m/s (0.5–2.5 mph) across the RCTs, with only one RCT that specified speeds closer to functional walking speeds.[35] The duration across all RCTs ranged from 10 to 68 sessions. Recent studies[35,41,42] have consistently shown that treadmill training (with or without BWS) at higher speeds (ie, higher intensity) is more effective at improving walking after stroke than training at slower speeds. Therefore, a major limitation to the conclusions from the systematic reviews of treadmill training after stroke that were conducted prior to these more recent studies is the lack of consistency and intensity in the intervention and specified protocols. Due to this conflicting evidence, we specifically designed this study to address the evidence related to treadmill training with BWS as our intervention of task-specific training.

The design of our poststroke walking rehabilitation study was influenced by the literature on LE strength training and task-specific locomotor training. We posed 2 distinct clinical questions, each with a specific hypothesis. First, we wanted to determine whether a resisted cycling program that incorporated some of the weight-bearing and task-related demands of walking in a cyclical leg cycling task as described by Brown et al[43] was as effective in improving walking outcomes in adults with chronic stroke who had walking disability (ie, walking speeds at <33% of adult norms) as a high-intensity, task-specific treadmill training protocol with BWS. As this cycling exercise uses whole-limb cyclic locomotor-like movements that emphasize LE extensors and flexors as muscle groups, the effectiveness of a resisted cycling task to improve walking after stroke is an important and relevant clinical question because the cost of additional personnel and workload demands on the clinician of body-weight–supported treadmill training (BWSTT) are high. If a resisted cycling task can achieve the same walking outcomes in individuals after stroke, then a more cost-effective treatment option may be identified.

Second, we wanted to determine whether walking outcomes after stroke would be enhanced if a high-intensity, task-specific locomotor training program was combined with a moderately high progressive-resistive LE exercise program. Therefore, we developed 2 intervention programs that combined the BWSTT protocol with resistive exercise programs that are representative of options physical therapists may have in the clinic. One intervention program combined BWSTT with the resisted cycling task described above. The other intervention program combined BWSTT with a muscle-specific progressive-resistive exercise protocol designed to strengthen the paretic hip flexors and extensors, knee flexors and extensors, and ankle dorsiflexors and plantar flexors. This resisted exercise program used the 10-repetition maximum (RM), with loading provided by equipment typically present in the clinic such as elastic bands of varying resistance and cuff weights, and included muscle-specific exercises that clinicians use with their patients.

The challenge for using a muscle-specific resistive exercise program in individuals with stroke is the motor control problem associated with loss of movement selectivity. Therefore, we designed an exercise program incorporating movement activation based on the individual's movement capability that was either independent or within synergy movement patterns, as determined by the motor tasks of the lower-extremity Fugl-Meyer (LE-FM) motor assessment.[51]

Finally, we designed an upper-extremity (UE) ergometry exercise that was to serve as a "sham" task to be combined with the BWSTT and resisted cycling exercise. Previous studies that have used low-intensity UE exercise as a comparison control have demonstrated that there is no effect of low-intensity UE exercise on walking outcomes.[23,25] There is substantial evidence that physical therapy interventions that include intensive, task-specific strength or endurance training are more effective than standard care or no care.[44–47] Therefore, there is little value in comparing interventions with a no-treatment control. In contrast, the design of meaningful rehabilitation clinical trials requires the use of a parallel trial paradigm.[48] A parallel trial design includes the random assignment of study participants into 2 or more intervention groups that are equated for exposure both to the therapeutic intervention as well as to the therapist. This design discriminates between the positive changes in behavior that occur when a person is being observed[49] and the hypothesized treatment effect[50] and can result in clinical trials that have *practical clinical relevance.*[51,52]

The Strength Training Effectiveness Post-Stroke (STEPS) RCT was designed to make specific comparisons among 4 intervention groups that were equated for frequency (4 sessions per week), intensity (1 hour of moderate-intensity, task-specific gait training or strengthening exercise), and duration (6 weeks for a total of 24 sessions) and included interventions that are available and gaining popularity in the clinic despite the lack of strong evidence of their effectiveness. The use of this design should provide valuable comparisons that reveal the practical benefits of task-specific training or combined programs to improve walking outcomes after stroke. Thus, we proposed 2 separate *a priori* hypotheses. First, we hypothesized that a resisted limb-loaded cycling task that incorporated locomotor-like movements would be as effective at improving walking outcomes (ie, speed and distance) as a high-intensity, task-specific intervention of treadmill training with BWS. Second, we hypothesized that intervention programs that combine moderate-intensity strengthening (ie, resisted cycling or muscle-specific strengthening) with task-specific training (ie, BWSTT in this study) would be more effective at improving walking outcomes than task-specific training alone.

Method

Participants

Eighty participants with chronic stroke were recruited for this phase II, single-blinded, multisite, randomized intervention trial from stroke groups and outpatient clinics in the greater Los Angeles, Calif, and Chicago, Ill, communities. Three study sites participated: (1) University of Southern California (USC), Division of Biokinesiology and Physical Therapy, Los Angeles, Calif; (2) Rancho Los Amigos National Rehabilitation Center (RLANRC), Pathokinesiology Lab, Downey, Calif; and (3) Northwestern University (NU), Department of Physical Therapy and Human Movement Sciences, Chicago, Ill.

Participants who were beyond the period of spontaneous neurologic recovery and who were ambulatory but had significant walking disability that limited their community ambulation were screened for eligibility based on the following *a priori* inclusion criteria: (1) age 18 years or older; (2) 4 months to 5 years after first-time onset of a ischemic or hemorrhagic cerebrovascular accident (CVA) confirmed by computed tomography, magnetic resonance imaging, or clinical criteria; (3) able to ambulate at least 14 m with an assistive or orthotic device and assistance of one person (minimum of Functional Ambulation Classification level II) with a self-selected walking speed of ≤1.0 m/s; (4) voluntarily provided informed consent; and (5) approval of their primary care physician to participate.

Exclusion criteria included health conditions that would interfere with safe participation in a moderately high exercise program or recent exercise study participation that might interfere with the treatment effects of our protocol. Specific exclusions included: serious medical conditions; resting systolic blood pressure greater than 180 mm Hg, resting diastolic blood pressure greater than 110 mm Hg, or resting heart rate greater than 100 bpm*; lower-limb orthopedic conditions such as prior joint replacement or limitations in range of motion; spasticity management that included botulinum toxin injection (<4 months earlier) or phenol block injection (<12 months earlier) to the affected LE and intrathecal baclofen or oral baclofen (within the past 30 days); Mini-Mental State Exam score of <24; currently receiving LE strengthening exercises or gait training; past participation in any study examining the effects of long-term BWSTT (>4 weeks of training); limb-loaded pedaling or LE strengthening; or plans to move out of the area within the next year or no transportation to the study site for all evaluations and intervention sessions.

Study Design and Outcome Measures

Informed consent was approved by the institutional review board of each institution. After informed consent was obtained and baseline assessments were completed, participants were balanced for walking severity based on self-selected overground walking speed (severe: <0.5 m/s or moderate: ≥0.5 m/s but <1.0 m/s) and randomly assigned to 1 of 4 comparison exercise groups that included 4 treatment sessions per week for 6 weeks (total of 24 treatment sessions). Severity strata cutoffs were determined *a priori* based on a previous pilot study.[35] Severity was balanced within groups to ensure that numbers of participants at moderate and severe levels were not disproportionate between groups; stroke severity is a factor that has been demonstrated to affect responsiveness to locomotor training.[29,35]

Baseline measures of patient demographics, stroke characteristics (including onset), and outcome measures were assessed prior to randomization to treatment group. All measurements were performed by physical therapists who were trained to perform standardized assessment procedures and blinded to group assignment; these therapists did not provide the interventions. Consistent with the health impact of disabling conditions adopted by the Physical Therapy Clinical Research Network (PTClinResNet), outcome measures were selected to measure relevant poststroke outcomes at the primary body function, activity, and participation levels of the *International Classification of Functioning, Disability and Health*.[55] Outcome measures were selected based on

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* Cardiovascular exclusions and preexercise and postexercise tolerance guidelines were based on findings of a previous study of exercise training in individuals with stroke[53] and are consistent with the *American College of Sports Medicine Guidelines for Exercise Testing and Prescription*.[54] In addition, because graded exercise testing with an electrocardiograph was not conducted in our study, medical clearance was required by a primary care physician or cardiologist for each participant. If indicated by the personal physician, more conservative cutoffs for systolic blood pressure and diastolic blood pressure were used for exercise termination.

their known reliability and validity in the population of adults with stroke.

The primary outcome measure was overground self-selected walking speed.[2,56] Secondary walking outcome measures were fast-walking speed and 6-minute walk distance.[57,58] Walking speed was determined by the therapist as the participant's time (measured in seconds with a stopwatch) to walk the middle 10 m of a 14-m walkway with the assistive device or ankle-foot orthosis typically used for community ambulation. Data for 2 trials were collected for the self-selected pace followed by collection of data for 2 trials for the fast pace. Measurements for both trials were averaged for each respective walking speed. Six-minute walk distance was determined by the therapist as the distance that the participant walked in 6 minutes with the typically used assistive device or ankle-foot orthosis on an oval walkway between 2 chairs positioned 18 m apart. Standardized encouragement was provided at each minute, and participants could stop and rest at 1 of 4 chairs positioned on the walkway.

Additional secondary outcome measures included the LE-FM motor score[59]; Berg Balance Scale[60]; the 16-item Stroke Impact Scale (SIS-16), version 3.0[61,62]; Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), version 2.0 (physical health and mental health components)[62,63]; and LE isometric peak torque (bilateral hip flexors, hip extensors, knee flexors, knee extensors, and ankle dorsiflexion and plantar flexion).[64]

We decided to measure isometric torque due to the known deficits in movement selectivity after stroke and the range of motor severity we expected to observe in our participants. Isometric torque was measured, bilaterally, on a Biodex dynamometer,[†] with test positions selected based on optimal anatomical muscle length (ankle plantar flexion at 5°, ankle dorsiflexion at 15° of dorsiflexion, knee flexion and extension at 45° of knee flexion, hip flexion at 60° of hip flexion, hip extension at 90° of hip flexion) and body stability considerations. Hip torque was measured with participants in a supine position, and knee and ankle torque were measured in the seated position with both the knees and hips flexed to 90 degrees. Prior to each measurement, the weight of the limb due to gravity was measured and subtracted from the recorded measurement. Participants were instructed to perform the isometric muscle contractions as hard as they could and then rest for about 1 minute between the 3 efforts. Three peak torque measurements were taken from each muscle group and averaged for data analysis.

The primary and secondary walking outcome measurements were collected at baseline, after 12 treatment sessions, after 24 treatment sessions, and at the 6-month follow-up. All other outcomes were measured at baseline, after treatment, and at a 6-month follow-up, except for SIS scores, which were obtained only at baseline and at the 6-month follow-up.

Only the primary and secondary walking outcomes from the activity-level measures related to walking speed and endurance will be presented in this article, along with composite extensor and flexor isometric muscle torque measurements (ie, the sum of the 3 extensor torque values and the sum of the 3 flexor torque values) as an explanatory variable from the body function level. We elected to analyze composite strength scores rather than individual muscle torques because the strengthening interventions tested in this study target either whole-limb activities (limb-loaded cycling and treadmill training) or specific muscle groups but are individualized based on each participant's initial pattern of weakness. We separated composite scores into extensor and flexor scores because these muscles tend to work together both in function and in the whole-limb exercises. Moreover, the magnitude of torque production is greater in the extensors than in the flexors, and separate composites would prevent the changes in extensor torques from obscuring the changes in the flexor values.

Interventions

The goal of the treatment sessions was to have each participant engage in a 1-hour physical therapy program that included a moderate-intensity progressive exercise protocol that is representative of what therapists may do in a usual treatment session. Intervention consisted of physical therapist–supervised exercise conducted in 1-hour sessions, 4 days per week, for 6 weeks. Protocol variations for missed visits were acceptable if the total 24 visits were accomplished within an 8-week period.

Four exercise interventions were used. Three exercise interventions were designed to improve gait speed or LE strength, and one UE exercise intervention was designed as a sham intervention, not to include any active component that would improve gait speed or LE strength. The exercise interventions were: (1) BWSTT, (2) limb-loaded resistive leg cycling (CYCLE), (3) LE muscle-specific progressive-resistive exercise (LE-EX), and (4) UE ergometry (UE-EX). (For video clips of these exercises, visit this article online at www.ptjournal.org). After baseline assessments, participants were randomly assigned to a combination exercise

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[†] Biodex Medical Systems Inc, 20 Ramsay Rd, Shirley, NY 11967-4704.

program that consisted of the following exercise pairs: BWSTT/UE-EX, CYCLE/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX. Participants engaged in the exercise 4 days per week. Exercise type was on alternate days (eg, BWSTT session on one day followed by CYCLE session on the alternate day). Based on participant preference, a rest day was provided on Wednesday or Friday, with no exercise on the weekend.

All participants received the same number of treatment sessions and contact time with a physical therapist in order to minimize the Hawthorne effect.[49] Two separate comparisons were conducted: (1) BWSTT/UE-EX and CYCLE/UE-EX and (2) BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX. The first comparison examined the efficacy of task-specific treadmill training with BWS compared with a resistive cycling program that emphasized LE strengthening of muscle groups used in gait. The second comparison allowed for an analysis of the efficacy of an exercise program that combines task-specific treadmill training with BWS with a progressive-resistive exercise program (either resistive LE cycling or LE muscle-specific progressive-resistive exercise) compared with task-specific treadmill training with BWS alone.

A brief description of each intervention is provided below and in the Appendix. A detailed description of methods, progression algorithms, and response to treatment will follow in subsequent publications.

During the BWSTT protocol, the participant was fitted with a harness attached to an overhead suspension system positioned over a treadmill. The BWSTT session required the participant to walk on a treadmill for four 5-minute training bouts at speeds within the range of 1.5 to 2.5 mph to achieve 20 accumulated minutes of treadmill walking time over the 1-hour intervention session. Details of the BWSTT protocol have been described in a previous publication.[35] As part of the task-specific training session, the participant received gait instruction in an overground setting over a 50-ft (15-m) distance, implemented specifically to reinforce the gait training that transpired while on the treadmill. The BWSTT session was provided on either a Robomedica[‡] (USC, RLANRC) or a Biodex[†] (NU) unweighting system.

The CYCLE training protocol required the participant to cycle with the LEs on a modified Biodex[†] semirecumbent cycle. The apparatus has a releasable seat, enabling it to slide along a linear track where up to ten 10-lb bungee cords can be attached to produce extensor muscle resistance similar to a leg press machine. Therefore, in addition to the regular crank-based resistance encountered during pedaling exercise, the limb extensor muscles primarily are required to overcome resistance to maintain a stable body position against the sliding seat. The goal of the exercise is for the participant to pedal while keeping the sliding seat from moving forward out of the target "exercise region." If the forces generated by the legs are not sufficient to overcome the pull of the seat, the seat will move forward out of the target region and the participant will be cued to "push out" back into the "exercise region."

Participants were asked to complete 10 sets of 15 to 20 revolutions in each session. Participants were given at least 2 minutes to rest between sets, during which heart rate, blood pressure, and signs of distress were monitored. The initial load setting was determined through a limb load test that counted how many cycles the participant was able to successfully pedal with the seat base located in the "exercise region." The number of successful revolutions completed by the paretic limb determined the load setting for the next set. After each set, the number of successful revolutions on the paretic limb was recorded. A successful revolution was defined as the completion of one extension phase with the seat base remaining in the "exercise region." The load settings were adjusted using this guideline for the remaining sets in each session, as described in the Appendix.

The LE-EX protocol required each participant to isotonically exercise the affected LE using external resistance (eg, gravity, resistive tubing, cuff weights of various increments). The therapist followed an exercise algorithm that accounted for the participant's strength as well as movement synergy level to determine a 10-RM for 6 specific muscle groups (hip flexors, hip extensors, knee flexors, knee extensors, ankle dorsiflexors, and ankle plantar flexors). For example, the starting position against gravity for the ankle dorsiflexors was the LE-FM position for testing ankle movements independent of synergy (ie, standing, knee extended, with foot dorsiflexed against gravity). If the participant could isolate ankle dorsiflexion in this position, the typical procedure to determine a 10-RM was used, and the dorsiflexor would be loaded with resistance typically used by a therapist (in this case, resistive tubing). If the participant could not isolate the dorsiflexors in the standing position, then dorsiflexion against gravity in a sitting position was used (ie, the less difficult position to activate the dorsiflexors in the LE-FM test). If the participant could not activate the dorsiflexors in a sitting position, then the participant was positioned supine and

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[‡] Robomedica, One Technology Park, Suite C-511, Irvine, CA 92618.

used hip and knee flexion to activate the dorsiflexors.

Progression included moving to a more isolated movement position or increasing resistance within a position where activation occurred. During the LE-EX session, each muscle group was exercised for 3 sets of 10 repetitions at 80% of the 10-RM. A progression algorithm was used to increase the workload across the 12 treatment sessions. The therapist progressed the exercise by either increasing the load within an exercise type or progressing the participant to the more difficult exercise-type level.

The UE exercise protocol required the participant to cycle with the UEs on an Endorphin EN-300 Hand Cycle.[§] The therapist adjusted the resistance on the cycle to a level where the participant could complete 20 revolutions, but no more (ie, 20-RM). The exercise session consisted of the participant completing 10 sets of a maximum of 20 revolutions. Forward and backward cycling were alternated for each set of exercise, and the therapist assisted the participant's hemiparetic UE with the cycling motion, as needed.

During intervention sessions, cardiovascular response was monitored by heart rate and blood pressure measurements prior to exercise, immediately after each exercise bout, and at the end of the exercise session. Prior to the start of exercise and at the end of the exercise session, each participant's heart rate and blood pressure needed to be within the following cardiovascular tolerance guidelines: while sitting at rest, systolic blood pressure had to be less than 180 mm Hg, diastolic blood pressure had to be less than 110 mm Hg, and heart rate had to be less than 100 bpm, and, with standing, systolic blood pressure could not drop more than 20 mm Hg. Immediately after exercise, the participant's systolic blood pressure had to be less than 200 mm Hg and diastolic blood pressure had to be below 110 mm Hg. Exercise intensity was no greater than 80% of age-predicted maximum heart rate; a rest was provided if the individual perceived a high rate of exertion.[‖] If any of the previous cardiovascular guidelines were not met, the exercise session was not started or, if already started, was stopped immediately. The participant's primary care physician was contacted if there were abnormal responses to exercise or if heart rate or blood pressure was higher then what was typical for the participant at rest. Medication adjustment was provided by the physician, if needed. If the physician or the investigators felt that the exercise intensity was too high for an individual, the participant was withdrawn from the study.

Each therapist passed a rigorous standardization procedure on his or her respective protocol before evaluating or intervening with a participant in the STEPS study. The standardization process included attendance at training sessions to develop psychomotor skills, videotaped performance of the therapist conducting the protocol on an individual with stroke, and 90% competency rating by peer review on a standardized assessment rating scale assessed by the research coordinator from a cooperating site other than the therapist's "home" site.

Adverse Event Monitoring

During the study, adverse events were reported to the PTClinResNet Administrative Core at USC, the Data Management Center (DMC) at USC, and the institutional review board at each site. An adverse event was defined as an unexpected health-related incident that occurred during the course of the study, regardless of its severity or potential relationship to the study. Adverse events were coded on the severity and potential relationship to the STEPS protocol.

Data Analysis

Because of concern that a simple randomization might yield noticeable imbalance with respect to treatment assignment and baseline walking severity, a blocked randomization treatment allocation procedure was used to ensure that 20 participants were assigned to each of the 4 intervention groups and that severity (moderate or severe walking impairment) was balanced within each group (BWSTT/UE-EX, CYCLE/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX). Allocation sequence was generated and intervention group assigned after baseline assessments by the DMC.

The primary outcome measure for the preplanned hypotheses (hypothesis 1: BWSTT/UE-EX versus CYCLE/UE-EX; hypothesis 2: BWSTT/UE-EX versus BWSTT/CYCLE versus BWSTT/LE-EX) was 10-m self-selected walking speed. Due to the nature of this phase II study, in which we were interested in the dose-response between intervention effects and long-term functional effects of our interventions, we decided to complete the analysis on the evaluable participants (ie, those participants who received the full dose of therapy). However, we also report the results of the more conservative intention-to-treat analysis of all randomized subjects using a carry-forward method by imputing the last

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[§] Endorphin Corp, 6901 90th Ave, North Pinellas Park, FL 33782.

[‖] Cardiovascular guidelines established for this trial were developed prior to the 2004 American Heart Association scientific statement on exercise guidelines for people who had survived a stroke.[65] Based on this more recent evidence, we would recommend a submaximal training heart rate of 70% of age-predicted maximum heart rate when an exercise tolerance test has not been done in an individual after stroke.

collected value for the posttreatment value for the primary outcome measure. Consistent with our prespecified analytic plan, an intent-to-treat analysis was completed between: (1) BWSTT/UE-EX and CYCLE/UE-EX (40 randomized participants) and (2) BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX (60 randomized participants) for the primary outcome measure and secondary walking outcome measures. Secondary outcome measures were 10-m fast walking speed and 6-minute walking distance. In addition, paretic and nonparetic extensor and flexor composite torque scores (ie, the sum of the 3 extensor torque values and the sum of the 3 flexor torque values) were used to characterize strength gains as a result of the interventions.

Power calculations were conducted for the expected posttreatment change (post–session 24 value − baseline value) in the primary outcome measure for each of the 2 preplanned hypotheses. For hypothesis 1, with a sample size of 18 in each of the 2 groups, a one-way analysis of variance (ANOVA) will have 80% power to detect a between-group effect size of 0.23 at the .05 level of significance. For hypothesis 2, when the sample size in each of the 3 groups is 18, a one-way ANOVA will have 80% power to detect a between-group effect size of 0.19 at the .05 level of significance. With an expected attrition rate of 10%, our recruitment goal was 80 participants, with an expectation that 72 participants (n=18 per group) with both baseline and posttreatment measures of comfortable walking speed would provide enough power to detect significant group differences for each of the hypotheses. Because our preplanned analytic strategy (see below) was to adjust for the severity level (moderate, severe) using an analysis of covariance (ANCOVA), in theory, our power to detect these effect sizes is larger than 80%.

Demographics, stroke history, and baseline functional assessments were compared across the 4 randomized groups using an ANOVA for comparison of means and chi-square and Fisher exact tests for comparison of proportions. Variables found to be statistically significant were used as covariates in the subsequent intention-to-treat analyses.

For hypothesis 1, one-way ANCOVA was used to compare the postintervention change in primary and secondary outcomes between the BWSTT/UE-EX and CYCLE/UE-EX intervention groups. Severity (moderate, severe) was the preplanned covariate. Paired *t* tests also were conducted within each of the intervention groups to evaluate changes after 24 sessions. Effect sizes were calculated as the between-treatment difference in mean change scores divided by the pooled standard deviation. Similar analyses were conducted to evaluate the persistence of the treatment effects at 6 months. In this case, the dependent variable was the 6-month change in the primary and secondary walking outcome measures (6-month follow-up value − post–session 24 value).

For the primary outcome measure, a 2-way repeated-measures ANOVA model was used to determine the interaction effects of group (BWSTT/UE-EX, CYCLE/UE-EX) and time (baseline, after 12 sessions, after 24 sessions, and after 6 months), with time as the repeated measure.

For hypothesis 2, similar analyses were conducted to compare outcomes among the BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX intervention groups. When significant differences across the 3 intervention groups were found, multiple comparisons were conducted using the Tukey adjustment procedure.

Similar analyses were conducted for the extensor and flexor composite torque scores. However, due to nonnormality, the Wilcoxon rank-sum and Kruskal-Wallis nonparametric tests were used to evaluate the treatment effect of BWSTT/UE-EX versus CYCLE/UE-EX after 24 sessions and the effects across all 3 BWSTT groups, respectively. The Wilcoxon signed-rank test was used to compare within-treatment differences in the torque measurements. Statistical analyses were conducted using SAS, version 9,[#] at the .05 level of significance.

Results

Recruitment and Retention

To achieve the planned sample size of 72 participants (18 per intervention group), a total of 284 individuals were screened by telephone or chart review. Of these individuals, 127 were evaluated for an in-person, physical screening examination (Fig. 1). A total of 80 participants (28%) were recruited and randomly assigned to the 4 exercise pairs between June 2002 and April 2005. Of the 204 participants who were not recruited, 173 (85%) did not meet the inclusion criteria, and 31 (15%) declined due to personal reasons. Table 1 summarizes the reasons for exclusion by clinical site.

Of the 80 randomized participants, 71 (89%) completed the full exercise protocol (Fig. 1). Reasons for dropping out during the intervention phase included abnormal cardiac response to exercise, musculoskeletal injury, medical illness, and personal reasons. Of the 71 participants from the intervention phase, 63 (89%) were evaluated at the 6-month follow-up examination. Reasons for

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[#] SAS Institute Inc, PO Box 8000, Cary, NC 27513.

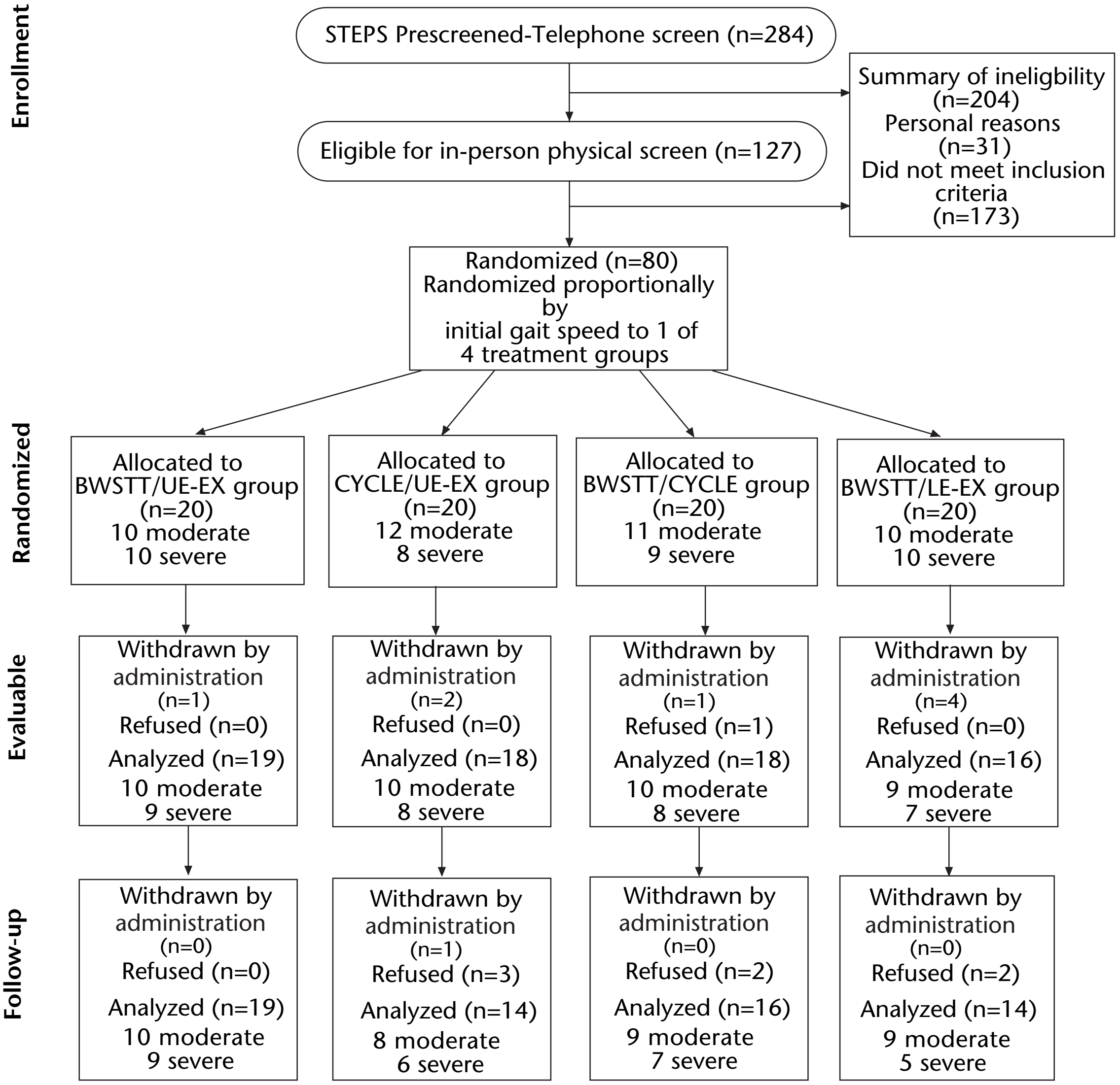

Figure 1.

CONSORT diagram. Flow of participants through trial. STEPS=Strength Training Effectiveness Post-Stroke study, BWSTT/UE-EX=combined body-weight–supported treadmill training and upper-extremity ergometry intervention group, CYCLE/UE-EX=combined resistive leg cycling and upper-extremity ergometry intervention group, BWSTT/CYCLE=combined body-weight–supported treadmill training and resistive leg cycling intervention group, BWSTT/LE-EX=combined body-weight–supported treadmill training and lower-extremity progressive-resistive exercise intervention group.

loss to follow-up included personal reasons and inability to locate the participant. Chi-square analysis revealed that participant follow-up rates (BWSTT/UE-EX group=0.95, CYCLE/UE-EX group=0.70, BWSTT/CYCLE group=0.80, and BWSTT/LE-EX group=0.70) were not significantly different across the 4 intervention groups (*P*=.17).

Table 2 summarizes the demographic and clinical characteristics for the 80 randomized participants by treatment assignment. No significant differences in baseline characteristics were found across the intervention groups. Overall, 45 (56%) of the participants were men. The average±SD (range) age and time after stroke were 60.9±12.4 (32.0–83.2) years and 25.0±16.2 (4.3–60.7) months, respectively. Stroke characteristics included 42 left CVA and 38 right CVA. Stroke type included 48 infarcts, 17 hemorrhages, and 15 not specified because these strokes were determined by clinical presentation. Baseline clinical outcomes, including the primary and secondary walking outcomes, stroke impairment severity (LE-FM motor score, Berg Balance Scale score), and

Table 1.
Summary of Ineligibility by Site: Strength Training Effectiveness Post-Stroke (STEPS) Study Recruitment Efforts Summary, June 2002 to April 2005, Composite Across Sites[a]

Reason Code														
Site	**TF**	**SS**	**TL**	**TG**	**MS**	**OP**	**OR**	**SI**	**CS**	**TP**	**MP**	**CP**	**Total Contacts**	**STEPS Subjects**
USC	4	5	5	2	2	12	3	0	2	2	4	2	78	35
RLANRC	3	0	1	1	1	11	5	0	1	0	1	0	42	18
NWU	75	2	3	12	0	8	2	6	0	20	0	9	164	27
Total	82	7	9	15	3	31	10	6	3	22	5	11	284	80

[a] TF=too far poststroke (>5 y); SS=second/multiple strokes; TL=too low on ambulation criteria; TG=free walking speed exceeded 1.0 m/s; MS=mental status (Mini-Mental State Exam score <24); OP=other problems (participant did not show or return telephone call, personal reasons for not participating, no reason for not participating, not able to participate 3–4 times per week); OR=orthopedic limitations (hip, knee, or ankle contracture; prior hip or knee replacement; leg-length discrepancy >5 cm; or premorbid gait disorder); SI=spasticity issues (receiving intrathecal baclofen, botulinum toxin injection within past 4 mo to affected lower extremity); CS=cerebellar stroke; TP=transportation problems; MP=medical problems (diagnosis other than stroke, other medical issues); CP=current participation in formal physical therapy program/clinical program or past participation in body-weight–supported training for >4 weeks; USC=University of Southern California; RLANRC=Rancho Los Amigos National Rehabilitation Center; NU=Northwestern University.

quality-of-life (SF-36 physical health and mental health scores, SIS-16 score) variables, are presented in Table 2 by treatment assignment. No significant differences were found across the intervention groups.

Comparison by severity level (data not shown) revealed that, as expected, the moderate group had higher values compared with the severe group for all of the primary and secondary outcome measures (self-selected overground walking speed: 0.71±0.20 m/s versus 0.25±0.12 m/s, fast walking speed: 1.00±0.30 m/s versus 0.34±0.18 m/s, and distance walked in 6 minutes: 258.07±86.71 m versus 93.94±60.52 m), LE-FM scores (26.14±3.45 versus 20.89±5.46), and Berg Balance Scale scores (49.61±7.26 versus 33.94±10.20). All differences were statistically significant at $P<.0001$. Stratification by severity was equivalent between all groups at baseline, as indicated by no significant differences in severity by group for all variables ($P>.05$).

Adverse Events and Protocol Variations

Across the intervention and 6 month follow-up period, there were 21 cumulative adverse events reported that occurred in 18 participants. There were 17 adverse events during the intervention period, 8 of which were not study related (4 falls in home, 1 report of low back pain, 1 controlled seizure, 1 participant diagnosed with colon cancer, 1 participant diagnosed with congestive heart failure after randomization but prior to starting intervention). Study-related events associated with the following intervention pairs included: (1) in the BWSTT/UE-EX group, minor hand abrasion and foot pain; (2) in the BWSTT/CYCLE group, foot pain, reduced blood pressure, and increased blood pressure (twice in 1 participant); and (3) in the BWSTT/LE-EX group, gluteus medius muscle pain and toe pain, with later diagnosis of toe stress fracture (2 occurrences in 1 participant). Four participants were withdrawn from the study by the administration due to the adverse events. Two adverse effects were adjudicated as related to the study (foot pain, toe stress fracture), and 2 adverse effects were considered not related to study but due to cardiac conditions (congestive heart failure, high blood pressure not responsive to medication). The participant with colon cancer withdrew from the study.

In addition to participant adverse events, there were 11 instances of unanticipated protocol variations. A committee of PTClinResNet and STEPS investigators assessed each unanticipated protocol variation to determine whether the participant should be included in the evaluable data set. The investigators determined that 8 were minor variations, and 3 were major variations. Minor variations included missing one session of exercise (for a reduced total of 23 out of 24 exercise sessions) and completing a total of 24 exercise sessions but not an equal number of each of the 2 exercises (eg, 11 sessions of one exercise and 13 sessions of the other exercise). Major variations were protocol deviations that were beyond the tolerances determined *a priori*, such as prolonged absences and doubling of exercises on single days. Data for participants with major protocol variations were included in the baseline analysis but were excluded from the final evaluable data analysis. Of the 71 evaluable participants, 8 were lost to the 6-month follow-up (1 died, 1 had sustained a myocardial infarction, and 6 refused to attend or could not be located).

Table 2.

Baseline Demographics, Stroke History, Primary Outcomes, and Participation Measures by Intervention Group (N=80)[a]

	BWSTT/ UE-EX (n=20)	**CYCLE/ UE-EX (n=20)**	**BWSTT/ CYCLE (n=20)**	**BWSTT/ LE-EX (n=20)**	***P*[b]**
Demographics					
Sex: male	10 (50%)	11 (55%)	13 (65%)	11 (55%)	.81
Age (y)	60.6 (13.7)	63.4 (8.6)	58.2 (15.2)	61.4 (11.2)	.63
Race/ethnicity					
Hispanic or Latino	2 (10%)	1 (5%)	2 (10%)	2 (10%)	.92
African American	6 (30%)	6 (30%)	2 (10%)	4 (20%)	.77
Asian	2 (10%)	4 (20%)	4 (20%)	2 (10%)	
White	12 (60%)	9 (45%)	13 (65%)	13 (65%)	
Undeclared	0 (0%)	1 (5%)	1 (5%)	1 (5%)	
Education level					
College: graduate	3 (15%)	10 (50%)	9 (45%)	9 (45%)	.13
College: postgraduate	6 (30%)	3 (15%)	4 (20%)	4 (20%)	
High school or less	11 (55%)	7 (35%)	7 (35%)	7 (35%)	
Stroke characteristics					
Time since stroke (mo)	27.5 (16.1)	28.4 (19.0)	23.1 (15.0)	20.7 (14.4)	.40
Right-sided weakness	12 (60%)	10 (50%)	11 (55%)	9 (45%)	.80
Right-hand dominance	19 (95%)	17 (85%)	19 (95%)	19 (95%)	.54
Type of stroke					
Hemorrhage	4 (20%)	4 (20%)	4 (20%)	5 (25%)	1.00
Infarct	12 (60%)	12 (60%)	13 (65%)	11 (55%)	
Clinical criteria	4 (20%)	4 (20%)	3 (15%)	4 (20%)	
Stroke severity					
LE-FM motor score (maximum score=34)	24.5 (5.5)	24.4 (4.5)	24.2 (4.0)	22.1 (6.3)	.49
Berg Balance Scale (maximum score=56)	42.1 (9.8)	42.6 (11.4)	45.2 (10.1)	40.4 (15.0)	.72
Primary and secondary outcomes at baseline					
Comfortable gait speed (m/s)	0.49 (0.24)	0.48 (0.28)	0.53 (0.28)	0.52 (0.35)	.93
Fast gait speed (m/s)	0.69 (0.38)	0.65 (0.42)	0.71 (0.38)	0.76 (0.50)	.88
6-min walk distance (m)	189.3 (99.9)	170.0 (115.2)	187.6 (99.9)	190.0 (135.4)	.93
Participation measures					
SF-36	(n=14)	(n=16)	(n=13)	(n=16)	
Physical health	39.3 (9.0)	41.9 (5.8)	41.5 (9.0)	37.4 (8.1)	.38
Mental health	52.3 (8.9)	55.4 (9.7)	49.9 (13.0)	55.7 (9.7)	.40
Stroke Impact Scale	(n=19)	(n=20)	(n=18)	(n=19)	
SIS-16	73.8 (14.0)	79.5 (10.9)	76.2 (13.0)	76.3 (14.7)	.60

[a] Values are mean±SD for continuous variables, frequency (%) for categorical variables. BWSTT/UE-EX=combined body-weight–supported treadmill training and upper-extremity ergometry intervention group, CYCLE/UE-EX=combined resistive leg cycling and upper-extremity ergometry intervention group, BWSTT/CYCLE=combined body-weight–supported treadmill training and resistive leg cycling intervention group, BWSTT/LE-EX=combined body-weight–supported treadmill training and lower-extremity progressive-resistive exercise intervention group, LE-FM=lower-extremity Fugl-Meyer motor score, SF-36=Medical Outcomes Study 36-Item Short-Form Health Survey, SIS-16=16-item Stroke Impact Scale.

[b] Chi-square test for categorical variables, one-way analysis of variance for continuous variables.

Table 3.

Primary and Secondary Gait Outcomes at Baseline, After 24 Treatment Sessions, and Change From Baseline by Group[a]

	BWSTT/ UE-EX (n=19)	CYCLE/ UE-EX (n=18)	BWSTT/ CYCLE (n=18)	BWSTT/ LE-EX (n=16)	P^b	P^c
10-m comfortable gait speed (m/s)						
Baseline	0.50 (0.23)	0.43 (0.25)	0.54 (0.28)	0.57 (0.35)		
Postintervention	0.63 (0.32)	0.44 (0.26)	0.63 (0.33)	0.67 (0.37)		
Change[d]	0.13 (0.14)	0.01 (0.07)	0.09 (0.12)	0.10 (0.07)	<.004	.70
P	.001*	.67	.004*	<.0001*		
10-m fast gait speed (m/s)						
Baseline	0.71 (0.37)	0.57 (0.36)	0.73 (0.39)	0.80 (0.51)		
Postintervention	0.81 (0.43)	0.58 (0.39)	0.81 (0.44)	0.90 (0.51)		
Change	0.10 (0.14)	0.01 (0.09)	0.08 (0.13)	0.10 (0.08)	<.03	.81
P	.008*	.79	.032*	.0002*		
6-min walk distance (m)						
Baseline	196.96 (96.4)	149.00 (99.6)	192.33 (102.3)	199.28 (137.87)		
Postintervention	219.46 (106.0)	164.52 (118.6)	217.79 (122.6)	244.60 (144.57)		
Change	22.5 (34.8)	15.5 (31.0)	25.5 (37.6)	45.3 (33.5)	.50	.17
P	.011*	.049*	.011*	<.0001*		

[a] Values are mean±SD. BWSTT/UE-EX=combined body-weight–supported treadmill training and upper-extremity ergometry intervention group, CYCLE/UE-EX=combined resistive leg cycling and upper-extremity ergometry intervention group, BWSTT/CYCLE=combined body-weight–supported treadmill training and resistive leg cycling intervention group, BWSTT/LE-EX=combined body-weight–supported treadmill training and lower-extremity progressive-resistive exercise intervention group. *$P<.05$ for baseline-postintervention comparison using paired *t* test.

[b] *P* value is comparison of BWSTT/UE-EX and CYCLE/UE-EX data using analysis of covariance (covariate=severity).

[c] *P* value is comparison of BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX data using analysis of covariance (covariate=severity).

[d] Postintervention change calculated by subtracting baseline value from post–session 24 value.

Posttreatment and 6-Month Follow-up Outcomes

In order to avoid bias in the primary analyses or initial interpretations, the principal investigators (KJS, DAB, SM) were blinded to group assignment until the final primary analyses were completed for the primary and secondary walking outcome measures for both the BWSTT/UE-EX and CYCLE/UE-EX comparisons and the BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX comparisons. Table 3 presents the means and standard deviations for each of the walking outcome measures at baseline and for session 24 as well as pretest-posttest change scores by experimental intervention group. Table 4 presents the means and standard deviations for each of the walking outcome measures for session 24 and the 6-month follow-up as well as the change scores calculated from the posttreatment measurement to 6-month follow-up for each intervention group.

BWSTT/UE-EX compared with CYCLE/UE-EX. Self-selected and fast walking speeds and walking distance increased significantly after the BWSTT/UE-EX intervention. In contrast, the CYCLE/UE-EX intervention resulted in improvements in walking distance but not in self-selected or fast walking speed. Paired *t*-test values for each within-group comparison are provided in Table 3.

Group analysis confirmed that the BWSTT/UE-EX intervention increased self-selected and fast walking speeds to a significantly greater extent than the CYCLE/UE-EX intervention. The ANCOVA with walking severity as the covariate revealed significantly greater increases in self-selected walking speed ($P<.004$, effect size=0.99) and fast walking speed ($P<.03$, effect size=0.68) for the BWSTT/UE-EX group compared with the CYCLE/UE-EX group. Treatment group differences were nonsignificant for the 6-minute walk test ($P=.50$, effect size=0.21). Figure 2

Table 4.
Primary and Secondary Gait Outcomes Change Scores From Post–Session 24 Assessment to 6-Month Follow-up Assessment (n=63)[a]

	BWSTT/ UE-EX (n=19)	**CYCLE/ UE-EX (n=14)**	**BWSTT/ CYCLE (n=16)**	**BWSTT/ LE-EX (n=14)**	***P*[b]**	***P*[c]**
10-m comfortable speed (m/s)						
Post–session 24	0.63 (0.32)	0.44 (0.28)	0.63 (0.35)	0.72 (0.36)		
6-mo follow-up	0.65 (0.33)	0.43 (0.26)	0.64 (0.32)	0.77 (0.03)		
Change[d]	0.02 (0.11)	−0.01 (0.11)	0.01 (0.10)	0.05 (0.09)	.35	.53
P	.38	.61	.68	.06		
10-m fast gait speed (m/s)						
Post–session 24	0.81 (0.43)	0.61 (0.42)	0.81 (0.47)	0.98 (0.49)		
6-mo follow-up	0.82 (0.44)	0.60 (0.42)	0.83 (0.43)	0.94 (0.69)		
Change	0.01 (0.10)	−0.01 (0.17)	0.02 (0.12)	−0.04 (0.37)	.57	.65
P	.52	.76	.54	.70		
6-min walk distance (m)						
Post–session 24	219.46 (105.95)	170.52 (122.80)	221.58 (128.53)	265.69 (141.87)		
6-mo follow-up	219.50 (116.85)	165.54 (116.13)	233.61 (131.31)	266.40 (133.03)		
Change	0.04 (55.54)	−4.98 (55.40)	12.03 (24.70)	0.71 (32.64)	.81	.65
P	1.00	.74	.07	.94		

[a] Values are mean±SD. BWSTT/UE-EX=combined body-weight–supported treadmill training and upper-extremity ergometry intervention group, CYCLE/UE-EX=combined resistive leg cycling and upper-extremity ergometry intervention group, BWSTT/CYCLE=combined body-weight–supported treadmill training and resistive leg cycling intervention group, BWSTT/LE-EX=combined body-weight–supported treadmill training and lower-extremity progressive-resistive exercise intervention group. **P*<.05 for baseline-postintervention comparison using paired *t* test.
[b] *P* value is comparison of BWSTT/UE-EX and CYCLE/UE-EX data using analysis of covariance (covariate=severity).
[c] *P* value is comparison of BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX data using analysis of covariance (covariate=severity).
[c] Six-month follow-up change calculated by subtracting post–session 24 value from 6-mo follow-up value.

shows the post–session 24 − baseline change scores for self-selected and fast walking speeds and distance walked for the BWSTT/UE-EX and CYCLE/UE-EX groups. Group differences were the same when the more conservative intention-to-treat analysis of all 40 randomized subjects using the carry-forward method was used for the primary outcome measure (*P*=.01).

At the 6-month follow-up, gains in walking speed and distance walked for the BWSTT/UE-EX group and in distance walked for the CYCLE/UE-EX group were maintained (Tab. 4, within-group comparisons). Additionally, the lack of change in walking speed from the posttreatment measurement to the 6-month follow-up in the CYCLE/UE-EX group adds validity to intervention effects rather than other factors such as natural recovery or individual experience. Group differences after treatment persisted for all walking outcome measures at 6 months (Tab. 4, between-group comparisons).

To better understand changes over the course of treatment (ie, effects of treatment duration) and for the 6-month follow-up, a 2-way repeated-measures ANOVA (with group as the between factor and session as the within factor) was conducted for the participants who completed all treatment sessions (baseline, post–session 12, and post–session 24 measures) and the 6-month follow-up measure. Data for 33 participants (19 in the BWSTT/UE-EX group, 14 in the CYCLE/UE-EX group) were included in this analysis. Figure 3 illustrates the longitudinal pattern of change for the primary outcome measure across the baseline, post–session 12, post–session 24, and 6-month follow-up measures. For self-selected walking speed, the repeated-measures ANOVA revealed significant main effects of group (*P*=.03) and time (*P*=.004) and a significant group × time interaction (*P*=.002). Multiple comparisons (using the Tukey method) revealed that the BWSTT/UE-EX group improved self-selected walking speed significantly more than the CYCLE/UE-EX group by session 24 ($P=.01$) and sustained this improvement 6 months later ($P=.02$).

BWSTT combined with strengthening regimens. Consistent with the BWSTT/UE-EX intervention, the BWSTT/CYCLE and BWSTT/LE-EX interventions resulted in significant increases in self-selected and fast walking speeds and walking distance (Tab. 3, within-group comparisons). Group analysis of the 3 BWSTT training interventions revealed that the addition of an LE strengthening protocol on alternate days to task-specific training did not result in additional gains in walking-related outcomes, including walking speed or walking distance. An ANCOVA with walking speed severity as the covariate comparing the BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX groups revealed no significant group differences for any of the walking outcomes (Tab. 3, between-group comparisons). Figure 2 shows the change scores for self-selected and fast walking speeds and distance walked for the BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX groups. Group differences were the same when the more conservative intention-to-treat analysis of data for all 60 subjects randomly assigned to the 3 BWSTT groups using the carry-forward method was used for the primary outcome measure ($P=.43$).

Table 4 summarizes the long-term beneficial effects of BWSTT on walking improvements. At 6 months, walking improvements were sustained regardless of whether the subjects were trained in the BWSTT/UE-EX, BWSTT/CYCLE, or BWSTT/LE-EX protocol, as demonstrated by nonsignificant differences in the change scores between the post–session 24 and 6-month follow-up measures (Tab. 4, within-group comparisons). An ANCOVA comparing the 3 groups that received BWSTT re-

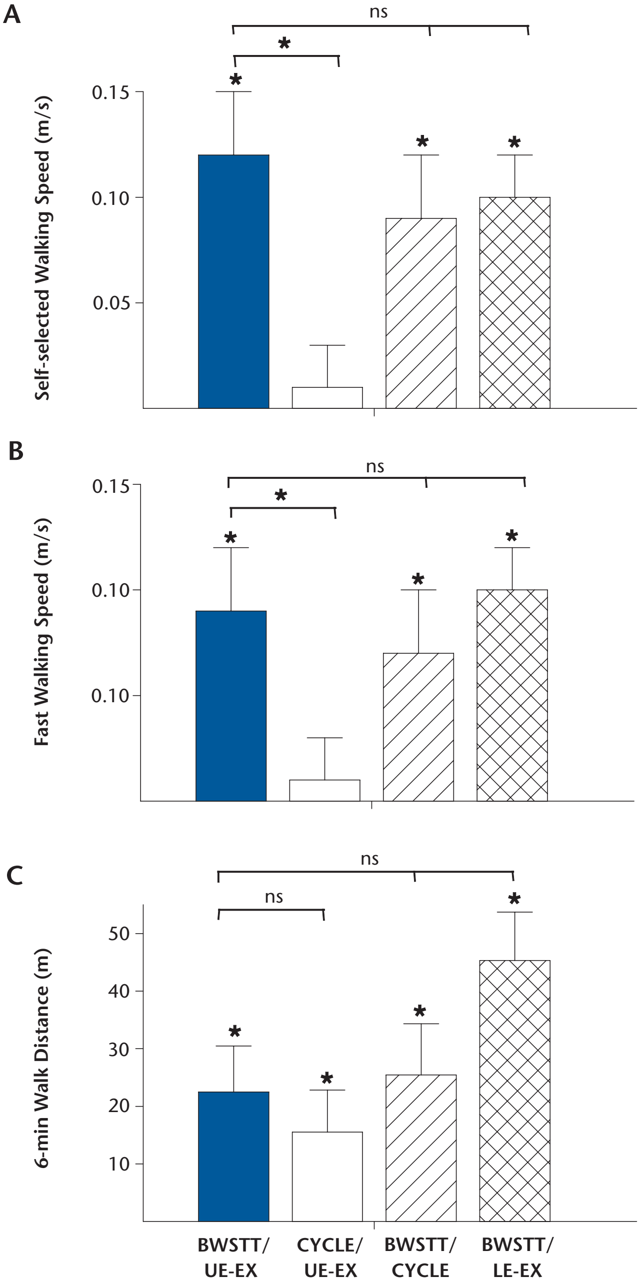

Figure 2.
Bar graphs of change (post–session 24 – baseline) by group (combined body-weight–supported treadmill training and upper-extremity ergometry [BWSTT/UE-EX], solid blue bars; combined resistive leg cycling and upper-extremity ergometry [CYCLE/UE-EX], white bars; combined body-weight–supported treadmill training and resistive leg cycling [BWSTT/CYCLE], lined bars; combined body-weight–supported treadmill training and lower-extremity progressive-resistive exercise [BWSTT/LE-EX], hatched bars) for the primary and secondary walking outcomes (mean±SEM): (A) self-selected walking speed, (B) fast walking speed, and (C) 6-min walk distance. Significant baseline to postintervention changes (paired *t* test, $P<.05$) indicated by asterisk above bar. Analysis of covariance (ANCOVA) for between-group differences for BWSTT/UE-EX and CYCLE/UE-EX comparisons indicated by lower horizontal bar; ANCOVA group differences for BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX comparisons indicated by top horizontal bar; significant group difference ($P<.05$) indicated by asterisk above lower horizontal bar; ns=not significant.

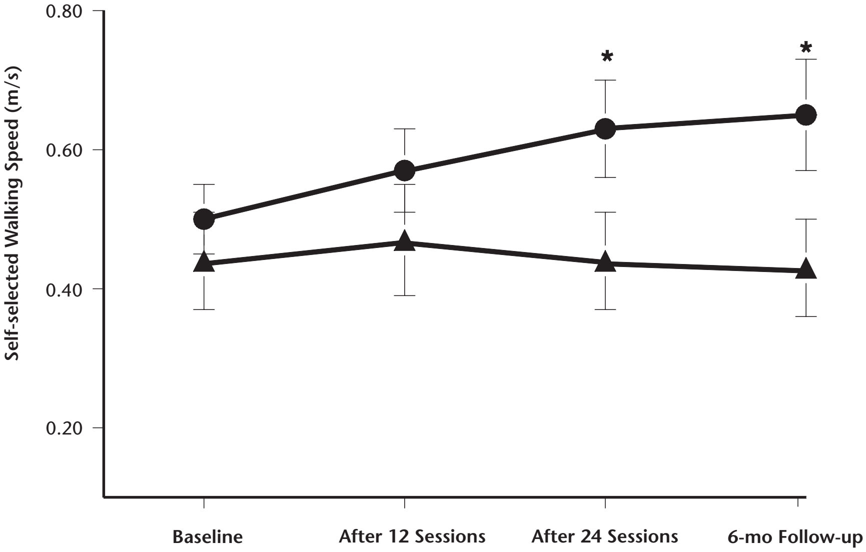

Figure 3.
Time series plot comparing combined body-weight–supported treadmill training and upper-extremity ergometry (BWSTT/UE-EX) (●) and combined resistive leg cycling and upper-extremity ergometry [CYCLE/UE-EX] (▲) group means (±SEM) at baseline, after 12 sessions, after 24 sessions, and at 6-month follow-up for the primary outcome of self-selected walking speed.

vealed that there were no group differences in 6-month follow-up change scores (Tab. 4, between-group comparisons). This analysis confirmed that, for all of the BWSTT groups, posttreatment walking gains persisted at 6 months.

Changes in isometric torque measurements. Composite torques for the extensors (sum of hip extensor, knee extensor, and plantarflexor measurements) and flexors (sum of hip flexor, knee flexor, and dorsiflexor measurements) were calculated for the nonparetic and paretic LEs. Medians (±1 interquartile range) for each group are shown in Table 5. In the BWSTT/UE-EX group, there was a significant increase in postintervention torque for the nonparetic extensors ($P=.004$) and the paretic flexors ($P=.02$). Although not statistically significant, the increase in postintervention torque for the paretic extensors approached significance ($P=.06$). For the CYCLE/UE-EX group, there was a significant increase in postintervention torque for the paretic flexors ($P=.01$). There were no significant postintervention increases in strength for either the BWSTT/CYCLE or BWSTT/LE-EX intervention (Tab. 5).

Group analysis revealed no significant group differences in composite torque changes between the BWSTT/UE-EX and CYCLE/UE-EX groups (Mann-Whitney *U* and Wilcoxon tests, $P>.05$ for all composite torque comparisons, Tab. 5). Similarly, group differences were not significant for the BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX groups (Kruskal-Wallis test, $P>.05$ for all composite torque comparisons, Tab. 5).

Discussion

The major finding of this study was that task-specific training using treadmill walking with BWS was more effective in increasing walking speed than a less task-specific, resisted cycling training program in individuals with chronic stroke who have limited community ambulation ability. Endurance improvements were evident for both the BWSTT-trained and resisted cycling–trained groups. Furthermore, our findings indicate that a moderate-intensity program of LE progressive-resistive exercise *alternated* daily with task-specific training did not provide an added benefit to walking outcomes after stroke. Regardless of whether treadmill training with BWS was combined with resistive LE exercise, an intense, task-specific walking program resulted in improvements in walking speed and endurance that were sustained at the 6-month follow-up.

Specificity and Intensity of Training

The primary finding from the STEPS trial, that treadmill training with BWS was more effective than resisted cycling in improving walking speed after stroke, may be explained, in part, by considering the combination of *specificity* of training intrinsic to walking on a treadmill and *intensity* of walking at challenging speeds. Several recent systematic reviews of physical therapy interventions have concluded that there is strong evidence that task-specific gait training can improve poststroke walking outcomes.[33,45,46] Treadmill training with BWS at challenging speeds is a primary example of a high-intensity, task-specific gait training intervention because it requires the participant to engage in repetitive walking practice with high demand during the training session. Consistently, long-term changes in performance are achieved when the conditions of task practice are similar to the task and conditions in which retention or transfer performance is expected.[66] In addition, task specificity effects are particularly strong for highly practiced skills, where motor abilities acquired with practice are specific to the task that is performed.[67] Keetch et al[67] demonstrated this with a highly practiced skill, free-throw shooting, in

Table 5.

Composite Flexor and Extensor Torques (in Newton-Meters) for the Paretic and Nonparetic Lower Extremities at Baseline and Postintervention Change (Median, Range) by Group (n=69)[a]

	BWSTT/ UE-EX (n=19)	CYCLE/ UE-EX (n=18)	BWSTT/ CYCLE (n=18)	BWSTT/ LE-EX (n=16)	P^b	P^c
Flexors, nonparetic						
Baseline	39.70 (30.93–50.23)	42.12 (33.23–53.47)	47.90 (38.63–62.73)	47.10 (32.20–56.73)		
Change[d]	−0.70 (−2.90–7.10)	−0.21 (−3.67–2.37)	0.47 (−6.93–6.17)	0.10 (−3.77–3.50)	.92	.72
P	1.00	.81	1.00	1.00		
Flexors, paretic						
Baseline	20.97 (10.27–32.07)	23.63 (13.93–32.13)	29.13 (14.67–33.30)	28.13 (20.63–34.50)		
Change	3.43 (1.53–7.63)	1.53 (0.57–7.33)	0.70 (−2.33–3.10)	−1.60 (−4.27–4.70)	.28	.07
P	.02*	.01*	.63	.61		
Extensors, nonparetic						
Baseline	87.97 (54.30–119.67)	96.97 (79.03–109.70)	95.30 (74.40–137.07)	107.93 (87.63–146.13)		
Change	9.17 (1.87–16.47)	1.48 (−11.83–15.53)	−0.20 (−6.67–16.23)	5.83 (−14.37–11.10)	.07	.16
P	.004*	.81	1.00	1.00		
Extensors, paretic						
Baseline	49.87 (36.17–67.10)	56.07 (35.07–82.47)	64.93 (47.60–83.67)	64.80 (49.43–91.13)		
Change	9.10 (−1.17–18.30)	3.02 (−8.80–16.83)	2.10 (−2.70–11.43)	7.67 (−15.07–12.43)	.35	.46
P	.06	.48	.33	.30		

[a] BWSTT/UE-EX=combined body-weight–supported treadmill training and upper-extremity ergometry intervention group, CYCLE/UE-EX=combined resistive leg cycling and upper-extremity ergometry intervention group, BWSTT/CYCLE=combined body-weight–supported treadmill training and resistive leg cycling intervention group, BWSTT/LE-EX=combined body-weight–supported treadmill training and lower-extremity progressive-resistive exercise intervention group. * $P<.05$ for baseline-postintervention comparison using the Wilcoxon signed-rank test.

[b] *P* value is comparison of BWSTT/UE-EX and CYCLE/UE-EX data using the Wilcoxon rank-sum test.

[c] *P* value is comparison of BWSTT/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX data using the Kruskal-Wallis test.

[d] Postintervention change calculated by subtracting baseline value from post–session 24 value.

expert basketball players. It is conceivable that highly practiced functional tasks such as walking also are influenced by similar task specificity effects.

For individuals after stroke, walking is a highly practiced functional task where the learner has to reacquire the motor abilities associated with gait function. In this study, all of the protocols that incorporated BWSTT were effective in improving immediate and long-term walking ability. Moreover, this ability transferred from the treadmill training environment to overground walking. In contrast, there was evidence that resisted cycling, which required the participants to coordinate a lower-limb cycling pattern with an LE extensor load, resulted in improvements in endurance but not in gait speed. Although it has been demonstrated that cycling with or without limb loading requires kinematic patterns and coordinated muscle activation patterns similar to those required for walking,[68–70] it appears that the specificity effects of this type of training affected distance walked but not speed in individuals with chronic stroke. This partial effect may be due to the nature of the CYCLE protocol used in this study, which involved 20 repetitions that were repeated for 10 sets per session. This type of training stimulus may be more effective in improving endurance that benefited walking distance versus walking speed.

We argue that the standardized intervention protocol for BWSTT used in the STEPS trial incorporated sufficient training specificity, intensity, and duration to achieve a significant change in walking speed in individuals with chronic stroke that was maintained at the 6-month follow-up. There were improvements in walking speed and walking distance across all 3 groups whose intervention incorporated BWSTT. The functional walking classification developed by Perry and colleagues[2] is a useful way to determine whether changes in walking speed are associated with clinically meaningful changes in walking outcomes at the level of participation (ie, community ambulation). Of the 53 participants who received an intervention that included BWSTT, more than 50% (27 out of 53) increased walking speed to an extent that would classify them at a higher functional walking level postintervention.

Based on an analysis of data of the participants who completed all 24 sessions of their randomization assignment, we found that BWSTT with initial BWS of 30% to 40% that was reduced across sessions, and at treadmill speeds of 1.5 to 2.2 mph for 20 minutes of walking time (with rests, as needed), for a minimum of 2 sessions over a 6-week period resulted in functionally significant changes in walking outcomes in a majority of the individuals after stroke who participated. Findings such as these provide information about an effective dosing of exercise and gait training needed to achieve functional poststroke walking outcomes. Additionally, it is interesting to note that an intense schedule of 12 sessions of treadmill training with BWS was enough of a training stimulus to increase walking speed, walking distance, and LE strength in individuals with chronic stroke. This was true when BWSTT was combined with either the UE "sham" exercise program or a progressive LE exercise program. The robustness of this finding is validated further by the comparable results of the intention-to-treat analysis for self-selected walking speed that included all randomized participants where we carried forward baseline or post–session 12 treatment data for missing post–session 24 treatment data.

Furthermore, the repeated-measures analysis that compared changes in walking speed over the course of training and the 6-month follow-up (Fig. 3) suggests that the significant change in walking speed was not evident between the BWSTT/UE-EX and CYCLE/UE-EX groups until session 24 (ie, the 12th BWSTT session). These findings replicate the pilot work by Sullivan et al[35] and demonstrate that both treatment intensity (ie, treadmill training speed of 2.0 mph) and duration (ie, minimum of 12 BWSTT training sessions) are factors associated with BWSTT training effectiveness. This phase II RCT cannot address the optimal training duration (ie, effect of increased training sessions) or timing (ie, early or late after acute stroke) for this type of locomotor training after stroke. In order to inform clinical practice, larger-scale rehabilitation clinical trials that include a larger poststroke population are required to address these factors.

Does BWS add a critical element to the training experience? Clearly, further studies would need to be specifically designed to adequately answer this question. However, the findings of a study by Visintin et al[31] and a follow-up analysis of the effects of stroke severity by this same group[71] would suggest that BWS during treadmill walking appears to be an "active" ingredient of this intervention. In our experience, there are many additional benefits of BWS provided by an overhead suspension system. First, the unweighting provides added support and positive reinforcement to the patients so that they are able to practice walking in a safe environment without fear of falling. Second, BWS is progressively decreased over the course of training, which allows the therapist to progressively increase the biomechanical demand (ie, body weight load to muscles) as the individual with stroke develops improved motor control and power during the stance and swing phases of gait. Indeed, one of the criteria for progression is for the therapist to decrease stepping assistance level as the patient increases motor control.

Third, the use of the harness and the progressive manipulation of BWS and therapist assistance are important therapeutic factors that result in more intense task practice of walking (ie, able to achieve faster walking speeds despite severity level) than would occur on a treadmill without BWS. Finally, the participants themselves reported a higher level of confidence in their walking skills. Consistently, participants reported that they felt that they were practicing something meaningful and that they enjoyed the walking sessions. Further study of how this type of training improves patient self-efficacy is warranted. In addition, the BWSTT groups did receive 50 ft (15 m) of overground walking reinforcement after the treadmill session. Though possible, it is unlikely that this low-intensity activity alone could have accounted for the strong effects of the BWSTT group or differences between the CYCLE and the BWSTT groups.

Evidence for Overtraining Effects

Contrary to our initial hypotheses, strength training added to task-specific BWSTT training did not provide an additive effect to walking outcomes. Our results suggest that BWSTT alternated with a UE "sham" exercise was more effective in increasing LE strength than a combined training program that included both task-specific and strength training (BWSTT/CYCLE, BWSTT/LE-EX). This appears counterintuitive in a population of adults with stroke, where motor control deficits are related to both weakness and the timing of muscle activation needed to support functional tasks such as walking.[72] However, evidence exists in the exercise science literature that exercise programs for young adults that combine high-volume and high-intensity endurance and resistive exercise programs can reduce the strengthening effect, particularly if the muscle groups recruited are used during both strength and endurance training (for reviews, see Kraemer and Ratamess[73] and Hunter et al[74]).

Recent investigations of the apparent interference of endurance training on strength development have studied older adults who were healthy, including 55- to 75-year-old men[75] and 60- to 84-year-old men and women.[76] Both studies controlled for frequency and duration between exercise groups over 20 and 12 sessions of training, respectively. Endurance training, including cycling or walking on a treadmill, was in the range of 60% to 80% of estimated heart rate reserve. Upper-extremity and LE resistance training on exercise machines ranged from moderate (20-RM) to high (8-RM) intensity levels, as defined by the American College of Sports Medicine guidelines.[54] Both studies demonstrated that, in older adults, cardiovascular training alone resulted in LE strength gains comparable to those achieved through either a low- or high-resistance or combined program.

The lack of a significant strength increase in the combined exercise groups in our study might be explained by a similar interference effect between resistance and endurance training. Significant increases in the nonparetic extensors and paretic flexors as well as a nonsignificant trend for the paretic extensors ($P=.06$) were found in the BWSTT/UE-EX group and for the paretic flexors in the CYCLE/UE-EX group, but not in the combined BWSTT/CYCLE and BWSTT/UE-EX groups. If there was no interference from the combined exercise groups, we would have expected the torque changes to be similar in all 3 BWSTT groups.

One possible explanation is that we had induced an overtraining effect in the combined exercise groups. The training intensities of our groups were moderately high for the BWSTT sessions, as validated by age-predicted maximum heart rates that averaged 62%±10.3% in session 1 and 67%±10.1% in BWSTT session 12 for our participants. For the LE-EX protocol, loads were adjusted for each muscle group such that the participants completed 8 to 10 repetitions for 3 sets at 80% of their 10-RM load. For the CYCLE protocol, the participants completed a minimum of 12 to 20 repetitions for 10 sets with as much load as could be tolerated. In both of the resistive exercise conditions, the perceived effort reported by the participants was high. For the exercise protocol used in this study, it appears that the best strength training stimulus for the LE occurred in the BWSTT/UE-EX group, where the LE muscle groups, progressively loaded through decreasing BWS, were provided adequate rest on the alternating UE-EX "sham" intervention days.

Smith et al[77] also reported LE strength gains in adults with chronic stroke who participated in a treadmill aerobic exercise program administered 3 times per week over 12 weeks. The results of their study and our study suggest that the benefit of task-specific training, and the associated increases in torque production, could be attributed to improved motor unit activation that occurs as individuals after stroke actively engage in functional tasks that demand muscle activation that is progressed across treatment sessions. The short-term increases in torque production over the 6-week training program that we observed would provide additional support for improved central activation.

Our findings need to be interpreted with caution. The STEPS protocol combined resistive exercise and a moderately high intensity of training on alternate days and induced what appeared to be an overtraining effect. However, recent findings by Patten et al[78] suggest that a dynamic high-intensity resistance training intervention (15 sessions over 5 weeks) followed by clinic-based gait training (9 sessions over 3 weeks) resulted in increases in gait speed and torque production for a group that received eccentric muscle strengthening. Together, these studies reveal the need for further work to determine the optimal dose response and scheduling of exercise interventions that combine resistance and task training to improve functional walking ability in individuals after stroke.

Study Limitations

There are several limitations associated with this study. We did not achieve the isometric strength gains that we projected with the CYCLE protocol. One explanation is that the exercise repetitions selected for this protocol were 12 to 20 repetitions for 10 sets, which is more effective for increasing muscle endurance.[73] Due to physical limits of the recumbent bicycle that we used, some participants progressed to the highest level of resistance (ie, 100 lb); therefore, the only method to progress the exercise was to increase repetitions. Some individuals actually completed as many as 40 repetitions per set. The increase in repetitions rather than load likely further enhanced the muscle endurance effect.

Another potential limitation is that the hemiparetic muscles were tested isometrically in isolated positions and potential gains in torque generation during full limb flexion or extension synergy patterns were not measured by these tests. Due to limitations in selective movement ability, this resulted in great variability in our torque data, with some differences in baseline torque values among groups. However, the longitudinal torque comparisons were consistent, regardless of whether parametric or nonparametric statistics were used (we used the more conservative nonparametric comparisons for this analysis), which suggests that a larger sample size may have provided more power for detecting group differences.

Clinical Relevance and Conclusions

This study investigated the effects of 4 standardized training protocols to improve walking ability in individuals with chronic stroke. This is the first rehabilitation RCT to use exercise control-comparison groups to report the effects of task-specific training, resistance training, and protocols that combined these 2 forms of exercise on measures of walking activity outcomes and strength after stroke.

The results of the present investigation indicate that treadmill walking with BWS that uses training parameters that ensure an adequate exercise frequency, intensity, and duration provided an important stimulus for walking speed, walking distance, and LE strength gains in individuals with chronic stroke. In contrast, an alternative progressive-resistive cycling exercise program matched for intensity and duration resulted only in changes in walking distance.

Lastly, and of special significance to the design of effective exercise programs for adults who have survived a stroke, training programs that combined task-specific treadmill training with BWS and moderate-intensity LE progressive-resistance exercise training on alternate days did not achieve an additive effect on walking outcomes or the isometric LE muscle torque gains that were realized by the task-specific treadmill training with BWS alone. Further work is necessary to determine how exercise programs that combine muscle strengthening protocols with task-specific training can be implemented to maximize function and voluntary muscle torque capability in individuals after stroke. Attention to the optimal scheduling of training sessions should be considered when programs that incorporate moderate- to high-intensity endurance and resistance training are combined for poststroke rehabilitation.

Invited Commentary and Author Response follow on page 1603.

Dr Sullivan, Dr Brown, Dr Mulroy, and Dr Azen provided concept/idea/research design. Dr Sullivan, Dr Brown, Ms Klassen, Dr Mulroy, and Ms Ge provided writing. Dr Brown, Ms Klassen, and Ms Ge provided data collection. Dr Sullivan, Dr Brown, Ms Klassen, Dr Mulroy, Ms Ge, and Dr Azen provided data analysis. Dr Brown and Ms Klassen provided project management. Dr Sullivan, Dr Brown and Dr Winstein provided fund procurement. Dr Sullivan, Dr Brown, and Dr Mulroy provided subjects and facilities/equipment. Dr Winstein provided institutional liaisons. All authors provided consultation (including review of manuscript before submission).

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Appendix.

Initial Intervention Training Parameters and Progressions for Each Exercise Protocol

	BWSTT	CYCLE	LE-EX	UE-EX
Exercise	Task-specific walking exercise using body-weight support and therapist assistance during treadmill training.	Lower-extremity cycling with the limb loaded in the extension phase of the cycling revolution.	Progressive-resistive exercise program for paretic hip flexors and extensors, knee flexors and extensors, and ankle dorsiflexors and plantar flexors.	Upper-extremity cycle ergometry as sham exercise condition.
Session 1	**Training Parameters** **TM speed:** optimal speed 2.0 mph (range=1.5–2.5 mph). **Trainer assistance:** up to maximum assist (3 trainers: 1 at each leg, 1 at hips) to enable proper gait kinematics. **BWS:** between 30% and 40% of participant's weight. **Training time:** 20 total minutes walking time (goal: four 5-minute walking periods, with additional rests, as needed).	**Training Parameters** **Resistance:** Start at level 4 (40 lb of resistance [four 10-lb resistance cords]). Determine 15- to 20-revolution maximum. If the participant completes fewer than 10 cycling revolutions, decrease one resistance level. If the participant completes 10 to 18 cycling revolutions, maintain resistance level. If the participant completes 19 to 20 cycling revolutions, increase one resistance level. **Cycling revolutions:** 15 to 20 revolutions in each set. **Sets:** 10	**Training Parameters** **Exercise selection and resistance:** Participant attempts the baseline exercise for each muscle group. The baseline exercise position for each muscle group specifically targets the isolated muscles and requires the participant to move in an antigravity range, deviating from synergy. If the participant cannot perform the baseline exercise movement deviating from synergy, a decrease in progression is made incorporating movement patterns within synergy. If the participant can complete the baseline exercise, the exercise is continued or progressive resistive loading is initiated until the 10-RM load is determined. **Repetitions:** 10 **Sets:** 3 (for each muscle group).	**Training Parameters** **Resistance:** Adjusted to the level where the participant can complete 20 cycling revolutions, but no more (20-RM). **Cycling rotations:** Forward and backward cycling revolutions are alternated for each set of exercise. **Trainer assistance:** Assistance is given to the participant's hemiparetic upper extremity as necessary to complete the cycling revolution. **Cycling revolutions:** 20 revolutions in each set. **Sets:** 10

(continued)

Appendix.

Continued

	BWSTT	CYCLE	LE-EX	UE-EX
Sessions 2–12	With the participant maintaining proper gait kinematics, the following training parameters are manipulated: **TM speed:** progressively increase to 2.0 mph (if not achieved in initial sessions) and above 2.0 mph, as tolerated by the participant. **Trainer assistance:** decrease from assistance level provided in session 1, with optimal goal of participant walking with no trainer assistance by session 12. **BWS:** decrease from support provided in session 1, with optimal goal of participant walking with no BWS by session 12. **Training time:** increase walking time in each training bout, with optimal goal of participant walking 20 min continuously by session 12.	**Resistance:** Determined by the number of successful cycling revolutions the participant is able to complete (maximum=20 cycling revolutions). If participant completes fewer than 10 cycling revolutions, decrease one resistance level. If participant completes 10 to 18 cycling revolutions, maintain resistance level. If participant completes 19 to 20 cycling revolutions, increase one resistance level. **Cycling revolutions:** 15 to 20 revolutions in each set. **Sets:** 10	**Exercise selection and resistance:** Determined by the participant's success in completing 10-RM. If the participant is able to perform 10 repetitions with ease, then a progression is applied (increase exercise level or resistance). If the participant is able to complete only 8 repetitions in each set, but can complete 10 repetitions with ease when the load is decreased, then the current exercise level or resistance is maintained. If the participant is able to do less than 8 repetitions in each set, then the exercise is decreased (either in exercise level or resistance). **Repetitions:** 10 **Sets:** 3	This intervention is designed to have no cardiovascular or lower-extremity training effect. Therefore, for sessions 2 to 12, the trainer always ensures that there is minimal physical exertion by the participant. To keep the participant interested in the exercise over the subsequent sessions, modifications can be made in: (1) the trainer assistance given to the participant's hemiparetic upper extremity, and/or (2) resistance on the bicycle (to maintain the 20-RM level). However, the trainer must always ensure that there is minimal physical exertion by the participant when completing the exercise.

[a] BWSTT=body-weight–supported treadmill training, CYCLE=resistive lower-extremity cycling, LE-EX=lower-extremity progressive-resistive exercise, UE-EX=upper-extremity cycle ergometry, TM=treadmill, BWS=body-weight support, RM=repetition maximum.