

ORIGINAL ARTICLE

Activity-Based Therapy for Recovery of Walking in Individuals With Chronic Spinal Cord Injury: Results From a Randomized Clinical Trial



Michael L. Jones, PhD, FACRM, Nicholas Evans, MHS, Candace Tefertiller, PT, DPT, Deborah Backus, PT, PhD, Mark Sweatman, PhD, Keith Tansey, MD, PhD, Sarah Morrison, PT

From the Virginia C. Crawford Research Institute, Shepherd Center, Atlanta, GA.

Current affiliation for Tefertiller, Craig Hospital, Englewood, CO; and Tansey, Emory University, Atlanta, GA.

Abstract

Objective: To examine the effects of activity-based therapy (ABT) on neurologic function, walking ability, functional independence, metabolic health, and community participation.

Design: Randomized controlled trial with delayed treatment design.

Setting: Outpatient program in a private, nonprofit rehabilitation hospital.

Participants: Volunteer sample of adults (N=48; 37 men and 11 women; age, 18–66y) with chronic (≥ 12 mo postinjury), motor-incomplete (ASIA Impairment Scale grade C or D) spinal cord injury (SCI).

Interventions: A total of 9h/wk of ABT for 24 weeks including developmental sequencing; resistance training; repetitive, patterned motor activity; and task-specific locomotor training. Algorithms were used to guide group allocation, functional electrical stimulation utilization, and locomotor training progression.

Main Outcome Measures: Neurologic function (International Standards for Neurological Classification of Spinal Cord Injury); walking speed and endurance (10-meter walk test, 6-minute walk test, and Timed Up and Go test); community participation (Spinal Cord Independence Measure, version III, and Reintegration to Normal Living Index); and metabolic function (weight, body mass index, and Quantitative Insulin Sensitivity Check).

Results: Significant improvements in neurologic function were noted for experimental versus control groups (International Standards for Neurological Classification of Spinal Cord Injury total motor score [5.1 ± 6.3 vs 0.9 ± 5.0 ; $P = .024$] and lower extremity motor score [4.2 ± 5.2 vs -0.6 ± 4.2 ; $P = .004$]). Significant differences between experimental and control groups were observed for 10-meter walk test speed (0.096 ± 0.14 m/s vs 0.027 ± 0.10 m/s; $P = .036$) and 6-minute walk test total distance (35.97 ± 48.2 m vs 3.0 ± 25.5 m; $P = .002$).

Conclusions: ABT has the potential to promote neurologic recovery and enhance walking ability in individuals with chronic, motor-incomplete SCI. However, further analysis is needed to determine for whom ABT is going to lead to meaningful clinical benefits.

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Traumatic spinal cord injury (SCI) leads to many well-documented and profound physiological changes. Perhaps most significant of these is paralysis, which occurs almost instantly after injury and may persist for a lifetime. Paralyzed limbs and

reduced muscle mass play a significant role in secondary health complications after SCI.¹⁻⁴ There is also evidence that forced inactivity resulting from paralysis may contribute to further neurological impairment. Research into neural recovery suggests that neural circuits in the spinal cord shut down with forced nonuse due to paralysis^{5,6} and that these circuits may be reactivated with intensive, repetitive training.⁷⁻¹³

Reports of the potential neurorestorative benefits of this activity-based therapy (ABT) have sparked considerable interest

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in this intervention among individuals with SCI. In response, programs have been developed offering ABT to promote neuro-recovery after SCI. Often at the individual's own expense, these programs offer the opportunity to continue work on recovery of function after conventional rehabilitation has been completed. Conventional therapy often focuses on the use of the preserved muscles to achieve compensatory functioning, whereas ABTs attempt to activate muscles below the level of the lesion, "with the goal of retraining the nervous system to recover a specific motor task."^{14(p185)}

There is a growing body of evidence to support the neuro-restorative benefits of ABT in individuals with SCI. Motor scores and injury classification from the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)¹⁵ are often used as measures of neurologic recovery, and studies have shown the interventions used in ABT to be effective in promoting recovery.¹⁶⁻¹⁹ Combined ABT interventions to promote neurologic recovery include locomotor training with or without body-weight support, functional electrical stimulation (FES), task-specific patterned motor activity, and resistance training targeting weakened muscles. Harness et al²⁰ reported significant increases in ISNCSCI motor scores for participants with motor-complete and motor-incomplete SCI who received 6 months of intensive ABT, including load-bearing activities, resistance exercise, and gait training. Similar outcomes in ISNCSCI motor scores were reported in a study of 23 participants with various ASIA Impairment Scale (AIS) grades who participated in outpatient ABT (9–15h/wk).²¹ Participants were involved in a range of treatment modalities including pre-gait activities, locomotor training, intensive therapeutic exercise, and FES-augmented static and dynamic activity. After approximately 3 months of treatment, significant improvements were observed in lower extremity motor score (LEMS). Beyond potential neurorestorative benefits of ABT interventions, other, arguably more clinically meaningful, outcomes have been reported in the literature, including improved gait speed, walking endurance, gait symmetry, standing balance, and overall functional ambulatory capacity.²²⁻²⁵

These studies offer encouraging evidence that the interventions used in ABT can promote recovery of lost function, including walking. To date, however, there have been no randomized controlled studies examining the impact of a comprehensive ABT program—which includes intensive strengthening and locomotor training—on recovery of walking after SCI. The present study evaluated, in a randomized controlled trial, the effects of ABT on neurological functioning, walking, functional independence, community participation, and metabolic function in individuals

with chronic, motor-incomplete SCI. This article reports the primary findings from the randomized controlled trial.

Methods

Participants

Participation of human subjects was approved by an institutional review board before the initiation of the study. Informed consent was obtained from all participants. Sample size was calculated on the basis of pilot data collected with previous participants of the ABT program at the research site. Calculations were based on observed changes in ISNCSCI motor scores compared with historic data on the proportion of patients with SCI likely to show changes in motor scores after the first year postinjury.²⁶ With an intended sample of 25 patients per group (restricted by financial constraints of the trial) and an alpha of .05, power was calculated at 81.24% to detect the expected experimental/control group differences in ISNCSCI motor scores.

Inclusion criteria for the trial were AIS classification of C or D, upper motor neuron injury, preserved tendon reflexes in the lower extremities, at least 1 year postinjury, and ages 18 to 66 years. Individuals who had significant changes in spasticity medication or participated in another ABT program in the 6 months before enrollment, had no motor preservation >3 levels below the level of injury, exceeded the weight limit (136kg) of the locomotor training devices used, or had significant health issues (eg, respiratory problems and cardiac instability) that may have compromised their ability to participate in rigorous exercise were excluded. Participants were recruited from among individuals who were on the waiting list for enrollment in the ABT program and from advertisements on the study site website. We enrolled a total of 48 participants. The sample was stratified by level of injury (tetraplegia/paraplegia) and baseline lower extremity motor functioning (LEMS≤25/>25), with random assignment to experimental and control groups. Randomization was achieved using predetermined (random) assignments by stratification blocks.

Table 1 presents the recruitment sampling frame, noting the number of participants enrolled (denominator) and the number completing pre- and posttest assessments (numerator) in each cell. Seven participants (6 experimental and 1 control) dropped out of the trial before completing posttest assessment. Reasons for dropping out included injuries related to participation in intensive exercise (n=2), injury or illness unrelated to the trial (n=2), and logistical issues, such as difficulty with transportation (n=3). The final sample

List of Abbreviations:

10MWT	10-meter walk test
ABT	activity-based therapy
AIS	ASIA Impairment Scale
FES	functional electrical stimulation
ISNCSCI	International Standards for Neurological Classification of Spinal Cord Injury
LEMS	lower extremity motor score
QUICKI	Quantitative Insulin Sensitivity Check
RNL	Reintegration to Normal Living
SCI	Spinal cord injury
SCI-FAI	Spinal Cord Injury Functional Ambulation Index
SCIM-III	Spinal Cord Independence Measure, version III
TUG	timed Up and Go

Table 1 Sampling frame for participant recruitment*

Variable	Experimental	Control
Tetraplegia (C2–T1)		
LEMS≤25	8/9	7/7
LEMS>25	7/10	9/9
Paraplegia (T2–10)		
LEMS≤25	1/1	1/2
LEMS>25	4/6	4/4
	20/26	21/22

* Numerator denotes the number of participants completing pre- and posttest evaluations; denominator denotes the total number of participants enrolled in each cell.

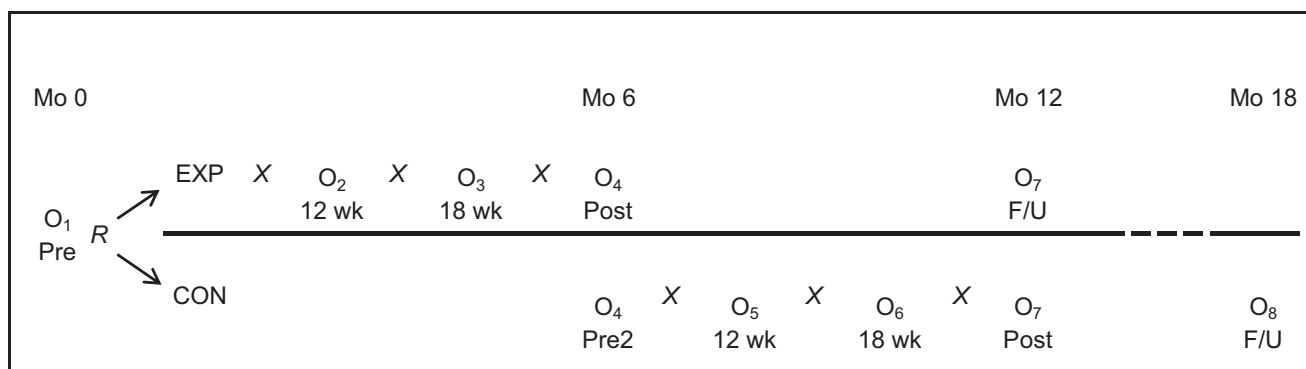


Fig 1 Graphical representation of delayed-treatment, control group design. Abbreviations: CON, control; EXP, experimental; F/U, follow-up.

consisted of 20 participants in the experimental group and 21 participants in the control group who completed pre- and posttest assessment for the experimental/control group comparison.

Design

A delayed-treatment design was used, wherein both experimental and control group subjects participated in the ABT intervention. **Figure 1** presents a graphic representation of the design. On conclusion of the enrollment visit (initial baseline assessment, O₁), each participant was randomly assigned to either the experimental group or the control group. Participants in the experimental group began the ABT program (X) within 2 weeks and continued for 24 weeks. Participants in the control group were asked to maintain their current level of activity and return in 24 weeks for a second round of assessments (posttest/second baseline, O₄, before the initiation of treatment). Participants in the control group subsequently completed the 24-week ABT intervention. Participants in both groups completed a final round of assessment (O₇/O₈) 6 months after the completion of the ABT intervention. To examine potential dose effects, interim assessments on all walking outcomes were completed 12 (O₂/O₅) and 18 (O₃/O₆) weeks after the initiation of the ABT intervention.

ABT intervention

Shepherd Center's Beyond Therapy program, the setting for the research, was established in 2005 in response to growing requests by former patients to participate in an activity-based exercise program after their traditional rehabilitation. Primary objectives of the Beyond Therapy program are to optimize functional recovery and decrease the likelihood of secondary complications.

Founded in principles of experimental psychology, exercise physiology, and neuroscience,^{14,16} the ABT interventions used in the Beyond Therapy program involve 3 elements: developmental sequence activities, progressive resistance training to build strength and endurance, and task-specific (locomotor) training. Developmental sequencing is focused on strengthening the primary stabilizing muscles of the trunk and pelvis because of their central role in core stability; this approach involves training in various positions thought to contribute to the attainment of upright function and walking. These include activities performed in quadruped (on all fours), kneeling, sitting, and standing positions.

The Beyond Therapy program is staffed by physical therapists and exercise specialists. A client entering the program is evaluated by a physical therapist who, in collaboration with an exercise

specialist, designs and implements an ABT program on the basis of the client's level of injury, neurologic impairment, and personal goals and preferences. Interventions may include robotic- or manually-assisted body-weight support locomotor training; FES-based synthesized gait restoration; active/passive, coordinated movement of all 4 extremities and the trunk; FES cycling; electrical stimulation to key muscle groups; core and extremity strengthening using weight training and resistance exercises; and aquatic therapy. Supplemental **Appendix S1** (available online only at <http://www.archives-pmr.org/>) provides information about a sample of exercises used in the trial.

Although each client receives individualized treatment, the program and subsequent progression is based on a treatment algorithm developed from current evidence, as well as clinical experience with more than 200 clients who participated in the Beyond Therapy program. Presented in **table 2**, the algorithm takes into consideration the client's functional status to prescribe an appropriate mix of developmental sequencing, resistance training, and locomotor training. Clients progress through the levels of treatment as they demonstrate functional improvement in walking ability.

The algorithm was used to standardize the intervention for the clinical trial. On the participant's functional status at baseline, the initial intervention "dose" was determined and the participant progressed through subsequent levels on the basis of improvement in functional status. Additional algorithms (presented in **figs 2 and 3**) were established to determine the progression of locomotor training and the use of FES to assist with stepping. Locomotor training was completed using the Therastride Body Weight Support System^a for manual-assisted and the Lokomat^b for robotic-assisted body-weight support locomotor training. In each case, subjects were suspended over a treadmill using a harness system with overhead support and body-weight support was provided using an adjustable winch system. The Therastride Body Weight Support System includes a treadmill platform and seat stations for trainers who manually facilitate (when required) appropriate stepping kinematics while subjects walk on a treadmill. Each treadmill session was followed by walking over ground. The NESS L300^c was used during manual-assisted locomotor training, with and without body-weight support, for participants for whom lower extremity FES was clinically indicated to facilitate stepping. Key muscles targeted using the NESS L300 included the tibialis anterior and peroneals. Where electrical stimulation of additional muscle groups was indicated during locomotor training sessions, FES was applied using self-adhesive gel electrodes^d and a trigger switch mechanism to stimulate gluteals, hamstrings, or quadriceps

Table 2 Clinical algorithm for client placement and prescription of treatment

Level	Client Functional Status	Developmental Sequencing (h)	Resistance Training (h)	LT
1	Motor incomplete with sparing of motor function >3 levels below the level of injury; unable to initiate 1 step w/o assistance	3	3	1h of OG training using FES; 2h of robotic LT
2	Able to initiate 1 step without assistance and walk <50ft (15.24m) with physical assistance	2	3	2h of robotic or manual LT; 2h of OG gait training with or w/o FES
3	Able to walk >50ft (15.24m) with 1-person assistance	2	2	2h of robotic or manual LT; 3h of OG gait training with or w/o FES
4	Able to walk >150ft (45.72m) without physical assistance	1	4 (emphasis on speed and agility)	2h of LT with or w/o body-weight support; 2h of OG gait training with or w/o FES

Abbreviations: LT, locomotor training; OG, over ground; w/o, without.

at the appropriate time during the gait cycle. Clinical indication for the use of FES was determined using a treatment algorithm (see fig 3) in which spasticity severity, independence with step initiation, and stance phase stability determined application in both treadmill and over-ground walking conditions.

The intended duration of treatment was 24 weeks, with up to three 3-hour training sessions per week. Thus, the maximum frequency of

treatment was 72 sessions over a 24-week span. The actual frequency of treatment averaged 49.9 ± 8.84 sessions, with a range of 24 to 74 sessions. The maximum possible time available for participation in treatment was 216 hours. However, this included the time needed to set up for exercise (eg, donning and doffing support harness for locomotor training and applying FES systems). The actual documented time engaged in treatment was 89.1 ± 22.1 hours and ranged

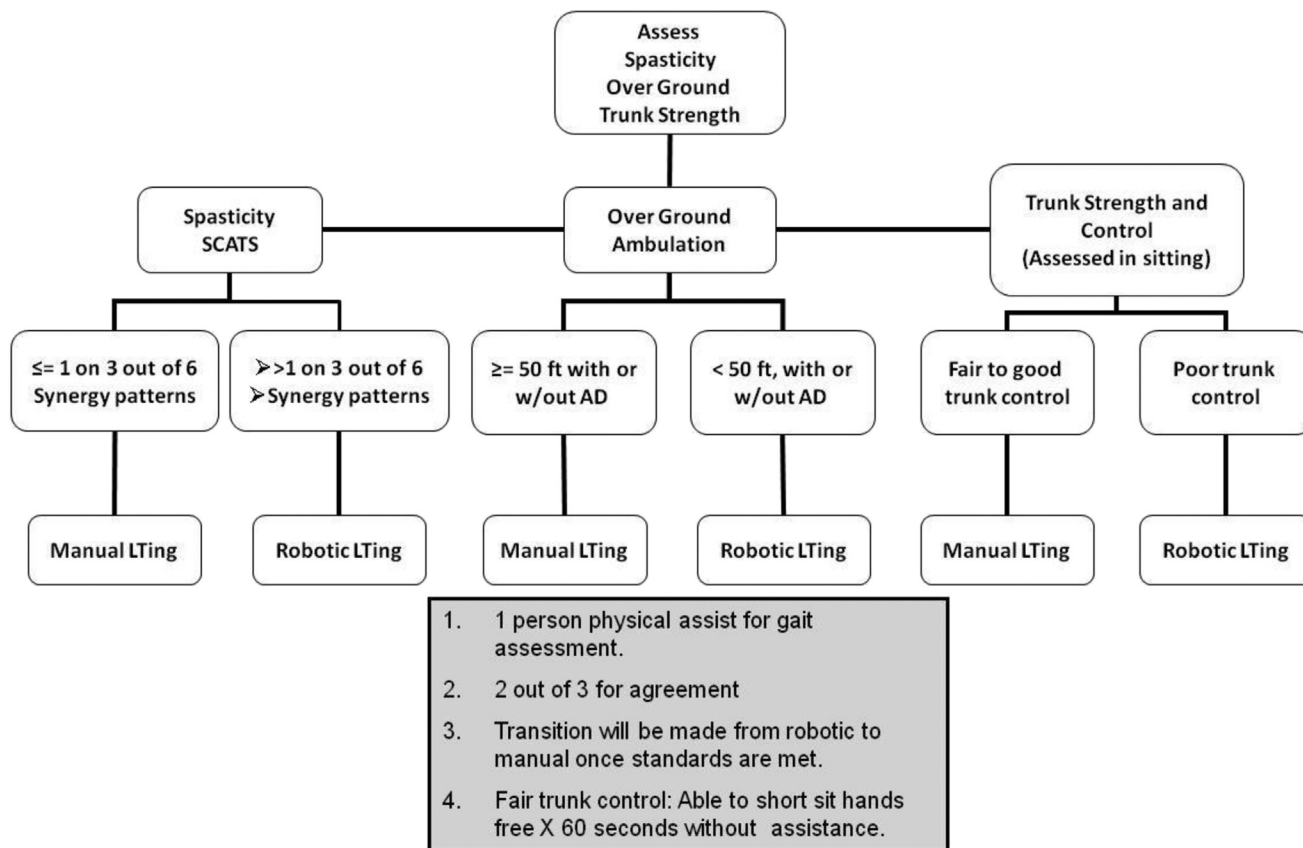


Fig 2 Training algorithm used to determine locomotor training progression. Abbreviations: AD, assistive device; LTing, locomotor training; SCATS, Spinal Cord Assessment Tool for Spasticity.

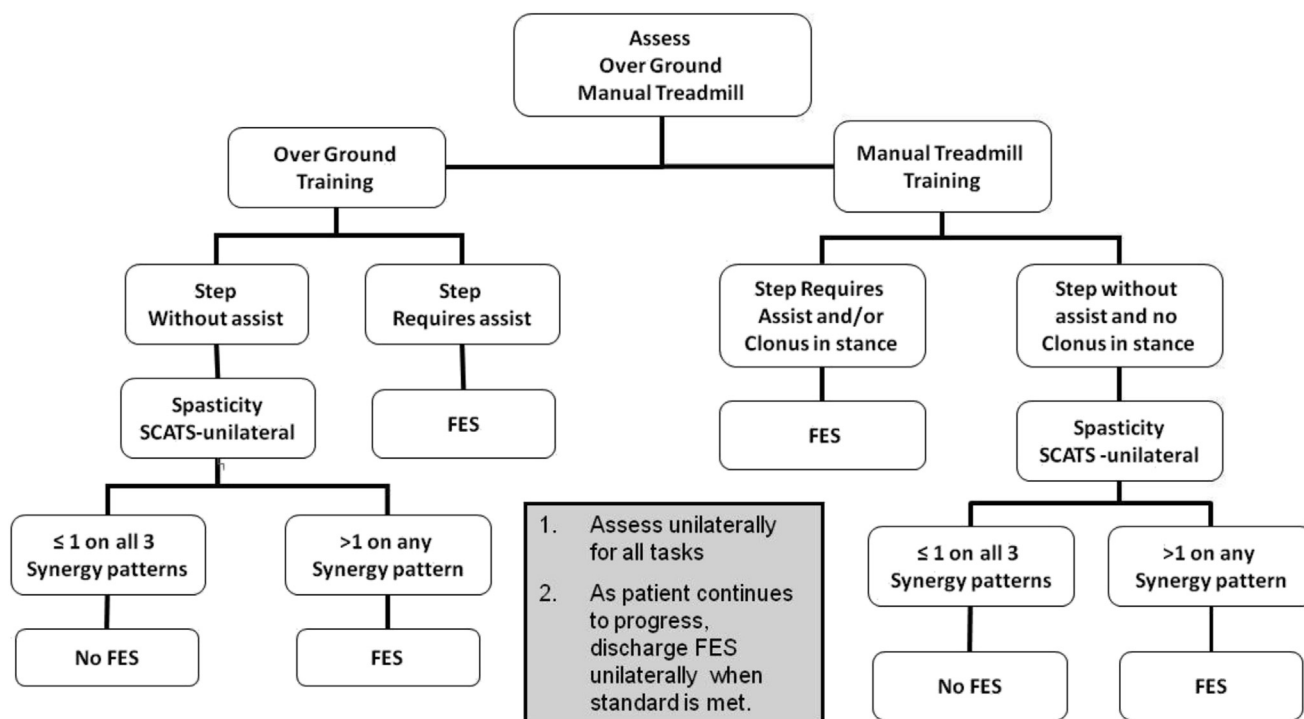


Fig 3 Training algorithm used to determine FES use and progression. Abbreviation: SCATS, Spinal Cord Assessment Tool for Spasticity.

from 21 to 150 hours. Participants spent an average of 48 ± 12.2 hours in locomotor training, 49 ± 15.9 hours in resistance training, and 41 ± 14.2 hours in endurance training.

In the course of completing the intervention phase, the therapy team designed an individualized maintenance program for each participant. The program was intended to maintain the gains achieved, using resources available to the participant for exercise and fitness training. If practical (given their home location, transportation, and assistance needs), the participant could join Shepherd Center's ProMotion fitness center—site of the Beyond Therapy program—and continue to access and use the facilities and equipment. Alternatively, staff consulted with fitness centers in clients' home communities to design a fitness program they could continue, with the resources available in their community. Home-based exercise was another option, using equipment and resources available in the home.

Measurement of outcomes

Details about the outcome measures used and data collection process are presented in supplemental [appendix S2](http://www.archives-pmr.org) (available online only at <http://www.archives-pmr.org>). The following dependent variables were assessed at each observational interval (O_1 – O_8 in [fig 1](#)): *neurologic* function was assessed using the ISNCSCI; walking was assessed using the 10-meter walk test (10MWT) and the 6-minute walk test; functional ambulation was assessed using the timed Up and Go (TUG)²⁷ test; components of the Spinal Cord Injury Functional Ambulation Index (SCI-FAI)²⁸ were used to account for changes in the use of assistive devices during walking and to assess qualitative aspects of gait; functional activity and community participation were assessed using the Spinal Cord Independence Measure,²⁹ version III (SCIM-III), and the Reintegration to Normal Living (RNL) Index³⁰; metabolic function was assessed by collecting lipid profiles and weight for participants at each assessment

interval. Lipid profiles were used to calculate the Quantitative Insulin Sensitivity Check (QUICKI).³¹

Data analysis

Independent-sample *t* tests were used to compare baseline characteristics of experimental and control groups. Analysis of covariance with Bonferroni correction for multiple outcome measures was used to examine between-group differences in posttest scores, using baseline scores as a covariate. All data analyses were performed using SPSS 14.0.^c Statistical significance was set at $P \leq .05$ for all statistical analyses. Values are presented as mean \pm SD, unless otherwise noted.

Results

Baseline characteristics

[Table 3](#) lists demographic and baseline information for participants in the experimental group and participants in the control group. The groups were comparable at baseline except for statistically significant differences noted for age, sex, and weight. On average, participants in the experimental group were 8 years older than participants in the control group. A greater proportion of men were randomized to the experimental group. Participants in the experimental group were, on average, 13.6kg heavier. This weight difference was not attributable to sex differences between groups.

Although participants were stratified on the level of injury, AIS grade, and LEMS, there were notable differences between groups in pretest performance on the 3 walking tests. Participants in the experimental group performed worse on all 3 walking tests at baseline, with a statistically significant difference noted for the TUG test ($P = .048$). There was also a notable difference between

Table 3 Demographic and baseline information*

Characteristic	Experimental (n=20)	Control (n=21)	P
Age (y)	42.20±13.03	34.14±12.03	.046 [†]
Sex	M=19/F=1	M=11/F=10	.002 [†]
Time postinjury (mo)	77.8±122.5	75.3±88.3	.939
Tetraparesis/paraparesis	15/5	16/5	.931
AIS classification	C=7/D=13	C=11/D=10	.274
ISNCSCI motor score	62.7±19.8	64.3±17.9	.789
ISNCSCI LEMS	24.8±13.4	28.1±11.6	.404
SCI-FAI	13.44±13.4	18.6±11.5	.294
10MWT speed (m/s)	0.227±0.304	0.363±0.411	.240
6MWT total distance (m)	73.11±92.57	117.6±132.8	.219
TUG test (s)	190.9±134.6	111.19±112.9	.048 [†]
SCIM-III	62.7±18.8	63.6±25.5	.891
RNL Index	78.3±18.0	80.0±17.1	.760
QUICKI	0.35±0.04	0.38±0.06	.071
Weight	197±44.79	167±46.35	.040 [†]
BMI	27.14±6.36	24.81±6.64	.260

NOTE. Values are mean ± SD.

Abbreviations: 6MWT, 6-minute walk test; BMI, body mass index F, female; M, male.

* P values derived from independent-sample t tests.

[†] P<0.05.

groups in the number of individuals who were unable to walk at the onset of treatment, with 9 randomized to the experimental group and 5 to the control group.

Differences between experimental and control groups

Table 4 presents pre-/posttest differences for experimental and control groups on each outcome measure, noting the mean and SD. P values are derived from analysis of covariance.

Neurological functioning

Significant improvements in neurologic function were noted for participants in the experimental group, as indicated by changes on

Table 4 Changes in primary outcome measures*

Outcome Measure	Experimental (n=20)	Control (n=21)	P
ISNCSCI motor score	5.1±6.3	0.9±5.0	.024 [†]
ISNCSCI LEMS	4.2±5.2	-0.6±4.2	.004 [†]
10MWT speed (m/s)	0.096±0.140	0.027±0.104	.036 [†]
6MWT total distance (m)	35.97±48.15	3.0±25.51	.002 [†]
TUG test (s)	-37.2±81.3	-6.2±18.1	.267
SCI-FAI	5.0±8.03	-0.21±2.83	.031 [†]
SCIM-III	1.35±5.2	0.0±4.53	.393
RNL Index	4.6±13.87	-2.0±10.01	.087
QUICKI	-0.002±.023	-0.012±0.045	.921
Weight	-0.20±8.29	5.03±14.05	.314
BMI	0.005±1.15	0.723±2.22	.288

NOTE. Values are mean ± SD.

Abbreviations: 6MWT, 6-minute walk test; ANCOVA, analysis of covariance; BMI, body mass index.

* P values derived from ANCOVA using baseline scores as a covariate.

[†] P<0.05.

the ISNCSCI total motor score and LEMS. Two participants in the experimental group and 2 participants in the control group converted from AIS grade C to D from pretest (O₁) to posttest (O₄) examinations. The magnitude of change in LEMS for those who changed classification was +3 and +8 for the 2 participants in the control group and +4 and +22 for the 2 participants in the experimental group converting from grade C to D.

Walking

Performance was substantially improved for participants in the experimental group versus participants in the control group on all 4 walking outcome measures. However, the differences in the TUG test elapsed time failed to achieve statistical significance. Although not significant, average time for completing the TUG test was substantially decreased for experimental (-37.2s) versus control group (-6.2s) participants. Significant improvements were also noted on the modified SCI-FAI for participants in the experimental group. Scores improved by an average of 5±8.03 points compared with no gain for participants in the control group, signifying improvements in gait parameters and less reliance on assistive devices as a result of the ABT intervention.

Functional activity, community participation, and metabolic health

The intervention had no immediate beneficial impact on functional activity and community participation, as judged by between-group differences on the SCIM-III and the RNL Index. However, participants in the experimental group posted modest gains on both measures. Similarly, no statistically reliable differences were noted on any measure of metabolic function.

Discussion

Statistically reliable differences were noted between experimental and control groups in measures of neurologic recovery (ISNCSCI total motor score and LEMS) and on 3 of the 4 measures of walking recovery. These findings are the first to verify the restorative benefits of comprehensive ABT on recovery of walking in people with chronic, motor-incomplete SCI in a randomized controlled trial.

Improvements in motor scores noted were comparable to those reported in other studies of ABT and locomotor training for individuals with SCI. For example, Harness et al²⁰ reported an average increase of 4.8 points in ISNCSCI total motor score and of 3.3 points in LEMS in a sample of 21 individuals with SCI who participated in 6 months of intensive activity-based therapeutic exercise. Participants in our experimental group evidenced an average increase of 5.1±6.3 in total motor scores and 4.2±5.2 in LEMS. Improved average gait speeds ranging from .05 to .09m/s have been reported after intensive locomotor training for individuals with chronic, motor-incomplete SCI.^{32,33} We noted an average improvement of .96m/s on the 10MWT among participants in the experimental group.

No significant changes were noted in functional activity (SCIM-III), community participation (RNL Index), or metabolic health (QUICKI and body mass index). Baseline scores on the SCIM-III were lower than previously published results for individuals with SCI 1 year postinjury.³⁴ Scores on the RNL Index at baseline for our participants were noticeably higher than published data for those with chronic SCI (mean ± SD of 79.1±17.4 vs 23.1±13.5)³⁵ but lower than normative data for survivors of stroke (84.3±14.4).³⁶ These comparisons suggest

that the lack of notable change is not likely due to ceiling effects in the instruments used.

With respect to the intervention effects on metabolic health, the limited impact may be due in part to the generally good health of participants at baseline. The average QUICKI value was $.37 \pm .05$ at baseline—well within the normal limits for healthy adults ($.35$ – $.45$)—and only 5 of 41 participants (12%) had values characteristic of diabetes. The average body mass index at baseline was $25.95 \pm 6.53 \text{ kg/m}^2$, and 42% of the participants had values in the overweight to obese range ($>25 \text{ kg/m}^2$). Although not trivial, this percentage compares favorably with the prevalence of obesity in the US population, as a whole, and among individuals with SCI.^{37–39}

Study limitations

A number of limitations of the study should be noted. First, we were limited in our sample size because of financial constraints posed by the trial. ABT is time and labor-intensive, and available funding for the trial was the primary driver of our intended sample size. Further complicating the small sample was a moderately high dropout rate (15%). But despite the small sample size, we were able to demonstrate statistically reliable differences between participants in the experimental group and participants in the control group on neurologic and walking recovery even with modest effect sizes.

A second limitation was the need to standardize therapy for purposes of the clinical trial. In practice, ABT modalities and intensities tend to be highly individualized on the basis of functional abilities and exercise limitations and preferences of the participant. This degree of individualization in a clinical trial would lead to virtually uninterpretable results, so we standardized therapy to the greatest extent possible, using the treatment algorithms and progression noted previously. Although this standardization may have limited the potential impact of ABT compared with its use in clinical practice, it did yield scientifically valid information about the effects of ABT more generally. Furthermore, the choice of interventions used in the trial was based primarily on clinical experience, and we tested only 1 potential algorithm for delivering ABT. The possibility remains that different interventions, or a different distribution of time spent on these various components, might yield different results.

Conclusions

This study demonstrates that intensive ABT has the potential to promote neurologic recovery and enhance walking ability in individuals with chronic, motor-incomplete SCI. In this trial, with the treatment dosage and patient population examined, no secondary health or quality-of-life benefit was evidenced from ABT. Considerable variability was also noted in response to therapy. Thus, further analysis is warranted to determine for whom ABT is most likely to lead to meaningful clinical improvement.

Suppliers

- a. Therastride (model no. BWTOIA100); Innoventor Engineering, 3600 Rider Trail South, St Louis, MO 63045.
- b. Lokomat (Software version 5.03a); Hocoma, Inc, 77 Accord Park Dr, Ste D-1, Norwell, MA 02061.
- c. Bioness, Inc, 25103 Rye Canyon Loop, Valencia, CA 91355.
- d. Restorative Therapies, Inc (RTI), 907 S Lakewood Ave, Baltimore, MD.
- e. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Keywords

Exercise therapy; Gait disorders, neurologic; Motor activity; Rehabilitation; Spinal cord injuries

Corresponding author

Michael L. Jones, PhD, FACRM, Shepherd Center, 2020 Peachtree Rd, NW, Atlanta, GA 30309. *E-mail address:* mike_jones@shepherd.org

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Supplemental Appendix S1. Sample Exercises for Trunk and Lower Extremity Resistance Training and Developmental Sequencing Activities*

Table 1 Trunk strengthening exercises noting the training device used, target muscle, and specific exercise selection for each training modality

Training Device	Rectus Abdominis	Internal/External Oblique	Erector Spinae
Total Gym (Power Tower)	<ul style="list-style-type: none"> Incline sit-up/abdominal crunch Medicine ball crunch pass Pullover w/trunk flexion Eccentric load trunk flexion 	<ul style="list-style-type: none"> Oblique sit-up/crunch Medicine ball side pass Crossover pullover w/trunk flexion Seated trunk rotation 	<ul style="list-style-type: none"> Not applicable
Tilt table	<ul style="list-style-type: none"> Incline sit-up/abdominal crunch Eccentric load trunk flexion Seated boxing drills 	<ul style="list-style-type: none"> Seated oblique boxing drills Reverse wood chop Medicine ball side pass 	<ul style="list-style-type: none"> Eccentric load trunk extension
Mat table	<ul style="list-style-type: none"> Sit-up/abdominal crunch Medicine ball crunch pass Cat stretch (quadruped) 	<ul style="list-style-type: none"> Side plank Oblique sit-up/abdominal crunch 	<ul style="list-style-type: none"> Prone trunk extension Long sitting trunk extension Supine bridge
Suspension training	<ul style="list-style-type: none"> Prone plank Reverse crunch Prone pike 	<ul style="list-style-type: none"> Lower extremity pendulum swing Side plank Kneeling oblique press-out 	<ul style="list-style-type: none"> Kneeling press-out Supine bridge
Standing (w/or w/out support)	<ul style="list-style-type: none"> Resisted trunk flexion Standing battling ropes 	<ul style="list-style-type: none"> Pelvic rotations Pelvic circles Lateral trunk flexion 	<ul style="list-style-type: none"> Standing trunk/hip extension Resisted trunk extension Standing battling ropes

Abbreviation: w/, with.

* Six to 8 exercises were selected for each training hour, with 3 to 5 sets of 8 to 15 repetitions completed per exercise.

Table 2 Lower extremity strengthening exercises

Training Device	Quadriceps Femoris	Biceps Femoris	Gluteal Muscles	Hip Flexor Group
Total Gym (Power Tower)	<ul style="list-style-type: none"> Squats (bi-/unilateral) Plyometric jumps (bi-/unilateral) 	<ul style="list-style-type: none"> Supine leg curl Straight leg raise 	<ul style="list-style-type: none"> Straight leg hip extension Squats (bi-/unilateral) 	<ul style="list-style-type: none"> Straight leg raise
Mat table	<ul style="list-style-type: none"> Short sitting knee extension 	<ul style="list-style-type: none"> Prone leg curl 	<ul style="list-style-type: none"> Supine bridge Kneeling hip extension Lateral Weight Shifts 	<ul style="list-style-type: none"> Supine hip flexion Kneeling hip flexion
Suspension training	<ul style="list-style-type: none"> Prone plank Supine leg extension 	<ul style="list-style-type: none"> Supine leg curl Supine bridge 	<ul style="list-style-type: none"> Supine bridge Kneeling hip extension 	<ul style="list-style-type: none"> Pike Reverse crunch Supine knee lift
Standing (stationary and dynamic)	<ul style="list-style-type: none"> Lunges Squats Plyometric jumps Step-ups 	<ul style="list-style-type: none"> Standing knee flexion Straight leg dead lift 	<ul style="list-style-type: none"> Lunges Backwards steps on knees Standing hip extension 	<ul style="list-style-type: none"> High knee drill Step-ups Walking on knees

Abbreviation: w/, with.

* Six to 8 exercises were selected for each training hour, with 3 to 5 sets of 8 to 15 repetitions completed per exercise.

Table 3 Developmental sequencing exercises

Training Position	Gluteal Muscles	Hip Flexor Group	Trunk
Quadruped	<ul style="list-style-type: none"> Lateral weight shifts Isolated kick back Pelvic stabilization 	<ul style="list-style-type: none"> Forward knee drive Quadruped crawling 	<ul style="list-style-type: none"> Cat stretch Anterior/posterior weight shifts Pelvic Stabilization
Full kneeling	<ul style="list-style-type: none"> Mini squat Isolated hip extension Lateral weight shifts Full kneel backward Walking 	<ul style="list-style-type: none"> Forward knee drive Full kneel forward Walking 	<ul style="list-style-type: none"> Trunk extension Lateral trunk flexion Trunk rotation
Half kneeling	<ul style="list-style-type: none"> Sit-backs 	<ul style="list-style-type: none"> Not applicable 	<ul style="list-style-type: none"> Pelvic circles Trunk rotation Medicine ball side toss

Abbreviation: w/, with.

* Six to 8 exercises were selected for each training hour, with 3 to 5 sets of 8 to 15 repetitions completed per exercise.

Supplemental Appendix S2. Measurement of Outcomes

Neurologic function was assessed using the ISNCSCI.¹ All examinations were performed by licensed physical therapists who were not involved in the study and blinded as to the subjects' participation in the study. All physical therapists at Shepherd Center are extensively trained in ISNCSCI evaluations and tested annually for reliability. To further ensure reliability of the motor score assessment, 2 physical therapists, both naive to the experimental or control group assignment of study participants, independently completed and scored the examination at each testing. Results were compared and agreement reached to determine a final examination score for each test. Initial reliability (agreement within 2 points on Total American Spinal Injury Association motor scores) between the 2 therapists averaged >75%.

Walking was assessed using the 10MWT and the 6-minute walk test. These timed walking tests have been shown to be valid, reliable, and sensitive measures of walking ability in individuals with incomplete SCI.² Two measures were calculated from each walking test. For the 10MWT, elapsed time (s) to complete the test and gait speed (m/s) were calculated. For the 6-minute walk test, total distance walked (m) and gait speed (m/s) were calculated. Gait speed was calculated for both tests because there is evidence to suggest that walking speed over an extended time period provides a more representative sample of functional walking ability.³

The TUG⁴ test was also used to assess functional ambulation. Both timed walking tests and the TUG test were completed by a physical therapist trained in the assessment protocol and blinded to participants' status in the study. Some participants were unable to walk or complete the TUG test at 1 or more observation intervals. For the 10MWT and the TUG test, a score of 300 seconds was assigned (instead of "0") if a participant was unable to complete the test within 5 minutes. This provided a basis for comparison in the event the participant was able to complete the test during a subsequent observation interval.

Components of the SCI-FAI⁵ were also used to account for changes in the use of assistive devices during walking and to assess qualitative aspects of gait. Video clips of participants taken during pre- and postwalking tests were simultaneously viewed and independently rated by 2 trained raters who were blinded to the timing of the video (pre- or posttest). The Gait Score (weight shift, step width, step rhythm, step height, foot contact, step length) and Assistive Devices (upper extremity balance/weight bearing; lower extremity orthosis) components of the SCI-FAI were used and scores summed for left and right sides for a maximum score of 34. Interrater reliability between 2 independent reviewers averaged >93%.

Functional Activity and Community Participation were assessed using SCIM-III⁶ and the RNL Index.⁷ Both measures were administered by the study coordinator during in-person or telephonic interviews with study participants.

The SCIM-III was used to determine any related functional changes in activities of daily living. The SCIM-III has been shown to be a more precise assessment than the FIM in individuals with SCI.⁸⁻¹⁰ The SCIM consists of 18 tasks, divided into 3 subscales of function: self-care, respiratory and sphincter management, and mobility. The RNL Index was developed to assess the degree to which individuals who have experienced traumatic illness or injury achieve reintegration into normal social activities (eg, recreation and leisure pursuits and mobility in the community). It comprises 11 declarative statements, with 8 addressing daily functioning and 3 representing "perception of self" (eg, "I feel that I can deal with life events as they happen"). Scores

range from 0 to 100, with a normative average score of 23.05±13.54 for individuals with chronic SCI.¹¹ Good to excellent reliability and validity among individuals with chronic spinal cord injury have been reported.¹²

Metabolic function was assessed by collecting lipid profiles and weight data for participants at each assessment interval. Lipid profiles were used to calculate the QUICKI.¹³ The QUICKI provides a reference measure of insulin resistance based on fasting glucose and fasting insulin levels. It has been shown to correlate highly ($r=.78$) with the criterion standard measure of insulin resistance, the glucose clamp study. A QUICKI index of .33 is generally considered the threshold for insulin resistance and an index above .38 is typical for healthy, nonobese adults.¹³ Weight and height were used to calculate the participant's body mass index at each interval.

Additional data were collected during each ABT session to document participation in therapeutic exercises (eg, duration or frequency of specific exercises completed). Finally, participants were asked to maintain an exercise diary, documenting their conformance with the recommended exercise regimen over the 6 months following the completion of the ABT intervention. The study coordinator contacted each participant (by phone or e-mail) on a titrated schedule (weekly to monthly) to prompt documentation of exercise compliance.

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