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ORIGINAL ARTICLE

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

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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 (≥12mo 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±0.14m/s vs 0.027±0.10m/s; $P=.036$) and 6-minute walk test total distance (35.97±48.2m vs 3.0±25.5m; $P=.002$).

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 neurorecovery 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 neurorestorative 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 al[20] 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 pregait 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.