

# The Effect of Aerobic Training on Rehabilitation Outcomes After Recent Severe Brain Injury: A Randomized Controlled Evaluation

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**ABSTRACT.** Bateman A, Culpan FJ, Pickering AD, Powell JH, Scott OM, Greenwood RJ. The effect of aerobic training on rehabilitation outcomes after recent severe brain injury: a randomized controlled evaluation. *Arch Phys Med Rehabil* 2001;82:174-82.

**Objective:** To examine the impact of fitness training with recently brain-injured inpatients on exercise capacity and functional and psychologic outcome measures.

**Design:** A randomized controlled trial of exercise versus relaxation training for 3 months. Blind assessments were conducted before and after the end of a 12-week training program, as well as at follow-up assessment 12 weeks posttraining.

**Setting:** Four regional neurologic inpatient rehabilitation units.

**Patients:** Of 157 patients recruited 24  $\pm$  14 weeks after single-incident brain injury, 142 patients were assessed at week 12, and 128 patients at follow-up.

**Interventions:** Patients were randomized between cycle ergometer aerobic training and a relaxation training control condition, which was theoretically inert with respect to cardiovascular fitness.

**Main Outcome Measures:** Validation of exercise training (peak work rate, peak heart rate, body mass index); mobility and physical function (modified Ashworth scale, Berg balance scale, Rivermead Mobility Index, 10-m walk velocity); disability and dependency (Barthel index, FIM™ instrument, Nottingham Extended Activities of Daily Living); and psychologic function (fatigue questionnaire, Hospital Anxiety and Depression Scale).

**Results:** Significant improvements in exercise capacity ( $p < .05$ ) in the exercise training group ( $n = 70$ ) relative to the control group ( $n = 72$ ) were not matched by greater improvements in functional independence, mobility, or psychologic function, at either 12 weeks or follow-up.

**Conclusions:** The benefits of improved cardiovascular fitness did not appear to extend to measurable change in function or psychologic state.

**Key Words:** Brain injuries; Disabled persons; Exercise; Nervous system diseases; Rehabilitation; Relaxation.

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**D**ISABILITY AFTER BRAIN INJURY results from the combined effect of neurologic damage and secondary problems that are potentially preventable or treatable. Some of the secondary problems result from immobility (eg, altered muscle function, reduced aerobic capacity). These secondary problems are likely to apply to patients with varying levels of severity of disability after discrete or diffuse brain injury.<sup>1</sup>

Regular aerobic exercise has been associated with various health benefits, including lower mortality rates, improved cardiorespiratory fitness, and enhanced psychologic well-being.<sup>2-4</sup> Conversely, with reduced aerobic stimulus, as occurs in normal individuals on prolonged bed rest, there is a measurable deterioration in fitness.<sup>5</sup> Loss of fitness also results from immobility caused by disease and chronic disability arising from various pathologies, including arthritis,<sup>6</sup> multiple sclerosis,<sup>7</sup> and stroke.<sup>8</sup> Furthermore, limited mobility (eg, resulting from hemiparesis), raises the metabolic cost of an activity.<sup>9</sup> The combined effect of reduced exercise capacity and increased metabolic cost of aerobic tasks, such as walking, makes these activities tiring.<sup>10</sup> These detraining effects are thought to affect ability to complete functional tasks and to participate fully in rehabilitation.<sup>11</sup>

A number of reports have shown impaired levels of exercise capacity in patients with neurologic disability resulting from brain injury. Hunter et al<sup>12</sup> found that 12 chronic brain-injured patients were able to achieve only 74% of age-predicted maximal oxygen uptake ( $\dot{V}O_2$ ) on treadmill testing. In another study of 14 patients with chronic brain injuries, Jankowski and Sullivan<sup>10</sup> reported a similar maximal  $\dot{V}O_2$  level, 67% of that predicted for normal subjects. They also reported a raised energy cost of walking, 161% of normal, calculated by comparing  $\dot{V}O_2$  of patients and controls while walking at submaximal speed.

Outcome measurements in existing training studies with brain-injured patients have focused predominantly on fitness impairment.<sup>8</sup> The standard measure of exercise capacity or cardiovascular fitness is expressed as the rate of oxygen uptake ( $\dot{V}O_2$ , mL/min). Typically, this has been estimated from readily available measures of heart rate and workload or distance traveled during a period of exercise.<sup>13,14</sup> Nonetheless, a few studies have measured  $\dot{V}O_2$  directly.<sup>10,12,15</sup> These studies have shown that aerobic training can successfully ameliorate fitness impairment in chronic brain-injured patients. Improvements in aerobic capacity after aerobic training have also been reported in other neurologically impaired patient populations.<sup>7,16,17</sup>

It is the gains in functional independence that may be achieved by participating in a rehabilitation program that are of key importance to patients, and to health care purchasers and providers. There have been suggestions, but little evidence, of a link between fitness and functional independence in the

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brain-injured population. For instance, among 8 chronic brain-injured patients who were employed in a protected workshop,<sup>10</sup> there was a significant correlation between peak  $\dot{V}O_2$  level and a ranking (by their supervisors) of worker productivity ( $r_s = .81$ ).

The relation of fitness to formal measures of activities of daily living (ADLs) and functional ability in brain-injured patients has not been established. In a randomized trial with 42 chronic stroke patients,<sup>15</sup> exercise capacity improved, but not Fugl-Meyer<sup>18</sup> measures of limb function and mobility. The issue has recently been further addressed in a pilot study of the effect of a home-based exercise training program on function in 20 recent stroke patients.<sup>1</sup> A mixed strength, balance, and endurance program was implemented with 10 of the patients for 3 1.5-hour sessions per week for 12 weeks. By the end of training, the 10 trained patients showed significant improvements, relative to the 10 untrained patients, in the Fugl-Meyer measures of lower limb motor function and in 10-meter walking speed. There were no significant changes in other functional and mobility measures, which included the Berg balance scale,<sup>19</sup> Barthel index,<sup>20</sup> and Lawton Instrumental Activities of Daily Living Scale.<sup>21</sup> Duncan et al<sup>1</sup> also found no improvement in fitness, measured indirectly by using a 6-minute walk test.<sup>22</sup> However, this may not be a sensitive measure of cardiovascular fitness in gait-impaired stroke patients.

These studies have failed to account satisfactorily for the effect of fitness training on mobility and functional independence early or late after brain injury. The studies with late brain-injured patients<sup>10,12</sup> showed improved fitness relative to a stable pretreatment baseline, but lacked standard measures of functional independence and a control patient group. Potempa et al<sup>8</sup> measured only mobility and not functional independence. With recent stroke patients, Duncan<sup>1</sup> measured functional independence, but did not directly measure fitness. All of these studies recruited relatively small sample sizes, and only Duncan<sup>1</sup> used blinded assessors. This is particularly important in controlling for assessment bias during exercise testing, so that, for instance, the extent of encouragement given to trained and untrained subjects is similar.

Studies of exercise capacity in brain-injured patients have been conducted on patients at least 6 months postinjury, with the exception of that by Duncan,<sup>1</sup> whose patients started training at approximately 9 weeks poststroke. To our knowledge, there has been no other investigation into the role of fitness training in patients early rather than late after brain injury. We set out to investigate the impact of aerobic training early in the rehabilitation process after severe brain injury, taking a representative and, therefore, heterogeneously causative sample of people engaged in an early inpatient rehabilitation program. We wanted first, to validate an aerobic exercise program in this population, and second, to explore whether this program, when added to typical inpatient rehabilitation programs, improved rehabilitation outcomes in the domains of mobility, functional independence, and psychologic status.

## METHODS

The study used prospective randomized controlled methodology to compare the efficacy of aerobic training in increasing cardiovascular fitness with a theoretically inert control, relaxation training, in recently brain-injured adult patients. Assessors were blinded to the training condition of all patients, and were not involved in their treatment. They measured exercise capacity, mobility, functional independence, fatigue, and aspects of psychologic state in exercised and control patients, before, during, and on completion of 12 weeks of training, and

3 months after completion of training that commenced during inpatient treatment.

## Subjects

Patients were recruited from consecutive admissions to 4 inpatient regional rehabilitation units for younger patients, aged 16 to 65, with complex disability. The units offered comparable programs that included physiotherapy, occupational therapy, speech therapy, neuropsychology, and other specialist services as required. In addition to group activities in each unit, each patient had a personal program to provide individual contact with therapists for approximately 15 hours per week.

Patients were recruited, after giving informed consent, if they had sustained a single-incident brain injury of any cause, usually traumatic or vascular; if they were able to comply with the planned interventions; and were able to sit on a cycle ergometer. Patients were not recruited if: it was anticipated that they would not remain as inpatients for most of the 3-month training period; their physical, cognitive, or behavioral impairments were sufficiently severe to prevent compliance with and participation in training; or they had known cardiac disease or other comorbidities (eg, unclipped aneurysms) precluding exercise training.

## Recruitment and Allocation

Patient recruitment commenced in June 1996. Informed consent was obtained from each patient if possible; otherwise, the assent of their guardians was sought. The responsible unit physician excluded occult cardiac disease. They were then randomly assigned to 1 of the 2 treatment groups; aerobic or relaxation training. Restricted randomization in blocks of 10 was used to ensure similar numbers in the training and control treatment conditions at each rehabilitation center; the allocations were made by using computer-generated random numbers. Numbered and sealed envelopes containing the treatment allocations were opened by the study physiotherapist at each center. In the explanation of the study to the patients, the potential benefits of exercise therapy and relaxation therapy were equally emphasized.

## Training Protocols

Four senior physiotherapists were recruited and specially trained to ensure delivery of similar training routines in each rehabilitation center. Both types of intervention were time-tabled to take place during 3 half-hour sessions per week over 12 weeks. Both treatment conditions were given on an individual basis. Patients participated in the intervention sessions over and above taking part in their individually designed multidisciplinary therapy programs. The target defining completion of training was set at 24 sessions over 8 weeks.<sup>3</sup> When possible, patients who were unexpectedly discharged home before completing training returned as outpatients to complete training.

Relaxation therapy was the control treatment. This intervention is theoretically inert with respect to cardiovascular fitness, but equivalent to the aerobic exercise program in terms of one-to-one contact with a therapist and in terms of face validity as a useful treatment after brain injury. An individualized program was designed by the study physiotherapists, within a general framework with supervision provided by the study clinical psychologist (JHP). The programs included breathing exercises, progressive muscle relaxation techniques, autogenic exercises, and visualization techniques.<sup>23</sup> The number of minutes patients engaged in relaxation exercise during each session

was recorded. The intervention was rationalized to patients as an opportunity to learn useful relaxation skills that could help with feelings of tiredness.

Aerobic training comprised up to half an hour of active resisted exercise on a cycle ergometer.<sup>a</sup> A Polar<sup>b</sup> chest strap was used to monitor heart rate during training. The patients were asked to maintain a steady cadence (~50 cycles/min). Work rate, cadence, and heart rate were recorded every 10 seconds for the duration of the training session and were displayed to provide visual feedback during training. Exercise time was increased as individually tolerated until the patients were able to cycle for 30 minutes. Work rate (in watts) was then adjusted to raise each individual's heart rate into a training zone: 60% to 80% of age-predicted maximum heart rate.<sup>3</sup> At the end of each session, the total number of minutes of exercise was recorded, as well as the number of minutes that the heart rate was below, within, and above the training zone. Feedback was given to patients to help motivate them to work toward specific fitness goals. This frequency, duration, and intensity of aerobic training is consistent with published guidelines that may be expected to improve exercise capacity among healthy adults.<sup>24</sup>

### Outcome Assessments

Measures of exercise capacity and body mass index (BMI), as well as the domains of mobility, functional independence, fatigue, and psychologic well-being were completed for each patient, at all 3 assessment points—week 0 (baseline), week 12 (end of training), and week 24 (follow-up). A fourth assessment point was also used, week 6, midway through the intervention, but for simplicity of presentation, those data are not reported here. There were 2 blinded assessors: 1 (FJC) undertook all the assessments at 3 of the rehabilitation centers; the other (AB) assessed patients at the base unit, and his assessments also included additional laboratory measures of muscle function and  $\dot{V}O_2$ , which will be reported elsewhere. To ensure that assessments were comparable between centers, the assessors undertook training together in the use of the measures, and established interrater reliability for all measures at the outset of the study ( $r = .94-.98$ ). Steps to ensure that the assessors remained blind to the training condition were consistent with recently published guidelines.<sup>25</sup> For instance, patients were not asked for information that might indirectly provide information about the training condition, and they were asked not to tell the assessors about their training.

**Validation of exercise training; exercise capacity.** A submaximal graded exercise test was performed by using a cycle ergometer<sup>a</sup> and Polar heart rate monitor.<sup>b</sup> After a 3-minute initial work rate of  $25 \pm 5W$ , work rate was increased by 10W every 2 minutes.<sup>3</sup> The test was discontinued when the patient was unable to continue, or had reached 80% of age-predicted maximum heart rate ( $210 - .65 \times \text{age}$ ).<sup>26,27</sup> Peak work and peak heart rates were recorded. Interrater reliability for the graded exercise test was assessed in 24 of our patients and found to be acceptable ( $r = .78$ ).

**Impact on rehabilitation outcomes: mobility and physical function.** Spasticity, impairment of motor function, and gait were measured by using the modified Ashworth scale,<sup>28</sup> the Berg balance scale,<sup>19</sup> and the Rivermead Mobility Index (RMI), respectively.<sup>29</sup> For those patients who were able to walk, walking velocity was calculated from a timed 10-meter walk indoors.<sup>30</sup> Nonwalking patients scored 0m/s.

The Ashworth scale is a rating of resistance to passive movement of a joint. Bohannon and Smith<sup>28</sup> have reported good interrater reliability (Kendall's  $\tau = .85$ ). The Berg balance scale has

been reported to be valid and to show high reliability in elderly and stroke patients for both test-retest and interrater assessments (intraclass correlation = .97 and .98, respectively).<sup>19</sup> Good interrater reliability (Spearman's  $\rho > .94$ ) and validity for the RMI was reported by Collen et al.<sup>30</sup> Interrater reliability for 10-meter walk times was assessed in 19 of our patients and found to be high ( $r = .98$ ).

**Impact on rehabilitation outcomes: disability and dependency.** Functional independence and disability were measured by the Barthel index,<sup>20</sup> FIM<sup>TM</sup> instrument,<sup>31</sup> and Nottingham Extended Activities of Daily Living Index (NEADLI).<sup>32</sup> The Barthel index is a scale that measures the patients' ability to perform 10 ADL tasks. It is recognized as easy to use and robust, but suffers from a low ceiling, limited sensitivity, and a narrow range of items.<sup>33</sup> Its reliability and validity in patients after stroke has been shown to be satisfactory.<sup>34,35</sup>

The FIM consists of 18 items rated on a 7-level ordinal scale. Smith et al<sup>36</sup> have reported team-based FIM scores to be reliable, and Ottenbacher et al<sup>37</sup> concluded that the FIM showed acceptable reliability across a wide range of settings, raters, and patient groups. However, it, too, is limited by ceiling effects once patients have returned to living in the community.<sup>38</sup>

Barthel index and FIM scores were routinely rated in some centers by the multidisciplinary teams; where ratings had been made within 10 days of a study assessment, these scores were used. Otherwise, the study assessor computed scores based on interviews with therapists, patients, and caregivers. The responses to individual FIM items were grouped to yield motor and cognitive scores (motor score, 13 items, max score = 91; cognitive score, 5 items, max score = 35).

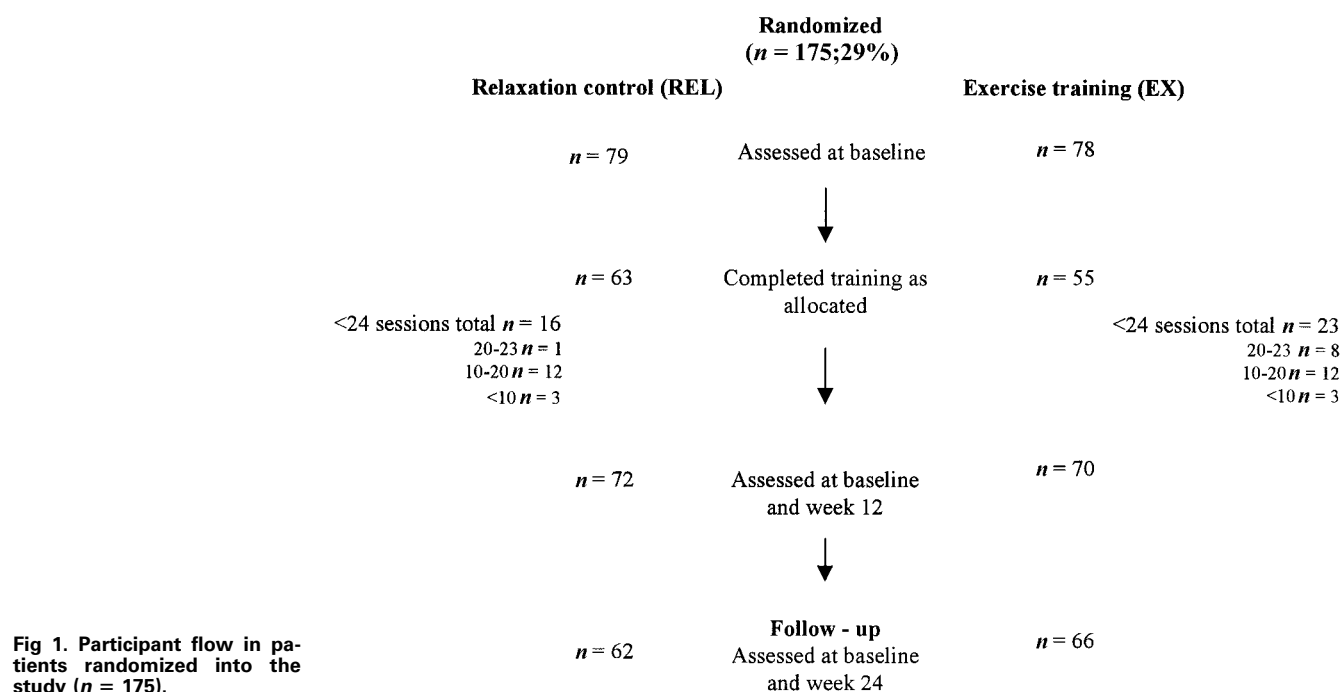
The NEADLI involves rating the patient's ability to perform more difficult functional tasks (eg, using public transport, performing housework, social activities). The NEADLI consists of 22 items, with a 4-level Likert scale; best possible performance scores 0, and the most impaired is indicated by a total score of 66. The patient completed the questionnaire with assistance from the assessor if needed. The NEADLI has been shown to be reliable after stroke.<sup>39</sup>

**Impact on rehabilitation outcomes: psychologic function.** When language skills permitted, patients' ratings of mental and physical aspects of fatigue were collected by using a modification of a fatigue scale developed by Chalder et al<sup>40</sup> and found to have reasonable reliability and validity in a sample of 274 people registered on a general practice list. There are 2 subscales, 6 items rating mental fatigue (max score = 18), and 8 items rating physical fatigue (max score = 24). Patients were asked to rate their sense of fatigue over the previous 7 days.

The Hospital Anxiety and Depression Scale (HADS)<sup>41</sup> was also administered as a well-established clinical instrument for assessing mood state. The anxiety and depression subscales both comprise 7 items relating to common symptoms that the patient rates for frequency or intensity over the previous 7 days. Maximum score on each scale is 21; scores of 10 or higher suggest mood disturbance of clinical severity. The HADS has been used in most medical settings; its good sensitivity, reliability, and validity have been reviewed recently.<sup>42</sup>

### Data Analysis

Unblinding took place when the training was completed in December 1998. Treatment allocation codes were added to the study database after the entry of outcome measure data had been completed.



We inspected the distributions for all data collected. There were minor departures from normality in some cases. The exception to this was the peak work rate variable that was grossly skewed, and this was addressed by logarithmic transformation. Given the known robustness of parametric methods (eg, analysis of variance [ANOVA]<sup>43</sup>) to such departures from normality, we proceeded with parametric statistics.

Independent sample *t* tests were used to compare the groups at baseline assessment. Within the full sample with data at baseline, Pearson's correlation coefficient was used to investigate relation between exercise capacity and functional capacity. Raw scores for all measures, except peak workload, which was subjected to a log transformation, were subjected to repeated-measures ANOVA with the between-subjects factor of Group (relaxation vs control) and the within-subject factor of Time (week 0, week 12, week 24). Because week 24 data were missing for some patients, the impact of treatment was evaluated in 2 separate ANOVAs. The first, which examined the short-term impact of training, compared baseline with week 12 and included data from all patients (ANOVA1). Second, for those subjects assessed on all 3 occasions (*n* = 128), we conducted ANOVA2 with 3 levels of Time, but using planned contrasts specifically for (1) baseline versus week 24, to determine whether changes from baseline to follow-up differed between the groups; and then (2) week 12 versus week 24, to examine patterns of change after the end of treatment. Results were analyzed on an intention-to-treat basis to avoid the potential confound of differential dropout from the 2 groups.

In this study the measurement of exercise capacity was used to validate the treatment given in the aerobic training (EX) group and was analyzed first. The other domains of outcome, mobility, functional independence, and psychologic state were the focus of this investigation. However, it was necessary to make some correction for the number of outcome indices measures. Therefore, the statistics reported on these measures for analysis of treatment effectiveness were adjusted by making a Bonferroni correction to maintain the type I error rate at 5%.

## RESULTS

### Patient Recruitment

The participant flow is shown in figure 1 and table 1. A total of 175 patients with acquired brain injury were randomly allocated to the exercise (EX, *n* = 90) or relaxation (REL, *n* = 85) training groups. This represented 29% of patients admitted to the 4 units during the period of recruitment. Because of unexpected early discharge or withdrawal from the study, 18 patients (6 REL, 12 EX) were excluded from analysis after recruitment and baseline assessments. The demographic details of the patients included in the analysis are shown in table 2; the control and treatment groups were comparable.

### Adherence to Training Protocol

Patients in each arm of the study attended a similar number of sessions (mean  $\pm$  standard deviation [SD]: REL, 23.8  $\pm$  5.95; EX, 23.5  $\pm$  5.95). These sessions were spread over similar periods (REL, 10.1  $\pm$  2.8wk; EX, 10.6  $\pm$  3.0wk).

A total of 39 patients (16 REL, 23 EX) did not meet the target of 24 exercise training sessions (fig 1). Reasons for early

**Table 1: Reasons for Nonrecruitment in Consecutive Admissions to 4 Rehabilitation Units June 1996-September 1998 (*n* = 600)**

	<i>n</i>
Not randomized	<i>n</i>
Medically unfit	101
Unable to cycle	97
Short stay	96
Had not sustained recent brain injury	104
Consent not obtained	12
Ceiling performance on all measures	10
Not known	4
Second injury	1
<b>Total</b>	<b>425</b>

Table 2: Demographic Details of Patients on Recruitment

	Control Group (REL) (n = 79)	Training Group (EX) (n = 78)	Difference
Age (yr) (mean ± SD)	44.7 ± 13.3	41.7 ± 14.3	NS*
Height (m) (mean ± SD)	1.72 ± 0.10	1.70 ± 0.10	NS*
Weight (kg) (mean ± SD)	71.4 ± 13.6	73.7 ± 15.5	NS*
Gender (women/men)	25/54	35/43	NS†
Cause of brain injury (n)			
Traumatic brain injury	22	22	
Stroke	32	38	
Subarachnoid hemorrhage	9	6	
Other†	16	12	
Time since injury at entry (wk) (mean ± SD)	25.5 ± 15.3	22.2 ± 12.4	NS*
IQR	15.0–32.7	13.3–27.1	
Barthel index at entry (mean ± SD)	13.5 ± 5.1	14.3 ± 4.1	NS*
IQR	10–19	11–18	

Abbreviations: NS, nonsignificant; IQR, interquartile range.

\* Independent samples *t* test.

† Chi-square test.

‡ Other causes: space occupying lesions (*n* = 12), viral infection (*n* = 7), hypoxia (*n* = 6), substance abuse (*n* = 2), surgery (*n* = 1).

termination included illness (1 EX), refusal (1 EX), withdrawal by patient's family (1 REL), and early discharge of patients who were unable to return to the unit for training after discharge (15 REL, 21 EX). There were no adverse reactions to training. Regarding the intention-to-treat analysis, 23 of 39 patients who did not complete the training were assessed at week 24 (ie, 9 REL and 7 EX patients were lost to the follow-up assessment [fig 1]).

The total time recorded for patients participating in the training routines was greater in the REL group (676 ± 180min), than in the EX group (552 ± 209min; *t* = 4.01, *df* = 155, *p* < .001). These total times reflect an average session duration of 28.4 ± 2.1 minutes for the REL group, and 23 ± 5.6 minutes for the EX group. This difference reflects the need to adopt progressive increases in training times for EX patients. As a result, during early training sessions, only 5 or 10 minutes of cycling was all that some of the weaker patients could manage. A similar progression of relaxation treatment occurred, however, longer initial treatment periods were tolerated.

Within the EX group, 9 patients were unable to exercise at an intensity sufficient to raise their heart rate to within or above the training zone. Five of them were receiving beta-blockers, which are known to reduce the heart rate response to exercise. The remaining 69 EX patients spent, on average, 56% ± 4% of the total training time within or above the heart rate training zone.

### Outcome Assessments

Every attempt was made to complete all assessments with each patient. However, this was not always possible because of factors such as patient fatigue, time constraints, or the absence of a caregiver or key worker when the patient returned for assessment as an outpatient after discharge from their rehabilitation unit. In the case of questionnaire data, language impairments sometimes led to an incomplete assessment.

At baseline assessment, there were no significant differences between EX and REL patients for any of the outcome measures. There were main effects of Time, on all measures other than HADS anxiety and depression scores, with patients in both groups showing significant improvements from baseline to week 12 and from baseline to week 24.

**Baseline exercise capacity, disability, and dependency.** At baseline assessment, across all patients, there were strongly

significant correlations between log peak work rate ( $\log_e$ ) and Barthel index scores ( $r = .61, p < .000, n = 146$ ), FIM motor ( $r = .54, p < .000, n = 130$ ), and NEADLI ( $r = -.61, p < .000, n = 138$ ). The critical questions, however, concerned the Group × Time interactions, where a significant effect would indicate relatively greater improvement in 1 group.

**Validation of exercise training: exercise capacity.** Peak work rate is shown in figure 2, and the  $\log_e$  (W) values are listed in table 3. The mean increase in peak work rate from baseline to week 12 was 25.8W for EX patients and 11.7W for REL patients. In ANOVA1 (baseline vs week 12), there was a significant Group × Time interaction, with EX patients showing a greater increase in peak work rates relative to REL patients ( $F_{1,136} = 5.3, p = .02$ ).

In ANOVA2, there was no Group × Time interaction for the baseline versus week 24 contrast for  $\log_e$ . However, as can be seen from the data in table 3 and figure 2, there was a significant interaction for the week 12 versus week 24 contrast. Increased peak work rates from week 12 to week 24 for REL patients contrasted with a slight decline for EX patients ( $F_{1,114} = 4.4, p = .04$ ).

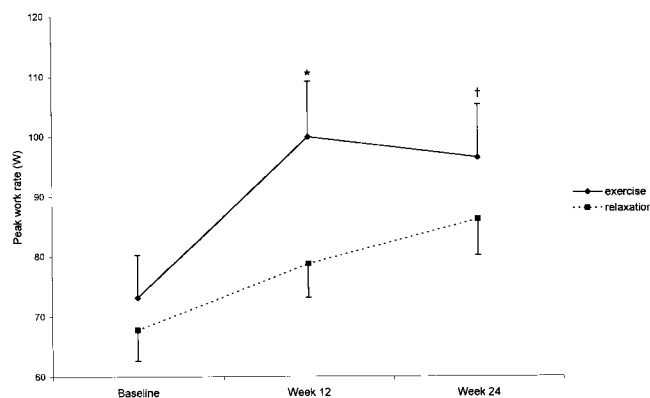


Fig 2. Peak work rate at baseline, week 12, and week 24. Values presented as mean ± standard error of mean. \* Baseline vs week 12 × Group, *p* < .05. † Week 12 vs week 24 × Group, *p* < .05.

**Table 3: Exercise Capacity, BMI, and Peak Heart Rate, Before and After Training**

Variable	Group	n	Participants Tested at Baseline and Week 12				Participants Tested at Baseline, Week 12, and Week 24					
			Baseline	Week 12	Baseline	Baseline vs Week 12 × Group	n	Baseline	Week 12	Week 24	Week 12 vs Week 24 × Group	Baseline vs Week 24 × Group
Log <sub>e</sub> (W)	EX	69	4.07 ± .56	4.37 ± .64	NS	*	57	4.11 ± .57	4.41 ± .67	4.38 ± .61	*	NS
	REL	69	4.06 ± .56	4.22 ± .57			59	4.06 ± .57	4.21 ± .58	4.29 ± .60		
BMI (kg/m <sup>2</sup> )	EX	64	25.6 ± 4.6	27.2 ± 4.2	NS	*	55	25.7 ± 4.6	27.3 ± 4.1	27.6 ± 4.3	NS	NS
	REL	63	24.4 ± 4.7	25.2 ± 5.1			54	24.6 ± 4.6	25.4 ± 5.0	25.8 ± 5.3		
Peak heart rate (bpm)	EX	64	136.1 ± 23.5	141.9 ± 24.4	NS	NS	57	134.2 ± 23.3	140.8 ± 24.9	143.4 ± 25.8	NS	NS
	REL	69	133.0 ± 25.7	136.6 ± 27.7			58	134.5 ± 26.5	136.3 ± 28.6	139.5 ± 30.1		

NOTE. Values presented as mean ± SD.  
Abbreviations: NS, nonsignificant; bpm, beats per minute.  
\* *p* < .05.

**Validation of exercise training: peak heart rate.** There were no significant interactions between Group × Time for peak heart rate in either ANOVA1 or ANOVA2.

**Validation of exercise training: BMI.** Mean BMI values by group at the 3 assessment points are shown in table 3. In ANOVA1, there was a significant Group × Time interaction, with EX patients showing a greater increase from baseline to week 12 in BMI compared with REL patients ( $F_{1,125} = 5.0, p = .03$ ). In ANOVA2, there were no Group × Time interactions for the baseline versus week 24, or week 12 versus week 24 contrasts for BMI.

**Rehabilitation outcomes: mobility and physical function.** For the physical performance measures (table 4), Berg balance scale, walk velocity, and RMI, there were no Group × Time interactions in ANOVA1 or in either of the contrasts in ANOVA2. There were trends for REL patients to improve more than EX patients on the Berg balance scale ( $F_{1,110} = 3.6, p = .06$ ) and RMI ( $F_{1,113} = 3.5, p = .07$ ) over the week 12 to week 24 contrasts.

At baseline, there were 6 patients (3 REL, 3 EX) with elbow flexor Ashworth scores greater than 2 of 5. Participation in exercise training was not found to be associated with increased spasticity: the same total number of EX (10) and REL (10) patients showed deterioration in Ashworth scores.

**Rehabilitation outcomes: disability and dependency.** Disability and dependence scores are shown in table 5. For the Barthel index, there was no Group × Time interaction in ANOVA1. In ANOVA2, there was no significant interaction for either planned contrast. Levels of disability, as measured by

the Barthel index, improved in parallel for both REL and EX patients (fig 3).

For FIM motor, total FIM, and NEADLI scores, there was no Group × Time interaction in ANOVA1. In ANOVA2, there were no interactions involving the baseline and week 24 contrasts, but trends toward significant interactions were found for the week 12 versus week 24 contrasts, with REL patients showing indications of greater improvement over the follow-up period (FIM motor: [ $F_{1,56} = 5.7, p = .02$ ]; total FIM: [ $F_{1,55} = 4.5, p = .04$ ]; NEADLI: [ $F_{1,100} = 5.2, p = .03$ ]). With the adjusted *p* values, these did not reach significance. There were no significant Group × Time interactions in either ANOVA for FIM cognitive scores.

**Rehabilitation outcomes: psychologic function.** The HADS and fatigue questionnaire scores had no significant Group × Time interactions in either ANOVA1 or ANOVA2 (table 6).

**DISCUSSION**

We recruited and assessed 157 recently brain-injured patients in this multicenter, randomized controlled trial of an aerobic training program. Training was completed as allocated with 118 patients (63 REL, 55 EX), and individuals unable to complete the training intervention were encouraged to complete the allocated assessments. Patient drop-out from the training program was mainly from early discharge home, and not adverse reaction to training.

Patients in both arms of the trial trained for an average of 10 weeks. We found that participation in each arm of the study was equally acceptable to the patients, as shown by a similar frequency of drop-out or noncompletion in the REL and EX

**Table 4: Mobility and Physical Function Before and After Training**

Variable	Group	n	Participants Tested at Baseline and Week 12				Participants Tested at Baseline, Week 12, and Week 24					
			Baseline	Week 12	Baseline	Baseline vs Week 12 × Group	n	Baseline	Week 12	Week 24	Week 12 vs Week 24 × Group	Baseline vs Week 24 × Group
Berg balance scale (max = 56)	EX	69	39.6 ± 16.6	46.5 ± 12.8	NS	NS	60	39.2 ± 16.8	46.2 ± 13.2	46.7 ± 13.2	.06	NS
	REL	71	37.7 ± 17.5	44.7 ± 14.1			61	37.8 ± 17.5	45.2 ± 13.9	47.3 ± 12.1		
Walk velocity (m/s)	EX	69	.65 ± .81	.97 ± .85	NS	NS	59	.65 ± .82	.97 ± .87	1.04 ± .74	NS	NS
	REL	70	.66 ± .77	.97 ± .82			59	.68 ± .77	1.00 ± .80	1.08 ± .79		
RMI (max = 15)	EX	67	8.2 ± 3.9	10.9 ± 3.6	NS	NS	58	8.1 ± 4.0	10.9 ± 3.6	11.1 ± 3.5	.07	NS
	REL	67	8.2 ± 4.4	10.6 ± 4.0			57	8.3 ± 4.6	10.8 ± 4.0	11.5 ± 3.6		

NOTE. Values presented as mean ± SD.  
\* *p* < .05.

Table 5: Disability and Dependency Before and After Training

Variable	Group	Participants Tested at Baseline and Week 12					Participants Tested at Baseline, Week 12, and Week 24					
		n	Baseline	Week 12	Baseline	Baseline vs Week 12 × Group	n	Baseline	Week 12	Week 24	Week 12 vs Week 24 × Group	Baseline vs Week 24 × Group
FIM motor (max = 91)	EX	44	65.7 ± 17.2	77.7 ± 14.7	NS	NS	28	64.1 ± 18.0	76.0 ± 17.4	76.6 ± 16.8	*	NS
	REL	47	62.9 ± 20.0	75.0 ± 15.1			30	60.8 ± 21.5	74.6 ± 16.1	80.5 ± 11.9		
FIM cognitive (max = 35)	EX	42	23.3 ± 7.2	27.5 ± 6.6	NS	NS	27	23.2 ± 7.1	28.0 ± 6.0	29.2 ± 6.0	NS	NS
	REL	46	23.4 ± 6.6	26.6 ± 6.4			30	22.7 ± 7.2	26.2 ± 7.3	28.5 ± 7.0		
Total FIM	EX	42	88.9 ± 20.4	105.6 ± 17.7	NS	NS	27	87.5 ± 20.0	104.8 ± 19.7	106.6 ± 19.7	*	NS
	REL	46	85.7 ± 21.9	101.4 ± 19.0			30	83.5 ± 24.4	101.0 ± 20.8	109.0 ± 16.9		
Barthel index	EX	63	14.2 ± 4.2	17.0 ± 3.5	NS	NS	52	13.9 ± 3.9	16.8 ± 3.6	17.3 ± 3.9	NS	NS
	REL	65	13.8 ± 5.0	17.3 ± 3.3			57	13.8 ± 5.1	17.2 ± 3.4	18.1 ± 3.2		
NEADLI†	EX	59	43.4 ± 17.0	32.1 ± 18.3	NS	NS	51	43.6 ± 17.2	32.2 ± 18.4	31.5 ± 16.8	*	NS
	REL	62	44.1 ± 16.0	32.5 ± 17.6			51	44.1 ± 16.8	33.1 ± 17.6	27.6 ± 17.8		

NOTE. Values presented as mean ± SD.

\*  $p < .05$ .

† For NEADLI, best possible score = 0; most impaired = 66.

training programs. Experienced physiotherapists giving one-to-one supervision of the patients were necessary to ensure that the patients adhered closely to the planned REL or EX program. The record of time in the heart rate training zone indicates that the EX patients achieved levels of exercise intensity as recommended by the American College of Sports Medicine for sedentary deconditioned individuals.<sup>3</sup> The exercise program was validated in this group of patients by the shown improvement in exercise capacity.

The mean baseline Barthel score of 14 of 20 for both groups indicated that the patients were moderately disabled at the baseline assessment. However, table 2 data reveal that there was a wide range in the levels of disability among the patients recruited to the trial. There were significant correlations between log<sub>e</sub> and disability and dependency scores at baseline (ie, low levels of functional ability were associated with low exercise capacity before training).

Participation in cycle training did not appear to increase the occurrence or severity of spasticity. We have reported here the change in Ashworth scores for elbow flexion. A similar pattern was noted for the other movements assessed but not reported in detail (ie, elbow extension, hip flexion, hip extension).

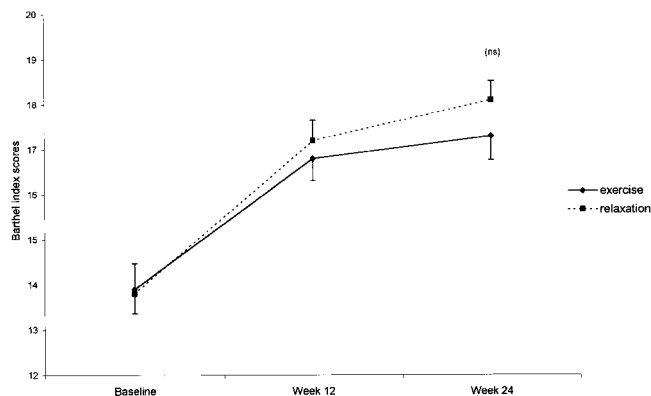


Fig 3. Barthel index at baseline, week 12, and week 24. Values presented as mean ± standard error of mean.

Although the EX patients showed greater improvement than REL patients in peak work rate from baseline to week 12, the groups did not differ in degree of change in functional independence of mobility over this interval. This finding of improved exercise capacity without an associated enhancement in functional abilities is consistent with previous studies of exercise training after chronic brain injury<sup>44</sup> and after early<sup>1</sup> and chronic stroke.<sup>15</sup>

The groups did not differ in degree of change in the psychologic measures (HADS, fatigue scale) as a result of EX training. HADS scores showed only a nonsignificant trend toward improvement over time, but it is noteworthy that patients rated their mood within normal limits on both occasions (ie, few patients were significantly anxious or depressed, and there was, thus, little scope for change in any event). We did note a significant correlation between the number of relaxation training sessions and improvement in anxiety by using the HADS questionnaire ( $r = -0.3$ ,  $p = .02$ ,  $n = 59$ ), indicating that the relaxation therapy achieved expected specific benefits. In contrast, the correlation between number of exercise sessions and change in anxiety was not significant ( $r = -0.1$ ,  $p = .4$ ,  $n = 55$ ).

Interestingly, after the end of treatment (week 12 vs week 24), REL patients made greater improvements than did EX patients in peak work rate, FIM, and NEADLI (tables 2, 4). Many patients in the study were discharged home during this period, suggesting that the comparative improvement in peak work rate shown by REL patients might have been the result of a training effect caused by the higher aerobic demands of living at home and not in a hospital. Substantial gains in peak work rate from baseline to week 12 were found in patients who received cycle ergometer training. These gains showed little decline at follow-up 3 months after training had ceased (fig 2). Improvement in peak work rate is thought to indicate increased leg strength, cardiovascular fitness, and cycling skill.<sup>8</sup> The changes in peak work rate during the follow-up period, improvement for REL patients, and plateaus for EX patients suggest that a functionally appropriate exercise capacity was achieved more quickly as a result of exercise training.

The significant increase in body mass might have resulted from increased muscle bulk or improved appetite as a result of

Table 6: Psychological Status Before and After Training

Variable	Group	Participants Tested at Baseline and Week 12					Participants Tested at Baseline, Week 12, and Week 24					
		n	Baseline	Week 12	Baseline	Baseline vs Week 12 × Group	n	Baseline	Week 12	Week 24	Week 12 vs Week 24 × Group	Baseline vs Week 24 × Group
HADS* anxiety	EX	55	5.6 ± 3.6	5.0 ± 3.9			49	5.9 ± 3.6	5.1 ± 4.0	4.5 ± 3.8		
	REL	59	6.1 ± 4.1	5.5 ± 3.5	NS	NS	49	6.2 ± 4.1	5.3 ± 3.4	4.2 ± 3.4	NS	NS
HADS* depression	EX	55	5.7 ± 4.2	5.5 ± 3.8			49	5.4 ± 4.1	5.4 ± 3.9	4.8 ± 4.1		
	REL	60	6.6 ± 3.9	5.8 ± 4.0	NS	NS	49	6.5 ± 3.8	5.9 ± 3.8	5.1 ± 3.7	NS	NS
Mental fatigue†	EX	54	5.7 ± 2.7	4.8 ± 3.0			48	5.6 ± 2.8	4.6 ± 3.0	4.6 ± 3.1		
	REL	55	5.3 ± 3.0	4.4 ± 2.6	NS	NS	46	5.4 ± 3.2	4.4 ± 2.4	4.1 ± 2.7	NS	NS
Physical fatigue†	EX	54	7.6 ± 3.9	7.1 ± 4.2			48	7.7 ± 3.6	7.1 ± 4.0	6.4 ± 4.5		
	REL	55	8.4 ± 4.2	7.4 ± 4.0	NS	NS	46	8.3 ± 4.2	7.2 ± 3.8	6.0 ± 3.1	NS	NS

NOTE. Values presented as mean ± SD.

\* Maximum score for HADS = 21; ≥10 suggest mood disturbance of clinical severity.

† Maximum score for fatigue scales: mental fatigue, max = 10; physical fatigue, max = 24.

exercise. Further research including anthropometric measures and records of food intake is needed.

It is possible that we might have missed a significant treatment effect in a subpopulation (eg, among the more severely disabled patients). To address this, further analyses divided the sample in various ways. To investigate the impact of pathology, we compared traumatic brain injury (TBI) versus non-TBI patients. The effect of severity disability was examined by categorizing patients according to walking ability and Barthel index scores at baseline. These analyses indicated no effects than even approached significance. Of course, when subdividing the sample in this way statistical power is reduced. These issues, therefore, remain open for further investigation in, for instance, a homogeneously causative sample, or a sample of patients with similar levels of initial disability.

The present data, especially in the context of the evidence from previous studies, suggest that there may be largely independent recovery curves for indices of exercise capacity and functional ability for patients recovering from recent brain injury. Two possible factors influencing these observations are discussed here, specificity of treatment and threshold values for functional performance.

First, with respect to specificity of effect, we found cycle training to have an impact specifically on cycling exercise tolerance. Wade<sup>45</sup> has argued that the emphasis on multidisciplinary teamwork in rehabilitation settings means that outcomes are unlikely to be influenced greatly by any single input. Here, fitness training did not enhance functional outcome when added to the complete rehabilitation programs provided by all 4 rehabilitation centers. Thus, measures of mobility, functional independence, and disability were found to improve equally in both the EX and REL groups. Change in functional independence must be understood either as a measure of response to total therapeutic input received by both groups of patients, or as a result of spontaneous recovery. The improvement in exercise capacity in the EX group is consistent with improvements that are expected in other groups as a result of an aerobic training program of this intensity.<sup>24</sup>

With respect to threshold effects for functional measures, it is clear from inspection of table 4 that both groups were scoring close to ceiling by week 12, and that both REL and EX groups moved in parallel from similar baseline levels. The additional gain in exercise capacity of the EX group did not provide additional benefit for dressing, getting in and out of a bath,

going up and down stairs, or other items measures by the Barthel index. It may be that there is a threshold level above which increasing fitness is not reflected by further improvements in functional independence. The fitness impairment we have observed in this sample of patients may be above this hypothetical threshold.

## CONCLUSION

The recovery of functional independence has been seen here to occur independently of aerobic training. We have shown that whereas cycle training can successfully accelerate improvements in physical fitness, it does not enhance gains in functional independence in patients with a wide range of impairments after brain injury who are participating in a rehabilitation program. However, given the known health benefits associated with improving exercise capacity,<sup>46</sup> this can be seen to be an appropriate performance goal for rehabilitation in and of itself. This may be a goal that is valid beyond the environment of the rehabilitation ward.

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#### Suppliers

- a. Model E450; Tunturi, Piispanristi, Finland.
- b. Polar Electro OY, Professorintie 5, fin-90440, Kempele, Finland.