J Rehabil Med 2009; 41: 247–255

ORIGINAL REPORT

EFFICACY OF A FITNESS CENTRE-BASED EXERCISE PROGRAMME COMPARED WITH A HOME-BASED EXERCISE PROGRAMME IN TRAUMATIC BRAIN INJURY: A RANDOMIZED CONTROLLED TRIAL

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Objective: **To compare the effects of a supervised fitness centre-based exercise programme with an unsupervised home-based exercise programme on cardiorespiratory fitness and psychosocial functioning in people with traumatic brain injury.**
Design: **Multi-centre, assessor-blinded, parallel group, randomized controlled trial.**
Participants: **Sixty-two participants with severe traumatic brain injuries, who could walk at a speed exceeding 1 m/sec, discharged from 3 brain injury units.**
Interventions: **The fitness centre group completed a combined fitness and strength training exercise programme supervised by a personal trainer in a local fitness centre 3 times per week for 12 weeks. The home group completed a similar exercise programme unsupervised at home.**
Main outcome measure: **Cardiorespiratory fitness measured using the modified 20-m shuttle test.**
Results: **Both groups improved in fitness: the maximal velocity achieved on the modified 20-m shuttle test increased with intervention and was maintained at follow-up. However, the difference between groups was not significant (mean between-group difference (95% confidence interval) 0 m/sec (–0.6 to 0.6) at the end of intervention). There were also no between-group differences in psychosocial functioning at the end of intervention or at follow-up.**
Conclusion*:* **Both interventions were equally effective at improving cardiorespiratory fitness in adults with traumatic brain injuries.**

Key words: brain injuries, exercise, physical therapy (specialty), rehabilitation, physical fitness.

J Rehabil Med 2009; 41: 247–255

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Submitted March 11, 2008; accepted October 8, 2008

INTRODUCTION

Cardiorespiratory deconditioning is a common secondary problem for people who have sustained a severe traumatic brain injury (TBI) (1, 2). Deconditioning is caused initially by prolonged bed rest and inactivity (3) and, in some instances, immobility from physical impairments (4), during an often extensive hospital admission. After discharge from hospital, the deconditioned state may persist due to psychosocial consequences of the TBI, such as lack of initiation (5) for physical activity and an altered mood state (6), which may reduce motivation for physical activity. In addition, barriers such as the environment (e.g. an uneven footpath) may also make physical activity more difficult (7).

Physical inactivity and the ensuing deconditioned physical state can be a serious consequence of TBI that impedes reintegration into previous vocational and leisure activities (8) and increases both the risk of secondary health conditions (e.g. coronary heart disease) and the economic burden of the injury (9). Effective prevention and treatment interventions are therefore crucial in reducing the impact of deconditioning on the outcomes of people with TBI.

Fitness training is an intervention that has the potential to reverse deconditioning. However, a recent Cochrane systematic review was not able to conclusively determine the effect of fitness training on deconditioning in people with TBI (10). The review incorporated 6 studies, 3 of which measured changes in cardiorespiratory fitness (11–13). The results were mixed, with one study showing a clear positive effect (12) and the other 2 studies showing no significant effect (11, 13). These conflicting results highlight the need for further studies to investigate the role of fitness training in reversing or preventing deconditioning after TBI.

Implementation of a fitness training programme at the time of inpatient discharge has not been investigated (10). This time-point is an important juncture in the rehabilitation process, with the transition from the supported hospital environment to reintegrating back into the community. It is also the time when the foundations for a sedentary lifestyle may be laid due to medical, physical and cognitive barriers preventing return to pre-injury activities. For this reason, a strong rationale exists for implementation of a fitness training programme to ensure adoption of a physically active lifestyle and to reverse deconditioning from the hospital admission.

 doi: 10.2340/16501977-0316 ISSN 1650-1977

The optimal way in which to structure a fitness training programme for people with TBI has also not been investigated. One commonly prescribed method is an unsupervised home-based exercise programme. However, adherence to this type of programme requires a high degree of motivation from the individual (14), which would indicate that it may not be suitable in the TBI population who commonly experience motivational difficulties (5). Furthermore, cognitive impairments (e.g. memory and executive dysfunction) may require an exercise programme with more external structure and organization (15). An alternative method which does provide increased structure is a supervised fitness centre-based exercise programme (16). The fitness centre promotes healthy living and regular physical activity (17), and is a motivating, supervised, non-disabled environment within which the individual may continue their recovery within their local community (16). This community-based environment may also positively affect other common problems experienced by people with TBI, such as depression (18) and poor community integration (19). Depression may be addressed by psychological mechanisms such as positive feedback from other people and social contact (18). Community integration may be improved by the person participating in a socially acceptable activity (i.e. attending a local fitness centre) regardless of their other deficits (8).

The primary aim of this study was to compare the effects of a supervised fitness centre-based exercise programme with an unsupervised home-based exercise programme on cardiorespiratory fitness in people with TBI, when first discharged home from inpatient rehabilitation. The secondary aim was to investigate whether a supervised fitness centre-based exercise programme was superior to an unsupervised home-based exercise programme in improving body composition and psychosocial functioning. Our hypothesis was that the fitness centre group would have better adherence and therefore better outcomes than the home group.

METHODS

Participants

Participants were recruited from consecutive inpatient admissions between October 2003 and September 2006 from 3 brain injury rehabilitation units in Sydney, Australia. All 3 units provide multidisciplinary rehabilitation programmes for people aged between 15 and 65 years who have sustained a TBI. Patients were invited to participate if they fulfilled the following eligibility criteria: (*i*) sustained at least a very severe TBI (measured by a post-traumatic amnesia period > 1 week assessed using either the Modified Oxford or Westmead Post Traumatic Amnesia Scales); (*ii*) inpatient hospital admission of > 1 month; (*iii*) able to walk independently at a speed ≥ 1 m/sec in a 10-m walk test; (*iv*) able to commit 3 h per week to an exercise programme on discharge; and (*v*) living within a reasonable travelling distance (not > 3 h) from 1 of the 3 units.

Patients were excluded from participating if the treating medical specialist and the site investigator clinically determined they had any: (*i*) concurrent medical condition for which moderate to high intensity exercise was contraindicated; (*ii*) cognitive or language impairments that would affect their ability to understand verbal instructions; and (*iii*) behavioural problems that would be inappropriate in a fitness centre environment.

Written informed consent was obtained from each participant. Ethical approval was obtained from the Sydney South West Area Health Service, Royal Rehabilitation Centre Sydney, Sydney West Area Health Service, and The University of Sydney Human Research Ethics Committees.

Recruitment and allocation

A block randomization schedule was prepared from a computer-generated list of random numbers by an investigator who was independent of the recruitment process. Sealed, sequentially numbered, opaque envelopes were prepared for each site incorporating stratification for recruitment site and injury severity; i.e. very severe (post-traumatic amnesia period of 1–4 weeks) and extremely severe (post-traumatic amnesia period of > 4 weeks). Patients who were screened by the site investigator as fulfilling the eligibility criteria were invited to participate by their treating physiotherapist. Once the participant gave informed consent and completed the baseline assessment (usually in the final week of their inpatient stay), the site investigator selected the next envelope to determine allocation to either the experimental group receiving a supervised fitness centre-based exercise programme, or to the control group receiving an independent home-based exercise programme.

Intervention

The exercise programme for both groups was based on guidelines set by the American College of Sports Medicine (ACSM) for people with a brain injury (4). Participants in the experimental group undertook the exercise programme at a fitness centre local to their home and were supervised by a personal trainer who was provided with written information about TBI, the study, and the intervention prior to the participant commencing. The trainers were re-contacted once the participant commenced to answer any queries regarding the prescribed intervention. The intervention involved the participant attending the fitness centre for 3 1-h sessions per week for 12 weeks. Each session included a 5-min warm-up; 20 min of strength training for 6 muscle groups (quadriceps, plantar flexors, abdominals, pectorals, triceps, back extensors) with a dosage for each muscle group of 2 sets of 15 repetitions or 3 sets of 10 repetitions (180 repetitions in total); 30 min of continuous cardiorespiratory fitness training set at a symptom-limited, moderate intensity such that they were breathing hard but able to talk; and a 5-min cool-down. The personal trainer determined how best to complete and progress the exercises; however, they were asked to use a walking or jogging exercise for at least one fitness session per week, due to the specificity of training (20) and our primary chosen outcome measure. They were asked to record the type and amount of exercise completed in each session in an exercise diary. The personal trainer in collaboration with the participant set 3-month goals relating to the intervention and 6-month goals relating to return to regular physical activity.

Participants in the active control group received usual care, i.e. they were prescribed an exercise programme before discharge from hospital by their treating physiotherapist. The programme was to be undertaken independently at home, with the training parameters prescribed as for the experimental group. The home-based exercise programme was designed specifically for this project to make it comparable to the fitness centre programme (although it represented "usual care"), and included photographs and written instructions. For each of the 6 muscle groups to be strengthened, 4–6 levels of progression were provided. The treating physiotherapist determined the initial level for each exercise at which the participant should commence, and demonstrated how to progress the exercise difficulty. Equipment (sandbags for weights; telephone books as steps) was provided as necessary to allow exercise progression. In line with current practice, no monitoring of adherence was carried out during the intervention phase; however, an exercise diary was provided to each participant to enable recording of the amount and type of exercise completed. Goal setting was conducted by the treating physiotherapist as for the experimental group. If participants in either group required ongoing physiotherapy for orthopaedic injuries or motor retraining, the treating physiotherapist was asked not to include any lower limb strengthening exercises or fitness training for the duration of the trial intervention phase.

Outcome measures

The primary (cardiorespiratory fitness) and secondary (body composition, psychosocial functioning, goal attainment, global perceived effect of treatment, and adverse events) outcomes were assessed at baseline, at completion of the intervention, and 3 months after the intervention ended. All assessors were trained in the administration of the outcome measures and were blinded to group allocation. In an effort to maintain the integrity of blinding, participants were reminded via written and verbal communication just prior to the assessment not to discuss their group allocation with the assessor. To assess blinding effectiveness, the assessor recorded instances of unblinding, and for blinded assessments guessed the participant group allocation. The majority of assessments were completed at the rehabilitation unit from which the participant was discharged; however, some were completed in the community if the participant was unable or unwilling to attend the unit.

The modified 20-m shuttle test (21), a valid (2) and highly reliable (21) assessment of fitness in an adult TBI population, was used to assess cardiorespiratory fitness. In this test the participant is required to walk or jog along a 20-m track between 3 markers each placed 10 m apart, keeping pace with an external audio recording (beep) that gets faster every minute. The test ends when the participant reaches volitional fatigue or is no longer able to keep pace with the test. The total distance in m and the maximal velocity attained (2) are recorded. Peak rating of perceived exertion using Borg's category ratio scale (22), and peak heart rate, were also measured.

The secondary outcomes were 3 assessments of body composition (body mass index (BMI), waist-to-hip-ratio (WHR), waist circumference), 4 measures of psychosocial functioning (Depression Anxiety Stress Scale (DASS), Profile of Mood States (POMS), Brain Injury Community Rehabilitation Outcome (BICRO-39), Sydney Psychosocial Reintegration Scale (SPRS)), and one measure of goal attainment, global perceived effect of treatment, and adverse events. The BMI is used as a screening tool to identify possible adiposity in adults (23). The WHR assesses truncal obesity (23). Waist circumference is used to assess cardiovascular risk (23). The same assessor took waist and hip measurements at standardized landmarks 3 times and the mean measurement was then recorded.

The DASS is a valid measure of the current symptoms of depression, anxiety, and stress (24). It comprises one subscale for each symptom, with a higher score indicating higher symptom levels. The POMS is a valid measure of mood in the domains of tension-anxiety, depression-dejection, anger-hostility, vigour-activity, fatigue-inertia, and confusion-bewilderment (25). The score for each item is converted to a *t*-score and subtotals are calculated for each domain. Except for the vigour-activity domain, a higher score denotes more mood problems. The BICRO-39 reliably assesses personal and social functioning problems experienced by people with brain injuries living in the community (26). It consists of 8 subscales, with a higher score indicating more problems with community reintegration. The SPRS validly and reliably quantifies activity limitation and participation restriction in people with TBI (27). The questionnaire uses 3 subscales to measure occupational activities, interpersonal relationships, and independent living skills. A higher score for each subscale and therefore also the total scale score, indicates better functioning.

End of intervention goals were rated as either achieved or not achieved by the personal trainer for the fitness centre group and by the site investigator for the home group. The 6-month goals were rated as either achieved or not achieved by the assessor at the end of the follow-up assessment. The site investigator, who was not blinded to group allocation, assessed the global perceived effect of treatment using a 5-point rating scale ranging from "completely recovered" to "worsened". They also assessed any adverse events via an open-ended question.

The fitness centre-based programme and the home-based programme were also examined both objectively and subjectively. Exercise diaries were analysed to determine adherence (where 100% adherence was defined as ≥ 36 sessions completed over the 12 weeks), mode of fitness training, frequency of exercise per week, average duration of fitness training, average number of repetitions of strength exercises, and progression of exercises. A questionnaire was administered during the end of intervention assessment by the site investigator to examine the perceived difficulty of the exercises and motivation issues.

Sample size

Twenty-five subjects were required for each group to provide an 80% chance of detecting a large effect for the primary outcome measure (0.8 standard deviation (SD) units) with alpha set at 0.05. To allow for drop-outs we planned to recruit 60 participants in total.

Statistical analysis

Data analysis was carried out using the computer software SPSS 14.0, and according to a pre-established analysis plan based on the CONSORT statement (28). Analysis was completed on an intention-to-treat basis. To deal with missing data, baseline missing data had the group mean value substituted, and end of intervention or follow-up missing data had the last known value carried forward. The exception to the intention-to-treat rule was for the measures that were introduced during the project (peak heart rate during the modified 20-m shuttle test, BMI, WHR, waist circumference), which were only reported for the sub-sample measured. Analysis of covariance (ANCOVA), with the baseline values entered as the covariate, was used to compare groups at the end of intervention and at follow-up for outcomes that were normally distributed (modified 20-m shuttle test, body composition, POMS). Analysis of variance (ANOVA) was used for change scores (29) for outcomes that were not normally distributed – follow-up minus baseline when a higher score denotes better outcomes (SPRS) and baseline minus follow-up when a higher score denotes worse outcomes (BICRO-39, DASS). Bonferroni adjustments were conducted for each set of outcomes to account for the large number of comparisons. Student's *t*-tests were used to compare groups for adherence to the training parameters (percentage of sessions completed) and goal attainment (percentage of goals achieved at 3 and 6 months). Categorical data collected from the end of intervention questionnaire was dichotomized and odds ratios (OR) or absolute risk reductions (ARR) were used to compare the 2 groups. The kappa statistic was used to assess the success of blinding. *Post-hoc* regression analysis was conducted to determine the effect of number of completed exercise sessions on changes in fitness from baseline to the end of intervention.

RESULTS

Participants

The flow of participants through the trial is presented in Fig. 1. Of the 523 patients that were screened during the 3 years of recruitment, 76% were ineligible, and half of the eligible patients consented and participated in the trial. The baseline characteristics of participants are shown in Table I.

Adherence to the trial protocol

Thirty-three personal trainers and 29 fitness centres were utilized for training participants in the fitness centre group. These participants had significantly better adherence to the prescribed exercise programme compared with the home group (mean (SD) percentage of completed sessions: 77 (25) vs 44 (42); mean difference (95% confidence interval (CI)) 34 (16–51); $p \leq 0.001$; $n = 62$). On average, the fitness centre group completed 2.4 (interquartile range (IQR) 1.8–2.9) sessions per week incorporating 28 min (IQR 25–30) of fitness training and 170 repetitions (IQR 147–201) of strength exercises. In contrast, the home group completed an average of 0.5 (IQR 0–3) sessions per week incorporating 15 min (IQR 0–31) of

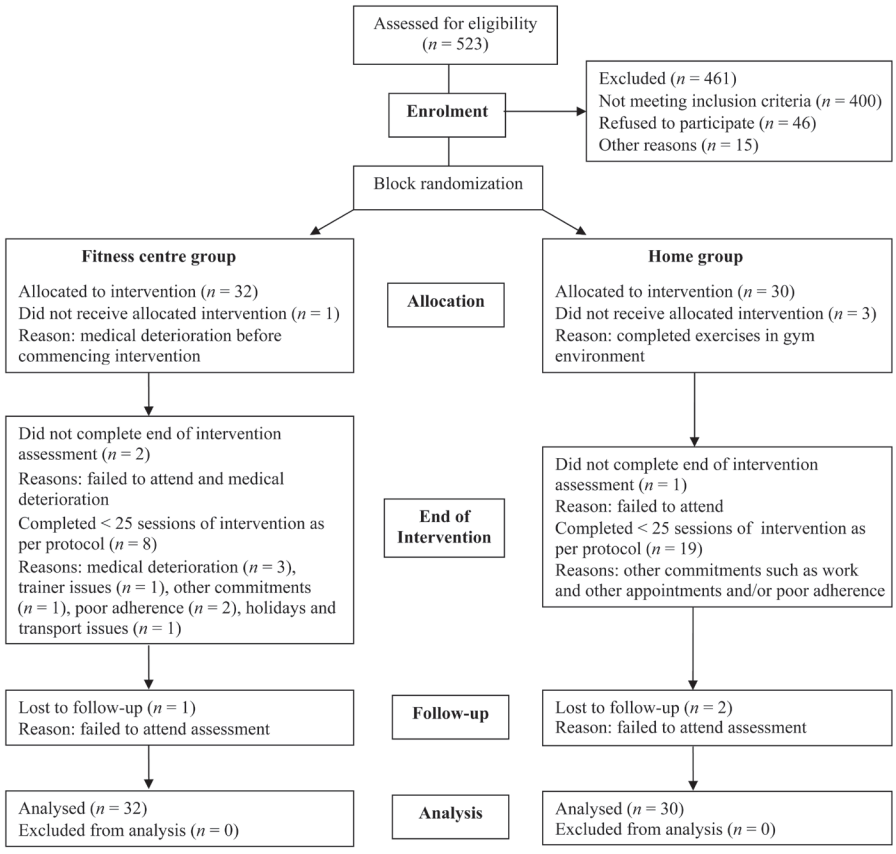

Fig. 1. Flow diagram of participants through the trial.

fitness training and 132 repetitions (IQR 0–175) of strength exercises. The primary mode of fitness training for both groups was walking or jogging exercise, completed either on the treadmill or outdoors. Fitness exercises were progressed in both groups by increasing the duration and/or speed; strength exercises were progressed by increasing weights, number or sets of repetitions, and for the fitness centre group also by changing from machines to free weights. There was no significant difference between groups regarding the perceived difficulty of the exercises (OR 2.7, 95% CI 0.5–15.3; $n = 57$). The fitness centre was more likely to be perceived as a very motivating or moderately motivating environment in which to exercise compared with the home environment (OR 4.1, 95% CI 1.3–12.3; $n = 57$).

Assessor unblinding occurred for 14 of the 62 participants. The primary reason for unblinding was the participant revealing their

Table I. *Baseline demographic data and injury characteristics for the fitness centre and home groups*

Variable	Fitness centre group ($n = 32$)	Home group ($n = 30$)
Sex, men/women, *n*	27/5	26/4
Mean (SD) age at entry to study, years	35.4 (14.6)	33.0 (11.8)
Median (IQR) time since injury at entry to study, months	2.6 (1.8–4.0)	2.3 (1.5–3.4)
Median (IQR) length posttraumatic amnesia, days	39 (24–56)	35 (24–49)*
Injury severity, very severe/extremely severe	9/23	11/19
Cause of injury, road traffic accidents/falls/acts of violence/other	17/8/4/3	13/8/8/1
Other injuries sustained, nerve/lower limb fractures/upper limb fractures	2/4/7	0/3/5
Referred to outpatient physiotherapy on discharge, yes/no	21/11	20/10
Pre-injury reported exercise frequency, ≥3 × per week/<3 × per week†	13/16	18/10
Marital status pre-injury, never married/married, de-facto/divorced/separated	17/12/2/1	17/12/1/0
Living with pre-injury, alone/parents or family/spouse/friends/other	3/13/14/2/0	3/11/12/3/1
Occupational status pre-injury, high skill/low skill/unemployed	14/15/3	19/10/1

*$n = 29$ as for one participant posttraumatic amnesia was determined to be >4 weeks, but the exact number of days was unknown.
†$n = 57$ as this information was collected as part of the end of intervention questionnaire and data were not available for 6 participants.
SD: standard deviation; IQR: interquartile range.

group allocation during the assessment. There was fair (30) agreement between the "guessed" group allocation and the actual group allocation for the 45 participants for whom the assessor did not become unblinded (Kappa statistic = 0.298; $p = 0.038$); suggesting that our attempts at assessor blinding were unsuccessful.

Primary and secondary outcomes

Both groups improved in fitness (i.e. increased distance and maximal velocity achieved on the modified 20-m shuttle test) at the end of intervention, and maintained this improvement at follow-up (Table II). There was no difference between the groups at the end of intervention or at follow-up (Table II), for example the mean between-group difference (95% CI) at end of intervention was 0 m/sec (–0.6 to 0.6). A clinically important difference is about 0.9 m/sec, which equates to one metabolic equivalent (MET) (2). Because the CI did not include this value, the between-group differences are unlikely to be clinically worthwhile. There was also no significant difference between groups for the other physical variables measured (Table II). On average 7 intervention goals (e.g. to be able to jog continuously for 20 min) and 2 follow-up goals (e.g. to return to soccer) were set for both groups (Table II). The fitness centre group was significantly more successful at achieving the intervention goals, but there was no significant difference between groups for achievement of the follow-up goals (Table II).

Depression, anxiety and stress were not clinically significant at entry to the study for either group, with the median score for each subscale of the DASS ranging between 1 (for depression) and 3 (for stress). There were no between-group differences in psychological functioning (Table III) or community reintegration (Table IV) at the end of intervention or at follow-up.

There was no significant difference between groups for the proportion of participants rating themselves as either "completely recovered" or "improved a lot" on the global perceived effect of treatment scale at the end of intervention (OR 2.0, 95% CI 0.7–6.4). Adverse events were reported significantly more in the fitness centre group than in the home group at the end of intervention (ARR –0.2, 95% CI –0.4 to 0.0). However, none of the 6 adverse events reported by the fitness centre group were serious cardiovascular events or musculoskeletal injuries

Table II. *Group data and between-group differences for primary and secondary physical outcomes and goal attainment*

		Fitness centre group		Home group		Mean between-group	
Variable	Time	*n*	Mean (SD)	*n*	Mean (SD)	difference (95% CI)*	*p*-value†
Primary physical outcomes							
Maximal velocity, m/sec	Baseline	32	6.8 (1.5)	30	7.6 (1.6)		
	End of intervention	32	7.8 (1.8)	30	8.5 (1.6)	0.0 (–0.6 to 0.6)	0.966
	Follow-up	32	7.9 (1.9)	30	8.7 (1.7)	–0.2 (–0.9 to 0.5)	0.542
Distance, m	Baseline	32	491 (199)	30	626 (272)		
	End of intervention	32	695 (358)	30	807 (365)	30 (–111 to 170)	0.675
	Follow-up	32	713 (374)	30	854 (398)	0 (–157 to 158)	0.995
Rate of perceived exertion, 0−10	Baseline	32	5 (2)	30	5 (2)		
	End of intervention	32	6 (2)	30	5 (2)	1 (0.1–2.0)	0.032
	Follow-up	32	6 (2)	30	5 (2)	0 (–0.6 to 1.3)	0.449
Peak heart rate, beats per min	Baseline	12	154 (27)	10	159 (25)		
	End of intervention	11	171 (10)	13	160 (25)	4 (–12 to 20)	0.63
	Follow-up	14	170 (12)	13	174 (20)	–4 (–19 to 12)	0.63
Percentage heart rate maximum, %	Baseline	12	82.6 (14.2)	10	87.4 (11.4)		
	End of intervention	11	92.1 (7.4)	13	88.1 (12.8)	1.9 (–8.1 to 11.9)	0.695
	Follow-up	14	89.9 (6.6)	13	95.2 (8.3)	–4.4 (–13.2 to 4.5)	0.303
Secondary physical outcomes							
BMI, kg/m^2	Baseline	15	24.0 (3.5)	12	22.3 (3.8)		
	End of intervention	15	23.9 (3.5)	13	23.4 (3.6)	–0.7 (–2.1 to 0.8)	0.347
	Follow-up	18	24.7 (3.8)	16	23.2 (3.6)	–0.4 (–2.1 to 1.4)	0.678
WHR	Baseline	14	0.87 (0.06)	12	0.86 (0.06)		
	End of intervention	15	0.88 (0.06)	12	0.90 (0.05)	–0.02 (–0.06 to 0.02)	0.286
	Follow-up	18	0.87 (0.06)	17	0.88 (0.05)	–0.02 (–0.05 to 0.01)	0.267
Waist circumference, cm	Baseline	14	83.5 (8.8)	12	81.1 (9.6)		
	End of intervention	15	83.6 (8.7)	12	82.4 (10.2)	0.17 (–3.1 to 3.5)	0.916
	Follow-up	18	84.3 (9.2)	17	81.1 (9.4)	0.84 (–3.0 to 4.7)	0.651
Total number of goals set	End of intervention	29	7.4 (1.2)	27	7.0 (1.5)	0.3 (–0.4 to 1.1)	0.351
	Follow-up	28	1.9 (0.8)	26	1.7 (0.6)	0.2 (–0.1 to 0.6)	0.207
Percentage of goals achieved	End of intervention	29	76 (31)	27	52 (31)	25 (8–41)	0.005
	Follow-up	28	68 (41)	26	73 (32)	–5 (–25 to 16)	0.650

*Data are ANCOVA-adjusted differences at end of intervention and follow-up (except for goals set and achieved). Positive between-group differences indicate that the fitness centre group is better than the home group for the primary outcomes and goals, but negative between-group differences indicate that the fitness centre group is better than the home group for body composition. $n = 10$–18 per group for peak heart rate, percentage heart rate maximum, and body composition as these measures were introduced during the study and are reported for a sub-set of participants only; goals are only reported for participants completing the end of intervention and follow-up assessments.
†Bonferroni adjustment of significance level was $p \leq 0.006$ for primary outcomes and $p \leq 0.005$ for secondary outcomes.
BMI: body mass index; WHR: waist to hip ratio; SD: standard deviation; 95% CI: 95% confidence interval.

Table III. *Group data and between-group differences for secondary outcomes of psychological functioning*

Variable	Time	Fitness centre group *n* = 32	Home group *n* = 30	Mean between-group difference (95% CI) *n* = 62*	*p*-value†
DASS depression subscale	Baseline	1 (0–5)	1 (0–2)		
(0−42)	End of intervention	5 (0–11)	1 (0–3)	–2 (–6 to 2)	0.238
	Follow-up	5 (0–12)	1 (0–6)	–1 (–5 to 3)	0.532
DASS anxiety subscale	Baseline	2 (1–5)	2 (0–4)		
(0−42)	End of intervention	2 (1–8)	1 (0–3)	–1 (–3 to 0)	0.132
	Follow-up	3 (0–7)	1 (0–4)	–1 (–3 to 2)	0.624
DASS stress subscale	Baseline	3 (1–6)	3 (0–6)		
(0−42)	End of intervention	4 (1–11)	2 (1–8)	–2 (–5 to 1)	0.131
	Follow-up	7 (1–14)	6 (1–10)	–2 (–5 to 2)	0.331
POMS vigour domain	Baseline	58 (10)	60 (7)		
(33−80)	End of intervention	56 (8)	61 (10)	–4 (–8 to 0)	0.059
	Follow-up	56 (8)	59 (10)	–3 (–7 to 2)	0.241
POMS tension-anxiety	Baseline	37 (6)	36 (4)		
domain (30−70)	End of intervention	38 (6)	37 (6)	1 (–2 to 4)	0.617
	Follow-up	38 (5)	37 (5)	1 (–2 to 3)	0.627
POMS depression-dejection	Baseline	40 (6)	39 (5)		
domain (32−75)	End of intervention	41 (7)	39 (7)	2 (–2 to 5)	0.334
	Follow-up	41 (6)	40 (6)	1 (–2 to 4)	0.579
POMS anger-hostility domain	Baseline	44 (6)	43 (6)		
(37−80)	End of intervention	47 (10)	43 (7)	2 (–2 to 7)	0.255
	Follow-up	46 (9)	44 (6)	2 (–2 to 6)	0.407
POMS fatigue domain	Baseline	46 (6)	44 (5)		
(34−74)	End of intervention	47 (7)	43 (6)	3 (–0 to 6)	0.070
	Follow-up	46 (8)	43 (5)	2 (–1 to 6)	0.178
POMS confusion-bewilderment	Baseline	40 (5)	41 (7)		
domain (30−70)	End of intervention	45 (6)	41 (6)	4 (1–7)	0.007
	Follow-up	45 (7)	42 (8)	3 (–1 to 6)	0.167

Group values are median (interquartile range) for Depression Anxiety Stress Scale (DASS) and mean (standard deviation) for Profile of Mood States (POMS). POMS values are *t*-scores converted from raw scores.

*Data are change scores (baseline minus end of intervention and baseline minus follow-up) for DASS, and ANCOVA-adjusted difference at end of intervention and follow-up for POMS. Positive between-group differences indicate that the fitness centre group has better psychological functioning than the home group for the DASS and POMS vigour domain, but negative between-group differences indicate that the fitness centre group has better psychological functioning than the home group for the other 5 domains of the POMS.

†Bonferroni adjustment of significance level was $p < 0.003$.

95% CI: 95% confidence interval; ANCOVA: analysis of covariance.

(3 participants reported musculoskeletal pains, one reported occasional blurred vision after a session, one reported restriction on social outings with friends, and one reported feelings of depression because of poor physical state and being unable to fund ongoing fitness centre membership).

Post-hoc analysis

A *post-hoc* analysis was conducted to explore if adherence with the exercise programme affected improvements in fitness from baseline to end of intervention, regardless of group allocation. The number of completed exercise sessions did not significantly affect improvements in fitness (i.e. modified 20-m shuttle test performance) ($r^2 = 0.04$; $p = 0.3$; Fig. 2).

DISCUSSION

The main finding of this pragmatic trial was that an unsupervised home-based exercise programme was as effective as a supervised fitness centre-based exercise programme at improving cardiorespiratory fitness in adults with TBI who were recently discharged from inpatient rehabilitation. In the modified 20-m shuttle test, participants in both groups increased the maximal velocity by an average of 1 m/sec. Using a predictive equation developed for the modified 20-m shuttle test (2), this equates

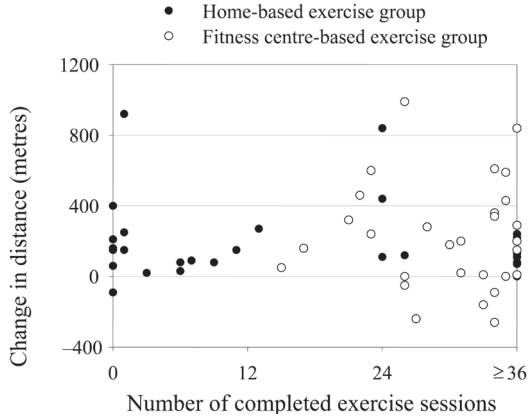

Fig. 2. Effect of number of completed exercise sessions on change in fitness (as measured by improvement in distance achieved on modified 20-m shuttle test). Note: some dots overlay each other, they represent more than one participant.

Table IV. *Group data and between-group differences for secondary outcomes of community reintegration*

Variable	Time	Fitness centre group $n=32$ median (IQR)	Home group $n=25330$ median (IQR)	Mean between-group difference (95% CI) $n=62$*	p-value†
BICRO-39 personal care sub-score (0−30)	Baseline	0 (0–0)	0 (0–0)		
	End of intervention	0 (0–0)	0 (0–0)	0 (–1 to 0)	0.491
	Follow-up	0 (0–0)	0 (0–0)	0 (–1 to 1)	0.704
BICRO-39 mobility sub-score (0−30)	Baseline	7 (0–11)	4 (0–15)		
	End of intervention	4 (0–10)	0 (0–2)	–3 (–7 to 1)	0.159
	Follow-up	1 (0–6)	0 (0–2)	–2 (–6 to 2)	0.380
BICRO-39 self organization sub-score (0−30)	Baseline	6 (2–15)	7 (2–12)		
	End of intervention	7 (2–12)	3 (0–7)	–2 (–5 to 0)	0.101
	Follow-up	3 (0–10)	1 (0–5)	–1 (–4 to 3)	0.615
BICRO-39 contact with partner subscale (0−10)	Baseline	6 (2–10)	6 (2–10)		
	End of intervention	6 (0–10)	6 (1–10)	0 (–1 to 1)	0.593
	Follow-up	6 (0–10)	6 (0–10)	–1 (–2 to 1)	0.385
BICRO-39 contact with parents subscale (0−15)	Baseline	6 (2–11)	6 (2–9)		
	End of intervention	7 (1–11)	5 (1–8)	0 (–2 to 1)	0.763
	Follow-up	5 (0–12)	7 (1–10)	0 (–2 to 2)	0.875
BICRO-39 socializing subscale (0−30)	Baseline	14 (11–18)	12 (8–16)		
	End of intervention	14 (9–19)	14 (11–19)	2 (–1 to 5)	0.120
	Follow-up	17 (12–21)	16 (13–19)	1 (–2 to 4)	0.465
BICRO-39 productive employment subscale (0−20)	Baseline	20 (17–20)	20 (17–20)		
	End of intervention	17 (16–18)	16 (15–19)	–1 (–3 to 1)	0.315
	Follow-up	16 (15–20)	15 (14–17)	–1 (–3 to 1)	0.163
BICRO-39 psychological subscale (0−30)	Baseline	7 (5–10)	7 (4–11)		
	End of intervention	10 (6–13)	7 (4–11)	–2 (–5 to 1)	0.136
	Follow-up	9 (6–11)	7 (3–12)	–2 (–4 to 1)	0.224
SPRS work and leisure subscale (0−24)	Baseline	14 (11–16)	14 (10–18)		
	End of intervention	14 (9–17)	14 (10–19)	–1 (–4 to 2)	0.376
	Follow-up	13 (8–20)	15 (11–20)	–3 (–7 to 1)	0.138
SPRS relationships subscale (0−24)	Baseline	22 (20–24)	22 (20–24)		
	End of intervention	20 (16–23)	22 (19–24)	–2 (–4 to 0)	0.073
	Follow-up	19 (14–22)	21 (18–23)	–2 (–4 to 1)	0.182
SPRS living skills subscale (0−24)	Baseline	21 (19–22)	22 (19–22)		
	End of intervention	20 (16–23)	22 (20–24)	–2 (–4 to –1)	0.009
	Follow-up	21 (17–23)	22 (20–24)	–1 (–3 to 2)	0.697
SPRS total score (0−72)	Baseline	59 (53–61)	57 (48–64)		
	End of intervention	51 (43–61)	56 (51–62)	–6 (–11 to –1)	0.033
	Follow-up	52 (42–63)	59 (47–66)	–5 (–13 to 3)	0.190

*Data are change scores (baseline minus end of intervention and baseline minus follow-up for the BICRO-39, and end of intervention minus baseline and follow-up minus baseline for SPRS). Positive between-group differences indicate that the fitness centre group has better reintegration than the home group.

†Bonferroni adjustment of significance level was $p \leq 0.002$.

BICRO-39: Brain Injury Community Reintegration Outcome; SPRS: Sydney Psychosocial Reintegration Scale; IQR: interquartile range; 95% CI: 95% confidence interval.

to an average increase of 14% in peak aerobic capacity (29 ml/kg/min at baseline to 33 ml/kg/min after intervention) and an improvement in fitness ranking (from below the 10th percentile for age at baseline to between the 10th and 20th percentile after intervention) (31). These improvements were maintained at follow-up, but there were no between-group differences at the end of intervention or the end of follow-up.

Our results were consistent with the re-analysis (10) of the "TBI only" data from Bateman et al. (11), but inconsistent with the training effects reported by Driver et al. (12). Re-analysis of the Bateman et al. data, an inpatient study of early TBI survivors who participated in a fitness programme on a cycle ergometer (30 min/session, 3 sessions/week, for 12 weeks) compared with a non-active control group (relaxation training) revealed no between-group differences in fitness: mean 21 watts (95% CI –12.3 to 55.3) (10). In contrast, in a community-based study of long-term TBI survivors who participated in an aquatic exercise group (60 min/session, 3 sessions/week, for 8 weeks) compared with a non-active control group (vocational training) (12), a significant between-group difference in fitness was found (59 watts, 95% CI 23.8–94.3) (10). Factors that may account for these between-trial differences in effect size include the different time periods post-injury when the interventions were implemented, the duration of each exercise session, and the Driver et al. (12) control group not participating in any physically active rehabilitation.

This trial was not able to compare a fitness training programme with a non-active intervention as it was current practice at the 3 recruiting units to prescribe an exercise programme on discharge from inpatient rehabilitation. Both interventions were

based upon the ACSM guidelines for people who sustain a brain injury (4), with the distinction between groups being the environment and the level of supervision. It was hypothesized that the home group would act as a control group because adherence was expected to be poor due to these 2 differences. For the most part, this assumption was correct with only one-third of the home group completing ≥ 25 sessions. There was, however, a small sub-group within the home group who exceeded the requirements of the prescribed programme by exercising more frequently and for a longer duration (e.g. one participant had a total walking time of 100 h over the 12 weeks, 82 h more than prescribed). This sub-group's results may have reduced the between-group difference and implies that an unsupervised home programme may be suitable for a sub-group of people with TBI. Predictive factors for adherence to this commonly prescribed programme will be explored in a separate paper.

Regardless of group allocation, *post-hoc* analysis revealed no effect of the number of exercise sessions completed on changes in fitness, and indeed that some participants in the fitness centre group who adhered to the programme, were assessed as having a lower fitness level at the end of intervention compared with baseline (Fig. 2). Issues that may account for this negative finding, as well as the lack of between-group differences in cardiorespiratory fitness in this trial include the timing of the intervention, the intensity of exercise achieved, and the participant selection criteria.

Discharge from inpatient rehabilitation was chosen as the time-point to implement a fitness training programme due to its strategic and clinical importance; that is, it may be the optimal time to potentially reverse cardiorespiratory deconditioning and to prevent the adoption of sedentary lifestyles. However, during this chosen timeframe, neurological recovery is still occurring, a small proportion of people deteriorate (32), and higher demands of living occur. The most rapid recovery time post-injury is the first 3–6 months (33); thus, participants in both groups may still have been making neurological gains which may have reduced any potential between-group difference. Four participants, by chance all in the fitness centre group, had significant neurological deterioration during the trial (2 had post-cranioplasty complications, one had post-traumatic epilepsy, and one had increased peripheral weakness and spasticity) which reduced their physical and psychosocial functioning compared with baseline. Also, living at home has a higher aerobic demand compared with hospital (11), and as such being discharged home may have provided a training effect for participants in both groups. This factor may have confounded the *post-hoc* analysis results.

Exercise training at a moderate intensity was anticipated in the fitness centre group due to one-on-one supervision; however intensity was not objectively determined using heart rate monitors for pragmatic reasons (e.g. coordinating the use of heart rate monitors between fitness centres). It is unclear if the exercise intensity was sufficient for cardiorespiratory adaptation for all the participants; however data from 6 monitored participants did indicate that they were working at a moderate to high intensity (range 72–92% heart rate maximum). The systematic monitoring of exercise intensity for all participants in future studies is recommended to enable accurate interpretation of the effects of exercise intensity on cardiorespiratory fitness in people with TBI.

The modified 20-m shuttle test, which is a reliable (21) and valid (2) measure of fitness for adults with TBI, was chosen as the primary outcome measure due to its portability and specificity (20). Portability allowed testing to be conducted at each site and in the community (for those participants not able to return to the centre for testing); a feature that minimized the number of drop-outs. Walking or jogging was the primary mode of fitness exercise for both groups so the modified 20-m shuttle test, which is a walking and jogging assessment, was specific for the exercise training mode. However, the inclusion criteria for this trial did not discriminate between people with and without gait dysfunction. Participants with significant gait dysfunction may have been limited in their ability to improve on the modified 20-m shuttle test due to neuromotor impairments restricting their capacity to increase their walking speed or to attempt to jog. Although clinically it is appropriate to prescribe a fitness programme for people with gait dysfunction, excluding people with significant gait dysfunction may have reduced the heterogeneity in our sample and provided sufficient power to detect a between-group difference (although this would also reduce the ability to generalize the results).

This trial found no significant effect on community integration and psychological functioning for attending a fitness centre compared with exercising at home. Exercise has been shown to positively influence levels of depression in 2 non-controlled studies in people with TBI (34, 35); however, it had no effect in one previous randomized controlled trial (11) or in this trial. The benefits of exercise on depression appear to be strongest in clinically depressed populations (36), thus the lack of effect may be because participants in both trials were assessed to be on average within the normal to mild levels of depression at all time-points assessed (24, 37).

Although there were no between-group differences for cardiorespiratory fitness, this trial did demonstrate that exercise in a fitness centre resulted in better adherence, was safe to implement, achieved more goals, and was a more motivating environment in which to exercise. It is likely that adherence was good in our supervised fitness centre-based exercise programme because it overcame commonly reported barriers to exercise participation in people with activity limitations, such as cost, transport, and not knowing what to do (7). These barriers were overcome through project funding of a 3-month fitness centre membership, transport if required, and 36 sessions of one-on-one personal training. The higher adherence compared with an unsupervised home-based exercise programme would suggest that a supervised fitness centre-based exercise programme provides the structure for participation in regular physical activity, which can provide many important health benefits (e.g. reducing the risk of developing secondary co-morbidities) (16).

This trial used a rigorous methodological design, including concealed random allocation, strategies to attempt to blind the outcome assessor, good retention of participants through to follow-up, and intention-to-treat analysis. This trial should

provide physiotherapists with confidence that patients with TBI can safely undertake moderate intensity exercise early in the recovery period. Confirming the effects of fitness training for people with TBI is important due to the very low level of cardiorespiratory fitness observed in this and other studies (e.g. 1), and may best be investigated in a chronic group in which neurological recovery has already plateaued, participants are medically stable, and a non-active control group can be utilized.

ACKNOWLEDGEMENTS

This research was funded by a grant from the Motor Accidents Authority of New South Wales, Australia; and by a scholarship from the Menzies Foundation (LMH). We would like to thank Lauren Gillett, Melanie Yap and Taryn Jones for data collection; the physiotherapists at the Liverpool, Ryde and Westmead Brain Injury Rehabilitation Units; the participating fitness centres and personal trainers; the participants and their families; and Rob Herbert for statistical advice.

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