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INDEPENDENT, COMMUNITY-BASED AEROBIC EXERCISE TRAINING FOR PEOPLE WITH MODERATE-TO-SEVERE TRAUMATIC BRAIN INJURY

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DISCLOSURES

Dr. Devine has nothing to disclose.

Dr. Wong has nothing to disclose.

Dr. Gervino has nothing to disclose.

Dr. Pascual-Leone serves on the scientific advisory boards for Nexstim, Neuronix, Starlab Neuroscience, Neuroelectrics, and Neosync; and is listed as an inventor on several issued and pending patents on the real-time integration of transcranial magnetic stimulation (TMS) with electroencephalography (EEG) and magnetic resonance imaging (MRI).

Dr. Alexander has nothing to disclose.
CORRESPONDING AUTHOR INFORMATION

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INDEPENDENT, COMMUNITY-BASED AEROBIC EXERCISE TRAINING FOR PEOPLE WITH MODERATE-TO-SEVERE TRAUMATIC BRAIN INJURY

ABSTRACT

Objective: To determine if people with moderate-to-severe TBI can adhere to a minimally supervised, community-based vigorous aerobic exercise program.

Design: Prospective trial.

Setting: Eastern Massachusetts YMCA facilities.

Participants: Ten community-dwelling volunteers (8 men, 2 women; ages 22-49) 6-15 months post moderate-to-severe TBI.

Intervention: Participants received memberships to local YMCAs and brief orientations to exercise, then were asked to independently complete ≥12 weeks of ≥3 training sessions/week, performed at 65-85% of maximum heart rate for ≥30 minutes per session. Participants could self-select exercise modality, provided they met intensity/duration targets. Programmable heart rate monitors captured session intensity/duration.

Main Outcome Measures: Independence with equipment/facility use, compliance with training goals (session frequency, duration, intensity and total weeks of training).

Results: All participants achieved independence with equipment/facility use. All met at least 2 of 4 training goals; half met all 4 goals. Participants averaged 3.3 sessions/week (SD +/- 0.7) for 13 weeks (range 6 – 24). Average session duration was 62 minutes (SD +/- 23), of which 51 minutes (SD +/- 22) occurred at or above individual HR training targets.
Conclusions: People in recovery from moderate-to-severe TBI can, with minimal guidance, perform vigorous, community-based exercise. This suggests decentralized exercise may be logistically and economically sustainable after TBI, expanding its potential therapeutic utility and rendering longer duration exercise studies more feasible.

Key Words: aerobic exercise; traumatic brain injury; community-based.
Habitual aerobic exercise improves cardiovascular endurance and positively affects mood and functional capacity. Increasing evidence suggests it also influences cognition in many populations, including stroke\textsuperscript{1,2}, brain injury\textsuperscript{3,4}, Alzheimer’s disease\textsuperscript{5,6} and people at increased risk of dementia\textsuperscript{7,8}. As impairments in cognition, endurance, functional capacity and mood are all sources of morbidity after TBI, aerobic exercise may represent a valuable non-pharmacologic adjunct. Improvements in cardiovascular endurance are demonstrable after 12-week aerobic exercise programs in most populations\textsuperscript{9}, while mood and cognition changes can take > 6 months to manifest\textsuperscript{5,6}. TBI survivors can safely perform vigorous exercise\textsuperscript{10} and comply with short, supervised group training\textsuperscript{3,4,10}.

However, they frequently have limited transportation access, which restricts participation in longer exercise programs requiring multiple weekly visits to distant training sites. Decentralized, independent exercise may offer an alternative, if reliable participation can be assured. The goal of this study was to determine if community-dwelling people with moderate-to-severe TBI could demonstrate the physical, cognitive and behavioral skills necessary to adhere to an independent, community-based cardiovascular exercise program, and whether they could maintain an intensity, duration and frequency known to improve cardiovascular endurance.

\textbf{METHODS}

\textbf{Screening:} After obtaining approval by the Committee for Clinical Investigation at Beth Israel Deaconess Medical Center and Braintree Rehabilitation Hospital, a query of Braintree Hospital’s admission database identified patients aged 18-50 with moderate-to-severe TBI during an 18-month period. Chart review identified those who met study criteria. Inclusion criteria were: 1) English speaking; 2) visual acuity adequate for safe participation; 3) resident of a community served by the participating Eastern MA YMCA; 4) competent to give informed consent. Exclusion criteria were:
1) Pre-morbid or injury-related musculoskeletal or neurological impairment that would render cardiovascular exercise dangerous; 2) Pre-morbid or injury-related medical disorders for which rigorous cardiovascular exercise is contraindicated (deep venous thrombosis, active coronary artery disease, valvular heart disease, peripheral vascular disease, obstructive lung disease, uncontrolled hypertension, uncontrolled diabetes). Figure 1 summarizes screening and enrollment.

Enrollment: Ten patients replied to telephone contact and completed in-person evaluations on a rolling, first-come basis, including history and physical examination with study physician. Where possible barriers to participation arose, participants furnished current medical records to confirm they could safely participate. Brain injury clinical diagnoses and injury severity were extracted directly from hospital notes. Neuropsychological screening showed residual memory and executive function impairments, but confirmed cognitive recovery sufficient to safely comply with pre-intervention exercise testing instructions.

Pre-Intervention Cardiovascular Testing: Participants underwent maximal effort cardiovascular testing (modified Bruce Protocol with continuous 12-lead ECG and blood pressure monitoring using treadmill or bicycle) to confirm cardiovascular safety for exercise. Observed maximum heart rates were used to calculate individual aerobic training zones (65-85% of maximum). Two participants withdrew from the study prior to intervention: participant #2 withdrew due to interval DVT diagnosis, and participant #10 withdrew when her nearest YMCA left the study.

Intervention: Participants received complimentary individual memberships at local YMCA’s for the duration of the study, where they had access to exercise equipment during normal hours. Each was asked to complete ≥ 12 weeks of exercise, maintaining ≥ 3 exercise sessions/week of ≥ 30
minutes/session, and to keep heart rates between 65-85% of their observed maximum. Participants received individually programmed, recordable heart rate monitors (HRM; Polar Electronics model RS-400) that continuously displayed heart rate, personal training zone and session duration, and wore monitors for all exercise. Initial sessions were supervised by study staff until participants showed they could: 1) exercise for ≥ 30 minutes at target intensity, 2) navigate the gym milieu [negotiate external facilities and entry, find and use locker room/restroom, find cardiovascular exercise area within facility, comply with facility rules], 3) safely operate at least two pieces of stationary exercise equipment, and 3) independently operate HRM. After demonstrating these skills, participants were permitted to exercise independently. Participants were given no additional support beyond what general YMCA members receive. YMCA staff was informed that participants were involved in an exercise study, given P.I.’s contact information and told to share any concerns if/when they arose. Participants were encouraged to exercise outdoors when safe opportunities existed, but received no additional financial support for this. In the event of technical/operational error with HRM’s, participants also kept training logs. Study staff met participants every 3 weeks at their YMCA to download HRM data and review training logs. HRM training intensity parameters were increased incrementally to insure continued cardiovascular challenge. Participants unable to perform exercise for medical reasons (illness, injury, surgery) during a given study week were permitted to make up sessions at the end of the 12-week period. Downloaded HRM data was analyzed individually for each participant to obtain individual total minutes of exercise and volume of time spent within individual target training zone.

RESULTS

Table 1 summarizes participant demographics and exercise performances.
Compliance: All participants achieved independence with use of YMCA facilities, demonstrated proficiency with programmable HRM’s and could safely and independently use 2 pieces of stationary exercise equipment within 4 training sessions or less. One participant was unable to write in a training log, but used a HRM for all training sessions.

Training performance: All 8 participants met goals for session duration and intensity. Half of participants (3, 7, 8, 9) met all of the training goals (session duration, intensity, session frequency and overall program duration. Two participants met 3 of 4 goals (#5 averaged 2.7 sessions/week; #6 completed 10 weeks of training). Participants 1 and 4 documented < 12 weeks of training and averaged < 3 sessions/week during weeks they exercised. Participant 4’s HRM was lost before final data extraction. Mean performance data was calculated for each participant; individual means were then used to create the group mean. This assured that each participant’s efforts were represented equally in summary statistics, regardless of how many sessions s/he completed. Participants completed a mean of 3.3 exercise sessions/week (SD +/- 0.7) for a mean of 13 weeks (range 6 – 24 weeks). Mean session duration was 62 minutes (SD +/- 24 minutes), of which 51 minutes (SD +/- 22 minutes) was spent at or above target intensity. This represented 81.9% of total training time spent at or above target intensity (SD +/- 0.1).

Adverse events: No serious events were reported during this study. Two participants developed overtraining injuries (ankle soreness, delayed onset muscle soreness) sufficient to briefly suspend exercise (≤ 7 days’ rest). Two participants (#4, #7) underwent planned outpatient surgery during the 12-week training period for pre-existing orthopedic injuries not impacted by exercise. Participant 7 resumed training once medically cleared and made up missed sessions at the end of the study. We
received no reports of inappropriate behavior in the training milieu, or of participants requiring support beyond what was available to all YMCA members. The most commonly cited reason for missed training sessions was lack of transportation (no ride, insufficient funds for public transit).

DISCUSSION

The purpose of this study was to see whether TBI survivors could independently exercise at the same intensity, frequency and duration known to cause a training effect, utilizing local facilities and common training tools. Our findings show that community-dwelling people with moderate-to-severe TBI can do this. With neither a structured exercise program nor therapist supervision, our participants safely and effectively performed aerobic exercise and met most frequency, duration and intensity goals. All were capable of independently navigating exercise facilities, using exercise equipment and operating programmable HRM’s. These findings suggest aerobic exercise may be promoted for TBI survivors independent of insurance or therapist supervision, and that exercise can be safely and effectively done in facilities convenient to participants, alongside the general population. Our findings further suggest that longer duration community-based exercise may be a viable alternative to centralized research interventions.

Without reliable, uniform exercise interventions, attribution of effect, or confirmation of non-effect is impossible. By using individually programmed HRM’s, we gave participants real time exercise guidelines, and confirmed intensity/duration were comparable both between sessions and among all participants. HRM’s supplied data unobtainable from training session attendance records alone, and eliminated recall bias as an error source – critical for populations with cognitive impairments.

Tailoring exercise intensities to individual baseline cardiovascular fitness and increasing intensity
throughout the study to maintain constant challenge insured our participants trained at an intensity that existing literature suggests is sufficient to provoke a cardiovascular training response.

STUDY LIMITATIONS

With eight participants generalizability is limited. Older individuals comprise a growing subgroup of TBI survivors; it is unclear whether independent exercise is equally safe for them. Our participants used standard gym equipment; mobility-impaired TBI survivors may require specialized equipment not widely available in the community. Only patients with interest in exercise replied to screening, biasing selection in favor of compliance. While this bias exists in all exercise trials, it is more problematical in those where degree of participation or some derivative thereof is an outcome.

CONCLUSIONS

People in recovery from moderate-to-severe TBI can, with minimal guidance, perform vigorous, community-based exercise. This suggests decentralized exercise may be logistically and economically sustainable after TBI, expanding its potential therapeutic utility and rendering longer duration exercise studies more feasible.
REFERENCES


SUPPLIERS

Programmable Heart Rate Monitors (Polar RS-400) supplied by Polar Electro Inc., 1111 Marcus Avenue, Suite M15, Lake Success, NY 11042-1034, telephone 1-800-227-1314.
## TABLE 1: Demographics and Exercise Performance

### DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Brain Injury Clinical Diagnosis</th>
<th>Mechanism of Injury</th>
<th>Inpatient Hospitalization (days)</th>
<th>Months post-injury at enrollment</th>
<th>Concomitant neuro/MSK Injuries</th>
<th>Pre-injury exercise experience</th>
<th>Distance from residence to YMCA (miles)</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>31</td>
<td>female</td>
<td>severe</td>
<td>fall</td>
<td>74</td>
<td>10</td>
<td>radial, mandibular fractures</td>
<td>regular aerobic &amp; resistance</td>
<td>0.6</td>
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<tr>
<td>2</td>
<td>48</td>
<td>male</td>
<td>moderate</td>
<td>motorcycle accident</td>
<td>11</td>
<td>6</td>
<td>mandibular fracture, pre-morbid chronic neck pain</td>
<td>regular aerobic &amp; resistance</td>
<td>10.4</td>
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<tr>
<td>3</td>
<td>26</td>
<td>male</td>
<td>severe</td>
<td>pedestrian vs. MVA</td>
<td>185</td>
<td>15</td>
<td>clavicular, rib, acetabular and femoral head fractures</td>
<td>physically demanding job</td>
<td>4.6</td>
</tr>
<tr>
<td>4</td>
<td>29</td>
<td>male</td>
<td>moderate</td>
<td>MVA</td>
<td>36</td>
<td>9</td>
<td>brachial plexus injury, femoral &amp; tibial fracture with foot drop</td>
<td>physically demanding job</td>
<td>4.2</td>
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<tr>
<td>5</td>
<td>22</td>
<td>male</td>
<td>severe</td>
<td>MVA</td>
<td>10</td>
<td>12</td>
<td>transient right hemiparesis</td>
<td>no prior exercise</td>
<td>4.4</td>
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<td>6</td>
<td>42</td>
<td>male</td>
<td>moderate</td>
<td>MVA</td>
<td>91</td>
<td>6</td>
<td>rib fractures</td>
<td>physically demanding job</td>
<td>8.4</td>
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<tr>
<td>7</td>
<td>49</td>
<td>male</td>
<td>severe</td>
<td>fail</td>
<td>≥ 47</td>
<td>6</td>
<td>clavicular, distal radius, wrist and digit fractures</td>
<td>no prior exercise</td>
<td>5.4</td>
</tr>
<tr>
<td>8</td>
<td>40</td>
<td>male</td>
<td>severe</td>
<td>pedestrian vs. MVA</td>
<td>40</td>
<td>7</td>
<td>tibia and fibular fracture, ankle fracture</td>
<td>no prior exercise</td>
<td>1.4</td>
</tr>
<tr>
<td>9</td>
<td>42</td>
<td>male</td>
<td>moderate-to-severe</td>
<td>MVA</td>
<td>67</td>
<td>7</td>
<td>left hemiparesis</td>
<td>no prior exercise</td>
<td>7.0</td>
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<tr>
<td>10</td>
<td>24</td>
<td>female</td>
<td>severe</td>
<td>--</td>
<td>121</td>
<td>9</td>
<td>vertebral, iliac wing, rib and hand fractures</td>
<td>former high school athlete</td>
<td>4.3</td>
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</table>

### EXERCISE PERFORMANCE

#### GOAL ACHIEVEMENT

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<th>Goal</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Mean</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent in facility, safely used equipment and HRM</td>
<td>yes</td>
<td>--</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Averaged ≥ 30 minutes per session</td>
<td>yes</td>
<td>--</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Able to sustain 65-85% max HR for 30 minutes</td>
<td>yes</td>
<td>--</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Averaged ≥ 3 sessions per week</td>
<td>no</td>
<td>--</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Completed 12 weeks of training</td>
<td>no</td>
<td>--</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>--</td>
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#### TRAINING DATA

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<th>Training Parameter</th>
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<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Mean</th>
<th>Standard deviation</th>
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<tr>
<td>Total Sessions</td>
<td>13</td>
<td>--</td>
<td>79</td>
<td>17</td>
<td>30</td>
<td>43</td>
<td>47</td>
<td>52</td>
<td>41</td>
<td>--</td>
<td>40</td>
<td>21</td>
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<tr>
<td>Total Weeks of Exercise</td>
<td>6</td>
<td>--</td>
<td>24</td>
<td>9</td>
<td>15</td>
<td>10</td>
<td>13</td>
<td>14</td>
<td>13</td>
<td>--</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>% weeks with &gt; 1 session</td>
<td>50</td>
<td>--</td>
<td>87</td>
<td>58</td>
<td>93</td>
<td>83</td>
<td>92</td>
<td>100</td>
<td>100</td>
<td>--</td>
<td>83</td>
<td>19</td>
</tr>
<tr>
<td>Mean sessions/week exercise</td>
<td>2.3</td>
<td>--</td>
<td>4.2</td>
<td>2.4</td>
<td>2.7</td>
<td>3.9</td>
<td>3.8</td>
<td>3.7</td>
<td>3.2</td>
<td>--</td>
<td>3.3</td>
<td>0.7</td>
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<tr>
<td>Mean session duration (minutes)</td>
<td>55</td>
<td>--</td>
<td>85</td>
<td>48</td>
<td>44</td>
<td>38</td>
<td>50</td>
<td>108</td>
<td>65</td>
<td>--</td>
<td>62</td>
<td>24</td>
</tr>
<tr>
<td>Mean training time at 65-85% max HR (minutes)</td>
<td>39</td>
<td>--</td>
<td>80</td>
<td>38</td>
<td>36</td>
<td>33</td>
<td>35</td>
<td>86</td>
<td>63</td>
<td>--</td>
<td>51</td>
<td>22</td>
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</tbody>
</table>

1. Participant withdrew from study for medical reasons prior to exercise intervention.
2. Participant withdrew from study for logistical reasons prior to exercise intervention.
FIGURE 1: Screening and Enrollment Pathway

Query to Admissions Registry
Braintree Rehabilitation Hospital

Identify patients aged 18-50 admitted for TBI who consented to participate in research

Review full admissions data; Exclude patients with mild TBI

38 patients

Review full charts for inclusion/exclusion criteria; contact eligible patients

16 patients not contacted

4 lived outside of study area
12 medically ineligible or non-English speaking

10 patients complete screenings and pre-intervention assessments

8 patients enter and complete intervention
1 patient withdrew for medical reasons (new deep venous thrombosis)

22 patients contacted by phone

8 patients did not reply to phone message
4 patients declined to participate

1 patient withdrew for logistical reasons (YMCA withdrew from study)
HIGHLIGHTS

Per Dr. Basford’s reply to us on April 11, 2016 (included in the uploaded “Response to Reviewers” document), is our understanding that Highlights and Graphical Abstract are optional. If this is not the case for this revision, we are happy to create and add these to our submission materials.

Thank you.