

A Randomized Clinical Trial of Plasticity-Based Cognitive Training in Mild Traumatic Brain Injury

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Abstract

Clinical practice guidelines support cognitive rehabilitation for people with a history of mild traumatic brain injury (mTBI) and cognitive impairment, but no class I randomized clinical trials have evaluated the efficacy of self-administered computerized cognitive training. The goal of this study was to evaluate the efficacy of a self-administered computerized plasticity-based cognitive training program in primarily military/veteran participants with a history of mTBI and cognitive impairment.

A multi-site randomized double-blind clinical trial of a behavioral intervention with an active control was conducted from September 2013 through February 2017 including assessments at baseline, post-training, and after a three-month follow-up period. Participants self-administered cognitive training (experimental and active control) programs at home, remotely supervised by a health care coach, with an intended training schedule of 5 days per week, 1 hour per day, for 13 weeks. Participants (149 contacted, 83 intent-to-treat) were confirmed to have a history of mTBI (mean of 7.2 years post-injury) through medical history/clinician interview and persistent cognitive impairment through neuropsychological testing and/or quantitative participant reported measure. The experimental intervention was a brain-plasticity-based computerized cognitive training program targeting speed/accuracy of information processing, and the active control was composed of computer games. The primary cognitive function measure was a composite of nine standardized neuropsychological assessments, and the primary directly-observed functional measure a timed instrumental activities of daily living assessment. Secondary outcome measures included participant-reported assessments of cognitive and mental health.

The treatment group showed an improvement in the composite cognitive measure significantly larger than that of the active control group at both the post-training (+6.9 points, CI +1.0 – +12.7, $P = 0.025$, $d = 0.555$) and the follow-up visit (+7.4 points, CI +0.6 – +14.3, $P = 0.039$, $d = 0.591$). Both large and small cognitive function improvements were seen twice as frequently in the treatment group than in the active control group. No significant between group effects were seen on other measures, including the directly-observed functional and symptom measures. Statistically equivalent improvements in both groups were seen in depressive and cognitive symptoms.

Results provide the first evidence for the efficacy of the self-administered remotely-supervised computerized plasticity-based cognitive training program in improving neuropsychological measures of cognitive function in people with a history of mTBI and cognitive impairment.

This trial was pre-registered at clinicaltrials.gov (NCT01640158).

Keywords

concussion, traumatic brain injury, cognitive training, brain plasticity, randomized controlled trial.

Abbreviations

AC: Active Control

ANAM: Automated Neuropsychological Assessment Metrics

BDI: Beck Depression Index

DW: Drop/Withdraw

ET: Experimental Treatment

EXAMINER: Executive Abilities: Measures and Instruments for Neurobehavioral Evaluation and Research

FrSBe: Frontal Symptoms Behavioral Scale ITT: Intent-To-Treat

MCS: Mental Component Score

MPAI: Mayo-Portland Adaptability Index mTBI: mild Traumatic Brain Injury

NSI: Neurobehavioral Symptom Inventory PCL: PTSD Check List

PCS: Physical Component Score

PRO: Participant-Reported Outcome

PTSD: Post-Traumatic Stress Disorder

RAVLT: Rey Auditory Verbal Learning Test

RNBI: Ruff Neurobehavioral Index

RULIT: Ruff-Light Trail Learning Test

s.d.: standard deviation

SF: Short-Form

TIADL: Timed Instrumental Activities of Daily Living TOMM: Test Of Memory Malingering

TBI: Traumatic Brain Injury

WMS: Wechsler Memory Scale