

Remotely-Supervised Cognitive Remediation is Feasible and Effective:

Results of a Pilot Study

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Objective

To determine the feasibility of a remotely-supervised cognitive remediation program in adults with multiple sclerosis (MS).

Background

Cognitive impairment is a common unmet treatment need in MS. Technological advances in cognitive remediation have led to internet-based computer-based approaches drive cognitive training with frequent repetitive tasks that adjust to a user's performance in real-time to maintain a consistent level of challenge. Individualized training is especially important in MS, where cognitive impairments can be highly variable. However, while this training approach has been shown to lead to cognitive improvements in other disorders, little is known about their efficacy in MS. Daily use is recommended, but there are no guidelines for targeted use.

An advantage of computer-based cognitive remediation is that training can be accessed remotely away from clinic. Home access offers a low-cost and easily-accessible treatment option for individuals living with MS.

We developed a protocol for remotely-supervised cognitive remediation and tested it in comparison to an active control program in MS participants using a randomized, double-blind design.

Methods

MS participants, all of whom were initiating fingolimod therapy, were recruited over the course of one year and were randomly-assigned to either an active cognitive remediation program (Lumosity.com, using a research version tailored to target the deficits most commonly found in MS) or a control condition software program of ordinary computer games (Hoyle Puzzle and Board Games). Potential participants were excluded if they had a condition other than MS contributing to cognitive impairment, as well as any recent (past month) relapse and/or steroid use.

After completing a baseline cognitive evaluation, participants were given a study-provided laptop computer and headphones, and instructed to complete the training program (active or control) for 30 minutes per day, five days per week, for 12 weeks. Study laptops were also installed with a third party monitoring software (WorkTime by Nestersoft) to remotely record the amount of training time.

In addition to remote monitoring of participants' program use, each received a weekly "check-in" call to address any compliance issues or technical problems. Technical support was available throughout the study period. After the training period, the cognitive evaluation was repeated.

The primary goal of the study was to determine feasibility of our remotely-supervised protocol for use in clinical trials. Program training was measured by number of days played and total time played, recorded in minutes. Compliant playtime was defined as completing at least 50% of the targeted training time, or 15 hours total.

Secondary (treatment) outcomes were determined by changes in cognitive and motor functioning following treatment, measured at the individual level by difference in a composite normative z-score created from representative measures for each test in the assessment administered at baseline and study end.

Results

A total of 20 MS participants were enrolled in the study, with n=11 assigned to the active condition and n=9 to the control condition. Both groups were matched in terms of age, years of education, and cognitive performance at baseline (Table 1).

Table 1: Sample Demographic and Clinical Characteristics

Characteristic	Active Condition (n=11)	Control Condition (n=9)	p value
Age (years)	Mean (SD) 38 (+10.58)	42 (+12.53)	0.42
	Range 24-55	19-55	-
Gender	Female (%) 63.6% (n=7)	77.7% (n=7)	-
Race	White (%) 72.7% (n=8)	66.7% (n=6)	-
	Black (%) 18.2% (n=2)	11.1% (n=1)	-
Ethnicity	Hispanic (%) -	11.1% (n=1)	-
	Non-Hispanic (%) 90.9% (n=10)	88.8% (n=8)	-
Education (years)	Mean (SD) 15.27 (+2.57)	13.88 (+1.90)	.18
	Range 12 - 20 years	11-16 years	-
EDSS	Median 2	2.5	0.23
	Range 0-3	0-3.5	-
ECog (Baseline)	Mean (SD) 67.73 (+18.55)	63.14 (+18.97)	0.62
WRAT-3 Reading	Mean (SD) 100.5 (+10.42)	102.3 (+6)	0.64
SDMT (Baseline)	Mean z-score (SD) -0.45 (+1.25)	-0.79 (+1.01)	0.50

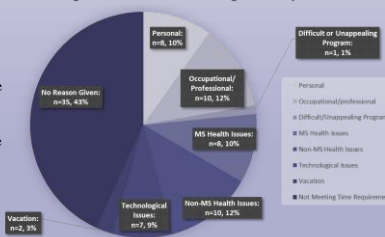
Compliance: For the full sample there was an 80% rate of compliance. Compliance did not differ significantly between the two conditions (25.69±8.26 vs. 24.16±15.55 hours, p=0.80). Only 4 participants (2 in each condition) did not meet the compliance goal (Table 2).

Table 2: Program Compliance

Time	Active (n=11)	Control (n=9)	Overall (n=20)
Mean total hours of game usage (SD)	25.69 (8.26)	24.16 (15.55)	25.00 (11.76)
Mean hours played per week (SD)	1.93 (0.64)	1.87 (1.13)	1.90 (0.87)
Percentage compliant to study requirements	81.8% (n=9)	77.8% (n=7)	80.0% (n=16)

Reasons for Noncompliance: Noncompliance (failing to meet at least 50% of targeted training) was most often attributed to non-MS related illnesses and occupational obligations (Figure 1).

Figure 1: Reasons for Training Noncompliance



Treatment Outcomes: Baseline and study end performances were characterized by composite scores created by averaging age-normative z-scores from representative measures from tests often found sensitive to MS-related impairment (Table 3).

The active vs. control training led to greater improvements in both cognitive and motor performance at study end, with a mean improvement in composite z-score for both cognitive (0.41±0.39 vs -0.01±0.45, p=0.05) and motor tests (0.40±0.71 vs -0.64±0.73, p=0.01) (Table 3).

Table 3. Preliminary Treatment Outcomes

Measure	Change Score		p value
	Active (n=11)	Control (n=9)	
Cognitive Composite	0.41 (+0.39)	-0.01 (+0.45)	0.05
Visual Span (Corsi Blocks)	0.39 (+0.99)	-0.04 (+1.45)	0.47
PASAT 2 Second Trials	0.40 (+0.66)	0.44 (+0.84)	0.90
DKEFS Trails 2/3 Combo	0.25 (+0.72)	-0.20 (+1.18)	0.34
SRT Learning Trials	0.43 (+1.34)	-0.09 (+1.30)	0.39
BYMT-R Learning Trials	-0.64 (+1.53)	-0.32 (+1.49)	0.17
WAIS-IV Letter-Number	0.42 (+0.43)	-0.16 (+0.91)	0.11
Motor Composite	0.40 (+0.71)	-0.64 (+0.73)	0.01
DKEFS Trail 5	0.03 (+0.29)	-0.11 (+0.24)	0.53
9-Hole Pegs Dominant Hand	0.50 (+1.33)	-0.59 (+0.87)	0.04
9-Hole Pegs Non-dominant Hand	0.36 (+0.86)	-0.66 (+1.53)	0.10
Timed 25-Foot Walk	0.28 (+1.13)	-1.43 (+2.45)	0.05

Conclusion

- Using a remotely-supervised protocol, adult participants with MS had high compliance (≥80%) for completing computer-based cognitive remediation programs from home.
- Preliminary results suggest a greater benefit from a program of games selected to target deficits common in MS and adapted to the individual user in real-time when compared to ordinary computer games.
- This protocol is useful for studying cognitive remediation and provides participants access away from clinic. A larger, controlled trial is currently underway.

References

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