The Effectiveness of TECH: Tablet Enhancement of Cognition and Health

NCT02955277

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OBJECTIVES

To establish the effectiveness of the 'Tablet Enhancement of Cognition and Health' (TECH), a novel cognitive intervention for improving global cognition, specific cognitive components, and health-related quality of life (HRQoL) in older adults with Mild Cognitive Impairment (MCI), compared with a control group.

METHODS

Study design

This is a single-blind randomized controlled trial (clinical trial number NCT02955277) with assessments administered pre and post the 5-week intervention, and at 6-month follow-up, by assessors blind to group allocation.

Population

Community dwelling older adults (>65 years) were recruited from two community geriatric clinics due to their memory problems, and were referred to the study by their family or geriatric physician. Inclusion criteria were as follows: a) a diagnosis of MCI, as determined by a score of 19-25 points on the Montreal Cognitive Assessment (MoCA), a valid and reliable tool, subjective memory complaints supported by a family member, and independence in basic and instrumental activities of daily living (BADL, IAD), b) normal or corrected vision and hearing, c) written and spoken fluency of the language, and d) ability to use a touchscreen tablet after an initial demonstration. Individuals were excluded if they experienced severe depressive symptoms (Geriatric Depression Scale> 10 points), and if they were diagnosed with dementia, or other neurological or psychiatric conditions. All participants signed informed consent forms before participating in the study.

Tools

Outcome measures

The **Primary outcome measure** was MoCA (Nasreddine et al., 2005), for assessing global cognition, which was also used to screen for eligibility. **Additional cognitive assessment** included the WebNeuro assessment (Silverstein et al., 2007) which is A valid computerized assessment battery including the assessments of the following specific cognitive components/domain (subtests): Sustained attention (Continuous Performance Task), 22 controlled attention (Verbal Interference Task), flexibility (Switching of Attention Task), inhibition (Go-NoGo Task), working memory (Digit Span Task), memory recall (Memory Recall Task), problem solving (Maze Task). For each domain a raw score was calculated, and then converted to a z score, with a normative average of 0, and a standard deviation of 1. Higher scores for each domain indicates better performance. The secondary outcome measures included The Tower of Hanoi (ToH) task (Simon, 1975), a commonly used goal-directed measure assessing problem-solving, and specifically, planning. A computerized version of the task was used (http://vornlocher.de/tower). The participants completed the first three (out of six) levels of the task. the number of moves per level, and time for completion were recorded. the 12-Item Short Form Health Survey (SF-12) (Ware, Snow, Koskinski, & Gandek, 1993) for measuring health-related quality of life; physical and mental composite summary scores (Wilson, Tucker, & Chittleborough, 2002), higher scores indicating better health measures (Ware et al., 1993). The General Self-Efficacy Scale (GSES) (Schwarzer& Jerusalem, 1995), which is highly reliable and valid scale for assessing optimistic self-beliefs to cope with a variety of difficult demands in life. It consists 10 statements such as

'I can solve most problems if I invest the necessary effort'. The total score ranges from 10 to 40. Higher scores represent higher levels of general self efficacy (Schwarzer &Jerusalem, 1995). In addition, demographic information and previous experience with technology use (computer, smartphone and tablet) were collected.

The Intervention

The TECH intervention (study group) included daily self-training facilitated by weekly group sessions. Participants received iPads to take home and were requested to play puzzle-game apps, which simultaneously provided practicing different cognitive components, 3-5 times a week X 30-60 minutes, for a total of 15-25 training sessions. Weekly one-hour sessions led by an occupational therapist (OT) took place in a small group setting (4-6 participants) over a five-week period. These sessions focused on teaching tablet operation, allowing participants to explore and practice new apps, and increasing their confidence and independence in using and activating the tablet.

Standard care (control group). Participants received standard occupational therapy care for MCI including either a) a single consultation in a group setting (4-6 participants) to encourage participants to engage in activities such as solving crossword puzzles or playing board or card games in their leisure time to stimulate cognitive function; or b) participation in a social group (six one-hour sessions of 4-6 participants) of playing puzzle board games, with no recommendation to perform self-training at home.

Procedure

Participants were approached by phone and were provided with information about the study. Those who were willing to participate were invited to the geriatric clinic for the assessment session. After signing an informed consent form, the MoCA, GDS, BADL,

and IADL questionnaires were administered to confirm eligibility. If the participants were found eligible, the remaining outcome measures were administered. Then participants were stratified according to low (19-22 points) or high (23-25 points) MoCA score and then randomly allocated to the TECH or control group using a 1:1 ratio. Allocation was concealed from the investigators and the enrolled participants. Participants were notified by phone about their allocation. The assessors, who were blind to group allocation, were OTs trained to assess the study. Participants who were invited to the post- and follow-up assessment sessions were asked not to discuss the intervention with the assessors.

Data analysis

'IBM SPSS Statistics 25' software was used for descriptive statistics to characterize the sample and outcome measures for the three assessments. Since the outcome measures were not normally distributed, non-parametric tests were performed. Intention-to-treat analysis was conducted with the last observation carried forward method, which is an acceptable data imputation method.[26] The percentage change was calculated for MoCA, WebNeuro, and SF-12 measurements between pre and post and between pre and follow-up using these formulas[(post-pre)/pre*100%], [(follow-up-pre)/pre*100%]. The difference between groups for the percentage change was tested using the Mann Whitney Test. Since significance tests are highly dependent on the sample size, the effect size was also estimated by using the effect size formula for non-parametric tests: Cohen's $r=Z/\sqrt{N}$. The Z value was retrieved from the Mann Whitney test U output. Cohen's r effect size values were considered small (0.1), medium (0.3), and large (0.5).

In each group, we calculated the percentage of participants who achieved the Minimal Clinically Important Difference (MCID) improvement in global cognition. MCID is defined as the smallest change in scores perceived by the patient as beneficial, which could lead to a change in the patient's treatment. In this study, the MCID of the MoCA was considered an improvement of at least 1.22 points, as found in Stroke Rehabilitation (since MCID data for individuals with MCI, to the best of our knowledge, have not yet been established).

The sample size was calculated using 'G*Power 3.1.9.4' software, according to a small effect size, based on previous studies assessing the effectiveness of computerized cognitive training for older adults with MCI, with 80% power and a significance level of 0.05. A sample size of 68 participants was calculated. Taking into consideration a 20% drop-out rate, 80 participants were required.