Wayfinding Intervention in High-Fidelity Long-Term Memory December 8, 2022
NCT 04253587

Statistical Analysis Plan:

Analyses were conducted under the intent-to-treat (ITT) principle, and data from all participants randomized to begin a training arm were included in the analyses. Each cognitive outcome measure is independent from the others (i.e., each measure uses a compartmentalized procedure, unique stimuli, and different metrics) and was considered as a potential measure of generalization of training effects in its own right. Therefore, the analyses of LDI scores and WALK scores were independent of each other.

Mixed models ANOVA were employed to examine the differences across the two conditions (Trackers and Control) between T1 (baseline) and T2 (post-training). Data were analyzed and statistics calculated using IBM SPSS Statistics release 20.0, and the threshold of statistical significance for false positives was set at $p < 0.05$.

Research Protocol Summary

Title: Wayfinding Intervention in High-Fidelity Long-Term Memory

Rationale: Therapeutic interventions have not yet been shown to demonstrate restorative effects for declining long-term memory (LTM) that affects many healthy older adults. Our motivation was to demonstrate a cognitive intervention based on spatial wayfinding through unfamiliar surroundings that induced beneficial gains in untrained measures of high-fidelity LTM, which is the most precise form of LTM.

Goals: Spatial navigation tasks have been applied to achieve environmental enrichment in animals, which refers to exposure and learning that have been linked to the vitality of the memory system in the brain. Labyrinth is a virtual reality (VR) spatial wayfinding game that mimics this environmental enrichment approach with the goal of improving, and potentially restoring, memory abilities in healthy older adults. The primary objective is to show training-induced gains in high-fidelity LTM (i.e., mnemonic discrimination).

Design: All participants provided informed consent under UCSF IRB 19-27586. Experiments enrolled 49 healthy older adults (mean 69 years of age) per protocol in a randomized controlled type interventional study. Outcome data were assessed at baseline (T1) and post-training timepoints (T2), and the primary outcome measures assessed two capabilities for high-fidelity LTM retrieval. The two treatment arms were Labyrinth VR training versus placebo control narrative games played on an iPad tablet computer. After orientation to their respective treatment games, all participants completed an expectancy survey regarding how their treatment would affect cognitive performance.

Methodology: Experiments used an HTC® VIVE™ VR system with the Unity cross-platform game engine (©Unity Technologies) to present our spatial wayfinding game. The cognitive intervention required approximately 12 hours game play of either Labyrinth VR treatment, or four commercially available narrative computer games as placebo controls, over four weeks.

MDT was one primary outcome measure and provided an LDI score for each participant at each timepoint in order to assess generalization of Labyrinth training to untrained capability for mnemonic discrimination as a measure of high-fidelity LTM. Mixed design ANOVA (repeated factors for time T1|T2 X between factors for condition Labyrinth-VR | Controls) was used for the analysis of LDI.

WALK was another primary outcome measure and provided an Items Recalled score for each participant at each timepoint in order to assess generalization of Labyrinth training to untrained capability for recent autobiographical memory as a measure of high-fidelity LTM. Mixed design ANOVA (repeated factors for time T1|T2 X between factors for condition Labyrinth-VR | Controls) was used for the analysis of Items Recalled.

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Mixed models ANOVA were employed to examine the differences across the two conditions (Trackers and Control) between T1 (baseline) and T2 (post-training). Data were analyzed and statistics calculated using IBM SPSS Statistics release 20.0, and the threshold of statistical significance for false positives was set at $p < 0.05$.

In consideration of a funding constraint, data were collected and analyzed only in the Experimental: LabyrinthVR Trackers and Placebo Comparator: Placebo Controls arms.