

Official Study Title:

Towards the development of a mobile-health technology designed to encourage the use of serious game-based interventions in patients with mild cognitive impairment outside the clinic

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Statistical Analysis Plan

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1. Participant Group

This study uses a two-period crossover design in which Group A and Group B alternate between an intervention and a non-intervention period over 24 weeks.

Group A will self-administer Neuro-World cognitive training games for 30 minutes per day, twice a week, for 12 weeks in a home setting (intervention period). This will be followed by 12 weeks without any therapist-supervised cognitive therapies (non-intervention period).

Group B will first complete a 12-week non-intervention period without therapist-supervised cognitive therapies. This will be followed by 12 weeks of self-administered Neuro-World cognitive training games for 30 minutes per day, twice a week, in a home setting (intervention period).

2. Statistical Analysis Plan

Paired t-tests will be conducted to evaluate changes in outcome measures between the intervention and non-intervention periods. The outcome measures include the Montreal Cognitive Assessment (MoCA), Mini-Mental State Examination (MMSE), Digit Forward Span (DFS), Digit Backward Span (DBS), Geriatric Depression Scale (GDS), SF-36 Mental Component Summary (MCS) Score, and the Lawton-Brody Instrumental Activities of Daily Living (IADL) Scale. The null hypothesis is that the intervention results in no improvement or worse outcomes compared to the non-intervention period. The alternative hypothesis is that the intervention leads to improved outcomes. All analyses will be conducted using Python, with a one-sided significance level of 0.05.