Study Protocol and Statistical Analysis Plan

Validation Study of VIRADIA: A Virtual Reality Diagnostic Platform for the Assessment of Neurological and Cognitive Functions

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Sponsor: GAMETHERAPY s.r.o.
Study Site: INNER s.r.o., Fatranská 873/12, 94901 Nitra, Slovakia

Purpose

The study aims to validate and assess the reliability of the VIRADIA Virtual Reality (VR) diagnostic platform designed for neurological and cognitive testing. The goal is to determine whether VR versions of nine standardized diagnostic tests measure the same constructs and provide comparable results to their traditional forms.

Study Design

Within-subjects, paired protocol. Each participant completes both the standard and VR versions of all tests. Order of administration is counterbalanced. Participants include healthy volunteers and patients with neurological diagnoses.

Tests Included

1. 9-Hole Peg Test (9HPT) 2. 6 Meter Walk Test (6MWT) 3. Timed Up and Go – Manual (TUG-M) 4. Functional Reach Test (FRT) 5. Symbol Digit Modalities Test (SDMT) 6. Clock Drawing Test (CDT) 7. Trail Making Test (TMT A/B) 8. Stroop Test 9. SATURN Test

Procedures

Participants provide informed consent and demographic data. Each completes both standard and VR tests in randomized order. A short post-assessment questionnaire evaluates tolerability of VR exposure.

Sample Size and Power

Target N ≈ 200 participants (100 healthy, 100 patients). Power analysis was based on paired ROC/AUC comparison (AUC $\geq$ 0.75, ΔAUC $\leq$ 0.05, α = 0.05, power = 0.90). 15% added to account for attrition and unusable data.

Timeline and Logistics

Each participant session lasts ~60 minutes. Various parallel testing stations allow ~4 participants per day. Total data collection time $\approx$ 50 working days for full sample.

Roles and Responsibilities

Principal Investigator: study supervision and report approval. Neurological Expert: clinical oversight and task safety. Study Coordinator: recruitment, scheduling, and QA. Administrators: conduct testing. Data Analyst: data cleaning, statistical analysis, and report generation.

Statistical Analysis Plan

Primary analyses: Pearson/Spearman correlations for convergent validity between VR and standard scores. Agreement analysis via Bland–Altman (bias, 95% limits of agreement). Discriminative validity through ROC/AUC (DeLong) between groups. All analyses performed with 95% confidence intervals.

Ethics and Safety

The study involves non-invasive diagnostic testing with minimal risk. All participants provide informed consent. Approved by the Ethics Committee of the Nitra Self-Governing Region (Approval No. 09I05-03-804).