

RESEARCH TRIAL PROTOCOL

Title: A Digital Twin Smart Educational Platform for Simulating Physical Obstacles and Safe Navigation Training for the Visually Impaired

Principal Investigator: [Abdellah Elfeky]

Affiliation: [King Salman center for Disability Research]

Trial Sponsor/Approval Body: Directorate of Special Education, Ministry of Education,
Jeddah, Saudi Arabia.

IRB Approval Reference: JED-SE-2026-ETH-096

Protocol Version & Date: 1.2

1. General Information

- **Protocol Title:** A Digital Twin Smart Educational Platform for Simulating Physical Obstacles and Safe Navigation Training for the Visually Impaired
- **Principal Investigator:** [Abdellah Elfeky]
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- **Trial Registration Identifier:**
- **Protocol Version & Date:** Version 1.2 – June 2026.

2. Project Summary and Objectives

The purpose of this clinical/educational trial is to evaluate the spatial orientation and mobility (O&M) efficacy of a dynamic non-invasive digital rehabilitation prototype. The platform bridges high-fidelity urban engineering modeling with adaptive instructional scaffolding to accelerate independent walking safety for visually impaired people (VIP).

Primary Objectives:

- To evaluate if adaptive virtual twin training lowers physical contact failure events during outdoor real-world urban navigation.
- To benchmark the execution latency of multi-modal binaural sound rendering and vibrotactile hardware actuators.
- To document behavioral technology acceptance vectors (TAM) across the target demographic group.

3. Study Design and Methodology

3.1 Trial Design

- **Structure:** A prospective, single-blind, randomized, two-arm parallel interventional controlled study.
- **Allocation Ratio:** (1:1) balanced random partition into an Experimental Arm and a Active Control Arm.
- **Blinding:** Single-blind. Participants are unaware of which training methodology is classified as the novel paradigm. Double-blind execution is implemented during post-intervention field score assessments via independent evaluation observers.

3.2 Participant Recruitment and Selection

- **Recruitment Channel:** Institutional databases through partnership networks at the Directorate of Special Education and local blind associations in Jeddah.

Inclusion Criteria:

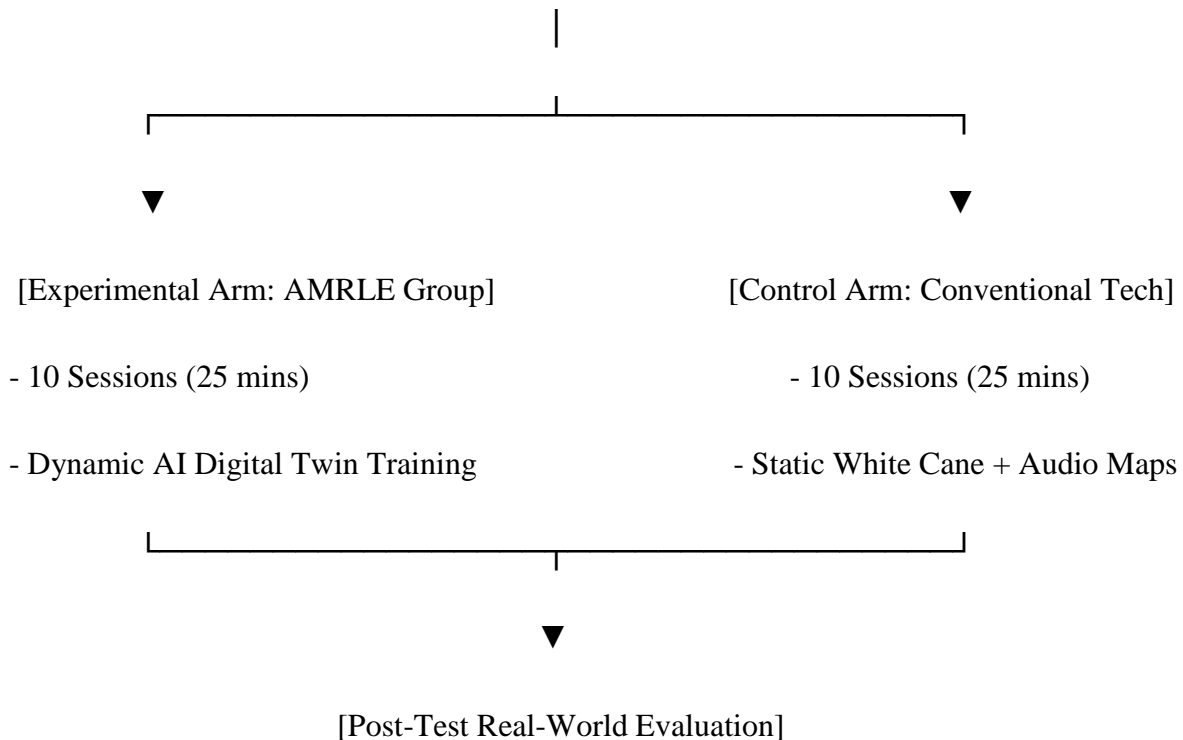
- Adults aged between 18 and 60 years old legally diagnosed with severe visual impairment or total blindness.
- Ability to walk unassisted for a minimum continuous duration of 15 minutes.
- Proficiency in screen-reader accessibility controls on smartphone user interfaces.

Exclusion Criteria:

- Co-occurring profound sensorineural hearing loss (preventing 3D spatial binaural discrimination).
- Active upper/lower-limb motor neuropathies disrupting haptic micro-actuator detection.
- Diagnosed vestibular syndromes or severe motion sickness history.

4. Intervention and Execution Plan

[Recruited Sample: N = 30 VIP]



4.1 The Experimental Arm (AMRLE Group)

Participants assignment code: Adaptive Multi-modal Reality Learning Environment (**AMRLE**).

- **Regimen:** 10 sessions distributed over 5 consecutive weeks (2 sessions per week). Each session lasts 25 minutes.
- **Environment:** Trainees walk inside a safe lab tracking frame wearing open-ear headphones and a custom Bluetooth-enabled 4-zone haptic belt.
- **Execution:** The backend logic tracks user location via an Octree spatial partition mesh. The AI updates environmental complexity (C_{t+1}) using real-time collision loops. The layout dynamically spawns physical blockades (e.g., Jeddah sidewalk construction gaps, unexpected street bins), forcing cognitive adjustments.

4.2 The Control Arm (Conventional Technology Group)

- **Regimen:** 10 sessions over 5 weeks (2 sessions per week, 25 minutes per session).
- **Environment:** Traditional indoor/outdoor spatial orientation tracks.

- **Execution:** Trainees receive conventional manual orientation and mobility (O&M) rehabilitation. This includes walking on fixed paths using standard white canes, combined with verbal description spatial audio scripts and layout orientation blueprints. No adaptive virtual elements are utilized.

5. Ethical Considerations and Safety Monitoring

5.1 Informed Consent and Assent

- **Delivery:** Information sheets are digitized into screen-reader compatible audio/HTML structures.
- **Execution:** Prior to baseline trials, participants sign a written or authenticated digital biometric thumbprint informed consent form. The document clearly communicates study risks, the right to exit, and explicit consent for capturing research photos with strict facial blurring protocols enforced for future academic dissemination.

5.2 Safety and Trial Discontinuation Protocols

- **Physical Setup:** The indoor virtual reality training environment is surrounded by padded handrails and supervised by an absolute close-proximity manual spotter.
- **Discontinuation Triggers:** Any instance of acute vertigo, simulator-lag sickness, performance anxiety panic, or physical trip event results in an immediate freeze of the system. The hardware is removed, and the participant is placed in a restorative recovery lounge. If symptoms persist beyond 10 minutes, the university on-call clinician or the Saudi Red Crescent (997) is alerted.

6. Data Management and Statistical Analysis

6.1 Assessment Instruments

- **Primary Metrics (System Telemetry):** Digital records capturing Time-to-Task Completion (**TTC**), Real-world Collision Rate (**RCR**), and Path Deviation Index (**PDI**).
- **Secondary Metrics (Psychometrics):** Post-trial deployment of a validated 5-point Likert Scale Technology Acceptance Model (TAM) instrument tracking perceived usefulness and ease of use.

6.2 Analysis Plan

- **Data Integrity:** Data anonymization is achieved via alphanumeric key mapping (e.g., VIP_JED_01). Missing data points will be addressed using multiple imputation mechanisms.
- **Hypothesis Testing:** Group mean differences will be verified using an Independent Samples (t)-test. Longitudinal skill growth across the 10 sessions will be tracked via a Two-Way Repeated Measures Analysis of Variance (**ANOVA**), setting statistical significance thresholds at an absolute value of ($\alpha = 0.05$). All calculations will run natively within SPSS or Python scipy libraries.