Study protocol

Title

Does a real-life Stressful Virtual Environment Change Balance and Mobility Performance? A pilot feasibility study

Author	Rebecca Winter

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Objectives and design

This non-randomised pilot feasibility study will evaluate the feasibility, safety, and tolerability of administering clinical balance and mobility assessments in an immersive virtual environment. A within-participant design will be used to compare assessments performed without a head-mounted display (noVR) and while wearing a head-mounted display presenting a virtual environment (VR). Exploratory analyses will describe differences in clinical performance between conditions.

Participants

Participants will be recruited over a predefined period. No formal sample size calculation will be performed; the sample size will be determined by the number of eligible participants providing informed consent during this period. Baseline information will include age, sex, height, weight, neurological conditions, visual status and correction, and previous VR experience. Eligibility criteria, recruitment setting, and recruitment dates will be specified separately.

Virtual environment

A virtual environment simulating a busy railway station will be presented using a Meta Quest 3 standalone head-mounted display. The environment will be developed using Godot Engine version 4.4 and spatially adapted to the clinical testing area. Moving pedestrian avatars, animated displays, and station sounds recorded during commuter peak times will provide visual and auditory distractions intended to increase attentional demands.

The headset fit and interpupillary distance will be adjusted individually, accommodating glasses where necessary. Before VR testing, participants will complete a brief familiarisation phase.

Assessment procedures

The same trained physiotherapist will administer the Mini-Balance Evaluation Systems Test (Mini-BESTest), Timed Up and Go (TUG), and 10-Meter Walk Test (10MWT) under both noVR and VR conditions.

Mini-BESTest: All 14 items will be administered to assess dynamic balance. Item scores and the total score will be recorded. Feasibility of performing each item in VR, participant-rated burden on a 0-10 scale, and assessor comments will also be documented.

TUG: Participants will stand from a chair, walk three metres, turn, return, and sit down. Single-task and cognitive dual-task versions will be administered in both conditions. During the dual-task version, participants will count backwards by threes from a randomly selected number between 20 and 100. Completion time will be recorded in seconds.

10MWT: Participants will walk along a 10-metre walkway at comfortable and fast walking speeds. The central six metres will be timed to allow for acceleration and deceleration. Two trials per speed and condition will be performed. Walking speed will be calculated in metres per second and averaged across the two trials.

Immediately after the final VR exposure, participants will complete the Virtual Reality Sickness Questionnaire (VRSQ) and the iGroup Presence Questionnaire (IPQ) to assess VR-related symptoms and perceived presence, respectively.

Feasibility and safety outcomes

Feasibility outcomes will be analysed descriptively against the following prespecified progression criteria:

Domain	Outcome and progression criterion
Protocol adherence	At least 80% of participants complete all planned assessments in both conditions.
Technical feasibility	Number and type of VR-related technical issues; no numerical progression threshold is specified.
Data completeness	At least 80% complete outcome data for each test and condition.
Assessment burden	VR assessments require no more than 20% additional time compared with noVR assessments.
Safety and tolerability	VRSQ scores and recorded adverse events; no adverse events requiring protocol modification.

Adverse events, including dizziness requiring interruption, near falls, falls, and other unexpected events, will be documented. Assessment interruptions, withdrawals, and their reasons will also be recorded.

Data analysis

Analyses will primarily be descriptive. Feasibility outcomes will be summarised using counts, proportions, and assessment durations, as appropriate. Clinical assessment scores, walking speeds, TUG completion times, and questionnaire scores will be summarised descriptively. Exploratory differences in TUG and 10MWT performance will be

calculated within participants as VR minus noVR values. No formal hypothesis testing will be performed.

CRF Pilot testing Virtual Environment

FEAR AND ATTENTION IN FALLERS AND NON-FALLERS: INCLUSION OF NEUROPSYCHOLOGICAL PARAMETERS IN CLINICAL FALL RISK ASSESSMENTS USING VIRTUAL REALITY

Participant-ID	
age	
sex	○ Male ○ Female
Neurological disorder	○ Yes ○ No ○ Epilepsy ○ Comment:
Vision	○ Good ○ Impaired ○ Corrected ○ Glases ○ Contacts
height	
weight	
Experience with VR	○ None ○ Little ○ Frequent player
Drop out/Stop of the measurement	○ no ○ yes reason:
Mini BEST without VR	

Vicon:

System Set up

Start Vicon 30min before measurements: in Black box main switch

Calibration Cameras	Cameras – Go Online --> Calibration
Calibration Origin	Set Origin
Force Plates	On the black box, set Force Plates to zero
VR	No chair, no obstacle A: start measurement B: black out Trigger: chair Grip: obstacle

New subject	F:Rebecca_VR/TESTING New subject: “Participant_nr”
Patient properties	Vicon: Subject: o Weight (kg) o Height (mm) o Leg Length (SIAS to medial malleolus) o Knee width (mm) o Ankle width (mm)
Start Trial	
T-Pose	“Static” (5sec) Reconstruct Initialize Run Pipeline and fill markers if necessary
Calibration HMD/Vicon	Start measuring: press “A” on controller Start Vicon --> Subject Head up and down 3 times
walking	“walking_noVR” 4 times normal speed --> CAVE force plate! “walking_noVR_fast”

	4 times fast speed
VR	
TUG	"TUG_VR" 2x
TUG_Dual task	"TUG_VR_count" 2x
Whole Mini-BEST	Mini Best in VR without Vicon o Checklist for each topic: y/n o Borg 0-10 o Individual Remarks

Questionnaires

- Virtual reality sickness questionnaire (VRSQ)
- Igroup Presence Questionnaire (IPQ)

Assessments

Participant nr	
Date	

Igroup Presence Questionnaire (IPQ)

Thank you for your interest in our survey. It'll take you about 20 - 30 minutes to fill in the questionnaire. You can work through the questionnaire offline, but in order to submit the results at the end you'll have to be online.
Please answer all question only with reference to one single episode of interaction with a virtual environment.

How long did you interact with the virtual world? ___min

Sub-Scale	Question							
Inv1	**How aware were you of the real world surrounding while navigating in the virtual world? (i.e. sounds, room temperature, other people, etc.)?**							
Extremly aware	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	not aware at all
Real1	**How real did the virtual world seem to you?**							
Completely real	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	not real at all
Sp4	**I had a sense of acting in the virtual space, rather than operating something from outside.**							
fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	fully agree
Real2	**How much did your experience in the virtual environment seem consistent with your real world experience ?**							
Not consistent	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	very consistent
Real3	**How real did the virtual world seem to you?**							
about as real as an imagined world	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	indistinguishable from the real world
Sp3	**I did not feel present in the virtual space.**							

Did not feel	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Felt present
Inv2	**I was not aware of my real environment.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree
G1	**In the computer generated world I had a sense of "being there"**							
Not at all	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Very much
Sp1	**Somehow I felt that the virtual world surrounded me.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree
Sp5	**I felt present in the virtual space.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree
Inv3	**I still paid attention to the real environment.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree
Real4	**The virtual world seemed more realistic than the real world.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree
Sp2	**I felt like I was just perceiving pictures.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree
Inv4	**I was completely captivated by the virtual world.**							
Fully disagree	○ -3	○ -2	○ -1	○ 0	○ +1	○ +2	○ +3	Fully agree

Participant nr	
Date	

VIRTUAL REALITY SICKNESS QUESTIONNAIRE (VRSQ)

Instructions: Circle how much each symptom below is affecting you right now.

1. General discomfort	None	Slight	Moderate	Severe
2. Fatigue	None	Slight	Moderate	Severe
3. Headache	None	Slight	Moderate	Severe
4. Eye strain	None	Slight	Moderate	Severe
5. Difficulty focusing	None	Slight	Moderate	Severe
6. Fullness of the Head	None	Slight	Moderate	Severe
7. Blurred vision	None	Slight	Moderate	Severe
8. Dizziness with eyes closed	None	Slight	Moderate	Severe
9. *Vertigo	None	Slight	Moderate	Severe

A = Sum of questions 1-4: _____ C = A/12 x 100: _____

B = Sum of questions 5-9: _____ D = B/15 x 100: _____

VRSQ Score = (C + D)/ 2: _____

Virtual Reality Sickness Questionnaire (VRSQ) is modified from the Simulator Sickness Questionnaire (SSQ).
Kim, H. K., Park, J., Choi, Y., & Choe, M. (2018). Virtual reality sickness questionnaire (VRSQ): Motion sickness measurement index in a virtual reality environment. *Applied ergonomics*, *69*, 66-73.

Original version of Simulator Sickness Questionnaire (SSQ): Kennedy, R.S., Lane, N.E., Berbaum, K.S., & Lilienthal, M.G. (1993). Simulator Sickness Questionnaire: An enhanced method for quantifying simulator sickness. *International Journal of Aviation Psychology, 3*(3), 203-220.

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Participant nr	
Date	

Mini BEST

	Scoring noVR	Scoring withVR	Feasibility in VR (Y/N)	BOR (0-10)	Remarks
1.Sit to Stand					
2. Rise to Toes					
3. Stand on one Leg					
4. Compensatory stepping correction – forward					
5. CSC – Back					
6. CSC – lateral right					
6. CSC lateral left					
7. Stance: eyes open, firm surface					
8. Stance: eyes closed foam surface					
9. incline – eyes closed					
10. Change in gait speed					
11. Walk with head					

turns horizontal					
12. Walk with pivot turns					
13. Step over obstacles					
14.1 TUG					
14.2 TUG Dual Task					

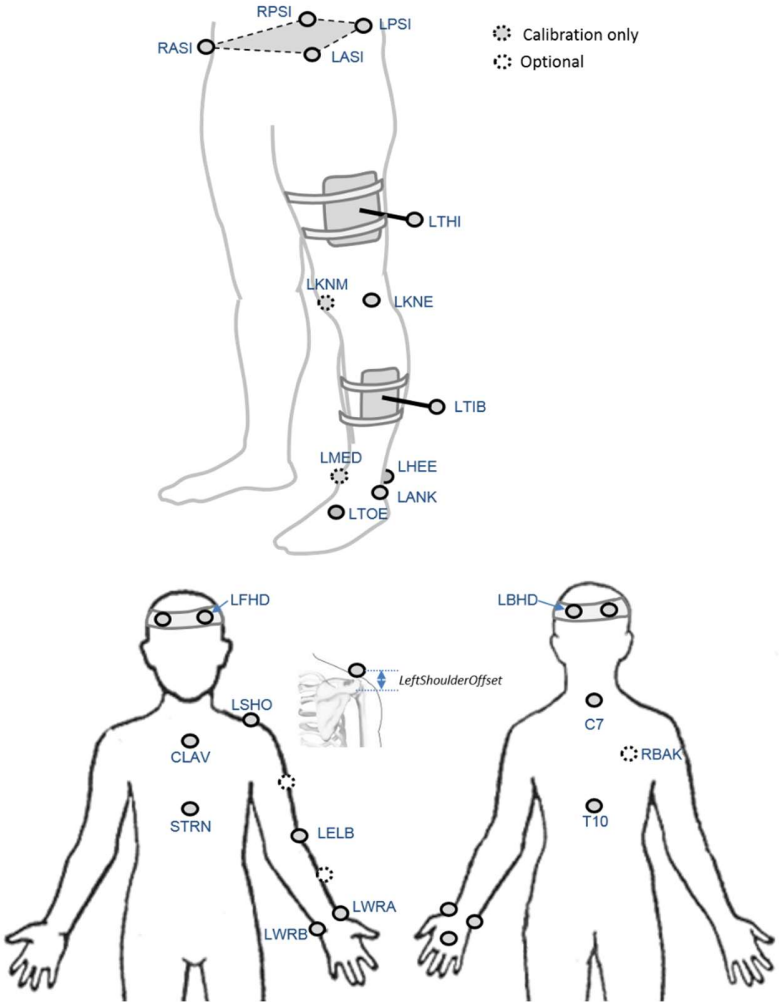


Figure 1: CGM21 and 22 markerset