



VNIVERSITAT
DE VALÈNCIA

Virtual Gait System Intervention in Older People (NCT05273229); 2022-01-01
STUDY PROTOCOL



Volunteers aged over 65 years were recruited through different older people's associations (i.e., *La Nau Gran* and *Asociación Grupo de Mayores de Telefónica*). The inclusion criteria were the following: i. elderly people (> 65 years), ii. pre-frail or frail based on the Fried criteria, iii. ability to walk with or without aids, and iv. ability to understand instructions (Mini-Mental State Examination > 23 points). Exclusion criteria were the following: i. traumatic pathology, ii. alterations of the central or peripheral nervous system, iii. alterations of the vestibular system, and iv. concomitant diseases.

Participants were divided into two intervention arms: Experimental Intervention (EI) group, in which VR and gait-specific physical exercises were administered and Control Intervention (CI) group, in which placebo virtual gait and the same exercise programme were administered. The allocation procedure used was the simple randomisation method with the Random Allocation Software conducted by an external assistant who was blinded to the study objectives. Randomisation and disclosure of group assignment occurred after the first evaluation session.

Pre-treatment assessment was conducted by a researcher blinded to group allocation (T1). The assessment procedure was repeated by the same researcher at the end of the 8-week treatment (T2) and four weeks after the end of the intervention (T3).

Interventions

Both interventions (EI and CI) lasted 8 weeks (3 days per week), and the sessions were carried out in groups of 4 people. Researchers recorded any adverse effects in each session.

EI consisted of 10 min of VR and 35 min of PE, while CI included 10 min of placebo VR and 35 min of PE:

- For the VR, the participant was placed in a standing position (with an ad-hoc-designed help system) in front of a mirror (upper body) and a screen (lower body) where a video of legs running on a treadmill was projected. The projected legs were adapted to each subject according to their height and weight.
- For the placebo VR, the set-up and duration were the same as for VR, although videos of landscapes without featuring any type of human or animal movement were projected, since mirror neurons do not report activation in response to the movement of objects.



- PE: lower-limb exercises were carried out for 35 min, including coordination, strength, balance and stretch exercises. The Borg Scale was used to measure each person's perception of their effort and exertion, breathlessness, and fatigue during each physical exercise. This scale was shown high reliability (ICC = 0.85-0.91).