Brief Title *Mindfulness Intervention Using Virtual Reality in Older Adults With Symptoms of Anxiety and Depression in Ecuador*

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Study design and participants

The study was a two-arm randomized controlled trial employing a delayed-start design, in which participants were randomized to either an immediate intervention group (experimental group) or a control group that received the intervention after a waiting period.

The objective was to evaluate the efficacy, acceptability, and feasibility of a ten-session mindfulness-based virtual reality intervention for older adults with symptoms of anxiety and depression in Ecuador. The intervention effects were assessed by comparing outcomes between the experimental group and a control group on a waiting list.

Participant recruitment took place between March and November 2023. The intervention began in March 2023 and continued until April 2024 as participants completed the ten-session program and follow-up assessments. Participants were recruited in Quito, Ecuador, through social media announcements and outreach at daytime clubs offering activities for older adults. Recruitment targeted community-dwelling older adults rather than individuals residing in institutional care settings.

A total of 158 individuals initially completed the screening process. Of these, 74 did not meet the inclusion criteria and were excluded from the study. The remaining 84 participants met the eligibility criteria and were enrolled in the study. Participants were assessed in person by researchers to ensure they met the inclusion criteria: non-institutionalized older adults aged sixty years or older who had the capacity to give consent and who had minimal cognitive impairment, anxiety, and depressive symptoms (CES-D >16 or GAD-7 >10). Exclusion criteria included a diagnosis of acute psychosis or mania; severe to moderate dementia (MoCA score <18); physical impairment affecting movement; blindness; hearing impairment; psychiatric disorders affecting the capacity to consent or comprehend the study; and dizziness of moderate to severe intensity. Assessments were conducted in person at participants' homes or in private spaces within community centers.

Randomization and blinding

The study was approved by the Human Ethics Committee of Universidad San Francisco de Quito (approval number: P22-034M). Potential participants first completed a screening procedure to determine eligibility. Those who met the inclusion criteria provided informed consent prior to participation. All data were anonymized and stored securely on password-protected institutional servers accessible only to the research team. Participants then completed the baseline assessment.

A total of 84 eligible participants were randomized. The random allocation sequence was generated by an independent third party, not involved in the study, using a computer-based random number generator. Simple randomization was used to ensure that each participant had an equal probability of being assigned to either the experimental or control group. The sequence produced 84 allocations labeled as experimental (E) or control (C).

Each allocation was placed in a sealed, numbered envelope prepared by the independent third party. The envelope number corresponded to the participant identification number and the initial of the group assignment. The envelopes were stored in an opaque bag, and at the time of participant enrollment, the researcher drew one envelope without opening it to determine group assignment. After the envelope was opened, participants were informed of their allocation. Due to the nature of the intervention, participants and psychologists delivering the sessions were not blinded to group allocation.

Intervention

Participants assigned to the experimental group received a weekly mindfulness session using virtual reality (VR) goggles for 10 weeks, beginning immediately after the baseline assessment Participants assigned to the control group underwent a 10-week waiting period. During this period, they received a brief weekly phone call to assess their emotional state, physical activity, and eating habits, and to maintain regular contact with the research team. The calls followed a structured script, lasted approximately 10 minutes, and were conducted by the same psychologists who delivered the intervention. During each call, participants' responses were transcribed and recorded in the study documentation. After the waiting period, participants in the control group also received the 10-session VR-assisted mindfulness intervention. .

All sessions were conducted individually, either in participants' homes or in quiet, private spaces in community settings, to minimize interruptions and ensure a comfortable environment for the intervention. The VR experience was delivered using the Sites in VR platform (http://www.sitesinvr.com), which provides immersive 360° environments. Natural landscape scenes available within the platform were used to facilitate the mindfulness exercises.

Each session lasted approximately 45 minutes and began with a 15-minute guided meditation delivered according to the intervention manual. During the VR experience, participants were guided by a trained psychologist to explore a virtual natural environment while focusing on the sensory aspects of the scene, including imagined sounds, smells, textures, and sensations of movement, to enhance immersion and attentional focus. Following the VR experience, participants engaged in a brief reflection and

discussion with the psychologist regarding their experience. All sessions were audio- and video-recorded to ensure adherence to the intervention protocol and consistency across sessions. Recordings did not include participants' identities; only the researchers were identifiable. Participants' attendance at each session was monitored to assess adherence.

Measurement

Several validated instruments were used to assess the study variables. All measures included in the study have demonstrated adequate reliability and validity in previous research and have been used in Spanish-speaking populations. A sociodemographic questionnaire collected information on sex, age, marital status, education level, and preexisting health conditions. The outcomes assessed included depression, anxiety, perceived stress, daily functioning, cognitive functioning, mindfulness, and dizziness.

Depressive symptoms were assessed using the 20-item Center for Epidemiologic Studies Depression Scale (CES-D) which measures the frequency of depressive symptoms experienced during the previous week. Items are rated on a 4-point scale ranging from less than one day to five days, with higher scores indicating greater depressive symptomatology.

Depressive symptoms were also evaluated using the Geriatric Depression Scale (GDS-15), a 15-item screening instrument specifically designed for older adults. Items are answered in a dichotomous yes/no format, with total scores ranging from 0 to 15. Scores of 0–4 indicate no depressive symptoms, whereas scores of 5 or higher suggest the presence of depressive symptomatology.

Anxiety was assessed using the Generalized Anxiety Disorder Scale (GAD-7) a seven-item self-report measure assessing the frequency of core symptoms of generalized anxiety disorder during the previous two weeks. Items are rated on a four-point scale ranging from "not at all" to "nearly every day," with higher scores indicating greater anxiety severity.

Perceived stress was assessed using the 10-item Perceived Stress Scale (PSS-10) which assesses the degree to which individuals perceive situations in their lives as stressful over the past month. Items are rated on a five-point Likert scale from 0 (never) to 4 (very often), with higher scores reflecting greater perceived stress.

Behavioral functioning in daily life was assessed using the Behavioral Activation for Depression Scale (BADS) a 25-item self-report measure assessing levels of behavioral activation and avoidance associated with depression. Items are rated on a seven-point Likert scale ranging from 0 (not at all) to 6 (completely), with higher scores indicating greater behavioral activation and engagement in goal-directed activities.

Cognitive functioning was screened using the Montreal Cognitive Assessment (MoCA) a brief cognitive screening tool designed to detect mild cognitive impairment. The MoCA evaluates attention, executive functioning, memory, language, visuospatial abilities, abstraction, calculation, and orientation. Scores range from 0 to 30, with scores of 26 or higher generally considered within the normal range.

Mindfulness was measured using the Mindfulness Attention Awareness Scale (MAAS) a 15-item self-report scale assessing the tendency to maintain attention and awareness of present-moment experiences. Items are rated on a six-point Likert scale, with higher scores reflecting greater mindfulness.

Dizziness and vertigo symptoms were assessed using the Dizziness Handicap Inventory (DHI) a 25-item questionnaire evaluating the functional, emotional, and physical impact of dizziness on daily life. Responses are scored as 0 (no), 2 (sometimes), or 4 (yes), with higher scores indicating greater perceived disability.

All instruments were administered by trained researchers following standardized procedures at pre-screening and post-intervention (or after the waiting period for the control group), except for the DHI, which was administered after each intervention session. The experimental group was additionally assessed at the 1-month follow-up.

Statistical analysis

To determine the effect of the VR intervention on the outcome measures, the investigators employed linear mixed-effects models with random intercepts for groups (experimental vs. control) and time points (baseline, post-intervention, and 1-month follow-up), including a group × time interaction term. Random intercepts were modelled at the participant level. This model specification enabled a comparison of differences in outcome trajectories after the experimental and control interventions within a single model. Separate regression models were performed for each outcome variable (i.e., CES-D, GDS-15, GAD-7, BADS, and MAAS total scores). Covariates were age, gender, whether the participant currently practiced yoga/meditation, and whether the participant was actively undergoing psychological or psychiatric treatment. Residual diagnostic plots for all models were inspected visually to confirm that linear regression model assumptions were met.

All primary analyses were adjusted for multiple comparisons using the Benjamini-Hochberg procedure based on false discovery rate (FDR). A total of ten comparisons were corrected, given that two comparisons were performed for each outcome variable

(experimental POST vs control WAIT and experimental F/U vs control POST). A statistical significance threshold of FDR $p < .05$ was used for the primary analysis. All statistical analyses were performed using R version 4.2.2.