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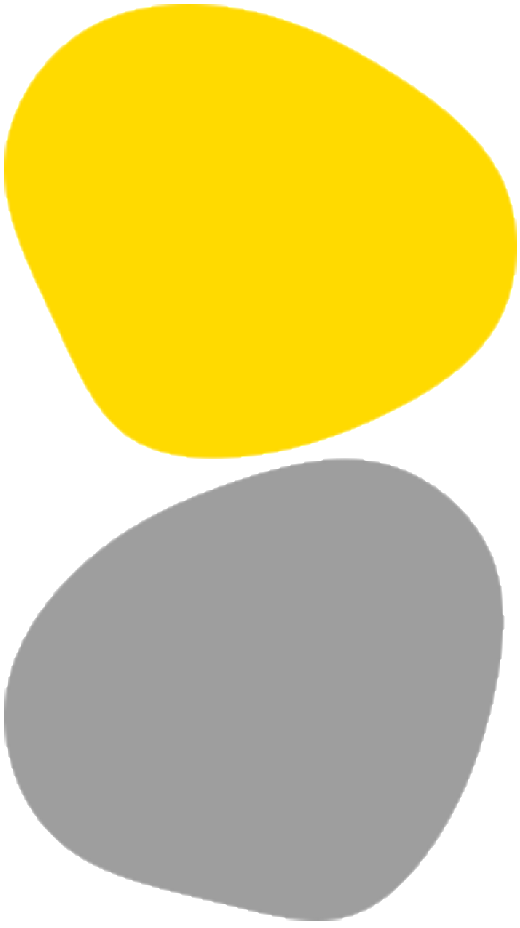
The Impact of a Virtual Reality Exposure Therapy Program on Well-being and Social Participation in Individuals with Social Phobia: study protocol of a randomized controlled trial

Beatriz Isabel Maia da Silva



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The Impact of a Virtual Reality Exposure Therapy Program on Well-being and Social Participation in Individuals with Social Phobia: study protocol of a randomized controlled trial

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Resumo

A ansiedade de falar em público constitui uma manifestação frequente da fobia social, com repercussões significativas no desempenho académico e profissional de estudantes do ensino superior. Estratégias tradicionais de intervenção têm demonstrado eficácia limitada, pelo que a realidade virtual (RV) surge como alternativa promissora.

Este protocolo descreve um ensaio clínico randomizado destinado a avaliar a viabilidade e eficácia de uma intervenção em RV na redução da ansiedade de apresentação oral e na perceção de competência comunicacional. O estudo segue um desenho de grupos paralelos, envolvendo estudantes do ensino superior alocados a um grupo experimental (simulações em RV) ou de controlo (métodos tradicionais). A intervenção integra uma componente teórica online e uma prática presencial.

Os resultados serão recolhidos em quatro momentos (T0–T3) através da Public Speaking Anxiety Scale (PSAS) e da Public Speaking Self-Assessment Scale (PSSAS). Durante a prática, serão obtidos dados fisiológicos com recurso ao Biosignalplux. A análise estatística será conduzida no SPSS v30, recorrendo a estatística descritiva e inferencial para testar as hipóteses.

O estudo obteve aprovação da Comissão de Ética da Escola Superior de Saúde do Politécnico do Porto. Todos os participantes fornecerão consentimento informado, sendo garantida a confidencialidade e o cumprimento do RGPD.

Palavras-chave: Ansiedade de Falar em Público; Realidade Virtual; Estudantes do Ensino Superior; Protocolo de Estudo

Abstract

Anxiety about public speaking is a common manifestation of social phobia, with significant repercussions on the academic and professional performance of higher education students. Traditional intervention strategies have shown limited effectiveness, so virtual reality (VR) emerges as a promising alternative.

This protocol describes a randomised clinical trial designed to assess the feasibility and effectiveness of a VR intervention in reducing oral presentation anxiety and improving perceived communication competence. The study follows a parallel group design, involving higher education students allocated to an experimental group (VR simulations) or a control group (traditional methods). The intervention includes an online theoretical component and a face-to-face practical component.

Results will be collected at four points in time (T0–T3) using the Public Speaking Anxiety Scale (PSAS) and the Public Speaking Self-Assessment Scale (PSSAS). During the practical component, physiological data will be obtained using Biosignalplux. Statistical analysis will be conducted in SPSS v30, using descriptive and inferential statistics to test the hypotheses.

The study has been approved by the E2S Ethics Committee of the Polytechnic of Porto. All participants will provide informed consent, and confidentiality and compliance with the GDPR will be guaranteed.

Keywords: Anxiety about Public Speaking; Virtual Reality; Higher Education Students; Study Protocol

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1. Introduction

1.1. Background and Rationale

Social phobia, particularly glossophobia (fear of public speaking), is a growing problem that significantly affects individuals' quality of life, academic performance and social integration. In a context where communication skills are increasingly valued, especially in higher education, it is essential to explore new therapeutic approaches that respond effectively, accessibly, and personally to the needs of young adults (Fehlmann et al., 2020; Gorinelli et al., 2023; Jim et al., 2025; Lacey et al., 2024; Lindner et al., 2019; Reeves et al., 2021; Shahid et al., 2024).

Anxiety disorders encompass a range of clinical conditions, including social anxiety disorder (SAD), also known as social phobia. This is characterised by an intense and persistent fear of social situations in which individuals may be observed, evaluated or criticised by others (Leichsenring & Leweke, 2017a; Melkam et al., 2023; Salehi et al., 2020).

SAD is one of the most prevalent mental disorders in the general population, with an estimated lifetime prevalence of between 12% and 16%. Anxiety disorders as a whole affect approximately 24.9% of individuals over their lifetime, with SAD accounting for around 13.3% of this burden (Kessler et al., 2012; Melkam et al., 2023; Pelissolo et al., 2019). Its prevalence is higher among women, younger individuals, those with lower levels of education, low socioeconomic status, and reduced social support (Reinhorn et al., 2020; Stein et al., 2017).

In addition, SAD is often associated with psychiatric comorbidities, presenting an increased risk of simultaneous occurrence of depressive disorders, other anxiety disorders, and substance use disorders. Symptoms usually begin between the ages of 10 and 19 and can persist into adulthood if left untreated (Pelissolo et al., 2019; Steinert et al., 2013). Compared to the general population, individuals with SAD are more likely to seek medical services, as well as to suffer from social dysfunction and disabilities that compromise productivity, functionality, and autonomy (Park et al., 2021; Pelissolo et al., 2019a).

Although the association between this phobia and physical illnesses is not yet well established, studies indicate that the physical and cognitive limitations associated with chronic diseases such as multiple sclerosis, rheumatoid arthritis, or inflammatory bowel disease can exacerbate an individual's difficulties in interacting in social contexts. (Reinhorn et al., 2020). Thus, it can be concluded that social phobia is a costly condition that compromises social, occupational, and recreational functioning, limiting the individual's active participation in society (Park et al., 2021; Stein et al., 2017).

The aetiology of social phobia involves a complex interaction between individual and environmental factors. (Spence & Rapee, 2016). Among individual factors, genetic influences, cognitive and behavioural

traits associated with specific emotional and cerebral characteristics stand out (Pelissolo et al., 2019). Neuroimaging studies show greater activation of the amygdala and fronto-striatal circuits in response to negative or threatening social stimuli (Nagata et al., 2015; Pelissolo et al., 2019). Among environmental factors, family factors and socioeconomic context stand out (Pelissolo et al., 2019a; Showraki et al., 2020).

According to clinical guidelines, Cognitive Behavioural Therapy (CBT) is the recommended first-line treatment for SAD. However, its accessibility is often limited, either by the availability of therapists or by long waiting times (Bandelow et al., 2022; Hickie et al., 2019; Leichsenring & Leweke, 2017b; Pelissolo et al., 2019b; Zwanzger et al., 2021). In response, innovative digital interventions have emerged, such as psychoeducation and self-directed behavioural tools (Hildebrand et al., 2022; Salehi et al., 2020), in which it stands out among these innovations, virtual reality (VR) what has emerged as a promising approach. This technology allows for the creation of controlled social scenarios in which individuals can be gradually exposed to anxiety-provoking situations in a safe virtual environment. This progressive and controlled exposure facilitates confrontation with social fears, while allowing for personalisation of the therapeutic process without the need for direct contact with real-life contexts (Caponnetto et al., 2021; Wolitzky-Taylor & LeBeau, 2023).

The integration of VR with CBT and exposure techniques contributes to more frequent, accessible, and personalised interventions, reducing waiting times and expanding access to treatment (Caponnetto et al., 2021; Morina et al., 2023; Pelissolo et al., 2019). This combination allows digital tools to complement and reinforce traditional therapeutic approaches, promoting greater clinical effectiveness (Andrews & Likis, 2015; Ranganathan & Aggarwal, 2018).

Many individuals with social phobia find it difficult to seek help due to discomfort in traditional therapeutic settings. In this context, VR emerges as an alternative that offers a private space where patients can practise social interactions without the stigma of public exposure (Caponnetto et al., 2021b; Hildebrand et al., 2022). Immersive repetition of social situations allows patients to gradually develop social skills, correct mistakes in real time, and get immediate feedback without any real negative consequences (Caponnetto et al., 2021; Shahid et al., 2024). In addition, scientific studies show that VR exposure therapy can be as effective as real exposure. Some research indicates that VR may even reduce the time needed to achieve significant improvements (Carl et al., 2019; Hildebrand et al., 2022; Horigome et al., 2020; van Loenen et al., 2022). Its flexibility allows therapies to be carried out in more comfortable environments with greater control by therapists (Hildebrand et al., 2022; Horigome et al., 2020).

Recent studies indicate that exposure to virtual reality environments can trigger physiological responses (increased heart rate and sweating) similar to those experienced in real emotional situations (Kisker et al., 2021; Marín-Morales et al., 2019; Weijs et al., 2023). This effect goes beyond what simple imagination or mental visualisation can achieve, providing a level of realism that favours training and habituation. Such technological advances have been explored in clinical and educational contexts, including Occupational Therapy, which focuses on promoting functionality and independence in activities of daily living. In this scenario, virtual reality stands out as a promising tool in the treatment of social phobias, such as glossophobia, especially when integrated into the practice of occupational therapists to facilitate social participation and occupational performance (Maples-Keller et al., 2017; Tsamitros et al., 2023).Thus, the combination of VR with other therapeutic approaches, such as relaxation and mindfulness techniques, creates complex interventions that aim not only to reduce anxiety symptoms but also to improve cognitive skills essential for communicative performance, such as thought organisation, eye contact, and self-confidence.

The fear of public speaking (glossophobia) is classified in the Domain as a barrier to occupational performance, interfering with participation in academic, professional, and social contexts. Within the Process, the use of virtual reality can be structured as a client-centred intervention, involving initial assessment, definition of functional goals, implementation of gradual training in a safe and controlled environment, and evaluation of results. This approach, based on the Occupational Therapy Practice Framework (OTPF), reinforces the role of Occupational Therapy in promoting functionality, independence, and social participation (Gomes & Ribeiro, 2021)

Taking these factors into account, this study aims to evaluate the effectiveness of a VR environment in the treatment of social phobia, comparing the effects of VR exposure therapy with traditional methods in the treatment of glossophobia in higher education students.

1.2. Objectives and hypotheses

The main purpose of this study is to contribute to the scientific understanding of the effectiveness of virtual reality (VR) exposure therapy in the context of social phobia, with a particular focus on glossophobia, or fear of public speaking. Thus, its main objective is to evaluate the effectiveness of virtual reality exposure therapy in reducing anxiety associated with glossophobia in higher education students, in the context of oral presentations.

Specific Objectives:

- Compare the effects of virtual reality exposure with those of the traditional method in reducing anxiety in public speaking situations;
- Assess the evolution of participants' perception of communication over different moments;

Research Hypotheses:

- H1: Participants who undergo the virtual reality intervention will show a reduction in social anxiety levels (assessed using the PSAS) compared to participants in the control group.
- H2: The improvement in perceived communication competence (assessed using the PSSAS) in the experimental group will be greater than that observed in the control group.
- H3: Participants in the experimental group will show a reduction in anxiety compared to the control group, as measured by physiological markers.

2. Methods

2.1. Patient and Public Involvement

This study was developed with a strong emphasis on the practical relevance of the intervention for its target population, grounded in both scientific evidence and needs identified within the academic context. To inform the methodological decisions, intervention design, and selection of assessment instruments, data from previous studies and the most current literature concerning social anxiety in higher education students.

2.2. Trial Design

This study is structured based on the most recent guidelines (SPIRIT updated guideline for protocols of randomised trials), taking the form of a randomised clinical trial (RCT) designed to identify, evaluate and interpret the relationships between measurable variables: specifically, social anxiety levels and the perception of communication skills within an academic context. The research unfolds across multiple intervention phases, allowing us to observe participants' evolution at various time points (Chan et al., 2025; Hróbjartsson et al., 2025).

A parallel-group design with two comparison arms was defined: an experimental group receiving a virtual reality (VR) intervention and a control group undergoing a traditional intervention without VR. Participants will be randomly allocated to groups using simple randomization with a 1:1 ratio, generated by an external investigator not involved in the intervention to ensure allocation concealment. Whenever

possible, investigators collecting data will also be blinded to reduce potential bias during the administration of psychometric instruments.

This trial operates within an exploratory paradigm as a pilot study. Its primary objectives are to assess the feasibility of the VR intervention and conduct a preliminary analysis of its therapeutic effects. From an ethical standpoint, the authors have commited to ensuring committed to ensuring all participants benefit from the VR intervention. This means the control group will receive a second practical phase with VR after completing the initial comparative phase.

2.3. Trial Setting

The trial will take place in an academic setting, specifically at the Escola Superior de Saúde do Politecnico do Porto (E2S), involving higher education students as the target population. All phases of the study – from the administration of the initial questionnaires to the implementation of practical sessions using virtual reality – will take place in controlled environments within the institution that have been prepared in advance for this purpose.

The virtual reality intervention sessions will be held in a specific room equipped to ensure a controlled, comfortable and immersive environment. This space will be selected based on technical suitability criteria, namely lighting, ventilation, privacy and safety, in order to avoid external distractions and ensure the well-being of participants.

The theoretical component of the training will be made available online via the Moodle platform, allowing for greater flexibility in student participation and academic time management.

In this way, the study combines a hybrid approach (face-to-face and online), ensuring accessibility, experimental control, and respect for participants' routines and commitments.

2.4. Eligibility Criteria

The sample for this study will consist of higher education students from different academic institutions. Participation is voluntary, and participants have the right to withdraw at any time without penalty. All data collected will be treated confidentially and anonymously, ensuring compliance with ethical principles and the General Data Protection Regulation (GDPR).

The inclusion criteria will include the following: (a) being between 18 and 40 years of age; (b) being regularly enrolled in a higher education institution; (c) being fluent in Portuguese; (d) Perception of intense anxiety or fear associated with public speaking situations. Exclusion criteria will include the following: (a) diagnosis of severe mental disorders that may compromise participation in the study; (b) previous

experience with virtual reality devices, in order to avoid biases related to technological familiarity; (c) medical conditions that contraindicate the use of virtual reality (e.g., epilepsy, severe vertigo); (d) pregnancy; (e) significant cognitive deficits; (f) uncorrected visual problems that prevent the proper use of VR glasses.

2.5. Interventions

This study compares two types of intervention for training communication skills in higher education students with glossophobia. The experimental group will undergo a programme using virtual reality (VR), and the control group will undergo a programme using traditional methodology (without VR).

Both groups will participate in structured training consisting of eight modules, involving theoretical and practical components. The theoretical component will take place online, via the Moodle platform (Figure 1 and Figure 2). The practical component will include face-to-face sessions (control group) and face-to-face sessions with VR technology (experimental group).

The practical sessions for the experimental group will take place in a controlled environment equipped with Oculus Quest 2 (Meta®) headsets, with motion sensors and integrated ambient sound. The application used will be Virtual Orator™, a platform developed specifically to simulate public presentations in realistic three-dimensional scenarios. This platform allows the number of audience members, facial expressions, behavioural reactions and other environmental parameters to be adjusted to customise the degree of difficulty (Figueres 3 to 7). All sessions will be accompanied by a trained with experience in mental health field, who will monitor the process in real time and ensure the safety of participants.

The control group will participate in the same theoretical sessions and in the practical component with simulations in traditional format (without the use of VR), consisting of face-to-face presentations, public speaking exercises, and role-play. This approach replicated the communication dynamics of a classroom or academic environment and will be supervised by researchers.

After completion of the main phase of the study, this group will also have access to an adapted version of the practical module with VR, to ensure equal access to the experimental intervention, as we can see in Table 1.

The training will be organised as follows:

- Modules 0 to 5 (online format): theoretical content on effective communication, communication styles, speech preparation, verbal and non-verbal expression, anxiety management, relaxation techniques and self-confidence development;

- Module 6 (face-to-face practice): practical simulations adapted to the group (VR or traditional method), with recorded presentations, peer feedback, self-assessment and specialised guidance;
- Module 7 (online): performance assessment and development of a continuous development plan;
- Module 6 – version 2: reserved exclusively for the control group, allowing them to experience the simulation with virtual reality after the main intervention;

Table 1: Course Plan

Modules	Main Content	Sessions
Module 0	Introduction	Session nº 0
Module 1	Fundamentals of Public Communication	Session 1, 2
Module 2	Presentation Preparation	Session 3, 4
Module 3	Verbal and Non-Verbal Expression Techniques	Session 5, 6
Module 4	Structure of Speeches and Presentations	Session 7, 8
Module 5	Anxiety Management and Self-Confidence Building	Session 9, 10
Module 6	Hands-on Simulation with or without VR	Session 11, 12, 13
Module 7	Post-presentation and Continuous Development Plan	Session 14, 15
Module 6 (control group - version2)	Posterior contact with VR	Session 11, 12, 13

To maximise adherence to the intervention, the following strategies will be adopted: (a) flexible schedules compatible with participants academic routines; (b) provision of asynchronous online sessions to facilitate access; (c) individual monitoring of attendance at sessions; (d) continuous supervision and technical support during VR sessions; (e) continuous positive reinforcement and personalised feedback. This protocol provides for concomitant care, intervening with students who present subclinical symptoms of anxiety, that is, symptoms that do not meet the formal diagnostic criteria for an anxiety disorder according to the DSM-5.

Figure 1. Course Plan

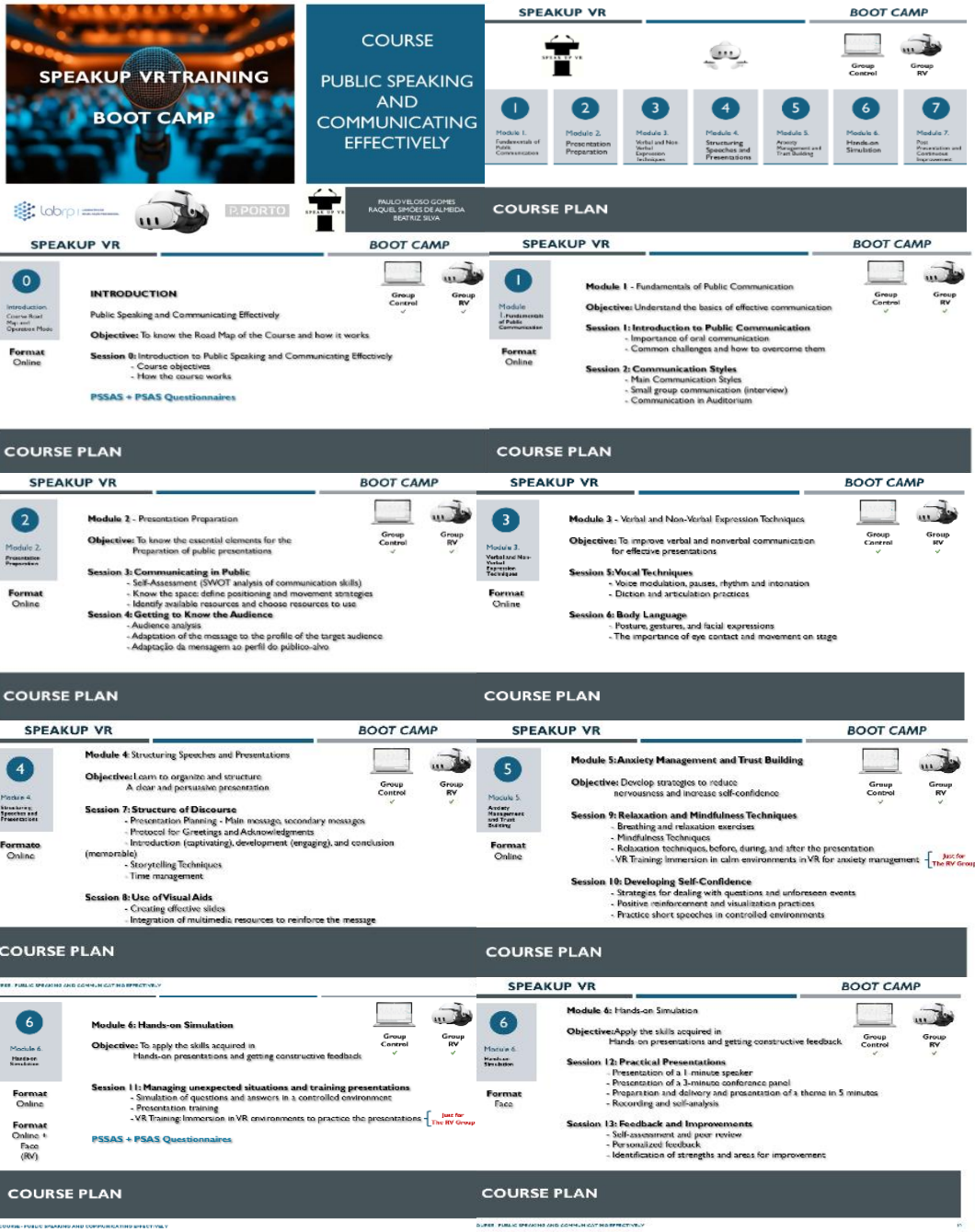

Figure 2. Course Plan

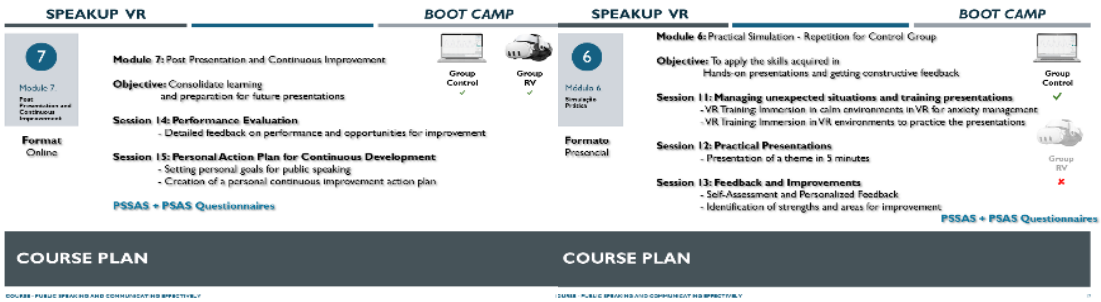

Figure 3. Personalization by number of participants – 0%

Figure 4. Personalization by number of participants –25%

Figure 5. Personalization by number of participants – 50%

Figure 6. Personalization by number of participants – 75%

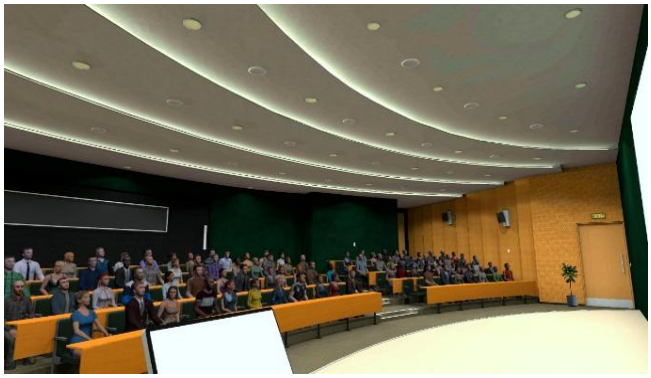

Figure 7. Personalization by number of participants – 100%

2.6. Outcomes

Considering the main objective of the study, the primary outcome will be defined as the level of social anxiety in public speaking contexts and the perception of communication competence in oral presentation contexts.

The level of social anxiety in public speaking contexts will be measured using the portuguese version of Public Speaking Anxiety Scale (PSAS) (Bartholomay & Houlihan, 2016; Silva Soares et al., 2020). This scale includes 16 items assessed on a Likert scale, with high reliability (α = 0.97 in the Portuguese version validated by Silva Soares et al., 2020). The perception of communication competence in oral presentation contexts will be assessed by the portuguese version of Public Speaking Self-Assessment Scale (PSSAS) (Hofmann & DiBartolo, 2000; De Lima Osório et al. 2008), consisting of 10 items with responses on a scale from 0 to 5. The Portuguese version demonstrated excellent reliability (α = 0,90 – De Lima Osório et al., 2008).

Measurements will be taken at three points in time: (a) before the intervention (baseline); (b) after the theoretical component; (c) after the practical component (post-intervention). In the control group, an additional assessment will be carried out after the VR simulation for comparative purposes.

Secondary outcomes will include acceptability and adherence to the intervention and complementary exploratory indicators, such as perceived self-efficacy in public communication situations and underlying physiological reactions. Acceptability and adherence to the intervention will be measured by recording attendance at sessions, number of dropouts, and qualitative feedback from participants. Biosignalsplux has an 8-channel wireless board and two dedicated sensors that accurately measure the skin's electrodermal activity (EDA) and heart rate (HR) (Affanni, 2020). EDA is a measure of sympathetic nervous system activity that is closely correlated with stress levels and emotional state, particularly in anxiety-inducing circumstances (PLUXBiosignals | Electrodermal Activity (EDA) Sensor, n.d.) As one of the main markers of physiological activity in stressful circumstances, heart rate variability will be observed by the HR sensor while individuals' heart rates are monitored.

Data will be collected through digital questionnaires, completed before, during, and after the intervention. All data collection was conducted by trained researchers, following standardised scripts, under controlled conditions.

2.7. Participant Timeline

The participant's schedule was structured to allow for monitoring of individual progress throughout all phases of the study, respecting their academic availability. The timeline of each participant's involvement follows four main data collection moments, which coincide with specific stages of training, as shown in Table 1.

Table 1: Time frame for the different stages of training

Fase	Moment	Experimental Group	Control Group
T0	Pre-intervention (baseline)	- Informed consent - Sociodemographic questionnaire - PSAS- PSSAS	- Informed consent - Sociodemographic questionnaire - PSAS- PSSAS
T1	Theoretical post-component	PSAS- PSSAS	PSAS- PSSAS
T2	Post-Practical Component	PSAS- PSSAS	PSAS- PSSAS
	During Practice Component	Biosignalplux	Biosignalplux
T3	VR post-exposure (control group)	–	PSAS- PSSAS
	During Practice Component	Biosignalplux	Biosignalplux

2.8. Sample Size

The sample size was determined based on feasibility and accessibility criteria, rather than a formal statistical power calculation. This decision was based on the following factors: (a) the logistical complexity of organising the practical sessions, spread over several training phases; (b) the need to reconcile participation with the students' academic commitments; (c) the limited technical and human resources available, namely the number of virtual reality devices and personnel trained to monitor them; (d) the purpose of the study, which focused on assessing the feasibility of the intervention and collecting preliminary data for future larger-scale randomised trials.

This sampling method considers the availability and voluntary interest of students in participating in the various phases of the study, which will allow for more stable adherence over time.

2.9. Recruitment

Recruitment channels and methods will be used, such as: (a) direct dissemination on the institutional platforms of the higher education institutions involved; (b) announcements on physical and virtual notice boards (e.g. Moodle); (c) contact via institutional email; (d) presentation of the study in face-to-face classes and information meetings; (e) individualised invitation to eligible students, based on availability and demonstrated motivation.

All potential participants will be duly informed about the objectives, phases and conditions of the study before agreeing to participate. The information will be provided through an informed consent document, which will include the rights of participants, the procedures to be adopted, the benefits of participation, as well as the guarantee of anonymity and confidentiality of data.

2.10. Assignment of Interventions

Participants will be assigned to the experimental (virtual reality) and control (traditional method) groups through simple randomisation, using a random number generator, such as the RAND function in Microsoft Excel or the Random.org platform.

The allocation sequence generated will be kept confidential by an external investigator not involved in the intervention, ensuring allocation concealment. In this way, the investigators responsible for data collection and monitoring of the intervention will not have prior access to the allocation of participants, minimising potential selection bias.

The researchers involved in collecting psychometric data will be kept blind to the participants' experimental condition. This measure was intended to reinforce impartiality in the application of the questionnaires and ensure consistency in data monitoring.

In cases where blinding was not feasible (namely in practical sessions), standardised procedures and strict guidelines were adopted to minimise interference in the interaction with participants and in the interpretation of results.

No formal unblinding procedures are planned, as participants did not receive interventions with relevant therapeutic risk. However, any situation requiring clarification of the assigned condition will be managed by the responsible investigators, with a record of justifications and potential impact on the analysis of results.

2.11. Data Collection and Management

Data collection will be carried out through online questionnaires. As previously said,data will be collected using several instruments, including the Sociodemographic Questionnaire, the Public Speaking Anxiety Scale (PSAS), the Public Speaking Self-Assessment Scale (PSSAS), and records of attendance and participation. All questionnaires will be administered at three main time points: T0 (baseline); T1 (post-theoretical component); T2 (post-practical component); and T3 (only for the control group, after the VR experience). During their speeches, participants will use a heart rate monitor to track their heart rate and a galvanic response sensor to observe their electrodermal activity, allowing for the analysis of these physiological measurements (Table 1).

To ensure data quality, the following measures will be implemented: (a) automatic validation of responses in online forms (mandatory fields, scale limits); (b) manual verification of paper questionnaires before scanning; (c) training of researchers on standardised application procedures; (d) control of duplications and input errors; (e) cross-checking of data by two members of the research team.

The data collected will be organised into digital files, with access restricted to the research team. Data management will be carried out in accordance with the principles of the General Data Protection Regulation (GDPR). Access to the data will be restricted to members of the research team directly involved in the statistical analysis. Public access to the raw data is not planned, except upon justified request and ethical approval.

2.12. Statistical Methods

The statistical analysis of the collected data will be performed using IBM SPSS Statistics (version 28.0), adopting a significance level of 0.05 for all statistical tests.

Initially, a univariate descriptive analysis of the sociodemographic variables and dependent variables will be performed, calculating:

- Means and standard deviations (continuous variables);
- Absolute frequencies and percentages (categorical variables).

To assess the differences between the groups, inferential statistics will be used, employing the t-test and ANOVA.

As for normality tests, the distribution of dependent variables will be assessed using the Shapiro-Wilk test, complemented by graphical analysis (histograms, box plots, and Q-Q plots). This step will guide the choice between parametric and non-parametric tests in comparative analyses.

Regarding the comparative analysis between groups, to assess the effectiveness of the VR intervention, the evolution of results over time between the two groups will be compared:

- t-tests for independent samples or Mann-Whitney U tests for comparing differences between groups;
- t-tests for paired samples or Wilcoxon signed-rank tests for intra-group comparisons (pre- and post-intervention);

To compare three or more groups of data in a nonparametric way, the Kruskal-Wallis test should be used. This test is used when the data do not follow normal distribution, being an alternative to the ANOVA test. If there is a significant difference, it is common to perform post-hoc testing, such as the Dunn-Bonferroni test or the post-hoc jamovi comparison (DSCF), to identify which groups differ from each other.

These analyses will be applied to the PSAS and PSSAS scores at each assessment point (T0, T1, T2, T3).

The existence of missing data will be analysed in advance. In cases where data is missing at random (MAR), imputation of means or multiple regression methods may be considered, depending on the nature and extent of the omission. If the missing data compromises the analysis, participants may be excluded from the respective analysis (per protocol analysis).

The Wilcoxon test was used to compare the number of participants in relation to electrodermal activity (EDA) and heart rate (HR) between the first and subsequent presentations. This non-parametric test is suitable for comparing the median of the study population with a theoretical value (Marôco, 2018).

To compare EDA and HR values in the six public presentations using virtual reality, the Friedman test was applied. This non-parametric test is suitable for comparing two or more populations based on paired samples, where the dependent variable is at least ordinal (Marôco, 2018).

The electrodermal activity (EDA) signals will be processed through a fully automated pipeline implemented in Python 3.11.9, using the pandas, numpy, scipy and NeuroKit2 libraries. Data will be acquired with the BiosignalsPlux system at a sampling rate of 1000 Hz and stored as 16-bit digital values. To reduce artifacts associated with participant fit and movement, the first and last two minutes of each recording will be excluded from the analysis.

Raw digital values will be converted to skin conductance (µS) using the manufacturer's transfer function. The signals will subsequently be filtered with a fourth-order Butterworth low-pass filter at 5 Hz to suppress high-frequency noise while maintaining the relevant physiological components (< 3 Hz). The filtered data will be reduced to 20 Hz, providing a compromise between computational efficiency and signal fidelity.

Each recording will be divided into two three-minute segments (Start and End) to allow for intra-session comparisons. Signal decomposition will be performed using the eda_process() of the NeuroKit2, which extracts the tonic (skin conductance level, SCL) and phasic (skin conductance responses, SCRs) components.

For statistical analysis, the average SCL values will be calculated for each block and aggregated between sessions. These measures will be used to examine intra-session variability as well as intervention-related changes in autonomic arousal. The processed dataset will be exported to Excel format for subsequent analysis.

Heart rate (HR) data will be processed using a fully automated Python 3.11.9 pipeline with libraries such as pandas, numpy, and openpyxl. Raw HR data will be recorded using the Polar H10 system at 1 Hz and exported as Excel files. The first and last two minutes of each recording will be excluded to avoid movement artefacts and stabilisation of participants.

HR values outside the physiological range of 30 to 220 bpm will be filtered to remove artefacts. Heart rate values will be converted to RR intervals (ms) using the formula RR = 60000 / HR (bpm) to enable heart rate variability (HRV) analysis. An adaptive artefact filter will exclude RR intervals with changes greater than 20% between consecutive beats. After preprocessing, HRV metrics will be calculated in the time domain, including RR count, mean HR, RMSSD (reflecting parasympathetic activity), SDNN (general variability), and pNN50 (parasympathetic modulation). The processed data will be exported in Excel format for further analysis.

2.13. Monitoring

Given that this is a study without the administration of drugs or invasive procedures, an independent Data Monitoring Committee (DMC) will not be established. Overall supervision of the study will be provided by the research team responsible, composed of members with experience in research methodologies, the application of educational technologies, and psychological support in an academic context. This decision is in accordance with the guidelines for non-pharmacological intervention studies, in which the risk to participants is minimal.

During all phases of the intervention, safety and support measures were implemented to prevent situations of psychological or physical discomfort. Participants will be duly informed of the possibility of interrupting the session or withdrawing from the study at any time, without any prejudice or penalty. Any deviation from the original protocol must be recorded and justified in internal follow-up minutes.

2.14. Ethics and Dissemination

This study, under case number CE0060E (20/06/2024), was submitted to the E2S Ethics Committee for review and was approved. All procedures were conducted in accordance with the principles of the Declaration of Helsinki (2013) and the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679). Any relevant changes will be communicated to the competent ethics committee.

As this is a non-invasive study with no significant expected risks for participants, no additional care or post-study compensation is planned. In the event of any unforeseen circumstances, participants will be referred for appropriate institutional follow-up, with registration and reporting to the Ethics Committee.

Strict measures will be taken to ensure the confidentiality and anonymity of the data collected: (a) participants will be identified only by alphanumeric codes; (b) data will be stored in password-protected files on institutional servers; (c) access will be limited to the research team directly involved in statistical processing; (d) all data will be deleted after five years, in accordance with good research practice.

The results of the study will be disseminated at national and international scientific events, namely conferences, seminars, and meetings in the fields of occupational therapy, psychology, education, and pedagogical innovation. The data will also be published in a peer-reviewed scientific journal, preferably in open access.

All results will be presented in aggregate form, ensuring the protection of participants' identities. Priority will be given to sharing knowledge with the academic community and with the participants themselves, who may request a summary of the main results after the study is completed.

3. Discussion

Anxiety about public speaking remains one of the most prevalent fears among higher education students, negatively impacting their academic performance, self-esteem, and professional (Dwyer & Davidson, 2012; Russell & Topham, 2012). Despite the proven effectiveness of traditional intervention methods, such as behavioural training and cognitive restructuring, barriers to adherence persist, namely the absence of controlled environments and realistic exposure to the feared situation (Andrade et al., 2016; García-Lopez et al., 2020).

In this context, virtual reality (VR) emerges as an innovative and promising technology for simulating social situations in a safe, immersive environment that can be adjusted to the user's anxiety level. Recent studies point to its effectiveness in reducing social anxiety and improving communication skills, with emphasis on its applicability in an academic context (Parsons & Rizzo, 2008; Anderson et al., 2013; North et al., 2018). The integration of VR into psychoeducational programmes allows for a more engaging, personalised and motivating approach, enhancing the development of skills in higher education students (Maples-Keller et al., 2017).

By proposing a structured intervention using VR, this protocol aims to fill gaps identified in the literature, such as the absence of programmes contextualised to the Portuguese academic reality and the scarcity of experimental studies with methodological rigour in this area. The use of validated instruments, randomisation of groups and data collection at different times allow for a robust assessment of the intervention's effectiveness, in line with methodological recommendations for educational clinical trials (Chan et al., 2025; Hróbjartsson et al., 2025).

In summary, this study may contribute to the production of relevant knowledge about new methodologies for intervening in public speaking anxiety, promoting not only the well-being of students but also pedagogical innovation in higher education. Furthermore, the findings can be interpreted through the lens of the Model of Human Occupation (MOHO) (Kielhofner & Burke, 1980). By using virtual reality training as a meaningful activity, the intervention supports students' volition, fostering motivation and self-efficacy in communication. It also contributes to the development of new habits and roles (habituation), such as becoming more confident presenters in their academic and professional contexts. In terms of performance capacity, the intervention promotes regulation of physiological and emotional responses, enabling more effective occupational performance in situations that demand public speaking. Finally, the simulated but realistic environments created in VR highlight the importance of context in occupational engagement. From an Occupational Therapy perspective, this study illustrates how

innovative, technology-mediated approaches can strengthen participation, autonomy, and well-being in meaningful occupations that involve communication and social interaction.

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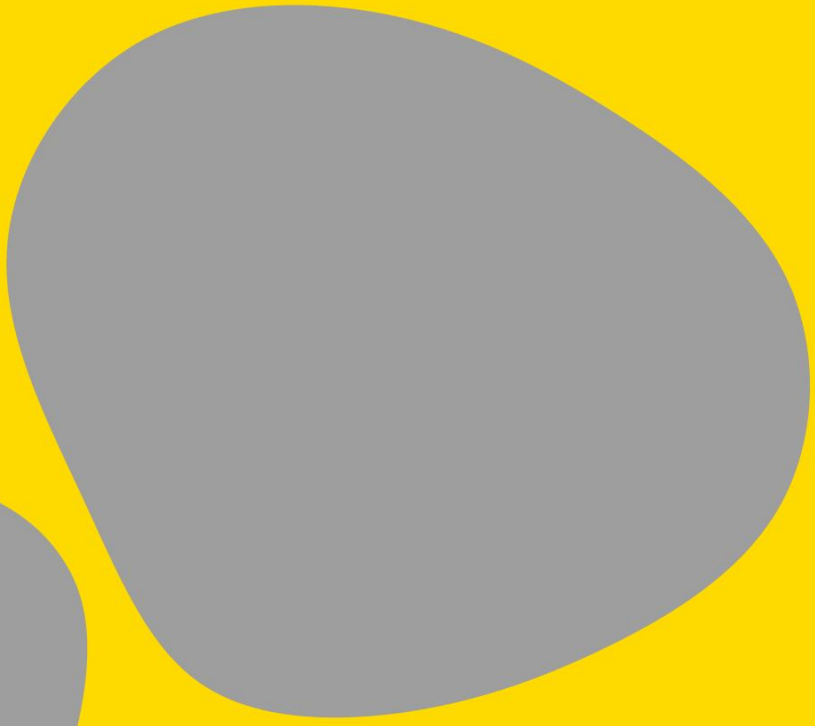
P.PORTO

ESCOLA SUPERIOR DE SAÚDE



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MESTRADO

TERAPIA OCUPACIONAL