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A pilot study of virtual reality exposure therapy that alternates calming and mildly stressful scenarios for adults with anxiety

Submission date
13/01/2026

Recruitment status
Recruiting

Registration date
13/01/2026

Overall study status
Ongoing

Last Edited
13/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
According to the Contrast Avoidance Model (CAM), people with Generalized Anxiety Disorder (GAD) may maintain worry to avoid sudden emotional shifts from calm to distress and may benefit from exposure to such emotional contrasts. This study explores whether virtual reality (VR) sessions that alternate between calming and mildly anxiety-inducing scenarios could support this approach in people with GAD.

Who can participate?
Adults (18+) with a prior clinical diagnosis of GAD and moderate anxiety symptoms.

What does the study involve?
Three in-person VR sessions (approximately 1 hour each) over 3 weeks, plus online questionnaires at baseline and 1-month follow-up. During sessions, participants wear a VR headset and heart rate monitor while experiencing calming and anxiety-inducing scenarios.

What are the possible benefits and risks of participating?
Participants may gain insight into their emotional responses and practice relaxation techniques. Risks include temporary anxiety during scenarios and possible VR-related discomfort (e.g., dizziness), which are minimized through continuous monitoring and in-VR guided relaxation segments.

Where is the study run from?
York University, Toronto, Canada

When is the study starting and how long is it expected to run for?
February 2026 to August 2026

Who is funding the study?
Charles University Doctoral Scholarship Program

Who is the main contact?
Mgr. Barbora Darmova, Charles University

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Public, Scientific

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Study information

Scientific Title
Feasibility and preliminary efficacy of virtual reality emotional contrast exposure therapy for adults with Generalized Anxiety Disorder: a single-arm pilot study

Study objectives
1. To assess feasibility (recruitment and retention, delivery of the intervention as planned, and acceptability) of a Contrast Avoidance Model-based virtual reality exposure intervention for adults with generalized anxiety disorder.
2. To estimate preliminary changes in anxiety symptoms and distress from baseline to post-intervention and 1-month follow-up.
3. To characterize autonomic reactivity during the alternating relaxation and anxiety-inducing virtual reality segments across the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/07/2025, Human Participants Review Committee (HPRC), Office of Research Ethics (ORE), York University (Kaneff Tower, 4700 Keele Street, Toronto ON, M3J 1P3, Canada; +1 416-736-2100; ore@yorku.ca), ref: e2025-225

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Generalized Anxiety Disorder (GAD) with moderate-to-severe anxiety symptoms.

Interventions
Participants will receive a single-arm virtual reality emotional-contrast exposure intervention delivered in person over three visits (~45–60 minutes each), scheduled approximately one week apart. Each visit will follow a fixed structure of alternating guided relaxation segments and mild anxiety-inducing virtual reality scenarios, ending with a final relaxation segment. Five distinct anxiety-inducing scenarios will be used; each scenario will last 2 minutes and relaxation segments will last ~3–5 minutes. The order of the anxiety-inducing scenarios will be counterbalanced across participants using a Latin square. No control intervention will be used and participants will not be randomized to study arms.

Intervention Type

Behavioural

Primary outcome(s)
1. Generalized anxiety symptom severity measured using the Generalized Anxiety Disorder-7 (GAD-7) total score at baseline (online pre-session), immediately post-intervention (after Session 3), and 1-month follow-up (online)

2. Within-session subjective distress measured using the Subjective Units of Distress Scale (SUDS) rated 1-9 at after each anxiety-inducing VR scenario and after final relaxation segment within each of the three sessions

3. Within-session emotional state measured using the Self-Assessment Manikin (SAM) valence, arousal, and dominance subscales (each rated 1-9) at after each anxiety-inducing VR scenario and after final relaxation segment within each of the three sessions

Key secondary outcome(s))
1. Heart rate reactivity measured using heart rate (HR) in beats per minute recorded via Polar H10 chest strap at continuous recording during all VR segments (anxiety-inducing and relaxation) across three sessions

2. Heart rate variability measured using the Root Mean Square of Successive Differences (RMSSD) derived from beat-to-beat intervals via Polar H10 chest strap at continuous recording during all VR segments (anxiety-inducing and relaxation) across three sessions

3. Somatic and cognitive anxiety symptoms measured using the Beck Anxiety Inventory (BAI) total score at baseline (online pre-session), immediately post-intervention (after Session 3), and 1-month follow-up (online)

4. State and trait anxiety measured using the State-Trait Anxiety Inventory (STAI) state and trait subscale total scores at baseline (online pre-session), immediately post-intervention (after Session 3), and 1-month follow-up (online)

5. Depressive symptoms measured using the Beck Depression Inventory-II (BDI-II) total score at baseline (online pre-session), immediately post-intervention (after Session 3), and 1-month follow-up (online)

6. VR-induced cybersickness measured using the Simulator Sickness Questionnaire (SSQ) total score at immediately after each of the three VR sessions

7. Sense of presence in VR measured using te Igroup Presence Questionnaire (IPQ) total score at immediately after each of the three VR sessions

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Age 18 years or older.
2. Prior clinical diagnosis of generalized anxiety disorder (self-reported).
3. Meets the study’s screening threshold for at least moderate anxiety (GAD-7 ≥ 10).

4. Able to provide informed consent in English.
5. Able and willing to complete all study procedures, including three in-person VR visits and the 1-month follow-up assessment.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of epilepsy or other photosensitive seizure disorder.
2. Severe motion sickness or vestibular disorder likely to be triggered by virtual reality.
3. Severe uncontrolled medical condition that could increase risk during induced anxiety (e.g., serious heart problems).
4. Severe psychiatric comorbidity that could increase risk during induced anxiety (e.g., active psychosis).
5. Pregnancy (excluded as a precaution).

Date of first enrolment
01/02/2026

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
Canada

Sponsor information

Organisation
York University

ROR

https://ror.org/05fq50484

Funder(s)

Funder type

Funder Name
Univerzita Karlova v Praze

Alternative Name(s)
Charles University, Charles University in Prague, Univerzita Karlova, Karls-Universität zu Prag, UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date