# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## A Gamified VR Exercise Approach for Advancing Emotional Health in Risk-Averse Older Women: An Interdisciplinary Examination Based on the Broaden-and-Build Theory

## Protocol summary


**Study aim**

The aim of this study will be to evaluate the effectiveness of a gamified virtual reality exercise program in improving emotional health and subjective well-being among risk-averse older women. Specifically, the study will examine whether gamified VR exercise, compared with conventional exercise, can improve overall happiness, positive affect, and life satisfaction while reducing negative affect. The maintenance of these changes will also be assessed at a 30-day follow-up.

**Design**

A two-arm, parallel, randomized controlled study with 138 participants (69 per group) will be conducted. Participants will be allocated 1:1 using a computer-generated random-number sequence. As a non-drug trial, no clinical trial phase applies. Outcome assessors will be blinded to group allocation.

**Settings and conduct**

The study will be conducted in psychological service centers and public and private hospitals in Tehran, Iran. After baseline assessment and eligibility confirmation, participants will be randomly allocated to the VR exercise or conventional exercise group. The intervention will include 12 sessions over 4 weeks. Outcome assessors will remain blinded to group allocation.

**Participants/Inclusion and exclusion criteria**

Inclusion: Women aged 60–80 years with high risk aversion, adequate physical health, and informed consent. Exclusion: Activity-limiting conditions, active major psychiatric disorders, epilepsy, or photosensitivity.

**Intervention groups**

Intervention group: Gamified VR exercise, 12 sessions over 4 weeks, 30–40 minutes per session. Control group: Conventional balance, agility, and coordination exercises with matched frequency and duration.

**Main outcome variables**

Overall happiness; Positive affect; Negative affect; Life satisfaction


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20260623069931N4**
Registration date: **2026-10-02, 1405/07/10**
Registration timing: **retrospective**

Last update: **2026-10-02, 1405/07/10**
Update count: **0**

**Registration date**

2026-10-02, 1405/07/10


**Registrant information**

**Name**
Hossein Faridniya
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University of Tehran
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2026-05-30, 1405/03/09

**Expected recruitment end date**

2026-06-30, 1405/04/09

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Gamified VR Exercise Approach for Advancing Emotional Health in Risk-Averse Older Women: An Interdisciplinary Examination Based on the Broaden-and-Build Theory

**Public title**

Effect of Gamified Virtual Reality Exercise on Emotional Well-Being in Risk-Averse Older Women

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women aged 60–80 years Clinically verified high risk aversion Scores above the predefined cut-off on the Health/Safety and Recreational domains of the DOSPERT scale Sufficient literacy to complete the study questionnaires Adequate physical health to perform light-to-moderate physical activity, confirmed by a physician Willingness to participate and provision of written informed consent

**Exclusion criteria:**

Cardiovascular conditions that will prevent safe participation in the exercise program Musculoskeletal or balance disorders that will prevent safe participation in the exercise program Active major psychiatric conditions, such as psychosis or untreated major depression A history of epilepsy or photosensitivity that will be incompatible with safe use of a virtual reality headset

**Age**

From **60 years** old to **80 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **138**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After completion of the baseline assessments and confirmation of eligibility, participants will be randomly allocated to the intervention and control groups in a 1:1 ratio. Simple randomization will be performed at the individual level. The allocation sequence will be generated using a computer-generated random-number sequence by a researcher who will not be involved in participant recruitment or intervention delivery. Allocation will occur only after eligibility confirmation and completion of baseline assessments to reduce allocation bias.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Due to the nature of the intervention, participants and researchers responsible for intervention delivery will not be blinded to group allocation. Outcome assessors responsible for collecting and evaluating questionnaire data at baseline, post-intervention, and the 30-day follow-up will be blinded to participants' allocation to the intervention or control group. Participants will also be instructed not to disclose their group allocation or intervention type to the outcome assessors during assessments.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of the Sport Sciences Research Institute (SSRI)

**Street address**

No. 3, 5th Alley, Mir Emad St., Ostad Motahari St.

**City**

Tehran

**Province**

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**Postal code**

1587958711

**Approval date**

2025-05-03, 1404/02/13

**Ethics committee reference number**

IR.SSRC.REC.1404.029

## Health conditions studied

### 1

**Description of health condition studied**

High risk aversion in older women

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Overall happiness score measured using the Oxford Happiness Inventory (OHI).

**Timepoint**

At baseline (before the intervention); immediately after the 4-week intervention; 30 days after the intervention (follow-up)

**Method of measurement**

Oxford Happiness Inventory, consisting of 29 items

## Secondary outcomes

### 1

**Description**
Positive affect score measured using the Oxford Happiness Inventory.
**Timepoint**
At baseline (before the intervention); immediately after the 4-week intervention; 30 days after the intervention (follow-up)
**Method of measurement**
Oxford Happiness Inventory, consisting of 29 items

## Intervention groups

### 1

**Description**
Intervention group: Participants will complete a 4-week gamified virtual reality exercise program consisting of 12 sessions (3 sessions per week), with each session lasting 30–40 minutes, using Pico 4 Enterprise headsets. Exercises will include balance activities in virtual environments, walking on virtual platforms, balancing on narrow pathways, and simulated gliding activities. Gamification elements will include progressive levels, scoring, immediate feedback, and achievement badges.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ziaeian Hospital, Tehran University of Medical Sciences
**Full name of responsible person**
Hossein Faridniya
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tehran University of Medical Sciences
**Proportion provided by this source**
5
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
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Hossein Faridniya
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**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
De-identified individual participant data, including baseline characteristics and primary and secondary outcome data, will be available after publication of the study results upon reasonable request from researchers. No personally identifiable information will be shared.

**When the data will become available and for how long**
From 6 months after publication of the study results until 5 years after publication.

**To whom data/document is available**
Academic and scientific researchers, upon reasonable request and approval by the principal investigator.

**Under which criteria data/document could be used**
The data and documents will be used only for scientific and research purposes and related analyses. Applicants must provide the research purpose and proposed analysis plan. Access will be granted after approval by the principal investigator and under conditions that ensure participant confidentiality.

**From where data/document is obtainable**
Requests should be submitted to Hossein Faridniya, Principal Investigator, by email. Contact telephone: +98 936 387 5989.

**What processes are involved for a request to access data/document**
Requests will be reviewed by the principal investigator. The research purpose, analysis plan, and confidentiality requirements will be assessed. If approved, de-identified data will be provided within 30 days.

**Comments**