

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The Effect of Virtual Reality On Anxiety, Depression, Stress and Death Anxiety in Elderly

#### Protocol summary

##### Study aim

General Objective: Determining the effect of virtual reality on anxiety, depression, stress, and death anxiety in elderly

##### Design

Experimental study, with a control group, without blinding, on 60 elderly people, randomization with four blocks

##### Settings and conduct

The study design is an experimental one, which includes a control group and does not involve blinding. The participants will consist of 60 elderly individuals who meet the inclusion criteria and have be randomly assigned to either the intervention or control group using a four-block randomization process. The intervention involves placing participants in a virtual reality environment that includes natural landscapes, pilgrimage sites, tourist sites, flight, and deep sea, which they can interact with for six 15-minute sessions, twice a week for three weeks. The intervention will take place in a quiet room to ensure privacy. The control group will not receive any intervention during this period. This study is conducting in Ramsar city

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 60 and above experiencing symptoms of anxiety, depression, stress, and death anxiety. Non-entry criteria: History of mental disorders. History of epilepsy or seizures.

##### Intervention groups

The intervention group is exposed to a virtual reality environment consisting of natural landscapes, pilgrimage sites, tourist sites, flight, and deep sea scenarios. Participants can interact with and navigate through any of these environments under the researcher's supervision. The intervention takes place in a private, quiet room. Participants receive six 15-minute sessions, twice a week, for a total of three weeks. There is no intervention in the control group during this period.

##### Main outcome variables

Anxiety! Depression! stress! Death anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221130056669N1**

Registration date: **2023-03-06, 1401/12/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-06, 1401/12/15**

Update count: **0**

##### Registration date

2023-03-06, 1401/12/15

##### Registrant information

##### Name

Mohammadamin ShahrbaF

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3335 6985

##### Email address

mohammadaminshahrbaF@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-06, 1401/12/15

##### Expected recruitment end date

2023-06-05, 1402/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The Effect of Virtual Reality On Anxiety, Depression, Stress and Death Anxiety in Elderly

### Public title

Effect of Virtual Reality on Anxiety, Depression, Stress and Death anxiety in Elderly

### Purpose

Health service research

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Individuals aged 60 years and older Reading and writing literacy in Persian language Interest and informed consent to participate in the study Absence of visual, auditory, or tactile impairments Achieving a score of eight or above on the Abbreviated Mental Test (AMT) Absence of psychological disorders as determined by both file records and self-reported measures Absence of current use of psychiatric medications or narcotics as determined by both file records and self-reported measures. Absence of medical history pertaining to conditions such as epilepsy, dizziness, and convulsions, as confirmed by both file records and self-reported measures. Absence of self-reported prior participation in comparable programs Achieving a score of 14 or greater on the depression subscale of the Depression Anxiety Stress Scale-21 (DASS-21). Achieving a score of 10 or greater on the Anxiety subscale of the Depression Anxiety Stress Scale-21(DASS-21) Achieving a score 19 or greater on the Stress subscale of the Depression Anxiety Stress Scale-21(DASS-21) Achieving a score 7 and above in the Tampler Death anxiety Scale (DAS)

#### Exclusion criteria:

Sensory impairments in vision, hearing, and tactile Suffering from psychological disorders, according to the file and self-report Taking psychiatric medicine and narcotics according to the file and self-report Having a history of diseases such as epilepsy, dizziness and convulsions according to the file and self-report

### Age

From **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The sampling procedure involves the use of cluster sampling to select health centers. Once the clusters are identified, a random sample is selected from them, with the number of clusters chosen based on the desired sample size. Health centers within each selected cluster are then included in the sample. Eligible elderly participants from these health centers are then randomly allocated into blocks of four and assigned to either the

control or intervention group. This is done after they have met the entry criteria for the study. Random allocation into blocks of four means that for every four eligible elderly participants, two are randomly assigned to the intervention group and two to the control group. The randomization process is done using a computer-generated random number sequence. The blocks of four ensure that there are an equal number of participants in each group, which can help to reduce the risk of chance imbalances between the groups.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Other

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical sciences

##### Street address

Nursing and Midwifery School., Imam Sajjad Hospital., Shahid Motahari St

##### City

Ramsar

##### Province

Mazandaran

##### Postal code

۴۶۹۱۷۱۴۱۴۱

#### Approval date

2022-11-27, 1401/09/06

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.168

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F32.8

#### ICD-10 code description

Other depressive episodes

### 2

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41

## ICD-10 code description

Other anxiety disorders

### 3

#### Description of health condition studied

Stress

#### ICD-10 code

F43.8

#### ICD-10 code description

Other reactions to severe stress

### 4

#### Description of health condition studied

Death anxiety

#### ICD-10 code

F41

#### ICD-10 code description

Other anxiety disorders

## Primary outcomes

### 1

#### Description

Score from depression subscale, short form of depression, anxiety and stress scale

#### Timepoint

Before and after the intervention

#### Method of measurement

Short form of depression, anxiety and stress scale(DASS-21)

### 2

#### Description

Score from anxiety subscale, short form of depression, anxiety and stress scale

#### Timepoint

Before and after intervention

#### Method of measurement

Short form of depression, anxiety and stress scale(DASS-21)

### 3

#### Description

Score from stress subscale, short form of depression, anxiety and stress scale

#### Timepoint

Before and after intervention

#### Method of measurement

Short form of depression, anxiety and stress scale (DASS-21)

### 4

#### Description

Score from Tampler Death anxiety scale

#### Timepoint

Before and after intervention

#### Method of measurement

Tampler Death anxiety scale (DAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group will be using Samsung VR devices to be placed in a virtual reality environment. The virtual reality environment will consist of different settings, including natural landscapes, pilgrimage sites, historical sites, tourist sites, and deep sea or flight scenarios. The participants in the intervention group will interact with the virtual environment, which will be under the control of the researcher, and the intervention will take place in a quiet room that respects the privacy of the participants. The intervention will consist of six 15-minute sessions, conducted twice a week for three weeks, and will be held in the health centers.

#### Category

Other

### 2

#### Description

Control group: No intervention is done

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health centers

##### Full name of responsible person

Mohammadaminshahrbaf

##### Street address

South 35, Imam khomeini Blvd, Ramsar Health Center

##### City

Ramsar

##### Province

Mazandaran

##### Postal code

4691844447

##### Phone

+98 11 5525 6683

##### Email

Mohammadaminshahrbaf@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Rajabnia

**Street address**

Ganj Afrooz St

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶-۴۷۷۵۴

**Phone**

+98 11 3219 0558

**Email**

research@mubabol.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol University of Medical Sciences

**Proportion provided by this source**

100

**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**

Babol University of Medical Sciences

**Full name of responsible person**

Mohammadamin Shahrbaaf

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 19, Farzmafdi Alley., Padegan Ave.,

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**Province**

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**Postal code**

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**Phone**

+98 28 3335 6985

**Email**

Mohammadaminshahrbaaf@gmail.com

**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Mohammadamin Shahrbaaf

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Student

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**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

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Student

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**Email**

Mohammadaminshahrbaaf@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to

make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available