

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)

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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

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South 35, Imam khomeini Blvd, Ramsar Health Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

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

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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