Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Designing a Mindfulness-Based Cognitive Therapy Program in Virtual Reality Environment and Comparison of its Effectiveness with Traditional Mindfulness-Based Cognitive Therapy on Rumination, Cognitive Emotion Regulation, and Pain Perception Symptoms in Elderly.

Protocol summary

Study aim
This research aims to design and develop a virtual reality-based mindfulness-based cognitive therapy program and compare its effectiveness with traditional methods on cognitive distortions, emotion regulation, and pain perception in older adults

Design
The study has two experimental groups and one control group, with participants randomly assigned using simple randomization. Randomization was done with a random number table, and a single-blind method was applied to 45 participants.

Settings and conduct
Interventions in the first experimental group are group-based, while interventions in the second group are individual. Informed consent forms are obtained initially, and participants are blinded to their group assignment. Therapy sessions take place in a psychological clinic in Isfahan, with eight weekly sessions lasting 90 minutes each.

Participants/Inclusion and exclusion criteria
Study inclusion criteria: normal visual and auditory abilities, literacy in reading and writing, no history of psychiatric, cognitive, or physical disorders such as epilepsy. Exclusion criteria: history of cognitive disorders such as mild cognitive impairment, hospitalization, and psychiatric disorders.

Intervention groups
Interventions in the traditional mindfulness-based cognitive therapy group are conducted in a group format, teaching techniques such as breath awareness, body scan, cognitive restructuring, and acceptance. In the second experimental group, the same interventions are delivered through virtual reality videos. The control group is placed on a waiting list and receives the intervention after the completion of the study

Main outcome variables
Improvement in rumination; improvement in cognitive emotion regulation; pain perception

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230209057367N1**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**
Registration date
2023-04-26, 1402/02/06

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-05, 1402/02/15
Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing a Mindfulness-Based Cognitive Therapy Program in Virtual Reality Environment and Comparison of its Effectiveness with Traditional Mindfulness-Based Cognitive Therapy on Rumination, Cognitive Emotion Regulation, and Pain Perception Symptoms in Elderly.

Public title
Designing a Mindfulness-Based Cognitive Therapy Program in Virtual Reality Environment and Comparison of its Effectiveness with Traditional Mindfulness-Based Cognitive Therapy on Rumination, Cognitive Emotion Regulation, and Pain Perception Symptoms in Elderly.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Participants with normal visual acuity and hearing abilities will be included in the study to ensure an accurate perception of the interventions and assessments Participants who are literate in reading and writing will be included, as the study will involve written instructions, assessments, and interventions that require these skills. Participants with no history of serious psychiatric and psychological disorders, as assessed through self-report and/or clinical evaluation. Participants with no history of physical diseases, epilepsy, or cybersickness disease, as assessed through medical records and self-report. Age over 60
Exclusion criteria:
Participants with a history of psychiatric treatment, including hospitalization, psychotherapy, or psychotropic medication use, will be excluded, as this may confound the results and impact the effectiveness of the interventions. Participants with a history of cognitive disorders such as Alzheimer's disease, mild cognitive impairment, or Parkinson's disease, as diagnosed by medical records and/or clinical evaluation, will be excluded.
Age
From **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method will be employed in this research, with the individual as the randomization unit. Participants who meet the eligibility criteria will be randomly assigned to one of the three study groups, which include traditional cognitive therapy based on mindfulness presence, cognitive therapy based on mindfulness presence in a virtual reality environment, and a control group. Randomization will be performed using a table of random numbers, and opaque sealed envelopes with a random sequence will be used for concealment. The random numbers obtained will be written on the envelopes, and on the day of group assignment, the envelopes will be opened to determine the group assigned to each participant. This method of randomization and concealment aims to minimize bias and ensure an unbiased allocation of participants to the study groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The primary objective of this study is to develop a software package utilizing real scenes and videos of nature, incorporating virtual reality (VR) technology and 360-degree videos. The VR experience will be delivered through a smartphone equipped with a gyroscope and a VR headset, enabling participants to view the nature-based movies in an immersive manner. This innovative approach will allow for a realistic and immersive experience of nature within a controlled experimental setting, providing a novel way to investigate the effects of nature exposure on various outcomes.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mashhad Academic Center for Education, Culture and Research
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Mashhad Academic Center for Education, Culture and Research- University Campus-Azadi Square-Mashhad
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Approval date
2023-03-11, 1401/12/20
Ethics committee reference number
IR.ACECR.JDM.REC.1402.003

Health conditions studied

1

Description of health condition studied
Rumination in the elderly
ICD-10 code
F42.0
ICD-10 code description
Predominantly obsessional thoughts or ruminations

2

Description of health condition studied
Problem in the cognitive emotion regulation in the elderly
ICD-10 code
ICD-10 code description

3

Description of health condition studied
perceived pain in the elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The subjects' score in the rumination response style questionnaire should be lower than 44.
Timepoint
The rumination response style questionnaire will be administered in three stages, including a pre-test (prior to the implementation of the intervention), a post-test (immediately after the completion of the intervention), and a one-month follow-up (one month after the intervention completion).
Method of measurement
The Rumination Response Style Questionnaire consists of 22 four-point Likert items that assess various reactions to negative mood, including two subscales of rumination responses and distracting responses.

2

Description
The subject's score in the cognitive emotion regulation questionnaire
Timepoint
The cognitive emotion regulation questionnaire will be administered in three stages, including a pre-test (prior to the implementation of the intervention), a post-test (immediately after the completion of the intervention), and a one-month follow-up (one month after the intervention completion).
Method of measurement
The Cognitive Emotion Regulation Questionnaire is a multidimensional instrument commonly used to assess cognitive coping strategies employed following exposure to negative events or situations.

3

Description
The subject's score in the McGill Pain Questionnaire
Timepoint
The McGill pain questionnaire will be administered in three stages, including a pre-test (prior to the implementation of the intervention), a post-test (immediately after the completion of the intervention), and a one-month follow-up (one month after the intervention completion).
Method of measurement
The McGill Pain Inventory is a widely used and comprehensive scale for measuring pain perception, utilizing a lexical analysis approach, that was first published in 1975. This questionnaire assesses pain perception across four dimensions, including emotional pain, sensory pain, pain evaluation, and various pains.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1. Participants in this group receive a traditional mindfulness-based cognitive therapy intervention. The intervention is conducted in a group format, consisting of eight treatment sessions held once a week, with each session lasting 90 minutes. The intervention includes various mindfulness techniques, such as focused breathing, body scanning, acceptance, recognizing thoughts as mental events, and increasing awareness of thoughts and bodily sensations.
Category
Treatment - Other

2

Description
Intervention group: Group 2. Participants in this group receive an intervention that includes virtual reality videos. The intervention begins with mindfulness exercises followed by watching virtual reality movies through a headset. After removing the headset, the therapist provides additional training. This intervention is implemented over eight sessions, with each session lasting 90 minutes, conducted once per week.
Category
Treatment - Other

3

Description
Control group: Participants in this group will complete the questionnaires at three time points: pre-test, post-test, and follow-up. The participants in the control group will be placed on a waiting list, and after the intervention

of the experimental group, to adhere to ethical considerations, the intervention will also be provided to the control group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Experience garden of Isfahan

Full name of responsible person
Nasibeh Sarrami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
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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
Iranian academic center for education culture and research

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
Iranian academic center for education culture and research

Full name of responsible person
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Position
Ph.D. Candidate

Latest degree
Master

Other areas of specialty/work
Psychology

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data in this study consists of raw data and findings after statistical analysis. The first set of data is obtained from participant scores on questionnaires, which can be published after removing private information through an Excel file. The main research data, including descriptive tables, normality, post hoc tests, and analysis of variance with repeated measurements, is presented after statistical analysis using SPSS software version 25. The study protocol, which includes a detailed description of the intervention sessions in the experimental groups, will be shared as a Word file. The clinical study report will outline the method of conducting the research and will be published in the same format as compiled in the thesis. The informed consent form will also be published after de-identifying participants and removing personal information.

When the data will become available and for how long

The beginning of the access period is in September 2023.

To whom data/document is available

All people who work in the field of aging have the possibility to access the data. including researchers, policy makers and statesmen and people who work in the field of innovation, technology and making assistive devices for the elderly.

Under which criteria data/document could be used

The data obtained from this research can be utilized for planning and implementing health solutions for the elderly. However, it should be noted that due to the influence of time and place on research results, caution should be exercised in generalizing the findings to elderly populations in other cultures. To request access to the data, the following conditions must be met: Submission of an introduction letter from a reputable institution or company The researcher or student must provide details about the university and field of study Introduction of the project and sponsoring institution (for industry-related research)

From where data/document is obtainable

To receive data and documents, you can contact the researcher's email address: nasibehsar@gmail.com Or refer to the Research Vice-Chancellor of Yazd University of Science and Art: Yazd, Student Blvd., University of Science and Art (035) 38264080-9 (035) 38302184 89167-13335 info@sau.ac.ir

What processes are involved for a request to access data/document

To obtain the necessary documents, please send an email to the researcher clearly expressing your request. Once the email has been checked and approved by the researcher, the requested documents will be sent to the applicant within two weeks.

Comments