Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Solo versus Group-Based Virtual Reality Sports Tourism for Reducing Loneliness in Widowed Older Women

Protocol summary

Study aim
To examine the effects of solo and group-based virtual reality sports tourism on loneliness among widowed older women living in nursing homes, and to compare whether the group-based format produces greater reductions in loneliness than the solo format and usual care.

Design
Three-arm parallel randomized controlled trial with a 1:1:1 allocation ratio and assessments at baseline, post-intervention, and 30-day follow-up.

Settings and conduct
The study will be conducted in nursing homes in Tehran, Iran. Eligible participants will be screened, familiarized with virtual reality, randomized into three groups, and assessed at baseline, post-intervention, and 30-day follow-up.

Participants/Inclusion and exclusion criteria
Widowed women aged 60 years or older who will have been living in nursing homes for at least three months will be eligible if they will be able to provide informed consent, use virtual reality safely, complete the questionnaires, and tolerate the virtual reality familiarization session. Exclusion criteria will include severe cognitive, sensory, vestibular, neurological, cardiovascular, or psychiatric conditions, a history of epilepsy or seizure disorder, severe motion sickness, concurrent participation in structured interventions, or marked intolerance to virtual reality.

Intervention groups
Control group: Usual nursing home care, with no VR-based intervention. Solo VR group: Individual VR sports tourism using Meta Quest 3, delivered in 12 sessions over 4 weeks, three sessions per week. Group-based VR group: VR sports tourism in small groups of 3–5 residents using Meta Quest 3, delivered in 12 sessions over 4 weeks, with a brief post-session group discussion.

Main outcome variables
Loneliness will be measured using the UCLA Loneliness Scale Version 3.

General information

Reason for update

Acronym
VRST

IRCT registration information
IRCT registration number: **IRCT20260623069931N1**
Registration date: **2026-07-19, 1405/04/28**
Registration timing: **prospective**

Last update: **2026-07-19, 1405/04/28**
Update count: **0**

Registration date
2026-07-19, 1405/04/28

Registrant information

Name
Hossein Faridniya

Name of organization / entity
University of Tehran

Country
Iran (Islamic Republic of)

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+98 936 387 5989

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-24, 1405/05/02

Expected recruitment end date
2026-08-21, 1405/05/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Solo versus Group-Based Virtual Reality Sports Tourism for Reducing Loneliness in Widowed Older Women

Public title

Virtual Reality Sports Tourism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Participants will be women aged 60 years or older who will be widowed; will have been living in a nursing home for at least three months; will be able to understand the study instructions and provide informed consent; will have adequate vision and hearing to use VR and complete the questionnaires; will be able to participate safely in seated VR sessions; and will be able to tolerate the VR familiarization session without marked discomfort.

Exclusion criteria:

severe cognitive impairment; severe uncorrected visual or hearing impairment; a history of epilepsy or seizure disorder; severe vestibular problems or severe motion sickness; an unstable cardiovascular condition; severe psychiatric symptoms requiring immediate clinical care; concurrent participation in another structured psychosocial, behavioral, or medication-based intervention; or inability to tolerate the VR headset during the familiarization session because of marked dizziness, nausea, anxiety, or visual discomfort.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **115**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study will be conducted as a three-arm, parallel-group randomized controlled trial with a 1:1:1 allocation ratio. Participants will be allocated to one of three groups: usual care/control, solo virtual reality sports tourism, or group-based virtual reality sports tourism. Assessments will be conducted at three time points: baseline, immediately after the four-week intervention, and 30 days after the final session. Outcome assessors will be blinded to group allocation, but participants and facilitators will not be blinded because of the nature of the virtual reality intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Approval date

empty

Ethics committee reference number

2

Ethics committee

Name of ethics committee

Ethics Committee of Sport Sciences Research Institute

Street address

Tehran – Ostad Motahari St. – Mir Emad St. – Fifth Alley – No. 3

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Province

Tehran

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

Loneliness among widowed older women living in nursing homes

ICD-10 code

0

ICD-10 code description

0

Primary outcomes

1

Description

Total loneliness score measured by the UCLA Loneliness Scale Version 3.

Timepoint

At baseline, immediately after the 4-week intervention, and 30 days after the final intervention session.

Method of measurement

Persian version of the UCLA Loneliness Scale Version 3, a

20-item questionnaire scored on a 4-point Likert scale.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Participants will receive usual nursing home care and no virtual reality intervention.Intervention group 1: Participants will receive solo virtual reality sports tourism using Meta Quest 3 head-mounted displays. The program will include 12 sessions over 4 weeks, three sessions per week. Each session will last 30–40 minutes, including 20–25 minutes of virtual reality exposure.Intervention group 2: Participants will receive group-based virtual reality sports tourism in groups of 3–5 residents using Meta Quest 3 head-mounted displays. The program will include 12 sessions over 4 weeks, three sessions per week, followed by a 5–10-minute group discussion after each session.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranmehr Elderly Care Home

Full name of responsible person
Sajjad mohamadyari

Street address
No. 6, Farvardin Alley, 10th Street, South Piroozan Street, Hormozan, Shahrak-e Gharb, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

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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
20

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

Full name of responsible person
Hossein Fraidniya

Position
Researcher- phd candidate

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Tehran

Full name of responsible person

Hossein Faridniya

Position
researcher

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Other areas of specialty/work
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Person responsible for updating data

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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
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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
De-identified individual participant data, including group allocation, demographic variables, loneliness scores measured by the UCLA Loneliness Scale Version 3 at baseline, post-intervention, and 30-day follow-up, and adherence/safety information. No names, contact details, or personally identifiable information will be shared.

When the data will become available and for how long
De-identified participant data will be available from 6 months after publication of the main study results and will remain available for 5 years. Access will be provided only for scientific purposes upon reasonable request to the corresponding author and subject to ethical and confidentiality requirements.

To whom data/document is available
Qualified researchers affiliated with academic, scientific, or healthcare institutions may request access for legitimate scientific purposes, subject to ethical approval, confidentiality requirements, and approval by the corresponding author.

Under which criteria data/document could be used
Data may be used only for non-commercial scientific purposes, including verification of published results, secondary analysis, systematic reviews, or meta-analyses. Requests must include a clear research proposal, ethics approval or exemption when applicable, and a commitment to confidentiality. Data must not be used to identify participants, shared with unauthorized parties, or used for purposes outside the approved request.

From where data/document is obtainable
Requests for access to data or documents should be sent to the corresponding author: Hossein Faridniya. Email: Hossein.faridniya@ut.ac.ir

What processes are involved for a request to access data/document
Requests will be reviewed by the corresponding author within 4 weeks. Applicants must submit a written request including the study purpose, planned analyses, institutional affiliation, and ethics approval or exemption when applicable. Approved applicants will be required to sign a confidentiality and data-use agreement before receiving the de-identified data or documents.

Comments