Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Adaptive Virtual Adventure Sport Tourism on Positive Affect and Well-Being in Adults With Spinal Cord Injury

Protocol summary

Study aim
To examine the effect of a four-week adaptive virtual adventure sport tourism intervention on SCI-specific positive affect and well-being in adults with spinal cord injury

Design
Assessor-blinded, two-arm, parallel-group randomized controlled trial with 1:1 allocation and concealed computer-generated randomization

Settings and conduct
The study will be conducted at two specialist spinal cord injury rehabilitation centers in Tehran, Iran. Eligible participants will complete baseline assessments and will then be randomly assigned using the RAND function in Microsoft Excel to either the adaptive VR intervention or active control group. Interventions will be delivered in supervised sessions, and outcomes will be assessed at baseline, 24–72 hours after the four-week intervention, and at 30-day follow-up

Participants/Inclusion and exclusion criteria
Adults aged 18–65 years with SCI for ≥6 months and AIS grade A–D will be included. Major exclusions will be seizures, severe motion sickness, unstable medical conditions, active pressure injury, severe visual impairment, acute psychiatric crisis, cognitive impairment, or concurrent VR intervention

Intervention groups
Intervention group: Participants will receive 12 supervised sessions of adaptive immersive VR adventure sport tourism over 4 weeks using Meta Quest 3. Activities will include virtual kayaking, hand-cycling, accessible trail navigation, seated sailing, and destination exploration, with individualized accessibility and comfort adaptations. Active control group: Participants will receive 12 matched sessions of two-dimensional travel videos without immersion, interaction, navigation, or adaptive challenge

Main outcome variables
SCI-specific positive affect and well-being measured by the SCI-QOL PAWB SF10a T-score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260623069931N2**
Registration date: **2026-08-11, 1405/05/20**
Registration timing: **prospective**

Last update: **2026-08-11, 1405/05/20**
Update count: **0**

Registration date
2026-08-11, 1405/05/20

Registrant information

Name
Hossein Faridniya

Name of organization / entity
University of Tehran

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-16, 1405/05/25

Expected recruitment end date
2026-09-24, 1405/07/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Adaptive Virtual Adventure Sport Tourism on Positive Affect and Well-Being in Adults With Spinal Cord Injury

Public title
Virtual reality tourism for adult With Spinal Cord Injury

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18–65 years Spinal cord injury for at least 6 months AIS grade A–D Ability to perform light-to-moderate upper-limb activity while seated Adequate vision and hearing to participate in the intervention Successful completion of the VR familiarization session

Exclusion criteria:
History of seizure within the past year Severe vestibular disorder or motion sickness Acute or uncontrolled autonomic dysreflexia Unstable cardiovascular or respiratory condition Active pressure injury Severe uncorrected visual impairment Acute psychiatric crisis Cognitive or communication impairment preventing participation Concurrent participation in another VR-based intervention Planned change in mood-related medication during the study period

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized individually in a 1:1 ratio to the adaptive VR intervention or active control group using computer-generated permuted blocks of four and six. Randomization will be stratified by neurological level (tetraplegia vs paraplegia) and baseline positive affect and well-being score (below vs at or above the sample median). An independent researcher not involved in recruitment, intervention delivery, or outcome assessment will generate the allocation sequence. Group assignments will be placed in sequentially numbered, opaque, sealed envelopes and opened by the intervention coordinator only after completion of baseline assessment.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants and intervention personnel will not be blinded because of the visible differences between immersive VR and two-dimensional video viewing. Outcome assessments will be conducted by a research assistant who will not attend intervention sessions and will remain unaware of group allocation. Participants will be reminded not to disclose their assigned condition during assessments. For the primary analysis, groups will be coded as A and B, and the data analyst will remain blinded to group identity until the main analysis is completed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sport Sciences Research Institute Ethics Committee

Street address
No. 3, 5th Alley, Mir Emad St., Ostad Motahari St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1587958711

Approval date
2025-04-20, 1404/01/31

Ethics committee reference number
IR.SSRC.REC.1404.029

Health conditions studied

1

Description of health condition studied
Spinal Cord Injury

ICD-10 code
G82

ICD-10 code description
Paraplegia (paraparesis) and quadriplegia (quadriparesis)

Primary outcomes

1

Description
SCI-specific positive affect and well-being T-score

Timepoint
Baseline, 24–72 hours post-intervention, and 30-day follow-up

Method of measurement
SCI-QOL Positive Affect and Well-Being Short Form 10a

(SCI-QOL PAWB SF10a)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will receive 12 supervised sessions of adaptive immersive virtual reality adventure sport tourism over 4 weeks, with 3 sessions per week. Using Meta Quest 3, participants will engage in virtual coastal kayaking, hand-cycling, wheelchair-accessible trail navigation, seated sailing, and destination exploration. Activities will be adapted to participants' functional abilities and comfort

Category
Rehabilitation

2

Description
Control group: Participants will receive 12 supervised sessions of non-immersive two-dimensional travel videos over 4 weeks, with 3 sessions per week. Videos will be viewed on a 24-inch monitor with session duration, setting, and facilitator contact matched to the intervention group. The control condition will not include immersion, motion tracking, interactive tasks, performance feedback, adaptive challenge, or active navigation

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialist Spinal Cord Injury Rehabilitation Center, Tehran

Full name of responsible person
Hossein Faridniya

Street address
Rofeideh Rehabilitation Hospital

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1935973476

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali saberi

Street address
16 Azar Street, Enghelab Square, Tehran, Iran

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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
2

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 Faridniya

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Sport Medicine

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual participant data will not be publicly shared to protect participant privacy and confidentiality

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

No - There is not a plan to make this available

Analytic Code

No - There is not 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

Study protocol and related study documents

When the data will become available and for how long

After publication of the main study results

To whom data/document is available

Qualified researchers upon reasonable request to the corresponding author

Under which criteria data/document could be used

For academic and research purposes, subject to a reasonable request, approval by the study investigators, and compliance with ethical and confidentiality requirements

From where data/document is obtainable

The corresponding author of the study

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

Requests will be submitted to the corresponding author and reviewed by the study investigators for scientific purpose, ethical compliance, and confidentiality requirements

Comments