

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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)

Phone

+98 936 387 5989

Email address

hossein.faridniya@ut.ac.ir

Recruitment status

recruiting

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

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

City

Tehran

Province

Tehran

Postal code

1935973476

Phone

+98 21 2223 3010

Email

solal11.19966@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1417466191

Phone

+98 21 6111 3411

Email

hossein.faridniya@ut.ac.ir

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

Street address

16 Azar Street, Enghelab Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417466191

Phone

+98 936 387 5989

Email

hossein.faridniya@ut.ac.ir

Person responsible for scientific 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

Street address

16 Azar Street, Enghelab Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417466191

Phone

+98 936 387 5989

Email

hossein.faridniya@ut.ac.ir

Person responsible for updating data

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

Street address

16 Azar Street, Enghelab Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417466191

Phone

+98 936 387 5989

Email

hossein.faridniya@ut.ac.ir

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