Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessing the effectiveness of Virtual Reality (VR) therapy in patients with frozen shoulder

Protocol summary

Study aim
Assessing the effectiveness of Virtual Reality (VR) therapy in patients with frozen shoulder

Design
A randomised controlled clinical trial with parallel groups, and blinded outcome assessment, on 40 patients. Randomisation was performed using concealed envelopes.

Settings and conduct
The place of study is Akhtar Orthopedic Hospital, and on the patients who were diagnosed with frozen shoulder in the clinic of this hospital. Due to the nature of the intervention, unilateral or bilateral blinding was not possible. Although the statistical analysis was done blindly by a third party.

Participants/Inclusion and exclusion criteria
Inclusion criteria included a diagnosis of frozen shoulder based on clinical assessment, age between 18 and 65 years, and willingness to comply with the study protocol. Exclusion criteria encompassed individuals with a history of severe shoulder trauma or surgery, neurological conditions affecting shoulder function, uncontrolled systemic diseases, gait dysfunction, stability dysfunction, history of migraine and seizure

Intervention groups
Participants were randomized into two groups, namely, the VR group and the conventional group. Both groups underwent a 12-session program during four weeks. The conventional group participants received 40 minutes of conventional therapy, consisting of Continuous Passive Motion (CPM) and functional exercises including flexion, abduction and external rotation. The VR group received the conventional therapy module, plus 20 minutes of VR exergaming at the end of each session.

Main outcome variables
Shoulder pain, measured by VAS questionnaire Shoulder function measured by DASH questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230522058251N1**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**
Registration date
2023-07-31, 1402/05/09

Registrant information
Name
Mohammad Hossein Mahrooz
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-30, 1402/06/08
Expected recruitment end date
2023-09-21, 1402/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Assessing the effectiveness of Virtual Reality (VR) therapy in patients with frozen shoulder

Public title
Assessing the effectiveness of VR therapy in the treatment of frozen shoulder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of frozen shoulder Informed consent to comply with the study protocols age between 18 and 65 years
Exclusion criteria:
history of trauma or surgery in the affected shoulder history of any neurologic disease affecting the neuro-muscular function of the affected shoulder history of migraine history of seizure gait dysfunction vertigo or impaired stability
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Sealed envelope patient chooses a sealed envelope when he enters the study. The envelope contains either of the two labels reading control or intervention.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran national commettee for ethics in biomedical research
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town
City
Tehran
Province
Tehran
Postal code
1111111111
Approval date
2023-05-06, 1402/02/16
Ethics committee reference number
IR.SBMU.MSP.REC.1402.010

Health conditions studied

1

Description of health condition studied
Frozen shoulder (Adhesive capsulitis)
ICD-10 code
M75.0
ICD-10 code description
Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Shoulder function based on Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire
Timepoint
before the first session, and after the last session
Method of measurement
Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire

2

Description
Pain level based on Visual Analogue Scale questionnaire
Timepoint
before the first session and after the final session
Method of measurement
Visual Analogue Score

3

Description
Patient satisfaction level based on Visual Analogue Scale questionnaire
Timepoint
After the final session
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 12 sessions of physiotherapy during

4 weeks (3 sessions each week) was done. Each session lasts one hour. The first 40 minutes was the same in both groups, which contains twenty minutes of passive exercise with CPM machine, followed by twenty minutes of functional exercises including flexion, abduction and external rotation. In the next twenty minutes, the virtual reality device is placed on the patient's head and the patient finds himself in a game environment, wielding a sword in his hand and obliged to hit the obstacles that appear in the game. The speed of the appearance of the obstacles and their arrangement have been adjusted by the study team so that the patient's hand movements as a result of trying to hit the obstacles have a rehabilitative nature.

Category

Rehabilitation

2

Description

Control group: 12 sessions of physiotherapy in a period of 4 weeks, 3 sessions each week, was done. The duration of each session was 40 minutes. In each session, after twenty minutes of passive training with the CPM machine, twenty minutes of functional exercises including flexion, abduction and external rotation were performed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar orthopaedic surgery center

Full name of responsible person

Mohammad Hossein Mahrooz

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Azar deadend, SharifiManesh street, Shariati Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

5th floor, No2, Shahid Arabi street, Yaman avenue, Shahid Chamran highway

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Email

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Web page address

https://research.sbmu.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Hossein Mahrooz

Position

Medical intern

Latest degree

Master

Other areas of specialty/work

Orthopedics

Street address

Shahid Beheshti Medical University, Aarabi st., Daneshjoo Blvd., Shahriari sq., Velenjak

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Person responsible for scientific inquiries

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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

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

After de-identifying the participants (name removal), the data can be sent under an excel file including all demographic information and independent variables and results.

When the data will become available and for how long

all the specified data will be available 6 month after the publication of the results upon request from the corresponding author

To whom data/document is available

academic staff of all universities

Under which criteria data/document could be used

standard scientific citation, and only to the researchers conducting the same research

From where data/document is obtainable

corresponding author Mohammad Hossein Mahrooz mohamad.mahrooz@alum.sharif.edu Shahid Beheshti University of medical sciences, Tehran, Iran

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

A mail or e-mail, requesting the required data, along with an attestation of non-disclosure of information to a third party

Comments

for any further inquiries please contact the corresponding author via e-mail mohamad.mahrooz@alum.sharif.edu