Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Whole body vibration on muscle inhibition, cortical excitability and topographic map of quadriceps muscle in the brain of athletes following anterior cruciate ligament reconstruction

Protocol summary

Study aim

The effect of Whole body vibration on muscle inhibition, cortical excitability and topographic map of quadriceps muscle in the brain of athletes following anterior cruciate ligament reconstruction

Design

A Clinical trial with two control and treatment groups, with Parallel groups, single-blind, Randomization sequence was through randomization.com and balanced block randomization method.

Settings and conduct

Rehabilitation Tehran University of Medical Sciences, evaluation and treatment were performed in the control group and in the intervention group for 4 weeks and re-evaluated 48 hours after the last treatment session.The analyzer is not aware of the patient information group

Participants/Inclusion and exclusion criteria

Inclusion Criteria 18-40 years old Both genders Have a history of anterior cruciate ligament surgery (hamstring graft) without surgery for other ligament and meniscus injuries More than 6 months have passed since the surgery Edinburgh handedness inventory (EHI) questionnaire Tegner Activity Level Scale < 8 had no pain, inflammation or limited range of motion in the knee joint Team doctor approval WBV contraindication TMS contraindication Exclusion Criteria Inability to understand and/or perform the required maneuvers. Alcohol, caffeine and drug consumption on the day of the test. Participant dissatisfaction with the continuation of the program. Being absent for more than 2 sessions or for 3 times

Intervention groups

1- treatment group 2- control group. both groups are athletes with ACL Reconstruction surgery that take 12 treatment sessions. Treatment protocol for treatment group is exercise therapy and whole body vibration. Control group only take exercise therapy

Main outcome variables

Central Activation Ratio, Active Motor Threshold, Amplitude of Motor Evoked Potentials, Map Volume, Center of Gravity, 6m-Timed Hop Test Limb Symmetry Index, KOS-ADL Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220220054078N1**
Registration date: **2022-04-11, 1401/01/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-11, 1401/01/22**
Update count: **0**

Registration date

2022-04-11, 1401/01/22

Registrant information

Name

Sahar Zare pourhashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 4268

Email address

sahar.zp798@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Whole body vibration on muscle inhibition, cortical excitability and topographic map of quadriceps muscle in the brain of athletes following anterior cruciate ligament reconstruction

Public title

investigating the effect of Whole body vibration in athletes following anterior cruciate ligament reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-40 years old both of gender lll More than 6 months have passed since the surgery Edinburgh handedness inventory (EHI) questionnaire Tegner Activity Level Scale < 8 Have a history of anterior cruciate ligament surgery (all types of graft) without surgery for other ligament and meniscus injuries had no pain, inflammation or limited range of motion in the knee joint WBV contraindication: pregnancy, acute thrombosis, serious cardiovascular disease, pacemaker, acute hernia, discopathy, spondylolysis, severe diabetes, epilepsy, recent infections, severe migraine, tumors or kidney stones. TMS contraindication: having a history of seizures, epilepsy (first-degree person or family), head injury or brain injury, having metal in the head (outside the mouth) such as a surgical clip, implantation Welded cochlear implants, history of a bad reaction to an MRI or TMS, history of stroke, brain-related diseases such as MS or brain tumor, history of fainting, severe headache, pregnancy Or planning for pregnancy in the past 3 months, taking medications known to lower the seizure threshold such as imipramine & .... Have a history of anterior cruciate ligament surgery (hamstring graft) without surgery for other ligament and meniscus injuries

Exclusion criteria:

Inability to understand and/or perform the required maneuvers. Alcohol, caffeine and drug consumption on the day of the test. Participant dissatisfaction with the continuation of the program. Presence of pain at the time of the tests or any complication preventing the data collection. Being absent for more than 2 sessions or for 3 times during the whole procedure

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

individuals are randomly divided into two groups, which will be done using randomization sequence through randomization.com and balanced blocked randomization method. the size of the blocks is 4. also, for allocation concealment, sealed and numbered envelopes are used which are provided to the participants by the secretary.

Blinding (investigator's opinion)

Single blinded

Blinding description

patients are randomly divided into 2 groups of real treatment and control group who do not know the type of their group. the information obtained from the evaluation of patients is categorized by another person and analyst is not aware of the grouping of information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

School of Rehabilitation, corner of Safi Alishahi street, Pich E Shemi, Enghelab street

City

Tehran

Province

Tehran

Postal code

1148956111

Approval date

2022-02-17, 1400/11/28

Ethics committee reference number

IR.TUMS.FNM.REC.1400.206

Health conditions studied

1

Description of health condition studied

athletes following anterior cruciate ligament reconstruction

ICD-10 code

S83.51

ICD-10 code description

Sprain of anterior cruciate ligament of knee

Primary outcomes

1

Description
Central Activation Ratio
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using Biodex & stimulator

2

Description
Active Motor Threshold
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using Transcranial magnetic stimulation (MagPro X100)

3

Description
Amplitude of Motor Evoked Potentials
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using Transcranial magnetic stimulation (MagPro X100)

4

Description
Map Volume of quadriceps muscle in motor cortex
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using Transcranial magnetic stimulation (MagPro X100)

5

Description
Center of Gravity of quadriceps muscle's map in motor cortex
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using Transcranial magnetic stimulation (MagPro X100)

6

Description
6m-Timed Hop Test Limb Symmetry Index
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using chronometer

7

Description
Disability in Activities of Daily Living
Timepoint
At the start of the study and 48 hours after end of the treatment
Method of measurement
By using Knee Outcome Survey Activities of Daily Living Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
treatment group: Whole body vibration and exercise therapy including resistive exercises and perturbation exercises for 12 sessions in 4 weeks
Category
Rehabilitation

2

Description
Control group: exercise therapy including resistive exercises and perturbation exercises for 12 sessions in 4 weeks
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation school of Tehran university of medical Sciences
Full name of responsible person
Roya Khanmohammadi
Street address
School of Rehabilitation, corner of Safi Alishahi street, Pich E Shemi, Enghelab street
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rkhanmohammadi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Akbar Fotoohi
Street address
Deputy of research and Technology, sixth floor, Central University Organization, Corner of Quads street, Keshavarz Boulevard
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6511111489
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+98 21 8163 3686
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vcr@tums.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
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
Tehran University of Medical Sciences
Full name of responsible person
Roya Khanmohammadi
Position
Proffessor Assistant
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Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

Contact
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Tehran University of Medical Sciences
Full name of responsible person
Sahar Zare pourhashemi
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MSc student
Latest degree
Bachelor
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available