Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Spinal Excitability in People with Functional Ankle Instability Received Dynamic Versus Static Balance Exercise; A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of Spinal Excitability in People with Functional Ankle Instability Received Dynamic Versus Static Balance Exercise; A Randomized Clinical Trial

Design

A controlled clinical trial with parallel, double-blind, randomized groups on 57 patients. The randomized permutation block method will be used for randomization.

Settings and conduct

This study will be performed on people with functional ankle instability in the Research Center of the Rehabilitation Faculty of Semnan University of Medical Sciences. the lead researcher will perform all the treatment steps and the evaluation steps before and after the intervention will be the responsibility of the research assistant . The evaluator is not aware of the individual's treatment. Participants in each group will also be unaware of the treatment and type of intervention of the other group, so this study is a double-blind randomized clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18 to 35 years. History of no ankle sprain in the opposite limb. Having a score of 24> in the CAIT(cumberland ankle instability tool) questionnaire. Exclusion: History of seizures. History of concussion in the last 6 months. History of any surgery on any of the lower limbs. Existence of any limitation of function or range of motion of the ankle. History of vestibular injury, vision and balance.

Intervention groups

The first group (dynamic balance exercises): In this case, the plate under the person's foot is moving and will be on the stability level (9). Group 2 (static balance exercises): In this case, the plate under the person's foot will be fixed. The type of exercises is as follows: Third group (control group): did not do any exercises and will not be interfered with.

Main outcome variables

Evaluation of spinal excitability; postural stability; ankle functional disability in individuals with ankle functional instability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220220054068N1**
Registration date: **2022-06-21, 1401/03/31**
Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**
Update count: **0**

Registration date

2022-06-21, 1401/03/31

Registrant information

Name

Mansoureh Yadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5588 3470

Email address

myn.yadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Spinal Excitability in People with Functional Ankle Instability Received Dynamic Versus Static Balance Exercise; A Randomized Clinical Trial

Public title
Comparison of Spinal Excitability in People with Functional Ankle Instability Received Dynamic Versus Static Balance Exercise; A Randomized Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
History of no ankle sprains in the last 3 months History of non-ankle sprain in the opposite limb Having a score of 24> in the CAIT questionnaire Patients in whom the severity of the sprain was grade 2 or 3 but did not have surgery. Age between 18_35 years
Exclusion criteria:
Existence of pain in the ankle joint Existence swelling in the ankle joint Have a history of diabetes or any rheumatic disorder or systemic disease that may interfere with sensory input History of any soft or hard tissue damage to any of the lower limbs History of seizures History of concussion in the last 6 months History of any surgery on any of the lower limbs Existence of any limitation of function or range of motion of the ankle History of vestibular injury, vision and balance History of using a variety of sleeping pills and antidepressants and stress
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **57**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals who are eligible to study are randomly assigned to unblocked blocks in three groups. Will group randomly. The first group undergoes static balance exercises and the second group undergoes dynamic balance exercises. And in the third group, as an control group, there will be no intervention. Sampling method in this study is simple sampling. Samples are assigned (to three groups) randomly using the Permuted Block Randomization method with 6 blocks of 6 assigned to 3 groups. In this method, A will represent group one (static balance exercises), B will represent group two (dynamic balance exercises) and C will represent the control group. In this way, the order of interventions A, B and C in the form of blocks from 1 to 6 by the methodological consultant of the project is determined as described in the table below and provided to the executive supervisor of the project and the researcher to assign each qualified person to the supervisor. The executive gets the homework. The supervisor first selects the block using a random number generator (or dice) and then the eligible individuals are assigned to one of three groups A, B or C in a predetermined order.
Blinding (investigator's opinion)
Double blinded
Blinding description
To reduce the bias in the study, the lead researcher will perform all the treatment steps and the evaluation steps before and after the intervention will be the responsibility of the research assistant who is a physiotherapist with 5 years of clinical experience. The evaluator is not aware of the individual's treatment. Participants in each group will also be unaware of the treatment and type of intervention of the other group, so this study is a double-blind randomized clinical trial.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
No. 37, Bighdeli Alley., Mehran Ave., Shahrake Shariati., Khaniabadnoo
City
Tehran
Province
Tehran
Postal code
1894784863
Approval date
2022-05-25, 1401/03/04
Ethics committee reference number
IR.SEMUMS.REC.1401.049

Health conditions studied

1

Description of health condition studied

People with functional ankle instability; Spinal excitability; Postural stability;

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

1. Determining the effect of dynamic balance exercises on changes in spinal excitability of the soleus muscle when prone lying 2. Determining the effect of dynamic balance exercises on changes in spinal excitability of the soleus muscle while single leg standing 3. Determining the effect of dynamic balance exercises on changes in spinal excitability of soleus muscle while double leg standing 4. Determining the effect of static balance exercises on changes in spinal excitability of soleus muscle while prone lying 5. Determining the effect of static balance exercises on changes in spinal excitability of the soleus muscle while single leg standing 6. Determining the effect of static balance exercises on changes in spinal excitability of soleus muscle while double leg standing 7. Determining the effect of dynamic balance exercises on postural stability of FAI(functional ankle instability) individuals 8. Determining the effect of static balance exercises on postural stability of FAI individuals 9. Comparison of changes in spinal excitability of soleus muscle in prone position after treatment between the two intervention groups 10. Comparison of changes in spinal excitability of soleus muscle in single leg standing position after treatment between the two intervention groups11. Comparison of changes in spinal excitability of soleus muscle in double leg standing position after treatment between the two intervention groups 12. Comparison of postural stability after treatment between the two intervention groups 13. Comparison of functional disability of the affected limb after treatment between the two intervention groups

Timepoint

Measurements of spinal excitation, postural stability and functional disability of the ankle will be before the intervention and immediately after the intervention and one month after the intervention.

Method of measurement

Spinal excitability using Hoffman's reflex ratio to M-wave and using electromyography device; Postural stability using a Biodex device; Functional disability rate using Cumberland Ankle Instability Tool Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The balance exercise program is such that the exercises will be performed on a Biodex balance system.The first group (dynamic balance exercises): In this case, the plate under the foot of the person is moving and will be on the level of stability (9).The type of exercises are as follows: Week 1: Day 1: Standing on two legs with eyes open Day 2 and 3: Standing on two legs with eyes closed Week 2: Standing on one leg with eyes Open Week 3: Standing on one leg with eyes Week 4 package: Standing on one leg with your eyes closed, the exercise will be repeated in 3 sets of 10 so that the patient will rest for 1 minute sitting on a chair between each exercise. Rest between each set is 3 minutes while sitting on a chair.The duration of each exercise is 20 seconds. The patient should hold the marker in the center of the circle. Participants in each group (group one: dynamic balance exercises: the plate under the participant's foot is movable, group 2: static balance exercises: the plate under the participant's foot is fixed) balance exercises They will do it for 4 weeks (3 sessions per week).

Category

Rehabilitation

2

Description

Intervention group: The balance exercise program is such that the exercises will be performed on a Biodex balance system. Static balance): In this case, the plate under the person's foot will be fixed.The type of exercises are as follows: Week 1: Day 1: Standing on two legs with eyes open Day 2 and 3: Standing on two legs with eyes closed Week 2: Standing on one leg with eyes Open Week 3: Standing on one leg with eyes Week 4 package: Standing on one leg with your eyes closed, the exercise will be repeated in 3 sets of 10 so that the patient will rest for 1 minute sitting on a chair between each exercise. Rest between each set is 3 minutes while sitting on a chair.The duration of each exercise is 20 seconds. The patient should hold the marker in the center of the circle. Participants in each group (group one: dynamic balance exercises: the plate under the participant's foot is movable, group 2: static balance exercises: the plate under the participant's foot is fixed) balance exercises They will do it for 4 weeks (3 sessions per week).

Category

Rehabilitation

3

Description

Control group: The third group (control group) that no intervention will be performed

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person
Atefeh Aminianfar

Street address
Neuromuscular Rehabilitation Research Center, Ghods Ave

City
Semnan

Province
Semnan

Postal code
9837535196

Phone
+98 23 3332 8502

Fax
+98 23 3365 4180

Email
nmrrc@semums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Majid Mir Mohamad Khani

Street address
Semnan University of Medical Sciences, Basij Blvd

City
Semnan

Province
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Fax
+98 23 3344 8999

Email
rds@semums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Cyrus Taghizade Delkhosh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Semnan University of Medical Sciences, Basij Blvd

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Fax
+98 23 3365 4209

Email
Cyrustaghizadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Cyrus Taghizade Delkhosh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Semnan University of Medical Sciences, Basij Blvd

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Fax
+98 23 3365 4209

Email

Cyrustaghizadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Mansoureh Yadi Nojedehsadat

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
11th Unit, No. 37, Bigdeli Alley, Mehran Ave, Shariati Town, Khani Abad No

City
Tehran

Province
Tehran

Postal code
1894784863

Phone
+98 21 5588 3470

Email
Myn.yadi@gmail.com

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