

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The role of placebo and nocebo in the effectiveness of dynamic tape on the postural control, electrical muscle activity of selected muscles, and the performance of athletes with chronic ankle instability

Protocol summary

Study aim

This study aimed to determine the impact of placebo and placebo mentality on the effectiveness of dynamic tape on posture control, the electrical activity of selected muscles, and functional performance in athletes with chronic ankle instability.

Design

A clinical trial, crossover design, double-blind, randomized on 32 patients. A lottery is used for randomization.

Settings and conduct

The study will take place in the sports rehabilitation laboratory at Arak University. The participants will be athletes with chronic ankle instability. They will visit the laboratory on three separate days to perform tests under three different taping expectations.

Participants/Inclusion and exclusion criteria

The inclusion criteria: a history of ankle sprain two or more times; a sensation of fear and instability in ankle function; a score of 24 or lower on the Cumberland Ankle Instability Tool (CAIT $\leq$ 24); and confirmation of ankle functional instability; no history of using dynamic tape). The exclusion criteria include a history of previous surgery on the lower limb; a history of fracture or acute injury to the musculoskeletal structures or joints of the lower limb (such as sprains, fractures, etc.) within the three months prior to the study.

Intervention groups

We will conduct this study with one group under three different conditions, each with a different intervention: 1. The first intervention involves creating a positive expectation (placebo) about the dynamic tape. 2. The second intervention involves creating a negative expectation (nocebo) about the dynamic tape. 3. The third intervention involves creating a neutral expectation about the dynamic tape. 4. The fourth intervention: the measurement is performed in conditions without taping.

Main outcome variables

Posture control, the electrical activity of selected muscles, and functional performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046368N15**

Registration date: **2024-06-11, 1403/03/22**

Registration timing: **prospective**

Last update: **2024-06-11, 1403/03/22**

Update count: **0**

Registration date

2024-06-11, 1403/03/22

Registrant information

Name

Zahra Raeisi

Name of organization / entity

Arak University

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3492

Email address

z_raisi13@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-14, 1403/03/25

Expected recruitment end date

2024-08-15, 1403/05/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The role of placebo and nocebo in the effectiveness of dynamic tape on the postural control, electrical muscle activity of selected muscles, and the performance of athletes with chronic ankle instability

Public title
positive expectation, negative expectation and taping

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
A history of ankle sprain that requires medical treatment twice or more
Feeling of fear and instability of ankle function
Obtaining a score less than or equal to 24 from the Cumberland Questionnaire (CAIT $\leq$ 24)
Obtaining a score between -2 and +2 on a five-point Likert scale for individual mentality towards the influence of the taping
Exclusion criteria:
Having a history of previous surgery in the lower limbs
Having a history of fractures and acute injuries of the musculoskeletal structure or joints of the lower limbs (such as sprains, fractures, etc.) in the three months leading up to the research led to the loss of at least one day of physical activity.
History of using dynamic tape

Age
From **18 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are required to visit the sports science laboratory at Arak University on three separate days. Evaluations will be conducted under three conditions: positive mental induction, negative mental induction, and neutral, over three different days (sessions). The lottery is used to determine which criteria will be used to evaluate the tests in each session. At the start of the first session, the subject selects one of three different conditions through a lottery, and the tests are carried out accordingly. In the second session, a draw is conducted between the two remaining conditions. Then, in the third session, the third condition is tested.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants are unaware of the intervention due to

their positive, negative, and neutral mental expectations. Additionally, the collected data is provided to the analysts in code form, and they are unaware of the evaluated mentalities.

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Arak University
Street address
Arak University, Karbala Boulevard, Basij Square
City
Arak
Province
Markazi
Postal code
3848177584

Approval date
2024-01-31, 1402/11/11
Ethics committee reference number
IR.ARAKU.REC.1402.076

Health conditions studied

1

Description of health condition studied
Ankel instability
ICD-10 code
M25.373
ICD-10 code description
Other instability, unspecified ankle

Primary outcomes

1

Description
Electromyographic activity of muscle
Timepoint
With positive expectation from the dynamic tape, with negative expectation from the dynamic tape, with usual expectation from the dynamic tape
Method of measurement
Electromyography

2

Description
Postural control

Timepoint

With positive expectation from the dynamic tape, with negative expectation from the dynamic tape, with usual expectation from the dynamic tape

Method of measurement

Pedoscan

3**Description**

Functional performance

Timepoint

With positive expectation from the dynamic tape, with negative expectation from the dynamic tape, with usual expectation from the dynamic tape

Method of measurement

Functional test

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: In this condition, dynamic type will be applied on the ankle. The test will be taken with the usual mentality of the person.

Category

Prevention

2**Description**

Intervention group 1: In this condition, dynamic type is applied on the ankle and positive mental expectation is induced to the participants.

Category

Placebo

3**Description**

Intervention group 2: In this condition, dynamic type is applied on the ankle and negative mental expectation is induced to the participants.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arak university

Full name of responsible person

Zahra Raeisi

Street address

Shariati street

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3277 4031

Email

Z_raisi13@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak university

Full name of responsible person

Hamed Safikhani

Street address

Shariati street

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3262 2000

Email

d-research@araku.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak university

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**

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Basij Square, Arak University

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3417 3492

Fax

Email

Z_raisi13@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Basij Square, Arak University

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3417 3492

Fax

Email

Z_raisi13@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University

Full name of responsible person

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Position

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable