Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≤ 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
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Name of organization / entity
Arak University
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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≤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
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Sponsors / Funding sources

1

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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
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Position
Assistant professor
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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