Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Effectiveness of blood flow Restriction as a stand-alone treatment on muscle strength, dynamic balance, and physical function in female patients with chronic ankle instability

Protocol summary

Study aim
To investigate whether blood BFR as a stand- alone treatment would affect muscle strength, dynamic balance, and physical function in female patients with chronic ankle instability

Design
This study design was a multi-arm randomized clinical trial

Settings and conduct
All participants will be engaged in their assigned treatment protocols 3 times a week for 4 weeks. All measurements and training procedures were supervised and completed at the Physical Therapy Clinic, Collage of Applied Medical Science, Prince Sattam bin Abdulaziz University and all outcome assessors will be blinded to participants' group assignments. Participants will not participate in any other exercise except for the exercise programs provided in this study

Participants/Inclusion and exclusion criteria
Inclusion criteria; patients who have a history of unilateral lateral ankle sprain - a history of self-reported giving way and/or feelings of ankle instability of the involved ankle patients who have a score of ≤24/30 on chronic ankle instability tool. Exclusion Patients with a history of bilateral ankle instability or pathological joint laxity Patients with a history of ankle fracture. Patients undergone surgery of the hip, knee, and/or ankle patients who have uncontrolled hypertension, or any other chronic disease

Intervention groups
A total of 40 female patients with chronic ankle instability will volunteer to participate in this study. They will be matched by age and Cumberland Ankle Instability Tool scores and will be randomly allocated, , into one of the following experimental groups: 1) blood flow restriction with supervised rehabilitation group, 2) supervised rehabilitation group, and 3) BFR as a stand alone treatment group.

Main outcome variables
Muscle strength, dynamic balance, and physical function

General information

Reason for update

Acronym
BFR

IRCT registration information
IRCT registration number: **IRCT20210909052421N2**
Registration date: **2023-03-03, 1401/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-03, 1401/12/12**
Update count: **0**

Registration date
2023-03-03, 1401/12/12

Registrant information

Name
Nadia Radwan

Name of organization / entity
Prince Sattam Bin Abdulaziz University

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Saudi Arabia

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+966 11 588 6500

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10

Expected recruitment end date
2023-08-01, 1402/05/10

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

Scientific title
Effectiveness of blood flow Restriction as a stand-alone treatment on muscle strength, dynamic balance, and physical function in female patients with chronic ankle instability

Public title
Effect of blood flow Restriction on muscle strength ,balance and physical function in patients with chronic ankle instability
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients who have a history of unilateral lateral ankle sprain, which occurred at least 12 months before study enrolment, patients who have a history of self-reported giving way and/or feelings of ankle instability of the involved ankle during activities of daily living for at least 6 months patients who have a score of ≤24/30 on chronic ankle instability tool.
Exclusion criteria:
Patients with a history of bilateral ankle instability Patients who have pathological joint laxity (a positive result on the talar tilt test or anterior drawer test) Patients with a history of ankle fracture. Patients undergone surgery of the hip, knee, and/or ankle patients who have uncontrolled hypertension, or any other chronic disease Patients who have history of any musculoskeletal disorders
Age
From **30 years** old to **40 years** old
Gender
Female

Phase
0
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
- 45 female patients with chronic ankle instability will be randomly allocated, using block randomization, into one of 3 groups: 1)blood flow restriction plus supervised rehabilitation group, 2) supervised rehabilitation group, and 3) BFR as a stand- alone treatment group. - A drawing sealed non-transparent envelope with a specific code for each envelope was chosen by all participants for either group (group A, group B, and group c) under the supervision of a blinded independent assessor.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients were recruited and allocated randomly into on of the three groups. Based on the randomized block design, a drawing sealed non-transparent envelope with a specific code for each envelope was chosen by all participants for either group (group A and group B and C) under the supervision of a blinded independent assessor.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Prince Sattam Bin Abulaziz university
Street address
ALmanifeia, Alraghi building
City
Alkharj
Postal code
00966
Approval date
2022-10-31, 1401/08/09
Ethics committee reference number
SCBR-071-2022

Health conditions studied

1

Description of health condition studied
Chronic ankle instability
ICD-10 code
M25.30
ICD-10 code description
Other instability, unspecified joint

Primary outcomes

1

Description
Muscle strength assessment
Timepoint
pre and post the intervention period
Method of measurement
isokinetic dynamometer

2

Description
dynamic balance
Timepoint
pre and post the intervention period
Method of measurement
Biodex balance system

3

Description
physical function
Timepoint
pre and post the intervention period
Method of measurement
physical function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A- This group will receive blood flow restriction (BFR) (applied through a pneumatic occlusion cuff) while performing the rehabilitation program. The rehabilitation program consists of balance and strengthening exercise.
Category
Rehabilitation

2

Description
Intervention group B- In this group, The participants perform the rehabilitation program which consisted of balance and strengthening exercise. Participants wore a BFR cuff similar to that of group A, but the BFR cuff had no inflation.
Category
Rehabilitation

3

Description
Intervention group C. This group will receive only BFR without any exercise. All groups completed the rehabilitation program 3 times weekly for 4 consecutive weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Prince Sattam Bin Abdelaziz university hospital
Full name of responsible person
Mashael Alghamedi
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Web page address
https://hospital.psau.edu.sa/ar/directory

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Prince Sattam bin Abdul-Aziz university
Full name of responsible person
Mohammed Alshehri
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ALmanifeia, Alraghi building
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
self funding
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Prince Sattam bin Abdulaziz University
Full name of responsible person
Nadia Lotfy Radwan
Position
Lecturer

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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
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
Title and more details about the data/document
patient information sheet , raw data , results
When the data will become available and for how long
after publication
To whom data/document is available
public
Under which criteria data/document could be used
statistical analysis
From where data/document is obtainable
n.radwan@psau.edu.sa
What processes are involved for a request to access data/document
via email. research gate
Comments