Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effects of adding dry needling technique to Mulligan’s mobilization with movement technique along with exercise therapy on pain, range of motion, disability and balance in patients with knee osteoarthritis

Protocol summary

Study aim

Determining the effect of adding dry needling technique to Mulligan’s mobilization with movement technique along with exercise therapy on pain, range of motion, disability and balance in patients with knee osteoarthritis

Design

A randomized, double blind, sham controlled clinical trial with a parallel group design of 48 patients. Random allocation method is Permuted Block Randomization.

Settings and conduct

location: official centers of bushehr university of medical science. for group 1, mulligan's mobilization with movement technique with exercise therapy with dry needling is applied on patients. for group 2, these treatments are all applied while dry needling is sham. blinding: patient, researcher, therapist, outcomes assessor, data analyzer.

Participants/Inclusion and exclusion criteria

Inclusion: age 45 to 70; knee osteoarthritis with at least one active trigger point; knee pain more than 3 in visual Analogue Scale (VAS) and disability more than 25 in Western Ontario and McMaster Universities Arthritis Index (WOMAC) scale; at least 10 degrees loss in knee flexion range of motion. Exclusion: knee replacement surgery; neurologic disease; Rheumatoid Arthritis; steroid and analgesic injection in last 3 month in knee; fibromyalgia; inflammation or infection; pregnancy; diabetes; epilepsy; needle phobia; any trigger points treatment in last 3 month; vascular disease; fracture; physiotherapy in last 3 month for knee joint.

Intervention groups

Group 1: mulligan's mobilization with movement technique with exercise therapy with dry needling & 2: all above treatments but sham dry needling.

Main outcome variables

Pain; range of motion; disability; number of active trigger points in muscles around knee; local pain assessment in active trigger points; functional mobility; balance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221026056300N1**
Registration date: **2022-11-12, 1401/08/21**
Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**
Update count: **0**

Registration date

2022-11-12, 1401/08/21

Registrant information

Name

Maryam Eshghi Vasoukolaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3532 8595

Email address

maryameshghivasoukolaei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-01-19, 1401/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of adding dry needling technique to Mulligan’s mobilization with movement technique along with exercise therapy on pain, range of motion, disability and balance in patients with knee osteoarthritis

Public title
The effects of adding dry needling technique to manual therapy in treatment of patients with knee osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 45 - 70, Unilateral or bilateral knee pain and dysfunction, in bilateral knee pain, the knee with more pain will be cured, Knee osteoarthritis with grade 2 and 3 Kellgren & Lawrence, At least one active trigger point in muscles around knee that refer pain, Knee pain more than 3 in VAS scale, Ability to walk for 6 meters and more, Disability more than 25 in WOMAC scale, At least 10 degrees loss in knee flexion range of motion.

Exclusion criteria:
Neuropathic pain in lower limb, Knee replacement surgery, Surgery in other parts of lower limb in last 6 month. Radicular pain in knee, Neurologic diseases, Rheumatoid Arthritis, Steroid and analgesic injection in last 3 month in knee, Fibromyalgia syndrome, Patellar tendinopathy, Inflammation or active infection signs in knee, Pregnancy, Diabetes, Epilepsy, Immune system diseases like AIDS, Cancer, Hepatitis, Phobia of needle in dry needling technique, Any treatment for trigger points in considering muscles in last 3 month, Vascular disease associated with unusual bleeding, Treatment with Anticoagulants, Pain in lower limb associated with low back pain, Fracture or any other orthopedic problem in involved lower limb, Musculoskeletal disorders in other joints in lower limb (except osteoarthritis) Physiotherapy sessions in last 3 month for knee joint.

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation method in this study is Permuted Block Randomization. A represents the person who receives mulligan's mobilization with movement technique along with exercise therapy with dry needling technique and B represents the person who receives mulligan's mobilization with movement technique along with exercise therapy with sham dry needling technique. This method runs with considering 4 blocks that the number of all possible 4 permutations equals 6. (4 permutations blocks consist of: ABAB ،ABBA ،BAAB ،BABA ،AABB ،BBAA) We assign a number to each mode. Using Random Numbers Table, a list with 48 persons will be produced.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, main student doing initial assessment based on inclusion and exclusion criteria and treatments in patients. assistant student collecting data from patients and analyzing them. Allocation base on Permuted Block Randomization and for blinding in patients, sham dry needling applied in that way that the patient can't realize that it is not real.

Placebo
Used

Assignment
Parallel

Other design features
This study is added value study.it means that dry needling technique is added to mulligan's mobilization with movement technique.one group receives Mulligan’s mobilization with movement technique along with exercise therapy with dry needling technique and another group receives Mulligan’s mobilization with movement technique along with exercise with sham dry needling technique.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of shiraz university of medical sciences

Street address
Seventh floor, Central building of Shiraz university of medical sciences, Zand ave., Shiraz

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2022-10-19, 1401/07/27

Ethics committee reference number
IR.SUMS.REHAB.REC.1401.036

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Visual Analogue Scale

2

Description
Knee Range of Motion
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Goniometer

3

Description
Disability
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

4

Description
Number of active trigger points in muscles around knee
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Counting active trigger points

5

Description
Local pain of trigger points in muscles around knee
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Functional mobility
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Timed Up and Go test

2

Description
Balance
Timepoint
Before treatment, After treatment, 4 weeks after treatment
Method of measurement
Modified STAR Excursion Balance Test (mSEBT)

Intervention groups

1

Description
Intervention group: Mulligan's mobilization with movement technique along with exercise therapy with dry needling technique
Category
Rehabilitation

2

Description
Intervention group: Mulligan's mobilization with movement technique along with exercise therapy with sham dry needling technique
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Bushehr University of Medical Sciences
Full name of responsible person
Maryam Eshghi Vasoukolaei
Street address
Bushehr University of Medical Sciences, Moalem Ave., bushehr
City
Bushehr
Province
Boushehr
Postal code
7514633341
Phone
+98 77 3332 2081

Fax
+98 77 3332 3123
Email
maryameshghivasoukolaei@yahoo.com
Web page address
https://www.bpums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpour
Street address
Seventh floor, Central building of Shiraz university of medical sciences, next to hilal ahmar, Zand ave., Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 77 3235 7282
Fax
+98 77 3212 2430
Email
vcrdep@sums.ac.ir
Web page address
https://research.sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Eshghi Vasoukolaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Number 8, Farhang Avenue, Motahari Street
City
Khormouj
Province
Boushehr
Postal code
7541835981
Phone
+98 77 3532 8595
Fax
Email
maryameshghivasoukolaei@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Sara Abolahrari Shirazi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Physiotherapy Department, School of Rehabilitation Sciences, Shiraz University of Medical Sciences, Chamran Blvd., Abiverdi 1 Ave., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7194733669
Phone
+98 77 3627 1552
Email
sahrari@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Eshghi Vasoukolaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Number 8, Farhang Avenue, Motahari Street

City
Khormouj
Province
Boushehr
Postal code
7541835981
Phone
+98 77 3532 8595
Fax
Email
maryameshghivasoukolaei@yahoo.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