

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effectiveness of Biofeedback Therapy compared to Acupuncture for treatment of myofascial pain syndrome in neck and upper back area: A Randomized clinical trial

Protocol summary

Study aim

The aim of this study was to evaluate the efficacy of two complementary therapies, biofeedback and acupuncture, in the treatment of chronic neck and back pain and comparison of these two with each other

Design

Double blind randomized clinical trial with control group, sample volume of 50 patients and parallel groups

Settings and conduct

Using VAS for pain intensity, neck disability index for assessment of cervical function, algometer for pain pressure threshold and bubble inclinometer for range of motion of neck before. Evaluation and comparison will be done before, immediately and 12 weeks after treatment Department of physical medicine and rehabilitation, imam reza and shahid madani hospitals

Participants/Inclusion and exclusion criteria

Presence of neck and shoulder's muscles pain for more than 2 months and less than 1 year Presence of at least 3 trigger points around the neck and shoulder muscles, VAS between 4-10 The desire to participate in the study If there is radiculopathy based on history and the presence of one of radiculopathy's findings such as weakness, radicular pain, reduced DTR, paresthesia and positive spurling test Presence of confirmed cervical discopathy with MRI Presence of severe cervical degenerative changes History of surgery or cervical spine trauma History of therapeutic intervention for recent neck problems Presence of systemic diseases that prevent acupuncture or biofeedback therapy, such as hemorrhagic, rheumatologic or cardiovascular disorders Patients with history of depression or Taking psychological drugs People with diagnosis of fibromyalgia Pregnancy Malignancy

Intervention groups

Group A for biofeedback and group B for acupuncture

Main outcome variables

Pain intensity, pain pressure threshold, neck functional disability, Neck range of motion in flexion, extension and left and right lateral bending

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003217N12**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **prospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Biofeedback Therapy compared to Acupuncture for treatment of myofascial pain syndrome in neck and upper back area: A Randomized clinical trial

Public title
Effectiveness of Biofeedback Therapy compared to Acupuncture for treatment of myofascial pain syndrome in neck and upper back area: A Randomized clinical trial

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Presence of neck and shoulder's muscles pain for more than 2 months and less than 1 year Presence of at least 3 trigger points around the neck and shoulder muscles VAS between 4-10 The desire to participate in the study
Exclusion criteria:
 If there is radiculopathy based on history and the presence of one of radiculopathy's findings such as weakness , radicular pain, reduced DTR, paresthesia and positive spurling test Presence of confirmed cervical discopathy with MRI Presence of severe cervical degenerative changes History of surgery or cervical spine trauma History of therapeutic intervention for recent neck problems Presence of systemic diseases that prevent acupuncture or biofeedback therapy, such as hemorrhagic, rhomatologic or cardiovascular disorders Patients with history of depression or Taking psychological drugs People with diagnosis of fibromyalgia Pregnancy Malignancy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method has been done based on a random number table with computer software or computerized random number generator

Blinding (investigator's opinion)
Double blinded

Blinding description
Acupuncture is performed by a physiatrist and patient assessment before and after treatment is performed by a resident of the Rehabilitation who are unaware of the

type of group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Tabriz University of Medical Sciences
Street address
 Vice Chancellor of Research, Daneshgah Ave.
City
 Tabriz
Province
 East Azarbaijan
Postal code
 5123698741
Approval date
 2018-04-16, 1397/01/27
Ethics committee reference number
 IR.TBZMED.REC.1397.030

Health conditions studied

1

Description of health condition studied
Myofacial pain syndrome

ICD-10 code
R52.2

ICD-10 code description
Other chronic pain

Primary outcomes

1

Description
Pain intensity

Timepoint
Before, immediately and 3 months after treatment

Method of measurement
Visual analogue scale (VAS)

2

Description
Neck functional disability

Timepoint
Before, immediately and 3 months after treatment

Method of measurement
Neck disability Index questionnaire

3

Description

Pain pressure threshold

Timepoint

Before, immediately and 3 months after treatment

Method of measurement

Algometer

4

Description

Neck range of motion in flexion, extension, left and right lateral bending

Timepoint

Before, immediately and 3 months after treatment

Method of measurement

Bubble inclinometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients in group A were treated with biofeedback for 6 sessions. Patients, Before and after treatment(immediately and 12 weeks after treatment), were evaluated with VAS for pain intensity, neck disability index for assessment of function, algometer for pain pressure threshold and bubble inclinometer for range of motion of neck.

Category

Treatment - Devices

2

Description

Intervention group: patients in group B were treated with acupuncture for 6 sessions. Patients, Before and after treatment(immediately and 12 weeks after treatment), were evaluated with VAS for pain intensity, neck disability index for assessment of function, algometer for pain pressure threshold and bubble inclinometer for range of motion of neck

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Fariba Eslamiyan

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Sponsors / Funding sources

1

Sponsor

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ali pirani

Position

Resident of physical medicine and rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Associate professor of physical medicine and
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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

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