Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 thereshold 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 leats 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, rhomatologic 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 thereshold, 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

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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 leats 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 questionare

3

Description
Pain pressure treshold
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 thereshold 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 thereshold 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

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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
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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