Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effectiveness of traditional physiotherapy and High-Tone therapy vs. routine physiotherapy alone on pain, cervical ROM, disability level and quality of life in chronic non-specific neck pain subjects with trigger point in upper trapezius muscle

Protocol summary

Study aim
The effectiveness of routine physiotherapy and High-Tone therapy vs. traditional physiotherapy alone on pain, cervical ROM, disability level and quality of life in chronic non-specific neck pain subjects with trigger point in upper trapezius muscle

Design
The study has control group and is a randomized clinical trial, parallel and one-way blind.

Settings and conduct
Information questionnaire is completed by the patient and asked to determine the severity of neck pain based on the VAS, followed by the neck disability index questionnaire, neck pain and disability scale questionnaire and the SF-36 quality of life questionnaire. After initial assessments, individuals are treated for four weeks and re-evaluated four weeks after the last treatment session.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- People with chronic non-specific neck pain with or without referral to the upper limb without known cause that the pain lasts more than 3 months and has active trigger points in the upper trapezius muscle 2- Age 20-50 years 3- Ability to read and write in Persian Exclusion criteria: 1- Presence of neck pain symptoms of known origin 2- History of migraine 3- Peripheral nerve involvement 4- Fracture of the spine 5- Tumor in the spine 6- Musculoskeletal disorders of the shoulder area 7- Rheumatoid inflammatory diseases 8- Pregnancy 9-Receiving any kind of physiotherapy treatment 10-People are reluctant to participate 11-Simultaneous pain in other areas of the spine 12-Destructive changes 13-History of WIPLASH injury 14-History of shoulder and neck surgery 15-Fibromyalgia 16-Postural kyphosis or any Another posture

Intervention groups
Patients are divided into two groups: routine physiotherapy and hightone therapy (experimental group) or routine physiotherapy alone (control group).

Main outcome variables
Pain, range of motion of the neck, level of disability and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180728040618N5**
Registration date: **2021-08-01, 1400/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-01, 1400/05/10**
Update count: **0**

Registration date
2021-08-01, 1400/05/10

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-16, 1400/04/25
Expected recruitment end date
2021-08-06, 1400/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of traditional physiotherapy and High-Tone therapy vs. routine physiotherapy alone on pain, cervical ROM, disability level and quality of life in chronic non-specific neck pain subjects with trigger point in upper trapezius muscle

Public title
The effectiveness of traditional physiotherapy and High-Tone therapy vs. routine physiotherapy alone on trigger point in upper trapezius muscle
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with chronic non-specific neck pain Age between 20 to 50 years old Ability to read and write in Persian
Exclusion criteria:
Specific neck pain History of migraine Peripheral nerve involvement in shoulder and neck region Existence of fractures in the spine Existence of tumor in the spine Existence of musculoskeletal disorders in shoulder region
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with nonspecific chronic neck pain are randomly divided into two groups: routine physiotherapy and high-tone therapy (group A) and routine physiotherapy group alone (B) with a ratio of 1:1. Random allocation will be done by the method of balanced (permuted) block randomization, which consists of 4-letter blocks and are made of letters A and B. Then, the treatment allocation list obtained in letters A and B is placed inside the numbered envelopes. The letter A stands for routine physiotherapy and high-tone therapy, and the letter B denotes routine physiotherapy alone. The random assignment process is performed by someone outside the research team before the study begins. Block randomization tool will be done by Random allocation software. After the initial evaluation of the patient by the examiner, the envelopes will be numbered according to the number of each person entered in the study. Finally, after each patient enters the treatment sessions, the intervention provider adjusts the treatment interventions based on the letters in the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
The assessor will be completely unaware of the letters inside the envelopes at the random assignment stage. It should also be noted that after placing patients in the desired group, they are asked not to provide their grouping information to the assessor. All assessments will be performed by a physiotherapist. This person does not know the grouping of patients with chronic non-specific neck pain. In other words, at the time of the final evaluation of the patients, the assessor is not able to determine what type of treatment each patient has received. Therapeutic interventions will be performed by another physiotherapist.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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Tehran
Postal code
1449614535
Approval date
2021-06-28, 1400/04/07
Ethics committee reference number
IR.IUMS.REC.1400.290

Health conditions studied

1

Description of health condition studied
Chronic non-specific neck pain
ICD-10 code
M54.2
ICD-10 code description
Cervicalgia

Primary outcomes

1

Description
pain
Timepoint
Before the intervention and 4 weeks after the last treatment session
Method of measurement
visual analog scale

2

Description
neck range of motion
Timepoint
Before the intervention and 4 weeks after the last treatment session
Method of measurement
guniameter

Secondary outcomes

1

Description
neck disability
Timepoint
before the intervention and 4 weeks after the last treatment session
Method of measurement
neck disability index questionnaire

2

Description
quality of life
Timepoint
before the intervention and 4 weeks after the last treatment session
Method of measurement
quality of life questionnaire SF-36

Intervention groups

1

Description
Intervention group: Individuals with non-specific chronic neck pain who are in the routine physiotherapy and hightone therapy groups receive the same routine physiotherapy protocol twice a week for 4 weeks. In addition, individuals in the experimental group treated with hightone therapy. This study uses hightone currents with HITOP device (manufacturer: GBO Country of manufacture: Germany), which produces currents with a pulse width of less than 350 mA and less than 70 volts. The current starts with an initial frequency of 4096 Hz and reaches a frequency of 32768 Hz in more than 3 seconds. At frequency 32768, the current is maintained for a maximum of 3 seconds and then returns to the base frequency, and the intensity of the current increases to such an extent that the person does not feel pain or discomfort. Individuals in the experimental group receive Hightone currents for 20 minutes per session, twice a week for 4 consecutive weeks.
Category
Treatment - Other

2

Description
Control group: Individuals with chronic non-specific neck pain who are placed in the routine physiotherapy group alone receive the following protocol twice a week for 4 weeks.1- Heat (using infrared light for 10 minutes at the beginning of treatment) 2- Acupuncture-like current (TENS) (due to chronic pain) with a frequency below 10 Hz, pulse duration 150-250 microseconds. Four electrodes (two channels) are placed on the neck area and the sore spot of the trigger points for 15 minutes. 3- Ischemic pressure technique on trigger points: To apply this technique, the person is placed in a prone position and the upper trapezius muscle is placed in a shortened position. This technique involves continuous deep pressure using the thumb, which gradually increases to the patient's tolerance threshold. The pressure is relieved when either a tissue release is felt under the contraction or it lasts more than 60 seconds. This technique is applied 3 times per session for each trigger point with a 10 second rest interval. 4- Upper Trapezius Muscle Stretching Training: To stretch the each side of upper trapezius muscle, asked while sitting facing on chair, to bend the neck forward, and lateral flex to the opposite side, and rotate towards the affected. People are asked to do this exercise three days a week, 2 times a day, 10 repetitions each time, and 30 seconds for the involved side.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
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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?
No
Title of funding source
Iran 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
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Iran University of Medical Sciences
Full name of responsible person
Holako Mohsenifar
Position
Assistant Professor
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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Deidentified individual participant data collected for the primary and secondary outcome measures will be shared if necessary
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
The data will be available for physical therapists working in academic institutions and also clinicians working in the field of musculoskeletal disorders
Under which criteria data/document could be used
The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of hightone current and trigger points of upper trapzius muscle.
From where data/document is obtainable
Applicants can contact the researcher of this study Zamane bonyatpour by email. Email address: zamane94@gmail.com
What processes are involved for a request to access data/document
Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.
Comments