

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects Of Osteopathic Manipulation On Clinical Outcomes In Patients With Somatic Tinnitus: A Randomized Controlled Trial

Protocol summary

Study aim

To investigate the effects of osteopathic manipulation on tinnitus severity and pain in patients with somatic tinnitus.

Design

A randomized clinical trial, concealed, blinded, with a parallel control group, 80 patients, between March 2021 and December 2021, and followed for 9 months.

Settings and conduct

ENT Department University of Lahore Teaching Hospital, Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with somatic tinnitus; Aged 18-60 years; Both genders. Exclusion Criteria: history of ear surgery; history of cervical surgery; hypertension; history of head trauma; history of non-steroidal anti-inflammatory drugs usage; arteriosclerosis; arthritis; diabetes mellitus; continuous noise exposure.

Intervention groups

Intervention group: osteopathic manipulation along with traditional physiotherapy. Control group: traditional physiotherapy only.

Main outcome variables

Tinnitus severity; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201201049564N1**

Registration date: **2021-09-09, 1400/06/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-09, 1400/06/18**

Update count: **0**

Registration date

2021-09-09, 1400/06/18

Registrant information

Name

Anam Saeed

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 42 35451125

Email address

anasaeed63@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-10-30, 1400/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects Of Osteopathic Manipulation On Clinical Outcomes In Patients With Somatic Tinnitus: A Randomized Controlled Trial

Public title

Effects Of Osteopathic Manipulation On Clinical Outcomes In Patients With Somatic Tinnitus: A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with somatic tinnitus Aged 18-60 years Both genders.

Exclusion criteria:

History of any ear surgery
 History of cervical surgery
 Hypertension
 History of head trauma
 History of non-steroidal anti-inflammatory drugs usage
 Arteriosclerosis
 Arthritis
 Diabetes mellitus
 History of continuous noise exposure

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 66 participants was recruited into the study. The subjects were randomly assigned into two groups A or B (each containing 33 subjects) according to their selection by lottery method. There were 33 cards marked with group-A and 33 with group-B inside a box. Each participant was requested to randomly pick a card from the box. Slips that were picked by the participants, were not put back in the box.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor was unaware of the treatment given to the participant.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of University of Lahore

Street address

University Of Lahore, Defense road near buhbatian chowk, Lahore

City

Lahore

Postal code

54000

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IRB-UOL-FAHS/791/2020

Health conditions studied**1****Description of health condition studied**

Somatic Tinnitus

ICD-10 code

H93.1

ICD-10 code description

Tinnitus

Primary outcomes**1****Description**

Severity of tinnitus

Timepoint

baseline, 4th week, 8th week

Method of measurement

Tinnitus Handicap inventory

2**Description**

Pain

Timepoint

Baseline, 4th week, 8th week

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups**1****Description**

osteopathic manipulation (includes soft tissue mobilization/stretching of upper trapezius, infraspinatus, splenius capitis, splenius cervicis, sternocleidomastoid, METS of cervical, high velocity, low amplitude thrust of cervical) for the somatic tinnitus to reduce the pain and tinnitus severity. the treatment was given on alternate days for the period of 8 weeks.

Category

Treatment - Other

2**Description**

Control group: traditional physiotherapy was given with TENS for 10 min at 50 width and rate of 70 hz, Heating pad for 10 min along with tissue mobilization/stretching of upper trapezius, infraspinatus, splenius capitis, splenius cervicis, sternocleidomastoid, METS of cervical, high velocity, low amplitude thrust of cervical

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT Department. University of Lahore Teaching Hospital, Lahore

Full name of responsible person

Dr. Zahid

Street address

University of Lahore Teaching Hospital, University Road Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

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105-B, Block A-1 P&D society Canal road Lahore

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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-funded

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

University of Lahore

Full name of responsible person

Anam Saeed

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Name of organization / entity

University of Lahore

Full name of responsible person

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Position

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Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Name of organization / entity

University of Lahore

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Position

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available