Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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; Aged18-60 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 Aged18-60 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

City
Lahore

Postal code
54000

Phone
+92 42 32560865

Email
info@uol.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Lahore

Full name of responsible person
Anam Saeed

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

City
Lahore

Postal code
54000

Phone
+92 42 35451125

Email
anasaeed63@gmail.com

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

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

City
Lahore

Province
Punajb

Postal code
54000

Phone
+92 321 8191607

Email
anasaeed63@gmail.com

Person responsible for scientific 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

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

City
Lahore

Province
Punajb

Postal code
54000

Phone
+92 321 8191607

Email
anasaeed63@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of Lahore

Full name of responsible person
Anam Saeed

Position
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Street address
105-B, Block A-1 P&D society Canal road Lahore
City
Lahore
Province
Punajb
Postal code
54000
Phone
+92 321 8191607
Email
anasaeed63@gmail.com

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