

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Effectiveness of intensive laryngeal manual therapy on quality of voice in patients with muscle tension dysphonia

Protocol summary

Study aim

Investigating the effects of manual massage therapy in the form of intensive sessions (12 sessions (6 sessions per week)) on voice quality in people with dysphonia caused by muscle tension.

Design

The design of the study is single subject and each person is considered as her own control and we do not have a control group and treatment will be provided to all people.

Settings and conduct

Acoustic room of Hamadan Medical Sciences
Rehabilitation Faculty

Participants/Inclusion and exclusion criteria

Dysphonic participants who have muscle tension. They do not have polyps, nodules, spasmodic dysphonia, chronic fatigue syndrome, and a history of thyroid surgery (determined by laryngoscopy) and have type 1 MTD. Patients should not have any surgery history, temporomandibular joint problems, short neck, neurological and behavioral problems.

Intervention groups

In the first phase, no intervention is provided and the individual's speech sample is recorded for six days and every other day at three points for perceptual and acoustic evaluation. In the intervention phase, which includes 12 sound therapy sessions, MCT and LMT treatments will be provided. During the intervention, data collection is done at 6 points by perceptual and acoustic evaluation. During the follow-up phase, the basic evaluation process will be repeated.

Main outcome variables

maximum phonation time, jitter, shimmer, fundamental frequency, first formant, harmonic to noise ratio, Pain level, TENs level, GRBAS scores, age, sex, intervention

General information

Reason for update

Acronym

MTD

IRCT registration information

IRCT registration number: **IRCT20230403057804N2**

Registration date: **2023-07-03, 1402/04/12**

Registration timing: **retrospective**

Last update: **2023-07-03, 1402/04/12**

Update count: **0**

Registration date

2023-07-03, 1402/04/12

Registrant information

Name

Kowsar Baghban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1571

Email address

baghban.kowsar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-25, 1402/04/04

Expected recruitment end date

2023-07-01, 1402/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of intensive laryngeal manual therapy on quality of voice in patients with muscle tension

dysphonia

Public title

Investigating the effect of intensive manual therapy on the voice quality of patients with dysphonia caused by muscle tension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Do not have polyp, nodule, spasmodic dysphonia, chronic fatigue syndrome, and history of thyroid surgery (determined by laryngoscopy) and have type 1 MTD. Patients should not have any surgery history, temporomandibular joint problems, short neck, neurological and behavioral problems. Dysphonia score of people should be moderate to severe, and this score will be determined based on palpation test and extralaryngeal muscle tension. Patients should not use steroids, alcohol, or smoke for a long period of time. Patients should not have lung disease, flu, hearing disorder, upper respiratory tract infection, nervous disorder and hypothyroidism.

Exclusion criteria:

People do not want to continue cooperation until the end of the study. Do not have access to people to provide treatment every day.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 8

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

The study design is single subject and assessment-intervention-evaluation (ABA).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical

Sciences

Street address

Shahid Fahmideh St. in front of Hamadan University of Medical Sciences Mardom Park

City

HAMADAN

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.UMSHA.REC.1402.225

Health conditions studied

1

Description of health condition studied

Muscle tension dysphonia

ICD-10 code

R49.8

ICD-10 code description

other voice and resonance disorders

Primary outcomes

1

Description

fundamental frequency

Timepoint

Three evaluation points before the intervention and in the basic evaluation phase, six evaluation points during the intervention and three evaluation points during the follow-up and after the intervention.

Method of measurement

PRAAT software

Secondary outcomes

1

Description

voice quality

Timepoint

Three evaluation points before the intervention and in the basic evaluation phase, six evaluation points during the intervention and three evaluation points during the follow-up and after the intervention.

Method of measurement

PRAAT software

Intervention groups

1

Description

Intervention group: dysphonic people / In the first phase, no intervention is provided and the individual's speech

sample is recorded for six days and every other day at three points for perceptual and acoustic evaluation. In the intervention phase, which includes 12 sound therapy sessions, MCT and LMT treatments will be provided. During the intervention, data collection is done at 6 points by perceptual and acoustic evaluation. During the follow-up phase, the basic evaluation process will be repeated.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Speech Therapy Clinics in Hamadan University of medical science M

Full name of responsible person

Kowsar Baghban

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Kowsar Baghban

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

Speech therapy

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Person responsible for updating data

Contact

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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