

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Development and Effectiveness of Elective Laryngeal Manual Therapy in Comparison with Manual Circumlaryngeal Therapy in Patients with Primary Muscle Tension Dysphonia

Protocol summary

Study aim

This study intends to design and evaluate its effectiveness Elective Laryngeal Manual Therapy (ELMT) as a new method in laryngeal manual therapy, compared to Manual Circumlaryngeal Therapy (MCT) as a conventional method of laryngeal manual therapy in patients with Muscle Tension Dysphonia (MTD) based on the results of pre-, inter-and post-treatment evaluation in an RCT study.

Design

After diagnosing MTD, patients are divided into ELMT and MCT groups. Allocation between two groups is done using the law of random allocation. For 30 people, the sample size (15 patients in each group) is placed in a box in opaque envelopes. The lottery is performed by patients.

Settings and conduct

The study will be double-blind. Patients and evaluators do not know about the treatment group. Both methods have 6 sessions of treatment and 4 stages of evaluation. Treatments are twice a week in half-hour sessions. Evaluations are performed at the beginning, end, and end of sessions 2 and 4 to determine the variables to evaluate the effectiveness of treatments and also to compare the two treatments.

Participants/Inclusion and exclusion criteria

Participants are female MTD patients diagnosed based on the consensus of an ENT specialist and speech therapist. Patients should be 20 to 55 years and have had problems for 3months or more and should not have diseases that interfere with assessment and treatment.

Intervention groups

This study has 2groups receiving ELMT and MCT. The ELMT group will receive the new method designed in this study and the MCT group will receive conventional therapy. Each group will receive 6 sessions of treatment.

Main outcome variables

Overall severity of dysphonia and Strain Frequency and severity of vocal tract discomfort Pain, Tightness, Tenderness, Hypertrophy, Larynx height and movement Limitation Thyrohyoid and cricothyroid size Jitter, Shimmer, HNR, 1,2 and 3rd formants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211110053027N1**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and Effectiveness of Elective Laryngeal Manual Therapy in Comparison with Manual Circumalaryngeal Therapy in Patients with Primary Muscle Tension Dysphonia

Public title

Development and Effectiveness of ELMT in Comparison with MCT in Patients with Primary MTD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

In the present study, those MTD patients will enter the study who have the following criteria: After being informed of the conditions and manner of conducting the study, express their informed consent to participate in the study; 2. Be in the age range of 20 to 55 years and all be women; 3. More than three months have passed since the voice or voice-related complaints; 4. Receive a primary MTD diagnosis based on the consensus of the laryngologist and speech and language pathologist and the results of voice history, consensus auditory-perceptual evaluation of voice, palpation, and video laryngoscopy; Receive voice therapy or other voice-related therapies while performing the study.

Exclusion criteria:

Received voice therapy or other voice-related therapies for 90 days prior to the start of the study; Have had an upper respiratory tract infection or a cold during the study and up to three weeks before; Mass, wound or scar, presence of high fat tissue, history of surgery and radiotherapy in the neck area; Be during breastfeeding and pregnancy; Have an addiction to tobacco, drugs and alcohol; There are neurological disorders involving the larynx, hearing disorders, head and neck surgeries, and behavioral and psychological disorders.

AgeFrom **20 years** old to **55 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

For this purpose, the 30 sample size of this study is considered as three blocks of 10. Each of these three blocks of 10 contains 5 codes of the first method and 5

codes of the second method. Each block is placed in a separate box containing opaque envelopes containing the code of two treatment methods and the blocks are used one after the other based on the time required to enter and perform the study on 10 patients in each block. For this purpose, patients are asked to draw one of the envelopes and open it and present it to the researcher to be in the relevant group. In other words, blocking is done in such a way that the sample size is divided into three parts, each of which is called a block. First, selection, entry, evaluation, and treatment are done on a block containing 10 people and then we will move on to another block.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, laryngeal manual therapy is used to treat patients, which includes laryngeal muscle massage. There will be two techniques of laryngeal manual therapy in this study, which will differ in the type of massage and the location of the massage. In addition, the differences between the two laryngeal manual therapy techniques can only be detected by specialists using observation. By encoding the names of the two techniques and pulling opaque envelopes out of the lottery container, patients will not be informed of their technique. Of course, in the informed consent, they are told that we have two techniques of laryngeal manual therapy that you will be in a group using the lottery by yourself. In addition, in this study, patients will not see each other due to the provision of treatment at different times and in turn at specific times, and will not give each other information about the type of treatment provided. Evaluators will not be aware of the treatment provided to patients throughout the treatment. Therefore, with the lack of knowledge of patients and evaluators about the type of laryngeal manual therapy technique, this study will be double-blind.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, a new laryngeal manual therapy called Elective Laryngeal Manual Therapy (ELMT) will be designed to evaluate the effectiveness of patients with muscle tension dysphonia (MTD).

Secondary Ids

empty

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

School of Nursing and Midwifery and School of Rehabilitation - Tehran University of Medical Sciences

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Department of Speech Therapy, School of

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Approval date

2021-11-04, 1400/08/13

Ethics committee reference number

IR.TUMS.FNM.REC.1400.146

Health conditions studied

1

Description of health condition studied

Muscle Tension Dysphonia (MTD)

ICD-10 code

R49

ICD-10 code description

Voice and resonance disorders

Primary outcomes

1

Description

Voice self-assessment

Timepoint

In the initial assessments, the first and second intermediate assessments and the final assessment

Method of measurement

Each patient's perceptual judgment about their own voice quality is made using a Visual Comparative Scale (VAS) through interviews. In other words, in the present study, a 100 mm line is used to measure sound self-assessment, in which a score of 0 means natural sound quality and a score of 100 means the worst sound quality.

2

Description

Frequency and severity of vocal tract discomfort

Timepoint

In the initial assessments, the first and second intermediate assessments and the final assessment

Method of measurement

To evaluate the frequency and severity of the discomfort experienced in the vocal tract from the participants' point of view, the Persian version of the VTD scale called VTDp will be used. This scale is a self-perceptual questionnaire that will be provided to patients to comment on the frequency and severity of symptoms in the auditory canal.

3

Description

Pain, tightness, tenderness, hypertrophy, a trigger point in each of the target muscles, the height of the larynx in

the neck, limitation in lateral movement of the larynx, and the size of the thyrohyoid and cricothyroid space.

Timepoint

In the initial assessments, the first and second intermediate assessments and the final assessment

Method of measurement

In this study, palpation included examination of pain in the target muscles, tightness in each of the target muscles, sensitivity to palpation in each of the target muscles, hypertrophy in each of the target muscles, trigger points in each of the target muscles, laryngeal height, lateral movement limitation of the larynx is the size of the thyroid space and the size of the cricothyroid space. The evaluation method for each of the above is as follows: palpation is done using the index or middle fingers and the thumbs of both left and right hands while the patient is sitting on a chair and the evaluator is standing behind him.

Secondary outcomes

1

Description

Overall severity of dysphonia and Strain

Timepoint

Once in the initial assessments and the second time in the final assessments

Method of measurement

To assess the Auditory-perceptual voice assessment, two evaluators will listen to the recorded voice samples. Then, for the index of Overall severity of dysphonia and Strain from the Persian version of Consensus Auditory-perceptual assessment -voice profile (ATSHA), they will record a number between 0 and 100. According to, the (ATSHA) instructions, examples of recorded voice include /a/ and /i/ vowel prolong tasks, sentence reading, and continuous speech.

2

Description

Voice acoustic features involves the extraction of numerical value Jitter, Shimmer, Harmony to noise ratio, and First, second and third formants

Timepoint

Initial and final evaluations

Method of measurement

Acoustic measurement and analysis of patient voice characteristics is performed using praat software. For this purpose, the person's voice when saying vowels and continuous speech is recorded and analyzed using the mentioned software.

3

Description

Anteroposterior supraglottic constriction, mediolateral supraglottic constriction, and glottal closure

Timepoint

Initial and final evaluations

Method of measurement

The laryngeal examination is performed by observation and using video laryngoscopy technique by an Ear, Nose, and Throat specialist and Speech and Language Pathologist. After examination and review of video laryngoscopic films, the results related to the supraglottic anterior-posterior compression, supraglottic medial-lateral compression, and the model of the glottal closure were extracted and recorded in the relevant form.

4

Description

Voice acoustic features involves the extraction of numerical value Jitter, Shimmer, Harmony to noise ratio, and First, second and third formants

Timepoint

Initial and final evaluations

Method of measurement

Acoustic measurement and analysis of patient voice characteristics is performed using praat software. For this purpose, the person's voice when saying vowels and continuous speech is recorded and analyzed using the mentioned software.

Intervention groups

1

Description

Intervention group: According to the ELMT protocol by the first researcher, this study will be performed twice a week with 30-minute treatment sessions in the speech therapy ward of Amir Alam Hospital. If the patient needs to rest, during the massages, a maximum of 5 minutes of the treatment session will be provided for one-time or intermittent rest. The ELMT method begins with finding and recording tense muscles. According to the initial procedure, the target muscles in the ELMT method consist of eleven paired muscles. Nine pairs of these muscles include the extra-laryngeal muscles, and the two pairs, which include the inferior contractile and cricothyroid muscles, are the pharyngeal and internal laryngeal muscles, respectively. To perform this procedure, the patient lies on a normal hospital bed lying on his back with the therapist behind him. Tensed muscles are massaged using myofascial releases (Manheim and Duncan approach) and needling massages, and using the index (or third) fingers of both hands. Each of the massage techniques for the target muscle structures is performed according to the anatomical position of the muscle, the amount of access to the muscle, and the possibility of performing manual target treatment techniques in two ten-part periods with the time recommended in the sources. No lubricant is used during myofascial release massages because the therapist's fingers do not slip on the patient's skin. However, a small number of harmless lubricants, such as Vaseline or skin lotion, will be used during the binding, depending on the source.

Category

Treatment - Other

2

Description

Control group: The MCT method involves regular needling and massage of the laryngeal area. The therapist takes the protrusion of the hyoid bone with two thumbs and index fingers and then moves his fingers to the back, ie the large branches of the hyoid, and applies gentle pressure in a circular motion to this area. He then moves his fingers backwards from the origin of the thyroid slit and does the same rotational motion for this part again. The next step is to rotate the posterior edges of the thyroid cartilage (the anterior part of the sternocleidomastoid muscle). It then moves the larynx down slowly from the upper edges of the thyroid cartilage, applying downward pressure. During exercise, the patient is asked to produce vowels. In the event of a positive change in sound (clearer quality or less subtlety), exercises are performed on the production of the same sound with and without the use of manual techniques. Three laryngeal maneuvers are also used, including "hyoid push-back", "pull-down the larynx" and "combined medial compression and downward traction". "hyoid push-back" involves compressing the larynx by applying anterior back pressure up, up and down the hyoid bone with the index finger. As the patient makes a voice, pressure is applied inward and backward to a) the suprahyoid region at the root of the tongue b) the hyoid bone and c) the thyroid space. This maneuver is performed to assess the immediate effect of laryngeal descent on sound. "pull-down the larynx" means preventing the larynx from rising by applying downward pressure with the index and middle fingers on the upper part of the thyroid lamina. Like the previous maneuver, this maneuver is performed to assess the immediate effect of a laryngeal descent on the voice. "combined medial compression and downward traction" involves applying a combination of intermediate compression and lowering of the larynx to the upper thyroid to evaluate the combined effect of lowering and laryngeal compression on sound, which can affect patients with hyperactivity.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Head and Neck Clinic of Amir Alam Hospital and Speech Therapy Clinic of Tehran University of Medical

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

PhD Thesis in Speech Therapy, Tehran University of Medical Sciences

Grant code / Reference number

ندارد.

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amin Rezaee rad

Position

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Latest degree

Master

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Person responsible for scientific inquiries

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x

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

In the articles that will be published about this study, this will be done in the form of a demographic table and patient characteristics in accordance with the principles of confidentiality.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers and students related to medical sciences as well as patients participating in this study.

Under which criteria data/document could be used

For use in research and awareness of patients participating in this study about their disease status.

From where data/document is obtainable

Amin Rezaee rad

What processes are involved for a request to access data/document

Email or text message or contact Amin Rezaee Rad

Comments