

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effectiveness of resonant voice therapy and manual circumlaryngeal therapy on tension reduction in patients with primary muscle tension dysphonia

Protocol summary

Study aim

Comparison of the effect of changing the physiology of voice production using the resonance voice therapy method on the reduction of laryngeal tension from different clinical aspects and comparing its results with the manual circumlaryngeal therapy method.

Design

A clinical trial with randomized double-blind parallel groups is conducted on 30 patients. For randomization, 2 blocks and lottery are used.

Settings and conduct

The place of study is head and neck clinic and speech therapy department of Amir Alam hospital, speech therapy clinic of rehabilitation faculty of Tehran University of Medical Sciences. Study in 7 stages including 1) localization of RVT method assignments; 2) selection of participants; 3) pre-treatment assessments; 4) treatment; 5) intermediate evaluations, 6) post-treatment evaluations, and 7) follow-up. Patients and assessors are blinded to the treatment groups and the researcher is blinded to the names of the participants in the statistical data.

Participants/Inclusion and exclusion criteria

Patients who, according to the joint opinion of a laryngologist and an experienced speech and language pathologist in the field of voice disorders, receive a primary muscle tension dysphonia diagnosis

Intervention groups

1. Resonant voice therapy: By creating resonant voice (that is easy to produce with minimal effort) and using it in different communication context, it minimizes the possibility of damage to the larynx. 2. manual circumlaryngeal therapy : a treatment that balances the muscles by massaging the larynx and its surrounding areas.

Main outcome variables

Laryngeal muscle tension, larynx height, supraglottic

activity, and "intensity and frequency" of discomfort in the vocal tract are primary outcomes.

General information

Reason for update

Acronym

RVT

IRCT registration information

IRCT registration number: **IRCT20231024059840N1**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

Registration date

2024-02-07, 1402/11/18

Registrant information

Name

mojdeh mohamadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-08, 1403/01/20

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of resonant voice therapy and manual circumlaryngeal therapy on tension reduction in patients with primary muscle tension dysphonia

Public title

Comparing the effectiveness of resonant voice therapy and manual circumlaryngeal therapy on laryngeal tension

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

According to the joint opinion of a laryngologist and an experienced speech and language pathologist in the field of voice disorders, and based on the results of voice history, voice self-evaluation, larynx observation, auditory-perceptual evaluation of voice and palpation, the participants will receive a primary MTD diagnosis. Be in the age range of 18 to 55 years Have normal hearing Do not have evidence of neurological diseases Do not have a history of other voice disorders (such as weakness and paralysis of the vocal folds or laryngeal cancer). do not have a history of surgery, radiation therapy, trauma and intubation in the larynx and neck, chronic pain in the neck area, burns of the head and neck, and any kind of scar in the front of the neck and around the larynx. At least 14 days before the start of the study, do not have an active infection in the larynx and upper respiratory tract At the time of the study and before that, they have not received any other voice therapy program do not have a fat and short neck so that it is possible to perform a palpation

Exclusion criteria:

have not completed any of the assessment and treatment stages of the study Their audio samples are unanalyzable for any reason In the evaluation of the palpation of all the target structures, the score of muscle tension should be reported as zero

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Randomization will be done

using block, in such a way that all two people who enter the study will be placed in two treatment groups using lottery. The randomization unit is individual.

Randomization tool using lottery

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluators (speech therapists other than the researcher) who evaluate the patients on 4 occasions during the study are blinded to the treatment that the patients receive. Also, the patients do not know what treatments are offered in this study, and the researcher is also blind to the patients' evaluation reports (the reports are coded).

Placebo

Not used

Assignment

Parallel

Other design features

One of the therapeutic methods used in this research (resonant voice therapy) requires designing assignments in Persian language. Therefore, one of the products of this research is the design and preparation of valid and reliable tasks in Persian language.

Secondary Ids

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran. Enghelab ave. Rahabilitation school of tehran university of medical science

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Approval date

2024-02-06, 1402/11/17

Ethics committee reference number

IR.TUMS.FNM.REC.1402.212

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

Muscle tension dysphonia

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Muscle tension: The amount of tension of the paralaryngeal muscles, which can be measured by palpation.

Timepoint

Muscle tension is measured before the start of the treatment, in the third session of the treatment and at the end of the treatment and one month after the end of the treatment.

Method of measurement

Palpation

Secondary outcomes

1

Description

Vocal effort

Timepoint

Voice effort is measured before the start of the treatment, in the third session of the treatment, at the end of the treatment and one month after the end of the treatment.

Method of measurement

Vocal effort scale

2

Description

Cepstral analysis

Timepoint

It is measured before the start of the treatment, in the third session of the treatment and at the end of the treatment and one month after the end of the treatment

Method of measurement

Praat software

3

Description

Vocal fatigue

Timepoint

It is measured before the start of the treatment, in the third session of the treatment and at the end of the treatment and one month after the end of the treatment

Method of measurement

Vocal fatigue index

4

Description

Vocal struggle

Timepoint

It is measured before the start of the treatment, in the third session of the treatment and at the end of the treatment and one month after the end of the treatment

Method of measurement

The Consensus Auditory Perceptual Evaluation of Voice

5

Description

Glottal closure

Timepoint

It is measured before the start of the treatment and at the end of the treatment and one month after the end of the treatment

Method of measurement

Laryngeal stroboscopy and VALI form(form for reporting datas)

Intervention groups

1

Description

Intervention group: resonant voice therapy: This treatment method consists of 7 steps during which the patient learns how to produce resonant voice and how to use it in speech. The duration of the treatment consists of 6 sessions of 30 minutes, which are held twice a week.

Category

Rehabilitation

2

Description

Intervention group: manual circumlaryngeal therapy : In the MCT method, the patient sits on a comfortable chair; The therapist is placed next to the patient and manual therapy is performed with the therapist's superior hand and thumb and index (or middle) finger. Manual treatment starts from the target points where the patient has less pain and discomfort, but the parts that have more pain and discomfort; More attention is paid. The target points in this method are: 1. hyoid bone 2. Thyrohyoid space 3. The posterior border of the thyroid lamina 4. Middle and lateral suprahyoid muscles. duration of the treatment consists of 6 sessions of 30 minutes, which are held twice a week

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir aalam hospital

Full name of responsible person

دکتر مریم خدای

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Maryam khoddami

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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

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

Mojdeh mohamadi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

The results of evaluations and statistical data and the results of statistical analyzes will be published in articles

and thesis text.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working at Tehran University of Medical Sciences

Under which criteria data/document could be used

If the researchers of Tehran University of Medical Sciences conduct a study in the common field with the present plan, they can use the documents

From where data/document is obtainable

Dr. Maryam Khodami, Faculty of Rehabilitation, Tehran University of Medical Sciences

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

By using the application letter in which a brief description of the research is mentioned so that their research is related to the current research.

Comments