Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of tongue trill, lip trill, straw phonation, and water resistance therapy exercises in patients with primary Muscle Tension Dysphonia

Protocol summary

Study aim
Comparison of the effectiveness of tongue trill, lip trill, straw phonation, and water resistance therapy exercises in patients with primary Muscle Tension Dysphonia

Design
A clinical trial with a control group, parallel groups, double-blind, and randomized on 30 patients

Settings and conduct
The samples will be selected among the clients of the otolaryngology clinic of Amir Alam Hospital and speech therapy clinics of Tehran University of Medical Sciences using the available sampling method

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Be female, 2) The age range of 20-50 years, 3) Declare their informed consent to participate in the study, 4) Receiving the diagnosis of primary Muscle tension dysphonia Exclusion criteria: 1) Smoking cigarettes and drinking alcohol; 2) Suffering from hearing loss, hormonal diseases, and neurological diseases; 3) Having a history of laryngeal surgery or laryngeal trauma; 4) Being pregnant; 5) Being menopause; 6) Being menstruating at the time of pre- and post-treatment assessments; 7) Having an upper respiratory tract infection during the assessment days or one week before, and 8) Receiving another voice therapy program at the same time as the study is carried out

Intervention groups
This study has five intervention groups, including four experimental groups and one control group. The experimental groups include lip trill, tongue trill, straw phonation, and water resistance therapy. The control group will receive a vocal hygiene program. All 5 groups will practice their individual treatment plan across 2 weeks with a frequency of two 45-min sessions a week.

Main outcome variables
Maximum Phonation Time; First formant; F1_F0 difference; Cepstral peak prominence; Cepstral peak prominence-smoothed; Overall Severity of Dysphonia; Frequency and Severity of Vocal Tract Discomfort; Voice Handicap Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230307057649N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date
2023-09-05, 1402/06/14

Registrant information

Name
Roonak Aziz

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-19, 1402/06/28

Expected recruitment end date
2023-12-19, 1402/09/28

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of tongue trill, lip trill, straw phonation, and water resistance therapy exercises in patients with primary Muscle Tension Dysphonia

Public title
Comparison of the effectiveness of different semi-occluded vocal tract exercises in patients with primary Muscle Tension Dysphonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Be female The age range of 20-50 years Announce their informed consent to participate in the study Based on the consensus opinion of an otolaryngologist and an experienced speech therapist in the field of voice disorders and based on the results of voice history taking, larynx observation, palpation examination, auditory-perceptual assessment of voice and self-assessment, receive the diagnosis of primary muscle tension disorder
Exclusion criteria:
Patients who smoke and drink alcohol Patients suffering from hearing loss, hormonal and neurological diseases Patients who have a history of laryngeal surgery and laryngeal trauma Patients who have gone through menopause Patients who receive another voice therapy program at the same time as this study Patients who are pregnant
Age
From **20 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The studied samples will be randomly divided into five groups to receive one of the five treatments of tongue trill, lip trill, straw phonation, water resistance therapy, and vocal hygiene. Using the rule of random allocation in creating a random sequence and observing the concealment of random allocation is done by Permuted block randomization. For this purpose, 30 people in the sample size of this study are considered as six blocks of five. Each of these six blocks contains five 5 codes of the first to fifth methods. Each block is placed in a separate box containing opaque envelopes containing the codes of five treatment methods, and the blocks are used one after the other for the lottery. Patients are asked to draw one of the envelopes, take it out and open it and present it to the researcher to be placed in the relevant group
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, pre-and post-treatment assessments are performed by a speech therapist, and the presentation of therapeutic exercises is by another speech therapist who is the primary researcher of this study. Therefore, the outcome assessor will be blinded to the treatment group allocation, and the principal investigator will be blinded to the assessment results. From the beginning, we will explain to the participants that in this study we intend to compare the effectiveness of several voice therapy methods. We explain to them that these treatment methods have similar goals and are provided to facilitate voice production and solve their voice problems. Next, we explain that the effectiveness of these treatment methods has already been proven and we explain to them about the mechanism of these exercises that this mechanism is implemented using different voice exercises. They are supposed to be randomly placed in one of these treatment groups. Participants with knowledge of the above topics will enter the study if they declare their readiness to participate in this research through the informed consent form. Before the start of the assessment and treatment, the necessary arrangements are made so that the participants do not see each other during the entire period of treatment and assessment. Due to the fact that all participants are assessed and treated individually and will not see other patients, they will not be informed about the allocation of treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

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
Street address
Department of Speech Therapy, School of Rehabilitation, Pich Shemiran, Enghelab St., Tehran
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Tehran
Province
Tehran
Postal code
1148956111
Approval date

2023-04-15, 1402/01/26

Ethics committee reference number

IR.TUMS.FNM.REC.1402.004

Health conditions studied

1

Description of health condition studied

Primary muscle tension dysphonia

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

Primary outcomes

1

Description

Maximum phonation time

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Praat Software

2

Description

First Formant

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Praat Software

3

Description

The difference between the first formant and the fundamental frequency

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Praat Software

4

Description

Cepstral peak prominence

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Praat software

5

Description

Cepstral peak prominence-smoothed

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Praat software

6

Description

Overall Severity of Dysphonia

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Auditory-perceptual evaluation of voice, scale

7

Description

Vocal tract discomfort scale

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Self-assessment, The Persian version of the Vocal Tract Discomfort scale

8

Description

Voice Handicap Index

Timepoint

Before the start of the intervention and immediately after the completion of four treatment sessions

Method of measurement

Self-assessment, The Persian version of the VHI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: The first intervention group will receive voiced tongue trill exercise during four 45-minute sessions over two weeks

Category

Rehabilitation

2

Description

Second intervention group: The second intervention group will receive voiced lip trill exercise during four 45-minute sessions during two weeks

Category

Rehabilitation

3

Description
Third intervention group: The third intervention group will receive straw phonation exercise during four 45-minute sessions during two weeks
Category
Rehabilitation

4

Description
Fourth intervention group: The fourth intervention group will receive water resistance therapy during four 45-minute sessions during two weeks
Category
Rehabilitation

5

Description
Control group: The control group will receive the vocal hygiene program in four 45-minute sessions over two weeks
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Alam hospital
Full name of responsible person
Maryam Khodami
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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?
No
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
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Position
Master Student

Latest degree
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Person responsible for updating data

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Tehran
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Tehran
Postal code
1483793818
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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