

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison "vocal function exercises" and "Flow-resistant tube" using offline tele voice therapy in singers with muscle tension dysphonia: A randomized clinical trial

Protocol summary

Study aim

Compare VFE and FRT through offline remote voice therapy in singers with primary MTD

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 63 singers with primary MTD. A table of random numbers is used for randomization.

Settings and conduct

Evaluation of the participants is done by the evaluator before and after treatment at the voice laboratory and the evaluation of the laryngeal function of the school of Rehabilitation of Tehran University of Medical Sciences. After pre-treatment assessments, the participants are randomly assigned to one of three treatment groups. The participants in the FRT and VFE groups receive treatment plan offline and remotely. The participants do not know which of the three treatment groups they are placed in. The evaluator is not aware of the allocation of participants to treatment groups, and therapist is also not aware of the results evaluation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have at least one year of singing experience; Be in the age range of 18 to 60 years; Receive MTD diagnosis based on the voice self-assessment, voice history taking, larynx observation, and perceptual voice evaluation, ; Do not have vocal fold pathologies (benign or malignant); Do not have a history of voice therapy; Do not have an addiction to smoking or alcohol. Exclusion criteria: Have history of neurologic disorders, cancer, radiotherapy or surgery in head and neck; Have upper respiratory infection in the time of assessment or three weeks before.

Intervention groups

Eligible participants are randomly divided into three groups: 1) VFE ; 2) FRT and 3) control (no treatment).

Main outcome variables

Maximum phonation time; fundamental frequency;

Cepstral Prominence Peak(CPP); voice handicap index; Roughness; breathiness; strain, Overall severity of dysphonia; supraglottic activity; glottal closure pattern.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230913059426N1**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name

Seyyedeh Maryam Khoddami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-06-09, 1403/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison "vocal function exercises" and "Flow-resistant tube" using offline tele voice therapy in singers with muscle tension dysphonia: A randomized clinical trial

Public title

Offline tele voice therapy exercises in singers with muscle tension dysphonia

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Have at least one year of singing experience; Be in the age range of 18 to 60 years; Based on the results of voice self-assessment, voice history taking, larynx observation, and perceptual voice evaluation, receive a primary muscle tension dysphonia (MTD) diagnosis; Do not have vocal fold pathologies (benign or malignant); Do not have a history of voice therapy; Do not have an addiction to smoking or alcohol.

Exclusion criteria:

Have a history of diagnosis of neurological disorders as well as cancer, radiotherapy or of head and neck; Have an upper respiratory tract infection at the time of the evaluation and three weeks before the evaluation.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly divide the participants into three groups including control group, flow-resistant tube (FRT), and vocal function exercises (VFE), the method of simple randomization using a table of random numbers is used. Because the list of all patients is not known before initiation of the study and the confounding variable for classification is not introduced, available sampling is the appropriate method. So, with the entry of each patient based on the randomization list specified in advance, each participant is assigned randomly to one of the control, FRT, and VFE groups. Therefore, the unit for randomization is individual.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a double-blind clinical trial study. First, the purpose of the study is explained to the participants. They are informed that in this study, we will have three groups including the control group (no treatment), the FRT group and the VFE group, who will receive the treatment remotely and offline. Both FRT and VFE groups receive voice therapy methods, the effectiveness of which has already been confirmed by various studies for patients with voice disorders, including singers, in face-to-face treatments. Participants are unaware of which of the three groups they belong to. That is, the time of pre-treatment and post-treatment evaluations is set so that the study participants do not meet each other and are unaware of the treatment they are receiving. Participants will be randomly assigned to one of three study groups; Treatments are provided individually. Treatment is provided by a member of the research team. Evaluations before and after treatment are done by another evaluator. Therefore, both the therapist is unaware of the outcome evaluation results and the evaluator is unaware of the random allocation of participants and the content of the treatment. Other members of the research team are also unaware of the results of the outcome assessment and how the participants were allocated.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

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

Joint Organizational Ethics Committee of Nursing and Midwifery Faculty and Rehabilitation Faculty of

Street address

Secretariat of Ethics Committee in Biomedical Research, University of Tehran, Keshavarz Blvd., Intersection of Quds St., Central Building of Tehran University of Medical Sciences, 6th Floor, Room 604

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Province

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Postal code

1419733171

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.TUMS.FNM.REC.1402.109

Health conditions studied

1

Description of health condition studied

Muscle tension dysphonia

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

Primary outcomes

1

Description

Voice Handicap index

Timepoint

One week before treatment

Method of measurement

Self-evaluation by the participant

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vocal Function Exercises (VFE). The hierarchy of these exercises includes four steps as follows: 1) Phonating the /i/ sound in the musical note F3 for men and F4 for women (the selected note in this step can go up or down by two notes at most). Objective: To produce an "e" sound equal to the longest Articulation of "s" that each participant can produce. Your position should be in the front focus. All exercises should be done as softly as possible but not breathy; 2) Glide the word /knoll/ from the lowest note to the highest note. The goal is not to have voice breaks. Glide requires the use of all laryngeal muscles. The patient's lips are rounded and a supportive vibration should be felt in the lips. 3) Glide the word /knoll/ from the highest note to the lowest note. The goal is to produce without voice breaks. This exercise is done with a half yawn. The throat is open and the focus is on the perceptible vibration of the lips. 4) Phonating the five musical notes C-D-E-F-G (third and forth octave) as much as possible in the word /ol/ (selected notes can go up or down by two notes). The goal is the same as step one. Production is done with an open throat and vibrating lips. Participants receive their treatment plan, which is a four-week program, offline. Detailed information about VFE exercises in the form of a PDF file, educational videos related to the exercises suitable for Persian speakers, and a file related to common questions and answers prepared in advance by researchers under the supervision of experts, are presented to the participants via social network. will be. On the first day of the treatment period, all this information and videos related to the treatment are

provided to the participants. After receiving information about the exercises and watching the initial videos, the participants will perform the exercises related to their treatment plan according to the provided program. Daily exercises for the VFE group will consist of two eight-minute meals (morning and evening).

Category

Rehabilitation

2

Description

Intervention group: SOVT using Flow Resistant Tube(FRT) exercises. FRT exercises involve voice production through a plastic straw 14.1 cm long and 0.4 in diameter. Participants are asked to use the straw in such a way that airflow is exchanged only through the straw (not through the nose or around the straw). Also, the abdominal-chest (non-clavicular) breathing pattern should be used and the upper body position should be relaxed. Exercises should be done with full voice; However, due to creating a semi-occluded vocal tract, the perception of loudness has been reduced. The hierarchy of FRT exercises in the second group includes four stages as follows: 1) Glide of the /o/ sound from the lowest note to the highest note and from the highest note to the lowest note. This exercise should be repeated ten times. 2) Say a word starting with /o/ five to seven times. Repeat this exercise ten times. This exercise should be done by changing the pitch and loudness of the voice and by increasing the breathing support (in contrast to the vocal folds adduction). 3) A word starting with /o/ should be sung through a tube with a melody but without producing the word. Practice ten short songs of one verse or long songs equivalent to it. 4) Read from the text through a straw but without producing words. Read approximately five paragraphs of medium length (approximately five to ten sentences) for each exercise. Each of the FRT exercises is done in one minute. Participants receive their treatment plan, which is a four-week program, offline. Detailed information about FRT exercises in the form of a PDF file, educational videos related to the exercises suitable for Persian speakers and a file related to common questions and answers prepared in advance by researchers and under the supervision of experts, are presented to the participants via social network. On the first day of the treatment period, all this information and videos related to the treatment are provided to the participants. After receiving information about the exercises and watching the initial videos, the participants will perform the exercises related to their treatment plan according to the provided program. Daily exercises for the FRT group will include 4 meals of 4-minute (twice in the morning and twice in the afternoon).

Category

Rehabilitation

3

Description

Control group: No treatment. The control group will not receive any treatment program during the study period.

Category

Other

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

Faculty of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Dr Seyyedeh Maryam Khoddami

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Faculty of Rehabilitation, corner of Safi Alishah St., Pich Shamiran St., Tehran

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Web page address<https://rehab.tums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

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Web page address<https://rehab.tums.ac.ir/>**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

Dr Seyyedeh Maryam Khoddami

Position

The faculty of the director of the group

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**

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Position

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Wholes are divisible after identifying unidentifiable individuals.

When the data will become available and for how long

Access to the data starts six months after the paper printing of the study results in the form of an article.

To whom data/document is available

Data access is possible for researchers working in scientific and academic institutions.

Under which criteria data/document could be used

In order to access the data, the request should be sent to the editor of the journal in which the article was published. The data can only be used for studies similar to the present study to perform statistical analyzes by the relevant researcher or researchers.

From where data/document is obtainable

If the results of the study will be published in the form of an article, the applicants must send their request to access the data to the editor of the journal. If the journal allows the publication of the data, the authors of the article can submit their request to the following address. Department of Speech Therapy, School of Rehabilitation, Tehran University of Medical Sciences, Enghelab Avenue, Pitch-e-shemiran, Tehran 11489, Iran.

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

1- Sending an email to the editor of the magazine. 2- Send email to khoddami@tums.ac.ir

Comments
