

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Investigating the effect of voice therapy based on glottal closure improvement in singers with Muscle Tension dysphonia

#### Protocol summary

##### Study aim

The aim of current study is to investigate the effect of voice therapy based on glottal closure improvement in singers with Muscle Tension dysphonia.

##### Design

This randomised clinical trial has two parallel groups and three phases. A control group that receives manual therapy plus sham therapy and another group in spite of receiving manual therapy receives voice therapy of current study. This study with parallel group design will be enrolled on 20 patient between September 2020 and December 2020. In this study outcome assessment and grouping is conducted blinded. Outcome measures are evaluated before, after and two weeks after treatment sessions ended.

##### Settings and conduct

This randomized clinical trial will be held in Rehabilitation school of Iran university of medical science. We will try to improve glottal closure in singers suffering from MTD.

This study is double-blinded and all the subjects, therapists and judges were blind to the grouping design and data.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: at least 4 years of professional singing experience history of voice disorder during last month diagnosed with primary muscle tension dysphonia

Exclusion criteria before randomization : being smokers hearing impairment history of allergy, laryngeal blunt trauma, head injury and phonosurgery

##### Intervention groups

Current study include two groups. Control group: This group receives laryngeal manual therapy with sham therapy. Intervention group: This group receives laryngeal manual therapy plus exercises of "voice therapy based on glottal closure improvement".

##### Main outcome variables

acoustic measures, closure of vocal folds during vibration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151025024686N2**

Registration date: **2020-10-04, 1399/07/13**

Registration timing: **prospective**

Last update: **2020-10-04, 1399/07/13**

Update count: **0**

##### Registration date

2020-10-04, 1399/07/13

##### Registrant information

##### Name

Nassim Ahmadi

##### Name of organization / entity

Hamedan University of Medical Science, School of Rehabilitation

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1571

##### Email address

nassim.slp@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-05, 1399/07/14

##### Expected recruitment end date

2021-02-02, 1399/11/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating the effect of voice therapy based on glottal closure improvement in singers with Muscle Tension dysphonia

## Public title

glottal closure improvement in Muscle Tension dysphonia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

at least 4 years of professional singing experience  
history of voice disorder during last month diagnosed with primary muscle tension dysphonia (MTD)

### Exclusion criteria:

history of allergy, laryngeal blunt trauma, head injury and phonosurgery hearing impairment being smoker

## Age

From **18 years** old to **45 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted block randomization method with two blocks will be used. Considering sample size of 20 subjects, 10 double blocks will be generated using [www.sealedenvelope.com](http://www.sealedenvelope.com) website. Concealing of randomization will be performed using secret codes in a pocket. Subject will receive a pocket when entering the study and based on the code in the pocket will be divided to certain group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Therapists and subjects will be blind to the grouping of subjects. Pocket concealment was used to make participants and therapist blind to the grouping. Judges will also be blind to the grouping of subjects and also will not be aware of the phases that the voice and video samples belong to (before or after treatment). For this purpose the assessment results including voice and the video samples of participants' performance played for judges without name, study phase and grouping.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethnic committee of Iran University of medical science

##### Street address

Iran University of Medical Science, Hemmat highway, Tehran, Iran.

##### City

تهران

##### Province

Tehran

##### Postal code

1516846514

#### Approval date

2019-11-04, 1398/08/13

#### Ethics committee reference number

IR.IUMS.REC.1398.808

## Health conditions studied

### 1

#### Description of health condition studied

Dysphonia

#### ICD-10 code

R49.0

#### ICD-10 code description

Dysphonia

### 2

#### Description of health condition studied

Voice disturbances

#### ICD-10 code

R49.8

#### ICD-10 code description

Other and unspecified voice disturbances

## Primary outcomes

### 1

#### Description

Acoustic measures

#### Timepoint

Before intervention, after intervention, two weeks after intervention

#### Method of measurement

Acoustic analysis using Praat software

### 2

#### Description

Vocal fold closed quotient

### **Timepoint**

Before intervention, after intervention, two weeks after intervention

### **Method of measurement**

Electroglottography

## **Secondary outcomes**

### **1**

#### **Description**

Voice Quality

#### **Timepoint**

Before intervention, after intervention, two weeks after intervention

#### **Method of measurement**

Auditory-Perceptual Rating Instrument for the Operatic Singing Voice( EAI scale)

### **2**

#### **Description**

Singing voice handicap

#### **Timepoint**

Before intervention, after intervention, two weeks after intervention

#### **Method of measurement**

Persian version of Singing voice handicap index

### **3**

#### **Description**

Stroboscopic observational indices

#### **Timepoint**

Before intervention, after intervention, two weeks after intervention

#### **Method of measurement**

Voice-Vibratory Assessment With Laryngeal Imaging (VALI) Form

## **Intervention groups**

### **1**

#### **Description**

Intervention group: This group will receive laryngeal manual therapy performed by Mathieson LMT method. Also exercises of "voice therapy based on glottal closure improvement" is provided to these participants. Assessment and treatment is continued for nine weeks and participants will have two 30-minutes sessions each week. Vocal assessments are performed before, after and two weeks after treatment ending. Totally participants will have 3 assessment sessions and 10 treatment sessions.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: This group will receive laryngeal manual

therapy plus sham therapy for ten sessions. Laryngeal manual therapy is performed with Mathieson LMT method. In Sham therapy some information about larynx structure, voicing mechanism and laryngeal pathologies is provided. Assessment and treatment is continued for nine weeks and participants will have two 30-minutes sessions each week. Vocal assessments are performed before, after and two weeks after treatment ending. Totally participants will have 3 assessment sessions and 10 treatment sessions.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Speech therapy clinic

##### **Full name of responsible person**

Tahereh Shahrokhi

##### **Street address**

School of Rehabilitation, Iran university of Medical Science, Nezam street, Shahnazari street, Madar square, Mirdamad Blvd.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

4391 - 15875

##### **Phone**

+98 21 2222 8051

##### **Fax**

+98 21 2222 0946

##### **Email**

rehab@iums.ac.ir

##### **Web page address**

<http://rehab.iums.ac.ir/>

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Khatam-al- Anbya Hospital

##### **Full name of responsible person**

Dr Masoud Kazemi

##### **Street address**

Vanak Square, up the Mirdamad Boulevard, Rashid Yasemi St.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

۱۴۴۵۶۱۳۱۳۱

##### **Phone**

+98 21 8888 4040

##### **Fax**

+98 21 8879 0298

##### **Email**

hrmc@iums.ac.ir

**Web page address**

<https://www.khatamhospital.org/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Seyed Abbas Motavalian

**Street address**

Fifth floor, central Building, Iran University of Medical Sciences, Shahid Hemmat Highway,

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 2503

**Fax**

+98 21 8670 2503

**Email**

research@iums.ac.ir

**Web page address**

[http://vcr.iums.ac.ir/page\\_arch.php?slc\\_pg\\_id=4651&sid=22&slc\\_lang=fa](http://vcr.iums.ac.ir/page_arch.php?slc_pg_id=4651&sid=22&slc_lang=fa)

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Nassim Ahmadi

**Position**

PhD student of Speech and Language Pathology

**Latest degree**

Master

**Other areas of specialty/work**

Speech therapy

**Street address**

Iran University of Medical Science, School of Rehabilitation, Nezam Street, Shahid Shah Nazari Street, Madar Square, Mirdamad Blv.

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 21 2222 8051

**Fax**

+98 21 2222 8051

**Email**

nassim.slp@gmail.com

**Web page address**

<http://rehab.iums.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Farhad Torabinejad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

Iran University of Medical Science, School of Rehabilitation, Nezam Street, Shahid Shah Nazari Street, Madar Square, Mirdamad Blv, Tehran

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rehab@iums.ac.ir

**Web page address**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Nassim Ahmadi

**Position**

PhD student of Speech and Language Pathology

**Latest degree**

Master

**Other areas of specialty/work**

Speech therapy

**Street address**

Iran University of Medical Science, School of  
Rehabilitation, Nezam Street, Shahid Shah Nazari  
Street, Madar Square, Mirdamad Blv.

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Tehran

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available