

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)

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Email address

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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 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.

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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.

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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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Abbas Motavalian

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

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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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Farhad Torabinejad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Latest degree

Master

Other areas of specialty/work

Speech therapy

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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