

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparison of the effectiveness of face-to-face voice therapy and Telepractice in patients with Muscle Tension Dysphonia

#### Protocol summary

dysphonia severity,voice handicape,vocal tract discomfort,vocal fatigue,auditory-perceptual assessment

#### Study aim

compare the effectiveness of face-to-face and remote voice therapy in patients with dysphonia caused by muscle tension

#### Design

Clinical trial with control group,with parallel groups,double-blind,simple randomized,phase1 on 46patients.Randomization is done in a simple way through lottery.

#### Settings and conduct

The study is conducted on 46 MTD patients referred to otolaryngology clinics of Jundishapur University of Medical Sciences in Ahvaz.vocal facilitation techniques, including chewing, breathing exercises,yawn-sigh,open mouth, glottal fry,and confidential speech will be used for the first treatment group.In the online treatment, the those techniques will be presented to the clients in the same way,all the clients of the second group will receive all 6 techniques.voice facilitation techniques and voice health consultations are provided through video calls on the ZOOM platform in 18 sessions for six weeks.

#### Participants/Inclusion and exclusion criteria

Not having neurological diseases,voice disorders and lung problems.Not having any surgery that leads to hoarseness or bad effects on the voice.Not suffering from thyroid disease and hormonal problems.not taking drugs that affect voice.not suffering from colds and allergic and respiratory diseases for the past two months.no history of receiving voice therapy services.

#### Intervention groups

six vocal facilitation techniques, including chewing, breathing exercises,yawn-sigh,open mouth,glottal fry,and confidential speech will be used for the first treatment group.In the online treatment,the those techniques will be presented to the clients in the same way.voice facilitation techniques and voice health consultations are provided through video calls on the ZOOM platform in 18 sessions for six weeks.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230306057636N1**

Registration date: **2023-04-14, 1402/01/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-14, 1402/01/25**

Update count: **0**

##### Registration date

2023-04-14, 1402/01/25

##### Registrant information

##### Name

Zahra Sharifi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 149 5644

##### Email address

z.sharifi21377@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-04, 1402/01/15

##### Expected recruitment end date

2023-05-10, 1402/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of face-to-face voice therapy and Telepractice in patients with Muscle Tension Dysphonia

**Public title**

Comparison of the effectiveness of face-to-face voice therapy and Telepractice in patients with Muscle Tension Dysphonia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Ability to read and write Monolingual and Farsi-speaking patients Clients with dysphonia caused by muscle tension who have been diagnosed by an otolaryngologist and evaluated using video stroboscopy by a professional speech therapist with more than 15 years of experience.

**Exclusion criteria:**

record of receiving sound therapy services suffering from colds and allergic and respiratory diseases for the past two months (question from the patient) taking drugs affecting the voice having auditory system disease having thyroid disease and hormonal problems performing any surgery that leads to hoarseness or bad effects on the voice and these effects continue

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization is done in the form of a lottery, so that the name of each participant is written on the same size and similar papers. The names are placed in a container. After that, the names are placed in two groups in order of coming out. One person enters the intervention group and one person enters the control group (individuals receive remote treatment and couples receive face-to-face treatment) respectively. Randomization is done by a person who is not involved in the research process.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After providing the treatments, a speech therapist (separate from the therapist who provided the treatment) will evaluate the results without knowing the grouping of the clients. The researcher examines and

reports the results without knowing whether each data group is related to the control group or the intervention. The data analyzer analyzes the Spss file and does not meet the participants.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Ahvaz University of Medical Sciences

**Street address**

Ahvaz - Boulevard of Medical Sciences - Jundishapur Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2023-03-04, 1401/12/13

**Ethics committee reference number**

IR.AJUMS.REC.1401.573

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

Muscle Tension Dysphonia(MTD)

**ICD-10 code**

R49.8

**ICD-10 code description**

Other voice and resonance disorders

**Primary outcomes****1****Description**

The total score of the Dysphonia Severity Index (DSI)

**Timepoint**

Measuring the total score of dysphonia severity index before treatment and one month later.

**Method of measurement**

Dysphonia Severity Index

**2****Description**

The total score of the Voice Handicap Index(VHI)

**Timepoint**

Measuring the total score of Voice Handicap index before treatment and one month later.

**Method of measurement**

Voice handicap index questionnaire

**3**

**Description**

The total score of the Vocal Tract Discomfort index(VTD)

**Timepoint**

Measuring the total score of Vocal Tract Discomfort index before treatment and one month later.

**Method of measurement**

Vocal Tract Discomfort index questionnaire

**4**

**Description**

Vocal Fatigue Index (VFI) first part

**Timepoint**

Measuring the total score of Vocal Tract Discomfort index before treatment and one month later.

**Method of measurement**

Vocal fatigue index questionnaire

**5**

**Description**

Vocal Fatigue Index (VFI) second part

**Timepoint**

Measuring the total score of Vocal Tract Discomfort index before treatment and one month later.

**Method of measurement**

Vocal fatigue index questionnaire

**6**

**Description**

Vocal Fatigue Index (VFI) third part

**Timepoint**

Measuring the total score of Vocal Tract Discomfort index before treatment and one month later.

**Method of measurement**

Vocal fatigue index questionnaire

**7**

**Description**

Auditory-perceptual assessment (GRBAS)

**Timepoint**

Measuring the total score of Vocal Tract Discomfort index before treatment and one month later.

**Method of measurement**

GRBAS index, which examines 5 characteristics of the overall severity of the disorder, voice harshness, breathlessness, voice asthenia, and struggle.

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: 23 clients with muscle tension dysphonia, whose disorder was confirmed by an otolaryngologist and stroboscopic evaluations by a speech therapist, six voice facilitating techniques including exaggerated chewing, breathing exercises, sighing and yawning, open mouth, glottal fry and confidential speech in 18 half-hour sessions online and on the platform of ZOOM software.

**Category**

Rehabilitation

**2**

**Description**

Control group: 23 clients with muscle tension dysphonia, whose disorder was confirmed by an otolaryngologist and stroboscopic evaluations by a speech therapist, six voice facilitating techniques including exaggerated chewing, breathing exercises, sighing and yawning, open mouth, glottal fry and confidential speech in 18 half-hour face-to-face sessions

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Speech therapy clinics affiliated with Jundishapur University of Medical Sciences, Ahvaz

**Full name of responsible person**

Zahra Sharifi

**Street address**

Jundishapur University of Medical Sciences -Medical Sciences Blvd - Ahvaz

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Negin Moradi

**Street address**

Golestan area, Ostadan residential houses

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**Province**

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**Phone**

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neginmoradist@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Zahra Sharifi

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Speech therapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Negin Moradi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Master's student

**Latest degree**

Bachelor

**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**

There is 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