

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

City

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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

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**

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Associate Professor

Latest degree

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Other areas of specialty/work

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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

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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