

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the effect of Vocal Function Exercises on vocal fatigue in professional voice users

Protocol summary

Study aim

survey on the effect of vocal function exercises on the vocal fatigue index mean score in the bank workers after 14 days of exercises

Design

the two-staged parallel randomized trial (screening and prevalence estimation + intervention) with the control group, double-blind (participants and data analyzers), the four-levels blocked randomization (physical cards), sample size 42 (same distribution between control/intervention groups), and gender as the moderator variable, and simple random sampling (lottery)

Settings and conduct

1. questionnaire distribution: physical/electronic (Google form) 2. training of participants for the intervention stage: in-presence (in the bank branches) or online (WhatsApp) 3. double-blind: participants by uniforming and data analyzers by coding the data

Participants/Inclusion and exclusion criteria

1. age range: 18-50 2. at least three working days 3. at least 1.5 hours of daily speaking 4. maximum use of maternal language in a working position 5. maximum use of facial mask in a working position

Intervention groups

1. Vocal Function Exercises (VFEs): The VFEs will be practiced daily for two weeks, twice a day (day and night). The protocol parts are 1. The maximum Phonation Time (MPT) of vowel /i/ 2/3. Upward and downward gliding of vocal pitch, respectively; 4. The MPT at the five pre-determined musical notes (depending on the Gender class). 2. Control group: gathering the pre-term data; request to wait for two weeks; gathering post-term data; after that, training the VFEs. They aren't informed to be in the control group.

Main outcome variables

1. vocal fatigue index 2. voice handicap index

General information

Reason for update

spelling mistake in the English title

Acronym

Vocal Function Exercises (VFEs) + Vocal Fatigue (VF)

IRCT registration information

IRCT registration number: **IRCT20220116053728N1**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **prospective**

Last update: **2022-02-20, 1400/12/01**

Update count: **1**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Mohammad Sedigh Mahmoudzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8051

Email address

mmahmudzade.slps@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-07-05, 1401/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Vocal Function Exercises on vocal fatigue in professional voice users

Public title

Investigation about the effect of VFEs on VF

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The participant must work at least three days a week that directly contacts customers. The participant must have at least 1.5 hours of speaking on each working day. The participant should often use their maternal language to communicate with customers. The participant often uses a mask in the working environment.

Exclusion criteria:

The applicant has a history of neurological, respiratory, head and neck, pharyngeal/laryngeal, allergies, asthma, reflux, and/or hearing system diseases or surgeries. The applicant have a vocal training in the last six months ago.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In the intervention stage of the study, participants will allocate to the control or intervention group. According to previous studies, gender is considered as the intervening variable. we will use four level blocking method to guarantee the analogous and simultaneous distribution of participants between groups. In this way, all possible allocation groups (six) are determined and any specific groups will pack in the paper pocket that allows selective visualization of events in order. any gender groups deliver a category of allocation. A group of six-allocated groups six groups will select in the random method (random withdrawals of cards by another person). The next four participants will allocate in the control/intervention group that two participants will consider as control and two others will consider as the intervention but the order of this allocation remains unclear. This procedure will follow to complete the sample size of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants who will allocate to the intervention group will train to practice the VFEs exercises. Researchers inform them that their actual intervention will start after these two weeks of warm-up practices. Also, We will ask

control group participants to wait until the next two weeks that their training start. Both groups will give an approved voice exercise after gathering post-term data. The data will be coded then analyzed by an unaware statistician.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical committee of Iran university of medical sciences

Street address

Iran University of medical sciences, Hemmat freeway, next to Milad tower

City

Tehran

Province

Tehran

Postal code

14496-14535

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.IUMS.REC.1400.225

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

voice disorders

ICD-10 code

R49

ICD-10 code description

Voice and resonance disorders

2**Description of health condition studied**

Vocal fatigue

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

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

scores in the three sections of the vocal fatigue index (VFI)

Timepoint

On the day of training and one day before the start of training (in the intervention group) or one day before the start of the 14 days in the control group (pre-term data); One day after completing the 14-day training period (in the intervention group) or the waiting period in the control group (post-term data)

Method of measurement

Persian version of Vocal Fatigue Index

Secondary outcomes

1

Description

Total score of the voice handicap index (VHI)

Timepoint

On the day of training and one day before the start of training (in the intervention group) or one day before the start of the 14 days in the control group (pre-term data); One day after completing the 14-day training period (in the intervention group) or the waiting period in the control group (post-term data)

Method of measurement

Persian version of Voice Handicap Index

Intervention groups

1

Description

Intervention group: Participants in the intervention group will do VFEs practices. The VFEs is an organized vocal practice, structured as vocal pitch-based practice and designed in four sections. Section one is the vocal warm-up that is designed to engage the laryngeal system. Practically, this section is the maximum prolongation of the /i/ vowel on the musical note (F) above the middle (C) for females (349.23Hz), and (F) below the middle (C) for males. The goal is to sustain the /i/ for as long as you can sustain as /s/. The second section is the stretching that is designed to stretch vocal folds. The goal is that participants can smoothly glide from lowest notes to highest notes on the word "knoll" (sustain the "L"). The third section is the contraction that is designed to contract vocal folds. The goal is that persons can smoothly glide from highest notes to lowest notes on the word "knoll" (sustain the "L"). The fourth section is the low impact adductory power. In this section, participants sustain the musical notes (C-D-E-F-G) for as long as possible on the word "old" without the "d" (again, sustaining the "L" sound). using middle C for females, and an octave below middle C for males. in the last three sections, the goal is to produce the glide without voice breaks. The notes may be modified up or down to fit individual needs, but seldom by more than two notes in either direction. These participants will practice the VFEs for two weeks. According to the VFEs protocols, participants will do exercises every day. The vocal practices will execute two times daily, preferably

morning and evening. In addition, The sounds that will be used in this exercise are in the Persian language space (dialectical variation).

Category

Treatment - Other

2

Description

Control group: The participants who are allocated in the control group were asked to wait for the next two weeks without being informed that they are in the control group. The VFEs exercises will teach to them after gathering post-term data.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

many branches of Melli Bank in scattered cities of Iran

Full name of responsible person

Mohammad Sedigh Mahmoudzadeh

Street address

upper floor of Shahid Fahmideh Branch, No. 296, Ostad Motahhari St

City

Tehran

Province

Tehran

Postal code

1588644111

Phone

+98 21 8830 4010

Fax

+98 21 8830 3616

Email

Training@Bmi.Ir

Web page address

<https://amoozesh.bmi.ir/contactus.aspx?smnuid=31>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hoseyn Keyvani

Street address

Iran University of medical sciences, Hemmat freeway, next to Milad tower

City

Tehran

Province

Tehran

Postal code

14496-14535

Phone
+98 21 2222 8051

Email
keyvani.h@iums.ac.ir

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
Mohammad Sedigh Mahmoudzadeh

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Speech therapy

Street address
speech therapy department, rehabilitation school,
MadadKaran street, ShahNazari street, Madar square,
Mirdamad street

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
mmahmudzade.slps@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farhad TorabiNezhad

Position
Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work
Speech therapy

Street address
میرداماد- میدان مادر-خیابان شاه نظری- خیابان مددکاران-
دانشکده علوم توانبخشی-گروه گفتار درمانی

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
torabinezhad.f@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
mohammad Sedigh Mahmoudzadeh

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Speech therapy

Street address
speech therapy department, rehabilitation school,
MadadKaran street, ShahNazari street, Madar square,
Mirdamad street

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
mmahmudzade.slps@gmail.com

Web page address

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

1. Personal Information: gender; age
2. Medical History Information: Existence of any diseases listed
3. Lifestyle Information: Smoking and alcohol consumption (yes or not)
4. VHI and VFI scores: Total score of VHI, and scores of three sections of VFI

When the data will become available and for how long

A year after publishing the paper of project

To whom data/document is available

researcher in the Medical universities in Iran

Under which criteria data/document could be used

1. the research that will not approve by the applicant university
2. use of data for other purposes

From where data/document is obtainable

1. Information will be given in SPSS or EXEL file format.
2. Name: Mohammad Sedigh Mahmoudzadeh
3. address: speech therapy department, rehabilitation school, MadadKaran street, ShahNazari street, Madar Square, Mirdamad street
4. phone number: 0098 9186476306 E-mail: mmahmudzade.slps@gmail.com

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

The applicant must provide an official letter from his / her university. In this letter, they must clearly state the items they intend to use. The person must also commit to no other use.

Comments

This is a university project. So maybe the requests will not be accepted by our university system ultimately.