

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

comparison of The effect of speech therapy , music-therapy and combined speech and music therapy on the vocal characteristics of people with Parkinson's disease by using telerehabilitation

Protocol summary

Study aim

the effect of a combined speech and music therapy on speech function in Parkinson's disease through telerehabilitation. Our hypothesis is that patients in the combined therapy group will have more improvement in the outcome measure than speech therapy group and music therapy group after treatment and 1-month follow-up .

Design

A clinical trial with three groups, with parallel groups, one-way blind, randomized, on 33 patients, used the Rand function of Excel software for randomization.

Settings and conduct

Individuals selected from Parkinson's patients referred to speech therapy clinics, hospitals and clinics in Tehran. The method of study will be explained to them in face to face session . If they were willing to cooperate, The consent form is signed by them and the biography is taken from the people. These people are then evaluated. In this study, evaluator and patients will be blinded during the entire process.

Participants/Inclusion and exclusion criteria

idiopathic Parkinson's patients

Intervention groups

The present study includes three groups of therapy: speech therapy, music therapy and combined speech and music therapy .The Speech Therapy Group will receive common and routine speech exercises, including breathing exercises, loudness, pitch, and intelligibility. The music exercises will be designed based on the music therapy protocols of previous studies, which consists of five parts: Section 1: Motor exercises; Section 2: Breathing Exercises; Section 3: vocal Exercises; Section 4: Singing Exercises; Section 5: Final Conversation and Homework.The combination therapy group also receives both speech therapy and music therapy at the same time.

Main outcome variables

voice parameters (loudness, f0 , The highest and lowest frequency they can produce, jitter and shimmer),

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210622051667N1**

Registration date: **2021-06-30, 1400/04/09**

Registration timing: **prospective**

Last update: **2021-06-30, 1400/04/09**

Update count: **0**

Registration date

2021-06-30, 1400/04/09

Registrant information

Name

Zeinab Mohseny

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2222 8051

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-03, 1400/04/12

Expected recruitment end date

2021-08-03, 1400/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of The effect of speech therapy , music-therapy and combined speech and music therapy on the vocal characteristics of people with Parkinson's disease by using telerehabilitation

Public title

The effect of combined speech and music-therapy on the vocal characteristics of people with Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with idiopathic Parkinson's disease (IPD) Patients in terms of disease severity in stages 1-3 based on the Hoehn & Yahr test Patient or family complaints about individual speech Ability to use r telerehabilitation and have a smartphone Adequate vision and hearing Use of drug therapy No history of stroke, head injury, brain surgery and laryngeal diseases such as vocal cord nodules, etc. No other neurological disorders other than idiopathic Parkinson's disease Do not use treatments other than medication (such as deep brain stimulation surgery (DBS))

Exclusion criteria:

If a patient develops a stroke or other neurological complication during treatment, they are excluded from the treatment plan. • Lack of cooperation

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using SPSS software for numbers from 1 to 33, we produce three groups with 11 numbers from zero, one or two. By balloting, the speech therapy group was assigned number zero, the combination therapy group number one and the music therapy group number two. To hide the created list, all the mentioned steps are done by someone who does not do the research. Then, each of the groups of zero, one and two are placed inside the closed envelopes and the envelopes are numbered on them so as not to disturb them. After the patients are admitted to the study according to the inclusion and exclusion criteria, the envelopes are opened in order to determine which group each patient will be in.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the person performing the assessments did not know which group each patient was in. Finally, the data obtained from the study are provided for analysis to a person who is unaware of the therapy groups .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Department of Speech Therapy, school of Rehabilitation science, Iran University of Medical Sciences, Madadakaran St, ShahNazari Ave, Mother square, Mirdamad Ave, Tehran.

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Tehran

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1545913487

Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.IUMS.REC.1400.044

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

Parkinson's Disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

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

voice parameters (loudness, fundamental frequency , The highest and lowest frequency they can produce, jitter and shimmer)

Timepoint

Before the intervention, after the intervention, one

month after the intervention

Method of measurement

praat software

Secondary outcomes

1

Description

Voice Handicap Index

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Persian version of Voice Handicap Index

2

Description

maximum phonation time

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

The maximum amount of time a person can sustain phonation of "ah" is timed

3

Description

Speech Intelligibility

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

seven scale of Fodala rankings

4

Description

Swallowing Disturbance Questionnaire

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Persian version of Swallowing Disturbance Questionnaire

5

Description

Dysphagia handicap index

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Persian version of Dysphagia handicap index

6

Description

northwest dysphagia patient check sheet

Timepoint

Before the intervention, after the intervention, one

month after the intervention

Method of measurement

Persian version of northwest dysphagia patient check sheet

7

Description

quality of life

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Persian version of quality of life test 36 questions

8

Description

Geriatric Depressive Scale

Timepoint

Before the intervention, after the intervention, one month after the intervention

Method of measurement

Persian version of Geriatric Depressive Scale

Intervention groups

1

Description

Intervention group: Combined speech and music therapy using telerehabilitation.. This group receive speech and music exercises at the same time in each treatment session. Speech exercises includes routine breathing exercises, loudness, pitch and speech Intelligibility, and music exercises includes posture correction, breathing exercises, warm-up exercises, voice exercises and singing exercises.The duration of the intervention is 4 weeks and the exercises are performed three times a week by a speech and language pathologist and a music and song specialist via video call on WhatsApp.

Category

Rehabilitation

2

Description

control group 1: speech therapy. this Group performs common and routine speech exercises, including breathing exercises, loudness, pitch, and intelligibility, which are the authority to use LSVT therapy and voice exercises. The duration of the intervention is 4 weeks and the exercises are performed three times a week by a speech and language pathologist via video call on WhatsApp.

Category

Rehabilitation

3

Description

Control group 2: music therapy. The music exercises used in this study for music therapy group are designed

based on the music therapy protocols of previous studies and It consists of five parts: Part 1: Motor exercises; Section 2: Breathing Exercises; Section 3: vocal Exercises; Section 4: Singing Exercises; Section 5: Final Conversation and Homework. The duration of the intervention is 4 weeks and the exercises are performed three times a week by a speech and language pathologist via video call on WhatsApp.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

school of Rehabilitation, Iran University of Medical Sciences

Full name of responsible person

Dr. Nahid Jalilavand

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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 Kazem Malakouti. vice chancellor for research

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Vice chancellor for research and technology, 5 the floor, the Central Building, Iran University of Medical Sciences, between Shahid Chamran and Sheikh Fazlollah Nouri Highways Hemmat Highway, Tehran.

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1449614535

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Email

research@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

Reyhaneh Mohammadi

Position

Associate professor

Latest degree

Ph.D.

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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Zeinab Mohseni

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Latest degree

Master

Other areas of specialty/work

Speech therapy

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Latest degree

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data or results of the present study will be presentation in an article or some articles that will be published, also will be available through correspondence with the corresponding author.

When the data will become available and for how long

After completing the present study and publishing the resulting article or articles.

To whom data/document is available

All researchers in the field of the present study

Under which criteria data/document could be used

With the same goal as the present study and with mention of the present study as the reference. All intellectual property rights of the present study belongs to the Iran University of Medical Sciences.

From where data/document is obtainable

The corresponding author of the article or articles derived from the study

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

Written request from the author responsible fore the the present review after the publication of the article or articles

Comments