Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of 12 weeks of adding music therapy to exercise at home on the physical and cognitive performances of Alzheimer's patients

Protocol summary

Study aim
Evaluation of the effect of 12 weeks of adding music therapy to exercise at home on the physical and cognitive performances of patients with Alzheimer's disease

Design
In a clinical trial with the control group, with two parallel experimental groups, the sample size was estimated based on G-Power software estimates of about 15 individuals in each group. (In this study, a total of 45-48 people will be selected as subjects). The single-blind study, assignment of subjects in groups will be done randomly by a third person

Settings and conduct
The trainer will communicate with each patient individually via video call and the patient will do the exercises at the same time with the trainer at their home. For the music-exercise group, non-verbal and traditional Iranian music and sonatas from Mozart will be played simultaneously with training. in this study, single blinding will perform and the person who will take the tests and analyze data would be kept blind to the groups. The tests will be taken at Roozbeh Hospital and Kharazmi University.

Participants/Inclusion and exclusion criteria
inclusion criteria: age between 50 to 70, mild to moderate disease degree, having one companion at least, ability to do daily routines exclusion criteria: Any anomalies or defects or physical injuries, having severe Alzheimer's disease, the physician discretion

Intervention groups
1-Intervention group 1 (exercise + music) includes Alzheimer's patients who receive exercise at home with music. 2-Intervention group 2 (exercise without music) includes patients with Alzheimer's who receive exercise intervention at home without music. 3-The control group includes Alzheimer's patients who do not receive any intervention and continue to live a normal life.

Main outcome variables
handgrip strength, cognitive status, quality of life, verbal fluency, performance independence, sleep disorders, Chair Stand test.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210726051993N1**
Registration date: **2021-08-08, 1400/05/17**
Registration timing: **prospective**

Last update: **2021-08-08, 1400/05/17**
Update count: **0**

Registration date
2021-08-08, 1400/05/17

Registrant information

Name
Vahid Khedmati zare

Name of organization / entity
Kharazmi University

Country
Iran (Islamic Republic of)

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+98 21 6605 2670

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-11, 1400/05/20

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of 12 weeks of adding music therapy to exercise at home on the physical and cognitive performances of Alzheimer's patients

Public title
The effect of 12 weeks of music therapy to exercise on alzheimer's patients.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate Alzheimer's Patients age should be between 50 to 75 years The patient should have at least one companion the patient should have ability to walk, do light activity and daily routines
Exclusion criteria:
The patient have severe Alzheimer's disease The patients have any disability, injury or movement limitations Physician's discretion not to involve the patient
Age
From **50 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The third person who was not in the research team will divide the subjects into 3 groups using a simple block random method. Allocating subjects to the study groups (interventions and control) will be done through block randomization using blocks of size 6. This will be by the website (https://www.sealedenvelope.com/simple-randomiser/v1/lists). In each block, four subjects will be from the intervention groups (music group and exercise-music group) and two subjects from the control group, which will arrange randomly. Finally, eight blocks will use.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person who will take the tests and analyze the data is kept blind to the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of sport science research institute
Street address
No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1587958711
Approval date
2021-07-20, 1400/04/29
Ethics committee reference number
IR.SSRC.REC.1400.070

Health conditions studied

1

Description of health condition studied
Alzheimer's disease
ICD-10 code
G30.0
ICD-10 code description
Alzheimer disease with early onset

Primary outcomes

1

Description
quality of life
Timepoint
before and after doing intervention
Method of measurement
Quality of Life in Dementia questionnaire

2

Description
sleep quality
Timepoint
pre and post intervention
Method of measurement
Pittsburgh Sleep Scale

3

Description
hand grip strenght
Timepoint
pre and post intervention

Method of measurement
Dynamometer

Secondary outcomes

1

Description
Chair Stand test
Timepoint
before and after the intervention
Method of measurement
stopwatch

2

Description
cognitive status
Timepoint
pre and post the intervention
Method of measurement
MOCA and MMSE tests

3

Description
Verbal Fluency
Timepoint
pre and post the intervention
Method of measurement
Verbal Fluency Tes

Intervention groups

1

Description
Intervention group 1: music-exercise group: Exercise group with music: Participants will train for 30 minutes 3 days a week. The exercise will be in the form of standing and sitting movements, in the form of full body and based on body weight, which will be performed rhythmically. Exercises will begin with an intensity of 30-40% of the maximum heart rate, and a small overload will be applied each week by reducing the rest time between sets. Each session will be preceded by warm-up for 10 minutes before the start of the exercise and cool down for 4-5 minutes after the exercise with stretching movements. In this group, we will play Mozart's music at the same time as exercising. The total time of the intervention will be 12 weeks, which due to coronavirus pandemic, all exercises will be at home and in the form of video contact with the trainer.
Category
Rehabilitation

2

Description
Intervention group 2: exercise without music: Participants will train for 30 minutes 3 days a week. The exercise will be in the form of standing and sitting movements, in the form of full body and based on body weight, which will be performed rhythmically. Exercises will begin with an intensity of 30-40% of the maximum heart rate, and a small overload will be applied each week by reducing the rest time between sets. Each session will be preceded by warm-up for 10 minutes before the start of the exercise and cool down for 4-5 minutes after the exercise with stretching movements. The total time of the intervention will be 12 weeks, which due to the coronavirus pandemic, all exercises will be at home and in the form of video contact with the trainer.
Category
Rehabilitation

3

Description
Control group: This group will not receive exercise and music intervention during the study, but will participate in tests (pre-test and post-test).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouzbeh hospital
Full name of responsible person
Fateme Mohamadian
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Rouzbeh hospital, qzvin Sq, Kargar jonoubi St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
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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
Kharazmi University

Proportion provided by this source
10

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
Kharazmi University
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Assistant Professor
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Person responsible for updating data

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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
For ethical reasons and without permission, personal details will not be published
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