Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of neurological music therapy on older adults with mild cognitive impairment

Protocol summary

Study aim
To determine the effect of neurological music therapy on cognitive function, emotional well being and quality of life among older adults with mild cognitive impairment.

Design
randomization simple random sampling technique with lottery method, parallel group

Settings and conduct
allied hospital Faisalabad

Participants/Inclusion and exclusion criteria
Both Male and female Presence of MCI (Montreal Cognitive Assessment score < 26) Being able to walk safely A low level of physical activity assessed by means of a physical activity questionnaire. Age 60-80 years En Older adults with visual impairment and those with hearing problems History of cardiovascular disease Presence of neurological disorder (Parkinson's disease, multiple sclerosis) Patients having Serious motor deficits Patient having difficulty in moving and communicating Left-handed or ambidextrous Patient having diagnosis of severe cognitive impairment such as dementia. Presence of depression

Intervention groups
The MMT group participated in a multi task MMT program consisting of exercise therapy with music and use of the Naruko clapper. The STT group participated in exercise sessions that involved the same movements as those in the MMT group. However, in these sessions, the instructor (single task) counted out the movements without accompanying background music or the Naruko clapper.

Main outcome variables
• Cognitive function • Physical Function • Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240314061290N1**
Registration date: **2024-03-27, 1403/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-27, 1403/01/08**
Update count: **0**

Registration date
2024-03-27, 1403/01/08

Registrant information

Name
Irtasam Ahmad

Name of organization / entity
The University Of Faisalabad

Country
Pakistan

Phone
+92 304 6364049

Email address
ahmadirtasam@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-17, 1402/11/28

Expected recruitment end date
2024-03-30, 1403/01/11

Actual recruitment start date
2024-02-17, 1402/11/28

Actual recruitment end date
2024-04-30, 1403/02/11

Trial completion date
2024-05-02, 1403/02/13

Scientific title
Effect of neurological music therapy on older adults with mild cognitive impairment

Public title

neurological music therapy on older adults with mild cognitive impairment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both Male and female Presence of MCI (Montreal Cognitive Assessment score < 26) Being able to walk safely A low level of physical activity assessed by means of a physical activity questionnaire. Age 60-80 years

Exclusion criteria:

Older adults with visual impairment and those with hearing problems History of cardiovascular disease Presence of neurological disorder (Parkinson's disease, multiple sclerosis) Patients having Serious motor deficits Patient having difficulty in moving and communicating Left-handed or ambidextrous Patient having diagnosis of severe cognitive impairment such as dementia. Presence of depression

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **24**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

simple random sampling technique with lottery method.

Blinding (investigator's opinion)

Single blinded

Blinding description

he individuals responsible for assessing or measuring the study outcomes are kept unaware of the participants' treatment group assignments or intervention status.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics/technical committe for The University of Faisalabad

Street address

Faisal Town, West Canal Road, Faisalabad Punjab

City

Faisalabad

Postal code

38000

Approval date

2024-01-05, 1402/10/15

Ethics committee reference number

TUF/Addl Reg/SB/764

Health conditions studied

1

Description of health condition studied

Mild cognitive impairment

ICD-10 code

F06.7

ICD-10 code description

A disorder characterized by impairment of memory, learning difficulties, and reduced ability to concentrate on a task for more than brief periods. There is often a marked feeling of mental fatigue when mental tasks are attempted, and new learning is found

Primary outcomes

1

Description

• Cognitive function

Timepoint

Before and after 6 week of intervention

Method of measurement

Mini-mental state examination (MMSE)

Secondary outcomes

1

Description

• Quality of life

Timepoint

Before and after 6 week of intervention

Method of measurement

SF 36 for Quality of life

2

Description

• Physical Function

Timepoint

Before and after 6 week of intervention

Method of measurement

International Physical Activity Questionnaire (IPAQ)

Intervention groups

1

Description

Active Control group: In this control group, an instructor

will guide the participants through the same exercises that will perform in the MMT group by giving counts only, without accompanying background music or use of the Naruko clapper. Both interventions will conduct once a week for 12 weeks.

Category
Rehabilitation

2

Description
Intervention group: In the MMT intervention group, each MMT session started with a 20 min warm-up period including about 5 min of light exercise completed in synchronization with background music. The next 15 min involved exercises with background music that aimed to strengthen leg muscles for fall prevention.This was followed by 30 min of MMT during which the participants used the Naruko clapper to accompany the music will play for 4 min, followed by 'March of 365 steps' (3 min), 'Hakodatenohito' (3 min), 'Palm in the sun'(3 min), 'Kiyoshi's Zundoko' (4 min), etc. Each session, will select 2 songs music and will repeat them for 30 min. These songs will repeat three times per one song, two songs per a session. It will include an explanation of each move, times to wipe sweat and to water supply between song and song for 2 min. The session will end with relaxation exercises, as well as deep breathing and massage to accompanying background music.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Allied Hospital Faisalabad

Full name of responsible person
Dr. Irtasam Ahmad; PT

Street address
Dr. Tusi Rd, Faisalabad, Punjab

City
Faisalabad

Postal code
38000

Phone
+92 41 9210095

Email
ahmadirtasam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Dr. Syed Saqlain Babar; PT

Street address
Faisal Town, West canal Road, Faisalabad Punjab

City
Faisalabad

Postal code
38000

Phone
+92 315 6205017

Email
syedsaqlain264@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
The University of Faisalabad

Proportion provided by this source
100

Public or private sector
Private

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
The University of Faisalabad

Full name of responsible person
Dr. Zainab Boota;PT

Position
Consultant clinical physiotherapist

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
Faisal Town, West Canall Road, Faisalabad, Punjab

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
0092 41 3357916317

Email
zainboota9698@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Dr. Warda Jabbar;PT

Position
Consultant clinical physiotherapist
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Faisal Town, West Canal Road, Faisalabad, Punjab
City
Faisalabad
Province
Punajb
Postal code
38000
Phone
0092 41 313 8650848
Email
Wardah.jabbar5@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
The University of Faisalabad
Full name of responsible person
Dr. Irtasam Ahmad;PT
Position
Consulant clinical physiotherapist
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Faisal Town, West Canal Road, Faisalabad, Punjab
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 41 6977849
Email
ahmadirtasam@gmail.com

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
No - There is not 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
Effect of neurological music therapy on older adults with mild cognitive impairment
When the data will become available and for how long
15 days after publication
To whom data/document is available
Google scholar
Under which criteria data/document could be used
Access to the data will be facilitated through a specified mechanism, such as a secure online portal or data sharing platform. Requests for access will be reviewed by a designated committee or entity responsible for ensuring that they meet the established criteria and comply with relevant regulations and guidelines. Additional supporting information and documents may be provided to assist requesters
From where data/document is obtainable
The University of Faisalabad 38000 https://tuf.edu.pk/ 00924187509715
What processes are involved for a request to access data/document
To receive the documents or data files, the process typically involves the following steps: 1. Request Initiation: The applicant submits a formal request specifying the documents or data files they need. 2. Verification and Authorization: The organization verifies the request and ensures that the applicant is authorized to access the requested documents or data files. This may involve confirming the identity of the requester and checking their permissions. 3. Processing Time: The processing time varies depending on the complexity of the request, the volume of documents or data files, and any legal or regulatory requirements. It could range from a few hours to several weeks. 4. Document Retrieval or Data Extraction: Once the request is approved, the organization retrieves the documents from their archives or extracts the requested data from their databases. 5. Quality Assurance: Before releasing the documents or data files to the applicant, the organization may conduct quality checks to ensure accuracy and completeness. 6. Delivery: The documents or data files are delivered to the applicant through a secure channel, such as encrypted email, secure file transfer protocols, or a secure online portal. 7. Confirmation of Receipt: The applicant acknowledges receipt of the documents or data files, confirming that they have received the information they requested.
Comments