Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of physical and cognitive rehabilitation using in-person, hybrid, and virtual methods in improving occupational and cognitive performance in the elderly

Protocol summary

Study aim
Comparing the effectiveness of physical and cognitive rehabilitation using in-person, hybrid, and virtual methods in improving occupational and cognitive performance in the elderly

Design
A randomized clinical trial study with three parallel groups (two intervention groups and one control group), without blinding, phase 3 on 117 elderly individuals. Block randomization method is used for randomization.

Settings and conduct
This study is being conducted at Shahid Beheshti Hospital. Elderly individuals undergo one of the following rehabilitation methods: in-person, hybrid, or virtual.

Participants/Inclusion and exclusion criteria
Age over 60 years Informed consent to participate Absence of cognitive impairment based on the MMSE (Mini-Mental State Examination) Ability to attend intervention sessions and complete assessments.

Intervention groups
The intervention consisted of providing physical and cognitive rehabilitation sessions through face-to-face sessions (12 sessions, each session lasting 60 minutes, intervention group 1) or through face-to-face and virtual sessions (6 face-to-face sessions and 6 virtual sessions, each session lasting 60 minutes, intervention group 2). The control group received physical and cognitive rehabilitation sessions entirely virtually (12 sessions, each session lasting 60 minutes).

Main outcome variables
Occupational Performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251120068059N1**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-25, 1404/10/04**
Update count: **0**

Registration date
2025-12-25, 1404/10/04

Registrant information

Name
Maryam Koul

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
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Email address
marycool79615@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01

Expected recruitment end date
2027-03-20, 1405/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of physical and cognitive rehabilitation using in-person, hybrid, and virtual methods in improving occupational and cognitive

performance in the elderly

Public title
The effectiveness of physical and cognitive rehabilitation in improving performance in the elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 60 years Informed consent to participate Absence of cognitive impairment based on the MMSE (Mini-Mental State Examination) Ability to attend intervention sessions and complete assessments.
Exclusion criteria:
Presence of a definitive diagnosis of dementia or other neuropsychiatric disorders. Debilitating physical illness that prevents attendance at sessions. Severe visual, hearing, or speech impairments that make test administration impossible.
Age
From **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **117**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used for allocation. This will be designed by a methodologist using the website SealedEnvelope.com, with a block size of 6. Allocation Concealment: To ensure allocation concealment, the randomization list will be held exclusively by the first supervisor (Principal Investigator). To conceal the randomization process, the type of intervention will be written on 117 paper cards and These cards will be placed inside opaque (non-transparent) paper envelopes. Only the first supervisor (Principal Investigator) will be aware of the corresponding codes. The cards will be arranged inside a box according to the order of the randomization list. Once the interviewer (student/executor) confirms a participant's eligibility, the first supervisor will provide them with the envelope.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, GanjAfrooz street, Babol
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶۴۷۷۴۵
Approval date
2025-11-09, 1404/08/18
Ethics committee reference number
IR.MUBABOL.HRI.REC.1404.151

Health conditions studied

1

Description of health condition studied
elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Occupational Performance
Timepoint
Occupational performance outcome measures are measured at the beginning of the study (before the intervention begins), 6 weeks after the intervention begins, 12 weeks after the intervention begins (completion of the intervention), and 3 months after the end of the intervention.
Method of measurement
Canadian Occupational Performance Measure questionnaire

Secondary outcomes

1

Description
Cognitive flexibility
Timepoint
at baseline (before the intervention), 6 weeks after the intervention, 12 weeks after the intervention (completion of the intervention), and 3 months after the intervention.
Method of measurement
Wisconsin Card Sorting Test

2

Description
Cognitive inhibition
Timepoint
at baseline (before the intervention), 6 weeks after the intervention, 12 weeks after the intervention (completion of the intervention), and 3 months after the intervention.
Method of measurement
Stroop Test

3

Description
Working Memory
Timepoint
at baseline (before the intervention), 6 weeks after the intervention, 12 weeks after the intervention (completion of the intervention), and 3 months after the intervention.
Method of measurement
Adults Working Memory Questionnaire

Intervention groups

1

Description
First intervention group: This group will receive physical and cognitive rehabilitation entirely through in-person sessions (12 sessions, each session lasting 60 minutes).
Category
Rehabilitation

2

Description
Second intervention group: This group will receive physical and cognitive rehabilitation training combined through in-person and virtual sessions (6 in-person sessions and 6 virtual sessions, each session lasting 60 minutes).
Category
Rehabilitation

3

Description
Control group: This group will receive physical and cognitive rehabilitation entirely through virtual sessions (12 sessions, each session lasting 60 minutes).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Afsaneh Bakhtiari
Street address
Shahid Beheshti Hospital, Shahid sargord Qasemi Blvd, Babol
City
Babol
Province
Mazandaran
Postal code
4716681451
Phone
+98 11 3225 2071
Email
beheshti@mubabol.ac.ir
Web page address
https://beheshti.mubabol.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
رضا قدیمی
Street address
Babol University of Medical Sciences ,Ganj Afroz Street, Babol
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۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 3219 9592
Email
a.bakhtiari@mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person

Maryam Koul
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
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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 further information
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is potentially shared after de-identifying individuals.
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Any non-commercial use
From where data/document is obtainable
To receive it, please contact the author responsible for the project (Afsaneh Bakhtiari). email: afbakhiari@gmail.com,a.bakhtiari@mubabol.ac.ir
What processes are involved for a request to access data/document
The researcher must provide the corresponding author with the purpose of accessing the data and the ethics code (or study protocol registration number) in the form of an institutional outreach email.
Comments