Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the effect of evidence-based nursing care on the quality of life, cognitive performance, and psychological well-being of middle-aged individuals with mild cognitive impairment

Protocol summary

Study aim
Determining the impact of evidence-based nursing care based on Iowa model on the quality of life, cognitive function, and psychological well-being of middle-aged individuals with mild cognitive impairment

Design
The clinical trial will include a control group, with parallel groups, single-blind, employing a pretest–posttest design, with a total sample size of 60 participants, who will be systematically randomized into two intervention groups (30 participants) and one control group (30 participants).

Settings and conduct
After obtaining written consent from the participants, demographic, clinical, cognitive, psychological, and baseline quality of life information (T0) will be collected. The intervention will be conducted for 10 weeks for the intervention group, while the control group will receive the training at the end of the study. This study will be conducted at all healthcare centers under the supervision of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals with mild cognitive impairment aged 40 to 65 years. Ability to participate in digital platforms and social media. Informed consent from individuals to participate in the research. No known psychiatric or physical disorders and no substance abuse based on self-reporting. Exclusion criteria: occurrence of unexpected family events or withdrawal from the study.

Intervention groups
In this study, evidence-based nursing care based on Iowa model will be designed and developed after reviewing relevant studies, and after its validity is confirmed by five specialists in geriatrics and mental health, it will be implemented over a 10-week period through virtual sessions lasting two hours (once a week) using Google Meet.

Main outcome variables
Cognitive performance, psychological performance, and quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151003024312N8**
Registration date: **2025-09-14, 1404/06/23**
Registration timing: **prospective**

Last update: **2025-09-14, 1404/06/23**
Update count: **0**

Registration date
2025-09-14, 1404/06/23

Registrant information

Name
Fataneh Ghadirian Baharanchi

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 6105 4311

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2028-01-20, 1406/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of evidence-based nursing care on the quality of life, cognitive performance, and psychological well-being of middle-aged individuals with mild cognitive impairment

Public title
Effectiveness of evidence-based nursing care on the quality of life, cognitive performance, and psychological well-being of middle-aged individuals with mild cognitive impairment
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with mild cognitive impairment aged 40 to 65 years Meeting the Peterson criteria for diagnosing mild cognitive impairment of the amnestic type, either single-domain or multi-domain, as determined by the psychiatric nurse (researcher) Exclusion of dementia diagnosis based on self-reporting
Exclusion criteria:
Inability to participate in digital platforms and social media Existing known psychiatric disorders in the history and currently based on self-reporting Existing substance abuse based on self-reporting Having severe debilitating physical disorders or diseases currently (such as severe heart diseases, cancer, stroke, etc.) based on self-reporting Having severe sleep disorders based on self-reporting
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be conducted using a multistage method. In the first stage, the sampling center will be selected from among the comprehensive health service centers affiliated with Shahid Beheshti University of Medical Sciences through a non-random and convenience sampling approach. Within each center, individuals will be randomly allocated to the intervention and control groups. Specifically, based on the contact information extracted from the health records (SIB system), individuals who meet the study inclusion criteria will be identified and selected from the list using a systematic random sampling method (every other individual). This process will continue until the required sample size in each group is reached. In cases where a selected individual declines participation, a replacement sample will be chosen from the same list according to the same systematic random sampling method. Furthermore, to determine randomly whether the first individual is allocated to the intervention or control group, a lottery method will be applied.
Blinding (investigator's opinion)
Single blinded
Blinding description
The single-blind design means that the statistical analyst is unaware of the group allocation of the participants, which is intended to reduce bias in the data analysis process.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculties of Pharmacy, Nursing, and Midwifery – Shahid Beheshti University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, opposite Shahid Rajaei Heart Hospital, at the intersection of Valiasr Street and Ayatollah Hashemi Rafsanjani Highway.
City
Tehran
Province
Tehran
Postal code
1996835119
Approval date
2025-07-21, 1404/04/30
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.044

Health conditions studied

1

Description of health condition studied
Mild cognitive impairment
ICD-10 code
F06.7
ICD-10 code description
A condition characterized by cognitive decline that is greater than expected for a person's age and education level, but not severe enough to interfere significantly with daily life.

Primary outcomes

1

Description
Cognitive performance
Timepoint
During intervention and immediately after intervention
Method of measurement
Questionnaires, brief cognitive examination, and Montreal cognitive assessment

2

Description
Psychological performance
Timepoint
During intervention and immediately after intervention
Method of measurement
The 9-item Patient Health Questionnaire (PHQ-9) and the 7-item Generalized Anxiety Disorder Questionnaire (GAD-7)

3

Description
Quality of life
Timepoint
During intervention and immediately after intervention
Method of measurement
World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the present study, evidence-based nursing care refers to a Nurse-led Cognitive Support Toolkit, which will first be designed using the Iowa Model for evidence translation into practice, and then finalized as a toolkit through reviewing intervention studies delivered in cognitive support clubs. After validation of the toolkit by five experts in the fields of geriatrics and mental health, it will be implemented over a 10-week period in the form of weekly two-hour virtual sessions via Google Meet, accompanied by daily delivery of cognitive support materials and/or games/podcasts. The Cognitive Support Club refers to the group of patient participants engaged through an agreed-upon social media platform, where discussions, cognitive support, and coordination of sessions will take place.
Category
Rehabilitation

2

Description
Control group: They will receive routine therapeutic and care interventions.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shemiranat Comprehensive Health Center
Full name of responsible person
Behrokh Mahmodzadeh
Street address
Shariati St., Tajrish Sq.,
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Next to the Taleghani Hospital, Velenjak St.,
City
Tehran
Province
Tehran
Postal code
193954631
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Yalda Malek
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Fataneh Ghadirian Baharanchi
Position
Faculty member
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Ph.D.
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Person responsible for updating data

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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
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
Raw and final dataset of the clinical trial
When the data will become available and for how long
Access will only be granted upon formal request and with ethics committee approval.
To whom data/document is available
The data and documents related to the study will be accessible exclusively to researchers and members of the scientific community with legitimate research purposes. Access is contingent upon adherence to ethical guidelines, confidentiality agreements, and approval by the ethics committee.
Under which criteria data/document could be used
Data and documents may only be used for legitimate scientific research purposes and must comply with ethical standards. Applicants are required to submit a research proposal and commit to maintaining confidentiality and respecting participant rights. Use of the data is contingent upon approval by the ethics committee and written consent from the study's principal investigators.
From where data/document is obtainable
The data and documents related to the study will be obtainable from the Shahid Beheshti University of

Medical Sciences data repository as well as email at [ghadirian.fataneh@gmail.com].

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

Applicants must submit a formal request including their research objective, study proposal, and a commitment to confidentiality. The request will be reviewed by the research team and the ethics committee. Upon approval, access will be granted under specific and restricted conditions. Applicants are also required to sign a data use agreement, pledging to use the data solely for the stated purposes.

Comments