Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

"The Effect of Mandala-Style Coloring on Cognitive Function in the older adults"

Protocol summary

Study aim
The effect of mandala-style coloring on the cognitive function of the elderly
Design
Clinical trial with a control group, with parallel groups, randomized, sample size 42 people, randomization with four-way permutation blocks,
Settings and conduct
Elderly people will be selected from among the elderly in Gonabad city based on the inclusion criteria and randomly assigned to two study groups. After obtaining written consent, the intervention group will color ready-made mandala designs (one design per session, a total of 16 designs) with 6 colored pencils for 2 sessions per week for 8 weeks, 20 minutes each session. The control group will also color freely with black pencils during the same period.
Participants/Inclusion and exclusion criteria
Age over 60, visual and motor ability, giving informed consent, having mild to moderate cognitive impairment
Intervention groups
Intervention group: Coloring predetermined mandala designs with colored pencils, control group: Drawing with black pencils without a specific design.
Main outcome variables
Change in cognitive performance scores in the elderly

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251213068299N1**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **prospective**

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

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

Registrant information
Name
zohre nazari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8844 6697
Email address
zohrenazari1402@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-01-14, 1404/10/24
Expected recruitment end date
2026-03-04, 1404/12/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"The Effect of Mandala-Style Coloring on Cognitive Function in the older adults"

Public title
"The Effect of Mandala-Style Coloring on Cognitive Function in the older adults"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the research and providing written consent to participate in the research. Having

mild cognitive impairment (based on studies, a score of 24 (sometimes 23-25) is suspicious of cognitive impairment on the Montreal Cognitive Assessment Questionnaire). Absence of severe mental disorders or advanced dementia (based on family statements). Having the necessary physical and mental ability to perform the coloring activity. The ability to see and recognize mandala designs. Ability to communicate. No chronic diseases. Avoid taking medications that affect memory and cognitive function. No previous experience in coloring mandalas. Having at least basic reading and writing skills.

Exclusion criteria:

Physical or psychological problems that may prevent staining from occurring during the study. Unwillingness to continue research. Absence from more than two intervention sessions. Starting medications that affect cognitive function. The coloring process may cause significant stress or anxiety for the elderly person.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

They will be assigned to two intervention and control groups using four-way permutation blocks.for this purpose, the intervention group will be assigned the letter A and the control group will be assigned the letter B. The possible states in the four-state block of six states include AABB, BBAA, ABAB, BABA, ABBA, BAAB, each state will be written on a card and assigned to cards numbered one to six. Then, one of the six possible states will be selected using dice and the selected patients will be divided into two groups based on that. This process will continue until the sample size is completed.

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 Gonabad University of Medical Sciences

Street address

Imam Khomeini Street, Ghadir Square, Gonabad.

City

Gonabad

Province

Razavi Khorasan

Postal code

969169996

Approval date

2025-12-08, 1404/09/17

Ethics committee reference number

IR.GMU.REC.1404.103

Health conditions studied

1

Description of health condition studied

Mild Cognitive Impairment

ICD-10 code

G31.84

ICD-10 code description

Mild Cognitive Impairment, so stated

Primary outcomes

1

Description

Cognitive Function Of Older Adult

Timepoint

Before And After Intervention

Method of measurement

Montreal Cognitive Assessment Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Coloring mandala designs with 6 colored pencils, twice a week for 20 minutes for up to two months.

Category

Behavior

2

Description

Control group: Free coloring with black pencil without a specific pattern twice a week in 20-minute sessions for up to two months.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Vice President of Health, Gonabad University of Medical Sciences

Full name of responsible person
Javad Sadeghi Nasab

Street address
Naserkhosro Ave

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 0912

Fax

Email
sadeghinasab.j@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Ali Firoozi Chahak

Street address
Next to the Asian Road

City
Gonabad

Province
Razavi Khorasan

Postal code
96917-93718

Phone
+98 51 5722 3028

Email
ali_firoozi66@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Gonabad University of Medical Sciences

Proportion provided by this source
1

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
Gonabad University of Medical Sciences

Full name of responsible person
Zohre Nazari

Position
Post graduate student

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Next to the Asian Road

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 4946

Email
zohrenazari1402@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Hossein Ajam Zibad

Position
associated professor

Latest degree
Ph.D.

Other areas of specialty/work
Geriatrics

Street address
Next to the Asian Road, Faculty of Nursing, Gonabad University of Medical Sciences.

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Phone
+98 51 5722 3814

Email
moallef@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person

Zohre Nazari
Position
Master's Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing, Side of Asian Road, Gonabad University of Medical Sciences.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3084
Email
zohrenazari1402@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Not applicable
Title and more details about the data/document
Due to ethical considerations and to maintain the confidentiality of participant information, individual data from this study cannot be shared publicly. However, aggregated, de-identified data will be available upon request and with the approval of the lead researcher.
When the data will become available and for how long
The period of access to de-identified documents and data begins 6 months after the publication of the final results of the thesis, and this access will be maintained for 5 years.
To whom data/document is available
Requests for access to data are only possible by researchers working in reputable academic and research centers, and will be made after reviewing the research purpose and with the approval of the responsible researcher and the ethics committee.
Under which criteria data/document could be used
Access to data is subject to a formal request with a specific research purpose, and data use is permitted only for scientific, non-commercial purposes and within the framework of the stated goals. Confidentiality of information, no attempt to re-identify individuals, and final approval by the responsible researcher are mandatory.
From where data/document is obtainable
Applicants can submit their formal request through correspondence with the researcher responsible for the project via the email address listed in the IRCT system and, after review and approval, proceed to receive non-identifiable documents or data.
What processes are involved for a request to access data/document
After submitting the official request, the request will be reviewed by the responsible researcher within a maximum of 2 to 4 weeks, and if approved, de-identified data will be provided to the applicant.
Comments
There are no further details regarding data sharing.