Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mandala coloring on the sleep quality of hemodialysis patients in dialysis centers affiliated to Khomein University of Medical Sciences

Protocol summary

Study aim
Determining the effect of mandala coloring on the sleep quality of hemodialysis patients

Design
The clinical trial with a control group, with parallel groups, without blinding, randomized, on 82 patients, was used for randomization from the sealed envelope site.

Settings and conduct
Dialysis centers affiliated to Khomein University of Medical Sciences

Participants/Inclusion and exclusion criteria
The criteria for entering the research include: confirmation of the disease according to the diagnosis of a neurologist; history of hemodialysis for at least 6 months and having consent to participate in the research; minimum literacy of reading and writing. The criteria for leaving the research included: the inability of the patient to continue participating in the research for any reason; not wanting to continue cooperation. Changing the treatment method to peritoneal dialysis or Kidney transplant. Transfer to other medical centers; history of neurological disease.

Intervention groups
In the intervention group, for 4 sessions during 4 days in 2 weeks (two consecutive dialysis sessions per week), a mandala design will be done daily during dialysis for 30 to 60 minutes. In total, 4 identical designs are used for all people, but the use of designs in each session is at the discretion of the participants, and in fact, in each session, they can choose and color one of the 4 available designs. . And no intervention is done in the control group. At the beginning of the research, an explanation about mandala coloring and its effects and how to use it will be given to the participants. At the beginning of the mandala design, it is suggested to use colored pencils from the outside to the inside. . For this purpose, each participant will be given a box of 6 colored pencils

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240609062052N4**
Registration date: **2024-10-10, 1403/07/19**
Registration timing: **prospective**

Last update: **2024-10-10, 1403/07/19**
Update count: **0**

Registration date
2024-10-10, 1403/07/19

Registrant information

Name
Pouya Zeidy

Name of organization / entity
Khomein University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 86 4633 2435

Email address
zeidypouya@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-22, 1403/08/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mandala coloring on the sleep quality of hemodialysis patients in dialysis centers affiliated to Khomein University of Medical Sciences

Public title

The effectiveness of mandala coloring on the sleep quality of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least 6 months of hemodialysis experience Consent to participate in the research Literacy at least reading and writing

Exclusion criteria:

A history of neurodegenerative disease The inability of the patient to continue participating in the research for any reason Not wanting to continue cooperation Changing the treatment method to peritoneal dialysis or kidney transplant. Transferring to other medical centers

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, random blocks will be used in order to hide the randomized allocation (concealment) and balance (balance) during and after the study. By using the sealedenvelope site and based on the sample size, people will be randomly placed in blocks of 4 and 6. The randomized list will be available only to the researcher as an Excel file.

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 Khomein Faculty of Medical Sciences

Street address

Azadi Avenue

City

Khomein

Province

Markazi

Postal code

3881743364

Approval date

2024-09-24, 1403/07/03

Ethics committee reference number

IR.KHOMEIN.REC.1403.024

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

2

Description of health condition studied

Acute kidney failure

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

3

Description of health condition studied

Unspecified kidney failure

ICD-10 code

N19

ICD-10 code description

Unspecified kidney failure

Primary outcomes

1

Description

Sleep quality

Timepoint

The results are evaluated twice, once before the intervention from the time they entered the study and once after the intervention by the relevant questionnaire in the control and intervention groups.

Method of measurement

Pittsburgh Sleep Quality Questionnaire (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, for 4 sessions during 4 days in 2 weeks (two consecutive dialysis sessions per week), a mandala design will be done daily and during dialysis for 30 to 60 minutes. In total, 4 identical plans are used for all people, but the use of plans in each session is at the discretion of the participants And in fact, in each meeting, they can choose and color one of the 4 available designs. It is better to paint at the beginning of the morning and after waking up due to higher concentration. It is suggested to use colored pencils from outside to inside. For this purpose, each participant will be given a box of 6 colored pencils.
Category
Other

2

Description
Control group: In the control group, there is no intervention, and only the sleep quality of people like the intervention group will be measured at the beginning and end of the study (before and after the intervention).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center of Hazrat Zahra Khomein Hospital
Full name of responsible person
Safarabadi Mahdi
Street address
Beheshti Blvd.
City
khomein
Province
Markazi
Postal code
3881955533
Phone
+98 86 4633 9982
Email
khomeinhospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khomein University of medical sciences
Full name of responsible person
Farahani Abbas
Street address
Quds
City
Khomein
Province
Markazi
Postal code
3881743364
Phone
+98 86 4622 4142
Email
info@khomeinums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khomein 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
Khomein Faculty of Medical Sciences
Full name of responsible person
Mahdi Safar Abadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Quds square,khomein faculty of medical sciences
City
khomein
Province
Markazi
Postal code
3881743364
Phone
+98 86 4622 4142
Email
mahdisafarabadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khomein Faculty of Medical Sciences

Full name of responsible person
Mahdi Safar Abadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Quds square,khomein faculty of medical sciences

City
khomein

Province
Markazi

Postal code
3881743364

Phone
+98 86 4622 4142

Email
mahdisafarabadi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Khomein Faculty of Medical Sciences

Full name of responsible person
Mahdi Safar Abadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Quds square,khomein faculty of medical sciences

City
khomein

Province
Markazi

Postal code
3881743364

Phone
+98 86 4622 4142

Email
mahdisafarabadi@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
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
All information and data will be shared after de-identifying people.

When the data will become available and for how long
Access will start 1 month after the results are published.

To whom data/document is available
All people related to medical and health matters

Under which criteria data/document could be used
The use of data will only be subject to mention of the source of the study and the authors. It is definitely necessary to obtain permission from the authors and researchers of the study.

From where data/document is obtainable
With this email: mahdisafarabadi@gmail.com

What processes are involved for a request to access data/document
After submitting the request and explaining the reason for the request, Dr. Safarabadi, the scientific accountability officer, will review the request and finally, within 72 hours after the request, the result will be informed to the requester.

Comments