Clinical Trial Protocol
Iranian Registry of Clinical Trials
21 Jun 2021

Investigating the Impact of Mandala Coloring on Anxiety in Patients with COVID-19: A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of mandala staining on the anxiety of patients with COVID-19

Design
This research project is a randomized, controlled, double-blind, blind clinical trial with two parallel arms. They are randomly divided into intervention and control groups. And will be followed up for 6 days.

Settings and conduct
The study will be conducted in the wards of hospitalized patients with covid19 in Amir Al-Momenin Hospital. Studying on both sides will be double-blind. The intervention group included patients with Covid 19 who underwent Mandala staining for 6 consecutive days and 30 minutes each day. The control group included patients with Covid 19 who received only routine care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 15 to 60 years Have mild to moderate anxiety Stability of hemodynamic status
Exclusion criteria: Lack of willingness to continue participating in the study Patient discharge

Intervention groups
Intervention group: In this way, patients complete The State-Trait Anxiety Inventory - Spielberger questionnaire before starting the intervention, and then after 6 consecutive sessions of Mandala staining daily and every 30 minutes, The State-Trait Anxiety Inventory - Spielberger questionnaire is completed again and their anxiety is measured. Control group: In this group, patients do not receive any intervention from the researcher and only receive routine care.

Main outcome variables
Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: IRCT20180519039711N6
Registration date: 2020-06-29, 1399/04/09
Registration timing: prospective

Last update: 2020-06-29, 1399/04/09
Update count: 0
Registration date
2020-06-29, 1399/04/09
Registrant information
Name
Mohamad Golitaleb
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 3417 3506
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m.golitaleb@arakmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-19, 1399/04/29
Expected recruitment end date
2020-10-20, 1399/07/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Impact of Mandala Coloring on Anxiety in Patients with COVID-19: A Randomized Clinical Trial

Public title
Effect of mandala staining on anxiety in patients with
COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
- Age 15 to 60 years
- Have mild to moderate anxiety
- Stability of hemodynamic status

Exclusion criteria:
- Lack of willingness to continue participating in the study
- Patient discharge

Age
- From 15 years old to 60 years old

Gender
- Both

Phase
- N/A

Groups that have been masked
- Participant
- Care provider

Sample size
- Target sample size: 60

Randomization (investigator's opinion)
- Randomized

Randomization description
- Patients will be randomly divided into intervention and control groups. Sixty patients were randomly assigned to either the intervention or control groups, initially 6 blocks of 10 different T and C letters (which represent the intervention and control groups) (30) from the intervention group and 30 from the intervention group. People belong to the control group. Then, the blocks were randomly selected to obtain a 60-sided combination of blocks. It opens to tell which group the patient falls into.

Blinding (investigator's opinion)
- Double blinded

Blinding description
- Clinical caregivers, data analysts, and patients are not aware of being in the control or intervention group.

Placebo
- Not used

Assignment
- Parallel

Other design features

Secondary Ids
- empty

Ethics committees

1

Ethics committee
- Name of ethics committee
- Ethics committee of Arak University of Medical Sciences
- Street address
- Deputy of Education and Research, Campus University of Medical Sciences site, Basij square, Arak

City
- Arak

Province
- Markazi

Postal code
- 3848176941

Approval date
- 2020-05-31, 1399/03/11

Ethics committee reference number
- IR.ARAKMU.REC.1399.089

Health conditions studied

1

Description of health condition studied
- Covid 19

ICD-10 code
- U07.1

ICD-10 code description
- COVID-19

Primary outcomes

1

Description
- Anxiety

Timepoint
- At the beginning of the study and 6 days after the intervention

Method of measurement
- The State-Trait Anxiety Inventory -Spielberger

Secondary outcomes
- empty

Intervention groups

1

Description
- Intervention group: The researcher will use Mandala staining to investigate its effect on the anxiety of patients with hospitalized Covid-19. In this way, patients complete The State-Trait Anxiety Inventory -Spielberger questionnaire before starting the intervention, and then after 6 consecutive sessions of Mandala staining daily and every 30 minutes, The State-Trait Anxiety Inventory -Spielberger questionnaire is completed again and their anxiety is measured.

Category
- N/A

Recruitment centers

1

Recruitment center
- Name of recruitment center
Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamad Golitaleb
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. alireza kamali
Street address
Education and Research Deputy of Arak University of Medical Sciences, Basij Square, Arak
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Email
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Web page address
http://arakmu.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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 scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamad Golitaleb
Position
Instructor
Latest degree
Master
Other areas of specialty/work
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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Shared data including demographic and disease information, type and method of intervention, information about sleep quality of participants before and after intervention.
When the data will become available and for how long
Start the access period 6 months after the results are published.
To whom data/document is available
Researchers and people working in nursing education as well as nursing clinical staff.
Under which criteria data/document could be used
The data can be used for education, research and clinical nursing. The applicant must be in the nursing field The data applicant only uses data for teaching, research and clinical nursing.
From where data/document is obtainable
Mohamad golitaleb, Department of critical care nursing, school of nursing, Ara University of medical sciences E mail: Mohamadgolitaleb@gmail.com Tel: +989379366279
What processes are involved for a request to access data/document
After ensuring that the data applicant is in the nursing field, we will be immediately responded to the request form by email.
Comments