Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of mandala coloring on mindfulness, happiness, fear of sleep, and symptoms of post-traumatic stress disorder in war veterans

Protocol summary

Study aim
Determining the effect of mandala staining on mindfulness, happiness, fear of sleep and symptoms of post-traumatic stress disorder in veterans

Design
A controlled clinical trial with parallel, randomized groups on 84 patients. SPSS software will be used for randomization.

Settings and conduct
Regarding the presence of two separate wards at Milad psychiatry center, one of these wards is allocated randomly to the control group and the other ward is allocated to the intervention group. In the intervention group, by the end of each meeting, participants have to stain a Mandela plot which they have chosen in 15 minutes. The Mandela plot with the size of 20*20 centimeters will be provided for participants on an A4 page with a 12 color crayons box by the researcher. In the control group, a 12 color crayons box with an A4 page which only has a blank square with the size of 20*20 centimeters will be allocated to the patients and they have to color it for 15 minutes with their own manner.

Participants/Inclusion and exclusion criteria
Inpatients diagnosed with post-traumatic stress disorder; No visual impairment; No movement defect in fingers and hands; Age under 65 years; Absence of suicide and homicide thoughts; Lack of crisis experience; No psychotic disorders; No drug abuse

Intervention groups
The patients of the control group have to color an A4 page for 15 minutes with a 12 color crayons box. The patients of the intervention group have to mandala stain for 15 minutes with a 12 color crayons box.

Main outcome variables
Mindfulness, happiness, fear of sleep, symptoms of post-traumatic stress disorder

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210604051491N1**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **prospective**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date
2021-08-29, 1400/06/07

Registrant information
Name
Mohammadamin Nasiri
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-06, 1400/06/15
Expected recruitment end date
2021-11-06, 1400/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of mandala coloring on mindfulness, happiness, fear of sleep, and symptoms of post-traumatic stress disorder in war veterans

Public title
The effect of mandala coloring on the mental state of war veterans
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Identification of post-traumatic stress disorder based on the medical records. age : up to 65 years old
Exclusion criteria:
Existence of visual impairment (such as color blindness, presbyopia, etc.) that disrupt patient coloring based on medical records Existence of movement defects in fingers and hands Existence of suicidal and homicide based on medical records Crisis experience in the last 6 months base on medical records Suffering from psychotic disorders and schizophrenia Drug abuse
Age
To **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Due to the existence of two separate wards in Milad Psychiatric Center to control data dissemination between control and intervention groups, one ward will be randomly assigned to the control group and the other to the intervention group. To do so, wards numbers will be written on two separate balls and will be placed inside a bag. The control group is assigned to the first picked ball and while the remaining ball represents the intervention group. It should be noted that these two wards are not distinguished in terms of hospitalizing physicians, physical space, and type of patients. patients will be randomly allocated to the control or intervention group with the help of 4 block randomization created with SPSS during the admission. To do so, the hospital admission will contact the researcher during patient reception to determine the patient ward based on the prepared SPSS list. To prepare the SPSS list, first in the "variable" section, a variable named ID is created, then the "compute variable" is chosen in the "transform" toolbar. In the "Compute variable" window, "ALL" is chosen for the "function group" and "Casenum" for the "function and special variables". Next, the "A" variable is created based on the 0.1+(casenum/4)-0.49 formula. The "A" parameter is Rounded by choosing the "Rnd(1)" option in the "function and special variables" sub-window to create the "B" parameter. In the next step, a "random number" with a "uniform" distribution between 0-1 is created. After that, "the Rank case" is chosen in the "transform" toolbar, and the "uniform" variable is ranked based on the "B" variable. As a result, in the created variable, numbers 1.0 and 2.0 represent the control group, and 3.0 and 4.0 represent the intervention.
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 AJA University of Medical Sciences
Street address
AJA University of Medical Sciences, etemadzade avenue, Fatemi avenue,
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2021-06-01, 1400/03/11
Ethics committee reference number
IR.AJAUMS.REC.1400.054

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
Post-traumatic stress disorder
Timepoint
Beginning (before the intervention) and after the intervention (coloring)
Method of measurement
Post-traumatic stress disorder questionnaire

Secondary outcomes

1

Description
Mindfulness
Timepoint
Beginning (before the intervention) and after the intervention (coloring)
Method of measurement
Mindful attention awareness scale

2

Description
Happiness
Timepoint
Beginning (before the intervention) and after the intervention (coloring)
Method of measurement
Oxford happiness questionnaire

3

Description
Fear of sleep
Timepoint
Beginning (before the intervention) and after the intervention (coloring)
Method of measurement
Fear of sleep inventory-short questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group, before starting the group therapy, a training session will be held by the researcher to get acquainted with the mandala designs and how to color them. At the end of each group therapy session, participants will be required to paint a structured mandala design of their choice within 15 minutes. For this purpose, after completing the group therapy, the researcher will provide the 10 sets of mandala designs to each of the participants and will ask them to choose a design according to their interests and paint in the same place. Mandala designs in dimensions of 20 by 20 cm will be provided to the participants by the researcher on A4 paper along with 12 soft colored crayons. The intervention will take 5 weeks and patients will be required to paint 2 mandalas designs per week. The first week will be allocated to pre-test, the second, third, fourth week will be allocated to mandala coloring (2 sessions per week and a total of 6 sessions) and the fifth week will be allocated to post-test.
Category
Treatment - Other

2

Description
Control group: Due to the chronicity of patients admitted to Milad Center, according to the policies of the center, mindfulness group therapy sessions include exercises such as slow breathing, body scan, etc. on a weekly basis for patients in each ward separately under supervision of the psychologist of the center is held and in the present study, these sessions were considered as a routine intervention. In the control group, 12 soft colored pencils will be provided to patients along with an A4 paper with a blank square measuring 20 by 20 cm and they will be asked to do free staining for 15 minutes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad shahriar hospital
Full name of responsible person
Jafar salari
Street address
Milad Shahriar Hospital, Shahid Bababozorgi avenvue, Basij Square
City
Shahriar
Province
Tehran
Postal code
3711137773
Phone
+98 21 6527 1660
Email
Info@Milad-Hospital.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Doctor mojataba yousefi
Street address
AJA University of Medical Sciences, etemadzade avenue, Fatemi avenue
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Postal code
1411718541
Phone
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Email
jps@ajaums.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Mohammad amin nasiri
Position
Nurisng master student
Latest degree
Bachelor
Other areas of specialty/work
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studnet
Latest degree
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Person responsible for updating data

Contact
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Position
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Latest degree
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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
Due to the hospitalization of patients in a medical center under the supervision of the Armed Forces, it is not possible to publish data
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
No - There is not a plan to make this available