

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)

Phone

+98 25 3270 7520

Email address

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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 $0.1 + (\text{casenum}/4) - 0.49$ 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 avenue, Basij Square

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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

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AJA University of Medical Sciences, etemadzade avenue, Fatemi avenue

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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

Nurising master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Position

studnet

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Fax**Email**

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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