

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of art therapy (Mandala painting) on attention level of children with attention deficit/hyperactivity disorder (ADHD)

Protocol summary

Study aim

The effect of coloring mandala on attention level of children with attention deficit / hyperactivity disorder

Design

This research was a quasi-experimental before - after with the control group study, that was performed as a randomized clinical trial.

Settings and conduct

This study was conducted in the Nezam-Mafi clinic and meetings were formed in one of the rooms in the clinic and each group were composed of five. There were asked to color and finish one pre-drawn Mandela design on a sheet every session. In this study, the control group did not receive any intervention and did not attend any non-pharmacological intervention until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with mixed attention deficit/hyperactivity disorder based on psychiatrist diagnosis, Children 12-7 years old who go to school. Children and their parents have the motivation to cooperate and participate in the study. Children who have been treated with Ritalin for at least 3 months. Exclusion criteria: Children have other psychiatric disorders. Participation in non-pharmacological treatments during treatment, use of anti-anxiety and sedative drugs.

Intervention groups

Intervention group: Mandala Coloring Program was performed for 10 sessions (once a week) for the intervention group. Each session lasted 40-60 minutes. The Mandala method is every piece of artwork that is designed in a limited form (usually a circle). The Mandala designs are symbolic designs for generalization or integrity. The Mandala designs were selected from Mandala coloring books and were presented on A4 sheets. Control group: No intervention was performed in the control group and they did not participate in any other non-pharmacological treatments at the same time.

Main outcome variables

Attention level

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20190729044370N1**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **retrospective**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

zahra Borzabadi Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title

The effect of art therapy (Mandala painting) on attention level of children with attention deficit/hyperactivity disorder (ADHD)

Public title

The effect of mandala on Attention level

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with combined attention deficit / hyperactivity disorder based on a psychiatrist's diagnosis Children 12-7 years old who go to school Children and their parents have an incentive to collaborate and participate in the study. Children who have been treated with Ritalin for at least 3 months

Exclusion criteria:

Children with other psychiatric disorders. participating in other non-pharmacological treatments during the study. taking Anxiolytic and sedative drugs.

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, sample from 90 children who had the criteria to enter were selected by simple random sampling. Each of these children had equal chance to be selected in intervention and control groups. Each child's name was on a separate card and placed in a box. Then we mixed the cards and drew out the first 21 cards as the intervention group and the second 21 cards as the control group.

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 The University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin,Post code: : 1985713871

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Approval date

2018-09-15, 1397/06/24

Ethics committee reference number

IR.USWR.REC.1397.057

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description

Level of attention in Jordan's attention deficit disorder

Timepoint

Measurement of attention level before intervention and 2 weeks after intervention

Method of measurement

Jordan's attention deficit disorder

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mandala Coloring sessions were set up once a week for 40-60 minutes for the intervention group. In this method, the mandala patterns were chosen from Mandela coloring books. In order to hold meetings and to maintain attention and concentration, the intervention samples were divided into 4 groups, each comprising 5-6 members. In the first session, the children were introduced to the researcher and other

children and the goal of holding classes. then they colored and finished one pre-drawn Mandela design on an A4 sheet with provided colored pencils every session. In the Mandala coloring session children were totally free in color selection and the mode of coloring. The Mandalay designs presented at each session were different from the sessions before, and all the people in the groups painted a similar design every session. The patterns presented in each session were different. This method was in use until 10 sessions.

Category

Treatment - Devices

2**Description**

The control group: it was selected as a comparison group and received no intervention and there was no other non-pharmacological intervention until the end of the study.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nizam Mafia Rehabilitation Clinic

Full name of responsible person

Mahdi Khanke

Street address

Next to the Nizam Mafia S Mosque, after Jannatabad Road, Ayatollah Kashani Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name

Vice-Chancellor for Research and Technology

Grant code / Reference number

254

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

Yes

Title of funding source

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Zahra Borzabadi Farahani

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Part of the data, such as information about the level of attention, can be shared

When the data will become available and for how long

Start access period 3 months after publishing results

To whom data/document is available

The data will be available to all researchers and individuals working in academic centers and institutes.

Under which criteria data/document could be used

The data will be available to all researchers and individuals working in academic centers and institutes.

From where data/document is obtainable

Zahra Borzabadi Farahani farahani.z201625@gmail.com

What processes are involved for a request to access data/document

People can request data by email and will be responded as soon as possible.

Comments