Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Assessing of the Effect of Mandala Painting on Anxiety of 6 - 14 Year Old Children with Cancer

Protocol summary

Study aim
Determination of the effect of mandala painting on the anxiety of children aged 6 to 14 years with cancer
Design
Clinical trials with control group, Selection of samples based on purpose, Parallel group, no blind spot, Randomized
Settings and conduct
Interventions will be held in the oncology section of the Children's Medical Center Hospital affiliated to Tehran University of Medical Sciences. sampling will take place every other week. first week the intervention group And next week the control group will be selected.
Participants/Inclusion and exclusion criteria
inclusion criteria: interested to participate in the study, aged in 6 and 14, has one type of cancer, don't be in end stage of cancer, based on inventory doesn't have severe anxiety and don't use any drug for anxiety. exclusion criteria: discharge or transfer to another hospital, unwillingness to continue to participate in research, absence more than one session
Intervention groups
Hold mandala coloring sessions for 6 sessions And everyday of the week for an hour in the intervention group and do not intervention for control group
Main outcome variables
anxiety of children with cancer

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181112041618N1**
Registration date: **2019-02-28, 1397/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-28, 1397/12/09**
Update count: **0**
Registration date
2019-02-28, 1397/12/09

Registrant information
Name
Mona Moharamkhani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 5572 4326
Email address
monamoharamkhani@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-02-16, 1397/11/27
Expected recruitment end date
2019-05-21, 1398/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing of the Effect of Mandala Painting on Anxiety of 6 - 14 Year Old Children with Cancer

Public title
Effects of Mandala Painting on Anxiety of Children with Cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
don't have severe anxiety Interested in Participating in

Research Aged in 6 - 14 Year Old Not in End Stage of Cancer Don't use any Drug for Anxiety

Exclusion criteria:

Discharge or Transfer to other center Don't be interested to participating in Research Absence more than one session

Age

From **6 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Target-based sampling based on the criteria for entering the study Then the samples were assigned to two groups of intervention and control By random method and using random numbers table

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 committe of shahid beheshti university of medical sciences

Street address

No. 77, Eji Ave., Aboozar St., Qazvin Sq

City

tehran

Province

Tehran

Postal code

1366648918

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.154

Health conditions studied

1

Description of health condition studied

Anxiety of children with cancer

ICD-10 code

C00-D48

ICD-10 code description

Neoplasm

Primary outcomes

1

Description

Anxiety of Children with Cancer

Timepoint

Anxiety Measurement Before and After Intervention And one month after the last intervention session

Method of measurement

The spilberger's State-Trait Anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: held up mandala coloring sessions for six sessions and every day of the week for one hour

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's medical center hospital

Full name of responsible person

miss tahmineh naji

Street address

Doctor qarib st

City

tehran

Province

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Postal code

1419733151

Phone

+98 21 6693 0068

Email

cmc.tums@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
doctor Mahrokh Dolatian
Street address
vali-e-asr st
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Province
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1985717443
Phone
+98 21 8865 5366
Email
sbnmf@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
monamoharamkhani
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

at the end of the study, information on the main outcome can be shared.

When the data will become available and for how long

start the access period 6 months after printing results

To whom data/document is available

all people

Under which criteria data/document could be used

for use in similar studies with source mention and use of intervention in the hospital

From where data/document is obtainable

access to the published articles of this study and send a email to the main executor's ,to the address: monamoharamkhani@sbmu.ac.ir

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

waiting for two weeks after sending the message

Comments