Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the Effect of Internet-based Cognitive Behavioral Therapy (ICBT) and Art Therapy with Painting Approach in Generalized Anxiety Disorders in Children

Protocol summary

Study aim

Comparing the Effect of Internet-Based Cognitive Behavioral Therapy (ICBT) and Art Therapy with Painting Approach in Generalized Anxiety Disorders in Children

Design

Clinical Trial with Control Group, with Parallel Groups and One-Way Blind and Randomized with Number Table, Sample Size 45 People

Settings and conduct

Generalized Anxiety Disorder in Children Aged 8 to 10 Years Referred to Zare Hospital and Touba clinic, One-Way Blind

Participants/Inclusion and exclusion criteria

-Children 8 to 10 Years Old with Generalized Anxiety Disorder -No Severe Anxiety Disorder - Do Not Have Mood Disorders, Do Not Have Attention Deficit Hyperactivity Disorder, Do Not Have Bsessive-Compulsive Disorder -Absence of Suicidal Thoughts -Absence of Physical Illnesses and Disabilities -No Current Use of Psychotropic Drugs

Intervention groups

Cases of Anxiety Disorders are Matched as much as Possible, Then Randomly Divided Into Three Groups That Should be as Homogeneous as Possible and Cognitively Close to Each Other (Two Intervention Groups and a Control Group of Waiting List People They are Selected for Interventions and Will be Excluded From the Study Whenever They Develop Symptoms and the Necessary Measures Will be Taken for Them) -- Skype Service (Web-Based Training) ICBT by Assistant Psychiatrist and Art Therapy Based on Painting by Ms. Fattahi Master of Arts Who has a Certificate of Art Therapy with Work Experience with the Child and is Done in Person (For Each of the Treatment Groups 8 The Session is 45 to 60 Minutes and one Session Per week). -- The Control Group (Control) Does Not Receive Medication During the Course and Only Supportive Interventions are Considered for them.

Main outcome variables

The Main Purpose of This Study is to Achieve Practical Consequences and be Aware of the Effect of Two Specific Treatment Methods to Solve Children's Anxiety Disorders and Compare Them.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220512054830N1**
Registration date: **2022-09-20, 1401/06/29**
Registration timing: **retrospective**

Last update: **2022-09-20, 1401/06/29**
Update count: **0**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

ladan fouladi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3339 7305

Email address

ladanfouladi.1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-14, 1401/03/24

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Internet-based Cognitive Behavioral Therapy (ICBT) and Art Therapy with Painting Approach in Generalized Anxiety Disorders in Children

Public title

Comparing the Effect of Internet-based Cognitive Behavioral Therapy (ICBT) and Art Therapy with Painting Approach in Generalized Anxiety Disorders in Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 8 to 10 Years Old with Generalized Anxiety Disorder

Exclusion criteria:

Absence of Severe Anxiety Disorder No Mood Disorders, no Attention Deficit Hyperactivity Disorder No Obsessive Compulsive Disorder Lack of Suicidal Thoughts Absence of Physical Illnesses and Disabilities No Current Use of Psychotropic Drugs

Age

From **8 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Table 8 Blocks of Six by Block Randomization Method

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are Aware of The Group They are in and what Actions are to be Taken for them, but the Clinical Caregiver, Researcher, Evaluator, and Data Analyst are Unaware of it.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Saeed Fooladi's House, Danesh Alley, Felestin 13, Felestin Street

City

Sari

Province

Mazandaran

Postal code

4815655193

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.MAZUMS..REC.1400.9170

Health conditions studied

1

Description of health condition studied

Generalized Anxiety Disorders

ICD-10 code

F41.1

ICD-10 code description

Generalized Anxiety Disorder

Primary outcomes

1

Description

Spence Anxiety Questionnaire Score

Timepoint

Before the Intervention, Immediately After the Intervention and Two Months After.

Method of measurement

Spence Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: The Service is Done Through Skype (Web-Based Training) ICBT by a Psychiatric Assistant and Under the Supervision of a Child and Adolescent Psychiatrist. Intervention Group 2: Art Therapy Based on

Painting is Done in Person.

Category

Treatment - Other

2

Description

Control Group: They Do not Receive Medication During the Course and Only Supportive Interventions are Considered for Them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Psychiatric and Burn Hospital

Full name of responsible person

Ladan Fooladi

Street address

Zare hospital, Sari-Neka road

City

Sari

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Postal code

4843185774

Phone

+98 11 3328 3886

Email

ladanfouladi.1990@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ladan Fooladi

Street address

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City

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ladan Fooladi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information On the Main Outcome
When the data will become available and for how long
After Printing The Results
To whom data/document is available
Only Researchers Working In Academic Institutions
Under which criteria data/document could be used
Regarding Scientific Research
From where data/document is obtainable
Zare Hospital, Ladan Fooladi, 00989025436100
What processes are involved for a request to access data/document
Two Days After The Phone Call
Comments