

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

**Province**

Mazandaran

**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

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Zare hospital, Sari-Neka road

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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

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**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

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Resident

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Medical doctor

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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**