

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effectiveness of play therapy on social anxiety, depression and loneliness in children with dyslexia

#### Protocol summary

##### Study aim

Investigating the effectiveness of play therapy on social anxiety, depression and loneliness on children with dyslexia

##### Design

The sample size of this research is 30 people, which includes children who have dyslexia in elementary school and their selection is through simple random sampling (lottery) in such a way that the statistical population was given a number and they were included in We put a plastic bag and then took out the numbers one by one and wrote them down on paper until we reached the sample size

##### Settings and conduct

With the consent of the parents and the school staff, a random sampling of 30 people (3 people as a reserve) is carried out in the school and they are replaced in one of the two experimental and control groups of 15 people. The experimental group is subjected to play therapy during 7 sessions. obtained, but the control group was not subjected to game therapy sessions, and one-way blinding was applied in this research, and the students were not aware of the goals of these games.

##### Participants/Inclusion and exclusion criteria

The criterion for entering the research is the diagnosis of dyslexia with the help of specialists, the consent of the parents and also the consent of the children to participate in the study and no treatment at the same time as the intervention.

##### Intervention groups

The statistical population of this research is primary school children suffering from dyslexia, who were replaced by random sampling of 30 people (3 people were kept aside as reserves and replacements) and were replaced in one of the two experimental and control groups of 15 people. The experiment was subjected to play therapy during 7 sessions, but the control group was not subjected to play therapy sessions

##### Main outcome variables

In this research, the level of depression, social anxiety and feeling of loneliness in children with dyslexia are investigated by means of play therapy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240120060744N1**

Registration date: **2024-04-17, 1403/01/29**

Registration timing: **retrospective**

Last update: **2024-04-17, 1403/01/29**

Update count: **0**

##### Registration date

2024-04-17, 1403/01/29

##### Registrant information

##### Name

Elmira Khalilzade kolagar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2209 6746

##### Email address

khalilzade.el@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2024-02-26, 1402/12/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effectiveness of play therapy on social anxiety, depression and loneliness in children with dyslexia

**Public title**  
Investigating the effect of play therapy on social anxiety, depression and loneliness

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The conditions for entering this research are elementary school children with dyslexia in the first half of the school year.  
**Exclusion criteria:**

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

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Despite the fact that the parents of the students were aware of the objectives of this research, but the students who are the sample of this research were not aware of the objectives of this research.

**Placebo**  
Not used

**Assignment**  
Factorial

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Islamic Azad University, Zahedan branch  
**Street address**  
North Farhzad, Sartakh Alley, No. 13, Unit 4  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1981145984  
**Approval date**  
2024-01-20, 1402/10/30  
**Ethics committee reference number**  
IR.IAU.ZAH.REC.1402.095

## Health conditions studied

### 1

#### Description of health condition studied

Investigating social anxiety, depression and loneliness

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The effect of play therapy on social anxiety, depression and loneliness

#### Timepoint

Two groups are selected as intervention and control, and during 7 sessions, play therapy measures are provided for the intervention group and not for the control group.

#### Method of measurement

In this study, the measurement of social anxiety is based on the Social Anxiety Questionnaire for Adolescents (SAS-A), and the measurement of depression is based on the Beck Depression Questionnaire, and the measurement of feeling of loneliness is based on the Feeling of Loneliness Questionnaire (UCLA). .

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: There are 15 people who undergo play therapy in 7 sessions

#### Category

Behavior

### 2

#### Description

Control group: There are 15 people who don't undergo play therapy

#### Category

Behavior

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Education, District 12, Tehran

**Full name of responsible person**

Hamid Rostami

**Street address**

Shariati St., Zandi St., education and training of the region

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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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**Web page address**

<https://zahedan.iau.ir/>

**Grant name**

does not have.

**Grant code / Reference number**

10100

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

Yes

**Title of funding source**

Islamic Azad University, Zahedan branch

**Proportion provided by this source**

100

**Public or private sector**

Private

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Islamic Azad University, Zahedan branch

**Full name of responsible person**

Gholamreza, editor's spokesperson

**Position**

Assistant Professor, Department of Psychology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

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Vice Chancellor of the Faculty

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## Person responsible for updating data

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Province**

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**Postal code**

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**Phone**

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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**

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**

No - There is not 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**

Statistical data file - summary of the work - its results, treatment protocol.

**When the data will become available and for how long**

From March 2024 to one year after publication

**To whom data/document is available**

Students, professors and researchers

**Under which criteria data/document could be used**

It is for the purpose of further research and comparison of results.

**From where data/document is obtainable**

Islamic Azad University, Zahedan branch

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

The process takes about a month.

**Comments**