

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

City

tehran

Province

Tehran

Postal code

9815874558

Phone

+98 21 8670 5504

Email

ed.1361@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Zahedan branch

Full name of responsible person

Mr. Dr. Thanagovi, editor

Street address

Zahedan University Street-Islamic Azad University, Zahedan branch

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9815874878

Phone

+98 54 3322 1561

Fax

+98 54 3322 1561

Email

arjamandimuhaddeh@gmail.com

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

Street address

University Street - Islamic Azad University, Zahedan branch

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9815874558

Phone

+98 54 3322 1561

Email

el.1361@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University, Zahedan branch

Full name of responsible person

Gholamreza Thanagovi editor

Position

Vice Chancellor of the Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

University Street - Islamic Azad University, Zahedan branch

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9815874558

Phone

+98 54 3322 1561

Email

el.1361@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University, Zahedan branch

Full name of responsible person

Gholamreza Thanagovi editor

Position

Vice Chancellor of the Faculty

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Phone

+98 54 3322 1561

Email

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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