

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effectiveness of Empathy Training on Aggression, Adaptation and Social Responsibility of Preschool Children

Protocol summary

Study aim

The Effectiveness of Empathy Training on Aggression, Adaptation and Social Responsibility of Preschool Children

Design

This study has a control group and random selection. The study was conducted without blinding. The intervention was conducted on 42 subjects in two groups of 21 subject. Excel software function was used for randomization.

Settings and conduct

To conduct the research, firstly, two centers were selected from the preschool centers of the 1st district of Hamedan city, and after coordinating with the officials of these centers, a sample of 50 children was selected. Then the children were informed about the time and schedule of educational sessions. After selecting the sample, people were randomly assigned to two control and experimental groups, and training sessions were held for the experimental group. It should be noted that the people in the experimental group participated in 8 sessions training, which were held twice a week, and the training period lasted for one month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent of the child and parents. Exclusion criteria: presence of psychological disorder and use of any psychological intervention or psychiatric medication.

Intervention groups

The experimental group received the empathy intervention. In order to teach empathy to children, the Empathy educational program (Jan Bozorgi et al., 2013) was used, which is suitable for preschool and elementary school children. The control group did not receive any special intervention and remained in the waiting list.

Main outcome variables

Aggression, Adaptation, Social Responsibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059801N1**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **retrospective**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Abolghasem Yaghoobi

Name of organization / entity

Bu-Ali Sina University

Country

Iran (Islamic Republic of)

Phone

+98 81 3140 1804

Email address

yaghoobi@basu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

2023-09-01, 1402/06/10

Actual recruitment end date

2023-09-06, 1402/06/15

Trial completion date

2023-10-12, 1402/07/20

Scientific title

The Effectiveness of Empathy Training on Aggression, Adaptation and Social Responsibility of Preschool Children

Public title

The Effectiveness of Empathy Training on Aggression, Adaptation and Social Responsibility of Preschool Children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum age is 5 years old Maximum age is 6 years old

Exclusion criteria:

Having psychological disorders

Age

From **5 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the sample using the table of random numbers, the subjects were randomly replaced in the experimental and control groups. A table of random numbers is a collection of numbers that are generated completely randomly without a specific pattern or order and are presented as a table. In order to use the table of random numbers, the researcher must first determine the direction of reading the numbers in the table (for example, up, down, left or right, in this study left to right was chosen). The second assumption of the researcher is to consider numbers for different groups (even numbers were considered for the intervention group and odd numbers were considered for the control group). Then the researcher randomly selected one of the numbers and moved in one of the predetermined directions (from left to right in this study) and recorded the numbers and allocated them to the intervention and control groups, and this process continued until all the sample subject were selected.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bu-Ali Sina University

Street address

Chaharbagh Shahid Mostafa Ahmadi Roshan, Bu-Ali Sina University, Hamedan

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸-۳۸۶۹۵

Approval date

2023-07-10, 1402/04/19

Ethics committee reference number

IR.BASU.REC.1402.046

Health conditions studied

1

Description of health condition studied

Aggression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Aggression

Timepoint

Pre-test stage and post-test stage - one month interval

Method of measurement

Measure: Questionnaire

2

Description

Adaptation

Timepoint

Pre-test stage and post-test stage - one month interval

Method of measurement

Measure: Questionnaire

3

Description

Social Responsibility

Timepoint

Pre-test stage and post-test stage - one month interval

Method of measurement

Measure: Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention group (empathy training): To teach children empathy, empathy training programs (Jan Bozorgi, Noori and Agah Haris, 2014), which are suitable for preschool and elementary children. The program consists of four steps as follows: Step One: Introduction to physiological feelings such as hunger, thirst, fatigue, cold, heat. Step Two: Introduction to psychological feelings such as sadness, anger, happiness. Step Three: Focusing on the similarity and difference of your feeling with another and emphasizing your feelings. Step Four: Strengthening empathy responses. The intervention program was conducted by the researcher in the pre-school training classes. The intervention took place in eight sessions one hour.

Category

Behavior

2

Description

Control group: The control group did not receive any intervention in the present study and received the usual daily training during the intervention period in experimental group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hedayat preschool center

Full name of responsible person

Dr. Rasool Kordnoghi

Street address

No, 34, Besat Blvd., Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu Alisina University

Full name of responsible person

Dr Arash Ghorbani

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a.ghorbani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bu Alisina University

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

Bu-Ali Sina University

Full name of responsible person

Abolghasem Yaghoobi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable