

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effectiveness of Group Self-Care Education With Play-Therapy in Adherence To Treatment And Quality Of Life In Children With type 1 Diabetes

Protocol summary

Study aim

Comparison of the Effectiveness of Group Self-Care Education With Play-Therapy in Adherence To Treatment And Quality Of Life In Children With type 1 Diabetes

Design

Clinical trial;with a control group;Randomised

Settings and conduct

Individuals will be randomly assigned to three groups: skills training, play therapy, and control. Psychological skills that are taught in this study in an 8-session protocol as a group to children in the first group, including: training, cognition of emotions, identification, physical reactions to anxiety, relaxation training, identification of anxiety self-talk. Challenging and thinking training, problem-solving skills training, self-reward based on effort and performance, social skills training and courage. Diabetes-related physical self-care behaviors are also taught to the first group...in this study, play therapy in an 8-session protocol is performed in groups with children in the second group. Shakiba child play therapy consists of two stages: play alarm therapy and watchtower play therapy. Teaches children through games. The game is played in groups of 5 people. The third group, which is the control group, does not receive any intervention

Participants/Inclusion and exclusion criteria

Children 8 to 11 years old with type 1 diabetes;No emotional or behavioral problems.Not receiving psychotherapy for the past 6 months

Intervention groups

Self-care education;Play-therapy;control Group

Main outcome variables

Improving the quality of life and adherence to treatment in children with type 1 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040974N3**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **prospective**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

Fatemeh Zargar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

f.zargar@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Group Self-Care Education With Play-Therapy in Adherence To Treatment And Quality Of Life In Children With type 1 Diabetes

Public title

Effect Of Education With Play-Therapy In Treatment Of Children With type 1 Diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Children With type 1 diabetes

Exclusion criteria:

The child does not have emotional-behavioral problems

Age

From **8 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization;Individual;Random Number Table;Central Randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University Of Medical Sciences;Hezarjarib Blvd

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-23, 1399/04/03

Ethics committee reference number

IR.MUI.MED.REC.1399.255

Health conditions studied

1

Description of health condition studied

Type 1 diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Adherence to treatment in children with diabetes.Quality of life in children with diabetes.

Timepoint

Before intervention;after intervention

Method of measurement

Quality of life questionnaire-kidscreen

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Self-care group education.A mental and physical care education program is offered by a psychologist in 8 one-hour sessions.In these sessions, emotion recognition and control skills, relaxation skills, proper nutrition principles of insulin injection and coping with anxiety related to diabetes are trained.

Category

Treatment - Other

2

Description

Intervention group: Play_Therapy.A treatment game that offers tips on diabetes self-care is played with this group in 8 one-hour sessions.

Category

Treatment - Other

3

Description

Control group: Control

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Naimeh Haghshenas

Street address

No. 8, intersection of Hashtbehesht Street, Ostandari Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

DR Javanmard Haghjooy Shaghayegh

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Hezarjarib Ave;Isfahan University Of Medical Sciences

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Aileen Salmani

Position

masters

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

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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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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