

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of virtual painting therapy on anxiety, depression and self-efficacy amongst 8-12 years old children with type 1 diabetes referring to Imam Reza Diabetes Clinic, Shiraz, 2019

Protocol summary

Study aim

Determining the effect of virtual painting therapy on anxiety, depression and self-efficacy amongst 8-12 years old children with type 1 diabetes referring to Imam Reza Diabetes Clinic, Shiraz, 2019

Design

Clinical trial with control group, With parallel groups, Randomised

Settings and conduct

The place of the study will be Imam Reza Diabetes Clinic of Shiraz. Samples will be divided into two groups of intervention and control by using permutation block method and both groups will complete four demographic, anxiety, depression and self-efficacy questionnaires. Then, the intervention group will participate in 6 sessions of virtual painting therapy class for 6 weeks and the control group will receive usual care of diabetes clinic. After these 6 weeks, the anxiety, depression and self-efficacy questionnaire will be completed by both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1- The age range of children between 8 to12 years 2- At least 3 months have passed since the patient's diabetes diagnosis 3-The child has no chronic disease except type 1 diabetes 4-The history of mental and physical problems that lead to mental retardation in children was not mentioned in the file 5- Have a file in the diabetes clinic 6-Anxiety score of 45 and above 45 7- The child and parents tend to continue to collaborate in research : Exclusion criteria:1- For whatever reason the child absent from painting sessions

Intervention groups

Intervention group:6 sessions of two-hour virtual painting therapy class are held for 6 weeks for the intervention group. Control group: in control group no intervention is performed.

Main outcome variables

Anxiety : Depression : Self-efficacy

General information

Reason for update

Due to the limitations caused by Covid-19 disease and the impossibility of holding group painting therapy classes for amongst 8-12 years old children with type 1 diabetes referring to Imam Reza Diabetes Clinic, painting therapy sessions are held virtually.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046181N1**

Registration date: **2020-03-17, 1398/12/27**

Registration timing: **prospective**

Last update: **2020-09-12, 1399/06/22**

Update count: **1**

Registration date

2020-03-17, 1398/12/27

Registrant information

Name

Mina Zamanifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 4275

Email address

m_zamani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-30, 1399/01/11

Expected recruitment end date

2020-04-30, 1399/02/11

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of virtual painting therapy on anxiety, depression and self-efficacy amongst 8-12 years old children with type 1 diabetes referring to Imam Reza Diabetes Clinic, Shiraz, 2019

Public title
The effect of virtual painting therapy on anxiety, depression and self-efficacy amongst 8-12 years old children with type 1 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The age range of children between 8 to 12 years. At least 3 months have passed since the patient's diabetes diagnosis. The child has no chronic disease except type 1 diabetes. The history of mental and physical problems that lead to mental retardation in children was not mentioned in the file. Have a file in the diabetes clinic. Anxiety score of 45 and above. The child and parents tend to continue to collaborate in research.
Exclusion criteria:
For whatever reason the child absent from painting sessions

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
To determine intervention and control group, four-size blocks with 6 permutations are used. The permutations are numbered and selected randomly. Arrangement of selected permutation enters to table unit all samples in 2 groups are selected.

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 Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-01-15, 1398/10/25

Ethics committee reference number

IR.SUMS.REC.1398.1194

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spence Children Anxiety Scale (SCAS)

2

Description

Depression

Timepoint

Before and after intervention

Method of measurement

Children's Depression Inventory (CDI)

3

Description

Self-efficacy

Timepoint

Before and after intervention

Method of measurement

Diabetes management self-efficacy scale (SMSES)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 6 two-hour sessions of virtual painting therapy class for 6 weeks through Whats App software under the supervision of a psychologist for the intervention group will be held. These sessions include painting and depicting dreams and fears. Painting supplies including colored pencils, watercolors, Crayons and marker will be provided to the children, and the child will be encouraged to depict their feelings of sadness, anger, fear, and happiness by using colors. After 6 weeks of painting therapy class, anxiety, depression and self-efficacy questionnaire will again be completed by children in intervention and control group.

Category

Treatment - Other

2

Description

Control group: in the control group, no intervention will be performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Diabetes Clinic, Shiraz

Full name of responsible person

Razie Attar

Street address

Imam Reza Clinic Next to Namazi Hospital, Namazi Square, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice-Chancellor for Research & Technology - Seventh Floor - Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mina Zamanifard

Position

Master of Pediatric Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mitra Soltanian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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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