

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The impact of computer game on the behavioral distress associated with insulin injection in children with diabetes type 1 in Isfahan Endocrine & Metabolism Research Center

Protocol summary

Summary

Aim: The purpose of this study is to identify the effect of computer game on the level of behavioral distress of insulin injection in children with type 1 diabetes. For this purpose, 30 children [play group (15) and control group (15)] are selected by using available random sampling from 3-13 years old children of diabetes referred to Isfahan Endocrine and Metabolism Research Center. In this study, used to be demographic information and behavioral distress scale of observation Observational Scale of Behavioral Distress - Revised. OSBD-R scale is completed by mother during insulin injection to child at home. Before of intervention, distress behavior is measured in two groups. So the group played a computer game CD about insulin injections for(at least one a week) one week. In the control group (no intervention) and play group, behavioral distress is evaluated in during, immediately after and two weeks after the intervention. Finally, behavioral distress levels in two groups are compared together using inferential statistics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012123011941N1**
Registration date: **2014-03-26, 1393/01/06**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-03-26, 1393/01/06

Registrant information

Name

Fatemeh Ebrahimpour

Name of organization / entity

Islamic Azad University, khorasgan Branch, (Isfahan)

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Recruitment status

Recruitment complete

Funding source

Isfahan Endocrine & Metabolism Research Center

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of computer game on the behavioral distress associated with insulin injection in children with diabetes type 1 in Isfahan Endocrine & Metabolism Research Center

Public title

The impact of computer game on the behavioral distress associated with insulin injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The child and his parents, have volunteered to participate in the study; Child's physical

health disorders (such as cerebral palsy and seizure, etc.) are not; Child's mental and cognitive disorders (such as autism, mental retardation, etc.) are not; Children have access to a computer. Exclusion criteria: During the intervention, the incidence of conditions for children and families, following the intervention program used by them is not possible.

Age

From **3 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjrib Street

City

Isfahan

Postal code

۳۱۳-۸۱۷۴۵

Approval date

2013-08-24, 1392/06/02

Ethics committee reference number

12/4/0.5/162

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Behavioral Distress associated with insulin injection

Timepoint

before and during intervention, immediately after intervention and two weeks after the intervention

Method of measurement

Observational Scale of Behavioral Distress - Revised

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using the computer game CD called "Capable Child" for one week (at least once a week) at home.

Category

Other

2

Description

Control group: non intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Dr. Mostafa Najafi

Street address

Isfahan Endocrine and Metabolism Research Center, Khoram Street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Endocrine & Metabolism Research Center.

Full name of responsible person

Dr. Bijan Iraj

Street address

Isfahan Endocrine & Metabolism Research Center

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan Endocrine & Metabolism Research Center.

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University, Khorasgan Branch, (Isfahan)

Full name of responsible person
Fatemeh Ebrahimpour

Position
Student of Master of Nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty