

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of group spiritual care on adaptability and self-esteem among adolescents with diabetes type 1

Protocol summary

Study aim

The effect of group spiritual care on adaptability and Self-Confidence among adolescents with type 1 diabetes.

Design

This is an experimental clinical trial study that 52 adolescents with type 1 diabetes who are eligible for inclusion in the study are selected in a targeted manner, but their assignment is done randomly in two groups with the help of a random number table.

Settings and conduct

After verifying the validity of the package of spiritual care by a group of specialists inside and outside the country and passing the spiritual care workshop by researcher, the spiritual care program was conducted by the researcher through group education at the Diabetes Association for six consecutive days. Each session lasted 45-60 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 12 to 18 years old; having type 1 diabetes; being Muslim; having no other disease than diabetes; receiving insulin; living with the parents. Exclusion criteria: Teens aren't able to participate in research and collaborate.

Intervention groups

26 adolescents with type 1 diabetes who fulfilled inclusion criteria were included in the control group and they did not take any action, and 26 of those who had inclusion criteria were included in the intervention group and they received a spiritual care program in the form group meetings for 6 consecutive days.

Main outcome variables

Compatibility with disease, Self Confidence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171107037295N1**

Registration date: **2017-12-01, 1396/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-01, 1396/09/10**

Update count: **0**

Registration date

2017-12-01, 1396/09/10

Registrant information

Name

Sahar Fallahi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3872 0211

Email address

s_falahi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences and Health Services

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group spiritual care on adaptability and self-esteem among adolescents with diabetes type 1

Public title

The effect of spiritual care on diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

being at the age of 12 to 18 years being Muslim passing minimum six months of medical diagnosis of diabetes type 1 not involving in a tense experience (parental separation, loss of one close family member over the past year) There is no specific disease other than diabetes Receiving insulin

Exclusion criteria:

Teens who aren't able to participate in research and collaborate.

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

N/A

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

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

Street address

Daneshgah square (former Evin Square), Velenjak, Tehran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.SBMUPHNM.1395.639

Health conditions studied

1

Description of health condition studied

Type 1 diabetes

ICD-10 code

E10-E14

ICD-10 code description

IV Endocrine, nutritional and metabolic diseases.

Primary outcomes

1

Description

adaptability

Timepoint

Before the intervention- after the intervention- 3 weeks after the intervention.

Method of measurement

Lazarus and Fulkman Compatibility Questionnaire.

2

Description

Self Confidence

Timepoint

Before intervention - after intervention - 3 weeks after intervention.

Method of measurement

Rosenberg Confidence Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention group includes adolescents with type 1 diabetes who receive spiritual care. The spiritual care will be provided through a package which its content is confirmed by internal and external specialists. After passing the spiritual care workshop by researcher the spiritual care will be run through six 45-60 minute sessions during 6 days, at the Sanandaj Diabetes Association. The intervention is briefly summarized as follows: Familiarity with adolescents and the expression of goals, spiritual evaluation and identifying needs and concerns of adolescents, promoting beliefs and encouraging religious practices, expressing promising content, ending session. At the beginning and the end of the intervention, research tools are distributed among adolescents.

Category

Other

2

Description

Control group: The control group includes adolescents with type 1 diabetes at the Sanandaj Diabetes Association, which has criteria for entering the study and do not receive any interventions (no additional work).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sanandaj Diabetes Association

Full name of responsible person

دکتر خسرو خسروی کردستانی

Street address

Maadar square, Besat Boulevard, Sanandaj, Kurdistan Province, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Shirinabadi Farahani Azam

Street address

Valiasr - Niayesh Crossroad, Valiasr street.

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farahani1381@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sahar Fallahi

Position

Master student in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Province

Tehran

Postal code

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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