Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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.

City
Sanandaj

Province
Kurdistan

Postal code
6616754931

Phone
+98 87 3323 5163

Fax
+98 87 3323 5163

Email
info@diabetes-sanandaj.com

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.ر

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8865 5372

Email
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

Street address
Valiasr - Niayesh Crossroad, Valiasr street

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8865 5372

Fax

Email
s1394.falahi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Azam Shirinabadi Farahani

Position
Ph.D. in Nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Valiasr - Niayesh Crossroad, Valiasr street.

City
Tehran

Province
Tehran

Postal code

1985717443

Phone

+98 21 8865 5372

Fax

Email

farahani1381@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Valiasr - Niayesh Crossroad, Valiasr street

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5372

Fax

Email

s1394.falahi@gmail.com

Web page address

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