Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of stress management training with spiritual skills acquisition on glycemic control in children with type 1 diabetes and mental health of their mothers

Protocol summary

Study aim

The aim of this study was to evaluate the effectiveness of stress management training with spiritual skills acquisition on glycemic control in children with type 1 diabetes and mental health of their mothers.

Design

Randomized clinical trials with control group, community based and pragmatic with parallel groups, non blinded

Settings and conduct

In this study, 50 mothers with type 1 diabetic children younger than 12 years were enrolled into the study, using the convenience sampling method, from the Imam Ali (PBUH) Clinic in Shahrekord.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with type 1 diabetic children younger than 12 years, having children with type 1 diabetes for at least 3 months; exclusion criteria: history of stress management training.

Intervention groups

50 mothers with type 1 diabetic children under 12 years of age were randomly assigned to two groups of 25 (intervention and control) each. The intervention group received 6 sessions of stress management training with acquiring spiritual skills (at 2-week intervals) presented by a clinical psychologist. The content of the sessions included reviewing and acquiring life skills, spirituality, mental health, self-awareness, problem solving, forgiveness, recitations and their impact on spiritual well-being and homework. The control group did not receive any intervention.

Main outcome variables

Changes in blood glucose levels and hemoglobin glycosylated (HbA1c) in children; changes in the mental health level in mothers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043253N1**
Registration date: **2019-05-01, 1398/02/11**
Registration timing: **retrospective**

Last update: **2019-05-01, 1398/02/11**
Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name

Mohammadamin Esmaeeli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3826 8390

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ma.esmaeeli0983@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-09-06, 1397/06/15

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2019-03-20, 1397/12/29

Scientific title
Effectiveness of stress management training with spiritual skills acquisition on glycemic control in children with type 1 diabetes and mental health of their mothers

Public title
Effect of stress management training with spiritual skills in treatment of type 1 diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers with type 1 diabetic children younger than 12 years Children's having developed type 1 diabetes for at least 3 months
Exclusion criteria:
History of stress management training
Age
To **12 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **49**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups by simple random sampling using two categories of cards stating letters A and B.
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 Shahrekord University of Medical Sciences
Street address
Research Deputy, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2018-03-11, 1396/12/20
Ethics committee reference number
IR.SKUMS.REC.1396.256

Health conditions studied

1

Description of health condition studied
Type 1 diabetes mellitus
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Level of glycosylated hemoglobin (HbA1c)
Timepoint
Before the intervention, after the intervention
Method of measurement
Chromatography

2

Description
Level of blood glucose
Timepoint
Before the intervention, after the intervention
Method of measurement
Glucometer

3

Description
Mental health Level in mothers
Timepoint
Before the intervention, after the intervention
Method of measurement
Depression, Anxiety and Stress Scales (DASS); and Parenting Stress Index (PSI) questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They received 6 sessions of stress management training by acquiring spiritual skills (at two-week intervals) presented by a clinical psychologist. The content of the sessions included reviewing and acquiring life skills, spirituality, mental health, self-awareness,

problem solving, forgiveness, recitations and their impact on spiritual well-being and homework.

Category

Lifestyle

2

Description

Control group: The control group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Clinic of Shahrekord

Full name of responsible person

Doctor Masoud Nikfarjam

Street address

Emam Ali Clinic of Shahrekord, Shariati Street

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Email

nikmas140@gmail.com

Web page address

https://imamaliclinic.skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

Street address

Vice Chancellery for Research and Technology, Shahrekord University Of Medical Sciences, Kashani Boulevard

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Doctor Masoud Nikfarjam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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Faculty of medicine, Shahrekord University of Medical Science, Rahmatiyeh

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Latest degree

Ph.D.

Other areas of specialty/work

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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