Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Spirituality-based Self-care on Stress and Mother's Anger and Metabolic Control of Children with Type 1 Diabetes

Protocol summary

Study aim
Determining the effect of self-care based on spirituality on mothers' stress and anger and metabolic control of children with type 1 diabetes

Design
The clinical trial has an intervention group and a control group, each group has 35 people and they are randomly divided into two groups by tossing a coin

Settings and conduct
The trial in the field of support is conducted in the diabetes center of Zabul city. The intervention consists of 4 sessions of 60 minutes (session 1: familiarization with spiritual self-care methods, focusing on topics such as trust, patience, altruism, and the afterlife reward / 2: familiarization with the concepts of spirituality, spiritual methods and their effects / 3: familiarization with spiritual methods such as writing memories, talking and reading books, listening to music/4 familiarity with sports methods such as walking and yoga)

Participants/Inclusion and exclusion criteria
In this study, all mothers who have a child with diabetes under the age of 14, who have been diagnosed with diabetes for at least 6 months, are included. Mothers under 18 years of age / with chronic or mental and nervous illness / with another patient in the family / non-Persian language / not living in Zabul / stressful incident in the last 2 months are not allowed to enter

Intervention groups
The intervention group receives the intervention including the training of spirituality-based care methods during 4 sessions of 60 minutes every other day. The control group does not receive any program.

Main outcome variables
Care based on spirituality can reduce the stress and anger of the mother and increase the quality of care and better metabolic control of a child with type 1 diabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230426058000N1**
Registration date: **2023-12-12, 1402/09/21**
Registration timing: **retrospective**

Last update: **2023-12-12, 1402/09/21**
Update count: **0**

Registration date
2023-12-12, 1402/09/21

Registrant information

Name
Elham Keikha

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 6024

Email address
elham.keykha@zbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-07-06, 1402/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Spirituality-based Self-care on Stress and Mother's Anger and Metabolic Control of Children with Type 1 Diabetes

Public title
Investigating the Effect of Self-care Based on Spirituality on Mother's Stress and Anger and Metabolic Tests of Children with Diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a child with type 1 diabetes under the age of 14, who has been diagnosed for more than 6 months
Exclusion criteria:
Mother's age is less than 18 years Unwillingness to participate in the study Non-Persian mother tongue Inability to speak or hearing impairment No residence in Zabul city Having the responsibility of caring for a patient other than a child with diabetes Any mental, nervous or chronic illness in the mother A stressful event has happened to the mother in the last two months
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
through a coin toss
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of zabol university of medical sciences
Street address
Jihad square, the building of the vice-chancellor of treatment
City
zabol
Province
Sistan-va-Balouchestan
Postal code
9861663335
Approval date
2023-07-11, 1402/04/20
Ethics committee reference number
IR.ZBMU.REC.1402.031

Health conditions studied

1

Description of health condition studied
type1diabetes
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

2

Description of health condition studied
STRESS
ICD-10 code
M84.3
ICD-10 code description
Stress fracture

Primary outcomes

1

Description
Stress score of mothers in Abidin questionnaire
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
Abidin stress questionnaire

2

Description
Anger score of mothers in the Spielberger questionnaire
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
Spielberger Anger Questionnaire

3

Description
Children's metabolic test (TG-CHOL-HBA1C)
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group consists of 35 mothers of children with type 1 diabetes, who are given self-care training based on spirituality, and then the effect of the intervention on the stress and anger of the mothers, as well as the metabolic indicators of their children, is measured.

Category
Behavior

2

Description
Control group: 35 mothers have children with type 1 diabetes who do not receive any education

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Musa Al-Reza Specialized Clinic Diabetes Center

Full name of responsible person
Elham Keykha

Street address
No. 10, Hamon Street, Shahid Jahantigh Alley

City
Zabol

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Sistan-va-Balouchestan

Postal code
9861698935

Email
e.keykha66@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Elham Keykha

Street address
No. 10, Hamon Street, Shahid Jahantigh Alley

City
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e.keykha66@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Zabol University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Zabol University of Medical Sciences

Full name of responsible person
Elham keykha

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Elham Keykha

Position
student

Latest degree
Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available