

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 Zabol 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 Zabol / 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@zsbmu.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

#### Province

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

Zabol

#### Province

Sistan-va-Balouchestan

### Postal code

9861698935

### Email

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

#### Street address

No. 10, Hamon Street, Shahid Jahantigh Alley

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## Person responsible for scientific 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 updating data

### Contact

**Name of organization / entity**  
Zabol University of Medical Sciences  
**Full name of responsible person**  
Elham Keykha  
**Position**  
student  
**Latest degree**  
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**Other areas of specialty/work**  
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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