# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effect of a compassion-based program on resilience of mothers of children with type 1 diabetes in Isfahan Endocrine and Metabolism Research Center in 1399

## Protocol summary

**Study aim**

Determining the effect of a compassion-based program on resilience of mothers of children with type 1 diabetes at the Endocrine and Metabolism Research Center of Isfahan in 2016

**Design**

This study is a two-stage, three-stage clinical trial. Sampling To divide the intervention and control groups, the random. allocation method with the help of SPSS software is used. 31 people in each group was obtained

**Settings and conduct**

The research environment is Isfahan Endocrine and Metabolism Research Center First, After the phone call and explanation and justification of the client, those who wish to cooperate are invited to visit the center. After referring to the center and completing the informed consent form by the participants in designing and determining the intervention and control group, it will be necessary to talk and coordinate with people about the time, place .

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: having a child with type 1 diabetes - having the ability to understand the content and physical ability to participate in - having motivation to participate in - familiarity with the Persian language - not participating in other treatment or mental counseling - no disease Mental disorder Exclusion criteria:Reluctance to continue cooperation - not participating in more than one meeting.

**Intervention groups**

Each intervention session is held with the participation of 10-13 people. Number of intervention sessions: 8 sessions, with the titles of initial evaluation, compassion , forgiveness, acceptance, promotion of value sense, responsibility, skills training and final evaluation after the end of the research, if the control group wishes, intensive compassion therapy program , Will be held for them as well.

**Main outcome variables**

Perception of individual competenceو Trust in individual instinctsو Positive acceptance وControl وSpiritual effects, Tabulation

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201019049076N1**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **retrospective**

Last update: **2020-12-12, 1399/09/22**
Update count: **0**

**Registration date**

2020-12-12, 1399/09/22

**Registrant information**

**Name**

Marzieh Najafi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 3568 3820

**Email address**

ma.na6144@mail.mui.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-06-21, 1399/04/01

**Expected recruitment end date**

2020-07-22, 1399/05/01

**Actual recruitment start date**
2020-08-20, 1399/05/30
**Actual recruitment end date**
2020-09-20, 1399/06/30
**Trial completion date**
2020-12-20, 1399/09/30

**Scientific title**
The effect of a compassion-based program on resilience of mothers of children with type 1 diabetes in Isfahan Endocrine and Metabolism Research Center in 1399

**Public title**
The effect of compassion therapy on the resilience of mothers of children with type 1 diabetes
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having a child with type 1 diabetes Having the ability to understand the content mentally and the physical ability to participate in training sessions Having the motivation to participate in training sessions - familiarity with the Persian language Do not participate in other sessions of treatment or mental counseling at the same time Not having a mental disorder needs treatment
**Exclusion criteria:**
Reluctance to continue cooperation Do not attend more than one session
**Age**
No age limit
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **35**
Actual sample size reached: **32**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
After determining the sample size, a random sequence is created with the help of SPSS software.In this way, in the data view menu, the desired number was entered in the 72nd row. In the variable view menu, we change the name of the variable (group) and set the number of decimal places to zero. In the Transform menu, select the Compute Variable option. In the Target Variable field, enter the name of the variable. In the Numeric Expression section, we entered the command (RV.BINOM (72,0.5), meaning that half of these 72 people are in the control group and half are in the intervention group. Then, to hide random allocation, each random sequence is recorded on a card and placed inside a completely sealed envelope. Then, in the order of the presence of each participant, one of the envelopes is selected and given to the same participant. This step is performed by another person in the study.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
This is a parallel with Fixed size Design study

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of esfahan University of Medical Sciences
**Street address**
No 201, 26 Alley, falatoori Ave, esfahan Town
**City**
esfahan
**Province**
Isfehan
**Postal code**
8193769886
**Approval date**
2020-05-06, 1399/02/17
**Ethics committee reference number**
IR.MUI.RESEARCH.REC.1399.073

## Health conditions studied

### 1

**Description of health condition studied**
Resilience of mothers with children with type 1 diabetes
**ICD-10 code**
E10
**ICD-10 code description**
Type 1 diabetes mellitus

## Primary outcomes

### 1

**Description**
Resilience score in Questionnaire
**Timepoint**
The effect of compassion therapy on resilience of mothers with children with type 1 diabetes at the beginning of the study (before intervention) and immediately and one month after intervention
**Method of measurement**
The effect of compassion therapy on resilience using Connor and Davidson questionnaire

## Secondary outcomes

**1**

**Description**
Compassion score based on questionnaire
**Timepoint**
Periods of compassion measurement as a secondary consequence at the beginning of the study and immediately and one month after the intervention
**Method of measurement**
Neffs Self-Compassion Questionnaire

## Intervention groups

**1**

**Description**
Intervention group: First, all members of the group were contacted one by one, and after coordination and agreement on the timing of the meetings, they were invited to attend on the scheduled date. Compassion therapy sessions were held in 8 one-and-a-half-hour sessions. In the first session, the introduction and identification of each member and the rules of the group were determined, and compassion therapy was explained, and in subsequent sessions, each topic related to compassion was explained. Practice was done in the class and the homework was given for the next session. In the final session, the skills were taught during the previous sessions, and after that, the status of the exercises was followed up by phone within a month.
**Category**
Behavior

**2**

**Description**
2-Control group: Participants were contacted and invited to attend the center, then the questionnaire was completed by the participant and the researcher. During the training sessions for the intervention group, the control group received their routine intervention. At the end of the study, a short session of compassion therapy was performed for this group.
**Category**
Behavior

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Endocrine and Metabolism Research Center of Isfahan
**Full name of responsible person**
Marzieh Najafi
**Street address**
Tehran Gate, Khoram St., Sedigheh Tahereh Endocrine and Metabolism Research Center
**City**
Esfahan
**Province**
Isfehan
**Postal code**
8193769886
**Phone**
+98 31 3337 7664
**Email**
ma.na6144@gmail.com
**Web page address**
https://emrc.mui.ac.ir/

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shagayeg Hagjoo Javanmard
**Street address**
Shiraz Gate, Hezar Jerib St., Isfahan University of Medical Sciences, Building No. 4
**City**
Esfahan
**Province**
Isfehan
**Postal code**
8174673461
**Phone**
+98 31 3792 3060
**Email**
sh_haghjoo@med.mui.ac.ir
**Web page address**
https://research.mui.ac.ir/
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mousa Alavi
**Position**
Assistant Professor
**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib St.

**City**

Esfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3792 7586

**Email**

mousa_alavi@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mousa Alavi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery،University of Medical Sciences, Hezar Jerib St., Shiraz Gate

**City**

Esfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3792 7579

**Email**

mousa_alavi@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Marzieh Najafi

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

No 201,26 Alley, Falatoori Ave, Esfahan Town

**City**

Esfahan

**Province**

Isfehan

**Postal code**

8193769886

**Phone**

+98 31 3568 3820

**Email**

Ma.na6144@mail.mui.ac.ir

## 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**

Not applicable

**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