

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The Effect of Educational Intervention Based on Family Empowerment Model for The Modify of High-Risk Behaviors among Patients With Brucellosis In Rural Areas

#### Protocol summary

##### Study aim

This study will be done to determine the effect of educational intervention based on family empowerment model for the modify of High-Risk Behaviors among Patients With Brucellosis

##### Design

120 people were selected from the villages under study. The assignment of the groups was non-random, the villages of Torbat-e Jam are listed and 2 villages will be randomly selected as the intervention group. Then two villages will be selected as control group that are culturally and socially similar to the two intervention villages, but they are not geographically close. then 30 people are randomly selected from each village.

##### Settings and conduct

Educational intervention will be implemented with an emphasis on family empowerment model, for a maximum of 3 months on intervention group. Educational intervention will take place in 6 one-hour training sessions. The training sessions will be held in a group discussion. In this study, considering the characteristics of the target group and the objectives of the curriculum will be used various oral, written and combination methods and methods used by the media for training such as lectures with questions and answers, providing and presenting suggestions, group discussion, practical presentation, role play and the provision of educational media such as booklets, posters and educational CDs are provided in the form of a training package for independent study for learners

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Residence for at least 6 months in the research setting; Exclusion criteria: One of the family member has the Brucellosis

##### Intervention groups

Intervention group: Educational intervention is done with an emphasis on family empowerment model Control

Group: No intervention

##### Main outcome variables

preventive behavior of Brucellosis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160619028529N12**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-24, 1399/01/05**

Update count: **0**

##### Registration date

2020-03-24, 1399/01/05

##### Registrant information

##### Name

Hadi Tehrani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3853 8530

##### Email address

tehranih@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-05, 1398/12/15

##### Expected recruitment end date

2020-05-04, 1399/02/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Educational Intervention Based on Family Empowerment Model for The Modify of High-Risk Behaviors among Patients With Brucellosis In Rural Areas

**Public title**

The effect of intervention to promoting the preventive behavior of Brucellosis

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Residence for at least 6 months in the research setting

**Exclusion criteria:**

One of the family member has the Brucellosis

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Not randomized

**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 Mashhad University of Medical Sciences

**Street address**

Vice chancellor for research, Qoreishi Building, Daneshgah 18, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2019-10-12, 1398/07/20

**Ethics committee reference number**

IR.MUMS.REC.1398.199

**Health conditions studied****1****Description of health condition studied**

Brucellosis

**ICD-10 code**

A23

**ICD-10 code description**

Brucellosis

**Primary outcomes****1****Description**

preventive behavior of Brucellosis

**Timepoint**

before the intervention, immediately and, 2 months after the intervention

**Method of measurement**

Questionnaire, Behavioral View Checklist

**Secondary outcomes**

empty

**Intervention groups****1****Description**

"Intervention group": Educational intervention will be implemented with an emphasis on family empowerment model, for a maximum of 3 months on intervention group. Educational intervention will take place in 6 one-hour training sessions. The training sessions will be held in a group discussion. In this study, considering the characteristics of the target group and the objectives of the curriculum will be used various oral, written and combination methods and methods used by the media for training.

**Category**

Lifestyle

**2****Description**

Control group: No intervention

**Category**

Prevention

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

villages of Torbat-e Jam

**Full name of responsible person**

Maryam al-Sadat Shojaee

**Street address**

School of Public Health, between 16th and 18th  
Daneshgah, Daneshgah Street

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**Email**

ShojaeiM961@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Vice President of Research, Qoreishi Building,  
Daneshgah 18, Daneshgah Street

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ramresearch@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Hadi Tehrani

**Position**

Assistance Professor of Health Education and Health  
Promotion

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

Department of Health Education and Health  
Promotion. School of Public Health, Mashhad  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not 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**

Not applicable

**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

**Title and more details about the data/document**

Potential data is sharable after distinguishing people

**When the data will become available and for how long**

Start the access period one month after the publication of result

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

Data is sent through an official request and by email

**From where data/document is obtainable**

Dr Hadi Tehrani: tehranilh@mums.ac.ir

**What processes are involved for a request to access data/document**

Data is sent through an official request and by email

**Comments**