

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The randomized controlled trial comparing effectiveness of educational comprehensive plan based on Precede-Proceed model for prevention and control of Brucellosis among rural population.

Protocol summary

Summary

The study will aim to investigate effectiveness of educational intervention based on Precede-Proceed model for control and prevention of Brucellosis in Ahar;Tabriz. The participants including people with 15 years old and over that recruit to study through health houses from stratified randomized sampling. Ahar county have four area (north, south, east and west) that two health centers of each area (control and intervention) and a health houses of each health centers will selected in rural with high prevalence of Brucellosis. After that the selected rural randomly will placed in control and intervention groups (n=200 per arm). Participants randomly will select from household health records. Then, head of household or his/her substitutions who have consent to participate in the study will recruited to the study. The pre test will conducted using questionnaires including General Health questionnaire 12, Short Form 12 quality of life and the Brucellosis Precede Proceed prevention model. The intervention will be planned by a Precede Proceed prevention model on brucellosis based on pre test results. Post test will carry out after six month of the intervention. The control group will receive educational program after the study. Primary outcome will include prevalence of Brucellosis and secondary outcomes will include self efficacy, social environment, reinforcing factors, knowledge, attitudes and behaviours related to brucellosis and general health and quality of life.

General information

Acronym

Brucellosis

IRCT registration information

IRCT registration number: **IRCT201511078132N3**
Registration date: **2016-02-11, 1394/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-11, 1394/11/22

Registrant information

Name

Leila Jahangiry

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

jahangiry@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2015-12-11, 1394/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The randomized controlled trial comparing effectiveness of educational comprehensive plan based on Precede-

Proceed model for prevention and control of Brucellosis among rural population.

Public title

The Arasbaran comprehensive Brucellosis study

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: rural people living in Ahar county who have 15 and over years old; the consent to participate in the study. Exclusion criteria: Health center employee

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Closed envelope was used for randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Azadi Steet, Tabriz

City

Tabriz

Postal code

Approval date

2015-10-15, 1394/07/23

Ethics committee reference number

TBZMED.REC.1394.596.

Health conditions studied

1

Description of health condition studied

Brucellosis

ICD-10 code

A23

ICD-10 code description

Brucellosis

Primary outcomes

1

Description

Brucellosis prevallance

Timepoint

Before intervention and 6 month after intervention

Method of measurement

The brucellosis prevalence index

Secondary outcomes

1

Description

Self efficacy related to prevention of Brucellusis

Timepoint

Before intervention and 6 month after intervention

Method of measurement

questionnaire based on Precede Proceed Model

2

Description

Social environment related to prevention of Brucellusis

Timepoint

Before intervention and 6 month after intervention

Method of measurement

The questionnaire based on Precede Proceed Model

3

Description

Reinforcing factors related to prevention of Brucellusis

Timepoint

Before intervention and 6 month after intervention

Method of measurement

questionnaire based on Precede Proceed Model

4

Description

Knowledge related to prevention of Brucellusis

Timepoint

Before intervention and 6 month after intervention

Method of measurement

Questionnaire based on Precede Proceed Model

5

Description

Attitudes related to prevention of Brucellusis

Timepoint

Before intervention and 6 month after intervention

Method of measurement

questionnaire based on Precede Proceed Model

6

Description

Behaviour related to prevention of Brucellusis

Timepoint

Before intervention and 6 month after intervention

Method of measurement

Questionnaire based on Precede Proceed Model

7

Description

General health

Timepoint

Before intervention and 6 month after intervention

Method of measurement

General Health questionnaire (GHQ 12)

8

Description

Quality of life

Timepoint

Before intervention and 6 month after intervention

Method of measurement

Quality of life questionnaire Short form 12 (SF 12)

Intervention groups

1

Description

Control group: This group will receive the required educations after completion of study.

Category

Prevention

2

Description

Intervention group: receiving the comprehensive education based on Precede Proceed Model for prevention of Brucellosis that the number of education sessions will determine after pre-test and primary assessment.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rural Health Houses

Full name of responsible person

Babak Mahdavi

Street address

Rural Health Houses of Ahar, Ahar county, East Azarbayjan

City

Ahar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Asghari JafarAbadi

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht street, Azadi Street, Tabriz, East Azarbayjan

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Babak Mahdavi

Position

Health worker

Other areas of specialty/work

Street address

Ahar rural Health Services, Emam Street, Ahar, East Azarbayjan

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Postal code

Iran

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Fax

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Jahangiry

Position

PhD

Other areas of specialty/work**Street address**

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City

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Postal code**Phone**

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Jahangiry

Position

Assisatant Professor

Other areas of specialty/work**Street address**

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City**Postal code**

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Phone

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Fax**Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty