Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Brucellsis 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
+98 914 307 0128
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 comperhensive Brucellosis study
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criterial: 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
Gereal health
Timepoint
Before intervention and 6 month after intervention
Method of measurement
General Health queationnaire (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 willl 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
City
Ahar
Postal code
Iran
Phone
+98 41 3325 7580
Fax
Email
jahangiryleila@gmail.com
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
Health Education and Promotion departement, Public Health Faculty, Tabriz University of Medical Sciences, Golgasht street, Azadi Street, Tabriz

City
Tabriz

Postal code

Phone
+98 41 3325 7580

Fax

Email
jahangiryleila@gmail.com

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
Health Education and Promotion departement, Public Health Faculty, Tabriz University of Medical Sciences, Golgasht street, Azadi Street, Tabriz Tabriz

City

Postal code
5376166331

Phone
00

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