

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Aug 2026

The effect of program intervention (educational-implementation-environmental) based on PRECEDE-PROCEED model to promoting the preventive behavior of Leishmaniasis in households with children under 10 years old of Jajarm 2016-2017

Protocol summary

Study aim

Determining the effect of program intervention (educational-implementation-environmental) based on PRECEDE-PROCEED model to promoting the preventive behavior of leishmaniasis in households with children under 10 years old

Design

Among villages in Jajarm city, 5 villages will be randomly selected as intervention group and 5 similar villages of cultural and geographical location will be selected as the control group. Then from the villages of the intervention group 84 and from the control group villages 84 families will be randomly selected.

Settings and conduct

Educational intervention is done with an emphasis on the patterns of PRECEDE-PROCEED, for a maximum of 3 month.

Participants/Inclusion and exclusion criteria

Having a child under 10 years of old Residence is at least 6 months in the Sankhast district of Jajarm city

Intervention groups

Intervention group: Educational intervention is done with an emphasis on the patterns of PRECEDE-PROCEED, for a maximum of 3 month. Control group: There will be no intervention on the control group

Main outcome variables

preventive behavior of leishmaniasis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160619028529N8**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **prospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

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

2018-05-10, 1397/02/20

Expected recruitment end date

2018-09-11, 1397/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of program intervention (educational-implementation-environmental) based on PRECEDE-PROCEED model to promoting the preventive behavior of Leishmaniasis in households with children under 10 years old of Jajarm 2016-2017

Public title

The effect of intervention to promoting the preventive behavior of Leishmaniasis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a child under 10 years of old Residence is at least 6 months in the Sankhast district of Jajarm city
Exclusion criteria:
 One of the children of the family has the leishmaniasis

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **168**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 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
 2017-10-10, 1396/07/18
Ethics committee reference number
 221.IR.MUMS.REC.1396

Health conditions studied

1

Description of health condition studied
 Leishmaniasis
ICD-10 code
 B55
ICD-10 code description
 Leishmaniasis

Primary outcomes

1

Description
 preventive behavior of Leishmaniasis
Timepoint
 before the intervention, immediately and, three months after the intervention
Method of measurement
 Questionnaire, Behavioral View Checklist

Secondary outcomes

empty

Intervention groups

1

Description
 Intervention group: Educational intervention is done with an emphasis on the patterns of PRECEDE-PROCEED , for a maximum of 3 month.
Category
 Lifestyle

2

Description
 Control group: There will be no intervention on the control group
Category
 Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
 Villages in Jajarm city
Full name of responsible person
 Hosein Jajarmi
Street address
 Beheshti Street
City
 Jajarm
Province
 North Khorasan
Postal code
 74877-94149
Phone

+98 58 3222 1910

Email

jajarmi20@gmail.com

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

Hadi Tehrani

Position

Assistance Professor of Health Education and Health
Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Department of Health Education and Health
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Person responsible for scientific inquiries

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Hadi Tehrani

Position

استادیار گروه آموزش بهداشت و ارتقای سلامت

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

خیابان دانشگاه، بین دانشگاه 16 و 18، دانشکده بهداشت

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

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Province

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Fax**Email**

tehranirh@mums.ac.ir

Web page address**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

Hadi Tehrani: tehranirh@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