

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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 months.

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 months. 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

tehranilh@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

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Jajarm

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North Khorasan

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74877-94149

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+98 58 3222 1910

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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,
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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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Ph.D.

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Health Promotion

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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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Fax**Email**

tehran@ums.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: tehran@ums.ac.ir

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

Data is sent through an official request and by email

Comments