

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of educational intervention based on social cognitive theory in health volunteers on preventive behaviors of cutaneous leishmaniasis in volunteers and covered households

Protocol summary

Study aim

Determining the effect of education based on social cognitive theory in health ambassadors on preventive behaviors of cutaneous leishmaniasis in ambassadors and covered families in rural areas of Mashhad.

Design

A randomized, single-blind, randomized controlled clinical trial was performed on 220 participants selected by stepwise cluster sampling.

Settings and conduct

Internal medicine in the field of education for the prevention of leishmaniasis in health ambassadors in the intervention village is done through the Internet cyberspace and the presentation of educational texts based on social cognitive theory. Then the result of the intervention on the behavior of rural household members before, after, and 3 months after the intervention will be determined and analyzed. When entering information into the software, the information identifying the intervention and control group is hidden so that the analyst is blind to their findings.

Participants/Inclusion and exclusion criteria

Join as a health ambassador - Informed consent - Confirmation of disability or physical disability - Health Ambassador over the age of 15 - Not participating in health ambassadors training classes - Family members with the ability to read and write - Age between 15 to 40 years of family members Exclusion criteria: - Reluctance to cooperate

Intervention groups

Educational intervention to improve leishmaniasis prevention behaviors is performed for the experimental group in the intervention village. During the intervention, the control group did not receive training. But after the intervention, the training package is presented to the control group.

Main outcome variables

Preventive behaviors against leishmaniasis Scores of structures of self-efficacy, self-control, social support, outcome expectations, self-efficacy of overcoming obstacles, environmental perception, emotional adjustment, and outcome value.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200615047784N1**

Registration date: **2020-09-02, 1399/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-02, 1399/06/12**

Update count: **0**

Registration date

2020-09-02, 1399/06/12

Registrant information

Name

Mahmoud Fakhar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3847 4911

Email address

fakharm2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on social cognitive theory in health volunteers on preventive behaviors of cutaneous leishmaniasis in volunteers and covered households

Public title

The effect of educational intervention on social cognitive theory in health ambassadors on the preventive behaviors of cutaneous leishmaniasis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Health ambassadors and their parents have informed consent. Health ambassadors must be over 15 years old. Health ambassadors do not have a confirmed disability or physical disability. Have not attended health ambassadors training classes.

Exclusion criteria:

Not able to read and write. Family members covered by health ambassadors must be over 40 years old.

AgeFrom **15 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **220****Randomization (investigator's opinion)**

Randomized

Randomization description

With a multi-stage cluster method of comprehensive rural health service centers and health houses affiliated to Mashhad city health center number one, which consists of 51 rural centers and health houses in three clusters (clusters based on their geographical location relative to the city health center) Mashhad number one is considered) First, a cluster will be selected randomly by lottery method. Each health house will be given a number and by drawing a health house for the experimental group (individual number) and a health house It is assigned to the control group (even number). Then, in each of the selected health centers, the list of registered health ambassadors is extracted and according to the Word criteria, individuals are included in the study and sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the study analysts are kept blind to the

information of the intervention and control groups by assigning an unspecified title (for example, by titles of groups 1 and 3).

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences Ethics Committee

Street address

No. 16, Daneshgah Street, School of Health. Postal Code: 9137673119

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Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Approval date

2019-10-13, 1398/07/21

Ethics committee reference number

IR.MUMS.REC.1398.198

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

Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

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

Score of self-control.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

2**Description**

Scores of structures of self-efficacy.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

3**Description**

Scores of structures of social support.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

4**Description**

Scores of structures of outcome expectations.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

5**Description**

Scores of structures of barrier self efficacy.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

6**Description**

Scores of structures of environmental perception.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

7**Description**

Scores of structures of emotional adjustment.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

8**Description**

Scores of structures of outcome experiences.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

9**Description**

Score of preventive behavior of leishmaniasis.

Timepoint

Before the intervention - immediately after the intervention - 3 months after the intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

demographic variables

Timepoint

At one stage, preferably 3 months after training

Method of measurement

questionnaire

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

This study will be performed quasi-experimentally with a control group. First, a descriptive study is performed to determine the factors related to the preventive behaviors of leishmaniasis. In the second stage, intervention studies of before and after type are performed with a randomized control group. Based on the education of leishmaniasis and based on cognitive-social theory on preventive behaviors of leishmaniasis through health ambassadors will be performed on rural households in Mashhad 1. Training programs between 6 to 8 sessions; 2 face-to-face sessions (60 m) and other virtual sessions (via social media) will be held over a period of one month. The educational content will be in the form of pamphlets, tracts, educational videos, and slides. In 3 stages, the researcher-made questionnaire will be completed immediately after the training, immediately after the training, and 3 months after the training. The data will be analyzed with SPSS software. The teaching method should be measured.

Category

Behavior

2**Description**

Control group: Health ambassadors and members of their families do not receive training in the control group, but after the intervention, they will be given a training package.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

No. 1. Mashhad Health Center

Full name of responsible person

Mahmoud fakhar

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mahmoud Fakhar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mehrsadat Mahdizadeh

Position

Associate professor

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahmoud Fakhar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Razavi Khorasan

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable