

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effectiveness of Educational Intervention Based on the BASNEF Model on Preventive Behaviors of Leishmaniasis among First high school boy Students

Protocol summary

Study aim

Determining the effect of education based on the BASNEF model in control and prevention of cutaneous leishmaniasis in students

Design

This is a two arm parallel groups randomized trial. In Phase 2, 70 students who will be randomly divided to intervention and control groups will be enrolled in the study.

Settings and conduct

The sampling method in this study will be random sampling, so that among the cities of the eastern region of Isfahan, Nasrabad and Mohammadabad, which have a high prevalence of leishmaniasis, and are also similar in terms of demographic variables will be selected as the place of the study. Among these cities, one will be considered randomly to select the students of the intervention group and the other to select the control group. One high-school in each city and one class from each high-school will randomly be selected. All the students of the selected class will be enrolled in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1: Student of the first high-school in Nasrabad and Mohamadabad 2: Students and parent's consent to participate in the study Exclusion criteria 1: Absence from more than one educational session 2: incomplete completion of questionnaire

Intervention groups

This intervention will be done based on the BASNEF model's constructs. Three educational sessions is considered for the students and one session for their parents. The written content of sessions will be provided to students of the control group after ending training.

Main outcome variables

Improving BASNEF model structures (knowledge, attitude, abstract norms and enabling factors) in the

intervention group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049131N1**

Registration date: **2020-11-20, 1399/08/30**

Registration timing: **prospective**

Last update: **2020-11-20, 1399/08/30**

Update count: **0**

Registration date

2020-11-20, 1399/08/30

Registrant information

Name

Hossein Shahnazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3243

Email address

gh.alizadeh1397@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Educational Intervention Based on the BASNEF Model on Preventive Behaviors of Leishmaniasis among First high school boy Students

Public title

The effect of educational intervention based on the BASNEF model on preventive behaviors of leishmaniasis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Student of the first high school of Nasrabad and Mohammadabad Students and parent's consent to participate in the study

Exclusion criteria:

Absence from more than one training session Incomplete completion of the questionnaire

Age

From **12 years** old to **25 years** old

Gender

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **35****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization method will be used in this study. Group random allocation is considered to sample selection. At first, one of the two cities where the study will be conducted will be considered randomly to select the intervention group and the other to select the control group. A boys' high school is randomly selected from each city, and a class is selected from each high school, and all students in that class will be enrolled in the study.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical

Sciences

Street address

School of health- Isfahan University of Medical Sciences- Hezarjerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-11-07, 1399/08/17

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.463

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

CUTANEOUS LEISHMANIASIS

ICD-10 code

L00-L99

ICD-10 code description

Diseases of the skin and subcutaneous tissue

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

Knowledge

Timepoint

Before training and 2 months after training

Method of measurement

BASNEF Questionnaire

2**Description**

Attitude

Timepoint

Before training and 2 months after training

Method of measurement

BASNEF Questionnaire

3**Description**

Subjective norms

Timepoint

Before training and 2 months after training

Method of measurement

BASNEF Questionnaire

4**Description**

Enabling factors

Timepoint

Before training and 2 months after training

Method of measurement

Secondary outcomes

empty

Intervention groups1**Description**

This intervention will be done based on the BASNEF model's constructs. Three educational sessions is considered for the students using lecture, group discussion and role-playing and one session will be held for their parents with lecture and demonstration.

Category

Prevention

2**Description**

Control group: The written form of educational content will be provided to the students of control group after ending training sessions.

Category

Prevention

Recruitment centers1**Recruitment center****Name of recruitment center**

Isfahan Health Center

Full name of responsible person

Hossein Shahnazi

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Shahnazi

Position

Associate professor

Latest degree

Ph.D.

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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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the information about the main outcome

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers working in scientific institutions, local and education authorities

Under which criteria data/document could be used

Having permission from Isfahan University of Medical Sciences

From where data/document is obtainable

Isfahan University of Medical Sciences

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

The applicant for receiving the documents can submit his/her request through the Vice Chancellor for Research of Isfahan University of Medical Sciences one year after the publication of the results .

Comments