

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of a health intervention based on WHO food safety manual in Iran

Protocol summary

Study aim

The present research aimed to explore the effectiveness of a health intervention in the light of WHO five-keys in FCHVs' knowledge, attitude and behavior.

Design

The present empirical research was conducted as a census on all health volunteers in the target health centers. Health volunteers of three centers were taken as the experiment group (n=65) and the other two as the control (n=60). Due to the intervention nature of the study, no blinding study was performed.

Settings and conduct

This study was performed on all volunteer health care volunteers in health centers by census method.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: work as health volunteer in the target health center, consent to participate in the research and active participation in educational program. The exclusion criterion was a volunteer's unwillingness to continue with the research for any reason.

Intervention groups

The intervention group is a group that receives educational interventions to promote food safety.

Main outcome variables

Determining the mean score of knowledge, attitude and practice towards food safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160822029485N4**
Registration date: **2020-03-16, 1398/12/26**
Registration timing: **retrospective**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name

Ali Safari

Name of organization / entity

School of public health, Shahid beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 66 3275 5043

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-30, 1398/01/10

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-04-04, 1398/01/15

Actual recruitment end date

2019-07-16, 1398/04/25

Trial completion date

2019-08-01, 1398/05/10

Scientific title

Effectiveness of a health intervention based on WHO food safety manual in Iran

Public title

The Effectiveness of Health Intervention on Food Safety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Work as health volunteer in the target health centre

Consent to participate in the research and active participation in educational program
Exclusion criteria:
volunteer's unwillingness to continue with the research for any reason

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Of the six health care centers in the damavand city, three center were randomly assigned to the experimental group and the other three to the control group.

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 shahid beheshti University of Medical Sciences

Street address

Shahriari Square, Velenak

City

Tehran

Province

Tehran

Postal code

6831197193

Approval date

2014-02-23, 1392/12/04

Ethics committee reference number

SBMU.REC.1392.700

Health conditions studied

1

Description of health condition studied

Food safety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Awareness

Timepoint

The effect of educational intervention was evaluated before and two months after the intervention.

Method of measurement

WHO Questionnaire related to food safety

2

Description

Attitude

Timepoint

The effect of educational intervention was evaluated before and two months after the intervention.

Method of measurement

WHO Questionnaire related to food safety

3

Description

behaviour

Timepoint

The effect of educational intervention was evaluated before and two months after the intervention.

Method of measurement

WHO Questionnaire related to food safety

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The instructional content of each session was presented in accordance with learners' learning power using reliable scientific sources and experts' comments. To ensure of the correspondence between the educational content with participants' level of understanding, this content was provided to 10 health volunteers similar to those in the main research, as a pilot test. The intervention ran for one month in five 90-minute sessions in the form of lecture and PowerPoint presentation. Question and answer sessions were also held. Educational pamphlets were developed. Group discussions were held for the experiment group.

Category

Behavior

2

Description

Control group: This group will not receive any educational intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Damavand health center

Full name of responsible person

Mohtasham Ghaffari

Street address

Shahriari Square, Velenak

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1983535511

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Email

mohtashamghaffari@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Yadollah Mehrabi

Street address

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Tehran

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1983535511

Phone

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Email

mehrabi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyede Zenab Jafarian

Position

Student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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jafarian.zenab@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohtasham Ghaffari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyede Zenab Jafarian

Position

Student

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is accessible.

When the data will become available and for how long

Available immediately after publish.

To whom data/document is available

Policy makers, decision makers, and academics have access.

Under which criteria data/document could be used

Use of statistical data in accordance with ethical principles

From where data/document is obtainable

Refer to Scientific Response for documentation.

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

Individuals should receive the documentation with a full explanation of the research and having the necessary documentation to conduct the research related to the data.

Comments