

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Design and Evaluation of the Promotion Healthy and Safe Nutrition Behaviors Program in High School Female Students Using Health Action Model

Protocol summary

Study aim

Determination the effect of the educational program on healthy and safe nutrition behaviors of girl's students using health action model

Design

The sample size is determined after a pilot study on a small sample of the target group and the sampling is done by multi-stage random cluster and districts, schools and classes are selected randomly Simple with random numbers table.

Settings and conduct

Research is conducted in girls' government schools. After completing the consent form, a pre-test is performed in two groups of intervention and control with a questionnaire. Then the intervention is presented only in the intervention group. Two months after the end of the intervention, post-test is done in both groups.

Participants/Inclusion and exclusion criteria

The desire of eighth- grade girl's students of Governmental schools of Shiraz city to participate in the study

Intervention groups

In order to promote the nutritional behaviors of students in the intervention group, an educational program based on content designed using interactive methods in educational sessions is implemented. In addition, the pamphlet includes the key points related to the final conclusion of the topics discussed in each training session is provided and will be given to the students. After the end of the study, the educational content is placed available in the control group.

Main outcome variables

The main outcomes of this study contains to determine the predictive variables of healthy and safe nutrition behavior in girls students and to determine and compare the mean scores of health action model of constructs such as belief systems, motivational, normative, Self

(personality), behavioral intention, facilitating or enabling factors and health action behavior in the context of healthy and safe nutrition behavior of girls students in both intervention and control groups before and after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041100N1**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Leila Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 7799

Email address

lmoradi20072007@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and Evaluation of the Promotion Healthy and Safe Nutrition Behaviors Program in High School Female Students Using Health Action Model

Public title

Promoting Nutritional Behaviors in Students

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Eighth grade girl's students They are studying in governmental high schools in Shiraz. Students tend to participate in the study.

Exclusion criteria:

Unwillingness to cooperate Not attending in the training sessions more than 2 sessions Not attending in the post-test Exit from the study due to a transfer of students from the school, leave the school or immigration from Shiraz.

Age

From **14 years** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Multi-stage random cluster sampling is performed. In the first stage, from four districts of educational, two districts are selected randomly Simple. In the next stage, randomly simple, two Governmental girls' high schools are selected from each district. A school is considered as an intervention group and another school is considered as the control group and is selected from two districts of four schools. In the final stage, two classes of the 8th grade from each school are selected randomly Simple. A total of 4 classes of the 8th grade are placed in the intervention group and 4th classes of the 8th grade are placed in the control group. A random numbers table is used to select randomly Simple.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

National Ethics Committee in Biomedical Research

Street address

School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

City

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Province

Yazd

Postal code

035- 38209119

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.SSU.SPH.REC.1397.071

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

Design and Evaluation of Promoting Healthy and Safe Nutrition Behaviors Program in High School Girls Students Using Health Action Model

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Determine and compare the mean score of healthy and safe nutrition behavior of girl's students in two groups of intervention and control before and after intervention

Timepoint

At the beginning of the study (before the intervention) and 2 months after the end of the intervention.

Method of measurement

Researcher-made Questionnaire

Secondary outcomes

empty

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

Intervention group: Intervention is an educational type that is implemented in intervention group students to

promote healthy and safe nutrition behaviors. An educational program based on educational content designed using interactive methods in educational sessions will be implemented. In addition, the pamphlet contains key points related to the final conclusion of the topics discussed in each training session is provided and will be given to the students.

Category

Lifestyle

2

Description

Control group: High school girl students in Shiraz schools who do not receive any interventions.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Governmental High Girls Schools of Shiraz City

Full name of responsible person

Leila Moradi

Street address

No. 16, Alley 5, Qasr- Dasht Avenue, Shiraz, Iran

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lmoradi20072007@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Masoud Mirzaei

Street address

Yazd - Bahonar Square, First of Shahid Sadoughi South Avenue. Central University Building, Third Floor, Department of Research and Technology

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Leila Moradi

Position

Ph.D. student

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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Full name of responsible person

Dr Mohammad Ali Morowatisharifabad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data and documentation listed in above can be shared.

When the data will become available and for how long

Start the access to documentation, 3 months after the publication of the article

To whom data/document is available

Researchers that working in academic and scientific institutions

Under which criteria data/document could be used

The provision of documentation and data files is with condition that there is no interference in the data and documentation of the study without the consent of the researcher.

From where data/document is obtainable

Dr. Mohammad Ali Morowatisharifabad, School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran, Email: morowatisharif@yahoo.com Leila Moradi, School of Health, Shiraz University of Medical Sciences, Iran, Email: lmoradi20072007@yahoo.com

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

Send the email to the persons listed above and to review request the applicant and to provide information within a maximum of one month.

Comments