

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Investigate the effect of educational intervention program based on the theory of planned behavior associated with iron and vitamin D supplementation on components the model on Gonabad female high school students.

Protocol summary

Study aim

the effect of training base on planned behavioral theory on the intention to use iron supplements and vitamin D

Design

the study was performed based on the theory of planned behavior (TPB) on 175 female adolescents in two groups of control (n=92) and intervention (n=85) without randomization and blinding. Data collection was conducted through researcher-made questionnaire based on the TPB, with a confirmed validity and reliability. The data were analyzed in the SPSS statistical software (v. 20) using descriptive and inferential methods. The Significance level was set at 0.05 in all the tests. The study population was selected through cluster random sampling technique. At first, lists of all schools (rural and urban) with seventh-grade classes were arranged. Subsequently, two schools were chosen from the rural areas, and two schools were selected from the urban regions as the intervention group. Not Blinded, Not randomized.

Settings and conduct

This study was conducted on the seventh-grade female in Gonabad city (a city in the southeastern province of Khorasan Razavi, Iran).

Participants/Inclusion and exclusion criteria

The inclusion criteria : seventh-grade studentship, Gonabad residence, willingness to participate in the study. The exclusion criteria: Having absentee at training sessions,

Intervention groups

In this intervention study, a nutritional and supplementary education training course was conducted for 4 sessions of 2 hours for students in the experimental group for a maximum of one month. The strategy of providing educational content focused on constructs of attitude, subjective norm and perceived behavior control.

In addition, education content was provided for teachers, administrators and at least one parent.

Main outcome variables

After intervention program mean scores of All the constructs except the attitude in the intervention group were significantly higher than the control group (p <0.001).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040559N1**

Registration date: **2018-10-03, 1397/07/11**

Registration timing: **retrospective**

Last update: **2018-10-03, 1397/07/11**

Update count: **0**

Registration date

2018-10-03, 1397/07/11

Registrant information

Name

Alireza Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3851 4548

Email address

jafaria962@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-25, 1396/08/03

Expected recruitment end date

2017-11-23, 1396/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of educational intervention program based on the theory of planned behavior associated with iron and vitamin D supplementation on components the model on Gonabad female high school students.

Public title

Behavioral intention to use of vitamin D and iron supplements by adolescents: an application of the theory of planned behavior

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

seventh-grade studentship Gonabad residence
willingness to participate in the study

Exclusion criteria:

Having one or more session absentee at training sessions
Students who participated in the pre-test but were not present in the post-test changing their schools

Age

From **12 years** old to **14 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **175**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Imam Khomeini street

City

Gonabad

Province

Razavi Khorasan

Postal code

96917-93718

Approval date

2016-06-30, 1395/04/10

Ethics committee reference number

SDH/2/012

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

use of vitamin D and iron supplements

ICD-10 code

Z72.4

ICD-10 code description

Inappropriate diet and eating habits

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

knowledge

Timepoint

One month after the meeting and after the test made by questionnaire, the two groups will be measured

Method of measurement

questionnaire

2**Description**

Attitude

Timepoint

One month after the meeting and after the test made by questionnaire, the two groups will be measured

Method of measurement

questionnaire

3**Description**

Subjective norm

Timepoint

One month after the meeting and after the test made by questionnaire, the two groups will be measured

Method of measurement

questionnaire

4

Description

Perceived behavioral control

Timepoint

One month after the meeting and after the test made by questionnaire, the two groups will be measured

Method of measurement

questionnaire

5

Description

Intention

Timepoint

One month after the meeting and after the test made by questionnaire, the two groups will be measured

Method of measurement

questionnaire

Secondary outcomes

1

Description

behavioral intention

Timepoint

Baseline (pre-intervention) and one month after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, education based on the theory of planned behavior was performed with 4 sessions of 120 minutes

Category

Prevention

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Education Schools in Gonabad

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gonabad 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

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Gonabad University of Medical Sciences

Position

PhD Student
Latest degree
Master
Other areas of specialty/work
Health Promotion
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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

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

Alireza Jafari: jafaria962@mums.ac.ir

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

Data is sent through an official request and by email

Comments