

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of the educational intervention on health literacy level in the girl students of the high School in Siahkal (2016-2017)

Protocol summary

Summary

It is a randomized controlled trial (RCT) study that will be implemented after the approval of the Council of Guilan University of Medical Sciences. The study population included 394 secondary school female students who are selected randomly. These students were from two schools which will be chosen as the control and the intervention schools. Samples were obtained 57 students in each group using the Pukak formula. Due to this study and the possibility of losing 10% of the samples was considered the sample size with 63 students per group. Methodology: Based on the validity and reliability will be performed the pretest among the experimental and control groups at schools and all the students in the elected class. Inclusion criteria include the student's satisfaction and the exclusion criteria study consist of miss more than one educational sessions. According to the results of the pretest will be to design and implement appropriate educational intervention and then, in order to compare and determine the intervention effect, the posttest will be taken among the intervention and control groups on one months after intervention. Data were collected using the Health Literacy Measure for Adolescents (HELMA) questionnaire. The questionnaire comprise range of questions to assess personal and interpersonal factors associated with health literacy for adolescents. The final questionnaire was approved with 44 items split into eight sections. The sections were titled: gain access to, reading, understanding, use, communication, self-efficacy and numeracy. The current study is the first attempt to design and psychometric to measure health literacy for Iranian adolescents which implement in both qualitative and quantitative sections.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608131087N8**

Registration date: **2017-05-08, 1396/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-08, 1396/02/18

Registrant information

Name

Rabiollah Farmanbar

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1552 0149

Email address

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the educational intervention on health literacy level in the girl students of the high School in Siahkal (2016-2017)

Public title

The effect of the educational intervention on health literacy level in the girl students of the high School in Siahkal (2016-2017)

Purpose

Health service research

Inclusion/Exclusion criteria

Includes all students in the second grade secondary day schools interested in participating in the study. Exclusion criteria: absence more than once in training sessions

Age

From **16 years** old to **17 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

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

Guilan University of Medical Sciences

Street address

Gas Valves Vice Chancellor for Research and Technology

City

rasht

Postal code

Approval date

2016-10-30, 1395/08/09

Ethics committee reference number

IR.GUMS.REC.1395.292

Health conditions studied

1

Description of health condition studied

Health literacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health literacy

Timepoint

A period of one month after the intervention.

Method of measurement

HELMA questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The type of intervention is educational. After identifying the weaknesses in each of the sections, the educational intervention will be performing on any of them, and then, after one month, the questionnaires will be completed and evaluated again. The training will be in the form of lectures, discussions, brainstorming, poster, pamphlets and slides.

Category

N/A

2

Description

in the first phase, there will be no educational intervention in the control group after completing the questionnaire. In the second phase, the questionnaire will be completed with completing the questionnaire in the intervention group simultaneously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Two Girls Secondary School II

Full name of responsible person

Street address

City

Siahkal

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

University of Medical Sciences
Full name of responsible person
 Drshadman Nemati
Street address
 Valves for gas - martyr Beheshti Boulevard West -
 Opposite Bank Sepah - Iran's top representative
 radiators - Construction Vice Chancellor for Research
 and Technology
City
 rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor
organization/entity?
 Yes
Title of funding source
 Vice Chancellor for Research and Technology University
 of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact
Name of organization / entity
 Rasht School of Public Health Rasht
Full name of responsible person
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty