Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

farmanbar@gums.ac.ir

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

Mitra Kekhtari

Position

Graduate (masters) Student Health

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Associate professor of Department of Health and Health Promotion

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Person responsible for updating data

Contact

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Masters student health education

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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