Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 2026

The effect of life skills training using health literacy strategies on self-esteem and self-efficacy of female students in adolescence

Protocol summary

Study aim
The effect of life skills training based on health literacy strategies on self-esteem and self-efficacy of female students of puberty

Design
A randomized clinical trial study was conducted. At first, a district of education was selected randomly from among the education districts of Mashhad. Then two high school girls of the first grade were selected from that area. In the next step, two classes of the 7th grade students of each of the above schools were selected and finally, they were randomly assigned to a high school as a control group and the other as the test group. Sample size was determined based on the same texts and with 95% confidence and 80% test power, 35 students per group, which included 50 people per group, with a possible fall.

Settings and conduct
Two girls' high schools will be selected randomly, and 25 students from each high school in Mashhad will be randomly selected and entered into the study. At first, the test and control groups complete the self-efficacy and self-esteem questionnaires. Then the test group is trained in 5 sessions of life skills and the control group does not receive any training, immediately after training and 3 months later the questionnaires is completed by both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria:7th grade student girls- Conscientious dissatisfaction with participating in the study Non-compliance criteria: Physical or mental illness- pass life skills courses

Intervention groups
In the intervention group: The educational program designed for the intervention group consisted of five sessions of theoretical education and workshops with role play and presentation in the field of self-awareness skills, effective communication, problem-solving skills and assertiveness skills based on health literacy strategies. Is. Control group: No intervention received.

Main outcome variables
self efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160710028863N30**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

Registration date
2018-07-09, 1397/04/18

Registrant information

Name
Nooshin Peyman

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 915 502 6195

Email address
peymann@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-03, 1396/12/12

Expected recruitment end date
2018-03-06, 1396/12/15

Actual recruitment start date
2018-03-03, 1396/12/12

Actual recruitment end date
2018-03-06, 1396/12/15
Trial completion date
empty

Scientific title
The effect of life skills training using health literacy strategies on self-esteem and self-efficacy of female students in adolescence

Public title
The effect of life skills training using health literacy strategies on self-esteem and self-efficacy of female students in adolescence
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
7th grade student girls Willingness to participate in the study
Exclusion criteria:
pass life skills courses Having severe physical or mental illness
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: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
A cluster sampling method is used to select an education area from among the education districts of Mashhad. Then two heigh school girls will be selected from that district. In the next step, two classes of the 7th grade students of each of the above schools will be selected and finally, by random method, a high school will be considered as the control group and the other will be considered as the test group. These two high schools will have a geographically spaced distance between each other so that participants can not call together.
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 Mashhad University of Medical Sciences
Street address
School of Health, Daneshgah18 Street, Danshgah Avenue, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-03-03, 1396/12/12
Ethics committee reference number
IR.MUMS.REC.1396.396

Health conditions studied

1

Description of health condition studied
Puberty
ICD-10 code
E30
ICD-10 code description
Disorders of puberty, not elsewhere classified

Primary outcomes

1

Description
Self-efficacy level
Timepoint
Before The intervention, immediately and three months after intervetion
Method of measurement
Sherer self-efficacy Questionnaire

2

Description
self esteem level
Timepoint
Before The intervention, immediately and three months after intervention
Method of measurement
Cooper Smith self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The training program designed for the test group consisted of 5 sessions of 90 minutes of theoretical education and workshops with role plays and demonstrations in the field of self-awareness skills, effective communication, problem-solving skills and assertiveness skills based on health literacy strategies.

Category
Lifestyle

2

Description
Control group: This group did not receive any intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
First High School Girls in Mashhad

Full name of responsible person
Nooshin Peyman

Street address
Daneshgah18, Danshgah Avenue, Mashhad

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9138813944

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Email
peymann@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Vice chancellor for research, Mashhad University of Medical Sciences, In front of Daneshgah18, Danshgah Avenue, Mashhad

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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Nooshin Peyman

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person
Nooshin Peyman

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
Not applicable
Analytic Code
Not applicable
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
Dr Nooshin Peyman Peymann@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