

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of spiritual health education with family participation on quality of life related to the health of female adolescents

Protocol summary

Study aim

Investigating The effect of spiritual health education with family participation on quality of life related to the health of female adolescents

Design

A randomized controlled trial with parallel groups, one-sided randomized blind, on 60 adolescent girls aged 12-14 years, of which 30 were assigned to the control group and 30 to the intervention group. Simple randomization method will be used for randomization (lottery for each person)

Settings and conduct

8 sessions of 30-45 minutes of spiritual health training will be held at the health center, in person and virtually, for the intervention group, depending on the condition of the corona.

Participants/Inclusion and exclusion criteria

Inclusion criteria: not participating in similar educational programs, adolescent girl in the age range of 14-14 years, no history of mental disorders or cognitive disorders, no drug addiction, adolescent living with her parents. Conditions of non-entry: Adolescent age is under 12 years. Adolescents participate in a similar training program at the same time. The teen is addicted. Adolescents have a history of mental or cognitive illness. Teenagers live alone.

Intervention groups

The effect of spiritual health education on health-related quality of life of adolescent girls aged 12-14 years in the intervention group and comparing the health-related quality of life score of this group with the control group who have not received spiritual health education.

Main outcome variables

Spiritual health education; Overall health-related quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053621N1**

Registration date: **2022-03-02, 1400/12/11**

Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**

Update count: **0**

Registration date

2022-03-02, 1400/12/11

Registrant information

Name

Zinat Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

rahimiz9@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-04-08, 1401/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual health education with family participation on quality of life related to the health of female adolescents

Public title

The effect of spiritual health education with family participation on quality of life related to the health of female adolescents

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Adolescent girl in the age range of 12-14 years Having written consent to participate in the study Do not participate in similar training programs No history of mental disorders and cognitive disorders No drug addiction Teenagers live with parents Teens have a cell phone

Exclusion criteria:

Adolescents have a history of mental or cognitive illness Teenagers are addicted Teenagers live alone

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the 22 urban health centers of Mashhad Health Center No. 1, Sarafrazan Comprehensive Health Service Center will be selected as a test group based on purpose and available as an experimental group and x center will be selected as a control group after a simple lottery. (Due to the relationship between the adolescent girls of Sarafrazan Comprehensive Health Service Center and the possibility of information leakage, the control group was not selected from Sarafrazan Center itself). The lottery was such that the names of 22 urban centers covered by Health Center No. 1 were written on exactly the same sheets and placed in a box, then by removing one of the sheets, the center was identified as a control group. Then, in these two centers, the files of adolescent girls were reviewed and 30 people from each center, who are in the age range of 12-14 years, were randomly selected and after telephone or in-person counseling, with people who met the inclusion criteria. Necessary coordination will be made to attend the center.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, according to the type of intervention, which is an educational method, blindness cannot exist for participants as well as for evaluators. Blinding will only exist for statistical analysts.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the School of Nursing and Midwifery, Mashhad University of Medical Sciences

Street address

Mashhad School of Nursing and Midwifery

City

mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-02-11, 1400/11/22

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.089

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

Assessing the quality of life related to the health of adolescent girls 12-14 years old

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

Quality of life score related to adolescent girl health

Timepoint

The quality of life score is measured before, immediately and one month after the start of spiritual health education.

Method of measurement

Adolescent Health Quality of Life Questionnaire Kid Screen 27

Secondary outcomes

empty

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

Intervention group, 30 adolescent girls 12-14 years old, in 8 sessions of 45 minutes, two sessions per week,

which will last one month, spiritual health education (communication with God, communication with oneself, communication with others, communication with the world Creation) will be given according to the model of Razzaqi et al. This questionnaire will be filled in by the intervention group before the beginning of the trainings, immediately after the end of the trainings and one month after the end of the trainings.

Category

Other

2

Description

Control group: 30 adolescent girls aged 12-14 years who perform the usual educational activities of the school and at the end of the research, the educational materials provided for the intervention group are given to them in writing.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad number one health center

Full name of responsible person

zinat rahimi

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Mashhad School of Nursing and Midwifery

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rahimiz9@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

zinat rahimi

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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

Mashhad University of Medical Sciences

Proportion provided by this source

70

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

zahra emami moghadam

Position

Professor

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Data is shared after people are not identified.

When the data will become available and for how long

The access period will start immediately after the results are published.

To whom data/document is available

The data will be available for academic and scientific and... researchers.

Under which criteria data/document could be used

The data can be used for reference and further research.

From where data/document is obtainable

Mashhad School of Nursing and Midwifery - Tel:
05138591511 zahra Emami Moghaddam

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

The applicant can access the data by visiting the library of Mashhad School of Nursing and Midwifery.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

zahra emami moghadm

Position

Professor

Latest degree

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Other areas of specialty/work

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