

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of spiritual self-care on Stress and loneliness in first grade high school girls

Protocol summary

Study aim

Determining the effect of implementing a program to promote the spiritual health of stress and loneliness of high school girls in Gorgan in the year 1400

Design

This study has two groups of control and intervention. The sample size is 30 students for the intervention group and 30 students for the control group. In this study, the study plan is parallel.

Settings and conduct

Spiritual self-care training will be conducted on 30 teenage female students in a WhatsApp virtual group.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age group 14 to 16 years 2. Sex of the girl 3. Achieve a score of at least 140 and above the stress criterion 4. Achieve a score of at least 40 or higher from the criterion of feeling lonely 5. No psychiatric disorder or use of psychiatric medication Exclusion criteria 1. Occurrence of a stressful accident during the last 6 months 2. Not participating in two session

Intervention groups

In the intervention group, 8 sessions of 40 minutes (twice a week) of spiritual self-care training will be performed. In the control group, they do not receive training from the researcher and the procedure is performed routinely.

Main outcome variables

Feeling lonely Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211011052733N1**

Registration date: **2021-12-29, 1400/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-29, 1400/10/08**

Update count: **0**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

Hamideh Rahnama Araghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual self-care on Stress and loneliness in first grade high school girls

Public title

The effect of spiritual self-care on Stress and loneliness

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The age of adolescent between 14 to 16 years old. The gender of the girl Earn score 140 and above than

Adolescent Stress Questionnaire (ASQ) . Earn score 40 and above than Usher and Haima and Renshaw Loneliness Questionnaire (1984)

Exclusion criteria:

History of used drug psychiatric. En Participate in the other psychological programs to the during the intervention.

Age

From **14 years** old to **16 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in cluster randomization. Gorgan has 12 high schools. One high school from each region will be selected randomly. In each high school, the participants will be selected as a quota for the population of that area and they will be contacted for research. In the second stage, stratified randomization will be divided into intervention and control groups. Because of the scatter of samples in each high school and also the possibility of heterogeneity in some of the basic features in the groups, the classified randomization program will be used. In this study, the samples were based on the high school centers

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 University of Mashhad Medical Sciences

Street address

Mashhad, Ibn Sina St.-doctora Four-Way

City

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Province

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Postal code

9137913199

Approval date

2021-11-09, 1400/08/18

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.073

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Feeling lonely is an unpleasant condition that results from the difference between the relationship between the person that people tend to and the relationship that they have with others in real situations. This feeling is important because it is associated with both negative emotions and social poverty in adults, adolescents and children.

Timepoint

loneliness before the intervention, immediately after the intervention

Method of measurement

Usher and Haima and Renshaw Loneliness Questionnaire (1984)

2

Description

Stress

Timepoint

Stress before the intervention, immediately after the intervention

Method of measurement

Adolescent Stress Questionnaire (ASQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, after introducing the research and conducting the pre-test, 8 40-minute sessions (twice a week) of spiritual self-care sessions will be held. These interventions are in four areas: communication with God, communication with oneself, communication with others, and connection with the created world. The activities of the sessions will be: 1. Checking the pre-session assignments of the participants that have been assigned to them. 2. Giving

feedback to the participants by the researcher 3. Listing and summarizing the previous material to make a connection between the discussed material and creating mental preparation of the participants for the new discussion 4. Doing new exercises 5. Giving homework for the next sessions 6 Explain the explanations and conclusions about the topic of the meeting. Codified trainings will be organized by the researcher in the form of lectures and webinars along with slide shows, group discussions in cyberspace and presentation of assignments.

Category

Behavior

2**Description**

Control group: 30 Adolescent who will be randomly selected and will not receive any training, and completion of questionnaires will be conducted simultaneously with the intervention group.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Grade high school girls

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

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

Hamideh Rahnama Iraqi

Position

Master of Pediatric Nursing

Latest degree

Bachelor

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

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

Information about the outcome of the main message The ability to transfer the sharing

When the data will become available and for how long

One year after sharing results

To whom data/document is available

Our data will only be available to researchers working in academia.

Under which criteria data/document could be used

With the permission of Mashhad University of Medical Sciences, data will be available.

From where data/document is obtainable

Research Deputy of Mashhad University of Medical Sciences

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

You must apply for deputy from Mashhad University of Medical Sciences

Comments