

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of mindfulness-based counseling on the inactivity of adolescent girls

Protocol summary

Study aim

Determining the effect of mindfulness-based counseling on the inactivity of adolescent girls

Design

The clinical trial has a randomized control group, an intervention and a control group of 67 people each, the type of randomization was block randomization with the size of 4.

Settings and conduct

The place of the study is girls' high schools in Ahvaz city. The sample of the research is tenth grade students who meet the conditions to entering the study. The participants are randomly assigned to two control and intervention groups. There is no possibility of blinding in this study. In the control group, there is no intervention, and in the intervention group, the counseling based on mindfulness is used. The treatment program will be provided by the researcher in the form of an 8-session program (two sessions per week). Meetings will be held in groups. Contents and assignments will be presented to the intervention group on a weekly basis. The way to follow up the samples in 3 stages is to fill the questionnaire in the first session (pre-test), the last session (post-test) and one month after the last training session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Living together with parents, Written parental consent, Teenager's willingness to cooperate and participate in meetings, Age range from 14 to 16 years, Physical and mental health
Exclusion criteria: Suffering from any severe physical or mental illness that prevents physical activities, Reluctance to participate in the study, Receiving any psychological services during the last 6 months

Intervention groups

Participants are randomly assigned to two control and intervention groups. There is no intervention in the control group and counseling based on mindfulness is used in the intervention group.

Main outcome variables

Inactivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230728058952N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Sheida Momtaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3443 4867

Email address

sheidamom2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness-based counseling on the inactivity of adolescent girls

Public title

The effect of mindfulness-based counseling on the inactivity

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Living together with parents
Written parental consent
Teenager's willingness to cooperate and participate in meetings
Age range from 14 to 16 years
Physical and mental health
Low or moderate physical activity based on the physical activity questionnaire of children and adolescents (Score 1 to 3.66)

Exclusion criteria:

Suffering from any severe physical or mental illness that prevents physical activities.
Reluctance to participate in the study
Receiving any psychological services during the last 6 months
Any use of psychiatric drugs and addictive substances

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: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation, considering that we have two intervention and control groups, we will use a block of 4. In order to determine the allocation sequence using the 4 block method, random allocation sequence generation software (Random Allocation Software 2.0) will be used. In order to hide the sequence of allocation, the papers identifying the group of people are placed inside the envelopes in the opaque package and coded in the same order

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Deputy of research and technology, Esfand Ave., Golestan Blvd., Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2023-06-24, 1402/04/03

Ethics committee reference number

IR.AJUMS.REC.1402.196

Health conditions studied

1

Description of health condition studied

inactivity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

inactivity

Timepoint

Before the intervention, immediately after the intervention, one month after the intervention

Method of measurement

International physical activity questionnaire for children and adolescents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: adolescent girls receiving mindfulness-based counseling. Mindfulness-based counseling uses mindfulness meditation practices and psychological strategies. In this method, mindfulness is based on 4 principles including Body awareness (body position and body movement/activity), body sensations (including those related to emotions), mental states (including emotional states) and mental content (thoughts, images) are taught. Before starting the

treatment program, the training certificate of the mindfulness course will be received and attached to the study, then the mindfulness-based counseling program for inactivity in the form of an 8-session program during 8 weeks by The researcher will be presented. Meetings will be held in groups. Contents and assignments will be presented to the people of the intervention group on a weekly basis. It will be considered that the participants, whenever they have a problem in doing the assignments, have more interaction with the researcher in person or virtually to ensure the correctness of the assignments.

Category

Treatment - Other

2**Description**

Control group: Adolescent girls without receiving mindfulness-based counseling

Category

Treatment - Other

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

Education Department of Ahvaz city

Full name of responsible person

Massoud Hamidinejad

Street address

Basij Square, Khorram St

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63333363055

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+98 61 3333 4019

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Khouz.pr@chmail.ir

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

Ahvaz University of Medical Sciences

Full name of responsible person

Sahand Jorfi

Street address

Deputy of research and technology, Esfand Ave.,
Golestan Blvd., Ahvaz, Iran

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jorfi-s@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mojgan Javadnoori

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mojgan javadnoori

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after de-identifying individuals.

When the data will become available and for how long

It will be possible to access the research documents six months after the final statistical analysis.

To whom data/document is available

The data will be available only for the use of researchers of academic institutions

Under which criteria data/document could be used

In order to improve the health of adolescents

From where data/document is obtainable

In order to receive the data, people can refer to the main executive of the project, Dr. Mojgan Javadnoori, a member of the academic staff of Jundishapur University of Medical Sciences, Ahvaz. Email: mojganjavadnoori@gmail.com

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

After obtaining the necessary permits from the Jundishapur University of Medical Sciences and the Vicechancellor of Research and Technology of this university, the applicant can proceed to receive the documents.

Comments