Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

“The effect of mindfulness counseling on the health-related quality of life in adolescent girls”

Protocol summary

Study aim
General Objective:To investigate the effect of mindfulness counseling on the health-related quality of life in adolescent girls.

Design
Quasi-Experimental Clinical Trial with Parallel Control Groups. Sample Size: 106 participants (adolescent girls). Randomization: School-level cluster randomization. Blinding: Not possible for participants/researcher; only the statistician will be blinded. Phase: Clinical Trial (including pre-test, post-test, and a one-month follow-up).

Settings and conduct
This is a quasi-experimental clinical trial investigating the effect of 8 sessions of Mindfulness Counseling on the HRQoL of 106 adolescent girls in Ahvaz high schools. It uses school-level cluster randomization with pre/post/follow-up testing. Only the statistician will be blinded.

Participants/Inclusion and exclusion criteria
Population: Ahvaz high school adolescent girls. Sample: 106 participants. Inclusion: Age 15-18 (Grades 10-12), informed consent from parents/students, availability outside of exam periods. Exclusion: Recent major stressful event, diagnosed physical/mental issues, or substance use (drugs/smoking)

Intervention groups
The Intervention Group consists of students who will receive 8 weekly, 45-minute group sessions of Mindfulness Counseling. These sessions will be conducted by a trained student under the supervision of a psychology consultant.

Main outcome variables
The primary outcome variable of this study is Health-Related Quality of Life (HRQoL) in adolescents. This quality of life is measured across ten dimensions, including: Physical Health, Mental Health, Emotions and Mood, Self-Perception, Parental Relationship and Family Life, Social Support and Peers, School Environment, and Social Acceptance, among others.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251114067997N1**
Registration date: **2025-12-07, 1404/09/16**
Registration timing: **prospective**

Last update: **2025-12-07, 1404/09/16**
Update count: **0**

Registration date
2025-12-07, 1404/09/16

Registrant information
Name
Zeinab Sayahi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-01-04, 1404/10/14
Expected recruitment end date
2026-03-18, 1404/12/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
"The effect of mindfulness counseling on the health-related quality of life in adolescent girls"

Public title
The effect of mindfulness counseling on the quality of life of adolescent girls"

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Voluntary participation with informed consent from the adolescent and parents. Female students aged 15–18 years enrolled in high schools. Studying in girls' high schools in Ahvaz city. Availability during the intervention period (not during exam or vacation time).

Exclusion criteria:
Occurrence of a severe stressful event within the past six months, such as the death of a parent or close relative. Presence of diagnosed physical or psychological disorders, based on medical history or clinical evaluation. Use of cigarettes or any addictive substances by the participant. Lack of willingness to participate or continue in mindfulness counseling sessions. Inability to attend the intervention sessions regularly due to illness or family issues

Age
From **15 years** old to **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method used in this study is cluster randomization, where the unit of randomization is at the school level rather than the individual level. In this approach, two schools with similar characteristics are selected from the same district, and the roles of the intervention group (mindfulness counseling) and the control group are randomly assigned to these two schools to prevent contamination between groups. The random sequence will be generated using conventional methods such as a random number table. Due to the nature of the intervention, complete allocation concealment is not feasible; both the students and the facilitator are aware of the group assignments, but to maintain study validity, the statistical analyst will remain blinded.

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 University of Medical Sciences

Street address
Ahvaz, Jalali Alley, between Helali and Ghaznavi, No. 269

City
Ahvaz

Province
Khouzestan

Postal code
6144915167

Approval date
2025-09-27, 1404/07/05

Ethics committee reference number
IR.AJUMS.REC.1404.331

Health conditions studied

1

Description of health condition studied
Health-Related Quality of Life

ICD-10 code
F43.2

ICD-10 code description
Adjustment disorders

Primary outcomes

1

Description
The primary outcome variable in this study is Health-Related Quality of Life (HRQoL), which is measured to assess the effect of the 8-session Mindfulness Counseling intervention. Operationally, this variable is defined by the total scores obtained by participants across ten distinct domains of the kidscreen_52 questionnaire. These ten domains, which function as the specific primary outcome measures, include: Physical Health, Psychological Health, Feelings and Mood, Self-Perception, Autonomy, Parental Relationships and Family Life, Social Support and Peers, School Environment, Social Acceptance, and Financial Resources. The intervention's effect will be determined by comparing the scores across these domains at the pre-test, post-test, and one-month follow-up assessment points.

Timepoint
The time points for measuring the primary outcome

(HRQoL) are precisely:Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention.

Method of measurement

The standardized Kidscreen-52 Health-Related Quality of Life Questionnaire

Secondary outcomes

1

Description

The physical health of adolescent girls

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.

2

Description

Psychological Well-Being

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item 1-5

3

Description

Moods and Emotions

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item 12-18

4

Description

Self-Perception

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item19-23

5

Description

Autonomy

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item24-28

6

Description

Parent Relations and Home Life

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item29-34

7

Description

Social Support and Peers

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item35-40

8

Description

School Environment

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item41-46

9

Description

Social Acceptance (Bullying)

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item47-49

10

Description

Financial Resources

Timepoint

Before the intervention (Baseline), immediately after the completion of the intervention, and one month after the completion of the intervention

Method of measurement

the standardized Kidscreen-52 health-related quality of life questionnaire.item50-52

Intervention groups

1

Description
Intervention group: In this group, the “Mindfulness Counseling Program” is delivered in 8 weekly group sessions, each lasting 45 minutes. The content of the sessions includes training in mindfulness principles, mindful breathing, body scan, managing thoughts and emotions, mindful communication skills, and final consolidation. Participants complete the KIDSCREEN-52 questionnaire at three time points: baseline, post-intervention, and follow-up.

Category
Lifestyle

2

Description
Control group: In this group, no intervention is provided. Participants only complete the KIDSCREEN-52 questionnaire at three time points: baseline, post-intervention, and follow-up. After the study is completed, an educational brochure on mindfulness will be offered to the participants.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Girls’ High Schools in Districts 1 and 4 of Ahvaz

Full name of responsible person
DR. Nahid Javadifar

Street address
No. 269, Jalali Alley, between Helali Street and Ghaznavi Street, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
DR. Nahid Javadifar

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Grant name
No specific grant or external funding was used for this study

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
Zeinab Sayahi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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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
This dataset includes raw outcome-related variables (KIDSCREEN-52 scores and demographic variables), fully de-identified and coded to remove any personal identifiers."

When the data will become available and for how long
"Data will be available beginning 6 months after publication and will remain accessible for 3 years."

To whom data/document is available
Qualified researchers who submit a written request along with a valid research proposal and obtain approval from the Ethics Committee and the study team will be granted access

Under which criteria data/document could be used
Data may be used solely for research purposes and for secondary analyses related to adolescent health. Access requires a written request, submission of a valid research proposal, absence of conflicts of interest, and approval from the Ethics Committee and the study team. Use is permitted for non-commercial purposes only.

From where data/document is obtainable
Requests should be directed to Dr. Nahid Javadifar (Principal Investigator). Email: javadifar-n@ajums.ac.ir Affiliation: School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences

What processes are involved for a request to access data/document
The requester must first submit a formal written request along with a research proposal via email. The study team performs an initial review. If deemed appropriate, the request is forwarded to the university Ethics Committee for final approval. After ethics approval and signing a Data Use Agreement, the de-identified, coded dataset or document will be provided to the researcher

Comments