Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness training on loneliness, psychological well-being, and spiritual experiences of women-headed households

Protocol summary

Study aim
the effectiveness of mindfulness-based training on loneliness, psychological well-being, and spiritual experiences of female heads of households covered by welfare in Rasht city.

Design
Population, Sample and Sampling Method The statistical population of the study consists of all female heads of households covered by the Rasht City Welfare Organization in [1404]. The sample size was determined based on statistical power analysis and considering a confidence level of 95 and a test power of 80, 40 people (20 people in the experimental group and 20 people in the control group). After completing the demographic questionnaire and obtaining informed consent, eligible participants were randomly assigned to two experimental groups and Controls will be replaced.

Settings and conduct
, mindfulness training is defined as a standard intervention package. This package consists of 8 90-minute training sessions held weekly for the experimental group. The content of these sessions is designed based on validated protocols such as mindfulness-based stress reduction or mindfulness-based cognitive therapy and includes exercises such as breathing meditation, body scanning, and mindfulness in daily activities. The success of participants in this intervention is measured by their attendance and active participation in the sessions.

Participants/Inclusion and exclusion criteria
Willingness to participate in research,No drug or alcohol addiction,Absence of specific mental and physical problem،Literacy up to diploma,Age 20 to 50years

Intervention groups
The experimental group will undergo a mindfulness-based training program in 8 90-minute sessions (one session per week).

Main outcome variables
Feelings of loneliness; psychological well-being; spiritual experiences

General information

Reason for update

Acronym
AMK

IRCT registration information
IRCT registration number: **IRCT20251210068278N1**
Registration date: **2026-06-02, 1405/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-02, 1405/03/12**
Update count: **0**

Registration date
2026-06-02, 1405/03/12

Registrant information

Name
Fatemeh Kamrani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 396 5279

Email address
fatemekam123@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-29, 1405/03/08

Expected recruitment end date
2026-06-21, 1405/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness training on loneliness, psychological well-being, and spiritual experiences of women-headed households

Public title
Investigating the effect of mindfulness training on feelings of loneliness, psychological well-being, and spiritual experiences

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in research No drug or alcohol addiction Absence of specific mental and physical problems Age 20 to 50 years Age 20 to 50 years

Exclusion criteria:
UnWillingness to participate in research Having and addiction Having a severe physical or mental problem Age over 60 Illiterate

Age
From **20 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the lack of access to the entire community, they will be selected based on the willingness of individuals and the conditions of participation in the research using the convenience method. Convenience sampling is a method that can select the most accessible individuals for the study. Since it is not possible to have access to the entire community of female head of household, convenience sampling will be used to facilitate the work and be accessible to the community of female head of household of Rasht Welfare. After that, individuals will be selected for the experimental and control groups using a simple random method. Each of them will be given special codes and using a random number table (equal chances), 20 people will be placed in the experimental group and another 20 in the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tonekabon Azad University of Medical Sciences

Street address
Maskanmehr

City
Rasht

Province
Guilan

Postal code
4196955385

Approval date
2026-05-23, 1405/03/02

Ethics committee reference number
IR.IAU.TON.REC.1405.019

Health conditions studied

1

Description of health condition studied
focuses on the psycho-social vulnerability of female-headed households."

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Loneliness is an unpleasant subjective psychological experience arising from an individual's perception of a discrepancy between their desired and actual social relationships (Russell et al., 1984).

Timepoint
The research design is a quasi-experimental pretest-posttest design with a control group. The experimental group will participate in an 8-session mindfulness-based training program, consisting of one 90-minute session per week.

Method of measurement
In this study, loneliness is measured by the total score obtained from the Russell, Peplau, and Cortona Loneliness Scale (20-item version). The scores achieved by each participant on this scale serve as the operational indicator of their level of loneliness, with higher scores indicating a greater degree of loneliness.

2

Description
Psychological well-being extends beyond mere happiness

or the absence of mental illness. Based on Carol Ryff's (1989) theory, this concept refers to positive functioning and personal growth across six key dimensions: autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self-acceptance. This perspective links mental health to the continuous development and realization of an individual's potential.

Timepoint

The research design is a quasi-experimental pretest-posttest design with a control group. The experimental group will participate in an 8-session mindfulness-based training program, consisting of one 90-minute session per week.

Method of measurement

In this study, psychological well-being is measured using the total score and subscale scores from the Ryff Scales of Psychological Well-being (18-item short form). The scores achieved by each participant on this scale serve as the operational indicator of their level of psychological well-being, with higher scores indicating a greater degree of well-being."

3

Description

Spiritual experiences refer to personal subjective and emotional experiences, which include a sense of connection to something greater than oneself (such as God, nature, or the universe), finding meaning and purpose in life, and experiencing feelings of awe, peace, and oneness (Andrewood & Tracy, 2002).

Timepoint

The research design is a quasi-experimental pretest-posttest design with a control group. The experimental group will participate in an 8-session mindfulness-based training program, consisting of one 90-minute session per week.

Method of measurement

In this study, spiritual experiences are measured by the total score obtained from the Daily Spiritual Experience Scale (DSE) by Andrewood and Tracy (16-item version). The score achieved by each participant on this scale serves as the operational indicator of the extent and frequency of their spiritual experiences. Higher scores indicate more frequent and intense spiritual experiences.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The experimental group will undergo a mindfulness-based training program based on the book Attention Awareness Workbook by John Teasdale, Mark Williams, and Zindel Segal, translated by Dr. Anousheh Aminzadeh, in 8 90-minute sessions (one session per week). In these sessions, the main mindfulness techniques will be taught by Fatemeh Kamrani. The control group will not receive any psychological intervention during this time period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
بهزیستی کل استان گیلان

Full name of responsible person
Fatemeh Kamrani

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Maskanmehr

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۴۱۹۶۹۵۵۳۸۵

Phone
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Email
fatemekam@gmail.com

Web page address
http://fatemehkamrani.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Masoud Qane

Street address
Maskanmehr

City
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Grant name

Grant code / Reference number

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

No

Title of funding source

Welfare of Gilan Province

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

Islamic Azad University

Full name of responsible person

Fatemeh Kamrani

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Fatemeh kamrani

Position

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Full name of responsible person

Fatemeh Kamrani

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The participants are female heads of households covered by the Welfare Department, and permission to publish the participants has not been granted by the Welfare Department or the participating individuals.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available