Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Mindfulness based on cognitive therapy, Mind wandering, cognitive bias, Somatization

Protocol summary

Study aim
Investigating the effectiveness of mindfulness-based cognitive therapy on mind wandering, cognitive bias, and somatization.

Design
A clinical trial with a control group, blinded, voluntary available sampling, on 23 people in the intervention group

Settings and conduct
At first, the patients who were referred to Aram Clinic in Mashhad were invited to participate in the research. Interested people are identified and randomly divided into experimental and control groups. Then the subjects will be tested with three paper-pencil questionnaires. Once a week, participants in the experimental group will be invited to participate in mindfulness-based cognitive therapy. After the completion of the eight-session treatment, the experimental and control groups will be invited again for the post-test.

Participants/Inclusion and exclusion criteria
The criterion for entering the research is to refer to the public psychological counseling and services center in Beh Aram Mashhad, the presence of behavioral problems, mild psychological injuries such as mild depression, family and marital problems, mild psychological stress and confusion, and behavioral problems. Exclusion criteria include severe and major psychiatric disorders such as psychotic disorders, major depressive disorder, bipolar disorder, personality disorders, and substance abuse. Entry criteria are measured using self-reports and review of clients' files, and exit criteria are measured using clinical file review, physician's diagnosis, and brief psychiatric clinical interview based on DSM-5.

Intervention groups
The research sample comprises 45 people who refer to Aram Public Psychological Services and Counseling Center in Mashhad. After matching, 23 people will be assigned to the intervention group and 22 will be assigned to the control group.

Main outcome variables
Somatization, Cognitive Bias, Mind-Wandering

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231005059629N1**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date
2023-10-18, 1402/07/26

Registrant information

Name
Zaynab Raisianzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3821 8403

Email address
zaynab.raisianz1@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-16, 1402/07/24

Expected recruitment end date
2023-12-04, 1402/09/13

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Mindfulness based on cognitive therapy, Mind wandering, cognitive bias, Somatization

Public title

Mindfulness based on cognitive therapy, Mind wandering, cognitive bias, Somatization

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of behavioral problems mild psychological injuries such as mild depression Family and marital problems Having mild psychological stress, confusion, and behavioral problems. Referring to the Aram public psychological counseling and services center in Mashhad,

Exclusion criteria:

Severe and major psychiatric disorders such as psychotic disorders, major depressive disorder, bipolar disorder, personality disorders, Substance abuse

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Semnan University of Medical Sciences

Street address

Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

35147-99442

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.SEMUMS.REC.1402.126

Health conditions studied

1

Description of health condition studied

Somatization

ICD-10 code

F45.0

ICD-10 code description

Somatization disorder

2

Description of health condition studied

Mind-wandering

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Cognitive Bias

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Somatization

Timepoint

Before the Intervention and after the implementation of the eight-week intervention program

Method of measurement

Spoth & Dush Health Concerns Questionnaire-54

2

Description

Cognitive Bias

Timepoint

Before Intervention and after implementation of eight-weeks intervention program

Method of measurement

Woody, Chambless & Glass Cognitive Bias scale (1997)

3

Description

Mind-Wandering

Timepoint

Before the Intervention and after the implementation of the eight-week intervention program

Method of measurement

Carriere, Seli and Smilek Mind Wandering Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness-based cognitive therapy has been implemented in this group. The treatment protocol is based on Segal et al. (2018), which includes 8 treatment sessions, and each session includes 90 minutes of attendance and 45 minutes of home practice. Before and after the intervention, the participants were tested with somatization, cognitive bias, and mental wandering questionnaires.

Category

Treatment - Other

2

Description

Control group: No intervention is carried out on this group. Before and after the intervention in intervention group, the control group memrbers participants were tested with somatization, cognitive bias, and mental wandering questionnaires.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beh Aram Counseling and general psychological Center

Full name of responsible person

Dr Elham Pour Afrouz

Street address

No. 697, between 29 and 31 vakilabad., Vakil abad Blvd., Daneshjoo., Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

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

Semnan 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

The University of Semnan

Full name of responsible person

Zeinab Raiesian Zadeh

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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 data have been collected for a master's thesis, and only their descriptive and inferential analysis report will be published
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available