Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of resilience and mindfulness therapy in improving family relationships and reducing substance abuse relapse

Protocol summary

Study aim

General purpose: The general purpose of this research is to compare the effectiveness of resilience-based therapy and mindfulness-based therapy in improving family relationships and reducing substance abuse relapse.

Design

Clinical trial with control group, two intervention groups, in 45 patients. People will be randomly divided into three groups.

Settings and conduct

After giving written consent to participate in the research, people will be randomly divided into two experimental groups and one control group. First, all people enter the test and complete the research questionnaire. Then two test groups will be treated with treatment protocol. Meetings are held at Mohrhari Hospital in Shiraz. After the treatment, the research questionnaires will be completed again by all three groups and then analyzed using spss software.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include being over 18 years old and not suffering from an incurable disease. Exclusion criteria include taking neuropsychiatric drugs and suffering from chronic psychological diseases.

Intervention groups

Resilience Intervention Group: This Pennsylvania Resilience Program was designed based on the cognitive-behavioral model by Gillham et al. (1990) at the University of Pennsylvania. In the study of Khanjani et al. (2014), the content validity of the Pennsylvania Resilience Program was confirmed. The participants of the current research are given this training in 12 sessions. Mindfulness intervention group: The participants in this group are subjected to a relapse prevention treatment protocol based on mindfulness for 8 sessions and weekly. The content of this intervention is taken from the therapeutic protocol of Boen et al. (2011). Control group: no intervention is done for this group.

Main outcome variables

improving family relationships; Reducing substance abuse relapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240420061537N1**
Registration date: **2024-05-04, 1403/02/15**
Registration timing: **prospective**

Last update: **2024-05-04, 1403/02/15**
Update count: **0**

Registration date

2024-05-04, 1403/02/15

Registrant information

Name

amene zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3650 0291

Email address

amene1365z@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-07, 1403/02/18

Expected recruitment end date

2024-05-24, 1403/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of resilience and mindfulness therapy in improving family relationships and reducing substance abuse relapse

Public title
Comparing the effectiveness of resilience and mindfulness therapy in substance abuse relapse

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Not suffering from incurable physical diseases Over 18 years old
Exclusion criteria:
Use of neuroleptics The presence of other chronic psychological disorders in the participants

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The people participating in this research will be selected by available sampling method and will be randomly divided into three groups (two experimental groups and one control group).

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 Islamic Azad University, Arsanjan branch
Street address
Islamic Azad University, Arsanjan branch, Educational complex, University blvd
City
Arsenjan
Province
Fars
Postal code
7376153161

Approval date
2024-04-09, 1403/01/21

Ethics committee reference number
IR.IAU.A.REC.1403.005

Health conditions studied

1

Description of health condition studied
substance abuse

ICD-10 code
F19.1

ICD-10 code description
Other psychoactive substance abuse

Primary outcomes

1

Description
Substance abuse relapse score in Wright et al.'s questionnaire

Timepoint
Measuring the reduction of substance use relapse before and after the implementation of the intervention

Method of measurement
Wright et al.'s substance use relapse prediction scale (1993)

2

Description
The improvement score of family relationships in Ritchie and Fitzpatrick questionnaire

Timepoint
Measuring the improvement of family relationships before and after the implementation of the intervention

Method of measurement
Ritchie and Fitzpatrick family communication patterns scale (1990)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pennsylvania Resilience Program Protocol

Category
Treatment - Other

2

Description
Intervention group: Mindfulness-based relapse prevention treatment protocol
Category
Treatment - Other

3

Description
Control group: Control group, no treatment
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ostad Moharari Hospital for Neurology and Psychiatry
Full name of responsible person
Mojtaba Naqshvarian
Street address
Ostad Mohrhari Neurological and Psychiatric Hospital, in front of Niayesh settlement, Kilometer 13 of the Shiraz-Marvdast highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Arsanjan branch
Full name of responsible person
Mohammad Rostampour
Street address
Arsanjan branch, educational complex of Islamic Azad University, university boulevard, Arsanjan, Fars
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Phone
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Fax
+98 71 4352 2483
Email
mojtabamiraki1361@gmail.com
Web page address
https://arsanjan.iau.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Project student named Amene Zare
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University, Arsanjan branch
Full name of responsible person
Amene Zare
Position
freelance job
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

reducing substance abuse relapse, improving family relationships. All potential data can be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 5 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The descriptive statistics data and the data obtained from the analysis of variance test can be used to provide the background of the research in the future researches of other researchers.

From where data/document is obtainable

Refer to the Islamic Azad University, Arsanjan branch, and the project manager, Mrs. Amene Zare.

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

E-mail and call the academic unit and project manager

Comments