Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of cognitive-spiritual group therapy with spiritual care approach on improving the quality of life in people addicted to industrial drugs

Protocol summary

Study aim

The effectiveness of cognitive-spiritual group therapy with spiritual care approach on improving the quality of life in people addicted to industrial drugs

Design

A clinical trial with a control group and a control group, with parallel, randomized groups, on 30 patients. Random block sequencing website was used for randomization.

Settings and conduct

The sample of the present study was selected from the statistical population using available and random sampling methods from rescue camps and flight hope and considering the entry and exit criteria and divided into two groups of 15 people, namely an experimental group and a control group. Are randomly assigned. Studying on the one hand will be blind. The experimental group does not receive the protocol of the cognitive-spiritual group of addiction with the care approach and the control group does not receive any intervention.

Participants/Inclusion and exclusion criteria

Entry criteria: Minimum cycle level education, no use of psychiatric drugs and psychotropic substances during the last 3 months, receiving informed consent, not undergoing other psychological treatment at the same time, having a history of industrial drug use, and minimum age 20 and maximum 40 years. Exclusion criteria: Absence from more than 3 sessions and unwillingness to continue attending classes.

Intervention groups

The cognitive-spiritual intervention of the addiction with care approach was performed on the experimental group. The intervention was not performed on the control group and pre-test and post-test were taken.

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220628055304N1**
Registration date: **2022-07-05, 1401/04/14**
Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**
Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Saeed Foroughi

Name of organization / entity

Islamic azad university arak branch

Country

Iran (Islamic Republic of)

Phone

+98 916 664 1180

Email address

foroghi.s@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of cognitive-spiritual group therapy with spiritual care approach on improving the quality of life in people addicted to industrial drugs

Public title
The effectiveness of cognitive-spiritual group therapy with spiritual care approach on improving the quality of life in people addicted to industrial drugs

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum cycle level education, no use of psychiatric drugs and psychotropic substances during the last 3 months, receiving informed consent, not undergoing other psychological treatment at the same time, having a history of industrial drug use, and minimum age of 20 and maximum 40 years

Exclusion criteria:

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
A clinical trial with two control groups and a control group, with parallel, random groups, on 30 patients. For random allocation, the block-making method (quadruple blocks) is used. A list of blocks is written and numbers are assigned to them, and finally the treatment allocation list is determined based on random numbers. To do this, a random block sequencing website is used. Random block sequencing is given to a specific person outside the research team who is responsible for random allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
The experimental group participates in 8 sessions of the cognitive-spiritual treatment course of addiction with a caring approach and the control group does not receive any intervention. Attempts are made to schedule the meetings in such a way that the members of the control and intervention group do not collide with each other and are not informed about the content of each other's meetings. Also, the participant is not aware of the result.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Islamic Azad University- Arak Branch

Street address
Vice Chancellor for Research and Technology, Islamic Azad University of Arak, Amirkabir Town, 3 km of Khomeini Road University, Imam Khomeini Boulevard, Imam Khomeini Square, Arak

City
Arak

Province
Markazi

Postal code
3836119131

Approval date
2022-05-10, 1401/02/20

Ethics committee reference number
IR.IAU.ARAK.REC.1401.050

Health conditions studied

1

Description of health condition studied
People addicted to industrial narcotics

ICD-10 code
F11

ICD-10 code description
Opioid related disorders

Primary outcomes

1

Description
Quality of life

Timepoint
1 months

Method of measurement
World Health Organization short quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Cognitive-spiritual group therapy protocol of addiction with care approach: This therapy package is an 8-session

group intervention that follows the structure of cognitive group interventions. And creation are formulated. The main tool of this treatment is prayer, which after presenting the topics of spiritual care in each session, a specific prayer for each session is presented as a task.

Category

Treatment - Other

2

Description

Control group: The control group does not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Liberation and Hope Flight Camp, District 8, Tehran

Full name of responsible person

Saeid Foroughi

Street address

Tehran

City

Tehran

Province

Tehran

Postal code

6861886489

Phone

+98 916 664 1180

Email

Foroghi.s@lums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Arak Branch

Full name of responsible person

Ali Hasani Joshaghani

Street address

Vice Chancellor for Research and Technology, Islamic Azad University of Arak, Amirkabir Town, 3 km of Khomeini Road University, Imam Khomeini Boulevard, Imam Khomeini Square, Arak اراک، میدان امام خمینی (ره)، بلوار امام خمینی (ره)، کیلومتر 3 جاده خمین، شهرک دانشگاه امیرکبیر، دانشگاه آزاد اسلامی واحد اراک، معاونت پژوهش و فناوری

City

Arak

Province

Markazi

Postal code

3836119131

Phone

+98 86 4100 1021

Email

Ahj_ir@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University, Arak Branch

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 Azas University, Arak Branch

Full name of responsible person

Amin Ahmadi

Position

M.A. student in clinical psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Islamic Azad University of Arak, Amirkabir Town, 3 km of Khomeini Road University, Imam Khomeini Boulevard, Imam Khomeini Square, Arak

City

Arak

Province

Markazi

Postal code

3836119131

Phone

+98 935 425 9563

Email

Amin.ahmadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Arak Branch

Full name of responsible person

Saeid Foroughi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work
Nursery
Street address
Islamic Azad University of Arak, Amirkabir Town, 3 km of Khomeini Road University, Imam Khomeini Boulevard, Imam Khomeini Square, Arak
City
Arak
Province
Markazi
Postal code
3836119131
Phone
+98 916 664 1180
Email
Foroghi.s@lums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University, Arak Branch
Full name of responsible person
Amin Ahmadi
Position
M.A. student in clinical psychology
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Islamic Azad University of Arak, Amirkabir Town, 3 km of Khomeini Road University, Imam Khomeini Boulevard, Imam Khomeini Square, Arak
City
Arak
Province
Markazi
Postal code
3836119131
Phone
+98 935 425 9563
Email
ahmadi.amin1368@gmail.com

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
Because of moral issues
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