Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of spiritual interventions based on the Salim heart model on self-stigma in the family of drug users undergoing treatment

Protocol summary

Study aim
Determining the effect of spiritual interventions based on the healthy heart model on the level of self-stigma in the family of drug users undergoing treatment

Design
The clinical trial was conducted with two parallel intervention and control groups, each with 60 people. Allocation of people to two groups was done randomly using a coin toss.

Settings and conduct
The present study will be conducted in government and private substance abuse treatment clinics in Khorramabad city. The studied population is the family members of drug addicts undergoing treatment in Khorramabad clinics. In this study, blinding will not be done, but the completion of the questionnaires will be done by the researcher's colleague.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The participants have the interest and desire to participate in the meetings; The family member should live with help; Be in the age range of 18-65. Exclusion criteria: history of chronic physical illness; history of known mental illness; Dependence of a family member to drugs

Intervention groups
Intervention group (experimental): family members of drug dependent clients who participate in spiritual intervention sessions. Control group: family members of drug dependent clients who receive routine care.

Main outcome variables
Self-stigma in the family of drug users

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240220061053N1**
Registration date: **2024-08-29, 1403/06/08**
Registration timing: **retrospective**

Last update: **2024-08-29, 1403/06/08**
Update count: **0**

Registration date
2024-08-29, 1403/06/08

Registrant information

Name
zahra sedighifar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 3226 1030

Email address
zahrasedighi7474@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-19, 1403/01/31

Expected recruitment end date
2024-04-22, 1403/02/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of spiritual interventions based on the Salim heart model on self-stigma in the family of drug users undergoing treatment

Public title
Study of the effect of spiritual intervention on the self-stigma
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being interested to participate in the study The family member lives with the patient Being in the age range of 18-65.
Exclusion criteria:
Having a history of diagnosed mental illness Having a history of chronic physical illness Having a history of drug dependency
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the samples in the number of 120 people, they were given numbers from 1 to 120, then, we placed the first 60 people in the test group and the rest in the 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 Kermanshah University of Medical Sciences
Street address
Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2024-02-17, 1402/11/28
Ethics committee reference number
IR.KUMS.REC.1402.632

Health conditions studied

1

Description of health condition studied
Self-stigma in the families of drug users undergoing treatment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The effect of spiritual interventions on the level of self-stigma in the family of drug users
Timepoint
Measuring self-stigma in the family of drug users at the beginning of the study and 28 days after the last session of spiritual interventions
Method of measurement
Questionnaire of self-stigma in the family of drug users

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: spiritual intervention based on Salim's heart model, for the test group in 9 sessions of 1.5 hours of spiritual interventions, the topics of the session were designed based on past studies and authentic books, and was confirmed by experts as content validity. The group method and step by step and with sequence and based on the topic of self-stigma in the family of drug users undergoing treatment in different subjects in addition to the usual interventions of drug withdrawal clinics, was implemented on a weekly basis.
Category
Lifestyle

2

Description
Control group: In the control group, only the usual interventions of drug use clinics was performed, which included detoxification of clients and rehabilitation program.
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Public and Private Addiction Treatment Clinics in Khorramabad city

Full name of responsible person
Zahra Sedighifar

Street address
Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaei Square, Moalem Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Sirus Jalili

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Grant name
Kermanshah University of Medical Sciences

Grant code / Reference number
4030334

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Zahra Sedighifar

Position
master student

Latest degree
Bachelor

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Nursery

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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
All data can potentially be shared after de-identifying individuals.
When the data will become available and for how long
Data access time will be one month after printing the results
To whom data/document is available
Researchers working in scientific academic institutions as well as people who are also engaged in industry.
Under which criteria data/document could be used
Meta-analysis
From where data/document is obtainable
Researcher and project guide professors
What processes are involved for a request to access data/document
Emails to researchers and supervisors will be answered after checking the reason for the request for documents.
Comments