

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of Religious-Spiritual Group Training on Spiritual Health, Mental Health and Quality of Life in Opioid dependent Patients

Protocol summary

Study aim

Determining Effectiveness of Religious-Spiritual Group Training on Spiritual Health, Mental Health and Quality of Life in opioid dependent Patients

Design

In this research, 60 Opioid dependent Patient referring to Methadone Maintenance Therapy centers were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This research is being held at the "Tavallodi Dobare" Methadone Maintenance Center in Qom. sixty subjects of opiate users who were able to complete the program were selected by convenient sampling and were randomly assigned in two groups. Participants in two groups filled out Quality Of Life Scale(SF36), GHQ Scale and spiritual Health Scale-48 questionnaire as pre-test, post- test and two months after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 20-40 years, at least middle school education, at least one history of relapse, referred by a psychiatrist (diagnosis of drug dependence) based on DSM-5. Exclusion criteria: using Anti-psychotic drugs, having a long-term dependency on a substance simultaneously, the absence of more than two session.

Intervention groups

Intervention group: 8 Religious-Spiritual Group Training sessions; 8 session; 2 hours. The control group will receive general information about the addiction and will receive no regular intervention..

Main outcome variables

Spiritual Health; Mental Health; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160105025870N5**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

Registration date

2018-05-14, 1397/02/24

Registrant information

Name

Mehdi Yaghobi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 315554111

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-17, 1396/08/26

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2017-12-16, 1396/09/25

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

empty

Scientific title

Effect of Religious-Spiritual Group Training on Spiritual Health, Mental Health and Quality of Life in Opioid dependent Patients

Public title

Effect of Religious-Spiritual Group Training on Spiritual Health, Mental Health and Quality of Life in Opioid dependent Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being at the age of 20-40 years referred by a psychiatrist (diagnosis of drug dependence) based on DSM-5 at least one history of relapse at least middle school education

Exclusion criteria:

Use Anti-psychotic drugs (approved by psychiatrist), having a long-term dependency on a substance simultaneously Long-term dependence on multiple substances simultaneously

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, after entering the participants to study, the subjects were divided into two groups of 30 people by block randomization. In this method, block size of 4 which contain codes A and B is used. The code A and B represent the intervention and control groups respectively. In each block, how to place the code is as follows: AABB, BBAA, ABAB, BABA, ABBA, BAAB. Blocks are randomly selected and individuals are assigned to the intervention or control groups according to the order of the block. After allocating all the codes of a block, that block is added to the previous blocks and another block is selected randomly. This process will be continued until completing the sample size.

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 Qom University of Medical Sciences

Street address

No. 83, alley 4 , 1.1 avenue, Safashahr street, Qom

City

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Province

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Postal code

3593

Approval date

2017-12-05, 1396/09/14

Ethics committee reference number

IR.MUQ.REC.1396.117

Health conditions studied**1****Description of health condition studied**

Opiate dependence

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes**1****Description**

Spiritual Health

Timepoint

Before intervention; After intervention; 2 months After intervention

Method of measurement

Spiritual Health scale-48

2**Description**

Mental Health

Timepoint

Before intervention; After intervention; 2 months After intervention

Method of measurement

Mental Health scale (GHQ-28)

3**Description**

Quality Of Life

Timepoint

Before intervention; After intervention; 2 months After intervention

Method of measurement

Quality Of Life scale (SF36)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 8 Religious-Spiritual Group Training sessions; 8 2-hour sessions

Category

Behavior

2

Description

Control group: The control group will receive general information about the addiction and will receive no regular intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

"Tavalodi Dobareh" Methadon therapy Institutue

Full name of responsible person

Mohammad AbdeKhoda

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No. 2, alley 4 , Sadoghi street, Qom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Qom 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

Qom University of Medical Sciences

Full name of responsible person

Samira Khani

Position

Ph.D. in Pharmacology, assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Mehdi Yaghobi

Position

M.Sc in clinical psychology

Latest degree

Master

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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