Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 cods 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
Qom
Province
Ghoum
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 Institue
Full name of responsible person
Mohammad AbdeKhoda
Street address
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
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Ph.D. in Pharmacology, assistant professor
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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