Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Mindfulness Based Relapse Prevention Model on Spiritual Health, Quality Of Life and Relapse Prevention in Opioid dependent Patient

Protocol summary

Summary

Objectives: This study aimed to compare the effectiveness of Mindfulness based relapse prevention (MBRP)) on Impulsivity, Distress Tolerance and Relapse Prevention in Opiates dependent Patient at Qom. (2) Design: General plan of this study is consisted of experimental pre-test and post-test with follow-up period. (3) Setting and conduct: seventy subjects of opiates user who Beyond the period of detoxification and were able to complete the program were selected by convenient sampling and were randomly assigned in two groups (MBRP). Participants in two groups filled out Barratt Impulsiveness Scale-11scale, Simons JS, Gaher Distress Tolerance Scale questionnaire as pre-test and post- test and two month after intervention. The data were analyzed by SPSS-15 using the Multivariate Analysis of Covariance (MANCOVA). (4) Participants including major eligibility criteria: Inclusion criteria: Beyond the period of detoxification ; cycle degree; Age 20-40 years; at least once history of relapse; referred by a psychiatrist (diagnosis of drug dependence) based on DSM-IV; After more than a week of successful detoxification. Exclusion criteria: use Anti-psychotic drugs; having a long-term dependency on a substance simultaneously; the absence of more than two session; Get a history of other therapy during the past month. (5) Interventions: The intervention is consisted of 8 sessions (each session is 120 minutes) of Mindfulness based relapse prevention for the experimental group. (6) Main outcome measures: Main outcome measures variables in this research are Spiritual Health, Quality Of Life and Relapse Prevention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042825870N4**
Registration date: **2016-05-06, 1395/02/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-06, 1395/02/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-08-04, 1393/05/13

Expected recruitment end date

2015-09-04, 1394/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Mindfulness Based Relapse Prevention Model on

Spiritual Health, Quality Of Life and Relapse Prevention in Opioid dependent Patient

Public title
Effect of Mindfulness Based Relapse Prevention Model on Spiritual Health, Quality Of Life and Relapse Prevention in Opioid dependent Patient
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Beyond the period of detoxification ; cycle degree; Age 20-40 years; at least once history of relapse; referred by a psychiatrist (diagnosis of drug dependence) based on DSM-IV; After more than a week of successful detoxification. Exclusion criteria: use Anti-psychotic drugs; having a long-term dependency on a substance simultaneously; the absence of more than two session; Get a history of other therapy during the past month inclusion criteria: Beyond the period of detoxification ; cycle degree; Age 20-40 years; at least once history of relapse; referred by a psychiatrist (diagnosis of drug dependence) based on DSM-IV; After more than a week of successful detoxification. Exclusion criteria: use Anti-psychotic drugs; having a long-term dependency on a substance simultaneously; the absence of more than two session; Get a history of other therapy during the past month
Age
From **20 years** old to **40 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Kashan University of Medical Sciences and Health Services
Street address
Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran
City
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Postal code
Approval date
2015-06-05, 1394/03/15
Ethics committee reference number
IR.KAMUS..RES.1394.45

Health conditions studied

1

Description of health condition studied
opioid dependency
ICD-10 code
F11
ICD-10 code description
F11 Mental and behavioral disorders due to use of opioid

Primary outcomes

1

Description
Spiritual Health
Timepoint
before intervention, After intervention, 1 month after intervention
Method of measurement
Ellison Spiritual Well-being(SWB)

Secondary outcomes

1

Description
Quality Of Life
Timepoint
Before intervention, After intervention, 1 month after intervention
Method of measurement
Quality Of Life scale(SF36)

Intervention groups

1

Description
Mindfulness Based Relapse Prevention; 8 sessions; 2 hours, intervention group
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Apadana Methadontherapy Institu
Full name of responsible person
Mosavi panah hossein
Street address
Apadana Methadontherapy Institue،Doctors spetialist bulding،kamal almolk sq،Kashan،Iran.
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Full name of responsible person
Dr Qolam Ali Hamidi
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Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan
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Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Kashan University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty