

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

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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

Kashan

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

opiod dependency

ICD-10 code

F11

ICD-10 code description

F11 Mental and behavioral disorders due to use of opiod

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

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Apadana Methadontherapy Institue,Doctors spetialist bulding,kamal almolk sq,Kashan,Iran.

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Web page address**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

City

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**Contact****Name of organization / entity**

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Mehdi Yaghobi

Position

M.Sc Candidate in Clinical Psychology

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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