

# 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

Mehdi Yaghobi

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 315554111

###### Email address

yaghobi-me@mail.kamus.ac.ir

##### 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

**Street address**

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

**City**

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**Postal code****Phone**

+98 31 5554 0021

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mehdiyaghobi13110@gmail.comme@mail.kamus.ac.ir

**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

**Street address**

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

**Other areas of specialty/work****Street address**

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Web page address**

## **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*