

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison between the effectiveness of auriculotherapy and counseling based on spiritual therapy enhanced by cognitive-behavioral techniques on the pattern of substance usage among women

#### Protocol summary

##### Study aim

Comparison of the effect of auriculotherapy and enhanced spiritual counseling with cognitive-behavioral techniques on the pattern of female substance use in Kerman Women's Counseling Center in 2021

##### Design

A clinical trial with a control group, with parallel groups, randomized on 105 female drug users. For randomization using R software with a simple random assignment method, individuals will be divided into three groups.

##### Settings and conduct

First, after obtaining the code of ethics from the ethics committee of Kerman University of Medical Sciences and obtaining the code of clinical trial and presenting it to Kerman University of Medical Sciences, the researcher refers to the Kerman Women's Counseling Center with a letter of recommendation and thus prepares a list of women. They will be included in the study randomly if they have informed consent and inclusion criteria. The method of random sampling will be simple. There is correction for the control group and people who perform data analysis.

##### Participants/Inclusion and exclusion criteria

Login: Female gender - Methadone use - Literacy - Willingness to participate in the study - Physical and mental health (no severe underlying disease) - Believer in Islam  
Do not enter: Do not use methadone - Do not want to continue to participate in the study - Have any serious underlying disease - Use substances such as methadone to quit addiction at the same time

##### Intervention groups

The counseling group will receive 7 sessions of 90 minutes (one session per week) as a group counseling with a strengthened spiritual therapy and cognitive-behavioral approach. In this way, by stimulating the ear, it is attached to the Vakaria sides by a hand probe, and

women are asked to press them every hour for one minute, except at bedtime. The control group does not receive any treatment.

##### Main outcome variables

Material consumption pattern

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201027049164N4**

Registration date: **2021-12-15, 1400/09/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-15, 1400/09/24**

Update count: **0**

##### Registration date

2021-12-15, 1400/09/24

##### Registrant information

##### Name

Masumeh Ghazanfarpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5856

##### Email address

m.ghazanfarpour@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-10, 1400/09/19

##### Expected recruitment end date

2022-05-20, 1401/02/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison between the effectiveness of auriculotherapy and counseling based on spiritual therapy enhanced by cognitive-behavioral techniques on the pattern of substance usage among women

**Public title**

Comparison between the effectiveness of auriculotherapy and counseling based on spiritual therapy enhanced by cognitive-behavioral techniques on the pattern of substance usage among women under the supervision of women's counseling center in Kerman, 2021

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having a female gender Treated with a methadone maintenance dose Minimum literacy reading and writing Having a personal desire and conscious satisfaction to participate in the study Absence of severe physical illness (absence of severe underlying illness) Lack of any significant psychiatric disorders of anxiety and depression and significant psychiatric neurological symptoms Do not use any drugs that affect memory and cognitive function Believing in Islam Absence of severe cognitive disorders (Alzheimer's and dementia)

**Exclusion criteria:**

Use substances such as methadone to quit addiction at the same time Absence of more than two sessions in counseling sessions Having any severe underlying disease Do not use a methadone maintenance dose Reluctance to continue participating in the study

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **105****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples will be selected in an available way and then using a simple random method by numbering people from 1 to 105 and entering the numbers into the statistical software (R). With this software, people will be divided into three groups of 35 people. It should be noted that all participants in all three groups will be addicted to drugs and all three groups will use methadone maintenance treatment. 35 people will be assigned from counseling, uriculotherapy and control groups. In the

control group, in order to blind, while sticking labels on parts of the ear, the labels were gently touched to prevent any bias and also the researcher will be physically present with the people for 20 minutes but no intervention will be done. There is also blindness for people who do data analysis.

**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 Kerman University of Medical Sciences

**Street address**

Deputy of Research and Technology., ebne-e-Sina St., Jahad Blvd., Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

7619813159

**Approval date**

2021-10-18, 1400/07/26

**Ethics committee reference number**

IR.KMU.REC.1400.405

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

Pattern of drug use

**ICD-10 code**

Z63.72

**ICD-10 code description**

Alcoholism and drug addiction in family

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

Pattern of drug use

**Timepoint**

beginning of the study (before the intervention) and at the end of the intervention

**Method of measurement**

Drug use pattern questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Counseling with a spiritual therapy approach enhanced by the protocol of spiritual therapy Richard and Berlin (2006) in the counseling group at the Women's Counseling Center in Kerman and by a researcher who has previously approved the authority to perform counseling by the relevant specialist. They will find that this number will be divided into 5 groups of 7 people. The consultation will take place in the form of 7 sessions of 90 minutes (once a week) as a group in a quiet place with appropriate lighting.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: In the uriculotherapy group in the period without menstruation, one session per week (for 3 weeks) and a total of 6 sessions in two months in the points of my sand, nicotine, long point (lung), which includes long 1 and long 2, the thalamic point, sensory point, cerebral point, allergy point and liver point (liver) will be stimulated using a hand probe for 15 seconds and then Seyed Vakaria will be attached to the points. It is recommended to press each point for one minute. Do this every hour for one minute, except at bedtime. Do this for a week. The next week, the sidewalls will be reattached and the steps will be done again.

#### Category

Treatment - Other

### 3

#### Description

Control group: There will be no intervention in this group.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kerman Women's Counseling Center

##### Full name of responsible person

Fatemeh Esmaeili

##### Street address

Kerman University of Medical Science, Haft-Bagh Highway, Kerman, Iran

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 5278

##### Email

fateme.esmaeili1374b@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Dr. Abbas Pardakhti

##### Street address

Tahmasbabad cross road, Vice Chancellor for Research and Technology building

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

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##### Email

fateme.esmaeili1374b@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Kerman 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

Kerman University of Medical Sciences

##### Full name of responsible person

Fatemeh Esmaeili

##### Position

Master student

##### Latest degree

Bachelor

**Other areas of specialty/work**

Midwifery

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Kerman University of Medical Science, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran

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fateme.esmaeili1374b@gmail.com

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

Kerman University of Medical Sciences

**Full name of responsible person**

Masumeh Ghazanfarpour

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Fatemeh Esmaeili

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Begining of the axis of seven Alavi Garden, Campus of  
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and Midwifery

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fateme.esmaeili1374b@gmail.com

**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