

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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Email address

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

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Tahmasbabad cross road, Vice Chancellor for Research and Technology building

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

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Latest degree

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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