

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of emotion regulation-based educational program on the level of general health, adaptive and self-regulating emotion of patients with opioid abuse under methadone maintenance therapy

Protocol summary

Study aim

Determining the effect of education program based on emotion regulation on the level of general health, adaptation and self-regulation of emotion in patients with opioid abuse under methadone maintenance

Design

A clinical trial with a control group, with parallel, randomized groups, on 48 patients with opioid abuse who were randomly divided into two groups of experimental and control.

Settings and conduct

the samples from the Article 16 Injury Reduction Center of Isfahan will be selected by available sampling method and again by random sampling method using block classification will be assigned to two groups. The intervention group will participate in 6 training sessions based on emotion regulation during 3 weeks.

Participants/Inclusion and exclusion criteria

Entry requirements: Be able to read and write. Based on his report, he should have a suitable general situation to complete the questionnaire. Have more than six months of continuous opioid abuse (diagnosis of substance use disorder at the time of intervention) No entry conditions: Having severe physical and mental illnesses Participate in another similar study simultaneously

Intervention groups

Intervention group: In 6 sessions, emotion regulation training participates in a group and the interventions include 6 sessions of emotion regulation training based on the Gross model, which was held as a group (two sessions per week). The duration of each session is 90 minutes. All participants in the pre-test and post-test stages of the Goldberg General Health Questionnaire will complete the Garnefski Emotion Self-Regulation and Rabio Adaptation. Comparison group: During this period, they will receive the prescribed routine treatments. They only complete the mentioned questionnaires in the pre-

test and post-test stages.

Main outcome variables

general health, adaptation and self-regulation of emotion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020108N2**

Registration date: **2022-05-21, 1401/02/31**

Registration timing: **prospective**

Last update: **2022-05-21, 1401/02/31**

Update count: **0**

Registration date

2022-05-21, 1401/02/31

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3778 2856

Email address

musarezaie@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of emotion regulation-based educational program on the level of general health, adaptive and self-regulating emotion of patients with opioid abuse under methadone maintenance therapy

Public title
The effect of emotion regulation-based educational program on the level of general health, adaptive and self-regulating emotion of patients with opioid abuse

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Be between 18 and 65 years old Be able to read and write. Based on his report, he should have a suitable general situation to complete the questionnaire. Have more than six months of continuous opioid abuse (diagnosis of substance use disorder at the time of intervention Be interested and satisfied to participate in this research.

Exclusion criteria:
Having severe physical and mental illnesses Participate in another similar study simultaneously

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is a block with size 4. Randomization unit: individual. Random allocation software. Random chain concealment is by placing patient codes in opaque envelopes.

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
Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan University of
Street address
Isfahan University of Medical Sciences, Hezar Jerib St.,
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Approval date
2022-04-09, 1401/01/20
Ethics committee reference number
IR.MUI.NUREMA.REC.1401.035

Health conditions studied

1
Description of health condition studied
addiction
ICD-10 code
R78.4
ICD-10 code description
Finding of other drugs of addictive potential in blood

Primary outcomes

1
Description
general health
Timepoint
Immediately before the intervention and 21 days after the intervention
Method of measurement
Goldberg General Health Scale

2
Description
Emotional Adjustment
Timepoint
Immediately before the intervention and 21 days after the start of the intervention
Method of measurement
Emotional Adjustment Measure (EAM)

3
Description
Emotional self-regulation
Timepoint
Immediately before the intervention and 21 days after the intervention
Method of measurement
Garnofski Cognitive Emotion Regulation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will participate in 6 sessions of emotion regulation training in a group manner and the control group will receive the prescribed routine treatments during this period. The interventions include 6 sessions of emotion regulation training based on the Gross model, which were held in groups (two sessions per week). The duration of each session is 90 minutes.

Category

N/A

2

Description

Control group: During the research, the control group will receive only the medical treatments provided by the center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Harm Reduction Center Article 16 of the city of Isfahan

Full name of responsible person

Amir Musarezaie

Street address

Baharstarn, Qaleh Shor Road, Article 16 Damage Reduction Center

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

musarezaie@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Isfahan University of Medical Sciences, Hezar Jerib St.

City

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amir Musarezaie

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences, Hezar Jerib St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amir Musarezaie

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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

No - There is not a plan to make this available