Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Isfehan

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

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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

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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

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Person responsible for updating data

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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