Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

effectiveness of group narrative therapy on craving and relapse rates of addicts treating with methadone maintenance therapy in comparison with control group

Protocol summary

Study aim

Determining of the effectiveness of group narrative therapy on craving and relapse rates of addicts treating with methadone maintenance therapy

Design

The clinical trial for the control group is a single blind, with a sample population consisting of two groups of 64 people treated with methadone.The randomization method is a simple randomization method using sealed envelopes.

Settings and conduct

The study is conducted in one addiction treatment center in Garmsar, Semnan, Iran. Participants complete the relapse Prediction Scale (RPS) before the first group therapy session, in the last session, and one month later for follow-up. During this period, the slip behavior of the participants in each group is controlled according to the results of the urine test once a week without prior notice, when patients come to receive the daily dose of methadone. the present study is single blinded and data analyzer does not know the purpose and details of the research, and analyses the final data, impartially.

Participants/Inclusion and exclusion criteria

Inclusion criteria : the person should be treated with methadone for at a minimum of 3 months and at a maximum of 6 months , , absence of an acute physical illness and clinical psychiatric disorder, minimum education level of junior middle school Exclusion criteria:being under psychiatric treatment , other substance use disorder

Intervention groups

Subjects with the inclusion criteria are randomly assigned to two groups, including a group narrative therapy and a control group. The treatment group attends group narrative therapy sessions once a week for 10 weeks, and the control group does not receive any treatment.

Main outcome variables

craving , relapse rate

General information

Reason for update

due to the completing of the target sample size and generalizability of the results , the person should be treated with methadone for at a minimum of 3 months and 18 to 50 age range is considered

Acronym

IRCT registration information

IRCT registration number: **IRCT20210208050299N1**
Registration date: **2021-02-21, 1399/12/03**
Registration timing: **prospective**

Last update: **2021-04-29, 1400/02/09**
Update count: **1**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

mehdi derakhshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3455 4217

Email address

derakhshanim971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-09, 1399/12/19

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effectiveness of group narrative therapy on craving and relapse rates of addicts treating with methadone maintenance therapy in comparison with control group

Public title

The effect of Group Narrative Therapy in addiction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Interest in participating in research, and full observance of health protocols (social distancing, masking in group meetings, and hand washing before and after the meeting), the person should be treated with methadone for at a minimum of 3 months Age range 18 to 50 history of opioid use disorder (including opium and heroin) absence of an acute physical illness and clinical psychiatric disorder minimum education level of junior middle school.

Exclusion criteria:

Reluctance to participate in research, and non-observance of health protocols presence of physical illness that affects psychotherapy being under psychiatric treatment (receiving psychotherapy or pharmachotherapy) suicidal ideation other substance use disorder

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is a simple randomization using random allocation software

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, data analyzer does not know the purpose and details of the research, and analyses the final data, impartially.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mashhad University of Medical Sciences

Street address

13th floor , Block A, Treatment and Medical Education, Iran TV St. - Headquarters of the Ministry of Health, between South Flamek and ZarafshanGhods town (west)

City

Tehran

Province

Tehran

Postal code

ethics@behdasht.gov.

Approval date

2020-12-02, 1399/09/12

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.668

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

craving

Timepoint

Before the intervention, the last meeting of the intervention and 1 Month after intervention

Method of measurement

relapse prediction scale (RPS)

2

Description

relapse rate

Timepoint

Before the intervention, the last meeting of the intervention and 1 Month after intervention

Method of measurement

relapse prediction scale (RPS)

Secondary outcomes

1

Description
relapse
Timepoint
once a week
Method of measurement
opium test

Intervention groups

1

Description
Group intervention:First session: Introduction and giving self-assessment tests and the story of participant's life , obtaining valuable insights about the narrative therapy and assigning homework (Determining people's objectives and needs to change and being committed to work on their depression during their addiction to amphetamines)Second session: Started by externalization of problem and reviewing the effects of dominate story of people's life, asked them to create " my life story ", identifying first assumptions about self, teaching the way to revise ABCs every day and write them in a daily and assigning homework Third session: Started by checking homework, mind and body relaxation, improving eye contact skills, keep on everyday ABCs revisions and assigning homework.Fourth session: Checking homework, identifying the basic assumptions about addiction with group discussion on topic, training the way to create a new internal voice related to the basic assumption, continuing the practice of mind and body relaxation and other practices like asking them to paint their assumption about addiction and gave name to that, assigning homework Fifth session: Checking homework, training the way to identify addiction and group discussion on topic, teaching corrective thinking and adding D and E to ABCs, assigning homework Sixth session: Checking homework, training the way to change problematic behavioral pattern, using exposure techniques and response prevention and using techniques such as procrastination, diaphragm respiration, overcoming time, and assigning homework (using new behavioral techniques in different situations).Seventh session: Checking homework, setting up satisfactory relationship with self such as writing a letter and apologizing to self, writing positive points about self, and doing activities regarding health, fitness, stimulating activities like five senses and activities related to physical appearance, and assigning homework Eighth session: Started by group discussion about individual's feelings, desires and dreaming about themselves and assigning home work (to create a best story about self and rewriting the life story from past to future).Ninth session: Checking homework, Rewriting life story about now and future and give a new name to that , relaxation , teaching about how to create new story and individual helps, assigning homework (reviewing all sessions and finding best and worst parts of that).Tenth session: Checking homework, group discussion about the changes that have happened due to the sessions , the second investigation of self-assessment tests , identifying attitudes, training the assertive strategies to people
Category
Behavior

2

Description
Control group: Does not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized medical centers and addiction treatment camps in Garmsar city
Full name of responsible person
Mehdi.Derakhshani
Street address
8 , Sahid ozhagi street
City
Garmsar
Province
Semnan
Postal code
35493_35831
Phone
+98 23 3455 4217
Email
mehdi.derakhshani74@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology of Mashhad University of Medical Sciences
Street address
Deputy of Research and Technologynext to Hoveyzeh Cinema , Ghorashi Building , University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
Email
vcresraech@mums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mehdi.Derakhshani
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
8 , Sahid ozhagi street , Garmsar , Semnan
City
Garmsar
Province
Semnan
Postal code
35493-35831
Phone
+98 23 3455 4217
Email
mehdi.derakhshani74@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mehdi.Derakhshani
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
8 , Sahid ozhagi street , Garmsar , Semnan
City
Garmsar
Province
Semnan
Postal code
35493_35831
Phone
+98 23 3455 4217
Email
mehdi.derakhshani74@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mehdi.Derakhshani
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
8 , Sahid ozhagi street , Garmsar , Semnan
City
Garmsar
Province
Semnan
Postal code
35493_35831
Phone
+98 23 3455 4217
Email
Mehdi.Derakhshani74@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
Only part of the data, such as the original outcome information, is shared
When the data will become available and for how long
Get started 6 months after printing results
To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Documentation can be used to carry out new studies

From where data/document is obtainable

Refer to the corresponding author after publication
mehdi.derakhshani74@gamil.com

What processes are involved for a request to access data/document

After reviewing the application, will be provided by the corresponding author

Comments