

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effectiveness of group supportive counseling and group existential psychotherapy on improving the feeling of social exclusion and anxiety in patients with comorbid psychiatric disorders and substance abuse

Protocol summary

Study aim

Comparison of the effectiveness of group supportive counseling and group existential psychotherapy on improving the feeling of social exclusion and anxiety in patients with comorbid psychiatric disorders and substance abuse

Design

In this research, two experimental groups and one control group will be used.

Settings and conduct

To carry out the research, the pre-test phase will be done first for both the experimental and control groups. So that after obtaining written consent and necessary permits, the researcher will invite the qualified people to Razi Psychiatric Hospital on a certain date through a phone call. Then, based on the intervention protocol, supportive counseling intervention sessions for members of one experimental group and existential psychotherapy intervention sessions for the other experimental group will be held separately in Razi Psychiatric Hospital by a social worker and a psychiatrist.

Participants/Inclusion and exclusion criteria

Research participants will be selected by available sampling from among patients with comorbid psychiatric disorder and drug use. The criteria for entering the study are: 1-Age over 18 years old 2-Having the required ability to participate in group meetings 3-Diagnosis of psychiatric disorder by a psychiatrist 4-Diagnosis of drug use history by hospital specialists and the exclusion criteria from this study were: 1- Absence of more than two meetings and 2- Unwillingness to continue cooperation.

Intervention groups

Based on the intervention protocol, supportive counseling intervention sessions for the members of one of the test groups and existential psychotherapy

intervention sessions for the other test group will be held separately in the psychiatric hospital.

Main outcome variables

Feeling of social exclusion and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230411057882N1**

Registration date: **2024-03-01, 1402/12/11**

Registration timing: **prospective**

Last update: **2024-03-01, 1402/12/11**

Update count: **0**

Registration date

2024-03-01, 1402/12/11

Registrant information

Name

Maryam Latifian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7173 2000

Email address

maryamlatifian1993@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of group supportive counseling and group existential psychotherapy on improving the feeling of social exclusion and anxiety in patients with comorbid psychiatric disorders and substance abuse

Public title

Feeling of social exclusion and anxiety in patients with comorbid psychiatric disorders and substance abuse

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old Having the required ability to participate in group meetings Diagnosis of psychiatric disorder by a psychiatrist Diagnosis of drug use history by hospital specialists

Exclusion criteria:

Not being able to read and write Unwillingness to participate in the study

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are non-randomly divided into case and control groups. The control group receives routine hospital services, and the case group receives relevant interventions. Due to the fact that the implementation of the interventions is done by specialists based in the hospital, therefore, the researcher, the outcome assessor, the data analyst, and the data safety and monitoring committee are completely unaware of these divisions.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of university of social welfare and rehabilitation science

Street address

Kodakyar Ave., Daneshjo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2024-01-24, 1402/11/04

Ethics committee reference number

IR.USWR.REC.1402.216

Health conditions studied

1

Description of health condition studied

Psychiatric disorder

ICD-10 code

F99

ICD-10 code description

Mental disorder, not otherwise specified

Primary outcomes

1

Description

Feeling of social exclusion

Timepoint

Pre-test - post-test - follow-up after 3 months

Method of measurement

Exclusion Perception Scale

2

Description

Anxiety

Timepoint

Pre-test - post-test - follow-up after 3 months

Method of measurement

DASS-21 anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Supportive counseling: Supportive counseling sessions based on self-compassion will be done in a group based on a protocol with the components of a supportive counseling approach. The content of this educational protocol includes things such as teaching empathy, teaching sympathy, teaching forgiveness and accepting mistakes, teaching acceptance of problems, and teaching the development of valuable and sublime feelings. This protocol will be implemented in 8 1-hour sessions (weekly) by a trained social worker with a doctorate in social work.

Category

Other

2

Description

Group existential psychotherapy: group meaning therapy sessions will be conducted based on a protocol with components of the existential therapy approach based on the framework of Hotzel's treatment plan. The content of this educational protocol includes things such as philosophical education of the nature of being human, education of meaning and inner self-exploration, education of the concepts of loneliness, interpersonal, intrapersonal and existential types in very simple language, education of recognition of responsibility and accountability as an inevitable part of the human condition and responsibility. that man is responsible for the difficult conditions of life, training to control negative thoughts and ruminations; It is searching and trying to find meaning in various aspects of life and in the worst conditions of life and rebuilding oneself and getting familiar with all kinds of experimental, attitudinal and creative values. This protocol will be implemented in 10 1-hour sessions (weekly) by a trained social worker with a doctorate in social work.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital

Full name of responsible person

Maryam Latifian

Street address

Shahid Rostgar Blvd., Taghi Abad, Ray city

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7612016186

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Kianoush Abdi

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Maryam Latifian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Social Services

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

University of social welfare and rehabilitation sciences

Full name of responsible person

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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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the principle of confidentiality, the data file of the participants will not be published.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available