

# 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

##### City

Tehran

##### Province

Tehran

##### Postal code

7612016186

#### Phone

+98 21 3340 1220

#### Email

razi@uswr.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Kianoush Abdi

##### Street address

Kodakyar Ave., Daneshjo Blvd., Evin

##### City

Tehran

##### Province

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##### Postal code

1985713871

##### Phone

+98 21 2218 0083

##### Email

pr@uswr.ac.ir

#### 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

##### Street address

Kodakyar Ave., Daneshjo Blvd., Evin

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Tehran

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maryamlatifian1993@gmail.com

**Person responsible for scientific 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 updating data****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Maryam Latifian

**Position**

Assistant Professor

**Latest degree**

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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