

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

The effectiveness of schema therapy on antisocial behavior, emotion regulation and psychological well-being of female prisoners

Protocol summary

Study aim

The effectiveness of schema therapy on antisocial behavior, emotion regulation and psychological well-being of female prisoners.

Design

"This is a parallel-group clinical trial with two arms (intervention and control). Participants were randomly assigned to the groups. The sample size consists of 30 participants, with 15 in the intervention group and 15 in the control group."

Settings and conduct

This study was conducted in Shahrekord women's prison. The intervention consisted of schema therapy sessions conducted by a psychologist, It was also unblinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having appropriate psychological insight, agreeing to participate in the research, not receiving any other treatment program, and remaining at least 2 months out of prison. Exclusion criteria: more than 2 absences, not doing homework, being in solitary confinement or being transferred to another prison.

Intervention groups

"The intervention group will undergo schema therapy over 10 weekly sessions, while the control group will not receive any psychological treatment."

Main outcome variables

Schema therapy; Antisocial behaviors; Emotion regulation; Psychological well-being; Imprisoned women.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240908062982N1**

Registration date: **2024-09-28, 1403/07/07**

Registration timing: **retrospective**

Last update: **2024-09-28, 1403/07/07**

Update count: **0**

Registration date

2024-09-28, 1403/07/07

Registrant information

Name

Farima Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3228 4492

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info @ iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-01-19, 1402/10/29

Actual recruitment start date

2023-11-06, 1402/08/15

Actual recruitment end date

2024-01-19, 1402/10/29

Trial completion date

2024-02-29, 1402/12/10

Scientific title

The effectiveness of schema therapy on antisocial behavior, emotion regulation and psychological well-being of female prisoners

Public title

The effectiveness of schema therapy on the behavior and psyche of female prisoners

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having proper psychological insight Patient consent to participate in the research Not receiving any other training or treatment program At least 2 months of their imprisonment are left Regular participation in therapy sessions

Exclusion criteria:
Absent more than 2 sessions Not doing homework People who were in solitary confinement Transfer to another prison or early release

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

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

Ethics Committee of Islamic Azad University,
Najafabad branch

Street address

University of Najafabad, Imam Khomeini Blvd

City

Najafabad

Province

Isfahan

Postal code

۸۵۱۴۱۴۳۱۳۱

Approval date

2024-04-25, 1403/02/06

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1403.048

Health conditions studied

1

Description of health condition studied

Antisocial Behavior, Emotion Regulation, Psychological Well-being

ICD-10 code

6D10.Z

ICD-10 code description

اختلال شخصیت ضداجتماعی

Primary outcomes

1

Description

The primary outcome variable is the score of antisocial behaviors, which is measured using the Robinson and O'Leary-Kelly Antisocial Behavior Questionnaire. Changes in the score will be evaluated before and after the intervention to assess the effectiveness of schema therapy.

Timepoint

The measurement of outcome variables will be conducted at two time points: before the intervention (at the beginning of the study) and after the completion of therapy sessions (following 10 weekly sessions).

Method of measurement

The measurement of the score of antisocial behaviors is conducted using the Robinson and O'Leary-Kelly Antisocial Behavior Questionnaire

2

Description

Emotion Regulation Score: This variable is measured using the Cognitive Emotion Regulation Questionnaire (CERQ) developed by Garnefski and Kraaij. Changes in the score are assessed before and after the therapeutic intervention.

Timepoint

The emotion regulation score will be measured at two time points: before the intervention (at the beginning of the study) and after the completion of therapy sessions (following 10 weekly sessions).

Method of measurement

The emotion regulation score will be measured using the Garnefski and Kraaij's Cognitive Emotion Regulation Questionnaire (CERQ).

3

Description

"Psychological well-being is measured using the Ryff Psychological Well-being Questionnaire. Changes in the scores of this questionnaire will be examined before and after the therapeutic intervention."

Timepoint

"Psychological well-being scores are measured at two time points: before the intervention (at the beginning of the study) and after the completion of the therapy sessions (following 10 weekly sessions)."

Method of measurement

"The Ryff Psychological Well-being Questionnaire is used

to assess psychological well-being scores."

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in this group will receive schema therapy. The intervention consists of 10 weekly sessions, each lasting 90 minutes, conducted by a trained psychologist. These sessions are designed based on Young's schema therapy model and focus on identifying maladaptive schemas, restructuring thought patterns, and enhancing emotion regulation strategies.

Category

Behavior

2

Description

Control group: The control group will not receive any intervention and will only serve as a baseline comparison to evaluate the effects of schema therapy in the intervention group. Their scores on psychological well-being, emotional regulation, and antisocial behavior will be measured at the start and after the completion of the therapeutic sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Central Prison of Shahrekord

Full name of responsible person

Hamidreza Heydari

Street address

Sarvestan 3 St., Kooshesh Sharghi St., Sanat St.,
Sanat Industrial Hub, Shahrekord

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Shahrekord

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arezo Vasili

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods
Town

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Farima Fathi

Position

Master's student in clinical psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Full name of responsible person
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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

"Effectiveness of Schema Therapy on Antisocial Behavior, Emotion Regulation, and Psychological Well-being of Female Prisoners." The dataset includes anonymized participant data, focusing on key outcome measures such as antisocial behavior, emotion regulation, and psychological well-being. The dataset is derived from standardized questionnaires like Ryff's Psychological Well-being (2002), the Robinson & O'Leary-Kelly Antisocial Behavior Scale (1998), and the Garnefski & Kraaij Cognitive Emotion Regulation Questionnaire (2006).

When the data will become available and for how long

the dataset will be accessible starting six months after the publication of the research results. Access will remain open for a period of two years.

To whom data/document is available

the dataset will be available to academic researchers affiliated with universities and research institutions. Requests from researchers in non-academic sectors will be evaluated on a case-by-case basis.

Under which criteria data/document could be used

the dataset is provided for academic research purposes, such as replication of results, meta-analysis, and further studies on the effectiveness of schema therapy. Usage must comply with data protection regulations, and no attempt to re-identify participants is allowed.

From where data/document is obtainable

Name: Abbas Mokhtari Email: Mokhtari_20001@yahoo.com Phone Number: +98 9132894600 Name: Farima Fathi Hafshejani Email: psyfathii@gmail.com Phone Number: +98 9100865650

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

Requests for data access will be reviewed within 30 days. Approved applicants will receive a data-sharing agreement, outlining the terms and conditions for using the dataset. Upon signing, the dataset will be made available.

Comments

No additional fees will be charged for data access. Researchers are encouraged to cite the dataset in any publications resulting from its use.