Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

The Effect of Counseling Based on Dialectical Behavior Therapy on the Intention of High-Risk Behavior in female Prisoners in Ahvaz

Protocol summary

Study aim

The effect of counseling based on dialectic behavior therapy on intention to high-risk behaviors among female prisoners in Ahvaz. -the effect of counseling based on dialectic behavior therapy on: - attitude to high-risk behaviors - subjective norms to high-risk behaviors -perceived control to high-risk behaviors - intention to sexual high-risk behaviors - intention to substance abuse - intention to violence

Design

This research is a controlled trial. 60 eligible female prisoners will be selected and randomly assigned to two groups of 30 (30 in the intervention group and 30 in the control group) using a four block-based method.

Settings and conduct

The participants are female prisoners in the serious crimes ward of Sepidar prison in Ahvaz. after obtaining written informed consent, the questionnaire will be filled by two groups before and after the intervention. intervention group will take part in 8 weekly group counseling sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Being literate; 2- Having a court verdict of committing a felony and having at least three months left until the end of the sentence. 3- at least two item scored3 or more at questionnaire exclusion criteria: 1- Suffering from a mental illness (bipolar disorder, attention deficit disorder) according to medical records; 2- Incomplete response to the questionnaire; 3- Absence more than two sessions.

Intervention groups

The intervention group are women undergoing dialectical behavior therapy (DBT) counseling. eight weekly counseling sessions will be hold at the counseling room for groups of 6-8 woman. the control group will receive only the routines.

Main outcome variables

attitudes to high risk behaviors-subjective norms to high risk behavior-perceived control to high risk behavior-intention to substance abuse- intention to sexual high risk behavior- intention to violence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250821066936N1**
Registration date: **2026-02-06, 1404/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-06, 1404/11/17**
Update count: **0**

Registration date

2026-02-06, 1404/11/17

Registrant information

Name

Farydeh Shomeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 2242

Email address

ferrysho32@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2026-05-20, 1405/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Counseling Based on Dialectical Behavior Therapy on the Intention of High-Risk Behavior in female Prisoners in Ahvaz

Public title
The Effect of Counseling Based on Dialectical Behavior Therapy on the Intention of High-Risk Behavior in female Prisoners .

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Being literate. . Having a court verdict of committing a felony and having at least three months left until the end of the sentence. at least 2 Item with score 3 at the questionnaire of intention to high risk behavior
Exclusion criteria:
Suffering from a mental illness (bipolar disorder, attention deficit disorder) according to medical records Incomplete response to the questionnaire Absence more than two counseling sessions

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
participants will be individually and randomly assigned to intervention or control groups in blocks of four. The randomization process will be performed by a person who is not belonged to research team using Sealed 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
Ethics Committee of Ahvaz University of Medical sciences
Street address
Ethics Committee of Ahvaz Jundishapur University of Ahvaz, Golestan Boulevard, Esfand street.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794

Approval date
2025-07-15, 1404/04/24

Ethics committee reference number
IR.AJUMS.REC.1404.202

Health conditions studied

1

Description of health condition studied
High Risk behavior

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary outcome of this trial is intention of female prisoners who intend to engage in high-risk behaviors."

Timepoint
Pre- and post-intervention test

Method of measurement
Researcher-made high-risk behavior questionnaire

Secondary outcomes

1

Description
This study does not have a secondary outcome variable.

Timepoint
Before and after the study

Method of measurement
researcher-made questionnaire on intention to engage in high-risk behavior

Intervention groups

1

Description
Intervention group: Intervention group: In this study, participants in the intervention group will undergo group counseling based on dialectical behavior therapy (DBT). Dialectical behavior therapy is a structured approach to cognitive-behavioral therapy designed to increase emotion regulation skills, distress tolerance, promote mindfulness, and improve interpersonal skills. The

intervention is implemented in groups of 6 to 8 people by a trained researcher in the counseling room of Ahvaz Women's Prison. This program consists of 8 face-to-face sessions held one a week, each session lasting 90 to 60 minutes. The content of the sessions includes training and practice of mindfulness skills, distress tolerance, emotion regulation, and communication and interpersonal skills. The sessions will be conducted in a counseling room, with appropriate group chairs and arrangements, printed educational pamphlets, standard pre- and post-test questionnaires, and a whiteboard. This study is non-pharmaceutical and does not use any chemicals or drugs.

Category

Behavior

2

Description

Control group: The female prisoners in the control group (30 people) will not receive any additional intervention (DBT) and will only receive the usual and routine prison care (health services, general counseling available in the prison, etc.) as in the intervention group. After the study period is completed and post-test data are collected, a brief educational pamphlet on high-risk behaviors and prevention methods will be provided to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sepidar prison in Ahvaz

Full name of responsible person

Akram Nadery

Street address

Sepidar prison Sepidar, Ahvaz, Khozestan,

City

Ahvaz

Province

Khouzestan

Postal code

6138673353

Phone

+98 61 3227 0235

Email

ferrysho32@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Abdolla rafee

Street address

AAhvaz Jundishapur university of Medical Sciences, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3311 4115

Email

hnfo@ajumsac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farydeh Shomeili

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Jundishapur University of Medical Sciences and Health Services, Golestan Boulevard, Highway Golestsn

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3311 4115

Email

ferrysho32@jmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Mozhgan Javadnoori

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Ahvaz Jundishapur University of Medical Sciences
Golestan Boulevard, Esfand street

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3314 0000

Email
mojganjavadnoori@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Farydeh Shomeili

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Jundishapur University of Medical Sciences and Health Services, Golestan Boulevard, Golestan Highway,

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8538

Email
ferrysho32@jmail.com

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
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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
after ending the study, findings will be published as a journal paper

When the data will become available and for how long
after the study was ended

To whom data/document is available
researchers

Under which criteria data/document could be used
research

From where data/document is obtainable
Dr. Mozhgan Javadnoori

What processes are involved for a request to access data/document
via email to principal investigator

Comments