

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

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

#### Protocol summary

intention to substance abuse- intention to sexual high risk behavior- intention to violence

#### 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 scored 3 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-

#### 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

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+98 61 3227 0235

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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

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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

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Mozghan Javadnoori

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## **Person responsible for updating data**

### **Contact**

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student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## **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. Mozghan Javadnoori

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

via email to principal investigator

**Comments**