

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Assessing the impact of prison environmental design on prisoners' behavioral mental health and reducing violence-related harms

Protocol summary

Study aim

Determining and comparing the average mental-behavioral health scores of male and female prisoners in Shahrekord Prison, before and after implementing an environmental design intervention, in the intervention and control groups.

Design

A controlled clinical trial with parallel groups, no blinding, randomized, phase 2, 94 subjects. A random number table will be used for randomization.

Settings and conduct

The study will be conducted using a pre-test-post-test method among prisoners in Shahrekord Central Prison. Participants will be divided into two intervention and control groups, and the evaluation of psychological, behavioral, and prison environmental variables will be conducted using standard and researcher-made questionnaires before and after the implementation of the prison environmental design.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18, ability to answer questions, length of stay in prison equal to the pre-test and post-test periods. Exclusion criteria: Severe mental disorder or documented acute crisis, severe speech/hearing impairment that prevents response, active use of psychotropic substances/medications that interfere with results, very serious crimes with security restrictions.

Intervention groups

Intervention group: Received prison environmental design Control group: Did not receive prison environmental design

Main outcome variables

Average mental health score (depression, anxiety and stress) Average aggression score Average prisoners' environmental perception score Average prison environmental objective assessment score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040555N5**

Registration date: **2026-02-17, 1404/11/28**

Registration timing: **prospective**

Last update: **2026-02-17, 1404/11/28**

Update count: **0**

Registration date

2026-02-17, 1404/11/28

Registrant information

Name

Zohreh Karimiankakolaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3336 1047

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-19, 1405/02/29

Expected recruitment end date

2026-10-21, 1405/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the impact of prison environmental design on prisoners' behavioral mental health and reducing violence-related harms

Public title

Assessing the impact of prison environmental design on prisoners' behavioral mental health and reducing violence-related harms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 Prison stay equal to pre-test and post-test period Ability to respond

Exclusion criteria:

Severe documented psychiatric disorder or acute crisis
Severe speech/hearing impairment impeding responsiveness
Active use of psychoactive substances/medications interfering with results
Very serious crimes with security restrictions

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, due to the nature of the intervention (environmental design at the level of physical spaces), the randomization unit at the prison ward level will be considered as a cluster. In order to control the effect of potential confounding variables such as [e.g., ward population density, security or semi-security status of the ward], the existing wards will first be stratified (classified) based on these variables. Then, in each stratum, the wards will be randomly assigned to two intervention groups (recipients of the new environmental design) and control (with usual environmental conditions) using a random number table. To comply with the principle of allocation concealment, the randomization sequence will be prepared by someone outside the implementation team and kept in sealed, opaque envelopes to avoid bias in ward selection. Also, to reduce bias in the evaluation of the results, the evaluators of mental health and behavioral outcomes will be unaware of the ward allocation status (intervention or control).

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, Shahrekord Branch

Street address

University Street, Islamic Azad University of Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

881373339

Approval date

2026-01-14, 1404/10/24

Ethics committee reference number

IR.IAU.SHK.REC.1404.331

Health conditions studied

1

Description of health condition studied

Behavioral mental health

ICD-10 code

Z65

ICD-10 code description

Problems related to other psychosocial circumstances

Primary outcomes

1

Description

Mean score mental health (depression, anxiety, stress)

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Mental Health Questionnaire (DASS-21)

Secondary outcomes

1

Description

Mean score of aggression

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Bass and Perry Aggression Questionnaire (AQ)

2

Description

Mean score of Prisoners' Environmental Perception

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Prisoners' Environmental Perception Questionnaire

3

Description

Mean of score Objective Correctional Environment

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Objective Correctional Environment Checklist

Intervention groups

1

Description

In the intervention group, prisoners residing in wards that are subject to the environmental design package will receive a 4-week intervention. The package will be designed and validated by a multidisciplinary team (architect, psychologist, social worker, and health) based on pre-test findings and valid scientific evidence. Interventions include optimizing lighting using warm white light to regulate circadian rhythms, painting spaces with calming blue and green colors to reduce irritability, creating green corners with natural plants or nature images to connect with the natural environment, improving the meeting room to reduce stress and improve emotional connection with the family, and organizing common spaces with standard shelving to reduce visual clutter. All changes will be implemented in coordination with prison authorities and in full compliance with security considerations.

Category

Behavior

2

Description

Control group: No environmental design intervention is implemented in this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Central Prison

Full name of responsible person

Mojtaba Khoram

Street address

Shariati Street, Chaharmahal and Bakhtiari Province Prisons Organization

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Chahar-Mahal-va-Bakhtiari

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Email

mojtabakhorram60@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chaharmahal and Bakhtiari Province Prisons Organization

Full name of responsible person

Mojtaba Khoram

Street address

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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

Chaharmahal and Bakhtiari Province Prisons Organization

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zohreh Karimiankakolaki

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some data, such as information related to the main outcome or the like, can be shared after being de-identified.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Non-personally identifiable data from this study will be made available to researchers solely for the purpose of conducting advanced statistical analyses, including secondary analyses, combined analyses with other studies, and complementary analyses with more advanced methods. Applicants for data and documentation must be qualified researchers (faculty members, postdoctoral researchers, or graduate students) from accredited academic or research institutions and must submit their application along with a written research proposal that has been approved by the ethics committee of the applicant institution. Acceptance and signing of a confidentiality and data use agreement is mandatory, according to which applicants undertake to use the data only for approved research purposes, refrain from any attempt to re-identify individuals, not provide the data to third parties, and provide the final results to the main research team. The use of documentation such as questionnaires and intervention protocols is permitted solely for research and educational purposes and any commercial use is

prohibited. In all publications based on this data, it is mandatory to cite the original source and reference the basic study.

From where data/document is obtainable

Principal Investigator Zohreh Karimiankakolaki
Zohrehkarimian68@gmail.com

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

Send an email to the principal investigator stating the reasons and conditions and respond within one working week.

Comments