# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Oct 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)

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+98 38 3336 1047

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**Recruitment status**
**Recruitment complete**

**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, Shaherekord 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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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Chaharmahal and Bakhtiari Province Prisons Organization
**Full name of responsible person**
Mojtaba Khoram
**Street address**
Shariati Street, Chaharmahal and Bakhtiari Province Prisons Organization
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mojtabakhorram60@gmail.com
**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**