

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of spiritual care and aromatherapy on anxiety and sleep patterns of emergency referrers to Korsestan province prisons clinics

Protocol summary

Study aim

Comparison of the Effect of Spiritual Care and Aromatherapy on Anxiety and Sleep Pattern of Emergency referrer to Provincial Clinics

Design

Experimental group 1 received lavender extract with aromatherapy for 20 minutes with spiritual care. In the group, 2 spiritual ritual interventions included providing short texts of the Holy Quran emphasizing patience and prayer. Next, two storybooks related to the above verses, patience and restraint will be provided. Finally group discussion (reading the Quran and story) will be held in limited groups (about 3-5 people).

Settings and conduct

Interventions in three of the three alternate 5-day periods (couple or individual) for each of the mentioned samples will be conducted for approximately 20 minutes, with the guidance of the researcher and with the assistance of the prison cultural representatives, for each of the sample inmates at approximately 7-9 pm. Group 3 (control group) receives only routine care in prison.

Participants/Inclusion and exclusion criteria

Men residing in prisons in Kurdistan province aged between 30 and 60 years. Has the physical and mental ability to read and write to answer questions

Intervention groups

Group 1 (Spiritual Care with Aromatherapy) and Number 2 for Group 2 (Spiritual Care) and Group 3 (Control Group)

Main outcome variables

Anxiety and sleep pattern of the study samples will be measured three times before and one month after the intervention using Spielberger Anxiety Inventory and Pittsburgh Sleep Quality Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045659N2**

Registration date: **2020-01-27, 1398/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-27, 1398/11/07**

Update count: **0**

Registration date

2020-01-27, 1398/11/07

Registrant information

Name

Sefollah Alaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 23 3365 4190

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alaei@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of spiritual care and aromatherapy on anxiety and sleep patterns of emergency referrers to Korsestan province prisons clinics

Public title

Comparison of the Effect of Spiritual Care and Aromatherapy on Anxiety and Sleep Pattern of Emergency referrers to Prison Clinic

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Men residing in prisons in Kurdistan province Adequate literate, physically and mentally capable to answer the questions No Mental Illness (Based on Documentation or Doctor's Approval) No record of criminal problems such as murder No history of allergies and respiratory diseases, according to the patient No previous record of being in prison more than once

Exclusion criteria:

History of receiving painkillers and narcotic drugs 24 hours in advance Prisoners with olfactory problems Anxiety score less than 31 (mild anxiety)

Age

From **30 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are divided into three groups by simple random method. The groups are separated by giving them a random code, such as number one for group 1 (spiritual care with aromatherapy) and number two for group 2 (spiritual care) and number 2. Three will be performed for group 3 (control group).

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

The aforementioned proposal was submitted by the Forty-fourth Century Ethics Committee Of Semnan Uni

Street address

Semnan University of Medical Sciences, Damghan Road,

City

Semnan

Province

Semnan

Postal code

3514993437

Approval date

2019-12-16, 1398/09/25

Ethics committee reference number

IR.SEMUMS.REC.1398.238

Health conditions studied

1

Description of health condition studied

Anxiety and stress

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety

Timepoint

Anxiety will be measured three times before, immediately and one month after the intervention.

Method of measurement

Anxiety will be measured by using the Spielberger Anxiety Inventory.

2

Description

The sleep patterns

Timepoint

The sleep patterns of the study samples will be measured three times before, immediately before and one month after the intervention.

Method of measurement

The sleep patterns of the study samples will be measured by using of the Pittsburgh Sleep Quality Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group 1, 2 drops of lavender extract will be impregnated with 2 x 2 gas and attached to the prisoners' collar. This aromatherapy treatment was performed for 20 minutes inmates in 3 intermittent 5-day phases with spiritual care. Aromatherapy for the third stage is using a fumigation machine containing 2 liters of water and 20 drops of lavender extract.

Category

Lifestyle

2

Description

Intervention group: In group, 2 interventions included providing short texts of the Holy Qur'an that emphasized patience and prayer. It should be explained that the main focus is on the 10 verses of the Holy Quran (which have been recommended for patience and prayer). In addition, the beautiful text of the above verses will be provided to the participants and, if possible, an audio file containing the above verses will be provided. Next, two storybooks, one related to the above verses and the other a short story about patience and restraint, will be provided. In the research process, participants will be encouraged to share the story with others. To do this, meetings will be held in limited groups (about 3 to 5 people) if the conditions for spiritual intervention (reading the Quran and story) are available. It should be noted that the 3-step intervention mentioned will be performed in 3 alternate 5-day stages (couple or individual) for each of the mentioned samples. The mentioned intervention is provided for about 20 minutes under the guidance of the researcher and with the assistance of the prison cultural representatives, for each of the sample inmates at approximately 7-9 pm.

Category

Lifestyle

3

Description

Control group: Group 3 (control group) receives only routine care in prison

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Prisons in Kurdistan Province

Full name of responsible person

Milad Abdul Maleki

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Km 12 Hamedan road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Reza Askari

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Milad Abdul Maleki

Position

Nursing master Graduate Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Sefollah Alaei

Position

Assistant Professor Semnan University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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

Yes - There is 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

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

Clinical Study Report

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

Analytic Code

No - There is not 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

The data are related to the anxiety and sleep patterns of prisoners referred to Kurdistan Prison Clinic receiving spiritual care and in the other group spiritual care with aromatherapy.

When the data will become available and for how long

Access to a portion of this information will be contain of the published articles, which will be released with the permission of the Semnan University of Medical Science and Kurdistan prisons Managers.

To whom data/document is available

Semnan University of Medical Sciences and Prisons Organization, if the article is published, everyone can access this section of information.

Under which criteria data/document could be used

Planning for improving prisoners 'health as well as conducting studies on prisoners' health

From where data/document is obtainable

Semnan University of Medical Sciences and Prisons Organization

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

Written request to Semnan Prison Organization and Medical University

Comments