

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Assessment of the Effect of a Nursing Care Program Based on the Roy's Adaptation Model on the Quality of Sleep of People with Opioid Abuse under Methadone Maintenance Therapy

Protocol summary

Study aim

Determining the effect of a Nursing Care Program Based on the Roy's Adaptation Model on the Quality of Sleep of People with Opioid Abuse

Design

Intervention group: the researcher uses the Assessment form based on the Roy's Adaptation Model, conducts and evaluates the research and recognition based on the nursing process in the test group, and evaluates the nursing process based on the Roy model for them for three months. He also completes the questionnaires immediately before the intervention and three months after the start of the study. Comparison group: During this period, they will receive the prescribed routine treatments. They only complete the mentioned questionnaires in the pre-test and post-test stages.

Settings and conduct

the samples from the Article 16 Injury Reduction Center of Isfahan will be selected by available sampling method and again by random sampling method using block classification will be assigned to two groups. The intervention group will be cared for for 3 months based Roy's Adaptation Model.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be able to read and write. Based on his report, he should have a suitable general situation to complete the questionnaire. Have more than six months of continuous opioid abuse Exclusion criteria: Having severe physical and mental illnesses Participate in another similar study simultaneously

Intervention groups

A clinical trial with a control group, with parallel, randomized groups, on 60 patients with opioid abuse who were randomly divided into two groups of experimental and control.

Main outcome variables

Quality of Sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020108N6**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3778 2856

Email address

musarezaie@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the Effect of a Nursing Care Program Based on the Roy's Adaptation Model on the Quality of Sleep of People with Opioid Abuse under Methadone Maintenance Therapy

Public title

Assessment of the Effect of a Nursing Care Program Based on the Roy's Adaptation Model on the Quality of Sleep of People with Opioid Abuse

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Be able to read and write. Based on his report, he should have a suitable general situation to complete the questionnaire. Have more than six months of continuous opioid abuse

Exclusion criteria:

Having severe physical and mental illnesses Participate in another similar study simultaneously

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is a block with size 4. Randomization unit: individual. Random allocation software. Random chain concealment is by placing patient codes in opaque 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

Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan University of

Street address

Research Ethics Committee, Faculty of Nursing and

Midwifery, Isfahan University of Medical Sciences, Hezar Jarib St, Isfahan, Isfahan Province, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.088

Health conditions studied

1

Description of health condition studied

Drug addiction

ICD-10 code

Z63.72

ICD-10 code description

Alcoholism and drug addiction in family

Primary outcomes

1

Description

Quality of Sleep

Timepoint

Immediately before the intervention and three months after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the researcher uses the Assessment form based on the Roy's Adaptation Model, conducts and evaluates the research and recognition based on the nursing process in the test group, and evaluates the nursing process based on the Roy model for them for three months.

Category

Other

2

Description

Control group: During this period, they will receive the prescribed routine treatments. They only complete the mentioned questionnaires in the pre-test and post-test stages.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Harm Reduction Center Article 16 of the city of Isfahan

Full name of responsible person

Amir Musarezaie

Street address

Article 16 Damage Reduction Center, Qaleh Shor Road, Baharstarn, Isfahan, Iran

City

Isfahan

Province

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81746-73461

Phone

+98 31 3668 0048

Email

musarezaie@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Building number 4, Isfahan University of Medical Sciences, Hezar Jarib St, Isfahan, Isfahan Province, Iran

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Amir Musarezaie

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jarib St, Isfahan, Isfahan Province, Iran

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Faculty instructor

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

musarezaie@nm.mui.ac.ir

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amir Musarezaie

Position

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Email

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

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

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