Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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
Isfehan
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

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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
Amir Musarezair

Position
Faculty instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir Musarezaie

Position
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Street address
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Province
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Email
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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
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