

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Effect of Roy Adaptation Model on the Quality of Life of People with Opioid Abuse under Methadone Maintenance Therapy

Protocol summary

Study aim

Determining the Effect of "Roy" Adaptation Model on the Quality of Life of People with Opioid Abuse under Methadone Maintenance Therapy

Design

Single-blind clinical trial study, Selection of available samples from among 72 patients, Assigning samples to two groups of test and control randomly with a random number table

Settings and conduct

After receiving a letter of introduction from the Vice Chancellor for Research of Isfahan University of Medical Sciences and the management of the Article 16 Harm Reduction Center in Isfahan, sampling was done according to the inclusion criteria among patients residing in that center. The purpose and method of research was explained for the samples included in the study. Patients entered the study with informed consent.

Participants/Inclusion and exclusion criteria

Be able to read and write; Do not have severe physical and mental illnesses; Have the interest and satisfaction to participate in this research

Intervention groups

Based on the Roy adaptation model in the intervention group, after assessment and recognition, the nursing process was performed. The control group benefit from the interventions after the evaluation.

Main outcome variables

Changing the quality of life of people with opioid abuse under methadone maintenance therapy; Changing the costs of short term and long term interventions in people with opioid abuse under methadone maintenance therapy; Changing the quality of nursing care in people with opioid abuse under methadone maintenance therapy

General information

Reason for update

Changes considered by the Vice Chancellor for Research;
Changes considered by the University Ethics Committee

Acronym

IRCT registration information

IRCT registration number: **IRCT20211121053121N1**

Registration date: **2021-11-26, 1400/09/05**

Registration timing: **prospective**

Last update: **2022-04-28, 1401/02/08**

Update count: **1**

Registration date

2021-11-26, 1400/09/05

Registrant information

Name

Seyed Abbas Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7504

Email address

a_hoseini@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2021-12-24, 1400/10/03

Actual recruitment start date

2021-12-22, 1400/10/01

Actual recruitment end date

2021-12-24, 1400/10/03

Trial completion date

2022-03-20, 1400/12/29

Scientific title

Effect of Roy Adaptation Model on the Quality of Life of

People with Opioid Abuse under Methadone Maintenance Therapy

Public title

Effect of Roy Adaptation Model on the Quality of Life of People with Opioid Abuse under Methadone Maintenance Therapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Be able to read and write Do not have severe physical and mental illnesses Have the interest and satisfaction to participate in this research

Exclusion criteria:

Try to quit opium less than twice Has no history of using private or public addiction treatment centers

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were randomly divided into intervention and control groups with a random number table. So that the method of reading numbers by the researcher from top to bottom and even numbers were assigned to the intervention group and odd numbers to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients in the intervention and control groups did not know the difference between routine interventions and interventions in this study.

Placebo

Not used

Assignment

Parallel

Other design features

The present study is a single-blind clinical trial and includes two intervention and control groups. The whole study was conducted over a period of three months. The control group was evaluated in the first month and a half and the intervention group in the second month and a half.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St., Isfahan University of Medical Sciences, School of Nursing, Management and Rehabilitation

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.159

Health conditions studied

1

Description of health condition studied

Quality of Life

ICD-10 code

Z72.9

ICD-10 code description

Problem related to lifestyle, unspecified

2

Description of health condition studied

Opioid Abuse

ICD-10 code

F11.188

ICD-10 code description

Opioid abuse with other opioid-induced disorder

3

Description of health condition studied

Methadone Maintenance Therapy

ICD-10 code

T40.3X5D

ICD-10 code description

Adverse effect of methadone, subsequent encounter

Primary outcomes

1

Description

Quality of life in people with opioid abuse under methadone maintenance therapy

Timepoint

Before intervention and immediately after intervention

Method of measurement

Short Form (36) Health Survey

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention was based on the Roy adaptation model in four areas: physiological, self-perception, role-playing and independence, and belonging based on observation, interview, and measurement by the researcher. After determining the maladaptation, the interventions in the framework of the nursing process were continued as follows: 1.

Determining standard nursing diagnoses that include maladaptive behaviors and behaviors that may be maladaptive in the future. 2. Planning and setting goals, in which the goals were determined on a need-by-case basis. Then the necessary nursing care to achieve the desired goals was identified. Nursing care included interventions in which the primary, underlying, and residual stimuli were modified until the primary stimulus was in the direction of individual adjustment. 3.

Execution, in which the researcher acted as an external moderator to expand the scope of individual adaptation and establish a consistent behavior. The researcher changed or adjusted stimuli and conditions, not persons, thus promoting the relationship of individuals with the environment and was effective in maintaining health. At this stage, based on the needs of patients, interventions were performed individually or in groups. 4. Evaluation, in which the researcher re-evaluates pre-defined goals and plans. At this stage, the researcher examined the amount of achievement of goals and determined the degree of adaptation in the areas of health and disease.

Category

Rehabilitation

2

Description

Control group: After the evaluation in the intervention group, if the interventions will be useful, the necessary training, recommendations and interventions will be provided to the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Harm Reduction Center Article 16

Full name of responsible person

Soheyla Pezeshkzad

Street address

Qaleh Shor Road, south of Isfahan city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib St.

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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

Seyed Abbas Hoseini

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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