

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effectiveness of applying continuous care model on lapse and craving of patients that are treated with methadone maintenance therapy in Razi Educational and Treatment Center of Urmia 2016

Protocol summary

Summary

Objective: To determine the effectiveness of applying continuous care model on lapse and craving of patients that are treated with methadone maintenance therapy in Razi Educational and Treatment Center of Urmia in 2016. **Design:** The current study is an experimental study. The population of the study is the drug-dependent patients who are treated with methadone maintenance therapy in Razi Educational and Treatment Center of Urmia. The Inclusion criteria for this study are: being between 18-48 years old, the diagnostic criteria for opioid dependence, according to psychiatrist, passing at least 3 months of being treated with methadone maintenance therapy and residence in the city of Urmia and the exclusion criteria are psychological disorders that require hospitalization, use of antipsychotics and anticonvulsants at the time of entering the study and lack of willingness or ability to participate in the continuous care meetings. The sample size is 95 persons, which will be randomly assigned to one intervention group and one control group. For randomization of intervention and control groups we use sealed envelopes that containing the names of intervention and control groups. **Intervention:** We will implement continuous care model. This model will comprise of four steps: Orientation, Sensitization, Control and Evaluation. This model will be executed on the intervention group. Each patient will participate in four sessions individually. During the study, the patients will be under continuous care directly or with a phone call by the end of three months. The control group only will receive the current care. **Main outcome variable:** Reduction of lapse and craving of patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042816564N6**

Registration date: **2016-06-08, 1395/03/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-08, 1395/03/19

Registrant information

Name

Molood Radfar

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1275 4961

Email address

radfar.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Science

Expected recruitment start date

2016-05-30, 1395/03/10

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of applying continuous care model on lapse and craving of patients that are treated with methadone maintenance therapy in Razi Educational and Treatment Center of Urmia 2016

Public title

The effectiveness of applying continuous care model on lapse and craving of patients that treated are with methadone maintenance therapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being between 18-48 years old, the diagnostic criteria for opioid dependence, according to psychiatrist, passing at least 3 months of being treated with methadone maintenance therapy and residence in the city of Urmia Exclusion criteria: Psychological disorders that require hospitalization, use of antipsychotics and anticonvulsants at the time of entering the study and lack of willingness or ability to participate in the continuous care meetings

Age

From **18 years** old to **48 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **95**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences and Health Service, Next Emergency Center, Resalat Blvd

City

Urmia

Postal code

5714783734

Approval date

2016-05-18, 1395/02/29

Ethics committee reference number

ir.umsu.rec.1395.95

Health conditions studied

1

Description of health condition studied

Opioid Dependency

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

2

Description of health condition studied

Cannabis drug dependence

ICD-10 code

F12

ICD-10 code description

Mental and behavioural disorders due to use of cannabinoids

3

Description of health condition studied

Sedative or hypnotic drug dependence

ICD-10 code

F13

ICD-10 code description

Mental and behavioural disorders due to use of sedatives or hypnotics

4

Description of health condition studied

Cocaine dependence

ICD-10 code

F14

ICD-10 code description

Mental and behavioural disorders due to use of cocaine

5

Description of health condition studied

Hallucinogenic drug dependence

ICD-10 code

F16

ICD-10 code description

Mental and behavioural disorders due to use of hallucinogens

Primary outcomes

1

Description

lapse

Timepoint

During the 3 months and 3 months before the study intervention

Method of measurement

Nominal-Lapse and absence check list

2

Description

Craving

Timepoint

before and during the 3 months of intervention

Method of measurement

Craving Questionnaire after leaving

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Continuous Care Model will be implemented on intervention group over a period of 3 months. This model consists of 4 stages which will be done individually. Orientation stage: This stage involves introduction, indicating obviously the objectives and expectations of nurse in the study, determining the expectations of patient, complete the consent, agreement and determining the appointment time and telephone meeting. This stage will be implemented for one session about 20 to 40 minutes. Sensitization stage: At this stage the aim is to involve the patient in the implementation of continuous care and understand the nature of addiction. And also, care consultation will be given about addiction features, substances withdrawal and intoxication signs, how to prevent them, tempting and risk factors and the need to avoid them, the need to continue the treatment and timely and regular visits to addiction treatment center, the importance of physical activity and sport and distraction, healthy relationships and participate in social activities, encourage to use the experiences of treated people, the necessity of leaving bad habits and the importance of continued health behaviors. Counseling and continuous care lead to increase patients' confidence. Control stage: In this stage, the goal is to change fundamentally and persistently the health behaviors in order to protect and promote leaving state. Then, we will continue to have face to face and telephone counseling and control care needs, the process of care, new problems, persistence of health behaviors, and adherence to treatment. Evaluation stage: That is the fourth and final step which will be considered in all stages. At this stage, care process,

successes and failures and respective indices y filling out the questionnaires and recorded clinical findings will be evaluated.

Category

Prevention

2

Description

Orientation stages will be implemented as well as for the control group but will differ in terms of time and expectations and future programs slightly. Because the purpose of the orientation stage to the control group is only encouraging the cooperation in implementing periodical controls to complete the intended data. This group will be controlled and treated with usual and ordinary care approaches that are available in the center.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Razi Academic Psychiatric Hospital

Full name of responsible person

Dr. Rahim Khalilzadeh

Street address

km 3 of salmas road-Razi Academic Psychiatric Hospital-Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences, Vice Chancellor of Research

Full name of responsible person

vice chancellor for research, .urmia University of Medical Sciences

Street address

Next Emergency Center, Resalat Blvd Urmia, University of Medical Sciences and Health Service

City

Urmia

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urmia University of Medical Sciences, Vice Chancellor of Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Postal code

5756115111

Phone

+98 44327549614

Fax

+98 44 3275 4921

Email

Radfar.m@umsu.ac.ir; mradfar1343@gmail.com

Web page address

nm.umsu.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Urmia University of Medical Science

Full name of responsible person

Javad Namazpoor

Position

Nursing Masters student

Other areas of specialty/work**Street address**

No.9- 11Alley- Azari Alley-Taavon 2 eve- Ahandost Blvd -Urmia

City

Urmia

Postal code

5715876663

Phone

+98 44 3346 4788

Fax

+98 44 3272 2931

Email

razi_psychitry@umsu.ac.ir

Web page address

razi.umsu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Urmia University of Medical Science

Full name of responsible person

Javad Namazpoor

Position

Nursing Masters student

Other areas of specialty/work**Street address**

No.9- 11Alley- Azari Alley- Taavon 2 eve- Ahandost Blvd- Urmia

City

Urmia

Postal code

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Phone

+98 44 3346 4788

Fax

+98 44 3272 2931

Email

razi_psychitry@umsu.ac.ir

Web page address

razi.umsu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Faculty of Nursing & Midwifery

Full name of responsible person

Moloud Radfar

Position

PhD of nursing

Other areas of specialty/work**Street address**

No. 24- Fourth alley- 14 m third- rodaky Blvd- Urmia

City

Urmia

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty