

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Study of the effect of giving cervical cancer screening consultation using protection motivation theory to addicted women who consume Methadone on their action to undergo the screening test

Protocol summary

Summary

The aim of this quasi experimental study is to determine the effect of giving cervical cancer screening consultation using protection motivation theory to addicted women attending drug addiction treatment center of Hamadan city in 2015 on their action to undergo the screening test. The inclusion criteria are as follows: passing at least 3 years after the first sexual intercourse or married women over 21 years old; not having had Pap test in the past three years; not to suffer cervical cancer; and to consume Methadone. The exclusion criteria are unwillingness to continue participation in the study and receiving formal training by other organizations during the study. The samples size will be determined by census. Participants will be matched in accordance to their age and duration of addiction. Also, the participants will be divided into control and experimental groups based on random permutation method. The objectives of this study will be described to participants by the researcher. The meeting duration will be 45 to 60 minutes. Explaining the study purpose will be based on the GATHER counseling. Also consent form and questionnaire will be filled out by the participant or by the researcher through an interview if the participant is illiterate. After filling out the forms, people will be counseled and then, questionnaire will be completed again. Also this method will be done for the control group but they will not be trained. After one or two months, behavior of both groups will be assessed. This assessment will be conducted in personal meeting by examining the test sheet. After that, the questionnaire will be given to the two groups. After completion of the study, the control group will receive counseling service.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052722448N1**

Registration date: **2015-08-12, 1394/05/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-12, 1394/05/21

Registrant information

Name

Elham Fakouri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 249 4556

Email address

e.fakouri@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2015-06-08, 1394/03/18

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of giving cervical cancer screening consultation using protection motivation theory to addicted women who consume Methadone on their action to undergo the screening test

Public title

Study of the effect of giving cervical cancer screening consultation using protection motivation theory to addicted women attending drug addiction treatment center on their action to undergo the screening test

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: The inclusion criteria for eligibility into the study are as follows, passing at least 3 years after the first sexual intercourse or married women above 21 years; not having had Pap test in the past three years; not to suffer cervical cancer and to consume Methadone. Also the participants will be studied with their consent. Exclusion criteria: Exclusion criteria are unwillingness of the community members to continue participating in the study and formal training by other organizations during the study.

AgeFrom **20 years** old to **100 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The participants will be divided into control and experimental groups based on random permutation method, so that first patient of each group will be selected from drawing lots. Other members of the addicted women community are put in control and experimental groups alternately.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmih Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code**Approval date**

2015-02-28, 1393/12/09

Ethics committee reference number

16/35/9/6389/پ

Health conditions studied**1****Description of health condition studied**

cervical cancer

ICD-10 code

c53

ICD-10 code description

Malignant neoplasm of cervix uteri

2**Description of health condition studied**

consulting

ICD-10 code

Z71.9

ICD-10 code description

Counselling, unspecified

3**Description of health condition studied**

drug addiction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

Primary outcomes**1****Description**

Pap smear and cervical cancer awareness

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

2**Description**

Self efficacy

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

3**Description**

Function

Timepoint

Before the intervention, one to two months after the intervention.

Method of measurement

Observed test papers

4**Description**

Response Efficacy

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

5**Description**

Vulnerability Perceived

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

6**Description**

Perceived severity

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

7**Description**

Response costs

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

8**Description**

Motivation

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

9**Description**

Fear

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

10**Description**

Perceived rewards

Timepoint

Before the intervention, immediately after the intervention, one to two months after the intervention.

Method of measurement

Researcher made questionnaire

Secondary outcomes**1****Description**

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Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Intervention group: The objectives of this study will be described by researcher at a session to the participants courteously and friendly. The meeting time will be 45 until 60 minutes. Explaining the study purpose will be based on the GATHER counseling. The participants will be assured that their information will be published anonymously. After that, questionnaire will be completed. When questionnaire was filled out by the participants, will be asked them about Pap test and their problems on this topic. Educational content that it is based on the structural model of motivation-protect, will be explained to experimental group individually. Educational content is as follow: brief description of the uterus anatomy and the cervix and genital emission, introduce groups who are at risk for cervical cancer (perceived vulnerability), the prevalence and the consequences of the disease (perceived severity), raise awareness about screening, to be referred a doctor at right time, the screening ways (perceived self-efficacy), benefits Pap test, the importance of early diagnosis (effective response) and anticipate problems and cost of the screening (the cost of the response). After that, the participants will be asked to talk about the issues and

their problems. Advisor will explain the available solution. Advisor assists participant with help to decision making. If it be needed to more explanation, the benefits and costs of Pap test will be explained to participant. After consultation, questionnaire will be given to the participants again. We will request from participant for refer to us after one or two months in order to their behavior is examined.

Category

Early detection

2

Description

Control group: Members of the control group will be selected in accordance with inclusion criteria. They will receive the questionnaire without any training. Behavior of both groups will be assessed after one month. This assessment will be conducted in personal meeting by observation of the test sheet. The questionnaire will be given to member of the control group, again. After completion of the study, the control group will receive counseling service.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Hananeh counseling center

Full name of responsible person

Dr.Atefeh Tavana

Street address

Number 190, Mirzadeh Eshgi street, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person

Dr.Shamsaiee

Street address

No. 307, Fahmideh Street, Hamadan University of Medical sciences, Hamadan

City

Hamadan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Hamadan University of Medical Sciences

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

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing & Midwifery Faculty; Hamadan University of Medical Sciences.

Full name of responsible person

Elham Fakouri

Position

Student

Other areas of specialty/work

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Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Rafat Bakht

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Person responsible for updating data

Contact

Name of organization / entity
Nursing & Midwifery Faculty; Hamadan University of
Medical Sciences.
Full name of responsible person
Elham Fakouri
Position
Master Student of Midwifery Advisory
Other areas of specialty/work
Street address
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City
-
Postal code
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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