

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The Effect of Educational Intervention Based on Information- Motivation and Behavioral Skills(IMB) Theory on Sexual Assertiveness and Self efficacy of Women with High-risk Sexual Behaviors

Protocol summary

Study aim

Determining the Impact of Educational Intervention Based on Information- Motivation and Behavioral Skills(IMB) Theory on Sexual Assertiveness and Self efficacy of Women with High-risk Sexual Behaviors

Design

Clinical trial with control group, with parallel groups, one blind, randomized

Settings and conduct

This study will be conducted on 70 women with sex risky behaviors at two DIC centers. each center will be allocated to one of intervention and control groups. In each group 35 patients are entered in the study.

Participants/Inclusion and exclusion criteria

she should have a written informed consent. be Iranian. be Muslim. she shouldn't have speech, audio or accent problems that prevent communication with the researcher. she should be 18 to 50 years old. she should not have psychological disease (according to medical records) that impedes concentration and education. she should have at least one of the following: prostitution in exchange for money; Multiple sexual partners in the last year; Having a sex partner with more than one partner; Having sex partners who inject drugs; History of drug injection.

Intervention groups

Individuals are entered into the study after obtaining informed consent; upon completion of relevant questionnaires, intervention group pass four educational courses based on IMB Theory with 2-3 days intervals; post-test and follow-up are immediately after completing training sessions and 8 weeks after completing initial questionnaires, respectively. Group control has not received intervention by researcher and at the same time they complete related questionnaires like the intervention group, and finally they receive a compact training pamphlet of education.

Main outcome variables

Sexual Assertiveness and Self efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180525039826N1**

Registration date: **2018-09-06, 1397/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-06, 1397/06/15**

Update count: **0**

Registration date

2018-09-06, 1397/06/15

Registrant information

Name

Marzieh Hassanshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3432 3301

Email address

hasanshahim941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The Effect of Educational Intervention Based on Information- Motivation and Behavioral Skills(IMB) Theory on Sexual Assertiveness and Self efficacy of Women with High-risk Sexual Behaviors

Public title
The Effect of Educational Intervention on Sexual Assertiveness and Self efficacy of Women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

she should have a written informed consent to engage in research. she should be Iranian. she should be Muslim. she should be 18 to 50 years old. According to the case at the center or personal statements, she should have at least one of the following: prostitution in exchange for money, multiple sexual partners in the last year, having a sex partner with more than one partner, having sex partners who inject drugs, history of drug injection

Exclusion criteria:

she has speech, audio or accent problems that prevent communication with the researcher. she has a psychological disease (according to medical records) that impedes concentration and education.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
we hold a lottery using a black plastic, from which two DIC (drope in center) especial centers of women, the first one is assigned as control group and the other to the intervention, then at each center, sampling in an accessible manner was performed with informed consent.

Blinding (investigator's opinion)
Single blinded

Blinding description
To prevent the publication of information, each center is randomly assigned (through the center-name lottery) to one of the two intervention or control groups And women do not know which groups are assigned and what training is given in the other group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology, Mashhad University of Medical Sciences, No 18, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.MUMS.REC.1397.053

Health conditions studied

1

Description of health condition studied

sexual assertiveness and self efficacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual Assertiveness Score

Timepoint

Before the intervention, immediately after the completion of training sessions and eight weeks after the pre-test

Method of measurement

Sexual Assertiveness Questionnaire

2

Description

Sexual Self efficacy Score

Timepoint

Before the intervention, immediately after the completion of training sessions and eight weeks after the pre-test

Method of measurement

Sexual Self efficacy Questionnaire

Secondary outcomes

empty

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Intervention groups

1

Description

Intervention group: In the intervention group, four 90-minute training sessions based on the information - motivation and behavioral skills model(IMB) was performed within 2 to 3 days intervals. Classes format includes lecture, video broadcasting, role playing and group discussion.

Category

N/A

2

Description

Control group: Do not get an intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Toos Women's DIC Center

Full name of responsible person

Moosavi

Street address

Toos Boulevard

City

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Province

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2

Recruitment center

Name of recruitment center

Khaje Rabi Women's DIC Center

Full name of responsible person

Bakhtiyari

Street address

Balal Street

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Razavi Khorasan

Postal code

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Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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University Deputy of Research and Technology,
Mashhad University of Medical Sciences, Daneshgah
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Marzieh Hassanshahi Raviz

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Raheleh Babazadeh
Position
PhD in reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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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