Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Teory 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 AssertivenessQuestionnaire

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

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
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
hasanshahim941@mums.ac.ir

2

Recruitment center
Name of recruitment center
Khaje Rabi Women's DIC Center
Full name of responsible person
Bakhtiyari
Street address
Balal Streat
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
hasanshahim941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
University Deputy of Research and Technology, Mashhad University of Medical Sciences, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
hasanshahim941@mums.ac.ir
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
Street address
Ghaffari Street
City

Rafsanjan
Province
Kerman
Postal code
7718637513
Phone
+98 34 3432 3301
Fax
Email
hasanshahim941@mums.ac.ir

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
Street address
School of Nursing and Midwifery, Doctora Intersection, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
babazadehr@mums.ac.ir

Person responsible for updating data

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
Street address
Ghaffari Street
City
Rafsanjan
Province
Kerman
Postal code
7718637513
Phone
+98 34 3432 3301
Fax
Email
hasanshahim941@mums.ac.ir

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