

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of health education based on the health belief model on self efficacy addicted women in prevention risky behaviors

Protocol summary

Summary

This study aims to evaluate the effect of education based on a health belief model on self efficiency of addicted women in prevention of risky behaviors. This is a semi-experimental clinical study which is effectuated in two intervention and control groups. The constant sampling is done by haphazard allocation through random number table. The study population selected from, women who referred to harm-reduction centers or self-help centers, which are related to Tehran Welfare. Samples are 110 addicted women (Include: All addicted women who referred to harm reduction centers or self-help centers and have record; at least 18 years old; have sexual relation; least literacy reading and writing) who with failure to attend two sessions or withdrew from the study are excluded from participation in the study. The intervention group was trained for 4 sessions and each session lasting for 2 hours based on the health belief model and at the end of each session they received a pamphlet regarding the present subject. The curriculum contains the definition of risky behaviors, the outbreak of these behaviors, the consequences of committing these behaviors and benefits as well as barriers of preventive behaviors. Knowledge and model components and self efficacy evaluated by questionnaires that are conducted before training and 12 weeks after the end of training by the intervention and control group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312033034N11**

Registration date: **2014-01-31, 1392/11/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-31, 1392/11/11

Registrant information

Name

Mansoureh Jamshidimanesh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, school of nursing and midwifery, Tehran university of medical science

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of health education based on the health belief model on self efficacy addicted women in prevention risky behaviors

Public title

Effect of health education based on the health belief model on self efficacy addicted women in prevention risky behaviors

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: All addicted women referred to the centers harm reduction and self help and have record; at least 18 years old; have sexual relation; least literacy reading and writing Exclusion criteria: Failure to attend two sessions;withdrew from the study

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **110**

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 Tehran University of Medical Sciences

Street address
6th floor, Central building, Ghods street, Bolvar Keshavarz, Tehran

City
Tehran

Postal code

Approval date
2013-11-25, 1392/09/04

Ethics committee reference number
130/1930/92/3

Health conditions studied

1

Description of health condition studied
substance use

ICD-10 code
F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

2

Description of health condition studied
substance use

ICD-10 code
F10

ICD-10 code description
Mental and behavioural disorders due to use of alcohol

3

Description of health condition studied
substance use

ICD-10 code
F12

ICD-10 code description
Mental and behavioural disorders due to use of cannabinoids

4

Description of health condition studied
substance use

ICD-10 code
F13

ICD-10 code description
Mental and behavioural disorders due to use of sedatives or hypnotics

Primary outcomes

1

Description
Component H.B.M (sensitivity, severity,benefit, barrier) perceived and knowledge

Timepoint
Before the intervention, and 12 weeks after intervention

Method of measurement
Component model and knowledge questionnaire

Secondary outcomes

1

Description
Addicted women self efficacy in preventing risky behavior.

Timepoint
Before intervention and 12 weeks after end of intervention

Method of measurement
Self efficacy questionnaire

Intervention groups

1

Description
The intervention group was trained (4 sessions lasting 2

hours each) based on the health belief model through lecture and Q & A group discussions and picture views. The first session involves the identification and prevalence of high risk behaviors in drug users and the second session discusses committing these behaviors. The third and fourth sessions deal with the effect of preventing these behaviors and barriers to commit preventing such behaviors. Knowledge questionnaire and model components and self efficacy are conducted before training and 12 weeks after the end of training by the intervention group.

Category

Other

2

Description

In the control group, addicted women in the initiation of intervention and 12 weeks after intervention fill out the questionnaire awareness and self-efficacy models components.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Welfare Organization

Full name of responsible person

Fariba Ilka

Street address

Dastgerdi Ave, Vali Asr St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Cheraghi

Street address

School of Nursing and Midwifery, University of Medical Sciences, N. Eastern Ave, Tohid Square, Tehran

City

Tehran

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, Tehran 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

School of Nursing and Midwifery, Tehran University of Medical Science

Full name of responsible person

Mansureh Jamshidimanesh

Position

MSc Midwifery, Master of science

Other areas of specialty/work

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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