Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Developing and Evaluating the Effectiveness of Educational Package on Sexual Health promotion in couples engaging to marriage

Protocol summary

Summary

Objective:The aim of this study is developing and evaluating the effectiveness of educational package on sexual health promotion in couple engaged to marriage. Design: A controlled clinical trial Setting: 120 couples referred to premarriage counseling (Golabchi health center) in Kashan will divided randomly into 2 intervention and control groups (60 couples in each group). The intervention group will received 8 sexual educational sessions and control group will receive one lecture that will be presented normally in the premarriage counseling. Participants and eligibility criteria: Participants consisted of couples that referred to premarriage counseling center with including criteria: the first marriage؛ literacy؛ Iranian؛ consent to participate in the study؛ the desire to have sex with his wife for at least five months after the intervention؛not to participate in other programs of sex education and have not to the specific conditions that prevent sexual relationship with the wife and with exclusion criteria: lack continued cooperation in study؛ lack of access to samples in follow-up after the intervention؛ becoming pregnant during the study. all samples fill sexual awareness, attitude questionnaires. Intervention: International groups (men and women separately) with 30 sample in each group will received education issues such as sexual response cycle, unsafe sexual behavior and sexual communication and probability of pregnancy in 8 session. just and six months after intervention will be assessed sexual knowledge and attitude by questionnaire also all samples complete questionnaires of the sexual function and sexual Quality of life six months after the intervention. Main outcome variables: Sexual knowledge and attitude, sexual function and sexual quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506063413N2**
Registration date: **2015-08-14, 1394/05/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-14, 1394/05/23

Registrant information

Name

Zohreh Sadat

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tarbiat Modares University,

Expected recruitment start date

2014-07-07, 1393/04/16

Expected recruitment end date

2015-05-06, 1394/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing and Evaluating the Effectiveness of Educational Package on Sexual Health promotion in couples engaging to marriage

Public title
Developing and Evaluating the Effectiveness of Educational Package on Sexual Health promotion in couples engaging to marriage
Purpose
Prevention
Inclusion/Exclusion criteria
Main inclusion criteria:The first marriage؛ literacy؛ Iranian؛ consent to participate in the study؛ the desire to have sex with his wife for at least five months after the intervention؛not to participate in other programs of sex education؛ not treatment for sexual problems and have not to the specific conditions that prevent sexual relationship with the wife. Main exclusion criteria: lack continued cooperation in study؛ lack of access to samples in follow-up after the intervention؛ becoming pregnant during the study؛ the couple separated after entering the study such as divorce؛ psychological problem and drug using for treatment sexual conditions
Age
From **15 years** old to **45 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **240**
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 Tarbiat Modares University
Street address
South East Gisha bridge,Tarbiat Modares University, Tehran
City
Tehran
Postal code
1411713116
Approval date
2014-05-17, 1393/02/27
Ethics committee reference number
52/1640

Health conditions studied

1

Description of health condition studied
Sexual problems
ICD-10 code
f52
ICD-10 code description
Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Sexual attitude and knowledge
Timepoint
Before, just and 6 months afterintervention
Method of measurement
SKAS-CEM

Secondary outcomes

1

Description
sexual quality of life
Timepoint
6 months after intervention
Method of measurement
SQOL-F, SQOL-M

Intervention groups

1

Description
The control group will receive one lecture that will be presented normally in the premarriage counseling program
Category
Behavior

2

Description
The intervention group will received 8 educational sessions in issues such as sexual health, the sexuality response cycle,safe and unsafe sexual behavior and sexual communication.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Gholabchi health center in Kashan city
Full name of responsible person
Zohreh Sadat
Street address
Imam Khomeiny Rod, Gholabchi health center, Kashan
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mansoureh Movahedin, Vice chancellor for research,Tarbiat Modares University,
Full name of responsible person
Mansoureh Movahedin
Street address
Building No. 1, School of Medicine, South East Gisha Bridg, Tarbiat Modares University, Tehran
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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
Mansoureh Movahedin, Vice chancellor for research,Tarbiat Modares University,
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

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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