

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Aug 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.

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)

Phone

+98 36 1555 9956

Email address

sadat@kaums.ac.ir

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

General information

Acronym

IRCT registration information

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 after intervention

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

Tehran

Postal code

1411713116

Phone

+98 21 8288 3869

Fax

+98 21 8288 3869

Email

ghofranipour@gmail.com

Web page address

http://www.modares.ac.ir/en/Schools/med/Academic_Staff/~ghofranf

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

City

Tehran

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

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Fazlollah Ghofranipour

Position

Professor

Other areas of specialty/work

Street address

Building No. 1, School of Medicine, South East Gisha
Bridg, Tarbiat Modares University, Tehran

City

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Fazlollah Ghofranipour

Position

Proffesor

Other areas of specialty/work

Street address

Building No. 1, School of Medicine, South East Gisha
Bridg, Tarbiat Modares University, Tehran

City

Tehran

Postal code

1411713116

Phone

+98 21 8288 3869

Fax

+98 21 8288 3869

Email

ghofranipour@gmail.com

Web page address

http://www.modares.ac.ir/en/Schools/med/Academic_Staff/~ghofranf

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Zohreh Sadat

Position

Ph.D student in health education

Other areas of specialty/work

Street address

Building No. 1, School of Medicine, South East Gisha
Bridg, Tarbiat Modares University, Tehran

City

Tehran

Postal code

1411713116

Phone

+98 21 8288 3869

Fax

+98 21 8288 3869

Email

sadat_z2003@yahoo.com; z.sadat@modares.ac.ir

Web page address

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