

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of sexual counseling versus no counseling on knowledge, attitude and sexual anxiety of women on the eve of marriage: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of sexual counseling versus no counseling on knowledge, attitude and sexual anxiety of women on the eve of marriage

Design

This is a randomized clinical trial, in which 124 eligible women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible women who will refer to Health Centers of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 35 years; literate; first marriage; at least a one-month interval from marriage; physical and mental health. Exclusion criteria: addiction to opioids; participation in sexual counseling in the past.

Intervention groups

Intervention group: routine education before marriage plus sexual counseling for 60 minutes weekly for 4 weeks. Control group: just routine education before marriage.

Main outcome variables

assessing the sexual anxiety; assessing the knowledge and attitude toward sexual relation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N238**

Registration date: **2018-09-29, 1397/07/07**

Registration timing: **prospective**

Last update: **2018-09-29, 1397/07/07**

Update count: **0**

Registration date

2018-09-29, 1397/07/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-17, 1397/07/25

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sexual counseling versus no counseling on knowledge, attitude and sexual anxiety of women on the eve of marriage: a randomized clinical trial

Public title

Effect of sexual counseling versus no counseling on knowledge, attitude and sexual anxiety of women on the eve of marriage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years
Literate
First marriage
At least one-month interval from marriage
Physical and mental health

Exclusion criteria:

Addiction to opioids
Participation in sexual counseling in the past

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.401

Health conditions studied

1

Description of health condition studied

Anxiety disorder

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Assessing the sexual anxiety

Timepoint

Before intervention and one month after intervention

Method of measurement

Using Davis sexual anxiety questionnaire

2

Description

Assessing the knowledge and attitude toward sexual relation

Timepoint

Before intervention and one month after intervention

Method of measurement

Using SKAS sexual knowledge and attitude questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine education before marriage plus sexual counseling for 60 minutes weekly for 4 weeks

Category

N/A

2

Description

Control group: Just routine education before marriage

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Hamadan City

Full name of responsible person

Laya Hemati

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Laya Hemati

Position

Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Fertility Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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