Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of sexual counseling based on the EX-PLISSIT model versus control group on help-seeking and sexual health literacy of newly married women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of sexual counseling based on the EX-PLISSIT model versus control group on help-seeking and sexual health literacy of newly married women

Design
This is a randomized clinical trial with a control group with parallel groups without blinding, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Comprehensive Health Centers in Hamadan city, involving 106 eligible newly married women. The patients will be randomly assigned to the intervention and control groups through the block randomization. It should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 40 years Newly married women in the last year First marriage Iranian nationality Being literate Exclusion criteria: Having a child Being pregnant History of hip surgery

Intervention groups
Intervention group: Reproductive health care in addition to sexual counseling sessions based on the EX-PLISSIT model for 45 to 60 minutes once a week for four weeks Control group: Reproductive health care

Main outcome variables
Primary outcome: Sexual health literacy Help-seeking

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N537**
Registration date: **2024-11-09, 1403/08/19**
Registration timing: **prospective**
Last update: **2024-11-09, 1403/08/19**
Update count: **0**

Registration date
2024-11-09, 1403/08/19

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
2025-01-24, 1403/11/05

Expected recruitment end date
2025-09-27, 1404/07/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of sexual counseling based on the EX-PLISSIT model versus control group on help-seeking and sexual health literacy of newly married women: a randomized clinical trial

Public title

Effect of sexual counseling based on the EX-PLISSIT model versus control group on help-seeking and sexual health literacy of newly married women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 40 years Newly married women in the last year First marriage Iranian nationality Being literate

Exclusion criteria:

Having a child Being pregnant History of hip surgery

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2024-10-26, 1403/08/05

Ethics committee reference number

IR.UMSHA.REC.1403.519

Health conditions studied

1

Description of health condition studied

Reproductive health

ICD-10 code

O09.2

ICD-10 code description

Supervision of pregnancy with other poor reproductive or obstetric history

Primary outcomes

1

Description

Sexual health literacy

Timepoint

Before the intervention and one month later

Method of measurement

Using the Sexual Health Literacy Questionnaire (SHLQ)

2

Description

Help-seeking

Timepoint

Before the intervention and one month later

Method of measurement

Using the General Help-Seeking Questionnaire (GHSQ) and the Actual Help-Seeking Questionnaire (AHSQ) and

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Reproductive health care in addition to sexual counseling sessions based on the EX-PLISSIT model for 45 to 60 minutes once a week for four weeks (including: getting to know the anatomy and physiology of the reproductive system, expressing the participants' desires, needs and beliefs about sex, explaining the areas of sexual performance and its changes in different periods and ages of fertility, explaining the four stages of the sexual response cycle and the physical and psychological differences between men and women,

familiarizing with sexual disorders, explaining the factors affecting sexual relations and correcting misconceptions about sexual relations, familiarity with diseases transmitted through sexual contact, improving mental skills to strengthen and stimulate sexual stimulation in women and training skills to create variety in sexual relations, explaining the factors affecting sexual satisfaction and marital satisfaction)

Category

Prevention

2

Description

Control group: Reproductive health care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Dr. Azita Tiznobeik

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, 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. Reza Shokoohi

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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

Sarah Hajizadegan Bidgoli

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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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

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Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Professor of Epidemiology

Latest degree
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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