

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Aug 2026

Investigating the effect of counseling based on the sexual health model on the Sexual compatibility and Intention to have children of newly married women

Protocol summary

Study aim

determining the impact of sexual health model counseling on sexual compatibility and childbearing intention of new women

Design

the clinical trial was performed with pre - test and post - test and active control group. blinding in this study will not be possible . random allocation will be made using online allocation.

Settings and conduct

this study was an interventional study of a parallel randomized clinical trial with pre - test - post - test and active control group which will be done on women referring to the comprehensive health center of yazd city. women with poor to moderate sexual compatibility and inclusion criteria in the study were allocated to two intervention groups (32 person in person and virtual consulting) and control group (32 persons of virtual education package) . the sessions will be held in four sessions of group counseling for 90 minutes . immediately after consulting and also 4 weeks later, both groups will complete the sexual compatibility questionnaire and intention to childbearing online .

Participants/Inclusion and exclusion criteria

women aged 15 to 45 years old , married to 12 - 3 months of marriage in the apple system of health center of yazd city .

Intervention groups

32 people in the intervention group will receive sexual health counseling for 4 sessions of 90 minutes . the intervention group in the first session , in the form of training in the form of training and the rest of the sessions , will be placed in person under training and by presence or virtual consulting . education is based on sexual health model and focusing on sexual compatibility in groups 6 - 8 . the active control group also received training on sexual health dimensions and sexual

compatibility and childbearing as a weekly and virtual educational package .

Main outcome variables

Sexual compatibility, intention to have children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251206068227N1**

Registration date: **2026-08-03, 1405/05/12**

Registration timing: **retrospective**

Last update: **2026-08-03, 1405/05/12**

Update count: **0**

Registration date

2026-08-03, 1405/05/12

Registrant information

Name

Fatemeh Poorhakkak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3624 5975

Email address

f.poorhakkak242@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2026-07-23, 1405/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of counseling based on the sexual health model on the Sexual compatibility and Intention to have children of newly married women

Public title
Investigating the effect of counseling based on the sexual health model on the Sexual compatibility and Intention to have children of newly married women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Being Iranian and literate Being monogamous Having regular sexual activity (at least once a week) Having weak to moderate sexual compatibility based on the Hurlburt Sexual Compatibility Questionnaire (score less than 64) A maximum of one year has passed since the marriage Having access to a smartphone and the internet 7. Permanent marriage Permanent marriage
Exclusion criteria:
Previous marital history for both partners Experience of a severe problem or stressful event (such as the death of a loved one or financial bankruptcy) in the past 6 months for both partners (self-reported) Having a physical illness (including no sexual dysfunction, sexually transmitted diseases, and medical illnesses such as diabetes) or a major mental illness based on the couples' self-report History of treatment for sexual dysfunction by a psychologist, urologist, or gynecologist Participation in similar sexual counseling courses in the year before the study (both groups received only premarital sexual counseling) Presence of acute marital conflict (including lawsuits, infidelity) History of use of drugs, alcohol, and sexual enhancement drugs or drugs that affect sexual function Presence of a known abnormality in sexual anatomy and function Pregnancy (self-reported) Forced marriage

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
the sample size is 64 .after the number of qualified people has reached 64 , the random allocation of block is done using the online allocation online site (<http://www.randomization.com>) and 32 people in the intervention group (32 members of the first session

under training in the form of educational presence classes) and the rest of the sessions will be placed online via sky and 32 people in active control group (32 people) .participants are informed that the probability of their placement in each group of control and intervention groups is 50 % .the random allocation process consists of two stages : 1) generating a pre - nasal random assignment , using a computer random number table .the table of random numbers is used to use the online method in online software .2) concealment : the implementation of the sequence in a way that masks the interventions until the participants are formally assigned to their groups (by one of the health care providers outside the research team) .

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features
We have two intervention and control groups. The intervention group (32 people will be trained in the first session in the form of in-person educational classes and the remaining sessions will be in-person or virtual online via Sky Room, depending on the preference of the people) and 32 people will be placed in the active control group (32 people will receive a virtual training package).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd University of Medical Sciences

Street address

Yazd, Safaiyeh, Bu Ali St., opposite the Infertility Center

City

yazd

Province

Yazd

Postal code

7744389168

Approval date

2025-11-05, 1404/08/14

Ethics committee reference number

IR.SSU.REC.1404.121

Health conditions studied

1

Description of health condition studied

sexual compatibility

ICD-10 code
ICD-10 code description

2

Description of health condition studied

Intention to have children

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

sexual compatibility score in Hurlbert sexual compatibility questionnaire

Timepoint

before intervention and 4 and 8 weeks after intervention

Method of measurement

Hurlbert sexual compatibility questionnaire

2

Description

the mean of childbearing intention in the questionnaire of childbearing intention

Timepoint

before intervention and 4 and 8 weeks after intervention

Method of measurement

questionnaire of effective component on childbearing intention

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group received counseling and question and response therapy sessions during 4 sessions of 90 - minute sessions of counseling that will be received in the first session of counseling in the form of educational presence classes and the rest of sessions , depending on the willingness of individuals under training or virtual consulting . education is based on sexual health model and focusing on sexual adaptation in groups 6 - 8 .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

haji maghsoudi health center (centre for marriage consulting)

Full name of responsible person

fatemeh poorhakkak

Street address

Yazd, Safaieh, Ashraf Martyrs Boulevard, Javadalaameh St., Kherad St.

City

yazd

Province

Yazd

Postal code

۸۹۱۳۷۸۳۱۱۵

Phone

+98 35 3838 0923

Email

F.poorhakkak242@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mehran Karimi

Street address

Yazd, Bahonar Square, Central Building of Shahid Sadoughi University of Medical Sciences

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3724 0171

Fax

+98 35 3725 4750

Email

info@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

fatemeh poorhakkak

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Chamran Street, 17th Shahrivar Street

City

yazd

Province

Yazd

Postal code

8914687795

Phone

36245975

Email

F.poorhakkak242@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mahshid Bekai

Position

Master of Midwifery Consulting

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Bu Ali Street, Faculty of Nursing and Midwifery

City

Yazd

Province

Yazd

Postal code

7744389168

Phone

+98 35 3824 1751

Email

mah_bokaie@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

fatemeh poorhakkak

Position

Master's degree student in consulting in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Chamran Street, 17th Street, Shahrivar

City

yazd

Province

Yazd

Postal code

8914687795

Phone

36245975

Email

F.poorhakkak242@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data, including proposals, raw data, and project reports

When the data will become available and for how long

Data is accessible via request from the legal system for two years, 6 months after publication.

To whom data/document is available

All natural and legal persons will have access upon request to the Vice President for Research of Yazd University of Medical Sciences.

Under which criteria data/document could be used

For legal matters and the need to use data in future studies

From where data/document is obtainable

Fatemeh Pourhakkak, Mahshid Bokaie

What processes are involved for a request to access data/document

After submitting the application to the Yazd Medical Sciences Research and Technology Vice-Chancellor, a call will be issued to the executor to provide data.

Comments