Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Aug 2026

Comparing the effectiveness of midwife-led integrative couple counseling with routine care on sexual desire discrepancy in couples after their delivery

Protocol summary

Study aim
Comparing the effectiveness of midwife-led integrative couple counseling with routine care on sexual desire discrepancy in couples after their delivery

Design
A randomized controlled clinical trial with two parallel intervention and control arms

Settings and conduct
Visiting health centers, urban family doctor and selected gynecologists' offices, identifying eligible people, dividing patients into two intervention and control groups randomly, completing questionnaires by both groups, evaluating results using Porsline through the network Eitaa or WhatsApp social media will be done.

Participants/Inclusion and exclusion criteria
Declaration of written consent of both couples to participate in the study/ women of childbearing age / at least 10 weeks have passed after their delivery / return of menstruation / living with a spouse / access to a smartphone (to complete the form and questionnaires in the Porsline) / availability in length of the study / No other chronic physical diseases / No addiction / No pregnancy / No mental disorders (depression, anxiety and stress based on the DASS-21 questionnaire) or physical diseases that interfere with their daily functioning/ No consumption Psychiatric drugs/ lack of participation in educational and counseling courses related to improving sexual function in the last 6 months/ lack of history of genital or pelvic surgeries (such as hysterectomy) that affect their sexual desire.

Intervention groups
Couple counseling sessions will be conducted in 5 sessions of 60 minutes at an interval of one week. Control group: In addition to routine midwifery care, after completing the study, a pamphlet containing educational materials will be provided to them during a session.

Main outcome variables
Sexual desire discrepancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161126031117N17**
Registration date: **2024-11-12, 1403/08/22**
Registration timing: **prospective**

Last update: **2024-11-12, 1403/08/22**
Update count: **0**

Registration date
2024-11-12, 1403/08/22

Registrant information

Name
Soghra Khani

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date
2025-01-20, 1403/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of midwife-led integrative couple counseling with routine care on sexual desire discrepancy in couples after their delivery

Public title

The effectiveness of integrative couple counseling on sexual desire discrepancy after delivery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Declaration of written consent of both couples to participate in the study Women of childbearing age At least 10 weeks have passed after their delivery Return of menstruation Living with a spouse Access to a smartphone (to complete the form and questionnaires in the Porsline) Availability in Length of the study

Exclusion criteria:

Other chronic physical diseases Addiction Pregnancy Suffering from mental disorders (depression, anxiety and stress based on the DASS-21 questionnaire) or physical diseases that interfere with their daily functioning. Consumption Psychiatric drugs Participating in educational and counseling courses related to improving sexual function in the last 6 months History of genital or pelvic surgeries (such as hysterectomy) that affect their sexual desire

Age

From **18 years** old to **54 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the samples are matched based on the duration of marriage, the number of births and breastfeeding, and the block method will be used for the random allocation of the samples. For this purpose, two blocks will be considered. Two possible blocks are TC and CT, where T is for the intervention group and C is for the control group. The numbers will be generated randomly (with the RANDBETWEEN command in Excel software and in domain 1 and 2) And according to the production values of one of the blocks (production number 1 for CT block , production number 2 for TC blocks) will be selected and samples will be allocated. The sampling method will be done in convenience method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluation of the consequences will be done using the PORSLINE through the social networks Eitaa or WhatsApp. The researcher and the evaluator do not know the group to which the participant belongs when evaluating the outcome.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Moalem Square, Moalem Street

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2024-10-01, 1403/07/10

Ethics committee reference number

IR.MAZUMS.REC.1403.304

Health conditions studied

1

Description of health condition studied

sexual desire discrepancy of couples

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

Primary outcomes

1

Description

sexual desire discrepancy of couples

Timepoint

Determining the sexual desire discrepancy of couples before, immediately and 4 weeks after the intervention

Method of measurement

Using Halbert Sexual Desire Questionnaire, the sexual desire score of each couple will be calculated. The couple's desire discrepancy scores will be calculated as the difference between the couple's sexual desire scores

in the Halbert questionnaire, after standardization. That is, men's Z score from women's Z score will be reduced. For the discrepancy to be significant, the absolute value of the Z score with a 95% confidence interval should be greater than 1.96.

Secondary outcomes

1

Description
Sexual satisfaction
Timepoint
Determining the sexual satisfaction of couples before, immediately and 4 weeks after the intervention
Method of measurement
Larson's standard sexual satisfaction questionnaire

Intervention groups

1

Description
Intervention group: Counseling sessions with the presence of couples will be conducted for an average of 60 minutes and during 5 sessions with an interval of one week. People will be contacted once or twice a week to ensure that they complete their assignments. Immediately after the completion of the intervention sessions, there will be a post-test and a session to follow up and re-evaluate the two groups in terms of the couples' sexual desire discrepancy and sexual satisfaction, four weeks later.
Category
Behavior

2

Description
Control group: Control group: In addition to receiving routine midwifery care, after completing the study, they will be provided with a pamphlet containing educational materials about sexual desire discrepancy of couples and sexual satisfaction after delivery and solutions to improve it in a session.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers, urban family doctor bases
Full name of responsible person
Dr. Soghra Khani
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Vesal Street, Amir Mazandarani Boulevard, Sari, Mazandaran Province,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Fatemeh Tousheh
Position
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Person responsible for updating data

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Web page address

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
The information related to the research is shared with the aim of keeping the names of the people and keeping their identities confidential and complying with the 31 code of ethics
When the data will become available and for how long
Since 1404
To whom data/document is available
All researchers and those interested in research
Under which criteria data/document could be used
To conduct review and supplementary research and for the use of Therapists and counselors of couples' sexual disorders
From where data/document is obtainable
In order to receive documents or data, the corresponding author can be reached by email at khanisog343@gmail.com and counseling student in midwifery at f.tousheh@gmail.com. If the article is published according to the journal address, you can refer to that journal.
What processes are involved for a request to access data/document
First, you should send an email to the responsible author of the article and make your request, and if the responsible author and the research team deem it appropriate, the documents and files will be provided in a short period of time.
Comments