Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

The efficacy of Tele-based sexuality councelling on sextual function and sextual distress of primiparous women with exclusive breastfeeding and their spouses

Protocol summary

Study aim

The efficacy of Tele-based sexuality councelling on sextual function and sextual distress of primiparous women with exclusive breastfeeding and their spouses

Design

The study includes two groups and each group includes 70 people. nonblinded. To determine the sequence of allocation by the block method of four, random allocation sequence generation software "STATA" will be used.

Settings and conduct

The study is conducted among lactating primiparous women referring to Qazvin health centers and their spouses. They are invited to participate in the study based on their willingness, the intervention group will receives 5 counseling sessions. before and after the study, the questionnaires are completed by both control and intervention groups. nonblinded study

Participants/Inclusion and exclusion criteria

Inclusive criteria: Primiparit, Married life, Exclusive breastfeeding, Have a Singleton term birth, Being in the first six months after delivery, Availability within the next two months, Healthy child without physical problems or special diseases, Having a smartphone, Exclusive criteria: Absence of sexual activity with the spouse during the postpartum period, Severe marital conflicts and the occurrence of an unfortunate event, History of chronic mental and physical illness,

Intervention groups

The intervention group will receive a 5-session online training package . Each session is 30-45 minutes. The control group only receives routine care

Main outcome variables

Primary outcome: couples' sexual performance/couples' sexual distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054637N2**
Registration date: **2022-10-18, 1401/07/26**
Registration timing: **prospective**

Last update: **2022-10-18, 1401/07/26**
Update count: **0**

Registration date

2022-10-18, 1401/07/26

Registrant information

Name

Sara Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4241 4105

Email address

mahhaid1371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The efficacy of Tele-based sexuality councelling on sextual function and sextual distress of primiparous women with exclusive breastfeeding and their spouses

Public title
The efficacy of Tele-based sexuality councelling on sextual function and sextual distress of primiparous women with exclusive breastfeeding and their spouses

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Primiparity Living with a spouse Have exclusive breastfeeding Have a singleton full-term birth (after 38 weeks) Being in the first six months after delivery Being accessible within the next two months Have a healthy child without physical problems or special diseases Have smartphone

Exclusion criteria:
Lack of sexual activity with spouse during the postpartum period Severe marital conflicts and the occurrence of unfortunate events (death of loved ones, accidents, etc.), Having a history of chronic mental and physical illness (check the records in the file and history)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
We will use block of four for random allocation. In order to determine the sequence of allocation by the four block method, random allocation sequence generation software will be used. In order to hide the sequence of allocation, the papers identifying the group of people are placed inside the envelopes in the opaque package and coded in the same order. In this case, a questionnaire with the same code will be completed for the person who receives the intervention.

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 of Qazvin medical university

Street address
University campus building,Bahonar Blv

City
Qazvin

Province
Qazvin

Postal code
3419759811

Approval date
2022-07-19, 1401/04/28

Ethics committee reference number
IR.QUMS.REC.1401.106

Health conditions studied

1

Description of health condition studied
Sextual function , Sextual distress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sextual function score

Timepoint
Before and immediately after the end of the study, one week, one month and two months after the intervention

Method of measurement
Female Sexual function Index FSFI-6,International index of erectile function: (IIEF-5)

Secondary outcomes

1

Description
The level of sexual distress of couples

Timepoint
Before and immediately after the end of the study, one week, one month and two months after the intervention.

Method of measurement
Female Sexual Distress Scale (FSDS_R)

Intervention groups

1

Description
Intervention group: Before the intervention, the questionnaire link will be sent through the "Whatsapp

"application and the people will be coded. In addition to routine postpartum care, the intervention group will receive five counseling sessions through video calls on "Whatsapp" messenger. Sessions include couples and counselors (three people). "My wife" book (skill training in marital and sexual relations) and the textbook of sexual disorders are considered as educational resources. Counseling sessions are held every 5 days, and after the end of each counseling session, a phone call is made in order to explain more about the training and not to forget the exercises within five days until the next counseling session. Videos, images and educational content related to each session will be provided to couples through social messengers.

Category
N/A

2

Description
Control group :the usual postpartum care will be received, and a pamphlet including the usual postpartum sex counseling will be provided for them ,in addition to receiving routine care , at the end of the study, based on the obtained information, if couples in control group needs counseling, a counseling session will be held for them.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Center No. 12-Minoodar

Full name of responsible person
Hashem Alijani

Street address
Center No. 12 - Minodar , Behind the mosque , Dehkhoda Blvd , Dehkhoda square

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3379 4450

Fax

Email
mahhaid1371@gmail.com

Web page address
https://qums.ac.ir/

2

Recruitment center

Name of recruitment center
Center No. 8 - Nawab

Full name of responsible person
Hashem Alijani

Street address
Center No. 8 - Next to the former traffic light , The beginning of North Nawab St.,

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 6889

Email
mahhaid1371@gmail.com

3

Recruitment center

Name of recruitment center
Pakrovan health center

Full name of responsible person
Hashem Alijani

Street address
Pakrovan health center, Next to Shahada Park, At the end of Heydari St.

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3332 4006

Email
mahhaid1371@gmail.com

4

Recruitment center

Name of recruitment center
Center No. 6- Waliasr

Full name of responsible person
Hashem Alijani

Street address
Center No. 6- Waliasr, Nabovat St., Beheshti Blvd

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3334 5057

Email
mahhaid1371@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person
Doctor Seyed Mahdi Mirhashemi

Street address
Qazvin University of Medical Sciences.,Shahid Bahonar Blvd.,Qazvin

City
Qazvin

Province
Qazvin

Postal code
3419759811

Phone
+98 28 3333 6001

Fax
+98 28 3332 4970

Email
medicine@qums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Sara Heydari

Position
Midwife

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
No.7-Peyman building., Andrezgoo 5th .,Andrezgoo St.

City
Saveh

Province
Markazi

Postal code
3918847835

Phone
+98 86 4241 4105

Fax

Email
mahhaid1371@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Sara Heydari

Position
Midwife

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Peyman building ., Andrezgo 5th ., Andrezgo St., Saveh

City
Saveh

Province
Markazi

Postal code
3418847835

Phone
+98 86 4241 4105

Fax

Email
mahhaid1371@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Sara Heydari

Position
Midwife

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Peyman building ., Andrezgo 5th ., Andrezgo St., Saveh

City
Saveh

Province
Markazi

Postal code
3418847835

Phone
+98 86 4241 4105

Fax

Email
mahhaid1371@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
None of the personal information of the samples can be accessed, but non-identifiable data and things like study protocol documentation, data analysis program will be shared.

When the data will become available and for how long
Year 1402

To whom data/document is available
Other researchers

Under which criteria data/document could be used
If permission is obtained from the authors of the work

From where data/document is obtainable
Sara Heydari-Contact number: 09361742070 Peyman building-Andrezgo 5-Andrezgo St- Saveh. Email: mahhaid1371@gmail.com

What processes are involved for a request to access data/document
The request should be sent via e-mail, and the data file will be sent to them via e-mail within a maximum of one month

Comments