

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of counseling based on health promotion awareness in newly married women's selfcare needs: a clinical randomized controlled trial

Protocol summary

Study aim

Determining the effect of counseling based on health promotion awareness in newly married women's selfcare needs

Design

A randomized, double-arm clinical trial will be performed on 64 newly married women aged 15 to 40 years old. Participants will be assigned to two groups using RAS software in 4 and 6 blocks with a 1: 1 ratio, and They will be followed up 4 weeks after the intervention.

Settings and conduct

This study will be performed on newly married women aged 15 to 40 years old, whose details are available in health centers in Tehran. Participants will be randomly assigned to two groups. Before the intervention and 4 weeks after the intervention, the questionnaire of sexual self-care and reproductive needs and sexual health literacy will be completed by both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: married women 15 to 40 years old (that have been married at least six months); score for sexual and reproductive self-care needs more than 142.53; literacy for reading and writing. Exclusion criteria: cancer or a history of cancer; history of participating in previous educational and interventional programs related to sexual and reproductive health; intellectual disability; any psychological illness according to the person.

Intervention groups

For the intervention group, 40- to 60-minute individual counseling sessions will be conducted for 4 consecutive weeks. If needed, one or two more sessions will be held. For the control group, a 60-90 minute consultation session on mental health during pregnancy will be held.

Main outcome variables

Comparison of the score of sexual and reproductive self-care needs will be measured 4 weeks after the intervention by the sexual and reproductive self-care needs questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N7**

Registration date: **2021-09-21, 1400/06/30**

Registration timing: **prospective**

Last update: **2021-09-21, 1400/06/30**

Update count: **0**

Registration date

2021-09-21, 1400/06/30

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0649

Email address

mehrabie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on health promotion awareness in newly married women's selfcare needs: a clinical randomized controlled trial

Public title

The effect of counseling based on health promotion awareness in newly married women's selfcare needs: a clinical randomized controlled trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women 15 to 40 years old (that have been married at least six months) Score for sexual and reproductive self-care needs more than 142.53 Literacy for reading and writing

Exclusion criteria:

Cancer or a history of cancer History of participating in previous educational and interventional programs related to sexual and reproductive health intellectual disability Any psychological illness according to the person

Age

From **15 years** old to **40 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

Participants will be assigned to the two groups receiving the intervention and control through simple random blocking using RAS software with 4 and 6 blocks with a ratio of 1: 1. The allocation type will be written on paper and numbered in a series of opaque envelopes (Allocation concealment). The envelopes will be opened in the order in which the participants enter the study.

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 Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz,Ira

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2021-04-12, 1400/01/23

Ethics committee reference number

IR.TBZMED.REC.1400.020

Health conditions studied**1****Description of health condition studied**

Reproductive and sexual self care needs

ICD-10 code

Z30

ICD-10 code description

Encounter for contraceptive management

2**Description of health condition studied**

Sexual and reproductive health literacy

ICD-10 code

Z70

ICD-10 code description

Counseling related to sexual attitude, behavior and orientation

Primary outcomes**1****Description**

Sexual and reproductive self-care needs

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Sexual and Reproductive Self-Care Need assessment Questionnaire

2**Description**

Reproductive and sexual health literacy

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Sexual health literacy for adults Questionnaire (SHELA)

Secondary outcomes

empty

+98 21 5582 3055

Email

khnsalfrshth@gmail.com

Intervention groups

1

Description

Intervention group: for the intervention group, 40- to 60-minute individual counseling sessions will be conducted for 4 consecutive weeks. If needed, one or two more sessions will be held.

Category

Behavior

2

Description

Control group: for the control group, a 60-90 minute consultation session on mental health during pregnancy will be held

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Fazel Comprehensive Health Service Center

Full name of responsible person

fereshteh kohansal

Street address

Sazmane Aab St. Hejab St.

City

Tehran

Province

Tehran

Postal code

1359987867

Phone

+98 21 8895 6888

Email

khnsalfrshth@gmail.com

2

Recruitment center

Name of recruitment center

Nematabad Health Center

Full name of responsible person

Fereshteh Kohansal

Street address

Sadeghieh Town, Shahid Poulad Street, Saveh Road

City

Tehran

Province

Tehran

Postal code

1375767962

Phone

3

Recruitment center

Name of recruitment center

Dadush Comprehensive Health Service Center - South of Tehran

Full name of responsible person

Narges Mohseni

Street address

Pooneh, Sabalan, Shokoofeh Boulevard

City

Tehran

Province

Tehran

Postal code

1894115999

Phone

+98 21 5588 3656

Email

khnsalfrshth@gmail.com

4

Recruitment center

Name of recruitment center

Abozar health center

Full name of responsible person

Ali Asadi

Street address

Golestan 15th, Southern Nabard

City

Tehran

Province

Tehran

Postal code

1777933112

Phone

+98 21 3302 1605

Email

khnsalfrshth@gmail.com

5

Recruitment center

Name of recruitment center

North Tehran Health Center

Full name of responsible person

Nematollah Mohammadinia

Street address

No. 2/16, Ishraqi Alley, Near to Seyed Khandan Bridge, Shariati St.

City

Tehran

Province

Tehran

Postal code

1798733547

Phone

+98 21 8851 1361

Email

khnsalfrshth@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

Central Building, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5613974156

Phone

+98 41 3335 7310

Email

samiei.moh@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Fereshteh Kohansal

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, South Shariati, Azadi St.

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

khnsalfrshth@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Esmat Mehrabi

Position

دکتری بهداشت باروری

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Faculty of Nursing and Midwifery, End of South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

b.mehrabi@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Esmat Mehrabi

Position

Ph.Din Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Faculty of Nursing and Midwifery, South Shariati, Azadi St.

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available