Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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

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
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Postal code
1359987867
Phone
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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
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3

Recruitment center
Name of recruitment center
Dadush Comprehensive Health Service Center - South of Tehran
Full name of responsible person
Narges Mohseni
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Pooneh, Sabalan, Shokoofeh Boulevard
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4

Recruitment center
Name of recruitment center
Abozar health center
Full name of responsible person
Ali Asadi
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5

Recruitment center
Name of recruitment center
North Tehran Health Center
Full name of responsible person
Nematollah Mohammadinia
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No. 2/16, Ishraqi Alley, Near to Seyed Khandan Bridge, Shariati St.
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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.
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5613974156
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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
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Faculty of Nursing and Midwifery, South Shariati, Azadi St.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Reproductive Health
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Person responsible for updating data

Contact
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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