Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of sexual counseling with Ex-PLISSIT model on sexual self-concept of women on the verge of marriage:A Randomised Controlled Trial.

Protocol summary

Study aim

1)Comparison of the mean score of sexual self-concept
2)Comparison of the mean score of sexually dysfunctional beliefs

Design

This study is a randomized controlled trial with a sample size of 64 people. Assignment of samples with a 1: 1 allocation ratio to the two intervention and control groups will be done by random blocking method (blocks of 4 and 6) .

Settings and conduct

The research setting is premarital counseling centers is in Tabriz. The researcher will refer to premarital counseling centers in Tabriz and for the women who intend to get married, the goals and study method will be fully explained. If they wish to participate in the study and attend counseling sessions, we will be reviewed for entry and exit criteria . If they are eligible, individuals will be selected in an easy or accessible way, and after obtaining informed consent, a questionnaire of demographic-social characteristics, a multifaceted questionnaire of sexual self-concept and a questionnaire of dysfunctional sexual beliefs will be completed through interviews. Then participants will be assigned to the intervention and control groups randomly. For the intervention group, sexual counseling with EX-PLISSIT model will be held and the control group will only participate in premarital counseling programs. Four weeks after the intervention, the post test questionnaires will be completed.Due to the nature of the research, it is not possible to blind the participants and the researcher, and only data collectors and analysts are blind.

Participants/Inclusion and exclusion criteria

-Healthy women on the verge of marriage - Age 15 years and older -Have a minimum of secondary education

Intervention groups

For the intervention group, sexual counseling with EX-PLISSIT model individually will be held and the control group will only participate in premarital counseling programs.

Main outcome variables

sexual self-concept

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110922007618N10**
Registration date: **2020-10-12, 1399/07/21**
Registration timing: **prospective**

Last update: **2020-10-12, 1399/07/21**
Update count: **0**

Registration date

2020-10-12, 1399/07/21

Registrant information

Name
Soheila Bani

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1479 6770

Email address
banis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sexual counseling with Ex-PLISSIT model on sexual self-concept of women on the verge of marriage:A Randomised Controlled Trial.

Public title

The effect of sexual counseling on sexual self-concept

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy women on the verge of marriage Age 15 years and older Have a minimum of secondary education Not having any mental illness

Exclusion criteria:

Previous marriage history A history of current mental health problems or a history of hospitalization in a psychiatric hospital Physical disability

Age

From **15 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 intervention (counselor) and control groups by a non-involved person in the study using random blocking method with the size of four and six blocks with a 1: 1 allocation ratio. In order to hide the allocation (Allocation Concealments), the type of intervention will be written on paper and placed in opaque envelopes and in closed and numbered packages. The envelopes will be opened in the order in which the participants enter the study and the type of group of people will be determined.

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

Vice Chancellor for Research, Tabriz University of Medical Sciences

Street address

Golgasht St. - Tabriz University of Medical Sciences - Central Building No. 2 Floor 3 - Research Deputy

City

Tabriz

Province

East Azarbaijan

Postal code

5138947-977

Approval date

2020-07-13, 1399/04/23

Ethics committee reference number

IR.TBZMED.REC.1399.386

Health conditions studied

1

Description of health condition studied

sexual self-concept

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improving sexual self-concept

Timepoint

Before the intervention, 4 weeks after the last intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Improve the score of inefficient sexual beliefs

Timepoint

Before intervention, 4 weeks after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention Sex counseling session with EX-PLISSIT model for 60-90 minutes and if necessary repeat

sessions every one week

Category

Other

2

Description

Control group: The control group will only participate in premarital counseling centers programs.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

maryam nematzadeh

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Tabriz School of Nursing and Midwifery, Shariaty 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

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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

maryam nematzadeh

Position

Masters in Midwifery Counseling Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Soheila Bani

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact
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Full name of responsible person
maryam nematzadeh
Position
Masters in Midwifery Counseling
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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
There is no further information.
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
Not applicable
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available