

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of a sex education package on sexual beliefs and function in pregnant women: a randomised controlled trial

Protocol summary

Summary

The aim of this randomized controlled trial is to determine the effect of a sex education package on sexual beliefs and function in pregnant women. We will recruit 22 pregnant women from each of the four selected public health centers in Karaj, Iran. After getting written informed consent, participants will complete a self-administered questionnaire about demographic and reproductive history and questions about sexual beliefs and function. Then we will randomly allocate them into intervention and control groups with assignment ratio of 1:1 using permuted block randomization with block sizes of 4 and 6 concealed in sequentially numbered, sealed, opaque envelopes. We will implement the sexual education in the intervention group and a nutritional education in the control group. The groups will be educated in two sessions, approximately sixty minutes each session, once a week for two consecutive weeks. One of the research team members, a midwife with special short education in sexual health in pregnancy, will teach at the interventional group sessions using an educational book written by the research team. The book will be given to the pregnant women at the end of the first session. The subjects and their husbands in the interventional group can also get telephone counseling about sexual health. The participants will complete post-test questionnaires in three time points, 4 weeks after intervention, 24-28 weeks gestational age, and 36-40 weeks gestational age.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105163706N7**

Registration date: **2011-07-19, 1390/04/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-07-19, 1390/04/28

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-07-27, 1390/05/05

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a sex education package on sexual beliefs and function in pregnant women: a randomised controlled trial

Public title

Effect of a sex education package on sexual beliefs and function in pregnant women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1- Pregnant women in 8-14 weeks of pregnancy 2- Having family health records in Karaj city health centers. 3-No contraindication for sexual activity due to medical reasons, like: threatened abortion, twin pregnancy, history of habitual abortion or incompetent cervix, history of infertility, history of preterm labor or PROM. 4-No history of addiction or habitual alcohol consumption by the woman and/or her husband. 5-Not currently taking drugs that may affect on sexual response (anti-hypertension, Thiazide diuretics, anti-depression, anti-histamines, Barbiturates, narcotics, diazepines, amphetamines, cocaine. 6-Not currently suffering from physical or psychological disease. 7-Not known disorder in sexual function 8-No severe emotional stress in past 3 months 9-Be able to fill in the questionnaire. 10- live with a permanent spouse. Exclusion criteria: occurrence of severe emotional stress; conditions which need to restrict sexual activity and starting to take drugs which may affect sexual response.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research deputy-Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

51665118

Approval date

2011-06-12, 1390/03/22

Ethics committee reference number

915

Health conditions studied

1

Description of health condition studied

Sex education in pregnancy

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual function

Timepoint

Before intervention, 4 weeks after intervention, in 24-28 weeks of pregnancy,in 36-40 weeks of pregnancy

Method of measurement

Female Sexual Function Index (FSFI) that will be self-administered and will be put into a sealed box

Secondary outcomes

1

Description

Sexual beliefs and function in pregnant women

Timepoint

Before intervention, 4 weeks after intervention, in 24-28 weeks of pregnancy,in 36-40 weeks of pregnancy

Method of measurement

Through self-made questionnaire in sexual beliefs and sexual function in pregnancy that will be self-administered and will be put into a sealed box

Intervention groups

1

Description

Intervention group: implementation of a sex education package, i.e. At first, group education will be conducted in groups with 5-11 women in the selected health centers in two sessions, approximately sixty minutes each session, once a week for two consecutive weeks. One of the research team members, a midwife with special short education in sexual health in pregnancy, will teach at the sessions using an educational book written by the research team. The book will be given to the pregnant women at the end of the first session. The women will be asked to study the book (themselves and their husbands) till the second educational session and ask their questions in the session. The subjects and their husbands in the interventional group can also get

telephone counseling about sexual health.

Category

Lifestyle

2

Description

Control group: implementation of a nutritional education package, i.e. At first, group education will be conducted in groups with 5-11 women in the selected health centers in two sessions, approximately sixty minutes each session, once a week for two consecutive weeks. One of the research team members, a midwife will teach at the sessions using an educational book written by the research team. The book will be given to the pregnant women at the end of the first session. The women will be asked to study the book (themselves and their husbands) till the second educational session and ask their questions in the session. The subjects and their husbands in the interventional group can also get telephone counseling about nutrition.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Fardis Shohada

Full name of responsible person

Malihe Afshar

Street address

Fardis Sq. West Canal

City

Karaj

2

Recruitment center

Name of recruitment center

Fardis Valyasr

Full name of responsible person

Malihe Afshar

Street address

Anbar Naft Square

City

Karaj

3

Recruitment center

Name of recruitment center

Tabatabaie

Full name of responsible person

Malihe Afshar

Street address

Mohamad shahar-Bakhtyari street

City

Karaj

4

Recruitment center

Name of recruitment center

Meshkin dasht

Full name of responsible person

Malihe Afshar

Street address

Shahid Hemmatkar street

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

Street address

Research deputy, Tabriz university of medical sciences, Golgasht Ave

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of nursing and midwifery

Full name of responsible person

Malihe Afshar

Position

Master of sciences student in midwifery

Other areas of specialty/work

Street address

Faculty of nursing and midwifery, south shariati

City

Tabriz

Postal code

Phone

+98 41 1555 8876

Fax**Email**

mlh.afshar@gmail.com; ma_af_afshar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Faculty of nursing and midwifery, Tabriz university of medical sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Assistant professor/PhD in Reproductive Health

Other areas of specialty/work**Street address**

Faculty of nursing and midwifery, South Shariati

City

Tabriz

Postal code**Phone**

+98 41 1477 2699

Fax**Email**

smaalch@yahoo.com

Web page address

alizades@tbzmed.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Malihe Afshar

Position

Master of sciences student in midwifery

Other areas of specialty/work**Street address**

Faculty of Nursing and Midwifery, South Shariati

City

Tabriz

Postal code**Phone**

+98 26 1222 1400

Fax**Email**

mlh.afshar@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty