Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Oct 2026

The Study of Effect of Education of Sexual Health Promotion Package on Sexual Health Dimensions of Pregnant Women

Protocol summary

Study aim
To determine the effect of education of sexual health promotion package in woman during pregnancy

Design
This study is a longitudinal clinical trial. 225 pregnant women referred to Health Centers were randomly divided into three groups of 75 (intervention, self-educated, control).

Settings and conduct
In this study, 225 participants of the samples (75 participants in each groups) referred to Health Centers (The State-run Hospitals and health service centers) in Rasht, were selected randomly. In the intervention group, the training was given by lecture method, the second group were self-educated and the third group were control group (without education).

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age less than 14 weeks; women's age between 15- 45 years; Having informed consent to participate in the study; Lack of history of medical diseases; lack of consumption of the medication that affect sexual function; lack of drug addiction; lack of high risk pregnancy criteria; lack of experience of an acute stress during recent years such as child's death, acute illness, etc. Exclusion criteria: happening any problem during the study.

Intervention groups
In the intervention group, women was taught 90 minutes through lecture, question and answer method in 3 sessions. In the self-educated group, sexual health package (package of pregnant women) was given to them. In the control group was without education.

Main outcome variables
Changes in pregnancy sexual response (PSRI) score; Change in sexual function score; Change in sexual quality of life score; Change in sexual violence score.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190427043398N1**
Registration date: **2019-06-02, 1398/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-02, 1398/03/12**
Update count: **0**

Registration date
2019-06-02, 1398/03/12

Registrant information
Name
Shiva Alizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8865 5466
Email address
shiva.alizadeh@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-01, 1397/06/10
Expected recruitment end date
2019-06-20, 1398/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The Study of Effect of Education of Sexual Health Promotion Package on Sexual Health Dimensions of Pregnant Women

Public title

To Determine the Effect of Education of Sexual Health Promotion Package in Woman During Pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: gestational age less than 14 weeks; women's age between 15- 45 years; Having informed consent to participate in the study; Lack of history of medical diseases; lack of consumption of the medication that affect sexual function; lack of drug addiction; lack of high risk pregnancy criteria; lack of experience of an acute stress during recent years such as child's death, acute illness, etc.

Exclusion criteria:

Unwillingness of pregnant women to participate in the study

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **225**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was done by cluster random sampling in areas of Rasht. In the beginning, Rasht was divided into five regions (East, West, North, South, and Center). The name of the five regions was written separately on paper. Simple randomly was drawn and three regions (East, West, Center) were selected. Then again, in each cluster (region), the name of comprehensive health care centers was written separately on a paper and was simple randomly drawn. In the lottery, the first name of the center was in the intervention group; the second name of the center was in the self-education group and the third in the control group (Three centers in each area).

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 committtee of Shahid Beheshti University of Medical Sciencesty

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2016-07-18, 1395/04/28

Ethics committee reference number

IR.SBMU.PHNM.1395.495

Health conditions studied

1

Description of health condition studied

Sexual Health

ICD-10 code

Z70.9

ICD-10 code description

Sex counseling, unspecified

Primary outcomes

1

Description

Sexual Response in pregnancy

Timepoint

Before intervention; At the beginning of each subsequent intervention; Four weeks after the last intervention

Method of measurement

Pregnancy Sexual Response Inventory (PSRI)

2

Description

Sexual function

Timepoint

Before intervention; At the beginning of each subsequent intervention; Four weeks after the last intervention

Method of measurement

Female Sexual Function Index (FSFI)

3

Description

Sexual Quality of life

Timepoint

Before intervention; At the beginning of each subsequent intervention; Four weeks after the last intervention

Method of measurement
Sexual Quality of life Questionnaire

4

Description
Sexual Violence
Timepoint
Before intervention; At the beginning of each subsequent intervention; Four weeks after the last intervention
Method of measurement
Sexual Violence Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: Face-to-Face training is provided to pregnant women in three sessions -90 minute- during pregnancy (first session in the first trimester, second session in the second trimester, third session in the third trimester); through lecture, Question and Answer training provided by the researcher. The Sexual Health Package was designed based on the clinical guidelines of NICE. According to this pattern, the package was designed after searching in the guidelines, books, sexual health packages of various countries, as well as articles. Then, the sexual health package was validated by the Delphi method, using the opinions of specialists and experts in various cities of Iran. This package (In two parts for health care providers and pregnant women) was designed to provide educational content that include the most important aspects of sexual health during pregnancy (for each trimester of pregnancy, an educational session).
Category
Behavior

2

Description
Second intervention group: Self-educated group: Sexual health package (package of pregnant women) was given to them at the beginning of pregnancy.
Category
Behavior

3

Description
Control group: Just Routine care was taken in the control group and they did not receive any training packages and intervention. Routine care is prenatal care, which is done based on Iran's Ministry of Health's Pregnancy Care Guidelines and WHO guidelines, such as vaccination, blood pressure control, weight measurement, nutrition counseling for pregnant women.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Service Centers in Rasht
Full name of responsible person
Shiva Alizadeh
Street address
Mozhdeh building., Second Alleyway., Bayanii Street., Heshmat Intersection
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Rasht
Province
Guilan
Postal code
4194644184
Phone
+98 13 3366 9930
Email
shiva.alizadeh@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Vele.njak
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Province
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Postal code
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Phone
+98 21 2243 9781
Email
Intl_office@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shiva Alizadeh

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niayesh intersection., Vali-e-Asr street.,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associated professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

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City

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Province

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Postal code

1985717443

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A report including An Introduction, Methodology, Results and Discussion

When the data will become available and for how long

The data will be accessible 6-12 month after publishing the results.

To whom data/document is available

researchers in academic institutes were allowed to access data

Under which criteria data/document could be used

with stating the reference

From where data/document is obtainable

sending email to corresponding author through: g.ozgoli@gmail.com

What processes are involved for a request to access data/document

A application letter must include the name of the applicant, used item, scientific title of the research project or article.

Comments