

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2022

Investigation of the effect of education on modifying dysfunctional sexual beliefs of pregnant women by using Text Message

Protocol summary

Study aim

(GENERAL OBJECTIVES): Determining the effect of sexual education by sending text message on modifying dysfunctional sexual beliefs in pregnant women
(SPECIFIC OBJECTIVES): 1-Determination and comparison of the mean of dysfunctional sexual beliefs score in pregnant women, before and after education in the intervention group 2-Determination and comparison of the mean of dysfunctional sexual beliefs score in pregnant women, before and after education in the control group 3-Determination and comparison of the mean of dysfunctional sexual beliefs score in pregnant women, before and after education in 2 groups of intervention and control

Design

Randomized, controlled clinical trial, in parallel with a control group

Settings and conduct

This study was performed on 82 pregnant women who referred to Prenatal Care Center (Emam Ali and Kamali Hospital). Samples are randomly distributed from each center (40 people per center) based on entrance criteria and randomly assigned to each intervention and control group.

Participants/Inclusion and exclusion criteria

18-45 years age of healthy pregnant women, with gestational age of 14-28 weeks, married with monogamous life, Iranian nationality, speaking Persian, having minimum ability of reading and writing, having personal cellphone, not having abortion and Marital incompatibility history, having dysfunctional sexual beliefs according to the questionnaire

Intervention groups

Intervention group: 41 Pregnant women will be placed in the intervention group according with the entry criteria and in 8 weeks such every other day on specified hour, totally 24 sexual text messages will be sent for them. Data will be collected before and immediately after the intervention by Demographic characteristics, Marital

compatibility questionnaire and dysfunctional sexual beliefs questionnaire.

Main outcome variables

dysfunctional sexual beliefs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161230031662N9**

Registration date: **2019-07-15, 1398/04/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-15, 1398/04/24**

Update count: **0**

Registration date

2019-07-15, 1398/04/24

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-10-12, 1398/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of education on modifying dysfunctional sexual beliefs of pregnant women by using Text Message

Public title

The effect of education on modifying dysfunctional sexual beliefs of pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of pregnant women : between 18-45 years
Gestational age :14-28 weeks (Based on LMP or Sonography) with Prenatal Care sheet Having ability to read and write Wanted pregnancy No use of Drugs Affecting Sexual Function Physical Health of the Mother Married monogamous life Having personal Cellphone Iranian nationality Fluency in Persian

Exclusion criteria:

Known Psychiatric diseases Having history of sexual dysfunction or any untreated Psychiatric disorder before pregnancy in married couples Using psychiatric drugs such as: Anti-Depression drug Addiction of husband or wife High-risk pregnancy such as: Vaginal bleeding, Placenta Previa, Cervix Insufficiency, Cervical Cerclage, Twinings, Fertility by ART, Threat to abortion, Chronic medical diseases(Diabetes, Blood Hypertension, Cardiovascular disease and...) Previous abortion history Having Marital incompatibility Announcing opt-out from continuing the study

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: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization Individual randomization Online randomization Allocation concealment: Using opaque envelopes

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 Alborz University of Medical Sciences

Street address

North Taleghani , Azimiyeh

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.ABZUMS.REC.1398.024

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

Pregnancy

ICD-10 code

Z70.0

ICD-10 code description

Counseling related to sexual attitude

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

Dysfunctional sexual beliefs

Timepoint

Before intervention, Immediately after intervention

Method of measurement

Dysfunctional Sexual Beliefs Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 41 pregnant women will receive sexual educational text messages three times a week(every other day) totally 24 SMS.

Category

Prevention

2

Description

Control group: 41 pregnant women just receive routine prenatal care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali teaching hospital

Full name of responsible person

Shirin Khoddam

Street address

Emam Ali medical-educational center-Azimieh Junc,
First of the Chalus Road

City

Karaj

Province

Alborz

Postal code

3155683119

Phone

+98 26 3250 0123

Fax

+98 26 3254 7128

Email

EMAMALI@abzums.ac.ir

Web page address

<https://emamali.abzums.ac.ir>

2

Recruitment center

Name of recruitment center

Kamali teaching hospital

Full name of responsible person

Shirin Khoddam

Street address

Kamali Hospital, Kamali Street, Taleghani Street,
Shohada Square

City

Karaj

Province

Alborz

Postal code

3134877179

Phone

+98 26 3222 2021

Email

Hospital.Kamali@Abzums.ac.ir

Web page address

<https://kamali.abzums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Alborz University of
Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

Street address

North Taleghani street, Azimiyeh

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 4255

Email

dr.noorisepehr@abzums.ac.ir

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

Yes

Title of funding source

Vice chancellor for research, Alborz 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

Karaj University of Medical Sciences

Full name of responsible person

Shirin Khoddam

Position

BsC in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Medicine, University of Medical Sciences
Campus, University of Art, End of West Bou Ali Street,
Nabovvat Square, Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3419 7685

Email

shirinkhoddam@yahoo.com

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

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

1st Golestan Street, South Eshteraki Boulevard,
Baghestan

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 912 765 5855

Email

lotfi_razieh@yahoo.com

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

Karaj University of Medical Sciences

Full name of responsible person

Shirin Khoddam

Position

BCs in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Medicine, University of Medical Sciences
Campus, University of Art, End of West Bou Ali Street,
Nabovvat Square, Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3419 7685

Email

shirinkhoddam@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total potential data can be shared after unidentifiable people

When the data will become available and for how long

Data will be in access 6 months after publishing the results.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Scientific studies

From where data/document is obtainable

Using Email Address:marmarmzf@gmail.com

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

Up to a week after sending the email address

Comments