

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of multimedia educational intervention based on health promotion model on doing relaxation and anxiety among primigravida women

Protocol summary

Study aim

Determining the effect of a multimedia educational intervention based on health promotion model on performing relaxation and anxiety among primigravida women in Busher

Design

A quasi-experimental study, two groups of intervention and control, multi-stage sampling, parallel groups, sample size of 84, Primigravida women, phase I

Settings and conduct

This study will be conducted in comprehensive Health Care Center in Bushehr. Five centers will be selected as control and 5 as the intervention groups. The blinding is not possible, but in order to prevent selection bias, the centers selected as intervention and control groups are separated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First pregnancy experience, Gestational age of 28 to 32 weeks, Having an anxiety score higher than the median, Not having a history of mental illness, Not using anti-anxiety drugs, Having read and writing skills, Having a computer or device that can play video from a flash drive, The desire to participate in the study. Non-entry criteria: Unwilling to participate in the study

Intervention groups

The educational package will be designed after the development of educational content based on the health promotion model structures for the intervention group in the form of multimedia, Which will be available to participants through flash memory. For participants in the intervention group, weekly 2 text message reminders will be sent by SMS from the interval between the completion of the training program to one month later. There is no intervention for women in the control group and their anxiety levels are measured as the intervention group. Before intervention and then two weeks and one

month after the intervention, the questionnaires will be completed by the intervention and control groups

Main outcome variables

Awareness: perceived benefits: perceived barriers: perceived self-efficacy: perceived social support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180529039898N1**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Zeinab Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2018-10-12, 1397/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multimedia educational intervention based on health promotion model on doing relaxation and anxiety among primigravida women

Public title

The effect of multimedia educational intervention on doing relaxation and anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

First pregnancy experience Gestational age (28 to 32 weeks based on the exact date of the first day of the last menstruation) Having an anxiety score higher than the median score No history of mental illness (such as depression, schizophrenia, etc.) according to the electronic record Not taking anti-anxiety drugs based on electronic records Having reading and writing skills Having a computer or device that can play video from a flash drive The desire to participate in the study

Exclusion criteria:

Unwilling to participate in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

we use simple random sampling for selecting comprehensive healthcare centers. Then, 5 centers will be randomly selected as the control groups and 5 as the interventions groups. In the next step, based on the records in the SIB (Integrated Health System) system, individuals with inclusion criteria will be selected according to the sample size of 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 Busher University of Medical Sciences

Street address

Busher University of Medical Sciences, Salman farsi street, Risher

City

Busher

Province

Boushehr

Postal code

7518759577

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.BPUMS.REC.1396.217

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

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

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

Anxiety Scale in Pregnancy Anxiety Questionnaire

Timepoint

Before the Intervention, Two Weeks and One Month After the Intervention

Method of measurement

Pregnancy Anxiety Questionnaire

Secondary outcomes**1****Description**

Awareness

Timepoint

Before the Intervention, Two Weeks and One Month After the Intervention

Method of measurement

Awareness Questionnaire(Researcher made)

2**Description**

Perceived Barriers

Timepoint

Before the Intervention, Two Weeks and One Month After the Intervention

Method of measurement

Perceived Barriers Questionnaire(Researcher made)

3

Description

Perceived Benefits

Timepoint

Before the Intervention, Two Weeks and One Month After the Intervention

Method of measurement

Perceived Benefits Questionnaire(Researcher made)

4

Description

Perceived Self-Efficacy

Timepoint

Before the Intervention, Two Weeks and One Month After the Intervention

Method of measurement

Perceived Self-Efficacy Questionnaire(Researcher made)

5

Description

Perceived Social Support

Timepoint

Before the Intervention, Two Weeks and One Month After the Intervention

Method of measurement

Perceived Social Support Questionnaire (Researcher made)

Intervention groups

1

Description

Intervention group: The educational package will be designed after the development of educational content based on the health promotion model structures in the form of multimedia, including text, graphics, audio and videos, which will be available to participants through flash memory. Participants in the intervention group have one week time to view the received educational content. In order to ensure that the educational content is viewed, they will be contacted after a week and questions about the educational content will be asked. Those who have not seen the content of the training at the specified time will be given three days added time. Finally, people who do not see educational content during this period will be excluded from the study. Also, a reminder text message (SMS) will be sent twice a week during one month (from the completion of the training program to one month later).

Category

Lifestyle

2

Description

Control group: Pregnant women in the control group will not receive any intervention. Before intervention and then two weeks and one month after the intervention, the questionnaires will be completed by the control group. After doing the final measurement, the educational content is given to the participants in the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kheybar Health Services Center

Full name of responsible person

Nasrin Shabankareh

Street address

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2

Recruitment center

Name of recruitment center

Hafta tir Health Services Center

Full name of responsible person

Zeinab Sarkhosh

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Koosha special school alley, Imam Street

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Recruitment center

Name of recruitment center

Nabi akram Health Services Center

Full name of responsible person

Maryam Mohammadi

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Bazargani Alley, Motahhari street

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Recruitment center

Name of recruitment center

Meraj Health Services Center

Full name of responsible person

Azarossadat Tabarestani

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Recruitment center

Name of recruitment center

Ghods Health Services Center

Full name of responsible person

Leyla Savamery

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Recruitment center

Name of recruitment center

Sahebzaman Health Services Center

Full name of responsible person

Rahimeh Jalilvand

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Recruitment center

Name of recruitment center

Shohada Health Services Center

Full name of responsible person

Zahra Hojabri

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In front of cemetery, Behesht Sadegh Street

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Recruitment center

Name of recruitment center

Shahid Beheshti Health Services Center

Full name of responsible person

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Recruitment center

Name of recruitment center

Hazrat Zeinab Health Services Center

Full name of responsible person

Farzane Agha

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Recruitment center

Name of recruitment center

Ali Ebne Abitaleb Health Services Center

Full name of responsible person

Soodabeh Zalpour

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In front of the Sheikh Saadoun mosque, Kooti street

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soodabeh.zalpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholam Reza khamisipour

Street address

University of medical sciences, Salman farsi street,
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Province

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Postal code

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khamisipoor@Bpums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Mahnoosh Reisi

Position

Ph.D in Health Education and Health Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahnoosh Reisi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Zeinab Mohammadi

Position

Master Student Health education

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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