

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Explanation, design and evaluation of intention reproductive behavior education program of married women of reproductive age: Mixed Method Study

Protocol summary

Study aim

Explain reproductive behavior and then design and determine the effect of educational program on the intention of reproductive behavior of married women of reproductive age in Rasht

Design

: Mixed Method Study. quantitative and qualitative stage, with control group, parallel groups, randomized, 114 samples, Random allocation software

Settings and conduct

The combined study will be done in two quantitative and qualitative stages. The study units are married women of reproductive age who refer to comprehensive health centers in the city.

Participants/Inclusion and exclusion criteria

Minimum age 15 and maximum age 49 years Covered by comprehensive health centers in Rasht Absence of infertility problems with female and male factors Willingness to participate in the study Two years have passed since the marriage

Intervention groups

Qualitative stage: In the qualitative stage, the inductive-deductive approach will be used. Needs assessment is performed using semi-structured and in-depth interviews with married women of childbearing age. Quantitative study (implementation): This part of the study is a quasi-experimental study (educational intervention) with a control group. The research units are randomly assigned to two groups of test and control. Before the training program, the questionnaire of reproductive behavior in the two groups of intervention and control is completed by the research units and then the educational software will be installed on the mobile phones of the intervention group and these people will receive training. The control group did not receive any intervention from the researcher.

Main outcome variables

intention reproductive behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040364N2**

Registration date: **2022-01-12, 1400/10/22**

Registration timing: **prospective**

Last update: **2022-01-12, 1400/10/22**

Update count: **0**

Registration date

2022-01-12, 1400/10/22

Registrant information

Name

Parisa Farzi karamolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5058

Email address

parisa.farzi92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-03, 1400/11/14

Expected recruitment end date

2022-07-05, 1401/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Explanation, design and evaluation of intention reproductive behavior education program of married women of reproductive age: Mixed Method Study

Public title

Explanation, design and evaluation of intention reproductive behavior education program of married women of reproductive age: Mixed Method Study

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum age 15 and maximum age 49 years Covered by comprehensive health centers in Rasht Absence of infertility problems with female and male factors Willingness to participate in the study Two years have passed since the marriage

Exclusion criteria:**Age**From **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **114****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. Random allocation software is also used for randomization tools. In addition to simple randomization, random sequence generation software is able to generate random sequences by block generation method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes) in which in this method each of the random sequences created is recorded on a card and the cards in the envelopes to They are placed in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

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**

Research Ethics Committees og Guilan University of Medical Sciences

Street address

Rasht - Namjoo St. - Shahid Siadati St. - in front of Shahrivar Hospital - Vice Chancellor for Research and Technology

City

Rasht

Province

Guilan

Postal code

4146939114

Approval date

2021-11-23, 1400/09/02

Ethics committee reference number

IR.GUMS.REC.1400.418

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

intention reproductive behavior education program of married women of reproductive age

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

intention reproductive behavior

Timepoint

Before and after the intervention

Method of measurement

Reproductive Behavior Intention Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: educational content based on the intention of women's reproductive behavior before the training program, a questionnaire in both intervention and control groups will be completed by the research units and then the educational software will be installed on the mobile phones of the intervention group. During the installation, the participants will be taught how to use and work with the software, and 1 week after installing the program on the mobile phone of the intervention group, they will be contacted and answered any questions and problems regarding the use of the software. will be given. The duration of training is 8 weeks.

Category

Other

2

Description

Control group: Control group: The control group is not subject to any intervention by mobile phone software and is not aware of the implementation of the training program in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers

Full name of responsible person

Zahra Bostani Khalesi

Street address

Comprehensive Health Center, Pasteur Three Ways, Rasht

City

Rasht

Province

Guilan

Postal code

4471683835

Phone

+98 13 3382 0051

Email

z_bostani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

mohammad Reza Naghipoor

Street address

In front of 17 Shahrivar Hospital, Shahid Siadati St.Namjoo St.

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4146939114

Phone

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z_bostani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani Khalesi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Shahid Beheshti School of Nursing and Midwifery, Student Park, Ice Square, Rasht

City

Rasht

Province

Guilan

Postal code

4146939841

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+98 13 3355 5056

Email

z_bostani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Zahra Bostani Khalesi

Position

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

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

Main and general data

When the data will become available and for how long

One year

To whom data/document is available

Faculty members of Shahid Beheshti School of Midwifery and Nursing, Rasht

Under which criteria data/document could be used

In order to check the accuracy of the data and with a written request in hand And approved by the Vice Chancellor for Research, Shahid School of Nursing and Midwifery Beheshti Rasht

From where data/document is obtainable

Library of Shahid Beheshti School of Midwifery and Nursing and also Written request from the project manager

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

Permission from the librarian of Shahid Beheshti School of Midwifery and Nursing in Rasht Written form and contact with the project manager and make a moral agreement

Comments