

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Feb 2023

Effect of Trans- theoretical model-based education on reproductive age women's knowledge, attitude and decision making toward childbearing

Protocol summary

Summary

The general goal of the study is determining the effect of Trans- theoretical model-based education on knowledge, attitude and decision making toward childbearing in reproductive age women who referring to community health centers in Amol city. The specific objectives of this plan are to determine and compare the attitudes, knowledge, decision-making balances, self-efficacy, and stages of behavior change towards childbearing in two groups, the test and control are before and after intervention. The type of this study was experimental, multi-stage sampling method and the selection of samples in each group was random and simple, and the number of samples was 76 in each group (152 in total) which are randomly selected from the two health centers of the urban community of Amol. Inclusion criteria are marriage; fertility; being healthy; aged 18 to 35, exclusion criteria are marital conflicts; Prohibition of childbearing. Training sessions are 5 one-hour sessions and various methods such as lecture with slideshow (with issues of importance and benefits of childbearing, healthy lifestyle before pregnancy, pre-conception counseling, etc.), video, question and answer, small group meetings. Primary outcomes are knowledge and attitude towards childbearing. Secondary outcomes are Structures such as stages of behavior change, self-efficacy and decision-making balance. Independent variable is Trans-theoretical model-based education. Dependent variables are attitude and knowledge about childbearing, self-efficacy, decision-making balance and the stages of behavior change.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017083131117N4**

Registration date: **2017-10-27, 1396/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-27, 1396/08/05

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 8918

Email address

s.khani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Trans- theoretical model-based education on reproductive age women's knowledge, attitude and decision making toward childbearing

Public title

Effect of education on women's knowledge, attitude and decision making toward childbearing

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Marriage; living with husband; aged 18 to 35; fertility; having a maximum of 2 children; having passed at least one year of marriage; using a contraceptive method; interval between pregnancy more than 3 years; lack of planning for the current or future pregnancy despite the desire to have a child; access to the mobile phone; to be in pre-contemplation, contemplation and preparation groups based on trans-theoretical model. Exclusion criteria: absence in the first training session; unwillingness of woman or her husband to participate in a research project; infertility; severe family conflicts; more than 3 times cesarean section; certain chronic diseases and any prohibition of childbearing

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

table of random number will be used.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

vice chancellor for research, Mazandaran University of Medical Sciences, Moalem Square

City

Sari

Postal code**Approval date**

2017-08-13, 1396/05/22

Ethics committee reference number

IR.MAZUMS.REC.1396.3112

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

childbearing

ICD-10 code

-

ICD-10 code description

-

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

childbearing knowledge toward childbearing

Timepoint

Before the intervention, 3 and 6 months after the completion of the educational intervention

Method of measurement

validated Researcher-made questionnaire on childbearing

2**Description**

childbearing attitude toward childbearing

Timepoint

before the intervention, 3 and 6 months after the intervention

Method of measurement

questionnaire

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

stages of behavior change construct

Timepoint

Before the intervention, 3 and 6 months after the completion of the educational intervention

Method of measurement

Decision-making questionnaire for childbearing based on a trans-theoretical model (Dr. Abolhassan Naghibi)

2**Description**

self efficacy construct

Timepoint

before the intervention, 3 and 6 months after intervention

Method of measurement

decision making about childbearing questionnaire

3

Description

decision making about childbearing construct

Timepoint

before the intervention, 3 and 6 months after intervention

Method of measurement

decision making about childbearing questionnaire

Intervention groups

1

Description

The control group: This group will receive common education for promoting childbearing on the basis of new population policies in accordance with the Ministry of Health's instructions from the relevant center along with the intervention group.

Category

Behavior

2

Description

The intervention group: This group will receive training in accordance with their behavioral stages: 2 sessions of the precontemplation group (with topics: importance of childbearing in sociology, awareness of childbearing and the consequences of delay, discontinuation of contraceptive methods, healthy lifestyle before pregnancy), 2 sessions of the contemplation group (with topics: Interruption of contraceptive methods, healthy lifestyle, preconception counseling), and 1 session of the preparation group (with topics preconception counseling, embryo developmental stages, maternal health and discussion of teratogens, pregnancy symptoms and how to deal with it, importance of embryo screening during pregnancy, proper pregnancy care for childbearing), with various method such as lecture with slide show, question and answer, video, small group meetings. Each session will be 60 minutes long. At the end of each session a pamphlet summarizing its educational materials session will provide. After the completion of the training program, text messages will be provided on a weekly basis. In case of need, the test group can receive telephone or textual advice.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

two healthcare centers of Amol city

Full name of responsible person

Street address

City

Amol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Dr Enayati

Street address

Moalem square, vice chancellor for research of Mazandaran University of Medical Sciences

City

Sari

Grant name

Grant code / Reference number

1396.3112

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

Yes

Title of funding source

vice chancellor for research of Mazandaran 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

Mazandaran University of Medical Sciences, Sexual and Reproductive Health Research Center

Full name of responsible person

Dr Soghra Khani

Position

PhD, Moderator (owner) of project

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Modarator (owner) of [project/ PhD]

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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