Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Design, implementation, and evaluation of childbearing intention program based on Multi -theory model in women of reproductive age referring to comprehensive health centers in Yazd

Protocol summary

Study aim

Determining the effect of Design, implementation, and evaluation of childbearing intention program based on multi -theory model in women of reproductive age referring to comprehensive health centers;Yazd

Design

A clinical trial with a control group, parallel groups, randomized, on 100 patients(50 people in each group). Random Allocation software will be used for randomization.

Settings and conduct

The pre-test involves women completing a self-reported questionnaire via an internal messaging network. The educational intervention includes at least four sessions: (three sessions, 45-60 minutes each, twice a week for women at the Comprehensive Health Center and a joint session with their husbands.) These sessions, led by Ph.D student under professor supervision, are based on pre-test results and interviews, following the Multi-Theory Model. Participants will receive updates, materials, and session reminders via the messaging network and SMS, with opportunities to ask questions through voice or private chat.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be literate in reading and writing and reproductive age; Not planning pregnancy before the study; First marriage of the woman; Has one child; having an active sexual and marital relationship; At least 18 months since the previous pregnancy; Access to cell phones and virtual social networks; No medical contraindications for pregnancy; The only wife of her husband

Intervention groups

The research population consists of women of reproductive age with one child who refer to comprehensive health centers in Yazd. The intervention consists of at least 4 sessions, and the control group receives routine care at the health center

Main outcome variables

Changing the behavior of pregnancy intention and the mean scores of the constructs of the beginning and Sustaining pregnancy behavior change.

General information

Reason for update

-Modify "assess" to "evaluation" in the title. -Renaming one of the Inclusion criteria for entering the study from "To have a common bed with her husband" to "having an active sexual and marital relationship." -Insert the full name of the research committee, the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd. - Change the target group from "Women with one and two children" to "Women with one child" - Modify the overall aim of the study to "Determine the effect of the childbearing intention program based on a multi-theory model in women of reproductive age referring to comprehensive health centers in Yazd city

Acronym

IRCT registration information

IRCT registration number: **IRCT20170802035446N3**
Registration date: **2024-10-18, 1403/07/27**
Registration timing: **prospective**

Last update: **2025-04-02, 1404/01/13**
Update count: **1**

Registration date

2024-10-18, 1403/07/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3252 6897

Email address
arianmokhtari2@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-04-09, 1404/01/20
Expected recruitment end date
2025-07-23, 1404/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Design, implementation, and evaluation of childbearing intention program based on Multi -theory model in women of reproductive age referring to comprehensive health centers in Yazd

Public title
evaluation of childbearing intention program based on Multi - theory model in women of reproductive age referring to comprehensive health centers in Yazd
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Be literate in reading and writing. Be of reproductive age. Not intending to get pregnant before starting the study Be The first marriage of the woman At least 18 months have passed since her previous pregnancy Access cell phones and virtual social networks Participants do not have medical contraindications for pregnancy (class 4 heart disease, patients using Teratogenic drugs for epilepsy or rheumatoid arthritis, and malignancies). Be the only wife of her husband. having an active sexual and marital relationship have one children
Exclusion criteria:
Occurrence of pregnancy (during and before the intervention) The unwillingness of the wife or her husband to continue participating in the plan
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, for the greater diversity of participants, among the 23 comprehensive health centers of Yazd city, in each of the north, south, east, and west parts of Yazd city, a total of four comprehensive health centers will be selected by cluster sampling method and Simple randomization, two centers will be selected for intervention and two centers for control. Sampling centers for the intervention and control groups are selected in such a way that they are similar in economic, social, and cultural terms. In the intervention phase, 100 women will be included in the study, using random allocation software, in a simple random manner. They are divided into two intervention groups (50 participants) and control group (50 participants).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The present study will be of a combined exploratory type that will be conducted in three phases and stages.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Shahid Sadoughi University of Medical Sciences in Yazd, Iran.
Street address
Imam Hossein (AS) square., Vice-chancellor for Research of Yazd University of Medical Sciences., Yazd
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۱۸۸۶۳۷
Approval date
2024-06-24, 1403/04/04
Ethics committee reference number
IR.SSU.SPH.REC.1403.069

Health conditions studied

1

Description of health condition studied
Childbearing behavior
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Changing the behavior of pregnancy intention. Behavioral intention means starting the behavior of having children, performing pre-pregnancy care behaviors in the health center by completing the pre-pregnancy care form, starting to take folic acid, and not using contraceptive methods.

Timepoint

Before the intervention based on the Multi-theory model in two groups. One month later and three months after the completion of the intervention based on the Multi-theory model in two groups. before, one month after, and three months after the completion of the intervention based on the multi-theoretical model in each group.

Method of measurement

Questionnaire

2

Description

Change in the mean scores of the constructs of the beginning of pregnancy behavior change (participatory dialogue, behavioral confidence, change in the physical environment)

Timepoint

Before the intervention based on the Multi-theory model in two groups. One month later and three months after the completion of the intervention based on the Multi-theory model in two groups. before, one month after, and three months after the completion of the intervention based on the multi-theoretical model in each group.

Method of measurement

Questionnaire

3

Description

Change in the mean scores of the constructs of maintaining and Sustaining pregnancy behavior change (emotional transformation, change in the social environment, practicing for change)

Timepoint

Before the intervention based on the Multi-theory model in two groups. One month later and three months after the completion of the intervention based on the Multi-theory model in two groups. before, one month after, and three months after the completion of the intervention based on the multi-theoretical model in each group.

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Pregnancy rate

Timepoint

Three, six, and nine months after the intervention based on the Multi-theory model I

Method of measurement

Phone interview

Intervention groups

1

Description

Intervention Group: To participate in the pre-test, the questionnaire link will be provided to all participating women via the authorized internal messaging network, where they will complete it in a self-reported format. The educational intervention will consist of at least four sessions (including three 45-60 minute in-person sessions for women, held twice a week, and a joint session with their husbands). These sessions will be conducted by students under the supervision of esteemed professors and will involve lectures, group discussions, educational videos, pamphlets, recommendations of educational books, and training based on insights from pre-test results and interviews, aligned with the structures of the Multi-Theory Model (MTM). The topics will cover:• Having children• The importance and position of children from the Islamic perspective and Quranic teachings• Benefits of having children• The ideal age for having children• The drawbacks of having few or only one child• Strategies to address challenges related to raising and caring for childrenIf necessary, based on pre-test results and the research team's judgment, the number of sessions will be increased. Through the internal messaging network, participants will receive updates on meetings and educational materials, and they will have the opportunity to ask questions via voice or private chat with the researcher. Session assignments will also be sent via SMS as reminders. Since the participation and support of husbands are crucial for having children, husbands will also receive training and counseling on the significance of childbearing, the appropriate timing and age, and additional related topics. A joint session with spouses (in the intervention group) will be invited at the Yazd Municipality Cultural Center, where they will receive necessary training during a group session conducted by experts trusted and approved by them.

Category

N/A

2

Description

Control Group: During this period, the control group will receive routine care from the comprehensive health center. All participating women in both groups will complete the questionnaire again one month and three months after the intervention. Pregnancy occurrence will be followed up by telephone calls to the women (in both groups) at three, six, and nine months after the intervention. Upon completing the follow-ups, and per ethical principles, the educational materials and package will be made available to the women and their spouses in

the control group through a virtual network, where their questions will be answered.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Centers (Rahmat Abad and Farabi), Shahid Dashti Blvd, Yazd; comprehensive healt

Full name of responsible person
Tayebeh Mokhtari Sorkhani

Street address
Mohabbateh Alley, Imam Reza Street, Modares Blvd., Yazd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
دکترامیرهوشنگ مهرپرور

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Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Tayebeh Mokhtari Sorkhani

Position
PhD Candidate

Latest degree
Master

Other areas of specialty/work
Health Promotion

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Person responsible for updating data

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arianmokhtari2@gmail.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
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
All potential data can be shared after making people unidentifiable, for example, in a qualitative study, how to code and themes obtained, and the psychometrics of the final questionnaire and the result of the intervention phase.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions and policy makers of the Ministry of Health, Treatment and Medical Education

Under which criteria data/document could be used
The results of the study can be used in other provinces with the permission of the researchers

From where data/document is obtainable
Tayebeh Mokhtari Sorkhani 00989138417584 arianmokhtari2@gmail.com

What processes are involved for a request to access data/document
After receiving the email, the files will be sent in less than a week

Comments