

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of the lifestyle modification educational package on the attitude to childbearing

Protocol summary

Study aim

Determining the impact of the lifestyle modification educational package on childbearing

Design

The study will be conducted on 260 women who are randomly placed in two intervention and control groups. Block randomization method will be used for randomization using internet tools.

Settings and conduct

Sampling will be done in health centers located in the west and east of Karaj. At first, the researcher calls the eligible people using the phone number listed in their file and after explaining about the objectives and method of conducting the research and the confidentiality of the obtained information, she invites the eligible people to complete the questionnaires online. Each eligible person is placed in a list with a row number, block randomization is used for random allocation (block randomization internet tool).

Participants/Inclusion and exclusion criteria

Women aged 18-45, not suffering from chronic mental or physical illnesses, willingness to participate, not participating in similar educational-counseling programs

Intervention groups

This research is a randomized clinical trial study on married women referring to the West and East Karaj Health Center, who have the characteristics of the research unit, will be conducted from 08/30/1401. In the intervention group, group meetings will be held in 5 groups of 26 people. In order to implement the lifestyle modification training package in the intervention group, 5 sessions of 30-45 minutes each week will be held by a midwife and a psychiatrist with experience in the field of lifestyle modification training and with the coordination of the patients in a group.

Main outcome variables

Increasing awareness and desire for childbearing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220704055367N4**

Registration date: **2022-12-09, 1401/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-09, 1401/09/18**

Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Fatemeh Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

fatemeh.abdi87@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the lifestyle modification educational package on the attitude to childbearing		Not used
Public title	Designing an educational package for increasing childbearing	Assignment Parallel
Purpose	Education/Guidance	Other design features
Inclusion/Exclusion criteria		Secondary Ids empty
Inclusion criteria:	Being married Interest in participation in the study Being able to read and write	Ethics committees
Exclusion criteria:	Suffering from chronic mental or psychical disorder Participation in other similar programs	1
Age	From 18 years old to 45 years old	Ethics committee
Gender	Female	Name of ethics committee Research Ethics Committee of Alborz University of Medical Sciences
Phase	N/A	Street address Alborz University of Medical Sciences, Shahrake Edari, North Taleghani, Azimieh, Karaj
Groups that have been masked		City Karaj
	• Outcome assessor • Data analyser	Province Alborz
Sample size	Target sample size: 260	Postal code 3149779453
Randomization (investigator's opinion)	Randomized	Approval date 2022-11-12, 1401/08/21
Randomization description	Block randomization method is used in the present study. This will be done using a random block internet tool via http://www.sealedenvelope.com/simple-randomiser/v1/lists . Block size is determined 4 and allocation was done upon arrangement of codes in the blocks. Randomization will be concealed in sequentially numbered, sealed, opaque envelopes. After producing randomization sequence, 112 opaque envelopes will be provided and each randomization sequence is recorded on a card, then placed in the envelope in order. To keep concealment, envelopes are numbered too. The envelope is sealed and placed in a box in order. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened and the assigned group of the participant will be determined.	Ethics committee reference number IR.ABZUMS.REC.1401.218
Blinding (investigator's opinion)	Single blinded	Health conditions studied
Blinding description	This study is a blinded clinical trial. Therefore, blinding will be implemented in the evaluators who will analyze the study data. For this purpose, the questionnaires that will be completed by the researchers in all three groups, in the form of a contract between the researchers. Also, it will be specified with one of the English letters above it, which questionnaire was completed by the participants of which of the study groups; However, the evaluators of the data analysis will not be aware of the English letter of agreement between the researchers assigned to each group.	1
Placebo		Description of health condition studied childbearing
		ICD-10 code
		ICD-10 code description
		Primary outcomes
		1
		Description The average score of the questionnaire of childbearing desire developed by Ganjovi
		Timepoint Before the intervention and 1 month after the end of the intervention
		Method of measurement Ganjovi's questionnaire of childbearing desire
		Secondary outcomes empty
		Intervention groups
		1
		Description

Intervention group: In order to implement the lifestyle modification training package in the intervention group, 5 sessions of 30-45 minutes each week will be held by a midwife and a psychiatrist with experience in the field of lifestyle modification training and with the coordination of patients in a group. The content of the lifestyle modification package from the pre-pregnancy diet chapter from the pregnancy nutrition book: a complete guide to healthy eating translated by Akram and Karmi, the pre- and post-pregnancy care book translated by Fatemeh Sohba and the pre-pregnancy exercise chapter from The book Motherhood (before pregnancy) written by Flora Tajiki will be prepared. The content of the sessions will include the following: Session 1: introduction and familiarization, stating the general goals of the intervention, stating how to perform the interventions, stating the topics of the sessions. Session 2: Pyramid of food, vitamins and minerals. Session 3: Start proper nutrition. Session 4: Suitable sports. Session 5: Teaching health tips.

Category

Lifestyle

2

Description

Control group: Receive routine services of selected centers

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centres located in west and east of Karaj

Full name of responsible person

Fatemeh Abdi

Street address

Resalat crossroad

City

Karaj

Province

Alborz

Postal code

3154646695

Phone

+98 26 3254 6372

Email

emamali@abzums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Street address

Alborz Univeirsity of Medical Sciences (ABZUMS),
Northern Taleghani boulevard,Taleghani square

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3419 7000

Email

info@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Fatemeh Abdi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Fax

Email

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Person responsible for scientific inquiries

+98 26 3433 6007

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Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of nursing, Eshteraki street, Baghestan BLVD,
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City

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3146883811

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Email

fatemeh.abdi87@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of nursing, Eshteraki street, Baghestan BLVD,
Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3146883811

Phone

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to the main outcome and general demographic information can be shared.

When the data will become available and for how long

The access period starts 3 months after the results are published

To whom data/document is available

Doctors, nurses, midwives, researchers working in universities and medical centers and hospitals, Policy-makers

Under which criteria data/document could be used

In order to use it for scientific purposes and by mentioning the source used and requesting the journal in which the article will be published.

From where data/document is obtainable

Communication through e-mail (if possible to share information from a legal and ethical point of view, such as sharing the primary outcome of the study) To receive information, contact the following email address: fatemeh.abdi87@yahoo.com In the case of sending letter with regard to the current study, the following postal address of the corresponding author is available: School of nursing, Eshteraki street, Takhti Park, Baghestan BLVD

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

Finding the responsible author's email, stating the reason, complying with ethical and legal issues; In this case, a quick response will be given to the requester.

Comments