

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of an educational intervention based on the integration of the theory of planned behavior and the theory of social cognition on performing health behaviors before pregnancy of single-child couples: a clinical trial

Protocol summary

Study aim

Determining the effect of the educational intervention based on the integration of the theory of planned behavior and the theory of social cognition on performing health behaviors before pregnancy of single-child couples

Design

Clinical trial with control group, with parallel groups, randomized

Settings and conduct

This study will be conducted in Mashhad. Eligible people for the study will be extracted through the electronic system in health centers and will be randomly divided into two intervention and control groups, the intervention group will receive the designed training. The control group will also receive routine pre-pregnancy care in women.

Participants/Inclusion and exclusion criteria

inclusion criteria:Iranians and residents of Mashhad city, age 15-50 for men and 18-45 years for women with a single child at least 12 months old, having a health record in comprehensive health service centers, having at least elementary education. Declaration of consent to participate in Research. Criteria for exclusion from the study: withdrawal of one or both of the couples from continuing to cooperate in the research, secondary infertility, failure to participate in one or more of the training sessions, absolute and relative prohibition for pregnancy, incomplete completion of the questionnaire

Intervention groups

The intervention group will receive group training with lectures, group discussions and questions and answers. The control group will receive routine pre-pregnancy education

Main outcome variables

awareness, attitude, self-efficacy, behavioral intention,

abstract norm, outcome expectation, facilitating conditions, Health behavior before pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220629055321N1**

Registration date: **2022-09-14, 1401/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-14, 1401/06/23**

Update count: **0**

Registration date

2022-09-14, 1401/06/23

Registrant information

Name

Fatemeh Ghaffari sardasht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

ghaffarif891@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of an educational intervention based on the integration of the theory of planned behavior and the theory of social cognition on performing health behaviors before pregnancy of single-child couples: a clinical trial

Public title
The effect of educational intervention on performing health behaviors before pregnancy of single-child couples: a clinical trial

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Iranians and residents of Mashhad Age 15 to 50 years for men and women 18 to 45 years with only one child at least 12 months old Having health records in comprehensive health service centers Having at least primary education Declaration of consent to participate in the research
Exclusion criteria:
 Secondary infertility Relative or absolute prohibition for pregnancy

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of fertile age couples to intervention and control groups will be done randomly with a random sequence generated using the randomization site, in such a way that for random assignment to the number of samples, we will get a code (code A and B) from the randomization site and We put these codes in a separate envelope in the same order as we got them from the site. Then we stack the envelopes in the order of the codes obtained from the aforementioned website. It should be noted that before starting the sampling, we will conduct a lottery to determine which of the A and B codes obtained from the randomization site will be considered as the intervention group and which code will be considered as the control group. During sampling, the first person who agrees to participate in the intervention takes the first envelope, and after opening the envelope, it is determined whether he is part of the control group or the intervention, and in the same way random allocation for all study samples. will be done. It should be

noted that the person who creates the random sequence is different from the person who is involved in the registration process or allocation of participants.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants do not know in which group (intervention and control) they will be placed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Shahroud University of Medical Sciences
Street address
 hafte-tir square
City
 shahroud
Province
 Semnan
Postal code
 73943- 36147

Approval date
2019-05-08, 1398/02/18

Ethics committee reference number
IR.SHMU.REC.1398.025

Health conditions studied

1

Description of health condition studied
Performing the health behaviors before pregnancy

ICD-10 code
Z34

ICD-10 code description
Encounter for supervision of normal pregnancy

Primary outcomes

1

Description
Knowledge about health care before pregnancy, which is a set of health information to promote health before pregnancy.

Timepoint
Before, immediately and one month after the intervention

Method of measurement

A person's knowledge of pre-pregnancy health care is based on answering the questions in the knowledge section. which is given "one point" for correct answer to each question and "zero point" for each wrong answer or I don't know. The tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

2

Description

Attitude towards pre-pregnancy health behaviors, which is the degree of desirability or undesirability of pre-pregnancy health behavior from a person's point of view.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

The person's attitude is investigated with a questionnaire based on a 7-point Likert scale with a completely correct to completely incorrect spectrum, the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

3

Description

The abstract norm about pre-pregnancy health behaviors expresses the understanding of approval or rejection from family, friends or health workers to perform pre-pregnancy care.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

The abstract norm in the individual is investigated with a questionnaire based on a 7-point Likert scale with a completely correct to completely incorrect spectrum, the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

4

Description

Perceived behavioral control regarding pre-pregnancy health behaviors refers to a person's understanding of the difficulty or ease of doing a task.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Perceived behavioral control in a person is investigated with a questionnaire based on a 7-point Likert scale with a completely correct to completely incorrect range, the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on

two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

5

Description

Behavioral intention regarding pre-pregnancy health behaviors indicates the amount or extent of a person's motivation to perform health behaviors.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Behavioral intention in a person is investigated with a questionnaire based on a 7-point Likert scale with a completely correct to completely incorrect range, the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

6

Description

Self-efficacy in performing prenatal health behaviors, which is one's perception or judgment of one's ability to perform a specific action successfully.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

The self-efficacy in carrying out the health behavior of the person is investigated with a questionnaire according to a 7-point Likert scale with a completely correct to completely incorrect range, the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

7

Description

Expectancy of consequences regarding pre-pregnancy health behaviors, which represents the individual's opinion about the probability of various consequences of the behavior.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

The expectation of the outcome in the individual is examined with a questionnaire based on a 7-point likert scale from completely agree to completely disagree.the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

8

Description

Facilitating factors regarding the performance of pre-pregnancy health behaviors, which indicate a person's understanding of tools, resources or environmental changes that facilitate the formation of new behavior.

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Facilitating factors in the individual are investigated with a questionnaire based on a 7-point Likert scale from completely agree to completely disagree, the tool used psychometric questionnaire for describing and predicting health behavior before pregnancy based on two theories of planned behavior and social cognition theory resulting from the doctoral thesis of Mrs. Roghieh Bayrami in 2014

Secondary outcomes

1

Description

Performing health behaviors before pregnancy

Timepoint

Before and one month after the intervention

Method of measurement

The health behavior questionnaire is divided into two parts. One section is about performing preconception health behaviors, which are answered as never, rarely, sometimes, often, and always. There are also some questions about pre-pregnancy care that can be answered with yes and no. The instrument used is a psychometric questionnaire to describe and predict health behavior before pregnancy based on the two theories of planned behavior and the theory of social cognition resulting from the doctorate thesis of Mrs. Ruqieh Bayrami in 2014

Intervention groups

1

Description

Intervention group: The intervention will be held in the form of 4 group training sessions (10 couples in each group) and in-person training using lecture, question and answer methods. The first session: the concept of health, physical and mental health, women's health, the importance of women's health, setting up a health plan, self-care, self-care areas, the second session: reproductive health, ovulation, menstrual cycle, reproductive life plan, age and fertility, reproductive period, the effect of age on fertility in men and women, pregnancy problems in old age (over 35 years) and young age (under 18 years old), the third session: having children, the effects and benefits of having children, the target group of having children, the appropriate age gap between children, the best time Having children, single children and its disadvantages, family planning and fertility control and the fourth session: Pre-pregnancy

care, importance of pre-pregnancy care, importance of pre-pregnancy health, healthy lifestyle, pre-pregnancy health assessment, how to perform pre-pregnancy care In health centers, the method of physical and mental preparation for pregnancy (mental health, sexual health, oral and dental hygiene, nutrition and medicinal supplements, physical activities, smoking) was designed. The content of the educational intervention was designed based on the needs of couples (resulting from a qualitative study), experts' opinions, and the most up-to-date studies in the field of pre-pregnancy health.

Category

Other

2

Description

Control group: they will receive routine pre-pregnancy training from health centers. And the researcher will not interfere in their education.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

community health centre in Mashhad

Full name of responsible person

Zahra Motaghi

Street address

Hafte-tir Square, Shahroud University of Medical Sciences, Faculty of Medicine, Department of Reproductive Health

City

shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 5054

Email

zmotaghi8@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Hefte- Tir Square, Shahroud University of Medical Sciences and Health Care Services, Research and Technology Vice-Chancellor

City

shahroud

Province
Semnan

Postal code
3614773943

Phone
+98 23 3239 5054

Email
pishgiri@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahrood 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
Shahrood University of Medical Sciences

Full name of responsible person
zahra motaghi

Position
associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Hafte-Tir Square, Shahrood University of Medical Sciences, Faculty of Medicine, Department of Reproductive Health

City
shahroud

Province
Semnan

Postal code
36147-73943

Phone
+98 23 3239 3962

Email
zmotaghi8@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahrood University of Medical Sciences

Full name of responsible person

fatemeh ghaffari sardasht

Position
student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Hafte-tir Square, Shahrood University of Medical Sciences, Faculty of Medicine, Department of Reproductive Health

City
shahroud

Province
Semnan

Postal code
3614773943

Phone
+98 23 3239 3962

Email
ghaffarif891@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahrood University of Medical Sciences

Full name of responsible person
fatemeh ghaffari sardasht

Position
student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Hafte-Tir Square, Shahrood University of Medical Sciences, Faculty of Medicine, Department of Reproductive Health

City
shahroud

Province
Semnan

Postal code
3614773943

Phone
+98 23 3239 3962

Email
ghaffarif891@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
Not applicable

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data can be published after the completion of the thesis

When the data will become available and for how long

One year after finishing the thesis

To whom data/document is available

Mashhad and Shahrood University of Medical Sciences - academic researchers

Under which criteria data/document could be used

After analysis, the data will be available to others through publication in scientific research journals.

From where data/document is obtainable

fatemeh ghaffari sardasht . Email:
ghaffarif891@gmail.com

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

Information will be available through printing the article.
But if a person wants more information, he can express his request through email.

Comments