

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of online men's reproductive health education before childbearing on knowledge, attitudes, and behaviors of preconception health in couples

Protocol summary

Study aim

The effect of online men's reproductive health education before childbearing on knowledge, attitudes, and behaviors of preconception health in couples

Design

The randomized clinical trial with a control group and parallel design, without blinding, will be conducted on 168 couples (84 couples in each group). 4 random blocks with a 1: 1 allocation ratio will be used for randomization. Thus, after listing all possible situations of block 4 and assigning a number to each of them using a computer random number table with a 1: 1 ratio, participants will be allocated into intervention and control groups. For allocation concealment, the type of intervention will be written on paper and kept in a series of opaque envelopes.

Settings and conduct

This study will be performed in Bushehr, Iran. Eligible participants will be recruited through the SIB system in Bushehr health centers and will be randomly divided into intervention and control groups. The intervention group will receive men's preconception health-related education designed by the research team, and the control group will receive routine preconception health education.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15-50 years old for men and 18-45 years old for women; intend to have children in the next year. Exclusion criteria: employees and students of the Bushehr University of Medical Sciences; having a history of infertility treatment; known chronic disease; spouse pregnancy

Intervention groups

The intervention group will receive group education based on the importance of preconception health in men and a healthy lifestyle. The control group will receive routine preconception education in women.

Main outcome variables

Knowledge and attitude of men's preconception health; healthy behaviors before conception; satisfaction with education

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052271N1**

Registration date: **2022-05-21, 1401/02/31**

Registration timing: **prospective**

Last update: **2022-05-21, 1401/02/31**

Update count: **0**

Registration date

2022-05-21, 1401/02/31

Registrant information

Name

Zeinab Rabiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 3962

Email address

zeinab.rabiei66@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-31, 1401/03/10

Expected recruitment end date

2022-12-01, 1401/09/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of online men's reproductive health education before childbearing on knowledge, attitudes, and behaviors of preconception health in couples

Public title
The effect of online men's reproductive health education before childbearing on knowledge, attitudes, and behaviors of preconception health in couples

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Be Iranian Literacy for reading and writing Age 15-50 years old for men and 18-45 years old for women Intend to have children Have the consent and cooperation to participate in the study
Exclusion criteria:
Reluctance to continue collaboration at any stage of research Employees and students of the University of Medical Sciences Having a history of infertility treatment Having a known chronic disease Spouse being pregnant

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **336**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible couples will be randomly assigned into two groups using block randomization with a block size of 4 and an allocation ratio of 1:1. Thus, after listing all possible situations of 4 blocks and assigning a number to each of them using a computer random number table with a 1: 1 ratio, participants will be allocated into intervention and control groups. For allocation concealment, each couple will receive a code and all codes will be kept in an opaque envelope until the time of intervention. Sequencing of allocation and preparation of envelopes will be done by a person that will not involve in sampling and data collection. The researcher and the participant will not aware of the groups and the intervention that they received until the commencement of the intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment

Parallel

Other design features
Present intervention is the result of designing a men's reproductive health program before childbearing by the research team.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Haft Tir Square, Tehran Ave.

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

IR.SHMU.REC.1400.015

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Men's preconception health knowledge

Timepoint

Before, end and 2 months after intervention

Method of measurement

Researcher made questionnaire

2

Description

Attitude to men's preconception health

Timepoint

Before, end and 2 months after intervention

Method of measurement

Researcher made questionnaire

Secondary outcomes

1

Description

Healthy behaviors before having children

Timepoint

Before, and 2 months after intervention

Method of measurement

Researcher made questionnaire

2

Description

Satisfaction with preconception education

Timepoint

End of the intervention

Method of measurement

Researcher made questionnaire

Intervention groups

1

Description

Intervention group: the intervention will consist of four group education sessions (each group with 14 couples) and online on Skyroom. Three sessions of non-sexual content will be conducted by a reproductive health specialist (researcher), and one session of sexual content will be conducted by a general practitioner and a reproductive health specialist (for men and women, respectively). Session 1: Defining male reproductive health and individual and non-individual risk factors affecting reproductive health before childbirth - Reproductive lifestyle plan, Healthy lifestyle and nutritional recommendations before childbearing, the effect of parental age on fertility, and neonatal outcomes. Session 2: The effect of chronic diseases in men on reproductive health and drugs that have a negative effect on sperm and fertility. Session 3: The best time for intercourse for pregnancy and fertility chance in the month - sexually transmitted infections and their effect on reproductive and fetal health. Session 4: The physiological changes that occur during pregnancy and how to adapt to them. The content of the educational intervention was designed based on the needs of men (resulting from a qualitative study), the opinion of experts, and the most up-to-date studies in the field of men's preconception health.

Category

Other

2

Description

Control group: will receive routine preconception education from health centers, and the researcher will not be involved.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers affiliated to Bushehr University of Medical Sciences

Full name of responsible person

Zahra Motaghi

Street address

Haft Tir Square - Shahroud University of Medical Sciences and Health Services

City

Shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 3962

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

Haftam Tir Square , Shahroud University of Medical Sciences and Health Services, Vice President of Research and Technology

City

Shahroud

Province

Semnan

Postal code

3614773943

Phone

+98 23 3239 6714

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

Shahroud University of Medical Sciences

Proportion provided by this source

1

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
Shahroud 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
Department of Reproductive Health, School of
Medicine, Shahroud University of Medical Sciences,
Haft Tir Square
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
Shahroud University of Medical Sciences
Full name of responsible person
Zeinab Rabiei
Position
Ph.D. candidate in Reproductive Health
Latest degree
Master
Other areas of specialty/work
Reproductive Health
Street address
Shahroud University of Medical Sciences, Haft Tir
Square
City
Shahroud
Province
Semnan
Postal code
3614773943
Phone
+98 23 3239 3962
Email
zeinab.rabiei66@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
zeinab rabiei
Position
Ph.D. candidate in Reproductive Health
Latest degree
Master
Other areas of specialty/work
Reproductive Health
Street address
Shahroud University of Medical Sciences, Haft Tir
Square
City
Shahroud
Province
Semnan
Postal code
3614773943
Phone
+98 23 3239 3962
Email
zeinab.rabiei66@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 accomplishment of
the dissertation

When the data will become available and for how long

One year after completing the dissertation

To whom data/document is available

Bushehr and Shahroud University of Medical Sciences-
Academic researchers

Under which criteria data/document could be used

Data will be available after publication in journals

From where data/document is obtainable

zeinab rabiei, Email:zeinab.rabiei66@gmail.com

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

The information will be available through the publication
of the article. But if more information is needed, the
request should be sent via email.

Comments

