

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determining the effectiveness of a health-promoting lifestyle training program in infertile couples under Assisted Reproductive Technologies (ART).

Protocol summary

Study aim

Determining the effectiveness of health promotion lifestyle training program in infertile couples candidates for assisted reproductive technologies.

Design

A blocked randomized parallel design clinical trial conducted by random numbers obtained from the site (www.randomization.com). Randomization in quadratic blocks is then performed on 150 pairs of candidates for assisted reproductive technology.

Settings and conduct

The clinical trial will be a hospitals in Tehran. Patients will be blinded and screened by sealed envelopes. The assigned numbers are placed in the envelope and are assigned upon the patient's arrival.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Interested in participate in the study
2- Infertile couples are candidates for Assisted Reproductive Technologies
3- Could read and write
4- First or second time of fertility treatment
Exclusion criteria: 1- Any mental or psychotic disorder
2-Any chronic diagnosed illness,

Intervention groups

The intervention group will receive a training program related to lifestyle enhancement in the field of aerobic physical activity by walking, Mediterranean diet modification and stress management with mindfulness. The control group will receive training on breastfeeding.

Main outcome variables

1- Primary outcome of chemical pregnancy diagnosed by beta human chorionic gonadotrophin (B-hCG blood test).
2- clinical pregnancy (Diagnose heart beat at 6 weeks by ultrasound), .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190529043754N1**

Registration date: **2022-03-29, 1401/01/09**

Registration timing: **prospective**

Last update: **2022-03-29, 1401/01/09**

Update count: **0**

Registration date

2022-03-29, 1401/01/09

Registrant information

Name

Padideh Malekpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4421 4300

Email address

malekpour@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effectiveness of a health-promoting

lifestyle training program in infertile couples under Assisted Reproductive Technologies (ART).

Public title

The effect of health promoting lifestyle educational program on infertile couple who candidate for Assisted reproductive technology.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Interested in participating in the study, Assisted Reproductive Technology candidate couples Could read and write First or second infertility Treatment,

Exclusion criteria:

Diagnosed for mental or psychotic disorders Diagnosed for Chronic illnesses

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **150**

More than 1 sample in each individual

Number of samples in each individual: **75**

There will be 75 people in the intervention group and 75 in control group.

Randomization (investigator's opinion)

Randomized

Randomization description

After primary selection, the samples will be divided into two groups by simple sampling method, using a random block of 4, with an allocation ratio of 1: 1. Then, by listing all the Possible mods of blocks of 4 and assign numbers to each of them, with use computer random numbers with 1:1 allocation ratios, Participants will be divided into two groups of intervention and control. Community Verified icon

Blinding (investigator's opinion)

Double blinded

Blinding description

The sequence is provided to the researcher by a statistical consultant using a website. Then sealed envelope will be used According to the sequence produced, the blocks are designed and placed in closed envelopes. As soon as the eligible patient enters, the envelopes are opened in order and According to the letter. side them, they will assigned to one of the groups' treatment or control. Patient information will recorded by the research team.

Placebo

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

Sharoud medical science and health service university, Hafte tir square, Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۳

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.SHMU.REC.1399.008

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Primary outcome: Chemical pregnancy by Beta human chronic gonadotrophin (B-hCG) blood test.

Timepoint

4 and 6 week after pregnancy

Method of measurement

Blood test to diagnose pregnancy by (Beta-hCG) test

2

Description

Clinical pregnancy (diagnosis of fetal heart rate at 6 weeks with ultrasound)

Timepoint

Weeks 4 and 6 of pregnancy

Method of measurement

Hearing the sound of the fetal heart during the 6th week of pregnancy by ultrasound

Secondary outcomes

1

Description

Live Birth

Timepoint

Delivery after 24 week of pregnancy

Method of measurement

Neonate delivered via natural or cesarean

Intervention groups

1

Description

Intervention group: The intervention group will included 75 infertile couples (men and women) undergoing infertility treatments. The training program will be in three dimensions. 1- physical activity: The intervention group will perform physical activity home-based exercise and balanced walking with progressive muscle relaxation. in the end of activity they will do deep diaphragmatic breathing. exercise. Pattern of activity will be 3 times a week, for 45 minutes, In moderate intensity in 8 sessions before the onset of ovulation stimulation. Diet: In the intervention group, nutrition will include adjusting calorie intake based on participants' body mass index classification along with receiving the standard 5 main food groups with Mediterranean diet in 8 sessions before the onset of ovulation stimulation. The food frequency questionnaire will be completed. Stress management: In the intervention group, stress management will be based on the Mindfulness program. Training and counseling sessions will be held in personally and virtually for 8 sessions of 60 minutes, once a week. The content of the sessions begins with an introduction and welcome, then will continue to introduce stress and the mechanism of the effect of stress on the body, familiarity with the reproductive system, causes of infertility and infertility treatment methods. Training in the next sessions will include progressive muscle relaxation, ecstasy, diaphragmatic breathing, self-help, strengthening self-reconciliation, recognizing strengths and weaknesses, problem solving, forgiving oneself and others, compassion for oneself and others, sharing experiences. Training will be done 6 sessions before the onset of ovulation and 2 sessions in the waiting period until the pregnancy test is positive. Pre-test and post-test will perform.

Category

Lifestyle

2

Description

Control group: 75 infertile under treatment couples in the control group will receive lactation education.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Dr.Mozhghan Javedani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Padideh Malekpour
Position
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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 dissertation

When the data will become available and for how long

One year after completing the dissertation

To whom data/document is available

Shahroud University of Medical Sciences; Hospital and university researchers

Under which criteria data/document could be used

Data will be available after publication in journals

From where data/document is obtainable

Padideh Malekpour padideh_66@yahoo.com
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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