

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of Relaxation with Guided imagery on stress in IVF candidates of infertile women

Protocol summary

Study aim

Determining the effect of Relaxation with Guided imagery on stress in IVF candidates of infertile women

Design

The present study is a randomized clinical trial. The sampling method is block randomization and participants with probabilities AABB,ABBA,ABAB,BBAA,BAAB,BABA divided into control and intervention groups.

Settings and conduct

The study population was infertile women candidates for IVF. The research environment is Arash hospital in Tehran. The experimental group will receive mentally guided imagery training for 3 weeks, twice a week, each session for 45 minutes through virtual training, but the control group will receive routine therapies. Upon completion of the research, a summary of the training will be provided to the control group. Data collection tools will include a questionnaire related to demographic information, fertility information and Newton questionnaire. The Newton questionnaire will be completed by individuals in both groups before and immediately after the intervention.

Participants/Inclusion and exclusion criteria

Ages between 18-49 years, lack of known physical or mental illness, not attending other psychotherapy courses, women IVF candidates for the first time or several times, being in the moderate stress group of the Newton Questionnaire (score 92-184) , Iranian nationality and having a minimum literacy

Intervention groups

The experimental group will receive mentally guided imagery training for 3 weeks, twice a week, each session for 45 minutes through virtual training, but the control group will receive routine therapies. Upon completion of the research, a summary of the training will be provided to the control group.

Main outcome variables

Guided imagery, stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160821029446N9**

Registration date: **2021-09-03, 1400/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-03, 1400/06/12**

Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

Maryam Damghanian

Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Relaxation with Guided imagery on stress in IVF candidates of infertile women

Public title

The effect of Relaxation with Guided imagery on stress in IVF candidates of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages between 49-18 years Lack of known physical or mental illness Not participating in other psychotherapy courses Women candidates for IVF for the first time or several times Being in the moderate of Newton questionnaire (score 92-184) Iranian nationality Have a minimum literacy

Exclusion criteria:

Get a low or high score on the Newton Infertility Stress Questionnaire Reluctance to participate in the study

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals will be selected by available sampling and the randomization method in this study is block randomization. Samples will be randomly divided with probabilities AABB, ABBA, ABAB, BBAA, BAAB, BABA in the control and intervention groups. Then we write all the permutation combinations of the letters A, A, B and B, which are 6 different combinations, on 6 cards. Then we choose a digit at random from digits 1 to 6 (with the help of a table of random numbers or we ask patient number one to choose a card at random). For example, if the number 2 is selected, it means that the first person in the intervention group will be the next two people in the control group and the fourth person in the intervention group, and we will continue this operation until the sample size reaches the quorum

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

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Tohid Square, Dr. Mirkhani St. (Eastern Nusrat), School of Nursing and Midwifery, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.TUMS.FNM.REC.1400.065

Health conditions studied**1****Description of health condition studied**

Stress in infertile women IVF candidates

ICD-10 code

O09.0

ICD-10 code description

Supervision of pregnancy with history of infertility

Primary outcomes**1****Description**

stress

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Newton Infertility Stress Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The experimental group will be subjected to mentally guided imaging training for 3 weeks, twice a week, each session for 45 minutes through virtual training. The training sessions are summarized as follows: First session: Introducing the purpose of research and explanation in relation to the intervention and training. second session: Identify your

misconceptions and irrational thoughts. third session:
Guided imagery technique training. fourth Session:
Teaching breathing techniques with healing energy balls
fifth Session: Mountain meditation technique Sixth
Session: Practice making love

Category

Other

2

Description

Control group: The control group will receive routine treatments. Upon completion of the research, a summary of the training will be provided to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Comprehensive Hospital

Full name of responsible person

Maryam Damghanian

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School of Nursing & Midwifery, East Nosrat Ave,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

reaserch dean of Tehran University of Medical
Sciences

Full name of responsible person

Esmat Karimi

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No23, Dameshgh street, Valiasr street, Tehran, Iran

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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

reaserch dean of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Samira Noorzaie

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Damghanian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data analysis will be presented in the form of findings.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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