Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 21 6692 7171

Email address
m-damghanian@sina.tums.ac.ir

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
Street address
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

Street address

School of Nursing & Midwifery, East Nosrat Ave, Towhid Square.Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4222

Email

maryam_damghanian@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

reaserch dean of Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

Street address

No23, Dameshgh street, Valiasr street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4222

Email

maryam_damghanian@yahoo.com

Web page address

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

Street address

Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

snoorzaie1374@gmail.com

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

Midwifery

Street address

Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Email
maryamdamghanian@gmail.com

Person responsible for updating data

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
Midwifery
Street address
Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Email
maryamdamghanian@gmail.com

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