

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Problem Solving Skills Training Effect on Women's Anxiety of Intra Uterine Insemination Candidates

Protocol summary

Study aim

Determining the effect of problem-solving skills training on women IUI candidates

Design

49 women with iui candidate and admission criteria were assigned to two groups of intervention and control by simple random method. subsequently, the intervention group was trained in problem- solving skills and the control group did not receive any training.

Settings and conduct

An experimental study was a pre-test and post-test type and conducted in Moheb Yas Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Women candidates for IUI; minimum reading and writhing education; no history of any psychological counseling; no history of antidepressant and anti-anxiety medication; no drug addiction; failure to receive other assisted reproductive techniques.

Intervention groups

Problem-solving skills training

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037912N1**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **retrospective**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

Fateme Zarekia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-08-22, 1394/05/31

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

2015-08-22, 1394/05/31

Actual recruitment end date

2015-12-16, 1394/09/25

Trial completion date

empty

Scientific title

Problem Solving Skills Training Effect on Women's Anxiety of Intra Uterine Insemination Candidates

Public title

Problem Solving Skills Effect on Anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women candidates for IUI Minimum reading and writhing education No history of any psychological counseling No history of antidepressant and anti-anxiety medication No drug addiction Failure to receive other assisted reproductive techniques

Exclusion criteria:

Gain score less than 8 from the Beck Anxiety Inventory

Failure of the treatment process due to oocyte growth

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Actual sample size reached: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 49 female candidates of iui were matched in different levels of anxiety and were randomly assigned to two groups of intervention and control. Randomization was done as a draw. In this way, candidates in each of the three levels of anxiety, were randomly assigned to each other through a lottery in each intervention and control group.

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

Ethics committee in Golestan University of Medical Science

Street address

Sixty Kola

City

Gorgan

Province

Golestan

Postal code

49165-567

Approval date

2015-08-20, 1394/05/29

Ethics committee reference number

IR.GOUMS.REC.1394.72

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Those who received Beck Anxiety Inventory (8 and above) were included in the study. The subjects were ranked according to the levels of anxiety and were randomly assigned to intervention (25 subjects) and control (n = 24).

Timepoint

From the beginning of the sampling and teaching the problem-solving skills to the intervention group, by the end of the training and the Beck anxiety inventory questionnaire were completed by all intervention and control group participants, 15 weeks were spent.

Method of measurement

Beck anxiety inventory (BAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Moheb Yas Hospital

Full name of responsible person

Fatemeh Zarekia

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North Villa Rd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Gorgan University of Medical Sciences

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Shast Kolla

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Province

Golestan

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4934174515

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Grant name

36470000

Grant code / Reference number

92158105

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

Yes

Title of funding source

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Fatemeh Zarekia

Position

student

Latest degree

Master

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

Some sample sized are not satisfied.

Study Protocol

Undecided - It is not yet known if there will be 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