Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of positive thinking versus control group on stress and spermogram results on infertile men: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of positive thinking versus control group on stress and spermogram results on infertile men

Design
This is a randomized clinical trial, phase III, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible infertile men referring to the Fatemiah Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 40 years; Infertility; Abnormality of at least one of the semen parameters; Monogamy; Body mass index less than 30; Exclusion criteria: Using hormonal drugs; Using traditional medicines to treat infertility; Infertility-related organic disorders; Drug or alcohol use; Psychopathy; Use of drugs that interfere with spermatogenesis such as methotrexate, nitrofurantoin, colchicine, and chemotherapy; History of testicular surgery; Contact with pesticides, heavy metals, and solvents; Under diet for weight loss

Intervention groups
Intervention group: Routine treatment plus positive thinking counseling 45-60-minute sessions weekly for a maximum of 8 sessions including (preparation; increasing knowledge and awareness; identifying personal abilities; reproductive ability; awareness of the impact of exercise, music, and meditation on body and spirit health; creating positive excitement and mentioning blessings; enjoying the present and good events in life and the joy of becoming a father and having a warm and intimate family; teaching lifestyle and life skills and improving relationships with others; increasing positive thinking) Control group: Just routine treatment

Main outcome variables
Primary outcome: Semen parameters; stress; positive thinking;

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120215009014N402**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**
Update count: **0**

Registration date
2021-08-14, 1400/05/23

Registrant information

Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-06, 1400/06/15
Expected recruitment end date
2022-02-04, 1400/11/15
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of positive thinking versus control group on stress and spermogram results on infertile men: a randomized clinical trial

Public title

Effect of positive thinking versus control group on stress and spermogram results on infertile men

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years; Infertility; Abnormality of at least one of the semen parameters; Monogamy; Body mass index less than 30;

Exclusion criteria:

Using hormonal drugs; Using traditional medicines to treat infertility; Infertility-related organic disorders; Drug or alcohol use; Psychopathy; Use of drugs that interfere with spermatogenesis such as methotrexate, nitrofurantoin, colchicine, and chemotherapy; History of testicular surgery; Contact with pesticides, heavy metals, and solvents; Under diet for weight loss

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action is repeated until the sample size is reached.

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 of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-07-31, 1400/05/09

Ethics committee reference number

IR.UMSHA.REC.1400.353

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Semen parameters

Timepoint

Before intervention and 8 weeks later

Method of measurement

Using spermogram

2

Description

Stress

Timepoint

Before the intervention and 8 weeks later

Method of measurement

Using the Infertility Stress Questionnaire or Newton Infertility Problems

3

Description

Positive thinking

Timepoint

Before the intervention and 8 weeks later

Method of measurement

Using the Ingram and Wisnicki positive thinking questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus positive thinking counseling 45-60-minute sessions weekly for a maximum of 8 sessions including (preparation; increasing knowledge and awareness; identifying personal abilities; reproductive ability; awareness of the impact of exercise, music, and meditation on body and spirit health; creating positive excitement and mentioning blessings; enjoying the present and good events in life and the joy of becoming a father and having a warm and intimate family; teaching lifestyle and life skills and improving relationships with others; increasing positive thinking)

Category

Other

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiah Hospital in Hamadan city

Full name of responsible person

Maryam Eghbalian

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

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Hamadan

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6517838695

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+98 81 3828 3939

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Eghbalian

Position

MSc in Midwifery Consulting

Latest degree

Master

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Seyedeh Zahra Massumi

Position
Reproductive Health Specialist

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Jalal Poorolajal

Position
Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available