

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 Fatemeh 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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

##### Province

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##### Postal code

6517838695

##### Phone

+98 81 3828 3939

##### Email

eghbalianmaryam123@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

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##### Province

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##### Phone

+98 81 3838 0717

##### Email

info.research@umsha.ac.ir

#### 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

##### Street address

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

##### City

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##### Province

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+98 81 3838 0572

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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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zahramid2001@yahoo.com

## 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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**Email**

poorolajal@umsha.ac.ir

## 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