Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Comparison of the effect psycho-sexual therapy and pharmacotherapy Bupropion interventions on improvement of sexual function in infertile women

Protocol summary

Summary

This is a randomized clinical trial(RCT) study will conduct on qualified infertile women in the Fatemeh Alzahra Infertility and Reproductive Health Research Center of the Babol University of Medical Sciences in 2014-2015 years after the approval of the Ethics Committee. Informed consent will obtain from each woman participant before enrolling in the study. The subjects will complete the Female Sexual Function Index (FSFI), Beck Depression Inventory (BDI), Spielberger State-Trait Anxiety Inventory (STAI), General health questionnaire (GHQ), Pittsburgh Sleep Quality Index (PSQI), Couple Burnout Measurement (CBM), and Body Image Assessment before and after interventions. A psychologist will conduct a clinical interview based on the diagnostic criteria of DSM-V. After identifying 99 infertile women with sexual dysfunction and without severe depression, the subjects were randomized to three groups of 33 each as follows: 1-psycho-sexual therapy group: This group will participate in a two-hour group session for 10 weeks. Each group consists of 8–12 members. Therapeutic model is a combination of mind fullness-Based cognitive therapy and sexual skills. Sexual behavioral program is based on Crowe and Ridley model. 2-pharmacotherapy group: Subjects will take a tablet of Bupropion SR (150 mg) daily (evening) (manufactured by D Abidi plant) for two months after the interview by a psychiatrist. 3- Control group: Participants will complete questionnaires at the beginning of the study and two months afterward. In order to observe the ethics of research, members of this group will be referred to sex therapy clinic at the end of two months of treatment.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015042721955N2**
Registration date: **2015-08-02, 1394/05/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-02, 1394/05/11

Registrant information

Name

Hajar Pasha

Name of organization / entity

Infertility and Reproductive Health Research Center, Health Research Institute, Babol University of

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 0597

Email address

hpasha@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Comparison of the effect psycho-sexual therapy and pharmacotherapy Bupropion interventions on improvement of sexual function in infertile women

Public title
A Comparison psycho-sexual therapy and pharmacotherapy Bupropion interventions on improvement of sexual function in infertile women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria included: The less or equal score of 26.55 from Female Sexual Function Index(FSFI); The final diagnosis with clinical interview is based on DSM-V criteria by psychologist; duration of infertility more than 1 year; women infertile who did not decide to undergo fertility treatment until 2 months afterward; aged between 15-45 years; ability to read and to write; having a stable sexual activity(at least for recent four weeks); availability of the husband; no remarrying of couples; no history of sterilization; no foster child. Exclusion criteria included: drug abuse; severe psychiatric disorders(major depression, bipolar disorder, patients with suicidal idea or psychosis); history of physical illness(diabetes mellitus, cardiovascular diseases, hypertension, hyperthyroidism, hypothyroidism, epilepsy, hepatic dysfunction); physical problems(spinal cord injury, limb deformity); mental health problems under the treatment of a physician; drugs consumers causing sexual dysfunction such as barbiturates, benzodiazepines , antidepressants, ant hypertensions; having psychological support(psychotherapy sessions, relaxation techniques, yoga); experiencing a stressful event in the past three months(death or serious illness in the family, a major change in living conditions).

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description

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
The Ethics Committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganjafrouze Street, Mazandaran Province, Iran

City
Babol

Postal code
4717647745

Approval date
2014-12-10, 1393/09/19

Ethics committee reference number
4930

Health conditions studied

1

Description of health condition studied
Sexual Dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
sexual function

Timepoint
Before and two months after of intervention

Method of measurement
Female Sexual Function Index (FSFI), and clinical interview based on the diagnostic criteria of DSM-V.

Secondary outcomes

1

Description
Depression, Anxiety, General health, Sleep Quality, Couple Burnout, Body Image

Timepoint
Before and two months after of intervention

Method of measurement
Beck Depression Inventory (BDI), Spielberger State-Trait Anxiety Inventory (STAI), General health questionnaire (GHQ), Pittsburgh Sleep Quality Index (PSQI), Couple Burnout Measurement (CBM), and Body Image Assessment, and clinical interview based on the diagnostic criteria of DSM-V

Intervention groups

1

Description
Psycho-sexual therapy group: This group will participate in a two-hour group session for 10 weeks. Each group consists of 8–12 members. Therapeutic model is a combination of mind fullness-Based cognitive therapy and sexual skills. Sexual behavioral program is based on Crowe and Ridley model.

Category
Treatment - Other

2

Description
Pharmacotherapy group: This group will take a tablet of Bupropion SR (150 mg) daily (evening) (manufactured by D Abidi plant) for two months by a psychiatrist. Subjects will receive 30 tablets after the interview, and will refer to center monthly to receive their medication. Duration of treatment will be two months.

Category
Treatment - Drugs

3

Description
Control group: Participants in this group will complete questionnaires at the beginning of the study and two months afterward. In order to observe the ethics of research, members of this group will be referred to sex therapy clinic at the end of two months of treatment. All groups will complete questionnaires in the beginning and ending of the study.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh Alzahra Infertility and Reproductive Health Research Center of the Babol of Medical Science

Full name of responsible person
Hajar Pasha

Street address
Fatemeh Alzahra Infertility and Reproductive Health Research Center of the Babol University of Medical Sciences, Tork Mahalleh, Babol, Mazandaran province, Iran

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Ali Akbar Moghadamnia

Street address
Babol University of Medical Sciences, Ganjafrouze Street, Mazandaran Province, Iran

City
Babol

Grant name
387-12 6/8/1393 مورخ

Grant code / Reference number
2385

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

Title of funding source
Babol University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Hajar Pasha

Position
Assistant Professor of Babol University of Medical Sciences, Midwife (MSc)

Other areas of specialty/work

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Midwifery Department, Babol University of Medical Sciences, Ganjafrouze Street, Mazandaran Province, Iran

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Fatemeh Alzahra Infertility and Reproductive Health Research Center of the Babol University of Medic

Full name of responsible person
Zahra Basirat

Position
Gynocologist and Professor of Babol University of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Fatemeh Alzahra Infertility and Reproductive Health Research Center of the Babol University of Medic

Full name of responsible person
Hajar Pasha

Position
Midwife(MSc), Assistant Professor of Babol University of Medical Sciences

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty