Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of effectiveness of "mindfulness -based sexual relationship therapy" and "cognitive behavioral sex therapy" On disorder’s symptoms in women with orgasmic disorder

Protocol summary

Study aim
Comparison of the effectiveness of "mindfulness-based sexual intercourse therapy" and "sexual cognitive-behavioral therapy" on the disorder syndrome in women with orgasmic disorder

Design
informed consent - Completion of sexual function questionnaire and researcher-made questionnaire on the quality of orgasm experience - Random allocation between two groups (intervention group and a control group), 25 people each - Basic training (sexual anatomy of couples and response processes Sex) - In intervention group , mindfulness-based sex therapy protocol will be implemented as a group for clients and their husbands, and in the control group sexual cognitive-behavioral therapy-At two time points immediately after the end of the treatment program and quarterly follow-up, two questionnaires of sexual function and a researcher-made questionnaire on the quality of orgasm experience in all individuals are completed.

Settings and conduct
an experimental clinical trial.- participation of qualified individuals from those who refer to family clinics, sexual dysfunction clinics and university psychiatric clinics.

Participants/Inclusion and exclusion criteria
1- Be married.2- diagnosis of female orgasm disorder 3- Do not have physical disorders related to this disease 4- According to the the SCL-4 questionnaire, the total score less than the disruptive cutting point 5-in the last 2 months do not use psychedelics and alcohol.6- Not during pregnancy and lactation. 7- no other sexual dysfunctions in couples. Exclusion criteria: 1-Failure to meet the inclusion criteria 2-Reluctance to cooperate with the study at any stage of the project

Intervention groups
intervention group (mindfulness-based sex therapy),control, sexual cognitive-behavioral therapy

Main outcome variables
Orgasm disorder, treatment or improvement of orgasm disorder, sexual function, quality of orgasm experience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180310039024N2**
Registration date: **2020-12-27, 1399/10/07**
Registration timing: **prospective**

Last update: **2020-12-27, 1399/10/07**
Update count: **0**

Registration date
2020-12-27, 1399/10/07

Registrant information

Name
Mehrdad Kazemzadeh Atoofi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6655 1666

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-07-22, 1400/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of effectiveness of "mindfulness -based sexual relationship therapy" and "cognitive behavioral sex therapy" On disorder’s symptoms in women with orgasmic disorder

Public title
The effectiveness of "mindfulness -based sexual relationship therapy" and "cognitive behavioral sex therapy" On disorder’s symptoms in women with orgasmic disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
In this project, among the patients referred to family clinics, sex disorder clinics and university psychiatric clinics, 50 women are invited to do the research who meet the conditions for inclusion in the study as follows: 1- Be married. 2-The diagnosis of female orgasm disorder has been set for them) Criteria for diagnosing the opinion of experts in the field of sexual disorders. 3- Do not have physical disorders related to this disease with the approval of a gynecologist. 4-According to the findings of the SCL-4 questionnaire, the total score of the person is less than the disruptive cutting point . 5-in the last 2 months do not use psychedelics and alcohol. 6- Not during pregnancy and lactation. 7- According to the experts in the field of sexual disorders, there are no other sexual dysfunctions in couples.
Exclusion criteria:
1-Reluctance to cooperate with the study at any stage of the project
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
after first educational session, according to the simple random method, at the individuals level, by execution table, among all eligible individuals participants assign to two groups (intervention group and control group (25 people each group).
Blinding (investigator's opinion)
Double blinded
Blinding description
While clients are not morally barred from receiving the necessary services and interventions, and it is explained that the evaluation of their interventions is a study, participants in the study will not know which group is the experimental group. Also, to fill in the outcome assessment forms and to analyze the data, all data based on blind codes are provided to the evaluator and analyst.
Placebo
Not used
Assignment
Parallel
Other design features
1. Since the studies conducted on the mentioned objectives are scattered, by examining the above objectives, important information can be identified and information gaps can be clarified.2. Considering that mindfulness-based treatment methods have recently been considered by researchers in various fields of physical and mental disorders, the design and implementation of this study can provide practical evidence on the effectiveness of these methods in treatment of orgasmic disorders in women.3. In this study, a treatment package is presented in which the goal is to pay attention and focus on sexual intercourse processes. In this package, some of Mr. and Johnson's sex therapy methods as well as stress reduction exercises based on mindfulness will be used to increase the pleasure experience and orgasm experience.4. In addition, it is important to note that the limited studies that have been published in this field have mainly focused on the role of mindfulness-based interventions in the treatment of sexual arousal and less attention has been paid to examining the impact of these intervention in treatment of orgasmic disorders in women.5. On the other hand, the results of this study, along with suggesting the fields of future supplementary studies, can be a suggestion for comparing other factors such as cost-effectiveness and side effects of drugs in clinical decisions.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of MedicalIran University of Medical Sciences
Street address
Tehran, Hemmat Highway next to Milad Tower, Research Deputy Headquarters Building
City
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Tehran
Postal code
1445613111

Approval date
2020-12-22, 1399/10/02
Ethics committee reference number
IR.IUMS.REC.1399.1018

Health conditions studied

1

Description of health condition studied
female orgasmic disorder - Quality of Sexual Function
ICD-10 code
F52.31
ICD-10 code description
Female orgasmic disorder

Primary outcomes

1

Description
Orgasm disorder
Timepoint
before intervention, Immediately after the end of the treatment program and quarterly follow-up
Method of measurement
questionnaires

2

Description
sexual function
Timepoint
before intervention, Immediately after the end of the treatment program and quarterly follow-up
Method of measurement
questionnaires

3

Description
quality of orgasm experience
Timepoint
before intervention, Immediately after the end of the treatment program and quarterly follow-up
Method of measurement
questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: mindfulness -based sexual relationship therapy Mindfulness therapy is the ability to focus attention on the internal and external experiences that are taking place and help the person become more aware of the present and increase non-judgmental observation and subsequent Reduce auto responders. In the forthcoming intervention, this method is designed using the mindfulness-based stress reduction method and the Masters and Johnson sexual therapy method in order to increase attention and focus on the sexual intercourse process and increase the pleasure and quality of orgasm. This method consists of eight intervention sessions.
Category
Treatment - Other

2

Description
Control group: cognitive behavioral sex therapy It is one of the treatment methods for mental illnesses that tries to treat various problems from anxiety and depression to various personality disorders by relying on human mentality and behavior. In the field of treatment of sexual disorders, cognitive-behavioral interventions are used as a common and well-known model, the therapeutic consequences of which have been confirmed in several studies. This method consists of eight intervention sessions
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Family clinics Sexual disorders clinics and university psychiatric clinics
Full name of responsible person
Mehrdad Kazemzadeh Atoofi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Faculty of Behavioral Sciences and Mental Health, IUMS
Full name of responsible person
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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
Vice Chancellor for Research, Faculty of Behavioral Sciences and Mental Health, IUMS

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
Iran University of Medical Sciences
Full name of responsible person
Mehrdad Kazemzadeh Atoofi
Position
Master of Clinical Psychology, Faculty of Behavioral Sciences and Mental Health, and Executive Vice
Latest degree
Master
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

The results and findings of the study will be published in the form of reports, articles, presentations and lectures in accordance with the diversity of stakeholders and in accordance with the objectives of the study.

When the data will become available and for how long

After the end of the study around August 1400

To whom data/document is available

Research team and study supervisors

Under which criteria data/document could be used

Other researchers, clinical therapists, counselors, and health-related field managers

From where data/document is obtainable

Principle Investigator: atoofi.m@iums.ac.ir

What processes are involved for a request to access data/document

Send an email stating the reasons for requesting the use of the data

Comments