

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Develop a quantitative psychological correlates of sexual arousal / arousal disorders correlations and compare the effectiveness of intervention based on it with behavioral activation therapy on sexual self-concept, menopausal attitude, sexual dysfunction, relationship satisfaction and communication intimacy of postmenopausal women

Protocol summary

Study aim

Developing a quantitative model of psychological correlates of sexual desire/arousal disorder and comparing the effectiveness based on it with activation-behavioral therapy on sexual self-concept, menopausal attitude, sexual dysfunctional beliefs, relationship satisfaction and relational intimacy of postmenopausal women.

Design

Clinical trial with control group, with parallel groups, single blind, randomized, on 45 postmenopausal women with sexual desire/arousal disorder. Excel software is used for randomization.

Settings and conduct

The method of conducting the present research will be quantitative and semi-experimental, and before entering each of the steps and starting the research, the necessary permits for the implementation of the research, such as the letter of introduction to sexual counseling and psychotherapy centers and the code of ethics, will be obtained and after the approval of the authorities Medical centers will collect data

Participants/Inclusion and exclusion criteria

Postmenopausal women with sexual desire/arousal disorders over 50 years old, who have been 6 months since their menopause, who do not take any drugs or medical interventions or do not miss more than two sessions during the session, and do not have premature menopause.

Intervention groups

The participants will be randomly assigned to two experimental groups and one control group, and behavioral activation therapy package (8 sessions of 90 minutes), therapy package based on the quantitative

model of psychological correlates of sexual desire/arousal disorder (8 sessions of 90 minutes) for Treatment groups will be implemented.

Main outcome variables

Sexual self-concept, menopause attitude, dysfunctional sexual beliefs, elationship satisfaction and relational intimacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230524058276N1**

Registration date: **2023-12-10, 1402/09/19**

Registration timing: **prospective**

Last update: **2023-12-10, 1402/09/19**

Update count: **0**

Registration date

2023-12-10, 1402/09/19

Registrant information

Name

somayeh heidary shadehi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Develop a quantitative psychological correlates of sexual arousal / arousal disorders correlations and compare the effectiveness of intervention based on it with behavioral activation therapy on sexual self-concept, menopausal attitude, sexual dysfunction, relationship satisfaction and communication intimacy of postmenopausal women

Public title

The effectiveness of the intervention based on the quantitative model of psychological correlates of sexual desire/arousal disorder and activation-behavioral therapy on sexual self-concept, menopausal attitude, sexual dysfunctional beliefs, relationship satisfaction and relational intimacy of postmenopausal women.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Menopausal women whose menopause has been 6 months old Being over 50 years old Having a sexual desire/arousal disorder Not taking drugs and drug interventions Not receiving treatment interventions at the same time

Exclusion criteria:

Having at least 2 absent sessions in the intervention process Having other sexual dysfunctions other than sexual desire/arousal Having early menopause

Age

From **50 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The purpose of random allocation is that the clinician cannot predict the treatment of the disease. Random allocation of the type of treatment or random allocation is the heart of the clinical trial study. The samples will be determined by random block method and using random number table, Random Allocation Software. Blocking and allocation sequence will be done for concealment by a person not involved in the research (Allocation

Concealment). Blocking: This method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization ensures that there is no significant imbalance between groups at any time during randomization. At certain points, the number of participants in each group is equal. For this method, the size of each block must be determined first (for example, a block of four), then write the list of blocks and assign numbers to them (AABB(1)-ABAB(2)-ABBA(3)-BBAA(4)-BABA) (5) - BAAB (6)), then choosing random numbers between 1 and 6 (for example 1, 4, 5 and ...) and finally specifying the treatment allocation list based on the previous random numbers (...AABB-BBAA-BABA-) They will be placed in three groups including two intervention groups and one control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants, or in other words, the people who are invited to participate in the study and are classified into intervention groups after obtaining informed consent, may not know the main purpose of the study, these people only know that in a study They participate, which will lead to the improvement of their psychological problems, and they are only unaware of the assignment of groups. Statistical analysts do not know the content of therapy sessions, but they know the assumptions, goals and questions of the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan Islamic Azad University (Khorasgan).

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Unit 18- Ramin Complex- 1st sub-section- 8 East sub-section- Taleghani Blvd.

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Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.IAU.KHUISF.REC.1401.408

Health conditions studied

1

Description of health condition studied

Sexual desire/arousal disorder

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

Primary outcomes

1

Description

Sexual self-concept is a part of individuality and self-sexuality; In other words, a person's understanding of his sexual desires and tendencies is the same as his sexual self-concept

Timepoint

At the beginning of the study, after the intervention and 45 days after the intervention

Method of measurement

Sexual self-concept in this research is the score that the subjects get from Ansel's (2013) sexual self-concept questionnaire. This questionnaire contains 78 questions and 18 subscales. The range of scores in each subscale is 5 to 25. Scores higher than the average in each subscale indicate that the individual has more of that characteristic (tendency). If the scores of the questionnaire are between 1 and 20, the variable rate in this society is weak. If the scores of the questionnaire are between 21 and 60, the variable amount is at an average level. If the scores are above 60, the level of the variable is high.

2

Description

Attitude is a set of beliefs, emotions and behavioral intentions towards an object, person or event. In other words, it is a relatively stable desire for a person, something or an event that manifests itself in feelings and behavior

Timepoint

At the beginning of the study, after the intervention and 45 days after the intervention

Method of measurement

Menopause attitude in this research is the score that the subjects got from Neugarten's attitude towards menopause questionnaire (1963). This questionnaire contains 35 items, in this questionnaire, each item is given a score with a 5-point range from 0 to 4, and the total score is added after counting all the items, and higher scores are given to positive attitudes and grades. lower was attributed to negative attitude. The cut-off point is considered to be 40, and a score of 40 and above is considered a positive attitude, and a score below that is considered a negative attitude.

3

Description

Sexual dysfunctional belief is a set of attitudes and

stereotypes about sexual performance that endangers the sexual relationship of couples.

Timepoint

At the beginning of the study, after the intervention and 45 days after the intervention

Method of measurement

In this research, the meaning of sexual dysfunctional belief is the scores that will be obtained in response to the questionnaire of Neuber, Pinto and Govia (2003). In this questionnaire, scoring is done in a direct way and a higher score indicates a greater impact of sexual dysfunctional beliefs on sexual performance. It is women and men.

4

Description

Relationship satisfaction is defined as the level of satisfaction that a person has in his closest adult relationship with another person in different dimensions. This level includes communication and honesty, intimacy and closeness, resolving conflicts and arguments, satisfaction with his role in the relationship and Satisfaction with another's role in the relationship and overall satisfaction with the relationship

Timepoint

At the beginning of the study, after the intervention and 45 days after the intervention

Method of measurement

The meaning of relationship satisfaction is the score that each subject obtained in the 7-item relationship satisfaction scale of Burns and Cyrus (1988). The scores of the groups of this questionnaire range from 0-10 indicating a very dissatisfied person, 20-11 indicating a dissatisfied person, 21-25 indicating a relatively dissatisfied person, and 30-26 indicating a somewhat dissatisfied person, 31-35 indicating a somewhat satisfied person. 36-40 indicates relatively satisfied and 41-42 indicates a very satisfied person.

5

Description

ommunication intimacy is the need to communicate and share all emotions, including positive emotions (joy, ecstasy, and excitement) and negative emotions (sadness, failure, fear, guilt, loneliness, and depression) with the spouse.

Timepoint

At the beginning of the study, after the intervention and 45 days after the intervention

Method of measurement

Communication intimacy means the score that each subject obtained in Shafer and Olson's (1981) 36-question communication intimacy scale. The overall score of this questionnaire is between 1 and 120. The amount of difference between two scores of received intimacy and expected intimacy indicates the level of satisfaction of the person with intimacy.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Behavioral activation therapy is also treated during 8 sessions of 90 minutes based on the training package of Dimidjin et al. (2008). It is taught simply. The second session of behavioral activation is taught by focusing on the interaction between the person and the environment based on the principles of silence, shaping, elimination and mental review, distance distraction, procedural skills and observational thinking. Providing homework, review and feedback. The third session of healing processes is taught with four topics of advice in the general context of the disease, choosing the appropriate treatment method for the individual's condition, motivational topics and the interaction of the individual with other people and the use of their experience, providing homework, review and feedback. The fourth session is review of the form. The use of verbal positive reinforcement is taught through the expression of positive and hopeful sentences, the presentation of homework, review and feedback. The fifth session of using metaphor is taught in the course of verbal positive reinforcement, the presentation of homework, review and feedback. The sixth session of cognitive reconstruction, Psychosocial aspects of the problem, coping skills, assertiveness skills and treatment in case of recurrence, referral to a psychologist is taught, assignments are given, feedback is taught. In the seventh session, problem solving skills are taught, which includes defining the problem, identifying the factors preventing problem solving, and the problem solving process. , committing to implement the solution, planning to implement the best solution and implementing the best solution, providing homework, feedback. The eighth session of summarizing, summarizing, and teaching preventive solutions

Category

Lifestyle

2

Description

Intervention group: ntervention group: treatment package based on the quantitative model of psychological correlates of sexual desire/arousal disorder (Heidari, Sajjadian and Manshai, 1402). Eight 90-minute intervention sessions

Category

Lifestyle

3

Description

Control group: a group that does not undergo any intervention. They only complete the questionnaires before and after the study. If they wish, they can undergo intervention after the end of the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Andisheh Counseling Center

Full name of responsible person

Ali Sharifi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

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Grant name

Grant code / Reference number

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

No

Title of funding source

دانشگاه آزاد اسلامی واحد اصفهان (خوراسگان)

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Somayeh Heidary Shadehi

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Data file of the participants only in general and without mentioning the name and address of the participants (number-gender-age-education). The study protocol can also be published as a table. The statistical analysis map can be published in the form of tables and statistical results obtained. Informed consent can be published in its entirety. Applied research results can be published. Statistical methods and statistical analysis can be published. The obtained data can be published in the form of tables. All the above items can be provided in accordance with the guidelines of the magazines and if there is no harm to the participants.

When the data will become available and for how long

The access period starts with the opinion and agreement of the relevant journals

To whom data/document is available

It will be accessible to all people who have access to reliable sources of publishing articles such as reliable magazines and the results of this research can be used for them.

Under which criteria data/document could be used

All cases of using the documents will be possible with the permission of the university of the place of study and professors related to the research and in compliance with the existing rules and regulations.

From where data/document is obtainable

Reputable journals in which articles related to research are published. The e-mails of the advisors and advisors and the student implementing the project and their university website will be made available to the applicants to use the results in compliance with the rules and regulations and maintaining the confidentiality of the participants.

What processes are involved for a request to access

data/document

If the laws related to the research documents are followed, the possible requests will be answered as soon as possible.

Comments

All of the above can be done within the framework of the rules and regulations of research and publication in the relevant journals and universities. If an item is not within the scope of these rules, it will not be published. The special case to be mentioned is maintaining the confidentiality of the participants' information and not harming them.