Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effectiveness of cognitive-behavioral hypnotherapy on the sexual function, satisfaction, and intimacy of married women of reproductive age

Protocol summary

Study aim

_Determining the effectiveness of cognitive-behavioral hypnotherapy on sexual function, satisfaction and intimacy in married women of reproductive age

Design

Randomized clinical trial with two arm parallel groups, one is the intervention group and the other one is the control group

Settings and conduct

Counseling sessions are held at a private midwifery counseling center. The center has a separate room with the necessary facilities for individual counseling sessions, including an audio system for playing non-verbal music during hypnotic suggestions.

Participants/Inclusion and exclusion criteria

Iranian nationality, Being married, Age 18 to 40 years, Living in Sabzevar city, At least three years have passed since the marriage, No severe marital conflicts, Having at least one child, Not taking psychiatric or hormonal medications, Not seeing a psychologist, counselor, or psychiatrist during the study, Sexual function test score lower than 28 and hypnotizability score more than 5.

Intervention groups

The intervention group receives 4 sessions of cognitive-behavioral hypnotherapy treatment weekly and as individual counseling, and the control group undergoes a sexual health training session with relaxation only at the end of the research and after completing the post-test questionnaires just to observe ethical principles. Cognitive-behavioral hypnotherapy is a combination of hypnotherapy with cognitive-behavioral therapies and concepts.

Main outcome variables

The main outcome variables of this study are sexual function, satisfaction and intimacy in married women of reproductive age. All three variables are evaluated before, immediately after and one month after the end of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048009N1**
Registration date: **2020-08-25, 1399/06/04**
Registration timing: **prospective**

Last update: **2020-08-25, 1399/06/04**
Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Zeinab Alavizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 3330

Email address

zeinabmid@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of cognitive-behavioral hypnotherapy on the sexual function, satisfaction, and intimacy of married women of reproductive age

Public title

Evaluation of the effectiveness of cognitive-behavioral hypnotherapy on the sexual function, satisfaction, and intimacy of married women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Being married Living in Sabzevar city At least three years have passed since the marriage Stable living with husband No severe marital conflict (by self-expression) Having at least one child At least one year has passed since the last delivery Middle school and higher education Having no diseases that affect sexual function (cardiovascular, mental, thyroid, cancers, etc.) No history of mental illnesses (based on self-reported) Not taking psychiatric and sleeping pills and hormonal drugs Being available in the next two months Not attending to sex health classes and workshops at other institutions and clinics during the intervention Not seeing a psychologist, counselor, or psychiatrist during the intervention No exposure to the death of loved ones or a seriously stressful event during the last 3 months No addiction to drugs or alcoholic drinks Female sexual function test score lower than 28 Hypnotizability score higher than 5

Exclusion criteria:

Lack of necessary cooperation with the researcher Being pregnant Being away from her husband for more than ten days

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the participants enter the study over time and also for an equal number of people in the intervention and control group, random allocation by 4-block method is used. Sequences were determined using the website https://www.sealedenvelope.com/simple-randomiser/v1/lists using the block method to volume 4. Random sequencing is done by someone outside the research team. Initially, 8 comprehensive health centers in Sabzevar are divided into three categories or homogeneous groups in terms of social and economic status. A center is randomly selected from each category and we sample it according to the population of people covered by that category. Effective communication will be made with women who go to selected health centers for any reason, and if they meet the entry criteria, they will be tested for hypnosis and will be given a sexual function questionnaire. Women who score acceptable will be listed by the researcher and will be coded. The codes will be recorded in the central list. To assign participants to two groups, the person who has the allocation sequence will be determined and this will not be done by the project manager. This assigns individuals to groups in advance and does not create any bias in assigning individuals to groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the nature of the intervention is such that it is in the form of cognitive-behavioral hypnosis sessions, the participants in the intervention can not be blinded. Participants are aware of their group, However, to prevent information leakage, the meeting place will be held outside the comprehensive health centers and away from the eyes of the control group. To blind the data collector, the basic questionnaires are completed before assigning individuals to the two groups, and after the intervention, a person who is not familiar with the group of individuals completes the questionnaires. The data analyst will also not be informed of the group of people.

Placebo

Not used

Assignment

Parallel

Other design features

HIP(Hypnotic Induction Profile) hypnosis testing is used to screen women for hypnotic ability. Hypnotic Induction Profile (HIP) is a five-minute clinical assessment method that is standardized in a clinical population and meets the required criteria. The overall test score indicates the convergence of the three characteristics of "indoctrination" with "absorption" and "separation", as well as the evaluation of the degree of "unconsciousness" in the person. The subject experiences a state of hypnosis, and potential functional anxiety is reduced in both the subject and the test taker. The main and specific goal is not to create a state of hypnosis, but to test the capacity of the hypnotic experience. So there is no failure or wrong answer, our goal is to evaluate the response rate. The test begins with the rotation of the eye, which is considered a measure of biological ability and inherent in the individual's experience. During the test, the patient is told to roll her eyes: "Keep your head straight and look up, and while your head is straight, look up at your eyebrows, and now at your head. Close your eyes slowly as you look up." The eye-rolling is graded on a scale of zero to four based on the amount of sclera (white of the eye) that is visible between the lower eyelid and the

symmetrical lower margin. If convergence also occurs inside the eye, a degree between one and three is assigned and the convergence score is added to the rotation score. This step takes about five seconds. Eye rolling is part of the induction of hypnosis and is considered as a primary indicator of the ability to experience hypnosis. Also, in many patients, eye-rolling can be a rapid spontaneous induction of hypnosis. Then patients are asked to keep their eyes closed but to relax and focus on an inner feeling of floating. While the subject is doing this, She is told that her left hand will feel light and floating and will float in the air, and this will continue even after the end of the official hypnotic experience, unless the end sign (touching the left hand) to be given. The following seven headings are used to score hypnosis induction: 1- The amount of encouragement that is needed for the subject to create lightness and floating in her left hand and arm. 2. The degree of separation that is experienced after the first-hand flight. 3. The amount of verbal encouragement needed to raise the subject's hand again after the therapist lowers the hand. 4. The presence or absence of a sense of incontinence. 5. The amount of encouragement needed to respond to the end sign 6. The presence or absence of self-forgetfulness 7- Changes in awareness of physical sensation during hypnosis experience. The degree of hypnosis is reflected as an "induction scale score" from zero to 16. A score of five or lower means a lack of usable hypnosis.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahroud University of Medical Sciences

Street address
7th of Tir Square, Shahroud University of Medical Sciences and Health Services

City
SHahroud

Province
Semnan

Postal code
36147-73947

Approval date
2020-06-27, 1399/04/07

Ethics committee reference number
IR.SHMU.REC.1399.066

Health conditions studied

1

Description of health condition studied
Sexual function, satisfaction and intimacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual function: It is an essential part of life and is part of a woman's health. It is a multidimensional phenomenon and is influenced by psychological biological factors. A person's sexual function is a set of expressions of desire, sexual arousal, and orgasm that occur continuously in a person or couple, enabling the couple to fall in love.

Timepoint
Sexual function questionnaire is evaluated three times by individuals in both intervention and control groups: at the beginning of the study (before the intervention), 4 weeks after the beginning of the study (immediately after the end of the counseling sessions). And 4 weeks after the end of the intervention.

Method of measurement
The Women's Sexual Function Index is a 19-item questionnaire that measures a woman's sexual function in six areas of sexual function, including sexual desire, sexual arousal, vaginal lubrication, orgasm, satisfaction, and pain during sexual intercourse. A person's total score is equal to the sum of the person's scores in each area, which is a maximum score of 36, and a score of less than 28 indicates undesirable sexual function. A higher score indicates better sexual function.

2

Description
Sexual satisfaction: Sexual satisfaction is a person's pleasant feeling of sexuality and her ability to create mutual pleasure. Sexual satisfaction is the measure of a couple's awareness of the fulfillment of their and their partners' sexual expectations and needs. One of the most important factors in a person's evaluation of marital life and its continuity is the level of sexual satisfaction in couples.

Timepoint
Sexual satisfaction questionnaire is evaluated three times by individuals in both intervention and control groups: at the beginning of the study (before the intervention), 4 weeks after the beginning of the study (immediately after the end of the counseling sessions). And 4 weeks after the end of the intervention.

Method of measurement
Larson Sexual Satisfaction Questionnaire: The 25-question questionnaire was developed by Larson, Anderson, Niemann, and Holman to assess couples' levels of sexual satisfaction. The subject's response to each material is scored on a five-point scale from never (1) to always (5). A high score on this scale indicates sexual satisfaction. The scores are between 25 and 125, and sexual dissatisfaction is characterized by a score below 50, low satisfaction with a score between 50-75, moderate satisfaction with a score between 76-100, and

high satisfaction with a score of more than 100.

3

Description

Sexual intimacy: Sexual intimacy involves the sharing of romantic experiences, the need for physical contact, sexual intercourse, and relationships designed to arouse, stimulate, and satisfy sexual satisfaction. Intimacy is the feeling of closeness, similarity, and romantic or emotional relationship with a partner. This component, as one of the dimensions of marital intimacy, is one of the key factors in assessing a person's quality of life.

Timepoint

Sexual intimacy questionnaire is evaluated three times by individuals in both intervention and control groups: at the beginning of the study (before the intervention), 4 weeks after the beginning of the study (immediately after the end of the counseling sessions). And 4 weeks after the end of the intervention.

Method of measurement

In 2010, Botlani et al. Prepared a sexual intimacy questionnaire based on reliable scientific sources. The questionnaire asks 30 questions, each of them has a range of 4 options (always, sometimes, rarely, never) with scores of 1 to 4. The maximum score is 120 and the minimum is 30. Higher scores indicate more sexual intimacy between couples.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Initially, effective communication will be established with women who go to selected health centers for any reason, and if they meet the entry criteria, they will be tested for hypnosis and will be given female sexual function questionnaire. Individuals who get an acceptable score will be listed by the researcher and will be coded. These women will be randomly assigned to two groups of intervention and control using random appointment software for the clinical trial. They fill the female sexual function questionnaire, Larson's sexual satisfaction, and the standard sexual intimacy questionnaire. For these people, in coordination with themselves, weekly and for 4 weeks in a row, counseling sessions with the cognitive-behavioral hypnotherapy approach will be held. Cognitive Behavioral Hypnotherapy will present by the researcher, which includes 4 individual 60-minute sessions per week. The test is completed immediately after and 1 month after the end of the sessions. The counseling sessions will be conducted by a researcher under the supervision of a counselor who has the necessary education and skills in behavioral cognitive hypnotherapy.

Category

Behavior

2

Description

Control group: Initially, effective communication will be established with women who go to selected health centers for any reason, and if they meet the entry criteria, they will be tested for hypnosis and will be given female sexual function questionnaire. Individuals who get an acceptable score will be listed by the researcher and will be coded. These women will be randomly assigned to two groups of intervention and control using random appointment software for the clinical trial. They fill the female sexual function questionnaire, Larson's sexual satisfaction, and the standard sexual intimacy questionnaire. For control group members, no action is taken until the end of the intervention, except for routine care. The researcher accurately records the date of the counseling sessions and the beginning and end of the sessions for each person and completes the post-test forms on time for each person. The control group also completes the post-test forms 1 month later (equivalent to 4 sessions in the intervention group), and the follow-up forms one month later. In order to observe ethics in research for the control group, after the end of sampling and intervention, for these women 1 training session on sexual health with relaxation is held by the researcher.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Sabzevar city health center

Full name of responsible person
Somayye Fadavi

Street address
Taleqani Ave. Sabzevar city health center

City
Sabzevar

Province
Razavi Khorasan

Postal code
96186-13146

Phone
+98 51 4464 5200

Email
Vc.health@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Aliakbar Roudbary

Street address
Haft-e Tir Square, Shahroud University of Medical

Sciences and Health Services

City
Shahroud

Province
Semnan

Postal code
36147-73947

Phone
+98 23 3239 5054

Email
info@shmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Zeinab Alavizade

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
No. 17, 19th Daneshgah Ave., Daneshgah Blvd

City
Sabzevar

Province
Razavi Khorasan

Postal code
96188-46388

Phone
+98 51 4464 3330

Fax

Email
zeinabmid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Zeinab Alavizade

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
No. 17, 19th Daneshgah Ave., Daneshgah Blvd

City
Sabzevar

Province
Razavi Khorasan

Postal code
96188-46388

Phone
+98 51 4464 3330

Fax

Email
zeinabmid@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Zeinab Alavizade

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
No. 17, 19th Daneshgah Ave., Daneshgah Blvd

City
Sabzevar

Province
Razavi Khorasan

Postal code
96188-46388

Phone
+98 51 4464 3330

Fax

Email
zeinabmid@gmail.com

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
Yes - There is 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
Yes - There is 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

Title and more details about the data/document

The study protocol can be shared at the end of the study along with the details and full content of the counseling sessions, as well as the informed consent form of the participants.

When the data will become available and for how long

Since no specific time can be set for the end of the study, access to the said items can begin three months after the results are published.

To whom data/document is available

Researchers working in academic institutions can apply for the said items by presenting a valid degree and with the aim of conducting studies similar to the one conducted.

Under which criteria data/document could be used

This data is provided only so that the researcher knows how to conduct the study. The analysis or other uses must be done with prior notice and the consent of the principal investigator.

From where data/document is obtainable

Applicants can contact the given e-mail to receive documents and data. zeinabmid@gmail.com

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

The applicant will receive a response within a week after sending the message to the email address provided, explaining why they need the data.

Comments