Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Study of the Effect of Hypnotherapy on Sexual dysfunction in Postmenopausal Women: A Randomized Controlled Clinical Trial

Protocol summary

Study aim
Determining the effect of hypnotherapy on sexual dysfunction in menopausal women

Design
A randomized controlled clinical trial with parallel groups will be conducted on 100 patients. Randomization will be performed using block randomization with Microsoft Excel software.

Settings and conduct
Sampling will be conducted in health centers in Iran and in the city of Sari. For each patient in the intervention group, eight hypnotherapy sessions will be planned, with the first session conducted face-to-face and individually. Subsequently, the remaining seven hypnotherapy sessions for patients in the intervention group will be held weekly, individually, online.

Participants/Inclusion and exclusion criteria
Postmenopausal women with amenorrhea for 12 months or longer, who are married, aged between 45 and 55 years, and have a score below 26.5 indicating sexual dysfunction. Participants are willing to participate in the study and have stable mental health. They are not receiving hormone replacement therapy.

Intervention groups
participants in the intervention group will receive hypnotherapy. For each patient in the intervention group, eight hypnotherapy sessions are planned. The first session will be conducted face-to-face, individually, and will last 50 minutes. Subsequently, the remaining seven hypnotherapy sessions for patients in the intervention group will be held weekly, individually, online. Participants in the control group will receive at least general counseling and educational information regarding sexual health during menopause throughout the study period (without hypnotherapy techniques). After completion of the research process the audio recordings of the hypnotherapy sessions will be provided to participants in the control group.

Main outcome variables
Sexual dysfunction is the primary outcome. Satisfaction with the intervention and adherence to treatment are secondary outcomes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110827007422N7**
Registration date: **2026-02-14, 1404/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-14, 1404/11/25**
Update count: **0**

Registration date
2026-02-14, 1404/11/25

Registrant information

Name
Zhila Ganji

Name of organization / entity
Mazandaran University of Medical Scinces

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 7342

Email address
zhila.ganji@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the Effect of Hypnotherapy on Sexual dysfunction in Postmenopausal Women: A Randomized Controlled Clinical Trial

Public title
Effect of hypnotherapy on sexual dysfunction in menopausal women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Postmenopausal women with amenorrhea for 12 months or longer who are married. Aged between 45 and 55 years. Scoring below 26.5 on the Female Sexual Function Index (FSFI), indicating sexual dysfunction. Willing to participate in the study and able to provide written informed consent. Having stable mental health and no history of severe psychiatric disorders (such as uncontrolled depression, schizophrenia, or bipolar disorder). Not receiving hormone replacement therapy (HRT) that could affect sexual function. No history of severe chronic diseases such as uncontrolled diabetes, cardiovascular disease, thyroid disorders, multiple sclerosis (MS), etc. Having moderate to high hypnotizability according to the Stanford Hypnotic Susceptibility Scale. Having access to the internet and the ability to use mobile devices and online tools. Not currently using complementary therapies such as cognitive-behavioral therapy (CBT), yoga, meditation, or similar interventions.
Exclusion criteria:
A history of recent gynecological or obstetric surgeries that may affect sexual function. Absence from more than two sessions during the study. Individuals with severe levels of stress and anxiety as assessed by the DASS-21 questionnaire. Current use or discontinuation within the past three months of any medications known to negatively affect sexual function, such as antidepressants, antipsychotics, antiepileptics, anticancer drugs, or newly identified drugs with adverse effects on sexual function. Unwillingness to continue participation in the study.
Age
From **45 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method in this study will initially be convenience sampling to identify eligible postmenopausal women. Subsequently, participants will be allocated into two groups, C (control group) and T (intervention group), using block randomization. The block randomization process will be performed using Microsoft Excel software. Therefore, participants will be placed into 25 blocks of four (total sample size = 100) using one of the following six types of 4-part blocks: TTCC, TCTC, TCCT, CCTT, CTCT, and CTTC, where T represents the intervention group and C represents the control group. Using Excel, 25 random numbers will be generated with the RANDBETWEEN function within the range of 1 to 6. Each generated number will correspond to one of the six block types (e.g., the number 1 corresponds to the CTTC block, 2 to CTCT, and so on), and participants will be assigned accordingly. For example, if four participants visit the center and two are to be assigned to the intervention group and two to the control group, a random number, for instance 2, is generated in Excel. Therefore, these four participants are assigned according to the CTCT block. In this block, the first participant is assigned to the control group, the second to the intervention group, the third to the control group, and the fourth to the intervention group.
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 mazandaran University of medical sciences
Street address
Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Square
City
sari
Province
Mazandaran
Postal code
4816715793
Approval date
2026-01-31, 1404/11/11
Ethics committee reference number
IR.MAZUMS.REC.1404.556

Health conditions studied

1

Description of health condition studied
Sexual dysfunction in Postmenopausal Women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual dysfunction
Timepoint
Before the intervention, immediately after the intervention, and three months after the intervention.
Method of measurement
Female Sexual Function Index (FSFI)

Secondary outcomes

1

Description
Consent to intervention
Timepoint
3 months after the intervention
Method of measurement
Client Satisfaction Questionnaire-8

2

Description
Adherence to treatment
Timepoint
3 months after the intervention
Method of measurement
The mean number of hypnotherapy sessions attended by women in the intervention group, the number of participants who completed the at-home assignments, and the number of participants who fully completed the questionnaires.

Intervention groups

1

Description
Intervention group: This group includes postmenopausal women with sexual dysfunction. Hypnotherapy will be conducted by a trained researcher who has completed training at the Iranian Scientific Association of Clinical Hypnotherapy and holds a valid certification. Each participant in the intervention group will receive eight hypnotherapy sessions. The first session will be conducted face-to-face, individually, and will last 50 minutes. The remaining seven sessions will be held weekly, individually, online (via the WhatsApp virtual platform), each lasting 50 minutes. In addition to WhatsApp, two domestic messaging applications (Eitaa and Baleh) will also be included as alternative options.At the end of each session, an audio recording of the session will be sent to each participant so that they can perform hypnosis exercises at home at least twice daily (for 30 minutes each time) and record the number of practice sessions in a form provided to them. Once per week, participants will be contacted via telephone interview to report the frequency of performing the hypnosis exercises.The Female Sexual Function Index (FSFI) questionnaire will be administered at three time points: before the intervention, immediately after the intervention, and three months after the intervention.Treatment adherence in this study will be assessed using three criteria: the mean number of hypnotherapy sessions attended by participants in the intervention group, the number of participants who completed the at-home assignments, and the number of participants who fully completed the questionnaires.Treatment satisfaction will be measured using the Client Satisfaction Questionnaire-8 (CSQ-8), which evaluates overall satisfaction with the treatment, perceived usefulness of the sessions, the extent to which participants' treatment needs were met, and the likelihood of recommending the intervention to others.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers
Full name of responsible person
Dr. Zhila Gangi
Street address
The square of the martyrs, the boulevard of Mullah magdadin.
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 911 326 4459
Email
zhila.ganji@yahoo.com

2

Recruitment center
Name of recruitment center
Health centers
Full name of responsible person
Dr. Zhila Gangi
Street address
Amir Mazandaran Boulevard, Roodaki Street
City
Sari
Province
Mazandaran
Postal code

4816715793

Phone
+98 911 326 4459

Email
zhila.ganji@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Zhila Ganji

Street address
Amir Mazandarani Street - Vesal Shirazi Street - Nasibe Nursing and Midwifery College

City
Sari

Province
Mazandaran

Postal code
48167715793

Phone
+98 911 326 4459

Email
zhila.ganji@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
monireh babouyeh darabi

Position
Master's student in Midwifery Counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Amir Mazandarani Street - Vesal Shirazi Street - Nasibe Nursing and Midwifery Faculty

City
Sari

Province
Mazandaran

Postal code
4816715793

Phone
+98 11 3324 6697

Email
monirehbabouyehdarabi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr.Zhila Ganji

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Amir Mazandarani Street - Vesal Shirazi Street - Nasibe Nursing and Midwifery Faculty

City
Sari

Province
Mazandaran

Postal code
4816715793

Phone
+98 11 3336 7344

Email
zhila.ganji@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
monireh babouyeh darabi

Position
Master's student in Midwifery Counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Amir Mazandarani Street - Vesal Shirazi Street - Nasibe Nursing and Midwifery Faculty

City
Sari

Province
Mazandaran

Postal code
4816715793

Phone
+98 11 3324 6697
Email
monirehbabouyehdarabi@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
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