Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of self-care intervention based on self-efficacy theory on self-esteem, happiness and sexual quality of life of menopausal women

Protocol summary

Study aim
Determining and comparing self-esteem, happiness, and quality of sexual life of menopausal women before intervention, immediately, and 2 months after intervention in three groups: face-to-face intervention, virtual intervention, and control.

Design
A controlled clinical trial with parallel groups, without blinding, randomized by simple randomization method, on 150 postmenopausal women.

Settings and conduct
This unblinded study will be conducted in selected health centers in Tehran with the participation of 150 menopausal women. After obtaining informed consent, participants will be randomly divided into three groups. The educational content will be approved for scientific validity by 5 members of the faculty of the School of Nursing and Midwifery. After the intervention, questionnaires will be provided to the participants three times before the intervention, immediately after the intervention, and two months after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian women aged 45 to 60 years, 1 to 10 years after menopause, married and living with a spouse, at least literate, access to a mobile phone, no use of hormonal drugs in the last 3 months, spouse's health. Exclusion criteria: Mental health-threatening events, chronic debilitating diseases

Intervention groups
The in-person intervention consists of 6 2-hour sessions of self-care education in the form of lectures, questions and answers, and group discussions. In the virtual intervention, menopausal women participate in social media groups and educational content is presented in the form of micro-learning over 6 weeks and online group discussions are conducted. The control group receives virtual education individually but does not join any social groups and does not interact with anyone.

Main outcome variables
Self-esteem, happiness, and quality of sex life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250825066990N1**
Registration date: **2025-09-19, 1404/06/28**
Registration timing: **prospective**

Last update: **2025-09-19, 1404/06/28**
Update count: **0**

Registration date
2025-09-19, 1404/06/28

Registrant information

Name
Mozhgan Hashemzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2026-02-19, 1404/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of self-care intervention based on self-efficacy theory on self-esteem, happiness and sexual quality of life of menopausal women

Public title
The effect of self-care intervention based on self-efficacy on self-esteem, happiness and sexual quality of life of menopausal women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian women aged 45 to 60 years At least one year and a maximum of 10 years have passed since the cessation of menstruation Married and living with spouse Having at least basic reading and writing skills Access to a mobile phone with social media access No use of hormonal medications in the last three months Spouse's health (self-declaration)
Exclusion criteria:
Mental health threatening events Having chronic debilitating diseases
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method of the present study is as follows: first, two health centers will be selected from among the comprehensive health centers affiliated with Tehran University of Medical Sciences based on the high number of menopausal patients. Then, using the simple random sampling method, samples will be selected from among the people who meet the conditions for entering the study in each center. In this method, first, the letters A, B, and C are written on 50 sheets of paper (a total of 150 sheets) and placed in sealed envelopes. We place these envelopes in a box and ask each participant to take one envelope and not put that envelope back in the box. Finally, in order to determine the in-person intervention group, virtual intervention, and control group, a lottery will be held between the letters A, B, and C.
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
Research Ethics Committee of the Faculty of Nursing and Midwifery and the Faculty of Rehabilitation,
Street address
Tohid Square, Dr. Mirkhani Street (East Nosrat), Faculty of Nursing and Midwifery, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2024-12-07, 1403/09/17
Ethics committee reference number
IR.TUMS.FNM.REC.1403.160

Health conditions studied

1

Description of health condition studied
Self-esteem, happiness, quality of sex life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Self-esteem score on the Rosenberg Self-Esteem Questionnaire
Timepoint
Self-esteem assessment before intervention, immediately and 2 months after intervention
Method of measurement
Rosenberg Self-Esteem Questionnaire

2

Description
Happiness score on the Oxford Happiness Questionnaire
Timepoint
Happiness assessment before the intervention, immediately and 2 months after the intervention
Method of measurement
Oxford Happiness Questionnaire Short Form

3

Description
Quality of sexual life score in the Simond et al. sexual quality of life questionnaire
Timepoint
Assessment of sexual quality of life before intervention, immediately and 2 months after intervention
Method of measurement
Women's Sexual Quality of Life Questionnaire by Simond et al.

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In-person self-care training based on self-efficacy theory during menopause, 6 weekly training sessions, each session lasting 2 hours, in the form of lectures, questions and answers, and group discussions.
Category
Lifestyle

2

Description
Second intervention group: Virtual self-care training based on self-efficacy theory during menopause, sending 6 sessions of educational content (in the form of micro-learning) to groups on a social network weekly at the beginning of each week, and receiving feedback and online discussion in the group at the end of the same week.
Category
Lifestyle

3

Description
Control group: This group receives virtual training individually but does not join any social group and as a result will not interact with anyone.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
South Tehran Health Center
Full name of responsible person
Mohammad Reza Salmani Nadushan
Street address
Keshavarz Boulevard, Vesal Shirazi Street, Abbas Shafiei Alley, South Tehran Health Center
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Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
Street address
Keshavarz Boulevard, corner of Qods Street, Central University Organization, 6th Floor, Vice President for Research and Technology
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mahdieh Alipour
Position
Student

Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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
Not applicable
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