

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of couple communication skills training using multimedia software on menopausal symptoms, quality of life and marital satisfaction among women in menopausal transition

Protocol summary

Study aim

Determining the effect of couple communication skills training using multimedia software on the severity of menopausal symptoms, quality of life and marital satisfaction in women of menopausal age

Design

Clinical trial with control group, with parallel groups, without blinding, random allocation on 84 samples

Settings and conduct

This study will be performed on 84 couples (each group has 42) in Gonabad city. The intervention group will receive a training program in 6 sections (2 hours each) in two sessions per week, but the control group will not receive any program. At the beginning of the study, after the training program and 12 weeks after the training program, both intervention and control groups will complete the menopause symptom severity, quality of life and marital satisfaction questionnaires. Blinding will not be performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ● Age 40 to 55 years ● Having written consent to participate in the study ● Having the ability to use WhatsApp Messenger . Being married and living with a spouse Exclusion criteria: ● Untimely death of a couple ● Absence of more than one session Unwillingness to continue reading

Intervention groups

The intervention group includes couples in menopausal age who receive the intervention of the educational program. The control group includes couples who are in menopause and do not receive the training program.

Main outcome variables

Severity of menopausal symptoms, quality of life and marital satisfaction in women of menopausal age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211205053281N1**

Registration date: **2021-12-30, 1400/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-30, 1400/10/09**

Update count: **0**

Registration date

2021-12-30, 1400/10/09

Registrant information

Name

Akram Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3130 8772

Email address

helya.gholami1397@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of couple communication skills training using multimedia software on menopausal symptoms, quality of life and marital satisfaction among women in menopausal transition

Public title

The effect of training couples communication skills using multimedia software on menopausal symptoms, quality of life and marital satisfaction

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

40-55 years old having written consent to participate in the study having literacy having the ability to use WhatsApp messenger being married and living with a spouse not having hormone replacement therapy no history of hysterectomy or ovariectomy no Using herbal remedies to reduce menopausal symptoms not being diagnosed with mental and sexual disorders (according to the participant) not taking psychiatric drugs or addiction (according to the participant) not having physical and ground disease In couples (such as cancer, cardiovascular disease, stroke) no adverse life events in the last 6 months

Exclusion criteria:

Untimely death of one of the spouses absence of more than one session unwillingness to continue studying

Age

From **40 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

2 Comprehensive centers for providing health services based on the lottery, will be assigned to intervention groups (training of couple communication skills using multimedia software) and control group (one center each). Then in the centers, samples will be entered into the study based on available (easy) sampling. Randomization is simple and the randomization units are clustered and randomization is done by tossing coins.

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 Gonabad University of Medical Sciences

Street address

Phase Two Army

City

birjand

Province

South Khorasan

Postal code

9744163459

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.GMU.REC.1400.106

Health conditions studied

1

Description of health condition studied

Menopausal and other perimenopausal disorders

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Severity of menopausal symptoms

Timepoint

At the beginning of the study, immediately after the intervention, three months after the intervention

Method of measurement

Menopause Symptoms Rating Scale

Secondary outcomes

1

Description

Quality of life

Timepoint

At the beginning of the study, immediately after the intervention, three months after the intervention

Method of measurement

Quality of life questionnaire

2

Description

Marital Satisfaction

Timepoint

At the beginning of the study, immediately after the intervention, three months after the intervention

Method of measurement

Marital Satisfaction Questionnaire

1256897451

Phone

+98 51 5722 4083

Email

helya.gholami1397@gmail.com

Intervention groups

1

Description

Intervention group: Forming an intervention group in WhatsApp software, conducting training programs in 6 sections (2 hours each section) during two sessions per week for the participants of the intervention group. Intervention in the multimedia group will be as follows: A schedule will be provided to the intervention group, according to which the training sections will be sent to them in WhatsApp messenger (separately for each couple). Each educational section will include educational materials prepared according to the program along with images, audio, content, videos, etc., which will help to better understand the content. The scientific content of the educational program sections will be prepared using the latest reference books and also according to the content of the booklets and educational materials published by the Ministry of Health and Medical Education and will be available to 10 reproductive health specialists and gynecologists for approval. And counseling will be included. The topics of the sessions include: introducing the expression of goals and methods of work, self-awareness, recognizing the healthy personality, the importance of self-confidence, marital life skills, heart dialogue, intimacy, love commitment, intimacy, resilience conflict, satisfying sexual relaxation

Category

Behavior

2

Description

Control group: Form a control group in WhatsApp software. Only PDF tutorials are included in this group and also three questionnaires to complete

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonabad Urban Community Health Centers

Full name of responsible person

Gonabad University of Medical Sciences

Street address

Gonabad - Asian Roadside - University Campus

City

Gonabad

Province

Razavi Khorasan

Postal code

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Narjes bahri

Street address

Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9156137374

Phone

+98 51 5722 0575

Email

nargesbahri@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Akram gholami

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Phase Two Army

City

Birjand
Province
South Khorasan
Postal code
9744163459
Phone
+98 56 3130 8772
Email
helya.gholami1397@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Narjes bahri
Position
Faculty member of Gonabad University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Gonabad - Asian Roadside - University Campus
City
Gonabad
Province
Razavi Khorasan
Postal code
000000000000000
Phone
+98 51 5722 0575
Email
nargesbahri@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person

Akram gholami
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Phase Two Army
City
Birjand
Province
South Khorasan
Postal code
9744163459
Phone
+98 56 3130 8772
Email
helya.gholami1397@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