

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Designing a menopausal self-care application and examining its effect on the severity of menopausal symptoms in postmenopausal women referring to health centers in Jiroft in 2020

Protocol summary

Study aim

Determining the effect of menopause application on the severity of menopausal symptoms

Design

Clinical trial with control group, without blinding, randomized, On 60 menopausal women, A simple random method will be used for randomization.

Settings and conduct

After random selection of people referring to health centers in Jiroft,, explanation of goals and obtaining informed consent, the pre-test questionnaire will be completed by both groups (intervention and control). Then, the application made via Bluetooth will be installed on the smartphones of the people in the intervention group and they will be taught how to use it. After two and eight weeks (two stages), the questionnaire will be given and completed again as a post-test by going home or inviting women to health centers.

Participants/Inclusion and exclusion criteria

Admission: Age 45 to 60 Complete cessation of menstruation in the last 12 months without the use of medication or surgery Literacy and access to smart phones Withdrawal: Use any medication to reduce menopausal symptoms Having any mental illness

Intervention groups

Intervention group: an application made via Bluetooth will be installed on their smartphone. In fact, the intervention is educational-consulting content available in the application. Control group: will receive routine care.

Main outcome variables

Severity of menopausal symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201226049833N1**

Registration date: **2021-05-28, 1400/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-28, 1400/03/07**

Update count: **0**

Registration date

2021-05-28, 1400/03/07

Registrant information

Name

Najmeh Pourshahrokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4331 6719

Email address

n.pourshahrokhi95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing a menopausal self-care application and examining its effect on the severity of menopausal

symptoms in postmenopausal women referring to health centers in Jiroft in 2020

Public title

The effect of menopausal self-care application on the severity of menopausal symptoms in postmenopausal women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 45 to 60 Complete cessation of menstruation in the last 12 months without the use of medication or surgery
Literacy and access to smart phones

Exclusion criteria:

Use any medication to reduce menopausal symptoms
Having any mental illness

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To assign people to two groups, cards called control A and intervention B will be designed and these cards will be placed in an envelope and the person will randomly pick up a card from the envelope. If he picks up card A, he enters the control group and if he picks up card B, he enters 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 Jiroft University of Medical Sciences

Street address

Jiroft - Sepah Square - Nomadic Martyrs Building -
Headquarters of Jiroft University of Medical Sciences
and Health Services

City

Jiroft

Province

Kerman

Postal code

7861634204

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.JMU.REC.1399.011

Health conditions studied

1

Description of health condition studied

Severity of menopausal symptoms

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Severity of menopausal symptoms

Timepoint

Before starting the study And after the intervention in two shifts, the second and eighth week will be measured.

Method of measurement

Menopause Rating Scale (MRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For members of the intervention group, an application made via Bluetooth will be installed on their smartphones and they will be taught how to use them. In fact, our study intervention is educational-consulting materials available in the application, which will be provided to the intervention group for 8 weeks. Content of educational-counseling materials in the form of multimedia contents such as video, image and audio and with graphic and visual features appropriate to the age group of adults, including education on physical and mental symptoms of postmenopausal women and ways to reduce them, nutrition, exercise, Personal hygiene, sexual issues, supplementation and danger signs of women in this period. No training session will be held. The application was designed and implemented with the cooperation of two gynecologists, two senior midwives, two psychiatrists, one medical informatics specialist and two software experts. In order to develop the application under the Android platform using the Java language, the technical requirements for this purpose

will be identified and first the trial version and then the final version of the application will be created. The application can be easily installed and run with common hardware. Researchers will be in touch with members of the intervention group by telephone and will contact them twice a week, asking them to read the contents of the application, and if the members of the intervention group have any questions, They respond and encourage them to read the content in the app

Category

Other

2**Description**

Control group: The created application will not be available to the control group and they will receive the usual care for postmenopausal women. Routine care includes care such as blood pressure control for all middle-aged men and women in health centers.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Jiroft Comprehensive Urban Health Service Center No. 3 Shahid Beheshti

Full name of responsible person

Farzaneh Barkhouri

Street address

Pasdaran 10 Comprehensive Urban Health Service Center No. 3 Pasdaran Blvd.Jiroft.kerman

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n.pourshahrokhi95@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Jeeroft University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology of Jiroft University of Medical Sciences

Street address

Jiroft - Pasdaran Boulevard - Vice Chancellor for Research and Technology, Jiroft University of Medical Sciences and Health Services

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Web page address**Grant name**

Vice Chancellor for Research and Technology of Jiroft University of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Jeeroft 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**

Jeeroft University of Medical Sciences

Full name of responsible person

Neda Dastyar

Position

coach

Latest degree

Master

Other areas of specialty/work

Midwifery

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dr.neda@yahoo.com

Person responsible for scientific inquiries**Contact**

Name of organization / entity
Jeeroft University of Medical Sciences
Full name of responsible person
Neda Dastyar

Position

Faculty

Latest degree

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Other areas of specialty/work

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Web page address

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

After the data is not identifiable, part of the data related to the main outcome of the study will be published.

When the data will become available and for how long

Start of access period from article printing up to 6 months after

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If you send a written request from the academic and scientific institutions, data file unrecognizable to them and they will be allowed to perform paired t-test, independent t-test, chi-square test and analysis of covariance are.

From where data/document is obtainable

A written request should be sent by the University and Scientific Institute with the name and personal details to the e-mail address n.pourshahrokhi95@gmail.com.

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

First, a written request will be sent to the mentioned e-mail address, and after reviewing the request by the relevant person, and within 2 weeks, the result will be sent to the requesting person via e-mail.

Comments

Person responsible for updating data

Contact

Name of organization / entity
Jeeroft University of Medical Sciences
Full name of responsible person
najmeh pourshahrokhi

Position

Director of Virtual Training Center

Latest degree

Master

Other areas of specialty/work

Medical Informatics

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