

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Investigating the Effectiveness of Online Counseling with a Therapeutic Approach Based on Acceptance and Commitment on Health-promoting Behaviors in Middle-aged Women

Protocol summary

Study aim

Determining the effect of online counseling with a therapeutic approach based on acceptance and commitment on health-promoting behaviors in middle-aged women

Design

This interventional research will be conducted as a parallel clinical trial in two intervention and control groups, with a one-month follow-up and without blinding. 68 samples will be selected based on the study's entry and exit criteria and will be assigned to two control and intervention groups using a randomization site.

Settings and conduct

The place of study is Haji Maghsoudi Comprehensive Health Center of Shahid Sadougi University of Medical Sciences, Yazd. The population studied is middle-aged menopausal women covered by this center and blinding is not done, but random allocation is done by a person who is not aware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian middle-aged women aged 40-60 years; Having a desire to participate in the study and giving an informed consent; Having a smart mobile phone and the ability to use it for virtual classes; Having an authorized virtual network; Having a minimum education degree. Exclusion criteria: Recent unfortunate events such as death of first-degree relatives, divorce from spouse, etc.; Consumption of cigarettes, alcohol, drugs and psychotropic drugs; Previous participation in lifestyle promotion counseling classes; Suffering from acute physical and mental illnesses under treatment

Intervention groups

For the intervention group, 8 weekly 45-minute online counseling sessions will be held in Sky Room. The control group will receive the health promotion behavior training booklet.

Main outcome variables

Average score of health promoting behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230302057588N1**

Registration date: **2023-04-20, 1402/01/31**

Registration timing: **prospective**

Last update: **2023-04-20, 1402/01/31**

Update count: **0**

Registration date

2023-04-20, 1402/01/31

Registrant information

Name

Zahra Rezvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4662 2210

Email address

z.rezvani@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effectiveness of Online Counseling with a Therapeutic Approach Based on Acceptance and Commitment on Health-promoting Behaviors in Middle-aged Women

Public title

The effect of counseling based on acceptance and commitment on health-promoting behaviors of middle-aged women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian middle-aged women aged 40-60 years Having a desire to participate in the study and informed consent Having a smart mobile phone and the ability to use it for virtual classes Having an authorized virtual network Having a minimum education degree

Exclusion criteria:

Recent unfortunate events such as death of first-degree relatives, divorce from spouse, etc. Consumption of cigarettes, alcohol and drugs and psychotropic drugs Previous participation in lifestyle promotion counseling classes Suffering from acute physical and mental illnesses under treatment Concurrent participation in another similar study Self-reported drug use due to psychological illnesses

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

A number of middle-aged people are selected after checking the information of the applicants' files. 68 middle-aged people who meet the study entry criteria and informed consent are selected as samples. Each person is given a number and randomly divided into control and intervention groups using the RANDOM.ORG - Sequence Generator site.

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-03-01, 1401/12/10

Ethics committee reference number

IR.SSU.REC.1401.104

Health conditions studied**1****Description of health condition studied**

Health promoting behaviors

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Average score of health-promoting behaviors in middle-aged women

Timepoint

In the baseline, the completion of the intervention in week 8 and the follow-up period in week 12 in two groups

Method of measurement

Health Promotion Lifestyle Questionnaire (Walker et al.)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group receives health-promoting behavior counseling based on an acceptance and commitment approach by a trained student under the supervision of a supervisor and a fellow psychologist during 8 sessions of 45-minute once

a week online on the Sky room platform. For the intervention group in the authorized virtual network, before the start of counseling sessions, the link of online sessions and training on how to use this space will be provided to them. In each session, the contents of the previous sessions will be reviewed and assignments will be reviewed. The content of the sessions includes the introduction of therapy and education, mindfulness, constructive frustration, clarification of values, fault and its techniques, self-observation, acceptance and committed action. At the end of each session, people's questions are answered.

Category

Behavior

2

Description

Control group: They will receive the training booklet on health-promoting behaviors and they will complete the relevant questionnaire in all three times before, immediately after and one month after the end of the intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Haji Maghsoudi Comprehensive Health Center

Full name of responsible person

Behnaz Enjezab

Street address

Javad Al-Aameh

City

Yazd

Province

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Postal code

8916877443

Phone

+98 35 3838 0920

Email

enjezabbehnaz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amir Hoshang Mehrparvar

Street address

Central Organization of Shahid Sadoughi University of Medical Sciences, Dr. Bahnar Square, Yazd

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Email

ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

All personal data of study participants can be shared after de-identification.

When the data will become available and for how long

After results publication

To whom data/document is available

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

Under which criteria data/document could be used

Scientific use

From where data/document is obtainable

enjezabbehnaz@yahoo.com

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

One week after receiving the applicant's email

Comments