Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of virtual education on the burden of care in caregivers of breast cancer patients

Protocol summary

Study aim
Determining the effect of virtual education on the burden of caregivers of breast cancer patients

Design
Clinical trial has a community-based control group, with parallel groups, a blind, randomized strain

Settings and conduct
In the intervention group, after an attendance meeting, the training package will be implemented within two months through virtual social networks. The intervention group will not receive intervention. Before, immediately and one month after the end of the intervention, caregiver burden will be compared in the two groups.

Participants/Inclusion and exclusion criteria
Entry requirements: Literacy for reading and writing. Not having disorders such as anxiety and depression. Access and ability to use virtual social networks. Passes at least 3 months of diagnosis. Not participating in training courses in the last three months. Exit Conditions: Unwillingness to continue to study. Attending a similar training program. No full use of educational content.

Intervention groups
In the intervention group after an introduction, educational package will be implemented using cyberspace. Training will be implemented within two months through their social networks, whatsapp. The intervention group will not receive intervention.

Main outcome variables
Supply of basic knowledge and scientific evidence for organizations and institutions responsible for implementing preventive programs. Helping community health workers about the design of future cyberspace interventions. Improving the level of health and reducing cares in carers in patients with breast cancer.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210930052640N1**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date
2021-11-08, 1400/08/17

Registrant information

Name
Maryam Nouri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3353 9584

Email address
Nouri.maryam98@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-06, 1400/08/15

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of virtual education on the burden of care in caregivers of breast cancer patients

Public title

The effect of virtual education on the caregiver burden

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy for reading and writing . Not having disorders such as anxiety and depression Access and ability to use virtual social networks. Passes at least 3 months of diagnosis. Not participating in training courses in the last three months.

Exclusion criteria:

Unwillingness to continue to study. Attending a similar training program. No full use of educational content.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by randomized block design with quadruple blocks. The letter A is for the intervention group and the letter B is for the control group. Then we write all the permutation compounds, which are 6 different compounds, on 6 cards as follows: 1. AABB, 2. ABBA, 3. ABAB, 4. BAAB, 5. BABA, 6. BBAA, Then we will choose a digit from numbers 1 to 6 by drawing. For example, if the number 2 is selected, it means that the first person in the intervention group will be the next two people in the control group and the fourth person in 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 Zanjan University of Medical Sciences

Street address

No. 99,Ghamat Bayat Alley, Airport St ,Zanjan city, Iran

City

Zanjan

Province

Zanjan

Postal code

4518959385

Approval date

2021-09-30, 1400/07/08

Ethics committee reference number

IR.ZUMS.REC.1400.284

Health conditions studied

1

Description of health condition studied

The effect of virtual education on the burden of caregivers of breast cancer patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Care load score less than 20

Timepoint

Caregivers whose patients have passed three months after diagnosis's three stages before and one month after the intervention

Method of measurement

Zarit Care burden Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After a face-to-face session to familiarize the training program the written training will be implemented using cyberspace.The general content of the training will be based on a review of texts related to the problems and educational needs of caregivers regarding the reduction of the care burden.But in compiling educational content after pre-test analysis,focus on the problems that had the most frequency and are in fact the educational needs of our target group.More time will be given and emphasized.These tutorials will be provided in the form of audio and video files.The training will take place over two months through the social networks they use WhatsApp.

Category

Behavior

2

Description

Control group: The control group will not receive any intervention.Before, immediately and one month after the intervention,the care burden of the two groups will be measured in person by completing questionnaires and the two groups will be compared in terms of the care load.If the intervention is effective,the control group will receive the intervention after the study.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehraneh Specialized Clinic

Full name of responsible person

Fereshteh Mohammad Khani

Street address

Mehraneh Specialized Clinic, Mehraneh Boulevard, Gavazang Road, Zanjan, Iran

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4515743551

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mehraneh.markazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Din Mohammadi

Street address

South private road of Zanjan University of Medical Sciences, Zanjan, Iran

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Province

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Phone

+98 24 3342 0651

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mdinmohammadi@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Maryam Nouri

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No. 99, Ghamat Bayat Alley, Airport Street, Zanjan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Position

Nurse

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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Zanjan University of Medical Sciences

Full name of responsible person

Dr. Nasrin Jafari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Zanjan

Postal code

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Phone

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