

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of Coping Strategy Educational Intervention on Quality of Life and coping strategy among Primary Caregiver of Jordanian Women with Breast Cancer

Protocol summary

Study aim

The general objective of this study is to develop, implement, and evaluate the effect of Coping Skill Education Intervention on the coping strategy and quality of life among primary caregiver for women with breast cancer in Jordan.

Design

Cluster Randomized Control Trial

Settings and conduct

Jordanian MOH hospitals

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Primary caregiver of age 18 years or older. 2. Able to read and write in Arabic language. 3. Primary caregiver who provides care and living together with the woman with breast cancer at least for 6 months before the study. Exclusion criteria 1. Caregivers professionally trained or work as health care provider. 2. Caregivers who previously participated in the intervention research (e.g, Cognitive Behavior Therapy, psychoeducational intervention).

Intervention groups

Participants will be randomly assigned to the experimental group and the control group. Both coping skill training programs and non-communicable disease (NCD) education will be performed in the experimental group, and only NCD education will be performed in the control group at the same consequences for experimental group.

Main outcome variables

Quality of life and coping strategy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048056N1**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **prospective**

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

Registration date

2020-07-26, 1399/05/05

Registrant information

Name

Jawad Obaidi

Name of organization / entity

Universiti Putra Malaysia

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Jordan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-02, 1399/05/12

Expected recruitment end date

2020-11-22, 1399/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Coping Strategy Educational Intervention on Quality of Life and coping strategy among Primary Caregiver of Jordanian Women with Breast Cancer

Public title

Effect of Coping Strategy Educational Intervention on Quality of Life and coping strategy among Primary Caregiver of Jordanian Women with Breast Cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary caregiver of age 18 years or older. Able to read and write in Arabic language. Primary caregiver who provides care and living together with the woman with breast cancer at least for 6 months before the study.

Exclusion criteria:

Caregivers professionally trained or work as health care provider. Caregivers who previously participated in the intervention research (e.g, Cognitive Behavior Therapy, psychoeducational intervention).

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

In Jordan, there are different types of hospitals that classified as military, public, private and specialized hospitals. Unfortunately, all of this hospitals provided healthcare services in different policies and guidelines except the public hospitals. There are 32 governmental and universities hospitals cover all cities, taking into account that there are at least one or two hospitals in each city. Due to the type of sample and the population density, hospitals in Amman, in Al-Zarqa, and Irbid will be selected for this study. These hospitals are consider adequate to obtain the estimated sample size for this study. A. In the first stage: a list for all governmental hospital was done. According to the following eligible criteria four hospital will be selected: first, provide service for breast cancer patient. Second one, following Jordanian ministry of health policy. These four hospitals will randomly allocated for intervention and control group. B. In the second stage: all the eligible participant in the four hospitals will be identified and selected to participate in this study according to the inclusion and exclusion criteria to reduce the selection and consent bias. Randomization will be taken by using random sequence number generation to randomize in level of hospitals by following consort 2010 guidelines. A list will be done for all eligible hospitals. The hospitals will be allocated equally to the intervention or control group (1:1). The four hospital will take sequentially number (1-4). An independent researcher (Jordanian external supervisor) who will be asked to carry out the randomization procedure. The odd number (1 and 3) will

be taken as the intervention hospitals and the even numbers (2 and 4) will be taken as the control hospitals by using random sequence number generation. After the completion of baseline collecting data, the researcher will check the questionnaire if completed by all recruited primary caregiver. The researcher will set number for the corresponding from (1 to 124). An independent researcher (external supervisor) who assigned for this study to avoid selection bias will provide a list of equal groups for all cluster. Each group contains 6-8 participants. Allocation Concealment The allocation concealment will be based on hospitals and individual level. The cluster allocation list will concealed from those involved in the research and place the numbers in sealed, opaque envelopes until the start of the intervention. Individual groups list for both arm of the study made by external supervisor will be concealed in sealed, opaque envelopes before one week of begging of the intervention each group will be contacted by hospital staff. Implementation The next step of randomization will be conducted by hospital administrator, someone who is not involved in all previous steps will open the sealed envelope and contact the four hospitals staff to inform the participants about their group time, and prepare them for first session.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind, the principle investigator the only person know the allocation of participants. The research assistances that will perform the outcome assessment will be blind to group allocation of the primary caregiver. The benefits of this step will be explained to researcher assistances and they will be instructed not to ask the primary caregivers about their allocations, and the primary caregivers will be instructed not to discuss their study treatment with anyone. The CSEI will be performed and be held in separate room. Different team of data collectors will be hired for all study sitting.

Placebo

Not used

Assignment

Parallel

Other design features

Cluster Randomized Control Trial

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

ETHIC COMMITTEE FOR RESEARCH INVOLVING HUMAN SUBJECT

Street address

43400

City

Serdang

Postal code
603
Approval date
2019-11-23, 1398/09/02
Ethics committee reference number
UPM/TNCPI/RMC/1.4.18.2(JKEUPM)

Health conditions studied

1

Description of health condition studied

Breast cancer caregiver quality of life and coping

ICD-10 code

ICD-10 code description

quality of life

Primary outcomes

1

Description

Quality of life

Timepoint

Before and after intervention and 4 weeks after intervention

Method of measurement

Questionnaire

2

Description

Coping

Timepoint

Before and after intervention and 4 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Demographical

Timepoint

before the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

This section discusses the four-session training program, which will be presented to the intervention group, which will be lasted for 1 day for each group. The training will be conducted in the hall of the Oncology Unit of the hospital and will be coordinated by the research assistants. Participants will be randomly assigned to the

experimental group and the control group. Both coping skill training programs and non-communicable disease (NCD) education will be performed in the experimental group, and only NCD education will be performed in the control group at the same consequences for experimental group. This design is more ethical and close to practical reality, as patients with breast cancer will all be provided with usual care mostly at their visit to the hospitals. The coping strategy training education consists of four sessions a day and will be performed only in the experimental group. Three health professionals will act as facilitators. They will receive 1-day training with detailed guidance of the study protocol. Researcher will provide coaching on caregivers' responses to diverse situations to enable caregivers learn more skillful responses within four sessions. All caregivers will be encouraged by interventionists to practice the specific coping strategy at home after sessions end by regular phone calls. The primary goals of the coping skill educational program are: 1) to teach caregivers a variety of coping strategies; and, 2) to help the caregiver acquire and maintain positive coping strategy. The themes were: (1) introduction of Breast Cancer (BC) and importance of caregiver, (2) coping strategy (problem-focused strategy), (3) coping strategy (emotion-focused strategy) and (4) quality of life. Methods Teaching strategies are based on three components: 1-Audio-Visual: this strategy will provide the education module using a video comprising audio and visual contents. 2. PowerPoint presentations, markers, board, flip charts, projector, computer, and training guide. 3. Group discussion. each session will include 6 participants First session 9:00 AM - 10:10 AM (70 Min) break 10:10-10:20AM (10Min) Second session 10:20 AM -11:20 AM (60 Min)Break 11:20 AM-11:30AM (10Min)Third session 11:30 AM- 12:20PM (50 Min)Break 12:20 PM - 01:00PM (40 Min)Fourth session 01:00 PM - 02:00 PM (60 Min)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Jordanian Ministry of health

Full name of responsible person

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

No

Title of funding source

Self Finance

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries

Contact**Name of organization / entity**

Universiti Putra Malaysia

Full name of responsible person

Jawad Ghaleb Obaidi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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