

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of using combination learning on the empowerment of caretakers of cancer patient under chemotherapy referred to clinics

Protocol summary

Study aim

Determining the Effect of Combined Learning on the ability of caregivers of Cancer Patients Under Chemotherapy Referring to Clinics

Design

Participants are randomly divided into intervention and control groups and each participant is assigned a code

Settings and conduct

This clinical trial is blinded and conducted in Shiraz chemotherapy centers in such a way that six sessions of the training class will be held for the intervention group and will not be conducted for interventional control group.

Participants/Inclusion and exclusion criteria

The conditions for entry into this study are not personnel of the health team and the program and the training class have not passed the care of the cancer patient and the conditions for withdrawal from this study are excluded from the questionnaire that are not completely completed and the reluctance to continue cooperation during the study They have the right to leave

Intervention groups

For the intervention group, six sessions of the class will be held and will not intervene for the intervention group

Main outcome variables

Health Knowledge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160404027216N9**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **retrospective**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Fatemeh Vizeshfar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4258

Email address

vizeshfarf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2019-01-04, 1397/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using combination learning on the empowerment of caretakers of cancer patient under chemotherapy referred to clinics

Public title

Use Combination Learning

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years. Nationality is Iranian Be able to speak

Persian or read Persian and understand it Do not hurt the health personnel The program and the training course on caring for a cancer patient have not been passed Do not have hearing, vision or speech problems.

Exclusion criteria:

Questionnaires that are not completely completed are deleted. Unwillingness to continue working during the study If you have more than one absentee session, you will be dropped out of the classroom If a person's psychological disorders develop, he or she will be excluded from the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The centers of chemotherapy are randomly assigned to the centers. Subsequently, the samples are determined individually

Blinding (investigator's opinion)

Double blinded

Blinding description

En Since the questionnaire is given to all participants, no one is aware of being in the control and intervention group. The person who analyzes the information is also unaware of who is in the intervention and control group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences,opposite Phalestine Street, Zand Blvd,

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.SUMS.REC.1397.703

Health conditions studied

1

Description of health condition studied

The ability of caregivers of cancer patients

ICD-10 code

Z55.8

ICD-10 code description

Other problems related to education and literacy

Primary outcomes

1

Description

The ability of carers for cancer patients

Timepoint

Pre- intervention, post- intervention and one month after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group: training materials on the common side effects of chemotherapy and how to deal with them are given face-to-face training, and at the end of the training CD containing the same The materials are for home use.

Category

Other

2

Description

The intervention group is two: The training about the common complications of chemotherapy and how to deal with them is only done in the form of a training CD and not face-to-face training.

Category

Other

3

Description

Control group: There is no training in the control group and, at the end, to comply with the ethical requirements

of the CD Is given to people.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Chemotherapy centers

Full name of responsible person

Nahid Karimi

Street address

School of Nursing and Midwifery, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Phone

+98 71 3647 4252

Email

nahid.karimiii72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

School of Nursing and Midwifery, Shiraz, Iran

City

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Postal code

71348-14336

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nahid Karimi

Position

Bachelore

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Shiraz, Iran

City

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Vizeshfar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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City

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Fars

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71936-13119

Phone

+98 71364742548

Email

vizeshfar@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nahid Karimi

Position

Bachelor of science

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

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Postal code

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Email

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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

Due to the confidentiality of the data

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Publish in domestic and foreign publications and present in credible seminars

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Research team members

Under which criteria data/document could be used

As statistical information in research such as meta-analysis, which requires these data

From where data/document is obtainable

Nahid Karimi

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

Send an email to the public responsible

Comments