

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of a care program based on the Roy adaptation model on fatigue in Elderly patients with cancer undergoing Chemotherapy

Protocol summary

Study aim

Determining the effect of a care program based on the Roy adaptation model on fatigue in Elderly patients with cancer undergoing Chemotherapy

Design

A clinical trial with a control group, with parallel group design, without blindness, randomized through a random numbers table

Settings and conduct

This study was conducted in the oncology ward of three Hospitals of imam hossein, shohadaeh tajrish a taleghani in Tehran. Using the available sampling method, individuals were selected and randomly assigned to intervention and control groups. The samples of both groups completed Multidimensional Fatigue Inventory-20. For the intervention group, training sessions were conducted in six sessions. The post-test was taken one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in research and having cooperation; Minimum age of 65 and a maximum age of 80 years old; Do not have a history of cognitive impairment. Non Inclusion criteria: participation in the previous same care program in Last three months

Intervention groups

Intervention group: For the intervention group, an educational program is implemented including 1. Determining maladaptive behaviors in four physiological dimensions, self-understanding, role play, independence and dependence 2. Need help during problems 3. Identify measures to help to solve problems through nursing diagnoses 4. Identify possible barriers to the care plan 5. Set up an app for the elderly and follow up on the phone. In the intervention group, there are 6 60-minute training sessions (two sessions a week) will be performed. Control group: The control group receives routine care.

Main outcome variables

Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190512043563N1**

Registration date: **2019-05-22, 1398/03/01**

Registration timing: **retrospective**

Last update: **2019-05-22, 1398/03/01**

Update count: **0**

Registration date

2019-05-22, 1398/03/01

Registrant information

Name

Mozhgan Hajalimohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8355 3970

Email address

mozhgan.nurse.beheshti@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-09-16, 1397/06/25

Actual recruitment start date

2018-04-19, 1397/01/30

Actual recruitment end date

2018-09-16, 1397/06/25

Trial completion date

2018-09-16, 1397/06/25

Scientific title

The effect of a care program based on the Roy adaptation model on fatigue in Elderly patients with cancer undergoing Chemotherapy

Public title

The effect of a care program based on the Roy adaptation model on fatigue in Elderly patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in research and having cooperation Ability to communicate effectively with the researcher Ability to handle meetings and prepared to respond to questions physically and mentally Minimum 65 and a maximum of 80 years old Do not have a history of cognitive impairment

Exclusion criteria:

participation in previous same care program in Last three months

Age

From **65 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Actual sample size reached: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method was used for randomization. Firstly, all eligible patients were selected based on the criteria of entry and assigned a special code. Then, according to the sample size and the same number, the coin was thrown, and the heads subjects in the intervention group and the tails subjects in the control 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 Shahid beheshti University of Medical Sciences

Street address

in front of Shahid Rajaei Heart Hospital, Intersection of Niayesh, Valiasr St

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.SBMU.PHNM.1396.970

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

Cancer

ICD-10 code

c18

ICD-10 code description

Malignant neoplasm of colon

Primary outcomes**1****Description**

fatigue

Timepoint

Before and one month after intervention

Method of measurement

Multidimensional Fatigue Inventory-20

Secondary outcomes

empty

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

Intervention group: For the intervention group, an educational program is implemented including 1. Determining Maladaptive behaviors in four physiological dimensions, self-understanding, role play, independence and dependence 2. Need help during problems 3. Identify measures to help solving problems through nursing diagnoses 4. Identify possible barriers to the care plan 5. Set up an app for the elderly and follow up on the phone. In intervention group, there are 6 60-minute training sessions (two sessions a week) will be performed. Control group.

Category

Rehabilitation

2**Description**

Control group: received routine care
Category
N/A

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Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Mozhgan Hajalimohammadi
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Shahid madani St
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2

Recruitment center

Name of recruitment center
Shohadayeh Tajrish Hospital
Full name of responsible person
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3

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Mozhgan Hajalimohammadi
Street address
Shahid Aarabi St, Yaman St, Shahid Chamran
Highway
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Tehran
Province
Tehran
Postal code
1985711151

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Aarabi St, Yaman St, Shahid Chamran
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1983963113
Phone
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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mozhgan hajalimohammadi
Position
Nurse
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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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