Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Rajaee 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Mozhgan Hajalimohammadi

Street address

Shahid madani St

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 3000

Email

mozhgan.nurse.beheshti@gmail.com

2

Recruitment center

Name of recruitment center

Shohadayeh Tajrish Hospital

Full name of responsible person

Mozhgan Hajalimohammadi

Street address

Shahrdari St

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 9201

Email

mozhgan.nurse.beheshti@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

mozhgan.nurse.beheshti@gmail.com

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 Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9780

Email

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

Street address

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

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
mozhgan.nurse.beheshti@gmail.com

Person responsible for scientific 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
Street address
in front of Shahid Rajaee Heart Hospital, Intersection of Niayesh, Valiasr St
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
mozhgan.nurse.beheshti@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mozhgan Hajalimohammadi
Position
Nures
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
in front of Shahid Rajaee Heart Hospital, Intersection of Niayesh, Valiasr St
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
mozhgan.nurse.beheshti@gmail.com

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