Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of distance nurse-led fatigue management on fatigue, sleep quality and self-efficacy in colorectal cancer patients (a randomized clinical trial)

Protocol summary

Study aim
Determining the effect of distance nurse-led fatigue management on fatigue, sleep quality and self-efficacy in colorectal cancer patients

Design
Clinical trial with intervention and control group, without blinding, randomized, on 60 patients. Alternative block randomization technique was used for randomization.

Settings and conduct
Eligible patients visiting Ayatollah Khansari Hospital in Arak will be enrolled in this non-blinded, two-group clinical trial. The intervention group will receive fatigue management training via non-face-to-face sessions through Skyroom, while the control group will continue to receive standard hospital care without the intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 30-50 years; Be able to read and write and fluent in Persian; The patient or their family members must have the ability and facilities to use the Skyroom platform; Interested in participating in the study; The diagnosis of colorectal cancer has been confirmed by a specialist physician; Do not have a clear mental disorder or physical illness that results in limited mobility; At least one chemotherapy session has begun; The patient's chemotherapy sessions should be outpatient. Exclusion criteria: Known cases of multiple sclerosis, anemia, thyroid disease, orthopedic or neurological diseases such as epilepsy, of which fatigue is one of their symptoms

Intervention groups
The intervention group will participate in fatigue management training guided by a nurse. This training will be conducted via Skyroom. Meanwhile, the control group will continue to receive comprehensive standard hospital care without this specific intervention.

Main outcome variables
Fatigue; sleep quality; self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240707062354N2**
Registration date: **2025-05-17, 1404/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-17, 1404/02/27**
Update count: **0**

Registration date
2025-05-17, 1404/02/27

Registrant information

Name
Fatemeh Moghadasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3221 9231

Email address
fatemehmoghadasi03@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-16, 1404/02/26

Expected recruitment end date
2026-05-16, 1405/02/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of distance nurse-led fatigue management on fatigue, sleep quality and self-efficacy in colorectal cancer patients (a randomized clinical trial)

Public title
The effect of distance nurse-led fatigue management in colorectal cancer patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 30-50 years Be able to read and write and fluent in Persian The patient or their family members must have the ability and facilities to use the Skyroom platform. Interested in participating in the study The diagnosis of colorectal cancer has been confirmed by a specialist physician Do not have a clear mental disorder or physical illness that results in limited mobility At least one chemotherapy session has begun The patient's chemotherapy sessions should be outpatient

Exclusion criteria:
Known cases of multiple sclerosis, anemia, thyroid disease, orthopedic or neurological diseases such as epilepsy, of which fatigue is one of their symptoms

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The research units will be selected as available and then randomly allocated in two intervention and control groups using the alternative block randomization technique.10 blocks with 6 modes will be used. The letter A will represent the participant of the intervention group and the letter B will represent the participant of the control group. The samples in the two intervention and control groups will be randomly selected from among the blocks based on the sequence of entry and according to the block pattern and will be assigned to the intervention and control groups.

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 Arak University of Medical Sciences

Street address
University complex of the great prophet, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2025-05-04, 1404/02/14

Ethics committee reference number
IR.ARAKMU.REC.1404.041

Health conditions studied

1

Description of health condition studied
Sleep quality and self-efficacy in patients with colorectal cancer.

ICD-10 code
Z73.6

ICD-10 code description
Limitation of activities due to disability

Primary outcomes

1

Description
Fatigue level based on the Cancer Fatigue Scale

Timepoint
At the beginning of the study (before the intervention)

Method of measurement
Cancer Fatigue Scale

2

Description
Sleep quality based on the Pittsburgh Sleep Quality Index questionnaire

Timepoint
At the beginning of the study (before the intervention)

Method of measurement
Pittsburgh Sleep Quality Index Questionnaire

3

Description
Self-efficacy level based on Schwartz General Self-Efficacy Scale

Timepoint
At the beginning of the study (before the intervention)

Method of measurement
Schwartz General Self-Efficacy Scale

Secondary outcomes

1

Description
Fatigue level based on the Cancer Fatigue Scale at the end of the intervention
Timepoint
At the end of the intervention
Method of measurement
Cancer Fatigue Scale

2

Description
Sleep quality based on the Pittsburgh Sleep Quality Index Questionnaire at the end of the intervention
Timepoint
at the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Index Questionnaire

3

Description
Self-efficacy level based on Schwartz General Self-Efficacy Scale at the end of the intervention
Timepoint
At the end of the intervention
Method of measurement
Schwartz General Self-Efficacy Scale

Intervention groups

1

Description
Intervention group:The intervention group will participate in fatigue management training guided by a nurse. This training will be conducted via Skyroom which will cover strategies for energy conservation, relaxation breathing exercises, sleep hygiene education, and home exercise protocols. Each subject will be covered in two sessions, totaling eight sessions, with each session lasting between 60 to 90 minutes. Each week, a non-face-to-face training session and telephone follow-up by a nurse will be conducted once a week (for at least 15 minutes) based on the training content of the previous session and patient assessment will be conducted based on an implicit checklist that can be changed based on the training content of each session. The Fatigue Scale, Pittsburgh Sleep Quality Index, and Schwartz General Self-Efficacy Scale will be completed by both groups after the intervention.
Category
Behavior

2

Description
Control group:The control group will not receive the intervention but will receive other hospital care without any reductions.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khansari Hospital, Arak city
Full name of responsible person
Fatemeh Moghadasi
Street address
Ayatollah Khansari Hospital, End of University Street, Arak city, Central province
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Province
Markazi
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3818649433
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Email
info_khansari@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Behzad Khansarinejad
Street address
University complex of the great prophet, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3383 8319
Email
behzad.khansarinejad@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Moghadasi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

3rd floor, corner of Nizamzadeh Alley, Shahid Abdullahi Alley, Abuzar Street

City

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Province

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Postal code

3814187476

Phone

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Email

fatemehmoghadasi03@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Moghadasi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after publication.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions 6 months after publication.

Under which criteria data/document could be used

6 months after the publication of the results, researchers working in academic and scientific institutions can refer to Ms. Fatemeh Moghadasi, the person in charge of the project, and use the data of the project by mentioning the source.

From where data/document is obtainable

Ms. Fatemeh Moghadasi by email to the following address: fatemehmoghadasi03@gmail.com

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

6 months after the results are published, the applicant can contact the person in charge of the project, Ms. Fatemeh Moghadasi, at the following email address. fatemehmoghadasi03@gmail.com And between 7 - 10 days later, the documents and data files will reach them.

Comments