# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effectiveness of a nursing program for non-pharmacological management of fatigue on the quality of life and fatigue level in patients with cancer undergoing chemotherapy

## Protocol summary


**Study aim**
To determine the effectiveness of non-pharmacological nursing interventions for fatigue management on fatigue severity and quality of life among cancer patients undergoing chemotherapy.

**Design**
A randomized controlled, two-arm parallel-group trial will be conducted among 108 patients with individual 1:1 allocation. Permuted block randomization with variable block sizes will be performed using SPSS, with allocation concealed by opaque, sealed envelopes.

**Settings and conduct**
The study will be conducted in oncology departments of hospitals affiliated with Shahid Beheshti University of Medical Sciences in 2026. After screening and informed consent, patients will be randomly allocated to two groups and the intervention will be delivered according to the study protocol.

**Participants/Inclusion and exclusion criteria**
Cancer patients receiving chemotherapy, with cancer- or chemotherapy-related fatigue and adequate communication, physical, and cognitive status, will be included. Patients with severe cognitive or consciousness impairment, acute or unstable illness, severe physical limitation, or concurrent similar fatigue-management programs will be excluded.

**Intervention groups**
The intervention group will receive non-pharmacological nursing interventions according to the study protocol. The control group will receive routine care.

**Main outcome variables**
1. Fatigue severity: 2. Quality of life:


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20260802070488N2**
Registration date: **2026-10-03, 1405/07/11**
Registration timing: **prospective**

Last update: **2026-10-03, 1405/07/11**
Update count: **0**

**Registration date**
2026-10-03, 1405/07/11


**Registrant information**
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**Recruitment status**
**Not yet recruiting**

**Funding source**

**Expected recruitment start date**
2026-11-11, 1405/08/20

**Expected recruitment end date**
2027-04-09, 1406/01/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effectiveness of a nursing program for non-pharmacological management of fatigue on the quality of

life and fatigue level in patients with cancer undergoing chemotherapy

**Public title**

Investigating the Effects of Non-Pharmacological Nursing Interventions on Fatigue and Quality of Life in Cancer Patients Undergoing Chemotherapy

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

1. Having a confirmed diagnosis of cancer documented in the medical record and established by the treating physician 2. Currently receiving chemotherapy at the time of enrollment 3. Experiencing fatigue related to cancer or chemotherapy, as determined by an initial assessment using a standardized fatigue assessment instrument 4. Being able to understand the study instructions and communicate effectively with the researcher 5. Having adequate physical and cognitive capacity to participate in the interventions planned in the study 6. Willingness to participate in the study and provision of written informed consent. 7. Having no medical contraindication to participation in the non-pharmacological interventions under investigation, based on assessment by the treating physician and/or research team.

**Exclusion criteria:**

1. Cognitive impairment, altered level of consciousness, or severe communication difficulties that prevent understanding the study questions, receiving the educational content, or participating effectively in the intervention 2. An acute or unstable medical condition that makes participation in the non-pharmacological intervention medically inappropriate or unsafe 3. Severe physical limitations that prevent participation in the planned intervention 4. Concurrent participation in another structured program similar to the study intervention for fatigue management outside the study 5. Any medical or treatment-related condition that, in the opinion of the treating physician or researcher, makes participation in the study inappropriate or unsafe 6. Unwillingness to provide written informed consent or withdrawal of willingness to participate before randomization.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After confirmation of all eligibility criteria, absence of exclusion criteria, and obtaining written informed consent, eligible participants will be individually allocated to the intervention and control groups in a 1:1 ratio. A permuted block randomization method with variable block sizes will be used. Block sizes of 4 and 6 will be used to reduce the predictability of the allocation sequence. Within each block, the number of allocations to the intervention and control groups will be equal. The random allocation sequence will be generated using SPSS statistical software by an individual who is independent of participant screening, recruitment, baseline assessment, and intervention delivery. Eligible participants will be assigned sequential identification numbers according to their order of enrollment, and each participant will be allocated to either the intervention or control group according to the pre-generated randomization sequence. The individual participant will be the unit of randomization, and cluster randomization will not be used. Stratified randomization will not be applied. To ensure allocation concealment, the allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes. The envelopes will be prepared before participant recruitment by an individual independent of participant screening, recruitment, and intervention delivery. After final confirmation of eligibility and obtaining written informed consent, the envelope corresponding to the participant's identification number will be opened and the assigned group will be revealed. The envelopes will be securely stored with restricted access until allocation. The researcher responsible for screening and recruitment will remain unaware of the participant's upcoming group assignment until allocation. No quasi-random allocation method, including allocation according to the day of attendance, date of birth, medical record number, odd/even numbers, or any other predictable procedure, will be used.

**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 the Schools of Pharmacy and Nursing & Midwifery, Shahid Beheshti University of M

**Street address**

Ethics Committee of the Schools of Pharmacy and Nursing & Midwifery, Shahid Beheshti University of Medical Sciences Valiasr Street, intersection with Niayesh, opposite Shahid Rajaei Heart Hospital, School of Nursing & Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran Postal Code: 1996835119

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**Postal code**
1996835119
**Approval date**
2026-07-20, 1405/04/29
**Ethics committee reference number**
IR.SBMU.PHARMACY.REC.1405.120

## Health conditions studied

### 1

**Description of health condition studied**
cancer
**ICD-10 code**
R53.0
**ICD-10 code description**
Neoplastic (malignant) related fatigue

## Primary outcomes

### 1

**Description**
Outcomes: Fatigue Severity
**Timepoint**
Study outcomes will be assessed at three time points: baseline (before the intervention), at the end of Week 4 (immediately after completion of the intervention), and one month after the end of the intervention (follow-up). At all three time points, cancer-related fatigue will be assessed in both the intervention and control groups using the same standardized instruments.
**Method of measurement**
Fatigue Severity Fatigue severity will be assessed using the Fatigue Severity Scale (FSS) . The FSS was developed by Krupp et al. in 1989 and consists of nine items assessing the impact of fatigue on daily activities and functional performance. Each item is rated on a seven-point Likert scale ranging from 1 (“strongly disagree”) to 7 (“strongly agree”). The total score ranges from 9 to 63. The mean FSS score will be calculated by dividing the total score by the number of items. Higher scores indicate greater fatigue severity and a greater impact of fatigue on daily functioning. According to the criteria adopted in this study, a mean score below 4 will indicate mild fatigue, a mean score of 4 or higher will indicate clinically significant fatigue, and a mean score of 5 or higher will indicate severe fatigue. Both instruments will be administered to participants in the intervention and control groups at three assessment time points: baseline (before initiation of the intervention), at the end of Week 4, and one month after completion of the intervention . Changes in fatigue severity and quality-of-life scores over time and between the two groups will be compared.

## Secondary outcomes

### 1

**Description**
Quality of life
**Timepoint**
Study outcomes will be assessed at three time points: baseline (before the intervention), at the end of Week 4 (immediately after completion of the intervention), and one month after the end of the intervention (follow-up). At all three time points, quality of life will be assessed in both the intervention and control groups using the same standardized instruments.
**Method of measurement**
Quality of life will be assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) . The questionnaire consists of 30 items covering five functional scales (physical, role, emotional, cognitive, and social functioning), three multi-item symptom scales (fatigue, nausea and vomiting, and pain), six single-item symptom measures (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties), and two items assessing global health status and overall quality of life. Items 1–28 are rated on a four-point response scale, while items 29 and 30 are rated on a seven-point scale. Scores will be transformed to a 0–100 scale according to the EORTC scoring guidelines. Higher scores on the functional and global health status/quality-of-life scales indicate better functioning and quality of life, whereas higher scores on the symptom scales indicate greater symptom severity and poorer health status. Quality of life will be assessed at three time points in both groups: baseline, at the end of Week 4, and one month after completion of the intervention. Changes in quality-of-life scores over time and between the intervention and control groups will be compared.

## Intervention groups

### 1

**Description**
Intervention Group The intervention was developed based on an evidence-based nursing protocol and will be delivered by a trained nurse (student researcher). The intervention consists of two components as follows: 1. Face-to-Face Education Following completion of the baseline assessment and before the start of chemotherapy or during one of the scheduled chemotherapy sessions, participants in the intervention group will receive a 30–45-minute individual, face-to-face educational session . The session will be conducted in a quiet and appropriate setting within the hospital chemotherapy unit. The educational content will be developed based on the latest scientific evidence and established guidelines for the management of cancer-related fatigue and will include the following:* **Understanding cancer-related fatigue , including its definition, causes, and factors that may exacerbate fatigue. Energy conservation and fatigue-management strategies , including prioritizing activities, daily planning, balancing activity and rest, delegating non-essential activities, and using simple strategies to

facilitate daily activities. Safe and individualized physical activity appropriate to the patient's condition, including light aerobic exercise (e.g., walking) and stretching exercises, while observing appropriate safety precautions, intensity, and duration. Relaxation and stress-management techniques , including deep breathing, progressive muscle relaxation, and simple mindfulness-based recommendations to reduce psychological tension. **Nutritional recommendations** appropriate for patients undergoing chemotherapy, including adequate energy and protein intake, sufficient fluid consumption, small and frequent meals, and dietary strategies to help reduce fatigue. At the end of the session, sufficient time will be provided for participants to ask questions. Each participant will also receive a standardized educational booklet containing a summary of the educational content, practical recommendations, and a suggested daily self-care plan. 2. Remote Follow-up and Support To reinforce learning, promote adherence to the intervention, and address potential difficulties, participants will receive four weeks of remote follow-up . Follow-up will be conducted **once weekly (four sessions in total) via telephone call or online session, according to the participant's preferred method of communication. Each follow-up session will last approximately 10–15 minutes .During each follow-up session, the following aspects will be assessed and documented: The participant's adherence to the educational recommendations; The level of physical activity and adherence to energy-conservation strategies; The implementation of relaxation techniques and adherence to nutritional recommendations; The severity of fatigue and any difficulties or barriers encountered in implementing the program; Participants' questions and provision of appropriate guidance; Reinforcement of motivation to continue the intervention and adjustment of recommendations according to the participant's individual condition, needs, and limitations, without changing the core components of the intervention. If a participant does not answer the follow-up call, up to two additional attempts will be made at different times on the same day or the following day. If contact cannot be established after these attempts, the reason for unsuccessful contact will be documented.

**Category**

Rehabilitation

**2**

**Description**

Control group: During the study period, participants in the control group will receive only the usual care provided by the hospital, including routine medical follow-up and standard clinical care. They will not receive any structured education on non-pharmacological fatigue management or additional educational follow-up related to fatigue management during the study period. After completion of the study, and in accordance with ethical considerations, the educational content of the multicomponent nursing program for non-pharmacological fatigue management will be made available to participants in the control group.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Shohada-e Tajrish Hospital، Imam Hossein Hospital، Taleghani Hospital

**Full name of responsible person**

soolmaz moosavi

**Street address**

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Valiasr Street, at the intersection with Niayesh Street, opposite Shahid Rajaei Heart Hospital, Tehran, Iran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Vice-Chancellor for Research and Technology

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**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**

soolmaz moosavi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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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**

No. Individual participant data, even in de-identified form, will not be publicly shared after completion of the study. The study data will be used solely for research purposes, statistical analysis, and reporting of the study findings, while maintaining the confidentiality and privacy of the participants.

**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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable