Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of group motivational interviewing method versus feedback-oriented training method on fatigue and self-efficacy of patients with cancer undergoing chemotherapy: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of group motivational interviewing method versus feedback-oriented training method on fatigue and self-efficacy of patients with cancer undergoing chemotherapy

Design
This is a randomized clinical trial with control group, phase III, in which 96 eligible patients with cancer undergoing chemotherapy will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Beheshti Hospital in Hamadan city on 96 eligible patients with cancer undergoing chemotherapy. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years Having a cancer undergoing chemotherapy Persian language Ability to make phone calls Information about his/her illness Receiving at least three chemotherapy courses Exclusion criteria: Impaired consciousness or dementia Mental disorder Severe anemia Malnutrition

Intervention groups
Intervention group 1: Routine treatment plus a motivational interview for 45 to 60 minutes once a week for 5 weeks (including teaching and practicing the stages of change, brainstorming about the strengths and weaknesses of behavior and its relationship with fatigue and self-efficacy reduction, identifying and prioritizing values, providing recommendations to improve fatigue) Intervention group 2: Routine treatment plus feedback-oriented training for 45 to 60 minutes once a week for 5 weeks (including explanations about cancer and its common treatments, explaining the side effects of drugs, the effect of fatigue on life, improving nutritional status, improving sleep quality) Control group: Just routine treatment

Main outcome variables
Primary outcome: Fatigue; self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N463**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **prospective**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date
2023-02-20, 1401/12/01

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date
2023-05-20, 1402/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of group motivational interviewing method versus feedback-oriented training method on fatigue and self-efficacy of patients with cancer undergoing chemotherapy: a randomized clinical trial

Public title
Effect of group motivational interviewing method versus feedback-oriented training method on fatigue and self-efficacy of patients with cancer undergoing chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 years Having a cancer undergoing chemotherapy Persian language Ability to make phone calls Information about his/her illness Receiving at least three chemotherapy courses
Exclusion criteria:
Impaired consciousness or dementia Mental disorder Severe anemia Malnutrition
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2023-02-05, 1401/11/16
Ethics committee reference number
IR.UMSHA.REC.1401.981

Health conditions studied

1

Description of health condition studied
Fatigue
ICD-10 code
R53.82
ICD-10 code description
Chronic fatigue, unspecified

Primary outcomes

1

Description
Fatigue
Timepoint
Before the intervention and 4 and 6 weeks later
Method of measurement
Using the Cancer Fatigue Scale (CFS)

2

Description
Self-efficacy
Timepoint
Before the intervention and 4 and 6 weeks later
Method of measurement
Using Chronic Disease Self-Efficacy Scale (CDSES)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1:Routine treatment plus a motivational interview for 45 to 60 minutes once a week for 5 weeks (including teaching and practicing the stages of change, brainstorming about the strengths and weaknesses of behavior and its relationship with fatigue and self-efficacy reduction, identifying and prioritizing values, providing recommendations to improve fatigue)
Category
Treatment - Other

2

Description
Intervention group 2:Routine treatment plus feedback-oriented training for 45 to 60 minutes once a week for 5 weeks (including explanations about cancer and its common treatments, explaining the side effects of drugs and specifically the complication of fatigue, the effect of fatigue on life, improving nutritional status, improving sleep quality, managing energy reserves)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan
Full name of responsible person
Zahra Rahmani Ini Olia
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Beheshti Hospital, Eram Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Rahmani Ini Olia
Position
Nursing Student
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Position
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Nursery

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Person responsible for updating data

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Professor of Epidemiology

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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