

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 (CDESES)

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

Street address

Beheshti Hospital, Eram Ave.

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6517838695

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+98 81 3838 0283

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zahra.rahmani.iniolia@gmail.com

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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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Morteza Shamsizadeh

Position

Master of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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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