

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of individual and group self-care education on quality of life in patients undergoing chemotherapy: A randomized clinical trial

#### Protocol summary

##### Summary

Educating Patients suffering from cancer about their disease and treatment is a vital component of their nursing care. Management of treatment side effects and maintaining the quality of life could be achievable only by adequate and organized self-care education. With regards to the importance of the concept of cost-effectiveness in health care providing system, this study is going to assess the effects of patient education on the quality of life in patients receiving chemotherapy and also to compare these effects between individual patient education and group education methods. Methods: one hundred two patients with breast, esophagus and stomach cancer referred to Chemotherapy Unit in Omid hospital were randomly allocated to two groups: Group teaching and Individual teaching methods. Fifty-one received three individual teaching sessions. Three group teaching sessions were conducted for the other fifty one patients. All subjects were interviewed by the same interviewer three times (before the first chemotherapy, second and third session) using EORTC QLQ-C30 quality-of-life questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201011305282N1**

Registration date: **2010-12-28, 1389/10/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-12-28, 1389/10/07

##### Registrant information

Name

Fatemeh Heshmati

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1842 6083

##### Email address

heshmati\_nabavi@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2006-06-22, 1385/04/01

##### Expected recruitment end date

2007-10-23, 1386/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of individual and group self-care education on quality of life in patients undergoing chemotherapy: A randomized clinical trial

##### Public title

The effect of individual and group self-care education on quality of life in patients undergoing chemotherapy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with breast or gastric cancer aged 18-50. Exclusion criteria: other cancer treatment before 3 month ago, metastases.

##### Age

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Mashhad University of Medical Sciences

**Street address**

Central building of Mashhad University of Medical Sciences, Daneshgaah street

**City**

Mashhad

**Postal code****Approval date**

2006-04-07, 1385/01/18

**Ethics committee reference number**

85018

**Health conditions studied****1****Description of health condition studied**

Breast and Gastric cancer

**ICD-10 code**

C00-D48

**ICD-10 code description**

Neoplasms

**Primary outcomes****1****Description**

Quality of Life

**Timepoint**

each month

**Method of measurement**

questionnaire

**Secondary outcomes****1****Description**

Coping

**Timepoint**

each month

**Method of measurement**

questionnaire

**Intervention groups****1****Description**

Individual self-care education

**Category**

Lifestyle

**2****Description**

Group self-care education

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Omid Hospital

**Full name of responsible person**

Dr Fateme Heshmati Nabavi

**Street address**

Omid hospital, Alandasht squer, Koohsangi Street

**City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Reza GHavam Nasiri

**Street address**

Omid Hospital, Koohsangi Street

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Ghavam Nasiri

**Position**

Associate Professor, Oncologist-Radiotherapist

**Other areas of specialty/work****Street address**

Alandasht Squer, Koohsangi Street

**City**

Mashhad

**Postal code****Phone**

+98 51 1842 6083

**Fax****Email**

ghavamnasirimr@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Heshmati Nabavi

**Position**

PhD in Nursing

**Other areas of specialty/work****Street address**

Faculty of Nursing, Daneshgaah Street, Ebn Sina Street

**City**

Mashhad

**Postal code****Phone**

+98 51 1859 1511

**Fax****Email**

heshmati.nabavi@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Heshmati Nabavi

**Position**

PhD in Nursing

**Other areas of specialty/work****Street address**

Faculty of Nursing, Daneshgaah Street, Ebn Sina Street

**City**

Mashhad

**Postal code****Phone****Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*