

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intervention Self-Management Model 5 A's on severity fatigue and depression of cancer patients undergoing chemotherapy.

Protocol summary

Summary

The purpose behind this study is to determine the effects of Self-Management on fatigue and depression in cancer patients undergoing chemotherapy. The study is a clinical trial in two groups of Intervention and Control. Self-Management 5 A's program includes 5 steps: Assess, Advise, Agree, Assist, Arrange. Intervention group is 5 sessions for each session to be between 60 to 90 minutes in 12 weeks. And Control group enjoys only the usual cares. The main criteria for inclusion in the study include having the age of 18 to 70, being on the list of chemotherapy patients, and lack of known depression disorder. The main criteria for exclusion from the study are Lack of desire for continuing, and having depression score over 28 using Beck Questionnaire. Therefore, the total sample size in this study is 60 samples from which 30 patients are in Intervention group and 30 patients in Control group. Before the beginning of intervention, the questionnaire will be given to the samples. Then, at end of in the Intervention group, a quiz is taken from the samples and they are asked to complete Beck Depression Questionnaire and MFI Questionnaire;

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080829266N1**

Registration date: **2016-08-30, 1395/06/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-30, 1395/06/09

Registrant information

Name

Marjan Rozitalab

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7251

Email address

daman_nurses@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2016-08-31, 1395/06/10

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intervention Self-Management Model 5 A's on severity fatigue and depression of cancer patients undergoing chemotherapy.

Public title

Effect of Self-Management on cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent for collaboration
Having the age of 18 to 70
Being on the list of chemotherapy patients
Having a minimum degree of literacy – Having acceptable listening and speaking

abilities Lack of known depression disorder Exclusion criteria: Lack of desire for continuing Provided during the research for a new effective drug; new drugs be added to patients' medications, Depression score over 28: , using Beck Questionnaire Presence of acute complications arising from chemotherapy during the research Death of the patient depression score between13-28 :fatigue score between 20-100. Exclusion criteria included: lack of patient motivation to continue intervention : exacerbations leading to hospitalizations cancer patients in the hospital for the duration of the intervention:migration and death.

Age

From **18 years** old to **70 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

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

Yasuj University of Medical Sciences

Street address

Nursing and Midwifery College, Shahid Dr. Jalil St.,

Yasuj

City

Yasuj

Postal code

7591994799

Approval date

2016-07-23, 1395/05/02

Ethics committee reference number

IR.YUMS.REC.1395-85

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

c76.c80

ICD-10 code description

Malignant neoplasms of ill-defined, secondary and unspecified sites

Primary outcomes

1

Description

Fatigue

Timepoint

Early intervention and immediately after the intervention.

Method of measurement

Multidimensional Fatigue Inventory

Secondary outcomes

1

Description

Depression

Timepoint

Early intervention and immediately after the intervention.

Method of measurement

Beck Depression Inventory

Intervention groups

1

Description

The control group received only routine care and not done any intervention by the researcher .

Category

Other

2

Description

The patients in self-management training , in time proportional with the convenience and patient request and in coordination with him, in 4 sessions self-management training, now taken 60-90 minutes.The training by the researcher ,2 sessions for face to face and 2 sessions for group training with a question and answer booklets will be The training by the researcher, for face to face training with a question and answer booklets with educational content include defining self-management , causes of disease, risk factors, symptoms, cancer self-management behaviors such as adherence diet, proper exercise, medication adherence, side effects will be teaching.researcher followed this group in 12 weeks with telephon and face to face weekly .Call time up to 15 minutes between the hours of 8 am to 8 pm and

time to be determined in agreement with the patient. If you have questions or problems can be patient for 24 hours in contact with the researcher. In this type of track on a weekly basis about the patient's health status and health behaviors strengthen asked to adhere to treatment regimens and the need for referral is examined. on your daily monitoring available to researchers and the feedback he has received.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Motahhari clinic

Full name of responsible person

Nazafarin Hosini

Street address

Shiraz-NamaziSquare-Shiraz Motahhari clinic

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yasuj University of Medical Sciences

Full name of responsible person

Doctor Mehdi Akbartabar turi

Street address

Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd.

City

Yasuj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Nazafarin Hosini

Position

Community Health Nursing PhD - Associate Professor

Other areas of specialty/work

Street address

Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj

City

Yasuj

Postal code

7433235141

Phone

+98 74 3323 5141

Fax

Email

hosseinichenar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Science

Full name of responsible person

Nazafarin Hosini

Position

Community Health Nursing PhD - Associate Professor

Other areas of specialty/work

Street address

Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj

City

Yasuj

Postal code

7591994799

Phone

+98 74 3323 5141

Fax

Email

hosseinichenar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yasuj University of Medical Science

Full name of responsible person

Marjan Rozitalab

Position

MS student of Community Health Nursing

Other areas of specialty/work

Street address

Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj

City

Yasuj

Postal code

7591994799

Phone

+98 71 3839 2629

Fax**Email**

daman_nurses@sums.ac.ir

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