

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluate the effect of training based on PRECEDE Model, on the control of chemotherapy side effects , in patients with cancer.

Protocol summary

Summary

This study was done to determine the effect of education on PRECEDE(PREDISPOSING, REINFORCING, ENABLING CONSTRUCTS IN EDUCATIONAL DIAGNOSIS AND EVALUATION) Model on chemotherapy side effects in patients with cancer under chemotherapy. This study is experimental, pre test-post test in control group and was done with selection and participation of 50 patients with cancer under chemotherapy referred to Aja hospitals in two groups (each group, n =25). After the samples were divided into two groups randomly, using the questionnaires based on PRECEDE Model and the Checklist questionnaire are determined the severity of chemotherapy side effects in patients Before the intervention in the experimental and control groups. Then comprehensive program of training was conducted based on Precede Model face-to-face and individually and According to the recognized needs of patients in the experimental group during two cycles of chemotherapy. Again the questionnaires based on Precede Model and Checklist questionnaire were completed the severity of chemotherapy side effects by experimental and control groups. The obtained data before and after the implementation of the program were analyzed in the experimental and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100530163N1**

Registration date: **2017-01-02, 1395/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-02, 1395/10/13

Registrant information

Name

Jalal Torkashvand

Name of organization / entity

AJA University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 217765400

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Medical Science
University Of AJA

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effect of training based on PRECEDE Model, on the control of chemotherapy side effects , in patients with cancer.

Public title

The Effect of training based on managing the chemotherapy side effects

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:: patients should be older than 18 years; able to communicate verbally with the researcher

and have received a chemotherapy session and aren't with other chronic diseases and they have the minimum literacy and also receiving the chemotherapy drugs as outpatient or inpatient in the oncology wards. Exclusion criteria: unwillingness of patient to continue training and consulting sessions and are also required to use other treatments such as radiotherapy, photodynamic therapy, hyperthermia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Ethics committee of Aja University of Medical Sciences

Street address

Etemadzadeh Street

City

Tehran

Postal code

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

ir.ajaums.rec.1395.09

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description

chemotherapy side effects

Timepoint

Before and one month after the intervention

Method of measurement

the questionnaires developed by researchers based on Precede Model and checklist questionnaire of symptoms related to chemotherapy

Secondary outcomes

1

Description

Needs assessment based on the predisposing factors, enabling factors, reinforcing factors of chemotherapy side effects

Timepoint

Before the intervention, 1 month after the intervention

Method of measurement

The needs assessment questionnaire based on structures of Precede Model

Intervention groups

1

Description

Intervention group: Training sessions will be based on the patient's needs, held for the intervention group according to the result of self-made questionnaire. in order to change knowledge, attitude and self-efficacy is used the different training methods such as short lectures, face-to-face and individually, questions and answers

Category

Behavior

2

Description

Control group: no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Aja hospital 501

Full name of responsible person

Jalal Torkashvand, Master of science nursing student

Street address

Faculty of Nursing, Kaj St, Shariati St.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of AJA University of Medical Sciences

Full name of responsible person

Dr. Kamran Azma

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AJA University of Medical Sciences, Etemadzadeh St., Fatemi St

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Tehran

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 of AJA 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

AJA University of Medical Sciences

Full name of responsible person

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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