

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

#### Email address

torkashvandgalal@gmail.com

### 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**

Tehran

## 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

**Street address**

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

**City**

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**

Fahimeh Dadgari

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Master of Science in Nursing

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## inquiries

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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*