

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Education based on Pender Health Promotion Model on Self-Efficacy and Quality of Life in Patients with leukemia referred to Shiraz medical sciences clinic 2018

Protocol summary

Study aim

Determining the effect of educational intervention based on the Pender Health Promotion Model on self-efficacy and quality of life in patients with leukemia who referred to the clinics of Shiraz University of Medical Sciences in 2018

Design

A clinical trial with a control group, with a parallel group, blind, randomized assignment, a total of 60 qualified candidates entered the study, in which the target population, patients with a history of cancer, aged 18 years and older, between November 2018 and January 2018

Settings and conduct

The study site is an Amir hospital located in the Farhangshahr. The educational program is conducted in four sessions by the researcher and lectures on providing a booklet on leukemia and methods for increasing self-efficacy and quality of life in patients with leukemia based on the components of the Health Promotion Model. The questionnaires will be provided to the samples of both intervention and control groups after the last training session and one month later.

Participants/Inclusion and exclusion criteria

Adult patients (18 years and older) who have leukemia. Entry Requirements: o Adult patients (18 years and older) who have leukemia. o tend to participate in the study. o Six months from the definitive diagnosis of the disease. Exit terms: o Have a history of attending classes on self-efficacy and quality of life. o Classes have more than one absentee session. o Patients discontinue the study.

Intervention groups

The training is based on the health promotion model and its impact on the self-efficacy and quality of life of patients with leukemia referred to clinics affiliated to Shiraz University of Medical Sciences is reviewed. Then,

the pamphlet control group and educational pamphlets are given.

Main outcome variables

Quality of life and self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121208011691N7**

Registration date: **2018-12-15, 1397/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-15, 1397/09/24**

Update count: **0**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

Fariba Ghodsbin Jahromi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4250

Email address

ghodsbin@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-21, 1397/07/29

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Education based on Pender Health Promotion Model on Self-Efficacy and Quality of Life in Patients with leukemia referred to Shiraz medical sciences clinic 2018

Public title

The Effect of Education based on Pender Health Promotion Model on Self-Efficacy and Quality of Life in Patients with leukemia

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients (18 years and older) who have leukemia tend to participate in the study Six months from the definitive diagnosis of the disease.

Exclusion criteria:

Have a history of attending classes on self-efficacy and quality of life. Classes have more than one absentee session. Patients discontinue the study.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to group the samples according to simple random assignment method, 2 cards (A, B) are assigned to each test and control group. Patients, without knowing each group card, can choose one of their two cards And then enter one of the test or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Questionnaires will be collected by a researcher who does not know which intervention group and which one is a controller. Data analysis will be done by the statistics professor who is unfamiliar with both control and intervention groups until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-10-01, 1397/07/09

Ethics committee reference number

IR.SUMS.REC.1397.647

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

leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukaemia

2**Description of health condition studied**

leukemia

ICD-10 code

C90

ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

3**Description of health condition studied**

leukemia

ICD-10 code

C92

ICD-10 code description

Myeloid leukaemia

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

Quality of life and self-efficacy

Timepoint

Immediately and a month later

Method of measurement

Quality of life questionnaire and self-efficacy

Secondary outcomes

1

Description

Knowledge

Timepoint

Immediately and 1 months later

Method of measurement

Pender Model Questionnaire

Intervention groups

1

Description

"Intervention group": The intervention group participates in 4 sessions of 2 hours (weekly one session), which is provided by the researcher in lecture, question and answer, and providing a booklet on leukemia and ways to increase self-efficacy and quality of life. In patients with leukemia, it is based on components of the Pender Health Promotion Model. The contents of each training session will be given to the intervention group on the same day and the lesson will be briefed at the beginning of the class. The questionnaires will be provided to the intervention group after the completion of the last training session. One month later, the questionnaires are again filled in to evaluate the educational longevity.

Category

Lifestyle

2

Description

"Control group": The questionnaires will be provided to the control group before the intervention and immediately after the end of the intervention as well as one month after the end of the intervention. In order to observe ethical points after the end of the intervention, the content of the training will be provided to the control group as a training manual.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Oncology Hospital

Full name of responsible person

Seyed Omid Reza Zakavat

Street address

Farhang shahr-Amir Oncology Hospital

City

Shiraz

Province

Fars

Postal code

7187915998

Phone

+98 71 3632 3732

Fax

+98 71 3632 5655

Email

amirhosp@sums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Unes Ghasemi

Street address

Zand street, Central Building of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 0050

Fax

+98 71 3233 6853

Email

www@sums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fariba Ghodsbin

Position

PhD / faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shiraz, Zand Avenue, Namazi Square, Faculty of Nursing and Midwifery, Hazrat Fatemeh (S)

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3647 4254

Fax

+98 71 3647 4252

Email

ghodsbin@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Fariba Ghodsbin

Position

PhD / faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shiraz, Zand street, Namazi Square, Faculty of Nursing and Midwifery, Hazrat Fatemeh (S)

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3647 4254

Fax

+98 71 3647 4252

Email

ghodsbin@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Zeydani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shiraz, Zand street, Namazi Square, Faculty of Nursing and Midwifery, Hazrat Fatemeh (S)

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3647 4254

Fax

+98 71 3647 4252

Email

maryamzeydani2000@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available