

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of a Partnership Care Model on Quality of Life and Anxiety in Patients with Hematological Cancer.

Protocol summary

Study aim

The main goal : Determination the effect of a Partnership Care Model on Quality of Life and Anxiety in Patients with Hematological Cancer. Sub-goals: 1) Comparison of Quality of Life and its different domains in Patients with Leukemia in the "intervention" group before and after intervention. 2) Comparison of Quality of Life and its different domains in Patients with Leukemia in the "control" group before and after intervention. 3-4) Comparison of Quality of Life and its different domains in Patients with leukemia; Between the Intervention and Control groups before and after intervention. 5) Comparison of anxiety in Patients with Leukemia in the intervention group before and after intervention. 6) Comparison of anxiety in Patients with Leukemia in the control group before and after the intervention. 7-8) Comparison of anxiety in Patients with Leukemia in between intervention and control group before and after intervention.

Design

Clinical trial with control group ;paralleled, unblinking, randomized groups with a sample size of 60 persons.

Settings and conduct

Intervention in Oncology Ward of Firouzgar and Rasoul Hospitals of Tehran was carried out. With coin throwing and randomly, the Oncology Ward of the Firouzgar Hospital was investigated an intervention group and Oncology Ward of Rasoul Hospital was investigated as a control group.

Participants/Inclusion and exclusion criteria

The population of the study included all Adults patients with Leukemia admitted in the oncology departments of Rasoul-e-Akhram and Firoozghar hospitals affiliated to Iran University of Medical Sciences.

Intervention groups

Intervention group: Patients in the Oncology ward of the Firouzgar Hospital, and the intervention method is a Participatory Care Model. Control group: Patients in the Oncology ward of Hazrat Rasoul Hospital.

Main outcome variables

Quality of life; Anxiety

General information

Reason for update

Acronym

PQAH

IRCT registration information

IRCT registration number: **IRCT20181019041381N1**

Registration date: **2018-12-06, 1397/09/15**

Registration timing: **retrospective**

Last update: **2018-12-06, 1397/09/15**

Update count: **0**

Registration date

2018-12-06, 1397/09/15

Registrant information

Name

shaqayeq sediq

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5502 1516

Email address

sediq92m@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2018-02-21, 1396/12/02

Actual recruitment end date

2018-03-19, 1396/12/28
Trial completion date
 2018-07-23, 1397/05/01

Scientific title
 The effect of a Partnership Care Model on Quality of Life and Anxiety in Patients with Hematological Cancer.

Public title
 The effect of a Partnership Care Model on Quality of Life and Anxiety in Patients with Hematological Cancer.

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of hematological cancer in a patient's medical records by a doctor Ability of communication Ability of seeing and listening Ability to reading and writing Ability to come back to hospital after Intervention Do Not having a known psychological disorder The presence of a family member of the patient in all participatory-educational sessions
Exclusion criteria:
 Patient's death Failure of the client or his family to attend to even 1 section of intervention Another illness that leads to hospitalization. Cases of malignant diseases and other chronic diseases after entering the study.

Age
 From **18 years** old to **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**
 Actual sample size reached: **55**

Randomization (investigator's opinion)
 Randomized

Randomization description
 With the coin throwing method between Rasoul Akram Hospital and Tehran Firouzgar Hospital ; A hospital was selected as the control hospital and the other as an intervention hospital.

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 Iran University of Medical Sciences

Street address

Nursing and Midwifery Faculty of Iran University of Medical Science ,Rashid Yasemi Alley,Valiasr St.

City

Tehran

Province

Tehran

Postal code

1883973843

Approval date

2018-01-22, 1396/11/02

Ethics committee reference number

.ir.iuums.fmdrec.1396.9411686008

Health conditions studied

1

Description of health condition studied

Hematological Cancer

ICD-10 code

C95.9

ICD-10 code description

Leukemia, unspecified

Primary outcomes

1

Description

Measurement of Quality of Life in patients with "Quality of Life questionnaire in Patients with cancer" or in brief QLQ-C30 and Measurement of Anxiety in patients with "Beck Anxiety Inventory Questionnaire".

Timepoint

Measurement of quality of life and anxiety in patients before intervention and one and three months after intervention.

Method of measurement

Cancer Quality of Life Questionnaire and Beck Anxiety Inventory questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 30 patients were randomly selected and a Partnership Care Model was performed on them. Then, The Quality of life of cancer patients questionnaire and Beck anxiety inventory questionnaire were filled before intervention and one and

three months after the intervention by patients.

Category

Lifestyle

2**Description**

Control group: 30 Patients were randomly selected in this group. Then, the Quality of life of patients with cancer and Beck anxiety inventory questionnaires were completed before and one and three months later by patients.

Category

Lifestyle

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

Firuzgar hospital

Full name of responsible person

Shaqayeq sediq

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1593747811

Phone

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sediq92m@yahoo.com

2**Recruitment center****Name of recruitment center**

Hazrat Rasool hospital

Full name of responsible person

Sedq Shaghayegh

Street address

Rasul-e-akram Hospital , Mansuri St , Satarkhan St

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

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Full name of responsible person

Alice khachian

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1996713883

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

shaqayeq sediq

Position

Master student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shaqayeq Sediq

Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data is available in the Library of the Faculty of Nursing, in Iran University of Medical Sciences after completion of the dissertation.

When the data will become available and for how long

Data is always available in the Library of the Faculty of Nursing, in Iran University of Medical Sciences after completion of the dissertation.

To whom data/document is available

Data is always available to the public in the Library of the Faculty of Nursing, in Iran University of Medical Sciences after completion of the dissertation.

Under which criteria data/document could be used

Data is always available in the Library of the Faculty of Nursing, in Iran University of Medical Sciences after completion of the dissertation. It is possible to use by mention the source of the data.

From where data/document is obtainable

Data is always available in the Library of the Faculty of Nursing, in Iran University of Medical Sciences after completion of the dissertation.

What processes are involved for a request to access data/document

Data is always available in the Library of the Faculty of Nursing, in Iran University of Medical Sciences after completion of the dissertation.

Comments