Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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.iums.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

Street address

Firuzgar hospital, Behafarin St, Valiasr Sq

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1600

Email

sediq92m@yahoo.com

2

Recruitment center

Name of recruitment center

Hazrat Rasool hospital

Full name of responsible person

Sediq Shaghayegh

Street address

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

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

sediq92m@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Alice khachian

Street address

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

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1000

Email

sediq92m@yahoo.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1883973843

Phone

+98 21 4365 1000

Email

sediq92m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Shaqayeq Sediq

Position
Mater Student

Latest degree
Master

Other areas of specialty/work
Nursery

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

City
Tehran

Province
Tehran

Postal code
1883973843

Phone
+98 21 4365 1000

Email
sediq92m@yahoo.com

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
1883973843

Phone
+98 21 4365 1000

Email
sediq92m@yahoo.com

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