

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of implementing care program on quality of life and uncertainty of adolescents with cancer aged 15-20 years of old

Protocol summary

Summary

The aim of current study is to determine the effect of implementing a care program on quality of life and uncertainty of adolescents with cancer in Isfahan city and is a kind of clinical trials with random allocation in two groups (experiment and control) and before-after test. Inclusion criteria are age between 15-20, cancer diagnosis, and exclusion criteria are unwillingness to participation and obvious psychological disorder. Sample size is 60 (30 in experiment group and 30 in control group). In this study designed program based on adolescents need include self-care education, psychological consult and nutrition consult will implement for one month in experiment group and its effect will be assessed on quality of life and uncertainty. Control group will receive routine care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053128185N1**

Registration date: **2016-07-01, 1395/04/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Parastoo Oujian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3773 3771

Email address

p_oujian@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Current study is funded by Isfahan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing care program on quality of life and uncertainty of adolescents with cancer aged 15-20 years of old

Public title

The effect of implementing care program on adolescent with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: adolescents with cancer age between 15-20 years of old; at least one time hospitalized for diagnostic and treatment procedures in Seid-o-Shohada center Exclusion criteria: unwillingness to participate in any time and for any reason; confirmed psychological disorder by physician; failure to complete questionnaire

Age

From **1 year** old to **96 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Isfahan University Of Medical Sciences

Street address

Isfahan University Of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

8174643446

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

393502

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C80.9

ICD-10 code description

Malignant neoplasm, unspecified

Primary outcomes

1

Description

EORTC QLQ-C30-Version 3.0 Quality of life Scale

Timepoint

before-after intervention

Method of measurement

questionnaire

2

Description

Conner-Davidson Resilience Scale

Timepoint

before-after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First step of intervention is self-care education provided by a nurse including personal hygiene, side-effects control and disease course education at least for 3 one-to-one sessions during adolescent hospitalization.

Category

Other

2

Description

Second part of intervention is psychological consult , coping strategies education at least for 1 one-to-one session by a psychologist during adolescent hospitalization.

Category

Other

3

Description

Third part of study is nutrition consult and providing nutrition regime during adolescent hospitalization.

Category

Other

4

Description

Control group will receive routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seid-o-Shohada Education and Treatment Centre

Full name of responsible person

Parastoo Oujian

Street address

Isfahan, Khayam Highway, Koye Nahre Farshadi

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

Street address

Isfahan University Of Medical Sciences, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan University Of Medical Sciences

Full name of responsible person

Parastoo Oujian

Position

Phd Student

Other areas of specialty/work

Street address

Nursing and Midwifery school, Isfahan University Of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3792 7516

Fax

Email

p_oujian@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Masoud Bahrami

Position

Associate Professor

Other areas of specialty/work

Street address

Nursing and Midwifery school, Isfahan University Of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3792 7516

Fax

Email

bahrami@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University Of Medical Sciences, Nursing and Midwifery school

Full name of responsible person

Parastoo Oujian

Position

PhD student

Other areas of specialty/work

Street address

Nursing and Midwifery school, Isfahan University Of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

Phone

Fax

Email

p_oujian@nm.mui.ac.ir

Web page address

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