

# 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**

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## 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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan University Of Medical Sciences, Nursing and Midwifery school

**Full name of responsible person**

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**Position**

PhD student

**Other areas of specialty/work**

**Street address**

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**City**

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**Postal code**

**Phone**

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**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*