

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Study of Brief Psychosocial Intervention (BPI) effectiveness on quality of life of primary caregivers of children with cancer

Protocol summary

Summary

It is known that childhood cancer has a great effect on primary caregiver's quality of life. This randomized controlled trial study will examine the effectiveness of a Brief Psychosocial Intervention (BPI) on quality of life of Primary Caregivers of Children with Cancer (PCCCs). BPI including 5 counseling sessions and 5 phone calls follow up will be conducted by trained social workers. Data will be collected using the Caregiver Quality of Life Index, Cancer, Persian version (CQOLCP) prior to intervention and post intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031521487N1**
Registration date: **2015-06-07, 1394/03/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-07, 1394/03/17

Registrant information

Name

Atefeh Safarabadi Farahani

Name of organization / entity

University of social welfare and rehabilitation sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 5455

Email address

atefeh_farahani@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-04-19, 1394/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Brief Psychosocial Intervention (BPI) effectiveness on quality of life of primary caregivers of children with cancer

Public title

Study of Brief Psychosocial Intervention (BPI) effectiveness on quality of life of primary caregivers of children with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: be primary caregivers of children with cancer, be present at hospital at least one day per week, aged 18 or over; exclusion criteria: absence in more than 2 intervention sessions, the child's death

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
randomized: blocked randomization method

Secondary Ids

1
Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of university of social welfare and rehabilitation sciences of Tehran
Street address
Kodakyar Ave, Daneshjo Blvd, Evin, Tehran
City
Tehran
Postal code
1985713834
Approval date
2014-09-15, 1393/06/24
Ethics committee reference number
911693011

Health conditions studied

1
Description of health condition studied
quality of life
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1
Description
Quality of life
Timepoint
Before intervention, after intervention and 1 month after

intervention
Method of measurement
The caregiver quality of life, cancer: CQOLCP

Secondary outcomes

1
Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1
Description
Intervention group: they will receive usual hospital intervention plus BPI. The BPI is a brief intervention designed to help improve the quality of life for PCCCs during all phases of the child illness. It will be accomplished by providing PCCCs with information and support through individual counseling sessions conducted by trained social worker. Several core components will be covered in a five session, 60 minute individual counseling and five phone call follow ups after each session. While the program has core components, each session will be tailored to fit the needs of PCCCs in the particular phase of child illness. The sessions will address individual psychosocial concerns. The first session will aim to engage and motivate PCCCs to participate and open communication. Second session will focus on optimistic attitude and include encourage optimistic thinking, sharing fears and negative thoughts and identify family strengths and weaknesses. Providing information about treatments and medication and help PCCCs live with uncertainty are aims of the third session. Fourth session will help PCCCs cope with stress and emphasize techniques to reduce stress, active coping strategies, and healthy lifestyle behaviors. In the fifth session self care strategies will be educated. PCCCs will be given homework assignments at each session and the assignment tasks will be reviewed at the start of the next session. Five phone calls follow up will be performed for all PCCCs.

Category
Lifestyle

2
Description
Control group: they will receive usual hospital intervention.
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

MAHAK highly specialized pediatric cancer hospital and research center

Full name of responsible person

Atefeh Safarabadi Farahani

Street address

Kodakyar Ave, Daneshjo Blvd, Evin, Tehran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Atefeh Safarabai Farahani

Street address

Kodakyar Ave, Daneshjo Blvd, Evin, Tehran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Atefeh Safarabadi Farahani

Position

student/ MSc

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Masoume Maarefvand

Position

Assistant Professor

Other areas of specialty/work

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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