

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Effect of Spiritual Care Based on Ghalbe Salim on Anxiety and Self-Esteem in children with Cancer

Protocol summary

Study aim

Determining the effect of spiritual care based on Ghalbe Salim on the anxiety and self-esteem in children with cancer

Design

40 children with cancer were selected randomly and divided into two intervention and control groups and each participant was assigned a code.

Settings and conduct

In this study, while explaining the research objectives to 40 children with cancer under the treatment of Dr. Sheikh Mashhad Educational and Medical Center, March children's anxiety questionnaire and Cooper Smith's self-esteem were given to two control and intervention groups. Spiritual care sessions for the intervention group were performed in 5 sessions of 60-45 minutes. The control group received only routine training during reception and hospitalization, and after 5 sessions, both groups were reexamined.

Participants/Inclusion and exclusion criteria

The criteria for entering this study was the ability to have a suitable communication with the researcher, willing to participate in research, physical and mental preparation, at least ability to read and write, able to speak in Persian, be Muslim and have a Shiite religion. Participants who did not wish to continue the study, those with mental disorders such as depression, anxiety, and those who missed more than one session were excluded from the study.

Intervention groups

Intervention group: spiritual care training in the form of 5 face-to-face sessions. Each session is presented for 60-45 minutes. The control group is not given any training. There were no meetings for the control group. They received only routine hospital training, including several pamphlets containing brief information on disease and care in chemotherapy.

Main outcome variables

Level of anxiety and self-esteem ; Ability to spiritual care

based on Ghalbe Salim ; Child care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170512033932N9**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Hosein Motahariniya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 4908

Email address

h_hojjati@aliabadiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

2018-05-06, 1397/02/16

Actual recruitment end date

2018-10-12, 1397/07/20

Trial completion date

2018-10-12, 1397/07/20

Scientific title

The Effect of Spiritual Care Based on Ghalbe Salim on Anxiety and Self-Esteem in children with Cancer

Public title

The Effect of Spiritual Care Based on Ghalbe Salim in children with Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The ability to have a suitable communication with the researcher during the initial interview. Be willing to participate in research and be able to tolerate meetings. Have the necessary physical and mental preparation to answer the questions. Have at least ability to read and write Be able to speak in Persian. Be a Muslim and have a Shiite religion

Exclusion criteria:

Suffering from mental disorders such as depression and anxiety

Age

From **7 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is done with sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B they will be tested

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 for Biological Researches at the Azad University of Shahrood

Street address

Azad University Ave, Shahrood Azad University

City

Shahrood

Province

Semnan

Postal code

43189-36199

Approval date

2018-04-28, 1397/02/08

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.003

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

D70.1

ICD-10 code description

Agranulocytosis secondary to cancer chemotherapy

Primary outcomes

1

Description

Self Esteem Score by Cooper Smith Self-Esteem Questionnaire

Timepoint

Before the intervention begins and after intervention

Method of measurement

Based on total self-esteem score

2

Description

En Anxiety Scale from Marx's Anxiety Inventory

Timepoint

Before the intervention begins and after intervention

Method of measurement

Based on total score of anxiety

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group in this study is training on spiritual care and focusing on the religion of Islam for patients in five sessions (45-60 minutes per session), which are described below: session 1: Introduce and familiarize members with each other, learn about the reasons for forming a group and get acquainted with the rules of the

group such as confidentiality, respect each other's opinions and tolerance of different views, number and time of meetings and the need for continuous attendance until the end of treatment. Session 2: The role of trust and recourse coping with stress caused by a child's illness. Familiarity with the theoretical foundations of recourse, stages and effects of recourse, the concept of recourse, familiarity with shrines, familiarity with the books of pilgrimage, the role of recourse in coping with stress, recourse against stress, familiarity with psychological pressure, recourse against stress, the effect of recourse on life pressure control or effective skills in recourse. Session 3: The role of prayer and supplication in solving problems and familiarity with the effect of prayer on one's relationship with God, oneself and others. Session 4: gratitude and its effect on reducing the negative emotions and teaching the effective beliefs in the effect of gratitude to reduce negative emotions. Session 5: steps of patience and training on the value of patience, patience and effective beliefs in patience, existence of a merciful God, the effect of patience on changing thoughts, patience as an effective strategy in coping with childhood illness.

Category
Behavior

2

Description

There were no meetings for the control group. They received only routine hospital training, including several pamphlets containing brief information on disease.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shaikh Mashhad Learning Pediatric Center
Full name of responsible person
Hamid Farhangi
Street address
St. Sa'id Qarani Ave Dr. Sheikh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ruholah Samie
Street address
Azad Univercity Blvd, Azad Univercity
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h_hojjati1362@yahoo.com

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Islamic Azad University

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
Islamic Azad University
Full name of responsible person
Mozhde Vazifiedust
Position
MSC Student of pediatric nursing
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available