Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 leastability 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9919991766

Phone

+98 51 3801 2469

Fax

+98 51 3801 2469

Email

mozhde.vd@gmail.com

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

City

Aliabad Katun

Province

Golestan

Postal code

4941793451

Phone

+98 17 3422 4500

Fax

+98 17 3422 4500

Email

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 Vazifedust

Position

MSC Student of pediatric nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Azad University, Azad Blvd.

City

Aliabad Katul

Province

Golestan

Postal code

4916845118

Phone
+98 17 3212 8035
Email
mozhde.vd@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mozhde Vazifedust
Position
MSC Student of pediatric nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Azad Ave, Azad Univercity
City
Aliabad Katul
Province
Golestan
Postal code
4941793451
Phone
+98 17 3422 4500
Email
mozhde.vd@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hamid Hojjati
Position
Associate Professor Of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Islamic Azad University, Azad Blvd.
City
Aliabad Katul
Province
Golestan
Postal code
4941793451
Phone
+98 17 3422 4500
Email
h_hojjati1392@yahoo.com

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