Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of self-care empowerment program by multimedia on the level of spiritual health and caring stress in the cancerous children's family

Protocol summary

Study aim
The Impact of Self-care Empowerment Program in the Family of Cancer Children

Design
Using Altman Nomogram the number of samples per group (considering 10% loss) 29 samples. Samples were randomly divided into intervention and control groups using block randomization (4 blocks)

Settings and conduct
In this before and after, clinical trial study, 72 parents of cancerous children referred to Baqiyatallah Hospitals and Children's Medical Center were selected by target sampling, after informed consent and based on entry criteria . The instruments used in this study were: demographic checklists, care burden index , Ellison spiritual well-being, general health, depression, stress, anxiety. The intervention was carried out by donating multimedia software and communicating with families through a telegram channel. The intervention lasted 4 months. Questionnaires were completed before and after intervention by both groups

Participants/Inclusion and exclusion criteria
Entry requirements: being able to communicate Not having chronic mental illness history No use of psychoactive drugs Persian language Not having a child with another illness

Intervention groups
Intervention was conducted, with the donation of training software and the establishment of a social network for the test group. Training took place in 4 months. The control group received routine care. At the end of the intervention, the questionnaires were completed again by both groups. The results were compared with each other and then the software was also given to the control group and their questions were answered.

Main outcome variables
1- Self-care empowerment 2 spiritual health 3 General Health Levels 4 Anxiety 5 depression 6 Stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130611013636N2**
Registration date: **2019-07-31, 1398/05/09**
Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**
Update count: **0**

Registration date
2019-07-31, 1398/05/09

Registrant information

Name
Minoo Asadzandi

Name of organization / entity
Baqiyatallah Nursing Faculty

Country
Iran (Islamic Republic of)

Phone
+98 21 2264 8520

Email address
zandi498@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-17, 1397/04/26

Expected recruitment end date
2018-11-01, 1397/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of self-care empowerment program by multimedia on the level of spiritual health and caring stress in the cancerous children's family

Public title
The effect of self-care education through multimedia in the family of cancer children

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being able to communicate to complete the questionnaire; Do not list the history of chronic mental illness in the past and now (no use of psychotherapy); Non-use of psychotropic drugs. 4. Familiarity with Farsi language. 5. Not having a child with other illnesses in the family.

Exclusion criteria:
No desire to continue research; Coincident in another research; The emergence of an important life crisis in addition to the child's disease crisis during the study.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **29**

Randomization (investigator's opinion)
Randomized

Randomization description
By using random block method (formation of four blocks), the samples were divided into intervention and control groups.

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
University of Baghiat Allah

Street address
Tehran,: Vanak Square, Mullasadra Street, after Sheikh Bahai Street

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2017-06-03, 1396/03/13

Ethics committee reference number
IR.BMSU.REC.1396.560

Health conditions studied

1

Description of health condition studied
Cancerous children's family

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Caregiver's questionnaire has 24 phrases that have objective and subjective care pressure. The questionnaire has five subscales: time-dependent care pressure, evolutionary care pressure, physical care pressure, social care pressure and emotional well-being.

Timepoint
3 months after the end intervention

Method of measurement
The Palutzin and Ellison Spiritual Wellness Questionnaire : Contains 20 terms that are divided into two groups of religious health and existential health. Ten sentences for each episode. The total score is 20- 120

2

Description
GHQ General Health Questionnaire: for investigating non-psychiatric disorders and assess mental health status. It has 28-item with four scales. Each scale has seven questions. Four categories of non-psychotic disorders include: 1. Physical syndrome 2. Anxiety and sleep disorder 3. Disorders of social function 4. Detection of depression and suicidal tendency.

Timepoint
3 months after intervention

Method of measurement
Anxiety , Depression, Stress Questionnaire: Investigates depression, anxiety and stress (emotional reactions). This questionnaire was first presented by Leviband and Leviiband in 1995.

Secondary outcomes

1

Description
Spiritual well-bein at the score

Timepoint

3 months after intervention

Method of measurement

Spiritual health questionnaire:The questionnaire contains 20 sentences, which correspond to the Likert scale of six (I totally agree, agree, agree, slightly agree, rather disagree, totally disagree). This scale is divided into two groups of religious health and existential health, each containing ten sentences and a score of 10 to 60. The total spiritual health score is the sum of these two subgroups, which range between 120-20 The ranking of grades will be as follows.

2

Description

General Health Score

Timepoint

3 months after intervention

Method of measurement

General Health Questionnaire: The 28 questions of this questionnaire, which are used in this study, have four levels, and each scale has seven questions. Four categories of non-psychotic disorders include: 1. Physical syndrome 2. Sleep disorder anxiety 3. -Discussion of social functions 4. -Depression

3

Description

Anxiety،depression،strees

Timepoint

3 months after intervention

Method of measurement

questionnaire depression anxity stress :A standardized questionnaire that examines depression, anxiety and stress (DAS), which has 21 statements, includes the most common, low, moderate and high options. The lowest score for each question is zero and the highest score is 3.

4

Description

Care pressure score

Timepoint

before and after the intervention

Method of measurement

Twenty-four-item care-intensive care questionnaire has been developed to measure objective and subjective care pressure. The questionnaire has five subscales: time-dependent care pressure, evolutionary care pressure, physical care pressure, social care pressure and emotional well-being.

Intervention groups

1

Description

The intervention and control groups completed the questionnaires before intervention. Then the training software was given .to intervention group. Follow up was done through a telegram channel with intervention group for 4 months. After the intervention both groups completed the questionnaires. Spiritual strategy for counseling:1 Cancer, causes and methods of treatment and care, coping with the complications of the disease.2 -problems of cancerous children home care. Care pressure, causes and consequences.3 -Empowerment, strategy to reduce the pressure of care.4 Empowerment Factors: Knowledge and Skills, Trust in God, Development of Communications, Strengthening Motivation 5 Family Spiritual Empowerment Program", Definition of Spirituality, Positive Impact of Spirituality on Health, Spiritual Health 6 - Spiritual well-being, having sound heart, soul abilities, effects spiritual health on the bio- Psycho - social health.7 - Characteristics of spiritual health, characteristics of the owners of the sound heart , Imam Ali (as) a perfect man 8 - When do we need spiritual self-care? Who are the providers of spiritual care? Parents as spiritual counselors 9 - Causes of physical and mental illness, spiritual distress, "frustration of God's mercy", cause of spiritual illness 10 - The disease as a divine test, the philosophy of human testing, strategies for coping with stress (patience, faith, piety , submission to God's will, attention to the presence of God and the instability of hardship)11 - Creating the courage to face the disease by developing contact with God, faith-therapy (remembrance of God, prayer, hope, positive thinking)12 - Prayer therapy, effects of prayer, touch with healing prayers, Islamic ritual of sleep 13 - Spiritual self-care, the need to pay attention to spiritual illnesses, types of spiritual distresses 14 - Spiritual self-awareness, spiritual care guidelines based on religious evidence 15 - Character of spiritual caregivers, ways to communicate with a sick child, family, and friends. Generosity, pardon another mistake, kindness 16 - Use of nature blessings, motivation and motivational enhancement methods

Category

Diagnosis

2

Description

The control group: : They completed the questionnaires before the intervention. They received only routine care.Care was taken at home based on the doctor's order. After 4 months, completed the questionnaires. Then the educational software was donated. Questions were answered

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

the Baqiyatallah hospital, and Children's Medical Center

Full name of responsible person

Safora Shahrabi Farahany

Street address

میدان ونک ، ملاصدرا، بیمارستان بقیه الله میدان توحید ، مرکز طبی کودکان

City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 2350 1000
Email
zandi498@bmsu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Minoo Asadzandi
Street address
Hospital Baqiyatallah, Vanak Square - Mulla Sadra St. - intersection
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8805 0435
Email
shahrabi.safora@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
40
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Minoo asadzandi
Position
Academic Organization of the University of Allah
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Academic Organization of the University of Allah
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 7743 6665
Email
zandi498@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Minoo Asadzandi
Position
The faculty of the rest of Allah (AS)
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Vanak Square - Mulla Sadra Street - intersection of Sheikh Baha'i
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۷۱
Phone
+98 88050436
Email
zandi498@bmsu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
MInoo Asadzandi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address

Vanak Square - Mulla Sadra Street - intersection of Sheikh Baha'i - Hospital Baqiyatallah Al'azim (AS)

City

Tehran

Province

Tehran

Postal code

1941736534

Phone

+98 21 2264 8520

Email

zandi498@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The need for confidentiality of personal information

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