Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Impact of spiritual care on the hope and spiritual well-being of cancer patients

Protocol summary

Study aim

Determine the effect of spiritual care on the hope and spiritual well-being of cancer patients

Design

This study is a clinical trial that has control and intervention group and will be done without blinding. Participants fall into the groups by block random allocation. The number of samples, with a drop of 10%, is projected to be 88. After the formation of the groups, the intervention of the spiritual care will be carried out in accordance with the Bussing protocol. The data were collected through two questionnaires of hope and a questionnaire of Pulotzin and Ellison, and data analysis was done using SPSS version 21.

Settings and conduct

The way of spiritual care intervention is based on the Bussing et al. (2010) protocol in four main religious areas (Excellence), being (meaning and purpose), emotional (relaxation) and social (communication) in 5 sessions, 2 hours before starting chemotherapy in the department Will be executed by the project executives. The duration of each session varied between 45 and 60 minutes.The location of the study is Shahid Rajaee Hospital in Yasuj

Participants/Inclusion and exclusion criteria

The population of this study is cancer patients referred to the chemo department of the Shahid Rajaie Hospital in Yasuj in 1396-97. The criteria for entering the study include a definitive diagnosis of cancer by the oncologist, chemotherapy, age range of 20 to 60 years, the patient's knowledge of his diagnosis, the absence of known psychological and mental disorders other than cancer, obtaining a low level score Spiritual well being (20-40) and hope score less than 32 are willing to participate in the study consciously. The reluctance of the company, the criticality of the patient's clinical condition so that they are unable to attend the intervention sessions and the patient's death will be the exit from the study.

Intervention groups

The intervention group is a group that includes cancer patients undergoing chemotherapy for which spiritual care is provided.

Main outcome variables

Hope rate, Spiritual health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121208011692N2**
Registration date: **2018-03-07, 1396/12/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-07, 1396/12/16**
Update count: **0**

Registration date

2018-03-07, 1396/12/16

Registrant information

Name

Ardeshir Afrasiabifar

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-15, 1396/10/25

Expected recruitment end date

2018-04-14, 1397/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of spiritual care on the hope and spiritual well-being of cancer patients

Public title

Impact of spiritual care on the hope and spiritual well-being of cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of cancer by the oncologist Chemotherapy treatment Age range 20 to 60 years Awareness of the patient's diagnosis Not having known psychological and mental disorders other than cancer Gaining a low level of spiritual health score (20-40) and a score of hope less than 32 Conscious willingness to participate in the study

Exclusion criteria:

Unwillingness to participate Criticizing the patient's clinical condition in a way that is not able to attend intervention sessions. Immigration from the study site death

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization

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

کمیته اخلاق در پژوهش دانشگاه علوم پزشکی یاسوج

Street address

School of Nursing and Midwifery, Shahid Ghorbanali Jalil st.

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591937770

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.YUMS.REC.1396.137

Health conditions studied

1

Description of health condition studied

Patients with cancer who referred to the chemo department of Yasuj Shahid Rajaei Hospital

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

hope rate

Timepoint

Before the intervention, one week after the intervention

Method of measurement

Schneider Hope Questionnaire

2

Description

spirituality health

Timepoint

Before the intervention, one week after the intervention

Method of measurement

Pulootzin and Ellison Spiritual Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention method of spiritual care based on the protocol of Bussing et al. (2010) in 4 main religious areas (Excellence), Being (meaning and purpose), emotional (relaxation) and social (communication) in 5 sessions, 2 hours before the onset of chemistry Therapy in the department will be performed by the performers. The duration of each session varied between 45 and 60 minutes.

Category
Behavior

2

Description
the control group, spiritual care is not taken and will only take the usual care of chemotherapy patients. If the results of the study were significant, in order to comply with the ethics, they will be provided with the necessary information through CDs and pamphlets.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasuj Shahid Rajaee Hospital
Full name of responsible person
Dr. Zahra Rezaei
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Yasuj, Imam Hossein Square
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zahra.zarei@YUMS.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Hossein Maryoriad
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Shahid motahari Blvd, yasuj University of Medical Science, Yasuj
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oryad.hossein@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
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
Yasouj University of Medical Sciences
Full name of responsible person
Ardashir Afrasiabifar
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Non-faculty trainer

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Information about the major outcomes of the data, including the amount of hope and spiritual well-being, will be shared.

When the data will become available and for how long
Data is available after the completion of the study in September 2019.

To whom data/document is available
Data will be available to researchers at universities and institutes.

Under which criteria data/document could be used
Data will be provided to the University of Medical Sciences if the University of Medical Sciences permits it, and merely using its results for further research.

From where data/document is obtainable
Ardashir Afrasiabifar Tel: 00989173411267 Email: afrasiabifar@yums.ac.ir

What processes are involved for a request to access data/document
The applicant must submit a written request to the author of the article via email and the author will provide information to the applicants after obtaining permission from the Yasuj University Medical Sciences for a maximum of 7 days.

Comments