

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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)

Phone

+98 74 2223 4115

Email address

afrasiabifar.ardashir@yums.ac.ir

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
Kohgiluyeh-va-Boyer-Ahmad

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 chemotherapy. 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
Street address
Yasuj, Imam Hossein Square
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Kohgiluyeh-va-Boyer-Ahmad
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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
Street address
Shahid motahari Blvd, yasuj University of Medical Science, Yasuj
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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

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Asadolah Mosavi

Position

Non-faculty trainer

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Other areas of specialty/work

Medical Education

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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