Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of spiritual self-care education on anxiety and life expectancy of patients after bone marrow transplantation

Protocol summary

Study aim
Determining the effect of spiritual self-care training on anxiety and life expectancy after BMT

Design
A clinical trial study with a control group and without blinding, the method of randomization is block random sequence, and the sample size is 60 people, who are divided into two intervention and control groups of 30 people using sealed letters

Settings and conduct
The people in the intervention group are given the necessary training on spiritual self-care, and these classes are conducted on the Internet by a spiritual care specialist in 6 sessions of 60 minutes, before and after, we ask people to answer two questionnaires (anxiety and Life expectancy).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Receiving a BM; Age between 18-64 ;Not suffering from acute BMT complications ;Consent to participate in the study; Must be a Muslim(Shia religion) ;Ability to speak, read and write in Persian Exclusion criteria: having anxiety or mental disorder; Participation in spiritual care courses

Intervention groups
Intervention group: including 30 people who met the conditions for entering the study and underwent BMT, in addition to routine hospital care after discharge, in spiritual care sessions taught by an expert in this work in at least 6 sessions They participate in 60-minute sessions. In these sessions, topics such as strengthening the real relationship with God, teaching patience, achieving self-esteem, strengthening the relationship with others, and strengthening the relationship with nature are discussed. Control group: including 30 people who met the conditions for entering the study and underwent BMT, receive only routine hospital care after discharge, and at the end of the intervention, all spiritual care sessions are recorded in video format. These people are placed

Main outcome variables
Anxiety; life expectancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240205060909N1**
Registration date: **2024-10-06, 1403/07/15**
Registration timing: **prospective**

Last update: **2024-10-06, 1403/07/15**
Update count: **0**

Registration date
2024-10-06, 1403/07/15

Registrant information

Name
zohre shoorvazdi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4261 9727

Email address
zohre.shoorvarzi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-10, 1403/07/19

Expected recruitment end date
2024-10-30, 1403/08/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of spiritual self-care education on anxiety and life expectancy of patients after bone marrow transplantation

Public title
Spiritual self-care education after bone marrow transplantation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Receive a bone marrow transplant Age between 18-64 years Absence of acute bone marrow transplant complications Consent to participate in the study Muslim and Shia religion Ability to speak, read and write in Persian

Exclusion criteria:
Having known anxiety disorder or mental illness Participation in spiritual care courses

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After visiting the Bone Marrow Transplant(BMT) Clinic of Shariati Hospital, people who meet the entry criteria are selected and after necessary explanations and obtaining informed consent, they are randomly grouped into two control and intervention groups. The website https://www.sealedenvelope.com is used to generate the block random sequence and sealed opaque envelopes are used to hide the random allocation. Each of the generated random sequences is recorded on a card and the cards are placed in the letter envelopes. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. The lids of the letter envelopes are glued and placed in a box respectively. The participants open one of the envelopes and enter one of the groups based on it.

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
Research Institute of Oncology, Hematology and Tuberculosis Therapy, Tehran University of Medical Sc

Street address
North Kargar St., Jalal Al Ahmad Street, in front of Faculty of Economics, Dr. Shariati Research and Treatment Center, Tehran

City
Tehran

Province
Tehran

Postal code
1411713135

Approval date
2023-12-12, 1402/09/21

Ethics committee reference number
IR.TUMS.HORCSCT.REC.1402.044

Health conditions studied

1

Description of health condition studied
Patients after bone marrow transplantation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention, four weeks after the intervention

Method of measurement
State-Trait Anxiety Inventory (STAI)

2

Description
Life expectancy

Timepoint
Before the intervention, four weeks after the intervention

Method of measurement
Miller hope scale (MHS)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group consists of 30 people who are grouped into three groups of 10 people. Our intervention is the training of the spiritual self-care program, which is done by a spiritual care specialist. The duration of the intervention is 6 weeks in the form of 60-minute sessions .In the first session, the goal is to introduce and familiarize the members of the group and the leader to each other, in the second session, the goal is to improve and strengthen the relationship with God, and in the third session, to teach patience and its difference with tolerance. In the fourth session, the goal is to strengthen and connect with oneself and to achieve self-esteem. The fifth is strengthening communication with others and preparing people for the end of the sessions, and the sixth session is improving and strengthening communication with nature, and in each session, the patients do the tasks that have been said, including communication techniques, waiting, etc., and in the session They give feedback later.Before and after the intervention, the participants must answer two anxiety and life expectancy questionnaires

Category

Other

2

Description

The control group: includes 30 people who met the conditions for entering the study, but they were not taught the spiritual self-care program and only answered the anxiety and life expectancy questionnaire before and after the intervention. It should be noted that after At the end of the study, the file of all sessions is provided to the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

karimi rozveh , Ali

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North Kargar St., Jalal Al Ahmad Street, in front of Faculty of Economics, Dr. Shariati Research and Treatment Center, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz.Granmaye

Street address

Tehran Province, Tehran, District 6, Nosrat St,

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zohre.Shoorvazdi

Position

Master student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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zohre.shoorvazdi
Position
master student
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Bachelor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
Part of the data of the people participating in the study that is related to the outcome will be published
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and medical centers
Under which criteria data/document could be used
Use with references Compliance with ethical protocols
From where data/document is obtainable
For the convenience of patients, they can contact the contact number of the responsible author. 09916669162 Zohre Shoorvazdi.
What processes are involved for a request to access data/document
From the time of sending the written request, she will have access to the data for a maximum of two weeks if the protocols are followed.
Comments