Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of family-oriented dignity therapy on depression and spiritual well-being of patients and families of cancer patients.

Protocol summary

Study aim
Determining the effect of family-oriented dignity therapy on depression and spiritual well-being in patients and families of cancer patients.

Design
A clinical trial with a control group, using available sampling method, randomized, block allocation with 4 blocks on 66 patients and family members (33 control group, 33 intervention group)

Settings and conduct
After obtaining consent to conduct the study, demographic, depression and spiritual well-being questionnaires will be provided to the intervention and control groups. The family-centered dignity therapy protocol will be performed on the intervention group during 3 sessions, and after a week, the questionnaires will be provided to the two groups again; During the implementation of the family-centered dignity therapy protocol, common treatments will be provided to the intervention group and the control group; The place of study is selected hospitals of Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
having a medical file with a diagnosis of stage III or IV cancer, 2- being at least 18 years old, 3- hearing and speaking ability to participate in the study, 4- being aware of the disease and being interested in participating in the study, 5- Not having cognitive impairment 6- Have a family caregiver. Also, family caregivers who are at least 18 years old, have sufficient education and are the main caregivers of cancer patients; Deterioration of the patient's condition and unwillingness to participate in the research

Intervention groups
In addition to routine treatments, family-oriented dignity therapy protocol will be implemented on the intervention group and only routine treatments will be implemented on the control group.

Main outcome variables
family-oriented dignity therapy; depression; Spiritual well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240813062741N1**
Registration date: **2024-09-05, 1403/06/15**
Registration timing: **prospective**

Last update: **2024-09-05, 1403/06/15**
Update count: **0**

Registration date
2024-09-05, 1403/06/15

Registrant information

Name
Atefeh Jafarbegloo

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 26 3430 8256

Email address
atefehbeglu20@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-04-19, 1404/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of family-oriented dignity therapy on depression and spiritual well-being of patients and families of cancer patients.

Public title
The Effect of family-oriented dignity therapy on depression and spiritual well-being of patients and families of cancer patients.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having a medical file with a cancer diagnosis in stage III or IV At least 18 years old Listening and speaking ability to participate in the study Being aware of the disease and being interested in participating in the study Having no cognitive impairment (according to the medical records, no mental illness has been recognized and confirmed by a doctor) Have a family caregiver Family caregivers who are at least 18 years old They have sufficient literacy and are the main caregivers of cancer patients

Exclusion criteria:
The patient's condition worsened Disinclination to continue studying Not consenting to participate in the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples of this study will be among the cancer patients who meet the inclusion criteria, referring to selected hospitals affiliated to Tehran University of Medical Sciences, along with active family members as caregivers who meet the inclusion criteria, using available sampling method. became. Then, the sample members will be divided into two control and intervention groups by random block allocation method with blocks of 4. For this purpose, blocks of 4 will be selected, so that the letter A will be assigned to the intervention group and the letter B will be assigned to the control group. Six possible states will be written on separate cards and each card will be assigned a number from one to six, which will be as follows: 1) "AABB" 2) "ABBA" 3) "ABAB" 4) "BBAA" 5) "BAAB" 6) "BABA" Then the numbers will be written on paper and poured into a container, and then a number from one to six will be randomly drawn until the expected number of samples is completed (the number of each number in the envelope in the package will be and the researcher is not aware of the numbers) and every time the numbers are returned to the container. In fact, 15 numbers will be randomly drawn from the container and the sequence of observed numbers will show the sequence of blocks.

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
Nursing and Midwifery Ethics Committee of Tehran University of Medical Sciences

Street address
Nosrat St, Tawheed Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2024-06-09, 1403/03/20

Ethics committee reference number
IR.TUMS.FNM.REC.1403.067

Health conditions studied

1

Description of health condition studied
Cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Depression score in the Beck questionnaire

Timepoint
The effect of family-oriented dignity therapy on depression before the start of the study and 10 days after the intervention

Method of measurement
Beck depression questionnaire to measure depression

2

Description
spiritual well-being score in the Polotzin and Ellison spiritual well-being questionnaire
Timepoint
The effect of family-oriented dignity therapy on spiritual well-being before the start of the study and 10 days after the intervention
Method of measurement
Polotzin and Ellison spiritual well-being questionnaire to measure spiritual well-being

Secondary outcomes

1

Description
Age
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

2

Description
Sex
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

3

Description
Marital
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

4

Description
Employment status
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

5

Description
Education
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

6

Description
Type of cancer
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

7

Description
Duration of cancer diagnosis
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

8

Description
Family caregivers of cancer patients
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

9

Description
Relative to the patient
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

10

Description
Duration of care
Timepoint
At the beginning of the study and 10 days after the intervention
Method of measurement
Demographic questionnaire

Intervention groups

1

Description
Intervention group: 3 demographic questionnaires, Beck depression questionnaire and spiritual well-being questionnaire will be used for this study; Before the intervention, the questionnaires will be given to the intervention and control groups, and after completing the questionnaires, the family-oriented dignity therapy

protocol will be implemented in the intervention group. In order to carry out the dignity therapy method, three sessions of 30-60 minutes will be considered for 3 weeks. In the first session, the researcher, while introducing the goals of the research, familiarized the participant with the questions of the family-oriented dignity therapy protocol and provided the necessary opportunity to think about their statements in the next interview session. In the second session, which is 2 to 3 days after The basic meeting will be held, the researcher will guide the client during the interview with the patient-family couple and using the guiding questions of the family-oriented dignity therapy protocol to talk about the patient's life experiences in the context of the family. The participant's statements will be recorded during the interview while obtaining his permission. Then the recorded interviews are transcribed and edited (the questions are focused on eliciting the patients' life experiences in relation to their families, while the caregivers' answers are used to enrich the patients' narratives). In the third session, which is usually held 3 days after the third session, the therapist invites the patient and his family and provides them with the final version of the text to share with them. After the family-centered dignity therapy interventions, the questionnaires will be provided to the intervention and control groups again.

Category

Rehabilitation

2

Description

Control group: 3 demographic questionnaires, Beck's depression and spiritual well-being questionnaires will be provided to the patients before the intervention and 10 days after the intervention. At this time, only routine treatments are performed for the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected hospitals of Tehran University of Medical Sciences

Full name of responsible person

Atefeh jafarbegloo

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Nursing And Midwifery School, Tehran University Of Medical Science, Nosrat St, Tawheed Square, Tehran, Iran

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fnm@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari Sari

Street address

Central Building of Tehran University of medical sciences, Keshavarz Blvd, intersection of Qods Street, Tehran,Iran

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...

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Tumspr@tums.ac.ir

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

Atefeh jafarbegloo

Position

Nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nursing And Midwifery School, Tehran University Of Medical Science, Nosrat St, Tawheed Square, Tehran,

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

Contact

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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
Non-identifiable data of the participants such as age, gender, education, marital status, type of cancer and its stage, relative to the family caregiver, duration of diagnosis and employment status will be included in the research without giving the names and addresses of the participants. Also, for the clinical study report, the research results will be provided to the researchers.

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
Access to the data is free for researchers interested in this topic

Under which criteria data/document could be used
In order to use in other researches and to use the data to improve the treatment of cancer patients

From where data/document is obtainable
To access the data, you can use the email: atefehbeglu20@gmail.com or contact number 09100747091

What processes are involved for a request to access data/document
In order to access the data correctly, the applicant can contact the researcher through the email or the contact number that is included in the article, and the data will be available to her within 2 weeks.

Comments
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