Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of dignity therapy on sense of dignity and quality of life in cancer patients

Protocol summary

Study aim
Effect of Dignity Therapy on sense of Dignity and Quality of Life of Cancer Patients Referring to the Entekhab Palliative Care Center

Design
Clinical trials with control group,Community based and pragmatic, With parallel groups, double blind, randomized

Settings and conduct
Before the intervention, the members of the two groups completed a three-part questionnaire including demographic information, human dignity and quality of life, and then interventions were conducted on randomly selected individuals. A dignity therapy is a session for about an hour, during which the patient is encouraged to talk about important aspects of his life and his speeches are recorded and then given to the recipient in the form of a booklet, and after two weeks, the questionnaires are re- It is given to the patient. Double-blind study is blind because neither the participants nor the statistical analyzers are aware of the control and intervention group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: At least 18 years old Listening and speaking ability to participate in the study Stage 3 or 4 metastatic cancer Patients admitted to the palliative care center

Intervention groups
Intervention and control groups include 25 cancer patients receiving palliative care

Main outcome variables
Quality of Life, Sense of dignity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180306038977N1**
Registration date: **2018-06-08, 1397/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-08, 1397/03/18**
Update count: **0**

Registration date
2018-06-08, 1397/03/18

Registrant information

Name
Mahsa Zaki nejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 3522 4029

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-06-22, 1397/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of dignity therapy on sense of dignity and quality of life in cancer patients

Public title
Effect of dignity therapy on sense of dignity and quality of life

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
At least 18 years old Listening and speaking ability to participate in the study Stage 3 or 4 metastatic cancer Patients admitted to the palliative care center
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method will be used.
Blinding (investigator's opinion)
Not blinded
Blinding description
According to the intervention, blinding of patients, healthcare providers and outcome assessors is not possible.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee on Research in Nursing and Midwifery Faculty and Faculty of Rehabilitation
Street address
Tehran Province, Tehran, District 6, Nosrat St
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2018-03-04, 1396/12/13
Ethics committee reference number
IR.TUMS.FNM.REC.1396.4700

Health conditions studied

1

Description of health condition studied
cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of Life
Timepoint
Measurement of quality of life using a quality of life questionnaire for patients receiving palliative care before intervention and two weeks later.
Method of measurement
Questionnaire of Human Dignity of the Patient Quality of Life

2

Description
Sense of dignity
Timepoint
The study of sense of diginity by using the Human Dignity Questionnaire before the start of the intervention and two weeks later
Method of measurement
Human Dignity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group consisted of 25 cancer patients who first filled in the questionnaire of dignity and quality of life, and a dignity therapy was performed on these individuals.
Category
Treatment - Other

2

Description
Control group: Includes 25 cancer patients who fill the questionnaire of dignity and quality of life, and no interventions will be made on these individuals
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Entekhab Soothing Medicine Center at Firoozgar Hospital

Full name of responsible person
Arpi manookian

Street address
Tehran Province, Tehran, District 6, Nosrat St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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manookianarpi@gmail.com

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
Mahsa Zaki Nejad

Position
Master student of nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
A portion of the data, such as the key outcome information, or the like, after being unidentifiable, is shareable.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
The data file will only be available to researchers in academia and academia
Under which criteria data/document could be used
For use in articles or dissertations by citing the name of the researcher
From where data/document is obtainable
To get data, call 09126982521
What processes are involved for a request to access data/document
The data file will be delivered to the requestor within two weeks
Comments