

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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)

###### Phone

+98 24 3522 4029

###### Email address

zakinejad-m@razi.tums.ac.ir

##### 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 dignity 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

**City**

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**Postal code**

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**Phone**

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**Email**

zakenezhadmahsa@yahoo.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Arpi Manookian

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**Email**

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 scientific inquiries

#### Contact

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**Position**

Associate professor

**Latest degree**

Bachelor

**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**

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**Position**

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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**