

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of Dignity therapy on quality of life and hope in patients with cancer

#### Protocol summary

##### Study aim

Determine the effect of Dignity therapy on quality of life and hope in patients with cancer

##### Design

This is a two-group experimental research with pre test – post test design. 78 patients with cancer were involved in the study after obtaining informed consent. They were randomly assigned in two groups; 36 patients as the intervention group and 36 patients assumed to be the control group.

##### Settings and conduct

dignity therapy was performed in the Iran Mehr Center in patients with cancer. This therapy is an individual psychotherapy interview.

##### Participants/Inclusion and exclusion criteria

Cancer patients older than 18 years living in Birjand who are aware of their illness and have no history of taking psychotropic drugs are included in the study. Patients who have not reached the admission stage of the disease are also excluded from the study.

##### Intervention groups

dignity therapy group: dignity therapy is done  
Control group: dignity therapy is not done

##### Main outcome variables

quality of life: hope

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190604043820N1**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **retrospective**

Last update: **2019-10-13, 1398/07/21**

Update count: **0**

##### Registration date

2019-10-13, 1398/07/21

##### Registrant information

###### Name

Zahra Karimi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 58 3723 7846

###### Email address

zahra.karimi3404@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

2019-01-21, 1397/11/01

##### Actual recruitment end date

2019-05-31, 1398/03/10

##### Trial completion date

2019-05-31, 1398/03/10

##### Scientific title

The effect of Dignity therapy on quality of life and hope in patients with cancer

##### Public title

The effect of Dignity therapy in patients with cancer

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Willing to participate in the research and complete the informed consent form be aware of their disease At least 6 months have passed since diagnosis be aged 18 years or older having the ability to reading and writing (in

order to answer the questionnaire) having physical ability without cognitive impairment (according to Mini Mental Status Examination Score) to attending in the interviews and responding to the questionnaire not having major psychiatric disorders (such as Schizophrenia and major depression) and not using effective psychiatric drugs not travelling more than 4 weeks and not immigrating from Birjand to other cities during the next one month

**Exclusion criteria:**

Patients who are still in the process of denying the disease and have not accepted it

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **78**

Actual sample size reached: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization The names of the eligible patients will be written on the sheets and put in a box and removed by individual names into two groups of control and intervention.

**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**

Ethics committee of Birjand University of Medical Sciences

**Street address**

Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9۷۱۷۸۵۳۵۷۷

**Approval date**

2019-01-13, 1397/10/23

**Ethics committee reference number**

IR.BUMS.REC.1397.267

**Health conditions studied**

**1**

**Description of health condition studied**

patients with cancer

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

quality of life

**Timepoint**

Immediately before intervention and one month after intervention

**Method of measurement**

Quality of Life Questionnaire-Core 30(QLQ-C30)

**2**

**Description**

hope

**Timepoint**

Immediately before intervention and one month after intervention

**Method of measurement**

Herth Hope Index

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: During an interview for 30 to 45 minutes, the therapist will give the patient the opportunity to recall aspects of life such as when he feels proud or issues that are meaningful to him and is part of the history of life he likes. Then, during the two 30- to 45-minute sessions, the patient's statements will be recorded, transcribed, and edited, and if confirmed, the patient will be returned to him in a document producing the patient to share it with those who would like to.

**Category**

Treatment - Other

**2**

**Description**

Control group: Received routine care

**Category**

N/A

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

IranMehr radiotherapy and oncology center

**Full name of responsible person**

Doctor Ahmad Reza Sebzari

**Street address**

Ayatollah Ghaffari Avenue, IranMehr radiotherapy and oncology center

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Birjand

**Province**

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zahra.karimi3404@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Doctor Tooba Kazemi

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Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences

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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**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Doctor Ahmad Nasiri Forag

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**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**

Undecided - It is not yet known if there will be 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