Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

۹۷۱۷۸۵۳۷۷۷

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
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۴۴۴۷۱
Phone
+98 56 3162 6800
Email
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
Street address
Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3244 0388
Email
drtooba.kazemi@gmail.com

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
Street address
Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1406
Email
Zahra.karimi3404@gmail.com

Person responsible for scientific 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
Street address
Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1406
Email
zahra.karimi3404@gmail.com

Person responsible for updating data

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
Street address
Ayatollah Ghaffari Avenue, Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1406
Email
zahra.karimi3404@gmail.com

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