Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of dignity therapy on quality of life, anxiety and depression in patients with chronic obstructive pulmonary disease

Protocol summary

Study aim
The effect of dignity therapy on quality of life, anxiety and depression in patients with chronic obstructive pulmonary disease

Design
This is a two-group experimental research with a pre test – post test design. 62 patients with COPD will be involved in the study after obtaining informed consent. They will be randomly assigned in two groups; 31 patients as the intervention group and 31 patients will be assumed to be the control group.

Settings and conduct
dignity therapy will be performed in Khorshed Research and Educational Hospital Comprehensive Respiratory Clinic in COPD patients. This therapy is an individual psychotherapy interview. Personal interviews with patients in two or three sessions of 30 to 45 minutes will be performed.

Participants/Inclusion and exclusion criteria
Samples tend to participate in the study the age range of 18-70 years Have a minimum reading and writing ability (to answer the questionnaire) grade 3 and 4 diseases based on GOLD scale Physical ability and no cognitive impairment (based on the mental status examination questionnaire to participate in sessions and answer the questionnaire) No major mental disorders (schizophrenia, paranoid disorders and major depression)

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

Main outcome variables
Anxiety, Depression, Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211130053227N1**
Registration date: **2022-05-24, 1401/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-24, 1401/03/03**
Update count: **0**

Registration date
2022-05-24, 1401/03/03

Registrant information

Name
Iran tahmineh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3268 7283

Email address
tsh.nurse69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-08, 1400/11/19

Expected recruitment end date
2022-07-10, 1401/04/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of dignity therapy on quality of life, anxiety and depression in patients with chronic obstructive pulmonary disease

Public title
The effect of dignity therapy on quality of life, anxiety

and depression in patients with chronic obstructive pulmonary disease

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Sample tend to participate in the study age 18-70 years. Have a minimum reading and writing ability (in order to answer the questionnaire) grade 3 and 4 diseases based on GOLD scale Physical ability and no cognitive impairment (based on the mental status examination questionnaire to participate in sessions and answer the questionnaire) No major mental disorders (schizophrenia, paranoid disorders and major depression)

Exclusion criteria:

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method in this study is simple with random allocation. In this way, all patients who have acceptable conditions to enter the study will be selected. Then samples randomly will be divided into intervention and control groups using the RANDOM ALLOCATION software.

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 Isfahan University of Medical Sciences

Street address
Hezar Jarib Avenue, Isfahan University of Medical Sciences

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-09-22, 1400/06/31

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.132

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease

ICD-10 code
J40–J47

ICD-10 code description
Chronic lower respiratory diseases

Primary outcomes

1

Description
Anxiety

Timepoint
Before and one month after intervention

Method of measurement
Hospital Scale Depression and Anxiety

2

Description
Depression

Timepoint
Before and one month after intervention

Method of measurement
Hospital Scale Depression and Anxiety

3

Description
Quality of life

Timepoint
Before and one month after intervention

Method of measurement
St. George Respiratory Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Three 30–60 minute sessions will be considered for dignity therapy implementation. The interval between sessions will be scheduled at the patients’ convenience, usually within 1 to 3 days. In the first session, a dignity therapy trained healthcare professional will introduce the objectives of the dignity therapy method, to make the participants familiar with the questions of this protocol.

In the second session (24 to 48 hours later), as the implementation of this method start, the researchers guide the participants with the help of specific questions form of the dignity therapy protocol. Participants will be free to speak about important aspects of their life and anything they want to record as a memory. At the end of the recorded interview it will be transcribed and reviewed. At the third session (3 days later), the prepared text will be read to the participants and corrected if necessary. Lastly, a version of the final text will be given to the participants to share with any loved person (family members, friends, relatives, etc.). Finally, the questionnaire will be re-done 2 weeks after dignity therapy finishing.

Category
Treatment - Other

2

Description
Control group: Received routine care

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Khorshed Research and Educational Hospital Comprehensive Respiratory Clinic

Full name of responsible person
Doctor Vajiheh Atashi

Street address
Ostandari Avenue , Khorshid Medical Education Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Doctor Mansur siavash

Street address
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research@mui.ac.ir

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Doctor Hojatollah Yousefi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
No - There is not 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
Not applicable
Data Dictionary
Not applicable