

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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**

Isfahan

###### **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 Vajihah Atashi

##### Street address

Ostandari Avenue , Khorshid Medical Education  
Center

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8145831451

##### Phone

+98 31 3222 2127

##### Email

nour@mui.ac.ir

##### Web page address

<https://nour.mui.ac.ir>

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Doctor Mansur siavash

##### Street address

Hezar jarib Avenue, Isfahan University of Medical  
Sciences

#### City

Isfahan

#### Province

Isfahan

#### Postal code

81746-73461

#### Phone

+98 31 3668 8138

#### Email

research@mui.ac.ir

#### Web page address

<https://research.mui.ac.ir/fa>

#### 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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Hezar jarib Avenue, Isfahan University of Medical  
Sciences, Faculty of Nursing and Midwifery

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##### Email

yousefi@nm.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Tahmineh Sharifmoradi

**Position**

Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Other areas of specialty/work**

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**Email**

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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