

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of telephone and text messaging follow ups of empowerment program on quality of life and fatigue of people with chronic obstructive pulmonary disease(COPD)

Protocol summary

Study aim

Comparing the effect of telephone and text messaging follow ups of empowerment program on quality of life and fatigue of people with chronic obstructive pulmonary disease

Design

Three arm parallel group, blinded randomized trial with control group and sample size of 105 People. Randomisation will centralize and computerize with concealed randomization sequences carried out at an external site.

Settings and conduct

After entering the samples to study and spending 6 sessions of empowerment program in HajarHospital of Shahrekord, patients will randomly assigned to one of three groups of follow-up, telephone, SMS and control. follow-ups will be conducted twice a week in the first month and once in the second and third months. The control group will receive only routine care. Blindness will also be in the form of data collection by someone other than the researcher.

Participants/Inclusion and exclusion criteria

inclusion: clinical diagnosis of COPD grade 2 and 3 according to the GOLD criteria. Willingness to participate in the study. Ability to speak and communicate and ,Able to Read and write .Having a mobile phone ,Able to use SMS service .No enrolled in other empowerment programs during the past 6 months.No history of mental disorder according to medical record and physician's opinion exclusion: Unwillingness to participate in the study, Diseases that make the patient's condition unstable

Intervention groups

Intervention group1: Telephone follow-up by calling to patient by researcher for the first month twice a week and for the second and third months, once. Intervention group2: SMS follow-up,-prepared SMS will sent to the

patient by researcher two days a week and then once a week for the second and third months. The control group :receive only routine care.

Main outcome variables

quality of life, fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170122032101N4**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **retrospective**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Haydeh Heidari

Name of organization / entity

Medical University

Country

Iran (Islamic Republic of)

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+98 33346699

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-05, 1398/06/14

Expected recruitment end date

2019-12-05, 1398/09/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of telephone and text messaging follow ups of empowerment program on quality of life and fatigue of people with chronic obstructive pulmonary disease(COPD)

Public title
Comparing the effect of telephone and text messaging follow ups in chronic obstructive pulmonary disease(COPD)

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of COPD Grades 2 and 3 of COPD according to the GOLD criteria Willingness to participate in the study Ability to speak and communicate Having Reading and writing skills Having a mobile phone Ability to use SMS service having at least 40 years of age No enrolled in other empowerment programs during the past 6 months No history of mental disorder according to medical record and physician's opinion
Exclusion criteria:
Diseases that make the patient's condition unstable Unwillingness to participate in the study

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
by using the random number table The numbers 1-105 prepared in the sixth session of each group are divided so that each person has a unique number.after the empowerment for all patients, each individual enters one of three groups according to the random number table.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
It is not possible for the patient to be blinded but for blinding, someone Except the researcher will collect data

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

ethics committee, University Headquarters, Kashani Blv, Shahrekord city, cheharmal va bakhtiari

City

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Chahar-Mahal-va-Bakhtiari

Postal code

8814814776

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.SKUMS.REC.1398.104

Health conditions studied

1

Description of health condition studied

chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

2

Description of health condition studied

chronic obstructive pulmonary disease

ICD-10 code

J44.8

ICD-10 code description

Other specified chronic obstructive pulmonary disease

Primary outcomes

1

Description

quality of life

Timepoint

Before empowerment sessions and before and after intervention

Method of measurement

St George's Questionnaire

2

Description

fatigue

Timepoint

Before empowerment sessions and before and after intervention

Method of measurement

The Piper Fatigue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Telephone follow-up: the researcher contact with the patient by using telephone twice a week for the first month, and for the second and third months, once a week, from 8 am to 8 pm, for 18-15 minutes depending on patient desire. At each meeting the content of the conversation is recorded by the researcher to evaluate the status of the achievement in subsequent calls. If the question is out of the nurse's knowledge, the nurse will inform the physician after consultation with the physician.

Category

Other

2**Description**

Intervention group: text messaging follow up: The text prepared by the researcher is sent to the patient twice a week and then once a week for the second and third months. Patients are asked to send a confirmation message to the researcher after viewing the text, and the patient can ask his/her questions. SMS charges will be charged by the gift SMS service if the patient's line is Irancell and for the other operators a gift charge will be send.

Category

Other

3**Description**

Control group: They receive routine care.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashani hospital

Full name of responsible person

Haydeh Heidari

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Kashani hospital, Parastar Ave, Shahrekord city, cheharmahal va bakhtiari

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2**Recruitment center****Name of recruitment center**

hajar hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

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kamal_solati@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Haydeh Heidari
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assisstant professor
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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