

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The Effect of Foot Stroke Massage on the Quality of Sleep in Patients with Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

The effect of foot stroke massage on the quality of sleep in patients with chronic obstructive pulmonary disease

Design

This Study Is A Randomized Clinical Trial.The Sample Size For Research Is 18 Subjects In Each Group.The Samples Will Be Selected By Convenience And Purposeful Sampling; Then They Will Be Assigned To The Intervention And Control Groups By Quadrilateral Permutation Block Method.

Settings and conduct

The Present Study Will Be Performed On Patients With Chronic Obstructive Pulmonary Disease With Sleep Disorder Referring To The Clinic Of Allameh Bohlol Gonabadi Hospital.Patients In Intervention Group Will Receive Foot Massage As Stroke Massage For 5 Consecutive Sessions And 20 Minutes For Each Session For A Total Of Two Legs. The Control Group Will Receive Routine Care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having Chronic Obstructive Pulmonary Disease Based On Internal Medicine Recognition 2-Having a Sleep Disorder , According To Pittsburg Ssleep Quality Questionnaire Score (Total Score Hhigher Than 5) Exclusion Criteria: 1-Non-Use Of Hypnotics And Anti-Anxiety Drugs 2-Lack Of Respiratory Tract Infection

Intervention groups

Patients In Intervention Group Will Receive Foot Massage As Stroke Massage For 5 Consecutive Sessions And 20 Minutes For Each Session For A Total Of Two Legs. The Control Group Will Receive Routine Care.

Main outcome variables

Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180116038400N1**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **retrospective**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

Registration date

2018-10-15, 1397/07/23

Registrant information

Name

Amin Nouroozi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 6490

Email address

nouroozi.m@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-31, 1397/03/10

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Stroke Massage on the Quality of Sleep in Patients with Chronic Obstructive Pulmonary Disease

Public title

The Effect of Foot Stroke Massage on the Quality of Sleep in Patients with Chronic Obstructive Pulmonary Disease	
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Having chronic obstructive pulmonary disease Age 30 to 60 years old Having healthy feet Ability to tolerate foot massage Having a sleep disorder, according to Pittsburg sleep quality questionnaire score (total score higher than 5)
Exclusion criteria:	specific disease (diabetes and stroke) use sleeping pills and anti-anxiety drugs infection of the respiratory system
Age	From 30 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 36
Randomization (investigator's opinion)	Randomized
Randomization description	The Subjects Were Randomly Selected and Assigned to Two Groups of Intervention and Control by Using Permutational Blocks.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee in Gonabad University of Medical Sciences
Street address	Research & Technology Dept, Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi
City	Gonabad
Province	Razavi Khorasan
Postal code	9691793718

Approval date	2018-05-14, 1397/02/24
Ethics committee reference number	IR.GMU.REC.1397.001
Health conditions studied	
<u>1</u>	
Description of health condition studied	Patients With Chronic Obstructive Pulmonary Disease
ICD-10 code	J44.9
ICD-10 code description	Chronic obstructive pulmonary disease, unspecified
Primary outcomes	
<u>1</u>	
Description	Sleep Quality
Timepoint	Before the Study (before the intervention) and Six Says After the Intervention
Method of measurement	Pittsburgh Sleep Quality Index
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Participants In This Group, The Stroke Massage Will Receive 15 Minutes For Each Foot For Five Consecutive Days at 5:00 pm.
Category	Other
<u>2</u>	
Description	Control group: Participants In This Group Will Receive only Routine cares
Category	Rehabilitation
Recruitment centers	
<u>1</u>	
Recruitment center	
Name of recruitment center	Clinic of Bohlol Gonabadi Hospital
Full name of responsible person	Amin Nouroozi
Street address	Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street,

Gonabad City
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5723 6828
Email
nouroozi.m@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Seyed Ali Sajjadi
Street address
Research & Technology Dept, Gonabad University of
Medical Sciences, Asian Roads, Gonabad, Khorasan
Razavi
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5722 0805
Email
sa_1344@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Amin Nouroozi
Position

Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street,
Gonabad City
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5723 6828
Email
nouroozi.m@gmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Amin Nouroozi
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Nurse
Latest degree
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Gonabad City
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5723 6828
Email
nouroozi.m@gmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Amin Nouroozi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street,

Gonabad City

City

Gonabad

Province

Razavi Khorasan

Postal code

96981-48471

Phone

+98 51 5725 6490

Email

nouroozi.m@gmu.ac.ir

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

Not applicable

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