

Investigation into the sleep benefits to a Chronic Obstructive Pulmonary Disease (COPD) sufferer using the SoeMac™ micro air conditioner

Submission date 26/03/2015	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/04/2015	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/01/2019	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

Background and study aims

Chronic obstructive pulmonary disease (COPD) is the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. There is no cure for the condition, but making lifestyle changes (such as stopping smoking) and taking medications (inhalers and/or tablets) can alleviate symptoms. The SoeMac™ unit is a micro air conditioner designed for home use and is sold as an alternative therapy product to help improve the quality of life for people with breathing disorders and fatigue issues. Responses from users have been very positive, and we have noticed particular benefits for COPD sufferers and improved quality of sleep. We want to test whether the SoeMac™ unit will improve quality of sleep for COPD patients.

Who can participate?

COPD patients from the Rivergreen Medical Centre, Nottingham (UK).

What does the study involve?

Participants are randomly put into two groups: half will use the SoeMac™ unit and the other half will use a dummy unit. The study is run over an 8-week period. Simple, non-invasive measures are recorded at the clinic fortnightly during the course of the study. A questionnaire is also filled in at the start and at the end of the study.

What are the possible benefits and risks of participating?

If the results of this study are good we hope to progress to a bigger and more formal clinical trial at the Queen's Medical Centre Campus in Nottingham.

Where is the study run from?

Rivergreen Medical Centre, Nottingham (UK)

When is the study starting and how long is it expected to run for?
May 2015 to July 2015

Who is funding the study?
SOE Health Ltd (UK)

Who is the main contact?
Mr Neil Stentiford
neils@soemac.com

Contact information

Type(s)

Public

Contact name

Mr Neil Stentiford

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Type(s)

Scientific

Contact name

Dr Michael Johnson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

179873

Study information

Scientific Title

Investigation into the sleep benefits to a Chronic Obstructive Pulmonary Disease (COPD) sufferer using the SoeMac™ micro air conditioner: a randomised controlled trial

Study hypothesis

Using the SoeMac™ for 8 weeks leads to improved quality of sleep for sufferers of COPD.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study has been submitted to IRAS for ethics approval reference number 15/LO/0750 - pending.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

Condition

Quality of sleep of 24 COPD patients

Interventions

24 volunteer COPD sufferers: 12 live/12 placebo.

Intervention Type

Device

Primary outcome measure

1. Improved quality of sleep for COPD sufferers

Secondary outcome measures

Recorded fortnightly at clinic:

1. Recording blood pressure
2. Blood oxygen saturation (blood sats)
3. Forced Vital Capacity (FVC)
4. Forced Expiratory Volume in one second (FEV1)

Recorded at start and end of trial at clinic:

5. St George's quality of life/sleep questionnaire

Overall study start date

01/05/2015

Overall study end date

01/07/2015

Eligibility

Participant inclusion criteria

1. COPD
2. Volunteers attached to Rivergreen Medical Centre

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

24

Participant exclusion criteria

1. Non-COPD sufferers
2. Not attached to Rivergreen Medical Centre
3. Not adults

Recruitment start date

01/05/2015

Recruitment end date

01/07/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Rivergreen Medical Centre
106 Southchurch Drive, Clifton
Nottingham
United Kingdom
NG11 8AD

Sponsor information

Organisation
SOE Health Ltd

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Sponsor type
Industry

Website
www.soemac.com

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

We have given Dr Michael Johnson full authority to publish the results in a way that he deems suitable.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration