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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

Registration date
10/04/2015

Overall study status
Stopped

Last Edited
30/01/2019

Condition category
Respiratory

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

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
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
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 objectives
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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Quality of sleep of 24 COPD patients

Interventions
24 volunteer COPD sufferers: 12 live/12 placebo.

Intervention Type
Device

Primary outcome(s)
1. Improved quality of sleep for COPD sufferers

Key secondary outcome(s)
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

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. COPD
2. Volunteers attached to Rivergreen Medical Centre

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

Date of first enrolment
01/05/2015

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation

SOE Health Ltd

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration