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The POSA Trial: Does positional therapy, delivered by a small vibrating neck device, improve the health and well-being of patients with positional obstructive sleep apnoea?

Submission date 23/09/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/10/2019	**Overall study status** Completed	
Last Edited 01/11/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnoea (OSA) affects one in ten adults in the UK. It occurs when muscles in the upper airway relax during sleep, and the airway becomes partially or completely blocked. Breathing restarts when the person wakes up, but frequent night-time awakenings cause daytime sleepiness. It can also cause long-term heart problems, and in older people increases the risk of having a stroke.

The best treatment is Continuous Positive Airway Pressure (CPAP); it blows air into the lung to prevent the airway closing, which in turn improves sleep, and quality of life and reduces negative health risks. However, CPAP can be uncomfortable and difficult to use, especially for older people.

Sleeping on the back makes breathing worse for some patients with OSA, and can even be the cause of OSA in others, due to the effect of gravity on the upper airway. New technology has resulted in devices that use gentle vibrational feedback from position sensors to prevent people sleeping on their backs.

Therefore, this study aims to determine whether Positional Therapy, using a small vibrating device fitted to the neck, can help to stop people from sleeping on their backs, and whether this helps to reduce the severity of their OSA. We also want to determine whether patients feel better and how easy the treatment is to use. We also want to compare the effect in older and younger people.

Who can participate?
Patients aged 18 or older with OSA and their partners or carers

What does the study involve?
Adult patients with positional OSA will be recruited from sleep centres across the UK

Respiratory Sleep Research Network. Positional OSA will be measured by a home sleep study. Eligible patients will attend two hospital visits at their local sleep centre; one at baseline and one at 3 months. At baseline, patients will be given the opportunity to try a Positional Therapy device (NightShift™; Advanced Brain Medical, US); a small vibrating device fitted around the neck. The device has a position sensor that detects when the patient attempts to lie on their back; it will then give gentle vibration feedback until the patient rolls off their back again. The device has 2 different modes; patients will be randomly allocated to receive either THERAPY mode, or MONITOR mode. The MONITOR mode will be a sham and will not give therapy but will continue to monitor sleep patterns for 3 months; ie. like a placebo.

Patients will wear the Positional Therapy device each night, for 3 months, while they sleep. After 4 nights, patients will be contacted by the Trial Sleep Therapist to discuss their experiences and help troubleshoot any difficulties. Ongoing support will be offered.
At baseline and at 3 months, the patients' subjective symptoms, wellbeing and quality of life, will be assessed by questionnaires; including questions about sleep quality, tiredness, energy, fatigue, mood and frailty. Partners or carers' perspective will also be captured by questionnaire.
A repeat home sleep study while using the NightShift device, at 3 months, will measure the effect of the therapy on the severity of OSA. Adherence to therapy will also be measured by the NightShift™ device.
At the end of the trial, patients will return to routine clinical care at their local centre and will discuss ongoing treatment options with their local team. All patients may keep the Positional Therapy device, at their own responsibility and risk. Those who were in the MONITOR mode, will be swapped to the THERAPY mode

What are the possible benefits and risks of participating?
The benefits of positional therapy in OSA have not been fully determined, which is our reason for carrying out the study. It is possible that patients may experience improvements in their sleep and subsequently in their quality of life when using the vibration device. Patients might experience an improvement in their snoring, as well as their breathing at night, and so we are also interested in any benefits that bed partners might experience.

Positional therapy is known to be a safe treatment that is well tolerated with very few side effects. Occasionally patients have reported discomfort in the neck or shoulders as a result of sleeping on their sides, particularly if their pillow(s) are too flat.

If patients receive the sham therapy, they may or may not notice an improvement in their symptoms. But at the end of the 3 months, they will have the opportunity to try the device in THERAPY mode to decide if it is a suitable treatment.

Where is the study run from?
Royal Brompton Hospital, UK

When is the study starting and how long is it expected to run for?
October 2019 to November 2022

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
1. Dr Julia Kelly, j.kelly@rbht.nhs.uk
2. Patrik Pettersson, p.pettersson@rbht.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Julia Kelly

Contact details
Clinical and Academic Department of Sleep and Breathing
National Heart and Lung Institute, Imperial College London
Royal Brompton Hospital
London
United Kingdom
SW3 6NP
+44 (0)207 3528121
j.kelly@rbht.nhs.uk

Type(s)
Scientific

Contact name
Mr Patrik Pettersson

Contact details
Research Office
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP
+44 (0)207 3528121 ext.88763
p.pettersson@rbht.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS: 42612

Study information

Scientific Title
Positional therapy for obstructive sleep apnoea: a randomised controlled trial to assess the effect on health and wellbeing in older and younger people

Acronym
POSA

Study objectives
Our primary objective is to determine the change in OSA severity, (defined by the apnoea-hypopnoea index (AHI) - number of breathing events every hour) 3 months post Positional Therapy in patients with positional OSA, compared to a control group (Sham-Positional Therapy)

Our Secondary Objectives are:
. To determine the difference in treatment effect between older (.65 years) and younger patients
. To determine the change in quality of life and symptoms of OSA, from baseline (pre-treatment) to 3 months post positional therapy in patients with positional OSA, compared to Sham-Positional Therapy, in older compared to younger patients
. To determine the change in sleeping position and objective sleep-disordered breathing from baseline (pretreatment)
to 3 months post positional therapy in patients with positional OSA, compared to Sham-Positional Therapy, in older compared to younger patients
. To compare treatment adherence and comfort in older compared to younger subjects
. To determine the partner/ carers' perspectives of Positional Therapy
. To investigate the cost-consequences of positional therapy in patients with positional OSA, compared to Sham-Positional Therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/07/2019, York and Humber-South Yorkshire NRES committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, HRA Jarrow, NE2 4NQ; +44 (0)207 104 8225; nrescommittee.yorkandhumber-southyorks@nhs.net), ref: 19/YH/0222

Study design
Randomized; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
This is a prospective, randomised, double-blinded parallel trial; Patients with positional OSA will be randomized to receive either Positional Therapy or Sham-Positional Therapy for 3 months. Study duration is expected to be 13 weeks for each participant; 1 week for sleep study testing and baseline visit, plus 12 weeks of 'therapy'.

Screening: Patients will be screened using a home sleep study (Apnealink Air; ResMed, Australia). If the study shows the patient is eligible, an information sheet will be offered and written Informed Consent will be obtained. For sites with an alternative first-line sleep monitoring device, consent will be sought before providing the trial specific Apnoealink Air home sleep study to patients with suspected positional OSA.

Baseline Visit: Participants will be given an opportunity to try the Night Shift™ device; including education on fitting and wearing, charging, and care. We have included a 10 minute run-in period where patients will self-fit the device, under instruction, and will experience the vibration sensation. The ability to tolerate the device during the run-in forms part of our study inclusion criteria. Participants may decline participation should they still have concerns about their use of the device. Baseline demographics will be collected and a basic medical history.
Participants will be asked to complete a series of questionnaires on sleep quality, tiredness, energy, fatigue, mood and frailty, which will take 45-60 minutes to complete.

Participants will then be randomised (Positional Therapy or Sham-Positional Therapy) by an unblinded staff member, other than the researcher/ clinician who is managing the patient. Randomisation will be performed using an online computer-generated randomisation schedule supplied by Oxford Respiratory Trials Unit, with minimisation based on age group, and OSA severity. Both participant and researcher will remain blinded to the study arm.

Participants will be asked to wear their device nightly. The device will be set to either 'TRIAL' (first night monitoring, vibration feedback from second night onwards) or 'MONITOR' (monitoring only, no vibration feedback). Lack of vibration in the sham arm will be accepted because vibration is delivered when the patient is asleep, and then the device adapts feedback intensity to minimize awakenings, therefore patients are not always aware of the delivered vibrations. Approximately one third of our patients report being unaware of the nocturnal vibrational feedback.

Monitoring and follow-up: To ensure consistent follow-up, all participants will be contacted after 4 nights (one night monitoring, 3 nights on Positional Therapy or Sham) by a blinded central Trial Sleep Therapist to discuss their experiences and troubleshoot difficulties.

Three month follow-up: Participants in both arms will attend their local service for their follow-up visit. Prior to this visit, participants will be posted the home sleep study kit (Apnoealink Air) to perform a repeat home sleep study while wearing the Night Shift™ device. At the visit, participants will repeat the baseline questionnaires and their sleep study data and Positional Therapy data will be downloaded.

The participant's participation in the trial is then complete. Patients will revert to routine clinical care at their local centre. Patients who wish to continue the treatment will be permitted to keep the device (free of charge; however because this device is not yet available through the NHS, continued use will be at the patients' own risk). Participants in the sham arm will also then have the opportunity to use the device in THERAPY mode and may also keep the device if they feel it is beneficial.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome measure
OSA severity measured by the apnoea-hypopnoea index (AHI; number of breathing events per hour of sleep) at baseline and 3 months

Secondary outcome measures
1. Objective Sleep measures:
1.1 Overnight oxygenation (SaO2) measured by respiratory polygraphy (home sleep test) at baseline and 3 months
2. Quality of life and symptoms of OSA at baseline (pre-treatment) to 3 months (post-Positional Therapy):
2.1 Daytime sleepiness measured using the Epworth Sleepiness Scale (ESS) at baseline and 3 months
2.2 Anxiety and Depression measured by the Hospital, Anxiety and Depression Scale (HADS) at baseline and 3 months
2.3 Healthcare Utilisation measured by a Healthcare Contacts Questionnaire and by the Euroquol (EQ-5D) Questionnaire at baseline and 3 months
2.4 Quality of Life measured by the Short Form-36 (SF-36; specifically Energy and Vitality) at baseline and 3 months
2.5 Independent Functioning measured by the Townsend Disability Scale at baseline and 3 months
2.6 Sleep Quality and daytime functioning measured by the Functional Outcomes of Sleep Questionnaire and the Pittsburgh Sleep Quality Index (PSQI) at baseline and 3 months
3. Positional Therapy:
3.1 Comfort and tolerance of the Positional Therapy device measured using a Visual analogue scale (VAS) at 3 months
3.2 Adherence measured by the NightShift device (hours per night; number of nights used) over 3 months (90 days)
3.3 Sleeping position (including % time supine) measured by the Nightshift device at baseline and 3 months

Overall study start date
01/07/2019

Completion date

30/11/2022

Eligibility

Key inclusion criteria
1. Aged > = 18 years
2. Ability and willingness to provide informed consent
3. AHI > 5 events/hour (AASM 2012 scoring criteria) with events occurring at a frequency of 2:1 when supine, compared to non-supine; total % supine sleep > 20, < 90% of total sleep; central apnoeas < 20% total apnoeas; recording of > = 4 hours of analysable signals
4. Ability to fit and tolerate wearing the device around the neck during treatment demonstration and initiation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 138; UK Sample Size: 138

Total final enrolment
120

Key exclusion criteria
1. Unstable cardiac disease
2. Cardiac arrhythmia corrected with an artificial pacemaker
3. Supplemental oxygen
4. Secondary sleep pathology e.g. Periodic Limb Movement Syndrome, Narcolepsy, Circadian Disorder, Obesity Hypoventilation Syndrome; or shift workers
5. Concerns about sleepy driving or any other potentially dangerous symptom from physician
6. BMI > = 40 kg/m2
7. Inability to sleep in a non-supine position
8. Skin sensitivity or an open wound around neck
9. Neck circumference < 12inches (30cm) or > 22inches (55cm)
10. Tics or tremors of the head
11. Sleep with head in upright position
12. A female of child-bearing potential that is pregnant or intends to become pregnant

Date of first enrolment
07/10/2019

Date of final enrolment

01/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton and Harefield NHS Foundation Trust
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Newcastle upon Tyne NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Aintree University Hospital NHS Foundation Trust
University Hospital Aintree
Fazakerley Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Royal Free London NHS FoundationTrust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Royal Brompton & Harefield NHS Foundation Trust

Sponsor details
Royal Brompton Hospital
Sydney Street
London
England
United Kingdom
SW3 6NP
+44 (0)207 3528121
P.Pettersson@rbht.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0817-20049

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 7.0	24/08/2022	17/10/2022	No	No
HRA research summary			28/06/2023	No	No