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Investigating customised positive airway pressure therapy masks versus usual care in the treatment of patients with sleep-disordered breathing

Submission date
07/12/2022

Recruitment status
No longer recruiting

Registration date
10/01/2023

Overall study status
Completed

Last Edited
02/06/2026

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the UK alone, there are 1.6 million people who have problems with their breathing during sleep. The best treatment is a breathing machine, which is attached via a tube with a tight-fitting mask to the patient face. However, people have different facial shapes, and these off-the-shelf masks sometimes leak air or are uncomfortable. This research will assess whether personalised face masks are better than off-the-shelf masks.

Who can participate?
Adults with sleep-disordered breathing with an apnoea hypopnea index (AHI) of more than 15 events/hour who need PAP therapy and adult patients who have never had PAP therapy.

What does the study involve?
People who are under the care of the Royal Free London NHS Foundation Trust's sleep and ventilation service and who need treatment for their sleep-disordered breathing with PAP therapy will be asked to test the customised masks. The research will look at how the customised masks compare to commercially available "off the shelf" masks. It will measure how the two masks affect how well the breathing machines treat breathing problems during sleep. Further tests will see if there is a difference in the following:
1. How well the mask fits
2. How much do patients use their breathing machine
3. How often do people get skin sores
4. People's wellbeing
5. Feedback on the comfort of the masks.

This is a randomised controlled trial, which means there will be two groups of patients. One group will be issued with an off-the-shelf mask and one group will be issued with a customised mask. A computer will randomly decide which group each patient will be in. Neither the participant, the research team nor anyone else involved in patient care can decide. If participants

decide to take part, each will be asked to complete a consent form and if partaking will be informed when the appointments are. Appointments will be made on a day and time that is convenient for everyone who wants to take part. Before being invited to test the masks, the masks will be tested on small scale in 10 healthy people and 10 people with sleep-disordered breathing. Taking part in this study will involve attending three to four sessions with a member of the research team.

The information below shows what is involved at each visit.
Visit number 1
Off-the-shelf mask group:
We will complete a physical assessment of you
You will be given your PAP machine (CPAP, NIV) and an off-the-shelf mask
We will ask you to complete some questionnaires
A scan of your face will be collected using a handheld scanner
Customised mask group:
A scan of your face will be collected using a handheld scanner
We will complete a physical assessment of you
We will ask you to complete some questionnaires

Visit number 2, 3 months after your first visit
Off-the-shelf mask group:
We will ask you to complete some questionnaires
We will ask you to complete a two-night sleep study
We will complete a physical assessment of you
We will download some information from your PAP machine
Customised mask group:
As soon as possible after your first visit
You will be given your PAP therapy device (CPAP, NIV) and customised mask

Visit number 3, 6 months after your first visit
Off-the-shelf mask group:
We will ask you to complete some questionnaires
We will ask you to complete a two-night sleep study
We will complete a physical assessment of you
We will download some information from your PAP machine
Customised mask group:
3 months after your first visit
We will ask you to complete some questionnaires
We will ask you to complete a two-night sleep study
We will complete a physical assessment of you
We will download some information from your PAP machine

Visit number 4, 6 months after your first visit
There are no actions for the off-the-shelf mask group
Customised mask group:
We will ask you to complete some questionnaires
We will ask you to complete a two-night sleep study
We will complete a physical assessment of you
We will download some information from your PAP machine
We will issue you with an off-the-shelf mask for ongoing treatment

The visit when patients are issued with a PAP machine (visit 1 or 2) will last a maximum of 2 hours. Visits after that will last a maximum of an hour and a half. It may be possible for some of these visits to be conducted via a video platform. If support is required in between the visits, patients will be able to contact the team via phone and email. Patients will be in the study for 6 months in total. The customised mask will have to be returned at the last appointment because the customised masks have not gone through the necessary government and regulatory approvals for long-term use.

What are the possible benefits and risks of participating?
By participating in the study patients will have additional monitoring and extra tests to check their condition. It is hoped that this new way of creating masks will help people to find it easier to wear their masks. It might reduce the side effects people experience from the mask. There is a possibility in the long term that it could reduce costs and waste to the healthcare system. Taking part in the study will take up some time. There is a small risk that people could develop a skin reaction to the materials used in both the off-the-shelf masks and the customised mask. The off-the-shelf masks are made from silicon with a low reported incidence of skin reactions. The customised masks will contain silicon, with a low reported incidence of skin reactions in other products. The customised masks will be based on polyacrylate and be cured to avoid irritation.

Where is the study run from?
Royal Free London NHS Foundation Trust (UK) and University College London (UK)

When is the study starting and how long is it expected to run for?
July 2021 to December 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) Academy (UK); Grant Codes: NIHR302337

Who is the main contact?
Stephanie Mansell, Stephanie.mansell.21@ucl.ac.uk (UK)

Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
275073

Central Portfolio Management System (CPMS)
54299

Study information

Scientific Title
The clinical impact of customised positive airway pressure (PAP) therapy interfaces versus usual care in the treatment of patients with sleep-disordered breathing

Acronym
3DPiPPIn 2

Study objectives
Customised interfaces will result in greater improvements in residual apnoea hypopnea index (AHI) compared to conventional interfaces

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2022, South Central – Hampshire B (Meeting held by video-conference via Zoom; +44 (0)207 104 8088, (0)20 7104 8289, (0)20 7104 8289; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0405

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory disorders

Interventions
The following examinations and investigations (if not already performed as part of routine standard of care) shall be performed for determining eligibility for enrolment into this Investigation:

RCT
A 3D scan using a hand-held scanner of all participants' faces will be collected.

Participants will undergo a physical assessment to collect sociodemographic and anthropometric data and measure the prevalence of pressure ulcers via the European Pressure Ulcer Advisory Panel (EPUAP) score. This will be conducted at baseline, 3 months and 6 months.

Participants will complete the following questionnaires at baseline, 3 months and 6 months: Epworth Sleepiness Scale (ESS), Sleepiness-Wakefulness Inability and Fatigue test (SWIFT), S3-non-invasive ventilation (S3NIV) and interface questionnaire.

Participants will undergo an initial 10-minute trial of PAP therapy with the customised 3D-printed mask to assess for mask leaks, skin reactions and comfort scores. If there are no serious adverse events/reactions during the PAP trial with the 3-D printed mask, patients will go on to have PAP therapy as per their normal PAP regime.

Participants will undergo a two-night cardiorespiratory sleep study at baseline, 3 months and 6 months.

Participants on NIV will have a capillary blood gas (CBG) at baseline, 3 and 6 months

Data from participants' PAP therapy devices will be downloaded at 3 months and 6 months, Specific data collected will be:
Compliance with PAP therapy, measured as hours and percentage of days PAP therapy used >4 hours/night over 28 days, measured prior to 3 months and 6 months in concordance with internationally recognised definitions of compliance.

Interface leak, measured as average L/min and percentage of the intentional leak over 7 days

Nested Qualitative study
Participants recruited for the nested qualitative study will undergo a 1:1 semi-structured interview at a location of the patients choosing.

Following their participation in the trial patients will receive ongoing care from the sleep and ventilation team as per standard care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
3D printing positive pressure interfaces

Primary outcome(s)
Apnoea hypopnea index (AHI) measured using the limited cardio-respiratory sleep study at 6 months

Key secondary outcome(s)
1. Apnoea hypopnea index (AHI) measured using the limited cardio-respiratory sleep study at 3 months
2. Interface leak measured using average L/min and percentage of the intentional leak over 7 days from positive airway pressure (PAP) therapy data downloads at 3 and 6 months
3. Residual AHI measured using PAP therapy data downloads for further validation of AHI at 3 and 6 months
4. Incidence of pressure ulcers measured using the European Pressure Ulcer Advisory Panel (EPUAP) score (0 to 4) at 3 and 6 months
5. Compliance with PAP therapy, measured as hours and percentage of days PAP therapy used >4 hours/night over 28 days, measured prior to 3 and 6 months
7. Symptoms measured using the Epworth Sleepiness Score (ESS) and Sleepiness-Wakefulness Inability and Fatigue test (SWIFT) at baseline, and 3 and 6 months.
8. Comfort as measured by the S3-non-invasive ventilation (S3NIV) questionnaire and the interface questionnaire, at baseline, and 3 and 6 months.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Randomised controlled trial:
1. Diagnosis of SDB (AHI >=15) confirmed with a home-based sleep study and requiring PAP therapy
2. Patients naive to domiciliary PAP therapy
3. Age >= 18 years

Nested Qualitative Study:
Patients participating in study 1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
160

Key exclusion criteria
Randomised controlled trial:
1. AHI <15
2. Excessive facial hair which they are unwilling to shave
3. Age <18 years
4. Existing facial pressure ulcers
5. Unable to provide informed consent
6. Known allergy to silicone
7. Keloid scarring
8. Previous domiciliary PAP therapy

Nested qualitative study:
Patients who are unable to provide informed consent

Date of first enrolment
16/01/2023

Date of final enrolment
09/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hospital
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/01/2026	28/01/2026	Yes	No
Protocol article		14/11/2024	15/11/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		06/05/2025	08/05/2025	Yes	No
Other publications		01/04/2026	21/04/2026	Yes	No
Plain English results			02/06/2026	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes