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Determining the benefits of improving communication in BPAP/CPAP users

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Minimal Risk Protocol

1. Protocol Title

Determining the benefits of improving communication in BPAP/CPAP users

2. Objectives

The purpose of this study is to determine the effectiveness of a non-invasive communication aid for BPAP/CPAP masks. This study also looks to determine the potential impact of the device on patients with obstructive sleep apnea (OSA) and the individuals that interact with the device.

The hypothesis is as follows: The non-invasive communication aid for patients receiving BPAP/CPAP therapy will deliver clear and effective communication between the patient and medical personnel. Furthermore, the device will increase the patient's efficacy at communicating with others.

3. Background

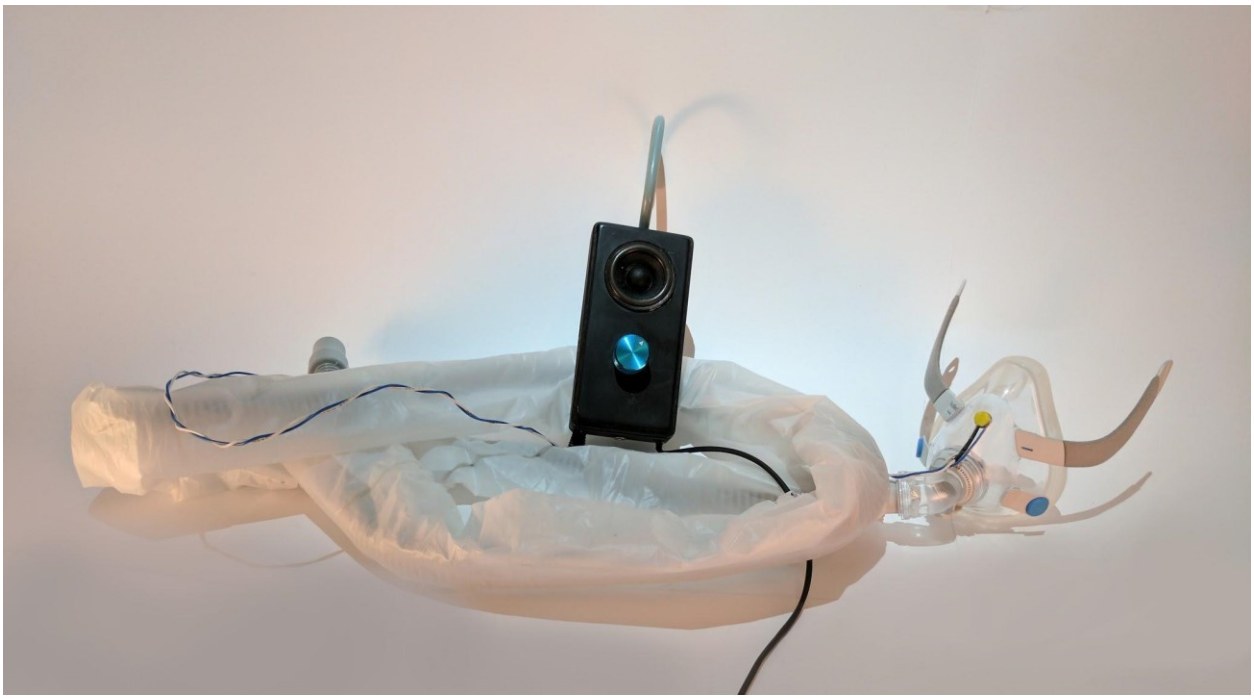
Non-invasive positive pressure ventilation (NIPPV) is a crucial tool used to treat respiratory distress and failure, especially in acute exacerbations of COPD. [1] Approximately 15-24 million US citizens have COPD. [2,3] Of these patients, acute exacerbations of COPD accounted for almost 700,000 hospitalizations in 2010, and are expected to increase annually. Exacerbations are dangerous - with mortality rates ranging from 2.5% to 28%, depending on severity - and expensive - with costs contributing to the $32.1 billion spent annually on COPD. [3,4]

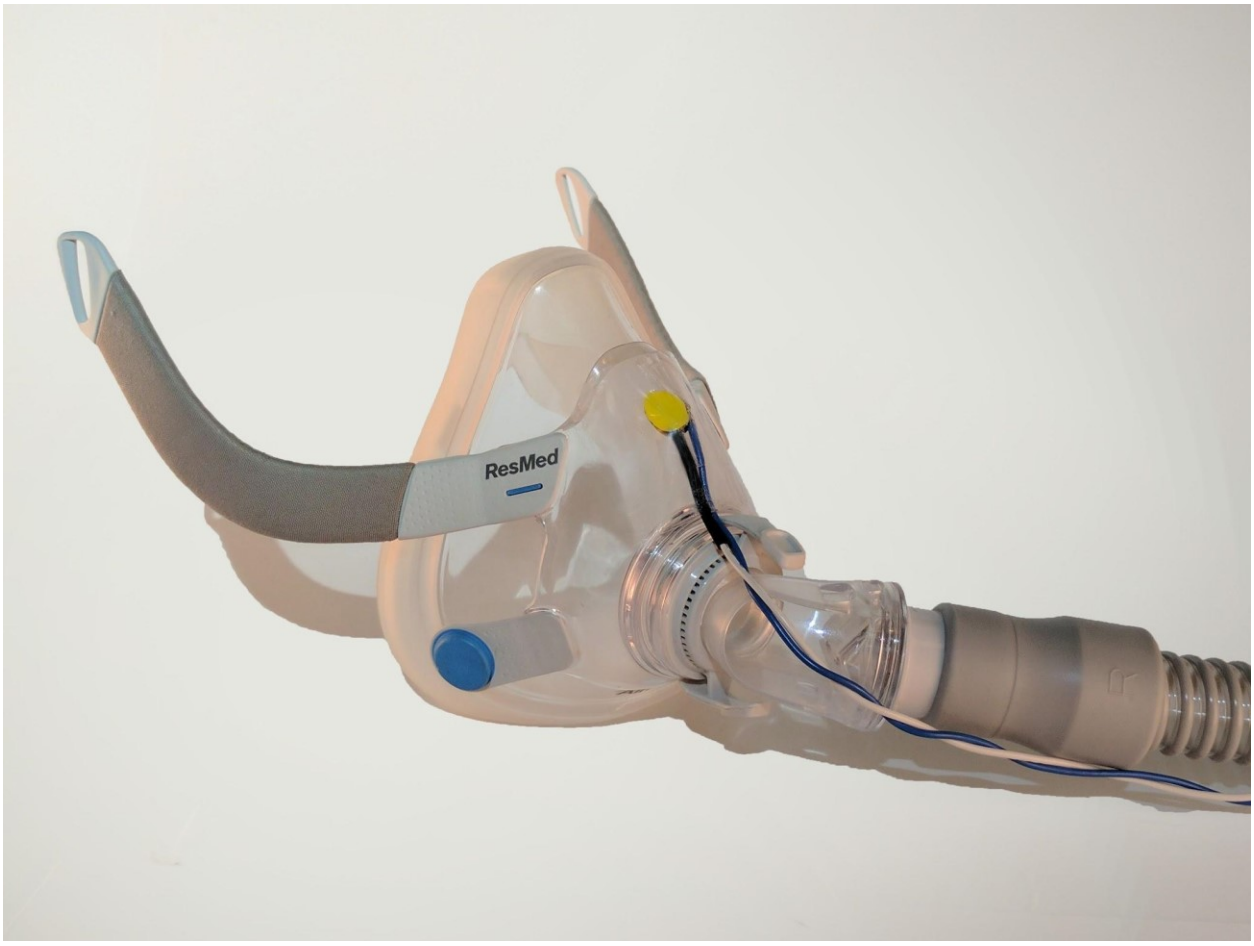
Current medical practice acknowledges that treating respiratory distress and preventing respiratory failure is a paramount concern. Given the nature of the NIPPV mask, communication impairment is a commonly accepted sacrifice to maintain a patient's respiratory condition. Anecdotally, the history and physical examination of a new patient comprises the majority of the data gathering necessary for making medical decisions. Communication is critical to providing context.

However, there is a growing body of work that indicates that limited communication can both increase length of stay and readmission rates. We can extrapolate such information from studies of communication limitations due to language barriers. For patients with language barriers, a 3-year retrospective study indicated that the absence of a professional interpreter on just admission and discharge alone significantly increased length of stay by 1.5 days and readmission rates by 63% (absolute increase 9.4%). [5]

We will therefore study the benefit that improved communication can provide for patients on

NIPPV.





4. Study Design

This is a single-blinded, randomized control trial.

The device tested will be referred to as a "communicator".

Every patient will be consented. If accepted, we will proceed. Each patient's partner will also be consented. Demographics, including age, race, duration of BPAP/CPAP therapy, will be collected at this time.

Block randomization will be used with variable block sizes of three and six. This guarantees that the 2:1 ratio is closely maintained throughout the trial. Sealed envelopes will be utilized, with "disable" being the placebo and "enable" being the treatment. The subjects are numbered from 1 to 42. If we randomize only 30 subjects, we will have 20 enable and 10 disable. If we have 30 subjects, then the power is 70%.

One interim analysis will be undertaken after fifteen subjects are evaluated for the primary pre-post outcome. The O'Brien-Fleming stopping rule will be used with a Type I error rate of 0.05.

Based upon the randomization envelope, we will randomize patients to the communicator or no-communicator arm. The study consenter will turn the device on if randomized to the

communicator and disable the device if randomized to the no-communicator arm. In both situations, the device will appear outwardly similar (i.e. power lights will still appear to be on).

The study will be conducted in three phases:

without the mask on, and

with the mask on and without the communicator attached, and

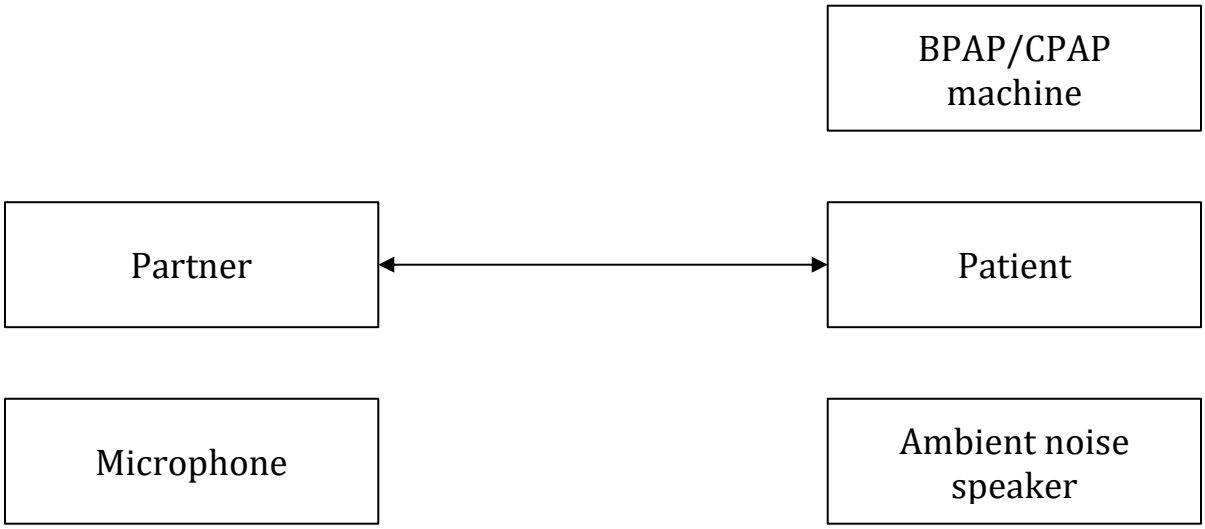
with the mask on and with the communicator attached.

We will recruit patients with both full face mask and nasal mask.

All patients will be issued a single-use hose and full face mask for the duration of the study. Mask fit will be determined by standard templates.

For all patients for the duration of the trial, we will provide a constant pressure of 10 cm H2O when on NIV.

We may, at our discretion, provide the CPAP/BPAP machine for the duration of the study.



The study coordinator will first instruct the patient on the study protocols. The patient and the partner will be seated a pre-specified distance from each other in a room. The patient and partner will be informed that the entire session will be recorded, and the microphone will be placed close to the partner. A speaker playing standard ICU background noises at a fixed volume will be placed near the patient. [6]

A list of single words and 5-word through 15-word sentences will be provided to the patient. Each single word may be read aloud up to two times. The partner must then select the read word out of a list of twelve possible words. Each sentence may be read aloud up to two times. The partner must transcribe each sentence on a standardized form. A survey will be provided to

evaluate the "mask off" period.

The patient will then put on the BPAP/CPAP mask, without the communicator attached.

Patients will be asked to speak normally with the same volume and effort they used when they were speaking without the mask on. Patients will have a trial period where they can read through single words and sentences. During this period, a study coordinator may show a sign to remind patients that they should not speak louder or overpronounce and overenunciate words.

A list of single words and 5-word through 15-word sentences will be provided to the patient. Each single word may be read aloud up to two times. The partner must then select the read word out of a list of twelve possible words. Each sentence may be read aloud up to two times. The partner must transcribe each sentence on a standardized form. A survey will be provided to evaluate the "mask on, communicator off" period.

The communicator will then be attached to the BPAP/CPAP mask. The study coordinator will either enable or disable the communicator, based on the randomization arm. A new list of single words and 5-word through 15-word sentences will be provided to the patient. The protocol will remain the same. Each single word may be read aloud up to two times. The partner must then select the read word out of a list of twelve possible words. Each sentence may be read aloud up to two times. The partner must transcribe each sentence on a standardized form. A survey will be provided to evaluate the "mask on, communicator on" period.

The audio recording will then be stopped.

At the end of this period, we will collect the communications devices. The survey collection will be optimized by medical record labels affixed to the surveys.

Audio recordings will be then evaluated by impartial judge(s), again graded for both single word and sentence readings. Once the data has been collected, the dataset will then be de-identified and stored for further analysis.

5. Study Population

a) Number of Subjects

The study intends to include approximately 30 volunteer subjects in a 2:1 assignment, across all hospital systems. This study is intended to be held at Grady Memorial Hospital / Emory University Hospital / Emory Midtown / Executive Park 12 (Brain Health).

b) Inclusion and Exclusion Criteria

Inclusion

Patients must be receiving BPAP/CPAP therapy in the outpatient setting (e.g. clinics, sleep centers).

Exclusion

Patients cannot be intubated or have a tracheostomy.

No vulnerable populations will be included (children, decisionally impaired adults, and prisoners).

Patients cannot have speech disabilities, or reading disabilities, dyslexia.

Partners cannot have speech disabilities, hearing disabilities, reading disabilities, or writing disabilities.

English must be their first language.

c) Vulnerable Populations

1. Children: will be excluded
2. Pregnant women: will be included given minimal risk
3. Decisionally impaired adults: will be excluded
4. Prisoners: will be excluded

d) Setting

Recruitment, consent process, and equipment administration will be performed by study coordinators or study staff at each location.

Initial data collection will be performed by study staff. Study staff may also participate in blinded data evaluation.

Emory/Grady will not be the coordinating center for any activities.

All sites will rely on the Emory IRB as a first IRB review. Each location will have their own research committee for further review.

Grady

We will apply to the Grady research oversight committee.

Emory Healthcare

We will apply to Emory research administration.

e) Recruitment Methods

Patients will be recruited from clinics involved in BPAP/CPAP therapy. Potential subjects will be identified by their use of BPAP/CPAP therapy as a form of NIPPV. We will advertise by posting signs in clinic rooms and waiting rooms. Additionally, a study staff member may approach

patients waiting in the clinic rooms to inform them about the study. Finally, a study staff member may call patients scheduled for upcoming appointments. Subjects (patients, family/friends, staff) will be asked to volunteer. We will offer $25.00 to each patient and partner in compensation ($50.00 total for each pair) in cash after completion of the full study protocol. The price of the communicator will be covered by Ataia, Inc. The devices will remain the property of Ataia, Inc. and will not be given to the patients.

f) Consent Process

Consent will be obtained upon arrival and agreement to participate in the study. Consent will be confirmed via the patient's or partner's signature on the consent form. The subject will be given an explanation of how the device is used and the benefits of participating in the study. The patient will be informed that if at any time they revoke consent, to inform the physician, respiratory therapist, nurse, or study coordinator.

6. Procedures

1. Patient is treated by a sleep specialist with BPAP/CPAP.
2. Study information and informed consent provided.
3. If accepted, a study communications device will be attached to the BPAP/CPAP machine.
    a. The standard of care does not have any kind of communications device attached to the mask. At the discretion of the clinical staff, communication boards or white boards may be provided.
    b. There are two separate arms in this study. The patient will be randomly assigned:
        i. to receive a non-functioning study communications device.
        ii. to receive a functioning study communications device.
4. All patients involved in the study will have their medical record number recorded for further chart review.
5. The patient and partner will be briefed by the study coordinator. Patient and partner demographics data will be collected at the time of consent.
6. The patient will meet with study staff to conduct the trial.
    a. Study coordinator will calibrate ambient speaker to desired loudness, as measured by decibel meter. Study coordinator will also calibrate other equipment for the trial.
    b. Patient and partner will be situated in a standard setting. A microphone will be set up adjacent to the partner.
    c. Example words and sentences will be provided to the patient and partner to practice protocol. No post-example survey will be provided at this stage.
    d. Words and sentences will be provided to the patient and the partner to learn how intelligible the patient is at baseline, without the BPAP/CPAP mask on. The patient will read each of the words and sentences - at most twice total - and the guest will attempt to either identify or write down what is heard.
    e. A survey will be provided to evaluate the "mask off" stage

f. The patient will then wear the BPAP/CPAP mask without the communicator and turn on the BPAP/CPAP machine. Patient will be instructed to use their home settings.
g. Patients will be asked to speak normally with the same volume and effort they used in the mask off phase.
h. The partner will subsequently ask the patient to read a new set of trial words and sentences, with the partner again trying to identify or write down the spoken content. During this period, the study coordinator will show a sign to the patient to remind them to avoid overenunciating or overpronouncing words, and to avoid raising their voice.
i. The patient will subsequently read a new set of words and sentences, with the guest again trying to identify or write down the spoken content.
j. A survey will be provided to evaluate the "mask on, communicator off" stage
k. The patient will then wear the BPAP/CPAP mask, with the communicator attached.
l. The patient will subsequently read a new set of words and sentences, with the guest again trying to identify or write down the spoken content.
m. A survey will be provided to evaluate the "mask on, communicator on" stage

7. Chart review of the patients.
8. Study judges blinded to the phase and study arm will transcribe the recorded audio.

7. Data and Specimens

Sharing of Results with Subjects

No lab tests or genetic tests will be performed. Study results will not be shared with subjects or their providers.

8. Data Analysis

Two-tailed parametric tests will be performed on the de-identified data to compare each arm to determine superiority. The primary goal of this study is to determine effect size and observe device usage.

Likert scales will be compared across patients and partners using a nonparametric test.

Randomization

Block randomization will be used with variable block sizes of three and isx. This guarantees that the 2:1 ratio is closely maintained througout the trial. Sealed envelopes will be utilized, with "disable" being the placebo and "enable" being the treatment. The subjects are numbered from 1 to 42. If we randomize only 30 subjects, we will have 20 enable and 10 disable. If we have 30 subjects, then the power is 70%.

Interim analysis

One interim analysis will be undertaken after fifteen subjects are evaluated for the primary pre-

post outcome. The O'Brien-Fleming stopping rule will be used with a Type I error rate of 0.05.

9. Privacy, Confidentiality and Data Security

All subjects will be assigned a study ID. Subject forms will be organized with medical record stickers for ease of use. Data collation and chart review will then be performed by authorized personnel.

During chart review, we will gather relevant clinical history, including but not limited to previous diagnoses (especially COPD or asthma), duration of BPAP/CPAP therapy, and any factors that may impair patient communication. Additionally, incidental relevant possible or probable complications will be recorded.

Once data collation and chart review has been completed, the data shall be de-identified and referred for statistical analysis.

All data will be encrypted, regardless of identified or de-identified. Certificates of confidentiality and other paperwork shall be stored in a secured location by authorized personnel.

10. Risks and Benefits

a. Risks to Subjects

This study involves a new device that assists in communication for patients requiring BPAP/CPAP, and does not disrupt the function of the BPAP/CPAP. The device will not be in direct contact with the patient. Based on its design, it is unlikely to interrupt BPAP/CPAP functionality. There are no additional lab tests or imaging that should be required to participate in this study. There may be other risks, discomforts, and side effects that are not yet known.

It is unlikely that a survey will pose any risk. It is further unlikely that recorded audio of provided words and sentences will pose any risk.

Chart review will be performed by approved personnel to further quantify side effects. Reviewed data will be de-identified prior to further analysis.

We will provide a mask and hose to the patient for the duration of this trial. It is unlikely that a standard single-use CPAP/BPAP mask will pose any risk for the duration of the trial.

For the duration of the trial, we will provide a constant pressure of 10 cm H2O when on NIV. It is unlikely that this pressure will pose any risk for the duration of the trial.

The patch, designed to adhere to the mask, is also designed to be completely removable within the first 8 hours after application. We will be able to remove any unwanted adhesive residue. In

the event that the patient's mask is unable to function in the original condition once the patch is removed, as per determined by the study staff, we will be able to replace the mask.

i. Adverse events

In the event that an adverse event occurs, the study staff conducting the experiment will record the circumstances. These forms will be submitted to the co-investigator and/or PI for review. Adverse event forms will be reviewed weekly.

These forms will also be sent to the Ataia Medical Quality officer.

b. Potential Benefits to Subjects

Taking part in this research may, if on the intervention arm, potentially benefit the patient and those interacting with the patient by facilitating communication. If assigned to the control arm of the study, there may be no direct benefit to the patient from taking part in this study. However, this research study may help us learn new things that may help patients in the future.

11. Disclosures

Dr. Wong has developed IP that has been released to Ataia Medical, a company interested in further developing the IP that is the subject of this publication. Dr. Wong serves as Chief Medical Officer and has ownership interests in Ataia Medical. The terms of this arrangement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.

References

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