Research Protocol

Randomised controlled trial on the efficacy of Audio-visual Health Educational materials on CPAP ADherence: The ADHEAD trial

Principle Investigators:
Dr Chinthaka Samaranayake, MBChB, Sleep medicine advanced trainee
Department of Respiratory and Sleep Medicine, Princess Alexandra Hospital
Email: chinthaka.samaranayake@health.qld.gov.au. Telephone: 07 3176 2698

Dr Claire Ellender, BSc, MBBS, FRACP, Respiratory and Sleep Physician
Department of Respiratory and Sleep Medicine, Princess Alexandra Hospital
Email: Claire.ellender@health.qld.gov.au. Telephone: 07 3176 2698

Mr Brett Duce, Scientific Director
Sleep Disorders Centre, Princess Alexandra Hospital
Email: Brett.Duce@health.qld.gov.au. Telephone: 07 3176 5751

INTRODUCTION

Sleep disorders, particularly obstructive sleep apnoea (OSA) are common conditions amongst the Australian adult population; over 10% of Australian men over aged 45 years have OSA and associated symptoms[1]. OSA is clinically defined as repeated episodes of obstruction of the upper airways during sleep resulting in sleep fragmentation, non-restorative sleep and daytime symptoms such as increased daytime sleepiness, daytime napping and poor mood. As such, sleep disorders are associated with significant cost burden to the Australian economy; OSA is estimated to cost $2.6 billion annually through lost productivity, mortality and absenteeism[1]. Of great significance is the 2-3 fold increase in all-cause mortality amongst individuals with severe untreated OSA[1].

The treatment of choice for moderate to severe OSA is continuous positive airway pressure (CPAP)[2]. By producing a continuous flow of positive airway pressure via a mask, airways that would otherwise obstruct in OSA remain patent. CPAP treatment has a well-established benefit in improving daytime somnolence, motor vehicle accidents risk and quality of life. Compliance with CPAP therapy however remains a challenge for many sleep physicians and their patients. Adherence to the recommended 4 hours or more a night on CPAP amongst individuals with OSA ranges from 40-60%[3]. CPAP compliance success depends on the balance between symptoms, perceived risks of negative outcomes, perceived barriers and perceived benefits[3]. Many of these factors can be optimised through patient education.

Health Literacy is a multifaceted concept defined as 'The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions[4]. In the USA it is estimated that only a third of adults have basic health literacy[4] and similarly only about 40% of adult Australian's have adequate health literacy[5]. Low individual health literacy is associated with higher rates of hospitalisation, emergency care, and adverse health outcomes [6].

A recent pilot project was conducted at the Princess Alexandra Hospital in 2018 to evaluate the Health Literacy of our Sleep Disorders Clinic patients. The results of this pilot study demonstrated in a sample of 101 patients using internationally validated questionnaires, 28% had inadequate health literacy and 37% had no further education beyond grade 10 (unpublished data). Of our cohort, 40% reported they do not always feel confident completing medical forms, and 31% do not always feel confident reading medical information themselves. These results are in keeping with the only other available Australian data[6].

Within the pilot project performed at the Sleep Disorders Clinic at Princess Alexandra Hospital, a needs analysis was included. This questionnaire asked patients their preferred method of health education delivery. A total of 64% of the 101 patients who participated reported they would like health information regarding their sleep disorder to be made available in an online video format. Similarly 64% reported that they can easily access video streaming sites such as Youtube® and 79% of our cohort reported having access to the Internet at home or on a mobile device (unpublished data).

With this information, a novel idea has been formed to evaluate whether the development and implementation of audio-visual health information can improve the sleep-specific health literacy and CPAP usage in our Sleep

Disorders Clinic patients. There have been very few trials in this area previously and thus far with negative results[7]. This novel study aims to ~~for the first time in an Australian setting,~~ randomise patients to an intervention group who watch audio-visual sleep health information or standard of care, for the first time in an Australian setting. CPAP adherence and health literacy will be evaluated to assess the ~~effect~~ efficacy of the new informational style in improving sleep related health outcomes.

RESEARCH QUESTION

Does additional health information delivered with audio-visual videos improve CPAP uptake and adherence in patients with OSA?

HYPOTHESIS

Delivery of health information with audio-visual sleep health information in the form of five video clips will improve CPAP uptake and adherence in patients with OSA.

STUDY AIM

This study aims to determine whether audio-visual sleep health information in the form of five video clips improves CPAP uptake and adherence in patients who attend a public sleep disorders clinic.

Aim 1 – To compare the CPAP uptake of patients who have watched sleep educational materials compared with standard of care over a 2-month and 12-month period.

Aim 2 – To compare the CPAP adherence of patients who have watched sleep educational materials compared with standard of care over a 2-month and 12-month period.

INTERVENTION

Five short audio-visual clips have been developed by the Department of Respiratory and Sleep Medicine.

Video	Topic and general content
1 – About ~~Obstructive~~ obstructive ~~Sleep~~ sleep apnoea	Introduction to the symptoms, initial consultation with GP and referral process to sleep specialist services
2 – About the sleep study	Review of the preparation needed for attending a sleep study and what is involved
3 – Accessing the Qld Health Sleep Disorders Program	Requirements and processes for qualifying for a Queensland Government funded CPAP machine
4 – What is CPAP and how does it work	Discussion of the indications, benefits and pitfalls of CPAP therapy
5 – CPAP trouble shooting	How to care for your equipment and ~~what~~ how to ~~do~~ deal with common device troubles such as mask leak

METHODS

Study Design: A prospective randomised control trial will be performed.

Participants and setting:

The Sleep Disorders Centre (SDC) holds multiple sleep medicine clinics that occurs in the 2F Respiratory and Sleep Medicine outpatient department at Princess Alexandra Hospital (PAH). Patients are referred from primary care physicians or other medical specialists drawing from a vast geographic catchment throughout Queensland and northern New South Wales. The clinic averages an attendance of ~45 patients per week and is run 45 weeks of the year.

Recruitment:

All treatment naïve new case sleep patients attending the SDC will be invited to participate. The sleep laboratory administration staff will send out a study information flyer with the standard appointment confirmation letters. This flyer will invite treatment naïve new case patients to participate in the study. Patients interested will be invited to participate at the end of their initial sleep consultation and provided the Patient Information and Consent Form (PICF) to take home and consider. Additionally as part of the standard telephone confirmation process prior to upcoming sleep students, sleep laboratory administration staff will offer the option of participation in the trial. Within the sleep database their details will be added to the research participation log.

Study procedure:

When eligible patients return to the sleep laboratory for their CPAP initiation sleep study, consent will be obtained by a research sleep scientist appointed as part of the study. At this point participating patients will be randomised to either Group 1 “Standard of care” or Group 2 “audio-visual clips”. Sealed envelopes containing cards method will be used. Equal number of cards for each arm will be placed in opaque envelopes. The envelopes will be placed in a box in a locked cupboard in the sleep laboratory. An independent staff member of sleep laboratory will pick an envelope after consenting the patient.

For patients in Group 1 “Standard of Care” education will be provided at night by the sleep scientists according to standard laboratory policy and procedures. This includes a two-page written patient handout about the study and OSA. The following morning, a sleep physician will review the patient’s data and counsel them on the results to implement a management plan (as per standard of care).

For those participants in Group 2 “Audio-visual clips” following their usual sleep study set up, with education from the night sleep scientific staff, a computer will be provided with Video 1 and Video 2 loaded, with assistance from the sleep scientists to play the video. The following morning, the reviewing Sleep Physician will perform data and interventions as standard of care. The participating patients will stay in the laboratory for an additional 20 minutes to watch video 3, 4 and 5.

As standard of care, participants from both arms will return to the laboratory and outpatient clinic at 2 months and 12 months following their studies for review of their CPAP machine. At these times CPAP uptake and adherence and Epworth Sleepiness Score questionnaire will be collected, as standard of care in both arms.

Inclusion and exclusion criteria:

Inclusion criteria

- All treatment naïve patients attending Sleep Disorders Clinic for sleep studies with suspected or proven obstructive sleep apnoea who able to provide informed consent.
- Adult patients (18 years and older).

Exclusion criteria

- Those unable to provide informed consent.
- Patients from non-English speaking background, as video clips will only be provided in English initially.
- Patients less than 18 years old.

Power calculation:

Previous studies have estimated a sample size of 200 patients are required to detect a 1 hour per night increase in CPAP adherence. Assuming an SD of 2.5 hours based on previous observational data and power of 80%, with a two-sided significance level of 0.05, the estimated total sample size is 208 patients[11].

End points:

Primary Outcome

The primary outcome of this study is to determine CPAP adherence (hrs) in both standard of care and audio-visual arms at 2-months and 12-months. CPAP counter metres are present in all modern CPAP devices. This is a tamper-proof method whereby machine usage hours are detected by in-device computers and is usually downloaded at clinic follow up.

Secondary Outcomes

- Non-scheduled sleep scientist time (phone calls and clinic consultation) measured in minutes. The Sleep Disorders staff at the Princess Alexandra Hospital already routinely collects this information via the Sleep Disorders database. The Study Co-ordinator will obtain this from the sleep database at 2-months and 12-months.
- CPAP therapy uptake at 2-months and 12-months.

Data collection

Data collection method and storage

A research sleep scientist and the principal investigator Dr Samaranayake will carry out all data collection. All data collected will be de-identified and no personal details of patients will be collected as part of this study.

Data will be collected on to a Microsoft Excel file which will be password protected. The collected data will be stored on a secure Queensland Health computer located at the Department of Respiratory and Sleep Medicine at Princess Alexandra Hospital.

As per the requirements stated in the Australian Code for the Responsible Conduct of Research, the data will be securely stored for 15 years from the date of completion of the project. If the principle investigator moves on from Queensland Health in that time period, access to the data will be provided to the senior associate investigator.

Data variables

Both groups will have demographic data and a number of internationally validated questionnaires (Epworth Sleepiness Score, quality of life questionnaires, insomnia questionnaires and depression questionnaires) and OSA diagnostic information collected at recruitment and the follow-up periods as outlined above; all of which is current standard of care. CPAP uptake and adherence data will also be downloaded from the CPAP machine and entered into the Sleep Disorders database as per usual practice, and collected as part of the study at the follow-up times.

Analysis

Statistical analysis plan:

The analysis will be carried out on an intention-to-treat principle. Estimated frequencies and proportions for the variables will be calculated in descriptive analysis. The Chi-Squared test will be used to compare the rates and t-test to compare means. The threshold for statistical significance will be established at 5%. Data quality will be assessed after data collection and potentially inform the analytical methods. The analyses will be carried out using Statistical Package for the Social Sciences version 24 (SPSS for Windows, IBM Corporation, Somers, NY, USA).

RISKS

There are no extra risks or disadvantages to patients by taking part in this study. Patients may be requested to stay an extra 30 minutes after their sleep study to watch the videos and complete a questionnaire. Rest of the management is all part of standard care.

TIMELINE

Expected start date: April 2019
Recruitment phase: 12 months
Expected completion date: April 2020

RESEARCH OUTPUTS

Results of this study will predominantly be distributed to the clinical staff involved in immediate care of patients with obstructive sleep apnoea through departmental presentations and internal reports. The results may also be presented at conferences and published in peer reviewed journals relevant to the field.

REFERENCES

1. Reawakening Australia: The economic cost of sleep disorders in Australia. . Sleep Health Foundation, 2011. (Accessed September 2015, at http://www.sleephealthfoundation.org.au/pdfs/news/Reawakening Australia.pdf.)
2. Australasian Sleep Association. Best Practice Guidelines for Provision of CPAP therapy2009.
3. Zozula R, Rosen R. Compliance with continuous positive airway pressure therapy: assessing and improving treatment outcomes. Current Opinion in Pulmonary Medicine 2001;7:391-8.
4. Kutner M, Greenberg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy (NCES 2006–483). Washington, DC: U.S. Department of Education; 2006.
5. Australian Commission on Safety and Quality in Health Care. Health literacy: Taking action to improve safety and quality. Sydney: ACSQHC,; 2014.
6. Li JJ, Appleton SL, Wittert GA, et al. The relationship between functional health literacy and obstructive sleep apnea and its related risk factors and comorbidities in a population cohort of men. Sleep 2014;37:571
7. Guralnick AS, Balachandran JS, Szutenbach S, et al. Educational video to improve CPAP use in patients with obstructive sleep apnoea at risk for poor adherence: a randomised controlled trial. Thorax 2017;72:1132.