Submitted in partial fulfilment of the Lancaster University Doctorate in Clinical Psychology

Doctoral Thesis

June 2024

The Relationship Between Sleep Apnoea and Psychological Distress

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Statement of Word Count

Thesis Section	Main Text	Appendices (including tables, figures, and references)	Total
Thesis Abstract	300	-	300
Literature Review	8,000	9,482	17,482
Empirical Paper	8,000	7,162	15,162
Critical Appraisal	4,000	2,404	6,404
Ethics Section	5,449	8,538	13,987
Total	25,749	27,586	53,335

Thesis Abstract

The reciprocal relationship between sleep and mental health is well-recognised. Yet, research in this area remains scarce, and as a result, clinical practice often overlooks this association, particularly in the context of sleep apnoea. Therefore, this thesis aimed to clarify the psychological implications of sleep apnoea and explore the barriers to treatment from a psychological perspective.

Section 1 is a scoping review of the current literature documenting an association between sleep apnoea and suicidality. Twenty-four papers were reviewed. Articles were included irrespective of quality, to provide a broad overview of the evidence-base. The review suggested an increased risk of suicidality in individuals with sleep apnoea and suggested preliminary evidence for the importance of continuous positive airway pressure (CPAP) in reducing this. The findings underscored the need for clinical psychologists to monitor mental health in individuals with sleep apnoea. Additionally, the review emphasised current gaps within the literature and provided a focus for future research.

Section 2 is an empirical research study investigating the impact of psychological distress on adherence to CPAP in people with Obstructive Sleep Apnoea (OSA). The first 28-days of CPAP usage of 47 individuals with OSA were monitored. Participants completed questionnaires measuring depression, anxiety, stress, and claustrophobia. Regression analyses revealed that depression was predictive of both frequency, and duration of CPAP usage. The findings suggest the importance of targeting psychological distress in interventions designed to improve CPAP adherence. However, the small sample size limits the findings; thus, future research is necessary.

Section 3 is a critical appraisal and summary of the review and empirical paper. Ethical issues and challenges experienced throughout are discussed, in addition to avenues for future research. Consideration is given to the under estimation of sleep, and the complex

relationship that exists between sleep apnoea and psychological distress brought to light by this thesis.

Declaration

This thesis presents work undertaken for the Doctorate in Clinical Psychology at Lancaster University. No portion of the work has been submitted to support an application for another degree or academic award. The work submitted is my own except where due reference has been made.

Signature: *J. Grayling*

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Date: 21st June 2024

Acknowledgments

Firstly, I would like to thank all of the people who kindly took their time to participate in this research project. Your willingness to take part, despite the lack of guaranteed reimbursement, demonstrated your good-will, and your motivation to contribute towards research within this area. I am grateful to each of you for your valuable contribution. I would also like to express my gratitude to Dr David Jones, who kindly aided with recruitment throughout this project. This thesis would not have been possible without you.

I would like to extend my thanks to my supervisors, Dr Katy Bourne and Dr Guillermo Perez-Algorta, for their passion, expertise, guidance, and invaluable advice throughout this journey. This project has had its complications and I am very grateful to you both for your kindness and support during challenging and emotional times.

A special thank you to my family for continuously helping me whenever, and however possible, and for their continued support and encouragement throughout the last three years, and always. I know I would not be where I am today without your unwavering love and faith in me. To my partner, Josh, for helping me throughout the entire doctorate. Thank you for always being there for me, for being patient and understanding, for motivating me when I needed it, and for always knowing how to make me smile when things have been tough. Lastly, I'd like to thank my brother, Dr Michael Grayling, who has helped me throughout. Thank you for answering my countless questions, and for all the proofreads, often at the drop of a hat, and even with two babies to look after! I genuinely cannot thank you all enough.

Contents

Section 1 : Literature Review

The Relationship Between Sleep Apnoea and Suicidality: A Scoping Review

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Prepared in accordance with author guidance for the journal *'Sleep'*

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Abstract

Study Objectives

The association between sleep difficulties and suicide has long been recognised. With suicide a major public health concern, much literature has attempted to determine the underlying mechanisms driving the relationship. One aspect that has been explored more recently is the role of sleep apnoea. A systematic scoping review was conducted to establish current knowledge and guide future research.

Method

PsycINFO, MEDLINE, CINAHL, and EMBASE databases were systematically searched. Studies investigating the association between sleep apnoea and suicidality were included irrespective of their methodological type or quality to ensure a comprehensive summary of the existing knowledge base and to highlight limitations and gaps. A narrative synthesis was conducted.

Results

Twenty-four papers were analysed. Current literature has investigated the risk and prevalence of suicidality in people with sleep apnoea, suicidality following a diagnosis, factors that affect the relationship, and the impact of treatment. Findings suggest individuals with sleep apnoea are at risk of suicidality. There is preliminary evidence for the benefits of treatment in reducing this risk.

Conclusions

This review provides a comprehensive assessment of present knowledge on the relationship between suicidality and sleep apnoea. Discussed key limitations and gaps in the current literature provide guidance for future research and systematic reviews. The findings suggest important implications, including monitoring suicidal ideation in people with sleep apnoea and the cruciality of clinical psychologists' involvement in sleep apnoea care, such as the

delivery of the diagnosis, and the design and implementation of interventions to improve adherence to sleep apnoea treatment.

Keywords: sleep, obstructive sleep apnoea, OSA, suicidality, scoping review

Financial disclosure: None

Non-financial disclosure: None

Introduction

Sleep apnoea is a sleep related breathing disorder (SRBD) and an umbrella term for disorders that cause frequent pauses in breathing during sleep. [1] The two main types of sleep apnoea are obstructive sleep apnoea (OSA) and central sleep apnoea. [2] Due to repeated awakenings, sleep if often disrupted. [3,4]

Disrupted sleep has been linked to changes in mood, [5] impacted daytime functioning, [6] impaired neuropsychological functioning, [7] dementia, [8] and many physical health conditions, including diabetes [9] and cardiovascular diseases. [10] Additionally, an association has been found between sleep problems and almost all psychological difficulties, [11] including anxiety [12-14] and depression. [15-17] Whilst sleep problems were originally thought to be a symptom of mental health difficulties, [18] there is growing research to suggest a bi-directional causation, with sleep disturbances also potentially playing a role in the development of psychological distress. [19-21] This suggests that improved sleep may prevent the onset of mental health conditions.

Suicidality comprises of suicidal ideation, suicide planning, suicide attempts, and suicide deaths. [22] Being one of the leading causes of preventable death, suicide is a pressing public health concern, [23] responsible for around 700,000 deaths each year. [24] Critical to reducing this is the identification of probable causes and risk-factors. Given suicidality is closely related with mental health, [25, 26] research has investigated its relationship with sleep. Several reviews have documented an association between disrupted sleep and suicidality. [27-31] Crucially, sleep difficulties predict suicide over and above other known predictors such as depression, [32] and appear to precede suicidality, rather than suicidality resulting in sleep problems. [33]

Unlike other risk-factors for suicide (e.g., age, gender), sleep disturbances are modifiable, [34] and thus targeting sleep could aid suicidality interventions. [35] As such, it

is imperative to enhance understanding of the link between sleep disturbance and suicidality by identifying the aspects of sleep disturbance that underlie the relationship. [36] Studies attempting to understand the association have found insomnia, [37, 38] nightmares, [39, 40] sleep onset, [41] sleep duration, [42, 43] and sleep quality, [44, 45] to influence suicidality. However, a 2016 review, examining the association between sleep difficulties and suicidality noted a lack of studies exploring the relationship between suicide and sleep apnoea. [28]

OSA is the most common type of sleep apnoea, [46, 47] impacting around one billion people globally. [48] OSA is characterised by repeated partial or complete collapses of the upper airway during sleep, resulting in disrupted sleep. [3, 4] As with general sleep disturbances, research has documented an association between OSA and mental health difficulties, including anxiety [49, 50] and depression. [51, 52] Additionally, since the 2016 review, [28] there appears to have been an increase in studies investigating the relationship between OSA and suicidality. For example, recent studies have documented OSA to be associated with an increased risk of suicidal ideation, suicide attempts and death by suicide. [53, 54]

There are numerous potential explanations for this association. From a psychosocial perspective it would be reasonable to assume that the sleep disruption and excessive daytime sleepiness (EDS) caused by sleep apnoea may hinder a person's abilities to engage in activities such as hobbies and social situations. Understandably, this may impact relationships, reduce social support, and limit valued action which could negatively influence mood. [55, 56] Conversely, as aforementioned, sleep apnoea confers higher risk for other physical health conditions including obesity, diabetes, and cardiovascular diseases, [9, 10, 57] and is more prevalent in men than women. [58] Given all these factors have been found to convey increased risk of suicidality, [59-62] it could be that the link between sleep apnoea

and suicidality is in some way mediated by the biopsychosocial impact of these co-morbid conditions, as opposed to sleep disruption alone.

Continuous Positive Airway Pressure (CPAP) therapy is considered the gold standard treatment for OSA. [63] By generating a continuous positive pressure to prevent the collapse of airways during sleep, [64] CPAP is effective in treating symptoms of OSA, such as EDS. [65, 66] Significantly, depression and quality of life in patients with OSA have also been found to improve when CPAP is utilised. [67-70] As suicidality is strongly linked to depression [71, 72] and quality of life, [73, 74] it is possible that CPAP may also reduce suicidality, which could contribute towards further research that may result in targeted interventions for suicidality.

Accordingly, this scoping review aims to collate the current evidence on the association between sleep apnoea and suicidality. It is hoped this will shed light on a potential relationship, identify current evidence gaps, and guide future research, to improve existing knowledge.

Method

Pham et al. [75] emphasise the importance of choosing a review approach suited to the aims, and topic of choice. Scoping reviews use a systematic approach to synthesise an emerging body of literature. [76] They aim to "map the literature on a particular topic or research area and provide an opportunity to identify key concepts; gaps in the research; and types and sources of evidence to inform practice, policymaking, and research". [78, p8] Scoping reviews are particularly suited when a topic has not been studied extensively and is heterogenous in nature. [79-81]

As recommended, a preliminary search of the literature was conducted [82] and revealed numerous studies examining the relationship between suicidality and sleep apnoea. However, a range of aims, designs and methodologies were noted. As such, a scoping review

was suited to examine the extent of the research and to present an overview of the findings whilst identifying gaps within the literature. [83-85]

Scoping reviews should be rigorous, transparent, systematic, and reproducible. [79, 86, 87] The use of frameworks and checklists increases transparency and allows the reader to judge reliability. [78] Accordingly, this scoping review followed the framework proposed by Arksey and O'Malley [79] and updated by Levac et al. [77] This included the following five key stages: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) charting the data, (5) collating, summarising, and reporting results. Findings are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist [85] (Appendix 1-A).

Stage 1: Identifying the Research Question

This review was guided by the following question: What is known from the existing literature about the association between suicidality and sleep apnoea? To address this question, this review sought to: (1) collate the current evidence-base for the relationship between sleep apnoea and suicidal ideation, suicide planning, suicide attempts and suicide deaths; (2) describe any potential risk-factors documented within the literature; (3) ascertain if any studies have investigated the impact of CPAP on suicidality in individuals with sleep apnoea; (4) identify gaps within the literature and opportunities for future research.

Stage 2: Identifying Relevant Studies

Date Sources and Search Strategy

Searches were conducted on 7th July 2023 in four databases: PsycINFO, MEDLINE Complete, CINAHL, and EMBASE: Excerpta Medica. The databases were chosen to cover a wide range of literature pertaining to psychology, medicine, and healthcare. A systematic search was created in consultation with a subject-specific librarian, as recommended. [81, 87, 88]

The population, concept, context framework, [89] was utilised to formulate the search, with people with sleep apnoea as the 'population', and suicidality as the 'concept'. As this review aimed to provide a broad overview of the relationship between sleep apnoea and suicidality, any 'context' was relevant. Preliminary searches, researchers' knowledge, and relevant systematic reviews informed free-text search terms. Free-text terms and subject headings were combined using the Boolean operator "OR" for the 'population' and 'concept' elements separately. The resulting 'population' and 'concept' searches were combined using the Boolean operator "AND". Results were limited to studies on humans and papers written in English. No date limits were applied. Truncations and the search syntax were tailored as appropriate for each database. Table 1 shows the full search strategy utilised in PsycINFO and Table 2 shows database specific alternatives.

Insert Tables 1-2 here

Citation Management

References were managed by Mendeley Reference Manager and duplications were removed. Remaining papers were imported to Rayyan [90] and were screened against the review criteria. Citation management ensured all references were accounted for and allowed for a transparent process.

Stage 3: Study Selection

Eligibility Criteria

The review team collaboratively developed the eligibility criteria. [77, 91] Studies were eligible for inclusion if they discussed an association between sleep apnoea and suicidality, or shed light on the relationship (e.g., risk-factors). As the aims of this scoping review were broad, no specific methodology of linking the population and concept were necessary. Both qualitative and quantitative studies were eligible for inclusion. Studies

including participants with either a diagnosis or probable diagnosis of sleep apnoea were eligible.

Scoping reviews allow for a wide range of study types [81] therefore abstracts, case studies, conference papers, and dissertations were eligible for inclusion, and papers did not have to be published in a peer-reviewed journal. As outlined by Arksey and O'Malley, [79] studies were selected for their relevance to the research question, as opposed to their methodological quality, to allow for an overview of literature.

Papers were excluded if they were (1) review articles; (2) protocols; (3) comments or responses on primary research; (4) not available in English; (5) studies including individuals with sleep apnoea and suicidality with no means of discussing a relationship; (6) studies exploring the relationship between suicidality and general sleep disturbances, or sleep disorders; (7) studies assessing the relationship between sleep apnoea and non-suicidal self-harm.

As sleep apnoea is the most common SRBD, initially, papers focusing on the association between suicidality and general SRBDs were eligible for inclusion. However, due to discovery of sufficient papers focusing specifically on sleep apnoea, the decision was made to exclude such articles, to avoid potentially including studies investigating another SRBD, which may have a differing relationship with suicidality.

Screening Process

Titles and abstracts were independently screened for relevance by two reviewers. The review team comprised of the primary researcher, and a researcher external to the research team. Full texts were then screened, and only papers that met the full eligibility criteria were included. Disagreements in either phase were resolved by discussion between the two reviewers. A third reviewer was available to resolve conflicts, if needed. There was a 99% agreement between reviewers during the title and abstract screening, and a 100% agreement

during the full text screening. Agreement percentages were derived by calculating the total number of agreements as a percentage of the total number of papers screened.

Stage 4: Data Extraction

A data extraction template was developed in Microsoft Excel. The data extracted from the eligible articles included: title, author(s), publication date, location, aims, study design, sample, methodology, method of identifying sleep apnoea, measure of suicidality, results relevant to the review questions, and limitations.

Stage 5: Data Summary and Synthesis

Data analysis was performed using the following steps. Firstly, study characteristics were summarised based on year of publication, location of study, and design of study. Next, results were summarised and presented narratively to describe the scope, nature, and outcomes of the current findings. Findings were grouped based on their means of associating suicidality and sleep apnoea. The analysis approach was chosen based on suitability to answer the research questions, alongside scoping review recommendations for data analysis and presentation. [77, 79, 85, 92]

Results

As summarised in Figure 1, 1273 articles were identified in the initial search across the databases, of which 349 were duplicates, leaving 924 unique articles. During the title and abstract screening, 884 articles were omitted, leaving 40 articles for full text screening. Of these, 17 articles were excluded (see Figure 1). The reference lists and main text of the selected papers were manually searched for relevant studies that may have been missed; one was found. The search was updated in November 2024; no new papers were identified. A total of 24 studies were included in this review. Table 3 summarises the studies.

Insert Figure 1 and Table 3 here

Study Characteristics

The papers were published from 2008 to 2023. Most studies (*n*=23, 96%) were published from 2015 onwards, and half were within the last four years (*n*=12, 50%). This suggests an increase in the study of suicidality in sleep apnoea, underscoring the timeliness of this review.

Over half of the studies (54%) were conducted within USA (*n*=9), and Taiwan (*n*=4). Other locations included Denmark, Canada, Slovak Republic, Sweden, South Korea, Tunisia, Australia, and Poland. One study did not specify a location.

The majority of studies used a cross-sectional design (*n*=14, 58%). Eight studies utilised a longitudinal design (33%) and two were case studies (8%). Most studies were quantitative (*n*=22, 92%), with the rest qualitative (*n*=2, 8%).

Tables 4-6 display descriptive statistics for the study characteristics.

Insert Table 4 here

Risk

Twelve studies investigated the association between sleep apnoea and suicidality by calculating the risk of suicidality in individuals with sleep apnoea.

Suicidal Ideation

Four of these studies investigated the risk of suicidal ideation specifically. Kaufmann et al. [93] asked people if they had been told by a medical professional that they had sleep apnoea in the past 12 months. They identified suicidal ideation through a single question. Sleep apnoea was associated with a 2.75 times increased risk of suicidal ideation. Bishop et al. [94] conducted a similar study, measuring suicidal ideation with a single question in individuals. They recorded self-reported sleep apnoea by asking participants if a medical

professional had told them they had sleep apnoea. Sleep apnoea was associated with 1.5 times the odds of suicidal ideation.

Another study assessed the risk of suicidal ideation in adolescents with sleep apnoea. Tseng et al. [95] asked adolescents if they had experienced suicidal ideation in the past week. When using the 7-item Epworth Sleepiness Scale [96] to assess OSA, students with suspected OSA had 3.25 increased odds of reporting suicidal ideation. Notably, this association remained significant after controlling for depression and perceived stress (2.25 increased odds). However, after incorporating a question about difficulty breathing whilst sleeping, to allow for a more stringent measure of OSA, the risk of suicidal ideation increased (7.38 increased odds), but this was non-significant once perceived stress and depression were controlled for.

Lastly, Silva et al. [97] investigated the relationship between suicidal ideation and sleep apnoea in individuals with a traumatic brain injury (TBI). They found no association between suicidal ideation and sleep apnoea. However, the authors questioned the accuracy of their measures as both suicidal ideation and sleep apnoea were assessed with a single self-report question.

Suicide Planning

One study investigated suicide planning. In the study by Bishop et al., [94] suicide planning was also assessed with a single yes or no question. Sleep apnoea was associated with a 1.56 increased odds of suicide planning.

Suicide Attempts

Suicide attempts were explored in five studies, with contradicting results. Chu et al. [98] conducted a longitudinal study of adults with sleep apnoea and matched controls. Sleep apnoea diagnosis was identified through the National Health Insurance Research Database (NHIRD) in Taiwan. At follow-up (at least one year after diagnosis), the database was

utilised to ascertain any suicide attempts. Individuals with sleep apnoea had an 82% higher risk of any suicide attempt and a 79% higher risk of repeated attempts than controls. Crucially, this was also true for individuals without any comorbid mental health difficulties, who had an 81% higher risk of suicide attempt and a 79% risk of repeated attempts.

Lin et al. [99] also identified suicide attempts and sleep apnoea diagnoses from the NHIRD in Taiwan. Adults with a diagnosis of sleep apnoea had an 87% higher risk of suicide attempts. Supporting this, Cheng et al. [100] conducted a similar study, with a larger sample size. An identical 87% increased risk of suicide was found for individuals with OSA compared to controls.

Contradicting this, in the study by Bishop et al., [94] previous year suicide attempt was not found to be significantly associated with sleep apnoea. However, it is noted that few individuals in the study attempted suicide, resulting in a small sample for this analysis, thus potentially influencing the ability to detect an effect. Additionally, in the study by Silva et al. [96] investigating individuals with TBIs, no association was found between suicide attempts and sleep apnoea. However, suicide attempts were also assessed with a single self-report question.

Suicide Deaths

Three studies assessed the risk of suicide deaths in sleep apnoea. Udholm et al. [54] used the Danish National Patient Registry to identify all citizens over 15 years of age who had received a diagnosis of OSA in a 20-year period. At a follow-up date, the registry was used to identify those who had died by suicide. In comparison to a reference cohort, those with OSA had a 56% increased risk of dying by suicide. Similarly, Kjær Høier et al. [101] also used the Danish Registry to identify suicide deaths and sleep apnoea in a larger sample of individuals 15 years old and above. Separating the risk by sex, they established that whilst males with OSA had a 1.2 times increased risk of suicide deaths, women had a 0.4 times

decreased risk of suicide. However, as the sample size of women with sleep apnoea was extremely low, these results should be interpreted with caution.

Contradicting this, Rod et al. [102] used the Swedish Patient Register to identify OSA and suicide deaths in individuals. In comparison to controls, men and women with OSA had a 64%, and 81% increased risk of suicide deaths, respectively.

Suicidality

Three studies investigated the relationship between suicidality and sleep apnoea, but either did not specify which level of suicidality (e.g., suicidal ideation) they investigated, or explored multiple levels combined.

Reddy et al. [103] and Reddy et al. [53] utilised samples of adults with diagnoses of bipolar disorder and major depressive disorder (MDD), respectively. Both studies utilised the national inpatient sample dataset to identify participants with a confirmed diagnosis of OSA. In those with MDD, OSA was associated with 1.27 times more odds of suicidality (suicidal ideation and suicide attempt) in comparison to those with MDD but not OSA. In the sample with bipolar disorder, OSA was associated with 1.36 times more odds of suicidality (suicidal ideation and suicide attempt) in comparison to those with bipolar disorder but not OSA. Neither study specified how suicidality was assessed.

Lastly, Singh et al. [104] measured OSA using an overnight at-home screening. Suicidality was assessed using the Mini International Neuropsychiatric Interview. No significant associations were found between OSA and suicidality. However, the authors note that few participants had ‘severe’ OSA and speculated that sleep apnoea may only be associated with suicidality in ‘severe OSA’ cases, thus impacting their ability to find an association.

Prevalence

Suicidal Ideation

Four studies investigated the prevalence of suicidal ideation in sleep apnoea. The prevalence ranged from 9.7% to 20.5%.

In the study by Bishop et al., [94] prevalence of suicidal ideation in individuals with sleep apnoea was 9.7% compared to 4.9% for those without sleep apnoea. Whilst this study assessed self-reported sleep apnoea, and established suicidal ideation through one question, other studies have assessed prevalence through more reliable measures. Timkova et al. [105] diagnosed OSA in adults using a polysomnography, which is the 'gold standard' test for OSA. [106] Suicidal ideation was measured through four items from the General Health Questionnaire. [107] Prevalence of suicidal ideation in individuals with OSA was found to be much higher than in the study by Bishop et al., [94] at 20.1%. However, there was no control group for comparison.

Supporting this, Choi et al. [108] also utilised polysomnography to diagnose OSA in adults. They used four questions from the Korean version of the Beck Depression Inventory II (BDI-II). [109] Prevalence of suicidal ideation was found to be 20.5% in those with OSA; a very similar rate to the study by Timkova et al. [105] Lastly, Edwards et al. [110] also utilised polysomnography and found a rate of 18.3% in individuals with OSA.

Suicide Planning

Only the study by Bishop et al. [94] investigated the prevalence of suicide planning in sleep apnoea. Suicide planning was more prevalent (3.4%) in the group with sleep apnoea, than controls (1.4%).

Suicide Attempts

Two studies investigated the prevalence of suicide attempts in sleep apnoea. The prevalence ranged from 1% to 1.7%.

Bishop et al. [94] found a suicide attempt prevalence of 1% in those with sleep apnoea, as opposed to 0.7% in those without. Reporting a similar prevalence, the

aforementioned study by Chu et al. [98] found 1.7% of those with sleep apnoea attempted suicide, versus 0.4% of controls. Additionally, 0.4% had repeated suicide attempts in the sleep apnoea group, whereas only 0.1% of controls had repeated attempts.

Suicide Deaths

No studies investigated the prevalence of suicide deaths in sleep apnoea. However, Kuczyński et al. [111] found that out of all causes of death in a 14-year period in a cohort of 8,675 people with sleep apnoea from Poland, 1.82% of deaths were caused by suicide (identified from medical charts).

Suicidality

One study investigated the prevalence of suicidality more generally in sleep apnoea (suicidal ideation and suicide attempt). The discussed study by Reddy et al. [53] established a prevalence of 49.5% in MDD patients with OSA, compared to 41.8% of individuals with MDD and no OSA. This difference was statistically significant.

Unsuspected OSA in Suicidal Individuals

One study utilised an alternative methodology to associate OSA and sleep apnoea. McCall et al. [112] aimed to investigate the prevalence of undiagnosed OSA in a cohort of individuals with MDD who were known to be suicidal. All participants were tested for OSA either by lab-based polysomnography, or one night of home portable testing. All participants had to be suicidal to be included, however, the paper does not specify how this was identified. Unsuspected OSA was found in 14% of suicidal patients; said to be clinically relevant.

Suicidality Following Diagnosis

One study investigated the impact of a receiving a sleep apnoea diagnosis on suicidality. Das [113] reported a case study of a 23-year-old man with post-traumatic stress disorder (PTSD) and MDD. Following receiving a diagnosis of OSA from a

polysomnography test, the man reported suicidal thoughts, which were not present prior to diagnosis. He became demoralised, stopped taking his medication, and acquired a gun, with plans to kill himself. His reasons were around believing OSA to be an extremely serious condition, and after being told he stopped breathing 37 times within one night, he became worried that he could die in his sleep at any time. After later being informed that OSA is common, with effective treatment options, immediate resolution of his suicidal ideation was observed.

Correlates

Seven papers discussed associated factors that impacted the relationship between suicidality and sleep apnoea.

Gupta et al. [114] explored the relationship between suicidality and sleep apnoea in 40 patients with PTSD. OSA was diagnosed through a home sleep apnoea test, and suicidal ideation was measured through four items on the Brief Symptom Inventory. [115] Participants were categorised into varying groups of OSA severity. The differences between these groups in relation to suicidal ideation was explored and the associations with depression, oxygen desaturation, intermittent hypoxemia, sleep quality, insomnia, sleepiness, PTSD severity age, and BMI were assessed. Only OSA severity and depression scores were significant predictors of suicidal ideation after controlling for the other factors. Furthermore, the relationship between OSA severity and suicidal ideation was partially mediated by depression.

Two other studies also found depression to impact the relationship between sleep apnoea and suicidality. In the study by Choi et al., [108] higher suicidal ideation was associated with depressive mood in OSA participants. Lastly, Gharsalli et al. [116] diagnosed adults with OSA using a polygraphy and utilised a clinical assessment to explore suicidality. Individuals with OSA who were depressed had significantly more suicidal ideation than

individuals with OSA that did not display depression. The same was also found to be true for anxiety.

Although Gupta et al. [114] did not find insomnia to be a factor associated with the relationship between sleep apnoea and suicidality, other studies have found contrasting results. Li et al. [117] found insomnia to be associated with suicidal ideation in individuals with polysomnography diagnosed OSA. The paper stated that this was after controlling for 'potentially confounding factors', however, these factors are unknown due to only an abstract being published. Additionally, in the previously discussed study by Choi et al., [108] higher suicidal ideation was associated with higher insomnia even after controlling for the influence of depression.

Choi et al. [108] also found higher suicidal ideation to be associated with more dysfunctional beliefs about sleep, a lower reported quality of life, and lower social support. Whilst this was the only paper identified exploring quality of life and dysfunctional beliefs about sleep, Timkova et al. [105] found contradictory findings in relation to social support; there was no relationship with suicidal ideation in individuals with OSA. Moreover, no relationship was found with daytime sleepiness. However, suicidal ideation in OSA was related to poor sleep quality and high fatigue. Specifically, sleep quality was found to mediate the relationship between OSA severity on suicidal ideation.

Another factor found to be associated with suicidal ideation in sleep apnoea was unmet need for mental health care, which was established to be significantly more common in the sleep apnoea group in the study by Kaufmann et al. [93] Lastly, in a study by Gupta, [118] patients with PTSD underwent a home sleep apnoea test and were grouped into two groups; those whose sleep-disordered breathing predominantly occurred during stage R sleep (rapid eye movement sleep), and those who's occurred predominately outside of stage R sleep. Whilst depression scores were the only predictor of suicidal ideation in the stage R

sleep dominant OSA group, both OSA severity and depression were significant predictors in the non-stage R sleep dominant OSA group. The author concluded that the contribution of OSA to suicidal ideation in PTSD was driven by non-stage R sleep OSA.

The Impact of CPAP

Four papers shed light on the impact of CPAP on the relationship between suicidality and sleep apnoea. In a case study by Krahn et al., [119] a 74-year-old man presented with fatigue, poor sleep, and disruptive snoring. He reported this to be impacting on his mood and felt suicidal. He planned to act on his thoughts as his life was not worth living given his level of disrupted sleep. The man agreed to partake in a sleep study utilising CPAP. After one night's use, his sleep objectively improved, and he reported decreased suicidal ideation. Two weeks after the study, he reported no symptoms of depression or suicidal ideation. This remained true at one, two, and three months follow-up. Whilst the study highlights the potential importance of CPAP for reducing suicidality in individuals with OSA, the nature of a case study means results are not generalisable and thus must be considered with caution.

Three studies utilised quantitative measures to investigate the impact of CPAP using larger samples. In the study by Edwards et al., [110] those with moderate and severe OSA commenced CPAP. Those who remained adherent (an average use of 5 or more hours per night) to treatment at a three-month follow-up were then reassessed using the PHQ-9. [120] Whilst 18.3 % of individuals reported suicidal ideation prior to commencing CPAP, this number dropped to zero after three months of treatment.

Further supporting this, Udholm et al. [54] reported a higher occurrence of suicide deaths in individuals with OSA that were not using CPAP (2.1%) compared to those utilising CPAP (1.4%). Finally, contrastingly, Chu et al. [98] found that CPAP treatment did not reduce the risk of any suicide attempt, nor repeated suicide attempts in individuals with sleep apnoea.

Discussion

This review aimed to assess the current literature on the relationship between sleep apnoea and suicidality to determine the type of evidence and current knowledge on the topic. In total, 24 studies were reviewed. Most studies established an association by assessing the risk of suicidality in people with sleep apnoea. With consideration to the limitations discussed below, the current evidence suggests that individuals with sleep apnoea may be at risk of suicidality, with findings documented across varying ages, locations, and populations. Whilst a minority of studies did not find an increased risk of suicidality in sleep apnoea, these analyses were based on small sample sizes. Therefore, it is possible that these studies may not have been sufficiently powered. Thus, these results should be interpreted with caution.

Many of the identified studies also assessed the prevalence of suicidality in people with sleep apnoea. Of these, all documented elevated rates of suicidality in comparison to those without sleep apnoea. Higher rates have been found in relation to suicidal ideation, planning, and attempts. However, it is important to note the limitations of these studies, which are discussed in depth below.

Nevertheless, the current evidence predominantly suggests an increased prevalence of suicidality in the sleep apnoea population. Two of the identified studies established the prevalence of suicidal ideation to be around 20%. Whilst one study found a lower prevalence, at 9.7%, the use of polysomnography to diagnose OSA in the former studies perhaps suggest the higher rates to be more accurate. This is alarming given that the annual prevalence of suicidal ideation in the general population is around 2%. [121] As such, it is critical to understand the mechanisms that underlie this association to support those with sleep apnoea, who may be at risk of suicide.

Seven of the identified papers attempted to understand the mechanisms that underlie this association by exploring potential associated factors. The review identified numerous

associated influences. These included factors specifically related to the type or severity of sleep apnoea, including oxygen desaturation, OSA severity and non-stage R sleep OSA. Similarly, factors resulting from the impact of sleep apnoea were also suggested to be associated, including sleep quality, insomnia, and fatigue. However, there was also evidence for the association of psychosocial factors such as depression, anxiety, quality of life, social support, unmet need for mental health care and dysfunctional beliefs about sleep, suggesting that factors related to the type and impact of sleep apnoea may not be the only influence driving the relationship between sleep apnoea and suicidality. However, research is currently limited and thus it would be premature to draw any conclusions.

The most studied factor was depression, with one study suggesting that depression mediates the relationship between suicidality and OSA severity. Considerable research has evidenced a higher incidence of depression and other mental health difficulties in individuals with sleep apnoea, [49, 51, 122, 123] and such factors are heavily associated with suicide. [124-126] Therefore, it may follow that much of the link between sleep apnoea and suicidality is driven by depression. Crucially, another study in this review, [95] found that the link between OSA and suicidality diminished when stress and depression were accounted for, suggesting that at least part of the association relates to depression.

However, this does not exclude the possibility that sleep apnoea is associated with suicidality independent of depression. Indeed, mental health difficulties do not wholly account for suicidality. [127] As such, the underlying mechanism may have different pathways; one that is linked to depression and one independent of depression. [95] Supporting this, several studies in this review established that individuals with sleep apnoea were still at greater risk of experiencing suicidality, after depression had been controlled for. Additionally, the study by Reddy et al. [53] evidenced that those with OSA in addition to MDD, have a significantly increased prevalence of suicidality than those with MDD but no

OSA. This provides preliminary evidence that there may be other underlying processes influencing the relationship between sleep apnoea and suicidality that cannot be accounted for by depression alone. [128]

Sleep disturbance has been proposed as one potential explanation. As discussed previously, the association between sleep disturbance and suicidality is well documented, [27, 28, 30, 36, 129, 130] with some studies even finding it a stronger predictor of suicidality than depression. [41] Due to recurrent awakenings, [131] individuals with a diagnosis of sleep apnoea frequently experience sleep disturbance, including fragmented sleep, [132, 133] and dysregulation of the hypothalamic-pituitary-adrenal (HPA) axis. [134] This chronic disrupted sleep can impact mental and physical energy, potentially rendering individuals with sleep apnoea less able to cope with psychological distress, [135, 136] leaving them more vulnerable to suicidality. [30] Equally, sleep apnoea typically results in intermittent hypoxia and re-oxygenation, [137] which can have adverse effects on the brain, [138,139] particularly the prefrontal cortex, hippocampus, and the amygdala. [140] This may lead to increased impulsivity, attentional deficits, emotional dysregulation, and impairments in memory, all of which may impact an individual's ability to avoid suicidal thoughts and behaviour. [129, 141-144] Indeed, executive dysfunction, attentional deficits, and memory impairment have been found in people with OSA, [145-147] and this has been found to be linked with an increased risk of suicide. [148,149] Whilst this would somewhat explain the association found between sleep quality, fatigue, oxygen desaturation, and OSA severity in relation to suicidal ideation in those with sleep apnoea, further research is necessary to determine the true mechanisms of the impact of sleep apnoea on suicidality.

If sleep apnoea does trigger suicidality through the impact of disrupted sleep and intermittent hypoxia, then given the efficacy of CPAP in treating sleep apnoea, [150] it may follow that CPAP could improve suicidality. The case study by Krahn et al. [119] provides

preliminary evidence for this. However, despite how effective the case study suggests CPAP to be in alleviating suicidal ideation, it is only based on the experience of one individual and thus cannot be generalised to the wider population. The large study by Udholm et al. [54] does support this though and suggests that CPAP may be key in helping to combat the increased risk of suicidality in sleep apnoea. Conversely, conflicting results are reported by Chu et al. [98] These opposing findings may be a result of the smaller sample, population locations, or due to the studies measuring variations of suicidality (suicide deaths compared to suicide attempts). It is also important to note that Chu et al. [98] reported low adherence to CPAP within their study. This is crucial, as the effectiveness of CPAP is reliant on adherence, [151] and thus a lack of adherence to CPAP may have impacted the ability to detect its clinical significance. Critically, the rate of adherence to CPAP is a pressing concern, with up to 70% of people considered to be non-adherent. [152] Unfortunately, Udholm et al. [54] did not measure CPAP adherence, and therefore, although possible, it cannot be concluded that their significant results were due to a higher rate of adherence in participants. Conversely, the study by Edwards et al. [110] demonstrated that when adherence is considered, rates of suicidal ideation drop from 18.3% to 0%. However, as only those who remained adherent were reassessed for suicidal ideation, this raises the potential of bias, as adherence may reflect a less severe level of suicidal ideation, thus impacting the results.

It is important to acknowledge that the studies in this review are approached from a heavily bio-medical viewpoint and do not consider psychosocial influences. Research has largely been conducted by medics and researchers and therefore most studies attempt to understand the association between sleep apnoea and suicidality from a biological perspective. From a psychosocial perspective, it should be considered that the disruption of sleep may lead to EDS [153], which may impact an individuals' ability to engage in work, social life, and hobbies, thus impacting relationships and in turn result in lower mood, and

suicidality. [55, 56] Furthermore, there is some evidence from insomnia literature highlighting how when people are awake at night, they have less support and thus may be vulnerable to suicidality. [154] Given sleep apnoea also results in disrupted sleep, this explanation may be of relevance, and the association with suicidality may be related to a lack of support when struggling. It is crucial that future research explores the association through a psychological lens and holistically considers the biopsychosocial impact of sleep apnoea that may be impacting on suicidality.

It is essential to recognise the current evidence within the context of its limitations, to help guide future research. Firstly, although this review has documented increased risk of suicidality in individuals with sleep apnoea, the reported statistics displayed variation throughout studies. Whilst this is likely somewhat due to the use of various populations, sample sizes, and differing study locations, it is important to highlight the wide array of utilised measures of suicidality and sleep apnoea that would no doubt impact the results. In relation to suicidality, various questionnaires were used, with some studies using a single question to assess participants' suicidality. Given the limitations of using single-item assessments of suicidality, [155] the measures may provide inaccurate estimations of suicidal thoughts and behaviours and thus the findings should be interpreted with caution. Furthermore, some studies did not differentiate between levels of suicidality (e.g., combining suicidal ideation and suicide attempt). Given that previous research has suggested the importance of distinguishing between suicidal thoughts and behaviours, [156,157] combining the two could have impacted the results, as differing levels of suicidality may have individual risk-factors.

The measures of sleep apnoea are subject to similar limitations. Only a small minority of studies utilised a polysomnography, which is the gold standard test for sleep apnoea diagnoses. [106] The most common method of identifying sleep apnoea was through a

database, whilst other studies utilised alternative sleep tests, or self-report measures. This raises several issues. Firstly, the validity of self-report measures is questionable as they rely on participants' subjective recall. Additionally, studies using questionnaires to measure symptoms may not be accurate given that the common symptoms of sleep apnoea are not specific to sleep apnoea alone. [158]

Secondly, the utilisation of a database, whilst perhaps more reliable than self-report, relies on a previous diagnosis, of which the validity is unknown. Moreover, this method, and self-reported diagnoses, will only capture those with a current diagnosis of sleep apnoea. Given that sleep apnoea often goes undiagnosed, [159, 160] this may confound the results, as there may be other participants within the sample that would meet the criteria for sleep apnoea yet not have a diagnosis. In line with this, studies utilising self-report measures have found lower rates of sleep apnoea in comparison to studies using polysomnography. [93] Furthermore, some studies noted that the databases only documented diagnoses made in hospital or specialised care setting, thus potentially excluding milder cases of sleep apnoea that may have been diagnosed in primary care. [102]

The studies that utilised objective measures of sleep apnoea are also subject to limitations. Scholle et al. [161] note that although one-night is sufficient to diagnose sleep apnoea, the impact of adjusting to the equipment, and being within a hospital, may impact sleep, and this has been found to result in a large variation of measures of OSA severity taken across two-night tests. [162] As such, this may impact the ability to find an association between OSA severity and suicidality. [108]

Another gap identified within the literature is the cross-sectional nature of most studies. It is vital when evaluating existing evidence to distinguish between risk-factors and correlates. For a variable to be considered a risk factor, it must *precede* the outcome of interest, [163] and therefore cross-sectional designs are insufficient to determine causality.

[164] As such, based on the current evidence, sleep apnoea cannot be classified as a risk factor for suicidality, and the related correlates noted within this review cannot be classified as risk-factors either. Longitudinal designs are thus necessary to assess the temporal precedence of variables. [163] Furthermore, research on the relationship between sleep disturbance and suicidality has previously noted that cross-sectional research produces larger effect sizes than longitudinal designs, [27] and thus cross-sectional research may overinflate the strength of the relationship between sleep and suicidality.

Future Research

While the findings of this review offer preliminary evidence of a potential link between suicidality and sleep apnoea, the research is still in its early stages, and as noted throughout, there are significant limitations within the current literature. The issues noted with measures of suicidality and sleep apnoea highlight the need for more accurate and thorough measures. Future studies should aim for greater specificity between types of suicidalities and evaluate this utilising more reliable measures, such as larger suicide scales, or comprehensive assessments. Additionally, future research should aim to ideally use two-night polysomnography, or polygraphy as an alternative, [165] to allow for an objective measure of sleep apnoea that allows for more precision, perhaps enhancing prediction. [166]

The review has highlighted significant gaps within the literature, with limited studies investigating CPAP and suicidality in sleep apnoea, and the few studies there are not controlling for CPAP adherence. As such, there is a necessity for further research to investigate the impact of CPAP on suicidality in sleep apnoea, and an importance for these studies to account for CPAP adherence.

Crucially, this review has brought to light an over-reliance on cross-sectional data within the current evidence base which limits the ability to draw conclusions on the

directionality of associations. Future well-designed, longitudinal studies with large cohorts are recommended to draw closer to establishing the predictors and risk-factors of suicidality.

Lastly, although there has been some research exploring correlating factors which may shed light on underlying mechanisms, more specific research investigating the explanatory mechanisms that may be driving an association is critical to advancing knowledge. Qualitative research may prove beneficial in gaining a better understanding of the relationship between suicidality and sleep apnoea by hearing individuals' experiences.

Implications

Although the nature of a scoping review limits its appropriateness to provide recommendations for clinical practice, [87] there are some suggested implications for both clinical psychology, and healthcare, to be aware of. Firstly, whilst the exact link between suicidality and sleep apnoea needs further research, the findings may suggest a higher risk of suicidality in individuals with sleep apnoea. Healthcare professionals (HCPs) involved in the care of people with sleep apnoea should be aware of this association and screen, and closely monitor the suicide risk of clients. This is of particular importance given the findings that nearly half of individuals who died by suicide had contact with an HCP in the month prior to death. [167] It would be helpful for psychologists and HCPs to utilise sleep apnoea as a means of discussing psychological distress. Given the stigma attached to suicide, [168] sleep may provide a useful vehicle to discuss mental health, which could result in early identification and prevention of suicide.

Although extremely limited, there is evidence that CPAP may alleviate suicidality. However, it is well-documented that despite its efficacy in reducing sleep apnoea symptoms, adherence to CPAP is low. [169] Given psychologists' responsibility to assist patients with adherence to treatment, [170] it would be beneficial for clinical psychologists to be involved in the design and delivery of interventions to improve adherence to CPAP, as the findings of

this review suggest poor adherence may not only be impacting physical health but mental health too. It is imperative that this is investigated further, as such knowledge may lead to effective interventions that could aid in reducing suicidality.

It is worth highlighting that only one study reported on suicidality following a diagnosis of sleep apnoea. Although not generalisable due to being a case study, the findings suggest the potential for suicidality to be triggered from receiving a diagnosis. As the study reported misinformation regarding the prognosis of and treatment options for sleep apnoea, this underscores the importance of clinicians providing a reassuring, informative diagnosis to help alleviate potential fear. It also highlights the importance of clients having access to a clinical psychologist following diagnosis, to assess the psychological impact the individual may be experiencing. Further research investigating the impact of receiving an OSA diagnosis is imperative.

Lastly, as discussed, sleep apnoea often goes undiagnosed. [159, 160] As such, it may be useful for mental health practitioners to be alert to recognising signs of suicidality co-occurring with symptoms of sleep disturbance and refer such clients for a sleep apnoea assessment.

Review Strengths and Limitations

There are some limitations to this review that are important to note. Firstly, scoping reviews are criticised for the absence of critical appraisal and risk of bias, [77, 78] meaning the quality of the reviewed studies is unknown. As such, scoping reviews cannot inform policies and guidelines. [171] Thus, although some implications have been discussed, these are limited by the nature of a scoping review [172] and further research is needed to evaluate the importance of these suggestions. Moreover, it is important to acknowledge that additional papers may have been published since the search was last updated. As such, further information on the topic may be available which is not covered in this review.

However, this review also has many strengths. Pham et al. [75] argue that scoping reviews should not be considered a less rigorous version of systematic reviews; rather they have their own purpose, and strengths. Scoping reviews are useful for detecting gaps within the literature and discovering potential systematic reviews, to guide future research. [81, 173] As well as the suggestions given throughout, this review has identified that a meta-analysis on the current risk of suicidality in sleep apnoea is both feasible, and useful for furthering knowledge on the topic and developing clinical guidelines. Moreover, although a formal quality appraisal was not conducted, effort has been made to discuss the general weaknesses of the current literature, which may be invaluable to guiding future research. Specifically, a scoping review has allowed for a comprehensive summary of a scarcely researched topic, providing professionals with an overview of current knowledge, and gaps, that would have not been possible if a more specific systematic review had been conducted. Additional strengths of this review include the comprehensive search strategy, adherence to scoping review guidelines, and use of multiple reviewers for screening.

Conclusion

To our knowledge, this is the first review on the relationship between suicidality and sleep apnoea. Its limitations notwithstanding, this review has provided a comprehensive synthesis of the current findings, identified research gaps, and offered directions for future studies. Although prospective research is limited, the evidence suggests that sleep apnoea may increase the risk of suicidality. Future research could enhance understanding by utilising well-designed longitudinal studies, using more reliable measures of suicidality and sleep apnoea, conducting a meta-analysis on the risk of suicidality in sleep apnoea, exploring the impact of diagnosis, and designing intervention studies to determine if CPAP is effective in reducing suicidality. This will help progress towards influencing care guidelines, which may

prove invaluable in reducing any potential vulnerability to suicidality in individuals with sleep apnoea.

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173. Pollock D, Davies EL, Peters MDJ, et al. Undertaking a scoping review: A practical guide for nursing and midwifery students, clinicians, researchers, and academics. *J Adv Nurs*. 2021;77(4):2102-2113. doi:10.1111/jan.14743

Tables and Figures

Table 1. Search Strategy for PsycINFO Database

Database: PsycINFO	Search Number	Search Field	Search Query
	1 (Population)	Title *OR* Abstract	(“sleep Apn#ea” OR “obstructive sleep apn#ea” OR “central sleep apn#ea”) OR “obstructive sleep” OR (“sleep-disorder* breathing” OR “sleep disorder* breathing”) OR (“sleep-related hypoventilation” OR “sleep related hypoventilation”) OR “parasomnia*” OR “sleep wake disorder*”
			OR
		Subject Headings	“sleep apnea” OR “sleep wake disorders” OR “sleep-related hypoventilation” OR “parasomnias”
	2 (Concept)	Title *OR* Abstract	“suicidal ideation” OR “suicidal thought*” OR “suicide*” OR “suicidalit*” OR (“suicide AND (plan* OR risk* OR attempt* OR completion”))
			OR
		Subject Headings	“suicide” OR “suicidality” OR “suicidal ideation”
	3 (Population AND Concept)	N/A	1 *AND* 2
	Limits Applied	English Language and Human	

Specific search terms including truncations, Boolean operators, and limits utilised in the 1st, 2nd and 3rd searches completed in the PsycINFO Database. *Note*. # Optionally replaces a single letter in a word
* Retrieves all alternate word endings

Table 2. Database Specific Alternatives

Database		Subject Headings	Limits Applied
MEDLINE	Population	"Sleep apnea Syndromes+" OR "sleep wake disorders" OR "Parasomnias"	English Language and Human
	Concept	"Suicide" OR "suicide, completed" OR "suicide, attempted" OR "suicidal ideation"	
CINAHL	Population	"Sleep apnea, central+" OR "sleep apnea, obstructive" OR "parasomnias" OR "sleep disorders" OR "sleep apnea syndromes"	English Language and Human
	Concept	"suicide" OR "suicidal ideation" OR "suicide, assisted" OR "suicide, attempted" OR "suicide risk (Saba CCC)"	
EMBASE	Population	"sleep disordered breathing" OR "central sleep apnea syndrome"	English Language and Human
	Concept	"suicidal ideation" OR "suicide" OR "suicidal behaviour" OR "suicide attempt" OR "automutilation"	

Population and concept subject headings and the applied limits in MEDLINE, CINAHL and EMBASE databases for the completed searches. *Note*. + indicates where a subject heading has been exploded

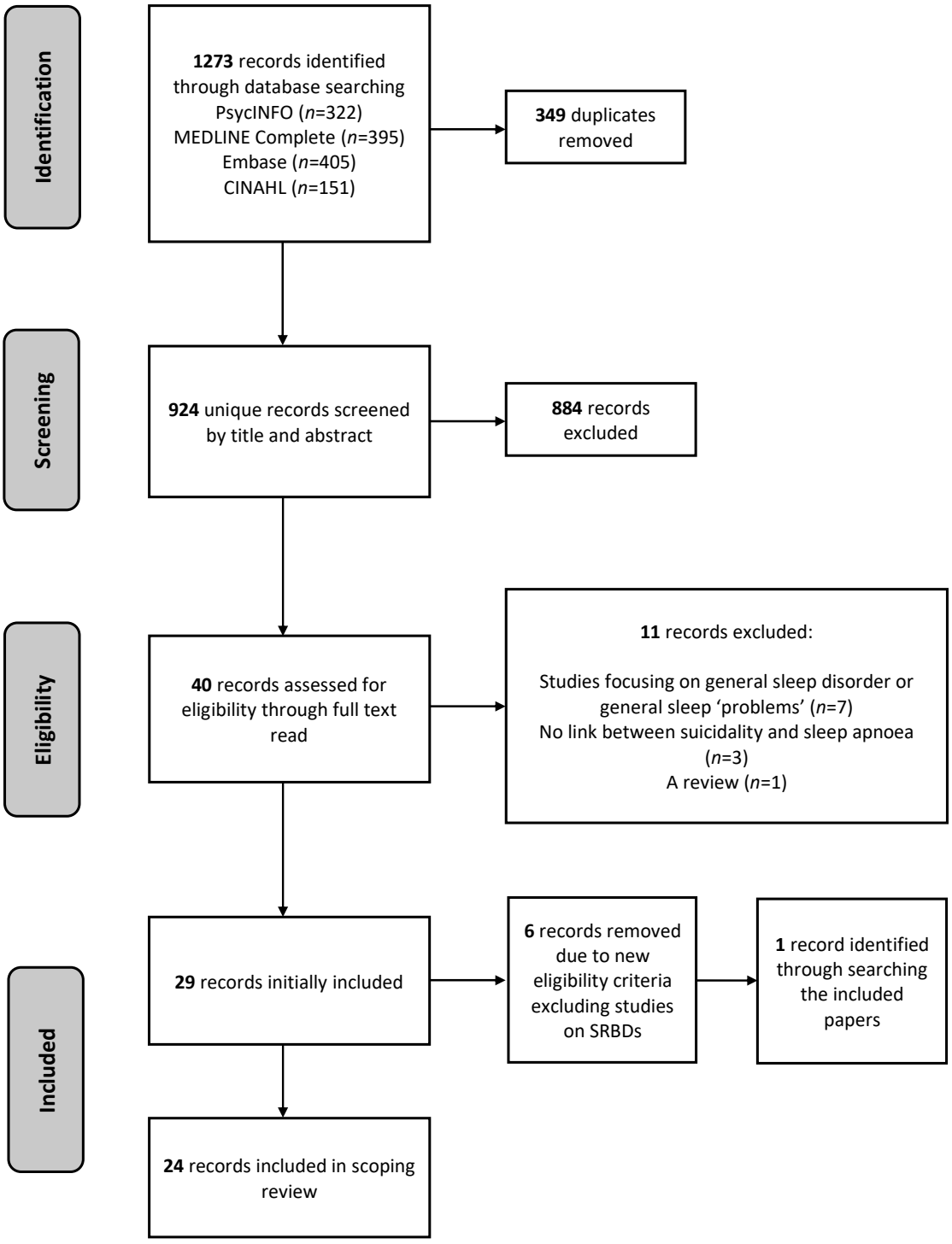

Figure 1. PRISMA Flow Diagram [85] to show the total number of retrieved articles from all databases following the initial search and the specific number retrieved from each database. The number of retained and excluded articles during the screening process are specified alongside the reasons for exclusion and the final number of articles included in the review.
Note. SRBDs = Sleep-related breathing disorders

Table 3. Summary of the Reviewed Studies

First Author (Year)	Location	Design	Sample		Suicidality		Sleep Apnoea Measure	Key Relevant Findings	Key Limitations
			N	Characteristics	Type	Measure			
Kaufmann et al. (2017) [93]	USA	Cross-sectional	264,653 of which 5,498 had sleep apnoea	18 years and older	Suicidal ideation	Single question: "at any time in the past 12 months, did you seriously think about trying to kill yourself?"	Single question: "In the past 12 months have you been told by a doctor or medical professional that you have sleep apnoea?"	• Sleep apnoea associated with AOR 2.75 (95% CI, 2.34-3.23). • Unmet need for mental health care was more common in sleep apnoea group for those with suicidal ideation (AOR .56; 95% CI, 1.23-1.98). • 8.3% of participants with sleep apnoea had suicidal ideation within the past year (SE=0.5), in comparison to 3.7% of participants without sleep apnoea (SE=0.1).	• Single item measure of suicidal ideation • Self-report measure of sleep apnoea • Did not distinguish between central sleep apnoea and OSA • Cross-sectional design
Bishop et al. (2017) [94]	USA	Cross-sectional	40,149 of which 1,155 had sleep apnoea	18 years and older US households	Suicidal ideation, suicide planning, suicide attempts	Yes or no questions regarding if they had seriously thought about, made plans, or attempted to kill themselves within the past 12 months	Single question: "In the past 12 months or within your lifetime, have you been told by a doctor or medical professional that you have sleep apnoea?"	• Prevalence of suicidality in sleep apnoea was 9.7% for suicidal ideation, 3.4% for suicide planning and 1% for suicide attempt, compared with 4.9%, 1.4% and 0.7% for those without sleep apnoea. • Sleep apnoea was associated with suicidal ideation (OR 1.5; 95%,	• Single item measures of suicidal ideation, suicide planning and suicide attempt • Self-report measure of sleep apnoea • Small sample size for suicide attempt

								CI, 1.18-1.91) and suicide planning (OR 1.56; 95% CI, 1.08-2.26), but not suicide attempt (OR 1.22; 95% CI, 0.66 - 2.26).	• Cross-sectional design
Tseng et al. (2019) [95]	Taiwan	Cross-sectional	746	Students (10-14 years old)	Suicidal ideation	Yes or no question regarding experiencing suicidal ideation within the past week	ESS 7-item/ single question from PSQI: "During the past month, how often have you had trouble sleeping because you cannot breathe comfortably"	• Students with suspected OSA (ESS only) were more likely to report suicidal ideation (59%), than those without (41%) ($p<0.0001$). • Students with suicidal ideation had OR 3.25 (95% CI, 1.90-5.56; $p<0.001$), this remained significant after controlling for stress and depression (OR 2.25; 95% CI, 1.23-4.25; $p=0.015$). • When PSQI question added, suspected OSA reduced from 33.1% to 3.8%. Risk of suicidal ideation non-significant (OR 2.87; 95% CI, 0.87-9.46; $p = 0.084$ after controlling for depression and stress.	• Single item measure of suicidal ideation • Potentially inaccurate measure of sleep apnoea • Small OSA sample size when using more stringent measure of OSA • Cross-sectional design

Silva et al. (2023) [96]	USA	Secondary analysis of longitudinal data	1,586	Veterans TBI 16 years and older	Suicidal ideation, suicide attempts	Single questions: suicidal ideation measured with PHQ-9 [120], suicide attempt measured with yes or no question regarding if they had attempted to kill themselves within the past year	Single question: "has a doctor or health professional ever told you that you have sleep apnoea"	• OSA diagnosis had no association with suicidal ideation or suicide attempt after accounting for known predictors.	• Single item measures of suicidal ideation and suicide attempt • Measure of suicidal ideation also asked about self-harm in conjunction • Self-report measure of sleep apnoea
Chu et al. (2023) [98]	Taiwan	Longitudinal – cohort design	7,095 individuals with sleep apnoea 28,380 controls	20 years and older	Suicidal ideation and repeated suicide attempts	Suicide attempt identified through Taiwan National Health Insurance Research Database	Taiwan National Health Insurance Research Database used to identify diagnosis	• Sleep apnoea group more suicide attempts (1.7% vs 0.4%) and repeated attempts (0.4% vs 0.1%) than control groups. • Those with sleep apnoea were more likely to attempt suicide (HR 4.53; 95% CI, 3.48-5.88; $p<0.05$), both males and females. • Those with sleep apnoea were more likely to develop repeated suicide attempts (HR 3.86; 95% CI, 2.27-6.57; $p<0.05$), both males and females. • CPAP treatment did not reduce the risk of any	• Potentially undiagnosed sleep apnoea in controls • Low adherence to CPAP may have impacted results • Potential selection bias as only those who sought medication and treatment were identified

								suicide attempt (HR 1.12; 95% CI, 0.76-1.25). or repeated suicide attempts (HR 0.86; 95% CI, 0.39-1.91).	
Lin et al. (2022) [99]	Taiwan	Longitudinal – retrospective cohort design	3,025 individuals with OSA 12,100 controls	20 years and older	Suicide attempts	Injury events identified through Taiwan National Health Insurance Research Database	Taiwan National Health Insurance Research Database used to identify diagnosis	• Intentional injury (suicide attempt) was higher in the OSA group than controls (AHR 6.51; 95% CI, 5.45-7.05; p<0.001).	• Potentially undiagnosed OSA in controls • Potential selection bias as only those who sought medication and treatment were identified • Did not control for those on CPAP
Cheng et al. (2021) [100]	Taiwan	Longitudinal – cohort design	6,915 individuals with OSA 27,660 controls	20 years and older	Suicide attempts	Taiwan National Health Insurance Research Database to identify suicide injuries	Taiwan National Health Insurance Research Database used to identify diagnosis	• Participants with OSA had higher risk of suicide (adjusted HR 6.683; 95% CI, 6.110-7.372; p<0.001).	• Potentially undiagnosed OSA in controls • Potential selection bias as only those who sought medication and treatment were identified • Did not control for those on CPAP

Udholm et al. (2022) [54]	Denmark	Longitudinal – cohort design	48,168 individuals with OSA 481,680 controls	15 years and older	Suicide deaths	Danish Register of Causes of Death to identify those who died by suicide	Danish National Patient Registry used to identify diagnosis	• Patients with OSA had an increased risk of dying by suicide by 6.68 fold compared with reference cohort (HR 1.29; 95% CI, 1.07-1.55) (sub-HR 1.23; 95% CI, 1.10% - 1.45%). • Higher occurrence of suicide attempts among patients using CPAP (2.1%), compared to those not (1.4%) (p=.057).	• Potentially undiagnosed OSA in controls • Potential selection bias as only those who sought medication and treatment were identified • Did not control for those on CPAP
Høier et al. (2022) [101]	Denmark	Longitudinal – cohort design	3,674,563 males 3,688,164 females	15 years and older	Suicide deaths	Death by suicide identified using the psychiatric central registry	Danish National Patient Registry used to identify diagnosis	• Males with sleep apnoea had IRR 1.8 (95% CI,1.5 to 2.2; p<0.03) for suicide deaths, when compared with no sleep disorder. • Females had IRR 0.4 (95% CI, 0.2 to 0.9; p<0.02) for suicide deaths.	• Potentially undiagnosed OSA in controls • Potential selection bias as only those who sought medication and treatment were identified • National patient registry does not identify those diagnosed in primary care • Did not control for those on CPAP

Rod et al. (2017) [102]	Sweden	Longitudinal – prospective cohort design	74,543 individuals with sleep apnoea 371,592 controls	Aged 16-64	Suicide deaths	Death by suicide identified using the National Cause of Death Register	Swedish Patient Register used to identify diagnosis	• Men with inpatient sleep apnoea were more likely to die by suicide (HR 1.76; 95% CI, 1.19-2.6) and women (HR 4.33, 95% CI, 1.96-9.56).	• Did not distinguish between OSA and central sleep apnoea • Suicide death sample size small • Details of how individual cases were diagnosed was not available • Potentially undiagnosed OSA in controls • Potential selection bias as only those who sought medication and treatment were identified
Reddy et al. (2021) [103]	USA	Cross-sectional	17, 895 individuals with sleep apnoea 71,575 controls	Adults with BPD	Suicidality (Suicidal ideation and suicide attempts)	Unspecified	National Patient Register used to identify diagnosis	• Rate of suicide attempt were similar in those with BPD and OSA and those with BPD and no OSA (3.5% vs 3.3%). • BPD with OSA group had increased odds of suicide (OR 1.36; 95% CI, 1.25- 1.48; p<0.001).	• Abstract only • Method of measuring suicidality unspecified • Potentially undiagnosed OSA in controls • Potential selection bias as

									only those who sought medication and treatment were identified
Reddy et al. (2022) [53]	USA	Cross-sectional	78,792 individuals with OSA 79,308 controls	Adults with MDD	Suicidality (Suicidal ideation and suicide attempts)	Unspecified	National Inpatient Sample used to identify diagnosis	• Suicidality (suicidal ideation and suicide attempt) was more prevalent in patients with OSA (49.5%) compared to without (41.8%) (P<0.001). • OSA was associated with 27% more odds of suicidality (OR 1.27; 95% CI, 1.2-1.35; P<0.001).	• National Inpatient Sample represents hospitalisations not individual people, therefore the same person may have been in the sample more than once • Potentially undiagnosed OSA in controls • Potential selection bias as only those who sought medication and treatment were identified • Did not control for those on CPAP • Observational design

Singh et al. (2022) [104]	USA	Cross-sectional	292	Recently unemployed	Suicidality	History of suicidality assessed using the Mini-international neuropsychiatric interview	At-home overnight screening for sleep apnoea	• No significant associations between severity of OSA, and suicidality. • Past suicidality for participants with Apnoea Hypopnea Index of < 5, ≥5 and <15, and ≥15 was 88.9%, 88.9% and 87.2% respectively.	• Combined multiple types of suicidalities • Few individuals had severe OSA • Diagnosis based on one night sleep
Timkova et al. (2020) [105]	Slovak Republic	Cross-sectional	149	18 to 65 years	Suicidal ideation	Four items relating to suicidal ideation from the General Health Questionnaire	Full night polysomnography	• Prevalence of suicidal ideation in OSA was 20.1%. • Suicidal ideation in OSA was related to poor sleep quality and high fatigue levels. • Sleep quality mediated the effect of OSA severity on suicidal ideation. • No relationship was found between social support and suicidal ideation in patients with OSA.	• Sample based on those visiting the clinic for overnight polysomnography therefore sample is biased towards clinical sample • Diagnosis based on one night sleep • Moderate sample size • Cross-sectional design
Choi et al. (2015) [108]	South Korea	Cross-sectional	117 individuals with OSA	Adults	Suicidal ideation	Four items from the Beck Depression Inventory II representing a	Diagnosed with OSA by one night polysomnography at sleep clinic	• Prevalence of suicidal ideation in OSA was 20.5%. • Higher suicidal ideation was associated with	• Diagnosis based on one night sleep • Moderate sample size

						continuum of suicide risk		higher insomnia (r_s = 0.25, p=0.008), dysfunctional beliefs about sleep (r_s =0.24, p=0.009), and depressive mood (r_s =0.57, p<0.001). • Suicidal ideation negatively correlated with social support (r_s =-.20, p=0.031), and quality of life (r_s =-.25, p=0.006). • Relationship between suicidal ideation and insomnia severity was insignificant after adjusting for depressive symptom severity.	• Cross-sectional design
Edwards et al. (2015) [110]	Australia	Longitudinal design	426 individuals with OSA. 293 commenced CPAP, of which 228 remained adherent	Adults from a sleep clinic	Suicidal ideation	Single item from PHQ-9 [120]	Polysomnography diagnosed sleep apnoea	• Of 293 participants, 228 remained adherent to CPAP after 3 months • Suicidal ideation reported in 18.3% of those diagnosed with OSA • 0% of those who remained adherent to CPAP after 3 months reported suicidal ideation	• Cross-sectional design • Single item measure of suicidal ideation • Measure of suicidal ideation also asked about self-harm in conjunction • Potential bias as those who did not adhere to CPAP were not

									reassessed for suicidal ideation
Kuczyński et al. (2020) [111]	Poland	Cross sectional - retrospective study	12, 485 individuals, of which 8,675 have OSA	Adults from sleep and respiratory centre, medical university of Lodz	Suicide deaths	Cause of death identified from medical charts	Polysomnography analysed retrospectively	• 1.82% of deaths were from suicide	• Polysomnography analysed retrospectively • Potential selection bias as clinical sample
McCall et al. (2019) [112]	USA	Cross-sectional	125	28-65 years old Diagnosis of MDD No current diagnosis of OSA	Suicidality	Unspecified	Either one night of home portable testing or one night polysomnography in clinic	• Rate of 14% for unsuspected OSA.	• Moderate sample size • Suspected OSA based off one night sleep • Potential selection bias as clinical sample
Das (2017) [113]	USA	Case Study	1	23-year-old Hispanic man with PTSD and MDD	Suicidal ideation, suicide planning	Observational: reported suicidal intent and planning	Polysomnography diagnosed sleep apnoea	• A man with became suicidal after receiving OSA diagnosis. After being informed more about OSA, he had immediate reduction of his suicidal ideation and resumed his medications and CPAP.	• Case study design • Had suicidal ideation and a suicide attempt prior to sleep apnoea diagnosis
Gupta et al. (2018) [114]	Canada	Cross-sectional	40	Diagnosis of PTSD	Suicidal ideation	Four items from the Brief Symptom Inventory	One or more nights of level 3 at home sleep apnoea test	• In whole sample, sleep apnoea severity ($r=7.57$, $p<.001$) and oxygen desaturation index	• Small sample size • Home sleep apnoea test

								(r=.633, P<.001) were directly related to suicidal ideation. • Sleep apnoea severity (p<.001) and depression (p=.002) were significant predictors of suicidal ideation (r^2 =0.718). • Depression was a significant mediator in the relationship between OSA severity and suicidal ideation, with OSA related intermittent hypoxemia contributing to this relationship only in the severe OSA group.	• Some diagnoses based on one night sleep • Cross sectional
Gharsalli et al. (2022) [116]	Tunisia	Cross-sectional	80	Adults referred to hospital	Suicidality	Clinical assessment	Polygraphy in clinic	• Both depressive and anxious patients with OSA had more suicidal ideas (p=0.002, p=0.019).	• Potential selection bias as clinical sample who were visiting the hospital – mild to moderate sleep apnoea likely not represented • Polygraphy may underestimate OSA severity • Cross-sectional

Li et al. (2015) [117]	Unreported	Cross-sectional	516	Adults referred to hospital	Suicidal ideation	Questionnaire – details unspecified	Polysomnography	• Insomnia was associated with the presence of suicidal ideation after controlling for potential confounding factors.	• Does not specify how suicidal ideation was measured • Abstract only
Gupta (2020) [118]	Canada	Cross-sectional	40	Adults with PTSD	Suicidal ideation	Four items from the Brief Symptom Inventory	Home sleep apnoea test	• In stage R sleep OSA the only predictor of suicidal ideation was depression. In non-stage R sleep OSA, both OSA severity and depression were predictors.	• Small sample • Home sleep apnoea test • Abstract only
Krahn et al. (2008) [119]	USA	Case study	1	74-year-old man	Suicidal ideation and suicide planning	Presented to primary care physician reporting suicidal ideation and suicide planning. Reported three different plans to end his life and recently had revised his will	Previously obtained overnight oximetry suggested OSA	• A man presented with disruptive snoring, poor quality sleep, severely depressed mood, fatigue, suicidal ideation with active planning, hopelessness, anhedonia. • After using CPAP in a sleep study, he described less intense suicidal ideation. His sleep improved objectively in-lab. • Two weeks after the sleep study, he denied all symptoms of depression.	• Case study design

Table to display the main characteristics, results, and key limitations for all 24 articles included within the scoping review. *Note*. OSA=Obstructive sleep apnoea, CPAP=Continuous positive airway pressure, TBI=Traumatic brain injury, BPD=Bipolar disorder, MDD=Major depressive disorder, PTSD=Post-traumatic stress disorder, PHQ-9=Patient Health Questionnaire 9,

ESS=Epworth-Sleepiness scale, PSQI=Pittsburgh Sleep Quality Index, SE=standard error, OR=odds ratio, AOR=adjusted odds ratio, IRR=incidence rate ratio, HR=hazard ratio, AHR=adjusted hazard ratio, 95% CI=95% confidence interval, r_s =Spearman's Rho, Stage R sleep= rapid eye movement sleep.

Table 4. Characteristics of Studies		Count (%)
Year of Publication		
	2008	1 (4%)
	2015	2 (8%)
	2017	4 (17%)
	2018	1 (4%)
	2019	2 (8%)
	2020	3 (13%)
	2021	2 (8%)
	2022	6 (26%)
	2023	2 (8%)
Location		
	USA	9 (39%)
	Taiwan	4 (17%)
	Denmark	2 (9%)
	Canada	2 (9%)
	Slovak Republic	1 (4%)
	Sweden	1 (4%)
	South Korea	1 (4%)
	Tunisia	1 (4%)
	Poland	1 (4%)
	Unreported	1 (4%)
Design		
	Cross-sectional	14 (58%)
	Longitudinal	8 (33%)
	Case Study	2 (8%)

Note. Percentages are rounded to the nearest whole number.

Appendices

Appendix 1-A: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist [85]

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	Title Page
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	4-6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	7-8
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	N/A
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	8-9
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7-10
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	7-8, 53-54
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8-10
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	10
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	7-10
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	10

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	10, 55
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	10-20, 56-67
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	10-20, 56-67
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	10-20, 56-67
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	20 to 29
Limitations	20	Discuss the limitations of the scoping review process.	28-29
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	29
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	N/A

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

Appendix 1-B: Author Guidelines for *Sleep*

Instructions to Authors

SLEEP® is the official publication of the Sleep Research Society (SRS).

Scope

SLEEP® is a monthly, peer-reviewed scientific and medical journal that is published online. SLEEP® publishes a wide spectrum of original basic, translational and clinical sleep/circadian research findings. The primary audiences are research and clinical professionals specializing in sleep and circadian science and medicine.

Increase exposure to your research by publishing in SLEEP®:

- Accepted papers are immediately available on the SLEEP® website for viewing by all SRS and American Academy of Sleep Medicine (AASM) members and journal subscribers.
- Accepted abstracts are available on PubMed as Ahead of Print.
- All articles are available free to the public twelve months after publication.
- Noteworthy manuscripts are promoted to various national and local media via the journal's public relations staff.

Categories of Manuscripts

The following types of manuscripts will be considered:

Original Articles

Original Articles present original research findings in the fields of sleep/circadian medicine and sleep/circadian science, broadly defined. There is no minimum or maximum length for Original Articles, but reductions in manuscript length (including numbers of figures and/or tables) may be required as an outcome of peer review. The submission of incomplete data sets, partial cohorts, or pilot data is discouraged. SLEEP® does not publish Original Articles that describe individual patient-based case reports or case series that lack a comparator or control group and thus lacks analytical components for hypothesis testing.

Review Articles

Review articles are critical evaluations of material that has already been published. An author of a review article should consider the progress of current research toward clarifying a problem. A review paper should summarize previous investigations in order to inform the reader of the state of current research; identify relations, contradictions, gaps, and inconsistencies in the literature; and suggests the next step or steps in solving the problem. The review section may also include summaries of symposia presentations at national or international meetings.

Details of Style

People-Centered Language

Guidance for improving the language researchers use to talk to and about people with studied health conditions has been issued in several fields. The Editors of SLEEP® endorse the use of people-centered language in research communications. Our recommendations for people-centered language for sleep/circadian research publications can be found on this page.

Language

Papers should be clearly and concisely written in good English. Authors whose native language is not English should consult someone fluent in English prior to submission of the manuscript. Alternatively, a professional language-editing service can be used. Manuscripts may be returned to authors for revision for English language.

Sleep Medicine Terminology

Follow the terminology usage recommendations in the AASM Style Guide for Sleep Medicine Terminology.

Abbreviations

Please note that journal style for the abbreviation of standard deviation is SD. Please do not use SD as an abbreviation for sleep deprivation.

Each abbreviation should be expanded at first mention in the text and listed parenthetically after expansion.

Drug Names

Use generic names in referring to drugs; trade names may be given in parentheses after the first mention, but the generic name should be used thereafter.

Reference Style

SLEEP uses the American Medical Association 10th Edition style guide.

For abbreviations of journal names, refer to "List of Journals Indexed in Index Medicus."

Manuscript Format Requirements

Format Neutral Submission: New manuscripts may be submitted format neutral, as a single Word, RTF, or PDF file. Technical formatting such as reference layout and order of components is not scrutinized for compliance at this initial stage. If the required information is present (complete title page, all author information, abstract, full text, figures and tables, references, etc.) the manuscript will be assessed solely on its scientific merit.

At any later stages of the submission process, your article will need to follow the below requirements.

Manuscript should be provided in Microsoft Word.

Pages should be numbered.

Lines should be double spaced.

Do not number the lines.

Manuscripts should be structured using the following components:

Title Page (Page 1 of manuscript)

- Title and Subtitle (if applicable). Please do not include a running title
- Authors and Author affiliations (identify the institution where the work was performed)
- Corresponding author's name, full address and current, valid email address

Abstract (Page 2 of manuscript)

Each original manuscript and review article must be preceded by an abstract. Abstracts are not required for letters to the editor and editorials.

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Results

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Section 2 : Empirical Paper

Psychological Distress in People with Obstructive Sleep Apnoea and its Impact on Continuous Positive Airway Pressure Adherence

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Abstract

Study Objectives

Poor adherence with continuous positive airway pressure (CPAP) remains the principal barrier to effective treatment of obstructive sleep apnoea (OSA). Previous literature investigating the impact of psychological distress on CPAP adherence is inconsistent, with findings unclear due to methodological limitations. This study explored the association between psychological distress and adherence using objective, comprehensive measures of CPAP usage.

Method

Individuals newly diagnosed with OSA completed the Patient Health Questionnaire-8, the Generalised Anxiety Disorder Assessment-7, the Perceived Stress Scale, the Claustrophobia Scale, and questions about current diagnoses and support for psychological distress. Participants' first 28-days of CPAP usage was collected. Regression analyses were performed to investigate the association of depression, anxiety, stress, and claustrophobia with the duration and frequency of usage.

Results

A total of 47 participants were recruited. Mean CPAP use was 5.94 hours (*SD* = 2.14), with 74% considered 'adherent'. Depression predicted mean daily CPAP use, frequency of days CPAP was used for four or more hours, and 'adherence', defined as four or more hours on average. The 'nonadherent' group also had significantly higher anxiety scores. No associations were found between adherence and stress or claustrophobia. The small sample limits the generalisability of these findings.

Conclusions

This study found depression and anxiety to be associated with CPAP usage in individuals with OSA. Depression and anxiety appear to be a 'risk factor' for 'nonadherence',

and a prime target for evidence-based interventions aimed at improving CPAP adherence. Additional research is needed to confirm these findings in a larger sample.

Keywords: adherence, continuous positive airway pressure, obstructive sleep apnoea, sleep, psychological distress

Financial disclosure: None

Non-financial disclosure: None

Introduction

Obstructive sleep apnoea (OSA) is the most common sleep related breathing disorder, [1] impacting approximately 22 percent of males and 17 percent of females, [2] resulting in nearly one billion cases globally. [3] OSA is a chronic condition characterised by repetitive episodes of complete (apnoea) or partial (hypopnea) upper airway collapse during sleep. [4] This causes intermittent hypoxemia and sleep arousals, resulting in sleep fragmentation and excessive daytime sleepiness (EDS). [5]

OSA is associated with many complications, including fatigue, [6] hypertension, [7] diabetes, [8] cardiovascular disease, [9] stroke, [10] cognitive impairment, [11] and mortality. [12] OSA is also associated with anxiety and depression, [13-16] bipolar disorder, [17] and a reduced quality of life. [18] Significantly, recent research has found OSA to be associated with a higher risk of suicide, [19] thus underscoring the severity of the condition. As such, with the prevalence of OSA only rising, [20] effective treatment is increasingly important for both the physical and psychological well-being of people with OSA.

Continuous positive airway pressure (CPAP) is the gold standard therapy for symptomatic OSA. [21, 22] CPAP requires people to wear a mask over their nose and mouth and works by generating pressurised air that acts as a ‘splint’ to prevent upper-airway collapse during sleep. [23, 24] CPAP has continually been found to be highly efficacious in treating OSA, including reducing EDS, [25] and improving both the physical [26-31] and cognitive [32, 33] complications. There is also evidence demonstrating that when used as prescribed, CPAP reduces depression [34-37] and anxiety, [38, 39] improves quality of life, [25, 40] and alleviates suicidality. [41]

However, the benefits of CPAP are limited in practice due to poor acceptance and adherence. [42] Adherence refers to “the capacity and readiness of the patient to abide by mutually agreed recommendations regarding treatment”, [43, p35] and is typically defined as

greater than four hours of CPAP usage per night. [44, 45] Based on this, 46 to 83 percent of people with OSA are considered ‘nonadherent’. [46-48] Moreover, around 50 percent of patients discontinue usage within one year of commencing treatment, [49] with up to 91 percent discontinuing within three years. [50] As such, adherence is a principal barrier for the effective alleviation of physical and psychological complications of OSA. Defining predictors of adherence is thus crucial, to inform evidence-based interventions.

Much early work attempting to establish predictors of CPAP adherence focused on investigating biomedical factors such as OSA severity, symptom improvement, patient age, and ethnicity. After extensive research, it is evident that only OSA severity and symptomatic improvement reliably predict adherence. [42, 46, 51, 52] Additionally, social factors have been researched, with socioeconomic status and partner support most often found to impact CPAP adherence. [42, 53-56] However, although significant predictors have been identified, much of the variance in non-adherence remains unexplained. [57]

A 2013 review highlighted the importance of adopting a biopsychosocial approach due to the increased recognition of the multifaceted nature of CPAP adherence. [46] Several health psychology models have been used to explain the impact of the various factors associated with adherence to treatment. [58] One of the most utilised is the Health Belief Model (HBM). The HBM postulates that a person’s readiness to adhere to treatment is contingent upon their perceived susceptibility to the condition consequences and the perceived severity of the condition, in conjunction with their beliefs about the benefits of the treatment, against the perceived barriers. The person’s self-efficacy (confidence) in being able to use the treatment despite the barriers, alongside cues to action (prompts to adherence) are also key components of the model. [59] However, whilst the biomedical and social factors associated with the model have been extensively investigated, psychological factors have

been largely under-researched. [46] As such, Crawford et al. [46] highlighted the need to first identify psychological factors associated with CPAP adherence.

Psychological distress is used here as a broad term used to describe a range of unpleasant emotions that occur when a person is overwhelmed by external stressors, and typically includes anxiety, depression, and stress. [60] Psychological distress is a known risk factor for non-adherence in a range of chronic conditions. [61] From the HBM perspective, psychological distress has been found to decrease self-efficacy, which may consequentially reduce adherence. [62] Furthermore, psychological distress may provide an additional barrier to treatment by amplifying current concerns or reducing individuals' ability to cope with challenges. Since psychological distress is both prevalent in people with OSA, and a risk factor for non-adherence, its effect on adherence warrants particular attention. However, the current evidence-base investigating psychological distress remains unclear. Whilst some studies have found depression [63-68] and anxiety [65, 66, 69] to be associated with adherence, other studies have failed to find an association. [70-76] This inconsistency in findings is likely explained by the heterogeneity of the research methodologies and various methodological limitations throughout the literature, limiting the ability to draw reliable conclusions.

Specifically, many of the studies have utilised small to modest sample sizes (25 to 100 participants), raising the possibility that they may have not been sufficiently powered to detect an effect. Furthermore, the studies vary in their methods of measuring psychological distress, with some utilising self-report measures of severity (e.g., Beck Depression Inventory, Hospital Anxiety and Depression Scale), [77, 78] others asking a single question, and several utilising medical records to establish a diagnosis. On examination, studies that utilised diagnoses have had more success in identifying an association between psychological distress and reduced CPAP usage, in comparison to those utilising self-report questionnaires.

[79, 80] Self-report questionnaires are not designed to be diagnostic tools [81]; they are only representative of psychological distress symptoms and can be influenced by sleep. [82] As such, it is possible that self-report questionnaires do not provide an accurate measure of psychological distress in OSA.

Lastly, the methods of measuring adherence have varied throughout studies. For example, many of the studies relied on self-reported CPAP usage, which has been found to be overestimated when compared to objective measures. [83-85] Similarly, some studies utilised machine-on time to measure adherence, which although more accurate than self-report, provides no assurance that the device is being worn, and has been found to overestimate usage by around 10 percent. [83] Additionally, definitions of 'adherence' have varied. The majority of studies calculated the average hours of CPAP usage and utilised a four-hour benchmark to dichotomise participants as either 'adherent' or 'nonadherent'. Given that adherence is not a binary outcome, this highlights a major limitation within the literature; dichotomising continuous variables discards much information, leading to a reduction in power, and potentially resulting in predictors being overlooked. [86, 87] This limitation is particularly pertinent given that the four-hour benchmark is arbitrary, originating from insurance criterion and holding little evidence basis. [88-90] As such, the four-hour benchmark must be questioned, especially in light of the literature evidencing a dose response relationship between CPAP treatment and symptom improvement. [26, 31, 91] Specifically, with every increase in CPAP usage comes subsequent improvement in symptoms. Therefore, any increase in hours of use would be clinically meaningful and a benchmark for 'good adherence' may be sup-optimal. [46]

What is more, averaging the hours of usage per night does not differentiate frequency of use from duration of use. Although limited, research has evidenced that whilst not predictive of average hours of use, the presence of a psychological diagnosis is predictive of

adherence, when adherence is operationalised as the percentage of nights with greater than four hours of use, [79] and the percentage of nights used at all. [80] However, these studies were conducted on samples of only veterans, meaning the results may not be generalisable to the wider population. In addition, neither study distinguished between type of psychological distress, instead grouping any psychological diagnosis together. Therefore, further research is required to provide insight into the type of psychological distress associated with adherence. Lastly, there is scarce research investigating the impact of claustrophobia and stress on CPAP adherence, with existing studies subject to similar limitations as those noted above. [72, 74, 92] Claustrophobia is an anxiety disorder associated with a fear of enclosed spaces, [93] including a fear of suffocation. [94] Given CPAP involves wearing a mask over the nose and mouth, it unsurprising that claustrophobia rates are higher among individuals with OSA. [95] As such, it would be reasonable to assume that individuals with claustrophobia may struggle to utilise the machine due to potential fear of suffocation. Therefore, further exploration of the association between psychological distress and CPAP adherence is needed.

The current study therefore aims to build on the evidence-base by investigating the association of depression, anxiety, claustrophobia, and stress with adherence to treatment in CPAP naïve individuals. For the purpose of this study, ‘psychological distress’ will be used as an umbrella term to describe anxiety, depression, stress and claustrophobia, due to their shared commonality with negative affect triggered through external stressors. From a psychological perspective it is important to acknowledge the overly diagnostic constructs of depression, anxiety, claustrophobia and stress which do not allow for an understanding of the unique factors contributing to the person’s distress and instead reduce complex human experience to a set of symptoms. However, although limited, these constructs provide a framework for the identification of people who may be experiencing mental health difficulties, thus aiding research by allowing for a more standardised comparison across

studies. [96, 97] As such, based on previous research, psychological distress will be measured using well-validated severity measures, in conjunction with assessing psychological diagnoses.

Given the importance of both duration and frequency of use, and the limitations related with dichotomising continuous variables, various adherence indicators will be utilised to establish a more comprehensive picture of adherence. In addition, the typical method of dichotomising adherence as four or more hours of usage on average will also be utilised to allow for comparison with the more comprehensive measures of adherence, and with previous studies that have used the four-hour benchmark. This will allow for a thorough assessment of the association of psychological distress with CPAP adherence, which could inform evidence-based interventions and allow for the identification of those who are most at-risk of struggling with adherence, who may benefit from additional support. [42, 98]

Specifically, the research aims to answer (1) if there is a significant association between various measures of psychological distress and CPAP usage (2) if psychological distress is more predictive of frequency of usage than duration of CPAP usage (3) if measures of psychological distress related to psychological diagnoses are more predictive of CPAP usage than measures based on severity questionnaires. The research hypotheses expected that all measures of psychological distress would be associated CPAP usage. Specifically, it was thought that psychological distress would be predictive of the frequency of CPAP usage. Furthermore, it was predicted that measures of psychological distress relating to diagnoses would be more predictive of CPAP usage than measures based on questionnaires.

Methods

Participants

A convenience sampling method was adopted based on the willingness of a local sleep clinic to aid with recruitment. Participants were recruited from a sleep service in the

North of England. Eligibility criteria were a new diagnosis of OSA, commencing CPAP or automatic airway pressure (APAP), and aged 18 or over. Exclusion criteria were a diagnosis of chronic obstructive pulmonary disease, congestive heart failure or central sleep apnoea, a prescription of bilevel positive airway pressure, inability to read English, inability to provide informed consent or answer the questionnaire, or currently participating in an intervention to promote CPAP adherence. The exclusion criteria were chosen based on previous literature and clinical experience suggesting that these factors may have an additional impact on adherence to treatment. [99, 100]

We aimed to recruit 85 participants as a G*Power [101] analysis revealed that, assuming a medium effect size, this would be sufficient for 80% power to assess whether R^2 deviates from zero in a multiple linear regression with four predictors ($\alpha = .05$). A total of 446 people were invited to participate. The final sample consisted of 47 individuals, an 11% response rate. Participant age ranged from 19 to 77 years ($M = 51.34$, $SD = 14.56$), while 62% were male and 38% were female. Most participants were white British (83%). The remainder were white Irish (6%), white other (4%), mixed race (white and black African; 2%), black Caribbean (2%), and Asian Pakistani (2%).

Measures

Due to previous research indicating that a diagnosis may be a better predictor of CPAP adherence than self-report questionnaires, for psychological distress variables, participants were asked if they had a diagnosis (or considered themselves to), and/or where appropriate, if they were receiving support. Questions relating to support were asked as consideration was given to the possibility that people may not have received a formal diagnosis but may likely meet the criteria if currently receiving support. Self-report severity questionnaires were also answered for each variable for completeness and comparison. All the chosen severity questionnaires are free, and quick to use, thus making them easy to

incorporate into clinical practice. For the purpose of the outcome analyses, all questionnaire scores were used as continuous variables.

Sociodemographic Information

Participants were asked their ethnicity and gender. Participants were also asked how often they share a bed when sleeping (never, sometimes, always).

Depression

To measure depression, participants answered (1) if they had a current diagnosis of depression; (2) if they were currently receiving support for depression; and (3) the Patient Health Questionnaire-8 (PHQ-8). [102] The PHQ-8 is an 8-item self-reporting questionnaire used commonly as a screening instrument for depression. Each item is scored from 0 to 3 (not at all to nearly every day). The total score, ranging from 0 to 24, indicates depression severity with higher scores indicating more severe depression.

The PHQ-8 was chosen as it is based directly on the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders-IV) [93] diagnostic criteria and has been shown to have acceptable diagnostic properties in a variety of populations [103-105]; it has high internal consistency [106] and has been found to be valid across a range of medical disorders. [107] Although it is not a substitute for a formal diagnosis, it can be used to make tentative diagnoses of depression in at risk populations. [108] The internal consistency of the PHQ-8 was assessed using Cronbach's alpha. The Cronbach's alpha was 0.87, indicating good reliability.

Anxiety

To measure anxiety, participants answered (1) if they had a current diagnosis of anxiety; (2) if they were currently receiving support for anxiety; and (3) the Generalised Anxiety Disorder Assessment-7 (GAD-7) questionnaire. [109] The GAD-7 is a 7-item self-reporting questionnaire used as a screening instrument for anxiety. Each item is scored from

0 to 3 (not at all to nearly every day). The total score, ranging from 0 to 21, indicates anxiety severity with higher scores indicating more severe anxiety.

The GAD-7 was chosen as it is based on the DSM-IV [93] diagnostic criteria and is a valid screening tool for anxiety. [109, 110] The GAD-7 also has high internal consistency [109, 111] and has been found to have the best performance characteristics for identifying anxiety when compared to other severity measures. [112] The internal consistency of the GAD-7 was assessed using Cronbach's alpha. The Cronbach's alpha was 0.94, indicating excellent reliability.

Stress

To measure stress, participants answered (1) if they were currently receiving support for stress; and (2) the Perceived Stress Scale (PSS). [113] The PSS is a stress assessment instrument and includes 10 items with a response range of 0-4 (never to very often). The total score, ranging from 0 to 40, indicates subjective stress experience, with higher scores indicating higher perceived stress. The PSS was chosen as it is the most widely used measure of stress valid in many contexts and has good internal consistency. [114] The internal consistency of the PSS was assessed using Cronbach's alpha. The Cronbach's alpha was 0.86, indicating good reliability.

Claustrophobia

To measure claustrophobia, participants answered (1) if they consider themselves to be claustrophobic; and (2) the Claustrophobia Scale (CS). [115] The decision was made to ask if participants considered themselves to be claustrophobic, rather than if they had a formal diagnosis, due to claustrophobia often going undiagnosed. [116]

For the CS, only the anxiety subscale was used for this study, as recommended by the author through personal correspondence due to a high correlation between the subscales. The CS anxiety subscale assesses subjective claustrophobia by asking how much anxiety would

be experienced in a given situation. The CS includes 20 items with a response range of 0 to 4 (none to very much anxiety). The total score ranges from 0 to 80, with higher scores indicating greater self-reported claustrophobia. The CS was chosen for feasibility and its excellent internal consistency. [115] The internal consistency of the CS was assessed using Cronbach's alpha. The Cronbach's alpha was 0.88, indicating good reliability.

CPAP Adherence

Participants' first 28-day CPAP adherence data was objectively measured via data downloaded from the online database (Res-Med), which records actual mask-on 24-hour CPAP use. This adherence data is routinely collected as part of patient care at the sleep service. Regardless of the day that participants completed the questionnaire, it was always the first 28 days of CPAP data that was collected. Whilst this meant that the questionnaire may have been completed after CPAP had been commenced, this allowed for sufficient time for participants to decide to partake, consistency in the time periods that adherence data was collected, and all adherence data to be from CPAP naïve individuals. The 28-day benchmark was chosen as previous research has shown that adherence patterns are generally established after the first week of use. [117] Consequently, it did not appear necessary to explore a longer period, however 28 days was expected to allow sufficient time to assess patterns in adherence.

Given the importance of assessing both frequency and duration of use, and of analysing the full continuum of data, adherence data was recorded on (1) the number of nights participants used CPAP at all over 28 days; (2) the number of nights that participants used CPAP for 4 hours or more over 28 days; (3) the average hours participants used CPAP over 28 days (for use nights only); and (4) the average hours participants used CPAP over 28 days, dichotomised as four or greater hours ('adherent'), or less than 4 hours per night ('nonadherent').

Design and Procedure

This study was approved by the National Health Service (NHS) ethics committee and Health Research Authority (reference: 23/YH/0119). The study utilised a cross-sectional within participants design. All individuals that received a new diagnosis of OSA from the sleep service and commenced CPAP or APAP between November 2023 and March 2024, were posted a flyer about the study. Flyers were mailed by a staff member at the hospital involved in the individual's routine care. Participants were principally expected to self-screen for their eligibility to partake in the study. This process was chosen to reduce the demands on an already pressured NHS service. Participants had the option to complete the consent form and questionnaire online via the Qualtrics platform, or utilising paper-based versions via mail. Nobody opted to participate via mail.

The online survey first displayed the participant information sheet, followed by the consent form. If consent was received, participants reached the self-report questionnaire. Participants were asked sociodemographic questions and information regarding depression, anxiety, stress, and claustrophobia.

Participants were informed that they had 28 days from the day they commenced treatment to complete the questionnaire. This was to allow sufficient time for individuals to choose to participate, whilst ensuring that the questionnaire was completed at a time close to when participants commenced CPAP. As such, the length of time between commencing CPAP and questionnaire completion varied. After completing the questionnaire, participants continued their routine care at the sleep service as normal. Participants were offered to be entered into a draw for a £30 voucher as a thank you for participating in the study.

OSA Diagnosis and CPAP Treatment

The presence of OSA was determined as part of participants' routine care at the hospital. All participants were given a diagnosis of OSA by a doctor after undergoing

standard home-based overnight polysomnography. Following diagnosis, participants were given a CPAP machine and provided an explanation and demonstration of how to operate the machine and how to select the correct size mask. As part of participants routine care at the sleep service, individuals are scheduled telephone follow-ups on day 2, 7 and 28 to troubleshoot any issues. Service users are also able to contact the sleep team at any time if needed with any queries, or to seek support.

Statistical Analysis

Data were analysed with IBM SPSS Statistics (version 28). Firstly, descriptive statistics were used to explore the data. Continuous data are reported through means and standard deviations. Categorical data are presented through frequencies.

Participants were divided into two groups: those who used CPAP for four or more hours a night on average ('adherent'), and those who used CPAP for less than four hours a night on average ('nonadherent'). This provided a measure of the traditional definition of adherence to allow for comparison with past studies. Analyses were conducted to determine any difference between 'adherent' and 'nonadherent' groups in relation to demographic and clinical information, and CPAP usage outcome data. This method was chosen as a means of describing the characteristics of the sample. Two-sample *t*-tests were utilised for continuous variables. For categorical variables, the data violated the assumptions of the Chi-square test of independence as the expected frequencies were less than five. As such, Fisher's exact test was employed.

To determine the effects of psychological distress on the frequency and duration of CPAP usage, regression analyses were conducted for each outcome measure of CPAP adherence. Prior to conducting the regression analyses, correlation analyses were conducted to retain only one measure of each construct (e.g., one for depression, one for anxiety) for each regression model. The choice of measures retained were based on the measures with the

highest Pearson correlation coefficients, regardless of statistical significance. This selection process was required because of the high correlation between measures for a given construct violates the requirements of conventional regression analyses.

Furthermore, correlation, tolerance, and variance inflation factors (VIFs), were also computed between predictor variables, to assess for multicollinearity. Highly correlated variables were excluded accordingly.

A binary logistic regression was used to predict 'adherent' or 'nonadherent' participants. Multiple linear regressions were used to predict CPAP adherence in terms of (1) average hours of CPAP usage; (2) days CPAP was used at all; and (3) days CPAP was used for four or more hours. All regression analyses were performed using the enter method and statistical significance was defined as $p<.05$.

Results

Timing of Questionnaire Completion

The number of days after commencing CPAP that participants completed the online questionnaire ranged from 2 to 27 days (M = 10.62, SD = 6.34).

Bed-Sharing Status

The majority of participants reported always sharing a bed (53%), 28% reported sometimes sharing a bed, and 19% never shared a bed.

CPAP Adherence

Mean CPAP usage was 5.94 hours (SD = 2.14), with 74% of participants considered 'adherent'. Appendix 2-A displays CPAP usage for continuous outcome data. To explore the sample in relation to demographic and clinical information, we used the 'adherent' and 'nonadherent' groups. Table 1 summarises the results. 'Nonadherent' participants were significantly more likely to have reported a diagnosis of depression, and to have reported receiving support for depression, than 'adherent' participants. Furthermore, 'nonadherent'

participants had a significantly higher GAD-7 score in comparison to ‘adherent’ participants. No other analyses were significant.

Insert Table 1 here

The ‘adherent’ and ‘nonadherent’ groups were also explored in relation to their CPAP usage data. Table 2 displays the results. ‘Nonadherent’ participants significantly differed in comparison to ‘adherent’ participants across all outcome measures; average hours CPAP used over 28 days, frequency of days CPAP utilised at all, and the frequency of days CPAP utilised for 4 or more hours.

Insert Table 2 here

Impact of Psychological Distress on Outcome Variables

Figure 1 displays correlation analyses between predictor variables and each outcome measure. Figure 2 displays correlations between predictor variables.

Insert Figures 1 and 2 here

‘Adherent’ or ‘Nonadherent’

Correlation analyses indicated that reporting receiving support for depression, GAD-7 score, PSS score, and reporting to be claustrophobic were the measures of depression, anxiety, stress and claustrophobia that correlated most with the outcome measure. However, as the GAD-7 measure was highly correlated with depression support and PSS score (.61 and .75 Pearson correlations respectively), it was not included in the regression model. Thus, a binary logistic regression was conducted to investigate the effects of reported depression support, reported claustrophobia, and PSS score on the likelihood of a being ‘adherent’ (Table 3). The model was significant ($\chi^2(3) = 10.20$, $p = .017$). It explained 29% (Nagelkerke R^2) of the variance in ‘nonadherence’. Only depression support significantly contributed to

the model (p = .010), with those receiving support for depression displaying an association with an increase in the likelihood of 'nonadherence' (OR = 13.74, 95% CI 1.88, 100.39).

Insert Table 3 here

Average Hours of Use

Based on correlation analyses, reporting receiving support for depression, GAD-7 score, receiving support for stress, and reporting to be claustrophobic were the most appropriate measures to include in the regression model. However, GAD-7 score was excluded due to its high correlation with depression support (.61). Thus, a multiple linear regression was conducted to determine if reported support for depression, stress, and reported claustrophobia predicted the average hours of CPAP usage (Table 4). The model was significant ($F(3, 43) = 3.24$, p = .031). It explained 13% ($R^2_{Adjusted}$) of the variance in average hours of CPAP usage. Only depression support was a significant predictor, with receiving support for depression being associated with a reduction in the average hours of CPAP use (β = -0.41, $t(46) = -2.66$, p = .011).

Insert Table 4 here

Days CPAP Used at All

Based on correlation analyses, PHQ-8 score, GAD-7 score, CS score, and PSS score were initially chosen to be included in the model. However, a preliminary analysis suggested evidence of multicollinearity. As such, it was decided to not include the variables PSS score and PHQ-8 score in the regression model, due to high correlations with the GAD-7 (.75 and .86 Pearson correlations respectively). Thus, a multiple linear regression was conducted to determine if GAD-7 score, and CS score, predicted the frequency of days CPAP was used at all (Table 5). The model was not significant ($F(2, 44) = 3.03$, p = .059). It explained 8% ($R^2_{Adjusted}$) of the variance in average hours of CPAP usage. Neither GAD-7 score, nor CS score had a significant effect.

Insert Table 5 here

Days CPAP Used for Four or More Hours

Reporting receiving support for depression, GAD-7 score, PSS score, and CS were the measures of depression, anxiety, stress and claustrophobia that correlated most with the outcome measure. However, as the GAD-7 variable was highly correlated with PSS score and depression support (.61 and .75 Pearson correlations respectively), it was excluded from the regression model. Thus, a multiple linear regression was conducted to determine if reported support for depression, PSS score, and CS score predicted the frequency of days participants used CPAP for four or more hours (Table 6). The model was significant ($F(3, 43) = 4.35$, $p = .009$). It explained 18% ($R^2_{Adjusted}$) of the variance in the frequency of days participants used CPAP for four or more hours. Only depression support was a significant predictor, with receiving support for depression being associated with a reduction in the frequency of days CPAP was used for four or more hours ($\beta = -0.47$, $t(46) = -3.17$, $p = .003$).

Insert Table 6 here

Discussion

This study aimed to provide further clarification around the association between psychological distress and CPAP use in individuals with OSA. It was predicted that depression, anxiety, claustrophobia, and stress in people with OSA would be associated with reduced CPAP usage, in comparison to those who did not display evidence of psychological distress. The findings partially supported this hypothesis. Specifically, this study found evidence that depression is associated with a reduction in both the frequency, and duration of CPAP usage in people with OSA. Additionally, anxiety was also associated with CPAP usage, although the high correlation between anxiety and depression meant anxiety measures did not appear to provide any predictive power above depression. However, contradicting the

hypotheses, the findings suggest little utility in the predictive power of claustrophobia and stress, with none of the utilised measures being found to be associated with any measure of adherence.

It is important to consider these findings in the context of past research. Firstly, the finding that depression is predictive of a reduction in CPAP usage contradicts much previous literature documenting no significant association between depression and CPAP adherence. [70-76] Furthermore, the results challenge previous literature suggesting that psychological distress is only predictive of frequency of use, but not duration of use. [79,80] Critically, this study found that depression was predictive of a shorter duration of CPAP usage on average, a reduced frequency of nights CPAP was used for four or more hours, and the typical definition of 'nonadherence'. As such, contrary to our hypotheses, the inconsistencies in findings between past studies and with current study, do not appear to be due to previously used inadequate definitions and incomplete exploration of adherence. It is thus a possibility that the contradictory findings in previous literature may be due to the aforementioned methodological limitations of past research, such as non-objective and inaccurate recordings of CPAP adherence, small samples sizes, and restricted samples.

Importantly, this study found evidence that depression is associated with both how long people with OSA use their CPAP machines, and the number of nights they use it more than four hours. However, contrary to our hypotheses, the frequency of nights CPAP was used at all was the only measure of CPAP adherence utilised in this study that depression was not found to predict. This may be due to a ceiling effect observed within this outcome measure. Critically, the vast majority of participants at least attempted to utilise their CPAP machines on all of the observed nights. As such, to observe an association with the frequency of CPAP use at all, further research may need to collect data over a period longer than 28 days.

Another aim of this study was to determine if measures self-reporting a diagnosis, or suggestive of a potential diagnosis would better predict CPAP usage than severity questionnaires. The results are unclear. In relation to depression, self-reportedly receiving support, or having a diagnosis of depression, appeared to have a greater association with CPAP usage than the PHQ-8 as assessed through both correlation analyses and analysis of differences between 'adherent' and 'nonadherent' groups. This may partially support our hypothesis. It is important to recognise the shared symptomatology of OSA and depression (e.g., fatigue, poor concentration), which could create false positives when utilising severity measures such as the PHQ-8. [41, 67, 118, 119] As such, it is possible that self-reported diagnoses or support for depression provide a more accurate measure than severity questionnaires such as the PHQ-8, that are more influenced by shared symptomatology with OSA than are diagnoses, which have the added benefit of clinical judgment. However, mean PHQ-8 scores were higher in the 'nonadherent' group, and likely with a bigger sample size would have also been significant. As such, it is possible that this is a random effect observed due to a small sample size, and that higher scores on the PHQ-8 are associated with a reduction in CPAP usage.

We chose to ask if participants were receiving support for depression, as well as if they had a diagnosis, based on the possibility that some may be experiencing depression, yet not have received a formal diagnosis. The results indicated a large overlap between the two measures, with all individuals receiving support reporting a diagnosis, and only two individuals with a diagnosis not receiving support. Depression support displayed a stronger correlation with all outcome measures, and thus was chosen as the measure to use in the regression model. However, both measures were associated with CPAP usage, and the higher correlation is possibly due to severity, with participants receiving support likely experiencing more severe depression.

The findings for anxiety contradicted those for depression. Whilst the GAD-7 was associated with CPAP usage, reports of diagnoses and support for anxiety displayed little association with any outcome measure. These findings also contradict previous literature suggesting that psychological diagnoses are predictive of CPAP adherence. [79,80] On examination, many people who self-reported a diagnosis, scored low on the GAD-7. The reason for these findings is unclear. One possibility is that people may have been given a diagnosis previously yet have experienced a reduction in anxiety since. This highlights a limitation of the study, as although we asked about "a current diagnosis", it is unclear how recent this diagnosis was made. Further, participants completed the questionnaire any time within their first 28-days of CPAP usage. Previous research has shown that CPAP can reduce anxiety. [120] As such, it is possible that those with a diagnosis may have experienced a reduction in anxiety due to the commencement of treatment, and thus the GAD-7 may have provided a more accurate measure of current anxiety. Nonetheless, although the GAD-7 was found to be associated with adherence, its high correlation with depression measures meant it was not included in the regression analyses, as they largely appeared to be measuring a similar variable. This is unsurprising given the known association between depression and anxiety, [121] and perhaps suggests that there is little value in utilising both measures to predict adherence within research. While within a clinical setting, either construct would likely indicate individuals most at risk of 'nonadherence'.

The finding that neither method of measuring stress was predictive of CPAP usage is supportive of the limited previous research, [72, 74] and suggests that this may not be a useful variable for research to continue to investigate. However, the finding that neither method of measuring claustrophobia is associated with CPAP usage contradicts that of a previous study which found higher scores on the Fear and Avoidance Scale (FAAS) to be associated with reduced adherence. [92] The inconsistencies in findings may be due to the

choice of questionnaires. Although both the FAAS and the CS have been found to be reliable and valid measures of claustrophobia in the general population, they are not specific to claustrophobia related to the CPAP mask. As such, it would be useful for further research to be conducted utilising a measure designed to assess claustrophobic tendencies specific to CPAP, such as the CPAP-FAAS.

When considering the potential mechanisms behind the findings within this study, the HBM provides a useful framework. Depression may operate to reduce CPAP adherence through various elements of the model. One explanation is that depression may amplify the perception of barriers to use or render individuals with less capacity to cope with barriers. Research has shown that negative side-effects of CPAP therapy are largely associated with a reduction in usage, and individuals with depression have been found to report more negative side-effects. [122] As such, it is possible that people with depression are less tolerant to the negative side-effects of CPAP therapy.

Another explanation is the impact on the perceived benefits of treatment. Depression is known to be associated with negative beliefs. [123] As such, people experiencing depression may be less likely to believe that CPAP can have a positive outcome on their health, thus reducing their motivation to use it. Similarly, the association with fatigue and sleepiness may have an important impact on perceived benefits. A reduction in EDS is one of the main factors known to be associated with increased CPAP adherence. Fatigue, a similar yet distinct concept to EDS, is associated with both OSA, and depression, yet studies have shown that in individuals with OSA, it is more closely related to depressive symptoms, than the severity of OSA. [124] Therefore, a reduction in sleepiness due to effective CPAP treatment may not be as noticeable if the person is still experiencing depression-related fatigue, and people may incorrectly conclude that CPAP is not working. [125]

A final explanation may be related to the impact of depression on self-efficacy. As noted, the HBM postulates that self-efficacy impacts adherence through an individual's confidence in their ability to use the treatment. Much research has indeed found self-efficacy to be associated with CPAP adherence. [126-128] It has also been suggested that depression can reduce self-efficacy. [129] As such, depression may operate to reduce adherence to treatment by lowering an individuals' belief in their ability to successfully adhere to treatment, and by reducing their motivation to do so. Further research is necessary to explore the mechanisms by which depression may reduce CPAP adherence.

It is important to note the level of adherence identified within this study. Specifically, utilising the typical measure of adherence, 74% of our sample were considered 'adherent'. This rate is higher than that reported in the majority of past studies, [47, 48, 85, 130, 131] and evidently contributed to the unanticipated ceiling effect observed in the number of days participants used CPAP at all. As discussed above, the majority of participants used their machines every night; contradictory to previous research evidencing people with OSA to use their CPAP machines between 10% to 40% of nights per week. [85]

There are numerous possibilities as to why the adherence of participants in this study may have been greater than that typically identified. Firstly, participants had to optionally consent to partake in the study, which may indicate some degree of tendency to comply, motivation to engage in treatment, and perhaps less ambivalence towards their disorder. It is highlighted that that only 11% of those invited to participate, completed the study. As such, there is a possible sampling bias towards people with a greater adherence. Secondly, it is important to note that the recruitment site utilised within this study routinely records adherence, and reviews this with patients at day seven. This is not true for some previous similar studies. Research has found that the level of involvement and patient-education from healthcare professionals at the beginning of treatment impacts adherence. [132] This is in-

keeping with the HBM, which highlights the impact of 'cues to action' such as follow ups with healthcare professionals on adherence behaviour. As such, there is the possibility that the level of education provided at this service, the knowledge that adherence is being monitored, and the seven-day follow-up to encourage usage, may have increased adherence in the current sample. Unfortunately, this is not a factor that we could control for. However, it is likely that this is more in keeping with real life clinical management of OSA with CPAP and thus provides a more ecologically valid assessment. Furthermore, the adherence rate found within this study is very similar to that observed in a large real-world study, [133] and thus it is less likely that any significant sampling bias exists.

Implications

The results of this study have many implications for clinical practice. Firstly, as depression and anxiety appear to be linked to poorer adherence, this provides support for the need for healthcare professionals to be aware of this association and provide long-term monitoring of mental health in OSA. Those individuals who are identified as displaying symptoms should be considered at risk for nonadherence and be provided with additional support from sleep services, both for increasing adherence, and for psychological distress. Additionally, given clinical psychologists role in improving adherence to treatment, [134, 135] the knowledge that depression and anxiety impacts CPAP usage should be used to inform evidence-based interventions to improve adherence to treatment in the OSA population.

Previous research documents the importance of the first week of CPAP usage in determining long-term adherence. [117, 136-138] Positive early experiences are beneficial to adherence, [139] whereas negative early experiences result in doubts in people's ability to incorporate CPAP into their life. [140] As the current study indicates that depression and anxiety could be a barrier to positive first experiences, this suggests it is vital screening for

psychological distress prior to the commencement of CPAP therapy, as well as long-term. It may therefore be useful to provide support for depression and anxiety prior to starting CPAP, to try and ensure a more positive early experience.

Crucially, even the participants in our study who were receiving support for depression had significantly lower adherence. It is important to note that we did not collect information regarding the type, or duration of support people were receiving. However, this may suggest more needs to be done to reduce the impact of psychological distress on early experiences of CPAP. As such, in conjunction with support for psychological distress, it may be beneficial to provide education around the impact of depression on symptoms, and support for negative side-effects, to attempt to help increase endurance to CPAP.

The current results provide support for the increasing need for clinical psychologists in multidisciplinary sleep services to provide support for psychological distress, and interventions for increasing adherence to treatment. [141] Additionally, the association between depression and adherence suggests a need for clinical psychologists in mental health services to be aware of this association. This may be particularly true for clients whose depression symptoms are not improving following receiving support. Literature shows that when unrecognised, OSA can worsen the symptoms of depression and impact the effectiveness of therapy. [13, 142, 143] Additionally, the large overlap in symptoms can result in misdiagnosing depression instead of OSA. [144, 145] As such, clinical psychologists and healthcare practitioners should be mindful of potentially co-morbid diagnoses in clients and emphasise that CPAP is an essential part of their support for psychological distress. This is critical given this study found those receiving support for depression were at a greater risk of nonadherence, and particularly pertinent given the evidence that CPAP can improve depression and anxiety in individuals with OSA. [41, 146, 147]

Lastly, the finding that depression is predictive of various measures of adherence has implications for future research. Although this study provides evidence that depression is predictive of 'adherence', as typically defined as four or more hours per night, the limitations of dichotomising continuous variables remain. Given that this four-hour benchmark is arbitrary, and depression was also predictive of the average hours of usage as a continuous variable, it remains important for future studies to assess a more comprehensive picture of adherence. This is particularly pertinent given that higher than four hours of CPAP usage per night has been found to be required to normalise functioning. [31, 148, 149] What is more, research has also shown that normalisation is person-dependent, with large variations in the number of hours of CPAP use required to relieve OSA side effects. [150] As such, the four-hour benchmark is not necessarily clinically relevant and thus it is likely more beneficial to utilise the full continuum of outcome data.

Strengths and Limitations

The findings of this study must be interpreted within the context of its limitations. Firstly, we must acknowledge the small sample size, which limits the generalisability of the results. A larger sample would have been desirable but was not possible due to time constraints and recruitment challenges, which may somewhat reflect the difficulties engaging this population.

Secondly, it is important to note that our study was conducted in a single sleep service, which consequently limits the generalisability of the findings. Specifically, this study was conducted in the North of England, thus results may not be applicable to locations with differing socioeconomic backgrounds to the studied region. Additionally, it is questionable whether findings from participants with usage monitor fitted machines can be generalised to people without this feature, as the latter may not have the same incentive to adhere. [151]

Thus, the findings of this study may not be applicable to sleep services that do not distribute machines with inbuilt adherence monitors.

Furthermore, it is vital to acknowledge that our predictive models only explained between 8% and 29% of the total variance in CPAP adherence. An individual's adherence to CPAP is likely multifaceted; comprised of not only psychological factors, but biological and social factors too. [46, 67, 125] The scope of the current study meant we were unable to measure and control for biological and social factors known to impact adherence, such as OSA severity, CPAP side effects, social support, and socioeconomic status. However, future studies should investigate the interplay between biological, psychological and social factors, to provide a comprehensive assessment of all factors known to impact adherence. Utilising the HBM to do so may prove beneficial to consider the various influences on CPAP adherence, including the role of the healthcare provider.

Other limitations include the self-certification of inclusion criteria, self-reported diagnoses, and the lack of ethnic and gender diversity in the sample. Further multi-centre research using a larger, more diverse sample and medical records to certify diagnoses and eligibility are needed. Lastly, the cross-sectional nature of this study means we cannot infer causality between adherence and psychological distress.

However, it is important to recognise the strengths of this study. We have provided a thorough assessment of the impact of psychological distress on CPAP usage that is representative of actual OSA management, thus making it generalisable to real-world sleep services. This is one of the only studies within the area to have evaluated both frequency and duration of usage, using both linear and logistic regression modelling, to provide a more comprehensive assessment of adherence. Psychological distress was measured using well-validated questionnaires in conjunction with questions indicating professional diagnoses to provide a more accurate measure of psychological distress that is not impacted by shared

symptomology. Lastly, adherence was recorded utilising accurate and objective actual mask-on time, thus addressing a key limitation of previous research.

Conclusion

In summary, the present study enhances the current understanding of the association between psychological factors and adherence to CPAP treatment in the OSA population. To our knowledge, this is the first study to explore the link between psychological distress and both frequency and duration of objective CPAP adherence in a generalisable sample. The study found that evidence of depression was significantly associated with reduced CPAP usage. Furthermore, anxiety scores were significantly higher in 'nonadherent' participants, in comparison to 'adherent' participants. Whilst the findings suggest preliminary evidence for anxiety and depression as important targets for evidence-based interventions aimed at increasing adherence, future research is imperative to confirm the findings in a larger sample. In addition, given our models only explain a small portion of the total variance in CPAP adherence, future research should build on the current findings by investigating the association of psychological distress in conjunction with biological and social factors.

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Tables and Figures

Table 1. Demographics and Psychological Distress Information for 'Adherent' and 'Non-adherent' Participants

Variable	'Adherent' (*n*=35)	'Nonadherent' (*n*=12)	*p* Value	Effect [95% CI]
Age, Mean (*SD*)	52.11 (13.69)	49.08 (17.33)	.540	3.03 [-6.85, 12.92]
Gender, *n*			.744	0.75 [0.19, 3.00]
Male	21	8		
Female	14	4		
Ethnicity, *n*			1.00	-[-]
White - British	28	11		
White - Irish	2	1		
White - Other	2	0		
Black – Caribbean	1	0		
Mixed – White and Black African	1	0		
Asian – Pakistani	1	0		
Bed Sharing Status			.322	-[-]
Always	19	6		
Sometimes	11	2		
Never	5	4		
Current diagnosis of depression, Yes, *n*	5	6	.020*	6.00 [1.37, 26.24]
Currently receiving support for depression, Yes, *n*	3	6	.005**	10.67 [2.08, 54.85]
PHQ-8 score, Mean (*SD*)	6.94 (4.97)	9.25 (7.50)	.232	-2.31 [-6.14, 1.53]
Current diagnosis of anxiety, Yes, *n*	9	5	.465	2.06 [0.52, 8.16]
Currently receiving support for anxiety, Yes, *n*	7	3	.700	1.33 [0.28, 6.26]
GAD-7 score, Mean (*SD*)	3.40 (3.82)	7.00 (7.78)	.040*	-3.60 [-7.02, -0.18]
Currently receiving support for stress, Yes, *n*	4	2	.637	1.55 [0.25, 9.77]
PSS score, Mean (*SD*)	13.57	15.92	.387	-2.35 [-7.76, 3.07]
Self-reported to be claustrophobic, Yes, *n*	5	4	.205	3.00 [0.65, 13.84]
CS score, Mean (*SD*)	19.83 (18.18)	25.25 (20.59)	-.393	-5.42 [-18.09, 7.25]

Results of t-tests and Fishers exact tests to evaluate the differences between 'adherent' and 'nonadherent' groups in relation to demographic and psychological distress variables. *Note*. *p<.05, **p<.01, ***p<.001. Effect refers to odds ratio for categorical variables and mean difference for continuous variables.
SD = Standard Deviation, CI = Confidence Interval. PHQ-8 = Patient Health Questionnaire, GAD-7 = Generalised Anxiety Disorder Assessment, PSS = Perceived Stress Scale, CS = Claustrophobia Scale.

Table 2. CPAP Usage Information for 'Adherent' and 'Non-adherent' Participants

Variable	'Adherent' (*n*=35)	'Nonadherent' (*n*=12)	*p* Value	Mean Difference [95% CI]
Average hours CPAP used of the nights CPAP used, Mean (*SD*)	6.64 (1.33)	3.13 (1.79)	<.001	3.50 [2.52, 4.49]
Days CPAP used at all, Mean (*SD*)	27.29 (1.63)	16.58 (10.02)	<.001	10.65 [7.17, 4.26]
Days CPAP used for 4 or more hours, Mean (*SD*)	24.66 (3.87)	7.75 (5.50)	<.001	16.91 [13.99, 19.82]

Results of t-tests to evaluate the differences between 'adherent' and 'nonadherent' groups in relation to CPAP usage outcome data. *Note*. *SD* = Standard Deviation, CI = Confidence Interval.

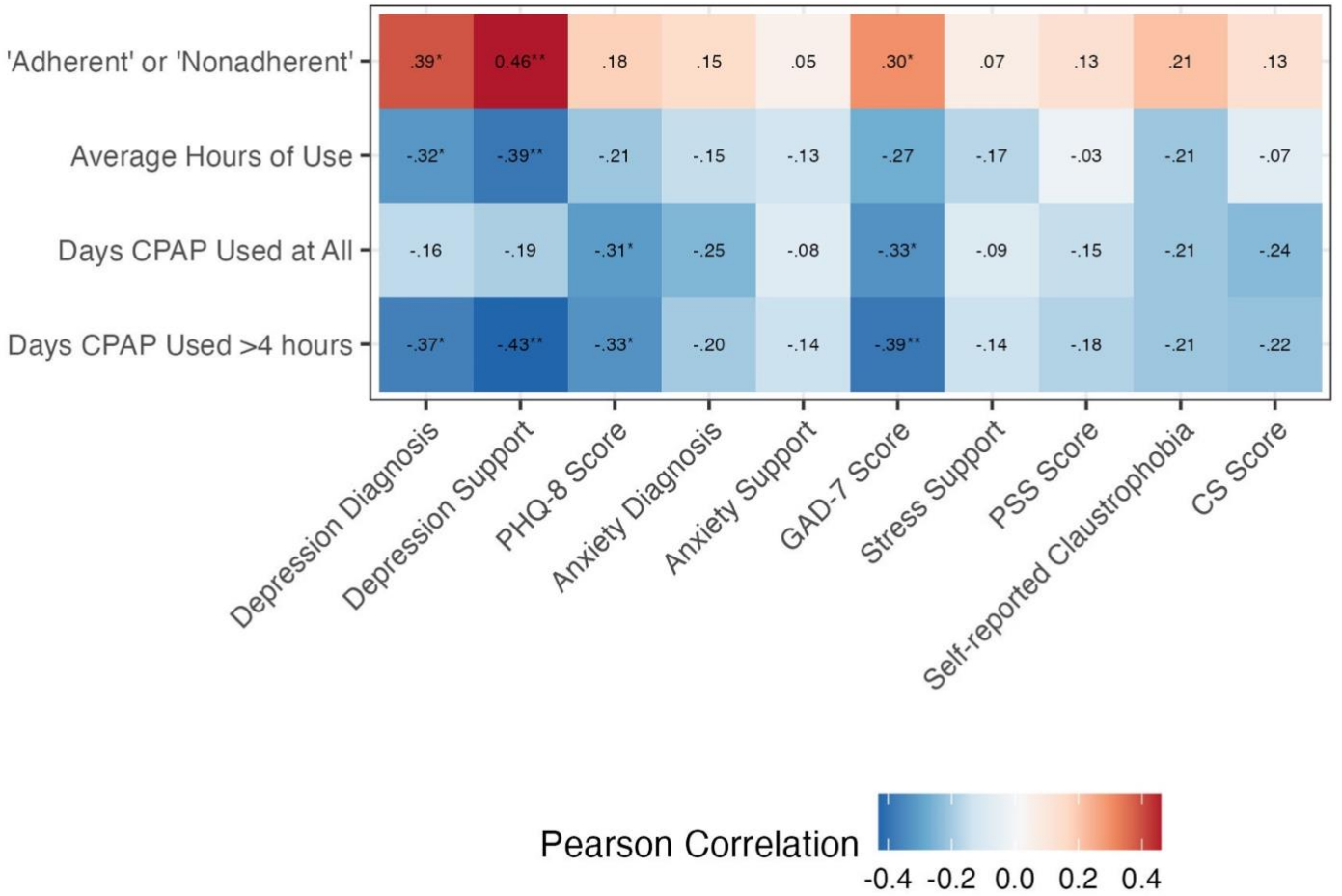


Figure 1. Pearson correlation coefficients between all outcome variables and each predictor variable. Correlations were used to decide which predictor variables to utilise for each regression model. One measure of each construct was chosen for each model (e.g., one for depression, one for anxiety). *Note*. PHQ-8 = Patient Health Questionnaire, GAD-7 = Generalised Anxiety Disorder Assessment, PSS = Perceived Stress Scale, CS = Claustrophobia Scale. **p<.05, **p<.01*

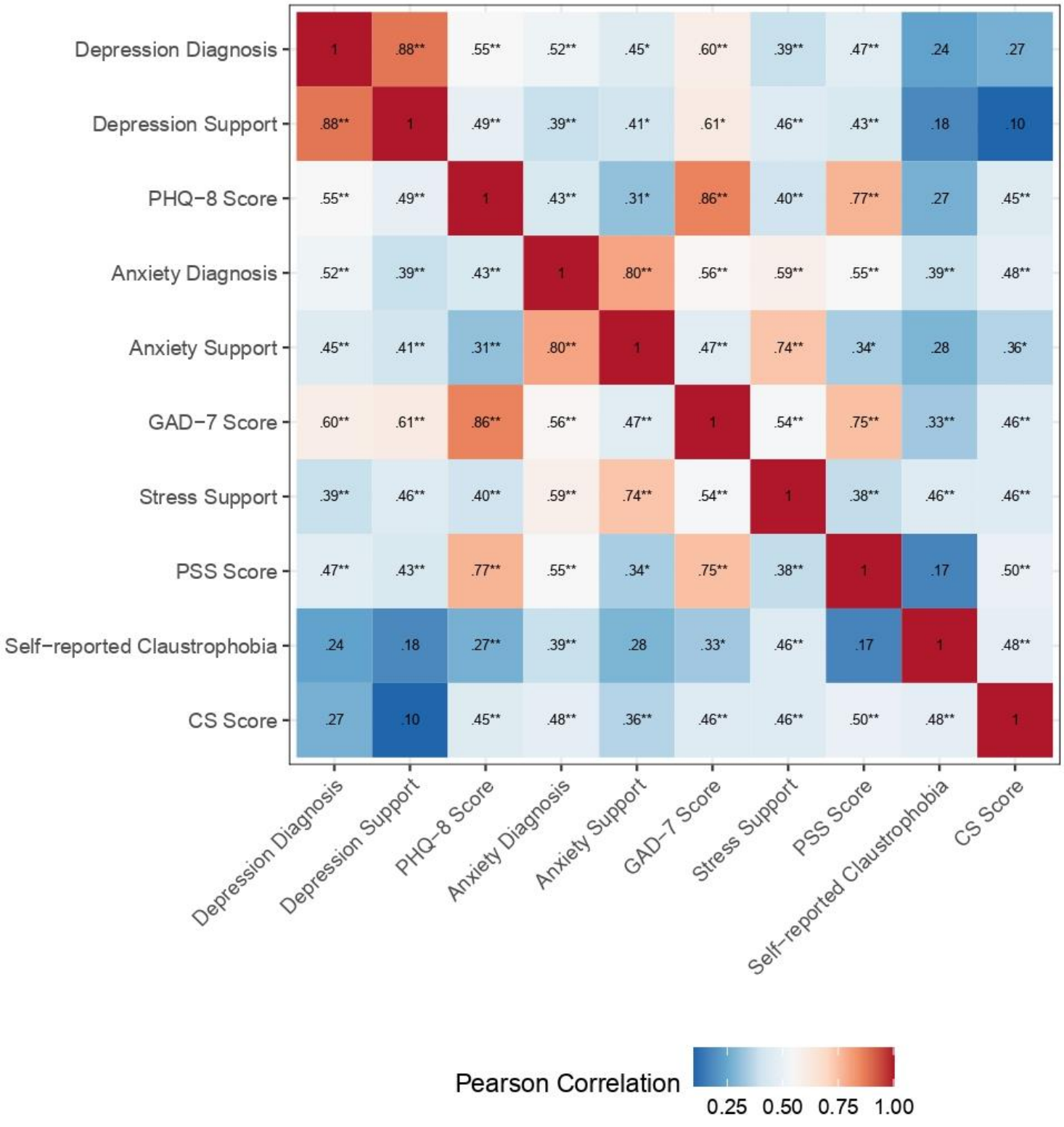


Figure 2. Pearson correlation coefficients between all predictor variables. Predictor variables that highly correlated with other measures were removed from the analyses to avoid multicollinearity. *Note*. PHQ-8 = Patient Health Questionnaire, GAD-7 = Generalised Anxiety Disorder Assessment, PSS = Perceived Stress Scale, CS = Claustrophobia Scale. **p<.05, **p<.01*

Table 3. Analysis of ‘Adherent’ and ‘Nonadherent’ Participants

	Estimate	Estimate *SE*	OR	95% CI for OR		*p* Value
				Lower	Upper	
Intercept	-4.98	1.60	.01			<.01
Depression Support (Yes)	2.62	1.02	13.74	1.88	100.39	.010
Self-reported Claustrophobia (Yes)	0.94	0.91	2.55	0.43	15.07	.302
PSS Score	-0.04	0.05	0.96	0.87	1.07	.497

Results of a logistic regression model evaluating the association between ‘adherent’ or ‘nonadherent’ participants and support for depression, self-reported claustrophobia, and PSS scores. *Note*. *SE* = Standard Error. OR = Odds Ratio. CI = Confidence Intervals, PSS = Perceived Stress Scale.

Table 4. Analysis of Average Hours CPAP Used

	Estimate	Estimate *SE*	Standardised Coefficient	95% CI for Estimate		*p* Value
				Lower	Upper	
Intercept	8.99	1.24	-	6.49	11.49	<.001
Depression Support (Yes)	-2.22	0.84	-0.41	-3.90	-0.54	.011
Self-reported Claustrophobia (Yes)	-1.02	0.84	-0.19	-2.70	0.66	.229
Stress Support	0.72	1.09	0.11	-1.49	2.92	.516

Results of a linear regression model evaluating the association between average hours of CPAP use and support for depression, self-reported claustrophobia, and support for stress. *Note*. *SE* = Standard Error. CI = Confidence Intervals, PSS = Perceived Stress Scale.

Table 5. Analysis of Days CPAP Used at All

	Estimate	Estimate *SE*	Standardised Coefficient	95% CI for Estimate		*p* Value
				Lower	Upper	
Intercept	26.98	1.51	-	23.94	30.02	<.001
GAD-7 Score	-0.37	0.21	-0.28	-0.79	0.05	.081
CS Score	-0.04	0.06	-0.11	-0.16	0.08	.494

Results of a linear regression model evaluating the association between days CPAP used at all and GAD-7 and CS score. *Note*. *SE* = Standard Error. CI = Confidence Intervals, GAD-7 = Generalised Anxiety Disorder Assessment.

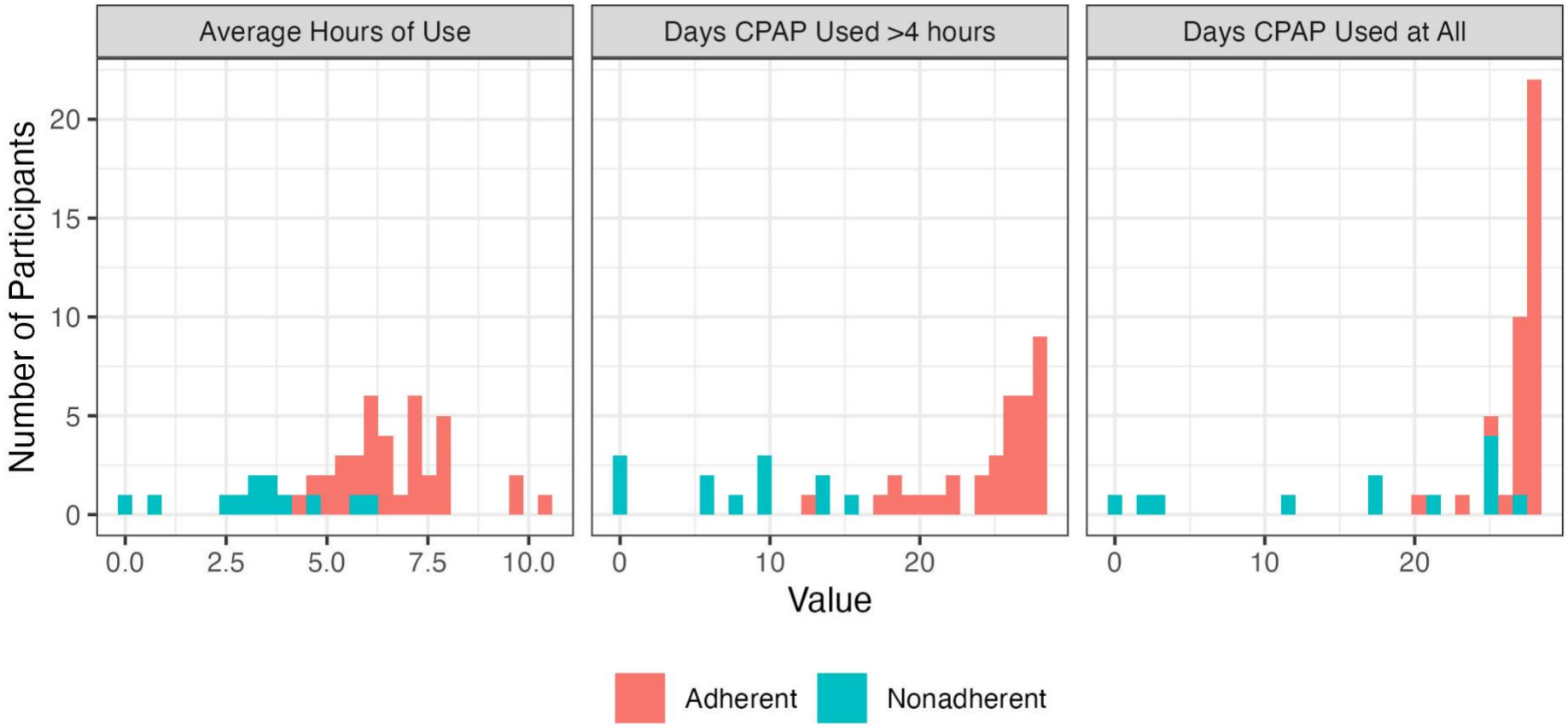
Table 6. Analysis of Days CPAP Used for Four or More Hours

	Estimate	Estimate *SE*	Standardised Coefficient	95% CI for Estimate		*p* Value
				Lower	Upper	
Intercept	32.64	3.75	-	25.08	40.20	<.001
Depression Support (Yes)	-10.25	3.24	-0.47	-16.78	-3.72	.003
CS Score	-0.11	.007	-0.25	-0.26	0.03	.119
PSS Score	0.16	0.18	0.15	-0.21	.054	.380

Results of a linear regression model evaluating the association between days CPAP used for four or more hours and support for depression, CS score, and PSS score. *Note*. *SE* = Standard Error. OR = Odds Ratio. CI = Confidence Intervals, CS = Claustrophobia Scale, PSS = Perceived Stress Scale.

Appendices

Appendix 2-A: Outcome Data



Figures to show the outcome data for average hours of CPAP use, days CPAP was used for 4 or more hours, and days CPAP was used at all. Data is further broken down to display ‘adherent’ and ‘nonadherent’ participants for each outcome measure.

Appendix 2-B: Submission Guidelines for *Sleep*

Instructions to Authors

SLEEP® is the official publication of the Sleep Research Society (SRS).

Scope

SLEEP® is a monthly, peer-reviewed scientific and medical journal that is published online. SLEEP® publishes a wide spectrum of original basic, translational and clinical sleep/circadian research findings. The primary audiences are research and clinical professionals specializing in sleep and circadian science and medicine.

Increase exposure to your research by publishing in SLEEP®:

- Accepted papers are immediately available on the SLEEP® website for viewing by all SRS and American Academy of Sleep Medicine (AASM) members and journal subscribers.
- Accepted abstracts are available on PubMed as Ahead of Print.
- All articles are available free to the public twelve months after publication.
- Noteworthy manuscripts are promoted to various national and local media via the journal's public relations staff.

Categories of Manuscripts

The following types of manuscripts will be considered:

Original Articles

Original Articles present original research findings in the fields of sleep/circadian medicine and sleep/circadian science, broadly defined. There is no minimum or maximum length for Original Articles, but reductions in manuscript length (including numbers of figures and/or tables) may be required as an outcome of peer review. The submission of incomplete data sets, partial cohorts, or pilot data is discouraged. SLEEP® does not publish Original Articles that describe individual patient-based case reports or case series that lack a comparator or control group and thus lacks analytical components for hypothesis testing.

Review Articles

Review articles are critical evaluations of material that has already been published. An author of a review article should consider the progress of current research toward clarifying a problem. A review paper should summarize previous investigations in order to inform the reader of the state of current research; identify relations, contradictions, gaps, and inconsistencies in the literature; and suggests the next step or steps in solving the problem. The review section may also include summaries of symposia presentations at national or international meetings.

Details of Style

People-Centered Language

Guidance for improving the language researchers use to talk to and about people with studied health conditions has been issued in several fields. The Editors of SLEEP® endorse the use of people-centered language in research communications. Our recommendations for people-centered language for sleep/circadian research publications can be found on this page.

Language

Papers should be clearly and concisely written in good English. Authors whose native language is not English should consult someone fluent in English prior to submission of the manuscript. Alternatively, a professional language-editing service can be used. Manuscripts may be returned to authors for revision for English language.

Sleep Medicine Terminology

Follow the terminology usage recommendations in the AASM Style Guide for Sleep Medicine Terminology.

Abbreviations

Please note that journal style for the abbreviation of standard deviation is SD. Please do not use SD as an abbreviation for sleep deprivation.

Each abbreviation should be expanded at first mention in the text and listed parenthetically after expansion.

Drug Names

Use generic names in referring to drugs; trade names may be given in parentheses after the first mention, but the generic name should be used thereafter.

Reference Style

SLEEP uses the American Medical Association 10th Edition style guide.

For abbreviations of journal names, refer to "List of Journals Indexed in Index Medicus."

Manuscript Format Requirements

Format Neutral Submission: New manuscripts may be submitted format neutral, as a single Word, RTF, or PDF file. Technical formatting such as reference layout and order of components is not scrutinized for compliance at this initial stage. If the required information is present (complete title page, all author information, abstract, full text, figures and tables, references, etc.) the manuscript will be assessed solely on its scientific merit.

At any later stages of the submission process, your article will need to follow the below requirements.

Manuscript should be provided in Microsoft Word.

Pages should be numbered.

Lines should be double spaced.

Do not number the lines.

Manuscripts should be structured using the following components:

Title Page (Page 1 of manuscript)

- Title and Subtitle (if applicable). Please do not include a running title
- Authors and Author affiliations (identify the institution where the work was performed)
- Corresponding author's name, full address and current, valid email address

Abstract (Page 2 of manuscript)

Each original manuscript and review article must be preceded by an abstract. Abstracts are not required for letters to the editor and editorials.

The abstract is limited to 250 words. The components of this format are (start each on a new line): Study Objectives, Methods, Results, Conclusions and Keywords. Conclusions should not simply restate results, but should address the significance and implications of the findings. Authors have the option of not using section headings and may submit a single paragraph, narrative abstract of 250 words maximum length. Abstracts should include as few abbreviations as possible, must follow the title page and should begin on a new page

Keywords

Abstracts must be followed by no fewer than three but no more than ten keywords that reflect the content of the manuscript. For guidance consult the Medical Subject Headings - Annotated Alphabetic List, published each year by the National Library of Medicine.

Graphical Abstracts

Authors of Original Articles are required at the revised submission stage to submit a graphical abstract in addition to a text abstract for their article. Authors of Review Articles and Perspectives are encouraged to submit a graphical abstract with their article in addition to the text abstract. Articles with no text abstract may not include a graphical abstract.

The graphical abstract should clearly summarize the focus and findings of the article and will be published as part of the article online and in the PDF. The graphical abstract should be submitted for peer review as a separate file, selecting the appropriate file-type designation in the journal's online submission system. The file should be clearly named, e.g., graphical_abstract.tiff. Please see Guidance on appropriate file format and resolution for graphics. Please ensure graphical abstracts are in landscape format.

Introduction

State the objective of the reported research, with reference to previous work.

Methods

Describe methods in sufficient detail so that the work can be duplicated, or cite previous descriptions if they are readily available.

Results

Describe results clearly, concisely, and in logical order. When possible give the range, standard deviation, or standard error of the mean, and statistical significance of differences between numerical values.

Discussion

Interpret the results and relate them to previous work in the field. Include a paragraph near the end of the discussion that briefly lists the limitations of the study.

Acknowledgments

The minimum compatible with the requirements of courtesy should be provided. Umbrella groups and specific author contributions may be listed in this section.

Disclosure Statement

The Disclosure Statement is required for all categories of papers (including letters to the editor,editorials and Journal Club reviews).

The Disclosure Statement includes:

- Financial arrangements or connections that are pertinent to the submitted manuscript. If there are no interests to declare use the statement: Financial Disclosure: none.
- Non-financial or conflicts of interest that could be relevant in this context should also be disclosed. If there are no non-financial interests to declare use the statement: Non-financial Disclosure: none

Citations within Text/Reference List

SLEEP uses the American Medical Association 10th Edition style guide. There is no limit on the number of references for original articles or reviews. The reference section should begin a new page at the end of the text.

A standard bibliography program such as EndNote or Reference Manager may be used. We cannot guarantee that citation/reference software will match

all SLEEP® author guidelines.
Accuracy of reference data is the responsibility of the author. Failure to initially comply with the journal's style requirements may result in manuscripts returned to authors for correction and may potentially delay publication.

SLEEP® does not allow citation of preprint manuscripts in final published articles. Prior to publication of accepted papers, preprint citations must be replaced with the final, peer-reviewed version of record. If the cited preprint work has not been published by acceptance, it must be removed from the reference list.

Citations within the Text

- Each reference should be cited in the text, tables, or figures in consecutive numerical order by means of Arabic numerals placed in brackets and outside periods and commas and inside colons and semicolons.
- When three or more references are cited at one place in the manuscript, a hyphen should be used to join the first and last numbers of a series.
- Commas should be used without spaces to separate other parts of a multiple-reference citation.

Sample citations within the body of a paper

- According to our previous work, [1, 3-8, 19]
- The patients were studied as follows [3, 4]

Reference List

- Provide all authors' names when fewer than seven; when seven or more, list the first three and add et al.
- Provide article titles and journal name. For abbreviations of journal names, refer to "List of Journals Indexed in Index Medicus."
- Provide year, volume, issue and inclusive pages.
- Provide DOIs and URLs when appropriate.

Sample references:

- Journal Article:
- Rainier S, Thomas D, Tokarz D, et al. Myofibrillogenesis regulator 1 gene mutations cause paroxysmal dystonic choreathetosis. Arch Neurol. 2004; 61 (7): 1025–1029.

- Lehert P, Falissard B. Multiple treatment comparison in narcolepsy: a network meta-analysis. Sleep. 2018; 41 (12). doi.org/10.1093/sleep/zsy185.

Book:

- Modlin J, Jenkins P,. Decision Analysis in Planning for a Polio Outbreak in the United States. San Francisco, CA: Pediatric Academic Societies; 2004.

Chapter of a book:

- Solensky R. Drug allergy: desensitization and treatment of reactions to antibiotics and aspirin. In: Lockly P, ed. Allergens and Allergen Immunotherapy. 3rd ed. New York, NY: Marcel Dekker; 2004: 585v606.

Figure Captions

A list of figures: Figure number, title and captions should appear in manuscript following references.

Figures and Tables

Figure Guidelines

The following graphics can be submitted as figures: charts, graphs, illustrations, and photographs. Use color where appropriate. There is no charge for color.

Remove figures from the manuscript: Submit figures separately, one per file.

Figures must be cited, consecutively, in the manuscript text.

Figures should be numbered using Arabic numerals (e.g., Figure 1, Figure 2 etc.).

Figure resolution must be a minimum of 300 dpi.

Unacceptable file types: Figures embedded as images in a Word document or in PowerPoint slides

Acceptable file types: .tif, .eps, or .pdf files.

Charts and graphs that are built in a Word document or an Excel spreadsheet can be submitted as a Word .doc file or an Excel .xls file.

Figure titles and captions should appear together in a list, placed after the manuscript text.

Multi-part figures: Assemble the parts into one file rather than sending several files. Do not submit Fig 1 a, Fig 1 b, Fig 1 c. Instead submit Fig 1 a-c.

Symbols and abbreviations should be defined within the figure or in the figure caption or together in a key.

Type within figures must be legible in the final pdf. Avoid the use of italic and bold unless necessary.

Table Guidelines

Tables must not duplicate data reported in the manuscript text or figures.

Each table must be self-contained and comprehensible without referring to the manuscript

Each table should begin a new page

Tables may be included in the manuscript document following the Reference List and/or Figure Captions List.

Alternatively tables may be submitted together in a separate file with the File Name: Tables.

Tables must be cited, consecutively, in the manuscript text.

Tables should be numbered using Arabic numerals (e.g., Table 1, Table 2 etc.)

Tables should be formatted to fit the width of the page (use landscape when necessary.)

Tables must be editable, created using the table function in Microsoft Word or in Excel.

Tables embedded as images in a Word document or tables in PowerPoint are unacceptable for publication.

Each table must have a corresponding short title above the table and caption below.

Symbols and abbreviations should be defined within the table caption or together in a key.

Footnotes should be marked with superscript lowercase letters or symbols and not marked with numbers (Arabic or Roman numeral).

All footnotes should be fully expanded in the table caption.

Type within tables must be legible in the final pdf. Avoid the use of italic and bold unless necessary.

Authors are responsible for obtaining full permission to publish tables that have been previously published. Permission from the original publisher must be obtained and all necessary attribution should be included in the table's caption.

Citations within Text/ Reference List

SLEEP® uses the American Medical Association 10th Edition style guide. There is no limit on the number of references for original articles. The reference section should be included starting on a separate page at the end of the text, following the style of the sample formats given below. A standard bibliography program such as EndNote or Reference Manager may be used. We cannot guarantee that citation/reference software will match all SLEEP® author guidelines. Accuracy of reference data is the responsibility of the author. Failure to initially comply with the journal's style requirements may result in manuscripts returned to authors for correction and may potentially delay publication.

Doctorate in Clinical Psychology | Lancaster University

Section 3 : Critical Appraisal

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This critical appraisal provides a summary of the main findings and considerations resulting from the literature review and empirical paper. Further evaluation of the project is provided, including strengths, value, and limitations. Reflections on the empirical study, incorporating challenges and ethical considerations will be offered, alongside thoughts for future research. The complex relationship that exists between sleep apnoea and psychological distress will be discussed in light of the findings from both chapters, in the context of each other. Lastly, the critical appraisal is concluded with consideration for the under recognition of sleep, which inspired this thesis.

Literature Review Summary

The aim of the review was to collate the current evidence on the association between suicidality in individuals with sleep apnoea. Disturbed sleep has long been known to impact mental health, including anxiety, [12-14] depression, [15-17] and suicide. [32, 54] Whilst numerous reviews have documented the association between sleep and mental health, [9, 10] to our knowledge, the association between suicide and sleep apnoea, has not been reviewed. Given the known link between sleep apnoea and mental health, the relationship between sleep apnoea and suicide warrants attention. Therefore, a scoping review was conducted to ascertain the current knowledge, identify gaps within the literature, and inform future research. Twenty-four papers were included and analysed. The review suggested a potential bi-directional relationship between sleep apnoea and suicidality, with individuals with sleep apnoea found to be at greater risk of suicidality, and people experiencing suicidality showing a higher rate of sleep apnoea compared to controls. Important implications for clinical practice were highlighted, including the cruciality of healthcare professionals (HCPs) to be aware of the association, and the potential for effective treatment of sleep apnoea to alleviate suicidality.

Empirical Study Summary

The aim of the empirical study was to investigate the impact of psychological distress on adherence to continuous positive airway pressure (CPAP) in individuals with sleep apnoea. CPAP is the gold standard treatment for obstructive sleep apnoea (OSA), [11, 12] yet despite its efficacy in alleviating the physical [13-16] and psychological effects of OSA, [17-20] adherence remains poor. [21] As such, much literature has attempted to identify predictors of CPAP usage. Thus far, psychological factors have received the least attention, with the current evidence-base investigating the impact of psychological distress on CPAP adherence inconclusive due to inconsistencies in findings and methodological limitations. We recruited 47 individuals newly diagnosed with OSA from a sleep service and investigated the impact of depression, anxiety, stress, and claustrophobia on their first 28-days of objective CPAP usage. Measures of depression were predictive of both frequency, and duration of CPAP usage. Additionally, CPAP 'adherent' participants had significantly higher anxiety scores. Claustrophobia and stress were not associated with adherence. The findings suggest that individuals with OSA experiencing depression or anxiety are at risk of 'nonadherence' to treatment, and thus psychological distress may be an appropriate target for evidence-based interventions. Given the small sample size, further research is required to confirm these results in a large multisite study.

Empirical Study Evaluation

The empirical study builds on past research investigating the impact of psychological distress on adherence to CPAP in people with OSA. This study provides a valuable contribution to research and clinical practice by addressing several methodological limitations evident in past literature.

Firstly, in contrast to much previous research, key strengths of the study are the utilisation of objective recording of CPAP usage, which provided a measure of actual mask-on usage, and recruitment through a specialist sleep service to ensure clinician diagnosed

OSA. Additionally, data were collected remotely, and the research team had no involvement with participants during the analysed period of CPAP usage. This allowed for minimal interference, which we hope resulted in participants being less mindful that their adherence was being monitored for research purposes, thus providing a more accurate representation of CPAP usage. Indeed, participants who consented to were sent a Qualtrics survey inviting them to provide feedback on their participation in the research (Appendix 3-A). Although there were varied reports on how mindful participants were of being monitored, overall, participants did not feel the study impacted their adherence (Appendix 3-B). Furthermore, participants reported positive experiences of the study, and reported feeling comfortable, and the questionnaire being easy to access and complete. The feedback provides support for the study protocol and suggests its feasibility to be replicated in sleep services that routinely collect adherence data. Although this means the impact of individual sleep service involvement cannot be controlled for, it allows for an accurate representation of real-world clinical management of OSA.

A further strength of the study was the comprehensive measures of psychological distress using self-reported professional diagnoses and support, and severity questionnaires designed to provide tentative diagnoses. It is well known that depression severity questionnaires can be influenced by physical health symptoms, [22, 23] thus the measures of depression diagnoses and support arguably provide a more reliable measure. However, due to the constraints of this study, diagnoses could not be confirmed through medical records, and thus future research should attempt to address this when replicating the protocol. Nonetheless, the comprehensive measures utilised in the study have helped to identify the most useful variables and measures to be used in future research.

As well as psychological distress, the comprehensive measures of adherence were a key contribution of this study. Traditional measures of adherence were used to allow for

comparison with previous research, in conjunction with the average hours of usage overall and measures of frequency of use. The importance of assessing not only the duration, but also the frequency of CPAP use was highlighted by Wohlegemuth et al., [24] who investigated the impact of self-efficacy on CPAP adherence in individuals with OSA. Using latent profile analysis, they identified three groups: non-adherers, attempters, and adherers. Non-adherers used CPAP 18.2% of nights for an average of 37 minutes and used CPAP more than four hours on 6.2% of nights. Attempters used CPAP 68.2% of nights for an average of 156 minutes and used CPAP more than four hours on 29.3% of nights. Finally, adherers used CPAP 95.4% of nights for an average of 392 minutes and used CPAP more than four hours on 86.2% of nights. This study highlighted the importance of comprehensively measuring adherence, as had the typical definition of 'adherence' been used, then 'attempters' would have been classified as 'non-adherers', despite evidence they were trying. Research has shown that 8% to 15% of individuals discontinue CPAP after the first night. [25] These individuals may be a challenging target for interventions to increase adherence, as they have likely decided against the treatment. However, individuals utilising CPAP for many nights, but for a short duration, may be a prime target for interventions, as they have not completely disregarded CPAP, but are struggling to endure the treatment. The results of the empirical paper suggested that although psychological distress may not have an impact on how many nights individuals attempt using CPAP, it can impact how many nights they are able to endure CPAP for a sustained period. Thus, there is preliminary evidence to suggest that depression and anxiety may be potential targets for interventions to increase the duration of CPAP usage.

Although two previous studies have investigated the impact of psychological diagnoses on both duration and frequency of CPAP usage, [26, 27] all participants were military veterans, limiting their generalisability. The present study contributes to the literature

by providing an evaluation in a more representative sample. It is important to note the incongruence in findings from these previous studies in comparison to the current study. Specifically, although both studies evidenced psychological diagnoses to impact frequency of usage, they failed to find an association with duration of usage. The reasons for the difference in findings in this empirical paper are unclear. It may possibly be due to the different sample populations. However, it is also noted that both past studies dichotomised psychological diagnoses as 'present' or not, and thus grouped all psychological distress as one. Given the current study found no evidence for the impact of stress and claustrophobia on CPAP usage, this highlights how different forms of psychological distress may impact CPAP usage differently. Thus, the study highlights the importance of distinguishing the type of psychological distress, and future research should consider this.

Despite its value, the empirical study is not without limitations necessary for future research to consider. Firstly, the small sample size warrants particular attention. Unfortunately, due to recruitment difficulties and time constraints of the Doctorate in Clinical Psychology, we were only able to recruit 55% of our original target. As such, the results must be interpreted with caution. Additionally, whilst we initially intended to calculate the prevalence of psychological distress in sleep apnoea, the difficult decision was made to exclude this analysis from the study, as it felt unreliable to draw conclusions regarding prevalence based on the sample size recruited. Thus, it is imperative for future studies to attempt to replicate the current findings and establish the prevalence of psychological distress in a larger sample.

Further considerations for future research also include the inclusion of biomedical and social factors as predictors. CPAP adherence is likely multifaceted, [23, 28, 29] and previous research has documented the predictive value of biomedical factors such as OSA severity and symptomatic improvement, [28, 30-32] and social factors such as socioeconomic status and

partner support. [32-36] The World Health Organisation postulates that “non-adherence is a multidetermined problem caused by the interplay of four factors”. [37, p8] These fours factors: the health care system, condition related factors, characteristics of therapy and patient-related factors, largely fit with the biopsychosocial model. [28] The biopsychosocial model suggests that biological, psychological, and social factors interact to influence physical health [38] and stresses the importance of normalising the influence of psychological factors on physical health conditions. [39] The importance of utilising a biopsychosocial model to identify predictors of CPAP usage, and manage OSA, has been highlighted. [28] However, there is first a need to identify potentially important psychological factors that have been largely under researched. [28] Despite its limitations, the empirical study provides initial evidence that depression and anxiety contribute towards CPAP adherence. Future research should aim to develop a testable model to assess the interplay of biological, psychological, and social factors and design future studies to investigate the impact of psychological distress alongside biological and social factors.

Ethical Considerations, Challenges, and Reflections

The main challenge that arose throughout the empirical study was the aforementioned recruitment difficulties. Prior to conducting the study, there was an awareness of low adherence rates to treatment within the OSA population. [32, 40-42] This provided some indication that recruitment may prove challenging, as this appeared to be a population who may be somewhat ambivalent to their disorder and therefore may not be as motivated to engage in related research. As such, methods to increase recruitment, and potential contingency plans, were considered. Firstly, the decision was made to offer a prize draw as a thank you for participating in the research, despite this not being standard practice in the Doctorate in Clinical Psychology. Discussions were also held with the sleep service to discuss feasibility. This provided some reassurance due to the reported large pool of potential

participants to recruit from. Indeed, throughout the study, 446 individuals were diagnosed with OSA and prescribed CPAP. Nonetheless, recruitment proved slow with a study uptake rate of 11%.

Recruitment difficulties were further complicated by an extensive National Health Service (NHS) and Health Research Authority ethics approval process and a delayed Research and Development (R&D) process at the recruitment site. These delays resulted in a reduced recruitment period, causing additional time pressures. Additionally, the lengthy R&D process meant expanding the study to include a second sleep service site would likely be difficult, given time constraints.

As such, the decision was made to extend the study in attempt to reach the target sample size. The recruitment period was extended twice and continued up until the limit of the standard Doctorate in Clinical Psychology course timeline. However, despite this, the original sample target was not achieved and thus, an ethical dilemma was reached. Thought was given to the ethical implications of closing recruitment prior to reaching the target sample, against collecting more participant data that may not make a substantial difference to the analysis. The average rate of recruitment was calculated to be around nine participants per month. As such, it was probable that a significant extension would be required to realise the planned sample size. Strong ethical consideration was given to the additional pressure that would be placed on the sleep service should a large extension be made, and thus the decision was made to stop recruitment and interpret the results with caution.

Significant efforts were made to increase recruitment during the active phase of the study. Firstly, amending the proposal to allow for participants to also be recruited outside of the NHS was considered. Recruiting through sleep services allowed for a medically confirmed diagnosis of OSA, and objective CPAP usage data. Whilst recruiting through social media and 3rd sector organisations would have increased the pool of potential

participants, it would have required participants to self-report a diagnosis of OSA, and their CPAP usage. Given non-objective CPAP adherence data is a key limitation of previous studies that the current study aimed to address, this option did not appear viable.

Consideration was also given to widening the eligibility criteria to include anyone under the service prescribed CPAP for OSA, not just new users. This would have significantly expanded the potential participant pool. However, CPAP adherence patterns are generally established within the first week. [43-45] Thus, studies examining the impact of depression in established CPAP users are open to selection bias, as if depression does impact adherence, it is likely they may have already discontinued CPAP, and thus self-selected out of potential recruitment. [23] Furthermore, given the clinical significance of being able to identify those at risk of non-adherence prior to commencing treatment, [46, 47] it was felt that the disadvantages of recruiting existing CPAP users, outweighed the benefits of a larger sample size.

The reason for the low recruitment rate is unknown. As noted, this may be somewhat due to potential ambivalence in the population. Equally, participants may have not been incentivised to participate due to reimbursement being a prize draw rather than guaranteed compensation. Although the questionnaire was only short and thus time commitment minimal, providing access to CPAP usage perhaps was considered invasive and thus participants may have felt a higher reimbursement would have been more appropriate. It is noted that within the feedback, most participants stated that they neither agreed nor disagreed that they were fairly compensated. However, one participant stated that they were “not compensated”. Importantly, the vast majority of participants reported that they ‘strongly agreed’ their participation was valued by the research team, suggesting partaking may have largely been driven by good-will. Future research may wish to not rely on personal

motivation and good-will and instead cost projects to provide proportionate reimbursement to participants.

Low recruitment yields from sleep clinics have been previously reported, particularly when there are numerous eligibility criteria such as no prior CPAP use. [48] Consequently, the need for a large pool of potential participants has been highlighted. [48] The empirical study provides support for this consideration in future research. Given the eligibility criteria is necessary to replicate the current findings, further funded research with greater resources and less time restrictions should consider expanding the pool by utilising multiple sites, and a longer recruitment time.

Further ethical considerations arose relating to participants disclosure of psychological distress without the ability to offer support. I noticed feeling uncomfortable when scoring psychological distress measures that indicated high levels of depression, anxiety and stress in participants who had reported that they were not currently receiving support. Details of support helplines were provided in the information and debrief sheets and participants were encouraged to contact their GPs should they need support. However, feelings of helplessness due to not being able to directly speak to participants to offer support or signpost elsewhere were noted. Reflecting on occupying the role of researcher as opposed to clinical psychologist during the study was thus key throughout the process. Nonetheless, future research may consider asking participants' consent to being contacted for signposting should their questionnaires indicate high levels of psychological distress.

Feelings of helplessness were common throughout the process, and I have reflected on how this is likely due to feeling 'distant' from the research. It is noted that the research team rarely had direct contact with participants. Recruitment was facilitated by the sleep clinic, questionnaires were all completed online, and data were retrieved remotely. This ignited a feeling of lacking control, which was particularly strong during recruitment

challenges as I wished to be able to do more to help. Nonetheless, as noted earlier, this 'distance' allowed for minimal interference with routine care, thus allowing for a more accurate representation of real-life support for OSA with CPAP. As such, 'sitting' with these feelings of discomfort were key throughout the study.

One final reflection relates to the lack of scoping review registration. Registering a literature review is good practice as it increases transparency, helps reduce bias, and avoids duplication of reviews. [49] At the time of commencing the review, PROSPERO did not accept scoping reviews. Unfortunately, I was unaware that scoping reviews could be registered on alternative platforms such as Open Science Framework until the review process had begun. I have reflected on how registering the review would have increased the credibility of the paper. However, I have taken this as a learning point and now have an increased awareness for future research.

The Complex Relationship Between Sleep Apnoea and Psychological Distress

The findings of the review and empirical study have revealed key insight into the relationship between sleep apnoea and psychological distress. Research has documented that psychological distress in the forms of anxiety and depression are associated with sleep apnoea. [10, 50-52] The findings of the review provide evidence that this association further extends to more severe forms of psychological distress, namely, suicidality. Several possible explanations for the mechanisms behind this association have been proposed. Sleep apnoea may contribute to psychological distress through intermittent hypoxemia and disturbed sleep, [53-57] or disruption of the hypothalamic-pituitary adrenal axis resulting in elevated cortisol levels and subsequently mood disturbances. [29, 65]

The association between psychological distress and sleep apnoea is further complicated by suggestions that the relationship may be bidirectional, [23, 59, 60] with sleep apnoea not only resulting in higher rates of psychological distress, but the reverse also being

true. Whilst the idea that psychological distress can lead to sleep apnoea has previously been criticised, [61] the current review found evidence of higher rates of OSA in individuals with major depressive disorder. Further research has also found depression to be a strong risk factor for incident OSA. [60] One explanation for this association is neurotransmitter dysfunction. The links between depression and abnormalities in the neurotransmission of serotonin have been well documented. [62] Additionally, serotonin can also reduce the upper airway size, which may potentially increase the risk of OSA. [63] Another explanation may be the pharmacological treatment for psychological distress, as this is known to cause weight gain, which is a risk factor for OSA. [59, 64] Similarly, it is plausible that the behavioural impacts of depression, such as decreased motivation and loss of energy, [65] may lead to weight gain, thus subsequently increasing the risk of OSA. [66]

Whilst the exact mechanisms driving the association between sleep apnoea and psychological distress are unknown, the relationship makes the findings of the empirical paper even more critical, given the evidence that psychological distress may reduce adherence to treatment. This is of paramount clinical significance given that the review suggested that elevated risk of suicide in people with sleep apnoea can be alleviated by CPAP treatment, with similar also being documented for anxiety and depression. [22, 67, 68] As such, there appears to be a vicious cycle, where untreated sleep apnoea exacerbates psychological distress, which in turn reduces the effectiveness of the treatment required to alleviate psychological distress. The relationship between psychological distress and sleep apnoea is thus complex and multidirectional, whereby the presence of one may worsen or lead to challenges in treating the other. [68] Though further exploration of the exact mechanisms is needed, there is a clear need for HCPs to be aware of the current knowledge and provide education to help individuals with sleep apnoea to understand that CPAP

adherence is not only crucial for the alleviation of physical symptoms of OSA, but also psychological distress.

The Under Estimation of Sleep

Sleep is fundamental to survival, [69, 70] indeed, the average person spends around one third of their life sleeping. [71] Unfortunately, sleep disturbances are highly prevalent, [72, 73] with between 23% and 56% of people experiencing at least one sleep related difficulty. [74] Disrupted sleep has been found to influence almost every facet of human function, including cardiometabolic, immune system, brain functioning, mental health, and quality of life. [75-77] Remarkably, even one night of poor sleep can have detrimental effects on cognition and mood. [78, 79] Despite this, the importance of sleep is still under recognised. [80]

The general population often diminishes the seriousness of sleep related difficulties and considers them to be low on the hierarchy of important health concerns. [80] Furthermore, HCPs poorly understand the importance of sleep and thus its impact is often under recognised in health settings. [81-83] On the basis of a large systematic review, Chattu et al. [80] concluded that there needs to be greater awareness of the consequences of poor sleep in professionals, and the public. The challenges that arose during the empirical paper perhaps display an interesting parallel between how people perceive sleep, and how people responded. Specifically, the slow ethics process, and low study uptake possibly reflect the perceived lack of importance of a topic such as sleep apnoea.

Due to the amount of time clinical psychologists spend with clients, they are well placed to assess, manage and educate individuals about the importance of disrupted sleep. [84] Yet, research suggests that clinical psychologists also have a limited understanding of sleep-related difficulties. Although originating from the United States and Canada, evidence shows that few clinical psychologists have received formal training in sleep, [84] with only

six percent of clinical psychology doctorate programs offering specific teaching on the topic. [85] This contrasts to the level of training in other physical health topics such as sexual health, where a much higher percentage of clinical psychologists report having received specific teaching. [86]

I have reflected on how these findings largely mirror my own experiences of the Doctorate in Clinical Psychology course, with no recollection of any specific teaching being provided related to sleep. Thus, there is a considerable need for increased teaching and awareness about sleep in clinical psychologists in the UK. It has been proposed that one possibility to facilitate this change may be for accrediting bodies to recognise sleep as important and specify it as a topic that clinical psychology programs must teach to receive accreditation. [84] The current findings provide further support for the implementation of this change.

There are numerous potential explanations for the lack of sleep teaching in training courses. Firstly, programs may share the public's perception that sleep lacks importance. Equally, people may be of the opinion that sleep is not a topic relevant to clinical psychologists. The results of the current review and empirical study suggest otherwise and highlight the necessity for clinical psychologists to provide support for the high rates of psychological distress in sleep apnoea and the subsequent impact on CPAP adherence. Furthermore, sleep is particularly relevant for clinical psychologists given it is a modifiable target for change that can be easily introduced into therapies. Thus, it is hoped that the findings contribute to an increase in recognition of sleep as a crucial factor for both physical and mental wellbeing and encourage further research to improve understanding in this under recognised area.

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Appendix 3-A: Blank Qualtrics Feedback Survey

Lancaster University

Feedback Survey

How would you rate your overall experience participating in this research study?

- ○ Very positive
- ○ Somewhat positive
- ○ Neutral
- ○ Somewhat negative
- ○ Very negative

How easy was the online questionnaire to access?

- ○ Extremely difficult
- ○ Somewhat difficult
- ○ Neither easy nor difficult
- ○ Somewhat easy
- ○ Extremely easy

How easy was the online questionnaire to complete?

- ○ Extremely difficult
- ○ Somewhat difficult
- ○ Neither easy nor difficult
- ○ Somewhat easy
- ○ Extremely easy

Did you feel comfortable during the research process?

- ○ Always
- ○ Most of the time
- ○ Sometimes
- ○ Rarely
- ○ Never

Throughout the study period, did you find yourself mindful that your CPAP usage data was being monitored for research purposes?

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Throughout the study period, did you feel your participation in the study impacted how you used your CPAP machine?

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Did you feel that your participation was valued by the research team?

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Did you feel fairly compensated for your participation in the research study?

- ○ Strongly agree
- ○ Somewhat agree

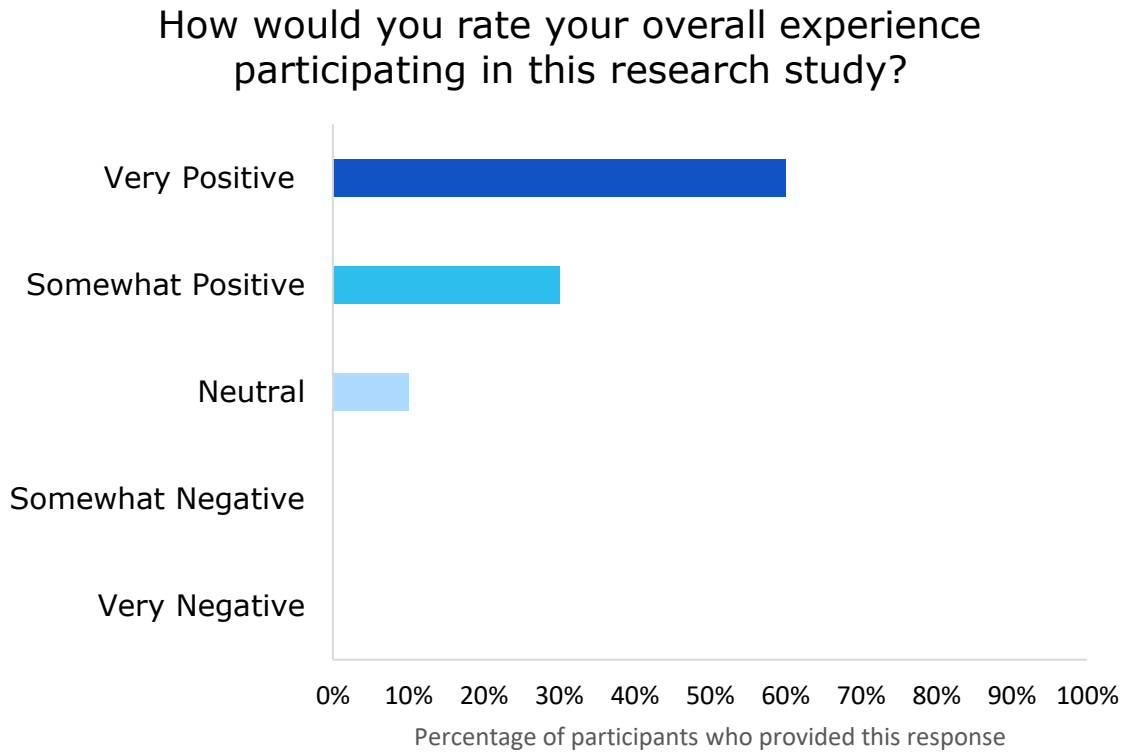
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

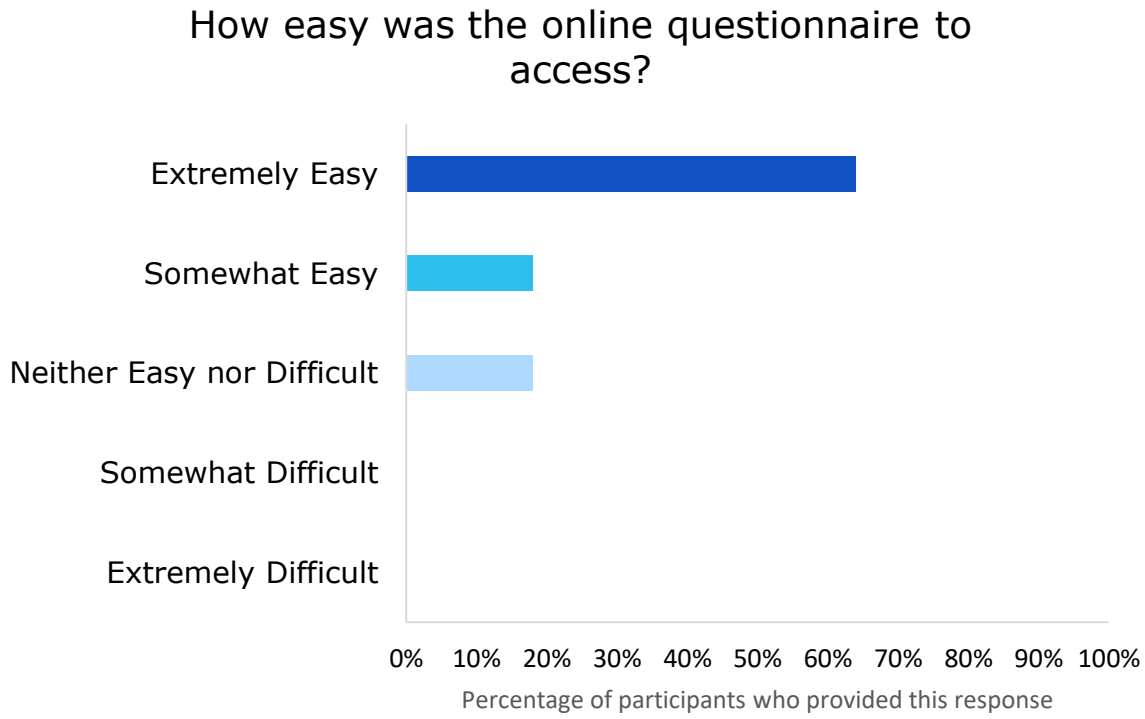
Do you have any other comments about your participation in the research?

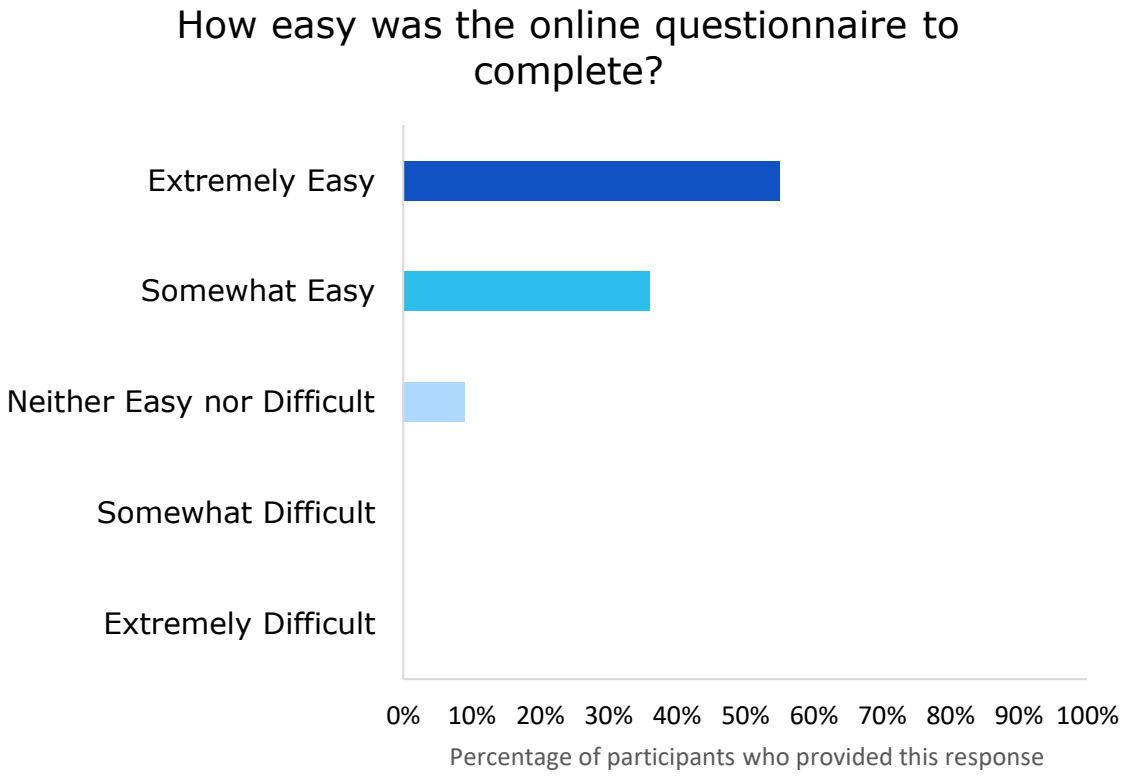
Do you have any suggestions for improving the research process in the future?

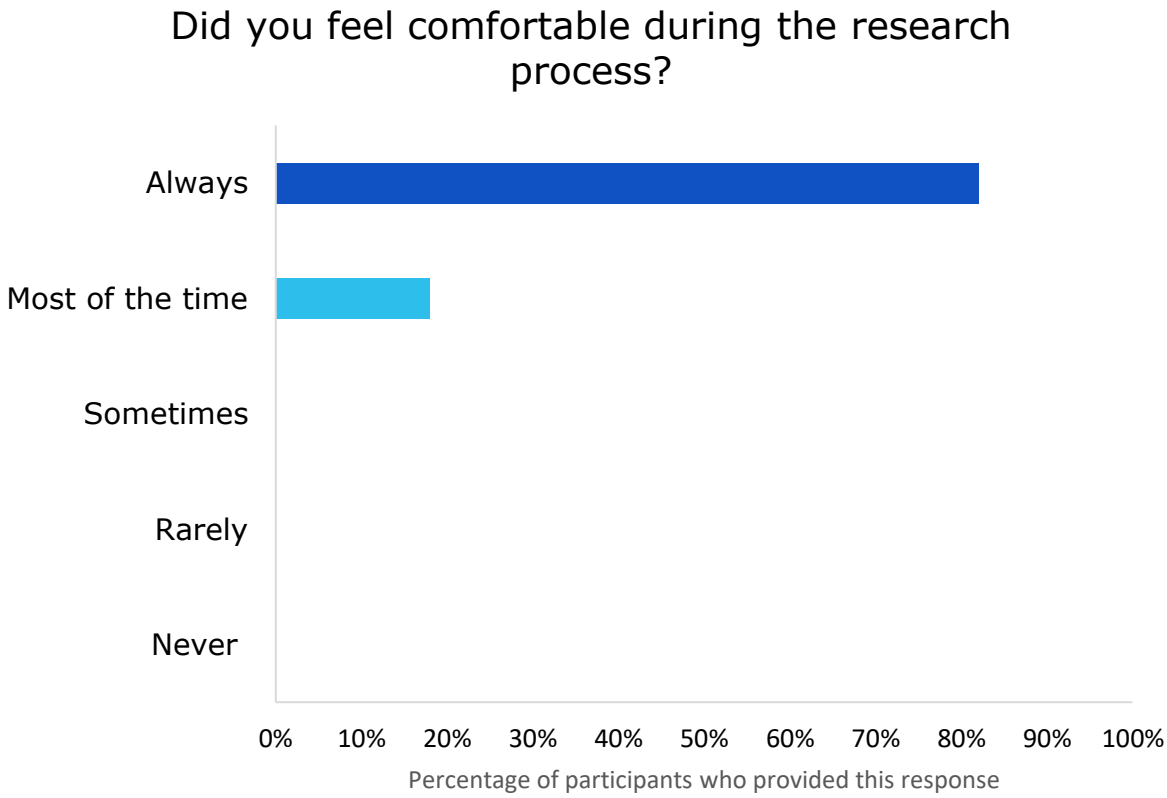
Appendix 3-B: Feedback Survey Responses

A total of 11 people responded to the feedback survey. Details of participant responses are displayed below.

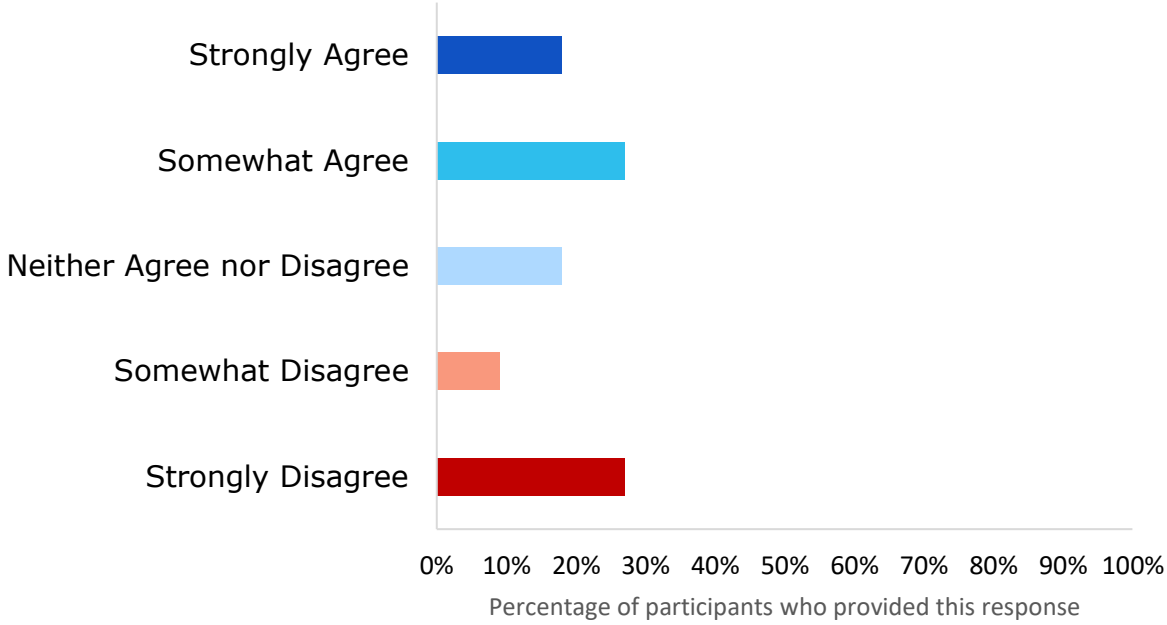




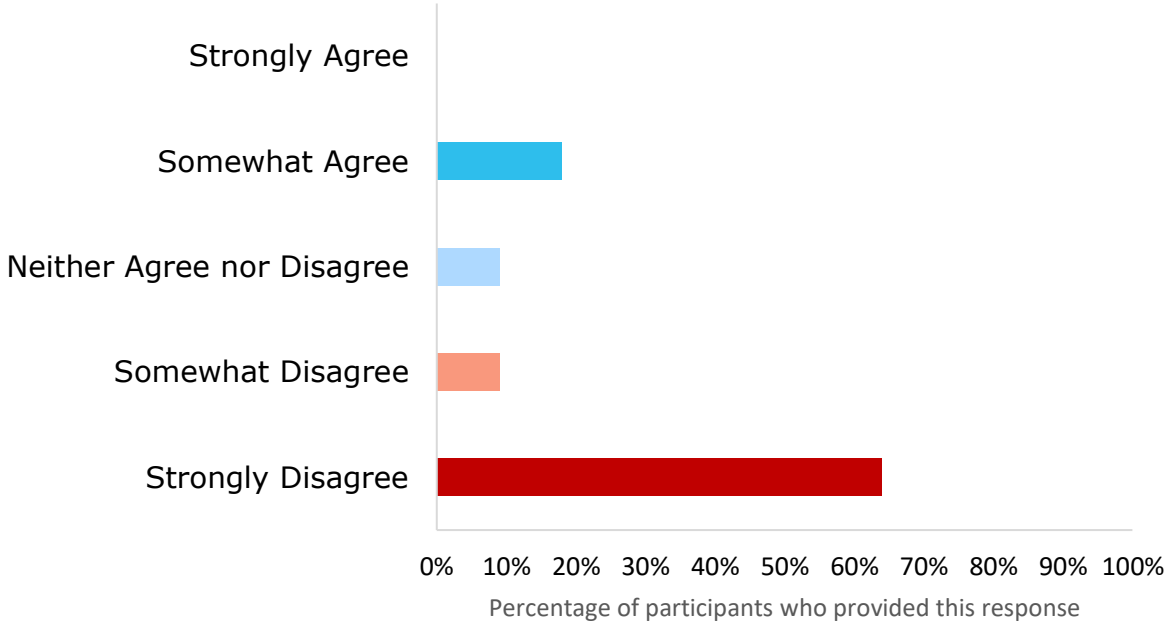

How easy was the online questionnaire to complete?
Extremely Easy
Somewhat Easy
Neither Easy nor Difficult
Somewhat Difficult
Extremely Difficult
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percentage of participants who provided this response

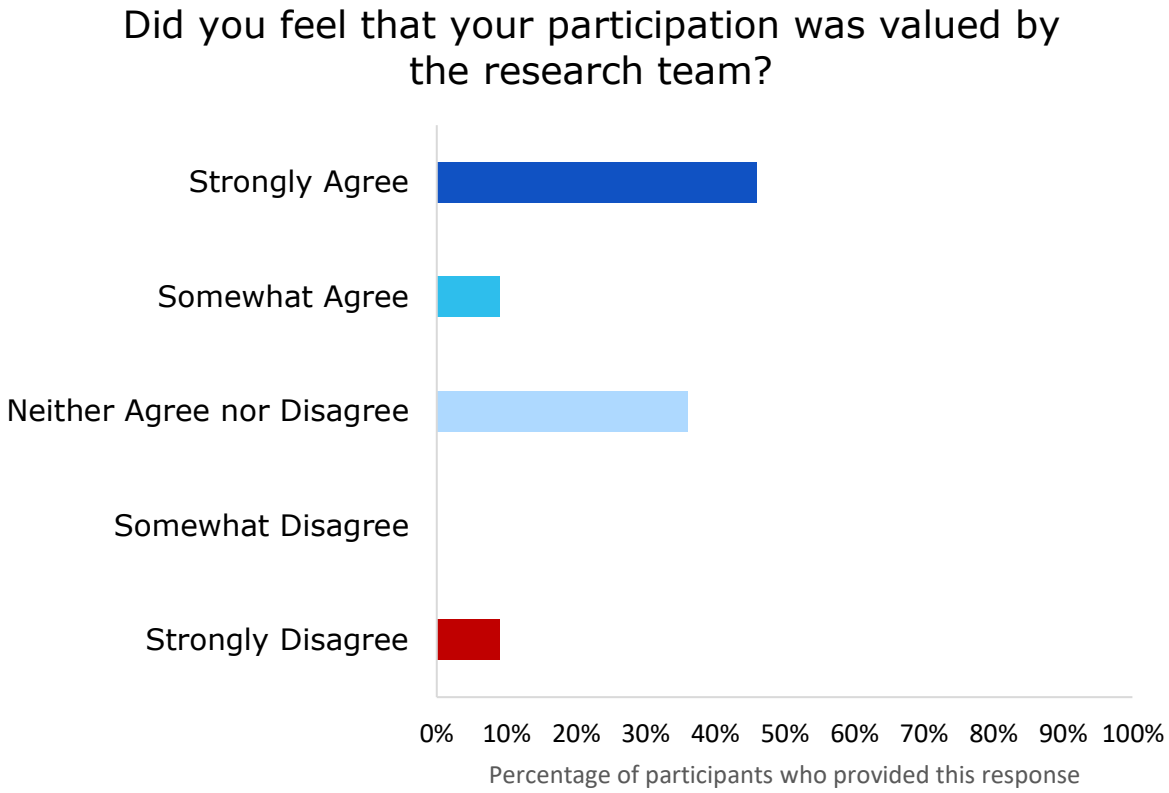

Did you feel comfortable during the research process?
Always
Most of the time
Sometimes
Rarely
Never
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percentage of participants who provided this response

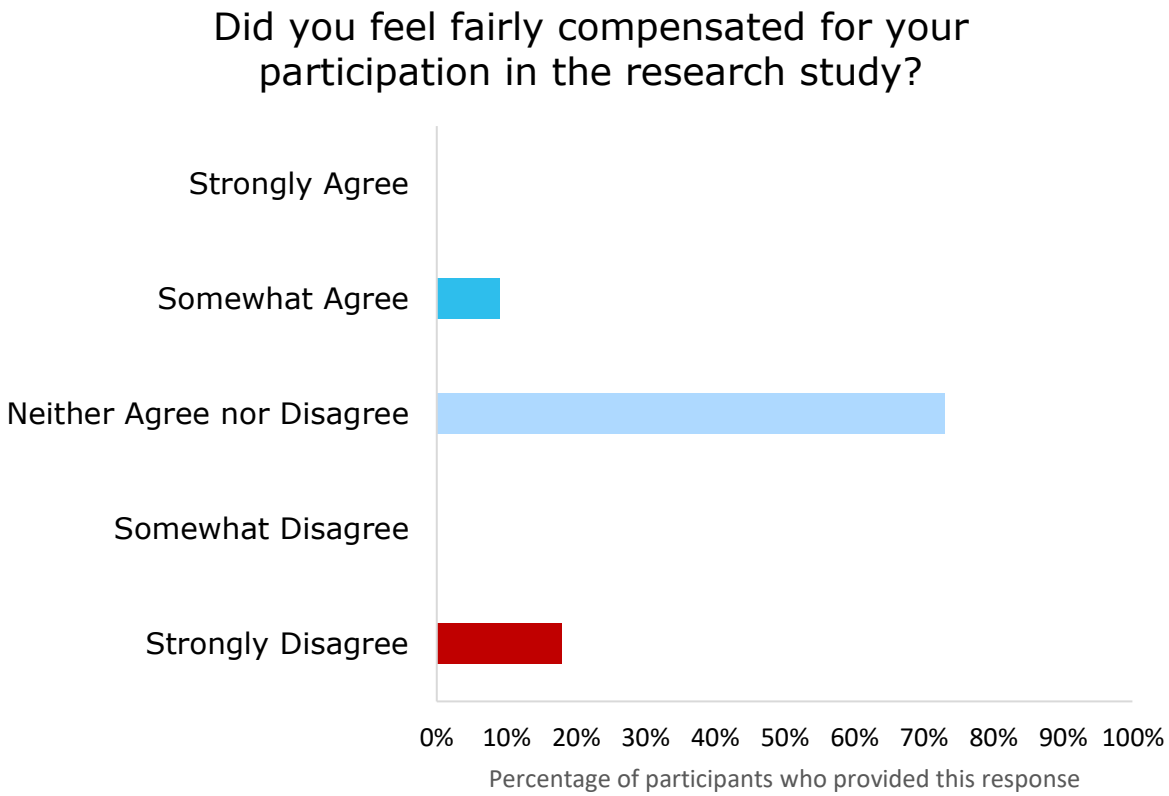
Throughout the study period, did you find yourself mindful that your CPAP usage data was being monitored for research purposes?



Throughout the study period, did you feel your participation in the study impacted how you used your CPAP machine?




Did you feel that your participation was valued by the research team?
Strongly Agree
Somewhat Agree
Neither Agree nor Disagree
Somewhat Disagree
Strongly Disagree
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percentage of participants who provided this response


Did you feel fairly compensated for your participation in the research study?
Strongly Agree
Somewhat Agree
Neither Agree nor Disagree
Somewhat Disagree
Strongly Disagree
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percentage of participants who provided this response

Do you have any other comments about your participation in the research?

1. “To be honest I totally forgot I was part of it”
2. “No”
3. “I didn't receive any compensation”
4. “No thanks”
5. “No”

Do you have any suggestions for improving the research process in the future?

1. “Maybe the odd email maybe a good idea”
2. “No”
3. “No”

Section 4 : Ethics Application and Documentation

Jennifer Grayling

Lancaster University

Doctorate in Clinical Psychology

All correspondence should be sent to:

Jennifer Grayling

Doctorate in Clinical Psychology

Health Innovation One

Sir John Fisher Drive

Lancaster University

Lancaster, LA1 4YW

Email: j.grayling1@lancaster.ac.uk

IRAS Ethics Application Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Psychological distress in sleep apnoea

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[✓] England

☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ HM Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This project forms part of a doctoral thesis for the qualification of Doctorate in Clinical Psychology. The trainee (student) is supervised by a member of staff of the DClinPsy team at Lancaster University, who will act as a Principal Investigator for the study.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Psychological distress in sleep apnoea

Please complete these details after you have booked the REC application for review.

REC Name:
Yorkshire & The Humber - Sheffield Research Ethics Committee

REC Reference Number:
23/YH/0119

Submission date:
12/05/2023

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Jennifer	Grayling
Address	Department of Clinical Psychology		
	Division of Health Research		
	Lancaster University		
Post Code	LA1 4YW		
E-mail	j.grayling1@lancaster.ac.uk		
Telephone	01524 594406		
Fax	316701		

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Katy	Bourne
Address	Department of Clinical Psychology		
	Division of Health Research		
	Lancaster University		
Post Code	LA1 4YW		
E-mail	k.bourne@lancaster.ac.uk		
Telephone	01524 594406		
Fax	316701		

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Guillermo	Perez Algorta
Address	Spectrum Centre and Department of Clinical Psychology Division of Health Research		
	Lancaster University		
Post Code	LA14YW		
E-mail	g.perezalgorta@lancaster.ac.uk		
Telephone	01524592282		
Fax	316701		

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Jennifer Grayling	☑ Dr Katy Bourne ☐ Dr Guillermo Perez Algorta

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Katy	Bourne
Post	Lecturer in Clinical Psychology		
Qualifications	DClinPsy		
ORCID ID			
Employer	Lancaster University		
Work Address	Department of Clinical Psychology Division of Health Research Lancaster University		
Post Code	LA1 4YW		
Work E-mail	k.bourne@lancaster.ac.uk		
* Personal E-mail			
Work Telephone	01524 594406		
* Personal Telephone/Mobile			
Fax	316701		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
		Becky	Gordon
Address	Lancaster University		
Post Code	LA14YT		
E-mail	sponsorship@lancaster.ac.uk		
Telephone	316701		
Fax	316701		

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	NA
Sponsor's/protocol number:	NA
Protocol Version:	2
Protocol Date:	31/03/2023
Funder's reference number (enter the reference number or state not applicable):	NA
Project website:	NA

Additional reference number(s):

Ref.Number Description	Reference Number
IRAS ID	316701

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Obstructive sleep apnoea (OSA) is a disorder where your breathing stops and starts while you sleep, causing you to repeatedly wake up. Because of this disrupted sleep, OSA often has an effect on mental health; however, the rate of this is unknown. This study firstly aims to research how common psychological difficulties such as depression, anxiety, stress and claustrophobia are in people with OSA. The second aim is to look into the impact of these factors on treatment for OSA. Although a treatment called "continuous positive airway pressure" is effective in treating OSA, usage is poor. While past studies have tried to understand the impact of psychological distress on treatment usage, issues with the methods used suggest a need for further research. Determining the frequency of psychological distress in people with OSA, and understanding how this impacts treatment usage, could help psychologists to identify people who are most at risk of not using their treatment. This information could then be used to come up with ways to support patients to use their treatment.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Ethical Issues

1. Confidentiality

Researchers will not have access to potential participants personal details without consent. Potential participants will be informed about the study by members of the sleep clinic team. If potential participants agree to participate in the study they will read the study information and sign an online consent form to allow researchers to access CPAP adherence data and the online questionnaire data.

2. Data storage

Initially it will be necessary to know which adherence data matches with which questionnaire data. To address this problem, name and date of birth will be collected during the questionnaire. Adherence data will then be matched with questionnaire data as soon as possible and then anonymised. Personal data will be kept separately from the questionnaire and adherence data. All electronic data will be stored on the secure university server. If a participant wishes to complete the questionnaire on paper via mail, all paper data will be stored in a secure locked location on university premises. Personal data (name and date of birth) and personal contact information will be deleted once the project is complete. Consent forms, CPAP usage data and questionnaire data will be kept securely for ten years. At the end of this period, they will be destroyed.

3. Risks to participants

It is considered that the study will pose little risk to participants as the study requires minimal input from participants outside of the questionnaire. However, it has been considered that asking participants about their psychological distress has the potential to trigger distress in participants as they are filling out the questionnaire. Participants may also reveal that they are not currently receiving any support for their mental health. This raises ethical concerns with asking participants to reveal this information but not having the capacity to offer support due to this being a research project. Lastly, participants may become aware of potential links between their sleep apnoea, CPAP usage and mental health and this may cause distress.
Therefore, information will be provided at the end of the questionnaire with details of support helplines e.g., Samaritans and Sleep Apnoea Trust. Participants will be encouraged to contact their GP's for a referral to psychology services should they feel they are experiencing psychological distress. Researchers contact details will also be provided to allow participants to contact us if needed so we can direct them to support services.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☑ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

What is the prevalence of psychological distress (depression, anxiety, claustrophobia, stress) in patients with obstructive sleep apnoea?

Does psychological distress have an impact on how patients use their CPAP machines?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Does psychological distress have a different impact on the frequency (number of nights used) of CPAP usage in comparison to the duration of CPAP usage (hours per night used)?

Is there a difference between using psychological distress severity questionnaires in comparison to asking about diagnoses when investigating the impact on CPAP usage?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Obstructive sleep apnoea (OSA) is a disorder where your breathing stops and starts while you sleep, causing you to

repeatedly wake up. Because of this disrupted sleep, OSA often has an effect on mental health.
Although a treatment called “continuous positive airway pressure” (CPAP) is effective in treating OSA, usage is poor, with between 29% and 83% of patients being considered as non-adherent.
Much research has been conducted to investigate the factors that may influence CPAP usage. However, most of the research has looked at biological and social factors and there is minimal research investigating the impact of psychological factors on CPAP usage. It may be expected that psychological distress such as depression, anxiety, claustrophobia and stress may influence how much people use their CPAP machines. However, the current evidence is unclear, with some studies suggesting psychological distress does impact adherence, and others failing to find a link. Furthermore, of the current research that has been conducted, most studies had small sample sizes and issues with the methods used such as poor measures of depression or anxiety. Therefore, additional research with a larger sample size and better methods is needed.
Additionally, some research has found that psychological distress may predict adherence when investigating the frequency of usage (amount of nights) but not as duration of use (average hours per night). These findings highlight a limitation of the research so far; the majority of studies calculated the average hours of CPAP usage per night and grouped this as less than four hours of use or greater than four hours. Not only does this not distinguish frequency of use (percentage of nights) from duration (hours per night), but it also ignores of lot of useful adherence information.
It is clear that further exploration of the impact of anxiety and depression on adherence to CPAP is needed. Additionally, other psychological factors such as claustrophobia and stress have been under-researched. The proposed study therefore plans to further investigate the impact of psychological distress on adherence to CPAP whilst taking the discussed limitations into consideration. Furthermore it would also be of use to gain an insight into how prevalent psychological distress is amongst people with OSA. Taken together, these two findings could be used to improve services by offering service users the necessary support to increase well-being and CPAP use.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Design

It is predicted that people with a diagnosis of obstructive sleep apnoea (OSA) may experience higher levels of psychological distress than seen in the general population. Identifying the rate at which psychological distress appears in people with OSA will be helpful to inform sleep apnoea clinics. It is also predicted that those who are experiencing psychological distress will find it harder to adhere to their CPAP treatment. Testing this will involve measuring the presence and level of psychological distress in people with sleep apnoea and looking at whether this can predict adherence to CPAP treatment. This will involve looking at numerous types of psychological distress (depression, anxiety, claustrophobia and stress), and different ways of measuring adherence (frequency and duration). It is hoped that this will help enhance understanding of how OSA impacts mental health and the impact that that can have on patients’ ability to engage in their treatment. Doing so may allow for an indication of those that are more likely to struggle to adhere to treatment, meaning support can be provided. It is predicted that those who are experiencing psychological distress will have a lower frequency of use of their CPAP machines.

Participants

It is intended that 85 people with a diagnosis of OSA who are commencing CPAP or automatic positive airway pressure (APAP) will be recruited. It is the aim to recruit this many participants as this was the number determined to provide enough power to obtain a robust conclusion.
All participants will have to have been provided with a diagnosis of OSA from a professional at the sleep clinic, have been prescribed CPAP as treatment, and be over the age of 18. This age range has been chosen to allow for as many participants to take part as possible that are of adult age, to gain a diverse sample. Participants must not have a diagnosis of chronic obstructive pulmonary disease (COPD), congestive heart failure or central sleep apnoea and must not be commencing Bi-level positive airway pressure (biPAP). The exclusion criteria has been chosen as it is felt that these factors may have an impact on adherence to treatment.
Participants must be able to read and comprehend English language and have the ability to give informed consent and answer the questionnaire. Additionally, those who are currently participating in psychological or behavioural treatment to promote CPAP adherence during the study time period will not be able to take part in the study. This is to rule out any differences in adherence that may be accounted for by adherence support.
All patients who have a diagnosis of OSA confirmed and have been prescribed CPAP or automatic positive airway pressure (APAP) treatment will be asked to participate in the study. A self-screening process will then take place, with participants required to confirm they meet the inclusion criteria. A self-screening process has been chosen to not place additional demands on already stretched NHS services by asking staff to determine if people meet the criteria. However, if staff are already aware that people do not meet the inclusion criteria, or meet the exclusion criteria, they will not give an invitation to the individual.
Participants will be recruited from sleep clinics in the UK. The sleep clinics chosen are those that have expressed a willingness to help with participant recruitment and have therefore been chosen on this basis. The study will be

advertised to people attending sleep clinics as part of their routine care.

Method

Step 1

The study will be advertised to new referrals attending sleep clinics as part of their routine care to commence treatment. All patients who have a diagnosis of OSA confirmed and have been prescribed CPAP or automatic positive airway pressure (APAP) treatment will be informed about the study by members of staff at the sleep clinic they are attending. They will be provided with a flyer stating information about the study. The flyer will contain a QR code and a website address linking them to the online questionnaire. The flyer will also state that should they wish to participate via paper format, that they could email the researcher to express their interest and paper copies of the information sheet, consent form and questionnaire will be sent out.

Step 2
After visiting the online questionnaire or emailing the researcher to express an interest to participate, participants will either see the online information sheet or have the information sheet posted to them (with stamped envelope to return). After reading the information sheet participants will be informed to contact the researcher (email provided), should they have any further questions.
If participants have no questions they will first answer the screening questions to confirm they meet the inclusion criteria. If participants have opted to complete the questionnaire via mail the screening questions will asked via email before the papers forms are sent out. Following the screening questions, participants will read and sign the consent form electronically or manually. This includes consenting to the questionnaire and also to allow the researchers to access their first 28 days of CPAP data. It is expected that the majority of people will complete the questionnaire prior to commencing treatment and therefore the 28 days of adherence data will be collected once participants have used their treatment for 28 days. However, if participants complete the questionnaire within 28 days of commencing treatment, the first 28 days of treatment adherence data will be collected retrospectively. This is to ensure consistency between the time periods of adherence data that are collected. This will be made clear to participants in the information sheet.

Step 3
Participants will then be able to complete the questionnaire either online or on paper. Questions will firstly collect sociodemographic data (age, ethnicity, gender, and bed sharing status). Next, participants will be asked if they have a current diagnosis of depression or a current diagnosis of anxiety or if they are currently receiving support for depression, anxiety, or stress. Participants will then be asked to complete 4 validated psychological distress measures (PHQ-8, GAD-7, PSS and Claustrophobia Scale). The whole questionnaire should take approximately 10 minutes to complete. At the end of the questionnaire, participants will be asked if they wish to receive a non-scientific report of the study and/or if they wish to provide feedback once they have completed the study and/or if they wish to be added into the £30 draw for an amazon voucher. If they say yes to any of these questions, they will be asked to provide a contact method to receive this.

Step 4
Participants will either be shown online, or have received a debrief sheet explaining the purpose of the study and providing contact details for the researcher and helplines in the event of them feeling they need support. Participants will be encouraged to contact their GP should they wish to be referred for psychological support.

Step 5
Participants will use their CPAP machine as normal. Data will be collected by researchers remotely. Participants do not have to do anything other than consent to this and use their machines as they would otherwise.

Step 6
Any participants who wished to provide feedback will be sent a feedback questionnaire either via email or post as requested.

Step 7
One participant will be contacted to be informed they have won a £30 amazon voucher, and this will be sent to them by their method of choice.

Step 8
Any participants who wished to receive a non-scientific report will be sent this by their preferred method.

Step 9
All personal information collected to match up data or for the prize draw and/or non-scientific summary dissemination will be deleted at the end of the study (once the thesis has been marked and any amendments have been submitted

and agreed).

Participant recruitment is expected to take part from around July 2023 until January 2024. Data analysis is intended to take place around January 2024. The final report is intended to be completed around March 2024.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Experts by experience organised through the sleep apnoea trust were consulted on the advertisement materials, information sheet, consent form, debrief sheet, questionnaire and methodology of the study. The sleep apnoea trust reported no concerns with the materials, but suggested to add themselves to the 'resources in events of distress'. They supported the necessity of the research and informed how they are suitable to provide support in the events of distress; having produced a leaflet on psychological distress relating to sleep apnoea and CPAP therapy. The resources in events of distress sections on the information sheet and debrief sheet were updated accordingly. The sleep apnoea trust felt that the materials and design of the study were acceptable.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [x] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal

- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [x] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Diagnosis of obstructive sleep apnoea
Prescription of continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP)
Aged 18 and over

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Diagnosis of Chronic obstructive pulmonary disease (COPD)
Diagnosis of congestive heart failure
Diagnosis of central sleep apnoea
Prescription of Bi-level positive airway pressure (biPAP)
Inability to read and comprehend English language
Inability to give informed consent
Inability to answer questionnaire e.g., due to intellectual disability or severe mental illness
Participating in psychological or behavioural treatment to promote CPAP adherence during the study time period

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Complete consent form and questionnaire	1		15 minutes	Can be completed online or on paper at participant's home in their own time
Opportunity to give feedback	1		0-5 minutes	Can be completed online or on paper at participant's home after adherence data has been collected
Contact to arrange receiving prize from prize draw (one participant only)	0-1		5 minutes	Chief investigator will contact participant via email or phone depending on their preference

A21. How long do you expect each participant to be in the study in total?

Participants will be involved in the study for approximately 4 weeks, however active involvement is only required for an estimated 10-15 minutes to complete the questionnaire. Following this, participants are not required to do anything

additional for the purpose of the study. They are encouraged to continue to use their CPAP machines as usual. Four weeks of CPAP adherence data will be collected remotely from participants devices.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Ethical considerations for this project are mainly around the issue of asking participants about their psychological distress. This has the potential to trigger distress in participants as they are filling out the questionnaire. Participants may also reveal that they are struggling with their mental health, and not currently receiving any support. This raises ethical concerns with asking participants to reveal this information but not having the capacity to offer support due to this being a research project. Therefore, information will be provided at the end of the questionnaire with details of support helplines e.g., Samaritans, sleep apnoea trust. Researchers contact details will also be provided to allow participants to contact us if needed so we can direct them to support services.
There is a risk of a breach of confidentiality as personal data will be collected. This risk will be minimised as much as possible. Initially it will be required for personal data to be matched to adherence data, this will be done by participant name and date of birth. This has been chosen as there is a risk that people may not know their NHS number and this may affect recruitment. Following this, data will be anonymised as soon as possible. Once this information has been used to match questionnaire data with CPAP adherence data, personal data (name and date of birth) will be kept in a separate secure file. Personal data will be kept until the end of the study (when the thesis has been marked and amendments have been submitted and agreed) and then it will be deleted. Personal data will be kept until this point in case it is needed to be checked. Participant contact information will be kept until participants have been contacted for the prize draw, for feedback and/or for a summary of the results, it will then be deleted.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

The questionnaire will ask potentially sensitive information about mental health and psychological distress. This has the potential to trigger distress in participants as they are filling out the questionnaire. Participants may also reveal that they are struggling with their mental health, and not currently receiving any support. Information will be provided at the end of the questionnaire with details of support helplines e.g., Samaritans, Sleep Apnoea Trust. Researchers contact details will also be provided to allow participants to contact us if needed so we can direct them to support services.

A24. What is the potential for benefit to research participants?

Participants may become aware that they are struggling with their mental health and may seek support for this.
All participants will be offered a non-scientific report of the study's findings.
Participants will contribute to a better understanding of how psychological distress impacts CPAP usage which may help inform psychologists and health professional on how to support those struggling to adhere to CPAP.
Participants will be entered in a prize draw for a £30 amazon voucher as a thank you for their time.

A26. What are the potential risks for the researchers themselves? *(if any)*

As all involvement with participants will be remote, there are no known risks to the researchers.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under*

arrangements with the responsible care organisation(s).

Potential participants who are currently accessing services from sleep clinics and commencing treatment will be informed about the study by members of staff during their routine clinic appointments. It will not be necessary to search any patient records to identify potential participants. To take part in the study, participants will need to visit the study website and sign the online consent form before completing the questionnaire. Alternatively, participants can email the research team to express interest in participating via mail and paper versions of the forms will be sent out via post with a pre-paid return stamp.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
Staff members at the sleep clinics currently involved in the care of potential participants will signpost participants to the study if they have a diagnosis of OSA confirmed and have been prescribed CPAP or automatic positive airway pressure (APAP) treatment.
A self-screening process will then take place, with participants required to confirm they meet the inclusion criteria. A self-screening process has been chosen to not place additional demands on already stretched NHS services by asking staff to determine if people meet the criteria. Staff will not be asked to search any personal data for the purpose of this study. However, if staff are already aware that people meet the exclusion criteria, they will not give an invitation to the individual, to ensure patients' time is not wasted.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

As mentioned above, staff will not search any personal data for the purpose of this study. However, as part of their existing clinical care team, it may be possible that staff happen to know that a patient does not meet the criteria to participate in the study and use this information to make a decision to not invite them to participate to ensure their time is not wasted. The research team will not have access to any information of potential participants until the participants consent to take part online or via paper format.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

( ) Yes (●) No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

(●) Yes ( ) No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Staff in the sleep clinics will hand patients a leaflet during their appointments. The leaflet will include the details of the study and a link and QR code to the online versions of the participant information sheet, consent form, questionnaire and debrief sheet.

A29. How and by whom will potential participants first be approached?

Potential participants who meet the inclusion criteria will be approached by members of staff at sleep clinics.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Potential participants will have access to a written online or paper version of the participant information sheet. Participants will also be able to email the chief investigator to ask any questions they may have before consenting to take part.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will have from when they are told about the study until 28 days after they have commenced CPAP treatment. This is to ensure that the questionnaire data collecting information about psychological distress is completed around the first 28 days of CPAP usage.
When data collection is complete the questionnaire will be closed and participants will no longer be able to participate in the study. Any incomplete data sets will be treated as drop outs. Participants will be informed that they can contact the researcher via email to request their data be removed until the study is complete. Following this, data will be anonymous and therefore it will not be possible to identify the data to withdraw.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

The questionnaire will be written in English and due to time constraints of this study, there is unfortunately not time to translate this questionnaire in to other languages. Therefore, participants must be able to read, comprehend and answer the questionnaire in order to take part in the study.
The participant information sheet is written in simple English and the online software (Qualtrics) that hosts the online questionnaire allows participants to adjust the size of the font and provides an audio version of all written information. Participants can also be sent a paper version of the participant information sheet in large font if required.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◉ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

○ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If at any point the participant or anyone involved in their healthcare contacted us to inform us that they are concerned a participant has lost capacity to consent, the participant and all identifiable data would be removed from the study. As we

do not collect contact information for all participants it would not be possible to make contact to check capacity and consent, therefore we would withdraw the participant. This will be specified to participants in the information sheet.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
Electronic transfer by computer networks will be used to transfer the CPAP adherence data from the NHS to a university computer. The chief investigator currently works in the trust that participants will be recruited from and will be able to transfer the data from the NHS trust shared drive to a secure OneDrive folder that only the research team have access to.
Personal data (name and date of birth) will be collected to match questionnaire data to CPAP adherence data. Data will be matched as soon as possible and then anonymised with a participant number. The personal data will then be kept separately to the CPAP adherence data and questionnaire data. This will be kept on the university secure network and will only be accessible by the research team.
If a participant has completed the study via mail, manual files including personal data will be stored in a locked cabinet on university premises and will only be accessible by the research team. These will be anonymised as soon as possible and transferred to the electronic file. The paper copy will then be securely destroyed.
Emails, telephone numbers and addresses will only be collected if participants wish to participate via mail, wish to provide feedback, wish to receive a summary of results, or wish to be entered in the prize draw. The personal contact information will be held on the university secure network and will be deleted once the study is complete.

A37. Please describe the physical security arrangements for storage of personal data during the study?

It is anticipated that most, if not all data will be stored electronically. If participants wish to participate via paper format,

personal data recorded on paper will be stored in a locked cabinet on university premises and will only be accessible by the research team.
Electronic data will be kept securely on university secure network and will only be accessible by the research team.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All personal data will be kept confidential in accordance with the NHS Code of Confidentiality, EU General Data Protection Regulation (GDPR) and the UK's Data Protection Act 2018. Published data will not be identifiable.
Personal data (name and date of birth) will be collected to match questionnaire data to CPAP adherence data. Data will be matched as soon as possible and then anonymised with a participant number. The personal data will then be kept separately to the CPAP adherence data and questionnaire data. This will be kept on the university secure network and will only be accessible by the research team.
Personal contact data will only be collected if participants wish to participate via mail, wish to provide feedback, wish to receive a summary of results, or wish to be entered in the prize draw. The personal contact information will be held on the university secure network. Only the research team will have access to the personal contact data.
All personal data will be kept until the study is complete (when the thesis has been submitted and any amendments have been submitted and agreed) and then will be destroyed.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Questionnaire data that may include personal information will be matched to CPAP data as soon as possible and anonymised. Personal data such as contact information will be kept securely to allow for contact of the participant if needed. Only members of the research team will have access to participant personal data. It will primarily be the student who accesses participant personal information, however members of the research team will also have access in case of absence of the student. Any personal data will be deleted as soon as the study is complete (when the thesis has been submitted and any amendments have been submitted and agreed).

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data will be analysed by the research team, primarily by the student. Data will be analysed on university's secure server. Analysed data will not be identifiable.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Katy	Bourne
Post	Lecturer in Clinical Psychology		
Qualifications	DClinPsy		
Work Address	Department of Clinical Psychology		
	Division of Health Research		
	Lancaster University		
Post Code	LA1 4YW		
Work Email	k.bourne@lancaster.ac.uk		
Work Telephone	01524 592282		
Fax	316701		

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ◉ 3 – 6 months

- ◯ 6 – 12 months
- ◯ 12 months – 3 years
- ◯ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

Participant name and date of birth will be deleted once the study is complete (when the thesis has been submitted and any amendments have been submitted and agreed). Personal contact details will be deleted within 6 months of study completion once the draw is complete and any feedback forms and summary of results have been sent out. Consent forms and research data (e.g. questionnaire data, CPAP usage data) will be kept for 10 years, this is in line with Lancaster University's data storage policy.
Any paper data that is collected will be kept for 10 years in a secure locked location on university premises. Only the research team will have access to this.
Electronic data will be kept for 10 years on the secure university network. Again, this will only be accessible to the research team.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes ◯ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
There will be a prize draw for a £30 amazon voucher for all participants who consent to take part in the research. This is regardless of if participants later withdraw from the study.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◯ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
The study is not a clinical trial. The resulting thesis will be made publicly available online via Lancaster University.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☑ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☑ Other (please specify)

A non-scientific report will be offered to all participants.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Identifiable information will not be included in the published results.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
All participants will be asked if they wish to receive a non-scientific report of the results. This will be sent out to participants once the study has finished and the report has been written up.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team

☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The design and methodology has been developed under supervision from an academic supervisor. This design and methodology has also been reviewed and approved by members of the Doctorate in Clinical Psychology Programme team at Lancaster University.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed?*Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☐ Review by company statistician

☐ Review by a statistician within the Chief Investigator's institution

☐ Review by a statistician within the research team or multi−centre group

☑ Review by educational supervisor

☑ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Katy	Bourne
Department	Doctorate in Clinical Psychology		
Institution	Lancaster University		
Work Address	Department of Clinical Psychology		
	Division of Health Research		
	Lancaster University		
Post Code	LA1 4YW		
Telephone	01524 594406		
Fax	316701		
Mobile	316701		
E-mail	k.bourne@lancaster.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Participants' scores on the measures of Depression (PHQ-8), Anxiety (GAD-7), Claustrophobia (The Claustrophobia Scale) and Stress (PSS) and participants' number of nights that they used CPAP at all over 28 days, number of nights that they used CPAP for 4 hours or more over 28 days, average hours they used CPAP over a 28 day period.

A58. What are the secondary outcome measures?*(if any)*

NA

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	85
Total international sample size (including UK):	85
Total in European Economic Area:	85

Further details:
NA

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

I will aim to recruit at least 85 participants. This is as a result of a G Power calculation revealing that for a multiple regression with 4 predictors, a sample size of 85 would be required to detect a medium effect.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Firstly, descriptive statistics will be used to explore the data and to calculate the prevalence of psychological distress. If participants are recruited from more than one clinic, descriptive statistics will also be used to analyse if there are any significant differences between participants at each clinic. The data will also be tested for normality of distribution. Correlation analyses will then be conducted between the various methods of measuring depression, anxiety and stress (e.g., do you have a diagnosis of depression, are you currently receiving support for depression, PHQ-8 score) and each of the outcome measures. This should help determine which method of measuring depression, anxiety, and stress is best suited as a predictor. Following this, multiple regressions with the measures of depression, anxiety, stress and claustrophobia will be conducted for each of the four outcome measures: the standard measure of dichotomising above or below an average of 4 hours of usage per night, average hours per nights as a continuous variable, percentage of nights used at all, and percentage of nights used above or below 4 hours. This will allow for exploration of the predictivity of psychological distress on adherence. Patterns of missing data will be explored, and decisions will be made accordingly (e.g. use of multiple imputation if missing data points are completely random). Analysis will be conducted using R software (van Hees et al., 2019) and SPSS.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: ○ NHS or HSC care organisation ◉ Academic

Commercial status: Non-Commercial

- ◯ Pharmaceutical industry
- ◯ Medical device industry
- ◯ Local Authority
- ◯ Other social care provider (including voluntary sector or private organisation)
- ◯ Other

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Becky
Family name	Gordon
Address	Lancaster University
Town/city	Lancaster
Post code	LA1 4YT
Country	United Kingdom
Telephone	316701
Fax	316701
E-mail	sponsorship@lancaster.ac.uk

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation	
Given name	
Family name	
Address	
Town/city	
Post code	
Country	
Telephone	
Fax	
E-mail	

A65. Has external funding for the research been secured?

Please tick at least one check box.

- ☐ Funding secured from one or more funders
- ☐ External funding application to one or more funders in progress
- ☑ No application for external funding will be made

What type of research project is this?

- ○ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant
- ◉ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Juliette	Novasio
Organisation	Manchester University NHS Foundation Trust (MFT)		
Address	Research Office, 1st Floor, Nowgen Building		
	29 Grafton Street		
	Manchester		
Post Code	M13 9WU		
Work Email	juliette.novasio@mft.nhs.uk		
Telephone	0161 291 5773		
Fax	316701		
Mobile	0161 291 5773		

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/07/2023
Planned end date: 01/01/2024
Total duration:
Years: 0 Months: 6 Days: 1

A71-1. Is this study?

◉ Single centre
○ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 2

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	1
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☑ Educational establishments	1
☐ Independent research units	
☐ Other (give details)	

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

There are no planned audits for external organisations. The research team will monitor study protocol adherence. The sponsor will be able to request audits to be undertaken.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

For those recruited via NHS sites, NHS indemnity will apply and those recruited at Non-NHS sites Lancaster University indemnity will apply.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ○ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name
IN1	○ NHS/HSC Site ◉ Non-NHS/HSC Site	Forename: Jennifer Middle name: Marie Family name: Grayling Email: j.grayling1@lancaster.ac.uk Qualification (MD...): BSc Psychology MSc Developmental Disorders Country: United Kingdom
	Institution name: Lancaster University Department name: Department of Clinical Psychology Street address: Division of Health Research Town/city: Lancaster Post Code: LA14YW Country: United Kingdom	
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site	Forename: Middle name: Family name: Email: Qualification (MD...): Country: [redacted]
	Organisation name: Address: Post Code: Country: [redacted]	

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.
10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Katy Bourne on 23/05/2023 15:16.

Job Title/Post:	Lecturer in Clinical Psychology
Organisation:	Lancaster University
Email:	k.bourne@lancaster.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr. Guillermo Perez Algorta on 24/05/2023 10:57.

Job Title/Post:	Senior Lecturer
Organisation:	Lancaster Univeristy
Email:	g.perezalgorta@lancaster.ac.uk

Academic supervisor 2

This section was signed electronically by Dr Katy Bourne on 23/05/2023 15:14.

Job Title/Post:	Lecturer in Clinical Psychology
Organisation:	Lancaster University
Email:	k.bourne@lancaster.ac.uk

Appendix 4-A: HRA Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Katy Bourne
Department of Clinical Psychology
Division of Health Research
Lancaster University
LA1 4YW

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

10 July 2023

Dear Dr Bourne

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence**
IRAS project ID:	**316701**
Protocol number:	**NA**
REC reference:	**23/YH/0119**
Sponsor	**Lancaster University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **316701**. Please quote this on all correspondence.

Yours sincerely,
Libby Williamson
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Becky Gordon*

Appendix 4-B: Research Protocol

Project Title: Psychological distress in people with sleep apnoea and its impact on CPAP adherence

Researchers:

Primary Researcher: Jennifer Grayling

Supervisor: Dr Katy Bourne

Second Supervisor: Dr Guillermo Perez Algorta

Introduction:

Obstructive sleep apnoea (OSA) is a sleep-related disorder characterised by repetitive partial (hypopnea) or complete (apnoea) upper-airway collapse during sleep (Greenberg, Lakticova, & Scharf, 2017); resulting in intermittent decreases in blood oxygen, sleep arousals, and persistent sleep disruption (American Association of Sleep Medicine, 2014). Cognitive impairment (Lal et al., 2012), poor quality of life (Coman et al., 2016), depression and anxiety (BaHammam et al., 2016; Rezaeitalab et al., 2014) are all also associated with OSA.

Continuous positive airway pressure (CPAP) is considered the gold standard treatment for OSA (Qaseem et al., 2013). However, despite its efficacy, CPAP adherence remains a barrier to effective treatment of OSA. Typically, adherence has been defined as more than four hours of CPAP use for at least 70% of nights (Sawyer et al., 2011). Based on this definition, between 29% and 83% of patients are considered non-adherent (Weaver & Grunstein, 2008).

In a report entitled “Guidelines for Psychological Practice in Health Care Delivery Systems”, published by the American Psychological Association (2013), it was stated that psychologists have a responsibility to assist patients with adherence to treatment. Clinical

psychologists should therefore be involved with implementing interventions that help improve patient adherence; understanding the underlying factors that influence non-adherence thus becomes essential to tailoring effective evidence-based interventions.

Whilst early research focused on biomedical factors' impact on CPAP adherence, more recent work widened its focus to psychological factors. In comparison to cognitive factors, there has been less quality research conducted on psychological distress. Whilst much of the evidence has not reported anxiety or depression to be predictive of adherence (e.g., Baron et al., 2020; Olsen et al., 2008; Stepnowsky et al., 2002), small sample sizes and methodological limitations raise the possibility that the studies were insufficiently powered to detect an effect. Many studies utilised measures of anxiety and depression designed to measure severity, which cannot be relied upon as diagnostic tools (e.g., HADS, BDI), and one study measured depression through the participants' answer to a single question ("In the past 7 days I felt depressed). Therefore, it is possible that these methods are not valid measures of depression and anxiety in OSA.

Literature has found that patients with psychological diagnoses use CPAP significantly less than those without a diagnosis (Dzierzewski et al., 2016; Means et al., 2010). Additionally, research has demonstrated that psychological distress may be predictive of adherence when adherence is operationalised as percentage of nights used, but not as average hours per night (Dzierzewski et al., 2016). This suggests that psychological co-morbidities may have a bigger impact on frequency of use, as opposed to duration of use. These findings highlight a key limitation of the research so far: that the majority of studies calculated the average hours of CPAP usage per night and dichotomised this as less than four hours of use and greater than four hours. Not only does this not differentiate frequency of use (percentage of nights) from duration (hours per night), but dichotomising continuous

variables discards much information, leading to a reduction in power (Altman & Royston, 2006; Senn, 2003).

As such, although the impact of anxiety and depression on adherence to CPAP has been researched, limitations with measures and small sample sizes question the reliability and validity of the current findings. It is clear that further exploration of the impact of psychological distress on adherence to CPAP is needed.

Consequently, this study therefore plans to investigate the impact of psychological distress on adherence to CPAP; whilst taking the aforementioned limitations into consideration. Furthermore, understanding how prevalent psychological distress is within the OSA population would also aid our current understanding. Therefore, this is an additional aim of my thesis. It is proposed that a sample size of 85 is used to address previous limitations of statistical power. In addition, psychological distress will be measured using well-validated outcome measures, along with also asking about psychological diagnoses to investigate if a diagnosis is more predictive than severity outcome measures. Lastly, effort will be made to explore CPAP adherence more thoroughly by using: the standard measure of dichotomising above or below an average of 4 hours of usage per night, average hours per nights as a continuous variable, percentage of nights used at all, and percentage of nights used above or below 4 hours.

It is hypothesised that the frequency of CPAP usage will be lower in those with psychological distress and that duration of CPAP usage will be lower in those with a psychological diagnosis.

Method:

Participants: Participants will be recruited from sleep clinics. XXXXXXXXXXXXXXX is willing to help with recruitment for the study and there is potential to expand this to further

sleep clinics if needed. In order to recruit participants, patients attending clinic appointments for diagnosis or assessment will be informed and asked to participate in the study by staff within the sleep clinics.

The participants will be individuals with a new diagnosis of sleep apnoea. All patients who have a diagnosis of OSA confirmed and have been prescribed CPAP or automatic positive airway pressure (APAP) treatment will be asked to participate in the study. A self-screening process will then take place, with participants required to confirm they meet the inclusion criteria. A self-screening process has been chosen to not place additional demands on already stretched NHS services by asking staff to determine if people meet the criteria. However, if staff are already aware that people do not meet the inclusion criteria, or meet the exclusion criteria, they will not give an invitation to the individual.

We will aim to recruit at least 85 participants. This is as a result of a G Power calculation revealing that for a multiple regression with 4 predictors, a sample size of 85 would be required to detect a medium effect.

Inclusion criteria:

- Diagnosis of obstructive sleep apnoea
- Prescription of continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP)
- Aged 18 and over

Exclusion criteria:

- Diagnosis of chronic obstructive pulmonary disease (COPD)
- Diagnosis of congestive heart failure
- Diagnosis of central sleep apnoea
- Prescription of Bi-level positive airway pressure (biPAP)
- Inability to read and comprehend English language

- Inability to give informed consent
- Inability to answer questionnaire e.g., due to intellectual disability or severe mental illness
- Participating in psychological or behavioural treatment to promote CPAP adherence during the study time period

Design: The study will use a cross sectional within participants design for feasibility. As the study aims to investigate prevalence of psychological distress and as to whether it can predict CPAP usage, a quantitative design will be used. The outcome measures will be, participants scores on the measures of depression, anxiety, claustrophobia and stress and participants number of nights that they used CPAP at all over 28 days, number of nights that they used CPAP for 4 hours or more over 28 days and average hours they used CPAP over a 28-day period, both as a continuous variable and dichotomised as greater or less than 4 hours per night on average.

Materials: Online questionnaires using Qualtrics will be used for the convenience of participants and to allow recruitment at multiple sites, to maximise participation and retention. However, an option for physical questionnaires to be posted will be planned for in case this method is required or preferred by any participants.
Questionnaires will collect: Sociodemographic data: age, ethnicity, gender, and bed sharing status. Personal data: name and date of birth (for the purpose of matching questionnaire data and CPAP data only).

Measures of depression: The PHQ-8 will be used as a severity measure of depression. It includes items related to symptoms of low mood such as “Over the last 2 weeks

how often have you been bothered by the following problem: Little interest or pleasure in doing things". The PHQ-8 is based off diagnostic criteria and has been shown to have acceptable diagnostic properties in different contexts (Moriarty et al., 2015; Wu et al., 2020). Although it cannot be substituted for formal diagnosis it can be used to make tentative diagnoses of depression in at risk populations (Haddad et al., 2013). In addition, participants will also be asked if they have been given a diagnosis of depression or are currently receiving any support for depression.

Measures of anxiety: To measure anxiety the GAD-7 will be used. It includes items related to symptoms of anxiety such as "Over the last 2 weeks how often have you been bothered by the following problem: Feeling nervous, anxious, or on edge". The GAD-7 is based on diagnostic criteria and has been shown to have good sensitivity, specificity and to be a valid screening tool for anxiety (Sapra et al., 2020; Spitzer et al., 2006). In addition, participants will also be asked if they have been given a diagnosis of anxiety or are currently receiving any support for anxiety.

Measures of stress: The Perceived Stress Scale (PSS) will be used to measure stress. This includes items related to symptoms of stress such as "In the last month, how often have you were on top of things". The PSS is a widely used measure of stress shown to be a brief, valid measure of stress in many contexts (Lee, 2012). In addition, participants will also be asked if they are currently receiving any support for stress.

Measures of claustrophobia: The Claustrophobia Scale will be used to measure claustrophobia as it was found to have a high internal consistency, with Cronbach's alpha coefficients of 0.97 for the Anxiety subscale and 0.81 for the Avoidance

subscale (Ost, 2007). The Claustrophobia Scale also has high test–retest reliability, concurrent and discriminant validity. Only the anxiety subscale will be used for this study. This is as recommended by the author due to a high correlation between the anxiety and avoidance subscales. It includes items such as "... rate how much anxiety you experience in the described situation today: Walking through a narrow passage". In addition, participants will also be asked if they consider themselves to be claustrophobic.

CPAP Usage Data: Adherence data will be provided by sleep services via remote access to CPAP machine usage. The first 28 days of usage will be analysed. This data is routinely collected by the sleep clinics as part of patients' 28 day review. This data will then be shared securely with the research team. The 28 day benchmark has been chosen as previous research has shown that adherence patterns are generally established after the first week of use (Aloia et al., 2007) and so it does not appear necessary to explore a longer period. However, 28 days should allow sufficient time to assess changes and patterns in adherence. As this data is already collected and assessed by the sleep clinics, this also removes added pressure on the service.

Procedure: Patients with face to face or virtual appointments at sleep clinics for commencing CPAP treatment will be informed about the study. They will be provided with a flyer with information about the study and given the opportunity to ask any questions they may have. The flyer will detail that if they wish to participate, they can use the QR code to open the online questionnaire relating to psychological distress. The flyer will also list the website in full and have the option to email the researcher if they wish to participate by paper format.

Prior to completing the questionnaire, the information sheet and screening questions will appear. The researchers contact details will be provided so participants can email any further questions they may have. If participants do not meet the exclusion criteria, the consent form will then appear and allow participants to sign digitally. The consent form will include consenting to give permission for the research team to access their first 28 days of CPAP adherence data. Participants will then complete the questionnaire which will include questions on sociodemographic information, then questions relating to mental health diagnoses and support, followed by the PHQ-8, GAD-7, PSS and The Claustrophobia Scale. The whole questionnaire should take approximately 10 minutes to complete. At the end of the questionnaire, participants will be asked if they wish to receive a non-scientific report of the study, if they wish to provide feedback, and if they wish to be entered in a draw for an amazon voucher. Following the completion of this questionnaire participants do not need to do anything else. There will be no follow-up, unless participants wish to contact the researcher. Participants who request a non-scientific report of the study or wish to provide feedback will be contacted after the study has finished. One participant will be contacted to inform them they have won the £30 amazon draw. Electronic data will be kept securely on university secure network and will only be accessible by the research team. If participants wish to participate via paper format, they will firstly email the research team to express interest. Screening will then occur via email and if met, paper copies of the information sheet, consent form, questionnaire and debrief sheet will be sent out with a prepaid envelope to send back. Alternatively, participants can scan and return the forms via email if they wish. Data recorded on paper will be stored in a locked cabinet on university premises and will only be accessible by the research team.

Proposed Analysis:

Firstly, descriptive statistics will be used to explore the data and to calculate the prevalence of psychological distress. The data will also be tested for normality of distribution. Correlation analyses will then be conducted between the various methods of measuring depression, anxiety, and stress (e.g., do you have a diagnosis of depression, are you currently receiving support for depression, PHQ-8 score) and each of the outcome measures. This should help determine which method of measuring depression, anxiety, and stress is best suited as a predictor. Following this, multiple regressions with the measures of depression, anxiety, stress and claustrophobia will be conducted for each of the four outcome measures: the standard measure of dichotomising above or below an average of 4 hours of usage per night, average hours per nights as a continuous variable, percentage of nights used at all, and percentage of nights used above or below 4 hours. This will allow for exploration of the predictivity of psychological distress on adherence. It is hypothesised that the frequency of CPAP usage will be lower in those with psychological distress and that duration of CPAP usage will be lower in those with a psychological diagnosis.

Practical Issues:

As data collection will occur predominantly via online questionnaire for the psychological distress data, and adherence data will already be routinely collected via the sleep clinic, there are little foreseen difficulties regarding the practicalities of collecting data. The main difficulty I foresee with this research is potential recruitment difficulties. To address these difficulties, we plan to discuss with the sleep clinics to assess feasibility and a £30 amazon voucher draw will be offered as a thank you for participants' time and data. Additionally, if recruitment appears slow, we will consider evaluating individuals who are already currently utilising CPAP (as opposed to newly starting CPAP).

Another challenge will be ensuring the data is anonymous, as initially it will be necessary to know which adherence data matches with which questionnaire data. To address this problem, adherence data will be matched with questionnaire data as soon as possible and then anonymised. Personal data and questionnaire/ CPAP data will be kept in separate files with a participant number assigned. Electronic data will be kept securely on university secure network and will only be accessible by the research team. Lastly, individuals may wish to partake in the research but have difficulties accessing an online questionnaire. Therefore, 20 questionnaires will be printed and prepared with pre-paid return envelopes for those who wish to complete the questionnaires and return via post. The cost of this will be covered by Lancaster University. If participants wish to participate via paper format, personal data recorded on paper will be stored in a locked cabinet on university premises and will only be accessible by the research team. All personal data will be kept confidential in accordance with the NHS Code of Confidentiality, EU General Data Protection Regulation (GDPR) and the UK's Data Protection Act 2018. Published data will not be identifiable.

Ethical Concerns:

Ethical considerations for this project are mainly around the issue of asking participants about their psychological distress. This has the potential to trigger distress in participants as they are filling out the questionnaire. Participants may also reveal that they are not currently receiving any support for their mental health. This raises ethical concerns with asking participants to reveal this information but not having the capacity to offer support due to this being a research project. Therefore, at the end of the information questionnaire, participants will be encouraged to contact their GPs if they are experiencing distress. Additionally, information will be provided with details of support for both mental health (Samaritans), and

sleep apnoea (Sleep Apnoea Trust). Researchers contact details will also be provided to allow participants to contact us if needed so we can direct them to support services.

Timescale:

Following approval, recruitment will begin around July 2023. Data collection will continue until around January 2024. This would only be extended should recruitment prove difficult and there not yet be enough recruited participants suggested by the power analysis. Results will be shared with participants around April 2024.

End of study:

This study will be complete by August 30th 2024.

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Appendix 4-C: Research Invitation

Doctorate in Clinical Psychology | Lancaster University

RESEARCH PARTICIPANTS NEEDED

DO YOU HAVE A DIAGNOSIS OF SLEEP APNOEA AND ARE STARTING TREATMENT?

In collaboration with Lancaster University, we would like to invite you to take part in a study on **psychological wellbeing and sleep apnoea.** This study is sponsored by Lancaster University.

SCAN HERE TO PARTICIPATE OR GO TO:
https://lancasteruni.eu.qualtrics.com/jfe/form/SV_9so6rFTP94DvnSe

WHO IS ELIGIBLE?

- Aged 18 and over
- Diagnosis of obstructive sleep apnoea
- Starting continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP)
- No diagnosis of chronic obstructive pulmonary disease (COPD), congestive heart failure or central sleep apnoea

DESCRIPTION OF THE STUDY

This study aims to investigate how common psychological distress is in people with sleep apnoea and to explore the impact that this may have on treatment usage. You will be required to complete a short 10-minute questionnaire and allow the research team to access the first 28 days of your CPAP/APAP usage data.

BENEFITS

As a thank you for your time you will be entered into a draw to win a £30 Amazon voucher.

INTERESTED?

If you are interested in participating, please go to https://lancasteruni.eu.qualtrics.com/jfe/form/SV_9so6rFTP94DvnSe or scan the QR code within 28 days of commencing treatment.
Alternatively, if you would like to participate via mail, please contact:
j.grayling1@lancaster.ac.uk

Appendix 4-D: Participant Information Sheet

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Participant Information Sheet

The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence

You are being invited to take part in a research study about psychological wellbeing and sleep apnoea. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully before deciding whether to take part. Thank you for taking the time to read this information sheet.

Who will conduct the research?

The study is being carried out by a team of researchers from Lancaster University. The project leads are, Jennifer Grayling (Trainee Clinical Psychologist, Lancaster University), Dr Katy Bourne (Clinical Psychologist, Lancaster University) and Dr Guillermo Perez Algorta (Clinical Psychologist, Lancaster University). The study is sponsored by Lancaster University.

What is the study about?

The purpose of this study is to explore psychological wellbeing in people with sleep apnoea, and to explore the impact that this may have on treatment usage.

If we find that psychological wellbeing is linked to using treatment in sleep apnoea, this could lead to better support to help people use their CPAP machines, improving people's lives.

Why have I been approached?

You have been approached because the study requires information from people aged 18 and over, who have a diagnosis of sleep apnoea and are commencing treatment.

Does anything mean I cannot take part?

You cannot take part if you:

- Have a diagnosis of chronic obstructive pulmonary disease (COPD)
- Have a diagnosis of congestive heart failure
- Have a diagnosis of central sleep apnoea
- Have a prescription of bi-level positive airway pressure (biPAP)
- Are participating in a psychological or behavioural treatment to promote adherence to treatment

If you have any questions about whether you can take part, please don't hesitate to contact:

j.grayling1@lancaster.ac.uk

Do I have to take part?

Participation is voluntary. It is up to you to decide if you would like to take part. If you do decide to take part, you will be asked to give your consent. Your decision will have no negative effect on any care that you are receiving now or may receive in the future.

What will I be asked to do if I take part?

If you decide you would like to take part, you will be asked to complete a short online questionnaire that asks questions about emotional wellbeing, along with demographic information. The questionnaire will take approximately 10 minutes. You will also be asked to consent to the research team accessing the first 28 days of data on your CPAP machine that records how often and for how long you have used your machine each night. This data is collected routinely as part of your care. You do not have to do anything in this stage other than provide consent; we will obtain your CPAP data via secure transfer if you agree to share this for the purpose of this study. We encourage you to utilise your CPAP machine how you would regardless of this study.

How long do I have to decide whether I would like to take part?

If you wish to take part, we encourage you to complete the questionnaire before commencing treatment, or as close to commencing treatment as possible. However, you can still decide to take part and complete the questionnaire up until 28 days after you commenced your treatment. Regardless of when you complete the questionnaire within this period, it will always be the first 28 days of your data we will access, from day 1 of starting treatment, to day 28.

Can I withdraw from the study?

It is important to note that if you decide to take part, you are free to withdraw and without giving a reason, until the study is complete and has been submitted for review. Following this, data will be anonymous and therefore it will not be possible to identify your data to withdraw. If you would like to withdraw your data before this point, please let the research team know by email. If you decide to withdraw while you are completing the questionnaire, all you need to do is close your browser; if you do this, your responses will not be kept or included in the study.

If during the study you or anyone involved in your care inform us that you no longer have capacity to consent to participation in the research, you will be withdrawn from the study, along with any identifiable data.

Are there any risks?

Taking part in this study is unlikely to cause any distress. However, we are asking questions regarding mental wellbeing and therefore this may trigger distress if this is a sensitive topic for you. If you do experience any distress following participation you are encouraged to inform the researcher and contact the resources provided at the end of this sheet.

Are there any benefits to taking part?

There are no direct benefits of taking part in this study, however at the end of the questionnaires you will be offered the opportunity to enter a draw to win a £30 amazon voucher as a form of thanks for your time. The draw will happen when all participants have finished taking part in the study and the winner will be contacted using their preferred contact information that they provided for the study.

Who has reviewed the project?

This study has been reviewed and approved by the NHS Research Ethics Committee (Yorkshire & The Humber - Sheffield), and by the Health Research Authority.

Data Protection and Confidentiality

How will we use information about you?

In this research study, we will use information from you. We will only use information that we need for the study. This information will include your name and date of birth. This information will only be used to match your questionnaire data with your CPAP usage data.

We will also ask for your contact details if you wish to receive a summary of the findings, wish to provide feedback, and/or wish to be entered into the draw for a £30 amazon voucher.

Will my data be identifiable?

Questionnaire data will be matched with CPAP usage data as soon as possible via name and date of birth and then all data will be made anonymous to ensure your data cannot be linked to you. Personal data (name and date of birth) will then be kept in a separate secure file to your CPAP data and questionnaire data and will be deleted when the study is complete.

Any personal contact information will also be stored separately to ensure your data cannot be linked to you. Any personal contact information collected will be deleted once the study is complete. We will save questionnaire and CPAP data in case we need to check it. All saved data will be unidentifiable, so no one can work out who you are from the data. No identifiable information will be reported in the final report.

Will my data be stored securely?

In accordance with data protection law, Lancaster University is the Data Controller for this project. This means that we are responsible for making sure that your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- Electronic data will be held securely on a secure university drive. Only the researchers involved will have access to this data.
- Any paper forms will be kept in a locked cabinet on university premises. Only the researchers involved will have access to this data.
- Personal information (name, date of birth) and questionnaire response data will be kept separately to maintain confidentiality.
- The research team will only have access to the first 28 days of CPAP data, following this we will not access your CPAP data again.

- Personal contact information will be stored separately and will be deleted once the project is complete and participants have been contacted for the prize draw and/or to receive a summary of findings and/or to provide feedback.
- Consent forms, CPAP usage data and questionnaire data will be kept securely for ten years. At the end of this period, they will be destroyed.

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to **j.grayling1@lancaster.ac.uk**

For more information, please see www.hra.nhs.uk/patientdataandresearch.

What will happen to the results?

The results will be summarised and reported in a thesis and may be submitted for publication in an academic or professional journal. However, as mentioned above, once your questionnaire and CPAP data have been matched, all data will be anonymous, so no one will be able to identify your contribution.
If you would like to receive a non-scientific summary of the results, there will be an opportunity to specify so during the questionnaire. Alternatively, please email Jennifer Grayling, at: j.grayling1@lancaster.ac.uk.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the research team:

Primary Researcher: Jennifer Grayling
Email*:* j.grayling1@lancaster.ac.uk
Telephone: 01524 592282

Supervisor: Dr Katy Bourne
Email*:* k.bourne@lancaster.ac.uk
Telephone: 01524 592282

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Ian Smith
Tel: +44 (0)1524 592282
Research Director
Email: i.smith@lancaster.ac.uk
Health Research
Furness College
Lancaster University
Lancaster
LA1 4YG

If you wish to speak to someone outside of Lancaster University Doctorate Programme, you may also contact:

Dr Laura Machin
Tel: +44 (0)1524 594973
Chair of FHM REC
Email: l.machin@lancaster.ac.uk

Faculty of Health and Medicine
(Lancaster Medical School)
Lancaster University
Lancaster
LA1 4YG

Resources in the event of distress

We are not expecting this study to cause you any distress.
However, should you feel distressed either as a result of taking part, or in the future, please contact your GP, who will be able to offer guidance and advice to best manage this.
Alternatively, the following resources may be of assistance:

For mental health support:
Samaritans
Telephone: 116 123
Email: jo@samaritans.org
Website: https://www.samaritans.org/

Mind
Telephone: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/

If you would prefer to text to receive support with your mental health:
Shout

Text “SHOUT” to 85258
Website: https://giveusashout.org/

For support with sleep apnoea, including impact on your mental health:
Sleep Apnoea Trust
Telephone 07776 243231
Email: https://sleep-apnoea-trust.org/patient-information/email-helpline/
Website: https://sleep-apnoea-trust.org

Thank you for taking the time to read this information sheet. We hope that you will be interested in taking part, if so, please complete the consent form on the following page.

Appendix 4-E: Consent Form

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Participant Consent Form

The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence

We are asking if you would like to take part in a research project looking at psychological wellbeing in people with sleep apnoea and the impact of this on CPAP usage.
Before you consent to participating in the study, we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you would like to ask questions before signing the consent form, please feel free to contact, Jennifer Grayling, *email:* j.grayling1@lancaster.ac.uk, *telephone: 01524 592282*

Statement	Initials
1. I confirm that I have read the information sheet (Version 2 31/03/23) and fully understand what is expected of me within this study.	
2. I confirm that I have had the opportunity to ask any questions and to have them answered.	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
4. I understand that once personal data (name and date of birth) has been deleted (when the study is complete) it might not be possible for my data to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.	
5. I understand that the researcher will discuss data with their supervisor as needed.	
6. I consent to Lancaster University keeping anonymised questionnaire and CPAP data for 10 years after the study has finished.	

7. I understand that my clinical team will access the relevant areas of my medical records to obtain the first 28 days of my CPAP usage data.	
8. I understand that my clinical team will share my first 28 days of CPAP usage data with the research team.	
9. I agree that any data collected may be published in anonymous form in academic books, reports, or journals.	
10. (Optional) I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study.	
11. (Optional) I agree that the researchers may retain my contact details in order to contact me if I am randomly chosen for the £30 amazon voucher.	
12. (Optional) I agree that the researchers may retain my contact details in order to contact me to provide feedback on taking part in the study.	
13. I consent to take part in the above study.	

I have read and understood the declarations above, and agree to my participation in this research:

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of the person taking consent	Signature	Date

(When completed: 1 copy for participant; 1 copy for research team; 1 copy to be stored in medical records)

Please use the addressed and stamped envelope that was enclosed with this form to return your completed consent form. Alternatively, if you prefer, you can scan the form and return via email to j.grayling1@lancaster.ac.uk.

Appendix 4-F: Questionnaire

Doctorate in Clinical Psychology | Lancaster University

Questionnaire

The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence

Full Name:

_____

Birthday (DD/MM/YYYY, e.g., 01/01/2001):

_____

For the following questions, please tick your response to indicate your answer:

What is your ethnic group? (Choose one option that best describes your ethnic group or background)

Asian or Asian British – Bangladeshi ☐

Asian or Asian British – Indian ☐

Asian or Asian British – Pakistani ☐

Asian or Asian British – Other Asian background ☐

Black or Black British – African ☐

Black or Black British – Caribbean ☐

Black or Black British – Other Black background ☐

Chinese ☐

Mixed – White and Asian ☐

Mixed – White and Black African☐

Mixed – White and Black Caribbean ☐

Mixed – Other mixed background ☐

White – British ☐

White – Irish ☐

White – Other White background ☐

Prefer not to answer ☐

Other – Please specify _____

What gender do you identify as? (Choose one option that best describes your gender)

Male ☐

Female ☐

Trans-gender ☐

Non-binary ☐

Prefer not to answer ☐

Other – Please specify _____

For the following questions, please circle your response to indicate your answer:

How often do you currently share a bed when sleeping? **Never / Sometimes / Always**

Do you have a current diagnosis of depression? ***No / Yes***

Are you currently receiving support for depression? ***No / Yes***

Do you have a current diagnosis of anxiety? ***No / Yes***

Are you currently receiving support for anxiety? ***No / Yes***

Are you currently receiving support for stress? ***No / Yes***

Do you consider yourself to be claustrophobic? ***No / Yes***

*Over the last 2 weeks, how often have you been bothered by any of the following problems? Please circle "**Not at all**" OR "**Several days**" OR "**More than half the days**" OR "**Nearly every day**" to indicate your answer:*

Little interest or pleasure in doing things	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Feeling down, depressed, irritable or hopeless	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Trouble falling or staying asleep, or sleeping too much	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Feeling tired or having little energy	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Poor appetite or overeating	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Feeling bad about yourself – or that you are a failure or have let yourself or your family down	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Trouble concentrating on things, such as reading the newspaper or watching television	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN***	***NEARLY EVERY DAY***

or restless that you have been moving around a lot more than usual			***HALF THE DAYS***	

*Over the last 2 weeks, how often have you been bothered by any of the following problems? Please circle "**Not at all**" OR "**Several days**" OR "**More than half the days**" OR "**Nearly every day**" to indicate your answer:*

Feeling nervous, anxious, or on edge	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Not being able to stop or control worrying	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Worrying too much about different things	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Trouble relaxing	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Being so restless that it's hard to sit still	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Becoming easily annoyed or irritable	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***
Feeling afraid as if something awful might happen	***NOT AT ALL***	***SEVERAL DAYS***	***MORE THAN HALF THE DAYS***	***NEARLY EVERY DAY***

*The questions in this scale ask about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. Please circle "**Never**" OR "**Almost never**" OR "**Sometimes**" OR "**Fairly often**" OR "**Very often**" to indicate your answer:*

In the last month, how often have you been upset because of something that happened unexpectedly?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you felt that you were unable to control the important things in your life?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you felt nervous and stressed?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you felt confident about your ability to handle your personal problems?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you felt that things were going your way?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you found that you could not cope with all the things that you had to do?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***

In the last month, how often have you been able to control irritations in your life?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you felt that you were on top of things?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you been angered because of things that happened that were outside of your control?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***
In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	***NEVER***	***ALMOST NEVER***	***SOMETIMES***	***FAIRLY OFTEN***	***VERY OFTEN***

*Below follow descriptions of a number of situations that can arouse fear, anxiety or other feelings of discomfort. Read each item and rate how much anxiety you experience in the described situation today. Please circle "**None**" OR "**A Little**" OR "**Somewhat**" OR "**Much**" OR "**Very much anxiety**" to indicate your answer:*

Standing in such a crowd that you cannot move at all	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Being in a small room without windows	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Trying out clothes in a small fitting room with the door locked	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***

Sitting by the window in the middle of an airplane	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Riding a small elevator by yourself	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Trying out garments that are narrow in the neck	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Sitting in the middle of a crowded cinema or theatre	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Sitting by the window in a crowded bus with someone in the aisle seat	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Being in a windowless room in the basement	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Going in the back seat of a two-door car	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Walking through a narrow passage	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Going in the back seat of a small car with two other people	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Riding a small elevator with the maximum number of passengers	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***

Standing in a crowded bus that stops at a red light	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Being outdoors in a fog when you only can see a few yards in front of you	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Entering a windowless lavatory and locking the door	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Going in a sleeper car with two fellow passengers	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Entering a windowless lavatory and closing the door behind you	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
Getting stuck between two floors in a small elevator	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***
The lock of the door to a small windowless lavatory has jammed	***NONE***	***A LITTLE***	***SOMEWHAT***	***MUCH***	***VERY MUCH ANXIETY***

Appendix 4-G: Debrief Sheet

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Participant Debrief Sheet

The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence

Thank you for taking the time to complete this study. The aim of this study was to investigate the impact of psychological distress on adherence to sleep apnoea treatment.

Although continuous positive airway pressure has proven to be effective in treating sleep apnoea, at times, people can find it difficult to use. Previous studies have found a link between psychological distress and how often people use their sleep apnoea treatment. This study therefore attempts to build on previous research by investigating this link to gain a better understanding of how psychological distress might impact CPAP use. It is hoped that it will help clinical staff to identify people who are most at risk of finding it more challenging to use their treatment. Furthermore, this information could be used to help support people's psychological wellbeing, which may help them make better use of their CPAP machines.

Your answers to the questionnaire are being handled confidentially, meaning your personal results are being processed anonymously and will not be used by anyone outside the research team. There is nothing else you need to do other than carry on with your treatment as normal. The research team will access your treatment usage remotely. I would like to remind you that you have the right to withdraw your data and withdraw permission to access your treatment data should you feel the need to do so.

If you have requested to be entered into the draw to win a £30 amazon voucher, you will be entered following completion of the study. If you have requested a non-scientific summary of the results or requested to provide feedback on the study, someone will be in touch to provide this once this study is complete.

Resources in the event of distress

We are not expecting this study to cause you any distress.
However, should you feel distressed either as a result of taking part, or in the future, please contact your GP, who will be able to offer guidance and advice to best manage this.
Alternatively, the following resources may be of assistance:

For mental health support:
Samaritans
Telephone: 116 123
Email: jo@samaritans.org

Website: https://www.samaritans.org/

Mind
Telephone: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/

If you would prefer to text to receive support with your mental health:
Shout
Text “SHOUT” to 85258
Website: https://giveusashout.org/

For support with sleep apnoea, including impact on your mental health:
Sleep Apnoea Trust
Telephone 07776 243231
Email: https://sleep-apnoea-trust.org/patient-information/email-helpline/
Website: https://sleep-apnoea-trust.org

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Ian Smith
Tel: +44 (0)1524 592282
Research Director
Email: i.smith@lancaster.ac.uk
Health Research
Furness College
Lancaster University
Lancaster
LA1 4YG

If you wish to speak to someone outside of Lancaster University Doctorate Programme, you may also contact:

Dr Laura Machin
Tel: +44 (0)1524 594973
Chair of FHM REC
Email: l.machin@lancaster.ac.uk
Faculty of Health and Medicine
(Lancaster Medical School)
Lancaster University
Lancaster
LA1 4YG

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the research team:

Primary Researcher: Jennifer Grayling
Email*:* j.grayling1@lancaster.ac.uk
Telephone: 01524 592282

Supervisor: Dr Katy Bourne
Email*:* k.bourne@lancaster.ac.uk
Telephone: 01524 592282

Once again, thank you for your time!

The Research Team

Appendix 4-H: Qualtrics Survey Screenshots

Doctorate in Clinical Psychology | Lancaster University

Participant Information Sheet

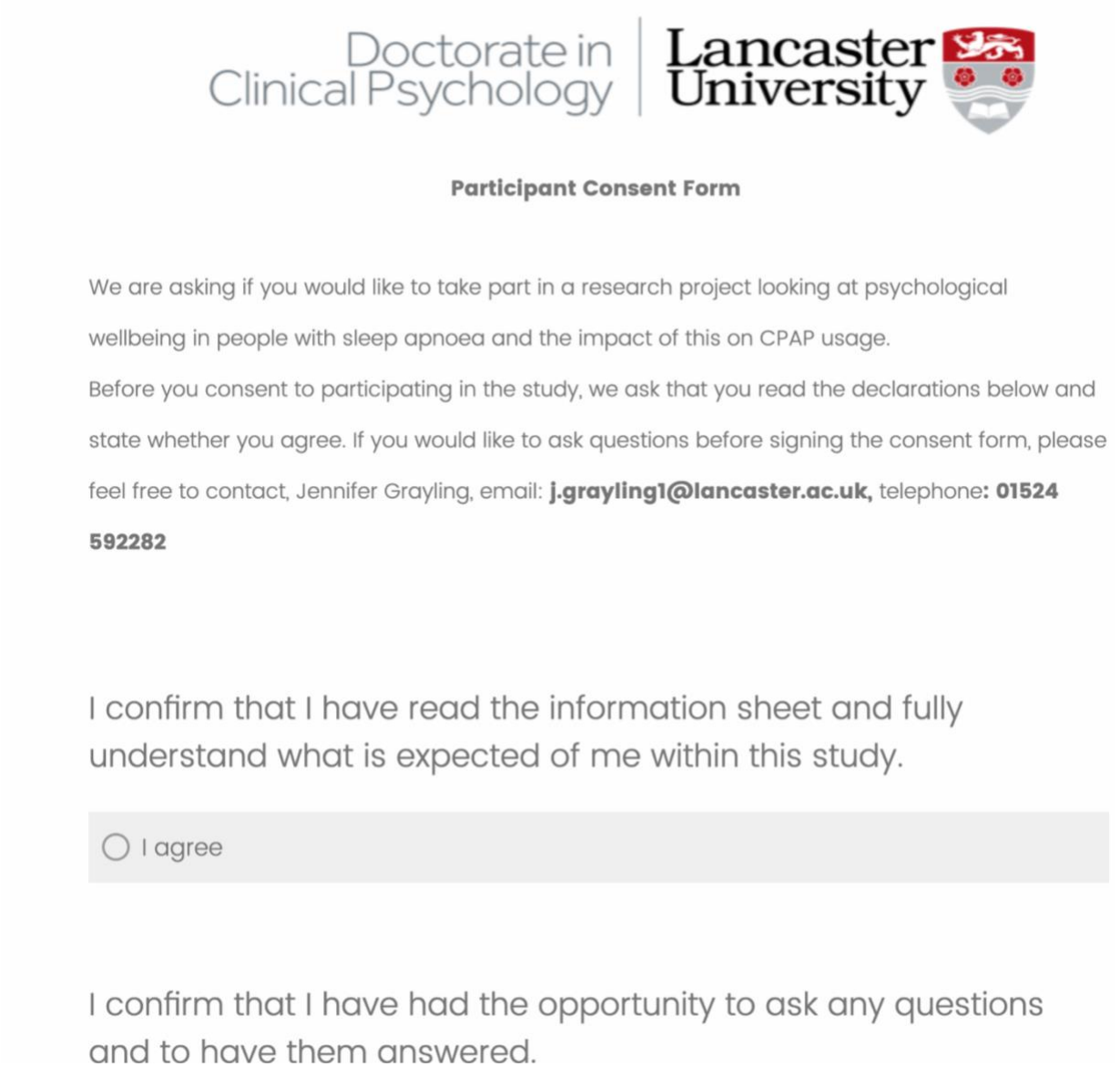
The prevalence of psychological distress in patients with sleep apnoea and its impact on Continuous Positive Airway Pressure (CPAP) adherence

You are being invited to take part in a research study about psychological wellbeing and sleep apnoea. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully before deciding whether to take part. Thank you for taking the time to read this information sheet.

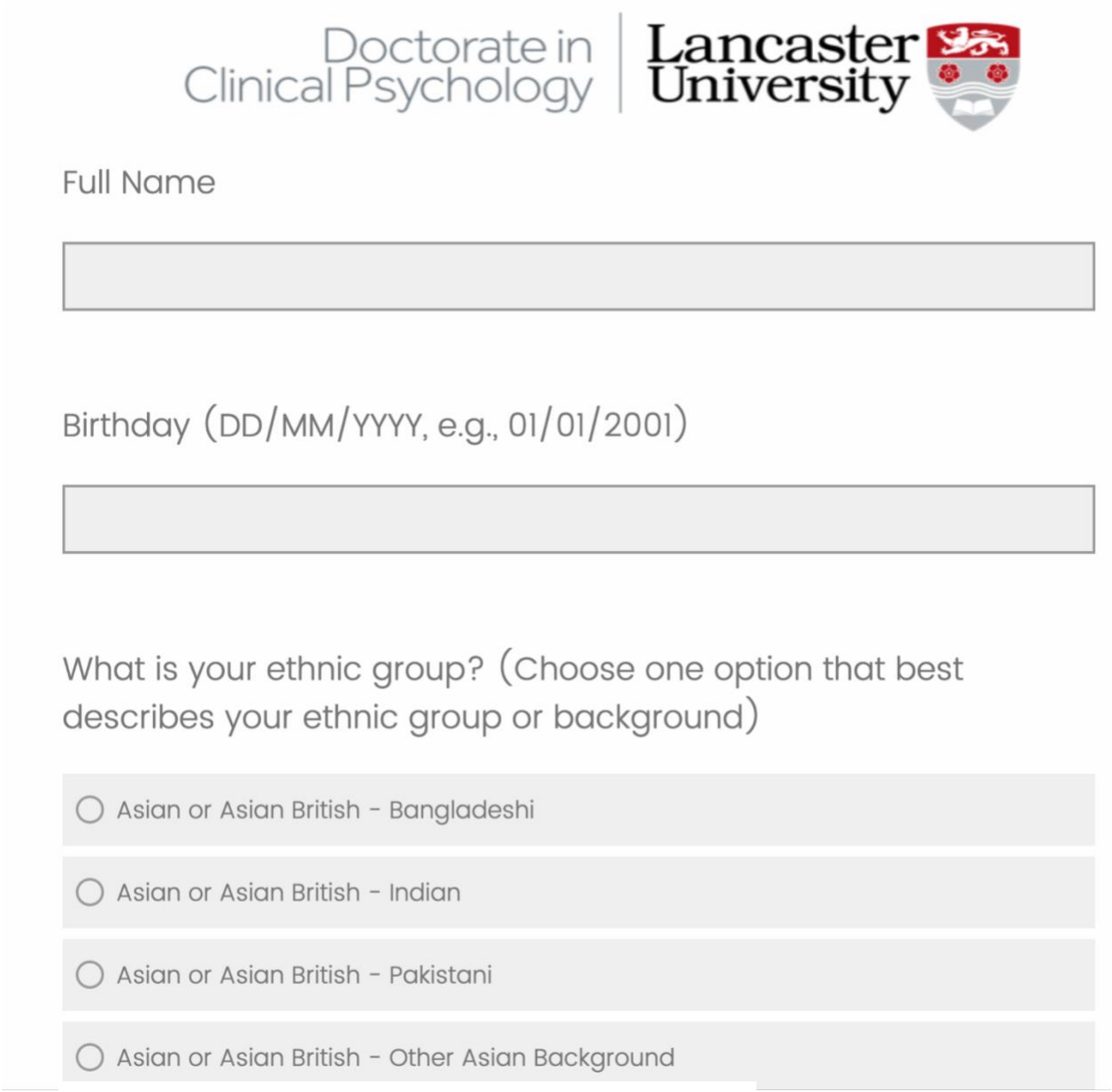
Who will conduct the research?

The study is being carried out by a team of researchers from Lancaster University. The project leads are, Jennifer Grayling (Trainee Clinical Psychologist, Lancaster University), Dr Katy Bourne (Clinical Psychologist, Lancaster University) and Dr Guillermo Perez Algorta (Clinical Psychologist, Lancaster University). The study is sponsored by Lancaster University.

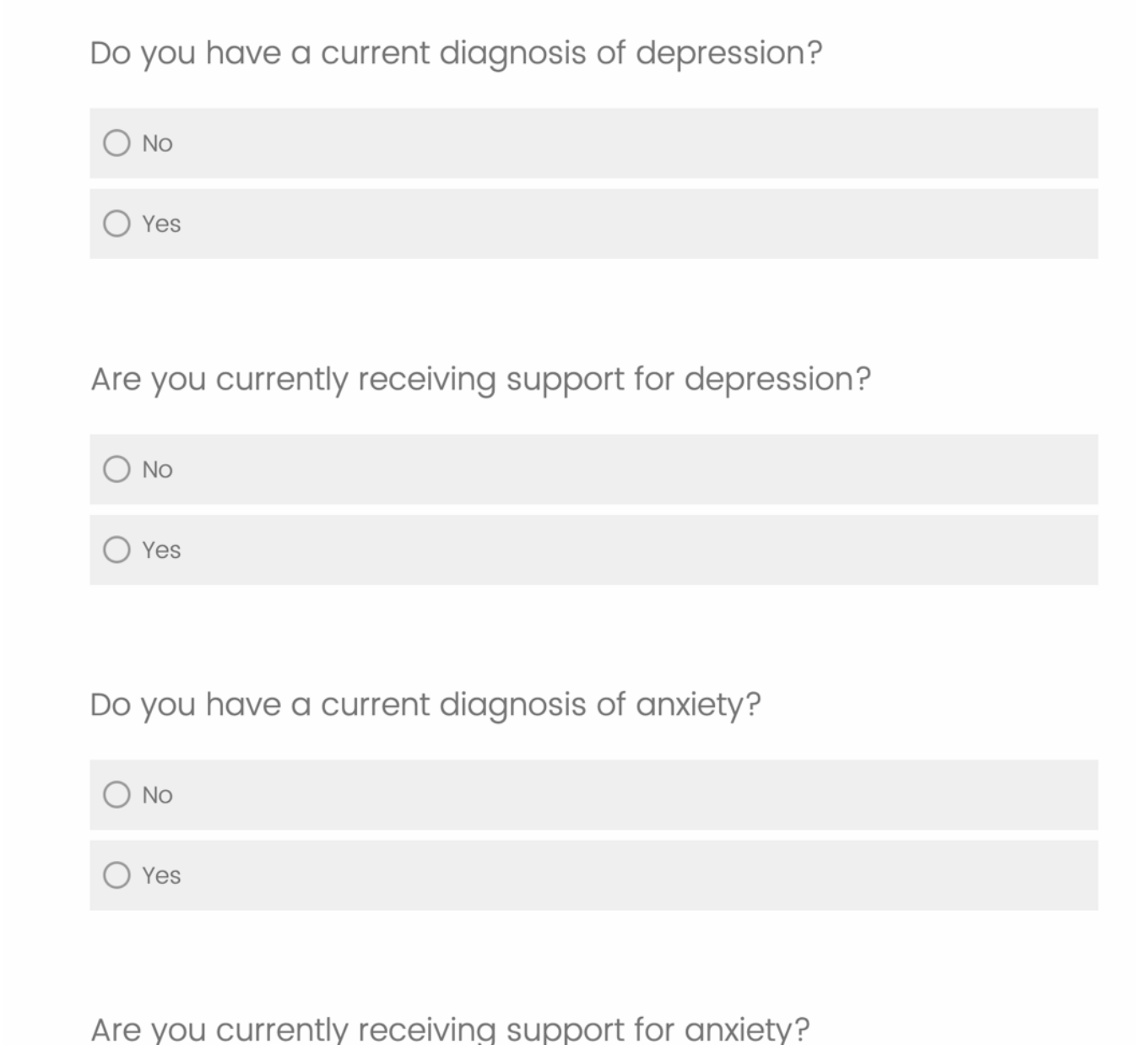
Qualtrics Example Screenshot 1: Information Sheet



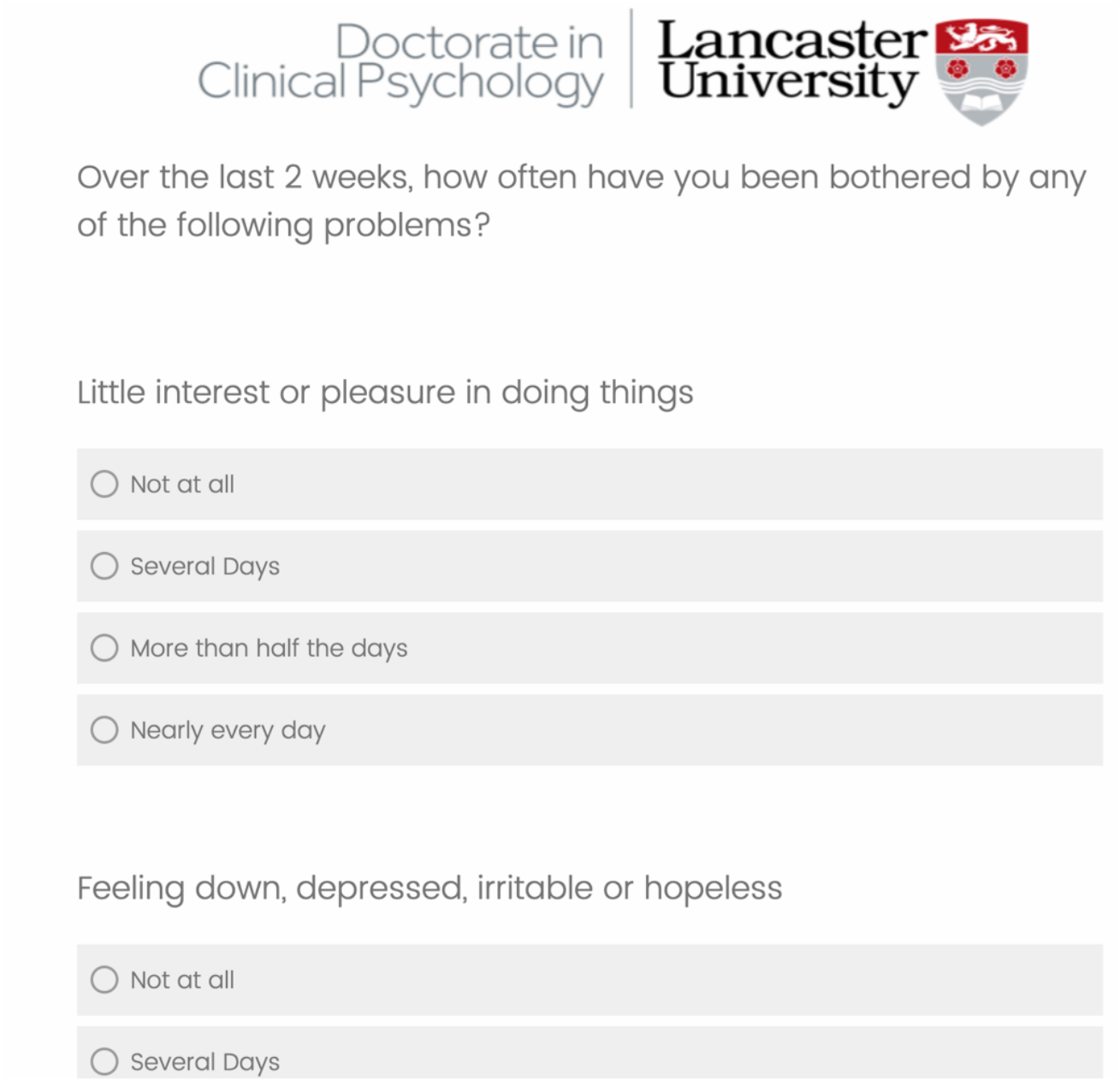
Qualtrics Example Screenshot 2: Consent Form



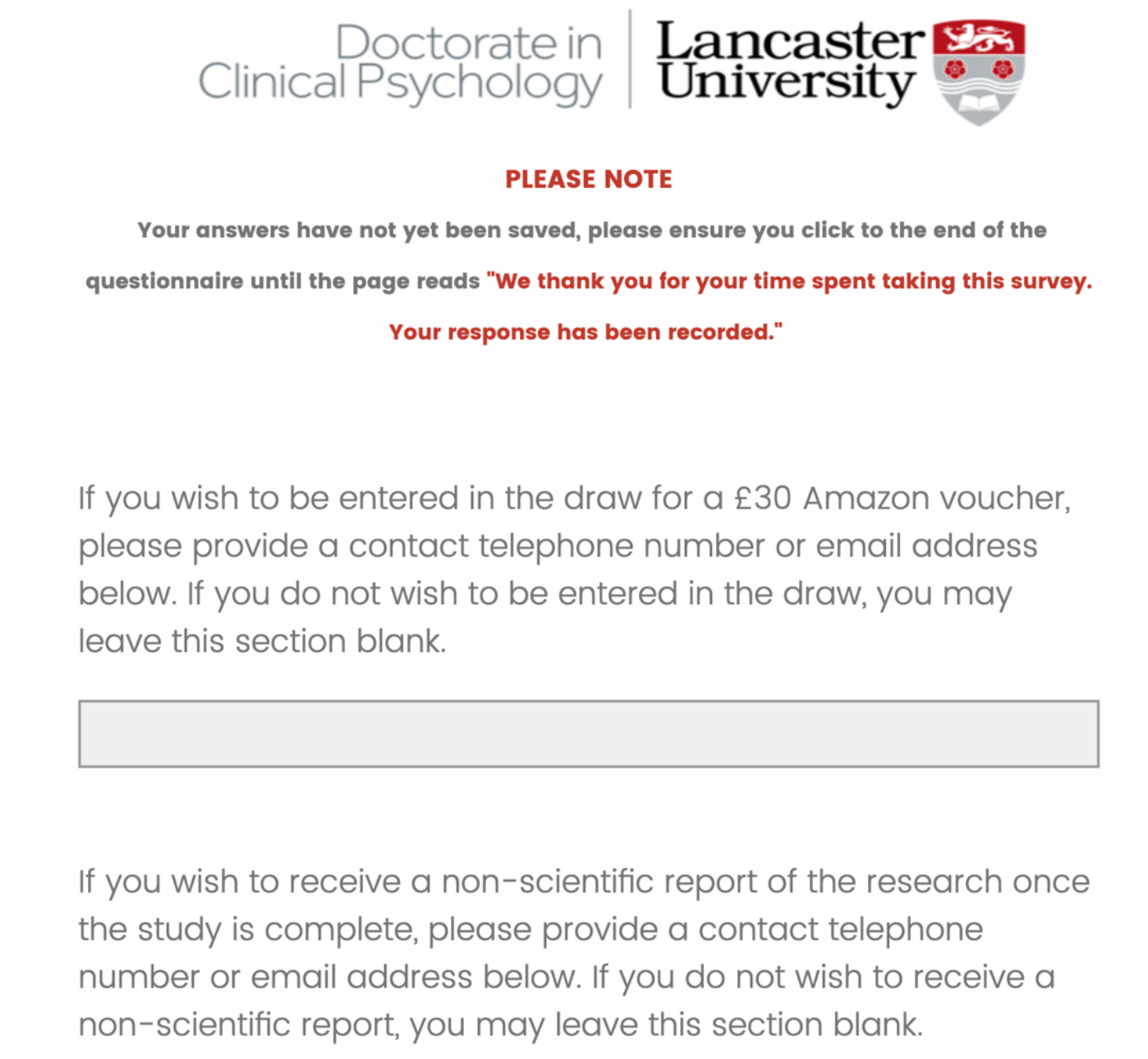
Qualtrics Example Screenshot 3: Demographic Questions



Qualtrics Example Screenshot 4: Self-report Psychological Distress Questions



Qualtrics Example Screenshot 5: Psychological Distress Severity Questionnaires



Qualtrics Example Screenshot 6: Contact Information Questions

results, someone will be in touch to provide this once this study is complete.

Resources in the event of distress

We are not expecting this study to cause you any distress.

However, should you feel distressed either as a result of taking part, or in the future, please contact your GP, who will be able to offer guidance and advice to best manage this. Alternatively, the following resources may be of assistance:

Samaritans – for mental health support

Telephone: 116 123

Email: jo@samaritans.org

Sleep Apnoea Trust – for sleep apnoea support

Telephone 07776 243231

Email: https://sleep-apnoea-trust.org/patient-information/email-helpline/

Website: https://sleep-apnoea-trust.org

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Qualtrics Example Screenshot 7: Debrief Sheet