CLINICAL PROTOCOL

Diagnosis and treatment of sleep apnea in shelter residents

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Contents

List of Abbreviations/ Terminology

• Apnea-Hypopnea Index (AHI) • Asthma Control Test (ACT) • Auto-titrating Positive Airway Pressure (APAP) • Beck Depression Inventory (BDI) • Epworth Sleepiness Score (ESS) • Functional Outcome of Sleep Questionnaire (FOSQ) • Chalder Fatigue Scale (CFQ) • Canadian Agency for Drugs and Technologies in Health (CADTH) • Continuous Positive Airway Pressure (CPAP) • Central Sleep Apnea (CSA) • Health Information Technology Usability Evaluation Scale (Health-ITUES)	• Health Information Technology Usability Evaluation Scale (Health-ITUES) Questionnaire • Health Insurance Portability and Protection ACT (HIPPA). • Infection Prevention and Control (IPAC) • Inner City Health Associate (ICHA) • Mandibular Advancement Device (MAD) • Oral Health Impact Profile - 14 (OHIP-14) • Oxygen Desaturation Index (ODI) • Obstructive Sleep Apnea (OSA) • Personal Information Protection and Electronic Documents Act (PIPEDA)	• Rapid Eye Movement (REM) • Research Ethics Board (REB) • Socio Economic status (SES) • University Health Network (UHN)

Protocol Summary

Title

Diagnosis and treatment of sleep apnea in shelter residents

Sample Size

n = 400

Study Population

Adults experiencing homelessness and living in shelters (shelter residents)

Accrual period

5 year

Study Design

This longitudinal study will collect data to assess the prevalence of sleep apnea in people living in shelters (shelter residents) and to investigate the effects of sleep apnea treatment on their quality of life. We will also collect information about the major complications of sleep apnea including cardiovascular disorders, respiratory diseases, and dental diseases. Several short questionnaires will be provided to the shelter residents, to assess sleep apnea-related quality of life, daytime sleepiness, and oral health, which is important for our proposed sleep apnea treatment based on oral appliances. A general survey will be

provided to shelter employees, shelter residents and healthcare providers to assess the barriers of the use of portable polysomnography and sleep apnea treatment options in people experiencing homelessness.

Eligible participants who screen positive for sleep apnea will be referred to the University Health Network (UHN) Centre for Sleep Health and Research for clinical diagnosis of sleep apnea and treatment. Definitive diagnosis would involve a complete medical history and examination, combined with an overnight polysomnography test. Treatment will be provided based on physician's recommendation and patient's preference, including continuous positive airway pressure (CPAP) or an oral appliance made specifically for the participant.

Study Duration

5 year

Primary Objectives

1. Assess the prevalence of sleep apnea in shelter residents
2. Evaluate the effects of preferred sleep apnea treatment on quality of life of the people experiencing homelessness

General Information

Protocol title	Diagnosis and treatment of sleep apnea in shelter residents
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Co-Investigator:	Tina Meisami, BSc., DDS, FRCD(C), DIP OMFS Valeria Rac, MD, PhD Owen Lyons, MB BCH BAO, MRCPI Mandeep Singh, MMBS, MD, MSc, FRCPC Andrew Boozary, MD, PhD
Fellows/Residents:	Research fellows of Azadeh Yadollahi, and Co-Investigators Michalina Seidl, Registered social worker
Study site(s)	1. Dixon Hall Housing Services department Add: 58 Sumach Street, Toronto, ON M5A 3J7 Tel: 416-863-0499 2. Fred Victor Add: 800 Bay Street, Suite 402, Toronto, ON M5S 3A9 Tel: 416-482-4103

Introduction and Background

People experiencing homelessness are at higher risk of getting infected, transmitting disease, and having poor health outcomes [1]. Access to medical care, even within a system of universal health insurance like the one in Canada, is decreased among people experiencing homelessness [2]. Even prior to the COVID-19 pandemic, the care-pathways of this populations were often characterized by a state of disconnected emergency room visits and hospitalization, rather than longer-term disease management [3]. While shelters offer basic necessities of living to this population, these community residences are not equipped to monitor the health status of their residents.

Compared to the general population, people experiencing homelessness sleep less, have excessive daytime fatigue, and greater use of substance to fall asleep at night or stay awake during the day. A common sleep problem is sleep apnea, which is characterized by repeated episodes of breathing cessation during sleep [4]. Sleep apnea is associated with the conditions that account for the leading causes of mortality in adults: hypertension [5], obstructive lung disease [6, 7], cardiovascular [8],[9] and cerebrovascular [10] diseases. What is known is that the prevalence of chronic diseases among the people experiencing homelessness is significantly greater than the general population, and likely, sleep apnea is no expectation [11-13]. However, there is no study on the prevalence of sleep apnea in people experiencing homelessness and observations suggest very low rates of treatment.

Also, individual, systemic, and environmental barriers in people experiencing homelessness lead to a higher rate of underdiagnosed and untreated sleep apnea. For example: **i)** care providers may consider sleep apnea less crucial than other challenges e.g. unstable housing or poverty. In contrary, high prevalence of chronic disorders and socioeconomic disadvantages should emphasize the importance of treating sleep apnea as a modifiable barrier to engage in daily activities e.g. work. **ii)** To be covered by health insurance (e.g. in Ontario), sleep apnea diagnosis should be done in a sleep laboratory which is challenging for people experiencing homelessness with family/childcare responsibilities. **iii)** Even if diagnosed, sleep apnea is hard to be treated in the people experiencing homelessness, because treatments such as CPAP devices are bulky, hard to store or transport, may be stolen, and need electricity which add to barriers. Alternative treatments such as mandibular advancement devices are not covered by health insurance and present a financial barrier. Unfortunately, all-cause mortality is 5-10 times higher in people experiencing homelessness than the general population, and sleep apnea remains a potential silent cause of morbidity and mortality, emergency department visits, poor mental health, and low quality of life in people experiencing homelessness.

Our goal is to diagnose and treat sleep apnea in marginalized people living in shelters and to examine the effect of patient-centered sleep apnea treatment on their quality of life.

Rationale

Previous studies have focused on chronic health conditions of people experiencing homelessness related to asthma, cardiology, and respiratory diseases, as well as the morbidity of overdose- and cardiology-related diseases [11-17]. But there is no literature on the prevalence of sleep apnea in the people experiencing homelessness. From past studies, chronic diseases have been shown to be more prevalent in the people experiencing homelessness versus the general population, with a particular emphasis on a high prevalence

of asthma and hypertension in the people experiencing homelessness. There was an average of 21.4% (range, 17.1%-24%) prevalence of asthma in the people experiencing homelessness from three North American studies and an average of 16.35% (range, 15.6%-17.1%) prevalence of hypertension in the people experiencing homelessness from two North American studies [11-13]. In comparison with the prevalence of asthma and hypertension in the general U.S. population, 11.5% and 7.4% respectfully, there is a significantly higher prevalence of both asthma and hypertension in the people experiencing homelessness [12].

There is already a well-established connection between the prevalence of sleep apnea in patients who have asthma and/or hypertension [18-21]. Previous studies have shown that 22%-55% of their sample population, having a previous diagnosis of hypertension, also had undiagnosed obstructive sleep apnea [9, 22, 23]. The number of patients with undiagnosed obstructive sleep apnea is even higher for resistant hypertension, with 71%-81% of patients having undiagnosed obstructive sleep apnea [9, 22-24]. Similar results are true for patients with pre-existing asthma. One study found the prevalence of obstructive sleep apnea to be 88%, 58%, and 31% in patients with severe asthma, moderate asthma, and no asthma, respectfully [25]. Meanwhile, another study found a 57.3% prevalence of obstructive sleep apnea in patients with a diagnosis of asthma and suspected obstructive sleep apnea [7].

Furthermore, there is an emerging link in the health sciences literature between socioeconomic status (SES) and health [26]. A systematic review of the literature, encompassing 17 studies from 1995-2016, found a significant association between SES status indices and obstructive sleep apnea in data gathered from around the world [27]. The authors noted that a definite health gradient could be observed from the few studies that analyzed the association between obstructive sleep apnea and individual SES indices [27]. Also, there are some literature shows the SES indices can be associated with the central sleep apnea (CSA) [28, 29].

Sleep apnea is already a highly undiagnosed condition in the general population [30, 31] and contributes to many other chronic health conditions [32-35]. Given the strong association of chronic cardio-respiratory disorders with sleep apnea, and the above average prevalence of these disorders in this population, it is reasonable to infer that there might also be a high prevalence of undiagnosed sleep apnea among the people experiencing homelessness.

Study Objectives and Hypothesis

Primary Objectives

1. To assess the prevalence of sleep apnea in shelter residents.
2. To evaluate the effects of preferred sleep apnea treatment on quality of life of the people experiencing homelessness

Hypotheses

1. The prevalence of sleep apnea in the people experiencing homelessness is more than 30%.
2. Treating sleep apnea in shelter residents will improve their quality of life.

Study Design

Measurements

Questionnaires

The following questionnaires will be provided to the participants to assess their sleep related quality of life and health.

- Participant Demographics questionnaire
- STOP-Bang [36-40],
- Insomnia severity index [41],
- Epworth sleepiness score (ESS) [42],
- Functional outcome of Sleep Questionnaire (FOSQ-10) [43, 44],
- Beck Depression Inventory (BDI) [45]
- Chalder Fatigue Scale (CFQ) [46]
- Health Information Technology Usability Evaluation Scale (Health-ITUES) Questionnaire [47]
- Oral Health Impact Profile - 14 (OHIP-14) [48]
- Asthma Control Test (ACT) [49]
- Primary care post-traumatic stress disorder (PTSD) screen (PC-PTSD-5) [50]
- A survey to help identify barriers to treatment in the people experiencing homelessness (General Survey)

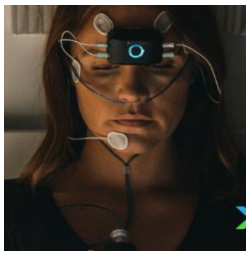
Sleep Apnea Screening

For another initial risk assessment, individuals are asked to complete a video-based task on a smartphone application developed by the Dr. Azadeh Yadollahi's research fellows. The task includes recording a video which asks the users to say the vowels loudly and clearly. After finishing the task, the application will process the facial landmarks from each frame of the video and analyze the speech of the individuals in parallel and mix them to feed a pre-trained neural network in order to assess the risk of sleep apnea. Also, the participants are asked to complete the list of previous questionnaires with the help of research assistant. The result of the application will be combined with the questionnaires for the final risk assessment.

Sleep Apnea Diagnosis

The Prodigy 2 (Figure 1): is a portable polysomnography device to assess sleep apnea in individuals at risk of sleep apnea. The Prodigy 2 has Health Canada Approval for home sleep study. The system is small, easy to use, and can be setup by a research technician at the shelter. Prodigy 2 measures thoraco-abdominal motion, nasal airflow, oxyhemoglobin saturation (SpO_2), cardiac function with electrocardiogram and leg movement. The main advantage of Prodigy 2 to other portable devices is that it has a simple headband to record forehead electroencephalogram to detect rapid eye movement (REM) and non-REM sleep stages. After processing Prodigy 2 signals, an apnea-hypopnea index (AHI) will be

Figure 1: The Prodigy



calculated for each participant based on the number of respiratory events (apneas or hypopneas) per hour of sleep [51]. We will measure AHI, REM AHI, non-REM AHI, AHI in different body postures, snoring duration, arousal index, sleep time with SpO_2<90%, oxygen desaturation index (ODI), and the sleep efficiency.

Sleep Apnea Treatment

Individuals who are diagnosed with sleep apnea, and are deemed eligible for treatment, will receive a treatment option based on Canadian Agency for Drugs and Technologies in Health (CADTH), physician recommendations, and the participant's preferences. In this study, auto-titrating positive airway pressure (Auto-CPAP) and Mandibular advancement device (MAD) will be the main modalities of treatment.

Auto-titrating positive airway pressure (Auto-CPAP or APAP): is a common variation of CPAP for sleep apnea treatment. Instead of delivering a fixed pressure, Auto-CPAP automatically delivers various pressures depending on the severity of pharyngeal airway collapse. Compared to CPAP, Auto-CPAP can be used without the need for an in-laboratory titration to determine the optimum air pressure. Therefore, it saves time and costs.

Mandibular advancement device (MAD): is an alternative treatment for sleep apnea. Patients who refuse to or are intolerant of APAP or patients who prefer to have MAD will be referred to Dr. Tina Meisami (Co-PI, Oral & Maxillofacial Surgeon). Custom made titratable oral appliances are the most effective and comfortable appliances available. MAD reduces sleep apnea symptoms by advancing the mandible and the tongue forward, decreasing upper airway collapsibility, and increasing oropharyngeal space to alleviate the airway obstructions. The degree to which the mandible must be advanced is specific to each patient. Dr. Meisami will prescribe, fit and titrate a custom made MAD for every patient. All patients would start MAD treatment at 50% of the maximum protrusion of the mandible. Then, their sleep apnea will be retested with the Prodigy and MAD will be further advanced if needed.

Data Collection Protocol

Patient recruitment

Two research assistant with strong knowledge of anti-oppressive, trauma-informed, and patient-centered care framework, will be the designated persons to contact shelters to establish a trusting and relatable relationship between the research team and the research participants. The research assistants will also conduct surveys. A poster specifying the nature of the study will also be designed and provided to shelters in and around the Greater Toronto Area.

Sleep Apnea Screening (Figure 3)

A trained research assistant with expertise in sleep assessment and a registered social worker with experience in shelter residents will go to the shelter to perform the screening phase of study. For individuals that agree to participate in the study, research personnel will obtain a signed copy of the study consent form (Consent Form A which relates to screening and diagnosis of sleep apnea). Participants will complete eleven questionnaires: Stop-Bang, Insomnia severity index,

Epworth sleepiness score (ESS), quality of life (FOSQ-10), Beck Depression Inventory (BDI), Chalder Fatigue Scale (CFQ), primary care post-traumatic stress disorder (PTSD) scale (PC-PTSD-5), Asthma control questionnaire (ACQ), OHIP-14, and Participant demographics. The RA will help the participants complete the questionnaires (~one and a half hours in total). At the end, the research assistant help the participant use the screening mobile application.

If the participant consents to complete the in-shelter sleep apnea diagnosis with in-shelter PSG devices, research assistants will schedule the date of study. For the in-shelter diagnosis, the research assistants will go to the shelter around 8PM and measure the participant's weight, height, neck, hip and waist circumferences, and blood pressure (Omron 3 inflatable cuff). Afterwards, research assistants set up the portable polysomnography (Prodigy 2, Figure 1), based on participant's preference. The next day at 7AM, the research assistant will return to the shelter to measure blood pressure and collect the measurement devices. Participants will fill Health-ITUES questionnaire in the morning.

In case of COVID that we cannot perform the study in person, the same protocol will be followed through Microsoft Teams (MS Teams). The research assistants will present the questionnaires to the participants through REDCap and help the participant to complete the questionnaire. The research assistants will guide the participants to use the sleep screening mobile application. The research assistants will guide the participants through MS Team to measure weight, height, neck, hip and waist circumferences, and blood pressure (Omron 3 inflatable cuff), and show the participants how to set up the portable polysomnography (Prodigy 2, Figure 1), based on participant's preference. The next day at 7AM, the research assistant will guide the participants (through MS Team) to measure blood pressure, remove the measurement devices, complete Health-ITUES questionnaire and put the measurement devices in safe locker in shelter which is assigned for this purpose.

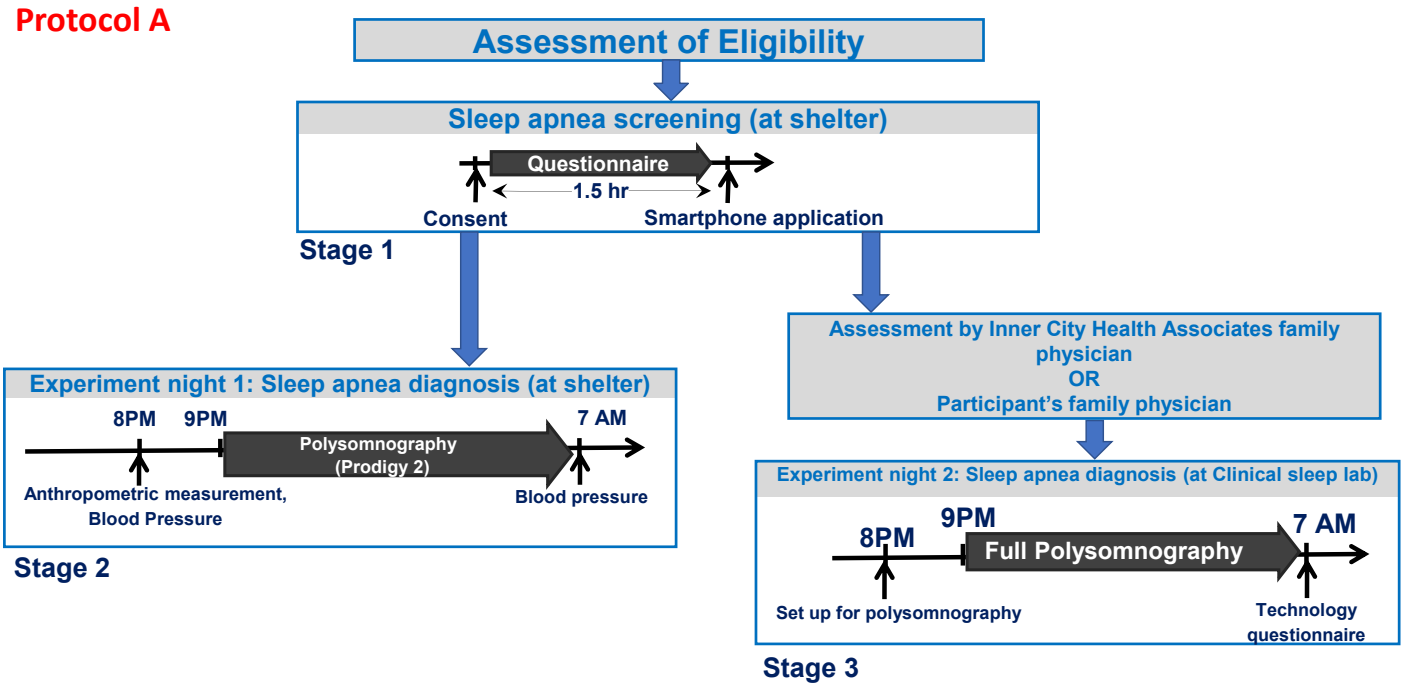
Sleep Apnea Diagnosis (Figure 3)

Individuals with moderate to severe sleep apnea score on the questionnaires will be asked to complete the second diagnosis phase. Based on the symptoms and clinical conditions, the physician will discuss the referral with individuals to the sleep physicians at UHN for definitive diagnosis based on overnight in-lab polysomnography (second diagnosis phase). If the participant has already been connected to a family physician, the research assistant will provide them with the printed referral form to ask their physician to complete and fax it to the sleep clinic. If the participant does not have a corresponding family physician, the physician at Inner City Health Associate (ICHA) clinic will complete the referral form and fax it to the sleep clinic.

The participants will attend a clinical sleep apnea diagnosis at the UHN Centre for Sleep Health and Research, which involves getting medical history in combination with an overnight

polysomnography test. Patients who are diagnosed with obstructive sleep apnea will be offered treatment with APAP or MAD at the UHN Centre for Sleep Health and Research.

Figure 3: Schematic of diagnosis phase (Protocol A)



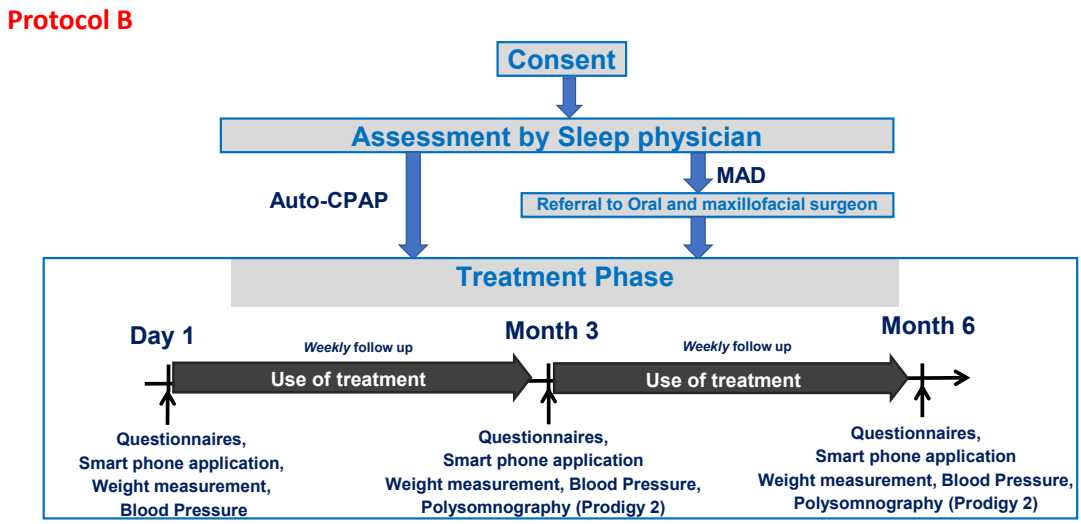
Sleep Apnea Treatment (Figure 4)

Patients who are diagnosed with sleep apnea will be recruited for six months of sleep apnea treatment. A sleep physician (Co-Investigators: Drs. M. Singh, O. Lyons), will analyze the polysomnography report and patient's symptoms to diagnose individuals with sleep apnea. The physicians will use a decision aid [54] to better match sleep apnea treatment with patient preference, which results in greater adherence and greater health outcomes [55]. Based on the decision aid, patient preference, and CADTH recommendations, the sleep physicians will recommend the participant to use Auto-CPAP or MAD for six months. For Auto-CPAP, a trained sleep technician will select the optimum mask size for the patients, train them on how to use the Auto-CPAP, and provide them with the Auto-CPAP. For MAD, the participant will be referred to an Oral and Maxillofacial Surgeon (Dr. T. Meisami, Co-PI) to treat and titrate with MAD for optimal disease control. The patient will later receive a customized MAD for treatment. Patients will use their Auto-CPAP or MAD for 6 months. Before treatment, and at 3 months and 6 months after treatment, participant's weight and blood pressure will be measured and they will fill insomnia severity index, ESS, FOSQ, BDI, CFQ, PC-PTSD-5, Health-ITUES questionnaires, and the general survey. Also, at these intervals (3, 6 months after starting the treatment) the participants are asked to complete the video task on the smartphone which was used at the sleep apnea screening stage. After 3 and 6 months of starting the treatment, the participants will also be asked about hospitalization and emergency department visits.

To increase adherence to treatment, once a week, a research assistant will contact the individuals by phone to solve the potential technical challenges with the APAP or MAD.

Diagnostic tests using the Prodigy 2 will be repeated after 3 and 6 months to assess sleep apnea severity. The treatment information will be stored on the study database on a secure driver within the UHN server system. The protocol of treatment phase is shown in Figure 4.

Figure 4: Schematic of treatment phase (Protocol B)



Data Analysis and Expected Results

Sleep Apnea Diagnosis (Primary Outcome 1)

The primary outcome of the study is to estimate the prevalence of sleep apnea in the people experiencing homelessness (primary objective 1). Polysomnography data will be scored by a qualified technician using standard techniques and criteria for scoring sleep stages, events, and arousals [14, 15]. Pulse oximetry data will also be analyzed to extract oxygen desaturation index (ODI). Oxygen desaturation index is defined as hourly average number of desaturation episodes, which is characterized by oxygen desaturation of 4% or more compared to the average oxygen saturation in the preceding 120 seconds which lasts more than 10 seconds [57]. Sleep apnea will be diagnosed and its severity will be assessed based on AHI and ODI. Individuals with AHI≥15 or REM-AHI≥15 or ODI≥5 will be considered as *sleep apnea*.

To assess the effectiveness of home-based technologies to diagnose sleep apnea in the people experiencing homelessness, we will follow signal processing techniques from previous studies to analyze the signals [52]. The Prodigy signals will be annotated automatically using Michele Scoring System. The system has the ability to preprocess the raw signals and extract distinguishable parameters which are conventionally extracted by human expert [58, 59]. Pulse oximetry data will also be analyzed to extract ODI. The AHI estimation of the Prodigy will be

compared with those from polysomnography results to assess the effectiveness of the at-shelter sleep study.

Statistical models: We will report the OSA prevalence rate within shelter residents, overall and by sex, type and severity. Using regression models, we will estimate the relationship between quality of life (FOSQ) measured on a continuous sale and severity of OSA among people with OSA, adjusted for sex, age, BMI, waist and neck circumference, ethnicity, sexual orientation, gender identity, menopausal status, comorbidities (hypertension, type 2 diabetes, BDI, PC-PTSD-5), and sleepiness. We will also assess the relationship between fatigue and OSA severity, adjusting for the same confounders. We will report obstructive AHI, central AHI, REM-AHI, non-REM AHI, AHI in various body postures, sleep time with SpO_2<90%, snoring duration, sleep efficiency, and alternative metrics[60] including apnea-hypopnea event duration, arousal intensity,[61] odds ratio product,[62] hypoxic burden,[63-66] and cardiopulmonary coupling, overall and by sex.[67] Using in-shelter polysomnography as the gold standard, we will report the sensitivity and specificity of the Stop-Bang questionnaire to identify participants with AHI≥5, AHI≥15, AHI≥30, REM-AHI≥15, or ODI≥5.

Expected results: The prevalence of sleep apnea in shelter residents will be >35%. OSA severity is a strong predictor of functional quality of life and fatigue. OSA phenotypes, such as REM vs. non-REM AHI, event duration, and sleep fragmentation will differ based on sex. The specificity of Stop-Bang to detect residents with AHI≥15 will be lower than its specificity in the general population (~30%).[36, 38]

Sleep Apnea Treatment (Primary Outcome 2)

The primary outcomes will be change in quality of life (FOSQ score)[44] and systolic and diastolic blood pressure, and adherence to treatment at three and six months. Adherence to treatment is measured as the number of hours/night and nights/week that participants use treatment. Auto-CPAP devices keep track of the usage and this data can be automatically extracted.

Statistical Analysis: We will use repeated measures ANOVA to assess the changes in the FOSQ-10 score from baseline to 3 and 6 months after treatment using each person as their own control. Regression models for FOSQ at 3 and 6 months will adjust for factors known to contribute to changes in the FOSQ global score, including baseline FOSQ-10 score, anthropometrics, BMI, sexual orientation, gender identity, AHI, age, treatment adherence, baseline blood pressure, and comorbidities (type 2 diabetes, hypertension, depression and PTSD scores). We will assess changes in systolic and diastolic blood measure using similar models in those with hypertension. We will report adherence to treatment. The usability of sleep apnea treatment will be assessed by a Health Information Technology Usability Evaluation Scale (Health-ITUES)[47] which is modified for our study.

Expected results: After treatment, FOSQ scores will increase (better quality of life) and systolic and diastolic blood pressure in patients with hypertension will decrease. Adherence to MAD and CPAP treatment will be ≥70%, which is similar to the adherence in the general population.[68-76]

Selection of Participants

Participants will be referred by a shelter manager, case worker, or another shelter employee from one of the shelters in and around the Greater Toronto Area. The eligibility criteria for participants will include residing in a shelter at the time of recruitment, and being >18 years old. Participants with allergies to medical tape will be excluded from the study. For treatment protocol, exclusion criteria for mandibular advancement treatment will be dental and oral health requiring extensive dental treatment or periodontal disease with tooth mobility.

Shelter setting: The patients and their community are central parts of this research. We have established strong partnership with institutes that provide care for experiencing homelessness.

Dixon Hall: serves more than 10,000 marginalized people in Toronto annually, including at-risk youth, women, seniors, adults with physical and health disabilities, people who need housing, individuals searching for employment, those with mental health issues, and newly immigrated individuals and their families. Dixon Hall's Housing Services department has been providing shelter services for the homeless and vulnerably housed in the city of Toronto for more than two decades. They provide overnight accommodation throughout the year to 500 residents through two emergency shelters, two respites and 3 hotels. Most residents in hotels use the housing service for a long period, average duration of six months/year, which provides a robust "living laboratory" for our proposed research.

Fred Victor: is committed to ending homelessness. Serving communities for over 125 years, Fred Victor has grown from a single mission at Queen and Jarvis to a multi-service organization with over 20 locations across Toronto. In addition to affordable housing, transitional housing, and emergency shelters, Fred Victor provides a constellation of supports to help people secure and maintain a safe place to live. Furthermore, Fred Victor has provided accommodation to more than 1000 residents through six different sites.

Privacy of Participants

Patient information will be held in the strictest confidence. All communications with participants will be done only by research staff, via phone or secure UHN email address. Participants will be informed of the data sharing protocols, as part of informed consent, and all email scripts as well as advertisements will include the email disclaimer for sharing personal data. All correspondence involving sharing personal and medical information will be handled with strict confidentiality and in accordance to the Personal Information Protection and Electronic Documents Act (PIPEDA) and Health Insurance Portability and Protection ACT (HIPPA).

Management of Adverse Events

To support the participants emotionally, the research assistant will stay affiliated with them throughout their involvement in the proposed research. The occurrence of any adverse event in this study is unlikely or minimal. However, in case of any adverse event associated with the study that is both serious and unexpected, the REB, and federal agency will be promptly reported.

Infection Control Measures

All the items that will be used in this study will be subject to the regular infection control measures in the sleep lab in accordance with UHN Infection Prevention and Control (IPAC) protocols. The electrodes of Prodigy 2 will be cleaned and disinfected based on the manufacturer's protocol.

Direct Access to Source Data/Documents

Only designated research staff will have access to participant consent forms, surveys, and other study documents. The sharing of study data and documents will be done by fax where possible, or via secure UHN email addresses that are only used for research purposes. Physical copies of study data and documents will be stored under lock and key, accessible only by designated research staff. Electronic data and documents will be stored on a secure driver within the UHN server system.

Quality Control and Quality Assurance Procedures

Conduct of the study and study data will be reviewed by the principal investigators and other research personnel during weekly research meetings.

Ethics

Consent Process

An important challenge will be to establish trust between participants and the research team. Due to the systemic barriers and traumatic healthcare experiences that these individuals may have had in the past, we will take a trauma-informed approach to our research. Potential participants will be informed that the information collected in the surveys will be for research purposes and that their participation is voluntary. For this study, two consent forms (A and B) are used in different stages of the study. Consent Form A, related to the sleep apnea screening and diagnosis in shelter residents, while the consent form B involves treatment stage of this study. A research assistant familiar with issues of trust and trauma-informed approach will contact the potential participants. The individuals will receive a brief summary of the research project, including: the purpose, the duration, and the procedures involved. The individuals will be informed that their regular care will not be affected even if they do not participate, or that financial compensation should not coerce them into participating. Individuals will be presented with both the reasonable and expected benefits of participation, in addition to any reasonable and foreseeable risks or discomforts. During the course of their participation, and in the event of subsequent treatment, it will be made known that alternative procedures or treatment options will always be presented, should they become available.

Participants will be assured that their identities will remain confidential and information accessible only by designated research personnel. Also, the participants will be informed that they can withdraw from the study at any time due to any reason. Participants will be asked to inform the research staff in case of withdrawal and the reason, if possible.

Data Handling and Record Keeping

Publication Policy

The findings of this study will be submitted for publication in a peer-reviewed journal and used for grant proposals. Participants will not be identifiable in any publications. Study findings will be fed back to the shelter community so they can learn about their community.

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