Enhancing Slow Wave Sleep in Older Adults Patients and Alzheimer's Disease Patients (Technical project)

The Effect of Unequal Demographic Representation in Medical Studies on Health Disparity (STS project)

A Thesis Prospectus In STS 4500 Presented to The Faculty of the School of Engineering and Applied Science University of Virginia In Partial Fulfillment of the Requirements for the Degree Bachelor of Science in Biomedical Engineering

By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments ADVISORS

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Introduction:

In the rapidly evolving domain of medical sciences, the intersection of technology and its societal consequences is becoming more pronounced. Sleep, an essential component of human existence, stands at this crossroads. Apart from being a physiological necessity, sleep is integral to our cognitive and emotional well-being (Walker, 2017). With an aging global population, understanding sleep patterns and quality in older adults is becoming increasingly relevant. Research indicates that as individuals age, there's a significant alteration in their physiological sleep patterns, with Slow Wave Sleep (SWS) seeing substantial reductions (Mander et al., 2017). SWS, also known as deep sleep, is a stage in the human sleep cycle that occurs before the deepest stage of sleep called Rapid Eye Movement sleep (REM) where most dreaming takes place. This stage is most commonly associated with memory retention and consolidation (Walker, 2009). This reduction in SWS due to aging, often correlated with cognitive declines and diseases that affect memory, emphasizes the need for technical solutions to enhance this sleep phase (Grandner et al., 2016).

With this, an emerging concern in the field of sleep research pertains to the representation of diverse demographics. Medical research, historically, has encountered challenges with adequate representation, often leading to results that aren't universally applicable (Benjamin, 2019). For example, the data used to calculate blood oxygen content through the use of infrared light in a pulse oximeter (pulse ox) included predominantly white patients. This led to inaccurate readings for people of color where the devices showed a higher blood oxygen content than what was accurate due to darker skin pigmentation; the melanin in the skin would absorb more of the infrared light coming through which is how the device determines how much oxygen carrying red blood cells there are. (Sjoding et al., 2020). This ties into the topic of medical research and how the racial and socioeconomic background of the participants can affect training datasets used to calibrate machines and AI in the medical field.

2

Thus, the Science Technology and Society (STS) topic that I will be discussing is the effect of unequal demographic representation in medical studies on health disparity. This relates to the technical topic of my capstone project which is enhancing slow wave sleep in older adults and patients with Alzheimer's disease; this project involves utilizing a wearable device that tracks sleep patterns using electrical impulses from the brain and emits pink noise to amplify the brain waves during SWS. These two have an important overlap, especially because the sleep device being designed will be trained using previous sleep data.

Technical Topic:

Alzheimer's Disease (AD) is the most common form of dementia, affecting 6 million individuals in the United States. The number of people projected to be affected by Alzheimer's Disease in Europe is projected to double by the year 2050 (Scheltens, 2021). The disease alters the way that neurons, specialized signal transmitting cells in our brain, interact with one another. AD is a progressive disease that begins with memory loss and eventually loss of communication skills. The overlap between memory retention and sleep has been a long topic within the medical, scientific, and psychology research fields. Within this, there is a promising connection to targeting SWS to improve memory consolidation, and therefore combat the progression of AD (Lee et al., 2020). The project led by Sequoia Neurovitality aims to use machine learning to track sleeping patterns to identify when the Slow Wave Sleep stage occurs and white noise to amplify those brain wave signals.

We plan to design and manufacture a comfortable and wearable headband device containing electrodes and wireless hardware for data collection during sleep. The headband device is to be comfortable and easy to correctly position such that the electrodes can be positioned at the F7, F8, Fpz, O1, O2, and Cz locations on the cranium, with a ground as well. The electrodes used will be dry electrodes and the pink noise will be utilized via a bone conduction transducer at pink noise frequencies, which are frequencies within the general human hearing range of 20 Hz to 20,000 Hz. The EEG technology used in the device mimics that of polysomnography, which is the test commonly used by somnologists and commonly known as a "sleep study" (Shrivastava, 2014). Sleep studies utilize breathing-measuring devices as well as additional electrodes, however the seven utilized in the headband device have been shown to aptly record brain activity.

The device will be wireless to improve comfortability during sleep, which also means that the internal mechanisms must maintain the ability to measure and predict the stages of sleep as well as output noise during SWS. Incorporating big data analytics can unravel intricate sleep patterns, leading to personalized sleep-enhancing strategies. This individual-centric approach is pivotal, given the unique sleep needs and challenges of older adults (Klerman & Dijk, 2008). This will be done by training an Artificial Intelligence (AI) using sleep data found online through EEG/ ERP data readily available online. Multiple datasets from tracking diverse patients through their sleep can be accessed and . This is where previously mentioned instances of implicit bias being built into devices or algorithms take precedence in this project. It is important for the dataset used to train the AI to consist of a diverse population in order to avoid bias.

Pink noise has been shown to affect the synchronization of brain activity and sleep consolidation and thus this device is to be utilized to implement this technology as a means to improve cognitive performance for patients with memory disorders (Zhou et. al, 2012). The closedloop Electroencephalogram (EEG) device also is going to be tested in detecting and predicting the sleep cycle in order to deliver acoustic stimulation during SWS. We are also going to develop a mobile app in order to collect feedback from the future subjects in this research study as well as provide digital feedback that the subjects and designers can see. This will be completed through the course of the year, and while the clinical trial period of the design process will likely not come until much later after all of the prototyping is complete and the Institutional Review Board (IRB) reviews and clears the project. The testing of the headband will be conducted on the participants of the capstone project as pseudo-pilot-trials in order to test for the efficacy of the sleep tracking.

This leads to the research question I will be aiming to answer: Can modern technological interventions, particularly a sleep headband equipped with sleep sage tracking and a pink noise transducer developed through Sequoia Neurovitality, augment the quality and length of SWS in Alzheimer's Disease patients?

STS Topic:

Scientific research, especially in medicine and health, holds profound influence over policymaking, clinical practice, and public perception. In this context, the skewed demographic representation in sleep studies becomes a grave concern, as it is capable of perpetuating, or even worsening, health disparities (Obermeyer et al., 2019). It is crucial to examine what the factors that shape how sleep studies are conducted at the University of Virginia Sleep Clinic are.

Historically, the composition of participants in medical research has favored certain demographics, particularly white males from economically advantaged backgrounds. Unfortunately, this leads to disproportionately represented groups where minority groups face disadvantages due to the medical technology being best trained for those similar to the research participants (Alsan et al., 2019). Such disproportionate representation not only curtails the generalizability of research findings but may also neglect crucial sleep-related health issues specific to marginalized groups (Grandner, 2020).

This relates to Pinch and Bijker's seminal work in *The Social Construction of Facts and Artefacts* (1984) which offers a lens through which to understand the unequal demographic representation as a result of the relevant groups shaping the status quo of sleep studies. Central to their argument is the idea that technological artifacts and facts are not only products of scientific discovery or

incremental advancement, but also the result of different groups placing their ideals into the technology as it undergoes iterations until it reaches an end point. This led to Pinch and Bijker constructing a framework for the social construction of technology (SCOT). In the context of sleep studies, the 'artifacts' could be seen as the research outcomes, methodologies, and study protocols. The way that sleep studies are advertised and conducted at the UVA Sleep Clinic has been shaped by the somnologists who work there, the patients who decide to use the technology, the administration at UVA health that aim to make the clinic profitable and reputable, and the stakeholders of UVA health that are only looking at the financial returns of investment.

Highlighted in the book *Just Medicine: A Cure for Racial Inequality in American Health Care*, many doctors carry implicit bias from their upbringing or limited worldview, usually accredited to their privilege, which results in unequal treatment of their patients (Matthew, 2015). This can lead to not only an implicit bias from somnologists while conducting sleep studies on racial minorities, but also a disconnect between the predominant demographic and underrepresented groups in using this service, as typically sleep disorders are not life threatening. This implicit bias in the doctors of the sleep clinics might be one of the social factors that most impacts the treatment of patients based on their background. In conjunction with the fact that patients from lower socioeconomic status or underrepresented groups might only come to the hospital as a last resort, the predominant demographic is likely one that is socioeconomically advanced and proliferate the difference in treatment between these two groups. The administration as well as stakeholders also likely care more about the statistics of the clinic as a whole; the orders from above are likely to provide good care efficiently to their patients to achieve high ratings from reviewing and ranking organizations. The stakeholders likely don't care about the demographics breakdown of the patients coming through the doors, and instead look at the amount of patients they are able to see and perform expensive

6

tests to make more profit. These groups, especially on the side of the medical professionals and their bosses, will be explored as they are the driving force of why the UVA Sleep Clinic functions the way it does currently.

Another key component of Pinch and Bijker's work is the idea of "closure and stabilization." Once a technological artifact achieves a certain level of societal consensus, it becomes 'black boxed," which means that it becomes the norm and is seldom questioned. In sleep studies, for example, when research heavily leans towards a particular demographic, the conclusions drawn can achieve this 'black-boxed' status. This phenomenon can lead to systemic health disparities as these conclusions inform clinical practices, policies, and public health interventions. In this case, the "relevant social groups," which are those with a direct stake in a particular technological artifact, need to be broadened in the context of sleep studies. When the demographics are not diverse, the "relevant group" becomes narrowly defined. This contributes to the cycle in medical research where the underrepresented groups continue to receive unequal treatment.

To address the unequal demographic representation in sleep studies and its implications, there is a need to deconstruct these socially constructed artifacts. For our technical project, incorporating data that represents groups outside of the norm will yield a product that is applicable to any individual who might seek to improve their cognitive capabilities, particularly those with Alzheimer's Disease. This is especially pertinent given that it has been found that women are at higher risk of developing AD, with a majority of Americans with Alzheimer's being women (Pike, 2016). This means the populations most being affected by AD are outside of the normal demographic of white, economically advantaged men. With this in mind, the following research question and methodology were formed.

7

Research Question and Methods:

The STS research question this has led me to is: What are the factors that shape how sleep studies are done at the University of Virginia Sleep Clinic?? To answer this question, I will interview medical doctors (MDs) at the Sleep Clinic at the University of Virginia Hospital in order to acquire anecdotal as well as statistical data regarding the racial and gender breakdown of their research participants and patients. In order to achieve further data, interviews might be extended to the adjacent clinic, the Pulmonary and Critical Care Clinic – also located in the University of Virginia. I will also complete literature review using the Claude Moore Health Science Library at UVA in order to look at the history of the Sleep Clinic.

Conclusion:

In my technical project, I will be developing a sleep headband technology that uses machine learning and pink noise to stimulate memory retention during slow wave sleep in Alzheimer's Disease patients. This is to prevent further cognitive decline by amplifying the SWS brain waves. In the STS deliverable, I will be investigating how the University of Virginia Sleep Clinic conducts their sleep studies in the context of race, sex, and socioeconomic background. By understanding the way that these two interrelate, my capstone group will aim to develop a device that mitigates bias. The intersection of these topics emphasizes the concept that medical technology and socially conscious research practices must be considered in tandem in order to achieve equitable outcomes.

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