

THE EFFECTS OF VIBRATIONAL THERAPY ON ANXIETY AND SLEEP QUALITY IN
YOUTH WITH ADHD: A DOUBLE-BLIND, RANDOMIZED SHAM-CONTROLLED TRIAL

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A DISSERTATION

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

Kinesiology – Doctor of Philosophy

2025

ABSTRACT

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most prevalent neurodevelopmental disorders and is associated with significant impairments in cognitive functioning. Moreover, the disorder is associated with increased anxiety and poor quality sleep, behaviors which may exacerbate and/or mimic ADHD symptomatology. As the autonomic nervous system (ANS) plays a critical role in modulating physiological levels of arousal, therapeutic strategies which target autonomic balance, such as vibrational therapy, may offer substantial benefits for anxiety and sleep. The Apollo system, a wearable vibrational therapy device designed for use on the wrist or ankle, has been found to promote greater autonomic balance by enhancing parasympathetic tone. However, its effects on sleep quality and anxiety levels in children with ADHD remain unclear. **Objective:** Therefore, the current study employed a double-blind, randomized sham-controlled design to evaluate the impact of the Apollo system on anxiety levels and sleep quality in children and adolescents (aged 8 to 17 years) with ADHD. **Method:** Participants were randomly assigned to either the active Apollo device, which delivers vibration to promote autonomic balance, or a sham device over a period of 8 weeks. Anxiety and sleep were assessed prior to and following this intervention period, using the Pittsburgh Sleep Quality Index (PSQI) and the trait subset of the State-Trait Anxiety Inventory (STAI). **Conclusion:** The findings indicate that utilizing a wrist/ankle-based vibrational therapy device 4 days per week for 2 hours a day over an 8-week period may be insufficient to meaningfully improve sleep outcomes and anxiety in children and adolescents with ADHD.

Keywords: Attention Deficit Hyperactivity Disorder, Sleep, Anxiety, Vibrational Therapy

For Kate, Betty, and Meryl, the intelligent and strong-willed women who came before me and always encouraged me to pursue my dreams, thank you.

ACKNOWLEDGEMENTS

First and foremost, I owe the world's largest thank you to my doctoral advisor, Dr. Matthew Pontifex. Matt, I am a better scholar, researcher, teacher, and human because of the continual guidance, knowledge, patience, and support you have provided me over the past five years. Thank you for believing in me always. To my committee, Dr. Janet Hauck, Dr. Natalie Moser, and Dr. Jason Moser, thank you endlessly for being my sounding board throughout my doctoral career. Your advice, kindness, and willingness to share your expertise have been invaluable to me. Additionally, I owe a sincere thank you to the many other faculty and staff who have assisted me along my way.

To the other HBCL graduate students, Colt Coffman, Dr. Oksana Ellison, and Dr. Madison Chandler, thank you for supporting me throughout my doctoral program, providing direction, creative insight, and wonderful company. To my research assistants, specifically Claudia, Will, Bailey, and Harris, it has been a joy to mentor and work alongside you all. Thank you all for the endless hours you have poured into data collection with me, it wouldn't have been nearly as fun without you. To the dear friends I have gained through this program, Darice Brooks, Faith Houck and Caitlin McCluggage, thank you all for your wisdom, encouragement, joining me for \$5 sushi Thursdays and making working in the basement of IM Circle a little less lonely.

Finally, thank you endlessly to my family and friends who have supported me throughout the past five crazy years. Mom and Dad, thank you for believing in me and encouraging me to stubbornly pursue my education and dreams. I am continually grateful for the hours you have poured into editing projects, papers, and assignments throughout my undergraduate and graduate schooling (you're welcome for the unexpected wealth of obscure knowledge you both now

possess after all these edits). To my sweet friends, I am immensely thankful to be loved and supported by you all. While you may not entirely understand what I do, you continue to show up for me and cheer me on and it is not lost on me. Ian, thank you for supporting me throughout this dissertation writing process, ensuring I never went without coffee, dinners, and laughter. And ultimately, Kaitlin Lewin, no words can express how grateful I am to have had you as a friend, roommate, and sounding board over the past five years, I could not have done it without you.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS	vii
INTRODUCTION	1
LITERATURE REVIEW	6
METHODOLOGY	32
RESULTS	38
DISCUSSION	46
BIBLIOGRAPHY	52
APPENDIX A: TABLES.....	72
APPENDIX B: FIGURES	74

LIST OF ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
ANS	Autonomic Nervous System
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EEG	Electroencephalography
GAD	Generalized Anxiety Disorder
HI	Hyperactivity / Impulsivity
IA	Inattention
PFC	Prefrontal Cortex
PNS	Parasympathetic Nervous System
PSG	Polysomnography
PSQI	Pittsburgh Sleep Quality Index
SATED	Satisfaction, Alertness, Timing, Efficiency, Duration
SNS	Sympathetic Nervous System
STAI	State-Trait Anxiety Index
WBV	Whole Body Vibration

INTRODUCTION

ADHD

Attention Deficit Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder characterized by developmentally different levels of inattention, distractibility, impulsivity, and hyperactivity (American Psychiatric Association, 2013). Current prevalence rates estimate that 5-6% of children and adolescents worldwide are diagnosed with ADHD, marking it as one of the most pervasive disorders of childhood (Bitsko, 2022; Faraone et al., 2021; Polanczyk et al., 2014). Moreover, ADHD is associated with difficulties across a variety of domains. In addition to deficits in cognitive functioning, children and adolescents with ADHD often experience more academic difficulties, engage in more risky behaviors, and experience greater social challenges than their peers without the disorder (Barkley, 2002; Baweja et al., 2015; Biederman et al., 2004, 2010; Hoza et al., 2005; Strine et al., 2006). ADHD is considered a chronic condition as symptoms persist into adulthood for many children with the disorder (30–60%; Barbaresi et al., 2013; Barkley et al., 2002; Sibley et al., 2016). Therefore, it is crucial that researchers continue to explore a variety of therapeutic options in order to ensure the best care for those with ADHD.

ADHD is an incredibly prevalent disorder with wide-reaching effects that are exacerbated by a lack of, or insufficient, therapeutic intervention. Current evidence-based treatments include behavioral and pharmacological intervention, or the combination thereof (Evans et al., 2018). However, many children and adolescents with ADHD continue to experience symptoms despite treatment (Antshel et al., 2012), and a significant proportion (10–25%) do not respond to medication therapies (Banaschewski et al., 2006). While current treatments ameliorate some symptoms, there are concerns about their long-term efficacy, implementation, and adherence.

Additionally, these treatments may fail to meaningfully impact, or may even negatively affect, related behaviors which in turn exacerbate ADHD symptoms, such as anxiety and sleep.

Anxiety and Sleep

In addition to continued symptomatology, many children and adolescents with ADHD experience continued or novel sleep disturbances and increased anxiety despite treatment (Hvolby, 2015; Koyuncu et al., 2022; Owens, 2005; Stein et al., 2012; Tannock, 2000). This is especially concerning when considering that youth with ADHD are at an already increased risk of experiencing heightened anxiety and worse quality sleep compared to their typically developing peers (Gregory et al., 2017; Koyuncu et al., 2022; Prevatt et al., 2015; Sung et al., 2008; Tannock, 2000; Yoon et al., 2012). As these problems are incredibly prevalent, it is also important to understand how they may impact presentation and treatment outcomes in youth with ADHD.

The presence of a comorbid ***anxiety*** disorder or elevated anxiety levels, even if subclinical, can significantly influence the presentation and severity of ADHD. Beyond the overlap in symptomatology between ADHD and anxiety disorders, such as increased fidgeting, difficulty with attention or focus, irritability, and impaired social functioning (Katzman et al., 2017); children and adolescents with comorbid ADHD and anxiety demonstrate poorer performance on working memory tasks compared to those with ADHD or anxiety alone (Bloemsma et al., 2013; Jarrett et al., 2016; Tannock, 2000). Furthermore, research indicates that children with both ADHD and anxiety exhibit greater impairments on continuous performance tasks, a measure of sustained attention, compared to their peers with ADHD alone and typically developing children (Ter-Stepanian et al., 2017).

Further, difficulties with *sleep* have also been found to significantly impact the presentation, management, and severity of psychiatric disorders like ADHD (Owens, 2005). Previous research has found that sleep quality and daytime sleepiness are associated with worsened performance on cognitive assessments of attention, memory, and global executive functioning (Anderson et al., 2009; Casavi et al., 2022) and exacerbation of ADHD-like symptomatology and inattention, and difficulty concentrating (Araújo & Almondes, 2014; Epstein et al., 1998; O’Brien, 2009; Owens, 2005; Sadeh et al., 2002). Given that high levels of anxiety and poor sleep may worsen or imitate ADHD symptomatology, as well as research suggesting that anxiety may reduce the effectiveness of pharmacological interventions (Koyuncu et al., 2022), and linking stimulant therapies with increased sleep problems (Stein et al., 2012), exploring the impact of alternative treatments on these outcomes is imperative.

Potential Therapeutic Alternatives

One potential approach for an adjunctive therapy to complement existing treatments and address residual symptoms and impairments such as poor quality sleep and anxiety involves targeting the autonomic nervous system (ANS) — which regulates physiological arousal in response to internal and external stressors. Autonomic tone represents the balance and modulation of activity between sympathetic nervous system (SNS) and parasympathetic nervous system (PNS) inputs, which are responsible for equipping the body to respond to a stressor and promoting growth and restorative processes respectively (Buijs, 2013; Goldstein, 2013; Porges, 1992). Research has found that children and adolescents with ADHD tend to experience irregularities in autonomic tone; specifically, those with ADHD were more likely to show SNS dominance (Bellato et al., 2020; Rukmani et al., 2016). In addition to self-regulation, the autonomic nervous system plays an important role in anxiety and sleep. Specifically, worsened

autonomic tone has also been associated with worsened sleep quality and higher rates of anxiety (Chawla et al., 2022; Park et al., 2023; Sharma et al., 2011). Therefore, a therapeutic option which promotes better autonomic tone may elicit beneficial effects for this population through supporting better sleep quality and diminishing anxiety levels.

Vibrational Therapy

Common methods for modulating autonomic tone involve invasive techniques, while research on the effectiveness of non-invasive, more discreet alternatives like vibrational therapy remains limited (Broncel et al., 2020). Emerging research suggests that vibrational therapy may be one approach to promote autonomic tone, enhance sleep quality, and reduce anxiety (Barralon et al., 2008; Chawla et al., 2022; Figueroa et al., 2012; Park et al., 2023; Wong & Figueroa, 2019). However, there remains limited evidence regarding the efficacy of such an approach for improving sleep and reducing anxiety among children and adolescents with ADHD.

Aims and Hypotheses

Therefore, the purpose of this dissertation was to investigate the effects of vibrational therapy on both trait anxiety and sleep quality in children and adolescents with ADHD. Specifically, the current study assessed the efficacy of the Apollo System (Apollo Neuroscience, Pittsburgh, PA), a wrist/ankle based vibrational therapy system, using an 8-week double-blind, sham-controlled Phase 2 clinical trial with random assignment and parallel design. Specific aims and hypotheses are below:

Specific Aim 1. To assess a wearable vibrational therapy device for ameliorating trait anxiety levels in youth with ADHD.

Hypothesis 1. It was hypothesized that participants with the commercial Apollo device would report decreased anxiety than those with the sham, no-vibration, control device.

Specific Aim 2. The secondary aim of this study was to examine the effects of vibrational therapy on dimensions of sleep quality, including satisfaction, alertness, timing, efficiency, and duration.

Hypothesis 2. It was hypothesized that participants with the commercial Apollo device would report better quality sleep compared to participants who received the sham-control, no vibration device.

LITERATURE REVIEW

To gain a comprehensive understanding of the relationship(s) between ADHD, anxiety, and sleep, and the potential therapeutic effects of vibrational therapy, it is essential to first review the existing literature across these domains. This chapter will begin by providing an overview of ADHD – including how the disorder is diagnosed, symptoms and functional outcomes, etiological factors, and current treatments – to offer context for the current sample. Relevant theoretical models will also be discussed. Next, this chapter will introduce the two primary outcomes variables of interest to this dissertation: anxiety and sleep. Each construct will be defined, with a brief review on how it is assessed in the literature; then, each will be examined within the context of ADHD, including shared deficits and implications for treatment. Following this, an overview of vibrational therapy will be presented, with a focus on current applications, associated physiological mechanisms, and a brief discussion of relevant, preceding vibrational therapy interventions. Finally, this chapter will conclude with a brief exploration of the relationship between ADHD, anxiety, sleep and vibrational therapy, providing a theoretical mechanistic framework and support for the rationale of the current investigation.

Attention Deficit Hyperactivity Disorder

ADHD is one of the most prevalent neurodevelopmental disorders, positioning it as a significant public health concern (Faraone et al., 2021). Current rates estimate that nearly six percent of children and adolescents in the United States are diagnosed with ADHD, with boys being diagnosed twice as often as their female peers (Bitsko, 2022; Faraone et al., 2021; Hinshaw et al., 2022; Mowlem et al., 2019; Polanczyk et al., 2014). ADHD is categorized by worsened levels of inattention, hyperactivity, impulsivity, and distractibility; and is associated with significant impairments across a variety of domains, such as cognition, academic

achievement, social skills, peer acceptance, self-perception, and more (American Psychiatric Association, 2013; Babinski et al., 2011; Barkley, 2002; Faraone et al., 2021; Rucklidge & Tannock, 2001). Given its high prevalence and broad impact, ADHD represents a critical area of concern for clinicians, educators, and researchers alike.

Diagnosis and Symptomatology

Originally coined *hyperkinetic syndrome*, early conceptualizations of ADHD emphasized symptoms such as hyperactivity, willfulness, and impulsivity (Conners & Wells, 1986; Littman, 2012; Martinez-Badía & Martinez-Raga, 2015). Over time, and following decades of clinical observation, a secondary symptom profile emerged, characterized primarily by inattention and distractibility, leading to the recognition of the inattentive subtype of ADHD (Littman, 2012; Nadeau et al., 2015). Contemporary diagnostic frameworks, as outlined in the Diagnostic and Statistical Manual (DSM-5), continue to dichotomize ADHD-related behaviors into two distinct, but often co-occurring, symptom domains: inattention and hyperactivity/impulsivity (American Psychiatric Association, 2013). Each domain includes nine representative symptoms, for a total of 18 diagnostic criteria. Hyperactive and impulsive symptoms include having difficulty remaining seated or still when expected, talking excessively and interrupting, fidgeting, and more. Inattentive behaviors include symptoms such as having difficulty focusing, avoiding tasks which require sustained mental effort, and being easily distracted.

Based on these symptom domains, children and adolescents may be diagnosed with one of three ADHD presentations, depending on their primary symptom profile: (1) predominantly inattentive presentation – meeting the diagnostic threshold for inattention but not hyperactivity/impulsivity; (2) predominantly hyperactive/impulsive presentation – meeting criteria for hyperactivity/impulsivity but not inattention; and (3) combined presentation –

meeting diagnostic thresholds for both domains (American Psychiatric Association, 2013). In addition to symptom presentation, the DSM-5 posits that symptoms should emerge before 12 years old and result in clinically significant distress or functional impairment. Diagnosis is typically informed through a multi-modal, multi-informant approach that includes behavior rating scales (e.g., parent, teacher, caretaker, self-report), performance based assessments of attention and executive functioning (e.g., working memory tests, interference control and response inhibition tasks), and a clinical interview conducted by a licensed practitioner to explore the context and impact of reported behaviors (Barkley, 2015b). Clinicians are encouraged to consider and assess alternative explanations, such as anxiety or other psychological conditions, before assigning a diagnosis (Barkley, 2015b). Additionally, lifestyle factors such as poor sleep should be assessed, as it can mimic or exacerbate attentional difficulties (Craig et al., 2017). Therefore, it is important to evaluate not only ADHD symptomatology, but also relevant behaviors and psychological factors.

Functional Impairments

Beyond diagnostic criteria, ADHD significantly impacts daily functioning and overall well-being. Children and adolescents with ADHD commonly report lowered self-esteem and reduced psychological well-being compared to their typically developing peers (Harpin, 2005; Mazzone et al., 2013; Peasgood et al., 2016). These challenges often manifest in academic and social contexts, with untreated ADHD leading to the most pronounced impairments (Daley & Birchwood, 2010; DuPaul et al., 2024; Ros & Graziano, 2018). Academically, individuals with ADHD tend to receive lower grades and are less likely to graduate and pursue post-secondary education than their typically developing peers (Barkley, 2002; Baweja et al., 2015; Biederman et al., 2010; Faraone et al., 2021). Socially, they experience more difficulty with initiating and

maintaining friendships, face greater peer rejection, and are more likely to engage in risky behaviors such as substance use (Barkley, 2002; Hoza et al., 2005; Ros & Graziano, 2018; Strine et al., 2006). In addition, children with ADHD are more likely to experience familial difficulties, including higher levels of home chaos, increased family conflict, and worsened parent-child relationships, all of which may affect symptom presentation (Harpin, 2005; Harvey et al., 2003; Johnston et al., 2012; Mokrova et al., 2010; Theule et al., 2013). Taken together, these outcomes underscore the broad and multifaceted impact of ADHD on youth development and highlight the importance of understanding its underlying causes.

Etiological Factors

To contextualize the relationship between ADHD and the outcome variables of interest in this dissertation, sleep and anxiety, as well as the potential effectiveness of vibrational therapy in this population, it is essential to consider relevant theoretical frameworks and etiological factors.

Relevant Behavioral Models. Despite variance in symptom presentation, all ADHD subtypes share core deficits in executive functioning, including impairments in working memory and inhibitory control (Barkley, 1997; Biederman et al., 2004; Diamond, 2013; Mullane et al., 2009; National Institute of Mental Health, n.d.; Willcutt et al., 2005). Two prominent behavioral models have attempted to explain the mechanisms underlying ADHD and the associated cognitive deficits. First, *Barkley's Model of Behavioral Inhibition* posits that the central deficit in ADHD is impaired inhibition (Barkley, 1997). According to this model, difficulties with response inhibition (i.e., stopping a prepotent, but incorrect, response) and interference control (i.e., the ability to ignore distracting stimuli) negatively impact other executive functions, such as emotional regulation, motivation, and arousal – ultimately contributing to the behavioral manifestations of ADHD (Barkley, 1997; Diamond, 2013; N. P. Friedman & Miyake, 2004;

Tiego et al., 2018). Empirical support for this model is drawn from studies demonstrating impaired response inhibition (Nigg, 1999; Pievsky & McGrath, 2018; Willcutt et al., 2005; Wodka et al., 2007) and interference control (Lansbergen et al., 2007; Mullane et al., 2009), as well as working memory deficits (Berlin et al., 2004; Kofler et al., 2018; Willcutt et al., 2005) in youth with ADHD. However, criticisms of Barkley's model note that some studies have failed to find a significant difference in inhibition between children with and without ADHD (Martella et al., 2020; R. Shaw et al., 2005). In response, the *Cognitive Energetic Model of ADHD* offers an alternative perspective, placing emphasis on the roles of arousal, attention, and effort in the expression of ADHD symptomatology (Sergeant, 2000). Biobehavioral studies lend support for this framework, as ADHD is often associated with neural hypoactivation and motor coordination difficulties (Barkley, 2015a; Goulardins et al., 2013; Martella et al., 2020). While no singular theory fully explains the etiopathogenesis of ADHD, both models underscore the central role of self-regulatory processes, including arousal.

Neurological & Developmental Differences. Research utilizing a variety of neuroimaging techniques has identified several structural and functional differences in the brains of children and adolescents with ADHD. Structurally, youth with ADHD often have a slightly smaller cortical surface area, along with reduced volumes in key regions of the frontal cortex, cerebellum, striatum – areas of the brain implicated in emotional and cognitive behaviors, such as planning and decision making (Barkley, 2015a; Castellanos, 2002; Faraone et al., 2021; Hoogman et al., 2017). In regard to developmental differences, a landmark longitudinal study by Shaw et al. (2007) found delayed cortical maturation, especially in prefrontal areas involved in self-regulated cognitive functioning. Additionally, some studies have found decreased white matter in children with ADHD, suggesting a delay in myelination as well (Barkley, 2015a; Silk

et al., 2008). Functionally, ADHD is linked to widespread, lowered activity in frontal brain regions, weaker connectivity between cognition-relevant brain areas, and reduced metabolic activity in right frontal regions (Barkley, 2015a). Together, these findings suggest that ADHD is characterized by delayed brain development and atypical functioning in regions critical for cognitive functions and self-regulation.

Physiological Differences. Beyond the brain, physiological processes, specifically those governed by the autonomic nervous system (ANS), play a significant role in governing aspects of attention and self-regulation (Holzman & Bridgett, 2017; Rukmani et al., 2016; Thayer et al., 2009). The ANS is comprised of distinct subsystems, including the sympathetic (SNS) and parasympathetic nervous systems (PNS) which work in tandem to regulate arousal (Waxenbaum et al., 2024). The SNS prepares the body to manage stressors through a cascade of physiological responses (“fight or flight”), while the PNS operates the “rest and digest” system. The *Neurovisceral Integration Model* (NVIM) posits that the same systems and brain regions which support ANS functioning are also involved in cognitive and inhibitory control (Thayer & Lane, 2000; Thayer & Sternberg, 2006). In line with this model, children with ADHD typically exhibit autonomic hypoactivation, characterized by decreased autonomic tone (or the balance between PNS and SNS inputs) and relative sympathetic dominance (Bellato et al., 2020; Rukmani et al., 2016). This dysregulation in autonomic tone, specifically SNS dominance, has been associated with poorer outcomes on measures of inhibition, cognition, attentional and emotional control (Barber et al., 2020; Dalise et al., 2020; Scott et al., 2021; Thayer & Lane, 2000; Thayer & Siegle, 2002), further substantiating the role of arousal dysregulation in ADHD. Collectively, these behavioral, neurological, and physiological models converge on a central theme: that the dysregulation of self-regulatory systems is central to ADHD. This multidimensional

understanding is essential when considering comorbid factors such as anxiety and sleep disturbances and provides a valuable context for evaluating the potential utility of interventions like vibrational therapy.

Current Therapeutic Options for ADHD: Benefits and Limitations

The most widely used evidence-based treatments for ADHD include behavioral interventions and pharmacological therapies (Evans et al., 2018; Faraone et al., 2021). Behavioral interventions encompass several modalities, with the most common being behavioral parent training (BPT), cognitive behavioral therapies (CBT), and school-based treatment programs (Toplak et al., 2008). BPT, which originated in the 1960s-1970s in response to the limited generalizability of clinic-based interventions, is designed to provide parents with strategies to manage disruptive behaviors in the home (Shaffer et al., 2014; Tharp & Wetzel, 2013). These programs aim not only to improve child behavior but also to increase parental efficacy and insight into the disorder. In addition to parent-focused interventions, child-centered behavioral therapies target school-relevant executive functioning challenges, such as cluttered backpacks and lockers, poor time management and study skills, and difficulty completing schoolwork (Evans et al., 2020). Other programs aim to improve emotion regulation and social skill deficits commonly observed alongside ADHD (Toplak et al., 2008). While behavioral interventions can be effective for specific symptom domains and offer scaffolding for long-term behavioral management, several limitations remain. Most notably, these interventions do not directly address the neurobiological mechanisms underlying ADHD. Their effectiveness is often contingent upon the sustained engagement and motivation of the child, parents, and clinicians, raising concerns about long-term maintenance and real-world generalization of treatment effects (Toplak et al., 2008; Waschbusch & Hill, 2003).

Pharmacological treatment, particularly with stimulant medications, represents another primary therapeutic modality for ADHD. These medications target underactive neural systems implicated in ADHD, often resulting in improved cognitive functioning and self-regulation (Den Heijer et al., 2017). The Multimodal Treatment Study of Children with ADHD (The MTA Cooperative Group, 1999) that medication was more effective than behavioral treatment alone in reducing core ADHD symptoms, and that combined treatment did not demonstrate significantly greater benefits than medication alone. Despite their efficacy, stimulant medications present several important limitations. Their effects are limited to periods of active use, and treatment adherence can be inconsistent among children with ADHD (Charach et al., 2004; Charach & Gajaria, 2008; Charach & Fernandez, 2013; Lichtenstein et al., 2012). Moreover, research highlights a substantial proportion of medication non-responders, estimated to range between 10–25% (Banaschewski et al., 2006), along with reports of adverse side effects such as appetite suppression, and sleep and mood disturbances (Charach & Fernandez, 2013; Morton & Stockton, 2000). Additionally, many parents express reservations about long-term psychostimulant use due to concerns about safety and developmental impact (Toplak et al., 2008; Waschbusch & Hill, 2003; Wilson & Jennings, 1996). These factors contribute to concerns about the sustainability and acceptability of pharmacological interventions as a stand-alone treatment for ADHD. Considering the limitations associated with current therapeutic options, it is critical that researchers continue to explore alternative, adjunctive treatments which can address these gaps.

While behavioral and pharmacological treatments can provide meaningful relief for individuals with ADHD, these interventions are not universally effective and often only address a subset of symptoms, leaving residual difficulties. ADHD is a chronic disorder, with persisting into adulthood for 30 – 50% of those diagnosed in childhood (Barkley et al., 2002; Faraone et al.,

2021; Sibley et al., 2016). When left untreated or under-managed, those with ADHD are at an increased risk of adverse psychosocial, academic, and functional outcomes (Shaw et al., 2012). Further, the manifestation of ADHD is highly influenced by contextual and environmental factors. Even with adequate treatment, challenges such as increased anxiety and poor sleep remain which may aggravate symptomatology. These concerns not only complicate the management of ADHD but also highlight the need for alternative, adjunctive interventions aimed at targeting residual impairments and addressing the broader behavioral, emotional, and social difficulties associated with the disorder.

Anxiety

While definitions vary, *anxiety* is broadly conceptualized as a mood state involving complex and often disproportionate cognitive, affective, behavioral, and physiological responses aimed at preparing the body for a perceived threat (Chand & Marwaha, 2025; Kong et al., 2022). Although occasional anxiety is a normal and adaptive part of the human experience, it becomes pathological when individuals consistently overestimates potential threats, resulting in unnecessary or excessive responses which cause significant distress or impairment (Chand & Marwaha, 2025). Generalized Anxiety Disorder (GAD), the most prevalent anxiety disorder, is characterized by persistent, excessive worry, tension, and fear concerning everyday problems and/or routine events (Organization, 1992; Ströhle et al., 2018). Similar to ADHD, anxiety is diagnosed using a combination of rating scales, structured observation, and diagnostic interviews with a clinician (Silverman & and Ollendick, 2005; Spence, 2018).

Beyond formal diagnosis, anxiety is also conceptualized as a relatively stable personality trait (Endler & Kocovski, 2001; Endler & Magnusson, 1976; Kong et al., 2022; Spielberger, 1972). In this context, anxiety can be dichotomized into state versus trait anxiety (Endler &

Kocovski, 2001; Spielberger, 1972). *State anxiety* refers to transient, situational experiences of anxiety in response to some specific event or stimulus, whereas *trait anxiety* reflects individual differences in sensitivity to threats across a wide variety of situations (Endler & Kocovski, 2001; Endler & Magnusson, 1976; Eysenck, n.d.; Kong et al., 2022; Spielberger, 1972). Trait anxiety has been established as a risk for anxiety disorders (Eysenck, n.d.), and can be assessed through parent- and self-report questionnaires, such as the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983). Multiple informants are particularly valuable in assessing anxiety in youth with ADHD (Spence, 2018), given the complexities of symptom presentation.

ADHD and Anxiety

Children with ADHD are at a significantly increased risk of being diagnosed with an anxiety disorder, with estimates indicating that approximately 25 – 35% meeting diagnostic criteria for a comorbid anxiety diagnosis (Bloemsma et al., 2013; Faraone et al., 2021; Koyuncu et al., 2022; Schatz & Rostain, 2006; Tannock, 2000; Tsang et al., 2015). Even in the absence of a formal diagnosis, adolescents and young adults with the disorder often report higher levels of anxiety across a variety of domains compared to their typically developing peers (Prevatt et al., 2015); specifically, research estimates that between 15 – 35% of children with ADHD experience significant anxiety (Pliszka et al., 1999). Moreover, a 2024 study reported that trait anxiety was significantly correlated with total ADHD symptoms and hyperactivity, but not inattention (Hare et al., 2025). Youth with the combined ADHD subtype have also been found to exhibit higher levels of trait anxiety than those with other subtypes (González-Castro et al., 2015). Notably, trait anxiety and ADHD symptoms also co-occur in non-clinical adult populations (de Zwaan et al., 2012), indicating a substantial overlap between symptomatology of the two disorders. Research consistently has found that children with ADHD and comorbid

anxiety experience more severe symptoms, including higher rates of attention difficulties, poorer overall functioning, and more mood difficulties compared to those with ADHD alone (Bowen et al., 2008; González-Castro et al., 2015; Koyuncu et al., 2022; Tsang et al., 2015). Therefore, children with ADHD are at an increased risk of being diagnosed with an anxiety disorder than their typically developing peers, report higher levels of trait anxiety than ADHD-only and healthy control kids, and experience aggravated ADHD symptomatology if experiencing comorbid anxiety difficulties.

Although the precise nature of the relationship between ADHD and comorbid anxiety remains complex, several hypotheses have been proposed. One view suggests that anxiety arises as a response to the challenges and negative experiences associated with ADHD symptoms, such as academic and social difficulties (Koyuncu et al., 2022; Tannock, 2000). Youth with ADHD do tend to endorse heightened concerns about their abilities and future, and frequently seek reassurance, potentially reflecting internalized worry (Tannock, 2000). ADHD is also associated with difficulties maintaining social relationships, potentially contributing to increased feelings of social anxiety (Barkley, 2002). Alternatively, the co-occurrence of ADHD and anxiety may be due to overlapping behavioral, neurological, and physiological deficits (Nigg et al., 2004; Tannock, 2000), which will be discussed more below. Importantly, these two hypotheses are likely both true to some extent and co-existing, as research suggests there is a bidirectional relationship in which ADHD symptoms elicit anxiety, and anxiety in turn exacerbates core ADHD symptomatology (Koyuncu et al., 2022; Schatz & Rostain, 2006; Tannock, 2000).

The overlap in core symptomatology between ADHD and anxiety. There is substantial overlap between the diagnostic criteria for GAD and ADHD in both the DSM IV and DSM 5, including restlessness, fidgeting, irritability, concentration difficulties, and impulsivity

(González-Castro et al., 2015; Koyuncu et al., 2022; Tannock, 2000). Overlap between sleep-relevant symptoms as well, such as insomnia, fatigue, and other sleep disturbances are also common across both disorders (González-Castro et al., 2015; Koyuncu et al., 2022). Given that youth with ADHD report elevated anxiety levels, it is critical to understand how anxiety might mimic or aggravate core ADHD symptoms.

Inattention. When considering overlapping symptoms researchers often point to inattention, however the true nature of the relationship between ADHD, anxiety, and inattention is incredibly complex. Some studies have found that high levels of trait anxiety and being diagnosed with a comorbid anxiety disorder can significantly interfere with sustained attention in youth with ADHD (González-Castro et al., 2015; Kong et al., 2022; Schatz & Rostain, 2006; Ursache & Raver, 2014). While others have found a protective effect wherein children with comorbid anxiety had less attentional difficulties than their peers with just ADHD (Vloet et al., 2010). Moreover, a 2015 study suggested that anxiety exacerbates cognitive difficulties specifically for individuals with increased inattentive symptomatology (Prevatt et al., 2015). Therefore, anxiety appears to differentially impact attention depending on context and symptomatology.

Distractibility. While less research has been conducted on distractibility and concentration, overall findings seem to suggest that individuals with ADHD and comorbid anxiety report more difficulty concentrating compared to typically developing and ADHD-only peers (González-Castro et al., 2015; Schatz & Rostain, 2006). Moreover, youth with ADHD who reported increased levels of trait anxiety also exhibited increased interference costs on a flanker task, indicating more difficulty in controlling distractor interference (Pacheco-Unguetti et al., 2010).

Hyperactivity. Although there were limited studies assessing hyperactivity patterns specifically, restlessness and fidgeting, symptoms associated with hyperactivity, were frequently noted as shared behaviors in both disorders (González-Castro et al., 2015; Koyuncu et al., 2022; Tannock, 2000).

Impulsivity. Similar to inattention, the relationship between anxiety and impulsivity in ADHD is complex and the literature is somewhat inconsistent (Vloet et al., 2010). While some studies have found that the presence of comorbid anxiety did not alter performance on tasks designed to assess impulsivity (Vloet et al., 2010), others suggest that anxiety may reduce impulsivity in youth with ADHD. Specifically, youth with ADHD and comorbid anxiety performed better on cognitive tasks as they were slower to respond and made less errors, suggesting that anxiety may selectively benefit motor inhibition, and in turn impulsivity (Ruf et al., 2017).

Inhibition. According to *Barkley's Model of Behavioral Inhibition*, inhibition is considered the core deficit underlying ADHD (Barkley, 1997). Given that anxiety is often associated with inhibitory control difficulties in children with and without ADHD, it is important to acknowledge that anxiety can sometimes mimic these hallmark behaviors (Ruf et al., 2017). Supporting this, a study by Ansari and Derakshan (2011) found that increased anxiety negatively impacted task performance and neuroelectric indices of inhibitory control on an anti-saccade task, similar to the deficits observed in ADHD. However, findings across the literature remain mixed. Some studies have reported that anxiety has no significant effect on inhibitory control (Vloet et al., 2010), while others suggest that anxiety might even attenuate inhibitory control deficits in certain contexts (Koyuncu et al., 2022; Ruf et al., 2017), potentially through increased cortical arousal.

The overlap between brain and nervous system alterations associated with ADHD and anxiety. There are also similarities in how each disorder affects the brain and nervous system. Nigg et al (2004) proposed two pathways in the development of these similarities, (1) that the early self-regulatory deficits associated with ADHD may lead to difficulty regulating anxiety, and (2) that increased anxiety may interrupt self-regulatory processes. Regardless of the timing, it appears true that ADHD and anxiety share similar structural and functional neural deficits in regions of the brain important for regulatory control. For example, Ströhle et al (2018) found that youth with anxiety showed deficits in the areas of the prefrontal cortex (PFC) and anterior cingulate gyrus which are responsible for inhibiting the amygdala. Bishop (2009) reported that trait anxiety interferes with the recruitment of prefrontal regions, such as the dorsolateral prefrontal cortex, which are critical for attentional control. Not only does anxiety mimic deficits seen in ADHD, but it also may exacerbate cognitive difficulties in youth with ADHD due to the overlap in neural functioning deficits (van der Meer et al., 2018). Overall, it appears that anxiety disrupts the top-down modulation of behavior, even in the absence of a specific threat (Ansari & Derakshan, 2011; Bishop, 2009; Pacheco-Unguetti et al., 2010). Moreover, anxiety has also been associated with physiological markers of worsened self-regulation. Specifically, anxiety has been linked with worse autonomic tone, similar to ADHD, which affects how the body reacts to stress and the ability to flexibly modulate arousal (Kong et al., 2022; Miu et al., 2009; Z. Wang et al., 2023). GAD is linked to reduced heart rate variability (HRV; Wang et al., 2023). While trait anxiety has been associated with decreased high frequency power, which indicates decreased adaptability and decreased parasympathetic nervous system activity (Miu et al., 2009).

Treatment of Comorbid Anxiety and ADHD

As comorbid anxiety in children with ADHD can have serious implications for functioning, it is essential to treat but also challenging. Early research from the Multimodal Treatment Study of Children with ADHD (MTA) highlight that ADHD with comorbid anxiety may represent a distinct clinical subtype with unique implications for assessment and intervention (Hinshaw, 2007; Jarrett et al., 2016; Jarrett & Ollendick, 2008; Jensen et al., 1999; Vloet et al., 2010). Several studies have attempted to assess how anxiety complicates ADHD treatment outcomes; however, the research is varied, especially on the efficacy of stimulant medications (Ter-Stepanian et al., 2017). While some evidence indicates that stimulant medications may exacerbate anxiety symptoms or produce side effects such as tics, dysphoria, and obsessive-compulsive behaviors (Tannock, 2000), other studies suggest that stimulants may actually reduce state anxiety, supporting the notion that anxiety may be secondary to ADHD (Pliszka, 2019). When stimulants successfully alleviate anxiety, it supports the possibility that the anxiety may be a secondary response to ADHD-related difficulties, supporting the possibility of an alternative treatment option which targets this anxiety specifically.

Sleep

Sleep is an essential physiological process characterized by a state of rest and restoration, and achieving good sleep is vital to overall health and wellbeing (Ramar et al., 2021). Quality sleep is associated with cognitive, emotional, and physical benefits, particularly during developmental periods in which sleep is fundamental for brain maturation and neuronal connectivity processes, and therefore optimal functioning (Alrousan et al., 2022; Ramar et al., 2021). Recommended sleep duration varies by age, with children (6 to 12 years old) being advised to sleep between 9 to 11 hours per night, while adolescents should sleep for 8 to 10

hours (Alrousan et al., 2022; Hirshkowitz et al., 2015). Regardless of age, good sleep hygiene, including consistent bed and wake times, sufficient duration, minimal disruptions, and subjective perceptions of high sleep quality, remains important for maintaining healthy sleep and wellbeing (Ramar et al., 2021). Chronically insufficient or poor quality sleep during key developmental periods may impede neural development with downstream effects of cognitive and psychosocial abilities, and has been implicated in the emergence of various disorders throughout childhood, including anxiety (Alrousan et al., 2022). Additionally, poor sleep is associated with decreased daytime alertness and increased sleepiness, mood disturbances, and worsened cognitive functioning (Alrousan et al., 2022; Dahl, 1996; Ramar et al., 2021).

Sleep is commonly assessed through both objective and subjective measures. The gold standard assessment in sleep research, polysomnography (PSG), combines objective measurements of brain activity (electroencephalography; EEG), heart rate, muscle tone, and eye movement (Berry et al., 2017; Dahl, 1996; Kirov & Brand, 2014; Rechtschaffen & Kales, 1968). From PSG data, insights into sleep architecture, or the transition between different sleep stages, as well as sleep quality, timing, and disturbances can be drawn. Alternatively, subjective measures including sleep questionnaires, offer valuable understandings into perceived sleep experiences, including difficulties in maintaining sleep, overall sleep quality, and daytime dysfunction (Kirov & Brand, 2014). Current literature has yet to identify an ideal subjective measure but instead encourages researchers to critically consider which tool to use (Van Meter & Anderson, 2020). The present dissertation utilized the Pittsburgh Sleep Quality Index (PSQI), as it provides insight into sleep quality, variability in sleep timing, duration, disturbances, and daytime dysfunction, which are all sleep outcomes which have been shown to be affected by ADHD (Buysse et al., 1989; Kirov & Brand, 2014; Scialpi et al., 2022).

Additionally, the PSQI has shown to be reliable and valid, and has been used widely to assess sleep quality, and dimensions of sleep, in children and adolescents (Buysse et al., 1989; Scialpi et al., 2022; Van Meter & Anderson, 2020).

ADHD and Sleep

Children and adolescents with ADHD frequently experience sleep difficulties, with the prevalence of sleep problems ranging from 70% to 85%; additionally, they are more likely to be diagnosed with a sleep disorder than healthy controls, suggesting an overlap in symptoms and outcomes between the two disorders (Cortese et al., 2009, 2013; Craig et al., 2017; O'Brien, 2009; Stein et al., 2012). Historically, restless sleep has even been included as a diagnostic criterion in earlier editions of the DSM (Kirov & Brand, 2014). Sleep problems in this population may emerge from several sources, including side effects of stimulant medication, comorbid psychiatric conditions, and unhealthy sleep habits, such as inconsistent sleep and wake times, excessive caffeine intake, and nighttime electronic use (Craig et al., 2017).

Although the precise etiology of sleep problems in youth with ADHD remains unclear, subjective reports consistently indicate increased sleep problems for this population (Cortese et al., 2009; Gregory et al., 2017; Kirov & Brand, 2014; Sung et al., 2008; Yoon et al., 2012). Subjective assessment of sleep in youth with ADHD found increased bedtime resistance and greater excessive daytime sleepiness (Becker, 2020; Cortese et al., 2009; Craig et al., 2017; Vigliano et al., 2016), and research indicates that daytime sleepiness may be linked to increased inattentive symptoms at both home and school (Craig et al., 2017). Objective sleep studies, however, have produced inconsistent findings, depending on the outcome measure (Cortese et al., 2009; Kirov & Brand, 2014). Studies utilizing PSG and actigraphy have found that youth with ADHD experience more fragmented and less effective sleep, more difficulties

falling and staying asleep, circadian rhythm abnormalities, and more variable sleep timing than controls (Becker, 2020; Cortese et al., 2009; Craig et al., 2017; Vigliano et al., 2016).

Additionally, periodic limb movements during sleep may be linked to hyperactivity symptoms at home and school (Craig et al., 2017). Combining these findings, it appears that children and adolescents with ADHD are at a specific risk for experiencing more sleep disruptions, lowered daytime alertness, worsened sleep efficiency (or the ease of falling asleep), and report overall worse sleep quality. Difficulties with sleep impact overall functioning for children with ADHD, leading to poorer family functioning and lowered quality of life, even after controlling for symptom severity (Craig et al., 2017; Sung et al., 2008).

The overlap between ADHD symptomatology and poor sleep. It is important to note that the relationship between sleep and ADHD is bi-directional, similar to that of ADHD and anxiety. Not only is ADHD associated with poor sleep outcomes across a variety of domains, but sleep problems can also mimic ADHD symptomatology. For example, chronically poor sleep elicits ADHD-like behaviors in a sample of children with pediatric sleep insomnia (Urbano et al., 2021). Additionally, in some cases, children with narcoleptic and other sleep disorders have been misdiagnosed as ADHD (Dahl, 1996). In addition to imitating ADHD symptoms, difficulties with sleep can also exacerbate ADHD behaviors (Dahl, 1996; Hiscock et al., 2007; Kirov & Brand, 2014; Langberg et al., 2013). For instance, inadequate sleep can aggravate symptoms such as hyperactivity, impulsivity, and poor inhibition (Dahl et al., 1991), and improving sleep outcomes may have a clinically significant effect on ADHD. Therefore, it is important to clearly understand the relationship between sleep and ADHD, as related to core symptomatology.

Inattention and Distractibility. Many studies have supported the idea that inadequate sleep, whether too short in duration or frequently disrupted, can negatively alter attention in

children with ADHD (Anderson et al., 2009; Casavi et al., 2022; Dahl, 1996; Schumacher et al., 2017). Additionally, lowered sleep quality and higher rates of daytime sleepiness are associated with more severe inattention, difficulty concentrating and increased distractibility (Araújo & Almondes, 2014; Epstein et al., 1998; Horne, 1993; O'Brien, 2009; Owens, 2005; Sadeh et al., 2002).

Hyperactivity & Impulsivity. Shortened sleep duration and sleep problems have been associated with increased hyperactivity and impulsivity from preschool to adolescence (Cassoff et al., 2012; Schumacher et al., 2017).

Inhibition. Finally, inadequate sleep in children has been associated with worsened inhibition, impulsivity, and poorer executive control (Dahl et al., 1991). Specifically, it appears that performance on tasks which are complex and socially/affectively salient, such as inhibition and interference control, may be the most sensitive to sleep problems (Sagaspe et al., 2006). Sleep may also moderate the relationship between maladaptive versus adaptive self-regulation strategy use across different levels of response inhibition (Schumacher et al., 2017).

Brain and nervous system alterations associated with ADHD and sleep problems. A growing body of research suggests a potential shared biological link between ADHD and sleep problems (Craig et al., 2017). Specifically, the systems regulating sleep, arousal, affect, and attention share overlapping neuroanatomical and physiological substrates, many of which are integrated within the PFC (Dahl, 1996). For example, sleep deprivation disrupts functional connectivity between the medial PFC and the amygdala during emotionally salient tasks, reducing inhibitory control (Yoo et al., 2007). Therefore, disruptions in these networks, particularly those involving the PFC, may underlie the interplay between sleep disturbances and ADHD symptoms (Dahl et al., 1991; Horne, 1993; Telzer et al., 2013). Excitingly, it appears that

some of the neuropsychological anomalies may be reversed following sleep restoration (Horne, 1993). Finally, sleep also seems to have a significant impact on autonomic nervous system functioning, such that adults with better sleep quality scores on the PSQI had higher HRV and high frequency power, indicating a bettered ability to vagally modulate heart rate and flexibility adapt to stress (Dahl, 1996; Kim & Kang, 2017; Shaffer & Ginsberg, 2017). Therefore, by supporting better autonomic and PFC functioning through modulating sleep quality, researchers may be able to provide ameliorative benefits for youth with ADHD.

Treatment of sleep disturbances in ADHD

Given the complex bidirectional relationship between ADHD and sleep problems, sleep disturbances represent a critical consideration for diagnosis and treatment of symptoms. Poor quality sleep can mimic symptomatology, leading to misdiagnosis, and can exacerbate existing symptoms, interfering with daily functioning and treatment efficacy (Kirov & Brand, 2014; Owens, 2005). Although stimulant medications are widely prescribed for ADHD difficulties, they are also associated with significant sleep disturbances. In one study by Craig et al. (2017), it was found that while children on higher doses of medication exhibited less school-based ADHD symptoms, they also had the highest rates of parent-reported sleep problems (Craig et al., 2017). Behavioral and pharmacological interventions targeting both ADHD and sleep are essential for effective management, with research highlighting the need for integrated approaches that consider sleep hygiene alongside ADHD symptomatology (Craig et al., 2017; Kirov & Brand, 2014).

The Relationship Between ADHD, Sleep and Anxiety

The relationship between ADHD, sleep, and anxiety is complex and multidirectional. Youth with ADHD are at an increased risk of experiencing excessive anxiety and more sleep

problems than their typically developing peers (Koyuncu et al., 2022; O'Brien, 2009; Tannock, 2000). Additionally, both poor sleep and anxiety can exacerbate ADHD symptomatology, and may even mimic symptoms in non-ADHD youth. As if this was not complex enough, research also has found interactions between sleep and anxiety in samples with ADHD. For instance, anxiety can negatively impact sleep quality and increase sleep disturbances daytime fatigue in children with ADHD (González-Castro et al., 2015; Tannock, 2000). Conversely, poor sleep may also aggravate feelings of anxiety. For example, better sleep quality has been associated with lower levels of trait anxiety (Kim & Kang, 2017), and sleep-deprived adults reported higher rates of anxiety on the State Trait Anxiety Inventory (Sagaspe et al., 2006). Despite treatment, many children and adolescents with ADHD continue to experience both persistent and new anxiety and sleep problems (Hvolby, 2015; Koyuncu et al., 2022; Owens, 2005; Stein et al., 2012; Tannock, 2000). Additional researchers have highlighted the importance of including measures of anxiety, arousal regulation, and sleep when exploring dysregulated attention (Craig et al., 2017; Dahl, 1996; Tannock, 2000). In combination with the aforementioned negative effects of anxiety and sleep problems, it is clear that research should explore adjunctive treatments which can target these behaviors.

Vibrational Therapy

Vibrational therapy represents a relatively inexpensive and accessible therapeutic addition which may improve ADHD symptoms, anxiety, and sleep disturbances across diverse populations (den Heijer et al., 2015; Fuermaier, Tucha, Koerts, van Heuvelen, et al., 2014; Park et al., 2023, 2023; Uher et al., 2018). Historically, vibrational therapy has roots dating back to the late nineteenth century, when French neurologist Jean-Martin Charcot developed a vibrating chair for patients with Parkinson's disease, which failed to impact tremor symptoms but did

alleviate sleep problems (Camargo et al., 2023; Uher et al., 2018). Current applications of vibrational therapy encompass a range of approaches, including administering vibration to the hand or upper body, soles of the feet, or the entire body (Uher et al., 2018). *Whole body vibration* (WBV) requires a patient to perform a dynamic movement or hold a static position, while *passive vibration* (PV) applies a vibrational stimulus to the body without necessitating voluntary muscle control (Wong & Figueroa, 2019). It has been explored as an alternative to traditional exercise in individuals with depression and metabolic disorders (Simon et al., 2024; Uher et al., 2018), as well as a potential rehabilitation tool for neurological disorders (Moggio et al., 2022). Other therapies analogous to vibrational therapy, such as vibroacoustic and vestibular stimulation therapies, have also shown promising effects in enhancing attention, cognition, and self-regulation across various populations (Bartel & Mosabbir, 2021; Bartel et al., 2017; Clark et al., 2008; Moore et al., 2025). Below is a review of the effects of vibrational therapies on ADHD, anxiety, and sleep in the current literature.

Vibrational Therapy Interventions for ADHD

ADHD is associated with poor balance and postural coordination, potentially mediated by vestibular contributions to the autonomic nervous system (Clark et al., 2008; Grabherr et al., 2015), and so early research on vibration-analogous treatments involved a variety of vestibular stimulation techniques. Although some studies have found a beneficial effect of vestibular, or inner ear, stimulation on attentional difficulties, Clark et al. (2008) failed to replicate these findings and urged researchers to include credible controls when exploring vestibular therapies. More recently, researchers have begun to explore WBV effects on ADHD symptoms. In a series of 2014 studies, a 2-minute session of WBV was shown to elicit acute improvements in inhibitory control and attention in adults, irrespective of ADHD diagnosis (Fuermaier, Tucha,

Koerts, van Heuvelen, et al., 2014; Regterschot et al., 2014). In a case study conducted by the same authors, a WBV intervention applied over 10 consecutive days, with three 15-minute sessions per day, improved cognitive functioning across various domains in a 25-year old patient with ADHD (Fuermaier, Tucha, Koerts, van den Bos, et al., 2014). However, these effects were not observed two weeks after the intervention ended, suggesting transient benefits. Regarding acute bouts of vibrational therapy, den Heijer et al. (2015) found that repetitive applications of 3-minute WBV treatments demonstrated the most substantial improvements in inhibition in healthy children. To date, no research has assessed the effects of passive vibrational therapy on ADHD symptoms in youth.

Vibrational Therapy and Anxiety

Evidence also suggests that WBV may be effective in reducing anxiety symptoms. For example, exercising on a WBV platform twice weekly for four weeks significantly reduced anxiety levels among healthy college students compared to exercise alone (Chawla et al., 2022). Among socially anxious adults, vibrational therapy applied during a computerized task reduced self-reported anxiety, although it did not influence physiological markers of anxiety (Macdonald, 2023). In pediatric contexts, a vibrational stimulus applied during an injection reduced anxiety, fear, and pain among children (Uzsen et al., 2024). Finally, in animal models, vibrational therapy administered for 10 minutes, five times per week, for five weeks led to decreased anxiety (Oroszi et al., 2022). To date, no study has assessed the effects of passive vibrational therapy on anxiety in youth, with or without ADHD.

Vibrational Therapy and Sleep

Vibrational therapy may also support bettered sleep outcomes in adults and older adults (Lin et al., 2020; Park et al., 2023; Uher et al., 2018). Specifically, WBV therapy delivered twice

weekly for six weeks significantly improved sleep quality and reduced daytime sleepiness in adults with metabolic syndrome ((Figueiredo Azeredo et al., 2019). To date, no study has assessed the effects of passive vibrational therapy on sleep in youth, with or without ADHD.

Proposed Mechanistic Framework and Conclusion

Finally, a proposed mechanistic framework is provided, drawing upon the aforementioned literature. Given the complex and dynamic interplay between ADHD, anxiety, and sleep, researchers should consider targeting overlapping areas of dysfunction rather than addressing these outcomes in isolation. Anxiety and sleep problems both mimic and aggravate ADHD symptomatology, while also negatively influencing each other, further underscoring the need for therapeutic options which address these issues simultaneously. The overlap between ADHD, anxiety, and sleep disturbances may, in part, stem from shared deficits in self-regulation and arousal processes implicated in all three conditions. Dahl (1996) posited that sleep and arousal are closely intertwined yet opposing processes, with arousal being highly sensitive to emotion, vigilance, and attention. The PFC, which plays a critical role in modulating self-regulation, arousal, and goal-directed behavior, is also affected by ADHD, anxiety, sleep disturbances (Bishop, 2009; Castellanos, 2002; Dahl, 1996; Horne, 1993; P. Shaw et al., 2007; Ströhle et al., 2018; Yoo et al., 2007). Moreover, research highlights ANS anomalies in children and adolescents with ADHD, such as sympathetic dominance, that are linked to difficulties in self-regulation (Bellato et al., 2020; Rukmani et al., 2016). Importantly, autonomic dysregulation has also been associated with poor sleep quality and elevated anxiety (Chawla et al., 2022; Park et al., 2023; Sharma et al., 2011). According to the NVIM, interventions that enhance ANS functioning could yield benefits across self-regulation, arousal, and related behavioral outcomes

(Clark et al., 2008; Dahl, 1996; Grabherr et al., 2015; Thayer et al., 2009; Thayer & Lane, 2000; Thayer & Sternberg, 2006).

Vibrational therapy has demonstrated promising effects on ANS regulation across various populations and modalities. Vibro-tactile stimulation applied to the forearm and wrist has been shown to elicit improvements in heart rate variability, which represents more flexible modulation of the ANS (Barralon et al., 2008). WBV training has also been associated with improved autonomic tone, primarily through reductions in sympathetic overactivity and enhancements in sympathovagal balance (Figueroa et al., 2012; Simon et al., 2024; Wong & Figueroa, 2019). Furthermore, a somatosensory musical intervention involving vibro-tactile stimulation significantly improved autonomic balance in adults with depression, further supporting the therapeutic potential of vibrational therapy for modulating the ANS (Wang et al., 2024).

Therefore, it is proposed that vibrational therapy, which has demonstrated positive effects on ANS functioning, may also confer downstream benefits for anxiety and sleep disturbances in youth with ADHD, who experience more autonomic dysfunction.

Unfortunately, the majority of the research investigating the effects of vibrational therapy on anxiety, sleep, and ADHD symptoms has been conducted in adult populations, raising concern for its generalizability to youth. Additionally, the most common delivery method, whole body vibration (WBV), may not be practical or appropriate for children and adolescents. WBV often requires the use of a vibrating plate, which could be disruptive during the school day and may increase sensory overload and distraction in this population. To move the field forward, additional research is needed to investigate more elusive and child-friendly delivery modes, such as wearable vibrational therapy devices. This dissertation represents the first attempt to explore a

wrist- or ankle-based passive vibrational therapy intervention aimed at ameliorating anxiety and sleep problems in children with ADHD.

METHODOLOGY

Participants

Participants were recruited from the mid-Michigan area through a combination of social media posting and email outreach to schools for participant recruitment. The sample used in the current study was drawn from an initial sample of 310 participants which were screened for eligibility. Exclusionary criteria included not having ADHD, falling outside of the 8 to 18 years age range, having started a new ADHD treatment within the past 30 days, presence of comorbid disorders associated with Hydrocephalus, Autism Spectrum Disorder, Schizophrenia, Conduct Disorder, Oppositional Defiant Disorder, active substance use, use of beta blockers, and uncorrected visual impairments. Participants were also excluded if they had previously used the Apollo system. Of the initial sample of 310 participants, 148 participants were determined to be eligible (48% of the screened sample), 67 of which (45% of the eligible sample) chose not to participate in the study; see Figure 1 for CONSORT diagram. Analyses were conducted on a final sample of 81 participants (mean age: 12.2 ± 2.7 years; 29 girls [35.8%]) who were enrolled and randomized into the clinical trial. All experimental protocols were approved by the Michigan State University Institutional Review Board, and all methods were carried out in accordance with those protocols and relevant guidelines and regulations regarding the use of human subjects.

Demographic data is provided in Table 1.

Intervention Procedure

The intervention followed a double-blind, sham-controlled, parallel design Phase 2 clinical trial. Participants were randomly assigned to either the active or sham-controlled group using sequential stratification accounting for biological sex, age and severity of ADHD symptomatology as reported by the parent/guardian. Participants/guardians were told that all

participants would receive an Apollo System device, with half of the devices using the commercial Apollo system vibrational patterns and the other half using a new ultra-low frequency pattern of vibrations (sham-control) in order to determine how the two vibrational patterns differed in their effectiveness. All participants connected their Apollo device to a smartphone or tablet using a specialized, non-commercial application which monitored wear-time and device usage. The application was preset for all participants to provide a scheduled course of vibrational therapy (7am Energy and Wakeup program; 8am, 10am, 1pm Clear and Focused program, 4pm Social and Open program, 6pm Rebuild and Recover program, 8pm Relax and Unwind program, 9pm Sleep and Renew program). However, in order to increase external validity of the intervention, participants and their parents/guardians were able to modify the scheduled programs to alter their timing throughout the day, and to add/remove scheduled programs to best fit their schedule.

Experimental arm. The active experimental group received the commercial Apollo System device. A total of 42 participants (mean age: 12.1 ± 2.6 years, 15 female) were randomized to the experimental arm.

Sham-Control arm. The control experimental group received a sham device that looked and felt like the commercial Apollo device but provided no vibration therapy. This device still connected to the specialized non-commercial application and provided the same feedback as the commercial Apollo System device. This group was told that the device uses a new ultra-low frequency pattern of vibration that most people are unable to perceive in order to reduce the likelihood that they felt the device to be a sham. A total of 39 participants (mean age: 12.2 ± 2.8 years, 14 female) were randomized to the sham-control arm.

Participants were then instructed to use their device at least three times per week during the 8-week intervention period while continuing any existing ADHD treatment as directed by their medical providers. To increase the likelihood of compliance, each week the parents/guardians of the participants were contacted to troubleshoot any issues or answer any questions about the device, and to prompt for greater device wear time if wear time fell below the three times per week goal. Parents/guardians of the participants were also asked to complete a medication/treatment use questionnaire to monitor for any changes in medication/treatment. The protocol of this investigation is registered at ClinicalTrials.gov [number NCT05308706].

Measures

Anxiety

Anxiety was assessed at pretest and posttest using the State-Trait Anxiety Inventory (STAI-T), a well-validated measure of trait anxiety which evaluates an individual's tendency to experience general anxiety across various situations (Spielberger, 2012; Spielberger et al., 1983). The STAI-T consists of 20-items rated on a 4-point Likert scale ranging from “almost never” to “almost always”, with higher scores indicating greater trait anxiety and a score of 40 or above indicating the presence of a clinical anxiety disorder. This measure has been used in both adolescent and adult populations and demonstrates strong psychometric properties, however as children younger than 13 may not be reliable reporters (Dol et al., 2022; Liu et al., 2021; Shain et al., 2020). Parent reported STAI-T scores were used as the primary outcome, with child reported scores assessed as the secondary outcome as the average age of the current sample indicates that participants may not be accurate self-reporters of anxiety.

Sleep

Sleep was measured using the Pittsburgh Sleep Quality Index (PSQI), a widely used assessment of sleep quality over the prior month, which is reliable, valid, and adequate for use in children and adults (Scialpi et al., 2022; Shahid et al., 2011). The PSQI assesses 7 sleep related domains: subjective quality, latency, duration, habitual sleep efficiency, disturbances, use of sleep medication and daytime dysfunction (Buysse et al., 1989). Scores are summated across the different domains, with a total PSQI score of greater than 5 being associated with poor sleep quality. Both self-report and parent-reported PSQI scores were assessed at pretest and posttest. Parent and child total PSQI score were used as the primary outcome variable. Additionally, the SATED sleep scale components (sleep satisfaction, daytime alertness, sleep timing, efficiency, and duration) were calculated for both parents and children and were utilized as a secondary outcome (Buysse, 2014). Sleep satisfaction was assessed as sleep quality overall, with higher scores indicating less satisfactory sleep. Daytime alertness represents a combination of daily enthusiasm to achieve things and difficulties remaining awake, with higher scores indicating less alertness and more dysfunction. Sleep timing is calculated as both the variability and timing of bedtime, with higher scores indicating worse sleep timing. Efficiency represents the ease of falling asleep and the ability to sleep throughout the night without disruption; higher scores indicate more difficulty falling and remaining asleep. Finally, sleep duration was calculated as the difference between actual sleep duration and the recommended average amount of sleep for each participant's age.

Procedure

During the pretest appointment, following completion of the informed consent/assent, participants completed a battery of surveys including the PSQI, and STAI-T. Simultaneously,

parents/guardians completed a similar set of questionnaires regarding participant demographics, as well as the PSQI, and STAI-T for their child. In order to remain blinded to the experimental arms, the devices were labeled “A” and “B”. After completing the surveys, participants were then randomly assigned to receive either device “A” or device “B” using sequential stratification randomization accounting for biological sex, age, and ADHD severity as reported by the parent/guardian at the pretest appointment. Following the eight-week intervention period, the posttest assessments followed the same protocol order as the pretest assessment.

Statistical Analysis

Data analyses were performed blinded to the experimental groups, using devices labeled “A” and “B” rather than the specific experimental arm the device was associated with; device assignment was unblinded following completion of all analyses. Analyses were conducted in R Version 4 (R Core Team, 2019) utilizing a familywise alpha level of $p = 0.05$. Prior to analysis, all outcome variables were assessed for potential outliers using a combination of median absolute deviation and visualization. Identified outliers were replaced with the nearest upper or lower median absolute deviation boundary. Analysis of the outcomes (sleep and anxiety) were then conducted using a 2 (Group: sham-control, Apollo system) \times 2 (Time: pretest, posttest) univariate multi-level model including the random intercept for each participant to determine the effectiveness of using the vibrational therapy devices over an 8-week period. Potential confounders such as ADHD severity and biological sex were examined for inclusion in the multi-level modeling approach as additional random intercepts associated with sleep and anxiety. However, as none of these variables were identified as statistically relevant (i.e., $p < 0.05$) nor did they alter the resultant outcomes, they were excluded from the modeling approach. The multi-level model analyses were performed using the Rmimic (Pontifex, 2020) package which

provides a standardized implementation wrapper and automated post-hoc decompositions utilizing the lme4 (Bates et al., 2015), lmerTest (Kuznetsova et al., 2017), and emmeans (Lenth et al., 2017) packages in R with Kenward-Roger degrees of freedom approximations and Benjamini-Hochberg false discovery rate control = 0.05 for post-hoc decompositions. Cohen's f^2 and d with 95% confidence intervals were computed as standardized measures of effect size, using appropriate variance corrections for within-subject (d_{rm}) comparisons (Lakens, 2013). Regardless of significance, planned post-hoc analyses were performed to examine the interaction of Group \times Time given the nature of this phase 2 clinical trial.

RESULTS

Randomization and Intervention

Analyses confirmed that the randomization approach was successful in mitigating differences in age, socioeconomic status, years of education, and ADHD severity at pretest (p 's ≥ 0.6) between participants who were randomized into receiving the sham comparator device (sham-control group) and participants who were randomized into receiving the Apollo system (experimental group). There were no group level differences in the intervention duration and number of days of device use per week; however, participants in the experimental group recorded fewer hours per day of device use (1.8 ± 1.2 hours) than participants who were randomized into the sham-control group (2.8 ± 2.6 hours); $t(71) = 2.0$, $p = 0.046$, $d_s = 0.48$ [95% CI: 0.01 to 0.94] (see Figure 2).

Anxiety

Parent Perception [primary outcome]

Analysis revealed a significant main effect of Group, with parents reporting higher anxiety scores for children in the experimental group (25.0 ± 9.1) compared to those in the sham-control group (20.7 ± 11.0), $F(1, 78) = 5.0$, $p = 0.028$, $d_s = 0.50$ [95% CI: 0.05 to 0.94]. A significant main effect of Time was also observed, $F(1, 73) = 17.5$, $p < 0.001$, $d_{rm} = 0.40$ [95% CI: 0.20 to 0.59], with STAI-T scores decreasing from pretest (24.6 ± 10.4) to posttest (21.2 ± 9.8). Although there was no significant Group x Time interaction, $F(1, 73) < 0.1$, $p = 0.9$, $f^2 < 0.01$ [95% CI: 0.0 to 0.02], planned post-hoc analyses indicated that the experimental group exhibited similar reductions ($d_{rm} \text{ experimental} - d_{rm} \text{ sham} = 0.1$) in parent perceived anxiety from pretest (26.9 ± 9.1) to posttest (23.0 ± 8.7), $d_{rm} = 0.46$, as observed in the sham-control group (22.1 ± 11.3 to 19.1 ± 10.6 , $d_{rm} = 0.36$) (See Figure 3.a.).

Self-Perception

No interaction was observed for the Group x Time interaction, $F(1, 74) = 0.6, p = 0.46, f^2 = 0.09$ [95% CI: 0.0 to 0.23]. Planned post-hoc analysis of the Group x Time interaction observed similar reduction (d_{rm} experimental - d_{rm} sham = -0.07) in self-reported anxiety over the course of the study for participants in the sham-control group (19.8 ± 8.4 to $17.9 \pm 9.0, d_{rm} = 0.17$), as compared to the participants randomized into the experimental group (21.6 ± 9.1 to $20.7 \pm 9.3, d_{rm} = 0.10$) (See Figure 3.b.).

Overall Sleep Quality

Parent Perception [primary outcome]

Analysis indicated a significant main effect of Group, $F(1, 78) = 5.4, p = 0.023, d_s = 0.52$ [95% CI: 0.07 to 0.96], such that participants in the experimental group were perceived to have worse quality sleep (5.3 ± 2.7) than those in the sham-control group (4.3 ± 2.3). There was also a main effect of Time, $F(1, 73) = 46.8, p < 0.001, d_{rm} = 0.70$ [95% CI: 0.47 to 0.93], with global PSQI scores decreasing from pretest (5.6 ± 2.7) to posttest (4.0 ± 2.1). Although the interaction between Group x Time was nonsignificant, planned post-hoc analyses indicated improvements in sleep quality from pretest to posttest in both groups with the experimental group showing a mildly larger (d_{rm} experimental - d_{rm} sham = 0.3) change (6.3 ± 2.5 to $4.2 \pm 2.4, d_{rm} = 0.84$) compared to the sham-control group (4.9 ± 2.7 to $3.7 \pm 1.7, d_{rm} = 0.54$) (See Figure 4.a.).

Self-Perception [primary outcome]

Similar to parental perceptions of overall sleep quality, there a main effect of Group in which participants in the experimental group (5.1 ± 1.8) reported significantly worse sleep compared to the sham-control participants (4.3 ± 1.7), $F(1, 78) = 6.6, p = 0.012, d_s = 0.57$ [95% CI: 0.12 to 1.01]. There was also a significant effect of Time, $F(1, 76) = 10.6, p = 0.002, d_{rm} =$

0.38 [95% CI: 0.14 to 0.62], with overall sleep quality being worse at pretest (5.1 ± 1.7) than at posttest (4.4 ± 1.8). There was no interaction of Group \times Time, $F(1, 76) = 0.2$, $p = 0.69$, $f^2 = 0.01$ [95% CI: 0.0 to 0.05]. Planned post-hoc analyses revealed that sleep quality improved from pretest to posttest for both groups, with slightly larger reductions (d_{rm} experimental - d_{rm} sham = -0.17) in PSQI score in the sham-control group (4.7 ± 1.7 to 3.9 ± 1.6 , $d_{rm} = 0.48$), compared to those in the experimental group (5.4 ± 1.7 to 4.8 ± 1.9 , $d_{rm} = 0.31$) (See Figure 4.b.).

SATED, Sleep Satisfaction

Parent Perception

Analysis revealed a main effect of Group, $F(1, 78) = 3.8$, $p = 0.05$, $d_s = 0.43$ [95% CI: -0.01 to 0.87], with parents reporting decreased sleep satisfaction for participants in the experimental group (1.1 ± 0.6) compared to those in the sham-control group (0.9 ± 0.6); however, this difference did not remain significant following false discovery rate control (Benjamini-Hochberg critical alpha = 0.042). There was a significant main effect of Time, $F(1, 73) = 12.9$, $p < 0.001$, $d_{rm} = 0.38$ [95% CI: 0.16 to 0.60], such that sleep satisfaction was higher at posttest (0.9 ± 0.6) than pretest (1.1 ± 0.7) for all participants. No interactions were observed for the Group \times Time relationship, $F(1, 73) = 0.2$, $p = 0.65$, $f^2 = 0.01$ [95% CI: 0.0 to 0.06]. Planned post-hoc analysis of the Group \times Time interaction observed a slightly larger increase in sleep satisfaction between pretest (1.2 ± 0.6) and posttest (0.9 ± 0.6) for participants in the experimental group, $d_{rm} = 0.46$ [95% CI: 0.14 to 0.77], as compared to those in the sham-control group (0.9 ± 0.6 to 0.8 ± 0.5 , $d_{rm} = 0.31$, (d_{rm} experimental - d_{rm} sham = 0.15) (See Figure 5.a.).

Self-Perception

There was no main effect of Group, $F(1, 78) = 2.3$, $p = 0.14$, $d_s = 0.34$ [95% CI: -0.10 to 0.77], or Time, $F(1, 76) = 3.2$, $p = 0.078$, $d_{rm} = 0.23$ [95% CI: -0.03 to 0.48], on participants'

self-reported sleep satisfaction, regardless of if they were randomized into the experimental or sham-control group. There was no interaction between Group x Time, $F(1, 76) = 0.1, p = 0.7, f^2 = 0.02$ [95% CI: 0.0 to 0.09]. Post-hoc analysis of the interaction suggested similar slight increases in sleep satisfaction over time for both the experimental group (1.1 ± 0.7 to 1.0 ± 0.7 , $d_{rm} = 0.19$) and those randomized into the sham-control group (0.9 ± 0.6 to 0.8 ± 0.6 , $d_{rm} = 0.26$; $d_{rm} \text{ experimental} - d_{rm} \text{ sham} = -0.07$) (See Figure 5.b.).

SATED, Alertness

Parent Perception

Analysis observed a main effect of time, $F(1, 75) = 29.8, p < 0.001, d_{rm} = 0.74$ [95% CI: 0.45 to 1.03], wherein parents reported greater alertness at posttest (0.7 ± 0.5) than pretest (1.0 ± 0.5). No interaction of Group x Time on perceived daytime alertness was observed, $F(1, 75) = 0.6, p = 0.44, f^2 = 0.02$ [95% CI: 0.0 to 0.08]. Planned post-hoc analyses indicated a slightly reduced ($d_{rm} \text{ experimental} - d_{rm} \text{ sham} = -0.22$) increase in alertness over the course of the study for participants in the experimental group (1.0 ± 0.4 to 0.7 ± 0.4 , $d_{rm} = 0.63$) as compared to those enrolled into the sham-control group (0.9 ± 0.6 to 0.6 ± 0.5 , $d_{rm} = 0.85$) (See Figure 5.c.).

Self-Perception

Analysis revealed a significant interaction between Group x Time, $F(1, 76) = 7.7, p = 0.007, f^2 = 0.66$ [95% CI: 0.32 to 1.24]. Post-hoc breakdown of the Group x Time interaction showed a significant increase in daytime alertness from pretest (0.8 ± 0.4) to posttest (0.6 ± 0.6) in the sham-control group, $t(76) = 2.9, p = 0.005, d_{rm} = 0.53$ [95% CI: 0.16 to 0.90] ($-d_{rm} \text{ experimental} - d_{rm} \text{ sham} = -0.35$). There was no significant difference in daytime alertness from pretest (0.8 ± 0.5) to posttest (0.9 ± 0.5) for those in the experimental group, $t(76) = 1.0, p = 0.3, d_{rm} = 0.18$ [95% CI: -0.17 to 0.53]. Further, analysis observed a statistically significant difference

in perceived alertness between the two groups at posttest, $t(137) = 2.5$, $p = 0.012$, $d_s = 0.59$ [95% CI: 0.13 to 1.04], with the sham-control group reporting greater daytime alertness (0.6 ± 0.6) than those in the experimental group (0.9 ± 0.5) (See Figure 5.d.).

SATED, Sleep Timing

Parent Perception

There was a main effect of Time, $F(1, 73) = 4.2$, $p = 0.044$, $d_{rm} = 0.22$ [95% CI: 0.01 to 0.43], such that sleep timing was reported as being marginally worse at posttest (1.2 ± 0.6) compared to pretest (1.0 ± 0.6); however this difference did not remain significant following false discovery rate control (Benjamini-Hochberg critical $\alpha = 0.020$). There was no interaction of Group \times Time, $F(1, 73) = 3.2$, $p = 0.079$, $f^2 = 0.39$ [95% CI: 0.14 to 0.78] for parent reported sleep timing. Planned post-hoc analyses indicated moderate differences in sleep timing changes across the groups (d_{rm} experimental - d_{rm} sham = -0.53), such that participants in the sham-control group reported worsening of sleep timing (i.e., later and more variable bedtimes) over the course of the study (1.0 ± 0.5 to 1.3 ± 0.6 , $d_{rm} = 0.55$), while sleep timing remained relatively stable in the experimental group (1.0 ± 0.6 to 1.1 ± 0.6 , $d_{rm} = 0.02$) (See Figure 5.e.).

Self-Perception

There was no significant interaction of Group \times Time, $F(1, 76) < 0.1$, $p = 1.0$, $f^2 < 0.01$ [95% CI: 0.0 to 0.01] on self-reported sleep timing. Analysis of the interaction showed stability in self-reported sleep timing from pretest to posttest for both the experimental (1.4 ± 0.9 to 1.4 ± 0.9 , $d_{rm} = 0.08$) and sham-control (1.2 ± 0.8 to 1.2 ± 0.6 , $d_{rm} = 0.12$) groups, (d_{rm} experimental - d_{rm} sham = -0.04) (See Figure 5.f.).

SATED, Sleep Efficiency

Parental Perception

Analysis indicated a main effect of Time, $F(1, 75) = 9.5$, $p = 0.003$, $d_{rm} = 0.43$ [95% CI: 0.15 to 0.71], such that parents reported greater sleep efficiency at posttest (0.9 ± 0.7) compared to pretest (1.2 ± 0.7) for all participants, regardless of group. There was no interaction of Group \times Time, $F(1, 75) = 2.1$, $p = 0.15$, $f^2 = 0.17$ [95% CI: 0.01 to 0.39], on parent perceived sleep efficiency. Planned post-hoc analysis observed moderately larger increases (d_{rm} experimental - d_{rm} sham = 0.44) in parent-reported sleep efficiency for participants enrolled in the experimental group from pretest (1.2 ± 0.7) to posttest (0.8 ± 0.8), $d_{rm} = 0.65$, as compared to those in the sham-control group (1.1 ± 0.7 to 0.9 ± 0.5 , $d_{rm} = 0.21$) (See Figure 5.g.).

Self-Perception

There was a main effect of Group, $F(1, 78) = 4.1$, $p = 0.046$, $d_s = 0.45$ [95% CI: 0.01 to 0.89], on self-reported sleep efficiency, such that participants in the experimental group reported worse efficiency (1.5 ± 0.8) than those in the sham-control group (1.2 ± 0.7). However, this difference did not remain significant following false discovery rate control (Benjamini-Hochberg critical alpha = 0.017). Similarly, there was also a main effect of Time, $F(1, 76) = 4.3$, $p = 0.041$, $d_{rm} = 0.25$ [95% CI: 0.01 to 0.48], wherein participants reported better efficiency at posttest (1.3 ± 0.6) than pretest (1.5 ± 0.8); however, this did not remain significant following false discovery rate control (Benjamini-Hochberg critical alpha = 0.008). No interaction was observed for Group \times Time, $F(1, 76) = 0.3$, $p = 0.58$, $f^2 = 0.03$ [95% CI: 0.0 to 0.11]. Planned post-hoc analyses showed similar, slight improvements in self-reported sleep efficiency for participants randomized into the experimental group (1.6 ± 0.8 to 1.4 ± 0.7 , $d_{rm} = 0.17$) as compared to those

in the sham-control group (1.3 ± 0.8 to 1.1 ± 0.6 , $d_{rm} = 0.34$, $d_{rm} \text{ experimental} - d_{rm} \text{ sham} = -0.17$) (See Figure 5.h.).

SATED, Sleep Duration

Parent Perception

Analyses observed a significant main effect of Time, $F(1, 73) = 8.8$, $p = 0.004$, $d_{rm} = 0.26$ [95% CI: 0.08 to 0.44], with parents reporting sleep durations closer to age-based recommendations at posttest (-0.9 ± 1.4 hours from recommendation) as compared to pretest (-1.3 ± 1.4 hours from recommendation). There was also a main effect of Group, $F(1, 78) = 7.5$, $p = 0.008$, $d_s = 0.61$ [95% CI: 0.16 to 1.05], with parents reporting less sleep for children randomized into the experimental group (-1.4 ± 1.1 hours from recommendation) compared to those in the sham-control group (-0.7 ± 1.6 hours from recommendation), although both groups achieved less sleep than recommended. There was no interaction of Group \times Time, $F(1, 73) < 0.1$, $p = 0.9$, $f^2 < 0.01$ [95% CI: 0.0 to 0.01]. Planned post-hoc analysis indicated that parents reported slightly longer sleep, closer to recommended durations, following the intervention for both the experimental (-1.6 ± 1.2 to -1.2 ± 0.9 hours from recommendation, $d_{rm} = 0.28$) and sham-control (-0.9 ± 1.5 to -0.5 ± 1.7 hours from recommendation, $d_{rm} = 0.27$) groups, ($d_{rm} \text{ experimental} - d_{rm} \text{ sham} = 0.01$) (See Figure 5.i.).

Self-Perception

For self-reported sleep duration, there was a main effect of Group, $F(1, 78) = 5.6$, $p = 0.021$, $d_s = 0.52$ [95% CI: 0.08 to 0.97], such that children randomized into the sham-control group reported achieving more sleep (-0.1 ± 1.6 hours from recommendation), compared to those in the experimental group (-0.7 ± 1.3 hours from recommendation). However, that difference did not remain significant following false discovery rate control (Benjamini-Hochberg critical alpha

= 0.010). There was no interaction of Group \times Time, $F(1, 76) = 0.4$, $p = 0.54$, $f^2 = 0.06$ [95% CI: 0.0 to 0.17]. Post-hoc analysis of the interaction indicated minimal differences in reported sleep duration over the study for participants in the experimental (-0.8 ± 1.3 to -0.6 ± 1.3 hours from recommendation, $d_{rm} = 0.14$) and sham-control (-0.1 ± 1.5 to -0.1 ± 1.6 hours from recommendation, $d_{rm} = 0.03$) groups (d_{rm} experimental - d_{rm} sham = 0.11) (See Figure 5.j.).

DISCUSSION

The current study evaluated the potential benefits of a wrist/ankle-based vibrational therapy on anxiety and sleep outcomes in children and adolescents with ADHD. The findings suggest that using the Apollo device approximately 4 days per week, 2 hours per day, over an 8 week period did not yield meaningful improvements. Although parent-reported anxiety scores decreased over time, similar reductions were observed in both the experimental and sham-control groups, indicating that the change was likely unrelated to the intervention. A comparable pattern emerged in overall sleep quality, with both parent and child reports showing slight improvements regardless of group assignment. A strength of the present approach was in utilizing a sham control group which provides some ability to characterize these changes in outcome measures as potential placebo effects or effects of device usage not specific to vibrational therapy — such as an increased awareness of monitoring behaviors and conscientiousness of device use. Comparison of effect sizes between the experimental and sham control group therefore suggests that the unique effect of vibrational therapy using the Apollo device with this protocol provided negligible effects ($|d| \leq 0.1$) for anxiety. While both groups did improve perceptions of overall sleep quality, the unique impact of vibrational therapy using the Apollo device was observed to provide small effects for both parent ($d = 0.3$) and self ($d = 0.17$) perceptions of sleep quality. Thus, while the effect was not observed to be statistically significant in the current investigation, power-analyses based upon a conservative t-test approach suggest that a larger intervention utilizing samples of at least 176 participants per group (352 total) and 545 participants per group (1090 total) would be necessary to detect a statistical difference between groups for parent and self-perceptions of sleep quality, respectively. However, as the unique effects are considered

small, it is unclear to what extent usage of this vibrational therapy protocol delivered using the Apollo device would result in clinically meaningful alterations in perceptions of sleep quality.

Beyond focusing only upon overall sleep quality, the present investigation conducted exploratory analyses on the SATED sleep scale components (sleep satisfaction, daytime alertness, sleep timing, efficiency, and duration) to provide further insight into the potential effects of vibrational therapy using the Apollo device. Similar to the primary outcomes of interest, scores on SATED domains were observed to improve over time across both groups, suggesting that these improvements were not attributable to vibrational therapy. Specifically, the unique effect of vibrational therapy using the Apollo device with this protocol provided negligible benefits for sleep satisfaction and the duration of sleep ($|d| \leq 0.15$). Parents did, however, generally perceive there to be unique beneficial effects for daytime alertness ($d = 0.22$) and sleep efficiency ($d = 0.44$; the ease of falling asleep and the ability to sleep throughout the night without disruption) of using the Apollo device. Further, as parents of participants in the sham control group reported that sleep timing (reflecting the variability and timing of bedtime) got worse over the course of the intervention; the lack of changes in parent reported sleep timing for those participants using the Apollo device could be interpreted as reflecting a unique beneficial effect ($d = 0.5$) which may have achieved statistical significance with a larger sample size of at least 64 participants per group (128 total). In contrast, however, participants appear to have perceived vibrational therapy using the Apollo device to negatively impact their daytime alertness ($d = -0.35$; which was observed to be statistically significant) and sleep efficiency ($d = -0.17$), with neither group perceiving changes in sleep timing. Given the inconsistency of these findings — as well as their relatively small magnitude — caution is warranted in not over-interpreting the potential clinical utility of vibrational therapy delivered using the Apollo device

in this population for promoting better sleep. Given the inconsistent findings between parent and participants, future investigations in this area may benefit from more objective assessment of sleep stages which might provide insight into the duration, efficiency, and timing aspects of sleep to a greater degree than parent or self-reported measures. Collectively, these results suggest that the intervention, as implemented, was insufficient to meaningfully impact anxiety or sleep-related outcomes in this sample as the observed improvements appear to reflect broader time-related changes rather than effects specific to the intervention.

Contrary to expectations based on prior research (Chawla et al., 2022; Oroszi et al., 2022; Park et al., 2023; Uzsén et al., 2024; X. Wang et al., 2024), the present study did not replicate improvements in anxiety and sleep following vibrational therapy. While previous studies — primarily utilizing whole-body vibration — have demonstrated benefits while employing shorter intervention periods (ranging from a single session to five weeks) in both human and rodent models weeks (Chawla et al., 2022; Park et al., 2023; Uzsén et al., 2024; X. Wang et al., 2024), the inability to replicate these findings may be indicative of insufficient implementation. It is possible that the vibrational dose delivered in this study was insufficient, the vibrational protocol poorly attuned to this population, or that applying the vibration to the wrist and ankle was too peripheral to meaningfully influence autonomic balance in children with ADHD, thereby failing to impact autonomically-regulated behaviors such as sleep and anxiety. Further research is thus necessary to specifically investigate the extent to which autonomic tone — reflecting the balance and modulation of activity between sympathetic nervous system and parasympathetic nervous system inputs — is even altered by vibrational therapy using the Apollo device in this population. As prior work has demonstrated that those with ADHD are more likely to show a dominance of the sympathetic nervous system (Bellato et al. 2020; Rukmani et al., 2016),

speculatively it may be that the impact of vibrational therapy using the Apollo device with the current dose and protocol is insufficient to override this dominance. Nevertheless, the present study represents the first attempt to assess the efficacy of vibrational therapy for improving sleep quality and reducing anxiety in children and adolescents with ADHD. It expands upon previous work exploring non-invasive, non-pharmaceutical interventions for youth with ADHD. However, the null findings suggest either a more intensive vibrational stimulus, or an alternative application methodology may be necessary to achieve therapeutic effects in this sample.

Limitations and Future Directions

Although the present findings do not align with the neurovisceral integration model, which suggests that modulating autonomic balance (via vibrational therapy in the current study) should enhance self-regulation (Thayer & Lane, 2000) and reduce anxiety (Friedman, 2007; Park et al., 2023; Trinder et al., 2001), they also fail to replicate previous research indicating that shifts in autonomic tone can improve sleep quality (Park et al., 2023; Trinder et al., 2001). Given that sleep is closely tied to ANS flexibility, it stands to reason that improved autonomic balance should support adaptive functioning during sleep, and in turn, should promote better sleep outcomes (Amelia et al., 2025; Cabiddu et al., 2012; Trinder et al., 2001). However, a key limitation of the current study is that autonomic tone was not directly assessed. Instead, a commercially available vibrational device was used to deliver an externally valid and easily implemented vibrational intervention. Therefore, it remains unclear whether the null findings reflect an ineffective intervention for the current sample, an insufficiently potent or targeted vibrational stimulus, or inadequate usage. For instance, vibro-tactile stimulation applied to the forearm has been shown to elicit greater improvements in heart rate variability (HRV) than stimulation at the wrist, suggesting that site-specific delivery can enhance autonomic benefits

(Barralon et al., 2008). Future research should continue to explore how varying doses and applications of vibrational therapy influence sleep and anxiety outcomes in youth with ADHD.

A second potential limitation of the current study concerns the treatment status of the sample, in that a majority of children were actively prescribed medication (67.9% stimulant; 19.7% non-stimulant) or enrolled in cognitive behavioral therapy (18.5%) during the study period. While this allowed for the evaluation of the Apollo system's adjunctive effects and enhanced external validity of the study, there is a possibility that participants current treatment approaches may have diminished the effectiveness of vibrational therapy delivered using the Apollo device. While it is important to acknowledge this as a possibility, some caution for such an interpretation is warranted given that neither pharmacologic or nonpharmacologic treatment approaches were observed to be statistically relevant for the analytic model for inclusion as random interceptions or as potential interactive factors for the Group \times Time interaction. Thus, while possible, this limitation reflects an unlikely impediment to interpreting the observed findings.

A more prominent limitation is that the current sample may ultimately reflect a subpopulation of children with ADHD who are generally treatment resistant. Indeed, despite engaging in active treatment participants continued to demonstrate persistent ADHD related symptomatology, a pattern consistent with findings from previous research (Adler & Nierenberg, 2010; Antshel et al., 2012; Charach et al., 2004). As such, vibrational therapy effects may be more detectable in populations who are more responsive to conventional interventions. Future research is necessary to explore the efficacy of vibrational therapy within the broader context of ADHD treatment approaches, including its potential synergies or comparatively to traditional therapeutic strategies.

Conclusion

This study provides a novel exploration into the feasibility of using a commercial vibrational therapy tool to target anxiety and sleep outcomes in a sample of children and adolescents with ADHD. Although the present findings indicated that the Apollo system, as employed in the current study, was insufficient for ameliorating feelings of anxiety and improving sleep in youth with ADHD, it is important that future research elucidates the reasoning behind this null finding. Continued investigation is necessary to examine the effects of varying dosages and methods of application of vibrational therapy, in order to determine its potential utility in enhancing outcomes for individuals with ADHD. Additionally, further research should explore how youth with ADHD respond to traditional versus novel treatment approaches, as it is possible that this sample was treatment-resistant, contributing to the lack of significant and clinically meaningful effects observed. Overall, this study was the first randomized, sham-controlled trial assessing the efficacy of vibrational therapy for children and adolescents with ADHD. By laying the groundwork for future investigation, this study contributes to the growing body of research which aims to identify innovative and accessible adjunctive treatment options to support the functioning and wellbeing of youth with ADHD.

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APPENDIX A: TABLES

Table 1. Participants demographic characteristics (mean \pm SD).

Measure	Sham comparator	Apollo System	<i>t</i>	<i>p</i>	cohens <i>d_s</i> [95% CI]
N	39 (14 females)	42 (15 females)			
Race	12.8% nonwhite	19% nonwhite			
American Indian or Alaska Native	0	0			
Asian	0	1			
Black or African American	0	2			
Native Hawaiian or other Pacific Islander	0	0			
Hispanic or Latinx	2	0			
White or Caucasian	34	34			
Multiracial	3	5			
ADHD Presentation					
Combined	29	39			
Predominately Inattentive	7	1			
Predominately Hyperactive/Impulsive	3	2			
ADHD Treatment					
Stimulant Medication	25	30			
Nonstimulant Medication	7	9			
Cognitive Behavioral Therapy	9	6			
Age (years)	12.2 \pm 2.8	12.1 \pm 2.6	0.2	0.8	0.05 [95% CI: -0.39 to 0.48]
Socioeconomic Status (0 [worst off] to 100)	65.9 \pm 11.3	64.4 \pm 12.4	0.5	0.6	0.13 [95% CI: -0.36 to 0.61]
Education (years)	7.0 \pm 2.9	6.0 \pm 2.7	0.2	0.8	0.04 [95% CI: -0.39 to 0.48]
Intervention Duration (days)	70.4 \pm 10.4	66.5 \pm 6.8	1.9	0.06	0.44 [95% CI: -0.02 to 0.90]
Device Use (days per week)	3.7 \pm 1.9	3.5 \pm 1.8	0.6	0.5	0.15 [95% CI: -0.31 to 0.61]
Device Use (hours per day)	2.8 \pm 2.6	1.8 \pm 1.2	2.0	0.05*	0.48 [95% CI: 0.01 to 0.94]

Table 1 (cont'd).

Measure	Sham comparator	Apollo System	<i>t</i>	<i>p</i>	cohens <i>d_s</i> [95% CI]
Clear and Focused Program Use (days per week)	3.2 ± 1.7	2.6 ± 1.5	1.7	0.1	0.39 [95% CI: -0.07 to 0.85]
Clear and Focused Program Use (hours per day)	1.1 ± 0.8	0.8 ± 0.7	1.8	0.08	0.41 [95% CI: -0.05 to 0.88]

* $p < 0.05$

APPENDIX B: FIGURES

Figure 1. CONSORT diagram showing enrollment and retention of participants throughout the study.

i) CONSORT Flowchart

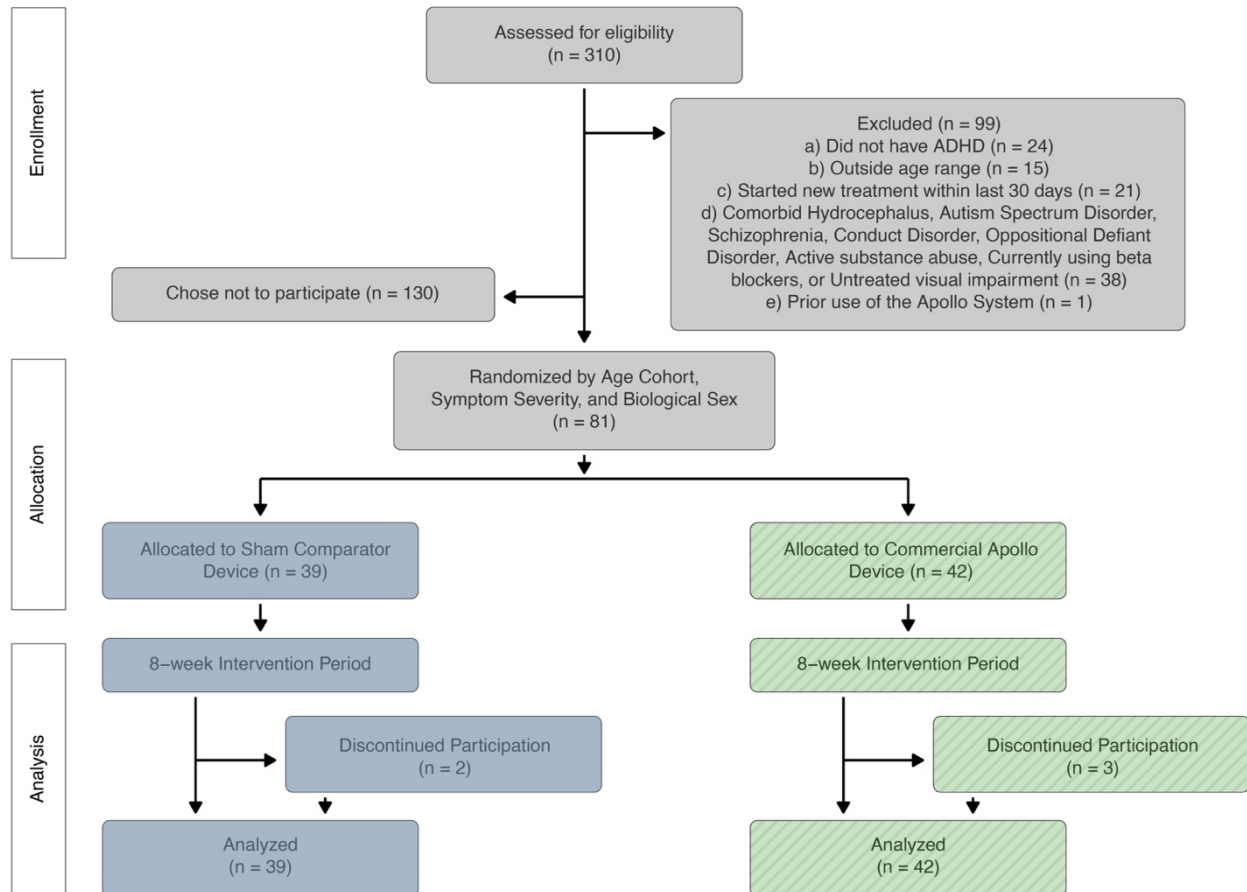


Figure 2. Mean (\pm SE) number of days of device use each week (a) and hours of device usage each day (b) by group allocation.

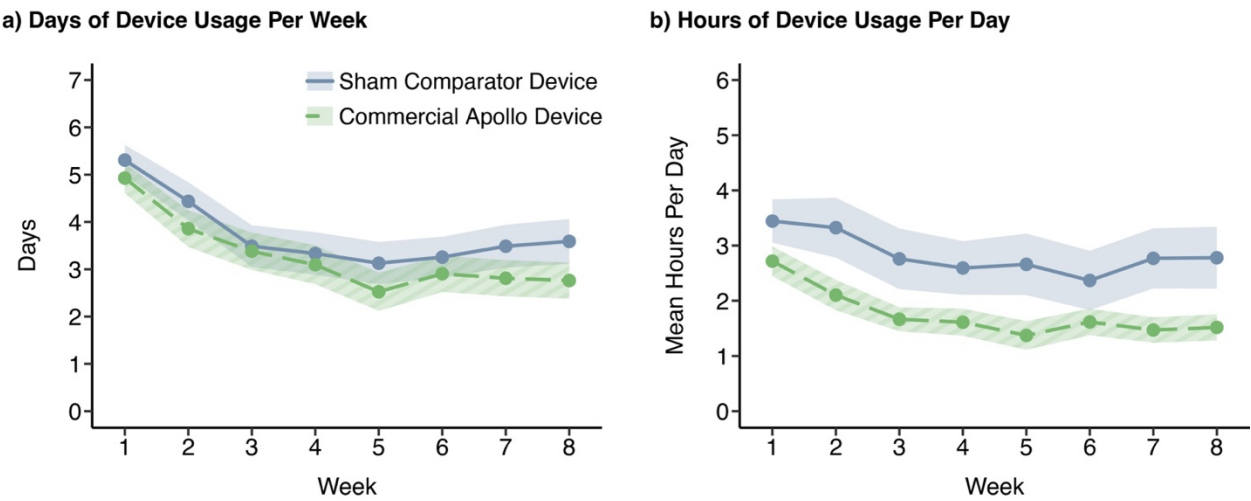


Figure 3. Mean (\pm SE) parent and child-reported trait anxiety scores by group allocation.

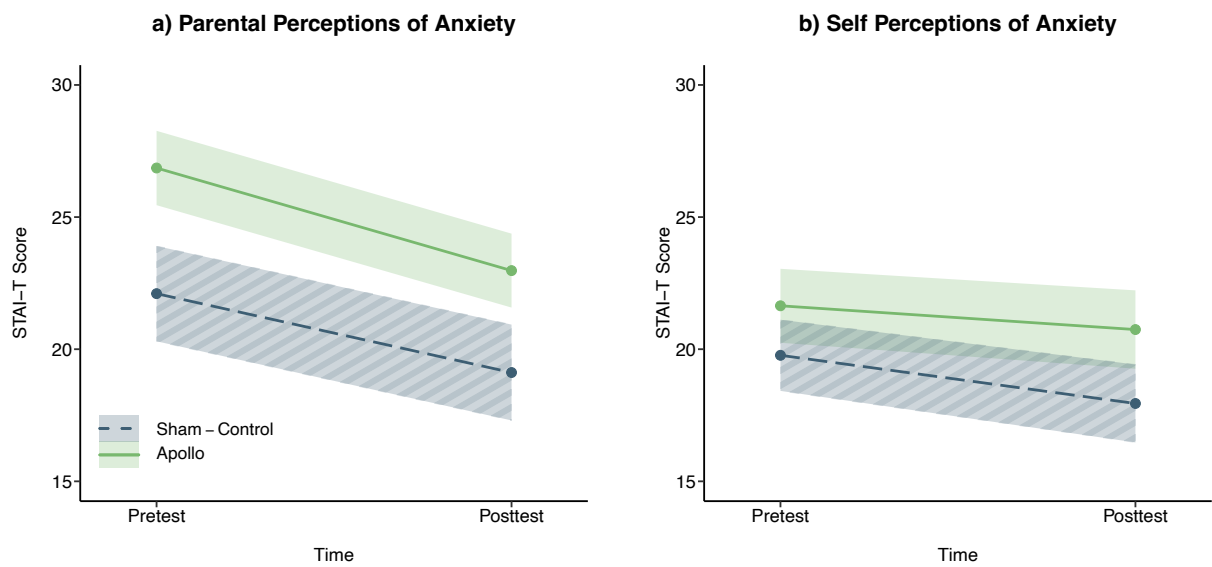


Figure 4. Mean (\pm SE) parent and child-reported global sleep quality by group allocation. Red, dashed lines indicate a PSQI global score of 5, above which is considered indicative of significant sleep disturbances.

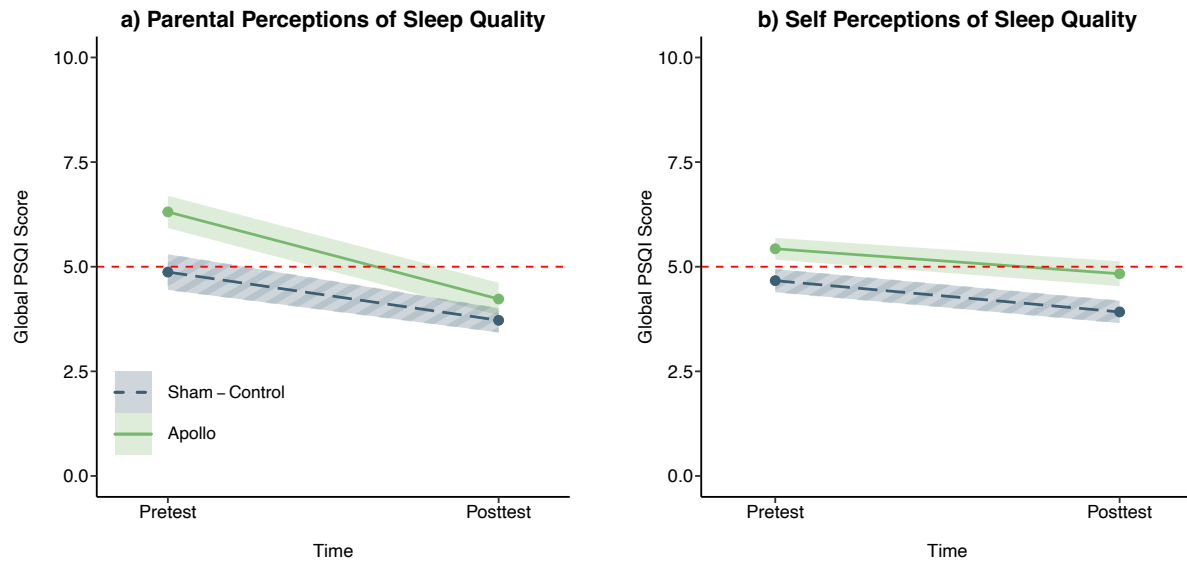


Figure 5. Mean (\pm SE) parent and child-reported scores for all SATED sleep dimensions by group allocation. All SATED outcome variables are reverse scored, with scores closer to 0 indicating better sleep outcomes. Specifically, lower scores indicated increased sleep satisfaction (a, b), more alertness throughout the day (c, d), less variable and earlier bedtimes (e, f), shorter sleep onset (g, h), and sleep durations closer to age-specific recommendations (i, j).

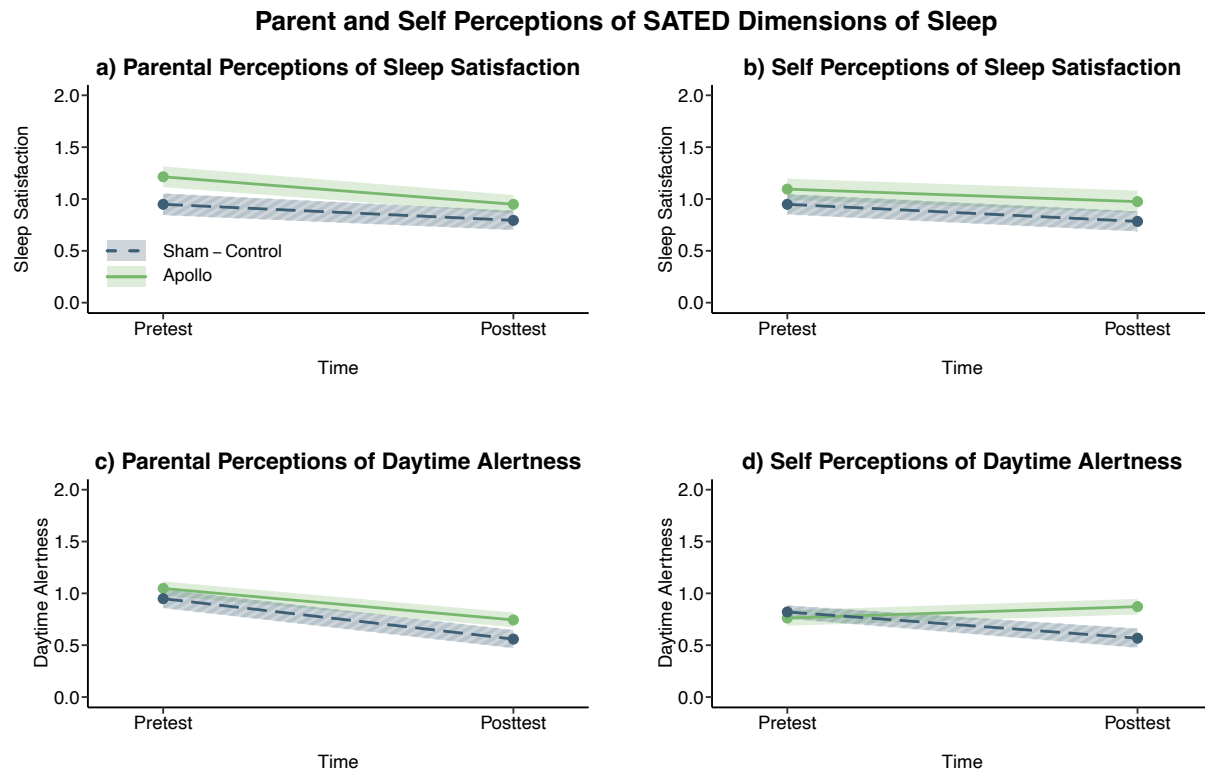


Figure 5 (cont'd).

