Effects of cyclical deep pressure applied by the FLOWpresso on sleep and anxiety.

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Abstract

Sleep is a fundamental primitive state of human beings and a daily basic need as we spend nearly one third of our lives asleep. Neuroimaging tracing the electrical circuitry of the brain shows sleep is not passive, or a mere state of rest and disconnection for the brain, but rather a complex and heterogenous state of neuronal activity, potentially aiding in brain functions such as neuroplasticity, immunity, memory consolidation and emotional processing. The decimation of sleep throughout most nations due to today's 24-hour society is an endemic in modern society. Large fractions of the global population are under slept, with one third of adults having sleep durations substantially below the recommended 7 to 9 hours sleep each night.

Sleep disturbances may be initiated by the demands of life stressors originating within an individual or in the context of the environment in which they live. Regardless of origin, poor sleep can become a potent life stressor, it is a major stress on the neuro-hormonal system of the body. The role of sleep is a vital process for affective brain regulation and recalibrating limbic cortical regions, with its potential palliative influence on anxiety and other emotional disorders. Insufficient sleep is pervasive and holds ecological relevance, with under-slept individuals having higher observations of over-anxious and mental distress presentations.

Though there is limited literature evaluating deep pressure therapy, recent studies show its benefits in reducing agitation and calming the body. This study reports on the use of a novel pneumatic compression device called the FLOWpresso that applies cyclical deep pressure squeezes to small regions of the body, from distal to proximal, in a rhythmic sequence, like a hug. The experimental chapter presents the effects of the FLOWpresso on sleep and

anxiety in two studies (Study A and B), with a large sample of adult first responders who are under daily psychological and sleep stress. Sleep and anxiety were investigated through validated self-reported questionnaires: the Patient Reported Outcomes Measurement Information System (PROMIS) sleep disturbance short form, and the Metagenics mood and stress form. All participants received three forty-minute FLOWpresso sessions over a 3-week period, with one session a week. Data was collected at two time-points: prior to first FLOWpresso session (Day 1), and 1 week after the third FLOWpresso session (Day 21). Pre and post scores were analysed using a two-paired samples t-test and the magnitude of difference of means was evaluated with Cohen's *d* effect sizes.

Results demonstrated that the FLOWpresso is an effective treatment for decreasing perceived sleep disturbance and reducing anxiety symptomology. In Study A, the *p*-values for the changes in sleep, anxiety, and stress scores were all considered significant (all $p < 0.002$). These changes were associated with a *large* effect size for sleep ($d = 1.15 \pm 0.32$), and *moderate* effect sizes for stress ($d = 0.57 \pm 0.30$) and anxiety ($d = 0.53 \pm 0.30$). In Study B, the *p*-values for sleep, anxiety, and stress scores considered significant (all $p < 0.001$). The size of the positive benefit attained over the three-week intervention were categorised as *large* ($d = 1.05 \pm 0.31$) for sleep and *moderate* for stress ($d = 0.71 \pm 0.30$) and anxiety ($d = 0.56 \pm 0.30$).

The positive effects observed in this cohort of first responders, demonstrates that one 40-minute FLOWpresso treatment per week for three weeks was capable of improving self-reported measures of sleep, anxiety, and stress. While it is acknowledged that there was no control group, the magnitude of the effects warrants further investigation in this cohort that is exposed to high levels of vocational stress. The results are noteworthy given the short duration (3-weeks) of the intervention and the frequency of the treatment exposure (one session per week). The health burden of poor sleep contributes to global concerns regarding stress and, anxiety. The FLOWpresso device may represent an important countermeasure with the potential to have a positive impact on health and mental well-being.

Table of Contents

List of Tables

List of Figures

Abbreviations

AASM – American Academy of Sleep Medicine
ACC – Anterior Cingulate Cortex
ACTH – Adrenocorticotrophic Hormone
ADAA – Anxiety and Depression Association of America
ANS – Autonomic Nervous System
APA – American Psychological Association
ASQ – Adolescent Stress Questionnaire
B – Unstandardized regression coefficient
BC – Before Christ
CI – Confidence Interval
COVID – Corona Virus Disease
DALY – Daily Adjusted Life Years
DNA – Deoxyribonucleic Acid
EEG – Electroencephalogram
EMG – Electromyogram
EMS – Emergency Medical Services
EPC – External Pneumatic Compression
ES – Effect Size
ESS – Epworth Sleepiness Scale
FIR – Far-Infrared
fMRI – Functional Magnetic Resonance Imaging
GAD-7 – General Anxiety Disorder (7 Item Scale)
GBD – Global Burden of Disease
HAD-A – Hospital Anxiety & Depression Scale – Anxiety
HF – High Frequency
HPA – Hypothalamic-Pituitary-Adrenal
HRV – Heart Rate Variability
Hz – Hertz
IL – Interleukin
IL-10 – Interleukin 10
IPC – Intermittent Pneumatic Compression

ISCD – International Classification of Sleep Disorders

LF – Low Frequency

LF/HF Ratio – Low Frequency/High Frequency Ratio

LSS – Life Stress Scale

M – Mean

MOH – Ministry of Health

NREM – Non rapid eye movement

NSF – National Sleep Foundation

NZ – New Zealand

OR – Odds Ratio

p - Probability

PET – Positron Emission Tomography

PROMIS – Patient Reported Outcomes Measurement Information System

PSG – Polysomnography

PSNS – Parasympathetic Nervous System

PSQI – Pittsburgh Sleep Quality Index

QPS Nordic – General Questionnaire for Psychological and Social Factors at Work

REM – Rapid Eye Movement

RSA – Respiratory Sinus Arrythmia

SAM – Sympathetic-Adrenal-Medullary

SD – Sleep Disturbance

SDI – Socio-Demographic Index

SNS – Sympathetic Nervous System

SOD – Superoxide Dismutase

SRI – Sleep Related Impairment

SRS – Sleep Research Society

STAI – State Trait Anxiety Inventory

T – calculated difference represented in units of standard error

UF – Uncinate Fasciculus

µm – micrometre

USA – United States of America

WB – Weighted Blanket

WHO – World Health Organization

WV – Weighted Vest

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Thesis Overview

The nature of this thesis involves the research into a novel FLOWpresso device that combines distal to proximal deep pressure with far infrared heat. A literature review has been substituted for in theoretical framework encompassing literature that supports the narrative for the clinical application of this device. The theoretical framework precedes an experimental section that is presented in the style format of a journal article; therefore, some information may be repeated.

Displayed as three chapters, Chapter One first introduces the reader to sleep issues, anxiety, and stress, as major components of physical and mental wellbeing. This section then provides supporting literature and possible biological mechanisms that underly a range of tools designed to improve sleep, anxiety and stress, before introducing the FLOWpresso device.

Chapter Two presents the results of two related scientific investigations summarising the effects of the FLOWpresso on sleep, anxiety, and stress. Two studies were undertaken in two separate cohorts with the identical methodology and statistical analysis for this thesis classified as Study A and Study B.

Chapter Three summarises the overall findings and the FLOWpresso's contribution, as well as providing limitations, practical applications, and recommendations for further research.

Chapter One: Literature Review

1.0 Introduction

Humans notice when things are going wrong, but no one notices when things go right. This discourse underlies the fact that approximately 95% of healthcare finances is directed at disease care, and only 5% allocated to health improvement (Bortz., 2005). The access to medical (disease) care is far removed from determining an individual's health status. Affiliated with this economic bias is medical research, committed financially and intellectually to the clarification of disease mechanisms and protocols for symptom relief. As detailed understanding of disease pathology occurs, the causative factors that underlie health remain uncharted, as it is easier to conceptualise a disease state than a healthy state of an individual (Bortz., 2005; Ayres., 2020). The primary method for treating disease is to block or downregulate these pathological responses or to remove the insult all together, rather than inducing, enhancing the pathways that work to maintain health. The traditional definition of health states "in the absence of disease or injury", this giving the impression that removing the source of the disease or injury will essentially restore health, but health is not a passive state nor mutually irreducible.

Health is an active process that is unique to each individual, it enables an organism to adapt to fluctuations, to adjust to the ebbs and flows in its internal and external environments (Ayres et al., 2020). Definitions have defined health as "a state of physical, mental and social wellbeing and not merely the absence of disease or infirmity" (World Health Organisation, 1946). For the experience of human health is in its totality, it involves the interplay amongst environmental, socio-cultural, economic-political, and internal biological contexts. Health is a state of the whole person and understanding the individualised physiology and societal domains can provide construct for redesigns in healthcare (Sturmberg et al., 2019).

The extraordinary plasticity of all parts of the human body exhibits how form follows function, and that the body is constantly trying to create order, stability, and balance in the environment in which it is immersed. As humans we have evolved adaptive mechanisms that promote healthy states of wellbeing, and these mechanisms are generally distinct from which those that drive disease and symptoms. In respects to scientific research rather than continuing to ask, “how can we treat this disease, this symptom?”. We might ask instead “what can be done to enhance, promote and maintain health and homeostasis in this individual?” These are not the same thing (Ayres., 2020). The proposal of good health can be in strengthening health promoting behaviours where self-efficacy at a personal and social level become cohesive. Following on from that perspective, the subsequent narrative reviews sleep, anxiety, and stress, highlighting the conceptual framework of these components as major contributors to health and mental wellbeing.

2.0 Sleep

Sleep is a daily basic need, and we spend nearly one third of our lives asleep. The relevance of understanding how sleep interacts with a range of physiological states to support health and well-being are well established. It is recognised that strategies to enhance sleep have the potential to improve physical and mental health.

2.1 Fundamentals of sleep

Sleep is a fundamental primitive state of human beings, documented as rapidly reversible, recurrent state of reduced (but not absent) perception of external stimulation and interaction with the environment (Cella et al., 2010). Neuroimaging tracing the electrical circuitry of the brain shows sleep is not passive, or a mere state of rest and disconnection for the brain, but rather a complex and heterogenous state of neuronal activity, potentially aiding in brain functions such as neuroplasticity, immunity, memory consolidation, and emotional processing (Dang-Vu et al., 2010). The vital neurobiological states of sleep are regulated by autonomic homeostatic and circadian processes and can be measured along many dimensions (Yu et al., 2011). Sleep assessment is a broad concept that encompasses many parameters such as sleep wake patterns, sleep efficiency, sleep disturbances, sleep rhythms, sleep duration, sleep latency, daytime sleepiness, perceived impact of poor sleep, and specific sleep related problems.

For humans and other mammals, the architecture of sleep is divided into two main states of activity: rapid eye movement (REM) sleep and non-rapid eye movement (NREM) sleep. Cycling approximately every 90 minutes between REM and NREM states, four to five times during sleep (Zielinksi et al., 2016). During each of these sleep phases there are dramatic alterations in functional brain activity and brain biochemistry. In NREM sleep, brain activity is organised by instinctive coalescent cerebral & thalamic rhythms, with 1-4 stages. During stages 3 and 4 of NREM, the brain moves into a deep state of sleep considered slow wave sleep, having low frequency, high amplitude oscillations ranging from 0.5 to 4.0 Hz (delta waves) (Dang-Vu et al., 2010; Krause et al., 2017). In contrast, REM sleep constitutes 20-25% of the sleep cycle, becoming more pronounced in the later cycles of sleep, it is characterised by high frequency, low amplitude desynchronised oscillations ranging from 4.0 to 9.0 Hz (theta waves) (Goldstein & Walker., 2014; Zielinski et al., 2016; Krause et al., 2017; Freeman et al., 2020).

Pioneering work in medical technology has provided the groundwork for comprehending the biological mechanisms that regulate sleep and the sleep phenomena (Zielinski et al., 2016). The advent of neuro-imaging studies, electroencephalogram (EEG), and polysomnography (PSG) have allowed scholars to reveal certain stages of sleep and correlating regions of our brain. Delta rhythms prominent in NREM sleep are found in the cortex, thalamus, hypothalamus, ventral basal ganglia, and medial septal nucleus (Zielinski et al., 2016); whereas theta rhythms prominent in REM sleep are found in the limbic system (hippocampus, hypothalamus, thalamus, amygdala, insula, basal ganglia, anterior cingulate cortex) and temporal-occipital areas. (Zielinski et al., 2016). These areas of activation illustrate sleep's biological role in cognition, memory consolidation, sensory processing, and emotional processing. (Dang-Vu et al., 2010; Goldstein & Walker., 2014).

For reliable and valid data assessing sleep, a multi-method approach that combines qualitative and quantitative aspects, as well as signs and symptoms is fundamental (Yu et al., 2011). Quantitative measures such as PSG, EEG, and more recently functional neuroimaging such as positron emission tomography (PET) and functional magnetic resonance imaging (fMRI), provide the opportunity for scholars to study brain structures participating in the generation and propagation of neural activity in sleep. These research tools provide reliable data, but for large scale population studies they are often impractical, expensive and time consuming (Hinz et al., 2017; Dang Vu et al., 2010). In the sense of prevalence and attaining qualitative measures of sleep, questionnaires and sleep dairies are an accessible alternative. The most widely used self- reported questionnaire measuring sleep quality is the Pittsburgh Sleep Quality Index (PSQI). This questionnaire consists of 19 items, and seven clinical domains. A global score can be calculated by adding the single scores together, with a range from 0 to 21. Global scores less than 5 are indicative of poor sleep (Hinz et al., 2017). The Epworth Sleepiness Scale (ESS) is also widely used for its assessment of daytime sleepiness and is cited in over 500 pieces of literature. The Patient Reported Outcomes Measurement Information System (PROMIS), Sleep Disturbance (SD) and Sleep Related Impairment (SRI) are self-reported questionnaires measuring sleep and sleep-related waking impairments, and are considered appropriate tools for evaluating the severity of sleep wake problems on a continuum (Yu et al., 2011).

2.2 Prevalence of poor sleep

The decimation of sleep throughout most nations due to today's 24-hour society, evening-based entertainment lifestyles, shift work, and prolonged work hours is a modern problem (Motomura et al., 2013). The effects of sleep deprived nights are known to all, those nights awake twisting and turning in bed, to forcing self to get up in the morning with less than 5 hours sleep, this can be the entry in to sleep debt if faced with multiple nights of sleep deprivation (Danielsson., 2013). From an evolutionary outlook, staying awake served as a primitive survival mechanism to guard self and others from outside threats (Klumpers et al., 2015). For modern society, insufficient sleep is a burden on the public health system, considered to be an epidemic that is linked to 7 out of the 15 leading causes of death in the USA (Chattu et al., 2019). Sleep disturbances are frequently found in the general population, with prevalence rates of poor sleep quality ranging between 10 to 48%. Discrepancies on this range is dependent on the sample criteria and measurement techniques used in data collection; nevertheless, it is a noteworthy finding and in concordance to showing the world is under slept (Hinz et al., 2017; Chattu et al., 2018).

The American Academy of Sleep Medicine (AASM) and the Sleep Research Society (SRS) prescribe the ideal sleep duration for adults aged 18 to 60 years old as more than 7 hours per night; whilst the National Sleep Foundation (NSF) recommends 7 to 9 hours of sleep for optimal sleep health in adults (Chattu et al., 2019). These recommendations are far from been achieved by the general population, as growing evidence in western countries supports the downward trends in the average night-time sleep duration (Stranges et al., 2012). National self-reported surveys in Canada and USA have indicated more than 20% of the general adult population suffer from insomnia (Stranges et al., 2012) and more than one third of Americans reporting sleep durations of less than 7 hours (Sheehan et al., 2020). These sleep statistics are consistent with other cohorts reporting insufficient sleep prevalence across different western countries.

A study conducted in Canada by Dai et al. (2020), revealed that about one third of Canadian adults sleep less than 7 hours a night. Highlighted in this study was the circumstance that sleep problems have reached epidemic proportions globally and are a major public health concern, with the observation that the trends in short sleep duration is still progressively deteriorating amongst the adult Canadian population (Dai et al., 2020). The Canadian study was proposed to determine whether sleep problems were associated with psychological wellbeing amongst adults. Findings suggested short sleep durations and insomnia were associated with higher odds of worse psychological wellbeing, with poorer scores (Odds Ratio: OR) in self-rated general health (Less than 5 hours sleep, OR = 4.75 (95% CI: 3.89, 5.81) and mental distress forms (Less than 5 hours sleep OR = 4.25 (95% CI: 3.26, 5.52) (Dai et al., 2020).

In the Netherlands, an investigation with over 20,000 adult participants found that 27.3% had a sleeping disorder (Chattu et al., 2018). A national sample of Netherland adults aged 18 to 70 years old completed a questionnaire from the International Classification of Sleep

Disorders (ICSD) revealing 32% of the sample complained of sleep disturbances and 43.2% suffered insufficient sleep (Chattu et al., 2018). Cohorts utilising the PSQI measuring tool indicated 32.1% of Austrians and 39.4% of Hong Kong citizens have poor sleep as classified by a PSQI global score under 5 (Wong et al., 2011; Hinz et al., 2017). A sample size of 9,284 individuals derived from a German community, 35.9% noted poor sleep (PSQI>5), whereas another German study with 753 participants found 34.7% were sleeping poorly (PSQI>5) (Hinz et al., 2017; Loeffler, 2015).

The percentages of poor sleep across these populations with the use of the PSQI criterion are nearly identical, demonstrating the widespread scale of impaired sleep across the globe. Public health initiatives have noted the increasingly higher prevalence of insomnia and sleep disturbances in Western countries, but the ongoing demographic and epidemiological transitions occurring in undeveloped countries, also appeared to be associated with larger segments of their population demonstrating sleep disturbances (Stranges et al., 2012). Stranges and colleagues (2012), multi-centre study obtained sleep data from eight undeveloped countries within Africa and Asia between 2006 and 2007. Three countries (Bangladesh, South Africa, Vietnam) showed the highest prevalence of sleep disturbances. Further analysis revealed 25.1% of women, 23.4% of men from Bangladesh reported severe problems not feeling rested during the day, with similar results for Vietnam: 21.4% of women and 15.2% of men. Severe problems falling asleep were reported in 43.9% of women, 23.6% of men from Bangladesh, with comparable data from Vietnam: 37.6% of women and 28.5% of men (Stranges et al., 2012). These intriguing figures amongst undeveloped countries emphasises the global dimension of sleep debt, and underline its emergence as a public health issue (Stranges et al. 2012).

2.3 Prevalence of poor sleep in New Zealand

New Zealanders, like the Americans, Austrians, Canadians, and Germans are not getting enough sleep. A study by Lee and Sibley (2019), looked at sleep duration and psychological well-being among New Zealanders, which revealed that only 58% of New Zealanders are getting the prescribed recommendation of 7 to 9 hours sleep a night, whereas 37% are getting less than 7 hours. Another finding from this study was the high proportion of those short duration sleepers had consistent associations with negative psychological well-being, linking sleep deprivation to mood and emotional impairments such as anxiety, depression, hyperarousal, and anger. (Saghir et al., 2018; Lee & Sibley, 2019).

2.4 Sleep as a health issue

Sleep disturbances may be initiated by the demands of life stressors originating within an individual or in the context of the environment in which they live (Daneilsson, 2013). Regardless of origin, poor sleep can become a potent life stressor, potentially aggravating inflammatory conditions, exacerbating hormonal imbalances, or provoking emotional dysregulation through ruminating worry, fear, anger, and avoidance. Thus, it is perhaps unsurprising to observe an association of poor sleep with hypertension, compromised immunity, infections, weight gain, diabetes, depression, and anxiety (Hinz et al., 2017).

Poor sleep, and especially short duration sleep, is a major stress on the neuro-hormonal system of the body, with consequences of day-time sleepiness, fatigue, as well as psychomotor and cognitive impairment, resulting in human errors and accidents. Clinical studies support that sleep and emotions also interact, such that sleep debt is linked with a deterioration of mental and emotional stability and can trigger symptoms of anxiety and confusion as the body overreacts to emotional stimuli (Yoo et al., 2007; Motomura et al., 2013). Motomura and colleagues (2013), kept healthy men in a laboratory for two 5-day sessions, session one the men were assigned to 8 hours sleep per night (sleep control), session two assigned to 4 hours sleep per night (sleep debt). Subjective questionnaires were answered immediately prior to fMRI. Subjective day time sleepiness was significantly higher in sleep debt conditions (3.21 ± 1.05) compared to sleep control (2.14 ± 0.66). Total time in REM sleep significantly shorter in sleep debt (51.7 ± 17.1) compared to sleep control (113.1 ± 21.2). Importantly, upon consciously viewing fear induced facial images, fMRI revealed that the sleep debt condition led to greater amygdala activation ($p = < 0.001$) and diminished functional connectivity between amygdala and anterior cingulate cortex (ACC) compared to sleep control conditions. These fMRI findings correlated with high subjective anxiety and mood questionnaire scores (higher scores suggestive of increased anxiety symptoms and mood deterioration). Intersession differences between sleep control and sleep debt revealed significant differences for anxiety state and tension when functional connectivity between amygdala and the anterior cingulate was diminished (Motomura et al., 2013). The data offers a neural foundation in which short term sleep loss can aggravate emotional irrationality especially in an increasingly sleep deprived society (Yoo et al., 2007, Motomura et al., 2013).

The recent uncertainty in global events where individuals are been cut off from connection and made to feel vulnerable, increases mental strain and ruminating stress which can perpetuate as negative mental distress, leading to insufficient sleep, and launching a vicious cycle. A longitudinal study by Monash University during 2020 indicated that poor sleep was linked to 2 to 3 times increased risk of reported anxiety, depression, and stress compared to good sleepers (Varma et al., 2021). Short sleep duration and sleep debt is often overlooked, though its contribution to the high level of mental distress seen in society is starting to emerge in research (Lee & Sibley, 2019).

Initially it was suggested that mental health conditions negativity impact sleep; however, the recent focus has identified a bidirectional relationship with a strong association between sleep disturbances and psychological disorders (Jamieson et al., 2019). A meta-analysis study using PSG showed sleep alterations to be present amongst most mental health disorders. Elements within these mental health disorders that showed increased susceptibility to sleep loss included increased state anxiety, decreased positive mood, poor emotional regulation, increased perception of pain, poor response inhibition, negative perception, and increased reactivity to neutral stimuli (Freeman et al., 2020). Though poor sleep is an identifiable symptom of anxiety, reciprocally, it can be a dynamic influence in the development and progression of anxiety (Goldstein-Piekarski et al., 2018).

Research has shown that a few nights of only 4 hours sleep impairs blood sugar regulation, at levels classified as pre-diabetic (Cziesler, 2015). The immune system requires sleep to function with individuals who get less than 7 hours sleep are 3 times more likely to get a rhinovirus infection (Cohen et al., 2009). Lack of sleep even impairs immune response to vaccines, the annual flu shot is 50% less effective in those sleeping less than 5 hours a night, a week prior to immunisation, with 50% less production of the normal antibody response compared to those that had 8 hours of sleep (Spiegel et al., 2002; Walker, 2021).

Sleep is a generous undertaking for the body, and it seems the brain receives arguably the most remarkable enrichment from slumber (Walker, 2021). Sleep is a homeostatic regulator for efficient brain responses, immune system function and repair, metabolic balancing, glymphatic cleaning, emotional reactivity, mood regulation, learning and memory. Sleep is a form of mental first aid, with scholars linking neurobiological processes and psychopathology in its emotional benefit. During the stages of NREM sleep there is downscaling of anxiety, a circadian construct with anxiolytic benefit. REM sleep seems to be of service to overnight therapy, dissipating and discharging painful or traumatic emotional experiences, as well as resetting limbic responsivity to these emotional events (Goldstein et al., 2013; Walker, 2021).

It is then no surprise that it is acknowledged that the majority of psychiatric conditions present alongside abnormal sleep patterns (Walker, 2021). Littlewood et al. (2017) in his systemic review publication quoted Mr E.J. Cossman who once said, "the best bridge between despair and hope is a good night of sleep". In context to this quote Littlewood et al. (2017), reviewed articles associated with sleep, emotional regulation, and suicide. The reviewed studies suggested forms of negative cognitive appraisals such as hopelessness, defeat, and entrapment could explain the relationship between sleep and suicidal thoughts.

Emerging neuropathological research is revealing the role of sleep as a vital process for affective brain regulation and recalibrating limbic cortical regions, with its potential palliative influence on anxiety and other emotional disorders (Goldstein-Piekarski et al., 2018). Sleep loss amplifies amygdala (area crucial for emotional processing) and anterior insula activity (responsible for emotional feelings) in which a profile of generalised anticipatory signalling within the amygdala and insula can potentially drive the brain in to a state of heightened threat alertness (Goldstein et al., 2013; Goldstein-Piekarski et al., 2018). As noted previously, neural measures utilising fMRI demonstrated that one night of sleep deprivation resulted in 60% amplification of amygdala signalling in response to viewing emotionally negative pictures, compared to a night of optimal sleep (Yoo et al. (2007).

The amygdala and anterior insula are subcortical structures of the brain and share many functional characteristics. Both are commonly connected by the activation of emotional and/or risky, threatening stimuli. Neuroimaging studies have proposed that these parts of the brain integrate interoception, emotion and social cognition (Ghaziri et al., 2018). Motomura et al. (2013) through fMRI analysis correlated diminished functional connectivity between the amygdala and anterior cingulate cortex (part of the prefrontal cortex involved in impulse control and emotion) in those with short sleep duration and mood changes of increased anxiety. Ben Simon et al. (2020) also observed changes in the brain, correlating the anxiogenic impact of sleep is linked to impaired medial prefrontal cortex (area crucial for high level cognitive function) activity in the brain and its disconnection to the amygdala. The data was able to outline a developing neuropathological model in which sleep loss contributes to the maintenance and/or exacerbation of anxiety and stress symptoms (Ben Simon et al., 2020). Mentioned within the discussion was even the slightest reductions in sleep quality (just one day of less than 7 hours sleep) impacted next day anxiety, demonstrating that sleep loss can casually and directionally instigate anxiety symptoms in individuals who were otherwise non-clinically anxious when well sleep rested (Ben Simon et al., 2020).

2.6 Sleep summary

The progressive erosion of sleep time sweeps rampantly through the world, impacting the quality of life, the satisfaction of life, mental wellbeing, and is linked with the onset of chronic physical disease (Dai et al., 2020). It seems necessary to shift the focus to prevention of sleep disorders and target interventions to promote sleep as part of public health strategies. Insufficient sleep is pervasive and holds ecological relevance, but at the same time it is a modifiable health behaviour. It is paramount to implement safe interventions properly to mitigate multiple burdens on individuals and society, a task of the future for those in research and health boards (Goldstein-Piekarski et al., 2018; Lee & Sibley., 2019; Dai et al., 2020).

3.0 Anxiety

The interaction between sleep and anxiety have been highlighted in the previous section. The following section describes the prevalence of anxiety and the health burden associated with the cumulative effects. It is recognised that strategies to decrease anxiety are of key importance for health and wellbeing.

3.1 Fundamentals of anxiety

Anticipation is an adaptive process, a primitive mechanism for preparation to an impeding threat or danger (Goldstein et al., 2013). However, excess anticipation of danger, harm or injury considered to be ruminating worry and apprehension, is maladaptive and associated with anxiety (Goldstein et al., 2013; Welcome, 2020). Anxiety disorders can manifest in difficulties controlling worry, fear, panic and sometimes a constant feeling of being overwhelmed. Other anxiety-related issues include restlessness, feeling on edge, irritability, sleep disturbances, muscle tension, and difficulty concentrating (Munir & Takov, 2021). Anxiety disorders can arise from the inability to deal with certain activities of daily living due to experiences of intense fear, distress, panic and worry in combination with other physiological symptoms (Global Health Metrics, 2020).

2.2 Prevalence of anxiety

The Mental Health Atlas (2020), released by the World Health Organisation (WHO) is considered to be the most comprehensive resource of global information on mental health. Countries around the world provide data which is assembled into this document as a universal resource (World Health Organization, 2021). The data provided by WHO reveals that one in thirteen adults worldwide suffer from an anxiety disorder. It is the most prevalent mental illness globally and has a prominent impact on loss of health (Yang et al., 2021; World Health Organization, 2021). United States alone has 40 million sufferers yearly, equivalent to 18.1% of their population (Anxiety and Depression Association of America, n.d.). When it comes to youth, 20 % of children/adolescents worldwide have a mental health condition, with anxiety affecting 25% of this cohort (World Health Organisation, 2021). Among American adults diagnosed with anxiety disorders, 38% will be displaying symptomology by the age of 15 years. In fact, 32% of American teenagers by age 16 years have exhibited anxiety at some point in their life, with 8% of this cohort reporting severe impairment from the anxiety (Mathew et al., 2019). These data indicate that anxiety symptoms emerge well before adulthood and perhaps contribute to suicide being the second leading cause of death worldwide amongst the age group 15 to 30 years old (World Health Organization, 2021).

The 2019 Global Burden of Disease (GBD) study collected data across the world. This study reported that the prevalence of anxiety worldwide was 301 million (95% CI: 253, 356) cases, an 11.2% increase (95% CI: 9.5, 13.0) in prevalence from 2010. Incidence (individuals who will develop the condition) of anxiety was 45.8 million (95% CI: 37.1, 55.6) cases with a percentage increase of 10.4% (95% CI: 9.0, 12.3) since 2010 (GBD 2019 Viewpoint Collaborators, 2020; Global Health Metrics, 2020). With no reduction in the global prevalence since 2010 despite the research into interventions to reduce the impact, it is no wonder anxiety is one of the most disabling mental health disorders - ranging lifetime prevalence of about 28% of the population globally (Alonso et al., 2018; Welcome, 2020; COVID-19 Mental Disorders Collaborators, 2021).

To fully comprehend the overall burden of anxiety, we can look at the time-based measure DALY (disability-adjusted life years), which constitutes a societal measure of the overall burden (expressed as the number of years) lost due to ill-health, disability, or early death due to a condition (Whiteford et al., 2015). Anxiety disorders account for 2.26% of the global burden of disease worldwide. This figure represents a total of 28.7 million DALYs (95% CI: 19.9, 39.3) worldwide. The DALY percent change for anxiety increased by 10.7% (95% CI: 9.0, 12.6) from 2010 to 2019. Global Health Metrics summary of anxiety DALY rates (per 100,000) illustrate regions of the world with the highest incomes and access to health care, also report the highest affliction rates. In low socio-demographic index (SDI) regions, age-standardised anxiety DALY rates ranged from 200 to 400 per 100,000 compared to high SDI regions, age-standardised anxiety DALY rates ranged from 200 to 800 per 100,000 (Global Health Metrics, 2020).

Recent stringent restrictions of living implemented by governments worldwide have adversely affected a significant proportion of the population and have not been without cost on societal mental wellbeing (Haung & Zhao., 2020). A systemic review of 19 studies explored the prevalence of symptoms during the pandemic and reported elevated rates of anxiety 6.33% to 50.9%, psychological distress 34.4% to 38%, and stress 8.1% to 81.9%. The researchers concluded that significant levels of symptomatology were of clinical relevance, and that precedence should be taken to alleviate the perilous effects of this pandemic on mental health internationally (Xiong et al., 2020; Gasteiger et al., 2021). Amid these mandated restrictions, the estimated global prevalence of anxiety disorders for 2020 was 3,824.9 per 100,000 of the world population, equivalent to 298 million individuals worldwide. It was estimated that an additional 76.2 million cases of anxiety disorders could be accounted for by the impact of the recent pandemic, therefore the adjusted statistical estimates were 4,802.4 per 100,000 population, equivalent to 374 million people having an anxiety disorder (COVID-19 Mental Disorders Collaborators., 2021). This data shows anxiety disorders are responsible for 44.5 million (95% CI: 30.2, 62.5) DALYs globally (COVID-19 Mental Disorders Collaborators., 2021).

2.3 Prevalence of anxiety in New Zealand

Looking closer to home, the New Zealand Health Survey is a continuous survey with sampling conducted as face-to-face interviews. The 2017/2018 NZ Health Survey found that one in six New Zealand adults have been diagnosed with a common mental health disorder (anxiety, depression, bipolar) at some time in their lives, with nearly 9% of adults experiencing psychological distress in the last four weeks (Ministry of Health., 2019; Mental Health & Illness, 2020). The 2018/2019 and 2019/2020 NZ Health Survey rates line up with 2017/2018 rates, with 8.2% and 7.4% of adults experiencing psychological distress in the last four weeks (Ministry of Health., 2020). The 2020/2021 NZ Health Survey was unable to be conducted in certain areas of New Zealand due to the face-to-face constraints imposed by COVID-19. As a result, the sample size is smaller, with the 2020/2021 survey identifying 9.6% of adults experiencing psychological distress in the last four weeks, an increase from 7.4% in 2019/2020 (Ministry of Health., 2021).

New Zealand contributes dramatically to the overall burden of mental health disorders worldwide. The WHO World Mental Health Survey Initiative identified five countries, one being New Zealand, in which more than one third of respondents had symptoms consistent with the existence of one or more lifetime mental disorders (Kessler et al., 2007). New Zealand was one of six countries projected to have more than half the population (47 to 55%) with a lifetime risk of a mental health disorder (Kessler et al., 2007). The data could be considered anecdotal as they are based on projected estimates; however, there is some empirical data available to support the high prevalence of mental health issues in New Zealand.

The 2019 Global Burden of Disease Study, results for New Zealand, revealed that anxiety disorders account for 5.74% of the New Zealand's total burden of disease with a DALY rate around 537.7 to 767.7 cases per 100,000 individuals (GBD 2019 Viewpoint Collaborators, 2020; Global Health Metrics, 2020). Self-harm and depression-related comorbidities with anxiety, had similar percentage scores of total DALYs. Alarmingly, self-harm was responsible for the highest proportion of deaths in New Zealand in 2019 for those aged between 15 and 49 years, accounting for 17.45% of deaths in this cohort (GBD 2019 Viewpoint Collaborators, 2020; Global Health Metrics, 2020).

In response to the current calamity in New Zealand, and consequences of strict lockdowns, mental wellbeing it is expected to pose an even more profound threat to psychological health. Cross-sectional studies verify the elevated rates of anxiety and stress during this restrictive time (April/May 2020) in New Zealand. Every-Palmer and colleagues (2020) conducted a study exploring the psychological distress and anxiety of the New Zealand population during the government-enforced lockdown. Of the 2010 participants who completed the survey, thirty percent reported moderate to severe psychological distress, with one in six participants (15.6%, 95% CI: 14.0, 17.3) and reported moderate to high levels of anxiety on the GAD-7 form (Every-Palmer et al., 2020). The GAD-7 form measures seven symptoms and the extent to which the individual is bothered by them over a two-week period, on a 4-point Likert Scale. A score of 10 or higher is indicative of high anxiety (Every-Palmer et al., 2020).

Of the same sample, 375 participants (18.2%, 95% CI: 16.5, 20.0) reported having previously been diagnosed with a mental health condition by a medical professional. A high proportion had more than one diagnosis, and 52.6% were currently diagnosed with an anxiety disorder. Of those with past histories of mental illness, 52.9% (95% CI: 47.6, 58.1), experienced increased (moderate to severe) psychological distress and one third (36.1%, 95% CI 31.2, 41.3) noting that their mental health worsened during the enforced lockdown (Every-Palmer et al., 2020). Gasteiger and colleagues (2021) explored mental well-being in the NZ population during the same restrictive time as Every-Palmer et al (2020) also using the GAD-7 form. These authors reported that 53% of the 681 study participants reported anxiety symptoms, with 24% reporting moderate to severe anxiety symptoms (Gasteiger et al., 2021).

2.4 Anxiety as a health issue

Prominent neural circuitry recognised in the development of emotional regulation include the medial prefrontal cortex, anterior cingulate cortices, amygdala and the uncinate fasciculus. The uncinate fasciculus (UF) is a white matter tract in the brain connecting the limbic system (amygdala, hippocampus, insula, thalamus) to the areas of the prefrontal cortex, and is one of the last white matter tracts to reach maturity continuing its development into early adulthood (Jamieson et al., 2020). It has been proposed that damage or underdevelopment of the medial prefrontal cortex results in the inability to inhibit salient fear responses that originate in the amygdala associated with anxiety disorders. Evidence for this hypothesis is demonstrated in research with individuals with pre-frontal cortex lesions having increased risk of anxiety symptomatology (Etkin et al., 2011; Jamieson et al., 2020). The increased emergence of anxiety observed in adolescence has led to propositions, that earlier age of emergence leads to earlier disruptions in brain development.

Additionally, loss of structural integrity of the UF interrupting the top-down executive control of emotional reactivity in the limbic system is a modulating factor for the development of anxiety. When individuals lose the ability to dampen fear conditioned stimuli, undesired emotional processing such as anxiety can start to appear (Yoo et al., 2007; Etkin et al., 2011; Jamieson et al., 2020). Sleep is paramount in white matter development especially during adolescence when white matter tract connectivity is still maturing. Yoo et al. (2007) found in sleep deprived individuals there was a hyper-limbic response to aversive stimuli, associated with loss in white matter connectivity between amygdala and prefrontal cortex, within the same group there was heightened connectivity between amygdala and brainstem (area of autonomic nervous system control). Though speculative, sleep deprivation can reduce the ability to dampen negative emotional stimuli but at same time coupled to activating the body into a hypervigilant fight/flight response (Yo et al., 2007; Jamieson et al., 2020).

On the 8th of October 2021, a news release from the WHO commented on the disappointing picture of the global effort to provide people with mental health services. Worldwide countries have failed to provide people with quality mental health services. With research highlighting the growing need for mental health support during this pandemic, none of the targets by any country have even been close to been achieved, especially regarding leadership, governance, and finances (Brunier, 2021). In 2020 only 52% of the countries met the WHO target relating to metal health promotion and prevention programmes, well below the target of 80% (Brunier, 2021). Two of the most common health conditions (anxiety and depression), cost the global economy US $1 trillion dollars each year just in loss of productivity, and that does not include medical costs. Currently, the global median of government health budget expenditure towards mental health is less than 2%.

The anxiety treatment gap, as highlighted by the WHO, is illustrated also by Alonso and colleagues (2018). Of the 21 countries surveyed, only 27.6% of individuals received treatment that met the criteria of an anxiety disorder. These authors stated that two-thirds of those with anxiety that perceived the need for treatment had not received any form of treatment, and that quality of treatment received by individuals with anxiety disorders was suboptimal. The authors concluded less than 1 in 10 individuals with anxiety disorders received adequate treatment in the last 12 months (Alonso et al., 2018).

2.5 Anxiety summary

The burden of anxiety disorders globally is well established and the substantial rise, combined with the impact of the global pandemic, only creates more demands on health services (Yang et al., 2021). An estimated, 75% of those suffering from anxiety remain uncared for, especially in developed countries, with approximately 1 million individuals taking their lives each year (WHO, 2021). It is understandable that Dr Tedros Adhanom Ghebreyesus (Director General of WHO) is extremely concerned. He stated "…. despite the evident and increasing need for mental health services, which has become even more acute during the COVID-19 pandemic, good intentions are not been met with investment….

we must heed and act on this wake-up call and dramatically accelerate the scale up of investment in mental health, because there is no health without mental health" (Brunier, 2021).

Epidemiological study initiatives like WHO World Mental Health Surveys and GBD have highlighted the age of onset, lifetime prevalence and projected lifetime risk of anxiety worldwide. Mental health disorders, especially anxiety, pose an immense burden globally, and the data reinforces that. It is not only the high prevalence of anxiety disorders that are seen in the community depriving individuals of quality of life, but also the high disability instigated by the chronicity and comorbidity of this disorder (Kessler et al., 2007; Alonso et al., 2018). Though there is no gold standard approach to lowering anxiety case figures, a greater investment in mental health care and investigations into effective intervention strategies are needed urgently.

3.0 Stress

Stress pervades our human existence; it is a focal construct in the domains of human health. While stress and stress responses are vital, repeated and prolonged stress is acknowledged to negatively affect coping capacity and physiological homeostasis. Again, effective strategies to counter excessive or non-adaptive stress are identified as a key component of ensuring health and well-being.

3.1 Fundamentals of stress

Though there is poor definitions and ambiguous modelling of 'stress', the fact remains, that considerable outgoings are poured into research looking at how stress affects health (Slavich & Shields, 2018). The original concept of stress has expanded significantly over the years, from the expression of a non-specific response utilizing our "fight or flight" sympathetic nervous system to a threatening stimulus, to the appreciation that the biology of stress is not a one-time threat response, but rather an enduring process, a composite multi-dimensional construct where critical interactions between body and mind adapt to daily encounters whether perceived stressful or not (Koolhaas et al., 2011; de Kloet et al., 2019; McEwen & Akil, 2020). What it is important to note when examining stress, is that a stressful event/stressor is a discrete situation in which has the potential to cause psychological alterations and disruptions within an individual. A stress response is the neurological, biological, and hormonal cascades that are initiated upon a stressful event (Croswell & Lockwood., 2020). Stress, and the responses to any exposure to potential threats (real or perceived), are essential for survival (Joels et al., 2018).

Under environmental, social, or mental adversity, the body launches neurological, physiological, and immunological responses, critical for survival. Input upon perceived threat is funnelled through the limbic system (hypothalamus, thalamus, amygdala, hippocampus, basal ganglia, cingulate gyrus), and brainstem. The evolutionary aspect to survival is seen in the limbic system, recognized as the oldest most primitive part of the brain. Perceptual processing of stressful events upregulates the sympathetic-adrenal-medullary (SAM) axis with its control centre in the brainstem and the hypothalamic-pituitary-adrenal (HPA) axis with its control centre in the hypothalamus.

The SAM axis releases the catecholamines, adrenaline and noradrenaline from the adrenal medulla into the body, increasing heart rate, blood pressure, respiration, sweating and pupil dilation. If the body continues to still perceive the stimuli as a threat, endocrinological upregulation occurs via the HPA axis resulting in the synthesis and release of glucocorticoids form the adrenal cortex. (Levine, 2005; Joels et al., 2018; de Kloet et al., 2019; Turner et al., 2020; Thau et al., 2021). The increased secretion of adrenocorticotrophic hormone (ACTH) from the anterior pituitary drives the release of cortisol (the main glucocorticoid released) into circulation, cortisol's job is to continue to keep the body and brain on high alert by providing energy, cortisol drives key systemic pathways to maintain glucose levels (Thau et al., 2021).

3.2 Prevalence of stress

Regardless of age, sex, race, religion, and body type, no one is immune to stress. Stress has a worldwide prevalence, and stress has increased across the globe over the last ten years (Wiegner et al., 2015). Annually the American Psychological Association (APA) conducts a survey to study the relationship between Americans and stress. This survey investigates how stressed Americans feel, what keeps them up at night and how they deal with the stress in their lives (American Psychological Association., 2017). In 2017, the survey revealed that Americans average stress levels (4.8 out of 10) was consistent with the 2016 results also 4.8 out of 10. 45% of Americans reported sleep disturbances such as lying awake at night as a stressor. Specifically, 63% of Americans reported that the biggest source of stress was the future of the nation, with money (62%) and work (61%) following behind as sources of stress. There was a significant finding in that 75% of Americans in 2017 experienced at least one symptom of stress in the last month and stress had increased in the past year (American Psychological Association., 2017). Stress is the top health concern for American teenagers with psychologists emphasizing the necessity for teenagers to learn healthy ways to manage stress or it could lead to serious chronic health implications (Global Organization for Stress., n.d.). Americans are not the only nation experiencing the burden of stress, 91% of Australians feel stress in at least one important aspect of their lives, with an average of 3.2 days absent from work each year due to stress costing the Australian economy $14.2 billion dollars (Global Organization for Stress, n.d.).

The current global pandemic is a time of elevated stress, with sources of stress such as confusion, anger, quarantine, isolation, fear, boredom, lack of supplies, inadequate information, financial loss, and loss of freedom impacting physical and psychological health (Sousa et al., 2021). Though it may be challenging to predict the consequences, this current global crisis is the foundation of mounting stress, with recent meta-reviews estimating from 2019-2021 the prevalence for psychophysiological stress as 32% (95% CI: 26.9, 37.6) in the general population and 38% (95% CI: 33.3, 42.5) in health care workers (Sousa et al., 2021). Resilience and ability to cope with the requirements of a new world is lagging, with perceived stress captured in China as moderate to severe by 53.4% of the population (Adamson et al., 2020).

Models of stress declare that stressors exist in all life, but stressful events influence only those that appraise them as stressful, therefore appraised stress is not solely determined by the stimulus/condition/event but rather by the individual's perceived interpretation of the environment and their perceived ability to adequately cope (Cohen, Kessler and Gordon., 1997). As developed by Cohen, Kamarck and Mermelstein, the Perceived Stress Scale (PSS-10) is the most widely used tool to measure stress in the world. A 10 item, 5-point Likert like type scale ranging from never (0) to always (4), with a total possible score of 40; low stress (0 to 13), moderate stress (14 to 26), and high stress (27 to 40). Depending on the scholars utilizing the PSS-10, some note that any score from over 20 is considered high stress (Haung et al., 2020; Adamson et al., 2021). Expanding on from Cohen, Kessler, and Gordon's (1997) model, the PSS-10 focuses on the appraisal of participants where they feel their lives are overloaded, uncontrollable, unpredictable that the demands tax or exceed their adaptive capacity to function (Haung et al., 2020). Adamson et al. (2021) aimed to capture the level of perceived stress worldwide during the pandemic utilizing the PSS-10, with an overall mean PSS-10 score as 19.1 ± 7.2 suggesting that on average moderate stress was perceived. In a survey conducted from March to April 2021 with respondents from 41 countries. The mean PSS-10 score was 17.6 ± 6.4, with female respondents reporting higher PSS-10 scores (18. 3 ± 6.2) compared to males (15.6 ± 6.4) (Gamonal-Limcaoco et al., 2021).

Mahmud et al. (2021) also conducted an extensive systemic review considering large numbers of studies. The aim was to investigate the prevalence of anxiety, stress, and insomnia over the pandemic, though its target was health professionals, it still provided a snapshot of the psychological crisis instigated by stress in an individual's environment. The review found high prevalence of stress in numerous countries diverse nations such as China (46.5% [95% CI: 26.4, 66.6]); Egypt (76.6% [67.9, 85.3]; India (52.8% [29.2, 76.3]), and Spain (55.2 % [0.75, 109.7]). Though future confirmatory analysis of these findings is required, they identify rising levels of stress collectively across the world with involuntary lifestyle changes as a primary risk factor (Mahmud et al., 2021).

3.3 Prevalence of stress in New Zealand

Internationally there is numerous narratives supporting the global burden of psychological and psychophysiological stress and its evolving character, however, there is a literature gap in New Zealand regarding the concept of stress and its health implications. One study by Signal et al. (2017) reported on stress prevalence in New Zealand with the Life Stress Scale (LSS). These authors found that 55% of Maori women reported significant life stress, compared to 30% of non-Maori women during their pregnancy. In a more recent New Zealand study, Gasteiger et al. (2021) used the PSS-4 to assess stress, and reported a mean score of 6.31 ± 3.3 compared to the published population normative data of 6.11 ± 3.1. The PSS-4 tool has 4 items with a total possible score of 16, with higher the score the higher the level of stress perceived. The New Zealand PSS-4 scores were higher compared to normative data, but lower than the UK (6.48 ± 3.3). Females had higher perceived stress levels (6.34 ± 3.3) compared to men (5.94 ± 3.5). Those who had higher perceived levels of loneliness, negative mood, and risk of getting infected had higher levels of stress, while those who participated in regular exercise had significantly lower levels of stress (Gasteiger et al., 2021). This study builds on the existing literature seen in other nations, but what is striking is the data of elevated levels of perceived stress in younger adults 18 to 24-years old (8.16 ± 3.0), with all other age groups having scores below 6.6.

The report of disproportionately elevated levels of stress in New Zealand youth at these present times of uncertainty is comparable to a study by Goddard and Dixon (2018) prior to the pandemic. The study investigated the levels of stress in a sample of adolescents with an online Adolescent Stress Questionnaire (ASQ). It contains 10 subscales measuring factors of stress at home and school on a 5-point Likert type scale ranging from (1) not at all stressful, to (5) very stressful with a total possible score of 270. Scores over 135 equate to high levels of stress. The mean total stress score was 143.78 ± 38.94, classified as moderate stress levels, however 20% of the adolescents scored over 180, and 8% over 200 demonstrating the high stress levels amongst adolescents in New Zealand (Goddard and Dixon, 2018). Although the differences in the total stress scores were not statistically significant across year levels, differences were apparent for gender, with females (150.57 ± 37.81) scoring higher than males (136.31 ± 38.84; p-value = 0.0005). These data align with those reported by De Vriendt et al. (2011), who found in European adolescents, females (127.4) scored higher in the ASQ compared to males (116.1). Of concern is the fact the New Zealand scores are higher than other nations, and that 20% scored over 180 in the ASQ indicating a high level of stress in our youth. These levels could seem reasonable based on the previous data in the anxiety section, with New Zealand having some of the highest rates of suicide and self-harm in the developed world.

3.4 Stress as a health issue

In the presence of a healthy physiological response, when an individual's defense reaction meets the environmental demands, effective learning from the setbacks can occur and restoration of homeostasis. Failure to cope under circumstantial demands with a situation outweighing an individual's coping skills, enhances the vulnerability to maladaptive damaging health behaviors (McEwen, 2019; de Kloet et al., 2019). The persistent need to adapt in response to daily stressful experiences (physical, physiological or psychosocial), can overload an individual's biology, and it is well recognized in literature that repeatedly prolonged stress not only inflicts wear and tear to the biological system, pulling an individual's biology further from homeostasis (Slavich & Shields, 2018). Stress whether interpersonal or intrapersonal, has been shown to increase the risk of developing a common respiratory cold (Cohen, Doyle & Skoner, 1999). The cumulative effects of excessive and/or dysregulated stress responses, play a contribution to damaging behaviors leading to disease over time (McEwen, 2019; Fava et al., 2019).

The chronic character of stress is noted throughout literature as a trigger for anxiety and other mental health disorders. The anxious brain perceives stressful threats (real or perceived), the distorted/enhanced perception to a potential threatening stimulus shifts and narrows attention to constantly monitoring the cues of threat (Harvey, 2002; Danielsson, 2013). Key neural brain circuits downgrade functional inhibitory responses which decrease the ability to terminate a stress response heightening arousal. The disproportionate negatively toned cognitive activity induces dysregulated behaviours such as worry, neuroticism, obsessions, hypervigilance, and avoidance as a form of coping or as a way for the brain to finetune this stress (Harvey, 2002; Danielsson, 2013; Croswell & Lockwood, 2020; McEwen & Akil, 2020). Changes in DNA repair, changes in gene expression, and telomere shortening within the brain have also been reported in response to (Croswell & Lockwood, 2020).

Animal studies subjected to stress demonstrated that chronic social defeat stress in mice increased anxiety (Welcome, 2020). In another study, Guedri et al. (2017), restrained rats for three hours consecutively for 14 days, the stress of the restraint induced anxiety and reduced motor activity in rats (Welcome, 2020). A human study on chronic stress reported 59% of 587 participants suffered more than just a little stress (level 2 or 3 using the QPS Nordic single item form). From this 59% (345 participants), 71% had symptoms of anxiety (Wiegner et al., 2015; Welcome, 2020). In the group with the highest level of stress, 87% reported symptoms of burnout, with 9 out of 10 women in the group reporting symptoms of anxiety. A Swedish waiting room cohort (n =1392) reported 29% had symptoms of anxiety based on the Hospital Anxiety and Depression Scale for anxiety (HAD-A); where a score greater than 7 was indicative of probable anxiety (Wiegner et al., 2015). Wiegner et al. (2015), concluded that both men and women afflicted with high stress levels had a high probability of accompanying anxiety symptoms.

3.5 Stress summary

With stress playing a critical role in the pathophysiology of mental health disorders, it is not surprising that focus into the underlying molecular mechanisms are under the attention of scholars. Research has demonstrated stress-related changes to the brain, with effects on cognitive and emotional function alongside elevated chronic inflammation, abnormal cortisol release, metabolic dysfunction, and disorganised neuronal circuitry. As the world clings in fear, terror and uncertainty to the adjustments transitioning around them, it only stresses more the landscape of mental health and sleep disorders. These areas of health already crumbing by the destructive forces of stigma and lack of resources (Sousa et al., 2021). Epidemiological studies confirm that experiencing stressful events and reporting chronic high perceived stress are associated with worse mental and physical health. Given the rapid increase and lack of literature around noncommunicable health issues, including stress, it is crucial to invest in the development of strategies for coping through adversities. Interventions to alleviate stress should form a cornerstone of well-being programs and public health initiatives.

4.0 First Responders

First responders are those that work to ensure the safety of our communities, they include but are not limited to police officers, fire fighters, paramedics, and rescuers (Carleton et al., 2019). These personnel provide multiple services during emergent and critical events (Jones, 2017). In such professions,

4.1 Traumatic exposure

Considering the nature and intensity of these professions, individuals are repeatedly at risk of being exposed to traumatic events, workplace stressors, and putting themselves in harm's way (Haugen et al., 2017; McKeon et al., 2021). A traumatic event is defined by the

Diagnostic and Statistical Manual of Mental Disorders Text Revision as "experiencing, witnessing, or being confronted with at least one event that involves actual or threatened death or serious injury, or a threat to the physical integrity of self or others" (Berger et al., 2012). As a result, first responders are more likely to suffer from mental health problems such as depression, anxiety, and substance dependency at a rate greater than the general population (Stogner et al., 2020; Menard & Arter, 2013; Berger et al., 2012). First responders are trained to be resilient and handle traumatic incidents; nevertheless, the long-term exposures to these severe critical situations provide a catalyst towards negative mental wellbeing (Chopko, Palmieri & Adams, 2018).

Despite the limited empirical data to support higher traumatic exposure frequencies in first responders compared to the general population, there are still studies that highlight high levels of exposure in specific cohorts. Corneil et al. (1999), demonstrated that 90% of Canadian and American firefighters are exposed to at least one potentially traumatic event each year, many encountering death by suicide, or graphic, deadly tragedies, never to be seen by majority of the general population (Corneil et al., 1999; Carleton et al., 2019). Chopko, Palmieri and Adams (2015; 2018), found among small to mid-size law enforcement agencies, that officers were exposed to approximately 188 potentially traumatic events on average over the course of their careers. Potentially traumatic events are defined to contain aspects of threats to the officer or witnessing harm to others (Chopko, Palmieri & Adams, 2018).

To deal with these traumatic and workplace stressors, it is not uncommon for first responders to employ maladaptive emotional management and coping mechanisms such as avoidance, reexperiencing, hyperarousal, drug, alcohol, and substance abuse. Hyperarousal represents a state of exaggerated startle response, hypervigilance, excessive worry, and trouble falling asleep or staying asleep (Chopko et al., 2021). The ability of the first responders to regulate and be guided by their emotions represents a fundamental process governing their personal lives, their mental health, and the ability to in interact in the community at a societal level (Goldstein & Walker, 2014).

Emotional events (positive or negative) are typically remembered more than neutral ones. Emerging data suggests that REM sleep through the recruitment of hippocampal/amygdala neocortical networks, is involved in the consolidation of emotional memory. These networks are enhanced during sleep and hindered when sleep deprived. Memory consolidation is a process in which primarily accountable emotional events are organized into long standing memories (Sterpenich et al., 2007). Goldstein and Walker (2014), have proposed that during REM sleep there is a decoupling of emotional potency from a memory in that we sleep to forget the emotional intensity of an event yet sleep to remember the memory of that emotional experience due to consolidation. In fitting with the role of REM sleep for emotional depotentiation Sterpenich et al. (2007), found with fMRI analysis, individuals that were not allowed to sleep the first night after exposure to averse emotional stimuli, failed to downregulate amygdala intensity to the same emotional event during a memory test, even if had slept the following nights. Recalled trauma can be challenging, especially if one is not able to get quality REM sleep in which to divorce themselves from the somatic and visceral charge of the event/s, while preserving the information to guide healthy behaviours in future events (Goldstein & Walker, 2014).

4.2 Disrupted sleep

Traumatic exposures maybe inevitable for first responders; however, they are not the only element impacting their mental health, stress, and sleep. Organizational pressure, agency culture, absence of public support, working conditions such as shift work, inconsistent shift scheduling, working under fatigue, and unpredictability can be consequential (Stogner et al., 2020). Sleep disruption and deprivation is common amongst first responders due to the hours of operation and the nature of the occupation. Sleep deprivation is defined as less than 4 to 6 hours of sleep in 24 hours. Well-documented in the literature is the outcomes of shiftwork on first responders, such as reduced quality of sleep, difficulties falling or staying asleep and shorter latency in sleep stages (Courtney et al., 2013; Jones, 2017; Angehrn et al., 2020).

Shift work leads to rearrangement of wake and sleep cycles, disrupting circadian rhythms, which in turn can cause biological desynchronization, physiological disturbances, and psychological imbalances (Gerber et al., 2010). Individuals with poor sleep are likely to report greater mental distress, increased use of medical services, self-medicating with alcohol or over the counter medication, increased absence from work, increased risk of traffic and work accidents, poorer health, less joy in social functioning and quality of life (Harvey, 2002; Angehrn et al., 2020; Chopko et al., 2021). Nonetheless for first responders the profound adverse consequences of sleep disturbances can show up as fatigue, impaired attention, poor concentration, diminished reaction time and compromised decision making, eroding the quality of care and relations in these safety critical professions (Angehrn et al., 2020; Chopko et al., 2021).

Neurobehavioral deficits such as lapses in attention, slowed working memory, reduced cognitive function can accumulate across days of partial sleep loss comparable to the same changes found in those who have 1-3 nights total sleep loss (Banks & Dingle., 2007). An experiment conducted by Van Dongen and colleagues (2003), involved healthy volunteers kept in the laboratory for 20 days, randomized to either 4, 6 or 8 hours of restricted sleep per night over 14 days or to 0 hours sleep over 3 days. The volunteers underwent neurobehavioral assessments every 2 hours during wakefulness states, the efficiency of behavioral alertness, working memory and cognitive function progressively declined in the 4-hour and 6-hour groups (Van Dongen et al., 2003). Chronic sleep restriction in the 4 and 6-hour groups also presented elevated subjective daytime sleepiness. The authors concluded that excessive wakefulness beyond the ability for the brain and body to maintain stable neurobehavioral functioning is causative for progressively deteriorating behavioral alertness, memory and cognitive in chronic sleep restriction and total sleep deprived individuals (Van Dongen et al., 2003).

The daily requirements for first responders are to respond quickly, be alert for various demands and perform complex cognitively demanding tasks, yet one-third of police officers in the United States sleep less than 6 hours per night sleep, is concerning for those on the frontline dealing with public safety (Angehrn et al., 2020; Smithies et al., 2021). In support of Van Dongen et al (2003) experiment reporting significant deficits in alertness and cognitive function after chronic sleep durations of less than 7 hours sleep per night, is an experiment by Belenky and colleagues (2003). Sixty-six volunteers kept in a laboratory for 14 days, randomized to one of four sleep conditions (3, 5, 7, or 9 hours sleep per night) for a total of 7 days. The Psychomotor vigilance test measures reaction time to a visual stimulus, in the 3-, 5-, and 7-hour groups response speed continued to decrease over the 7 days, and the 3-, and 5-hour group failed to recover to baseline in recovery phase, and remained significantly lower than that of the 9-hour group. Sleepiness ratings significantly increased across days of the experiment in the 3-hour group, whereas the other groups did not change over the 7 days. Of note, the 3- and 5-hour group failed to recover to baseline in recovery phase and remained significantly lower than that of the 9-hour group. The experiment highlighted that following chronic, mild to moderate sleep restrictions, even with 3 days of post recovery sleep there was no restoration of performance to baseline, that daily decrements in performance capacity are unavoidable. In the presence of sleep restriction, the brain undergoes self-adaptive modelling to maintain some level of performance, to still function. Such adjustable modelling may reduce or limit the operational functioning of the brain to prevent injury, which could occur if continued to face restricted sleep (Belenky et al., 2003).

Americans are not the only nationality of first responders sleeping substantially below the recommended 7 to 9 hours per night, in a Canadian study, 25% of Canadians articulated consistent symptoms of insomnia; whereas study Angehrn and colleagues (2020), revealed that 55% of Canadian First Responders had symptoms consistent of insomnia (Angehrn et al., 2020). The high prevalence rates of sleep disturbances in First Responders reported in the Angehrn et al. (2020) sample was consistent with previous international research documenting sleep difficulties in first responders. For example, 51% of Brazilian firefighters noted sleep disturbances (de Barros et al., 2013; Jones., 2017), shift work in Swiss Police increased sleep complaints (Berger et al., 2010), and a sample of Australian rural paramedics reported 70% suffering from severe sleep difficulties (Courtney et al., 2013; Jones, 2017).

4.3 Stress and mental health

As literature supports sleep problems serving as a mediator for hyperarousal, avoidance and reexperiencing symptoms, those with sleep disturbances commonly experience co-occurring mental health challenges. Nefariously, sleep loss amplifies limbic reactivity, and concurrently amplifies maladaptive coping mechanisms (Goldstein et al., 2013). With Jones commenting "it is clearly important to consider sleep quality when assessing mental health" (Jones., 2017). As noted by Mckeon et al. (2021), one in three first responders report having high or very high levels of daily psychological stress and are at more risk of experiencing poor mental health. The underestimated extent of mental health burdens experienced by first responders could be due to the lack of research, though the few studies published have demonstrated rates of anxiety and stress in excess of that observed in the general population. (Petrie et al., 2018).

A meta-analysis report on 18 articles demonstrated the prevalence of anxiety (15%) and psychological distress (27%) among ambulance personnel, concluding that rates of post-traumatic stress were considerably higher than seen in the general population (Petrie et al., 2013). A large Canadian study of first responders reported that 44.5% of participants screened positive for one or more mental health disorders (Carleton et al., 2019). A cross-sectional study with 40,299 police officers and staff across the Great Britain Police Force reported a prevalence for anxiety at 8.5% (95% CI: 8.2, 8.7) with 5.6% of the sample reporting more than one probable mental health disorder (Stevelink et al., 2020).

Within this same sample, when the prevalence of probable mental health symptoms amongst the police officers and staff who had reported a traumatic exposure in the last six months, was reviewed, different set of outcomes emerged. Specifically, the prevalence was approximately doubled (16.4%) those reporting anxiety symptoms. Further, higher prevalence was found in those using coping mechanisms like high alcohol consumption, with 32% meeting anxiety criteria. Over one quarter (27%), of recently trauma exposed staff met the criteria for post-traumatic stress disorder (PTSD). The police personnel/staff at higher risk of adverse mental health symptomology were those who had experienced a trauma in the last six months, or personnel with heavy alcohol consumption; a two-to-six-fold increase in probable mental health symptomatology (Stevelink et al., 2020).

Supporting the study of Stevelink et al. (2020), is a large study (16,857 participants) reporting 90% of police personnel experiencing trauma on the job with 8% going on to report symptoms of PTSD. Of the 80% of police personnel who did not go on to develop PTSD, around half of them reported symptoms of fatigue, anxiety, and sleep disturbances (University of Cambridge, 2019). A large cross-sectional survey study by Tsehay et al. (2021), of 385 frontline law enforcement officers also examined the prevalence and factors associated with anxiety, depression, and sleep problems. The prevalence of symptoms associated with psychological health problems among this cohort of police officers was high with 30.2% (95% CI: 28.2, 33.0) noting symptomatology of anxiety, and 15.9% (95% CI: 13.5, 17.2) for insomnia (Tsehay et al, 2021).

4.4 Under-reporting

The requirement for urgent intervention is affected by the under-reporting of symptoms and the stigma surrounding mental illness. Stevelink and colleagues (2020), mention that among military and first responder personnel there is a delay in seeking care for mental health difficulties. Frequently noted are the worries about career, repercussions, and confidentiality, as well as difficulties arranging an appointment or finding the right form of care. This stigma is not limited to the population of first responders, as it pervades society particularly New Zealanders, who as a culture traditionally pride themselves on self-reliance, strength and a “she’ll be right” mentality. Despite the stigma and frequently identified barriers to receiving care for public health problems (sleep and mental wellbeing) in first responders, there lacks recognition in current strategies. Therefore, facilitating research and new treatments aids are necessary to reduce the chronicity of post trauma psychopathology seen in first responders (Haugen et al., 2017).

4.5 First responder summary

As highlighted above, first responders endure work environments where the frequency, nature, and intensity of those environments and traumatic exposures, disrupted sleep and stress pose significant challenges to health, well-being, and quality of life. Whether the encounter of traumatic events on a daily basis causes or exacerbates mental health challenges or sleep disturbances is still unclear, and further biological research is required, but, regardless, it is a matter of health and safety for these individuals to address this multifactorial problem (Jones et al., 2017).

5.0 Selected strategies to counter sleep, anxiety, and stress

Identified strategies in the following sections are selected due to their relevance to the novel intervention investigated in the experimental chapter. The FLOWpresso device applies intermittent pneumatic cyclical deep pressure, from distal to proximal, in a rhythmic sequence and is combined with warming infra-red light.

5.1 Massage

In the recent decades, massage has become an important tool used by individuals as a form of relaxation (Seifert et al., 2018; Field et al., 2005). Massage therapy is one of the oldest and best-known body therapies, dating back to 400 BC. Ancient Greek Physicians believed in the healing effect of laying hands on the body and manual manipulation of soft tissue. Hippocrates defined this body therapy as the "art of rubbing" in which mechanical forces (soft or moderate) are applied to the musculoskeletal system of the body (Seifert et al., 2018; Tarsha et al., 2020).

Massage can aid in stress reduction, enhance immune function and inflammatory parameters, and reduce symptomology of anxiety, pain, depression, and anger. In addition, massage is reported to have a positive influence on regulating blood pressure and a healthy heart rate (Seifert et al., 2018; Tarsha et al., 2020). Massage not only alleviates somatic pathology but enhances psychological wellbeing. It has been recognised as an effective intervention for numerous age groups and populations. (Tarsha et al., 2020).

Cortisol output increases following stress, a heightened cortisol response can be induced in experimental conditions as well as be reduced following relaxing therapies such as massage (Field et al., 2005). Cortisol is a notable culprit in driving neurohormonal changes in the body under stressful conditions. Cortisol is the product of the "fight/flight" autonomic nervous system, released into circulation via the HPA axis. Supporting the efficiency of massage on the management of stress, is a study by Field et al. (1996), where thirty-two women with postpartum depression were randomly assigned to either massage therapy or relaxation therapy over a five-week period. Though both groups self-reported lower anxiety, it was only the massage therapy group that exhibited biochemical changes with decreases in anxious behaviours, salivary cortisol levels (↓ 28%) and urinary cortisol levels (↓ 28%) (Field et al., 1996; Field et al; 2005).

Children and adolescents that are hospitalized for mental health disorders are noted to have elevated cortisol and noradrenaline. In a study involving hospitalized children/adolescents, 52 children were given a 30-minute massage daily for 5 consecutive days, where the controlled group watched relaxing videos. The children that received the massage had lower symptoms of depression and anxiety, with nurses reporting them to be more cooperative with increased nighttime sleep. The massage group also have decreased salvia cortisol levels (↓ 34%) and decreased urinary cortisol levels (↓ 19%) (Field et al., 1996; Field et al., 2005).

Emergency medical services (EMS) staff are exposed to unpredictable stressful conditions consistently, if this stress is not properly managed it predisposes them to various physical and psychological symptoms. To review the effects of massage on stress, a randomized controlled trial of 58 EMS staff divided into a control group (n=29) and an intervention group (n=29) that received bi-weekly Swedish massages over 4 weeks was conducted. The analysed occupational stress levels for the control group showed no differences; however, the intervention group pre-test scores reduced from 130.20 ± 26.45 to 110.41 ± 21.75 (p value = 0.023) after a month of regular massage. The study showed a significant reduction in stress after receiving a massage, and that this form of therapy is effective, easy, and uncomplicated in reducing stress in a high stress profession (Mahdizadeh, 2019).

5.2 Deep Pressure Therapy

Deep pressure therapy is embedded in several universal forms of touch including hugging, cuddling, swaddling, and carrying infants (Case et al., 2020). It involves a deep tactile pressure exerted in a firm touch, hold, hug, swaddle, or squeeze (Chen et al., 2013). Other mammals use deep pressure touch for warmth, protection, and comfort by huddling together providing body to body pressure (Gilbert et al., 2010). To consider the clinical use of deep pressure touch, we must consider the skin organ. The skin and all its sensitive pressure receptors, are sites of events and processes crucial to the way we think about, feel about, and interact with one another, our environment, and ourselves. It is our tactile sense that is one of the first to develop in us humans (Eckstein et al., 2020).

On a practical level the sense of light touch or deep pressure touch helps us to discriminate the location of a stimulus on the skin surface, perceive objects tactually, warn us of danger or injury, and to identify and manipulate objects. It also contributes to an integrated sense of our body, where we are in space and proprioception (Morrison et al., 2010). One essential fact about touch, especially deep pressure touch, is that it can be pleasant. This aspect of tactile sensation is at the heart of the social domain, it allows positive hedonic experiences ranging from reassurance of a pat on the back, a calming hug, holding hands to rocking an infant for bonding all which can be distinguished from light touch that is more a superficial stimulation involving tickling, stroking of body hair, and brushing past something (Blair et al., 2007, Morrison et al, 2010).

Light touch has been observed to induce arousal of the sympathetic nervous system: the division of our autonomic nervous system that gets us biologically ready for fight or flight response. The arousal of the sympathetic nervous system leads to increased pulse rate, heart rate and respiration. In contrast, deep pressure touch has been noted to reduce pulse rate, heart rate and respiration activating the parasympathetic nervous system: the division of the autonomic nervous system involved in the functions of rest, digest, and calm (Diego et al., 2004; Blair et al., 2007; Diego & Field., 2009).

The physiological properties of deep and light pressure touch are supported in a study by Diego & Field (2009), in which participants that received moderate pressure massage exhibited an increase in heart rate variability, suggesting increased vagal efferent activity (a parasympathetic response); whereas those receiving a light stroking massage exhibited decreased heart rate variability associated with a sympathetic response. These outcomes are consistent with previous work by Diego & colleagues (2009), in which moderate pressure massage in premature infants displayed increased vagal activity and gastric motility.

In recent years deep pressure therapy has been rooted in the field of occupational therapy. Deep pressure therapy has been utilised successfully among those on the highly sensitive spectrum of autism as an intervention to calm the body ready for sleep and alleviate feelings of anxiety for these individuals (Chen et al., 2013). The application of deep pressure therapy to calm the nervous system and dates back to the Middle Ages. Mechanical shackles and chains wrapped around a person were used to manage agitated and violent people. In the late 1600s, body jackets replaced the chains, and they had a noticeable beneficial effect compared to the shackles and chains. Individuals no longer went into a primitive stress mode of howling, screaming, or thrashing around as they had done with the chains, but suppressed physical excitement and restored mental tranquillity. The body jacket was later dismissed for ethical reasons and was replaced by pharmacological interventions of sedative drugs and anti-psychotic medication (Krauss, 1987).

The confinement of body jackets raised the question of the possible role of temperature in the positive effects of deep pressure stimulation. Animal studies conducted by Harlow (1958), illustrated that baby monkeys deprived of their birth mother, preferred to cling to an unheated cloth surrogate mother than sit or lie on a warm heating pad, which they interpreted as evidence against the influence of temperature on inducing calm. As cited in Krauss (1987), and in the 1970's by Montagu a "snugly comforting environment," in which a person is tucked in and enveloped by sheets which does not allow air to the pass against the skin, provided the best form of reassurance and security to the body (Montagu., 1986). In the Krauss publication (1987), he quoted Albrecht Peiper "there is no better sedative than to be cradled in a mother's arms".

Years on, several devices have been designed to provide continuous deep pressure touch on the lateral and dorsal parts of the body. Of the first devices developed was by Temple Grandin called the 'squeeze machine' to overcome her problems of oversensitivity and extreme nervousness (Grandin, 1992). Grandin (1992), showed that 60% of participants that experienced the 'squeeze machine' reported relaxation. Furthermore, ratings were collected from 18 of the participants to investigate whether fast or slow rhythmic pressure induced relaxation. Relaxation was rated the highest following slow pulsating rhythmic pressure rather than fast pulsating pressure (Grandin, 1992; Eckstein et al., 2020). Grandin commented that the application of deep pressure touch may be beneficial for those individuals with sensitivity to sensory stimulation and/or those who suffer with acute or chronic anxiety, and that such an approach to care appears to have few, if any side effects (Grandin, 1999).

Grandin claimed that clinically applied deep touch pressure can be a beneficial intervention programme for those with challenging behaviour and severe anxiety. Those with challenging behaviours are often tranquilised by pharmacological interventions or physical restraint. Blairs and colleagues (2007), were interested in the claims that deep pressure touch could be of benefit in reducing agitation and distress, particularly in individuals with challenging behaviour. Observing one man with challenging behaviours and anxiety in a case study, they demonstrated that deep pressure touch as an intervention showed significant reductions in the use of both physical restraint and medication, as well as physiological changes in respiration, pulse rate, and blood pressure (Blairs et al., 2007). The number of incidents, restraints and times of medication usage were collated each month for five months prior to introduction of intervention (deep pressure touch programme) and seven months post intervention. It was observed that from the commencement of the deep pressure touch programme the amount of time the man was restrained, reduced from 1954 minutes pre-intervention to 240 minutes one-month post intervention. Reducing further to 35 minutes the next proceeding two months and 0 to 2 minutes the next four months. Medication usage was approximately 20 times a month prior to intervention with less than 5 times a month post intervention. Mean monthly pulse rate dropped from 84 bpm to 75 bpm and mean monthly blood pressure had a significant reduction from 180/100 to 119/78 mmHg post intervention. Blairs et al. (2007), concluded that psychotic pharmaceuticals and restraint appeared to have little effect on the man's challenging behaviour and anxiety, but the incorporation of deep pressure therapy into the man's daily routine was effective in reducing incidences of his challenging behaviour. Further research is required (controlled trials and controlled case studies) with an aim of increasing the provision of more appropriate safe effective forms of support for those with challenging anxious behaviours (Blairs et al., 2007).

The research into the actual neurological pathways in the brain that elicit the calming effect from deep pressure touch is still in infancy especially in an adult sample. Some research has grounded itself in the theory that it is likely due to the stimulation of dermal and/or subdermal pressure receptors that are innervated by vagal afferent fibres. Thus, signals are carried by the dorsal column system, and projected to the limbic system and hypothalamic structures involved in autonomic nervous system regulation. (Diego & Field, 2009; Reynolds, Lane & Mullen, 2015). There are theories that deep pressure touch may alter brain waves suggesting movement towards theta waves, the waves of slow wave sleep as measured by EEG (Field, 2019).

The influence through the autonomic system includes increases in parasympathetic activity, therefore increasing vagal tone (slowing the nervous system down) but at the same time decreases sympathetic activity, reducing the activation of the stress response and cortisol release from the HPA axis (Field et al., 2005; Reynolds, Lane & Mullen, 2015). Cortisol can be measured via salvia samples that document immediate effects of deep pressure touch responses to the ANS, and cortisol assayed from urinary samples typically assesses long term effects of deep pressure touch. Serotonin, another ANS neurohormone, is assayed from urine samples via the metabolite derivative (5HIAA), serotonin increases when the skin is touched, it calms the body and reduces stress responses by enhancing the production of dopamine and hindering the production of cortisol (Field et al., 2005). In a study conducted by Field (2004), 84 depressed pregnant women were assigned to a control group (standard pre-natal care) and an intervention group: 2x 20-minute massages each week for 16 weeks of pregnancy. At the end of pregnancy groups were compared. Immediately after the massage therapy sessions, women reported lower levels of anxiety and depressed mood. At the completion of the study the women in the massage group compared to the control had salivary cortisol levels reduced by 23%, urine dopamine levels increased 25%, and urine serotonin levels increased 23% (Field, 2004; Field et al., 2005).

5.3 Weighted Blanket

Another commonly used therapeutic modality in the mental health and occupational therapy setting is the weighted blanket (WB) and weighted vest (WV). The weighted blanket and vest have been increasingly employed in public health settings for those individuals with high levels of anxiety or arousal (Chen et al., 2013). Bothe WB and WV are commonly used as an intervention for young children or teens diagnosed with autistic spectrum disorder (Williamson & Anzalone, 1997; Watkins & Sparling, 2014). A sensory modulation treatment tool, where the deep pressure rebalances the proprioceptive system aiding in nurturing, soothing and calming hyper-aroused individuals (Mullen et al., 2008).

Subjective accounts of the weighted blanket suggest increases in the ability to feel safe, comforted, and grounded in the world. Sensory modulation occurs with increased activity in the parasympathetic division of the autonomic nervous system and lower sympathetic activity, as reflected in studies measuring heart rate variability (Chen et al., 2013). Heart rate variability (HRV) is a non-invasive assessment of the cardiac autonomic nervous system (ANS). It is considered to reflect the changes happening within the sympathetic and parasympathetic branches of the ANS (Mejia-Mejia et al., 2020). Three stress metrics in the frequency domain (LF, HF and LF/HF ratio) are calculated to indicate the activity of the ANS. A high LF reading indicates high stress (increase in sympathetic activity) while a high HF indicates low stress (increase in parasympathetic activity), and a large LF/HF value is interpreted as a high stress level (stronger influence of sympathetic and weaker influence of parasympathetic activity or both) (von Rosenberg et al., 2017).

Chen and colleagues (2019), proposed that the utilisation of a weighted blanket during the procedure could provide an alleviation strategy to the physiological arousal experienced due to tooth extraction. Dental anxiety is a type of fear experienced by many individuals, especially in the case of a molar extraction, which is an invasive dental procedure associated with high pain, stress, and anxiety. Chen et al. (2019), designed a randomised controlled crossover trial with adolescents who were allocated to either a control group (no weighted blanket) or experiment group (weighted blanket). HRV spectral metrics illustrated that under third molar extraction without the aid of the weighted blanket LF = 46.74 ± 2.92, HF = 33.34 ± 2.58, LF/HF Ratio = 1.41 ± 0.11. Whereas the experimental group with input from the weighted blanket during third molar extraction had results LF = 42.93 ± 3.10, HF = 40.08 ± 2.56, LF/HF Ratio = 1.08 ± 0.11. These data suggest that the WB decreased sympathetic activity (lower LF value), increased parasympathetic activity (higher HF value and a smaller LF/HF ratio), and thus exhibited characteristic parameters of lower stress occurring in the ANS.

One trial tested the hypothesis that a heavy WB (15 pounds) providing widespread pressure to the body would reduce chronic pain and show improvements in anxiety and sleep, compared to the use of a light weighted blanket. Anxiety and pain assessments were collected pre and post the seven nights subjects employed the weighted blanket during sleep. Results revealed significant reductions in the perception of chronic pain, with a more noticeable effect in those with high levels of anxiety after use of only the heavy weighted blanket (Baumgartner et al., 2021). The accessibility and low-cost aspects of a WB make it a great tool for the interoceptive properties it harnesses in the body under conditions of stress, anxiety, and pain. It was noted that the body requires a certain depth (moderate/deep) of pressure to stimulate certain receptors under the skin to activate "vagal tone" of the parasympathetic nervous system modulating the body back into a state of calmness (Chen et al., 2019).

5.4 Snug Vest

One recent development, and expansion on from the Temple Grandin 'squeeze machine', is the snug vest, a garment where deep pressure is applied to the body through the vest. Unlike the weighted vests that achieves deep pressure via added weights, the snug vest achieves deep pressure by manually inflating an internal airbag. (Watkins & Sparling, 2014; Reynolds, Lane & Mullen, 2015). A 2015 study, a snug vest called the Vayu Vest demonstrated deep pressure applied to the thorax with inflation of the vest reduced arousal (increased parasympathetic activity) in response to a stressor. Respiratory sinus arrhythmia (RSA) considers the variability of heart rate, accounting for changes in breathing. This RSA value is measured in milliseconds and, during the experiment, was at the highest when subjects were wearing the Vayu Vest indicative of a shift into parasympathetic activity. Non-specific skin conductance responses were lowest at the time of wearing the Vayu Vest, also indicative of less sympathetic activity. The observed shifts in both sympathetic and parasympathetic activity, can be reflected in the modulating effects of the ANS and the general feeling of calmness by the wearer (Reynolds, Lane & Mullen, 2015). Anecdotal reports from healthy adult participants included testimonials stating that the vest "immediately had calming effects" and produced a "quick sense of calm" (Reynolds, Lane & Mullen, 2015).

5.5 Hugging

Hugging is a form of deep compression touch, a nonsexual caring physical touch that can convey means of empathy, caring, reassurance, and calm, though very little attention has been put on this aspect of touch (Cohen et al., 2015; Field, 2019). Availability of caring support such as a hug has been perceived to protect individuals against stressful events that elicit physiological distress or increase the risk of physical morbidity and mortality (Cohen et al., 2015). In laboratory studies they have generally found that a hug from a trusted source buffers the usual effect of stress.

One study looking at the effects of hugging on illness engaged 404 adults exposed to a virus that causes a common cold, then quarantined them to observe signs of infection. The researchers assessed baseline antibody levels 5 days prior to viral exposure, in which a viral-specific antibody titer > 4 was associated with reduced odds of becoming infected (Cohen et al., 2015). They also measured post viral exposure, signs of illness and social support, with subjects that frequently hugged had efficient rapid nasal clearance. The percentage of days hugged were recorded and inversely related to infection risk, such that being hugged more frequently was associated with a decreased risk of infection (OR = 0.39 (95% CI: 0.16, 0.95; $p = 0.04$). Those who perceived low social support, with more frequent tension and conflict, had an increased probability of infection after viral exposure. The experiment supports the buffering stress effect of interpersonal touch such as a hug on physical health (Cohen et al., 2015; Field, 2019).

Another hugging study utilizing the collection of salivary and blood cortisol, demonstrated a large effect, with cortisol levels significantly reduced in the blood ($d = 1.13$), and saliva ($d = 1.45$), in the participants that hugged a huggable communication medium. They reported that physical touch (hug) produced an effect on the neuroendocrine system (HPA axis) suggesting its effective use in mental stress relief (Sumioka et al., 2013). This study highlighted the possibility that huggable communication mediums can have the positive effects seen in deep pressure touch independently of the physical touch of a human being.

5.6. Intermittent Compression Systems

The origins of the intermittent compression methodology are rooted in the treatment of lymphedema, with the development into a variety of compression devices to improve lymph hydrodynamic. Over the years intermittent compression devices have been adapted for thrombogenesis and the prophylaxis of deep vein thrombosis due to stasis (reduced blood flow velocity). The precise way stasis is prevented seems to be of less relevance than ensuring the systems are applied properly for each individual case (Morris and Woodcock, 2004). Nonetheless, understanding of the relative efficiency and underlying biological mechanisms of intermittent compression devices require further scientific exploration. All intermittent compression systems have an objective to squeeze blood from the underlying deep veins (assuming valves are proficient), distally to proximally. This process relies on the essence of a pump periodically inflating and deflating air compartments within sleeves that are wrapped around the limb (Morris and Woodcock, 2004). The majority of these compression systems are exclusive to the lower limb with sleeves that may cover the whole leg, the calf, or just the feet. The periodic inflation deflation cycle can be uniformly or sequentially, with graded pressures and inflation rates (rapid or moderate).

Today we see in literature the use of intermittent pneumatic compression (IPC) devices which can be interchangeable with intermittent compression systems. These IPC devices differ from forms of static compression in that they utilize inflatable sleeves that cover a whole limb. They operate by the mechanism of inflating and deflating a series of zones within the sleeves with pressures ranging from 20 to 100 mmHg. While it is postulated that IPC can exert local changes in the arteriovenous circulation, changing hemodynamics and improving post-exercise lactate clearance, these devices are comparable to lower limb massage which has been shown to reduce intramuscular inflammatory signaling (Haun et al., 2017).

On example of an intermittent pneumatic compression device, is the NormaTec (Newton Center, MA) that comprises of a wearable nylon sleeve for the entire length of the lower limb, with multi compartments that cyclically inflate and deflate, with a pneumatic pressure precisely calibrated in peristaltic waveform. This waveform applies dynamic pulsating compression simulating the skeletal "calf muscle pump" moving fluid in a distal-proximal flow with a compression sequence from distal to proximal (Talbot et al., 2012). Haun et al. (2107) reported changes on a cellular level, with 1 hour post NormaTec treatment, with a 31% increase in intramuscular phosphorylated ribosomal protein s6 levels. Other bioactive proteins that help to reduce tissue breakdown such as interleukin 10 (IL-10) and superoxide dismutase 2 (SOD2), were also increased 1-hour post IPC treatment. Seven consecutive days of moderate pressure by the IPC device upregulated sulfridoxin-1 mRNA expression occurs which encodes a protein that reduces oxidative stress.

The team concluded that intermittent pneumatic compression applied externally from the Normatec device as an adjuvant to sub-chronic resistance training induces biochemical changes upregulating recovery related responses and oxidative stress resilience. The data suggested that the device reduced muscle soreness and offset reductions in flexibility induced by resistance training, the mechanisms through which this occurs deserves more attention (Haun et al., 2017). The mechanical methods of IPC devices have been the mainstay for lymphoedema, venous stasis, and recovery from sport or training (e.g. Overmayer and Driller, 2018). Currently, however, little research has examined the utilization of whole body distal-proximal intermittent pneumatic compression on changes in neuro-behaviours, which leads us on to a device the FLOWpresso.

5.7 FLOWpresso

To date, the studies utilising the clinical application of deep pressure touch for which empirical data is available for evaluation has either involved children, and/or utilised specific devices such as weighted vests (Vandenberg, 2002), weighted blankets, or squeeze machines (Grandin, 1992). These interventions would not necessarily be acceptable or feasible for adults with anxiety and/or sleep disturbances. Therefore, to examine the clinical utility and efficiency of deep pressure therapy, an intervention should provide a standardised and effective deep pressure stimulation.

The focus of this thesis resides in examining the effectiveness of a novel mechanical device that utilises deep pressure therapy in alleviating anxiety and stress, and its effect on subjective sleep quality and psychological wellbeing. The FLOWpresso was engineered and developed in Tauranga, New Zealand by Medella Health Ltd. The origins in the innovation of this form of deep compression therapy are rooted in the lack of consistency to outcomes of whole-body lymphatic drainage, as well as the rarity centred around the impact of full body deep compression applications as opposed to a singular limb or one region of the body (D. De Spong, personal communication, January, 2021).

The vision to integrate emerging aspects of whole-body drainage features far infra-red (FIR) rays in this device. A form of electromagnetic energy, the wavelength (FIR, 5.6 to 1000 μm) of which is longer than visible light therefore invisible to the naked eye. Infrared rays facilitate multiple forms of energy to be transferred into subcutaneous tissue without the need to stimulate or heat the skin excessively. One study showed that skin temperature increased to 38 to 39 °C after 30 minutes to an hour of FIR treatment (Shui et al., 2015). This form of dermal therapy is understandable with literature showing FIR increases artery blood flow, peripheral blood circulation, improves endothelial function, reduces blood pressure, and promotes capillary dilation (Shui et al., 2015). The precise mechanisms underlying these systemic changes require more attention, nevertheless the application of far-infrared rays complementing the pressure therapy prompted the addition to the device.

The FLOWpresso is a wearable, non-invasive, and non-pharmacological medical device that combines far infra-red heat and individually controlled chambers, that inflate in a continuous sequential cycle. Specifically, a total of twenty-two individual chambers that inflate, ten on each side of the body, with an additional two chambers under the neck and upper back. To maximise coverage of the inflatable chambers, regions of the body are wrapped in individual wearable components including feet, legs, abdomen, arms, and an inflatable pad under the shoulders. Each inflatable chambers can take between 1 and 20 seconds to inflate depending on the pressure chosen by the individual logged into main controlling unit. They then deflate, moving on to the next chamber sequentially, moving from distal to proximal aspects of the body, repeating the cycle of inflation deflation for a total of 40 minutes.

The cycle starts at the bottom of the feet moving up regions of the ankles, calves, thighs, torso, upper back, and arms. Each time the individual chamber inflates, it applies a deep pressure squeeze to the surrounding small region of the body. Far infrared heat is emitted through the three regions of the body, the legs, the abdomen, and the arms. Heat applied can be varied between 35 to 50 degrees. Each chamber of the device can be individually adjusted, thus individual preference, or tolerance of heat or pressure, can be accommodated and manipulated. The diversified pressures that can be applied at different levels of the body in the FLOWpresso as well as the longer available compression times are supported by the publication of Zalenska et al. (2013), who observed the necessity to applying diversified pressures across multi chambered devices to generate effective transmural pressure for fluid movement.

A small pilot study looking at the effects of the FLOWpresso on sleep and fatigue in stressed individuals over six weeks of weekly treatments, reported a 25% improvement in sleep and 47% improvement in fatigue (Parkes, Beaven, & De Spong, 2020). Though this pilot study only had 11 of participants, it represented an initial effort to demonstrate responses to the typical treatment pressure and temperature settings of FLOWpresso and evaluate the potential effectiveness of weekly 40-minute sessions in a clinical setting over six weeks.

The positive findings of the small-scale pilot, prompted a larger scale intervention study in a cohort of first responders. Such an investigation into the effect of the FLOWpresso on the regulation of sleep, anxiety, and stress has not been previously conducted. Therefore, this initial research on the FLOWpresso aimed to determine its potential as a non-pharmaceutical intervention to improve sleep quality and assist in the reduction of anxiety and stress symptoms in first responders in New Zealand.

Research Aims

Based on pilot work, the current study aimed to investigate whether a 3-week intervention of deep pressure combined with far infrared heat applied by the FLOWpresso, had a positive effect on first responders' subjective sleep, anxiety, stress, and overall wellbeing.

Hypotheses

We hypothesise that over the course of three weeks of treatment via the FLOWpresso participants will observe:

1). A reduction in anxiety and stress symptoms assessed through a self-reported stress and mood questionnaire;

2). An improvement in subjective sleep quality assessed through the PROMIS sleep disturbance questionnaire; and

3). An improved overall wellbeing scored assessed via feelings score in the stress and mood questionnaire.

Chapter Two: Original Study

Effects of cyclical deep pressure applied by the FLOWpresso on sleep and anxiety

Abstract

Background: One-third of adults get less than seven hours of sleep. There are recognised consequences of poor sleep on the brain and nervous system that amplify basic emotional reactivity, and increase negative mood states like anxiety. Sleep appears to be vital to optimal emotional functioning, with under-slept individuals having higher observations of over-anxious and mental distress presentations. Although deep pressure therapy has been utilised in various cohorts to combat a range of pathologies, the effect on sleep and anxiety in individuals working in high stress vocations, such as first responders, is unknown. **Methods:** The effects of the FLOWpresso sequential cyclical deep pressure application on sleep and anxiety were assessed in in a total of 135 first responders in two related studies. Sleep, anxiety, and stress were investigated through a self-reported PROMIS sleep disturbance short form plus a stress and mood questionnaire. All participants received three, forty-minute FLOWpresso sessions over a 3- week period, with one session per week. Data was collected at two time-points: prior to first FLOWpresso session (Day 1); and 1-week after the third FLOWpresso session (Day 21). Pre and post scores were analysed via paired samples t-tests, and the magnitude of difference of means evaluated with Cohen's *d* effect sizes. **Results:** Across the two studies, FLOWpresso significantly lessened self-reported sleep disturbance ($p < 0.001$; $d > 1.05$), stress ($p < 0.001$; $d > 1.05$), and reduced anxiety symptomology ($p < 0.001$; $d > 0.57$). Sleep improved by 25% in both Study 1 and 2, anxiety deceased by ~32%, and self-reported stress was improved by 26 to 28%. **Discussion:** Though there is limited literature evaluating deep pressure therapy, recent studies show its benefits in reducing agitation and mental arousal and calming the body. The results from this study demonstrate the potential use of the FLOWpresso device to have a therapeutic influence on public health and mental well-being.

Take home message: FLOWpresso was effective at alleviating perceived sleep disturbance and improving stress in a sample of first responders.

Keywords: mental health, deep compression, anxiety, sleep, stress

Introduction

Historically health was considered a dynamic balance among interacting forces and required understanding the whole person for treating dis-ease in the body. However, modern approaches to physical health and mental health, is that they are separate, unconnected domains and that a discrete form of pathology must be uncovered and remediated for resolution (Koban et al., 2021). These approaches may be successful in some areas of allopathic medical but in other areas individuals have seen little progress in treatment or relief – for example sleep disorders, stress, anxiety, and psychiatric disorders. These examples share something in common, a network of interacting brain regions, such as frontal-cortical networks with the amygdala. A converging network with overlapping sensitivity to anxiety and physiological sleep, that needs feasible practices to address these issues. (Koban et al., 2021; Sousa et al., 2021).

Sleep is a fundamental primitive state of human beings, a biological requirement for survival just like food, water, and air. It is a daily basic need as we spend nearly one third of our lives asleep, though achieving this biological requirement entails individuals to participant in volitional behaviours (Grandner., 2017). Neuroimaging tracing the electrical circuitry of the brain shows sleep is not passive, or a mere state of rest and disconnection for the brain, but rather a complex and heterogenous state of neuronal activity, potentially aiding in brain functions such as neuroplasticity, immunity, memory consolidation and emotional processing (Dang-Vu et al., 2010). For humans and other mammals, the architecture of sleep is divided into two main states of activity: rapid eye movement (REM) sleep and non-rapid eye movement (NREM) sleep. Cycling approximately every 90 minutes between REM and NREM states four to five times during a night's sleep.

The decimation of sleep throughout most nations due to today's 24-hour society is an endemic in modern society. Large fractions (10-48%) of the global population are under slept, reporting one third of adults having sleep durations substantially below the recommended 7-9 hours sleep per night. Sleep disturbances may be initiated by the demands of life stressors originating within an individual or in the context of the environment in which they live. Regardless of origin, poor sleep can become a potent life stressor, it is a major stress on the neuro-hormonal system of the body. Sleep loss amplifies amygdala (area crucial for emotional processing) and anterior insula activity (responsible for emotional feelings) in which a profile of generalised anticipatory signalling within the amygdala and insula can potentially drive the brain in to a state of heightened threat alertness, increasing negative mood states like excessive worry, anxiety, and avoidance. The role of sleep is a vital process for affective brain regulation and recalibrating limbic cortical regions, with its potential palliative influence on anxiety and other emotional disorders.

New Zealand is one nation not getting enough sleep. A study by Lee and Sibley (2019), revealed that only 58% of New Zealanders are getting the recommended prescription of 7 to 9 hours sleep a night. Whereas 37% were getting less than 7 hours. Another finding from this study was a high proportion of those short duration sleepers had consistent associations with negative psychological well-being (Lee & Sibley, 2019). Similar results to the New Zealand study were found in a study performed in Canada by Dai and colleagues (2020), where they revealed that about one third of Canadian adults slept less than 7 hours a night. These authors also highlighted that sleep problems were associated with worse psychological wellbeing and are a major public health concern, reaching epidemic proportions globally.

Given the widespread impact of psychological stress on the quality of life, the satisfaction of life and the onset of chronic physical disease, it is necessary that targeting sleep and psychological stress should be an integral part of public health strategies. The 2017/2018 New Zealand Health survey found that one in six New Zealand adults have been diagnosed with a common mental health disorder (anxiety, depression, bipolar) some time in their lives, with nearly 9% of adults experiencing psychological distress in the last four weeks (Mental Health & Illness, 2019). The 2020/2021 NZ Health Survey revealed 9.6% of adults experience psychological distress in the last four weeks, an increase from 7.4% in 2019/2020 (Ministry of Health., 2021). Sleep duration problems are a modifiable health behaviour, therefore implementing safe interventions properly to mitigate its burden on individuals and society will be a task of the future in public health and research (Lee & Sibley, 2019).

A form of intervention that calms the body, activates the parasympathetic nervous system, and alleviates feelings of anxiety used among those on the highly sensitive spectrum of Autism is deep pressure stimulation therapy (Chen et al., 2013). It involves a type of deep tactile pressure exerted by firm touching, holding, hugging, swaddling and squeezing (Chen et al., 2013). Over the years, occupational therapists have observed that a very light touch can upregulate the sympathetic nervous system, while deep pressure on to the body promotes parasympathetic activation (Grandin., 1992). Several devices have been designed to provide continuous deep touch pressure on the lateral and dorsal parts of the body. Of the first devices developed was by Temple Grandin called the “squeeze machine” to overcome her problems of oversensitivity and nervousness (Grandin, 1992). Another commonly used intervention in the mental health care settings is the weighted blanket (WB), used for those individuals with high levels of anxiety or arousal. (Chen et al., 2013).

Another form of intervention that deepens the theory around deep pressure stimulation is a novel intermittent pneumatic device called the FLOWpresso. The FLOWpresso device is a wearable device that combines far infra-red heat and individually controlled inflatable chambers, that inflate in a sequential cycle from distal to proximal. The device offers the benefit of monitoring and adjusting the pressure and far infrared heat to each chamber compartment. A small pilot study looking at the effects of the FLOWpresso on sleep and fatigue in stressed individuals over six weeks of weekly treatments, showed a 25% improvement in sleep and 47% improvement in fatigue with feedback such as clearer thinking and a sense of improved wellness (Parkes, De Spong, & Beaven, 2020). Though this pilot study was limited, it indicated that the cyclic deep pressure applied to the body by the FLOWpresso could an effective strategy for improving perceived sleep.

It is vital to increase insight to new interventions that are effective and encourage enhanced sleep, as well as psychological well-being among the general public of New Zealanders. Therefore, the purpose of this study was to examining the effect of the FLOWpresso device on individuals with psychological and sleep stress. Main outcomes measures are those pertaining to self-rated sleep and clinical questionnaires assessing anxiety and stress. Based on pilot work, we hypothesised that the FLOWpresso device intervention would improve self-reported sleep and mental well-being in a cohort of first responders.

Methods

Design

The design of this study was a longitudinal (repeated measures) cohort study investigating a population of First Responders who are exposed to psychological and sleep stress through their working environment after three treatment sessions in the FLOWpresso device. There was no control group, with all participants receiving one weekly forty-minute FLOWpresso session, over three consecutive weeks. During the study period the population of first responders was observed and outcome measures collected on two assessment stages: Day 1 and Day 21 (1 week after the final FLOWpresso session). Main outcomes measures are those pertaining to self-rated sleep and anxiety (stress and mood) via Patient Reported Outcomes Measurement Information System (PROMIS) questionnaires (see below for details). A self-rated general wellbeing score was also included. As a result of the large amount of interest by the population of first responders, the experimental design was conducted twice in different cohorts; thus, this thesis presents two distinct with identical study methodologies: Study A and Study B.

Participants

Participants were recruited through Medella Health Ltd, and internal distribution of invitational emails for the study were sent directly to actively working first responders within five branches of a Bay of Plenty region government department in New Zealand. Upon volunteering and accepting the invitation to be involved in the study, the participants were provided an information sheet, outlining the aims, participant attendance, procedures and risks involved in the study. Inclusion criteria for the study included the following (a) male or female; (b) at least 18 years or older; (c) actively working in a first responder government department in the Bay of Plenty region; (d) had concerns about their sleep, and/or mental health and/or wellbeing; (e) had regular symptoms of disturbed sleep, and/or distress, and/or anxiety; (f) never been treated with the FLOWpresso before; (g) volunteered to participate in this study; (h) read the information sheet; (i) signed the informed consent prior to the first treatment session. Exclusion criteria for the study included the following: (a) pregnancy or breast feeding; (b) cardiopulmonary disorder; (c) any past symptoms of congestive heart failure; (d) malignancy; (e) pacemaker or defibrillator; (f) scoliosis; (g) heart or muscle related diseases; (h) history of blood clots or deep vein thrombosis; or (i) unstable psychiatric illness.

Experiment Setting

For both studies A and B, data collection and FLOWpresso treatment sessions were set up by Medella Health Ltd at five branches of first responder government department worksites in the Bay of Plenty (Tauranga, Rotorua, Taupo, Tokoroa, Whakatane). The FLOWpresso treatment sessions were performed in a cool quiet room, with the temperature of the treatment environment controlled by air conditioning devices at approximately 18 ± 2 degrees Celsius. Due to each branch having different availability and conditions of rooms not all environmental conditions such as lightening, air conditioning and noise could be controlled equally. To reduce stimulating sensory factors in the study environment participants wore an eye mask with a piece of soft tissue paper under it. To lessen the impact of any surrounding environmental sounds participants had headphones supplied that played sounds of nature (e.g. the sound of ocean waves). Participants were asked to keep all of their clothing on during the FLOWpresso treatment session, but to empty their pockets and remove any belts, watches, badges, phones, or pagers.

Experimental Procedures

Volunteered participants had details of the project sent to them email by their employer and once agreed on the terms of the study they were allocated their three-week FLOWpresso session integrated into their work schedule at their specific worksite (Tauranga, Taupo, Tokoroa Rotorua, Whakatane). FLOWpresso technicians trained by Medella Health Ltd provided participants with a FLOWpresso Research Consent Form (Appendix 1) and Participant Information Sheet (Appendix 2) which were signed to consent participation and indicate any health challenges. Upon signed consent, participants filled in their pre-FLOWpresso intervention questionnaires (PROMIS Sleep Disturbance Short Form and Metagenics Stress and Mood Form). Administration of the FLOWpresso intervention could not be blinded to the participants due to the inherent nature of the procedure and engagement.

After screening of the inclusion and exclusion criteria, participants were assigned to perform one initial forty-minute FLOWpresso session and the pressure settings adjusted to the subject's preference and tolerance. Participants received their forty-minute FLOWpresso session with pressure and temperature settings adjusted to the participants preference and tolerance, recorded for use during the rest of the study. For the following two weeks participants were instructed to return weekly to the FLOWpresso allocated room at their worksite, on their assigned day and one-hour time slot to undertake their next two forty-minute FLOWpresso sessions. To help keep schedules coherent for the first responders, the three sessions were organised on the same day at the same time slot each week over the consecutive three weeks.

A final assessment stage was conducted on week four (Day 21), a week after the last FLOWpresso session. The two self-reported questionnaires (PROMIS Sleep Disturbance

Form and Metagenics Stress & Mood Questionnaire) were sent to the participant as an email for them to complete online. They were given a week to complete the post-FLOWpresso intervention questionnaires, unanswered emails were given a follow up email a week later to encourage completion of the post-FLOWpresso intervention questionnaires.

Outcome Measures

Data collection instruments included two qualitative self-reported inventories: the PROMIS Sleep Disturbance Short Form (DSM-5), and the Metagenics Stress and Mood Questionnaire

PROMIS Sleep Disturbance Short Form (DSM-5)

The PROMIS Sleep Disturbance Short Form consists of eight items and analyses clinically relevant domains of sleep difficulties such as subjective sleep quality, sleep depth, restoration associated with sleep; perceived sleep difficulties relating to getting and staying asleep; and perceptions of the adequacy of and satisfaction with sleep, over a seven-day period. The PROMIS Sleep Disturbance questionnaire does not include items associated with specific sleep disorders nor does it provide calculated or estimated sleep quantities of the participant such as total amount of sleep or time to fall to sleep (Cella et al, 2010).

An overall subjective sleep disturbance score over a seven-day period can be calculated by adding up the scores of the relevant domain items. Each item of measure is rated on a 5-point scale: (1 = never; 2 = rarely; 3 = sometimes; 4 = often; and 5 = always), producing scores ranging from 8 to 40, with the higher scores indicating greater severity of sleep disturbance. The clinician reviews the participants score on each item of measure and indicates the raw score for each item. The raw scores of the 8 items are summed to obtain a total raw score. Next, the raw scores are converted to identify the T- score associated with the individual's total raw score. Reliability of the PROMIS Sleep Disturbance Short Form with the full bank form is 0.96, suggesting the short form is reliably measuring the same dimensions as the full item bank form from which it was drawn. The short form's bank's reliability is >0.88 across the score distribution (Cella et al., 2010). The short-from version used in the current study is provided in Appendix 3A.

Metagenics Stress and Mood Questionnaire

This Metagenics Stress and Mood questionnaire assess an individual's response to situations perceived as stressful. It measures levels of distress by total scores summed in a 12-item self-reported form. Participants read a series of statements assessing how they feel, and circle the number 0, 1, 2, or 3 that best describes their feelings or reactions with that statement over the past four weeks. However, to align with the study's final assessment which is one week post treatment course, participants were asked to rate how they are feeling over the last week since receiving their last FLOWpresso session. Responses to each item are made up on a 4-point scale from 0 (Never or not at all), 1 (Some of the time or mild), 2 (Often or moderately), 3 (Always or severely) producing a maximum score of 36. Higher scores indicate more symptoms of distress and altered mood, whilst score 0 indicates the absence of distress, or disturbed mood symptoms, rather more a state of positive mood. Each item is also related to the specific mood categories, with four items in the form denoted to either depression, anxiety, or stress. With each of these categories (depression, anxiety, or stress) a maximum score of 12 can be calculated, allowing observation of certain areas of mood and stress disturbances. Also at the bottom of this questionnaire is feelings score, indicative of a feelings towards own overall health and wellbeing. Scored from a scale 1 to 10, score 1 representing feeling great about own overall health and wellbeing with a score 10 representing not feeling great/hesitant about overall health and wellbeing The Metagenics Stress and Mood Questionnaire version used in the current study is provided in Appendix 3B.

Ethical Considerations

Anonymity was achieved in this study by identifying participants as numeric codes. All participants provided signed informed consent to participant in either study A or study B. The study protocol was approved by the University of Waikato Human Research Ethics Committee and the Health and Disability Ethics Committee. The whole study followed the ethical principles laid out by Code of Ethics of the World Medical Association (Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects). The approved ethics application is provided in Appendix 4.

Statistical Analysis

Data from the self-rated questionnaires were collected and entered into an Excel spreadsheet by the principal primary investigator. No identifiers were included on the questionnaires or into the spreadsheet except a numerical code assigned to each participant. Descriptive statistics reporting mean, standard error, median, mode, standard deviation, and count were calculated in customised Excel spreadsheets. All data is presented as means and standard deviation (±SD) unless stated otherwise. Differences across pre and post treatment data for each self-reported sleep disturbance, anxiety, stress, and feeling scores were calculated using paired two tailed *t*-test with $p < 0.05$ set as statistically significance. All descriptive statistics and two-tailed *t*-test analyses were performed using Microsoft Office 365 ProPlus Excel software (Microsoft Corporation, Redmond, WA, USA). Customised spreadsheets designed by Cambridge CEM (2021) were used for the purpose of calculating the dimension of effect size, standard error of effect size estimate, and 95% confidence intervals for the self-rated sleep disturbance, anxiety, stress, and feeling scores.

Effect size calibrates the difference between pre and post intervention (FLOWpresso). The metric of magnitude of effect size was estimated using Cohen's *d*, in which difference between mean values was standardised by the pooled standard deviation of the difference (standard deviation). Magnitude's of effect are presented as Cohen's *d* with 95% confidence intervals [lower, upper]. To aid the interpretation of effect sizes in this study the threshold of effect size based on Cohen's guidelines considered are: trivial ($d \leq 0.19$), small ($d = 0.20$ to 0.49), medium ($d = 0.50$ to 0.79) and large ($d \geq 0.80$) (Cohen, 1988). An effect size of ±0.2 was considered the smallest worthwhile effect with an effect size of <0.2 considered to be trivial. The effect was deemed unclear if its 95% confidence interval overlapped the thresholds for small positive and negative effects.

Results

A total of $n = 130$ participants enrolled in study (A) communicating their interest in the study at their workplace. Several participants data were incomplete due to not receiving all three weekly FLOWpresso treatment sessions, not completing all questionnaires, emergency call outs, or failing to complete to the post study forms. The final study A sample consisted of $n = 87$ (67% of the total initial sample intake).

A total of $n = 168$ participants enrolled in study. Of these, 68 participants data were excluded from the final data analysis due not showing up for one of the three weekly treatment sessions, emergency call outs, failing to email back post study questionnaires, or were caught in the emergency tsunami evacuation along the Bay of Plenty coast during the experiment period. Though the initial engagement of participants. The final study B sample consisted of $n = 86$ (51% of the total initial sample intake).

Study A Results

Descriptive statistics are presented for the 87 participants that completed each self-rated questionnaire outcome measure (sleep, anxiety, stress and feelings). The mean pre-FLOWpresso score for sleep was significantly higher ($p < 0.001$; Table 1) than the post-FLOWpresso scores indicating fewer sleep disturbances after the FLOWpresso intervention. Statistically significant differences were also observed for anxiety ($p < 0.001$), stress ($p < 0.001$) and feelings ($p < 0.001$; Table 1). The practical significance of these statistically significant results was assessed using Cohen's *d* effect sizes. All differences in the self- reported measures (sleep, anxiety, stress and feeling) were associated with clear effect sizes large enough to be considered meaningful in a clinical setting (Table 2). A forest plot of the effect size data is presented in Figure 1.

Table 1: Mean scores of self-reported questionnaire outcome measures before and after FLOWpresso intervention for Study A

Self-Reported Questionnaires	N	Pre FLOWpresso Scores $\bar{x}$ ± SD	Post FLOWpresso Scores $\bar{x}$ ± SD	Percent Change % ((Post/Pre)-1)x100)
Sleep	87	24.3 ± 5.4	18.2 ± 5.2	↓ 25.0%
Anxiety	87	2.4 ± 1.7	1.6 ± 1.5	↓ 32.3%
Stress	87	4.0 ± 2.0	2.9 ± 1.7	↓ 26.4%
Feelings	87	3.7 ± 1.3	3.0 ± 1.3	↓ 18.5%

N: number of participants; SD: standard deviation; ↓ decrease

Table 2: Mean difference (post-pre) of the self-reported feelings, stress, anxiety, and sleep scores effect size descriptors for Study A

Self-Reported Questionnaire	Mean Difference [95% CI]	*p*-value	Cohens *d* [95% CI]	Effect Size descriptor
Sleep	6.06 [4.48, 7.63]	< 0.001*	1.15 [0.82, 1.46]	*large*
Anxiety	0.77 [0.29, 1.24]	0.002	0.49 [0.18, 0.79]	*small*
Stress	1.05 [0.70, 1.74]	< 0.001*	0.57 [0.26, 0.87]	*moderate*
Feelings	0.69 [0.30, 1.08]	0.001	0.53 [0.23, 0.83]	*moderate*

CI: Confidence Intervals; * $p < 0.05$ statistically significant

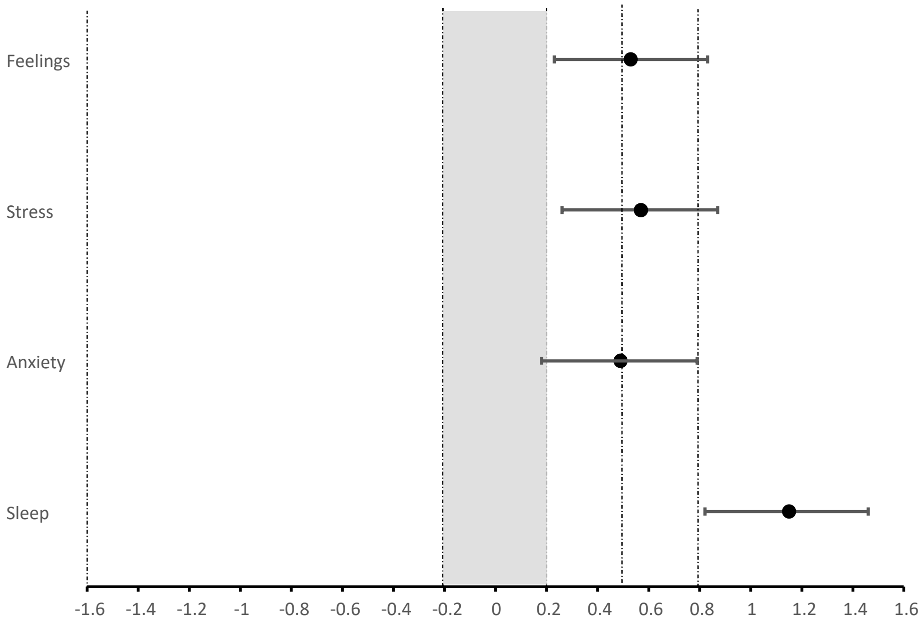

Figure 1: Forest plot illustrating the magnitude of the self-reported feelings, stress, anxiety, and sleep scores in Study A

When looking at the 87 participants, 92% of them reduced their sleep disturbance score post FLOWpresso, with 8% reporting no change or perceiving more sleep disturbance in the week following their last FLOWpresso session (Table 3). For stress, 61% reduced their self-reported post scores; while only 53% reported less symptomology of anxiety and 61% reported improved feelings toward their health.

Table 3: Proportion of participants who reduced, increased, or had no change at Day 21 in Study A

Questionnaires	N	Decreased Post Scores	Increased Post Scores	No Change Post Scores	Incomplete Post Scores
Sleep	87	92% (80/87)	7% (6/87)	1% (1/87)	0% (0/87)
Anxiety	86	53% (46/87)	9% (8/87)	37% (32/87)	1% (1/87)
Stress	86	61% (53/87)	15% (13/87)	23% (20/87)	1% (1/87)
Feelings	87	71% (62/87)	14% (12/87)	15% (13/87)	0% (0/87)

Study B Results

Descriptive statistics are presented for the 86 participants that completed each self-rated questionnaire outcome measure (sleep, anxiety, stress and feelings). Again, the mean pre-FLOWpresso score for sleep was significantly higher ($p < 0.001$; Table 4) than the post-FLOWpresso scores indicating fewer sleep disturbances after the FLOWpresso intervention. Statistically significant differences were also observed for anxiety ($p < 0.001$), stress ($p < 0.001$), but not feelings ($p = 0.075$; Table 4). All differences in the self- reported measures (sleep, anxiety, stress and feeling) were associated with clear effect sizes large enough to be considered meaningful in a clinical setting (Table 5). A forest plot of the effect size data is presented in Figure 4.

Table 4*:* Mean scores of self-reported questionnaire outcome measures before and after FLOWpresso intervention for Study B

Self-Reported Questionnaires	N	Pre FLOWpresso Scores $\bar{x}$ ± SD	Post FLOWpresso Scores $\bar{x}$ ± SD	Percent Change % ((Post/Pre)-1)x100)
Sleep	86	25.2 ± 5.9	18.2 ± 5.2	↓ 25.0%
Anxiety	86	2.7 ± 1.6	1.8 ± 1.6	↓ 32.8%
Stress	86	4.3 ± 1.8	3.1 ± 1.7	↓ 28.5%
Feelings	86	4.1 ± 1.7	3.7 ± 1.7	↓ 11.3%

N: number of participants; SD: standard deviation; ↓ decrease

Table 5: Mean difference (post-pre) of the self-reported feelings, stress, anxiety, and sleep scores effect size descriptors for Study B

Self-Reported Questionnaire	**Mean Difference ± SD [95% CI]**	***p*-value**	**Cohens *d* [95% CI]**	**Effect Size descriptor**
Sleep	6.31 ± 6.00 [4.51, 8.12]	< 0.001*	1.05 [0.73, 1.37]	*large*
Anxiety	0.90 ± 1.60 [0.41, 1.38]	< 0.001*	0.56 [0.25, 0.86]	*moderate*
Stress	1.22 ± 1.73 [0.70, 1.74]	< 0.001*	0.71 [0.40, 1.01]	*moderate*
Feelings	0.47 ± 1.71 [-0.05, 0.98]	0.075	0.27 [-0.03, 0.57]	*small*

CI: Confidence Intervals; * $p < 0.05$ statistically significant

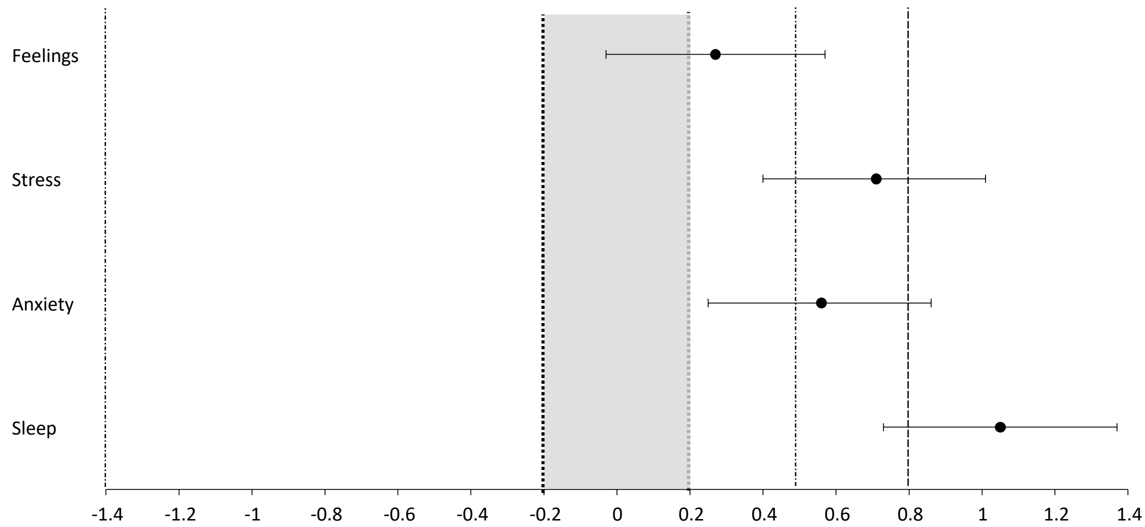

Figure 2: Forest plot illustrating the magnitude of the self-reported feelings, stress, anxiety, and sleep scores in Study B

Of the 86 participants 77% of them reduced their sleep disturbance score post FLOWpresso, with 23% reporting no change or perceiving more sleep disturbance in the week following their last FLOWpresso session (Table 6). For stress (63%) reduced their self-reported post scores. Approximately, half of the participants reported less symptomology of anxiety (55%) and improved feelings (50%) toward their health following the three FLOWpresso sessions.

Table 6: Proportion of participants who reduced, increased, or had no change at Day 21 in Study B

Questionnaires	N	Decreased Post Scores	Increased Post Scores	No Change Post Scores	Incomplete Post Scores
Sleep	86	77% (66/86)	16% (14/86)	7% (6/86)	0% (0/86)
Anxiety	86	55% (47/86)	17% (15/86)	28% (24/86)	0% (0/86)
Stress	86	63% (54/86)	8% (7/86)	29% (25/86)	0% (0/86)
Feelings	86	50% (43/86)	29% (25/86)	15% (13/86)	6% (5/86)

Discussion

This study sought out to investigate whether a 3-week intervention, comprising three, 40-minute sessions of deep pressure combined with far infra-red heat applied by the FLOWpresso device, had a positive effect on first responders' subjective sleep, anxiety, stress, and overall well-being. The over research aim was threefold: observing changes in subjective sleep quality through the PROMIS sleep disturbance questionnaire; observing changes in anxiety and stress symptomology through a self-reported stress and mood questionnaire; and observing changes in overall well-being via feelings score in the stress and mood questionnaire. The findings of the present study indicated that receiving deep intermittent pneumatic pressure combined with infra-red heat can significantly improve sleep quality, reduce anxiety, and stress symptomology, and increase feelings of well-being in first responders over a three-week intervention period. Thus, all three hypotheses proposed in this study were supported. Specifically, Hypothesis One was supported with 92% (Study A) and 77% (Study B) of first responders reducing their sleep disturbance questionnaire scores post FLOWpresso sessions. The lower the PROMIS sleep disturbance score is indicative of a significantly improved perception of sleep quality.

The most significant finding in this study was the positive outcome in improving perceived sleep quality in up to 92% the first responders. In both Study A and B, the 25% reduction in post scores compared to pre-scores was statistically significant and clinically relevant, with the magnitude of the effect sizes for both studies being *large* ($d > 0.8$). Sleep is a universal need for all humans. The absence of sufficient sleep quality and duration can have serious physiological consequences predisposing individuals to physical and physiological symptomology (Mahdizadeh et al., 2019). Numerous studies have reported on the association between sleep disturbances and mood disorders, that sleep, and emotions interact so when in sleep debt, mental and emotional stability deteriorates triggering symptoms of anxiety, confusion, overwhelm as the body overreacts to emotional stimuli (Yoo et al., 2007; Motomura et al., 2013). Sleep and anxiety share a similar pathogenic mechanism in which hyper-aroused states affecting sleep and mood, can dysregulate certain neural pathways such as GABA, in which the inhibitory control is lost. During states of hyperarousal and insufficient sleep, disruptions in the frontal cortex limbic circuitry can occur impairing adequate reactivity and regulation.

Though the study results showed a significant improvement in sleep quality, it is not possible to make conclusions about the specific barriers that might be contributing to the onset of these sleep disturbances. Throughout literature we see many interventions that promote healthy diet, physical activity, substance cessation and mindfulness. Unfortunately, it is apparent that relatively few studies focus on interventions to improve sleep. The absolute burden of sleep and its associated impact on health systems underlines the need for devices and therapies that do not just rely on pharmaceutical intervention. Sleep is a modifiable factor that has direct influence on many other illnesses and health disparities, it seems only plausible that targeting effective strategies to improve sleep would reduce the occurrence and symptomology of these health disparities. Sleep maybe a modifiable behaviour, but is a difficult behaviour to change, especially when occupied by hyper-arousal and anxiety, that tend to make going to sleep difficult because the mind and body are stuck in a state of anticipating threat (Chopko et al., 2021). Useful and effective strategies to complement sleep hygiene recommendations should continue to be explored.

The study presented here did not consider measuring pathogenic mechanisms of sleep and anxiety, but instead observed the actions of a therapy that could complement the methods of medicine in fostering a feasible practice that is effective in reducing sleep debt and psychophysiological distress. With the reduction of subjective sleep disturbance symptoms by 25% following the FLOWpresso intervention, there was also an analogous reduction in anxiety (31 to 33%) and stress (18 to 26%), supporting the role of sleep in brain regulation and mood. Sleep disturbances are potent life stressors and fuel aggravating emotions such as anxiety; thus, potentially minimising these disturbances with the FLOWpresso therapy appeared to concomitantly lessen the vulnerability or sensitivity to these emotions.

It was apparent therefore, that Hypothesis Two was also supported, with the majority of first responders decreased their post anxiety questionnaire scores, signifying that, following the three FLOWpresso sessions, they had *small-moderate* reductions in the severity or symptomology associated with anxiety. While these findings support research performed in autistic children (Edelson, Edelson, & Grandin, 1999), comparisons in healthy adults are difficult, due to a lack of literature. One study did investigate deep pressure touch that was applied by been sandwiched in a hug machine (Hug'm), from mid-chest to calves in 23 college students that had either high trait or low trait anxiety (Krauss., 1987). This study found no difference in heart rate or STAI state anxiety when the machine was on. Although both groups did show a significant decrease in mean STAI state anxiety from the baseline scores, upon comparison there was no significance ($p = 0.27$). These authors did report "encouraging" findings in the participants with high trait anxiety in which this group did register a significant decrease in subjective anxiety during the experiment protocols of the hug machine but not under control procedures (Krauss., 1987). Constant deep touch pressure applied using a weighted blanket, has also been demonstrated to reduce anxiety in a sample of 15 adult females during a dental procedure (Chen et al., 2011). This reduction in anxiety occurred alongside increases in parasympathetic activation assessed via heart rate variability.

Regarding subjective stress, the majority participants felt stress in their life had *moderately* lessened since completing three sessions of FLOWpresso therapy. There are few studies that have investigated the stress-reducing effects of mechanical devices, and the majority of these publications involve devices that apply a constant pressure, as opposed to the sequential, distal to proximal pressure applied by the FLOWpresso. Grandin (1992), reported a calming effect in a study of 40 healthy college students after 5 to 10 minutes, with pressure being applied laterally at 60 psi. This data is supportive of the results seen with the FLOWpresso as it incorporates lateral pressure to the feet, ankles, calves, thighs, abdomen, and arms, with participants feeling calmer with reduced anxiety and stress scores.

Another interesting insight mentioned in the literature was collected from 18 participants who reported the highest level of relaxation during slow pulsating pressure compared to fast pulsating pressure (Grandin, 1992). Other research has reported positive calming effects of pulsating deep pressure pulsating delivered using an oscillating compression sleeve as well as activation of brain regions associated with tactile stroking (Case et al., 2021). The FLOWpresso does not incorporate pulsating pressure, but rather a sequential cycle of deep pressure compressions slowly applied to a specific body area at one time moving on to the next in a slow controlled manner (up to 20 seconds to compress then decompress). The slow oscillating compression can mimic slow and controlled respiration with the inflatable component wrapped around the abdomen. As noted by Case et al. (2021), when humans huddle for warmth or sleep in close contact they experience deep pressure with an oscillatory pattern due to the respiratory cycle. With the above research highlighting the increased subjective relaxing properties of the slow rhythmic pulsating pressure, it is possible the nature of the cyclical rhythm of the FLOWpresso could contribute to the calming effects observed in this study of first responders. While the FLOWpresso therapy did exhibit positive effects on stress and anxiety, the underlying neural pathways that govern the modulations in the stress axes will require further exploration in studies with outcome measures better suited for that investigation.

Hypothesis Three was *moderately* supported in Study A, with a *small* but insignificant ($p = 0.075$) effect of three FLOWpresso sessions on overall feelings of well-being. As we experience a time in humanity with chronic exposure to unpredictable stressful events, sufficient attention to well-being is necessary. It is possible that the FLOWpresso device induces a cascade of reactions similar to tactile deep pressure massage, as seen with improved sleep, anxiety, and stress scores. The beneficial effects of deep pressure compressions to the skin may be mediated by tactile stimulation of dermal and/or subdermal pressure receptors that are innervated by vagal nerve fibres, eliciting an increase in vagal activity upon stimulation. This proposition is supported by Diego et al. (2004) which demonstrated that parasympathetic activity responds to moderate-deep pressure massage with a decreased heart rate.

It is crucial for the development and direction of health to mitigate this worsening scenario of under slept and overanxious humans. The encouragement of self-coping strategies, of awareness and therapies that can reduce the overload burden are desirable, as we look to pave the way to face similar future events and adversity. If improving sleep can support an individual's ability to successfully perform daily activities of life, engage in social, emotional, and organisation tasks without distress, it will be more than just an individual that will benefit but society. As sleep is a mediator for many negative health outcomes if not managed, effective interventions are vital. Taken together, the findings of this recent study advocate for cyclical deep pressure therapy and far infra-red heat applied by the FLOWpresso to elicit changes to subjective symptomology in sleep, anxiety, stress and feelings of health and well-being.

Chapter Three: Practical Applications, Strengths, Limitations, Future Directions and Conclusion

Practical Applications

The number of adults complaining of sleep disturbances is increasing annually in New Zealand as well as globally, and with anxiety and stress-based mood disorders being the leading diagnosis in the mental health sector, the FLOWpresso could potentially be utilised as a form of first line, or adjunctive treatment, in the public health system. Disturbed sleep and stress cause major problems in the workplace, schools, family systems as well as put pressure on district health boards and employers. Lack of sleep exacerbates social deficits, impairs daily living skills, and can negatively impact relationships. There is a shortage of desired treatments outcomes; thus, the FLOWpresso could be advantageous in supporting specific health sectors & workplaces with managing these issues. Targeted audiences from this study will be district health boards, essential first line workers, functional and biological medical centres, where sleep and stress-based mood disorders are prevalent. Also the FLOWpresso may offer new options for those who have an aversion or anxiety to touch by another human, or feel isolated from touch such as in nursing homes, psychiatric wards or rest homes.

The FLOWpresso delivers sequential pneumatic compression technology which has been a prescription for lymphedema for years. Even though the focus of this study was on the relationship between sleep, anxiety, stress and sequential deep pressure from this device, the design fits the physiological criteria for supporting lymph hydromechanics, therefore could be applied in clinical settings for conditions pertaining lymph or venous stasis. Another area of clinical application due to the design and components of sequential pneumatic compression and far infra-red heat is one associated with sports recovery.

Literature supports the use of the commercial external pneumatic compression devices for enhancing skeletal muscle adaptations after high intensity exercise (Haun et al., 2017).

Already in the sports recovery market is a lower limb external pneumatic compression device from NormaTec, that modulates post exercise inflammation, affects muscle proteolysis, and may improve post exercise lactate clearance (O'Connor et al., 2020; Huan et al., 2017; Kephart et al., 2015). The FLOWpresso utilises similar operating technology as external pneumatic compression devices such as the NormaTec; except that the sleeves cover whole limbs and abdomen. Therefore, based on the similarities and success of other external pneumatic compression devices the FLOWpresso, with intermittent pneumatic compression could potentially modulate systemic effects on functional recovery and intramuscular signalling. It is worth noting that the FLOWpresso also contains far infra-red heat that increases artery blood flow, peripheral blood circulation and improves endothelial function which are often therapeutic targets for muscle recovery and adaptation following exercise. Though there are no studies supporting the FLOWpresso in recovery of functional abilities, there is mechanistic support for a possible beneficial role in sports recovery.

Strengths

A strength of this research was that the experimental design was essentially conducted twice (Study A & Study B) with similar settings, population of participants, and outcome measures via self-reported questionnaires. While this was not necessarily a key intention, this provided the possibility of observing how replicable the outcomes and effect sizes were in the two data sets. What was clear, is that the results of the two studies, in different populations, at different times of the year, where remarkably similar.

Another strength was the availability of an introductory pilot study that allowed foresight into the experimental design weaknesses and strengths, outcome variables, and logistic considerations. The pilot study was conducted over six weeks, and thus had a longer treatment course. While the larger scales studies were constrained in terms of their duration, it is noteworthy that beneficial effects were seen in the shorter 3-week time periods used in the experimental studies presented here.

The results from this research are novel and may directly and indirectly benefit first responders, district health boards, the research community, clinical practitioners, and the public. The knowledge gained on the FLOWpresso device as an intervention to improve sleep and anxiety among first responders, means that it can be proposed to be a potentially useful implementation strategy. Importantly, the FLOWpresso device is easy to use and set up in a workplace or home, and the effects of deep compression therapy are non-pharmacological. In addition, the therapy can be delivered in a standardised way and thus, it is not reliant on a skilled masseuse, being completely independent of the technician or practitioner.

Limitations

The findings from this current study should be interpreted within the context of several limitations noted below. While the best attempts have been made to obtain reliable data, these limitations also provide critical directions for future research.

- The current study did not include a comparison or case-control group. Future research should consider including a control group, though when considering study design for health interventions regarding sleep and mental health, randomised controlled trials with controls may not be warranted or realistic, with time series more conducive.

- Sleep, stress and mood assessments were based on self-reported questionnaires (some of which were collected electronically) instead of clinical evaluation and diagnosis. This limitation has the potential to have missing data and questions being misinterpreted. Self-reported questionnaires can be limited in relation to qualitative assessment and judgements. Such data present results that are based on retrospective recall and responses made by a single focal point, but with that said, a systemic review and meta-analysis by Berger did not identify substantial differences in rates comparing self-reported assessments and interview assessments in first responders - rescue workers (Berger et al., 2012).
- Participants may have under-reported clinical symptoms and severity, even when anonymous. It is noted that there may have been concerns with First Responders disclosing anxiety and stress symptoms dues to the stigma the comes with reporting mental health issues.
- The sample was self-selected rather than being random and stratified. Participant intake was based on the participant actively putting their names down for the study from the five allocated workplaces under consideration, which means the results may not be broadly representative of a first responder population, or general public.
- While age, gender, and ethnic diversity was not specifically collected, it was noted that there was a lack of diversity which limits the generalizability of these findings to other samples or to broader characteristics of first responders and the general population. It also precluded incorporation of these variables as covariates.

- A large number of participants were unable to be included due to drop-out. The retention rate was only 49%, and although 168 participants began the study, many failed to complete the treatment course or fill in questionnaires. This limitation is acknowledged due to the naturalistic setting where there is no incentive or location ease to continue treatment and complete the final follow-up questionnaire.
- The FLOWpresso intervention was relatively brief (three weeks) and each session infrequent (once weekly). The current study is unable to address an optimal frequency or duration to maximise health benefits.
- The follow-up data at Day 21, was 7 days after the final FLOWpresso session. Although the study illustrated significant short-term benefits, the maintenance of these benefits long term is unknown.
- It is hard to dismantle the FLOWpresso intervention components such as the rhythmic deep pressure and infra-red heat, in determining causality and the relative mechanistic importance of each component.
- Finally, direct comparisons with other data sets are complicated as this a novel study.

Despite these limitations, this two-point collection series study, demonstrated statistical significance, and future iterations should consider building on the strengths and addressing the limitations highlighted above.

Future Directions

The data observed from this FLOWpresso study is promising regarding aspects of sleep and mental well-being; however, must be viewed as preliminary. This study has provided the foundation for further investigations into the beneficial contribution the FLOWpresso could have in a clinical health setting. While the statistically significant data sheds light on the effectiveness of the FLOWpresso in improving sleep quality, general well-being, anxiety, and stress symptomology after three weeks, its effects are isolated to a short period of time. Currently the long-term beneficial effects of the FLOWpresso have not been assessed, therefore longitudinal studies with larger sample sizes and extended periods of intervention are required to explore the ongoing impacts and benefits. The longitudinal studies will give the opportunity to better understand the directionality of the relationship between FLOWpresso and sleep, anxiety, mood, and stress over the long term.

Since this is a device built on the premise of improving the health and wellbeing of an individual, and therefore society, the use of time series design research will be valuable when considering the effect as an intervention in a clinical setting. This study did not collect age, gender, and race data, therefore lacks in age and gender diversity, to broaden the generalizability to other samples future studies should record the characteristics of the participants and involve a more diverse sample to be representative of the general population.

The utilization of cyclical deep compression and far infra-red light did yield some exciting results, but still the precise mechanism/s are not well understood, and scientific exploratory into these mechanisms could ascertain directions for future benefit. The effects of the cyclical deep compression and far-infrared light could be associated with cellular adjustments, but these were not investigated in this current study, with the use of measurement assessments like fMRI, EEG, and HRV, future investigations could link these cellular adjustments with the responses of the participants. Stress modulation by the

FLOWpresso can be a contribution to these positive results, the underlying physiological processes can result in short term or long-term production of certain mediators, to measure these biological correlations to stress, consideration in future research could include assessments of salivary and urinary cortisol, dopamine and serotonin, and immune markers such as proinflammatory cytokines. Cortisol is an established marker of HPA activity under stressful conditions, and is the most widely used physiological marker, the utilization of this in a study increases comparability among other studies (Eckstein et al., 2020). Pro-inflammatory states are not just exclusive to stress modulation but also in states of sleep deprivation. Inflammatory cytokines such as interleukins (IL-1, IL-6 & IL-17) and C-reactive protein (CRP) could provide key measuring outcomes on both sleep and stress.

Given the novelty of the FLOWpresso device, there is no consensus as to the array of physical and mental states that might benefit from the FLOWpresso, so following on from this study could include the investigation into other subpopulations such as those with head injuries, pain syndromes, fatigue, or hypertension. Finally, although the FLOWpresso has been generally regarded as safe clinical tool, future studies may also be directed at the long-term use of the FLOWpresso device, as well as the cost effectiveness compared to other common medical interventions.

Conclusion

This is the first, large-scale investigation on the sleep, anxiety, and stress effects of the novel intermittent pneumatic FLOWpresso device. A consensus on the role of the FLOWpresso in reducing sleep, anxiety, and stress disturbances does not currently exist, so therefore this is the first study to scientifically measure the effects of cyclical deep pressure and far infra-red applied by the FLOWpresso on sleep, anxiety, stress, and general feelings of wellbeing. In summary, the present thesis reports on the results of two independent studies that demonstrated a positive benefit of the FLOWpresso device on the reduction in anxiety and stress symptomology and an improvement in sleep quality in a cohort of first responders. These data are encouraging and should prompt future research into the underlying mechanisms, the use of the FLOWpresso in the public health sector, and inspire design directions of future medical devices to improve sleep and human well-being, a necessity for leading a healthy life.

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Appendices

Appendix 1: Research Consent Form

Medello Health

FLOWpresso – Research Consent Form

Office Use Only:
ENTERED: ☐
SCANNED: ☐

SECTION 1 - PERSONAL INFORMATION	
FIRST NAME:	PHONE:
PREFERRED NAME:	WORK PHONE:
LAST NAME:	MOBILE:
GENDER:	EMAIL:
DATE OF BIRTH:	ADDRESS:
NAME OF GP:	
MEDICAL PRACTICE:	POST CODE:
OCCUPATION:	ETHNICITY:

SECTION 2 - HEALTH HISTORY			
☐ Congested Heart Failure	☐ Heart problems	☐ Cancer	☐ Asthma/Respiratory/ Breathing
☐ Blood Clots	☐ Low Blood Pressure	☐ Pregnant	☐ Deep Vein Thrombosis (DVT)
☐ Skin Infections	☐ High Blood Pressure	☐ Kidney issues	☐ Acute Infection (affected limb)
☐ Spinal Curvature	☐ Pacemaker	☐ Circulation/Vascular Problem	☐ Other: ....
	☐ Phlebitis	☐ Ulcers	
	☐ Back/Hip issues		

MEDICATION

DECLARATION:	
I DECLARE – The information I have given is true and correct and that I have not withheld any information. I am aware I am part of a research trial and consent to be part of this.	
SIGNED: (If under 16 must be signed by parent/guardian)	DATED:

I have read, or have had read to me in my first language the Participant Information Sheet and I understand what it says.	Yes ☐	
I understand that any data or answers will remain confidential in regard to my identity through a coding & research numbering system. The data will be made publishable, so every effort will be made to ensure confidentiality and anonymity, however, anonymity cannot be guaranteed.	Yes ☐	
I have had the opportunity to talk with whānau or friends about the study.	Yes ☐	
I understand that taking part in this study is my choice and that I may withdraw from the study at any time without this affecting my health care.	Yes ☐	
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be used.	Yes ☐	
I consent to my doctor or other relevant health professional being informed about my participation in the study and to obtain any information regarding my condition if it is relevant for the study.	Yes ☐	No ☐
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: ______________________________

Signature: ______________________ Date: ______________

Declaration by member of Technician team:
I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Technician's name: ______________________________

Signature: ______________________ Date: ______________

Appendix 2: Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Study Title: Effects of cyclical deep pressure applied by the FLOWpresso on sleep and stress

Locality: Medella Health R&D Centre, 4/144 Third Ave, Tauranga

Principal Investigator: Ally Parkes

You are invited to take part in a study looking at the effects of cyclical deep pressure applied by the FLOWpresso on sleep and stress. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. Choosing not to take part won't affect you in any way and won't have any impact on any future health care. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It tells you why we are doing the study, what you need to do if you choose to take part, what the benefits and risks to you might be, and what happens after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not, you will take part in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form at your initial consultation.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study lies in examining the effects of cyclic deep pressure applied by the FLOWpresso on individuals with sleep stress, and/or life stress and/or psychological stress.

This study is being run by researchers based at the Medella Health R& D Centre, Tauranga.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Participants will be eligible for the study if they are (a) male or female; (b) at least 18 years or older; (c) have concerns about sleep disturbance or stress; (d) have weekly symptoms of disturbed sleep and/or stress and/or anxiety (e) never been treated with the FLOWpresso before; (g) are part of the selected corporate group associated with

Medella Health (h) volunteered to participate in this study; (i) volunteered to sign the informed consent.

You cannot participate if you are/have:
(a) pregnancy or breast feeding (b) cardiopulmonary disorder; (c) congested heart failure; (d) malignancy; (e) pacemaker or defibrillator; (f) scoliosis; (g) heart or muscle related diseases; (h) history of blood clots or deep vein thrombosis; (i) unstable psychiatric illness.

If you decide to take part in this study you will need to attend a one of the designated Aetiology Clinics: located in Tauranga, Rotorua, Taupo or Whakatane for an initial consultation with a Technician, where a Consent form, Stress and Mood (SM) Questionnaire and Sleep Disturbance Form (DSM-5) and Feeling Rating Score, will be completed. You will then undertake a 40min FLOWpresso session.

At session 2 and session 3 you will return for another 40min FLOWpresso session.

Post session 3 (week four) you will be emailed on Day 24 the SM and DSM-5 questionnaires to complete.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The anticipated benefits for this study can include improved quality and quantity of sleep, improved ability to cope with stress, improved mental state of mind and decreased occurrences of anxiety and panic symptoms.

The risks of participation in this study are you may experience increased urination for 24 hours and sleepiness.

WHO PAYS FOR THE STUDY?

There is no cost to you of being part of this study and there is no payment to you for your participation.

WHAT ARE MY RIGHTS?

It is your choice to participate in this study and you can pull out of the study at any time without giving any reason. If you do pull out of the study, you will not be disadvantaged at all.

You have the right to access any information about yourself that we have collected as part of the research. We will tell you if we find out anything about you, during the course of your participation in the study, that is relevant to your health and wellbeing.

No material that could personally identify you will be used in any reports.

You can consent for your doctor to be told that you are participating in this study. There is space for you to say whether you would, or would not, like your doctor informed of your participation on the Consent Form.

What happens after the study or if I change my mind?

All records and data collected during the study will be stored in a locked filing cabinet. Some data may be scanned electronically and if so it will be kept on a password protected computer. At the completion of the study, raw data in hard copy will be destroyed by shredding and files that must be kept long term will be stored in a locked filing cabinet at Medella Health Ltd. If you decide to pull out of the study, you may withdraw your assessment information.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Ally Parkes
Principal Investigator
Medella Health Ltd
Cell: 027 633 1557
E: flowpresso@gmail.com

Desiree De Spong,
Clinical Director
Medella Health Ltd
Cell: 0275443424
desiree@flowpresso.co.nz

Appendix 3A: PROMIS Sleep Disturbance Short Form Questionnaire

LEVEL 2 – Sleep Disturbance – Baseline

*PROMIS – Sleep Disturbance – Short Form

Candidate No: ________________________ **Sex:** ❑ **Male** ❑ **Female** **Date:** ________________

Instructions: Please respond to each item by asking (✓ or ✗) one box per row.

						Clinician Use
In the past FOUR (4) WEEKS…						
	Not at all	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**	
1. My sleep was restless.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
2. I was satisfied with my sleep.	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
3. My sleep was refreshing.	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
4. I had difficulty falling asleep.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
In the past FOUR (4) WEEKS…						
	Never	**Rarely**	**Sometimes**	**Often**	**Always**	
5. I had trouble staying asleep.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
6. I had trouble sleeping.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
7. I got enough sleep.	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
In the past FOUR (4) WEEKS…						
	Very Poor	**Poor**	**Fair**	**Good**	**Very good**	
8. My sleep quality was…	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
					Total Raw Score:	

Appendix 3B: Mood and Stress Questionnaire

MOOD & STRESS
QUESTIONNAIRE

Candidate No. : ______________________________ **Date:** ___________________________

Please circle your response to each statement as it applied during the past four (4) weeks. Some of the questions may be repeated, but please ensure you answer them all. There are no right or wrong answers. Don't think too much about your response – your first answer is the best one.

	Column I Never or not at all	Column II Some of the time or mildly	Column III Often or moderately	Column IV Always or severely
1. I am aware of dryness in my mouth	0	1	2	3
2. I find it difficult to work up the initiative to do things	0	1	2	3
3. I tend to overreact to situations	0	1	2	3
4. I worry about situations in which I might panic and make a fool of myself	0	1	2	3
5. I find it difficult to relax	0	1	2	3
6. I feel downhearted and sad	0	1	2	3
7. I am intolerant of anything that keeps me from getting on with what I am doing	0	1	2	3
8. I am unable to become enthusiastic about anything	0	1	2	3
9. I am aware of the action of my heart in the absence of physical exertion (e.g. increased heart rate or missed beat)	0	1	2	3
10. I find myself getting impatient when I am delayed in any way (e.g. traffic lights, lift, being kept waiting)	0	1	2	3
11. I feel close to panic	0	1	2	3
12. I can see nothing in the future to be hopeful about	0	1	2	3

FEELING SCORE: ____________

Appendix 4: Confirmation of Ethical Approval

The University of Waikato
Private Bag 3105
Gate 1, Knighton Road
Hamilton, New Zealand

Human Research Ethics Committee
Roger Moltzen
Telephone: +64021658119
Email:humanethics@waikato.ac.nz

THE UNIVERSITY OF
WAIKATO
Te Whare Wānanga o Waikato

21 January 2021

Dr Alison Parkes
By email: allomello@yahoo.co.nz

Dear Alison

HREC(Health)2020#86 : Effects of cyclical deep pressure applied by the FLOWpresso on sleep and stress

Thank you for your responses to our feedback.

We are now pleased to provide formal approval for your project.

Please contact the committee by email (humanethics@waikato.ac.nz) if you wish to make changes to your project as it unfolds, quoting your application number with your future correspondence. Any minor changes or additions to the approved research activities can be handled outside the monthly application cycle.

We wish you all the best with your research.

Regards,

____

Emeritus Professor Roger Moltzen MNZM
Chairperson
University of Waikato Human Research Ethics Committee