THE EFFECTS OF REPEATED WHOLE BODY WARMING ON SLEEP ARCHITECTURE

A Thesis
by
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Submitted to the Graduate School
at Appalachian State University
in partial fulfillment of the requirements for the degree of
MASTER OF SCIENCE

May 2016
Department of Health and Exercise Science

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Abstract

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Chronic low back pain (CLBP) is defined as chronic pain in the lower back for three or more consecutive months (Buchbinder et al., 2013). In the United States, approximately 84% of the population experiences low back pain, resulting in 23% of the total population developing CLBP. Altered sleep architecture is often associated with CLBP and sleep deficiency with concurring side effects can augment pain, further disrupting sleep. Current guidelines outlined by the American College of Physicians (ACP) and the American Pain Society (APS) recommend physical activity, spinal manipulation, and non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen for treatment of chronic low back pain. Yet, clinicians are primarily prescribing pharmaceuticals as a means of alleviating pain and an increased dependence on these medications has been observed. With the increasing diagnosis of CLBP in the United States, there are elevated economic and financial burdens associated with these medical costs and absenteeism with alternative solutions needing investigation to mitigate the reliance on pharmaceuticals. The current study

aimed to explore whole body heating as a potential therapy for CLBP. Subjects underwent seven consecutive evenings of heating, with completion of the protocol two hours prior to sleep latency onset. Pain was assessed via administration of the McGill Pain Questionnaire prior to the heating protocol (baseline), pre- and post heating on all experimental days and during a 48 hour and two week follow-up. Ability to perform specific tasks was assessed via the functional and symptoms scale, administered at baseline, prior to and following the seven day heating protocol, and during both the follow-up visits. A Sleep Profiler was used throughout the study to measure sleep architecture from the frontal cortex of the brain. A repeated measures ANOVA showed significant decreases in stage N1 sleep ($p < 0.05$) and increases in N3 sleep ($p = 0.001$) from baseline to post-treatment. Each subject's pain perception decreased and allowed for greater functional ability. These findings suggest that seven consecutive evenings of whole body heating protocol altered sleep architecture through the increased amount of restorative stage N3 slow wave, decreased stage N1 sleep, and decreased pain perception. Only small decrements in pain were observed 48 hours and two weeks after the cessation of the intervention.

Acknowledgments

I would like to personally thank Dr. Caroline Smith, Dr. Scott Collier, and Dr. Rebecca Kappus for their advice and direction throughout both the research and writing process. I would also like to extend my gratitude to the participants of this study for their compliance and the time they dedicated to completing this study.

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Chapter 1

Introduction

Chronic low back pain, defined as pain persisting or recurring for three or more months, is one of the most prevalent health complaints among the United States population and is continuing to rise (Buchbinder et al., 2013; Itz, Geurts, van Kleef, & Nelemans, 2013; Mafi, McCarthy, Davis, & Landon, 2013). Approximately 84% of the United States population will experience low back pain at some point in their lifetime, 23% develop chronic low back pain and approximately 11-12% of the population become disabled by this condition (Balague, Mannion, Pellise, & Cedraschi, 2012). When chronic low back pain develops, nearly 65% of chronic low back pain patients continue to experience symptoms twelve months after the onset of pain, which highlights the need for improved pain management strategies (Balague et al., 2012; Itz et al., 2013). Considering the increasing prevalence of chronic low back pain and subsequent healthcare consumed, alternative therapies need to be acknowledged.

Physicians have explicit guidelines by the American College of Physicians (ACP) and the American Pain Society (APS) outlining care for initial chronic low back pain visits (Haas & De Abreu Lourenco, 2015; Mafi et al., 2013). The treatment plan includes: non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen, a referral for physical therapy, increased physical activity, and cognitive relaxation techniques (Haas & De Abreu Lourenco, 2015; Mafi et al., 2013). However, these are not the most common treatments for chronic low back pain. Between 1999 and 2010, the amount of NSAIDs and acetaminophen prescription decreased from 36.9% to 24.5% (Mafi et al., 2013). Whilst this may indicate a decrease in

NSAID use, narcotic prescription increased significantly ($p < 0.001$) from 19.3% to 29.1% (Mafi et al., 2013). Neurotropic drugs, used to decrease nerve pain, are more widely prescribed and have become problematic due to the greater risk for adverse drug reaction (Patel, 2015). Similarly, opioids are used to decrease acute pain and are not to be used for more than a month. Yet, insurance companies are claiming that patients are still using them months to years later (Deyo, Von Korff, & Duhrkoop, 2015). Opioids are highly addictive and once patients begin a regimen with opioids they have difficulty ceasing and become addicted to the drug-induced state (Martell et al., 2007). Limited data are available on pharmacological use in chronic low back pain; however, available data show no significant differences between pharmacological treatment and placebo (Balague et al., 2012). Clinically, pharmacological treatments are heavily relied on, but do not solve the underlying issues associated with chronic low back pain and have deleterious side effects.

A common comorbidity of chronic low back pain is disordered sleep and the side effects that are associated with altered sleep architecture (Artner et al., 2013). Patients with chronic low back pain experience increased onset sleep latency and decreased deep sleep, which decreases physical and cognitive functioning, reduces pain thresholds, and lowers overall quality of life (Artner et al., 2013). There are four stages of sleep are wakefulness (awake), non-rapid eye movement sleep stage 1 (N1), non-rapid eye movement sleep stage 2 (N2), non-rapid eye movement sleep stage 3 (N3) and rapid eye movement (REM) sleep stage (Bajaj & Pachori, 2013). Stage N1 is the transitional sleep stage characterized by restlessness. Conversely, stage N3 is the deep, slow wave sleep, which augments restorative sleep (Bajaj & Pachori, 2013; Horne & Shackell, 1987). Increased pain perception leads to increased frequency of doctor visits and narcotics prescription, causing higher risk of adverse

reactions (Patel, 2015). Approximately 55% of all patients suffering from chronic low back pain have difficulty falling asleep or staying asleep throughout the night (Bahouq, Allali, Rkain, Hmamouchi, & Hajjaj-Hassouni, 2013). Even following a treatment with a sleep enhancing pharmaceutical, 42% of patients still experienced insomnia (Artner et al., 2013). Patients with lower pain thresholds or unsuccessful pain therapies and surgeries had higher perceived pain and were more likely to have decreased sleep quality (Artner et al., 2013). Sleep disorders are highly correlated with increased mortality and decreased quality of life (Andrew, Derry, Taylor, Straube, & Phillips, 2014). Increased pain and side effects of poor sleep quality are often not considered by clinicians, principally due to lack of resources or expertise available (Bahouq et al., 2013). Alternative therapies that restore restful sleep architecture should be given further consideration to provide patients with treatments for pain management (Artner et al., 2013).

The growing epidemic of chronic low back pain in adults in the United States emphasizes the need for alternative treatments. The current study investigated the effects of whole body heating on sleep architecture and pain perception as an alternative method to pharmacotherapy. We hypothesized that seven evenings of heating will decrease chronic low back pain perception and improve overall sleep architecture.

Chapter 2

Review of Literature

Introduction

Chronic low back pain (CLBP) affects millions of Americans each year, resulting in billions of dollars spent on healthcare (Balague et al., 2012; Itz et al., 2013). The current alternative treatments available have limited guidelines and are not widely used to treat CLBP (Chandler, Preece, & Lister, 2002; Nadler, 2004). A reliance on pharmaceuticals has inflated these medical costs and alternative methods must be explored in further detail.

Current Treatments for Chronic Low Back Pain

Current guidelines for chronic low back pain management outlined by the American College of Physicians (ACP) and the American Pain Society (APS) suggest inclusion of physical activity, spinal manipulation, acupuncture, and cognitive relaxation techniques in conjunction with prescription medication, such as non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen (Haas & De Abreu Lourenco, 2015; Mafi et al., 2013). There is a large reliance on pharmaceuticals as treatment for chronic low back pain with little focus on alternative treatments.

Pharmacotherapy

Patients are becoming dependent on pharmacotherapy and are at greater risk for developing multiple long-term side effects due to increased pain medication prescriptions (Mehra, Hill, Nicholl, & Schadrack, 2012; Patel, 2015). The most highly prescribed

medications are NSAIDs, neurotropics, and opioids for long-term treatment of low back pain (Lavigne, Nashed, Manzini, & Carra, 2011; Patel, 2015). NSAIDs have the fewest unfavorable side effects, which impacts approximately 13% of the prescribed population (Patel, 2015), including gastrointestinal distress, vomiting, and potential development of cardiovascular problems (Anwar, John Anwar, & Delafontaine, 2015; Patel, 2015). During a twelve month observational study comprising 300 subjects, Patel and colleagues observed neurotropics to increase drowsiness in 46% of subjects, fatigue in 23%, and dizziness in 19% (Patel, 2015). Most medications pose potential side effects, yet and the benefits must supersede the associated risks. Opioids are classified as one of the strongest pain pharmaceuticals and are increasingly being prescribed for low back pain (Deyo et al., 2015). Additionally, opioids have the greatest risk for severe side effects, including addiction (Deyo et al., 2015). Opioids are intended for acute care use of one month or less, nevertheless insurance companies report significantly longer use in 50% of cases (Deyo et al., 2015; Patel, 2015) From 1999 – 2010, opioid use for chronic back pain quadrupled and during this time period, addiction rehabilitation admissions for opioid use increased at the same rate (Deyo et al., 2015). The effectiveness, side effects, and addiction risk of opioids compared to NSAIDs or other pharmaceuticals has yet to be determined and many patients become addicted to opioids due to inadequate management of their chronic low back pain (Deyo et al., 2015; Martell et al., 2007). Approximately 25% of all patients prescribed opioids for chronic low back pain have developed addiction to the medication and show signs of drug abuse, but it is not recognized until the cessation of the prescription (Deyo et al., 2015; Martell et al., 2007). Opioids have also been shown to decrease both deep sleep and rapid eye movement (REM) sleep, leading to a greater pain perception associated with poor sleep quality (Lavigne et al.,

2011). The current pharmacological approach to chronic low back pain management is financially inefficient and the long-term physiological effects have not been thoroughly investigated.

Local Heat Therapy

Localized musculoskeletal heating has been widely utilized to decrease pain in many conditions, although its effects are confined to the region of application and the effects are short lived (Wright & Sluka, 2001). Localized superficial heat is commonly applied to the skin's surface via hot packs, heating pads, or warm water baths (Wellington, 2014). It has been noted that the application of superficial heat can reduce acute pain and associated muscle spasms (Nadler, 2004). Superficial heat applied to the lower back has however been shown to be superior in short-term pain relief over acetaminophen or ibuprofen (Chou & Huffman, 2007). For acute low back pain, Nadler, et al., showed that an overnight heating wrap could be used to reduce low back pain with limited side effects and safety risks (Nadler, Steiner, Petty, et al., 2003). However, this technique has not been investigated in patients with CLBP. Localized heat therapy also benefits the patient by stimulating the thermoreceptors in the skin and reducing the pain signals to the brain and simultaneously increasing range of motion and reducing stiffness (Chandler et al., 2002). In regards to heat application to the skin's surface, clinicians have limited or no guidelines for prescribing whole body heating therapy or even local heating protocols (Wellington, 2014). Unfortunately, due to the limited guidelines and safety precautions of these methods, local heating needs to be carefully monitored (Chandler et al., 2002; Wellington, 2014). Clinically, in hospital settings, local heating can be supervised to minimize the risk for burns and heat

related injury (Chandler et al., 2002). Patients need to be continuously monitoring the temperature of the local heating device while at home, since the safety standards are not met on these devices (Chandler et al., 2002). Superficial heat application is common practice to decrease chronic low back pain, but controlled whole body heat therapy needs further investigation in this patient population (Chou & Huffman, 2007; Wright & Sluka, 2001). The primary investigation of whole body heating as a therapy for chronic low back pain that has been completed thus far shows promise in reducing chronic low back pain (Wellington, 2014).

Whole Body Heating Therapy

Whole body heating has been shown to be beneficial in prior investigations; however, there are no current guidelines in place for clinical use. Previous studies have used whole body heating as a method to alleviate back pain (Kesiktas et al., 2012; Strauss-Blasche et al., 2002). Subjects showed significant increase in social function, general mental health, energy, and general health, while simultaneously observing decreases in physical limitations, body pain, and emotional problems (Kesiktas et al., 2012; Strauss-Blasche et al., 2002). Limitations of these studies are that the subjects were immersed in water cooler than the body's natural core temperature (Tc) of 37°C (Kesiktas et al., 2012). These studies do not consider the age of the person, core body temperature and skin temperature elicited, or length of time the subject subjects were exposed to heat and do not account for the physiological differences that exist between subjects (Andrew et al., 2014; Horne & Shackell, 1987; Kesiktas et al., 2012; Raymann, Swaab, & Van Someren, 2007; Strauss-Blasche et al., 2002).

Passive whole body heating, including hydrotherapy, balneotherapy, and spa therapy, dates back to classical Greek and Roman times as a type of therapy (Bender et al., 2005; Jackson, 1990). A previous study demonstrated that when subjects completed multiple spa therapies for three weeks that the overall severe chronic back pain was reduced significantly (Strauss-Blasche et al., 2002). Long-term pain reduction was also significantly observed in subjects who completed four to six therapies per day for three weeks (Strauss-Blasche et al., 2002). The limitations of this study included combining therapies together and thus, the authors could not determine which therapy decreased the subjects' pain (Strauss-Blasche et al., 2002). These subjects strayed from their typical schedules by including therapies six days per week, which may have impacted their perception of pain and confounded significant results (Strauss-Blasche et al., 2002). A similar study was conducted in which the subjects completed ten sessions of physical therapy or balneotherapy (Kesiktas et al., 2012). The subjects who underwent the balneotherapy had significant increases in social function, general mental health, energy, and general health, while simultaneously observing decreases in physical limitations, body pain, and emotional problems (Kesiktas et al., 2012). Limitations of this study are that the subjects who participated in balneotherapy were immersed in 36°C water, which is less than the body's natural core temperature (Tc) of 37°C (Kesiktas et al., 2012). Again, this protocol lacks one independent variable and may be due to the relaxing atmosphere, the warm water, the minerals added to the water, or the exercise that the study design incorporates (Kesiktas et al., 2012). These studies do not consider the age of the person, core body temperature and skin temperature elicited, or length of time the subject subjects were exposed to heat and do not account for the physiological differences that exist between subjects (Horne & Shackell, 1987; Raymann et al., 2007). It is important to account

for differences in body mass and composition because this may change the response to heating.

Cutaneous whole body heating has been shown to reduce sleep onset latency (Raymann, Swaab, & Van Someren, 2005). When there is increased distal temperature, such as in the hands and feet, there is a far better sleep quality than when this is not applied. This is due to the redistribution of blood flow and a minor decrease in core body temperature, the time to sleep onset is decreased and there is greater sleep quality throughout the night (Raymann et al., 2005).

Financial Burden and Need for Alternative Therapies

A majority of Americans will visit a clinician for low back pain; due to the amount of consumed healthcare and prescription medication, it is regarded as one of the greatest financial burdens nationwide (Balague et al., 2012; Buchbinder et al., 2013). In 2004, the estimated direct cost of low back pain was 102.6 billion dollars, which has increased by 12% during each subsequent year (Dagenais, Galloway, & Roffey, 2014). Indirect costs, such as decreased productivity and work absenteeism, accrue an additional 20 billion dollars annually (Mafi et al., 2013). Since 2000, the number of patients who have visited a physician for chronic low back pain has remained relatively constant, but physician costs have increased significantly (Balague et al., 2012). This financial burden has accumulated due to increases in costly prescription pain pharmaceuticals and increased diagnostic tests, such as magnetic resonance imaging (MRI) and computerized axial tomography (CT) scans (Dagenais et al., 2014; Haas & De Abreu Lourenco, 2015). Once chronic low back pain is diagnosed, neurotropic drugs are one of the most widely prescribed drug for treating chronic

low back pain and have the lowest cost efficacy (Patel, 2015). Physical therapy referrals remained the same in treating low back pain, but new and recurring patients seeking medical care from physicians increased from 6.8% in 2000 to 14.0% in 2010, which subsequently inflates the cost associated with lower back pain (Mafi et al., 2013). The ACP and APS guidelines for treating chronic low back pain do include prescription drugs, but rely more heavily on using physical activity and alternative and non-pharmacological therapies to manage pain (Balague et al., 2012).

Sleep Architecture and the Effects on Pain

It is well recognized that sleep can reduce the perception of pain in patients with chronic low back pain (Bunnell, Agnew, Horvath, Jopson, & Wills, 1988; Horne & Shackell, 1987; Lavigne et al., 2011). Chronic low back pain patients often have difficulty falling asleep or staying asleep throughout the night, which increases pain perception (Edwards, Almeida, Klick, Haythornthwaite, & Smith, 2008). The resulting deleterious cycle of sleep deprivation and increased pain is challenging to treat until an intervention can break the cycle (Lavigne et al., 2011). However, the sleep-pain cycle cannot be broken until a separate intervention is utilized to improve pain (Heffner, France, Trost, Ng, & Pigeon, 2011). Typically, clinicians treat the pain without consideration for the associated restorative sleep disturbances due to lack of resources or expertise (Bahouq et al., 2013). Limited data are currently available investigating how sleep can be altered to decrease pain perception in chronic low back patients.

Timing of Whole Body Heating and Effects on Sleep

There is a natural change in body temperatures throughout the day that mandates the wake and sleep of the human body (Lack, Gradisar, Van Someren, Wright, & Lushington, 2008). Whole body heating can be achieved by using a warm water bath or by using a water-perfused suit and previous studies have demonstrated that correctly timed whole body heating can be used as a therapy to increase restorative sleep (Di Nisi, Ehrhart, Galeou, & Libert, 1989; Dorsey et al., 1996; Horne & Shackell, 1987; Raymann et al., 2007). Whole body heating as a therapy to help increase restorative sleep is being investigated with several studies that demonstrate the effects of the whole body heating are largely dependent on timing of the therapy (Bunnell et al., 1988; Horne & Shackell, 1987; Raymann et al., 2007). Bunnell et al., investigated the best timing for this therapy by using water perfused suits to heat subjects for one hour in the morning, afternoon, early evening, and late evening (Bunnell et al., 1988). Participants underwent heating on four different days with one heating session per day (Bunnell et al., 1988). It was concluded that early evening was the best time for the whole body heating therapy because it showed an increase in restorative sleep and a decrease in the effects of sleep deprivation (Bunnell et al., 1988). Similarly, Horne and colleagues determined that a thirty-minute heat therapy session in the evening approximately two hours before sleep onset increased slow wave sleep and REM sleep (Horne & Shackell, 1987). Di Nisi, et al., experimented with passive body heating of young healthy males in the afternoon (Di Nisi et al., 1989). However, due to the extended heating periods of three hours from 2pm to 5pm, there were no significant differences. The authors concluded that this time of day and length of heating was inappropriate for changing the sleep architecture (Di Nisi et al., 1989). Another method that should be explored more is the methods used by Dorsey and

colleagues (Dorsey et al., 1996). Passive whole body heating was completed on two consecutive evenings using warm baths for thirty minutes (Dorsey et al., 1996). The baths lasted for thirty minutes each and the average rise in core temperature was 0.9°C (Dorsey et al., 1996). This phenomenon has not been investigated in patients with chronic low back pain.

Summary

There is a growing epidemic of chronic low back pain in adults in the United States. Typically, pharmacotherapy is prescribed to reduce this pain, but there are many side effects that coincide with this form of treatment. In the present study, the effects of repeated whole body heating on sleep onset latency, sleep architecture (slow wave sleep and REM sleep), and chronic low back pain will be investigated. In previous studies, whole body heating has been achieved via submersion in a warm water bath, often for a set time period (Horne & Shackell, 1987; Raymann et al., 2007). Notably, this does not account for variations in human physiology between subjects, such as body composition, age, or sex. In the present study, a set rise in Tc will be elicited using a water-perfused suit. It has been shown that heating approximately two hours prior to sleep onset can improve sleep architecture and reduce pain perception (Bunnell et al., 1988; Raymann et al., 2007). Therefore, the purpose of this study is to determine if whole body heating will decrease perception of low back pain that has persisted for more than one year and improve overall sleep architecture.

Chapter 3

Methodology

Subjects

Six subjects aged 30 to 65 years with chronic low back pain for at least one year were recruited. The Institutional Review Board (IRB) at Appalachian State University approved this study (Appendix A) and the study was verbally explained before all subjects completed an informed consent prior to participating in the study. All subjects underwent a physical health screening to determine that they were fit to participate in the study (Appendix B). Subjects were excluded from the study if they smoked, had known skin conditions, previous back surgery, prescribed medications known to alter cardiovascular or thermoregulatory control, medications which could alter sleep, were previously diagnosed with hypercholesterolemia, hypertension, cardiovascular disease, metabolic disease, or heat related illnesses.

Experimental Design

Each subject arrived at the Thermal and Microvascular Laboratory at Charleston Forge for a total of ten visits, as described below. The time of the study was customized to each participant to allow a time period of two hours post-heating before the subject's routine sleep latency onset. Follow-up visits were conducted 48-hours and two weeks following the completion of the seven day heating protocol.

Screening Visit

A screening visit was completed to determine if participants were suitable to complete the study. The subjects completed an informed consent and were provided with a verbal explanation of the study's objective and experimental procedures. The subject completed a BodPod (COSMED USA, Inc., Chicago, IL, USA) test to obtain body composition. The results were used to determine if the subject was obese, which is an exclusion criterion of the study. Next, baseline pain data were collected via the McGill Pain Questionnaire, the Functional Limitation Scale, and the Symptom Scale (Appendix C).

Baseline Sleep Profile

At the end of the screening visit, subjects took home an ambulatory sleep monitor: Sleep Profiler (Advanced Brain Monitoring, Inc., Carlsbad, CA, USA). Participants resumed ordinary evening and sleeping habits to avoid confounding variables. The Sleep Profiler is an electroencephalogram (EEG) and electrocardiogram (ECG) device that measures frontal lobe brain and heart activity, respectively, while the subjects slept. Baseline data were collected using the Sleep Profiler for three nights: two weekday and one weekend nights.

Whole Body Heating Protocol

Upon arrival to the laboratory, a urine sample was collected and urine specific gravity (USG) was measured using a refractometer (NSG Precision Cells, Inc., Farmingdale, NY, USA) to evaluate hydration status. The USG value of 1.02 units or lower was considered hydrated and was required for continuation of the protocol. If the USG was above 1.02, subjects were required to drink fluids with electrolytes and USG was re-tested until adequate

hydration was achieved. Other check-in procedures included measurement of heart rate, blood pressure, and sublingual temperature to assure that the subject was well and able to complete the protocol. A body weight and separate clothes weight were measured before commencing heating to determine the quantity of sweat lost throughout the experiment. Six copper-constantan thermocouples were placed on the body to measure skin temperature at the following locations: calf, thigh, abdomen, chest, upper arm, and upper back. A water perfused suit (Med-Eng, Ottawa, Ontario, Canada) and rain suit were donned by the subject and the feet were wrapped for the whole body heating protocol. This technique was used to prevent the evaporation of sweat and used to elevated core body temperature. To provide an index of core body temperature, a sublingual temperature probe (BIOPAC Systems, Goleta, CA, USA) was inserted under the subject's tongue. Beat-by-beat blood pressure was recorded throughout the protocol, including systolic, diastolic, mean arterial pressure (MAP), and heart rate (HR) using a Finometer (Finapres Medical Systems, Amsterdam, The Netherlands). After baseline values were recorded, whole body heating was initiated via perfusion of warm water through the water-perfused suits. The circulating water baths were set to 50°C with the temperature of the water being lower as it circulated through the water perfused suit. Subjects rested in a supine position until core body temperature has reached a 0.8°C rise (Figure 1). Core temperature, MAP, BP, HR, and thermal scale were continuously recorded throughout the protocol. Subjects were verbally asked to identify a value on the thermal scale at each at each 0.1°C rise in core temperature. The thermal scale ranges from zero to ten, with zero being very cold and ten being unbearably hot. The thermal scale is a subjective way for the participant to objectify his or her thermal threshold. The time of whole body heating was dependent on a combination of body composition, age, aerobic fitness, and

other individual characteristics, and ranged from approximately thirty to sixty minutes between subjects. The test was terminated if HR reached 85% of age predicted maximum, due to any erratic changes in BP or HR, or at the request of the subject. After completion of the whole body heating protocol, the subject was deinstrumented. This protocol was repeated for seven evenings, with completion being two hours prior to the subject's routine sleep latency onset.

Sleep architecture was measured each evening following whole body warming using the ambulatory Sleep Profiler.

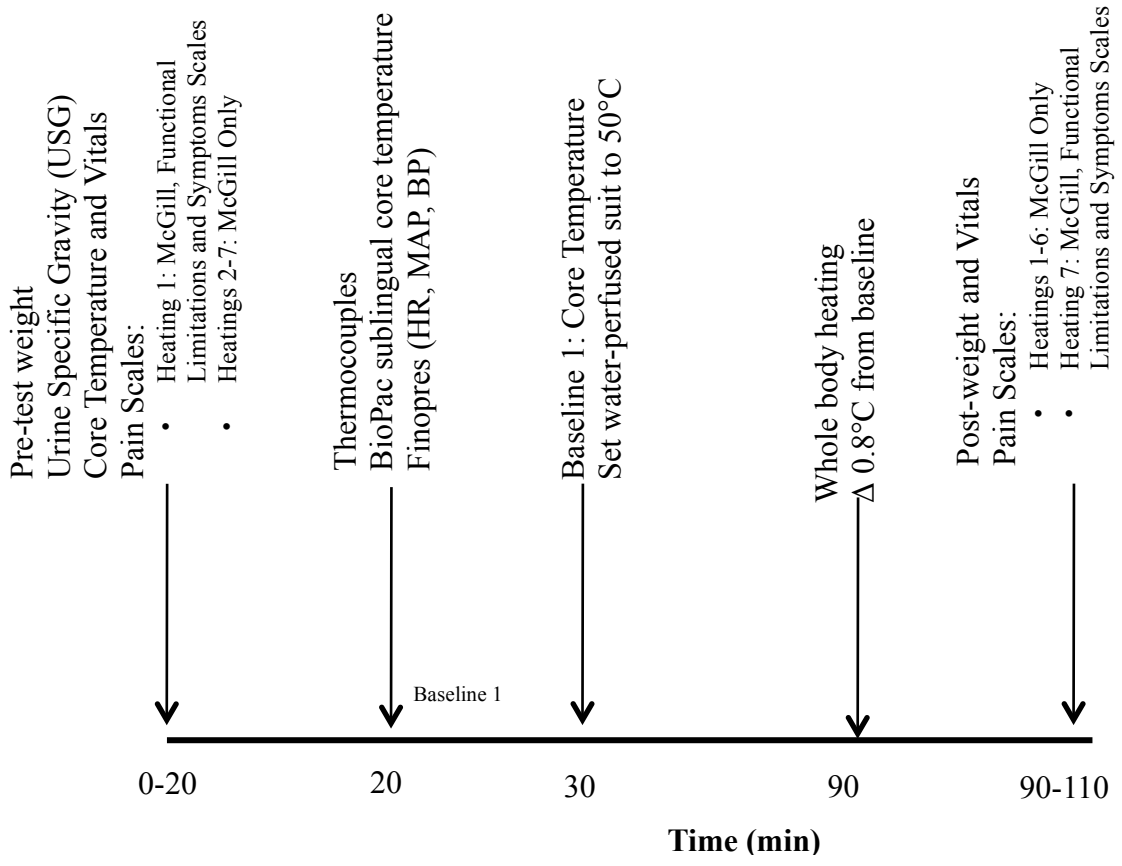

Figure 1. A schematic representation of the whole body heating protocol conducted on seven consecutive evenings.

Pain Scales

As illustrated in Figure 1, the subjects completed the Functional Scale, the Symptoms Scale and the McGill Pain Questionnaire. The Functional and Symptoms Scales were completed by subjects on days one (prior to heating) and seven (post heating) of heating. The McGill Pain Questionnaire was completed prior to and immediately following heating on all heating seven heating days. Pain Scales were administered prior to heating to determine the effects of the previous night's sleep on the perception of pain. The McGill pain scales were completed immediately post-heating was utilized to determine the effects of heating on pain.

Post-Intervention follow up

The subjects returned to the Charleston Forge lab 48 hours and two weeks after the last day of heating for a follow up and to complete the McGill Pain Scale, the Functional Limitation Scale, and the Symptoms Scale. On both occasions, the ambulatory sleep monitor was used to collect sleep data for the night following the 48-hour follow up and the night prior to returning to the lab for the two-week follow up. The post-intervention follow up was used to assess the rate of decay in the treatment effects.

Data Analysis and Statistics

Skin temperature (Tsk) signals were digitized at 40 Hz, recorded and stored for offline analysis using Windaq software and Dataq data acquisition (Windaq, DataQ Instruments, Akron, OH). Core temperature was measured using the BIOPAC sublingual probe (BIOPAC Systems, Goleta, CA, USA). The pain data from the McGill Pain Questionnaires, Functional Limitation Scale, and the Symptom Scale were analyzed to

determine changes in pain perception during the experimental intervention. Sleep data were analyzed to determine changes in sleep architecture, including stage N1, N3 and REM. The data were analyzed using a within-subject analysis and significance was set at $\alpha = 0.05$. The data were underpowered with six subjects. A repeated measures ANOVA was used to determine differences from baseline to the seventh evening of heating for stage N1, N3, and REM sleep.

Chapter 4

Results

Table 1. Subject Characteristics

Subjects (M, F)	Age, yr	Total body fat, %	Systolic BP, mmHg	Diastolic BP, mmHg	HR, bpm	Height, inches	Weight, kg
(3,3)	49.17 ± 1.45	26.6 ± 4.07	126 ± 2.9	79 ± 2.6	66 ± 3.6	67.3 ± 1.1	73.6 ± 3.5

Values are means ± SE. BP, blood pressure; HR, heart rate.

Sleep Architecture

Significant differences were observed in sleep architecture from baseline to the seventh evening of heating (H7) *($p < 0.05$)* and are clinically relevant. Mean absolute times for stages N1, N3, and REM (Table 1, Figures 3-4) showed a decrease in N1 and REM and an increase in N3 from baseline to H7. A repeated measures ANOVA showed significant differences over time for the heating treatment ($p < 0.05$). Paired t-tests showed significant differences between baseline and time point 7 of the heating therapy ($p = 0.001$). There were no differences between any time points in between days 1-6 of heating compared to baseline. Significant decreases were shown from baseline to H7 in stage N1 sleep time ($p < 0.05$). There were no observed differences in REM sleep or overall sleep time from baseline to H7.

Table 2. Descriptive statistics of mean absolute time ± standard error; $p < 0.05$*; $p < 0.001$***.

Sleep Stage	Baseline (hours)	Heating 1 (hours)	Heating 7 (hours)	2 week follow up (hours)
N1	0.40 ± 0.09	0.35 ± 0.09	0.34 ± 0.03	0.40 ± 0.06
N3	0.76 ± 0.35	0.73 ± 0.27	0.82 ± 0.43	0.76 ± 0.38
REM	1.22 ± 0.14	1.68 ± 0.40	1.38 ± 0.23	1.30 ± 0.22

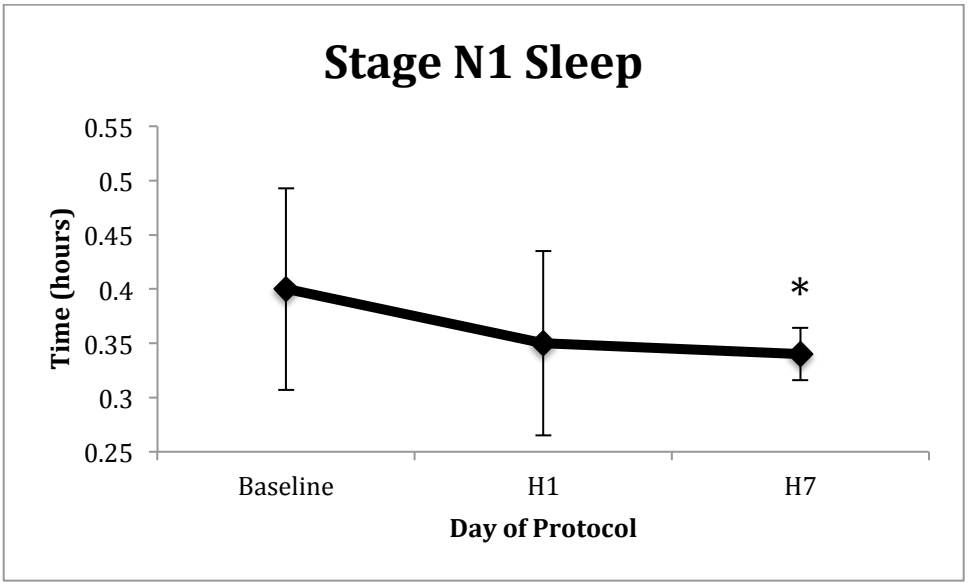

Figure 2. Changes in stage N1 sleep (± SE) from baseline to the seventh heating day. Significant from baseline; $p < 0.05$*.

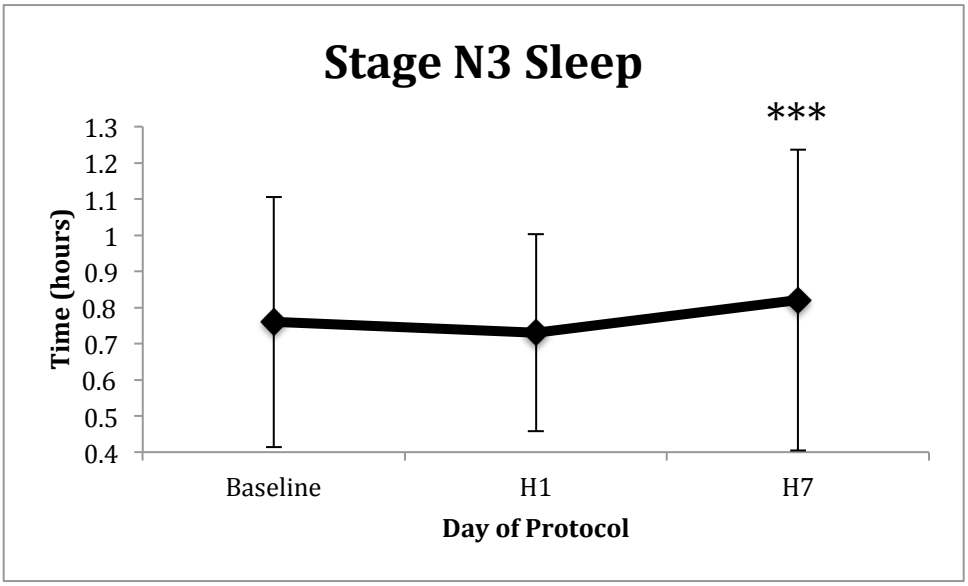

Figure 3. Changes in stage N3 sleep (± SE) from baseline to the seventh heating day. Significant from baseline; $p < 0.001$***.

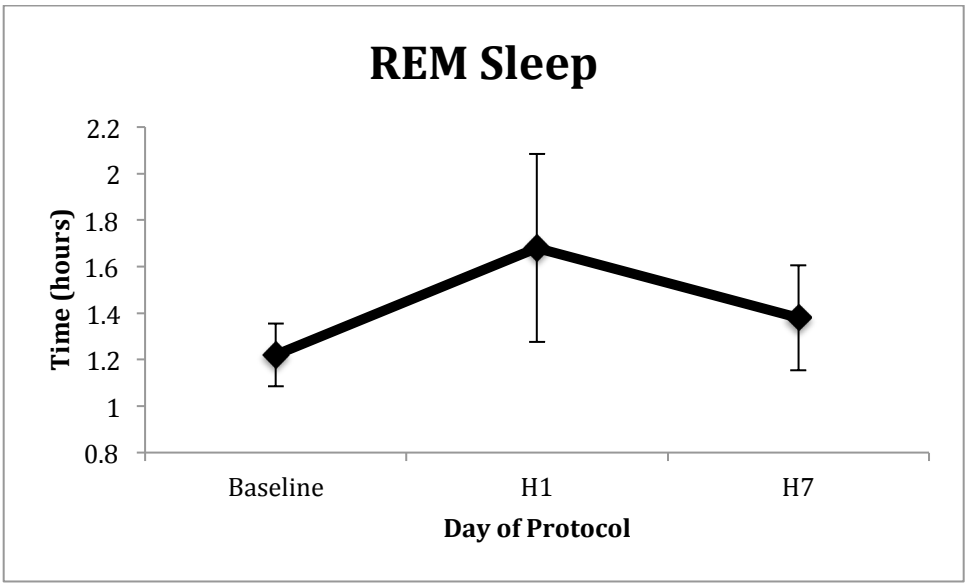

Figure 4. Changes in REM sleep (± SE) from baseline to the seventh heating day. No significant differences were observed in REM sleep.

Pain Perception

In each subject, pain decreased on the McGill Pain Questionnaire from baseline to post heating treatment (H7) and remained lower than baseline during the 48-hour and two week follow up visits (Figure 5). This scale ranges from zero points (no pain) to a maximum point value of 78 (severe pain). Mean data represent the overall changes in pain and show the same decrease in pain after the heating protocol (Figure 6). The Functional Scale was used to evaluate the ability of a subject to perform functional tasks on a daily basis (Figure 7). For this scale, the more points a subject scores, the lower the functional ability of the subject. For each subject, his or her low back pain limited function more at baseline than H7. The score on the Functional Scale remained lower than baseline values for all subjects after the 48-hour and two week follow up visits. The most limited function score is 168 points and a high functioning score is 28 points. The mean data for the Functional Scale show that the sample increased functional ability from baseline to H7. After the heating protocol the decline in

function was greater than at H7 but remained lower than baseline at both the 48-hour and two week follow up visits.

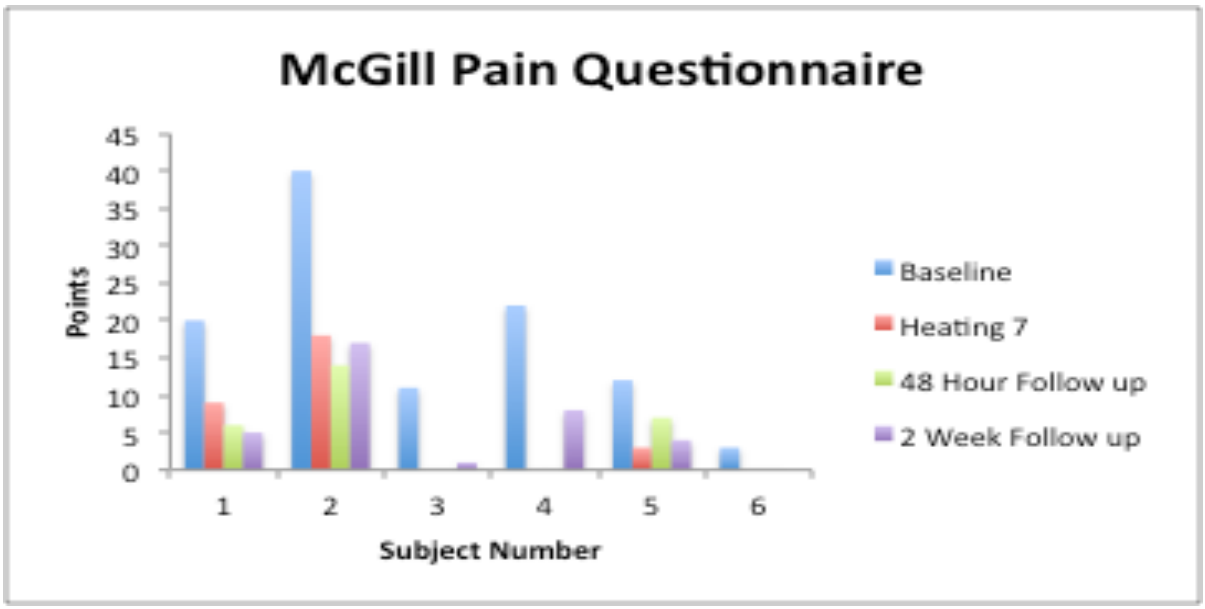

Figure 5. The McGill Pain Questionnaire from each subject at baseline, day 7 of heating, and the 48 hour and two week follow up visits. The McGill Pain Questionnaire ranges from 0 (no pain) to 78 (severe pain).

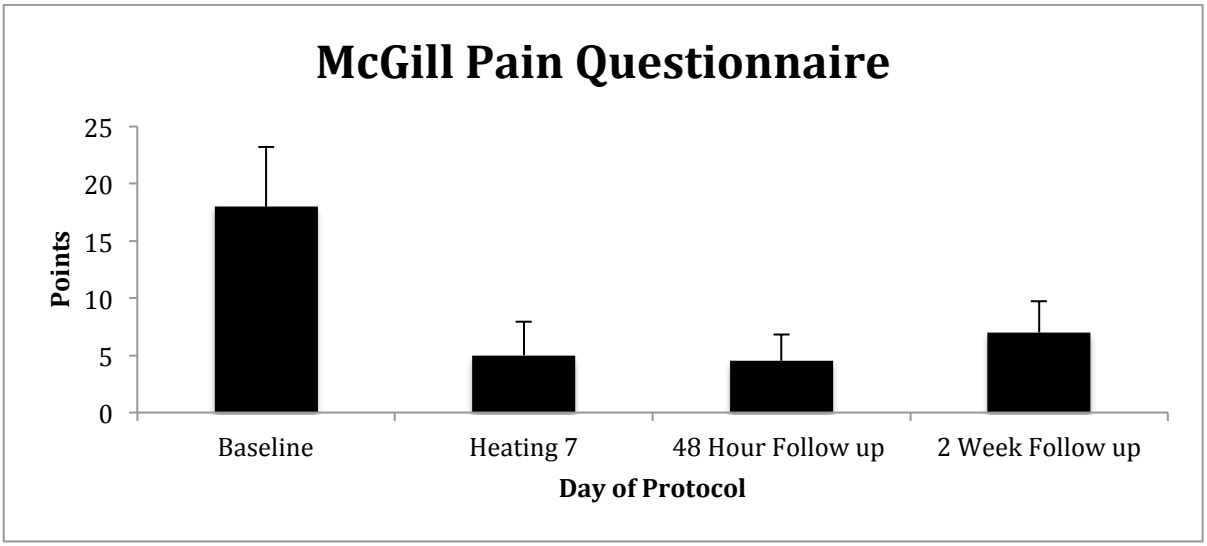

Figure 6. The mean data (± SE) McGill Pain Questionnaire quantifies the pain subjects experienced from 0 (no pain) to 78 (severe pain).

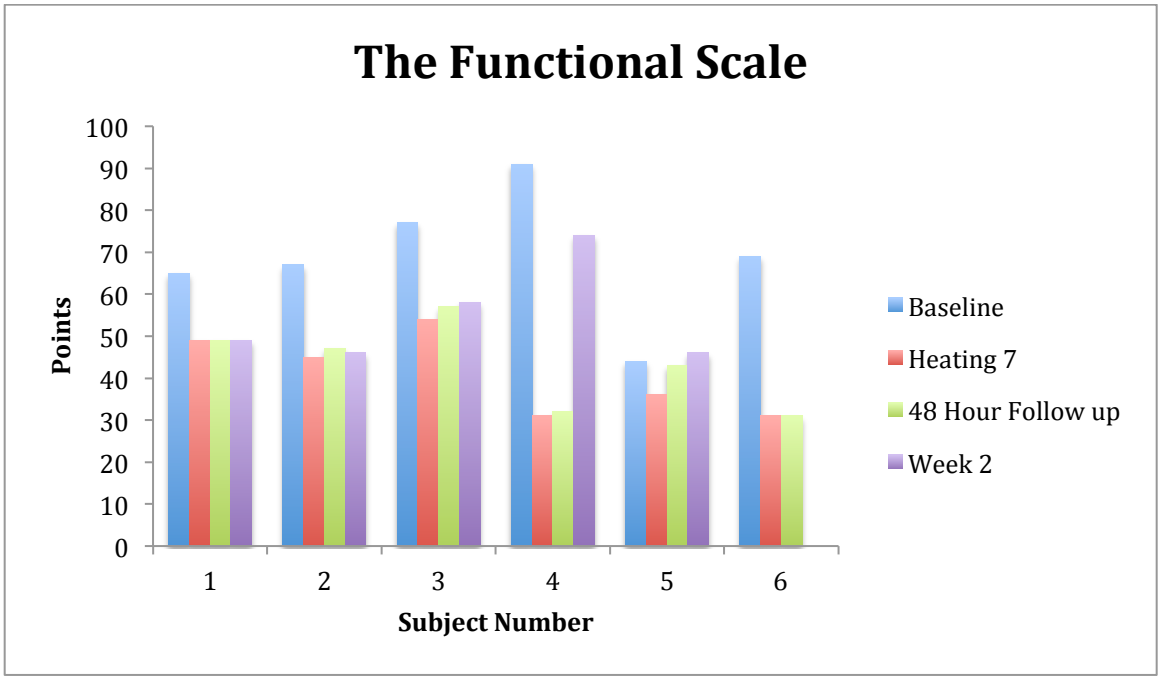

Figure 7. The Functional Scale evaluates the ability of a subject to perform daily tasks and how limitations caused by pain. This figure shows the This scale ranges from 28 (no limitations) to 168 (severely limited).

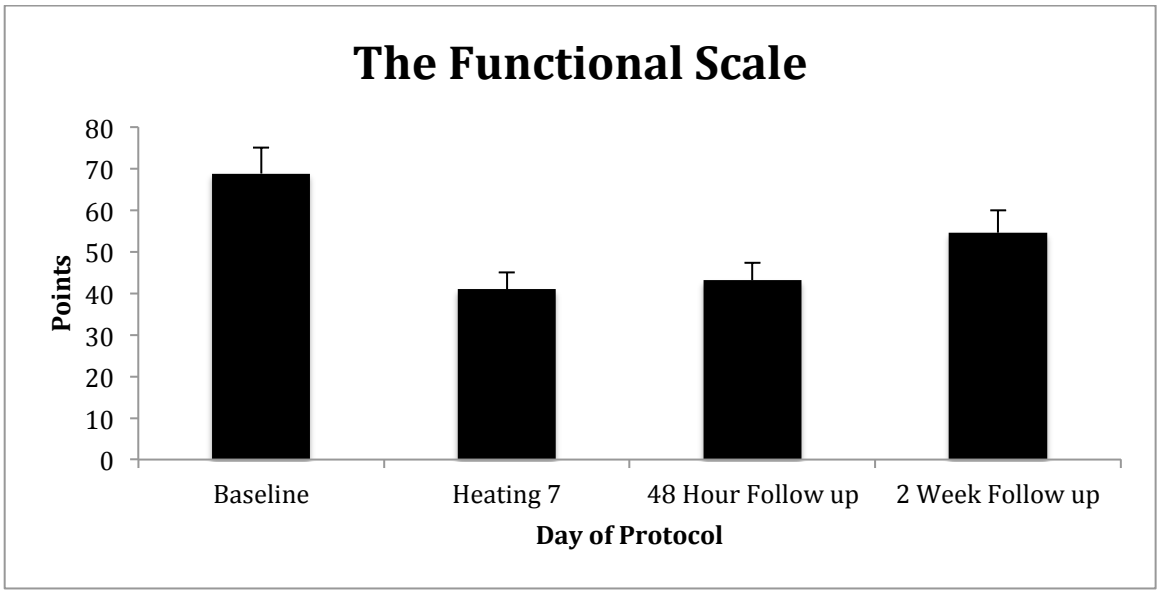

Figure 8. The Functional Scale mean data (± SE) are represented above. This scale evaluates the ability of a subject to perform daily tasks and how limitations caused by pain. This scale ranges from 28 (no limitations) to 168 (severely limited).

Chapter 5

Discussion

The primary findings of this study are that seven consecutive evenings of whole body heating in chronic low back pain sufferers 1) alters sleep architecture with increases in N3 and reductions in N1 sleep, 2) decreases pain perception following seven consecutive days of whole body heating treatment with 50°C water, and 3) only small decrements in pain perception and functional ability were observed two weeks following the cessation of the protocol.

The present preliminary sleep data indicate a decrease in Stage 1 (N1) sleep and an increase in Stage 3 (N3) sleep from the baseline sleep measures to the seventh evening of heating (H7). Slow wave sleep occurs in stage N3 sleep allowing for a more restorative sleep. Conversely, the N1 sleep stage is the more active, restless sleep. Slow wave sleep (N3), is characterized by the electroencephalogram (EEG) patterns, can increase the production of human growth hormone and protein synthesis (Bajaj & Pachori, 2013). Both have shown that these are the most active during the N3 sleep stage, which may restore tissue damage (Horne, 1983). The brain undergoes the most notable increases in restoration and function in stage N3 only (Horne, 1983). If an individual remains in the N1 sleep stage, the body does not repair itself via the aforementioned hormonal and cellular mechanisms (Horne, 1983; Horne & Shackell, 1987). By decreasing the amount of time in N1 sleep and increasing the amount of time in N3, a beneficial shift from greater restless sleep towards restorative sleep occurs. For subjects with chronic pain, more time spent in stage N3 may repair and restore the body and reduce pain (Heffner et al., 2011). Cellular physiological benefits of N3 sleep include increased energy levels through improved ATP production, increased mitosis for tissue

repair, and protein synthesis of the brain (Horne, 1983). Previous research has concluded that heating in the early evening at similar time to the present protocol increased stage N3 sleep in young, healthy subjects (Bunnell et al., 1988; Horne & Shackell, 1987; Horne & Staff, 1983). Limited data are available on sleep architecture and CLBP with the focus primarily on local application of heat therapy or cryotherapy (Drez, Faust, & Evans, 1981; Nadler, Steiner, Erasala, et al., 2003). By using a dual approach to acutely improve pain with whole body heating and indirectly via alterations in sleep architecture and pain perception, there is great potential for increased quality of life and to diminish the healthcare burden.

CLBP sufferers that are able to improve sleep quality reap multiple physiological benefits and may increase their quality of life. It has widely been reported that individuals suffering from chronic pain have low sleep quality (Rohrbeck, Jordan, & Croft, 2007). These individuals often have difficulty sleeping due to the pain they experience resulting in a deleterious cycle of poor sleep and increased pain perception. The present study used repeated whole body heating techniques to induce beneficial effects since the subjects reported little to no pain after each evening of heating. No significant decrease in sleep onset latency from baseline to H7 in the present study, but this may be due to being statistically underpowered, as other studies have shown a significant decrease in sleep latency onset time (Raymann et al., 2005, 2007). Overall, there were reductions in time spent in N1 sleep with a subsequent shift to greater absolute time spent in N3. Limited data indicate improvements in pain with increased sleep quality alone. However, this study illustrated that with the addition of the whole body warming therapy, the subjects were able to have more restorative N3 sleep in conjunction with the heating protocol.

The McGill Pain Questionnaire allowed subjects to identify their pain through descriptive words classifying their pain and quantifying the associated pain producing a cumulative score. The Functional Scale rates specific daily tasks and subjects are asked to rate from 1 (little to no limitation) to 6 (severely limited). In the present study, all subjects showed a reduction in pain and an increase in functional ability from baseline to the seventh evening of the heating protocol. Individuals with higher pain at baseline experienced a far greater reduction in pain after the seven evening of the heating protocol than subjects who indicated mild to moderate pain. The pain perception remained lower than baseline after subsequent follow-up visits. The minimal decay in the response to the McGill Pain Questionnaire and the Functional Scale two weeks after cessation of heating suggests promising potential for mitigating CLBP. Similarly, subjects indicated higher functional ability than baseline during the two follow up visits indicating the thermal therapy may be beneficial in improving daily functional ability. Previous studies have utilized local heating therapy for acute treatment of pain (Abramson, Tuck, Chu, & Agustin, 1964; Lehmann, Masock, Warren, & Koblanski, 1970). These studies concluded that local heating is an effective treatment for acute reduction in pain (Jette & Jette, 1996), but none of these methods have explicit treatment guidelines. Limited data are available for the effects of whole body heating techniques on pain perception. Available data are inconclusive and lack consistency in their methodological approaches, including change in core temperature, heating times, heating methods, pain assessment, and ultimately or pain reduction (Nadler, Steiner, Petty, et al., 2003; Wellington, 2014). The present study indicates a reduction in pain across all participants with the use of a water perfused suit at 50°C (~46 – 48°C water perfusing the suit) to induce a 0.8°C rise in core temperature for seven consecutive evenings.

A reduction in core temperature and an increase in skin temperature are typical before sleep latency onset (Horne & Shackell, 1987; Raymann et al., 2005). In the present study, core temperature was elevated two hours prior to sleep latency onset to exacerbate this decrease in core temperature and induce sleepiness. There are natural changes in core temperature throughout the day with the lowest core temperature at typically sleep latency onset in healthy individuals (Raymann et al., 2005). Beyond the changes in core temperature observed naturally throughout the day, other cellular mechanisms may be involved in reducing pain and altering sleep architecture. Whole body inflammatory responses may be altered during the consecutive days of whole body heating to 0.8°C rise in core temperature. Previously, interleukin-6 (IL-6) has been observed at higher levels in patients with chronic pain, which may interfere with sleep architecture (Heffner et al., 2011). There may be an association between CLBP, poor sleep quality, and IL-6 inflammatory responses that may be investigated in the future (Heffner et al., 2011). An immune response to the heating protocol may also be an underlying mechanism for the reduction in pain both acutely and throughout the follow up period. These potential mechanisms, in addition to other unknown possibilities, may be inducing the reduction of pain perception and the change in sleep architecture.

Limitations

One limitation of this study was the small sample size causing the statistics to be underpowered. Although nonsignificant trends were apparent in some of the outcome measures, more subjects would increase the statistical power. Additional CLBP subjects will be recruited at a latter stage. The inclusion of a control group, exposed to 33°C water, will be established to eliminate a potential placebo effect. Finally, the present study only included

CLBP subjects with nonspecific musculoskeletal causes, preventing this treatment being applied to other clinical groups, which may be explored in the future.

Clinical Significance and Future Direction

These data suggest promising potential for whole body warming as a nonpharmacological, low cost treatment for CLBP. Reduced pain and improved sleep quality may potentially reduce the overall economic and financial burden of CLBP sufferers. The use of thermal therapy in this population may help reduce prescription of pain medication and repeated physician and physical therapy visits. With this protocol, there are specific guidelines for individuals to adhere to without the risk of burns or ineffective therapy. Future direction of this research may include increasing the sample size to improve the statistical power. The addition of a placebo group with thermoneutral water (33°C water perfused suit) to examine sleep architecture and pain perception changes allows elimination of a placebo effect resulting from the protocol itself. At present, the timing and frequency of this consecutive heating protocol has been show to be effective. Adherence to the seven day whole body heating to a 0.8°C rise was effective in reducing pain and positively altered sleep architecture. Future research could further refine the protocol by reducing the core temperature rise and frequency of the heating treatment. The whole body heating therapy can be used as a nonpharmacological alternate therapy for treatment of CLBP with minimal risks and large benefits to the subject with no contraindications, for example prior heat-related illness. These adjustments warrant further investigation and potential expansion to other clinical groups. Once a definitive protocol is established, this study may undergo a clinical

trial to determine this treatment as a nonpharmacological alternate therapy for reducing pain in CLBP patients.

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Appendix A

Appalachian State University
Informed Consent for Participants in
Research Projects Involving Human Subjects

Title of Study: The Effects of Whole Body Heating on Sleep and Pain

IRB Study #: 15-0030

Background/Purpose:

You are being asked to participate in a research study that investigates if whole-body heating will aid your sleep which may lead to decreases in chronic pain symptoms such as fibromyalgia, lower back pain and arthritis. Scott Collier, PhD and Caroline Smith, PhD (Department of Health and Exercise Science at Appalachian State University) are conducting this study.

There is some recent evidence that heat used as a therapy shows beneficial effects on pain symptoms, which may be the result of a better night's sleep following the exposure to the warming therapy. "Warming therapy" could show great promise since it proves to be an alternative to drug therapies.

The aim of this study is to investigate if whole-body heating will increase an individual's quality of sleep and decrease their pain symptoms. You may qualify for this study if you presently have one or more of the following conditions; fibromyalgia, lower back pain and/or arthritis.

The remainder of this form will explain the study in greater detail. If you have any questions, please ask the study personnel that gave you this form.

Study Procedures:

If you choose to participate, you will one of approximately 20 participants. You will be asked to complete ***ONE screening visit*** lasting approximately one hour and **SEVEN consecutive days of whole body warming**, each lasting approximately 1.5 to 2 hours per day. Between visits you will be provided with equipment to measure your sleep. Details of what you will be required to do for each visit are described below.

Screening Day 1 (1 hour): Subjects will report to the Charleston Forge Laboratory where Dr. Caroline Smith and/or Dr. Scott Collier will perform screening procedures, including; manual blood pressure, heart rate, height, weight and body composition (Bod pod) testing**.** The BOD POD system determines the quantity of fat in your body as you sit quietly and comfortably in an air-tight pod. You will wear a tight fitting swim suit and swim cap. To ensure privacy, you will change into a swim suit in a private dressing room, with testing conducted where no one can watch (other than a staff person). You will first be measured for height and weight, and then enter the BOD POD. You will sit quietly for about 5-10 minutes. You can push an escape button if you feel nervous about sitting in the BOD POD.

Subjects will be familiarized with the lab and all the equipment and procedures that will be included in their next 2 visits. You will be asked to fill out a pain scale questionnaire and then will be outfitted with a Sleep Profiler ambulatory sleep system. This will require wearing a soft headband containing a sleep monitor (encephalograph) during your attempted nightly sleep episode the evening following your first lab visit. You will report back to the lab for the heating protocol and return the sleep system at this time (within 4 days of the familiarization).

During your first visit you will also be provided with instructions of suitable clothing to bring to the laboratory for the whole body heating, and will receive instructions for staying hydrated before the study.

EXPERIMENTAL PROCEDURES Lab visit 2 through 8 (1.5-2 hours)

NOTE: Visits 2-8 will be performed on 7 consecutive days and you will be required to do the following on each day:

Subjects may eat a typical days meals prior to arrival at the laboratory. Upon early evening arrival (5-9pm) at the laboratory, blood pressure and body temperature will be recorded and you will be asked to complete a pain scale questionnaire and give a urine sample for hydration status testing. Then, you will recline on a bed while wearing a whole-body heating suit and rain suit. You will be outfitted with a Finapres to measure blood pressure and heart rate. This involves wearing a small monitor and velcro strap on the middle finger of the right hand. Wires (thermocouples) are taped to the skin of the upper arm, back, abdomen, calf, thigh, and chest to measure skin temperature. A small plastic-coated wire (thermistor) will be placed under your tongue to measure oral temperature. Temperature of the water flowing through the water perfused suit is increased to 48°C (118.4°F). Whole body heating is conducted until a 0.8°C (1.4°F) rise in oral temperature is achieved (0.8°CΔT_{oral}) or until you wish to stop. If you experience a bad headache, feel dizzy or nauseous, you should tell the laboratory personnel immediately and may request to stop the study. The protocol will involve being heated in the suit for ~40-60 minutes. Once a 0.8°C increase in oral temperature is achieved the water temperature of the water perfused suit is reduced to decrease oral temperature to the level before the experiment. You will be asked to fill out a pain scale questionnaire following the heating protocol. Following the questionnaire, you will be outfitted with a Sleep monitor to take home. This involves wearing a soft headband containing a sleep monitor (encephalograph) during your attempted nightly sleep episode the evening following the lab visit.

EXPERIMENTAL PROCEDURES Lab visit 9 (20 minutes)

Sleep monitor drop off and questionnaire exam (20 minutes). You will return to the laboratory the following morning prior to 11 am to return the device to the study personnel and complete a pain questionnaire.

EXPERIMENTAL PROCEDURES Lab visit 10-11 (1 hour)

Two days following visit 9, you will be asked to report to the laboratory and answer pain scale questionnaires and will repeat the sleep protocol the following night. The next day you will be asked to report to the laboratory to return the sleep monitor and complete pain questionnaires. Your data will immediately be downloaded from the sleep monitor at each visit, and saved to password protected computer.

Follow-up Lab visit 12-13: (one hour): Two weeks following visit 9, the subjects will report to the laboratory and answer a pain scale questionnaire and will repeat the sleep protocol the following night. The next day the subject will report to the laboratory to repeat visit nine (equipment return).

Risks:

The risks and discomforts involved with participating in this study are:

Whole body heating: Some individuals experience headaches and mild dehydration during whole body heating, and mild dizziness when standing following the experiment. Whole body heating imposes a cardiovascular stress resulting in an increase in heart rate. Heat-related illness is a potential risk of whole body heating, however, core temperature will not exceed ~0.8ºC increase and heating (similar to that experienced during intense exercise or being in a sauna) will be stopped if any signs of abnormal symptoms are observed (cessation of sweating, arrhythmia, nausea, faintness), or you tell us that you are feeling nauseous, light-headed, or otherwise uncomfortable.
Whole body heating may have similar effects to the frequent use of saunas or hot tubs which may temporarily lower your sperm count (fertility) throughout the seven consecutive days of heating. Heating will feel similar to spending 30-40 minutes in a hot tub or sauna.

_____ INITIAL Limited research has suggested temporary reductions in male fertility when men are heated, similar to that experienced following a hot shower, hot tub, or in warm environments.

_____INITIAL If you are a female and pregnant you will be excluded from the study. If you are a female and agree to participate, we will administer a pregnancy test to confirm your eligibility to be heated.

Finapres and/or manual blood pressure: The researchers measure blood pressure using a blood pressure cuff and stethoscope or a continuous method that places a small cuff on your finger that acts the same way as an arm cuff. During the short time the researchers inflate the cuff, your arm may feel numb or tingly.

Ambulatory sleep monitoring: There may be minor risk of discomfort from wearing the blood pressure wrist-device and/or soft headband during your attempted nightly sleep. Both devices contain metal, and so there is a minor risk of allergic reaction if your skin reacts to metals.

Tape and adhesive disks: The tape or adhesive disks could cause a rash on your skin. During screening, please inform us if you are sensitive to tape. If a disk sticks very strongly, removing the disk could cause an abrasion. You could have an allergic reaction to the adhesive remover. The reaction could include rash, itching, fever, or breathing problems. Although rare, it could include changes in pulse, and/or blood pressure, convulsions, shock, and/or loss of consciousness. If a bad reaction should occur, medical help will be summoned.

Skin Temperature: We tape wires to your skin at several sites to measure skin temperature. There are no risks associated with this measure.

Medical Screening: The staff collects the information in a private and professional manner. You may feel shy about being measured. You may request someone of the same sex to conduct the screening.
Bod Pod: Use of this technique to calculate percent body fat poses no know risks to subjects. Some subjects may feel claustrophobic inside the chamber, however, there is a clear window in the front of the chamber, and subjects will be supervised at all times by a member of the laboratory personnel.

Answering Pain Questionnaires should not pose any risk to you.

Benefits:
You may benefit from the study by gaining information related to your sleep quality during the nights you wore the ambulatory sleep devices (information on both total sleep time as well as stages of deep, light, and REM sleep). Society may also benefit by using the findings of this study by instigating whole-body heating as a non-pharmalogical approach to increasing sleep quality and decreasing chronic pain.

Voluntary Participation:
Your participation in this study is entirely voluntary and you may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you would normally be entitled. Your decision about whether or not to participate in the study will not affect your relationship with Appalachian State University.

Questions:
If you have any questions about the research, or in the event of a research-related injury, please contact Scott Collier, PhD at (828) 262-7145, Caroline Smith, PhD (828) 265-8652. If you have any questions about your rights as a research subject, please contact the IRB Administrator at the Appalachian State University Institutional Review Board Office at (828) 262-2692, irb@appstate.edu.

In Case Of Injury:
In the rare event of an injury during testing, standard emergency procedures will be followed. If you get hurt or sick when you are not at the research site, you should call your doctor or call 911 in an emergency. If your illness or injury could be related to the research, tell the doctors or emergency room staff about the research study, the name of the Principal Investigators, and provide a copy of this consent form if possible. Call the principal investigators, Scott Collier or Caroline Smith as soon as you can. You will be responsible for any costs for medical care not paid by your insurance company. No other compensation is offered by Appalachian State University. We have no plans to give you money if you are injured. You have not waived any of your legal rights by signing this form.

Confidentiality of Research Data:
The information we collect about you in this study will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about the combined information. You will not be identified in any published or presented materials. Only the research personnel associated with this study, including the Principal Investigator, study coordinator, research assistants, and all other research staff, and the Appalachian State University Institutional Review Board (IRB), a committee responsible for protecting the rights of research participants, will have access to information that can identify you as a participant or the data obtained in this study. Your identity and the personal information we collect about you will be kept strictly confidential.

Consent To Participate In Research
If you have read this form, had the opportunity to ask questions about the research and received satisfactory answers, and want to participate, then sign the consent form to give your consent to participate and keep a copy for your records.

_____Date_____
Subject signature

This research project has been approved on June 11, 2015 by the Institutional Review Board (IRB) at Appalachian State University. This approval will expire on April 19, 2016 unless the IRB renews the approval of this research, per university policy.

Should you have any questions about this research or its conduct, you may contact:

Dr. Scott Collier, PhD at (828) 262.7145 or email him at colliersr@appstate.edu
Investigators Telephone/e-mail

Dr. Caroline Smith, PhD at (828) 265-8652 or email her at smithcj7@appstate.edu
Investigators Telephone/e-mail

Research Protections
Appalachian State University
Boone, NC 28608
irb@appstate.edu

Appendix B

Medical History Form

All information given is confidential. It will enable us to better understand you and your health and fitness habits.

Date: _____

Age: _____

Height: _____ Weight: _____

Sex:_____

Health History Questionnaire

	Yes	No
Do you ever get chest pains while at rest and /or during exertion?	____	____
If yes, has a physician diagnosed these pains?	____	____
Have you ever had a heart attack?	____	____
If yes, was your heart attack within the last year?	____	____
Do you have high blood pressure (i.e., a reading of more than 150 / 100)?	___	___
If yes, is your high blood pressure currently being treated by medication (e.g., "water pills")	___	___
Have you ever been diagnosed with high cholesterol?	____	____
Do you lose your balance because of dizziness or do you ever lose consciousness?	____	____
Are you currently being treated for any heart or circulatory condition, such as vascular disease, stroke, angina, hypertension, congestive heart failure, poor circulation, valvular heart disease, blood clots, or pulmonary disease?	___	___
Have you ever been diagnosed with a spinal problem or do you experience frequent low back pain?	____	____
Has your physician ever specifically told you not to do "heavy" or "hard" exercise?	____	____
Do you know of <u>any other reason</u> why you should not do physical activity?	____	____

Has your physician ever specifically advised you to avoid the heat? ____ ____

Yes **No**

Do you have a history of heat stroke or other heat intolerance? ____ ____

Have you been exposed to high temperatures frequently (~2 weeks) in the past 3 months (i.e. vacation in a hot country)? ____ ____

If yes, please explain:

_____

_____

Medical History

Do you have or have you ever had: (check if yes)

____ heart murmur
____ extra/skipped heart beats
____ chest pain or pressure
____ high blood pressure
____ heart attack
____ stroke
____ leg cramps
____ varicose veins
____ dizziness/fainting
____ back pain
____ shortness of breath
____ injuries to back, knees, ankles

_____ arthritis
_____ asthma
_____ bronchitis
_____ cancer
_____ diabetes
_____ emphysema
_____ epilepsy
_____ pneumonia
_____ rheumatic fever
_____ scarlet fever
_____ surgery
_____ joint pain

Explanations/Commments/Descriptions:_____

_____

_____

If you have ever been diagnosed with diabetes has your doctor ever identified the presence of peripheral neuropathy?

_____

_____

Do you have a history of rashes, skin disease or disorders of pigmentation, or known skin allergies?

_____
_____

_____
Other diseases/injuries/allergies/medical problems that we should be aware of:
_____
_____

Medicines/Drugs/herbal supplements you are now taking (please list dosages):
_____
_____

_____

_____

Family History

Please indicate the number of blood relative (mother, father, grandparents, siblings who have or have had the following:

Heart attack or stroke before age 50	_____
Heart attack or stroke after age 50	_____
Congenital heart disease	_____
Heart operations	_____
High blood pressure	_____
Diabetes	_____
Substantially overweight	_____
High cholesterol levels	_____

Remarks: _____

_____

Present Symptoms Review

Do you ever experience any of the following during exercise?

_____ Chest pain
_____ Shortness of breath
_____ Heart palpitations
_____ Cough on exertion

Health Inventory

Smoking Habits

Do you smoke cigarettes at present? Yes _____ No _____
If yes, how many per day? <1/2 pack _____ 1/2 to 1 pack _____
1 - 2 packs _____ >2 packs _____

Did you smoke cigarettes in the past and quit permanently? Yes _____ No _____

How may years has it been since you quit? _____
How many packs per day were you smoking before you quit? _____
How many years did you smoke before you quit? _____

<u>Female subjects only:</u>

Are you postmenopausal? Yes _____ No _____

When was the date of your last menstrual cycle (approximate if greater than 1 year):

_____

Have you had a hysterectomy, bilateral oophorectomy, tubal ligation? Yes _____ No _____

Appendix C

Pain Scales

McGILL PAIN QUESTIONNAIRE

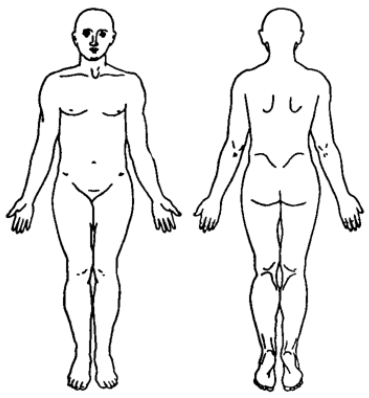
RONALD MELZACK

Patient's Name _____ Date _____ Time _____ am/pm

PRI: S _____ (1-10) A _____ (11-15) E _____ (16) M _____ (17-20) PRI(T) _____ (1-20) PPI _____

1 FLICKERING QUIVERING PULSING THROBBING BEATING POUNDING	11 TIRING EXHAUSTING	
2 JUMPING FLASHING SHOOTING	12 SICKENING SUFFOCATING	
3 PRICKING BORING DRILLING STABBING LANCINATING	13 FEARFUL FRIGHTFUL TERRIFYING	
4 SHARP CUTTING LACERATING	14 PUNISHING GRUELLING CRUEL VICIOUS KILLING	
5 PINCHING PRESSING GNAWING CRAMPING CRUSHING	15 WRETCHED BLINDING	
6 TUGGING PULLING WRENCHING	16 ANNOYING TROUBLESOME MISERABLE INTENSE UNBEARABLE	
7 HOT BURNING SCALDING SEARING	17 SPREADING RADIATING PENETRATING PIERCING	
8 TINGLING ITCHY SMARTING STINGING	18 TIGHT NUMB DRAWING SQUEEZING TEARING	
9 DULL SORE HURTING ACHING HEAVY	19 COOL COLD FREEZING	
10 TENDER TAUT RASPING SPLITTING	20 NAGGING NAUSEATING AGONIZING DREADFUL TORTURING	
	PPI 0 NO PAIN 1 MILD 2 DISCOMFORTING 3 DISTRESSING 4 HORRIBLE 5 EXCRUCIATING	

BRIEF	RHYTHMIC	CONTINUOUS
MOMENTARY	PERIODIC	STEADY
TRANSIENT	INTERMITTENT	CONSTANT



E = EXTERNAL
I = INTERNAL

COMMENTS:

The Functional Limitation Scale

Because of your **low back pain** problems, how do you manage to:	**How?** Answer 1-6
1. Stand?	
2. Walk?	
3. Sit?	
4. Lay down?	
5. Run?	
6. Carry?	
7. Lift?	
8. Throw?	
9. Put on and take off a sweater?	
10. Put on and take off socks?	
11. Bend your back forward?	
12. Bend your back backward?	
13. Sidebend your back to the right?	
14. Sidebend your back to the left?	
15. Turn your back to the right?	
16. Turn your back to the left?	
17. Walk upstairs?	
18. Walk downstairs?	
19. Squat down?	
20. Jump with both feet together?	
21. Lift your right leg, when lying down?	
22. Lift your left leg, when lying down?	
23. Lift your right leg, when sitting?	
24. Lift your left leg, when sitting?	
25. Do your work?	
What do you say about:	
26. The condition of your back?	
27. Your general health?	
28. Return to work?	

Answer with one of the figures 1-6

1. Very good, no problem,
   very satisfying,
   very likely.

2. Good, easily,
   satisfying,
   likely.

3. Rather good, rather easy,
   rather satisfying,
   rather likely.

4. Rather bad, rather difficult.
   rather dissatisfying,
   rather unlikely.

5. Bad, difficult,
   dissatisfying,
   unlikely.

6. Very bad, very difficult/impossible
   very dissatisfying
   very unlikely.

The Symptom Scale

Do you feel/experience:	**How often?** Answer 1-6	**How much?** Answer 7-12
1. Stiffness in your back?		
2. Soreness in your back?		
3. Swelling in your back?		
4. Tension in your back?		
5. Cracking sound in your back?		
6. Numbness in your leg?		
7. Tiredness in your back?		
8. Weakness in your back?		
9. Crick in your back?		
10. Sudden loss of control of your back?		
11. Problems with urination?		
12. Problems emptying the bowels?		
13. Problems with your stomach?		
14. Having a crooked back?		
15. Limping during walking?		
16. Disturbance of balance?		
17. Irritability, short tempered?		
18. Stressed?		
19. Depressed?		
20. Fumblingness in your legs/feet?		
21. Anxiety?		
22. Backache during activity?		
23. Backache during resting?		
Does your back problems affect:		
24. Your sleep?		
25. Your mood?		
26. Your sexlife?		
Do you use, because of back problems:		
27. Support, e.g. corset? Cane? Underline which!		

Note!

Fill in **both** columns!

How often?

Answer with one of the figures 1-6

1. Never/very seldom
2. Seldom
3. Rather seldom
4. Rather often
5. Often
6. Very often/always

How much?

Answer with one of the figures 7-12

7. Nothing/none at all
8. Weak/little
9. Rather weak/rather little
10. Rather strong/rather much
11. Strong/much
12. Almost unbearable/ unbearable, all/maximally

Vita

Megan Michelle Clarke was born in Syracuse, NY to Mary and George Clarke. She graduated from Appalachian State University with a Bachelor of Science in Exercise Science in 2014. She continued at Appalachian State University to pursue her Master of Science in Exercise Science under the direction of Dr. Caroline Smith. During her time at Appalachian State, she was able to present research in clinical exercise physiology at both university and regional conferences. After completion of her M.S. in May 2016, she will begin her Ph.D. at the Pennsylvania State University with a concentration in Exercise Physiology and specific research in thermal and microvascular physiology.

Megan is a member of the American College of Sports Medicine, the American Physiological Society, and was a senator for the university's Graduate Student Association Senate. While attending Appalachian State University for her graduate studies, Megan was able to mentor undergraduate honors students, which fueled her interest in research and academia. She plans to move to State College, PA in the fall to begin her Ph.D.