

TESTING THE UTILITY OF USING PHOTOBIOMODULATION THERAPY TO  
MITIGATE LONG COVID-19 SYMPTOMS: A COMMUNITY WELLNESS  
INITIATIVE

by

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## **Dedication**

This DNP project is dedicated in honor of my family and friends. They say it take a village, and it truly does! To my husband, Dylan, children Elowyn, Everett, and surprise baby, my father in heaven, Kenneth, mother and stepfather, MeiChin and Patrick, brother Trampus, and his family Dayna, Taryn, and MaKinley, Aunt Sherry and Uncle Scott, and our numerous friends thank you for your encouragement, love, and patience as I pursued this endeavor! I know each one of your sacrifices during this time was difficult but your constant belief in me is what drives me to make each of you proud and be the best wife, mother, sister, aunt, niece, friend, and professional I can. I am forever thankful for your grace and the tremendous support each of you have always provided without hesitation to make this dream a reality!

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## Abstract

**Background:** The objective of this research study was to evaluate the utility of global photobiomodulation therapy on subjectively reported symptoms of fatigue and dyspnea (shortness of breath) post COVID-19 infection in a community setting. The most common symptoms of long COVID are fatigue, dyspnea, headache, cognition impairment, hair loss, and sleep disturbances (Lopez-Leonet al., 2021). Reports of chronic fatigue and dyspnea are the most frequently occurring long COVID symptoms that bear the largest impact on daily function and quality of life (Fernández-de-las-Peñas et al., 2021). Long COVID is characterized by symptom persistence lasting greater than three weeks following infection of SARS-COV-2. To date, there are no Food and Drug Administration (FDA) approved treatments of long COVID (Gaffney, 2022). Difficulties that patients have experienced related to long COVID include increased healthcare costs, decreased quality of life, mistrust of the healthcare field, and lack of treatment, resources, and experienced long COVID providers. **Methods:** This study was a quasi-experimental time series research pilot in which participants utilized global PBM therapy up to three times a week at twelve-minute intervals for a total of 6 weeks. Participants were asked to answer a Fatigue Assessment Scale (FAS) questionnaire prior to session initiation, after 3 weeks, and after 6 weeks of sessions. Oxygen saturation was measured pre and post session at initiation, after 3 weeks, and after 6 weeks of sessions. **Results:** A one-way repeated measures ANOVA was conducted to assess the impact of PBM on FAS scores across three time periods (pre-treatment, 3-weeks, and treatment conclusion) for a total of 6-weeks. This showed statistical significance in FAS score improvement in 6-weeks, Wilks' Lambda = .25,  $F(2,11) = 16.77$ ,  $p < .01$ , multivariate partial eta squared = .75. A

one-way repeated measures ANOVA was conducted to assess the impact of PBM on pulse oximetry readings across three time periods (pre-treatment, 3-weeks, and treatment conclusion) for a total of 6-weeks. There was no significant interaction between PBM and pulse oximetry readings in 6-weeks indicating no improvement in pulse oximetry readings, Wilks' Lambda = .96,  $F(2,10) = .22$ ,  $p = .59$ , multivariate partial eta squared = .04. It is important to note mean scores at these intervals were 97.33%, 97%, and 97.83% which represents these scores were already in normal expected ranges. Conclusion: There was statistical significance in FAS scores with PBM treatment, indicating this was an effective treatment modality for alleviation of fatigue symptoms associated with long COVID. This evidence supports the need for further clinical research utilizing PBM therapy for mitigation of long COVID symptoms as this nonpharmacologic intervention poses many benefits for improving patient outcomes with no known side effect.

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**Testing the utility of using photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative.**

**CHAPTER ONE**

This chapter will discuss the impact long COVID imposes on patients, healthcare providers, and the management of chronic illness from a clinical background perspective. This chapter will disseminate the Doctor of Nursing Practice (DNP) quality improvement project's purpose, goals, AIMS, population impact, and operational definitions.

**Significance**

Since 2019, when the first case of the novel coronavirus appeared, the world of healthcare has significantly been devastated in many ways. This new viral threat, that quickly went from an epidemic to a pandemic, continues to wreak havoc as new variants emerge and leave varying degrees of damage on its victims. Unlike most disease processes there has not been a definitive treatment plan that has proven successful consistently, largely in part due to the atypical nature of this virus, as well as the varying degree of symptoms accompanying this contagion. In addition to uncertainty for treatment during an active infection of coronavirus (COVID-19), the rate of patients experiencing long term symptoms with lack of reliable interventions continues to rise (Menges et al., 2021).

COVID-19 is caused by the highly contagious SARS-CoV-2 virus and presents primarily as a respiratory illness that can cause mild, moderate, and severe symptoms (Centers for Disease Control and Prevention [CDC], 2022a). As of July 5, 2023, there have been 767,726,861 reported cases of COVID-19 and 6,948,764 COVID-19 related deaths globally (World Health Organization [WHO], n.d.-b). Although respiratory

symptoms such as difficulty breathing or shortness of breath is the primary presentation, additional COVID symptoms exhibited include loss of taste or smell, cough, fever, fatigue, sore throat, headache, rash, diarrhea, eye irritation, body aches, confusion, hypoxia, and chest pain (World Health Organization [WHO], n.d.-a). In severe cases, hospital intervention has been necessary for treatment and permanent damage sustained, due to the inflammatory nature of the virus. Most infections are mild to moderate in effect and may be treated at home with supportive care, as symptoms resolves by three weeks post onset without permanent impairment.

Symptoms may persist for longer than three weeks and can have a debilitating impact on the patient's quality of life. Research has shown that there has been an increase in reports of individuals suffering from persistent post-COVID conditions (Lopez-Leon et al., 2021). This increase in reports of chronic symptom occurrence has led to post COVID conditions taking many names such as, "long COVID," "chronic COVID," and "long-haul COVID," to describe patients who has experienced symptoms for longer than three weeks. Anyone who has contracted COVID-19 is at risk for developing post-COVID complications in the future, lending to long COVID being recognized as a disability by the Americans with Disabilities Act as of July 2021 (Centers for Disease Control and Prevention [CDC], 2022b).

The most common symptoms of long COVID are fatigue, dyspnea, headache, cognition impairment, hair loss, and sleep disturbances (Lopez-Leon et al., 2021). Reports of chronic fatigue and dyspnea are the most frequently occurring long COVID symptoms that bear the largest impact on daily function and quality of life (Fernández-de-las-Peñas et al., 2021). Identification of risk factors for long COVID fatigue and

dyspnea have a relationship to gender, presence of comorbidities, and quantity of acute symptoms presented (Fernández-de-las-Peñas et al., 2021). To date, there are no Food and Drug Administration (FDA) approved treatments of long COVID (Gaffney, 2022). Difficulties that patients are experiencing related to long COVID include increased healthcare costs, decreased quality of life, mistrust of the healthcare field, and lack of treatment, resources, and experienced long COVID providers<sup>2</sup>.

In the United States alone, as of July 5, 2023, there have been 103,436,829 and counting confirmed cases of COVID-19 (WHO, n.d.-b). Given the significant risk of developing long COVID in any patient who has contracted COVID, there is a potential that many will require assistance with the chronic management of care, further increasing the strain on our already taxed healthcare providers and system. Primary care providers are limited in treatment modalities with the lack of evidence-based guidelines and research to assist in this chronic disease management. In addition to limited proven treatment regimens, consultations for specialized expertise to facilitate care collaboration is not readily available delaying expedient care interventions.

Shortage of clinical expertise and delay of specialty referrals has left primary care providers managing symptoms to the best of their expertise in the interim. The persistence of long COVID necessitates an increase in appointment frequency to evaluate patient's response to interventions. Increased appointment necessity poses complications for patients with their employers as sick leave has been exhausted relating to their COVID infection, forcing patients to choose between improving their health or maintaining employment. Individuals who have lost employment as they are not able to perform their expected duties relating to long COVID impact, are left not only disabled

physically but also financially as they no longer have income or insurance coverage to support ongoing care. Primary care providers are limited in their symptom mitigation abilities due to not only patient financial affordability but also from an insurance perspective as providers must be able to justify treatment need. Supporting treatment plans is not only difficult due to lack of proven evidence-based treatment modalities but also the varying patient response to treatment complicates justifying why trialing multiple modalities are required (Menges et al., 2021).

This sense of uncertainty has reduced the confidence patients once held in their healthcare providers leading to disappointment as spirits begin to dwindle and hope is extinguished for patients and providers alike. Post-COVID care clinics promoting multidisciplinary rehabilitative care have been instituted, but their proximity in relation to the Eastern Panhandle of West Virginia inhibits convenient utilization of this resource. Identifying effective treatment modalities for mitigation of these lingering long COVID symptoms decreases provider and patient burden, increases positive patient outcomes, and cultivates a sense of hope for individuals who are frustrated with lack of long-term management resources.

Photobiomodulation (PBM) therapy utilizes non-thermal forms of light (laser, LED, and broadband light) in the visible infrared spectrum to reduce inflammation, provide pain alleviation, promote tissue regeneration, and wound healing (Mosca et al., 2019). PBM is an adjunctive therapy that has shown quantifiable symptomatic improvement in as few as one treatment but unlike pharmacological interventions holds little to no risks as it is noninvasive (Liebert et al., 2020). The mechanism of action with this therapy is to induce a biologic response with infrared light stimulating the electron

transport chain (ETC) of mitochondria cells through the cytochrome C oxidase (CCO) that aids in absorbing the red and near infrared light, thus increasing reactive oxygen species (ROS) that increases adenosine triphosphate (ATP). This response triggers cellular responses that in turn improve wound healing, aids in athletic enhancement by improving tissue regeneration, decreases pain and inflammation, increases immunity by reducing inflammatory markers, and has become a gold standard in the treatment of oral mucositis. The relation of PBM reducing inflammatory cytokine and promoting cytokine regulation has supported the justification of adding this novel treatment for long COVID complications amidst this crisis where other treatments have failed (Liebert et al., 2020) .

### **Problem Statement**

To date, there are no Food and Drug Administration (FDA) approved treatments of long COVID (Gaffney, 2022). Difficulties that patients have experienced related to long COVID include increased healthcare costs, decreased quality of life, mistrust of the healthcare field, and lack of treatment, resources, and experienced long COVID providers (Kingstone et al., 2020; Menges et al., 2021).

### **AIMS Statement**

The aim of this research study was to evaluate the utility of global photobiomodulation (PBM) therapy on subjectively reported symptoms of fatigue and/or dyspnea (shortness of breath) post COVID-19 infection in a community setting by outcome measurements of pulse oximetry and fatigue scale from June 2022 to July 2022.

### **Project Goals**

1. Identify members in the community affected by long COVID symptoms and determine population impact.

- a. Isolate symptom reports to chronic fatigue and/or dyspnea related to long COVID.
    - i. Recruitment with IRB approved advertisement, interview, email, and phone/text.
2. Identify alternative treatment modalities for chronic symptom management of long COVID fatigue and/dyspnea.
  - a. Identify benefits of PBM relating to long COVID symptoms of fatigue and/or dyspnea.
    - i. Conduct research study to determine PBM therapy effects on long COVID fatigue and/or dyspnea on participants.
3. Test the utility of PBM therapy for long COVID symptom management of chronic fatigue and/or dyspnea.
  - a. Measurement of fatigue and pulse oximetry
    - i. Fatigue Assessment Scale and pulse oximetry meter at initiation, 3 weeks, and at 6 weeks.
4. Answer the following research questions:
  - a. Is there a difference in fatigue assessment scores in a six week. Following PBM therapy use?
  - b. Is there a difference in oxygen saturation readings in a six week. Following PBM therapy use?

### **Population Impact**

As COVID-19 continues to mutate, it is difficult to mitigate the spread. This may be the result of patient's refusal of vaccines due to fears or personal preference, frequent

changes in infection control standards causing public confusion with guidelines, and/or noncompliance related to either reluctance or fear of novel treatments. Subsequently, patients are expected to return to work, possibly prematurely, and are financially burdened with increased expenses related to chronic management of the disease while facing provider shortages, limited specialty assistance, and overall, a decrease in their quality of life. This all leads to increased frustration and decreased faith in the healthcare system, which further prevents patients from seeking proper care. The stress of the illness as well as the barriers to proper care weigh heavy on the mental health of patients and healthcare providers alike (Sengupta et al., 2021).

### **Operational Definitions**

- COVID-19
  - Highly infectious disease caused by the SARS-CoV-2 virus that is spread by droplets and has affected individuals with symptoms ranging from a mild cold to severe respiratory failure that can last up to 3 weeks.
- Post COVID-19 conditions
  - Term to describe the condition of a person experiencing COVID-19 symptoms lasting greater than 4 weeks post COVID-19 diagnosis. Also known as long COVID, chronic COVID, and long-haul COVID.
- Oxygen saturation
  - Percentage measurement of oxygen being carried by hemoglobin in blood.
- Pulse oximeter
  - Tool used to measure oxygen saturation.
- Shortness of breath or Dyspnea

- Sensation of not being able to get enough air to breathe.
- Fatigue
  - the feeling of decreased energy or motivation
- Post COVID Fatigue
  - Persistent fatigue following COVID-19 infection lasting longer than 6 months.
- Fatigue Assessment Scale (FAS)
  - A 10-question survey that aids in the evaluation of fatigue level and impact on the patient from a physical and mental standpoint.
  - This questionnaire rates response to each question from 1 to 5, with 1 representing “Never” and 5 indicating a response of “Always” to questions investigating fatigue presence.
- Photobiomodulation Therapy
  - Therapy utilizing non-thermal forms of light (laser, LED, and broadband light) in the visible infrared spectrum to reduce inflammation, alleviate pain, promote tissue regeneration, and wound healing.

## **Summary**

As COVID-19 continues to mutate and its infectious reach widens, the devastation that is left in its wake is still causing decreased quality of life for many individuals with limited interventional hope in sight. The sheer magnitude of potential consequences associated with long COVID given the growing number of cases is proof that our already overwhelmed healthcare system cannot support the demands on that large of a scale

## CHAPTER TWO

In this chapter the theoretical framework chosen to guide the *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* quality improvement research project will be reviewed. Discussion in this chapter will also include the review of literature conducted in preparation for this project. In addition, the overview of the search process for literary resources relating to this research interest will be described.

### **Theoretical Framework**

The theoretical framework chosen for support of this DNP quality improvement research project was the Comfort Theory of Nursing. Comfort Theory (CT) is a middle range theory developed in the 1990s by Katherine Kolcaba that conceptualized comfort as a characteristic that when applied with holistic nursing art produces a means of great strengthening and relief (Smith & Parker, 2015). According Kolcaba's research the patient's comfort exists in three forms: relief, ease, and transcendence. Kolcaba held the following assumptions: comfort is a basic need, comfort is experienced holistically by a person, measures of self-comfort may be unhealthy or healthy, and comfort enhancement increases productivity. In her theory comfort occurs contextually for experiences that are physical, psychospiritual, environmental, and/or sociocultural (Kolcaba, 1991). The perception of comfort is dependent on the relationship between the comfort types and context occurrence. This relationship provides a use for identifying the areas comfort needs have not been met, planning of interventions for comfort attainment, and a basis for tracking intervention outcomes with proper documentation to truly shape comfort management.

The following concepts play a large part in understanding the relationship in CT (Smith & Parker, 2015). The first is health care needs which is simply the comfort needs that have been identified. Next is nursing interventions which are the intentional actions implemented to address said comfort needs. Intervening variables such as experiences, age, mindset, finances, or support system are described as the influences that determine the opinion of total comfort. Enhanced comfort is the state of being strengthened through the meeting of need addressment. Health-seeking behaviors (HSB) is the actions of an individual in health pursuit. HSB includes outcomes due to internal behaviors, peaceful death, and external behaviors (Kolcaba, 1994). Finally, institutional integrity refers to a large umbrella that holds hospitals, communities, and states that hold virtues of being sound and ethical to include adherence of best practice and best policies (Smith & Parker, 2015).

CT is comprised of three parts that can be utilized congruently or individually (Smith & Parker, 2015). The first part conditions that interventions based on comfort that are successfully performed will result in an increase in comfort for the receiver when compared to comfort prior to the intervention. If fullest comfort potential is not achievable it is necessary to consider the barrier possibilities and take initiative to transcend this barrier with alternative goals or interventions. This is represented by the concepts of healthcare needs, nursing interventions, and intervening variables leading to enhanced comfort. The second part forms that HSB is the effect of properly strengthened recipients negotiating goals to increase comfort (Kolcaba, 1994). Enhance comfort and HSB are strongly linked in this theory. The last part of CT states institutional integrity is boosted through added engagement with HSB to increase the institution's best practice

and policies providing numerous benefits such as strength, care quality improvement, and financial advantages (Smith & Parker, 2015). Institutional integrity is strongly dependent on HSB for not only patient satisfaction but institutional outcomes as well.

CT provides a framework to the quality improvement research project *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* as it focuses on enhancing comfort to not only long COVID sufferers but to the providers who are faced with the challenge of mitigating the associated chronic symptoms of long COVID. CT has been applied by institutions and numerous agencies to promote holistic health care adaptation as exhibited in national awards such as Magnet Status, the Beacon Award, and the Baldrich Award to unify goals for providing patient centered care that puts providing comfort in the forefront of care (Smith & Parker, 2015). CT's repeated application to nursing practice aspects with success supports its applicability to research dedicated to improving patient's outcomes with enhancing comfort through symptom relief (Kolcaba, 1994).

### **The Search Process**

A search using the keywords and phrases in literature: photobiomodulation therapy, COVID-19, long COVID-19 symptoms and treatment, photobiomodulation therapy in long COVID, fatigue, dyspnea, and shortness of breath, Long COVID impact, post COVID condition, fatigue assessment, and photobiomodulation therapy benefits were primarily conducted via electronic search methods. Use of scholarly databases included EBSCO, MEDLINE, CINAHL, PubMed, Cochrane Library, and Google Scholar. Search modifications included filters of source age from 2003 to current year, peer reviewed journals, and full text articles. Applications that were relevant to the

concepts, purpose, and theories that supported this DNP project were included as a reference.

### **The Review of Literature**

The effect of COVID 19 on the healthcare industry will be further discussed in the review of literature to include the categorical themes of impact, long COVID, and PBM. The major themes identified were the impact of COVID and long COVID in healthcare, long COVID research, and PBM treatment utility.

#### ***Impact***

The effects of COVID have had a rippling effect on the healthcare system that continue to be felt by patients and providers alike. The demands of the pandemic not only placed financial and political strains that held consequences effecting supply chains and care delivery methods but also identified the domino effect these demands hold in healthcare and the need for proper planning in the future. The Technical Resources Assistance Center and Information Exchange (TRACIE) compiled a summary to highlight the delivery impacts of COVID-19 with suggested mitigation efforts (2021a). The impact that was most alarming was the interruption in supplies that were critical for patient care leading to the need to better anticipate practice conservation of healthcare resources. TRACIE identified how COVID has caused not only delays in care but also a decrease in preventive screening and disturbed necessary management of disease treatments. TRACIE acknowledged the surge and need for outpatient care with increased incidence of long-term symptom continuation following COVID infections identifying the need for provider awareness and collaboration of care to alleviate complications in management and availability.

COVID-19 has had a detrimental effect on mental health. A 2021 systematic review of long-term effects of COVID-19 linked the pandemic with worsening psychiatric symptoms (Bourmistrova et al., 2022). Bourmistrova et al. found that of 6743 participants in 33 studies the report of short-term anxiety, depression, and sleep disturbances following COVID-19 was prevalent. Additionally, a 2021 study by Naidu et al. found that patients with COVID-19 following hospital discharge with completion of positive depression and trauma screening questionnaires were considerably more likely to have persistent long symptoms that included breathlessness, myalgia, anorexia, and confusion and were less likely to resume employment.

### ***Long COVID***

The increase in prolonged symptoms following COVID-19 infections has led to the need for universal recognition of long COVID, or post COVID conditions. It known that the most common symptoms of long COVID are fatigue, dyspnea, headache, cognition impairment, hair loss, and sleep disturbances (Lopez-Leonet al., 2021). Mehandru and Merad in 2022 reported that nearly 60% of patients reported these persistent symptoms at 6 months following infection with no relation to infection severity with proinflammatory cytokine presence. Stallmach et al., in 2022 described these symptoms lasting longer than 12 weeks as “post-COVID- syndrome” and elaborated on how symptoms affect multiple systems at various intensities, frequencies and duration. Chen et al., in 2022 reported on the global occurrence of post-COVID-19 condition to be estimated at 0.43 (95% CI,.39-.46), recommending further research be conducted as the impact on populations and healthcare pose colossal consequences.

The acute infection of COVID-19 symptoms and effective treatments have been explored but long-term consequences of COVID-19 are still unknown and vary, leaving no definitive treatment options to date. Menges et al. (2021) conducted a population-based cohort study in the Canton of Zurich, Switzerland that assessed 431 confirmed adult cases of SARS-CoV-2 from February 2020 to August 2020 to evaluate the percentage of cases reported not having fully recovered and continued reports of fatigue, dyspnea, and depression after six to eight months. Additionally included was the percentage of individuals that required further healthcare evaluation following initial diagnosis. This study concluded that 26% of participants reported not having recovered, 55% fatigue, 25% dyspnea, 26% depression, and 40% requiring further healthcare follow-up. Menges et al. concluded that the effects SARS-CoV-2 results in a proportional demand on healthcare emphasizing the importance of resource planning and integrative approaches for managing support and recovery.

Given the vast area of unknown associated with long COVID, one area that literature appears congruent on is the importance of high-quality management of symptoms of long COVID beginning in primary care. In a qualitative study conducted by Kingstone et al., (2020) in the UK via interview, the perspective of patients experiencing long COVID complications was assessed. This study concluded through the analysis of 24 interviews that lack of belief in affection, limited access to care, lack of knowledge and evidence of long COVID, and lack of uncertainty acknowledgement strongly impacted their long COVID journey. This study's implications for practice encourages the need for further research and understanding of long COVID to optimize and improve care for those affected.

Greenhalgh et al. touched on the need to approach care management in primary care setting following COVID-19 infection symptomatically with a holistic approach as evidence for treatment is limited. It was illustrated that it is necessary to be mindful with conservative investigation to avoid unnecessary testing and referrals. An important point also made was the need to acknowledge the prolonged effects of the disease while ensuring management coincides with comorbid disease management as primary care providers play a large role in supportive care during times of uncertainty. Atherton et al., (2021) similarly reported with the increase in patients being affected by long COVID that management should be focused in primary care with an emphasis on healthy provider and patient relationships to invest in continuity of care with delivery of high-quality and safe practice.

### ***PBM***

PBM has been researched for its analgesic, healing, and recovery enhancing effects. In 2019, Ezzati et al. conducted a systematic review of evidence that assessed the effects of low-level laser therapy (LLLT), such as PBM, on post operative pain. Of the 1194 papers found in search a total of 10 pieces met inclusion standards and were utilized. The pieces included surgeries such as mastectomy, episiotomy, tonsillectomy, hernia, and breast augmentation post-fracture and were rated on the PEDro scale to determine validity. This yielded 8 positive effects supporting this to be an appropriate treatment modality for reduction of postoperative pain with no side effects but further research for protocols and follow-up therapy is necessary.

In 2019, Tomazoni et al. conducted a randomized, triple-blind, placebo-controlled crossover trial that assessed the use of PBM in 22 high-level soccer players

and its effects on muscle damage, inflammatory and oxidative stress markers. The results concluded that PBM applied prior to exercise enhanced athletic performance and aided in post exercise recovery. In 2018 Rossato et al. conducted a study that assessed the response of time PBM therapy had on muscular fatigue of the knee extensor in 16 male participants. The study concluded that the application of PBM 6hrs before in addition to immediately before exercise was effective in reducing fatigue and should be considered for strength and conditioning training.

In 2019, Mosca et al. conducted a literature review that assessed the therapeutic use of PBM for healing of various wounds. Literary search yielded 218 articles that were narrowed down to 11 used in their review. Mosca et al. concluded that PBM held benefits for various chronic wound healing such as diabetic foot ulcers, pressure ulcers, venous ulcer, and burn wounds. This emphasized the importance of further clinical research to develop ideal clinical use protocols.

PBM has been widely researched in treatment of oral mucositis, a frequently occurring complication of cancer treatment, leading the way to further research for its use during oncological treatment. A case series published in 2019 by El Mobadder et al. evaluated the efficacy of PBM in supportive care for cancer treatment related complications of dysphagia, oral dryness, taste change, and the sensation of burning mouth. In this case series there were a total of three cases followed where the application of PBM in the suggested parameters/protocols was utilized. Outcomes of this case series confirmed the efficacy of PBM in the treatment of oral mucositis, oral dryness, dysphagia, taste changes, and the sensation of burning mouth. These positive outcomes support the need for further research to be conducted to optimize treatment protocols.

Zadik et al. in 2019 conducted a systematic review of literature to revise the evidence-based guidelines used in clinical practice for the use of PBM in prevention and treatment of oral mucositis in specific cancer patient populations. This evidence acquired in this review supports the use of PBM in the prevention of oral mucositis before hematopoietic stem cell transplant and head and neck radiotherapy with or without chemotherapy.

Another area that PBM research is investigating is its utility in chronic and acute respiratory disease. In 2018, Da Cunha Moraes et al. conducted a research study evaluating the effect of PBM intervention on lung inflammation in mice. They induced chronic obstructive pulmonary disease in mice over a 60-day period via cigarette smoke inhalation, following this they were exposed to PBM therapy for 15 days and then euthanized to assess morphologic and functional analysis of lungs. The results determined that PBM showed a significant reduction in cytokine secretion and inflammatory markers implying that PBM holds potential for treatment of pulmonary inflammatory diseases such as COPD.

In a case report conducted in 2021 by Pelletier-Aouizerate and Zivic assessed PBM as a treatment of acute infectious respiratory syndrome in two patients that may have had COVID early on when confirmatory testing had not yet been established. The patients were provided interventions based on their symptoms in addition to PBM three times a week for ten days in one case and two times a week for two weeks in the other. In both cases the patients showed improved oxygenation and reduced inflammatory response following PBM utilization.

Four investigatory studies assessed utilizing PBM in the treatment of acute COVID. Williams et al. in 2021 conducted a non-randomized 50-patient case study that

evaluated whole-organ transdermal PBM treatment effects on COVID positive patients. Results yielded 41//50 patients exhibiting symptom improvement in as little 4 days, with 50/50 of patients being symptom free within 3 weeks. Vetrici et al. in 2021 conducted a 10-patient randomized clinical trial that appraised PBM utility in the treatment of COVID-19 pneumonia. Outcomes reported showed that patients treated with PBM therapy exhibited rapid recovery in turn avoiding hospitalization, ventilation, and escalated levels of care. Additionally, patients treated with PBM showed no signs of lingering affection at 5-month follow-up post treatment. Comparatively in this study 60% of the control group was admitted to ICU and required mechanical ventilation due to the severity of their illness.

In 2020, Sigman et al. reported a case of a 57-year-old African American man who was severely affected by COVID-19 pneumonia and his response to PBM therapy. Patient outcomes following PBM treatment 4 times daily were a reduction in supplemental oxygen demands, improvement in oxygenation and lung function, improvement in radiological findings, and decrease in lab values indicative of infection and inflammation. Another important finding to note was his clinical recovery time totaled 3 weeks as opposed to the typical 6-8 weeks. Additionally reviewed were ten studies that provided the potential use of PBM in COVID treatment that congruently recommended future research to define treatment protocols.

## **Summary**

The literature points to the need for more studies pertaining to long COVID in relation to pathology and management, as well as the need for future planning to decrease the burden on our health care system. As Silva Andrade et al., in 2021, discussed in their

review the understood current pathology is driven by the cytokine storm resulting from COVID-19. PBM has shown positive reduction in cytokine related inflammation and its potential benefits for treatment use during active COVID infections, supporting the need for further research for its potential use in post-COVID conditions.

## **CHAPTER THREE**

This chapter of the project will discuss the methods and procedures of the project. Included will be the following topics: project design, procedures, instruments, data collection plan, data analysis plan, data storage plan, setting, participants, recruitment of participants, ethical considerations, key personnel, stakeholders, budget/resources needed, cost/benefit analysis, barriers to implementation, and sustainability.

### **Project Design**

This DNP project was a quasi-experimental time series research pilot study design that assessed the use of PBM to relieve symptoms of fatigue and shortness of breath in individuals affected by long COVID-19 over a 6-week period. Participants agreed to provide demographic information and receive global PBM therapy utilizing the NovoTHOR treatment bed three times a week for 6 weeks with measurement of fatigue and pulse oximetry at therapy initiation, 3 weeks, and conclusion of therapy. The study is considered a pilot research as exploration on the utilization of PBM therapy to mitigate symptoms of long COVID has not been conducted at the time. The quantitative data consists of demographic information provided, outcome measures of The Fatigue Assessment Scale (FAS) and the measurement of oxygen saturation or SpO2 via pulse oximetry monitoring.

### **Procedures**

This principal investigator (PI) obtained informed consent by providing educational information on the benefits of PBM therapy and session instructions/protocols prior to beginning sessions. Participants underwent global PBM sessions for 12 minutes 3 times a week for a total of 6 weeks. Participants were required

to enter a designated private room in the Photobiomodulation Center of Excellence, undress to their comfort level, access and lay in the sanitized NovoTHOR bed for the designated session time, and then exit the bed and redress. Participants were asked to answer a Fatigue Assessment Scale (FAS) questionnaire prior to session initiation, after 3 weeks, and after 6 weeks of sessions. Oxygen saturation was measured pre and post session at initiation, after 3 weeks, and after 6 weeks of sessions.

## **Instruments**

### ***Photobiomodulation Therapy***

Global PBM therapy sessions provided via the NovoTHOR bed. PBM therapy has proven to reduce inflammation and pain, promote tissue regeneration and healing, as well as modulate immune response (Mosca et al., 2019).

### ***Fatigue Assessment Scale***

The Fatigue Assessment Scale (FAS) is a 10-question survey that aids in the evaluation of fatigue level and impact on the patient from a physical and mental standpoint. This tool has been utilized in numerous studies in relation to fatigue and disease processes as it has proven to be a reliable and valid tool to measure fatigue (Serafini et al., 2021). This questionnaire rates response to each question from 1 to 5, with 1 representing “Never” and 5 indicating a response of “Always” to questions investigating fatigue presence.

### ***Pulse Oximetry Measurement***

The use of a pulse oximeter to measure the oxygen saturation of participants was utilized to monitor SpO<sub>2</sub> pre and post session at initiation, 3 weeks, and then at 6 weeks. This is a noninvasive tool that provided a numeric percentage value reflecting the amount

of oxygen carried by red blood cells. The limitations of this tool are compromised circulation, barrier to natural nail, extremity temperature, and excessive melanin affecting pigmentation (American Lung Association, n.d.).

### **Data Collection, Analysis and Storage Plan**

Prior to study initiation a request for 15 participants was elicited from the surrounding community of the wellness center via interview and advertised flier with the following inclusion criteria:

- Adult age 18 or older
- Independently mobile or have a care giver present.
- Previous COVID-19 infection and experiencing long term symptoms of fatigue and dyspnea.

Informed consent, participation agreement, and any written provider clearance necessary was collected prior to session. A short anonymous demographic survey was conducted prior to first session. Participants were asked to answer a Fatigue Assessment Scale (FAS) questionnaire prior to session initiation, after 3 weeks, and after 6 weeks of sessions. Oxygen saturation measurements occurred pre and post session at initiation, after 3 weeks, and after 6 weeks of sessions. This PI compiled results of surveys at session initiation, 3 weeks, and 6 weeks and performed statistical analysis utilizing SPSS Version 26.

Confidentiality and anonymity were maintained with survey submissions utilizing a 5-question assessment that requires alternating one letter or number answers to create a unique patient identifier. All paper copies of signed informed consent, patient agreements, and any surveys were immediately electronically scanned and stored on a

secured password protected electronic device and paper copies promptly destroyed. Password protected files will be stored electronically on a password and biometrically secured computer, and on a password protected server for 5 years and then destroyed.

### **Setting, Participants, Recruitment**

The project took place in the Photobiomodulation Center of Excellence within a rural university's community wellness center located in the mid-Atlantic region of the United States. This community wellness center offers services ranging from recreation programs, consulting services, membership opportunities, complementary access for current university students, dining, and community event rental opportunities. The facility is handicap accessible with amenities including access to fitness equipment, indoor track, racquetball courts, 14,000 square foot arena, 6 basketball/volleyball courts, locker room, 8-lane 25-foot indoor swimming pool, and 3,100 square foot multipurpose room.

The participants for this research study included adults aged 18 and older who suffered from long COVID symptoms of fatigue and/or dyspnea and volunteered to participate in this community wellness initiative. Participants were able to independently access or were accompanied by a care giver to assist in accessing of the NovoThor bed. Participants were not remunerated but with agreement to participate in sessions 3 times per week for a length of 6 weeks were provided sessions at no cost. Subjects were enlisted by PI via interview and/or response to flier. PI provided education regarding PBM, and usage protocols prior to session initiation with participation agreement and upon request prior to participation agreement.

### **Ethical Considerations**

PBM has demonstrated no known side effects when used according to treatment protocol (Elad,2018). There is no evidence to determine the positive or negative effects of PBM on cancer cells or fetus, therefore individuals who are pregnant were excluded and any individuals with known malignancy were required to provide documentation from healthcare provider clearing the individual for participation. The benefits of this study included reduction of inflammation, pain alleviation, and the potential to experience an improvement to quality of life by reducing and/or eliminating symptoms of fatigue and dyspnea.

Institutional Review Board (IRB) approval for review of research using human subjects was obtained to ensure the safety of participants. Protection of the rights and welfare of participants was upheld through execution of approved protocol plans outlined in IRB approval. IRB also aided in assurance of project integrity and ethics were endorsed by the adherence of institutional policies also defined in approval.

### **Key Personnel and Stakeholders**

The project's key personnel and stakeholders were comprised of not only this investigator and the members of the project committee but also include The Photobiomodulation Center of Excellence, technicians assisting with treatment administration, the university, IRB, the participants impacted by long COVID symptoms, the West Virginia Governor, potentially the PBM community, healthcare providers, and other long COVID sufferers. The project committee was comprised of the committee chair and three additional members to support and guide this PI. The Photobiomodulation Center of Excellence was instrumental in providing a location, equipment, and supportive staff to facilitate this project. The Dept. of Nursing, IRB, university president, and the

WV Governor were involved in assuring aspects of the project satisfied ethical requirements for participants safety and proper use of CARES Act funding was dedicated to COVID-19 relief.

The participants were key to identifying PBM utility in the treatment of long COVID. This project holds great value for the PBM community as it supports the progression for wider treatment acceptance amongst healthcare providers, FDA, and insurance entities. Healthcare providers and other long COVID sufferers benefits by the identification of a nonpharmacologic alternative treatment modality.

### **Resources Needed and Budget**

Participants suffering from long COVID conditions were an essential resource for this research project. Use of The Photobiomodulation Center of Excellence was another vital resource providing availability for Tuesdays, Thursdays, and Saturdays beginning June 6th to July 23, 2022 from 8:00 AM until 7:30 PM, the NovoThor treatment bed, training for use and sanitation of treatment bed, protective eyewear, proper sanitation materials utilized between treatments, and a trained technician to assist with facilitating treatment sessions on Tuesdays from 8:00 AM to 2:00 PM and when the PI was not available. The final resources necessary were miscellaneous items such as paper, ink, staples, clipboards, pens, and envelopes.

The estimated proposed budget for this project is \$12,000. This would cover treatment for up to 15 participants at three treatments a week for six weeks, three pulse oximeters, staff hourly wages for assistance, and miscellaneous items as previously stated. Complete funding for this project was made possible by the COVID relief allocations distributed by the governor of West Virginia with the CARES Act. Actual

budget spent from CARES Act totaled \$10,609 this was broken down with \$1,629 allocated to technician salary for their assistance, \$100 for the equipment which included three pulse oximeters, and \$8,880 for the cost of treatment sessions. Miscellaneous items totaled approximately \$100, bringing the total project cost to \$10,709. Actual project expenses are summarized in Table 1. Discrepancies in granted budget and actual budget spent were due to the commitment of 14 participants versus 15 participants and the costs associated with the decreased number of sessions utilized.

**Table 1**

*Project Expense Summary*

| Project Item                               | Expense  |
|--------------------------------------------|----------|
| Miscellaneous Supplies                     | \$100    |
| Equipment                                  | \$100    |
| Technician Salary                          | \$1,629  |
| Treatment Session Cost for 14 Participants | \$8,880  |
| Project Total Expenditure                  | \$10,709 |

**Barriers to Implementation**

Barriers to implementing this DNP quality improvement research project *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* were multi factorial and encompassed recruitment, funding time constraints, aspects of the facility, lack of buy-in, study commitment, staff availability, and session compliance. Time was the largest implementation barrier. Due to IRB approval being granted May 25<sup>th</sup> the window time for recruitment was limited due to time constraints placed on the approved CARES Act funding necessitating results of study be reported to the University President and Governor by mid-August. Recruitment

was permitted once IRB approval was obtained, given the study required six to seven weeks in total for data collection alone, and then time following the study to synthesize collected data for dissemination to necessary stakeholders, the study would need to begin no later than June 7<sup>th</sup> to end July 23<sup>rd</sup> reducing recruitment to 10 days. Session dates were prioritized and determined with full support of the Photobiomodulation Center of Excellence Director, but once set were not negotiable as staff schedules were dedicated for assistance and other vendors/appointments allotted around study requirements and were limited to open operating hours. Once recruitment was initiated it was difficult to elicit participants that were willing to join to a six-week study with commitments three times a week during normal work hours. Declination for participation during the recruitment period varied from inability to travel the distance to the Photobiomodulation Center of Excellence as they were not able to afford fuel, lacked means of transportation, and long COVID symptoms had caused loss of employment or prevented from working as normal resulting in financial hardships, inability to afford to take time from work to participate during working hours as sick/leave banks were already exhausted, lack of knowledge or interest/belief in PBM therapy, or previously planned summer vacations that did not allow for full participation during study window.

Session availability and compliance were the next largest barrier to implementation. The time necessary for each session and proper sanitation of the bed and eye protection required 30 minutes appointments for each participant for use of the one treatment bed available. This put a limitation to the amount of evening appointments available to accommodate work schedules. Session compliance yielded to be a difficult as again the study took place over the summer where many participants that had already

planned vacations would need to start a week later, or unexpected events, illness, and unplanned vacations prevented attendance adherence, or required frequent changes to set appointment times due to conflicts and schedule. COVID exposure protocols also prevented compliance involuntarily for participants and investigator alike as quarantine protocols regarding positive COVID exposures were strictly followed.

### **Sustainability**

This pilot research study not only aids in research dedicated to identifying an alternative treatment modality for chronic symptom management to improve long COVID sufferers' quality of life, but it also gives hope to patients and providers for future practice as the short-term and long-term impacts of COVID continue to be researched and understood and best practices can be updated using evidence-base. Symptom improvement reduces unnecessary medical visits, which allows for improved access to care and in turn reduces unnecessary medical spending. Restoration of institutional integrity through mitigation of chronic life debilitating symptoms also brings back faith in the healthcare system, promoting health seeking behaviors like prevention rather than interventions that slow down inevitable outcomes. Improving institutional integrity not only supports evidence-based practice continuation but also encourages stakeholder buy-in which assists in reducing healthcare costs competitively and promotes expansion for alternative treatments to be included and covered with medical insurance.

### **Summary**

This chapter examined the methods and procedures of the project to include details relating to project design, procedures, instruments, data collection plan, data analysis plan, data storage plan, setting, participants, recruitment of participants, ethical

considerations, key personnel, stakeholders, budget/resources needed, barriers to implementation, and sustainability. These components are all significant in guiding the quality improvement research project *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative*. Additional elements such as diagrams or supplemental information that pertain to this chapter can be viewed in Appendices A-C.

## CHAPTER FOUR

In this chapter the results of the study *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* will be illustrated. The findings of the six-week study will include the analysis of data collected, sample demographics, and the overall results of this research project.

### **Data Analysis**

Quantitative data was derived using the Fatigue Assessment Scale (FAS) and pulse oximetry monitoring. The FAS is a 10-question survey that aids in the evaluation of fatigue level and impact on the patient from a physical and mental standpoint. This tool has been utilized in numerous studies in relation to fatigue and disease processes as it has proven to be a reliable and valid tool to measure fatigue (Serafini et al., 2021). Internal consistency for this test reliability and validity is 0.90. This 10-question assessment utilizes a 5-point Likert scale, with 1= “Never”, 2= “Sometimes”, 3= “Regularly”, 4 = “Often”, and 5 indicating a response of “Always” to answer questions investigating fatigue presence. Possible scores can range from 10-50, with lower scores (less than 22) indicating low levels of fatigue, moderate scores (22-34) relating to mild-to-moderate fatigue, and higher scores (35 or greater) indicating severe fatigue. Reverse coding was used for questions 4 and 10 due to negative wording.

The use of a pulse oximeter to measure the oxygen saturation of participants pre and post session at treatment initiation, 3 weeks, and then at 6 weeks gave indication of participants respiratory in relation to reported shortness of breath. This is a noninvasive tool that provided a numeric percentage value that reflects the amount of oxygen carried by red blood cells. The limitations of this tool are compromised circulation, barrier to

natural nail, extremity temperature, and excessive melanin affecting pigmentation (American Lung Association, n.d.). Additional quantitative data was extracted from the demographic form each participant was required to complete. This data included general demographics such as age range, gender, ethnicity, race, date(s) of COVID infection, length of time long COVID has affected, COVID vaccine status, smoking status, and if the affection long COVID has impacted on the participants ability to work, or prevented from working any period of time, and if so, how long.

### **Sample Demographics**

This study included a total of 14 individuals who reported chronic fatigue and/or shortness of breath lasting longer than 3 weeks following COVID-19 infection(s). The sample characteristics of this study included the continuous variable of age and the categorical variables of gender, ethnicity, race, COVID vaccination status to included fully vaccinated and/or boosted, smoking status, and work affected by long COVID symptoms. Female participation was highest at 64.3% of 14 participants. Participant's ages ranged from 18-70 with highest frequencies occurring between ages 41-50 and 61-70. All participants identified as non-Hispanic, with occurrences of 85.7% Caucasian, 7.1% Asian, and one participant declined to identify race. A total of 64.3% of participants were fully vaccinated for COVID-19, and 35.7% were fully vaccinated and had received a booster. 100% of participants denied smoking. Most participants, 71.4%, reported work affection due to long COVID symptoms. A summary of these sample characteristics is included in Table 2. Length of time long COVID symptoms were provided in an open text format. Responses to this portion of the demographics varied from three or more weeks to two years.

**Table 2***Summary of Sample Characteristics*

|               |               | Frequency | Percent |
|---------------|---------------|-----------|---------|
| Gender        | Male          | 5         | 35.7    |
|               | Female        | 9         | 64.3    |
| Age           | 18-30         | 1         | 7.1     |
|               | 31-40         | 3         | 21.4    |
|               | 41-50         | 4         | 28.6    |
|               | 51-60         | 2         | 14.3    |
|               | 61-70         | 4         | 28.6    |
| Ethnicity     | Non-Hispanic  | 14        | 100     |
| Race          | Caucasian     | 12        | 85      |
|               | Asian         | 1         | 7.1     |
|               | Missing Entry | 1         | 7.1     |
| COVID Vaccine | Yes           | 9         | 64.3    |
|               | No            | 5         | 35.7    |
| COVID Booster | Yes           | 5         | 35.7    |
|               | No            | 9         | 64.3    |
| Smoker        | No            | 14        | 100     |
| Work affected | Yes           | 10        | 71.4    |
|               | No            | 4         | 28.6    |

**Study Results**

A one-way repeated measures ANOVA was conducted to assess the impact of PBM on FAS scores across three time periods (pre-treatment, 3-weeks, and treatment conclusion) for a total of 6-weeks. This showed statistical significance in FAS score improvement in 6-weeks, Wilks' Lambda = .25,  $F(2,11) = 16.77$ ,  $p < .01$ , multivariate partial eta squared = .75. A one-way repeated measures ANOVA was conducted to assess the impact of PBM on pulse oximetry readings across three time periods (pre-treatment, 3-weeks, and treatment conclusion) for a total of 6-weeks. There was no significant

interaction between PBM and pulse oximetry readings in 6-weeks indicating no improvement in pulse oximetry readings, Wilks' Lambda = .96,  $F(2,10) = .22$ ,  $p = .59$ , multivariate partial eta squared = .04. It is important to note mean scores at these intervals were 97.33%, 97%, and 97.83% which represents these scores were already in normal expected ranges.

### **Summary**

There was statistical significance in FAS scores with PBM treatment, indicating this was an effective treatment modality for long COVID fatigue symptoms. Significant improvement was noted at three weeks with a slight increase in scores for the final reading that still remained below initial score. This evidence supports the need for further clinical research utilizing PBM therapy for mitigation of long COVID symptoms as a nonpharmacologic intervention that poses many benefits for improving patient outcomes with no known side effects. In this study there was not statistical correlation to PBM intervention on pulse oximeter readings for these participants as their primary complaints were relating to fatigue and their mean scores were in normal expected ranges with little to no room for improvement.

## CHAPTER FIVE

This chapter explores the results and conclusions of the quality improvement research project *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative*. A discussion on the findings and their relation to theoretical framework and literature review along with facilitators and barriers, project limitations, implications for practice, and the dissemination of findings will also be elucidated.

### **Problem Statement**

*Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* confirmed with statistically significant results that PBM should be a candidate for treatment modalities. Expanded research regarding PBM's utility is warranted to reduce and/or relieve the difficulties patients have had to endure due to a lack of current FDA approved long COVID treatments.

### **AIMS Statement**

The aim of this project was to evaluate the utility of global photobiomodulation therapy on subjectively reported symptoms of fatigue and dyspnea (shortness of breath) post COVID-19 infection in a community setting by outcome measurements of pulse oximetry and fatigue scale from June 2022 to July 2022.

### **Findings Related to Theoretical Framework**

Health care needs are the needs for comfort, this could be provided by a support system, financial counseling or in this study the physical relief of fatigue and or dyspnea (Smith & Parker, 2015). Comfort interventions or the intentional actions to address the needs of the recipient for our study PBM as a complementary therapy. Intervening

variables are the influences that determine their perception of total comfort. This could be past experiences age, mindset, finances, or support system. Enhanced comfort is the holistic experience of being strengthened by addressing comfort needs.

PBM is an adjunctive therapy that supports holistic comfort as it addresses comfort needs. Health seeking behaviors is the subsequent outcomes related to health pursuit; this is done when with the healthcare team (Smith & Parker, 2015). Utilizing PBM as an adjunctive therapy is considered a positive form of health seeking behavior with the pursuit of relief (Kolcaba, 1991). Institutional integrity refers to a large umbrella that holds hospitals communities and states that possess qualities of being whole (Smith & Parker, 2015). They worked together to provide best practices and policies aimed to enhance evidence based high quality care. Institutional integrity promotes PBM implementation as it follows best practice policies and evidence-based practice providing comfort and reducing costs for medical treatment while also reducing the need for unnecessary provider visits.

Restoration of institutional integrity through mitigation of chronic life debilitating symptoms such as long COVID also brings back faith in the healthcare system, promoting health seeking behaviors like prevention rather than interventions that slow down inevitable outcomes (Smith & Parker, 2015). Improving institutional integrity not only supports evidence-based practice continuation but also encourages stakeholder buy-in which assists in reducing healthcare costs competitively and promotes expansion for alternative treatments to be included and covered with medical insurance.

### **Findings Related to Literature Review**

The literature review conducted prior to implementation of this project revealed there is still a great deal of unknown associated with long COVID, enforcing that further research is needed to fill in the knowledge deficits. It was clear in this review that long COVID is a growing health concern worldwide as the impending burden on health care systems has the potential to have a debilitating impact (Chen et al., 2022). It was also evident in literature that PBM holds the potential to lessen this impending burden with its positive therapeutic effects when used during active COVID infections (Sigman et al., 2020; Vetrici et al., 2021; Williams et al., 2021).

The findings of the quality improvement research project *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* were limited by sample size but did show statistical significance in reducing symptoms of fatigue with no effect on dyspnea measured by oxygen saturation. The significant reduction of cytokine secretion and inflammatory markers with PBM use as indicated by Da Cunha Moraes et al. in 2018 supported this project's finding of fatigue reduction as there is a relationship between systemic inflammation and chronic fatigue. It was noted that participants had the most improvement in fatigue seen after three weeks of treatment which was consistent with the 2021 case study conducted by Williams et al. as well as Sigman et al. in 2020 where symptoms had improved in three weeks with PBM treatment utilized during active COVID infection. This study's results were similar to the case report conducted in 2021 by Pelletier-Aouizerate and Zivic where inflammatory responses had been reduced but unlike their findings oxygenation had not improved as the measured oxygenation status was within normal range prior to

treatment. These findings provide a basis and encourage further research for utilization which is also congruent with the literature relating to PBM for use in COVID treatment.

### **Facilitators and Barriers to Implementation**

*Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms:* A community wellness initiative was facilitated by overwhelming support throughout the process. Project committee members were instrumental in project development and assisting with direction. The PBM Center of Excellence, director, and staff members went above and beyond to assist in implementation by making sure the facility, treatment bed, and staff were available for the duration of the project. Multiple entities of the University to include the School of Nursing and University President were supportive throughout the progress of this endeavor. The participants were the largest facilitator to project success with their commitment to participate for the duration of the research study. The state of WV also played a huge role in facilitation with the Governor granting funding for COVID relief and research through the CARES Act Grant making this research project possible.

Although the project was well supported, multi factorial barriers to implementation were present. Time was the most significant barrier which encompassed limitations for recruitment window, project completion deadlines, and participant's availability for participation commitment. Another substantial barrier was the session accessibility relating to general location and appointment availability within normal operating hours of the PBM Center of Excellence. Unforeseen circumstances such as illness and spontaneous vacations were contributory barriers that prevented session compliance and study commitment. Lack of knowledge and interest/belief in PBM

therapy from providers and potential participants also presented as a barrier for implementation as this prevented recruitment aid from local providers and willingness to commit to study duration.

### **Project Limitations**

The quality improvement research project, *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative*, held several limitations. The novelty of COVID resulting in reduced understanding presented a large limitation as there is no research regarding long COVID treatments with FDA approval, and limited research on the effects long COVID over time at the time this study took place. The lack of knowledge regarding alternative treatment modality options, such PBM, in combination with limitation in study duration due to deadlines had a significant impact on participation recruitment and compliance. Participation conflicts were largely related to scheduling conflicts with the limitation of one location, one treatment modality, and set schedule for implementation. Project participation size, in addition to recruitment time constraints, was another limiting factor.

It was determined through power analysis that the greatest statistical power for representation and generalization would require 44 participants. Study size was limited related to funding with max participant allowance of 15 individuals for this study. Data focus on quantitative measures also limited the opportunity of including beneficial qualitative data relating to participant satisfaction and experience. Alternative methods of dyspnea measurement should be explored in order to represent PBM impact as pulse

oximetry was not a strong indicator of abnormality given all participants had with in normal range oximetry with reports of dyspnea.

### **Project Implications for Practice**

The quality improvement project research pilot, *Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative*, showed with statistical significance that PBM is a potential treatment modality for mitigating symptoms of long COVID with numerous benefits for practice. This pilot study aids in shaping future research that promotes improving practice standards with an intervention option that is noninvasive with few to no risks (Liebert et al., 2020). By identifying a modality that can be used to mitigate the growing healthcare problem of long COVID this project aids in reducing the strain on the healthcare workforce by providing an option that provides comfort and reassurance for the patient during a time of uncertainty. This project serves as a foundation for continued research and basis for treatment protocols as well as encourages further exploration of PBM therapy benefits and its utility for healthcare practice in the future.

### **Recommendations for Sustaining the Intervention**

Recommendations for sustaining this quality improvement research project includes suggestions to improve and expand future research. Following this study several participants shared with this investigator positive impacts treatment sessions had left on other areas of their health. The inclusion of qualitative data such as patient experience and satisfaction would strengthen future data by providing insight to patient perspective of PBM and treatment benefits and aid in increasing awareness of PBM benefits. Testimonial inclusion would also strengthen support and be beneficial for stakeholder

buy-in influence. Expanding future research to include a larger sample size, multiple treatment beds and locations, and removing strict schedule windows would improve accessibility and session compliance to facilitate further implementation success.

Affordability is a significant factor for successful sustainability. Encouraging continued research for PBM use in mitigation of chronic symptom management to improve long COVID suffers' quality of life emboldens advocacy for reduction of unnecessary medical expense and supports the continuation of evidence-based practice persistence to improve patient outcomes. Eliciting grant funding to continue immediate research is necessary. Increasing data provides more insight not only into patient outcomes and refining treatment protocols but also sheds light on cost-benefit analysis for management of long COVID symptoms with nonpharmacologic treatment modality such as PBM. It is imperative to recruit support from stakeholders such as the FDA and insurance agencies to ensure PBM affordability and accessibility long term.

### **Dissemination of Findings Plan and Rationale**

*Testing the utility of photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative* study results and final project were made available for participants, facility, and stakeholders through request. This principal investigator conducted a final project defense to present findings to DNP committee with open invitation for attendance. This final project will be submitted to ProQuest, and profession publication sought to further disseminate findings. Publication also encourages replication, continuation, and expansion of this pilot study and should be accessible to all those who are interested. Dissemination of these findings provides increased knowledge of the growing health concern long COVID poses and treatment

benefits PBM therapy provide and will encourage practice improvements in healthcare as best evidence-based practices are continued to be sought through quality research.

### **Summary**

This quality improvement pilot research study has shed light on how COVID-19 has impacted our heavily burdened healthcare system and the potential devastation long COVID poses if effective management and treatment solutions are not sought. Owing to the novel nature of this growing health concern, large gaps in literature and lack of FDA approved treatments to mitigate symptoms of long COVID remain. This successful implementation of this project, although a pilot for research study, provides the first step in bridging the gap. The initiative provided a nonpharmacologic intervention option of global PBM therapy to mitigate symptoms of long COVID that provided immediate relief and showed success in as little as three weeks. The implications this study holds for practice provides hope to not only individuals suffering from long COVID, but also the healthcare providers who are confronting this upcoming healthcare crisis.

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# **DO YOU SUFFER FROM CHRONIC FATIGUE AND/OR SHORTNESS OF BREATH FOLLOWING COVID-19 INFECTION?**

***IF SO THIS MAY BE THE STUDY FOR YOU!***

**Study evaluating the use of Photobiomodulation Therapy to improve long COVID symptoms of fatigue and shortness of breath.**



Photobiomodulation therapy (PBM) utilizes non-thermal forms of light in the visible infrared spectrum to reduce inflammation, alleviate pain, promote tissue regeneration, wound healing, and muscle and joint recovery.

Looking for 15 individuals with chronic fatigue and/or shortness of breath since having COVID-19 willing to participate in this 6 week wellness initiative utilizing global Photobiomodulation therapy via the NovoTHOR bed at the Shepherd University Wellness Center in Shepherdstown, WV.

**Eligibility: Must be 18 years of age or older. Participants must be able to access the NovoThor treatment bed independently or be accompanied by a care giver to assist in mobility and tolerate laying flat for 12 minutes at a time. Participants will agree to partake in the treatment 3 times per week for a length of 6 weeks at no cost for treatment. Participants will complete anonymous surveys and have pulse oximetry readings pre and post treatment 3 times during the 6 weeks. Participants must have their own transportation. Individuals who have known cancer must provide clearance from healthcare provider to participate. No pregnant participants at this time.**

**TUESDAYS AND THURSDAYS 8AM-5PM, AND SATURDAYS FROM 8AM TO 4PM STARTING JUNE 7TH-JULY 16TH**

**FOR MORE INFORMATION OR INTEREST PLEASE CONTACT  
TIFFANY SOMMER, BSN,RN AT  
TBOYLE01@RAMS.SHEPHERD.EDU**

Shepherd University  
School of Nursing  
Informed Consent

*Testing the utility of using photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative.*

Dear Potential Participant,

You are invited to participate in the study, *Testing the utility of using photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative*. The objective of this quality improvement project is to evaluate the utility of global photobiomodulation (PBM) therapy in the subjectively reported symptoms of fatigue and dyspnea (shortness of breath) post COVID-19 infection.

As a participant of this study, you will be invited to participate in sessions three times a week (Tuesdays, Thursdays, and Saturdays) for six weeks. In addition, you will be asked to complete surveys and pulse oximetry measurements at study initiation, 3 weeks, and 6 weeks. Surveys includes a de-identified demographics, and a fatigue assessment scale. The purpose of the data collection is to document the effects of self-administration of global PBM sessions on long COVID symptoms of fatigue and dyspnea. The data may be included in publication submissions to professional journals, highlighting the successes/lessons learned from the study. No personal or identifying information is reported.

If you choose to participate in the study, you will be asked to read PBM session protocols and complete surveys and other documentation explained above prior to treatment.

Survey/documentation should take less than 10 minutes to complete.

Participation involves no more risk of harm than occurs in daily life. There are no known side effects of PBM when used according session protocols. The benefits of this study include reduction of inflammation, pain alleviation, and the potential to experience an improvement to quality of life by reducing and/or eliminating symptoms of fatigue and dyspnea.

Participation in this study is voluntary. You have the right to refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You have the right to withdraw from participating in the study at any point. Results of this study may be published or presented.

Data security and access: Confidentiality and anonymity will be upheld with survey submissions utilizing a 5-question assessment that requires alternating one letter or number answers to create a unique patient identifier. All paper copies of signed informed consent, patient agreements, and any surveys will be immediately electronically scanned and stored on a secured password protected electronic device and paper copies promptly destroyed. Password protected files will be stored

electronically on a password and biometrically secured computer, and on a password protected server for 5 years and then destroyed.

Future Use: The PI may use this protocol on other patients in the future.

You have the right to ask questions about this study and to have those questions answered before, during and after the study has been conducted. If you have any further questions regarding the study, you may contact me, Tiffany Sommer, BSN, RN, at [tboyle01@rams.shepherd.edu](mailto:tboyle01@rams.shepherd.edu) or Dr. Kelly Watson Huffer, DNP, CRNP, CNE at [kwatsonh@shepherd.edu](mailto:kwatsonh@shepherd.edu).

Any questions regarding your rights as a research participant may be addressed to the Shepherd University Institutional Review Board: Dr. Jason Best, IRB Chair, 304.876.5331. All research projects that are carried out by investigators at Shepherd University are governed by the requirements of the University and the Federal Government. In case of research related injury, contact the above person as soon as you are medically able.

Your signature below indicates that you have decided to volunteer as a research participant for the, *Testing the utility of using photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative*, and that you have read and understand the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Participant Name (Printed) \_\_\_\_\_

Participant Signature \_\_\_\_\_

Date \_\_\_\_\_

Investigator Signature \_\_\_\_\_

Date \_\_\_\_\_

## Photobiomodulation Therapy

Photobiomodulation (PBM) therapy is a form of low dose light treatment that has been shown to reduce pain or inflammation and promote healing. PBM uses visible and near-infrared light to selectively inhibit pain receptors or promote resolution of inflammation. It is also able to stimulate the inherent tissue healing and regeneration responses in the body. It has been shown to improve muscle performance and joint motion, by reducing inflammation wherever the light is applied. Treatments take between 12 minutes and is repeated up to three times a week in a light bed (NovoTHOR).

### CONTRAINDICATIONS FOR PHOTOBIMODULATION

Published research shows that there are no contraindications established currently to receive locally applied PBM treatments, following the manufacturer's User Instructions. Nonetheless, caution must be exercised with the following conditions, and generally the PBM Center will decline to permit use of a bed or canopy for persons in these categories:

**PREGNANCY:** Whole body PBM therapy should be avoided in pregnant women as the effects on developing fetus remains unknown. However, local PBM treatments may be used with caution on the pregnant woman as an adjunct to the other modalities to manage back pain or other complaints.

**CARCINOMA:** Direct PBM treatments on tumors are not recommended. However, application of PBM in other areas of pain is known to benefit supportive cancer care. Any PBM treatment must be performed in consultation with the oncologist, care-givers.

**PHOTOSENSITIVITY REACTIONS:** Some patients are known to be more photosensitive, and some drugs or natural remedies are known to exacerbate these reactions. A detailed history and careful observation after the first PBM session is recommended. In rare instances, even local treatment may be contraindicated.

- **RESTRICTIONS TO CONTINUING TREATMENTS:** Some patients may report a number of sensations, such as localized feelings of warmth, tingling, or an increase or decrease in symptoms, nausea or dizziness within the 24-hour period immediately following PBM treatments. In patients with persistent or severe treatment reactions, immediate physician consultation and discontinuation of further sessions are recommended.
- **INHERENT RISKS IN ANY THERAPEUTIC EXERCISE**  
Any individual person can possibly incur an adverse reaction to any therapeutic activity, even if all instructions are followed carefully, because every human body has unique characteristics. Each client has to make an informed judgment of whether to accept that statistically remote risk.

### PRE-SESSION INSTRUCTIONS

It is very important that you follow these recommendations for optimal benefits:

- **Initial consultation with your primary physician or caregiver.**
- Lotions, powder, deodorant, antiperspirant, perfume, makeup, or anything topical on the body may reduce benefit. It is recommended these items are not used within 1 hour prior to session.

- Let the technician know if you have had any recent skin lesions. For the protection of all the PBM bed users, all lesions must be covered with an adhesive bandage.
- Let the technician know if you have any questions prior to the Light Therapy Session.

#### **SESSION PROCESS**

- You will be asked to disrobe to your level of comfort, however light cannot easily penetrate thick fabric or layers of clothing so it is optimal for no/minimal clothing to be worn.

**For PBM Bed**

- You will lie on the bed face up for the duration of the session. Suggested session will be between 12 and 20 minutes. No prescription glasses or contacts should be worn. Sunglasses (non-prescription) or PBM recommended goggles should be worn.
- When the session is complete, the unit will turn off automatically. At that time, please exit the bed and get dressed.
- Notify the staff that you are finished and sit in the chair provided until you are assisted.
- The bed and goggles will be cleaned thoroughly with an approved cleaning solution prior to all PBM sessions.

**AFTER ANY SESSION**

- Drink 64-80oz water within 24 hours of PBM Session. Resume normal activity.

.....  
....

**CONSENT TO PBM THERAPY**

The signature made below is an acknowledgment that: 1) I have read and understand the information about Photobiomodulation Therapy and the protocols for the administration of the therapy. I have been given an opportunity to ask the staff questions and I have received all of the information I desire about the therapy and the procedures. I hereby give my authorization and consent for the administration of PBM therapy, as indicated here by my initials:

\_\_\_\_\_ Use of PBM Bed

I agree that I will comply with all instructions on the use of the PBM devices.

This CONSENT shall stand as long as I use the Equipment at the location now and in the future. I can revoke this consent verbally or in writing or by simply exiting the facility, but I do understand that during use of the PBM bed or canopy an attendant may not be instantly available for an immediate verbal revocation/ request to cancel the procedure.

I have read the instructions for proper use of the facilities and do so knowingly. I acknowledge that I am making an informed decision to assume risk, known and unknown, as to any damage or harm that I might incur due to use of the facilities. Because Photobiomodulation should be avoided under certain conditions, I affirm that I have stated all my known medical conditions and answered all questions honestly. I agree to keep the therapist updated as to any changes in my medical profile and understand that there shall be no liability on the therapist's part should I forget to do so.

\_\_\_\_\_  
Client Signature

\_\_\_\_\_  
Date

**CLIENT'S WAIVER AND RELEASE OF LIABILITY AND HOLD HARMLESS AGREEMENT (Release)**

I hereby confirm that no warranty or guarantee, or other assurance, has been made to me relating to the results of the Photobiomodulation Therapy and I assume all risk as to whether the Therapy will produce my desired results. I understand that Photobiomodulation therapy is provided for the basic purpose of relaxation, stress reduction, relief of muscular tension, recovery from muscular tension, and recovery from surgery, illness or injury. I agree to use all sessions within the terms of the contract dates and understand that refunds are not given on unused portions of purchased packages.

I further understand that Photobiomodulation should not be construed as a substitute for medical examination, diagnosis, ortreatment and that I should see a physician, chiropractor, or other qualified medical specialist for any mental or physical ailment that I am aware of. I understand that Photobiomodulation technicians are not qualified to perform skeletal adjustments, diagnose and/or prescribe, and that nothing said in the course of the session should be construed as such.

I have been advised of the risks and hazards connected with the use of the Devices and the PBM Therapy, including the risk of a physical injury; in the event of the remote risk of some injury, there is also a risk that some aspect of the injury may be permanent in nature. I assume all risk as to any known or unknown possible adverse effect.

In consideration for using the PBM device(s) and the administration of PBM Therapy to me, I hereby RELEASE, WAIVE, DISCHARGE, and HOLD HARMLESS Shepherd University, its officers, agents, employees and volunteers (hereinafter referred to as RELEASEES) from any and all liability, claims, demands, actions and causes of action whatsoever, known and unknown, arising out of or related to any loss, damage, or injury, that may be sustained by me, while using the devices or dueto the use of the devices for PBM therapy.

I acknowledge that this Waiver, Release and Hold Harmless Agreement shall bind the members of my family and spouse (if any), if I am alive, and my heirs, assignees and personal representative, if I am not alive, and shall be deemed as a RELEASE, WAIVER, AND DISCHARGE of the above named RELEASEES. I hereby further agree that this Waiver of Liability and HoldHarmless Agreement shall be construed in accordance with the laws of the State of WEST VIRGINIA.

In signing this RELEASE, I Acknowledge and Represent that I have read and understand the entire Agreement, and I am atleast eighteen (18) years of age and fully competent to manage my affairs. I understand that I am giving up certain possiblelegal claims and I execute this Release freely, voluntarily, under no duress or threat of duress, and without inducement, promise or guarantee being communicated to me other than the use of the PBM Therapy as stated in this document.

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Client's Printed Name

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Signature

---

Date

# Unique Identifier Form

*Please answer questions using one character or  
number unless otherwise indicated*

1. *What is the first letter of your middle name?* \_\_\_\_\_

2. *How many brothers do you have? Example:  
If you have no brothers your response is 0,  
may use multiple digits.* \_\_\_\_\_

3. *What is the first letter of your favorite color?* \_\_\_\_\_

4. *What is the number for your month of birth?  
Example: December = 12* \_\_\_\_\_

5. *How many pets do you have?* \_\_\_\_\_

# Demographics

Please check or circle:

1. Age Range

☐ 18-30

☐ 31-40

☐ 41-50

☐ 51-60

☐ 61-70

☐ 71-80

☐ 81 and older

2. Gender

☐ Male

☐ Female

☐ Other

☐ Prefer not to answer

3. Ethnicity:

☐ Hispanic or Latino or Spanish Origin

☐ Not Hispanic or Latino or Spanish Origin

4. Race:

☐ White

☐ Black or African  
American

☐ American Indian or  
Alaska Native

☐ Asian

☐ Native Hawaiian or  
Other Pacific Islander

5. Date(s) of COVID infection(s)

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6. Length of time long COVID has affected you? (i.e. 7 weeks, 6 months)

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7. COVID Vaccine:

- Have you received primary series of COVID Vaccine (2 doses of Pfizer/Moderna or 1 dose of J&J)?
  - ☐ Yes
  - ☐ No
- If previous question answered “yes”, have you received a booster (if eligible)?
  - ☐ Yes
  - ☐ No
- If yes to above, please indicate number of boosters received:  

---

8. Smoking

- ☐ Current Smoker
- ☐ No

9. Have long COVID symptoms impacted your ability to work or prevented you from working for any length of time? If yes, please explain below.

- ☐ Yes
- ☐ No
- ☐

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## Fatigue Assessment Scale (FAS)

The following ten statements refer to how you usually feel. Per statement you can choose one out of five answer categories, varying from Never to Always. Please circle the answer to each question that is applicable to you. Please give an answer to each question, *even if you do not have any complaints at the moment*.

1 = Never, 2 = Sometimes; 3 = Regularly; 4 = Often and 5 = Always.

|                                                                | Never | Sometimes | Regularly | Often | Always |
|----------------------------------------------------------------|-------|-----------|-----------|-------|--------|
| 1. I am bothered by fatigue                                    | 1     | 2         | 3         | 4     | 5      |
| 2. I get tired very quickly                                    | 1     | 2         | 3         | 4     | 5      |
| 3. I don't do much during the day                              | 1     | 2         | 3         | 4     | 5      |
| 4. I have enough energy<br>for everyday life                   | 1     | 2         | 3         | 4     | 5      |
| 5. Physically, I feel exhausted                                | 1     | 2         | 3         | 4     | 5      |
| 6. I have problems to start things                             | 1     | 2         | 3         | 4     | 5      |
| 7. I have problems to think clearly                            | 1     | 2         | 3         | 4     | 5      |
| 8. I feel no desire to do anything                             | 1     | 2         | 3         | 4     | 5      |
| 9. Mentally, I feel exhausted                                  | 1     | 2         | 3         | 4     | 5      |
| 10. When I am doing something,<br>I can concentrate quite well | 1     | 2         | 3         | 4     | 5      |

## Appendix B: Letters of Agreement with Clinical Agency

### Shepherd University *Wellness Center*

*Dr. Jennifer Flora- Director*

March 29, 2022

To Whom It May Concern:

I am aware that Tiffany Sommer is conducting a research study as part of her requirement for her degree completion. Tiffany Sommer is a nurse practitioner doctoral student at Shepherd University and has no affiliation with the Shepherd University Wellness Center professional services. Tiffany's research study focuses on the global use of Photobiomodulation on individuals who are experiencing effects from long COVID. Tiffany has shared with me the details of her project.

I give Tiffany Sommer permission to conduct her study at our agency, the Shepherd University Wellness Center, from June 2022 through July 2022.

The Shepherd University Wellness Center requests the agency name and identifiers of its clients be kept completely confidential in the research results

Sincerely,



Dr. Jennifer Flora  
Wellness Center Director  
Shepherd University

Shepherd University Wellness Center- 164 University Drive, Shepherdstown WV 25443  
304-876-5295

## Appendix C: IRB Approval



### *Institutional Review Board*

Wednesday, May 25, 2022

IRB Proposal Number: 506

Tiffany Sommer

Testing the utility of using photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative

Dear Tiffany Sommer:

On May 23, 2022, a member of the Shepherd University Institutional Review Board (IRB) completed a review of the revised materials for the research proposal entitled "Testing the utility of using photobiomodulation therapy to mitigate long COVID-19 symptoms: A community wellness initiative". The purpose of this research is to evaluate the utility of global photobiomodulation therapy on subjectively reported symptoms of fatigue and dyspnea (shortness of breath) post COVID-19 infection in a community setting. This research has been approved. Permit number 2022052501 has been issued for this research. Please be aware that your project will need continuation approval should it extend beyond May 25, 2023.

If you make any changes to the protocol during the period of this approval, you must submit a revised protocol to the IRB for approval before implementing the changes. Finally, you should file a Final Closure Report (available at <http://www.shepherd.edu/irb/irb-forms>) with the IRB chair upon termination of the project. If you have any questions regarding the IRB's decision, please contact me at 304-876-5331.

Sincerely,

Jason Best, Chair  
Shepherd University IRB

cc. Kelly Watson Huffer

## Appendix D: Tables

**Table 2**

*Project Expense Summary*

| Project Item                               | Expense  |
|--------------------------------------------|----------|
| Miscellaneous Supplies                     | \$100    |
| Equipment                                  | \$100    |
| Technician Salary                          | \$1,629  |
| Treatment Session Cost for 14 Participants | \$8,880  |
| Project Total Expenditure                  | \$10,709 |

**Table 2**

*Summary of Sample Characteristics*

|               |               | Frequency | Percent |
|---------------|---------------|-----------|---------|
| Gender        | Male          | 5         | 35.7    |
|               | Female        | 9         | 64.3    |
| Age           | 18-30         | 1         | 7.1     |
|               | 31-40         | 3         | 21.4    |
|               | 41-50         | 4         | 28.6    |
|               | 51-60         | 2         | 14.3    |
|               | 61-70         | 4         | 28.6    |
| Ethnicity     | Non-Hispanic  | 14        | 100     |
| Race          | Caucasian     | 12        | 85      |
|               | Asian         | 1         | 7.1     |
|               | Missing Entry | 1         | 7.1     |
| COVID Vaccine | Yes           | 9         | 64.3    |
|               | No            | 5         | 35.7    |
| COVID Booster | Yes           | 5         | 35.7    |
|               | No            | 9         | 64.3    |
| Smoker        | No            | 14        | 100     |
| Work affected | Yes           | 10        | 71.4    |
|               | No            | 4         | 28.6    |

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