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Mediation and Moderation of Sleep in Arthritis Fatigue

Jean L. Cody
University of Massachusetts Amherst

Mediation and Moderation of Sleep in Arthritis Fatigue

A Dissertation Presented

by

JEAN LEMIEUX CODY

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Jean Cody

Approved as to style and content by:

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Jeungok Choi, Chair

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Donna M. Zucker, Member

_____
Jing Qian, Member

_____
Cynthia S. Jacelon, Dean
College of Nursing

DEDICATION

To my patient and loving husband, Frank.

I am so blessed to have you in my life.

I could not have obtained my degree without your love and support.

Thank you for being you!

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ABSTRACT

MEDIATION AND MODERATION OF SLEEP IN ARTHRITIS FATIGUE

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JEAN LEMIEUX CODY, BSN, SAINT JOSEPH COLLEGE, MAINE

MS (NURSING), UNIVERSITY OF COLORADO, DENVER

PhD, UNIVERSITY OF MASSACHUSETTS, AMHERST

Directed by: Professor Jeungok Choi

Fatigue is a highly prevalent symptom for older adults with arthritis. Fatigue is a concerning symptom as it is associated with decreased activity and exacerbates co-morbidities. Physical activity and sleep quality have been shown to influence arthritis fatigue. However, the relationship between physical activity and sleep quality over time has not been clearly identified.

The purpose of this pilot study was to examine the relationship between physical activity, sleep and arthritis fatigue. This study examined the direct effects and the mediation and moderation of sleep upon fatigue. The study utilized an experimental, longitudinal repeated measures design using mediation and moderation methodology by Barron and Kenny. Older adults (n=24) with moderate arthritis fatigue from New England participated in the study. Physical activity was defined as simple walking. Participants wore an accelerometer for 6 weeks and kept a daily step count log. Fatigue and sleep disturbance were measured using PROMIS instruments at week 1, 4 and 6. In the cross-sectional study at week 1, the results demonstrated there is no mediation and moderation effect of sleep on arthritis fatigue. In the longitudinal study at week 4, the effect of

physical activity was increased when the variable, sleep, was added to the model from -.60 to -.83 indicating that sleep mediates the effect of physical activity on arthritis fatigue. In a follow-up longitudinal study at week 6, sleep did not mediate nor moderate the effects of physical activity on fatigue. No moderation of the effect of sleep was identified at week 1, 4 or 6. The study findings indicate that longitudinal designs are helpful to understand the relationships between physical activity, sleep and fatigue. The study results suggest that promoting physical activity and sleep may help with arthritis fatigue over time, however this result appears time limited.

Keywords:

Fatigue, Physical Activity, Sleep Disorders, Osteoarthritis, Rheumatoid Arthritis, Mediation, Moderation

TABLE OF CONTENTS

Page

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

Background and Significance

Fatigue and arthritis. Fatigue has been defined as "lack of energy and inability to maintain a usual routine" (Cella et al., 2010). While acute fatigue is generally linked to a specific cause and is often relieved by restorative managements such as rest, persistent fatigue is considered to be abnormal and pervasive, occurring in patients who generally gain no relief from usual restorative managements (Christodoulou et al., 2014). Fatigue is a concerning symptom in the older adult as it is associated with functional deficits (Hardy & Studenski, 2008a) and predicts 10-year mortality (Hardy & Studenski, 2008b).

Arthritis is also a condition of great public health importance. The prevalence of arthritis in the US is 23% or 54.4 million individuals resulting in 1 in 4 adults in the US having arthritis (Sandoval-Rosario et al., 2018). Arthritis is the leading cause of disability among older adults (Barbour et al., 2017). Arthritis clients bear a large burden of co-morbidities such as heart disease, obesity, and diabetes (Havens et al., 2017).

Arthritis is a musculoskeletal condition that affects the joints and surrounding connective tissues (muscles, tendons, ligaments) (Hootman et al., 2012). There are different types of arthritis; two types of interest are osteoarthritis and rheumatoid arthritis. Osteoarthritis (OA) is the most common type of arthritis, affecting approximately 30 million adults (CDC, 2020). OA is a classic age-related disorder and a chronic

degenerative disease (Anderson & Loeser, 2010). The risk factors for OA are obesity, physical inactivity, and joint injury (Hawker, 2019).

Rheumatoid Arthritis (RA), the second most common type of arthritis and affects more than 1.3 million adults in the US (Ma et al., 2014). The cause of RA is not known; it is thought to be related to genetic and environmental factors (Deane et al., 2017). RA is one of the most expensive health conditions treated at US hospitals, accounting for a total annual cost of $19.3 billion (Birnbaum et al., 2010).

Arthritis associated fatigue is of great concern because it is highly prevalent, occurring in up to 70% of arthritis clients, and interferes with their participation in usual daily routines (Gron et al., 2014; Kirwan et al., 2007; Overman et al., 2016). Arthritis fatigue is the strongest predictor of reduced subsequent activity (Murphy et al., 2013). Reduced activity for arthritis clients exacerbates arthritis symptoms and other co-morbidities they experience. Arthritis fatigue impacts clients by decreasing physical activity in the clinical picture where physical activity is known to be helpful in reducing fatigue symptoms and managing co-morbidities (Hootman et al., 2012)

When evaluating the covariates of arthritis fatigue, there are multiple factors (Hackney et al., 2019). Relationships between the modifiable variables of physical activity and sleep in clients with arthritis fatigue have been identified (Matura et al., 2018). Physical activity and sleep quality are behavioral factors that also play a role in managing the co-morbidities of heart disease, obesity and diabetes (Hootman et al., 2012). Therefore, this research focuses on the specific variables of physical activity and sleep and their relationship to arthritis fatigue.

Physical activity, fatigue, and sleep. Physical activity has been shown to decrease fatigue symptoms in arthritis clients (Durcan et al., 2014; Katz et al., 2018; Rongen-van Dartel et al., 2016). Physical activity is also associated with improvement in sleep quality and in arthritis patients (Durcan et. al, 2014). Several studies have demonstrated a correlational relationship of fatigue, physical activity and sleep. Among older people with OA, poor sleep is highly prevalent and significantly linked with fatigue (Hardy & Studenski, 2008a). Poor sleep is independently related to fatigue (Austad et al., 2017). RA fatigue is directly influenced by poor sleep and physical functioning (Rongen-van Dartel et al., 2016). Physical inactivity has also been shown to have an indirect association with fatigue, mediated by poor sleep, depression, and obesity (Katz et al., 2016). Research highlighting the relationships between fatigue, physical activity and sleep generally involves cross sectional research designs (Loppenthin, Esbensen, Ostergaard, et al., 2015; Puyraimond-Zemmour et al., 2017; Westhovens et al., 2014).

Cross sectional designs provide insight into various variables but it is difficult to determine causal relationship between them (Nikolaus et al., 2013; Solem, 2015). While physical activity and sleep are considered factors related to arthritis fatigue, the role of sleep in this relationship has not been clearly been identified (McKenna et al., 2017; Nikolaus et al., 2013). Additional research using randomized controlled trials or longitudinal designs will enhance the understanding of the mechanisms at work between the variables of fatigue, physical activity and sleep. This research adds to what is known regarding the relationship of arthritis fatigue, physical activity, and the role of sleep in a longitudinal design. This research also highlights the importance of second-generation research to improve clinical interventions in addressing fatigue.

Second-generation research. Physical activity and sleep have been identified as having a relationship with arthritis fatigue. The next step in advancing this knowledge is to understand the role of sleep as a third variable in the relationship. Guralnick (1993) described the value and role of first- and second-generation research through his work in childhood early intervention. These categories are applicable to nursing research and provide meaningful insight into the significance of third variable research (Guralnick, 1993).

First generation research involves the demonstration of the direct relationship between variables; one variable is tested for the main effect on another (Hopwood, 2007). First generation research focuses on the relationship between the independent and the dependent variable (MacKinnon & Luecken, 2008). However, there are limitations to direct effect research, especially as it may be applied in the clinical setting, in that one size does not fit all. Current evidence supports there is a relationship between the variables of interest, physical activity, sleep and arthritis fatigue.

Second-generation research was conceptualized in response to the utilization of first-generation research (Guralnick, 1993). Clinical research must establish more than an effect exists (Kraemer et al., 2002). It is important to understand how those effects operate and the boundary conditions for those effects. Second-generation research involves the specification of the characteristics that interact to optimize particular treatment under certain conditions (Hayes & Rockwood, 2017).

Second-generation research examines the conditions under which the main effect(s) operate between two (2) variables. This is represented through third (3^{rd}) variable research design (Hopwood, 2007). Examination of the role and value of third

variables and their effects is important to allow clinicians insight into and refine existing treatments to provide personalized care (Kraemer et al., 2002). This research examines the role of the third variable effect of sleep upon arthritis fatigue through mediation and moderation methodology.

Mediation and moderation methodology. Mediation and moderation methodologies provide a conceptual and statistical strategy for third (3^{rd}) variable designs that involves variables (or sets of variables) that influence relations between interventions and outcomes (Breitborde et al., 2010). Mediators help explain a relationship between two variables because the mediator is an intermediate in the causal sequence. This explains "how" the relationship works between the three (3) variables. Moderators consider the unique conditions in which two (2) variables are related. The relationship between the two (2) variables changes as levels of the moderator change. This explains "when and under what conditions" a variable outcome may be maximized. Mediators and moderators provide critical evidence for clinicians to fine tune interventions.

Significance. This second-generation, longitudinal design pilot examines the mechanisms between physical activity, sleep, and arthritis fatigue. Arthritis fatigue is multifactorial; this study focuses on two variables and how they interact on the outcome of arthritis fatigue (third (3^{rd}) variable design). Therapeutic measures (i.e. medications) alone do not diminish arthritis fatigue (Nikolaus et al., 2013). Cognitive behavioral interventions, such as health promotion to promote physical activity, are part of current arthritis management and can be targeted to alleviate fatigue. The significance of understanding the mechanism between physical activity, sleep and arthritis fatigue is that clinicians can refine existing treatments to maximize effectiveness and that interventions

can be tailored. The knowledge obtained from this study is helpful for the development of subsequent larger longitudinal clinical trials to evaluate the effect of physical activity and sleep upon arthritis fatigue. The study results also provide insight into fatigue management interventions that may be suitable in other contexts such as fibromyalgia, autoimmune disorders, and cancer-related fatigue.

Purpose

The purpose of this study was to examine mechanisms between physical activity, sleep, and arthritis fatigue. This research examined the direct, mediator and moderator effects of the variables based on the basic methodological approach of Baron and Kenny (Baron & Kenny, 1986). The initial analysis identified the direct effects of physical activity upon arthritis fatigue. The second phase examined the mediating effects of physical activity and sleep upon fatigue, the mechanism between the variables. Finally, the moderating effects of the variables were examined; the mechanisms in which physical activity and/or sleep constrain or amplify the relationship to arthritis fatigue

Aims

The first aim of the study was to determine if there was a relationship between physical activity and arthritis fatigue symptoms. The second aim of the study was to examine the mechanism of sleep as a mediator of physical activity on arthritis fatigue. The third aim was to determine if sleep has a moderating effect on physical activity upon arthritis fatigue.

Primary Research Questions

Direct Effects:

1.0 What is the direct effect of physical activity on arthritis fatigue?

Mediating Effect:

2.0 Does sleep mediate the effect of physical activity on arthritis fatigue?

Moderating Effect:

3.0 Does sleep moderate the effect of physical activity on arthritis fatigue?

Theoretical Framework

The theoretical framework of this study is based on the conceptual and statistical mediation and moderation model (Baron & Kenny, 1986). The variables of physical activity, sleep and fatigue were chosen based on two models in the literature; Biobehavioral Model of Fatigue in Osteoarthritis (Hackney et al. 2019) and Theoretical Model of RA fatigue (Katz et al., 2016). The Biobehavioral Model of Fatigue in Osteoarthritis (Hackney et al. 2019) identifies through a review of the literature the relationship between fatigue, sleep quality, and physical activity. The Theoretical Model of RA fatigue (Katz et al., 2016) identifies the relationship of physical activity sleep and sleep and their relationship to fatigue based on a cross sectional study of 158 RA patients. Hackney and Katz both highlight multiple factors identified as having a relationship to RA fatigue. However, this study has been designed to explore the relationship between the modifiable variables associated with arthritis fatigue, physical activity, and sleep.

Physical inactivity was found to have an indirect association with fatigue, mediated by other variables including poor sleep (Katz et al., 2016). However, there is no other research identifying any moderating affects that activity and sleep may have on arthritis fatigue. The remaining theoretical models for the study guide the examination of the direct effects, mediating effects and moderating effects of simple walking and sleep upon arthritis fatigue.

1.0) What is the direct effect of physical activity on arthritis fatigue?

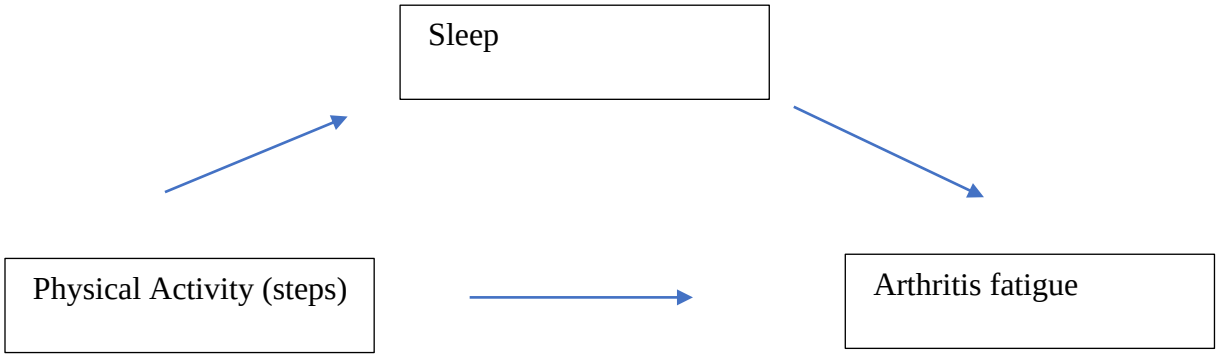
Figure 1

Direct Effect of Physical Activity on Arthritis Fatigue

2.0) Does sleep mediate the effect of exercise on arthritis fatigue?

Figure 2

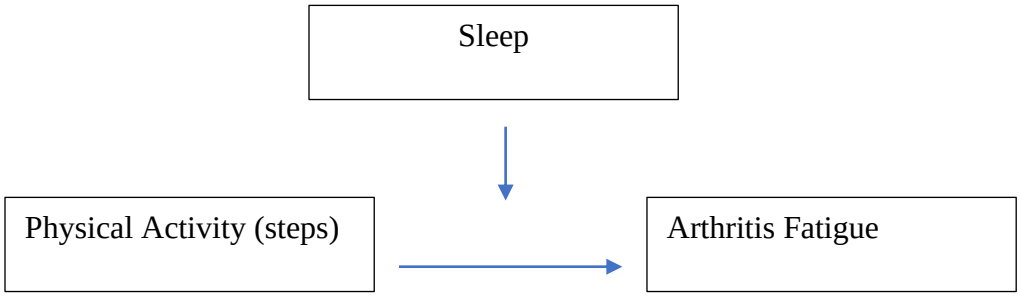
Mediation Analysis



3.0) Does sleep moderate the effect of physical activity on arthritis fatigue?

Figure 3

Moderation Analysis



Definition of Terms

Independent and dependent variables for this study were informed by the Biobehavioral Model of Fatigue in Osteoarthritis (Hackney et al. 2019) and Theoretical model of RA fatigue (Katz et al., 2016). Literature review helped to refine and guide the operational definitions for each variable. The descriptions of the theoretical and operational definitions for each variable are described in the following sections.

Demographic Variables

Demographic data collected in the study included sex, race, ethnicity, education level, marital status, household occupants, and current employment.

Independent (Predictor) Variables

The independent variables measured for this study were physical activity and sleep. Physical activity was conceptualized as simple walking. Walking is an activity in which the body advances at a slow to moderate pace by moving the feet in a coordinated fashion. The definition of walking is movement of an individual through the activities of daily living plus additional sessions of walking. No special equipment is required for simple walking outside of safe shoes and it may be done inside or outside. The operational definition of simple walking was through an off the shelf accelerometer that provides step count data. Off the shelf technology provides a reasonable measure over time and is a cost-effective strategy for home measurement. For an accelerometer, we used a Fitbit wristband to count daily steps over the study period.

The second independent variable was sleep. Sleep is a condition of the body and mind that *"typically recurs for several hours every night, in which the nervous system is*

relatively inactive, the eyes closed, the postural muscles relaxed, and consciousness practically suspended. Sleep is a purposeful activity that occurs every night provides individuals with rest and restoration" (Cella et al., 2010).

Sleep was measured by 8-item PROMIS Short Form v1.0 - Sleep Disturbance 8b (PROMIS SD-SF) (Yu et al., 2012). PROMIS SD-SF assesses self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep over the past seven days. Higher scores correspond to greater sleep disturbance or sleep-related impairment. Participant's sleep was measured at week 1, week 4 and week 6.

Dependent (Outcome) Variable

The dependent variable measured for this study was arthritis fatigue. Fatigue is defined as *"an overwhelming, debilitating, and sustained sense of exhaustion that decreases one's ability to carry out daily activities, including the ability to work effectively and to function at one's usual level in family or social roles"* (Cella et al., 2010). Study participant's fatigue was measured with the PROMIS Fatigue- Short Form (Lai et al., 2011). The PROMIS F-SF consists of eight items that measure both the experience of fatigue (e.g., severity) and the interference of fatigue on daily activities (e.g., physical, emotional, and social) over the past week. Response options are on a point Likert scale, ranging from 1 = *never* to 5 = *always*. Participant's fatigue was measured at week 1, week 4 and week 6.

Summary

Fatigue is a common and debilitating symptom of arthritis. Arthritis fatigue has been studied extensively in various cross-sectional designs. There is clear evidence that arthritis fatigue is a multifactorial issue and there are relationships between the variables of physical activity, sleep, and fatigue. Physical activity and sleep are modifiable variables that have impact on other co-morbidities.

This longitudinal study examined previously identified variables, physical activity and sleep, and their relationship to fatigue. This is second-generation research seeking to understand the operation and boundary characteristics of a third variable: sleep. This study used a mediation and moderation methodology to examine the relationships, building on what is known. This research is significant in several ways. The longitudinal findings from this study add to what is known from cross-sectional studies. This research is also significant because clinicians may be able to tailor interventions for clients with greater insight into how physical activity and sleep directly affect, mediate, or moderate the outcome of fatigue.

CHAPTER 2

REVIEW OF LITERATURE

Purpose and Search Strategy

The purpose of this section is to review the current literature as it relates to arthritis and the variables of interest: fatigue, physical activity, and sleep. This section describes the search strategy, review of the literature of the variables of interest, and discusses the opportunity for the conduct of this research proposal.

A comprehensive search of the literature was performed in August 2018 to February 2020 to determine studies that examine the relationship between the variables of fatigue, sleep, and physical activity. The following databases were searched: PubMed, EbscoHost (Science Citation Index, Academic Search Premier, CINAHL Complete, MEDLINE, PyschInfo, SPORTDiscus Direct) and Web of Science (WoS). All the listed databases were searched using the singular and combination of major MeSH search terms: “fatigue”, “physical activity”, “sleep disorders” and “osteoarthritis” or “rheumatoid arthritis”. The article inclusion criteria search parameters were published after 2000; peer reviewed; clinical trial; abstract present; English language; and humans. The article exclusion criteria were pharmaceutical trial; no abstract or abstract only. The titles and abstracts were then manually reviewed for relevance and the eligibility. There were 12 articles identified through the search process. See table 1 for details.

Table 1

Search Strategy

Search Strategy	Database	Items	Individual Review
Arthritis	PubMed	6,693	
Arthritis->Fatigue	PubMed	218	
Arthritis->Fatigue->Sleep	PubMed	33	
Arthritis->Fatigue->Sleep->Activity	PubMed	14	4
Arthritis	EbscoHost	19,993	
Arthritis->Fatigue	EbscoHost	1,039	
Arthritis->Fatigue->Sleep	EbscoHost	139	
Arthritis->Fatigue->Sleep->Activity	EbscoHost	17	6
Arthritis	Web of Science	127,877	
Arthritis->Fatigue	Web of science	2,183	
Arthritis->Fatigue->Sleep	Web of Science	388	
Arthritis->Fatigue->Sleep->Activity	Web of Science	100	2

Arthritis

Arthritis is a debilitating disease that in various forms affects approximately 54 million US adults (Barbour et al., 2017). Arthritis is a condition that affects the joints, tissues around the joints, and connective tissues leading to joint pain, stiffness, and deformity (National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), 2014). Arthritis symptoms diminish the ability to move making it the leading cause of disability (CDC, 2009). It is estimated that over 78 million adults will be afflicted with arthritis by 2040 (Hootman et al., 2016).

There are over a100 types of arthritis (CDC, 2019). The most prevalent forms of arthritis are osteoarthritis (OA) and rheumatoid arthritis (RA). While the arthritis pathophysiology differs, they share similar disease burden (Chua et al., 2019). The long-

term effects of OA and RA are joint symptoms, joint deformity, and disability (Hootman et al., 2012). Both types of arthritis are thought to have an inflammatory response (Arthritis Foundation, 2020; Hackney et al., 2019).

Osteoarthritis is the most common form of arthritis, affecting 30 million, predominantly female Americans over 65 years of age (Hawker, 2019). Osteoarthritis creates a mechanical musculoskeletal issue when the cartilage between bones breaks down and joints become painful, swollen and hard to move (Arthritis Foundation, 2020). The risk factors for osteoarthritis are age, sex, past injury, obesity, and genetics (Sakalauskiene & Jauniskiene, 2010). Osteoarthritis is not a natural consequence of aging (Ashford & Williard, 2014) and symptoms can be addressed to prevent deterioration and disability (Hootman et al., 2012)

Rheumatoid arthritis (RA) is the second most common form of arthritis. It is an autoimmune disease where the body attacks healthy tissues and cells (National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), 2014). RA causes chronic inflammation resulting in pain, swelling, stiffness and loss of function in the joints and organs (NIAMS, 2017). Approximately 1.5 million US adults are afflicted with RA (Hootman et al., 2016). The average age of onset is between 40-60 years (Scott et al., 2010) and RA is more prevalent in women than men (NIAMS, 2017).

Current Arthritis Treatment Overview and Role of Nursing

Arthritis treatment strategies fall under three basic categories: managing the disease process, maximizing cognitive behavioral processes, and addressing personal issues and individual needs (Hewlett et al., 2011). All three of the strategies involve

nursing expertise. Nursing care impacts the management of the disease process, utilizes cognitive behavioral approaches and participates in the management of personal issues such as the co-morbidities. This section describes the arthritis treatment overview and the role of nursing.

Managing the arthritis disease process may involve a variety of medical interventions. Treatment may require joint replacement (Hawker, 2019). In some cases, medications are used to diminish the inflammatory response and limit disease activity (Scott et al., 2010). There are still questions regarding the role of inflammation and disease activity in arthritis (Hackney et al., 2019; Matura et al., 2018). Medical management does not completely address all the symptoms clients endure (Hootman et al., 2012; Walter et al., 2018). Medical interventions provide some relief and improvement for arthritis clients. Cognitive behavioral interventions are promising as they provide complementary or alternative treatment options.

Cognitive behavioral interventions reflect the dynamics between thoughts, feelings, behaviors, and symptoms (Hewlett et al., 2011). Managing the whole person using cognitive behavioral strategies to promote behavior change has shown symptom improvements including pain and fatigue (Ferwerda et al., 2017). Interventions focused on limiting sitting time improved activity levels and physical function, and reduced levels of fatigue in sedentary patients with arthritis (Thomsen et al., 2017). Changing behaviors, such as health promotion activities of increasing physical activity, have a role in decreasing fatigue symptoms and improve function by 40% (Kelley et al., 2011). Cognititve behavioral interventions to promote a healthy lifestyle also can be individualized to meet the personal challenges each arthritis client faces.

The third component of arthritis treatment involves managing their unique personal factors. Caring for people with arthritis includes managing co-morbidities (Hewlett et al., 2011). Co-morbidities are a problem for arthritis clients. Approximately half of all adults with arthritis have diagnosed heart disease and one third with obesity (Chua et al., 2019; Tournadre et al., 2018). Arthritis, and resulting decrease in physical activity, makes it harder to manage the chronic conditions of heart disease and obesity.

Treating arthritis involves medical management of the disease, cognitive behavior interventions to promote a healthy lifestyle, and addressing personal issues unique to the individual, such as co-morbidities (Hewlett et al., 2011). Nurses are professionally positioned to assist in all these areas. Nurses contribute illness management and health promotion expertise to clients. This study advances knowledge and the relationship of two health promotion activities- physical activity and sleep- and provides additional information regarding their mechanism in arthritis fatigue.

Fatigue in Arthritis

Fatigue levels have been shown to be similar across different types of arthritis (Cross et al., 2008). Severe arthritis fatigue is most common in women, those not working, and those with less physical activity (Tournadre et al., 2018). Arthritis patients report that their overwhelming concern and priority is fatigue, yet it is often overlooked by care providers (Hewlett et al., 2005; Power et al., 2008). Arthritis fatigue is widespread, pervasive, and a priority for patients.

Physical Activity and Fatigue

A number of physical activity/exercise interventions (e.g., pool-based therapy, dynamic strength training, yoga, low-impact aerobics, etc.) have shown to have beneficial effects on alleviating fatigue (Cramp, Hewlett, et al., 2013; Katz et al., 2018). Physical activity interventions decrease fatigue by improving an individual's aerobic and functional capacity, thereby reducing the effort to perform daily tasks (Katz, 2017). Kelley, Kelley and Callahan (2018) reported that aerobic exercise significantly decreases fatigue symptoms. Katz and colleagues (2018) also reported that increasing physical activity through a walking intervention over a twenty one week period led to decreased fatigue in arthritis clients. Two recent meta-analysis studies also reported a significant moderate effect for these physical activity interventions (Cramp, Berry, et al., 2013; Rongen-van Dartel et al., 2016). Physical activity, in a variety of forms, appears to be beneficial for arthritis fatigue.

In considering which form of physical activity is best for arthritis patients, walking has been deemed a reasonable form of exercise (Baxter et al., 2016). Walking is an activity in which the body advances at a slow to moderate pace by moving the feet in a coordinated fashion. Walking is easy to learn with little professional guidance and equipment and is well suited to meet the needs of patients with fatigue who often have difficulties traveling to places outside the home for exercise training. One way to measure exercise is through the use of accelerometers to count steps; for example, Fitbit has been deemed accurate for frail older adults with slow gait (Case et al., 2015; Le Masurier & Tudor-Locke, 2003) and as a method of tracking walking as exercise (Paul et al., 2015).

Sleep Quality and Arthritis Fatigue

The majority of persons with arthritis report poor sleep quality (Fertelli & Tuncay, 2019; Goes et al., 2017). Older adults with arthritis exhibit a relationship between poor sleep and higher reported levels of fatigue (Hawker et al., 2010). Some studies have suggested sleep improvements can be made through increased physical activity (Dolezal et al., 2017). Arthritis clients with higher levels of physical activity experience more total sleep time (McKenna et al., 2018). This suggests a relationship between physical activity and sleep.

Relationship Between Arthritis Fatigue, Physical Activity and Sleep

The challenge in evaluating the mechanisms between arthritis fatigue, physical activity and sleep is there is limited research that 1) evaluates all the variables together; 2) uses consistent measurement tools; and 3) is behaviorally based, as opposed to a pharmaceutical trial. This section expands on the studies that use some form of all the variables of interest and includes cross-sectional and one randomized controlled trial (RCT) designs.

Increasing physical activity is associated with improved sleep and decreased fatigue symptoms in older adults (Christie et al., 2016). Twenty-two older adults (ages 65-81) participated in a study examining the relationship of physical activity, sleep quality, and fatigue in community dwelling adults. This study suggests a relationship between the variables; however, the study sample size was small, the duration of the study was over 7 days and the population was healthy adults, not those with arthritis.

A large study (n=384) by Loppenthin et al (2015a, 2015b) examined a population of arthritis clients to determine relationships between arthritis, physical activity, sleep as

well as other variables. The findings of these studies suggested that physical activity leads to less fatigue and that fatigue is associated with sleep quality (Loppenthin, Esbensen, Jennum, et al., 2015; Loppenthin, Esbensen, Ostergaard, et al., 2015). These studies address the components physical activity, fatigue, and sleep but do not clearly lay out relationships between the three variables. These studies are further limited by their cross-sectional design.

Factors supporting the relationship of arthritis fatigue, physical activity and sleep were identified by Rongen-van Dartel (2016). In this study of 228 arthritis clients, poor sleep and less physical functioning were directly related to higher levels of fatigue (Rongen-van Dartel et al., 2016). A relationship between the variables is suggested through this research, though the cross-sectional design does not provide direction for the relationship.

Physical activity was found to have an indirect association with fatigue, mediated by poor sleep (Katz et al., 2016). This research evaluated 158 arthritis clients to determine variables associated with fatigue. This study suggests the relationship exists between the variables, however, is limited by the cross-section design.

Sleep quality has an indirect effect on functional ability, which includes walking, through its relationship with pain and fatigue. Cross-sectional examination of the relationship between sleep quality and functional ability in 162 patients with arthritis determined fatigue and pain were mediators to sleep quality and disability (Luyster et al., 2011). While this provides some insight, there are limitations to this research in that the variables of interest are not directly examined. The researchers evaluated the mediators

to sleep quality and disability, however the cross-sectional design limits determination of causation, direction or magnitude.

There is one seminal piece of research in the literature. Durcan et al. (2014) evaluated the effect of exercise on sleep quality and fatigue using a randomized control trial study design. The intervention was a tailored 12-week exercise program developed by specialists after the baseline assessment with follow up every 3 weeks. The exercise program consisted of several treatment modalities, including resistance training, range of motion, and walking. There were 40 patients in the intervention group and 38 participants in the control group who received usual care and advice on the benefits of exercise with RA. There was a statistically significant improvement for the intervention group in sleep quality ($p = 0.04$) and fatigue ($p = 0.04$) (Durcan et al., 2014) indicating that the physical activity intervention improved sleep quality and fatigue symptoms. However, there are some limitations to this study. The exercise intervention is expert and time intensive; specialists (MD and physiotherapist) reviewed the baseline assessments to create an individualized 12-week program with follow up every 3 weeks. In addition, there were several treatment modalities, including resistance training, range of motion, and walking within the intervention, requiring an intensive amount of resources. Simple walking may be a sufficient intervention to produce this effect.

Opportunity for Research: The Gap

Implications of the previous study designs and results provide an opportunity to add to the evidence base of physical activity, sleep, and arthritis fatigue. The literature implies that a relationship has been identified between these variables in persons with

arthritis. However, much of the literature evaluates only two out of three of the variables of interest. Most of the studies reporting this relationship have been cross-sectional, so it is not possible to make claims other than correlations. The other challenging component of the literature available regarding fatigue, physical activity and sleep is the wide range of measurement tools used (McKenna et al., 2017). This makes it difficult to compare the study results. The relationship between physical activity, fatigue and sleep may not be a simple linear relationship. Exploring how and when the variables interact has not been clearly investigated.

Theoretical Framework: Mediation and Moderation Models

The theoretical framework in this study was developed based on two chronic illness fatigue models that informed the variable selection, Biobehavioral Model of Fatigue in Osteoarthritis (Hackney et al.) the Theoretical Model of RA Fatigue (Katz et al., 2016). The overall framework for the study is the mediation moderation model (Baron & Kenny, 1986). The proposed research explored the relationship between physical activity, arthritis fatigue and sleep quality.

The Biobehavioral Model of Fatigue in Osteoarthritis (Hackney et al., 2019) was developed through a systematic review. The authors developed a model of the correlates of fatigue. Physical activity and sleep quality are identified as behavioral factors suggested to have a direct relationship upon fatigue. A limitation of this model is that it has not been validated through research.

The second model used in this study is the Theoretical Model of RA Fatigue (Katz et al., 2016). The study used the findings from a study that explored the sources of

fatigue from a sample of 158 rheumatoid arthritis clients. The findings indicated a statistically significant relationship between physical inactivity, poor sleep, and fatigue. Mediation analysis indicated the physical inactivity had an indirect association with fatigue and this relationship was mediated by poor sleep (Katz et al., 2016). The study limitations are the cross-sectional design and the focus on inactivity versus activity. However, the relationships identified provide us with insight on the correlational relationships between these variables for continued exploration.

The overall framework to support the conceptual and statistical methodology of mediation and moderation are based on the work of Baron and Kenny (1986). Mediation and moderation are two distinct concepts and applications to describe the relationship between variables beyond the identification of a causal relationship (Baron & Kenny, 1986). The conceptual model of mediation and moderation is briefly discussed here; the statistical methodology is described in Chapter 3.

The review of the literatures indicates relationships related to arthritis fatigue and can be considered first generation research. The reviews suggest the next step in the progression of this knowledge is advancement towards second-generation research designed towards "how", "why", "for whom" and "under what circumstances" (Breitborde et al., 2010). Mediator and moderator methodology provide the framework to ask these second-generation research questions.

Mediation can be considered the "how" and "why" of variables. Identification of a mediator assists in explaining the process between the independent variable and the dependent variable in a causal relationship. The mediator is integral because if found it is

the intermediate in the causal sequence (Breitborde et al., 2010; MacKinnon & Luecken, 2008). A mediator can only exist where there is a causal relationship. The first aim of this study is to determine if a causal relationship exists between physical activity and arthritis fatigue. If that is indeed true, the second aim of this study is to determine the role of sleep in the causal pathway between physical activity and arthritis fatigue.

Moderators consider the unique conditions in which two variables are related. Moderators explain "when" and "under what conditions" variables are related. The relationship between the independent variable and the dependent variable change as the level of moderator changes (MacKinnon and Lueken, 2008). The third and final aim is the examination of the variables of physical activity and sleep, individually and combined, and their effect upon arthritis fatigue.

Summary

Arthritis is a debilitating chronic disease. Arthritis treatment revolves around several strategies: medical management of disease process (i.e. surgical or medical intervention), behavioral components (i.e. such as increasing physical activity, promotion of sleep), and other personal/individual needs such as co-morbidities. Behavioral opportunities are showing promise, and naturally fit into nursing activities and priorities.

This research examines the variables of interest, physical activity, arthritis fatigue, and sleep and explores the relationship between them using a mediation moderation model. In addition, this research uses standardized measurement tools, PROMIS, so that other PROMIS researchers can build on the results (Bartlett et al., 2015). Understanding

the relationship between physical activity, arthritis fatigue and sleep provides opportunity to improve nursing and medical clinical management and research efforts.

CHAPTER 3

METHODS

Introduction

The purpose of this pilot study was to explore the relationship between physical activity, arthritis fatigue, and sleep. This study is designed to examine the mediation and moderation effects of sleep over time upon the relationship of physical activity and arthritis fatigue. This chapter describes the study design, sample, intervention, instruments, procedures, and data analysis.

Study Design

The study utilized an experimental, longitudinal repeated measures design. Participants (n= 24) were evaluated on three outcomes: 1) daily steps, 2) sleep disturbance and 3) fatigue. The outcomes were collected at baseline, week 4 and week 6 through self-reported surveys and with daily steps collected via accelerometer.

Sample

The study was conducted in multiple rural New England communities and reflected the current mix of older residents of the area. Participants were recruited from a senior center and YMCA in western MA, Foundation of State Nurses, and a State Council on Aging. The sample consisted of 24 adults, aged 50-86, with moderate fatigue. Although sample size calculation was not conducted because of the pilot nature of the study, twenty-four subjects were chosen based on the recommendation that 10-15 per group is adequate when the purpose of the study is to examine the effect of the pilot intervention (Hertzog, 2008).

Study inclusion criteria were 1) age 50 or older 2) self-reported physician's diagnosis of osteoarthritis or rheumatoid arthritis, and 3) presence of greater than minimal fatigue scoring ≥17 on the PROMIS Fatigue Short Form v1.0 –Fatigue 8a (PROMIS F-SF) (Lai et al., 2011). Exclusion criteria were 1) non-ambulatory or presence of a condition that would limit the ability to walk (e.g., foot deformity, lower extremity joint surgery in past 6 months, stroke, severe chronic obstructive pulmonary disease, etc.); and 2) overt delirium, dementia, or any conditions indicating deteriorating cognitive status as determined by the Mini-Cog (Borson et al., 2000).

Instruments

Study subjects eligible for inclusion in the study were screened for the cognitive ability to participate. To assess cognition, Mini-Cog (Borson et al., 2005) was used. The Mini-Cog (Appendix A) consists of two components, a 3-item recall test for memory and a clock drawing test. It has a high level of sensitivity (76%) and specificity (89%) (Borson et al., 2005) and is not adversely influenced by age, language, or education (Borson et al., 2003).

A Fitbit accelerometer worn as a wristband was used to count steps. The Fitbit wristband was chosen because it has a long battery life lasting up to 6 months for easy wear without recharging and is accurate for tracking step counts of frail older adults with slow gait (Case et al., 2015). The Fitbit built-in application was used to track and record daily steps taken.

Participant's fatigue was measured with the PROMIS F-SF (Lai et al., 2011). The PROMIS F-SF (Appendix B) consists of eight items that measure both the experience of fatigue (e.g., severity) and the interference of fatigue on daily activities (e.g., physical,

emotional, and social) over the past week. Response options are on a 5-point Likert scale, ranging from 1 = *never* to 5 = *always*. Scores can range from 8 to 40, with higher scores indicating greater fatigue. PROMIS F-SF demonstrated good reliability with Cronbach's alphas of .72 to .88 (Ameringer et al., 2016). The scale also showed good validity across ethnically/racially diverse populations (Ameringer et al., 2016); concurrent validity was supported by moderate to high correlations between PROMIS F-SF and the Multidimensional Fatigue Symptom Inventory-Short Form (r = .70 to .85) and between PROMIS F-SF and the Brief Fatigue Inventory (r = .60 to .85); and discriminant validity was supported by moderate correlations with other measures of constructs that are related, but not alike, the Perceived Stress Scale (r =.62) and the Center for Epidemiological Studies-Depression (r =.64).

Sleep disturbance was measured by 8-item PROMIS Short Form v1.0 - Sleep Disturbance 8b (PROMIS SD-SF). PROMIS SD-SF (Appendix C) assesses self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep over the past seven days. Higher scores correspond to greater sleep disturbance or sleep-related impairment. The scale demonstrated excellent internal consistency with Cronbach's alphas > 0.9 (Fogelberg et al., 2015) as well as strong convergent-discriminant validity with high correlations with the Pittsburgh Sleep Quality Index (r=0.83 - 0.85) and low correlations with the Epworth Sleepiness Scale (r=0.25 - 0.30) (Yu et al., 2011).

Procedures

Institutional Review Board (IRB) approval for the study was obtained. A recruitment plan was used to focus on areas where arthritis clients congregated that was accessible to the PI. Areas of focus were arthritis support groups, arthritis exercise

groups and a state nursing research network. IRB approved flyers were posted in provider care offices; senior center bulletin boards; and included in State Center for Aging new letters. After determining interested individuals, the participants' informed consent was obtained. Participants were then screened for inclusion and exclusion criteria (see Sample**)**.

Eligible participants had a one-on-one introductory session by the PI (PhD student). The session covered details about the study purpose and procedure, and instructions of how to operate an accelerometer. At the end of the session, participants completed the demographic questionnaire and were given a Fitbit accelerometer to wear for 6 weeks. Participants were asked to demonstrate reading the step count from the Fitbit screen and charging instructions. They were also given an activity log to write down their step count each night at bedtime. Participants were given self-addressed stamped envelopes to mail in the activity logs every 2 weeks. At the end of the visit, participants were provided with a 6-week calendar of the study activities, information on the use of the Fitbit, a copy of the signed consent form, and contact information for the PI.

Each week, participants filled out the weekly activity log, capturing the daily steps each evening at bedtime. Over the course of the 6-week study, the PI contacted the participants each week to determine if there were any problems with the Fitbit and answer any study related questions. At the end of weeks 1, 4, and 6 participants completed the sleep disturbance and fatigue questionnaires. See Table 2 for the outline of variables and data collection schedule.

Table 2

Data Collection Schedule.

Variable	Variable Type	Measurement Tool	Week 1	Week 4	Week 6
Cognitive Status	Screening for eligibility	Mini-Cog	x	n/a	n/a
Steps	Independent	Fitbit	Daily	Daily	Daily
Sleep Disturbance	Independent	PROMIS SD-SF	x	x	x
Fatigue	Dependent	PROMIS F-SF	x	x	x

Data Analysis

Descriptive statistics such as mean, median, mode, and range were calculated for each of the variables of interest. Data on participant characteristics and outcome variables were preliminarily analyzed to determine adequacy of randomization and normal distributions. Additionally, the variables were analyzed for a mediation and moderation effect of sleep using the models suggested by Baron and Kenny (Baron & Kenny, 1986; Hayes, 2009; Zhao et al., 2010).

Mediation effect of sleep. To test the relationship of mediation, the first step was to analyze the direct effects of physical activity upon arthritis fatigue.

1.0) Research question #1. What is the direct effect of physical activity on arthritis fatigue?

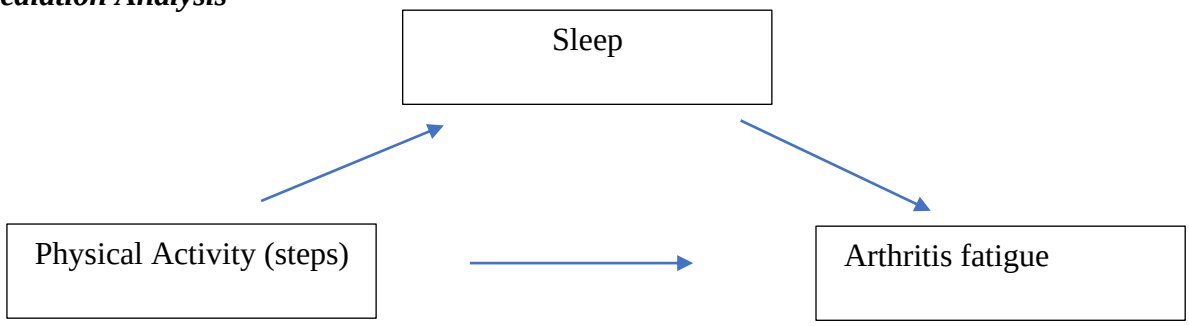
Figure 4

Direct Effect of Physical Activity on Arthritis Fatigue

2.0) Research question #2. Does sleep mediate the effect of physical on arthritis fatigue?

Figure 5

Mediation Analysis



To test the mediation effect of sleep, the following two regression models were built at three time points, week 1, week 4, and week 6. See Table 3.

Table 3

Regression Model for Mediation Analysis

Time		**Dependent Variable**	**Independent Variable(s)**
Week 1	Regression Model 1	Fatigue at week 1	Physical activity (steps) at week 1
			Sleep at week 1
	Regression Model 2	Sleep at week 1	Physical activity (steps) at week 1
Week 4	Regression Model 1	Fatigue at week 4	Physical activity (steps) at week 1
			Sleep at week 4
	Regression Model 2	Sleep at week 4	Physical activity (steps) at week 1

Week 6	Regression Model 1	Fatigue at week 6	Physical activity (steps) at week 1
			Sleep at week 6
	Regression Model 2	Sleep at week 6	Physical activity (steps) at week 1

The following three conditions were used to analyze if sleep mediates the effect of physical activity on arthritis fatigue (Baron & Kenny, 1986).

1. There is a significant relationship between physical activity (steps) and arthritis fatigue
2. There is a significant relationship between physical activity (steps) and sleep; and
3. The effect of physical activity (steps) on arthritis fatigue will disappear (or at least weaken) when sleep is included in the regression.

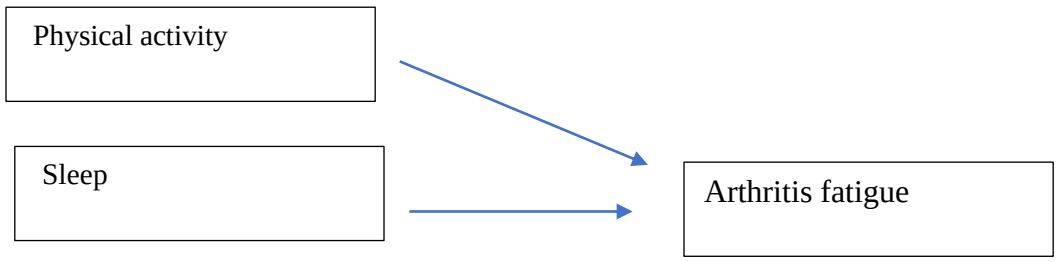
Moderation Effect of Sleep

3.0) Research question #3. Does sleep moderate the effect of exercise on arthritis fatigue?

To test the moderation effect of sleep, the following regression model was built at three time points, week 1, week 4, and week 6:

Figure 6

Moderation Analysis



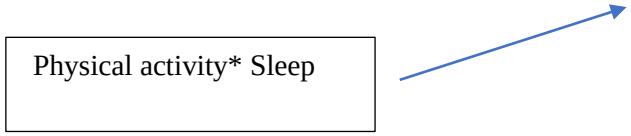


Table 4

Regression Model for Moderation Analysis

Time	**Dependent Variable**	**Independent Variable(s)**
Week 1	Fatigue at week 1	Physical activity at week 1
		Sleep at week 1
		Physical activity *sleep at week 1
Week 4	Fatigue at week 4	Physical activity at week 1
		Sleep at week 4
		Physical activity *sleep at week 4
Week 6	Fatigue at week 6	Physical activity at week 1
		Sleep at week at 6
		Physical activity *sleep at week 6

In the regression models, the statistical significance of the regression coefficient was tested. If significant, the result indicates the significant moderating effect of sleep on the relationship between physical activity (steps) and arthritis fatigue.

CHAPTER 4

RESULTS

Introduction

The purpose of this pilot study was to explore the relationship between physical activity, arthritis fatigue, and sleep. This study was designed specifically to examine the mediation and moderation effects of sleep over time upon the relationship of physical activity and arthritis fatigue. This section reports the results for each of the three research questions.

Demographics and Descriptive Statistics

The study sample consisted of 24 participants from New England who were ages 55-86. The sample ages were distributed evenly across the three decades. Two-thirds of the study population (n=16, 67%) reported rheumatoid arthritis and one-third (n=8, 33%) osteoarthritis. Most study participants were female (n=18, 75%); Caucasian (n=22, 92%); were married and living with a spouse (n=16, 66.7%). The sample population reported 25% (n=6) had a high school degree or less. The majority (n=18, 75%) were college prepared or more. Further descriptive data is displayed in Table 5.

Table 5

Demographics and Background

Variable	Frequency	Percent %
Arthritis diagnosis		

Rheumatoid arthritis	16	66.7
Osteoarthritis	8	33.3
Total	24	100.0
Age		
55-64	8	33.3
65-74	7	29.2
75-86	9	37.5
Total	24	100.0
Gender		
Female	18	75.0
Male	6	25.0
Total	24	100.0
Race		
White	22	91.7
African American	0	0
American Indian or Native Hawaiian or other	0	0
Asian	2	8.30
Total	24	100.0
Ethnicity		
Hispanic or Latino	0	0
Not Hispanic or Latino	24	100.0
Total	24	100.0
Education		

less than high school	1	4.2
high school	5	20.8
College	2	8.3
Master's degree	8	33.3
Doctoral degree	4	16.7
Professional degree (MD, JD)	4	16.7
Total	24	100.0
Marital Status		
Single, never married	3	12.5
Married or domestic partnership	16	66.7
Widowed	3	12.5
Divorced	1	4.2
Missing	1	4.2
Total	24	100.0
Living Status		
Living alone	6	25.0
Spouse	16	66.7
Friends	1	4.2
other	1	4.2
Total	24	100.0
Employment		
Employed	6	25.0
Self-employed	3	12.5
Retired	14	58.3

Unable to work	1	4.2
Total	24	100.0

Data was collected for the independent and dependent variables at weeks 1, 4, and 6. The PROMIS Fatigue (F-SF) and PROMIS Sleep Disturbance (SD-SF) instruments were scored by the HealthMeasures Scoring Service. De-identified survey data was converted by the service into a T-score for each participant. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation of 10. The Cronbach's alpha calculated from the PROMIS Fatigue (F-SF) results for weeks 1, 4, 6 ranged from 0.94-0.97. The Cronbach's alpha calculated for the PROMIS Sleep Disturbance (SD-SF) results for weeks 1, 4, 6 ranged from 0.87-0.95. Step counts were calculated from weekly averages of individual daily steps. The minimum, maximum, mean, and standard deviation were calculated for each variable at each measurement interval. This data is presented in Table 6.

Table 6

***Descriptive Statistics for Independent and Dependent Variables* (*n*=24)**

Time	Variable	Minimum	Maximum	Mean	Standard deviation
Week 1					
	Fatigue*	38.5	72.2	53.3	8.3
	Sleep*	42.4	66.7	53.7	6.7
	Step counts	1823.6	14655.9	6372.2	3113.2
Week 4					

	Fatigue	44.2	77.7	58.0	9.4
	Sleep	42.4	66.7	54.5	6.2
	Step counts	2026.5	14363.9	7097.6	3408.2
Week 6					
	Fatigue	38.5	77.7	53.2	8.0
	Sleep	42.4	66.7	55.4	6.3
	Step counts	1401.0	14830.6	6475.5	3336.0

*Fatigue and sleep scores are transformed to t-score with an average score of 50.

Week 1 results

Research question #1. What is the direct effect of physical activity on arthritis fatigue?

Week 1 is a cross-sectional analysis of the variables of physical activity, fatigue, and sleep. The results indicate there is no significant relationship between physical activity and arthritis fatigue (β=0.09, *t*=.42, *p*=.68). See Figure 4 and Table 7.

Figure 7

Week 1 Cross-sectional Analysis of Direct Effects

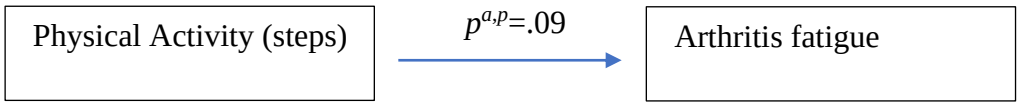


Table 7

Week 1 Cross-sectional Analysis Direct Effect

	Dependent. variable	Independent Variable	Standardized Coefficient (β)	*T*	Significance (*p*)

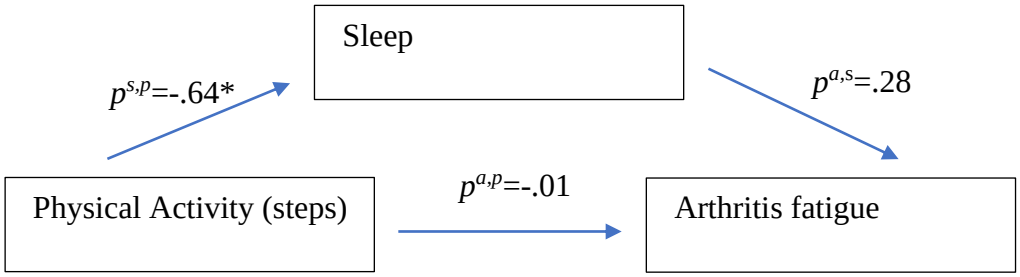
Regression	Fatigue	Step	.09	.42	.68

Research question #2. Does sleep mediate the effect of physical activity on arthritis fatigue?

Week 1 results consists of two regression analyses between physical activity, arthritis fatigue, and sleep (see Tables 8 and 9). The tables showed that step counts have a direct (path coefficient=-.01) and indirect (path coefficient=-.18) effect on arthritis fatigue, but the paths are not statistically significant. The results indicate sleep does not mediate the effect of step counts on arthritis fatigue. See Figure 5.

Figure 8

Week 1 Cross-sectional Mediation Analysis



* Path coefficient is significant at p <.05

Table 8

Week 1 Cross-sectional Regression Results for Mediation Analysis

	Dependent. variable	Independent variable	Standardized Coefficient (β)	*t*	Significance (*p*)
Regression 1	Fatigue	Step	-.01	-.03	.98

		Sleep	.28	1.11	.28
Regression 2	Sleep	Step	-.64	-2.52	.02

Table 9

Week 1 Cross-sectional Analysis Direct Effect and Indirect Effect

	Direct	Indirect	Total (Direct + Indirect)	Non-causal	Total effect + Non-causal
Step counts	-.01	-.64*.28=-.18	-.19	0	-.19
Sleep	.28	0	.28	(-.64)*(-.01)=.29	.57

Research question #3. Does sleep moderate the effect of physical activity on arthritis fatigue?

The interaction term between physical activity and sleep must significant for sleep to have a moderating effect on arthritis fatigue. In week 1 the results of physical activity*sleep interaction indicates there is no significant moderation effect of sleep (β=0.06, *t*=0.17, *p*=0.87). Sleep does not moderate the relationship between physical activity and fatigue. See Table 9.

Figure 9

Week 1 Cross-sectional Moderation Analysis

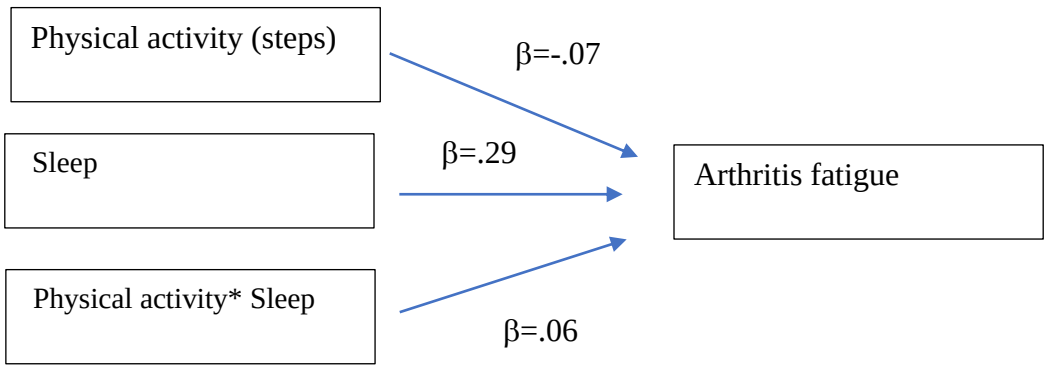


Table 10

Week 1 Cross-sectional Regression Results Moderation Analysis

Dependent variable	Independent variable	Standardized Coefficient (β)	*t*	Significance (*p*)
Fatigue	Step	-.07	-.14	.89
	Sleep	.29	1.09	.29
	Step*sleep	.06	.17	.87

Week 4 results

Research question #1. What is the direct effect of physical activity on arthritis fatigue?

The Week 4 longitudinal results indicate there is a significant relationship between physical activity and arthritis fatigue (β=-.19, *t*=-.40, *p*=.048). See Figure 7 and Table 11.

Figure 10

Week 4 Longitudinal Analysis Direct Effects

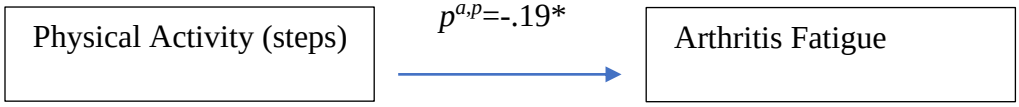


Table 11

Week 4 Longitudinal Analysis Direct Effect

	Dependent. variable	Independent variable	Standardized Coefficient (β)	*t*	Significance (*p*)

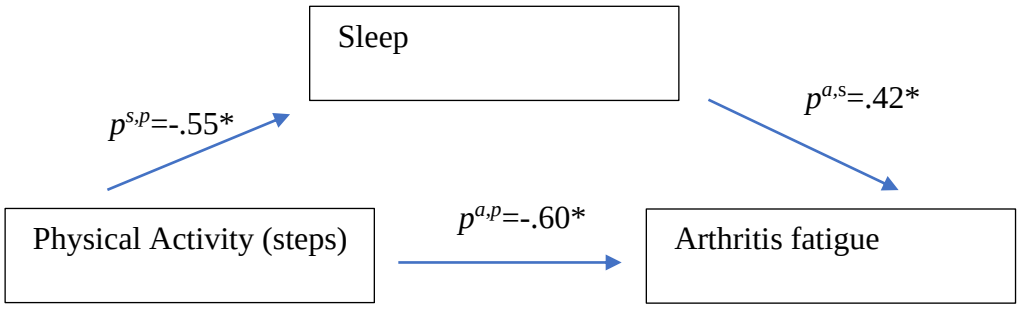
Regression	Fatigue	Step	-.19	-.40	.048

Research question #2. Does sleep mediate the effect of physical activity on arthritis fatigue?

Week 4 consists of two regression analyses between physical activity, arthritis fatigue, and sleep (see Table 12 and 13). The tables showed that physical activity has a direct (path coefficient=-.60) and indirect (path coefficient=-.23) effect on arthritis fatigue, and the paths are statistically significant. The results indicate that the effect of physical activity was increased when the variable, sleep, was added to the model from -.60 to -.83 suggesting that sleep mediates the effect of physical activity on arthritis fatigue. See Figure 8.

Figure 11

Week 4 Longitudinal Mediation Analysis



* Path coefficient is significant at p <.05

Table 12

Week 4 Longitudinal Regression Result for Mediation Analysis

	Dependent. Variable	Independent Variable	Standardized Coefficient (β)	*t*	Significance (*p*)

Regression 1	Fatigue	Step	-.60	-2.22	.04
		Sleep	.42	2.10	.049
Regression 2	Sleep	Step	-.55	-2.07	.049

* Path coefficient is significant at p <.05

Table 13

Week 4 Longitudinal Analysis Direct Effect and Indirect Effect

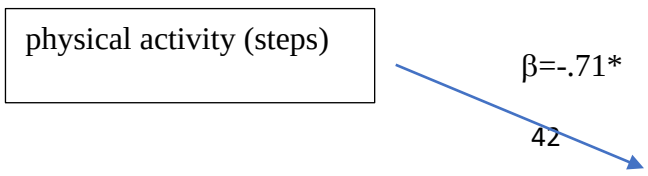
	Direct	Indirect	Total (Direct + Indirect)	non-causal	Total effect + non-causal
Step counts	-.60	(-.55)*(.42)=-.23	-.83	0	-.83
Sleep	.42	0	.42	(-.55)*(-.60)=.33	.75

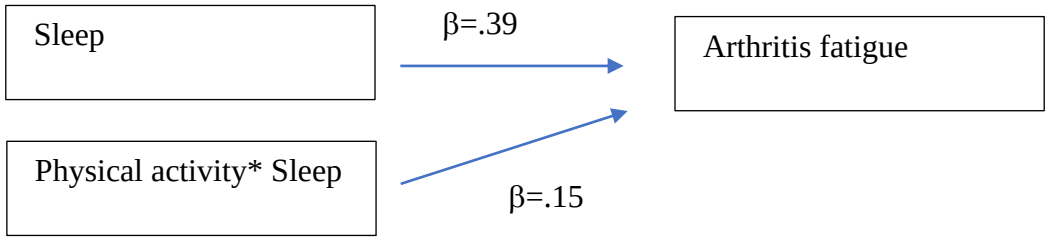
Research question #3. Does sleep moderate the effect of physical activity on arthritis fatigue?

To determine if sleep moderates the effect of physical activity on fatigue requires the interaction terms to be significant. In the week 4 results physical activity*sleep interaction is not significant (β=.15, *t*=.63, *p*=0.54). See Figure 8. Sleep does not moderate the relationship between physical activity and arthritis fatigue. See Table 13. However, there is a significant relationship between physical activity and arthritis fatigue ((β=-.71, *t*=-2.16, *p*=0.04).

Figure 12

Week 4 Longitudinal Moderation Analysis





* coefficient is significant at p <.05

Table 14

Week 4 Longitudinal Regression Results for Moderation Analysis

Dependent variable	Independent Variable	Standardized Coefficient (β)	*t*	Significance (*p*)
Fatigue	Step	-.71	-2.16	.04*
	Sleep	.39	1.86	.08
	Step*sleep	.15	.63	.54

* coefficient is significant at p <.05

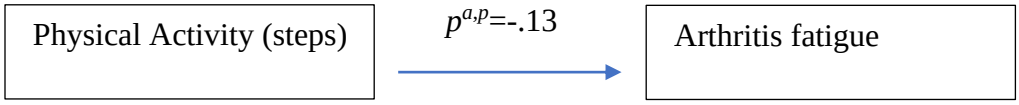
Week 6 results

Research question #1. What is the direct effect of physical activity on arthritis fatigue?

The Week 6 longitudinal results indicate there is no significant relationship between physical activity and arthritis fatigue (β=-.19, *t*=.60, *p*=.56). See Figure 10 and Table 15.

Figure 13

Week 6 Longitudinal Analysis Direct Effects



* coefficient is significant at p <.05

Table 15

Week 6 Longitudinal Analysis Direct Effect

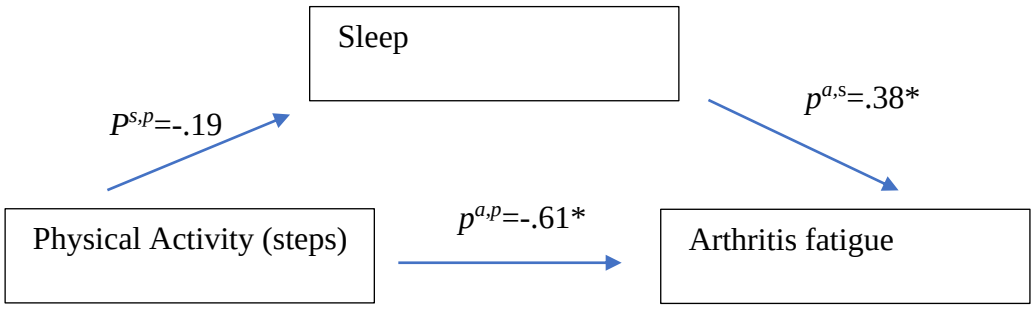
	Dependent. variable	Independent Variable	Standardized Coefficient (β)	*t*	Significance (*p*)
Regression	Fatigue	Step	-.19	.60	.56

Research question #2. Does sleep mediate the effect of physical activity on arthritis fatigue?

Week 6 results consists of two regression analyses between physical activity, arthritis fatigue, and sleep (see Tables 16 and 17). The tables show that physical activity has a direct (path coefficient=-.61) and indirect (path coefficient=-.07) effect on arthritis fatigue, however, the indirect path is not significant while the direct path is significant. The results indicate that sleep does not mediate the effect of physical activity on arthritis fatigue. See figure 14.

Figure 14

Week 6 Longitudinal Mediation Analysis



* Path coefficient is significant at p <.05

Table 16

Week 6 Longitudinal Regression Result for Mediation Analysis

	Dependent. variable	Independent Variable	Standardized Coefficient (β)	*t*	Significance (*p*)
Regression 1	Fatigue	Step	-.61	-2.59	.02
		Sleep	.38	2.18	.04
Regression 2	Sleep	Step	-.19	-.65	.52

Table 17

Week 6 Longitudinal Analysis Direct Effect and Indirect Effect

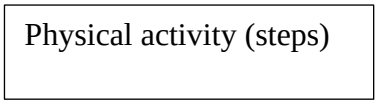
	Direct	Indirect	Total (Direct + Indirect)	non-causal	Total effect + non-causal
Step counts	-.61	(-.19)*(.38)=-.07	-.68	0	-.68
Sleep	.38	0	.38	(-.19)*(-.61)=.12	.50

Research question #3. Does sleep moderate the effect of exercise on arthritis fatigue?

The week 6 results to determine if sleep moderates the effect of physical activity on fatigue requires the interaction terms to be significant. In the week 6 results physical activity*sleep interaction is not significant (β=-0.003, *t*=-.01, *p*=.99). Sleep does not moderate the relationship between physical activity and arthritis fatigue. See Table 15.

Figure 15

Week 6 Longitudinal Moderation Analysis



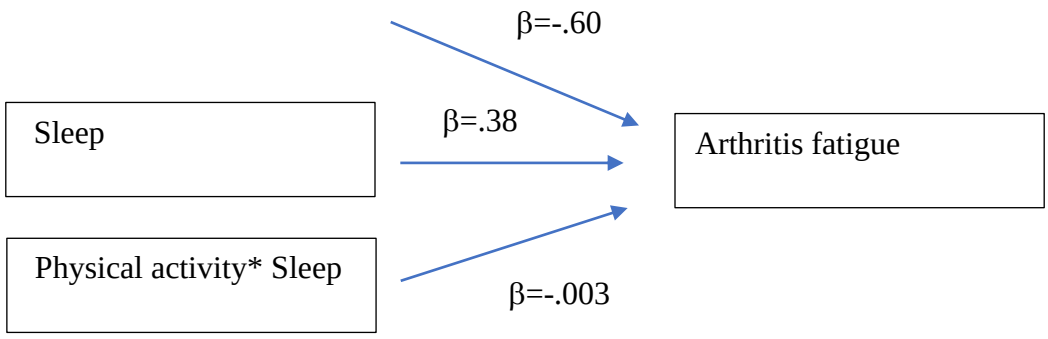


Table 18

Week 6 Longitudinal Regression Results for Moderation Analysis

Dependent variable	Independent Variable	Standardized Coefficient (β)	*t*	Significance (*p*)
Fatigue	Step	-.60	-2.04	.06
	Sleep	.38	2.04	.06
	Step*sleep	-.003	-.01	.99

CHAPTER 5

DISCUSSION

Study Overview

Fatigue is a highly prevalent symptom for older adults with arthritis. The purpose of this longitudinal pilot study was to examine the relationship between physical activity and fatigue and to explore the mediating and moderating effects of sleep on this relationship. In the cross-sectional results at week 1, the results demonstrated there is no mediation and moderation effect of sleep on arthritis fatigue. In the longitudinal results at week 4, the effect of physical activity was increased when the variable, sleep, was added to the model from -.60 to -.83 indicating that sleep mediates the effect of physical activity on arthritis fatigue. However, moderation effect of sleep was not identified. In the follow-up longitudinal results at week 6, sleep did not mediate nor moderate the effects of physical activity on fatigue.

Mediation Effect of Sleep

Mediators help explain the "how" and "why of a third variable in a causal relationship (Breitborde et al., 2010). The results of this longitudinal study indicate that mediation of sleep occurred at week 4. The findings are consistent with previous studies by Katz (2016) and Luyster (2011) which reported that sleep mediated fatigue symptoms. The standardized coefficients (β) for mediation were statistically significant and with a large effect size (β=-.83) according to (Cohen, 1988). In week 4, sleep had an additive effect by increasing the effect size from -.60 to -.83 when sleep was added on the

relationship between physical activity and arthritis fatigue. The findings suggest a clear and accurate relationships among three variables, especially a role of mediation of sleep.

In the week 6 results, sleep did not mediate the relationship between physical activity and fatigue. While the criteria for mediation was not met, two of the three pathways were significant. The path coefficients between physical activity and sleep was significant and with a moderate effect size (β=-0.61, t=-2.59, p=0.02) (Cohen, 1988). The relationship between sleep and fatigue was also significant with small effect (β=.38, t=2.18, p=0.04). When comparing with the week 4 results, the week 6 findings may suggest that the mediation of sleep on the relationship between physical activity and fatigue may be time constrained; the mediation effect was not as powerful after 4 weeks and disappeared at week 6.

Comparison of Sleep Mediation in Cross-sectional vs. Longitudinal Results

This framework for this study was based in part on the work of Katz et al. (2016): The Theoretical Model of RA Fatigue. Katz et al. outlined the potential explanatory variables associated with fatigue based on their cross-sectional research findings of 158 arthritis clients. Katz et al. found that physical inactivity had an indirect association with fatigue, mediated by other variables including poor sleep. The results of this study were consistent with some of the Katz et al. findings.

When comparing the mediation effect of sleep in the cross-sectional review at week 1 and the longitudinal review at week 4, the longitudinal study identified a significant mediation effect of sleep while the cross-sectional study did not. The findings might suggest that a cross-sectional design may not always capture exact relationships,

especially cause-and-effect relationships among variables because the relationships were not examined longitudinally. Since mediation and moderation relationships are conceptually defined as causal relationships between the variables (Barron & Kenny, 1986), a cross-sectional study design might not be the best approach to identify variable relationships.

Moderation

Moderators provide insight into the unique conditions that exist between two related variables. In this study, it was hypothesized that the relationship between the independent variable (physical activity) and the dependent variable (fatigue) would change as the level of the moderator (sleep) changes. This relationship was not found in a cross-sectional study at week 1 or at the study intervals of week 4 or week 6. The findings suggest that sleep may not be a moderator in the relationship between physical activity and arthritis fatigue.

There has been limited information regarding the role of sleep as a moderator between physical activity and fatigue up to date. One recent study found that sleep quality moderated the relationship between physical activity and fatigue in healthy adolescents (n=481) (Herring et al., 2018). Among poor sleepers there was a dose relationship with physical activity that led to decreased fatigue symptoms. The result by Herring et al. (2018) is not consistent with what we found in this this study. However, Herring et al. (2018) used cross-sectional design and the study population was different.

Strengths

There were several strengths to this study. The longitudinal study design using mediation and moderation methodology added to what is known about the impact of sleep upon the relationship of physical activity and fatigue. The study provided new information about the effect of sleep over time, specifically the mediating effects of sleep at week 4. This study suggests a longitudinal design may reveal an exact mechanism of how physical activity and sleep interact with each other and influence the arthritis fatigue.

This research supports the value of second-generation research as a focus for nurse researchers. First-generation research is the identification of a relationship between variables. Often there are many relationships; for example, there are many correlates of arthritis fatigue. Where does a clinician start to apply this to care? First-generation research provides useful information of cause and effect, but it is limited in how it is applied in the clinical setting (Guralnick, 1993). Second-generation research addresses how the effects of the relationships operate and the boundary of the conditions (MacKinnon & Luekin, 2008). For example, this study provided findings that sleep is a mediator in the relationship of physical activity and fatigue. This provides insight that the effect was not realized until week 4, suggesting that this interaction takes time. We also have insight that the effect may be time limited, as we did not find the effect at week 6. This may impact our recommendations for our clients.

This study highlighted the impact of useful behavioral strategies. Physical activity and sleep are behavioral factors that are modifiable and have implications beyond fatigue. Physical activity is a health promotion activity helpful with the large number of co-morbidities. Simple walking is an inexpensive physical activity available to most people. Comorbid conditions such as pain, falls, cancer, and chronic heart failure are

thought to interact with poor sleep as well as sleep impacts these comorbid conditions (Onen & Onen, 2018). Promoting good sleep hygiene is a health promotion activity that is helpful with fatigue and also may help with other comorbidities.

The off the shelf equipment, Fitbit, chosen for the study provided insight into tools for everyday life. The accelerometer, Fitbit, is widely available in stores. There are 100 million Fitbits in use worldwide and 28 million are currently activated (Associated Press, 2019). The results of this study may encourage other researchers to continue to examine the use of tools and interventions that are in the purview of everyday people with arthritis.

Limitations

There were several limitations to the study which include sample size, simple design, seasonal/holiday impact and weather. This study was designed to be a pilot study. The sample size consisted of 24 older adults with arthritis fatigue. Increasing the sample size would lead to more valid and reliable results.

Fatigue is a multifactorial symptom. Over 100 variables have been identified as having some kind of relationship with arthritis fatigue (Cramp, Hewlett, et al., 2013; Loppenthin, Esbensen, Jennum, et al., 2015; Loppenthin, Esbensen, Ostergaard, et al., 2015; Rongen-van Dartel et al., 2016). The variables of physical activity and sleep in fatigue were selected based on two theoretical models of arthritis fatigue (Hackney et al., 2019; Katz et al., 2016). Both models are multifactorial in order to capture the complexity of fatigue. In order to examine arthritis fatigue in this study, the mediation and moderation model simplified the relationships.

Therefore, it is possible that there were other significant variables that impacted our result. The Biobehavioral Model of Fatigue in Osteoarthritis (Hackney et al.) and the Theoretical Model of RA Fatigue (Katz et al., 2016) both identify non-modifiable and modifiable factors that impact fatigue symptoms. Non-modifiable factors include age, sex, and disease state. There are other modifiable factors that impact fatigue in addition to physical activity and sleep. Depression, pain, and obesity are other factors that are modifiable and are identified by the theoretical models. These additional variables were not addressed in this study and it is possible they could have affected the outcomes. Future research that measures their impact on fatigue is suggested.

There is also current research evaluating the use of wearable activity trackers, such as Fitbit, in older adults over time. Adults over 70 were found to stop using wearable activity trackers after 2 months (Li et al., 2019). Researchers continue to investigate reasons for tracker abandonment, such as ease of wear and use (Shin et al., 2019). This may be in part related to the novelty of wearing the activity tracker through a short period of time and is consistent with mediation at 4 weeks and no mediation at 6 weeks. Interest in simple walking may have changed over time and was not considered in our study.

The study recruitment was open over the year in New England. Weather in New England is unpredictable and impacts the older adult who seeks to walk outdoors. Study participants were encouraged to choose safe walking options. There were times when the weather was inhospitable for outdoor walking or driving to an indoor location where walking could occur. Weather is one of the factors associated with decreased outdoor walking in the older adult (Rantakokko & Wilkie, 2017). Over the course of the

recruitment period the average yearly precipitation was 46 inches; average annual snowfall was 36 inches; average high and low temperatures ranged from 82 degrees to 13 degrees Fahrenheit (*US Climate Data*, 2019). There was significant rainfall over 2019 (Page, 2019). One participant described her perspective on walking over a rainy week as: "I am not a duck".

In addition, participants experienced holidays and vacation periods that may have impacted the amount of walking possible. More than half (n=14, 58%) of our sample were retired. Over the course of the year participants travelled to visit family to attend anticipated and unanticipated events, holidays, and/or went on vacation away from their homes. Travel time, whether by car or plane, and new surroundings may have impacted the ability to walk over some of the weeks of the study period.

Clinical Significance for Nursing

Older adults with arthritis fatigue have complex care needs to address. Arthritis treatment strategies fall under three basic categories: managing the disease, maximizing the cognitive behavioral processes, and meeting the individual needs of the client (Hewlett et al., 2011). The study findings directly impact the latter two of the categories.

The study findings indicate that sleep mediates physical activity and fatigue over time. Maximizing the cognitive behavioral processes means nurses will work with clients to promote the modifiable, behavioral aspects of care. Nurses can promote physical activity, such as simple walking, knowing that over time this intervention may improve fatigue symptoms. Nurses can also promote good sleep hygiene, such as a routine sleep schedule with sleep promoting behaviors before bed. The study results

indicated that sleep mediated the relationship between physical activity and fatigue providing an additive effect in reducing fatigue symptoms.

The second clinical impact that the study has for nursing care is through meeting the individual needs of clients by addressing co-morbidities. Older adults with arthritis fatigue are saddled with a high prevalence of comorbidities such as heart disease, obesity and diabetes (Barbour, 2017). Physical inactivity due to arthritis and the constellation of symptoms that accompany it is not helpful in managing additional co-morbid conditions. Promoting physical activity and sleep and decreasing fatigue symptoms may provide additional incentive for the older adult to maintain activity.

Future Research

The study findings suggest future research should target strategies that may help keep clients walking over a longer time period. Interventions of motivational counselling and text messages have been shown to decrease sitting time in clients with arthritis (Thomsen et al., 2019). A topic of increasing interest in osteoarthritis is the supplementary role of behavior training in exercise interventions (Wellsandt and Golightly, 2018). Other strategies in the Chronic Obstructive Pulmonary Disease population that hold promise for promoting exercise over time include virtual peer groups (Burkow et al., 2018) and tele-coaching (Demeyer et al., 2017). Cognitive behavioral approaches have been found to be a helpful strategy in engaging obesity clients to increase activity overtime (Grave et al., 2010). Regardless of the method, future research should include interventions and measurement that encourage and support physical activity in arthritis clients.

Future research should encompass differentiation between the types of arthritis and the acuity of the disease process in sample participants. While there are similarities in disease burden across osteoarthritis and rheumatoid arthritis (Chua, 2019), examining a larger sample would enable moderation analysis to be compared across diagnosis type. This would allow for further clarification and ability of clinicians to tailor arthritis fatigue recommendations.

Future research should also encompass more sophisticated statistical methods such as Structured Equation Modeling (SEM). This study used Baron and Kenny's approach towards mediation and moderation utilizing linear regression to determine paths for analysis. SEM provides the opportunity to investigate relationships between multiple independent, dependent and correlate variables in one large model. SEM also has the advantage of being able to account for measurement error (Zhao, 2009).

Conclusion

This longitudinal study examined the impact of sleep upon the relationship of physical activity and arthritis fatigue using a mediation and moderation methodology. The study results indicate that at week 4, sleep was a mediator between physical activity and fatigue. Over the course of the 6-week study, sleep was not a moderator between physical activity and fatigue at any other time. This study was second-generation research seeking to understand the operation and boundary characteristics of a third variable: sleep. The results suggest that promoting physical activity and sleep may help with arthritis fatigue over time. This research is significant in several ways. The longitudinal findings build on what is known from cross-sectional studies. This research is also

significant because clinicians will be able to tailor their interventions to assist individuals with arthritis fatigue. The findings from week 4 suggest a clear and accurate relationships among three variables, especially a role of mediation of sleep, which can further benefit older adults with arthritis fatigue and their healthcare providers in a way to ensure sleep promotion when alleviating fatigue symptoms.

APPENDIX A

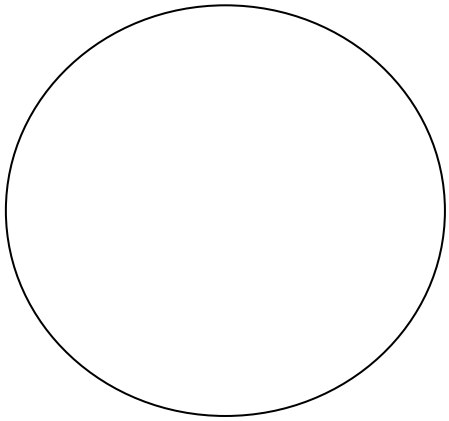
MINI-COG

1. Instruct the patient to listen carefully and repeat the following:

   APPLE WATCH PENNY

2. Administer the Clock Drawing Test

   Instructions: Inside the circle draw the hours of a clock as if a patient would draw them. Place the hands of the clock to represent the time “forty five minutes past ten o’clock”



3. Ask the patient to repeat the three words given previously

   _____ _____ _____

Scoring:

Number of correct items recalled _____ [if 3 then negative screen. STOP]

If answer is 1-2, Is Clock Drawing Test abnormal? No Yes

If No, then negative screen

If Yes, then screen positive for cognitive impairment

Reference

Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The mini-cog: a cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. Int J Geriatr Psychiatry. 2000;15(11):1021-1027.

APPENDIX B

PROMIS SHORT FORM V1.0-FATIGUE 8A

Fatigue

Please respond to each question or statement by marking one box per row.

During the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
1	I feel fatigued.	☐	☐	☐	☐	☐
2	I have trouble starting things because I am tired.	☐	☐	☐	☐	☐

In the past 7 days…

3	How run-down did you feel on average?	☐	☐	☐	☐	☐
4	How fatigued were you on average?	☐	☐	☐	☐	☐
5	How much were you bothered by your fatigue on average?	☐	☐	☐	☐	☐
6	To what degree did your fatigue interfere with your physical functioning?	☐	☐	☐	☐	☐

In the past 7 days…

7	How often did you have to push yourself to get things done because of your fatigue?	☐	☐	☐	☐	☐
8	How often did you have trouble finishing things because of your fatigue?	☐	☐	☐	☐	☐

APPENDIX C

PROMIS SHORT FORM V1.0 - SLEEP DISTURBANCE 8B

Sleep Disturbance

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
1	My sleep was restless	□	□	□	□	□
2	I was satisfied with my sleep	□	□	□	□	□
3	My sleep was refreshing	□	□	□	□	□
4	I had difficulty falling asleep	□	□	□	□	□

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
5	I had trouble staying asleep	□	□	□	□	□
6	I had trouble sleeping	□	□	□	□	□
7	I got enough sleep	□	□	□	□	□

In the past 7 days…

		Very poor	Poor	Fair	Good	Very good
8	My sleep quality was	□	□	□	□	□

APPENDIX D

IRB APPROVAL LETTER

University of Massachusetts Amherst
108 Research Administration Bldg.
70 Butterfield Terrace
Amherst, MA 01003-9242

Research Compliance
Human Research Protection Office (HRPO)
Telephone: (413) 545-3428
FAX: (413) 577-1728

Certification of Human Subjects Approval

Date: October 7, 2019
To: Jeungok Choi, Nursing
Other Investigator:
From: Lynnette Leidy Sievert, Chair, UMASS IRB

Protocol Title:A tablet-based simple walking intervention to improve self-management of Arthritis fatigue
Protocol ID: 2018-4832
Review Type:EXPEDITED - REVISION
Paragraph ID: 6,7
Approval Date: 10/07/2019
Expiration Date: 08/02/2020
OGCA #:118-1350

This study has been reviewed and approved by the University of Massachusetts Amherst IRB, Federal Wide Assurance # 00003909. Approval is granted with the understanding that investigator(s) are responsible for:

Revisions - All changes to the study (e.g. protocol, recruitment materials, consent form, additional key personnel), must be submitted for approval in e-protocol before instituting the changes. New personnel must have completed CITI training.

Renewals - All renewals need to be submitted at least 2 weeks prior to the expiration date listed on this approval letter.

Final Reports - Notify the IRB when your study is complete by submitting a Final Report Form in e-protocol.

Consent forms - A copy of the approved consent form (with the IRB stamp) must be used for each participant (Please note: Online consent forms will not be stamped). Investigators must retain copies of signed consent forms for six (6) years after close of the grant, or three (3) years if unfunded.

Use only IRB-approved study materials (e.g., questionnaires, letters, advertisements, flyers, scripts, etc.) in your research.

Unanticipated problems involving risks to participants or others - All such events must be reported in e-protocol as soon as possible, but no later than five (5) working days.

Please contact the Human Research Protection Office if you have any further questions. Best wishes for a successful project.

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