A FEASIBILITY STUDY OF USING HEADSPACE FOR MINDFULNESS AMONG INDIVIDUALS UNDERGOING SURGICAL REPAIR OF THE ROTATOR CUFF

by

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ABSTRACT

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Mindfulness-based interventions (MBIs) have been found to help reduce psychological distress and pain in chronic musculoskeletal conditions. However, very limited evidence exists determining the impact of mindfulness on psychological distress and pain in acute musculoskeletal conditions including rotator cuff tears. Among individuals undergoing surgical repair of a rotator cuff tear, it is not clear how mindfulness may be combined with usual care, given the requirement of intense training as part of frequently used MBI protocols. The purpose of the present study was to determine if it was feasible to combine Headspace, a mobile application for mindfulness training that can be used anytime and anywhere, with the usual treatment for a single-tendon rotator cuff repair. One individual was recruited to use Headspace for three weeks, from two weeks before to one week after their rotator cuff surgery. Feasibility of using Headspace was measured in terms of satisfaction in using Headspace and changes in mindfulness across three time points (2 weeks before surgery, 1 week before surgery, and 1 week after surgery). Regarding satisfaction with using Headspace, four main themes emerged including the improved ability to focus and concentrate, manage pain, cope with life stressors and the ability to use the application anytime and anywhere. Regarding mindfulness, scores increased on one facet and decreased in the four other facets of FFMQ-SF. In addition, the

participant reported becoming more mindful but still needed more practice with mindfulness. Based on our findings, we concluded that Headspace is an appropriate intervention to include in the treatment of rotator cuff repairs and can lead to the improved ability to concentrate, focus, manage pain, and cope with life stressors. However, given the short duration of the study, it is not clear how Headspace impacted mindfulness. Future studies should be conducted over a longer duration of time to examine the impact of Headspace on a person's mindfulness from pre-surgery to the end of rehabilitation.

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Chapter 1

Introduction

The Problem

The rotator cuff is a group of muscles composed of the supraspinatus, infraspinatus, teres minor, and subscapularis, (SITS) muscles and tendons. The SITS muscles serve to move the humerus while preventing upward migration by stabilizing the humeral head in the glenoid fossa of the scapula during shoulder motion (Favard et al., 2007). Rotator cuff disorders rank as one of the most common musculoskeletal disorders encountered in clinical practice (Warth & Millett, 2015). Rotator cuff disorders encompass any condition causing damage to the rotator cuff, including a tear, and can be associated with inflammation, tendonitis, bursitis or arthritis of the shoulder. Failure of the rotator cuff tendons may be caused by a major injury, wear and tear, repetitive strains or age-related attrition of the tendons (Matsen, 2008).

A rotator cuff tear occurs when there is a tear in one or more of the SITS muscles and/or their tendons that serve to connect the muscle to the head of the humerus bone of the shoulder (Shiel Jr, 2014). An individual experiencing a rotator cuff tear often presents with complaints of pain, decreased range of motion (ROM), muscular weakness and loss of function. This results in a decreased ability to participate in activities of daily living, including self-cares, household chores and overall decreased quality of life (Plessis et al., 2010). Rotator cuff tears are first approached with non-operative treatments including rest, anti-inflammatory modalities such as icing, ROM exercises, strengthening, isometrics and others (Cooper, 2013). Consideration for surgical repair is dependent upon the size of the tear and is supported in patients with large supraspinatus tears (greater than 6 mm) or tears extending to the infraspinatus and/or subscapularis tendons (Favard et al., 2007).

A rotator cuff repair can be divided into three separate surgical procedures including open surgery, mini-open surgery as well as arthroscopic surgery and have been found to have very little difference across the three approaches, with arthroscopic repairs resulting in shorter hospital stay (Favard et al., 2007). The goal of a rotator cuff repair is to lead to improved postoperative outcomes to reduce pain, regain normal shoulder function and increase engagement in functional activities as well as return to the workforce (Plessis et al., 2010; Mather et al., 2013; Day et al., 2012). Generally, a rotator cuff repair is usually followed by an immobilization period to allow for stabilization of the muscle tissues to prevent fatty degeneration which results in deterioration of tissue and diminished function of the affected muscle (Favard et al., 2007). At the end of the immobilization period, the patient begins a rehabilitation program to regain ROM, transitioning from passive to active motion exercises followed by strengthening exercise's (Cooper, 2013). Table 1.1 provides a layout of the rehabilitation protocol used by the orthopaedic surgeon of this study provided by Fritz et al. 2016. Therefore, rotator cuff repairs have a substantial impact on the American society due to their cost and average time of recovery. A study aimed to calculate costs of rotator cuff repair in an inpatient setting over a one-year period and found the mean total cost of the procedure to be $10,605. This total cost did not include additional costs for services such as physical therapy and radiologist fees (Vitale et al., 2007). Narvy (2016) assessed the direct costs of a rotator cuff repair in an outpatient setting and calculated the surgical costs to be $5,904.

Increasing evidence supports the notion that among individuals with musculoskeletal disorders, psychological factors including fear-avoidance beliefs related to pain, depression, anxiety and somatization impact a person's recovery during rehabilitation (Bair et al., 2003; Sindhu et al., 2012). Depression is recognized as one of the leading causes of disability in the

U.S. and it is estimated that 27% of patients with musculoskeletal pain conditions also have complaints consistent with major depressive symptoms (Bair et al., 2003). Fear-avoidance beliefs related to pain have been found to be present in a population of individuals with musculoskeletal conditions and can result in greater disability and functional limitations. A small but significant effect was found with elevated fear-avoidance beliefs resulting in poorer recovery in function of the upper-extremity with rehabilitation in the disease category of muscle, tendon and soft tissue disorders (Sindhu et al., 2012). These different psychological factors shine light on the need for incorporating a therapeutic approach that intertwines the biomechanical framework with the cognitive-behavioral approach. Psychologically informed practice is often presented as a secondary approach as an intervention that incorporates the individuals' beliefs, attitudes and emotional responses within the context of treatment. It is mostly implemented when usual care and treatment do not result in the appropriate outcomes. This type of practice has the potential to lead to improved clinical and occupational outcomes due to the consideration of biopsychosocial components of an individual (Main, C.J & George, S.Z, 2012).

Incorporating interventions accounting for how the body responds to the way we think, feel and act, also known as the mind-body connection, may potentially help to improve rotator cuff repair outcomes. One way in which this may be achieved is through the implementation of mindfulness practice. Mindfulness is the "awareness that arises through paying attention, on purpose, in the present moment, non-judgmentally" (Kabat-Zinn, 2003, p. 145). Mindfulness has been found to improve self-regulation in pain tolerance, improve quality of life, reduce psychological distress and anxiety in populations of somatic illness such as cancer, diabetes, heart disease chronic fatigue and chronic pain syndromes as well as generalized anxiety disorder, depression and other psychological disorders (Kingston et al., 2007; Grossman et al., 2007;

Zeidan, et al. 2010; Hofmann et al. 2010). Mindfulness has quickly become widely used in the development of mindfulness-based interventions within health care for the management of pain, stress, and anxiety while focusing on health, wellness and quality of life outcomes (Hardison & Roll, 2016).

The most widely recognized mindfulness-based intervention used in health care to date is the Mindfulness-Based Stress Reduction (MBSR) program, developed by John Kabat Zinn in 1979. The program was originally created for persons with chronic pain who were non-responsive to conventional therapy (Grossman, 2004). MBSR has been found to reduce pain severity, anxiety, as well as enhancing the ability to cope with the distress associated with a disability in the everyday life leading to enhanced well-being (Grossman, 2004; Reiner et al., 2013; Shennan et al., 2011; Chiesa & Seretti, 2009). However, MBSR has been found to have various limitations within the context of implementation in a clinical setting related to musculoskeletal conditions. The program is time intensive requiring weekly 2.5 to 3-hour training sessions for a period of eight weeks, 45 minutes per day to complete daily homework, and attending a weekend mindfulness retreat at the end of the program. Additionally, the course poses a limitation to those individuals who are financially restricted as the program costs range from $275 to $575 without the inclusion of travel expenses (Sound, 2015). The combination of the time-intensive schedule and the cost of the program are limitations and may not be suitable for individuals who are receiving rehabilitation services. In contrast, a new innovative way to benefit from mindfulness training has been developed through the use of a mobile application, Headspace (Headspace, 2016).

Headspace is a mobile application (app) that serves as a digital health platform in order to provide guided, bite-sized meditation sessions and mindfulness training to its users. The app

serves as a self-management tool that is cost-effective, accessible any time and anywhere, within the context of the user's environment, and can be used without supervision of a trained professional. Headspace has been found to increase mindfulness, reduce depressive symptoms, increase compassion and can promote better physical and mental health (Rosen,2016; Howells et al., 2014; Lin et al., 2015). A systematic review aimed to rate the quality of already existing mindfulness applications and found of 23 mindfulness applications, Headspace received the highest ranking of 4.0 out of a 5.0 scale (Mani et al., 2015).

However, the application has only been tested with individuals who are experiencing pain due to a rotator cuff tear. Therefore, there is a need to determine the feasibility of incorporating the use of Headspace as a mindfulness-training tool within a clinical population related to rotator cuff repairs. This clinical population was selected based on previous research completed in our research labs.

Background

Rotator cuff disorder is a condition in which one or more of the four tendons whose function is to stabilize the glenohumeral joint in the shoulder, are damaged from various causes. The muscles that make up the rotator cuff include the supraspinatus, infraspinatus, subscapularis and the teres minor muscles. The most common tendon tears begin at the inferior surface of the anterior aspect of the supraspinatus muscle. Dysfunction can be caused from an acute injury, age-related attrition or from repetitive strains, such as overuse (Matsen III, 2008). Rotator cuff disorders have been found to be one of the most common forms of a musculoskeletal disorders affecting up to 17 million individuals in the U.S (McElvany et al., 2015). Rotator cuff tendon failure caused by either wear or tear has been found to be the most common problem for shoulder conditions in a clinical setting resulting in more than 4.5 million visits to a physician

per year in the U.S (Matsen III, 2008). Rotator cuff disorder is so frequent that rotator cuff repairs have emerged as the most common orthopaedic procedure and furthermore the most common among all shoulder surgeries (Matsen III, 2008). Yamamoto et al. (2010) sought to find the epidemiology of rotator cuff tears in a population based study. The authors discovered multiple factors correlating with rotator cuff tears in the general population, including to be associated with elderly patients, male gender, affected dominant arm, occupation characterized by heavy labor, history of trauma, positive impingement sign, demonstrated lesser active forward elevation and decreased muscle strength in both external rotation and abduction. The authors further concluded the risk factors for rotator cuff tears included a history of trauma, dominant arm and age (Yamamoto et al., 2010). An additional risk factor for tears as suggested by Mayo Clinic is that there may be a genetic component involved with rotator cuff injuries due to family history (Mayo Clinic, 2010).

The American Academy of Orthopaedic Surgeons (AAOS) describes a tear as when a tendon is no longer fully attached to the head of the humerus bone and usually begins with a fraying effect. As the tear progresses, the tendon can result in a complete tear. There are two different types of tears including partial-thickness tears and full-thickness tears. Partial-thickness tears are characterized by damage to the soft tissue but does not result in a full severation from the bone. Partial tears are very common and rarely require surgery and are treated with non-operative treatment. These individuals will present similar to patients suffering from tendinosis with complaints of pain while lifting their arm over their head and typically have severe pain at night (Luks, 2010). Partial tears have been reported to be approximately 2 times as common as full tears and can increase in size or progress to a full tear if left untreated (Won Chung et al., 2014).

Full-thickness tears also known as complete tears, are characterized by the splitting of the soft tissue into two separate pieces and can usually be seen as an actual hole in the tendon (Armstrong, 2011). Full tears can be either acute or degenerative and are classified by sizes including small (tears less than 1 cm long), medium, and large (tears involving large percentages of the rotator cuff) (Luks, 2010). Individuals with a full tear may experience a sudden onset of decreased strength while elevating the arm after injury to the tendon caused by the upper extremity being forced to the side. This type of tear is best repaired within six weeks after injury as prolonging the time between diagnosis and surgical intervention can result in the detached tendon to retract and resorb while the muscle atrophies (Matsen III, 2008).

The primary goal of treating rotator cuff disorder is to restore an individual's functional capacity, decrease pain, and prevent long-term consequences from injury with the use of non-operative treatments or surgical interventions. Non-operative treatments include conservative therapies, (such as activity modification, icing, anti-inflammatory therapy, cryotherapy, ultrasound and a gentle exercising regimen), medication therapies, (Acetaminophen, anti-inflammatories, and nonsteroidal anti-inflammatory drugs (NSAIDs)), physical therapy, (joint mobilization, flexibility and strengthening exercises), and corticosteroid injections to name a few (Lin et al., 2008). A recent study found that non-operative treatment resulted in 75% pain relief of arthroscopically repaired full thickness rotator cuff tear (Ahmad et al., 2014). If non-operative means are not able to treat the presenting problem and is paired with persistent moderate to severe pain at rest or with function lasting more than three to six months, then the physician will begin to explore surgical interventions in the treatment of the rotator cuff disorder (Armstrong, 2011). Though this procedure is expensive, it has been proven to provide lifetime societal savings of $3.44 billion for approximately 250,000 rotator cuff repairs performed in the U.S

(Mather III et al., 2013). Rotator cuff repairs (RCR) are expensive, as indicated by direct cost estimates for RCR's ranging from $10,000 to over $17,000 per procedure (McElvany et al., 2015).

Patients can expect to have a long and difficult recovery encompassed by persistent pain after surgery, particularly at night, feelings of popping and catching during ranging of the shoulder are common but are normal (Armstrong, 2011). Fear-avoidance beliefs are present among individuals with musculoskeletal complaints including upper and lower extremity disorders, neck pain, and low back pain (Hart et al., 2009). The fear-avoidance model describes prolonged pain as a traumatic experience to the individual leading to pain-related fear, which leads to avoidance of physical activities. Avoidance results in negative psychological consequences including low mood and negative physiological consequences such as decreased blood flow (Geisser et al., 2004). With the psychological consequences, it is important for occupational and physical therapists to keep in mind the influence pain may have on the rehabilitation outcomes of their patients. One way in which therapists can address the psychological influences of fear-avoidance beliefs and pain is through the practice of mindfulness.

Mindfulness can be defined as resting the mind in its natural state of awareness free of any bias or judgment and directs the individual to be present, undistracted and in the moment. It is the key ingredient of most meditation techniques and goes above and beyond the formal aspect of sitting down with the eyes closed with a requirement of consistent practice and repetitive participation. Mindfulness can be used in any situation for any purpose but is easiest to learn as a new skill during meditation (Puddicombe, 2012). Mindfulness has been conceptualized as a state practiced in mindfulness meditation as well as a trait in regard to an individual's predisposition to

be mindful in everyday life (Kiken et al., 2014). Sitting down each day to meditate for even a short period of time can allow for the individual to apply the feeling of being present, aware and in the moment in the rest of their daily life (Puddicombe, 2012). Regular meditation leads to an increased capacity in maintaining mindfulness during everyday life. Long-term mindfulness training can improve self-regulation with regard to pain tolerance (Kingston et al, 2007). Mindfulness-based interventions (MBIs) involving extensive training have been used successfully while treating chronic pain conditions to improve quality of life, reduce psychological distress, and pain-related activity interference (Grossman et al., 2007). However, there is limited evidence on the effects of mindfulness on acute pain. One study had participants complete 30 minutes of mindfulness training per day over three consecutive days and found the individuals had a reduction in pain sensitivity from electrical shocks and further concluded mindfulness training can benefit pain control by reducing anxiety and improve attention focus to help the individual be in the present moment (Zeidan et al., 2010). Evidence has supported combining mindfulness training with self-regulation of intrinsic and extrinsic demands results in decreased pain in general and increased tolerance of acute pain (Evans et al., 2014). Training over time may build up an individual's self-regulatory resources and decrease the self-regulation demand of mindfulness (Puddicombe, 2012).

Mindfulness-based interventions (MBIs) are a rapidly growing field and are used in treatment programs taught and written by psychologists, scientists, athletes, lawyers, professors and more (Shonin et al., 2013). MBIs represent cost-effective, acceptable, and non-invasive treatments for a broad spectrum of psychological and somatic illnesses (Shonin et al., 2013; Chiesa et al., 2011; Fjorback et al., 2011). Meta-analytic studies of MBIs have reported

moderately pre-post effects for reduced anxiety and mood symptoms in populations of somatic illnesses such as cancer, diabetes, heart disease, and chronic fatigue (Hofmann et al., 2010).

Mindfulness-Based Stress Reduction (MBSR) is a commonly used MBI developed by Dr. Jon Kabat-Zinn at the University of Massachusetts Medical Center in 1979 (Cullen, 2011). MBSR is a structured eight to ten week, non-religious group-based mindfulness exercise program which combines mindfulness training and yoga. Participants attend weekly sessions for three hours followed by a single all-day meditation retreat on a weekend day. Additionally, the program includes daily homework practice amounting to approximately 45 minutes where meditation instructions are provided on an audio CD as well as logging daily records of participation in mindfulness exercises (Shonin et al., 2013; Vollestad et al., 2011). MBSR has been used with multiple problem areas including fibromyalgia, mixed cancer diagnoses, coronary artery disease, depression, chronic pain, anxiety, obesity, binge eating disorder, psychiatric populations as well as individuals who have been incarcerated. Findings suggest participation in MBSR may enhance general features of coping with distress and disability in an individual's everyday life. Improvements can be seen across a spectrum of standardized mental health measures (Grossman et al., 2007). Another study found evidence that indicates sustained beneficial effects mindfulness training has on anxiety disorders as well as related symptomatology relative to a control condition. (Vollestad et al., 2011). Although MBSR courses are cost-effective ranging from $275 to $575 on a sliding scale based on household income, it may be a viewed as a limitation for individuals facing financial restrictions on top of the pre-existing costs from surgery and outpatient therapy (Sound, 2015). Another limitation of MBSR is that it is a time-intensive intervention. Therefore, there is a need to explore

opportunities to find how mindfulness can be incorporated in the daily lives of individuals that is cost saving and can be used at any time such as a Smartphone application.

The use of mobile applications in the day-to-day lives of Americans is ever growing and becoming more dominant with developments in the emerging field of Mobile health (mHealth) (Mani et al., 2015). The World Health Organization defines mHealth as a "medical and public health practice supported by mobile devices" (WHO, 2015). The use of Smartphone's as well as other devices such as tablets, has created new opportunities for the user and healthcare professionals to have access to health care and preventive health services while remaining mobile in the community. One of the main benefits of using a mobile application is that it is accessible all the time and can cater to each individual's personal schedule (Mani et al., 2015). In 2015, two thirds of American adults owned a Smartphone, with two thirds of those individuals using their mobile device to search for healthcare-related information (Smith, 2015). The increasing use of Smartphone's for accessing healthcare related services shines light on the use of Smartphone applications for incorporating an easy to use mobile application that delivers guided-bite sized mindfulness sessions to its users. This type of service can be found when using the mobile application, Headspace.

Headspace is a mobile application that fits into the category of a mobile health services as it provides holistic services to the user via a Smartphone, tablet and through the web. Headspace was founded and launched by Andy Puddicombe and Rich Pierson in 2010, and has over 8 million users in more than 150 countries. Prior to the release of the mobile application, Puddicombe was enrolled at De Montfort University, studying sports science. One day at the age of 22, he decided to pack his bags to travel to Asia in order to become a Buddhist monk due to his inability to control the continuous experience of negative thoughts and emotions in his mind

each and every day. After ten years of practicing, Puddicombe decided to stop his practice as a monk in order to live as a lay person to integrate meditation into the everyday life and to demystify meditation, as well as making it an accessible and relevant practice for modern-day living (Puddicombe, 2012).

Puddicombe trains the Headspace user how to best approach the technique of meditation, followed by instruction on how best to practice it and how best to integrate the techniques into everyday life (Puddicombe, 2012). The practice of meditation is both a skill as well as an experience of being in the present moment and therefore requires an individual to practice meditation in order to fully appreciate its value. Headspace is not designed to make an individual become a different person, a new person or even a better person. It is about training in awareness and understanding how and why an individual thinks and feels the way they do in order to establish a healthy sense of perspective in the process. "Mindfulness is the key ingredient of most meditation techniques and goes far beyond the formal aspect of sitting down with your eyes closed. Meditation is simply the technique to provide an individual with the optimum conditions to practice the skill of mindfulness. It means to be present, in the moment, undistracted while experiencing life directly as it unfolds rather than being distracted, caught up and lost in thought. It implies resting the mind in its natural state of awareness, which is free of any bias or judgement" (Puddicombe, 2012, p. 18-19). Over time an individual will begin to experience the feeling of being present on a consistent basis as well as the feeling of being aware and in the moment, allowing for the incorporation of mindfulness into the everyday life and transitions from occurring on a conscious level to a subconscious level. The meditation sessions allow for the user to engage in daily meditation practice, bite-sized enough to fit into their schedule, yet long enough to make a difference (Puddicombe, 2012). The application uses a combination of

calming meditation and insight meditation. Calming meditation requires the individual to concentrate on a particular object, such as their breath, a mantra, visualization, physical objects, or physical senses within the body. Benefits include a quieter, more peaceful state of mind, and improved concentration. Insight meditation transforms the mind by developing qualities such as wisdom and compassion (Kabat-Zinn, 1994).

Specific Aims

The overall objective of this study was to assess the feasibility in one subject of using Headspace for self-management of psychological distress associated with surgical repair of the rotator cuff. The study explored user satisfaction when Headspace, a mindfulness-based intervention was implemented before and after rotator cuff repair. Our central hypothesis was that an individual undergoing a rotator cuff repair would be satisfied in using Headspace as a mindfulness-based intervention. Satisfaction was measured at follow up in terms of ease of use, cost, enjoyment, and recommendation to others for use. Our secondary hypothesis was that an individual undergoing a rotator cuff repair would report an increase in mindfulness after using Headspace. Mindfulness was measured at baseline and at follow up using the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) (Bohlmeijer et al., 2011).

Significance

This study is significant for 1) individuals undergoing a rotator cuff repair, 2) healthcare professionals and, 3) insurance companies paying for healthcare related services.

First, individuals receiving a rotator cuff repair have the potential to be impacted by this study as it provides a biopsychosocial frame of reference addressing the physical, mental and emotional aspects of an individual's health. The Headspace intervention has the potential to reduce levels of psychological distress, which if not treated, may negatively influence the

recovery process in these individuals. This in turn may reduce the length of time needed for participation in rehabilitation, as physical outcomes may be achieved sooner leading to reduced indirect costs. An additional benefit is that these individuals will have the opportunity to be educated and trained on learning a new coping mechanism that could lead to improved stress management, compassion for others as well as improved quality of life. Our study is clinically significant for this population as our methods are aimed to improve an individual's quality of life as mindfulness has been supported to increase life enjoyment, expand the ability to cope with an illness, and improve both physical and emotional health.

Second, healthcare professionals including orthopaedic surgeons and rehabilitation team members including both physical and occupational therapists may benefit from this study in a variety of ways. Surgeons will be provided with initial evidence to support the inclusion of mindfulness into rotator cuff repair treatment protocol that could lead to improved treatment outcomes such as improved pain management. The study will provide new ways for occupational and physical therapists to improve rehabilitation outcomes by incorporating interventions addressing psychological health through the use of information technology by testing an innovative self-management tool. Improvements may be seen as increased range of motion at a quicker rate as well as increased strength and reduced pain due to reduced fear-avoidance beliefs. Patients may be more compliant with completing their physical therapy exercises on a regular basis leading to improved rehabilitation outcomes. The use of a Smartphone application in addition to standard care is beneficial to the rehabilitation team as the therapist is not required to obtain further certification for the intervention implementation nor do they need to provide instruction during a therapy session on top of meeting productivity goals. Additionally, the study will provide preliminary evidence for the need of incorporating standardized assessments that

screen for psychological distresses that are commonly experienced before and after surgery in individuals receiving a surgical intervention. Screening for psychological distresses may result in improved treatment outcomes post-surgery, which in turn strengthens communication between interdisciplinary team members.

Finally, insurance companies may find significance in this study as it may reduce healthcare related costs associated with surgery. These companies will be provided evidence for recognizing the incorporation of an easy to use smartphone application that provides mindfulness training as a preventive self-management tool for various psychological distresses experienced in individuals undergoing rotator cuff repair. Insurance companies may see the benefit to cover costs of using mobile health related interventions in the treatment of rotator cuff repairs. The length of time needed for recovery may be reduced with the incorporation of a mindfulness-based intervention leading to reduced overall health related costs.

Previous Studies

A previous study was conducted to examine the influence fear-avoidance beliefs related to pain has on individuals with various shoulder impairments. A purpose of this study was to determine the influence of fear-related cognitions on recovery of functional status during rehabilitation across eight different diagnostic categories of musculoskeletal disorders of the shoulder. The study included secondary analysis of data collected from 3,362 individuals (1,828 women and 1,534 men) with musculoskeletal conditions of the shoulder. Upper extremity function was measured using the shoulder Computerized Adaptive Test at intake and discharge. Pain intensity levels were measured using an eleven-point numerical rating scale. A single-item screen was used in order to organize patients into groups with either low or elevated fear-avoidance beliefs at intake. A general linear model (GLM) was used to describe how change in

function from intake to discharge was affected by fear-avoidance in eight disease categories. Almost half of participants (49%), were classified as having chronic symptoms characterized by greater than 90 days from date of onset from intake to discharge. Improvement in function was found to be greater for the low fear group than for the elevated fear group in only two out of eight disease categories 1) muscle, tendon, and soft tissue disorders (Delta=1.37, P<.01) and 2) those with osteopathies, chondropathies, and acquired musculoskeletal deformities (Delta=5.52, P<.02). The authors found a small but significant effect of elevated fear-avoidance beliefs associated with poorer recovery in upper-extremity function with rehabilitation in only two out of eight disease categories. The category of muscle, tendon, and soft tissue disorders included rotator cuff tears and was found to be impacted by fear. Overall, the authors concluded the influence of fear-avoidance beliefs on change in functional status varies among specific shoulder impairments. This study served as a stepping-stone in selecting an appropriate clinical population for exploring the connection between the mind and the body. The present findings found that high levels of fear are associated with reduced functional outcomes and demonstrates the significant impact our emotions may have on the recovery process of rotator cuff tears (Sindhu et al., 2012).

An additional study assessed how rehabilitation outcomes were impacted among individuals experiencing a multitude of psychological risk factors. The purpose of this study was to determine the cumulative impact of depression, somatization and/or fear-of pain symptoms on rehabilitation outcomes in a population of individuals with lumbar spine disorders. 1,026 individuals who attended outpatient rehabilitation clinics with musculoskeletal conditions of the lumbar spine were used to conduct a secondary data analysis on data collected using the Focus on Therapeutic Outcomes (FOTO), Inc. system, Patient Inquiry. Function was measured using

the lumbar Computerized Adaptive Test (CAT) as well as pain-intensity, measured using a numeric rating scale (NRS) at intake and discharge. A single-item screen was administered at intake in order to classify patients into low versus elevated fear-of-pain as well as a self-reported clinical rating scale, the Symptom Checklist 90 Revised (SCL-90-R) in order to determine the presence of somatization and depression symptoms. Hierarchal regression analysis was used to determine the predictability of psychological factors on both functional status and pain-intensity outcomes. The independent variables were entered as three blocks to determine the amount of variance explained by each block. Block one included age and gender, block two included intake pain-intensity, intake functional status, change in functional status, as well as change in pain-intensity, and block three included fear-of-pain level, intake depression score, and intake somatization score. A standardized beta coefficient was used to determine the gradient of the regression line. The significance level was set as $p=.05$. Model R-squared change for block two was .589 ($p<.0001$) and for block three was .006 ($p=.002$) for pain-intensity. Depression score was found to be significant ($\beta=.06$, $t=2.25$, $p=.025$). Model R-Squared change for block two was .469 ($p<.0001$) and for block three was .008 ($p=.001$) for functional status. The psychological factors found to be significant were somatization ($\beta=.074$, $t=2.41$, $p=.016$), and fear-of-pain levels ($\beta=.057$, $t=2.45$, $p=.014$). All three psychological risk factors (depression, somatization and fear-of-pain) had small, yet statistically significant impacts on rehabilitation outcomes. These findings are clinically significant in that all patients should be screened for these three risk factors and should be further evaluated if an individual receives a high score for further evaluation and treatment in order to improve rehabilitation outcomes (Wannairaichi et al., 2015).

These findings are similar as the first study in that fear-avoidance beliefs have a negative impact on rehabilitation outcomes in persons diagnosed with lumbar spine disorders. Additional

evidence accounting for other psychological risk factors such as depression and somatization further supports the impact of the mind-body relationship on rehabilitation outcomes. Findings from both of these studies served as stepping-stones in developing a research protocol that incorporated an intervention that addressed the psychological risk factors associated with musculoskeletal disorders. The current study will use the same outcome measure, the fear-avoidance beliefs questionnaire (FABQ) for assessing fear and a modified version of the SCL-90-R to assess depression, somatization and in addition, anxiety symptoms in persons recovering from a rotator cuff repair. Patient satisfaction has not been assessed in order to identify an appropriate intervention to include in the treatment of individuals in these clinical populations prior to assessing in a larger scale and therefore supports this study.

Table 1.1

Rehabilitation protocol provided to the therapist of the study patient following a rotator cuff repair

Weeks 0-6

- Sling or immobilization to be worn at all times with ice pack to shoulder (20 minutes on; 20 minutes off)
- Remove sling 4 or 5 times per day for gentle Codman/pendulum exercise (move body, not arm)
- Active ROM to scapula, elbow, forearm, wrist, and hand starting 1 week postoperatively
- Passive ROM in all planes with minimal goal by week 6 as follows:
  - Shoulder flexion, 90-100 degrees
  - Abduction, 90-100 degrees
  - Internal rotation, 60-75 degrees
  - External rotation, 60-75 degrees
  - (Note: These are minimal values: may increase to full passive ROM as tolerated)
- Edema Control
- Postural education
- Soft tissue mobilization
- Monitor ROM to uninvolved joints (scapula, elbow forearm, wrist and hand).
- Home program: Codman/pendulum exercise, active ROM to uninvolved joints, passive ROM to shoulder (by family member of closed chain)

Week 6-8

- Continue passive ROM with goal of full ROM in all planes by week 8
- Being active ROM (with pulleys, cane, wall walks)
- May use high-voltage pulsed current or transcutaneous electrical nerve stimulation as needed

Week 8-10

- Gentle submaximal isometrics to affected shoulder in pain-free range
- Active ROM to affected shoulder
- Continue modalities and soft tissue mobilization as needed

Week 10+

- Continue modalities and soft tissue mobilization as needed
- Begin progressive resistance exercises with goal to meet preinjury status
- Perform stretching as needed
- Monitor scapula mobility

Chapter 2

Literature Review

In this chapter, the anatomical make-up of the rotator cuff, the clinical presentation of rotator cuff tears, risk factors for tears, how tears are diagnosed, treatment options for tears, rotator cuff repairs, complications from surgery, the impact of fear-avoidance beliefs, mindfulness-based interventions, and mindfulness in acute conditions will be discussed. In addition, the intervention Headspace will be discussed as well as evidential support will be provided for selecting this intervention.

Anatomical Make-Up of the Rotator Cuff

The shoulder girdle is formed by the tendons and ligaments that form connections between the scapula, clavicle and humerus bones. The glenohumeral joint is formed by the articulation of the head of the humerus with the glenoid cavity of the scapula (Huegel et al., 2015). This allows for a mechanism known as concavity compression, to have a stabilizing effect on the shoulder due to the compression of the humeral head against the glenoid cavity (Longo et al., 2011). A variety of ligaments serve to provide support to the shoulder including the superior and inferior acromioclavicular ligaments, the coracoclavicular ligaments, the coracohumeral ligaments, the coracoacromial ligament and the superior, middle and inferior glenohumeral ligaments (Huegel et al., 2015).

The four muscles that make up the rotator cuff include the supraspinatus, infraspinatus, teres minor and subscapularis (Huegel et al., 2015). The rotator cuff has an important role in multiple functions of the glenohumeral joint including stability as well as functional movements such as abduction and rotation. The cuff allows for the rotation of the humerus in respect to the scapula. The wide range of motion of the shoulder joint is allowed by the various rotational

moments of the cuff muscles due to the continuous insertions of the tendons around the head of the humerus (Longo et al., 2011). The supraspinatus muscle originates from the supraspinous fossa of the scapula bones and its tendon passes through the subcapsular space to insert on the superior and middle facets of the greater tuberosity (Huegel et al., 2015). Its function is to assist the upper extremity with initiating shoulder abduction as well as external rotation. When the glenohumeral joint is at a higher angle, the supraspinatus will have a major role in elevation (Otis et al., 1994). Both the infraspinatus and teres minor originate from the infraspinous fossa as well as the fibrous septum, and their tendons insert on the middle and inferior facets of the greater tuberosity. The subscapularis originates on the subscapular fossa and its tendon inserts on the lesser tuberosity (Huegel et al., 2015). The infraspinatus and subscapularis also play a small role in the abduction of the shoulder (Longo et al., 2011).

While tendons and ligaments are needed to create a stable joint, they are also dynamic tissues that respond to loading and change due to use and age. With the complexity of the anatomical makeup of the glenohumeral joint, specifically with the rotator cuff, it is not difficult to believe disorders of the rotator cuff are the most common cause of shoulder pain in primary care (Ostor et al., 2005).

Risk Factors for Tears

The most prevalent risk factor for rotator cuff disease is age. Age-related changes in the composition of collagen in the tendons of the rotator cuff are believed to predispose the tendon to inflammation seen in rotator cuff disease. Other intrinsic risk factors include obesity, smoking, diabetes mellitus, genetics, and various anatomical characteristics (Titchener et al., 2014). Important extrinsic risk factors to consider include occupational and sporting activities the individual may be engaged in. Professional and recreational athletes who engage in activities

with frequent overhead activity are at an increased risk for rotator cuff disease due to the persistent and severe biomechanical load on the muscles (Edmonds & Dengerink, 2014).

How tears are diagnosed

The examining physician evaluates disorders of the rotator cuff in multiple ways. The individual will first undergo a physical examination and will be assessed through observations in regard to muscle wasting, pain levels, visual inspections, palpation of the acromioclavicular joints for tenderness, swelling and deformity. Both active and passive range of motion should be conducted on the affected limb and further compared to the contralateral extremity (Whittle & Buchbinder, 2015). Magnetic resonance imaging (MRI), and MRI-related techniques have become standard for the evaluation of rotator cuffs in many clinical settings. This technique provides a detailed 3D image of the rotator cuff tendons and can detect labral tears, biceps tendon pathology and any other sources of pain within the shoulder (Connell et al., 1999).

Rotator cuff tears are one of the most common shoulder injuries affecting more than 40% of patients over the age of 60 resulting in 30,000-75,000 repairs annually (Ricchetti et al., 2012). Evidence suggests the number of medical visits due to shoulder pain as well as the number of rotator cuff surgical repairs performed in the United States will continue to grow (Colvin et al., 2012). Individuals suffering from rotator cuff tears are first encouraged to address their tear by non-operative means. These treatments include conservative therapies such as activity modification, icing, anti-inflammatory therapy, ultrasound, as well as through medications and physical therapy (Lin et al., 2008). If non-operative means are not able to treat the presenting problem and is paired with persistent moderate to severe pain at rest or with function lasting more than 3-6 months, then the physician will begin to explore surgical interventions in the treatment of the rotator cuff disease (Armstrong, 2011).

Rotator Cuff Repairs

The primary goals of a rotator cuff repair are to restore an individual's normal anatomy of the affected shoulder, improve strength, increase range of motion, and decrease pain levels (Walton & Murrell, 2012). Surgical techniques of rotator cuff repairs have evolved from traditional open repair, to arthroscopically assisted mini-open rotator cuff repair, to complete arthroscopic rotator cuff repair. Arthroscopic repairs are becoming more frequent due to its appeal to today's active society as a minimally invasive procedure that may result in an easier and earlier functional recovery. A study was conducted to compare early functional outcomes of mini-open and arthroscopic repairs. The authors found arthroscopic repairs are associated with significantly less pain at three and six months after surgery for both small and medium-sized chronic rotator cuff tears. The study also reported both the arthroscopic and mini-open surgical techniques had similar short-term outcomes for all functional parameters (Kang et al., 2007). Additional findings have found the use of arthroscopic repairs as a surgical technique resulted in less frequent extreme pain, earlier return of strength as well as passive range of motion, resulting in quicker recovery when compared to open rotator cuff repairs. Both groups reported similar pain levels with no significant differences for postoperative severity of pain during rest and activity as well as frequency of pain at night and during activity. The only statistically significant difference in pain between the two groups was in the open rotator cuff repair group, which resulted in significantly greater pain during at night six months post-surgery. Additionally, the operating time was significantly longer for open repairs than for the arthroscopic repairs. Individuals who had an arthroscopic repair rated their overall shoulder condition to be significantly better than those who received an open repair throughout a two-year follow-up period (Walton & Murrell, 2012).

Complications from Surgery

Complications from surgery include postoperative stiffness as well as tendon retear and thus requires rehabilitation protocols geared towards balancing early passive range of motion (ROM) against immobilization. Evidence suggests early ROM exercise results in accelerated recovery from postoperative stiffness for patients who receive an arthroscopic repair with proper healing of small to medium-sized tears (Riboh & Garrigues, 2014; Chang et al., 2014). Patients can expect to have a long and difficult recovery encompassed by persistent pain after surgery, particularly at night, feelings of popping and catching during ranging of the shoulder are common but are normal (Armstrong, 2011). The initial postoperative visit is to assess the recovery from surgery, ensure appropriate pain control, review of the home exercise program, as well as a client centered postoperative rehabilitation protocol (McCormick et al., 2015). Pain, joint stiffness as well as a reduction in function of the shoulder may result in a decrease of participation in activities due to fear-avoidance beliefs. Patients suffering from pain can result in fear of pain, fear of work-related activities, fear of movement, and fear of re-injury. The fear-avoidance model of musculoskeletal pain can be used to describe the psychosocial process in the development of chronic pain syndromes (Leeuw et al., 2006).

Fear-Avoidance Beliefs

Fear-avoidance can be defined as the avoidance of movements and activities based on fear related to pain. A model has been developed that outlines the role avoidance behaviors has on things such as disengagement in activities of daily living which can lead to the development of depression and disability (Vlaeyen & Linton, 2000).

The way in which an individual interprets and responds to pain sensations is a strong predictor of future pain experience as the model has two pathways an individual may follow

when experiencing pain. When an individual perceives their acute pain as non-threatening, they are likely to remain engaged in their activities of daily living. These individuals will most likely continue life without negative thinking which results in quicker recovery due to the acceptance of the pain. The absence of elevated psychological factors including pain catastrophizing, fear of pain and pain anxiety will result in a normal recovery (George & Stryker, 2011). While in contrast, an individual may fall into the vicious cycle that begins when the pain is misinterpreted by pain catastrophizing such as ruminating about irrational worst-case outcomes. Pain catastrophizing is the tendency to exaggerate a pain experience and feel helpless in the context of pain. The individual is unable to stop thoughts related to pain in anticipation of a painful encounter (Lethem et al., 1983; Quartana et al., 2009). Consequently, these individuals develop pain-related fear-avoidance and hypervigilance and enter a chronic pain phase characterized by disengagement, disability and depression (Leeuw et al., 2006).

Fear-avoidance beliefs are present among individuals with musculoskeletal complaints including neck pain, low back pain as well as upper and lower extremity disorders (Hart et al., 2009). Cross-sectional studies have found that patients with elevated fear-avoidance beliefs were more likely to have higher pain and disability scores (George et al., 2010; Waddel et al., 1993). Additional findings suggest elevated fear-avoidance beliefs can result in a higher probability of not returning to work and experienced poor treatment outcomes following physical therapy sessions (George et al., 2006, 2008). Fear decreases as a condition resolves for individuals with fewer fear-avoidance beliefs. Elevated fear-avoidance beliefs can lead to chronic pain, disability and reduced function. Over time, avoidance of physical activity can result in deconditioning of the musculoskeletal and cardiovascular systems and can lead to the development of chronic pain and disability (Vlaeyen & Linton, 2000). This brings to light the importance for occupational and

physical therapists to not only focus on the biomechanical factors of an individual in the rehabilitation process of a rotator cuff repair, but to also focus on the psychosocial factors, such as the influence of fear or pain. One way in which fear-avoidance can be treated is through the practice of mindfulness.

Schutze et al. (2009) found that low mindfulness predicts pain catastrophizing in the fear-avoidance model of chronic pain. A total of 104 individuals with chronic pain were asked to complete self-report measures on six variables found in the fear-avoidance models. These variables include 1) pain intensity, 2) negative affect, 3) pain catastrophizing, 4) pain-related fear, 5) pain hypervigilance and 6) functional disability. In addition, the study assessed mindfulness using the Mindful Attention Awareness Scale (MAAS) and the Five-Facets of Mindfulness Questionnaire (FFMQ). It was found that mindfulness formed the strongest negative association with pain catastrophizing and that mindfulness moderates the relationship between pain intensity and pain catastrophizing. In other words, an individual's ability to stay focused on the present moment depends on their perception towards their pain. Based on these findings, it was proposed for a revision to be made to include mindfulness as a variable within the fear-avoidance model between pain-intensity and pain catastrophizing. It was concluded that low mindfulness may be a predictor for engagement in distorted thinking or pain catastrophizing in relation to pain.

Pain catastrophizing, avoidance behaviors and other factors could negatively influence treatment outcomes of the rotator cuff repair. One way in which therapists can address the psychological influences of fear-avoidance beliefs and pain is through the incorporation of mindfulness-based interventions in addition to standard rehabilitation.

Mindfulness-based interventions

Mindfulness is derived from Buddhist practice and can be described as an intentional and non-judgmental awareness of the present moment (Kabat-Zinn, 1982). It is characterized by directing one's attention to the present moment with an orientation that is open to experiences, is curious, non-judgmental, non-reactive, insightful and decentered. In short, mindfulness is experiencing your thoughts and feelings without judging, rejecting or indulging them (Brown & Ryan, 2004; Kabat-Zinn, 1994; Lau et al., 2006; Walach et al., 2006). The fundamental path in developing mindfulness is through the practice of mindfulness meditation. Mindfulness meditation encompasses a wide range of practices that share the goal of strengthening one's mindfulness not only during a meditation session but also in daily life (Kabat-Zinn, 1994).

Mindfulness-based interventions (MBIs) encompass a variety of therapeutic programs that incorporate mindfulness training in the treatment of many diseases and have been successfully used in the treatment of chronic pain conditions in order to improve quality of life, psychological distress, and pain-related activity interference (Grossman et al., 2007; Kabat-Zinn, 1982). Additionally, MBIs may be effective in the treatment in a broad range of psychological disorders and somatic illnesses (Chiesa & Serretti, 2011; Fjorback et al., 2011). Meta-analytic studies of MBIs have found moderate effect sizes for reduced anxiety and mood symptoms in study populations with somatic illnesses such as cancer, diabetes, heart disease and chronic fatigue (Hofmann et al., 2010). MBIs have an impact on improvements in psychological well-being, cognitive functioning, and emotional regulation capacity in healthy-adult populations (Chiesa et al., 2011; Van Gordon et al., 2013). A further strength for the use of MBIs in addition to the versatility of programs, is the cost-effectiveness of treatments as they can be delivered at low rates or at no cost to the individual. There are five proposed mechanisms that make up

MBIs. These include 1) perceptual distancing leading to greater tolerance and acceptance of somatic pain and/or maladaptive cognitive or emotional processes, 2) increased exposure to thoughts and feelings leading to reduced fear as well as anxiety responses, 3) increased self-awareness and self-motivation resulting in improved psychosocial coping strategies, 4) decreased autonomic arousal leading to increased levels of relaxation and, 5) enhancement of immune and neuroendocrine system biological pathways (Baer, 2003; Ludwig and Kabat-Zinn, 2008; Compare et al., 2012). Two of the most common used mindfulness-based interventions include programs such as Mindfulness-Based Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy (MBCT) (Shonin et al., 2013).

MBSR was developed by Dr. Jon Kabat-Zinn at the University of Massachusetts Medical Center to initially manage mental health and chronic pain patients who were non-responsive to conventional therapy. This program has been implemented among patients with a wide variety of chronic clinical ailments as well as among relatively healthy individuals who wanted to improve their coping abilities when faced with the life's daily stressors (Grossman, 2004). The formal practices of MBSR include mindful movement with gentle hatha yoga with an emphasis on mindful awareness of the body, body scanning designed to systematically cultivate awareness of the body region by region, and sitting meditation with the awareness of the breath as well as the awareness of the body, feeling tone, mental states and mental contents (Cullen, 2011). MBSR is a structured eight to ten-week group program with class sizes to vary between ten and forty participants. Groups are variable and may be either heterogeneous or homogenous in respect to disorders or problem areas of participations. Participants are required to attend weekly sessions lasting on average around 2.5 to 3 hours. Each session is designed to cover particular exercises and topics within the context of mindfulness such as different forms of mindfulness meditation

practice, mindful awareness during yoga postures, and mindfulness during stressful situations as well as social interactions. Participants are required to complete 45-minute homework assignments that vary from meditation practice, mindful yoga, and applying mindfulness to everyday life situations. Additionally, participants are required to attend in a six-hour daylong retreat on the weekend (Grossman et al., 2004: Khoury et al., 2015). A meta-analysis was conducted to assess studies investigating MSR among medical patients with the following diagnoses: Fibromyalgia, mixed cancer diagnoses, coronary artery disease, depression, chronic pain, anxiety, obesity, binge eating disorders, and psychiatric patients. Overall, both controlled and uncontrolled studies demonstrated similar effect sizes of approximately 0.5 ($p < .0001$) with homogeneity of distribution. These results suggest MBSR may help a broad range of individuals to cope with their clinical and nonclinical problems (Grossman et al., 2004). Additional findings found MBSR to be moderately effective in reducing stress, depression, anxiety, and distress as well as improving the quality of life of healthy individuals (Khoury et al., 2015).

Evidence is limited in regard to the influence of MBSR in orthopaedic conditions, however a study was conducted to assess the influence of MBSR on a sample of low back pain patients. Medium size effects were found for health-related quality of life, health-related life satisfaction, depression, and affective pain perception which supports the incorporation of MBSR in the treatment of this population (Schmidt et al., 2015). The cost of these programs may be a limitation for individuals facing financial restrictions on top of the pre-existing costs from surgery and outpatient therapy with a cost range of $275 to $575 for MBSR (Sound, 2015). Another limitation of MBSR is that it is a time-intensive intervention and may not be feasible with individuals recovering from a RCR as they will be attending physical therapy on a weekly basis, follow up appointments as well as completing their home exercise programs.

Mindfulness Based Cognitive Therapy (MBCT) is a psychological therapy designed to prevent a relapse of depression with specificity to individuals diagnosed with major depressive disorder. The program combines the ideas of cognitive based therapy with meditative practices as well as attitudes based on the cultivation of mindfulness (Biley, 2009). MBCT was derived from MBSR and follows a similar 8-week structured program that is group-based and requires weekly meetings as well as guided mindfulness exercises. Classes meet on a weekly basis in a group and last around two hours. The course costs over $400 for the 8-week program. Additionally, the program provides CDs for self-practice to be completed once a day, six days per week, and also requires the participant to attend an all-day retreat. Since its development, MBCT has broadened the range of target illnesses and populations to include various mood-disorders, anxiety disorders, bipolar disorders as well as chronic fatigue (Shonin et al., 2013). The program teaches participants the skills to become more aware of thoughts and feelings in order to relate them to a decentered perspective as well as skills to stay well on a long-term basis with recurrent depression (Williams & Kuyken, 2012). Evidence suggests MBCT significantly reduces the rates of depressive relapse and recurrence when compared with usual care or a placebo. This resulted in a relative risk reduction of 35% (Piet & Hougaard, 2011).

Mindfulness in the treatment of Rotator Cuff Repairs

Current evidence has been provided for the positive impact of mindfulness on populations suffering from chronic conditions including fibromyalgia, chronic low back pain, anxiety, depression and others through the implementation of MBIs. To the best of our knowledge, there is little evidence to support the development of a treatment protocol that incorporates the use of mindfulness in the treatment of acute musculoskeletal conditions such as rotator cuff repairs. Additionally, evidence regarding the impact of a mindfulness-based

intervention on acute orthopaedic conditions has not been studied. Rehabilitation for a rotator cuff repair takes approximately twelve weeks of participating in physical therapy and a home exercise program. The intensive requirements of rehabilitation limit an individual who has undergone a rotator cuff repair in participating in MBIs such as MBSR and MBCT. Rotator cuff repairs are expensive, as indicated by direct cost estimates for repairs ranging from $10,000 to over $17,000 per procedure (McElvany et al., 2015). The costs from receiving a rotator cuff repair is staggering and shines light on the need to determine the impact of incorporating a cost-effective, self-managed and brief mindfulness-based intervention in addition to standard rehabilitation to assess if incorporating this intervention is feasible. Individuals may discover a shift in attitude and perspective allowing them to see the condition they are suffering from in a new light without the impact of fear on thoughts and behavior due to the incorporation of mindfulness.

Delivering Mindfulness through Smartphone Application

Currently, there is limited amount of research supporting whether delivering a mindfulness-based intervention on a digital platform such as a mobile application, has the same benefits as face-to-face mindfulness-based training programs such as MBSR and MBCT. The use of mobile applications in the daily lives of Smartphone users is increasing more and more each year with the number of applications increasing from 1.4 million applications to 2 million from 2015-2016 (Statistica, 2016). Health care professionals should be able to assess health applications for content that is high in quality and supported by evidence for future recommendation to patients (Mani et al., 2015). One way in which Smartphone applications can be assessed is by using the Mobile Application Rating Scale (MARS) (Stoyanov et al., 2015).

The MARS is made up of 23 items divided into the following 3 categories, 1) classification, 2) app quality, and 3) subjective quality. The classification category is aimed to collect descriptive information such as the app name, developer, user ratings, last update, cost, platform (Android, iPhone, iPad), brief description as well as selecting the applications focus, age group, and theoretical background. The app quality category includes 19-items ranging on a 5-point scale from 1 to 5, geared towards rating apps on four subscales of engagement, functionality, aesthetics and information quality. Each subscale has a mean score that is averaged to find the app quality mean score. The subjective quality section contains 4 items for the evaluation of the user's overall satisfaction including, "Would you recommend this app to people who might benefit from it?", How many times do you think you would use this app in the next 12 months if it was relevant to you?", "Would you pay for this app?", and "what is your overall star rating of this app?". These items are scored separately as individual items. The MARS was found to have excellent internal consistency of alpha 0.92, and interrater reliability of ICC = .85 (Stoyanov et al., 2015).

Web-based Mindfulness

It is important to note the evidential support for other mindfulness interventions that are delivered by technology means. Several quantitative studies have been conducted to assess the efficacy of these interventions among clinical populations. A brief web-based mindfulness training was administered to a group of participants in a randomized control pilot study. The participant's distress, perceived stress, mindfulness as well as mood and emotion regulation were investigated. The study found that the brief mindfulness training reduced negative affect and perceived stress in participants who completed at least half of the training (Gluck & Maercker, 2011). Another randomized control trial aimed to explore if a brief online mindfulness-based

intervention would increase mindfulness and reduce perceived stress as well as anxiety and depressive symptoms within a student population. 104 students were randomly assigned to the intervention and wait-list control group. The intervention group started a two-week self-guided online intervention. The intervention group participants were found to have significant improvements in mindfulness and a reduction in perceived stress as well as anxiety and depressive symptoms with small to medium effect sizes in intention to treat analysis. A strong association was found between reductions in self-reported stress, anxiety, depression and improvements in mindfulness (Cavanagh et al., 2013). A third randomized control trial assessed a similar internet-based mindfulness treatment intervention in persons with anxiety disorders. The mindfulness intervention consisted of 96 audio files paired with instructions for a variety of mindfulness meditation exercises. The study found the intervention group had a larger decrease in anxiety, depression and insomnia symptoms from pre to post-assessment than the participants in the group. Additionally, the intervention group achieved moderate improvement in quality of life scores (Boettcher et al., 2013). The results of these studies support the idea that web-based mindfulness programs may result in similar effects as face-to-face mindfulness interventions

Support for Headspace

To the best of our knowledge, Headspace is the only mindfulness-based Smartphone application to have been examined for efficacy as a mindfulness training app and therefore supported our decision to select Headspace as the intervention for this study.

A systematic review was conducted to evaluate mindfulness-based mobile applications for quality, using the MARS. Applications were included if they were secular, provided education on mindfulness practice, and incorporated guided mindfulness training. Searchers were conducted in both the Apple and Google App stores resulting in identifying a total of 700 apps

with 23 apps meeting the inclusion criteria. The Headspace application had the highest average MARS total of 4.0 out of 5.0 and subscale scores. Smiling Mind received a MARS score of 3.7 followed by iMindfulness and Mindfulness Daily with a MARS score of 3.5 (Mani et al., 2015). The Headspace app received scores of 3.8 for engagement, 4.8 for functionality, 4.7 for aesthetics, 4.0 for information, 4.0 for satisfaction and an overall score of 4.0. Additional evidence to support the use of Headspace has been conducted to support the usefulness of Headspace in order to increase mindfulness as well as for promoting better physical and mental health (Howells et al., 2014; Lim et al., 2015; Laurie & Blanford, 2016; Rosen, 2016).

Howells et al. (2014) conducted a randomized control trial explored the viability of delivering a positive psychological intervention in an application format (Headspace*)* to the research participants for ten days. Fifty-seven individuals received the mindfulness intervention whereas sixty-four participants received a control intervention. The authors found significant increases in positive affect with a medium effect size and reduction in depressive symptoms with a small effect size in the experimental group. Overall the authors conclude that the use of a smartphone-based intervention can significantly enhance the different elements of wellbeing.

Lim et al. (2015) examined how implementing either a three-week mobile application based training course in mindfulness or an active control condition of cognitive skills influenced an individual's prosocial behavior in regard to compassion. The individuals were observed while sitting in a waiting room and were assessed by whether they gave up their seat to an individual who entered the room on crutches wearing a surgical boot. Participants assigned to the mindfulness meditation condition gave up their seats more frequently than those assigned to the active control group.

Laurie & Blandford (2016) assessed how people use and experience the Headspace application as a digital mental wellbeing intervention as well as the applications enabling factors and barriers for effective use. A total of 16 participants (5 males, 11 females) were recruited for this study with a mean age of 32.5. The participants took part in the qualitative semi-structured interview study lasting between 30 to 40 days. The participants were interviewed before and after the study. The authors found that the main barrier for using Headspace was incorporating the application into their busy lives. Other impacting factors creating barriers included daily routines, thoughts about potential consequences of using the application, personal relationships, social norms as well as negative moods and emotional states. Benefits of the application included positive attitudes towards mindfulness, realistic expectations, and positive social influences. Twelve of the participants completed 10 or less sessions while the four individuals completed between 11 and 30 sessions. The authors reported that 9 users turned to Headspace for help with difficult emotions and in stressful situations. All participants reported Headspace was well designed and helped to facilitate meditation practice.

Rosen (2016) conducted a randomized control study to evaluate the impact Headspace had on improving quality of life among women with breast cancer. Participants were assigned randomly to an intervention group (n=48) and a waitlist control group (n=47). Data was collected at baseline, week 5, week 9 and at a 4-week follow-up session. The intervention group received access to the application for a total of 8 weeks while the waitlist control group received access to Headspace around the 4-week follow up. A minor improvement in quality of life scores was observed in the intervention group when compared to the control group by week 5 and further improved by week 9 and at the 4-week follow up across functional, emotional, social, and physical well-being domains. The authors did not find a significant change in mindfulness

between the two groups, but did find a detectable improvement in mindfulness after post hoc analysis in the intervention group when compared to the control group. The author concluded the delivery of mindfulness training using an app-based approach may be feasible in a population of women with breast cancer.

How do you measure mindfulness?

Selecting an appropriate outcome measure tool to assess for changes in mindfulness required literature analysis of already existing scales for the purpose of this study. The Five Facet Mindfulness Questionnaire (FFMQ), the Freiburg Inventory (FMI) and the Mindful Attention Awareness Scale (MAAS) were recommended for use by the Headspace research team for the purpose of this study and will be discussed in order to ultimately support the use of the FFMQ-SF.

The Five Facet Mindfulness Questionnaire-Short Form (FFMQ-SF) is a 24-item outcome measure tool that allows for an in-depth analysis of the five facets found to make up what is known as mindfulness. These facets include acting with awareness, observe, describe, non-judging of inner experiences and nonreactivity to inner experiences (Sauer, 2012). The short form version included four items for observing as well as five items for four of the five facets including describing, acting with awareness, non-judging and nonreactivity (Baer et al., 2006). The development of the short form is supported for researchers who want to use the instrument in the context of applied clinical research. The short form utilizes the same rating scale in which the participant is asked to rate how true each statement is to them ranging from 1 (never true or very rarely true) to 5 (very often or always true) on a 5-point Likert scale. The facet scores are computed by adding the scores on the individual items. The facet scores range from 8-40 with higher scores indicating greater mindfulness (Bohlmeijer et al., 2011). The FFMQ-SF was found

to be a reliable and valid measure with Cronbach's alpha of the subscales ranging from 0.75 to 0.87 (Bohlmeijer et al., 2011). Another study found Cronbach's alpha ranged from 0.71 to 0.82 for the five facets for the FFMQ-SF (van Son et al. 2014). The short form is derived from the original 39-item FFMQ outcome measure tool.

The Freiburg Mindfulness Inventory (FMI) is a 30-item scale designed to measure the concept of mindfulness built off of the premise of understanding Buddhist psychology as well as theory and requires its understanding by the tested individuals (Sauer et al. 2013). It was constructed from a combination of interviews by mindfulness experts, extensive literature analysis and review, and by testing 115 subjects that attended a mindfulness meditation retreat. The 30-item questionnaire was found to have strong psychometric properties with an internal consistency of Cronbach alpha = .93, significantly demonstrating an increase in mindfulness after the retreat. This allowed for the discrimination between experienced and inexperienced meditators (Buchheld et al., 2001). A 14-item short form version was developed to assess individuals who may or may not be informed about mindfulness in Buddhist theory. The sample included participants from Buddhist retreats, the general population as well as a clinical population. It was found that the 14-item version of the FMI was psychometrically stable with alpha = .86. The short form correlation with the long 30-item version was r = .95 and reliability as alpha = .86. The short scale was sensitive to change and can be used with subjects without previous meditation experience (Walach et al., 2006). The FMI has been used in both normative and clinical populations including morbid obesity, depression, healthcare professionals and cancer patients to name a few (Ouwens et al., 2015; Jimenez et al., 2011, Talisman et al., 2015 & Fish et al., 2014). The FMI utilizes a 4-pt Likert scale ranging from 1 (rarely) to 4 (almost always) for items such as 'I am open to the experience of the present moment', 'I sense my body,

whether eating, cooking, cleaning or talking', and 'I am able to appreciate myself'. The scorer is to add up all the items for a summary score after reversing one of the items scores. Higher scores are indicative of greater mindfulness (Walach et al., 2006).

The Mindful Attention Awareness Scale (MAAS) is the most widely used mindfulness scale to date in which assesses an individual's mindfulness as a state rather than a trait in both normative and clinical populations. The MAAS differs from other scales definition of mindfulness as it does not embrace both the emotional and attentional aspects and only accounts for the attentional aspect. In addition, the scale measures an individual's mindlessness (absence of mindful attention in various situations) versus their mindfulness (Sauer et al., 2013 & Brown et al., 2011). The scale has been validated in populations including college students, community adults, as well as individuals with cancer (Brown & Ryan, 2003; MacKillop & Anderson, 2007; Carlson & Brown, 2005). It is a 15-item self-report tool with items ranked on a 6-pt Likert scale rating from 1 (almost always) to 6 (almost never) for items such as, "I find myself doing things without paying attention", "I rush through activities without being really attentive to them" and "I find myself listening to someone with one ear, doing something else at the same time" (Brown & Ryan, 2003). Brown & Ryan (2003), found MAAS scores were moderately and positively correlated with scores on other measures of mindfulness, mindlessness, emotional intelligence, positive affect, and self-actualization. Additionally, high scores on the MAAS correlated moderately and negatively on somatization, depression, anxiety, negative affect as well as anger and hostility measures. The MAAS psychometric properties are strong with Cronbach's alpha indicating good internal reliability of alpha = 0.89.

The FFMQ-SF, FMI and MAAS scales have been found to measure changes in mindfulness in a wide range of populations. All three questionnaires are brief allowing for other

scales to be administered in a clinical population without overwhelming a participant. The brevity of the FMI was very appealing but it ultimately was not used for this study as the Buddhist component of the full version was seen as a potential limitation even if the short-version was supported for use in inexperienced mediators. The MAAS would have been our second choice if this were a larger study. The FFMQ-SF was ultimately selected based on its ability to provide data on five total facets versus one total score found in the FMI and MAAS. It is important to provide detailed information as well as data when using a case-study design. The FFMQ and FFMQ-SF were ultimately derived from the FMI and MAAS along with three other commonly used scales for measuring mindfulness. Based on currently available evidence on reliability, validity, and responsiveness, we have found the FFMQ-SF to be appropriate for measuring mindfulness for the purpose of this study.

The importance of Participant Satisfaction

In the world of healthcare, patient satisfaction is one of the most significant and frequently used measures in the assessment of quality healthcare. Satisfaction directly impacts efficient, timely, and client-centered quality of healthcare services (Prakash, 2010). Measurement of satisfaction is a mandate by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). Additionally, satisfaction can impact the reimbursement rate for hospitals and healthcare systems as it is a component of care as well as an outcome of care (Press, 2002). Satisfaction in regard to health care is largely dependent on an individual's pre-intervention goals and expectations. The individual is left feeling disappointed and unsatisfied if these expectations are not met (Haldeman, 2012). Therefore, it is important to provide education on the potential positive and negative outcomes that may occur when any intervention is

incorporated in the treatment of a patient. The overall importance of satisfaction within healthcare was the main reason for selecting it as the main outcome of this study.

Chapter 3

Methods

Study Design

The present study used a case-study design where one study participant's recovery treatment was followed when using a newly developed mindfulness treatment protocol. The case-study design was selected because it provides an opportunity for understanding the potential impact of the mindfulness intervention on an individual's condition. This design allowed for in-depth analysis of variables being examined, including the participant's health condition, emotions, thoughts as well as past and present occupations. In addition, this design was chosen to examine the impact of a new and innovative treatment approach, which in turn will give us the opportunity to disseminate creative ideas contributing to successful patient outcomes. A case-study design was appropriate because personal characteristics including age, gender, and comorbidities remained constant throughout the course of the experiment (Portney & Watkins, 2009).

Our study served as both a pilot study and feasibility study. This study was a pilot study for determining changes in mindfulness as well as assessing patient satisfaction when a mindfulness-based intervention was implemented pre and post-surgery in individuals undergoing a rotator cuff repair. This study was feasibility study as we wanted to identify if there were any conceptual problems in implementing the protocol, as well as if it was practical to incorporate the treatment into usual care. The primary disadvantage of using the case-study design was that it did not account for individual variability. The design only allowed for us to learn about one individual's response in detail. Therefore, the findings are dependent on the individual's patient characteristics and the findings may not be generalized to the population. Additional disadvantages include risks associated with the study design such as an increase in stress levels

based on the amount of time required to participate in the study intervention in addition to undergoing an invasive procedure.

This study was approved by the Institutional Review Board at the Medical College of Wisconsin.

Sample

One participant undergoing a surgical repair of a rotator-cuff tendon tear was recruited from the Medical College of Wisconsin Department of Orthopaedic Surgery at Froedtert Hospital located in Wauwatosa, WI. The inclusion criteria were (1) between the ages of 18 to 65 years, (2) English speaking and comprehension abilities at the eighth grade level (speaking, reading, writing), (3) have had shoulder pain for a year or less, (4) were scheduled to undergo surgical repair of a tendon rotator cuff tear within the month prior to data collection, (5) were willing to commit to participating in the intervention at least 5 days per week for 10-15 minutes per day, (6) not receiving treatment for a mental disorder at time of screening, (7) did not have a history of systemic illness such as rheumatoid arthritis (RA), (8) did not have a presence of neurological disorder resulting in motor impairment, (9) did not have a severe cognitive impairment, (10) was not pregnant, and (11) did not have history of visual or hearing impairment,

The exclusion criteria were (1) were under the age of 18 or over the age of 65, (2) were not English speaking or did not have comprehension abilities at an eighth grade level, (3) have not had shoulder pain for longer than a year, (4) were not willing to commit to participating in the intervention 5 days per week for 10-15 minutes per day, (5) were receiving treatment for a mental disorder at time of screening, (6) had a hearing or visual impairment, (7) had a history of systemic illness such as rheumatoid arthritis (RA), (8) had a presence of neurological disorder

resulting in motor impairment, (9) had a presence of severe cognitive impairment, (10) and were pregnant.

Materials & Equipment

Materials used in this study included both primary and secondary pencil-and-paper self-report assessments. The primary measures included the demographic questionnaire, the follow-up questionnaire and the Five Face Mindfulness Questionnaire-Short Form (FFMQ-SF). The secondary measures included the Fear-Avoidance Belief Questionnaire (FABQ) and The Brief Symptom Inventory 18 (BSI-18). Major equipment that was used included an Amazon Fire Tablet and a lab computer for data analysis.

Pencil-and-Paper Assessments

1) Five Facet Mindfulness Questionnaire-Short Form (FFMQ-SF).

Bohlmeijer et al. (2011) teamed up with the original authors of the Five Facets of Mindfulness Questionnaire in order to assess the psychometric properties of the FFMQ as well as to develop a short form version of the questionnaire that incorporated the same psychometric properties as the original version. The FFMQ-SF was developed and became a 24-item assessment of the five aspects of mindfulness that were found to be factors that make up mindfulness in the original development of the FFMQ. The short form version included 4 items for observing and 5 items for the describing, acting with awareness, non-judging and nonreactivity facets (Baer et al., 2006). The development of the short form is supported for researchers who want to use the instrument in the context of applied clinical research. The short form utilizes the same rating scale in which the participant is asked to rate how true each statement is to them ranging from 1 (never true or very rarely true) to 5 (very often or always

true) on a 5-point Likert scale. The facet scores are computed by adding the scores on the individual items. The facet scores range from 8-40 with higher scores indicating greater mindfulness (Bohlmeijer et al., 2011). The FFMQ-SF was found to be a reliable and valid measure with Cronbach's alpha of the subscales ranging from 0.75 to 0.87 (Bohlmeijer et al., 2011). Another study found Cronbach's alpha ranged from 0.71 to 0.82 for the five facets for the FFMQ-SF (van Son et al. 2014).

The Five Facet Mindfulness Questionnaire (FFMQ) was first developed by Baer et al. (2006) after determining the psychometric characteristics of five different mindfulness questionnaires in a population of 613 undergraduate students. The questionnaires include the Mindful Attention Awareness Scale (MAAS), the Freiburg Mindfulness Inventory (FMI), the Kentucky Inventory of Mindfulness Skills (KIMS), the Cognitive and Affective Mindfulness Scale (CAMS), and the Mindfulness Questionnaire (MQ). The authors found the MAAS, FMI, KIMS, CAMS, and MQ questionnaires to be internally consistent and correlated with each other, with meditation experience, and with several other variables. In addition, the study explored the factors of mindfulness within the five questionnaires. The authors combined the data set of the questionnaires including 112 items that were then subjected to exploratory factor analysis (EFA) using principal axis factoring with oblique rotation to allow for correlations among the factors. The initial EFA yielded 26 factors with eigenvalues greater than 1.0 and accounting for 64% of the total variance. A second factor analysis was conducted in order to specify the five factors that should be identified using principal axis factoring with oblique rotation. This analysis yielded a five-factor solution that accounted for 33% of the variance after factor extraction. Items with the highest loadings on the five factors derived from the EFA were selected for inclusion in facet

scales. The facets found from this study included observing, describing, active awareness, non-judgment, and nonreactivity (Baer et al., 2006).

The FFMQ was developed to include 39-items with 8 items for observing refers to the participant's ability to notice or attend to internal and external experiences. An example of an item that measures observing is "I pay attention to physical experiences, such as the wind in my hair or sun on my face." Describing has 8 items and is defined as labeling internal experiences with words. An example of describing is "I am good at finding the words to describe my feelings." There are 8 items for acting with awareness which means attending to one's activities of the moment. An example of acting with awareness is "I find it difficult to stay focused on what's happening in the present moment." There are 8 items for non-judging and is described as taking a non-evaluative stance toward thoughts and feelings. An example of non-judging is "I tell myself I shouldn't be thinking the way I'm thinking." Finally, there are 7 items for nonreactivity defined as allowing thoughts and feelings to come and go without getting carried away or caught up by them. An example of nonreactivity is "I watch my feelings without getting carried away by them" (Baer et al., 2006).

Each facet item was identified to reflect the underlying construct based on corrected item-total correlations and standardized factor loadings in a correlated five-factor (CFA) model. This CFA model displayed minimal cross-loadings as evidenced by the CFA modifications indices, and exhibited low error correlations with other items (Marsh et al. 2005). CFA showed good model fit for a correlated five-factor structure (Bohlmeijher et al., 2011). Statistical and content-related considerations while developing the short form resulted in the removal of 15 items found to have low total item correlations and/or standardized factor loadings and high content redundancy. Total facet scores of the short form were highly correlated with the original

version of the FFMQ, with Pearson Correlation Coefficients (r) equal to 0.96 for non-judging, 0.95 for nonreactivity, 0.92 acting with awareness and 0.89 for both observing and describing. The internal consistencies of the five facets was found to be acceptable, with Cronbach's alpha coefficients ranging from 0.75 to 0.87. The convergent and divergent validity of the short form was found to be a similar to the original scale as well as the sensitivity (Bohlmeijer et al., 2011).

Based on currently available evidence on reliability, validity, and responsiveness, we have found the FFMQ-SF to be appropriate for measuring mindfulness for the purpose of this study. Appendix A includes a full version of the FFMQ-SF and is freely available.

2. Initial Demographic Questionnaire.

The participant information questionnaire was completed at baseline (2 weeks before surgery along with other paper-and-pencil assessments. The questionnaire includes three different sections with inquiries related to 1) patient demographics, 2) mindfulness-related information, and 3) injury health-related information. The section on demographics asked for the participant's year of birth, their height, gender, as well as denoting hand dominance. The section on mindfulness-related information asked an open-ended question, 'What is your experience with mindfulness?' as well as a yes or no question inquiring about comfort level of practicing mindfulness independently to identify the participant's prior level of experience with mindfulness. Finally, the section on injury health-related information asked both open and close-ended questions regarding the participant's current condition, inquiries about previous injuries, experiences with sleep disturbances, as well as assessment and management of pain. Other health-related information questions asked if the individual has type I or type II diabetes as well as their smoking history. Appendix B includes a full version of the demographic questionnaire.

3) Follow-up Questionnaire.

The follow-up questionnaire was designed to obtain information about the individual's pain levels, compliance with the intervention and satisfaction with regard to the intervention. First, pain-related questions inquired about current pain, average pain over the previous week, and specific time of day when increased pain was experienced. Second, for compliance with the intervention, the participant was asked to indicate the number of sessions completed. Finally, the intervention satisfaction section asked 10 questions on a 5-point Likert scale ranging from 1 being false, to 5 being true. For example, 'the application was easy to use', 'I enjoyed the headspace application', 'Headspace was easy to do each day', etc. Open-ended questions regarding Headspace included questions about the interventions benefits, barriers, needs for improvement and impact on the participant's daily life. An example from this section included, 'what benefits do you think you've gained from your experience with Headspace. Appendix C includes a full version of the follow-up questionnaire.

4) The Fear-Avoidance Beliefs Questionnaire (FABQ).

The Fear-Avoidance Beliefs Questionnaire (FABQ) was created in 1993 by Waddell et al. in order to investigate fear-avoidance beliefs among people experiencing low back pain. The questionnaire helps identify individuals who have high pain-avoidance behaviors related to pain (Waddell et al., 1993).

The FABQ is a 16-item assessment with each item scored on a 7-point Likert scale ranging from zero (strongly disagree) to six (strongly agree), with higher numbers indicating increased levels of fear-avoidance beliefs (Swinkels-Meewisse et al., 2003). The FABQ comprises two subscales, the Physical Activity subscale (FABQ-PA) with five items, and the Work Subscale (FABQ-W) with eleven items. The FABQ-PA scores range from 0-24 and

include items such as, “physical activity makes my pain worse”, or “I should not do physical activities which (might) make my pain worse”. The FABQ-W scores range from 0-42 and include items such as “my pain was caused by my work or by an accident at work”, as well as “I should not do my normal work with my present pain” (Flynn et al., 2002; Fritz et al., 2001; Waddell et al., 1993). This assessment has previously been demonstrated to be reliable and valid in a population of individuals with chronic low back pain and is useful as a screening tool in order to identify acute lower back pain patients who will not return to work by four weeks (Fritz et al., 2001). In addition, the internal consistency was found to be acceptable for the physical activities ranging from 0.70 to 0.72 and for FABQ-W ranging from 0.82 to 0.83. Test-retest reliability of FABQ was found to be sufficient, with Pearson Correlation Coefficients (r) for FABQ-PA to be 0.64 and FABQ-W to be 0.80 (Swinkles et al., 2003). To the best of our knowledge, sensitivity and responsiveness have not been reported and is generally left untested (Lundberg et al., 2011). The participant was only evaluated for fear-avoidance beliefs related to physical activity for the purposes of this study.

Appendix D includes a full version of the FABQ Questionnaire.

5) The Brief Symptom Inventory 18 (BSI-18).

The Brief Symptom Inventory 18 (BSI-18) is a reduced version of the 53-item Brief Symptom Inventory (BSI) which looks at a broader spectrum of psychological symptoms and includes nine symptom scales for somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. It is a self-report symptom inventory in order to screen for both psychiatric disorders and psychological distress in both medial and community populations (Derogatis, 2001). The BSI is a shortened version of the Symptom Checklist 90 Revised (SCL-90-R), which is a self-assessment

instrument that assesses the same nine symptom scales assessed in the BSI. The 18 items of the BSI-18 were all taken from the BSI directly and were selected based on multiple considerations, including prevalence of the symptom, item analysis characteristics, and loading situations in factor analyses of the BSI and SCL-90-R (Boothroyd, 2003). Specific results of item analyses, factor loadings or pilot testing's were not reported in the BSI-18 manual. Construct validity of the BSI-18 was assessed by correlating the three symptom dimension scores and global severity index with the corresponding scores on the SCL-90-R. All correlations found were high, 0.91 for somatization, 0.96 for anxiety, and 0.93 for both depression and GSI. Standard error of measurement is also not reported for the BSI 18 (Derogatis, 2001).

We have selected to use the BSI-18 for the purpose of this study as it focuses specifically on the three symptom dimensions of anxiety, depression and somatization in contrast to the nine dimensions assessed by the SCL-90-R and the BSI.

The Brief Symptom Inventory 18 (BSI-18) is an 18-item self-report, norm-referenced questionnaire that gathers patient-reported data to help measure psychiatric disorders and psychological distress in medical and community populations on three scales. These scales include depression (DEP) measures core symptoms of various syndromes of clinical depression, anxiety (ANX) measures symptoms prevalent in most anxiety disorders including nervousness, tension, apprehension, and somatization (SOM) measures distress caused by the perception of bodily dysfunction with a focus on symptoms arising from gastrointestinal and other physiologic symptoms. The three scales were selected because they represent about 80% of the psychiatric disorders that occur in primary care practice (Derogatis, 2001). The global severity index score is a composite measure of psychological distress and is the best single indicator of the individual's overall emotional adjustment and psychopathological status.

Each scale is scored on a 5-point Likert-type scale ranging from 0 not at all, to 4 extremely. Scale scores can range from 0-24 and may be summed to obtain a total scoring ranging from 0-72. The BSI-18 was developed as a highly sensitive screen for psychiatric disorders and psychological disintegration and secondarily as an instrument to measure treatment outcomes (Boothroyd, 2003). The manual also indicates the BSI-18 may be useful in most clinical and research settings with a wide range of use in medical and community populations including people who have been diagnosed with cancer, who have a compromised immune system and/or who are experiencing chronic pain (Derogatis, 1993).

The BSI-18 can be administered to individuals 18 years and older and takes approximately four minutes to complete. Raw scores are converted to standardized T scores using a provided norm table. Gender specific normative data is provided on two samples including a community sample and an oncology sample (Derogatis, 1993).

The BSI-18 was found to have no significant differences in reliability in regard to the internal consistencies of the SCL-90-R with alpha ranging from 0.79 to 0.85 for the three scales. The one-dimensional scale structure of the BSI-18 was supported in a confirmatory factor analysis. The authors found the BSI-18 to be suitable for patients with affective disorders and is similarly appropriate to detect sensitivity change as the SCL-90-R. The three dimensional factor structure of the BSI-18 was replicated and therefore can be concluded that the BSI-18 is an economic alternative but can be regarded to as a psychometric improvement (Prinz et al., 2013). Further analysis was conducted to assess the psychometric and structural properties and found BSI-18 to have satisfactory test-retest reliability. Sensitivity to change was found to have statistically significant coefficient changes ($p < .001$) (Andreu et al., 2008).

Two advantages found to support the use of the BSI-18 over the BSI and the SCL-90-R are due to its brevity with both administration as well as scoring and the focus on the three scales of anxiety, depression and somatization. Appendix E includes a picture of the cover page of the BSI-18 assessment.

Headspace

Headspace is a mobile application that is accessible via smartphones, tablets, as well as through a desktop computer. It is a mindfulness-based intervention that provides short guided meditation sessions to the user.

To the best of our knowledge, there is no evidence to support the use of Headspace in people with rotator cuff repairs. There is however, evidence to support the usefulness of Headspace in order to increase mindfulness as well as for promoting better physical and mental health (Howells et al., 2014; Lim et al., 2015; Laurie & Blandford, 2016; Rosen, 2016).

Zeidan et al. (2010) conducted a study to examine whether a three-day mindfulness intervention requiring 20 minutes/day, or a sham mindfulness meditation intervention would improve mood and cardiovascular variables when compared to a control group. The authors found the brief mindfulness meditation training was effective in promoting self-regulation as well as improving heart rate. There was an 88% drop in negative mood when compared to a 32% drop by the sham group and a 34% drop by the control group. The mindfulness meditation reduced both depression and fatigue ratings. Overall the authors found implementing a brief meditation intervention was effective in reducing overall negative mood including depression, tension, fatigue, confusion, anxiety and lowering heart rate when compared to a sham meditation and control group.

Howells et al. (2014) conducted a randomized control trial explored the viability of delivering a positive psychological intervention in an application format (Headspace*)* to the research participants for ten days. Fifty-seven individuals received the mindfulness intervention whereas 64 participants received a control intervention. The authors found significant increases in positive affect with a medium effect size and reduction in depressive symptoms with a small effect size in the experimental group. Overall the authors conclude that the use of a smartphone-based intervention can significantly enhance the different elements of wellbeing.

Lim et al. (2015) examined how implementing either a three-week mobile-application based training course in mindfulness or an active control condition of cognitive skills influenced an individual's prosocial behavior in regard to compassion. The individuals were observed while sitting in a waiting room and were assessed by whether they gave up their seat to an individual who entered the room on crutches wearing a walking boot. Participants assigned to the mindfulness meditation condition gave up their seats more frequently than those assigned to the active control group.

The MARS is a 23-item assessment tool developed in 2015 to serve as a reliable measure for trialing, classifying and rating the quality of mobile health applications and assesses an applications engagement, functionality, visual aesthetics, information quality and subjective quality subscale features (Stoyanov et al., 2015). The MARS was found to have excellent internal consistency (alpha = .90) and interrater reliability intraclass correlation coefficient (ICC = .79) (Stoyanov et al., 2015). Of the 23 apps that met the inclusion criteria in a systematic review of mindfulness Smartphone applications, Headspace earned the highest average score of 4.0 out of 5.0 on the MARS scale (Mani et al., 2015).

Laurie & Blandford (2016) assessed how people use and experience the Headspace application as a digital mental wellbeing intervention as well as the applications enabling factors and barriers for effective use. Sixteen participants took part in the qualitative semi-structured interview study lasting between 30 to 40 days. The participants were interviewed before and after the study. The authors found that the main barrier for using Headspace was incorporating the application into their busy lives. Other limiting factors creating barriers included daily routines, thoughts about potential consequences of using the app, personal relationships, social norms as well as negative moods and emotional states. Benefits of the application included positive attitudes towards mindfulness, realistic expectations, and positive social influences. Twelve of the participants completed 10 or less sessions while the four individuals completed between 11 and 30 sessions. The authors reported that nine users turned to the app for help with difficult emotions and in stressful situations. All participants reported the app was well designed and helped to facilitate meditation practice.

Rosen (2016) conducted a randomized control study to evaluate the impact Headspace had on improving quality of life among women with breast cancer. Participants were assigned randomly to an intervention group (n=48) and a waitlist control group (n=47). Data was collected at baseline, week five, week nine and at a four-week follow-up session. The intervention group received access to the application for a total of eight weeks while the waitlist control group received access to Headspace around the four week follow up. A minor improvement in quality of life scores was observed in the intervention group when compared to the control group by week five and further improved by week nine and at the four week follow up across functional, emotional, social, and physical well-being domains. The authors did not find a significant change in mindfulness between the two groups, but did find a detectable improvement in mindfulness

after post hoc analysis in the intervention group when compared to the control group. The author concluded the delivery of mindfulness training using an app-based approach may be feasible in a population of women with breast cancer.

Headspace delivers guided mindfulness meditations through the use of both audio and video files. The entire application contains a total of 365 different guided meditations that are divided into five different series and packages. The six different Headspace series packs include the 1) foundation series, 2) sport series, 3) health series, 4) relationships series, 5) performance series, and 6) the Headspace pro series. For the purposes of this study, the participant was asked to complete a portion of the foundation series. The participant was to complete a minimum requirement of 5 sessions and a maximum of 7 sessions in the first and second week of the study and a minimum of 2 sessions during the week of surgery. In total, the participant was required to complete a minimum of 12 sessions and no more than 22 sessions by the end of the study.

The foundation series consists of 30 sessions in total that are divided into three separate levels. The first ten sessions fall into the level 1 category and are termed as the 'Take Ten' sessions. Take ten sessions are free and do not require a subscription to the application and serve to create a foundation for the individual to experience mindfulness in a meditative state of practice. Level one sessions are designed to last approximately ten minutes on average. All sessions are delivered through audio recordings and provide verbal cuing by Andy Puddicombe, to direct the user through practice of mindfulness meditation without any background sound or music. Video illustrations are used at the beginning of sessions one, three, five, seven and nine of level one. These videos last under three minutes and provide cartoon illustrations as a way to visually describe how the mind works such as imagining there is always a bright blue sky above stormy clouds. Following the video illustration, the session begins with the instruction to get

comfortable in any desired position, whether it is by sitting in a chair or on the floor, followed by cues to be aware of the space around you. The individual begins to take deep breaths in through the nose and out through the mouth, loud enough so if someone were next to them they could hear them. Simultaneously the individual brings awareness to the body softening with each breath. After a few minutes, the eyes are cued to close and to return the breath to its natural pattern. The user is cued to notice the physical senses including the weight of the body, contact between the arms and legs, feet on the floor as well as being aware of any sounds in the environment. Next, the participant performs a body scan in order to develop a mental picture of how the body feels by starting the scan at the top of the head ending at the toes. After a minute or two, the participant is cued to count their breaths as they pass in the following sequence, one with the rising breath, two with the falling breath, three with the rising breath, four with the falling breath and so on until the individual reaches the number ten. Upon reaching the tenth breath, the participant is instructed to start over beginning at one. If the individual forgets what number they are on, they can simply start over at the first breath. The final task in the session requires the individual to let go of any focus for a moment to allow the mind to do whatever it wants. Puddicombe asks the individual to bring the attention back to the body and the physical sensations they are experiencing and after a moment or two, to open the eyes and reflect on how the session felt.

The level two sessions include sessions 11 to 20 and directs the focus of the user to think about their motivation and intentions for practicing mindfulness mediation. The audio recordings last approximately 10 minutes, similar to the level one sessions but only have video illustrations in sessions 11 and 15. Session 11 begins with an introduction video from Puddicombe informing the user that the next level will be directed at improving their experience with Headspace. This

level will have the user analyzing how they see problems in their life, how they overcome these problems, and see how their problems may impact others involved in daily life. After the video illustration, the session begins and follows the same format as in the level one sessions but differs with a noticeable increase in periods of silence and reduced cuing from Puddicombe. Session 20 differs from the other nine sessions in level two as it lasts approximately 17 minutes.

The level three sessions include sessions 21 to 30 with the aim to integrate awareness in everyday life. This study only required the individual to complete the first two sessions of level three. Session 21 begins with an introduction video welcoming the participant to level 3 of the Headspace Foundation series. Puddicombe informs the user that this level is geared towards assessing how the user addresses obstacles and how they are able to integrate a sense of calmness and awareness in everyday life. The user is given the choice to continue their meditation practice in 10 minute sessions or they can increase their time to 20 minute sessions at the beginning of the level. If the user elects to increase the meditation time, they inevitably experience a large increase in periods of silence between cues from Puddicombe.

Amazon Fire Tablet.

The Amazon Fire Tablet is 7 inch in plane switching (IPS) display with a 1.3 Gigahertz quad-core processer. The tablet has both a rear and front-facing camera and costs around $49.99. It comes with 8 Gigabytes of internal storage with unlimited cloud storage at no cost to the user. The tablet allows for seven hours of reading, surfing the web, watching videos and listening to music. The Tablet also comes with screen sharing customer support as well as support through email, web and phone services. This will be important to assist participants in trouble shooting potential problems with the tablet. See Figure 3.7 for a picture of the Amazon Fire Tablet

Procedure

The procedures have been divided based on five phases, namely 1) participant recruitment phase 2) data collection phase, 3) participant compensation, 4) data management phase and the 5) descriptive data analysis phase. A timeline of completing various procedures related to the current study can be found in Figure 3.2.

Participant Recruitment

One individual was recruited from the Medical College of Wisconsin Department of Orthopaedic Surgery at Froedtert Hospital. Once the individual was scheduled for a rotator cuff repair, the Physician Assistant (PA) performed a screening of the individual's medical records to determine if they were eligible to participate in the study. The PA made contact with the individual after their appointment with the doctor and used the following script:

> "Hello my name is D.M. and I am a physician assistant working under Dr. G who is the surgeon completing your rotator cuff repair. I am meeting with you to see if you would be interested in partaking in a research study that will be completed at the Froedtert Hospital campus. Are you interested in learning more about this study?" If no, state the following, "thank you for your time and we look forward to seeing you at your upcoming surgery date." If yes, state the following, "A study is being conducted to assess various outcomes in regard to your postoperative recovery of the rotator cuff. Your condition has made you eligible to participate in this study. If you agree to participate, you will attend a brief training session (60-90 minutes) at which you will meet the researcher and be given further instruction about the study. Further participation will be required by attending a second and third session (lasting approximately 30 minutes) where you will be asked to fill out various questionnaires. You are also expected to complete the full intervention over the span of three weeks engaging in mindfulness-based practice sessions. You will be compensated $50 in gift cards for your time and cooperation with the study. Please let me know if you are interested in participating. We ask for your consent to provide your contact information and the best time to reach you so the student investigator may contact you to set up a time for the introductory session. (Please see Appendix E for a copy of the participant contact information consent form). Your contact information will be sent in an encrypted email and will be deleted immediately after the introductory session is scheduled by the student investigator. Do you have any questions for me at this time?" State the following if the individual does not have any questions, "Thank you for your time and interest in participating in our study. If you have any further questions you can contact the student investigator, H.P."

Once the individual agreed to participate in the study, the PA provided the contact information to the graduate student over the phone. This information was written down on a piece of paper and was destroyed once the introductory session was scheduled. The graduate student contacted the individual over the phone and followed the script below:

> "Hello, _____ (participant name),
>
> My name is H.P., and I am the graduate student working with Dr. G on the research study you recently spoke with D.M about. Are you free to set up a time to meet with me? If yes, "What days of the week and time work for you to meet at Froedtert?" If no, "When is best time to contact you?" "We will meet on _____(Date), at _____ (Time) in one of the conference rooms on the 5th floor at the Department of Orthopaedics Surgery at Froedtert. When you arrive, please inform the front desk you are here to meet with personnel from Dr. G's team and I will come to greet you in the lobby to take you back to the conference room. The appointment will last between 60-90 minutes and will inform you about your role in the study. Would you like me to send you a reminder call the week of the appointment? Would you like my contact information in case you need to cancel or reschedule? Thank you _____ (Participant name) so much for your time and I look forward to meeting you."

After the introductory session was set up, the graduate student contacted the administrative assistant to Dr. G by email to reserve a conference room for the introductory session.

Data Collection Phase

Introductory Session.

The purpose of this session was to obtain informed consent, inform the participant of their role in the study, and provide training on the intervention on the Amazon Fire Tablet. This session served as our baseline measurement and lasted approximately 90 minutes. The receptionist informed the graduate student investigator that the participant had arrived when the participant checked in at the front desk at Froedtert Hospital in the Department of Orthopaedic Surgery. The investigator met the participant and guided them back to the conference room to

begin the introductory session. During the introductory session, the participant went over and signed the informed consent form (ICF) and research participant data privacy acknowledgement form between the participant and Headspace. Appendix F and G include full versions of the ICF and the data privacy acknowledgement form documents. Once consent was obtained, the participant was introduced to the mindfulness intervention by watching a 1 minute and 46 video created by Headspace (Headspace, 2014). Additionally, the participant was asked to read through an informational sheet that described the Headspace app as well as mindfulness. Appendix H includes a copy of this informational sheet.

The participant was provided a designated Amazon Fire Tablet and power cord after completing the tablet use disclaimer form found in Appendix I. The investigator trained user on how to use Headspace on the tablet. Figure 3.1 provides an image of the Amazon Fire Tablet and accessories. The participant was given a pre-existing email address created by the graduate student investigator with a temporary password for the purpose of setting up an account for Headspace. The individual was instructed to create their own password for this free email account for confidentiality purposes. Once the password was changed, the participant created a Headspace account by clicking the already downloaded app on the tablet. The account was created by entering deidentified information provided by the investigator. The participant was cued to create a password for the Headspace login and was instructed to write it down for later use. They then took the "Headspace Tour" once the account was set up to become familiar with the application. The participants account was credited a six-month long subscription code provided by Headspace, using the steps as indicated in Table 3.2.

The student investigator downloaded the entire foundation series onto the tablet so the participant was not required to have Wi-Fi access. The participant went over a 'to-do list' document which outlined their role within the study see Appendix J. The participant was educated on their role in the study using the following script:

"We ask that you complete 4-5 Headspace sessions one week before your pre-operation appointment. You will then be asked to complete 5 more sessions prior to your surgery. You can complete sessions within any environment you deem suitable and at any time of the day. It is recommended you complete the sessions in the morning and at the same time each day. You are to complete a minimum of 12 sessions total but are allowed to complete as many as you would like. You will be assessed 3 times throughout the study. Once today, one week before surgery and one week after surgery. You will be required to complete 4 questionnaires today including the Fear-Avoidance Beliefs Questionnaire (FABQ), the Brief Symptom Inventory-18 (BSI-18), the Five Facets of Mindfulness Questionnaire (FFMQ) and a demographic questionnaire."

The participant received a $10 gift card after the introductory session and was provided a receipt after they completed the pencil-and-paper assessments including the demographic questionnaire, FFMQ-SF, FABQ, and the BSI-18. See Appendix K for the Gift Card Receipt Form and Appendix L for the UWM gift card disbursement log.

In addition, the participant was provided a folder to collect copies of a variety of documents from the introductory session. These items included the 1) informed consent form, 2) Headspace/mindfulness description sheet, 3) research participant data privacy acknowledgement form, 4) table use disclaimer form, 5) participant duties, 6) gift card receipt as well as the student investigators contact information. It was suggested to the participant to write down the password they created within their participant folder in case they were logged out of the account during the time of the study. The session concluded after the investigator read the following script:

"Thank you so much for your time. Please put your **Participant Folder** in a safe spot in case you need to look up your password or to find our contact information if you are to

have any concerns. I will see you next week on _____(date) at _____ (time) one week before your surgery. Please bring your tablet if you are to have any issues."

Pre-Surgery Follow-up Session.

The study participant returned to Froedtert Hospital for a follow-up session one week prior to surgery. The purpose of this session was to determine if there was any variability in mindfulness as well as psychological status from the introductory session. During this session the investigator checked with the participant regarding any study-related issues, and assessed the Amazon tablet for any physical damage. In addition, the participant completed the pencil-and-paper questionnaires including the follow-up questionnaire, FFMQ-SF, FABQ, and BSI-18. This session lasted approximately 30 minutes and concluded by providing the participant with a $20 Amazon gift card. They received a copy of the receipt for compensation of their time. The session concluded after scheduling the one-week follow-up session.

Post-Surgery Follow-up Session.

The purpose of this session was to determine if there was any variability in mindfulness and psychological status from both the introductory session, pre-surgery follow-up session and post-surgery. The participant met with the student investigator after the participant's one-week post-operative appointment with the surgeon. The participant completed all paper-and-pencil assessments including the follow-up questionnaire FABQ, BSI-18, and the FFMQ. The Amazon Fire Tablet was collected during this time. The participant was thanked for their time and received a free one-month subscription code to use on their own mobile device or computer to continue the Headspace journey. In addition, the participant was administered $30 and a receipt for their payment to compensate for time spent completing the final procedures of the study. This session lasted approximately 40 minutes in total.

Participant Compensation

The participant was compensated for their time while participating in the study by distributing a total of $50 in Amazon gift cards over three separate sessions. The participant received $10 after the introductory session, $20 after the pre-surgery follow-up session, and $30 after the post-surgery follow-up session upon the return of the Amazon Fire Tablet. Due to UWM policy and IRS regulations, we were required to obtain the participants name, address, and signature in order to issue gift cards. This information was kept separate from the deidentified information.

Data Management Phase

Data was collected at baseline, the pre-surgery follow-up, and the post-surgery follow-up sessions. All data collection sessions required the participant to complete three self-report measures including the FFMQ-SF, FABQ, and BSI-18 at each data collection session. An initial demographic questionnaire was completed in the first baseline session and a follow-up questionnaire at the pre-surgery follow-up and post-surgery follow-up sessions. Additional data was collected from Headspace on the participant usage data that was sent to the project investigator by email after the study was completed. The files were transferred to a locked filing cabinet in the Department of Occupational Science & Technology at UWM for data analysis by the student investigator. The data was entered on an excel document on a computer with a locked server located in one of the labs in the occupational therapy department. Table 3.1 provides detailed information as to what assessments were administered in each session as well as the amount of gift card money dispersed.

Descriptive Data Analysis

The present study analyzed the data by visual analysis to assess for changes in score for mindfulness, pain, as well as to assess the changes in the participant's psychological health status throughout the study. Summary statistics will be provided for patient satisfaction as well as for demographic information. Visual analysis will be conducted to assess minimal differences between the data points to assume there may be clinical implications for the use of a mindfulness-based intervention in the treatment of rotator cuff repairs.

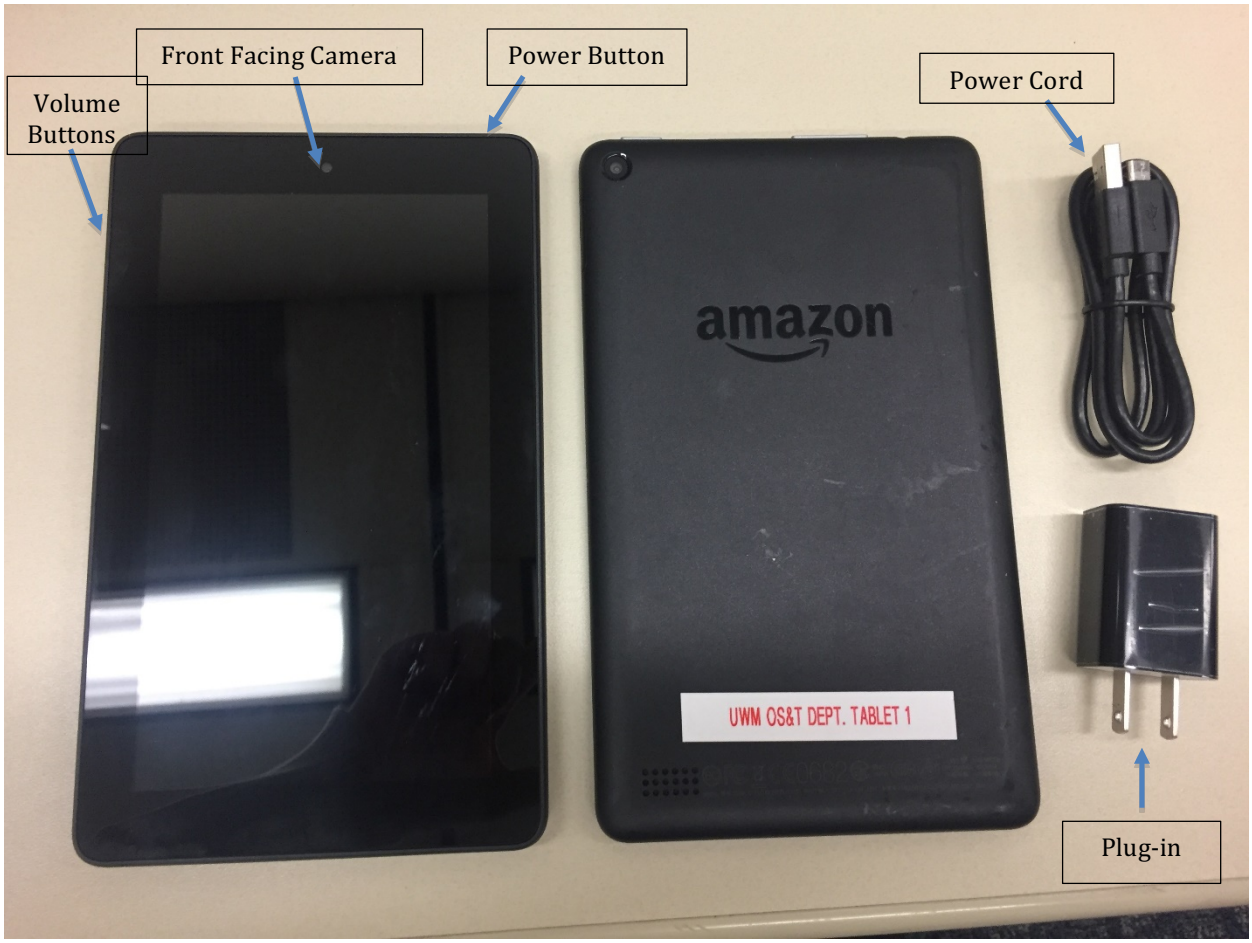

Figure 3.1 Provided equipment to the participant: Amazon Fire Tablet, Power cord, & Plug-in

Proposed Thesis	**IRB Approval Process**	**Participant Recruitment**	**Introductory Session**	**Pre-Surgery Follow-Up Session**	**Post-Surgery Follow-Up Session**	**Data Analysis**	**Thesis Defense**
December 15	April 16-June 16	August 16		September 16		October 16	November 16
			Intervention Period				

Figure 3.2 Timeline of completing various procedures related to the current study

Table 3.1

Description of assessments administered by data collection session and gift card disbursements

Data Collection Session	**Assessments Administered**	**Gift Card Disbursement Amounts**
Introductory Session	• Initial Demographic Questionnaire • FFMQ-SF • FABQ • BSI-18	$10
Pre-Surgery Follow-up	• Follow-up Questionnaire • FFMQ-SF • FABQ • BSI-18	$20
Post-Surgery Follow-up	• Follow-up Questionnaire • FFMQ-SF • FABQ • BSI-18	$30

Table 3.2

Step by step guide for redeeming Headspace subscription code for full access to the application for a six-month period

Step	Procedure
Step 1	Go to Headspace.com
Step 2	Click ‘Redeem Code’ located in the top right menu bar of the website next to the word ‘Login’
Step 3	Enter the provided subscription code by the student investigator
Step 4	Click the word, ‘Submit’
Step 5	Ask the participant to log in using the email address created by the student investigator as well as their own personal password
Step 6	Click the word, ‘Continue’
Step 7	Ask the participant to log out of the account on the computer (your account is set up with the subscription code)
Step 8	Grab the Amazon Fire Tablet
Step 9	Power on the device
Step 10	Click the power button located on the top right corner of the tablet
Step 11	Click the home button the tablet
Step 12	Tap the app for Headspace
Step 13	An image will come up asking you to create an account. Look below this to see where it says ‘Already have an account? Log In’. Click the ‘Log In’ link
Step 14	Enter your pre-existing email address and password. Click the ‘Log In’ button

Chapter 4

Results

Demographic Characteristics

The participant for this study was a 56-year old African American female from southeastern Wisconsin. After working at a factory for more than 20 years, the participant retired three years ago. Her daily routine consists of taking care of tasks around the house, caring for her grandchildren, attending church, and visiting her mother at a nursing home. Table 4.1 includes a summary of various demographic characteristics of the participant.

Health-Related Characteristics

In April of 2016, the participant first experienced pain in her right shoulder, which gradually worsened and consequently was unable to raise her arm above 90 degrees. As pain increased, she also reported disruption of activities of daily living such as washing her hair and doing laundry. The participant reported taking pain medication such as ibuprofen two times a day. Pain also resulted in sleep disturbances about four times per week causing the participant to sleep with a pillow under her right arm. In May 2016, the participant underwent a magnetic resonance imaging (MRI) by her primary physician and was diagnosed with a rotator cuff tear in her right shoulder due to overuse. In August 2016, the participant was examined by the study orthopaedic surgeon and was scheduled to undergo a single-tendon repair surgery in September 2016.

Prior Health History

Regarding prior health history, the participant reported she had a previous rotator cuff tear in her left shoulder after falling onto a concrete block outside her home in 2011. She underwent surgery in 2012 and had great functional outcomes and zero pain in her left arm post-

treatment. The participant reported she has had no history of a neurological disorder, diabetes, smoking, or arthritis. In addition, the participant was neither hearing or visually impaired but did require the use of reading glasses when completing the study questionnaires.

Research Question 1: Participant Satisfaction with using Headspace

To assess satisfaction with the use of Headspace, the participant was asked to answer ten survey questions on a scale of 1 to 5, with 1 being false, and 5 being true. The participant indicated the application was respective of time, easy to use, and that it helped to improve her overall mood. Additionally, she found the application to be helpful and effective in her everyday mindfulness and indicated she would purchase a subscription to the application based on her experience. In addition to the survey questions, the participant was asked to complete four open-ended questions as a part of the satisfaction survey. With regard to the following question, "What benefits do you think you've gained from your experience with Headspace?", the participant reported, "I am able to concentrate and focus much better. I can put things aside that are consuming my thoughts. I am able to listen with my mind more. I also learned how to better relax by controlling my pain based on my mindset." When asked, "What barriers, if any, did you experience while using the Headspace application?" the participant reported "I did not find that it was too time consuming. It really was convenient to do with my own schedule. I stopped participating in my sessions two days after my surgery only because I had a family emergency. I began using some of the techniques after things had calmed down in my personal life because I knew it would help me." The third question asked, "How do you think your experience with Headspace or mindfulness in general could be improved?", the participant stated, "I just needed more time to help practice and improve my meditation skills." Finally, the participant was asked "What changes, if any, have you noticed in your life since participating in the mindfulness

intervention?", and indicated, "I am better able to cope during various situations. I think it is a great coping skill to have and I noticed I was trying to be mindful during my family emergency to deal with my sadness and anxiety." Table 4.2 includes the individual responses to the ten survey questions pertaining to the Headspace application.

Participant Compliance.

Participant compliance with using the intervention was viewed as a component of participation satisfaction with Headspace. The participant completed a total of 13 Headspace sessions during the duration of the study meeting the minimum requirement of 12. She participated in the intervention seven days during the first week, three days in the second week and two days during the week of surgery. Sessions one through seven were completed between the introductory session and the pre-surgery follow-up session. Sessions eight through eleven were completed between the pre-surgery follow-up and the surgery date. It is important to note that the participant completed session ten before session nine as the student investigator had to perform some trouble shooting on the application that allowed for tenth session to become unlocked prior to completing session nine. Sessions nine and ten were completed on the same day which was discouraged during the study, resulting in participation in the intervention only three days of the week. The participant was required to participate in two sessions during the week of her surgery and completed session 12, on the evening on her surgery date and session 13, two days after her surgery date. Table 4.3 provides a layout of the participant usage data with regard to Headspace.

Research Question 2: Mindfulness using Headspace

The Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) was administered in order to assess for changes in mindfulness. The FFMQ-SF includes 24 questions asked on a

scale ranging from 1 to 5, with 1 being never or very rarely true, and 5 being very often or always true. Separate scores are reported for five different facets including 1) non-reactivity to inner experiences (non-react), 2) observing (observe), 3) acting with awareness (act aware), 4) describing (describe), and 5) non judging of inner experiences (non-judge). For the non-react facet, the participant scored 14 at both the baseline and pre-surgery follow-up sessions and with a 5-point increase for a score of 19 by the post-surgery follow-up. The observe facet resulted in scores of 15 at baseline and 14 at the pre and post-surgery follow-up sessions, demonstrating a 1-point decrease in the observe facet scores. The act aware facet resulted in a score of 18 at baseline, 19 at the pre-surgery follow-up and a 5-point decrease for a score of 14 by the post-surgery follow-up. For the describe facet, the participant scored 20 at baseline and 19 for both the pre and post-surgery follow-up sessions. Finally, the non-judge facet resulted in a score of 17 at baseline with a 2-point increase for a score of 19 at the pre-surgery follow-up session and a 3-point decrease for a score of 16 at the post-surgery follow-up.

Of the five facets, non-reactivity was the only facet to demonstrate an increase in scores from baseline to the post-surgery follow-up session. Both the describing and observing facets followed a similar pattern with a 1-point decrease in scores between baseline and the post-surgery follow-up session. The non-judging and acting with awareness facet scores initially increased between the baseline and pre-surgery follow-up sessions but consequently dropped in score by the post-surgery follow-up session. Figures 4.1 through 4.6 provide visual illustrations of the five facet scores individually as well as a figure for comparing all five facet scores.

Pain Intensity

In order to assess for changes in pain intensity, the participant was asked to report both her average pain over the previous week as well as her current pain at three different points in

time using a visual analogue scale (VAS). The VAS is on a 10 centimeter (100 millimeters) scale with scores ranging from 0-10, with 0 being no pain and 10 being the worst pain possible. Scores fall into one of the four categories based on ruler measurements including, no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm) and severe pain (75-100 mm) (Hawker et al., 2011). During the baseline assessment, the participant reported a moderate level of pain intensity, with a current pain intensity score of 40 mm and average pain intensity score in the prior week of 40 mm as well. During the pre-surgery follow-up assessment, the participant reported mild pain intensity with a current pain intensity score of 30 mm and moderate pain intensity score in the prior week of 44 mm. During the post-surgery follow-up assessment, the participant reported moderate pain with a current pain intensity score of 50 mm and a severe pain intensity score in the prior week of 75 mm. The pain intensity scores can be found in Figure 4.7.

Fear-avoidance beliefs

Fear-avoidance beliefs related to pain were assessed using the Fear Avoidance Beliefs Questionnaire (FABQ). The FABQ is a 16-item questionnaire with each item scores on a scale ranging from 0 to 6, with zero being complete disagree, and six being completely agree. The FABQ includes two subscales, the 4-item physical activity subscale (FABQ-PA) with a score range of 0-24, and the 7-item work subscale (FABQ-W) with a score range from 0-42. We did not assess the participants fear-avoidance beliefs towards work as the participant was retired. The participant scored 16 at baseline, 2 at the pre-surgery follow-up and 12 at the post-surgery follow-up. A score of 15 or greater in the FABQ-PA subscale is considered to be a high fear score based on previous studies (Crombez et al., 1999). The participants fear-avoidance beliefs towards physical activity generally decreased from baseline to the post-surgery follow-up session. The participant scores for FABQ-PA can be found in Figure 4.8.

Psychological Health

Psychological health was assessed using the Brief Symptom Inventory 18 questionnaire (BSI-18). The BSI-18 is an 18-item questionnaire with each item scored on a scale ranging from 0-4, with 0 being not at all, to 4 being extremely. The BSI-18 measures core symptoms of three syndromes including clinical somatization (SOM), depression (DEP), and anxiety (ANX). In addition, a composite score measure of psychological distress is computed as the Global Severity Index (GSI) score. Scores are presented as raw scores, with t scores in parentheses for each syndrome as well as for the GSI. There was an increasing trend seen for somatization with scores of 3 (53) at baseline, 4 (55) at the pre-surgery follow-up and a score of 14 (73) by the post-surgery follow-up. For depression, the participant scored 3 (55) at baseline, 1 (46) at the pre-surgery follow-up, and a score of 11 (67) by the post-surgery follow-up. There was an increasing trend seen for anxiety with scores of 1 (43) at baseline, 3 (48) at the pre-surgery follow-up and a score of 14 (68) at the post-surgery follow-up. The GSI composite score also had an increasing trend initially beginning at 7 (48) at baseline, increased to 8 (50) at the pre-surgery follow-up, ending at 38 (71) by the post-surgery follow-up. Of the four subscales, depression was the only subscale to decrease during the entire study. The decrease was seen during the period between the baseline session and the pre-surgery follow-up with a score of 3 decreasing to a score of one. Her depression score increased 10 points by the time of the post-surgery follow-up session. All other subscales increased from baseline to the post-surgery follow-up. Figures 4.9-4.12 provide separate graphs of the four subscales of the BSI-18. Figure 4.13 provides a visual illustration of the four subscales together during the three data collection points in raw scores. We decided to convert the raw scores using the clinical population norms as our population was clinical. For comparison, Figures 4.14 provides a visual illustration of the t-scores for clinical population

norms and Figure 4.15 provides the same illustration using the community population norms for comparison. There are only slight differences between the two population norms.

Table 4.1

Demographic Characteristics of 1 study participant with a single-tendon rotator cuff tear

Characteristics	Women (N=1)
Age (years)	56
Gender	Female
Height (inches)	61
Race	African-American
Marriage Status	Divorced
Dominant Hand	Right
Injured Extremity	Right
Work Status	Retired
Primary Language	English

Table 4.2

Results from the follow-up questionnaire regarding participant satisfaction in the use of Headspace during the post-surgery follow-up session evaluation

Question	1-False	2-Somehwat False	3-Neither True nor False	4- Somewhat True	5-True
1. The application was easy to use.					X
2. I Enjoyed the Headspace Application					X
3. I found the Headspace Application was helpful and effective in my everyday mindfulness				X	
4. I would purchase a subscription to this application to continue my mindfulness exercise				X	
5. I feel I can now be mindful without use of the application				X	
6. I feel that the Headspace Application had no effect on my mindfulness	X				
7. I would recommend use of the Headspace Application to a peer					X
8. Headspace helped improve my overall mood					X
9. Headspace was easy to do each day				X	
10. Headspace was too time consuming for my life	X				

Table 4.3

Descriptive participant data usage when participating in meditation sessions in the Foundation Series of the Headspace application

Foundation Series Level	Session Number	Date	Time
1	1	8/30/16	4:12 p.m.
1	2	8/31/16	4:47 p.m.
1	3	9/1/16	4:48 p.m.
1	4	9/2/16	3:47 p.m.
1	5	9/3/16	4:09 p.m.
1	6	9/4/16	4:45 p.m.
1	7	9/5/16	4:27 p.m.
1	8	9/6/16	4:30 p.m.
1	10	9/9/16	3:41 p.m.
1	9	9/9/16	4:08 p.m.
2	11	9/11/16	5:17 p.m.
2	12	9/13/16	2:56 p.m.
2	13	9/15/16	3:48 p.m.

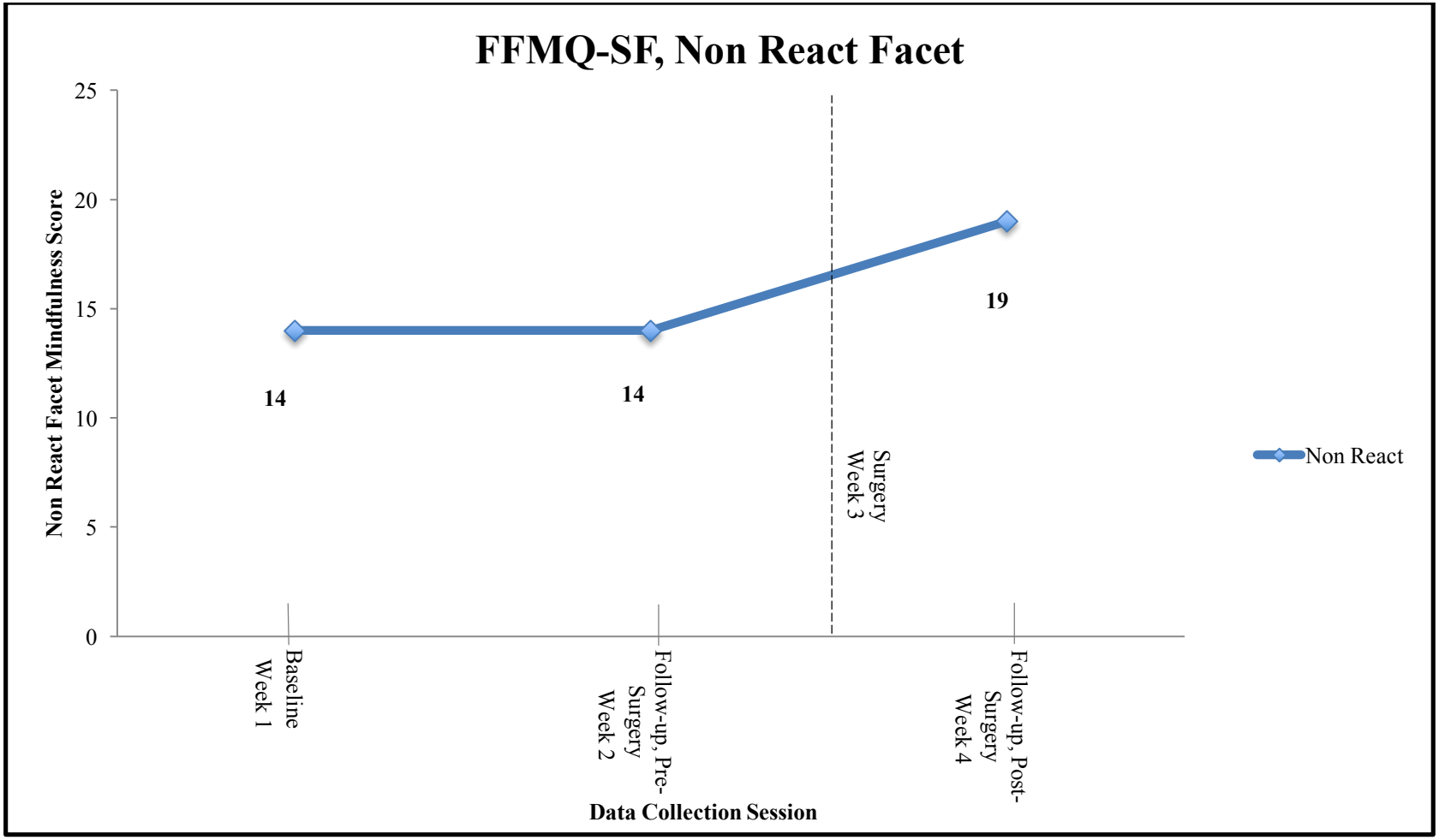

Figure 4.1 Participant scores for the nonreactivity to inner experiences (non-react) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

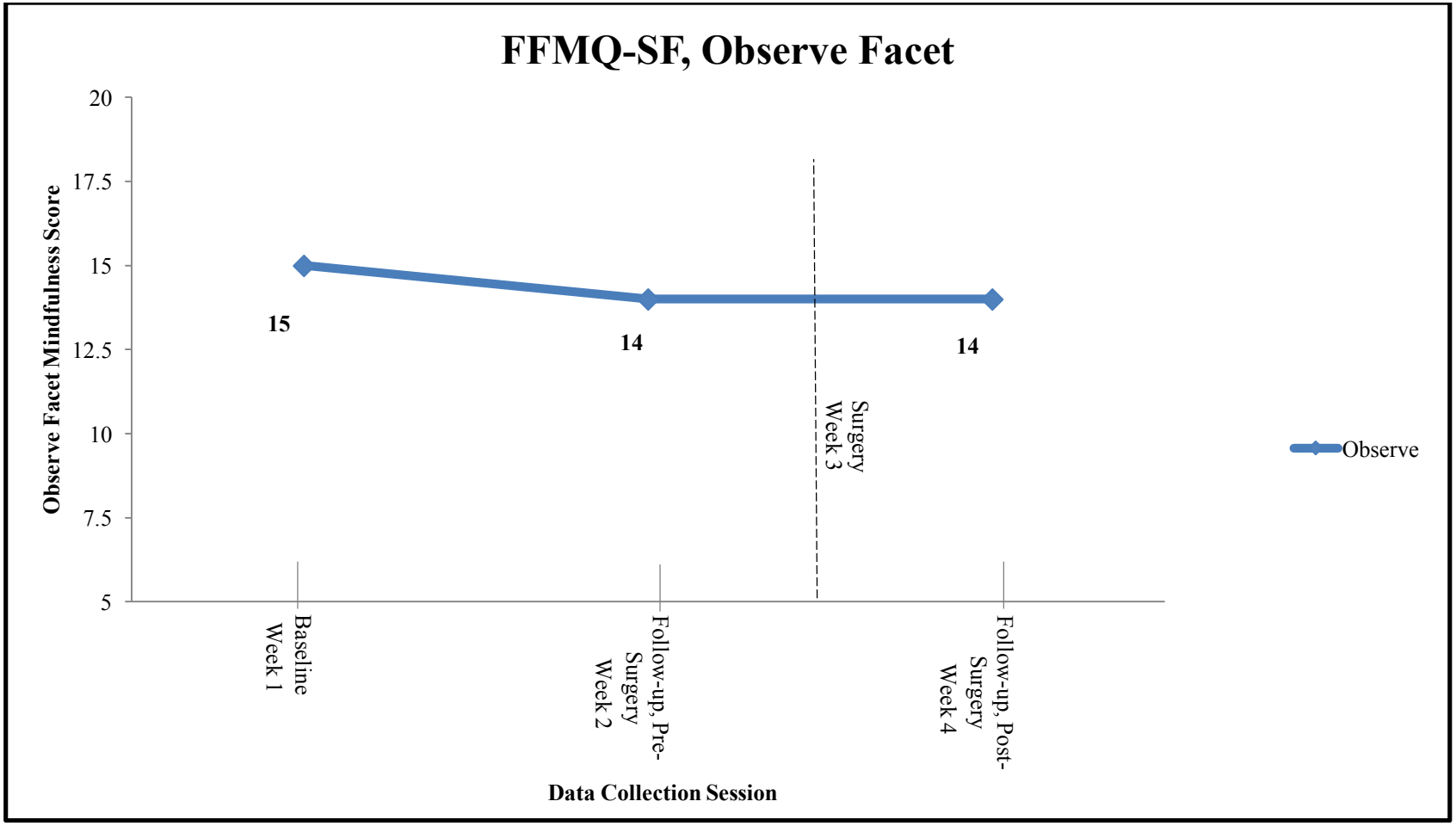

Figure 4.2 Participant scores for the observing (observe) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

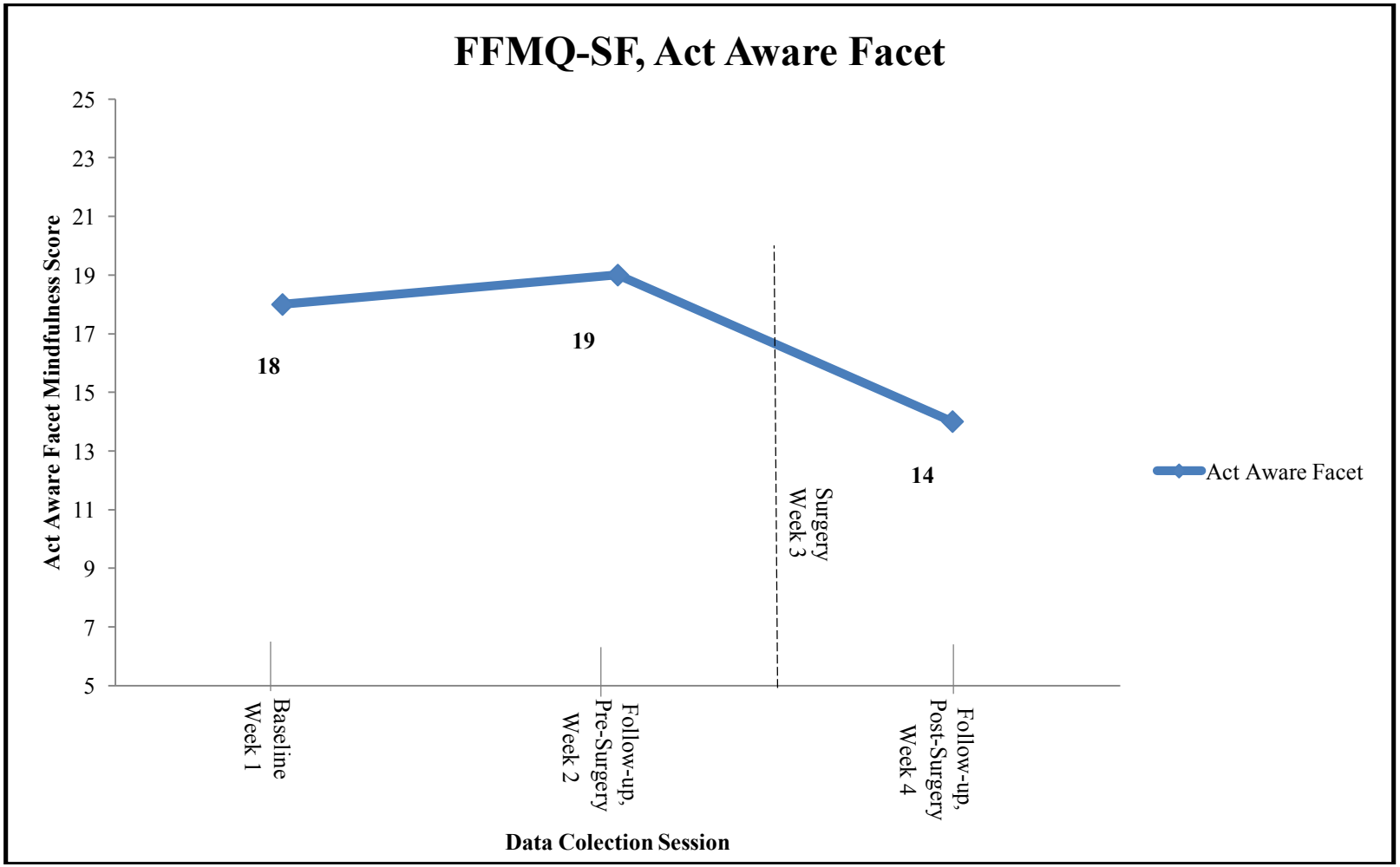

Figure 4.3 Participant scores for the acting with awareness (Act Aware) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

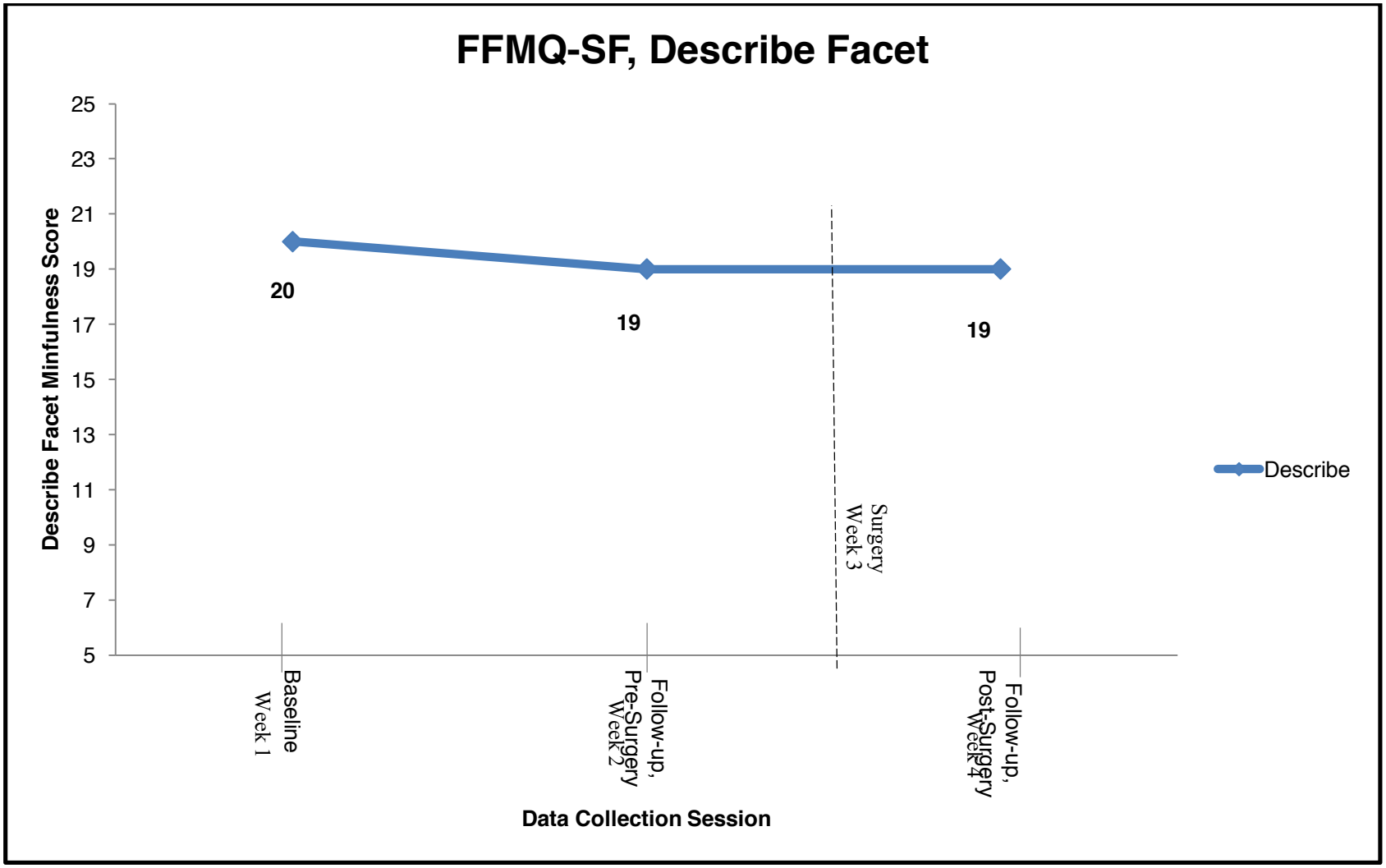

Figure 4.4 Participant scores for the describing (describe) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

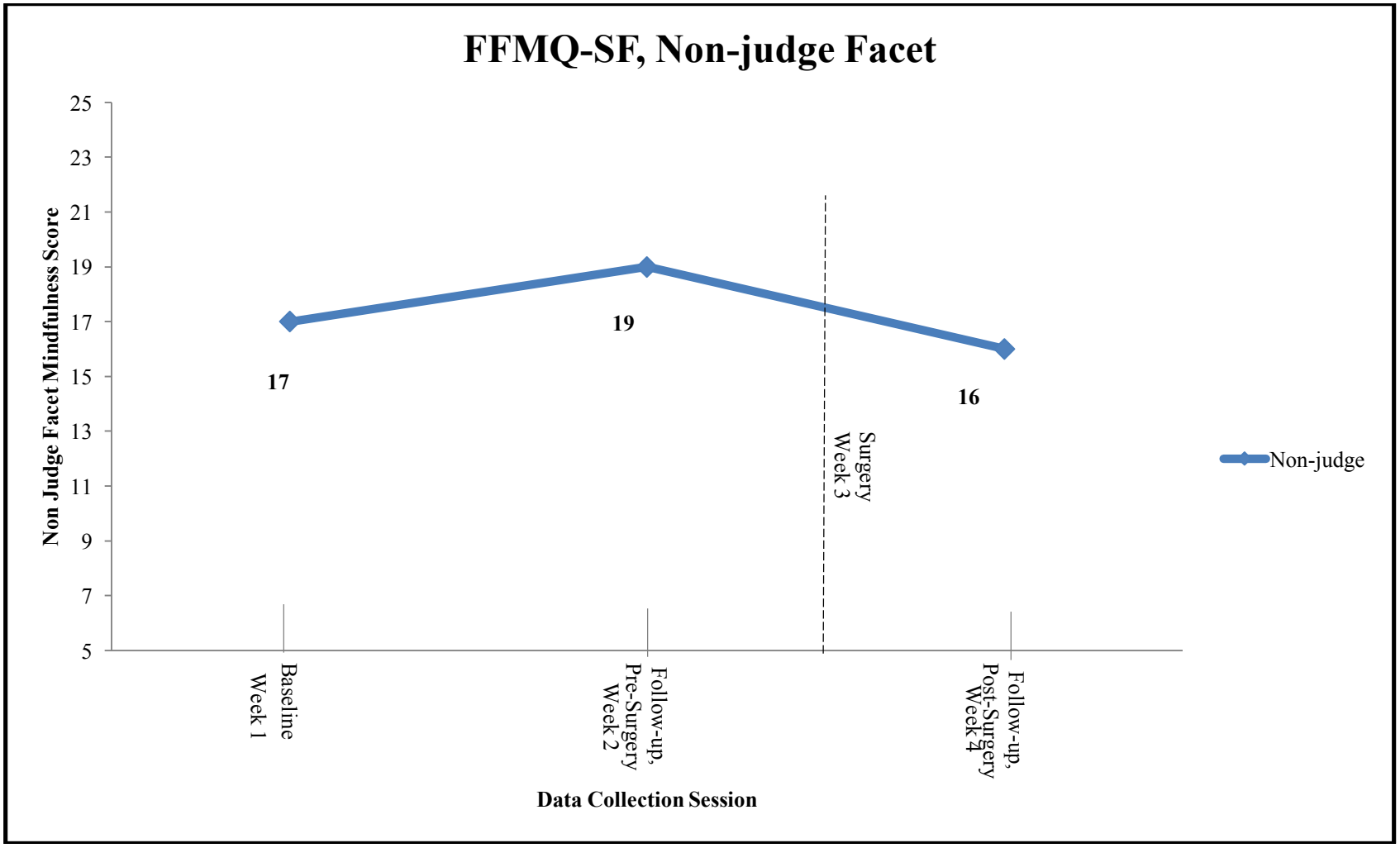

Figure 4.5 Participant scores for the non-judgement of inner experiences (non-judge) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

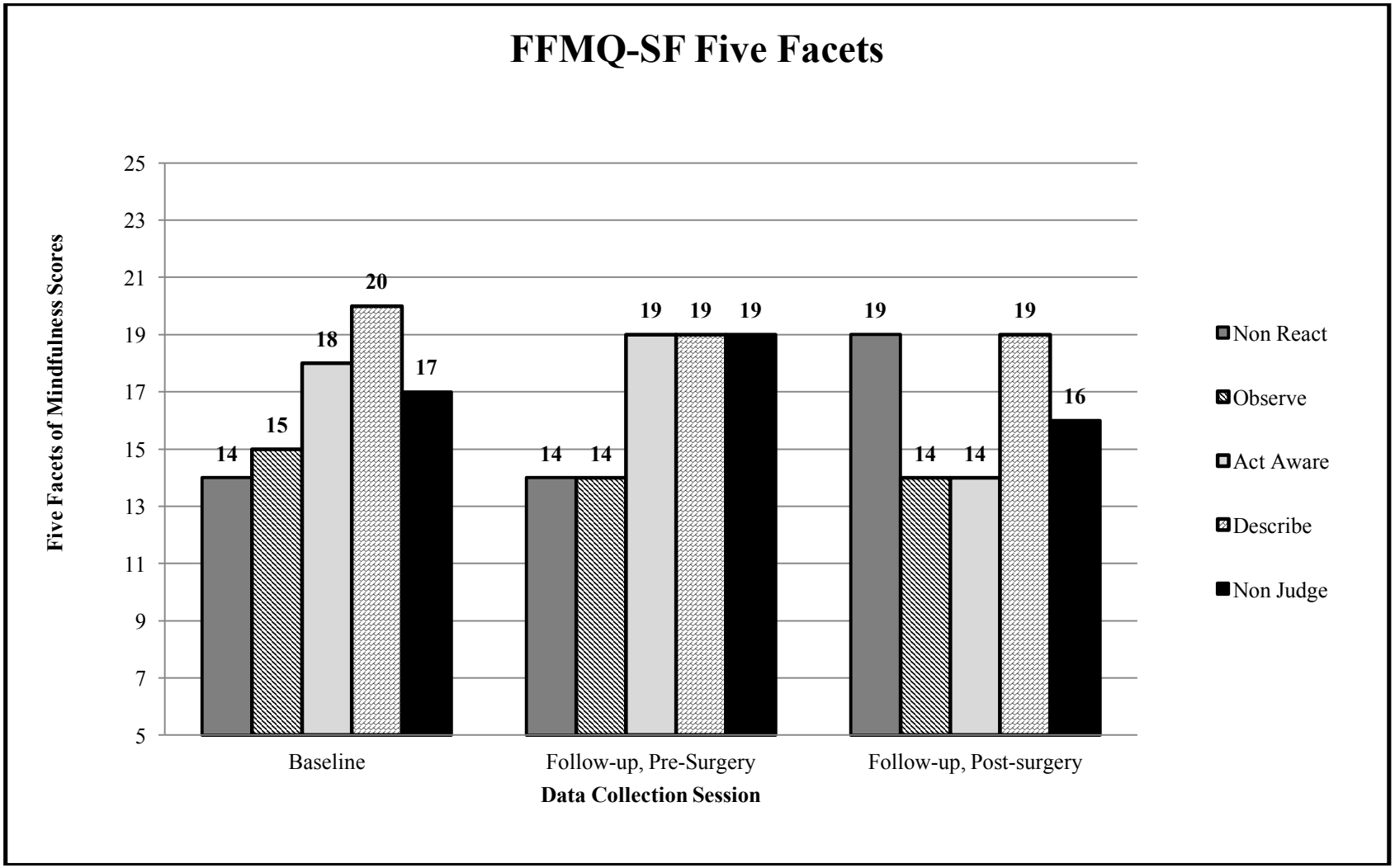

Figure 4.6 A comparative bar graph of the five facets scores from the Five Facets of Mindfulness Questionnaire Short-Form measured at three different points in time.

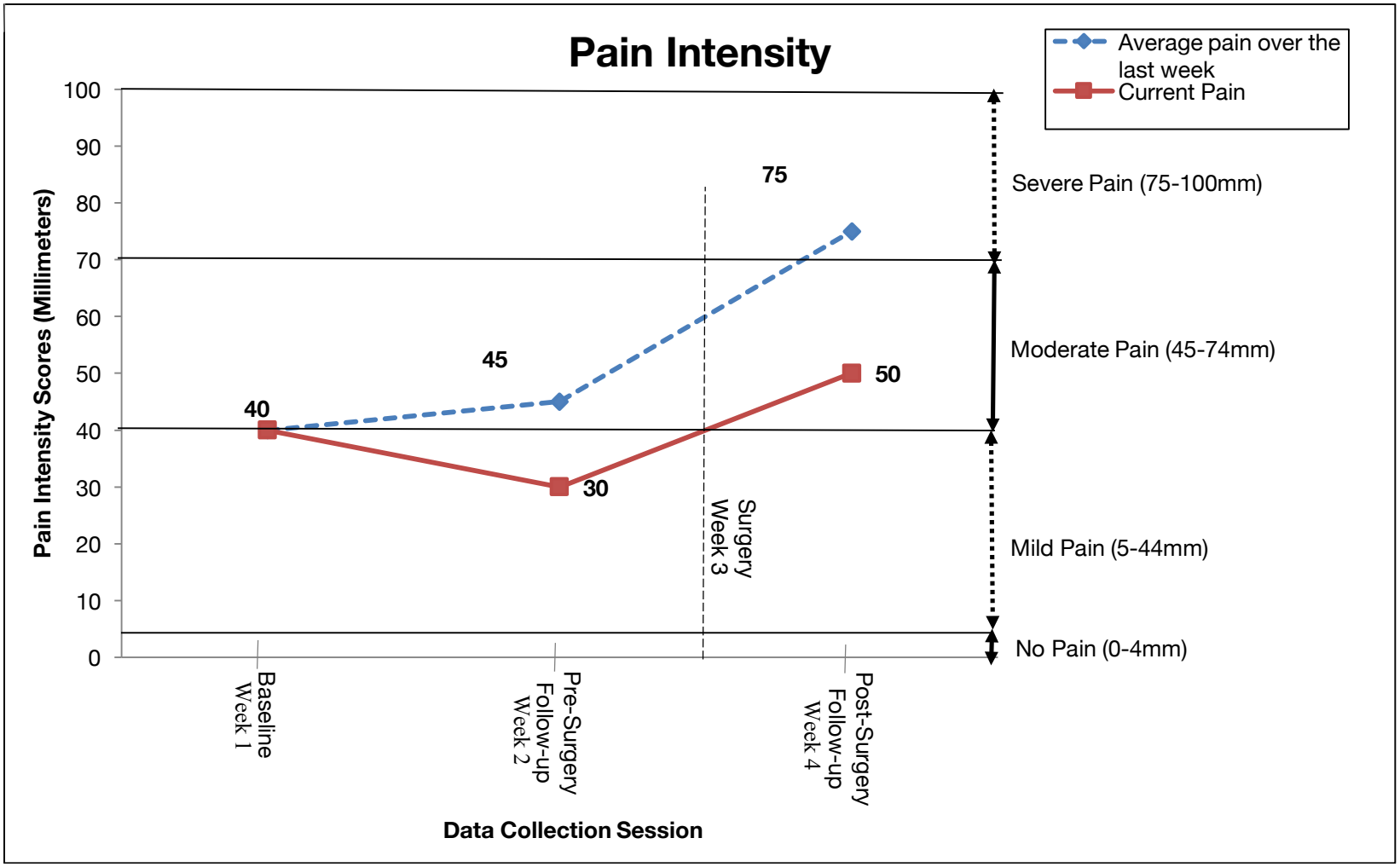

Figure 4.7 Participant's current pain intensity and average pain intensity over the last week scores collected at three different points in time using a Visual Analogue Scale (VAS)

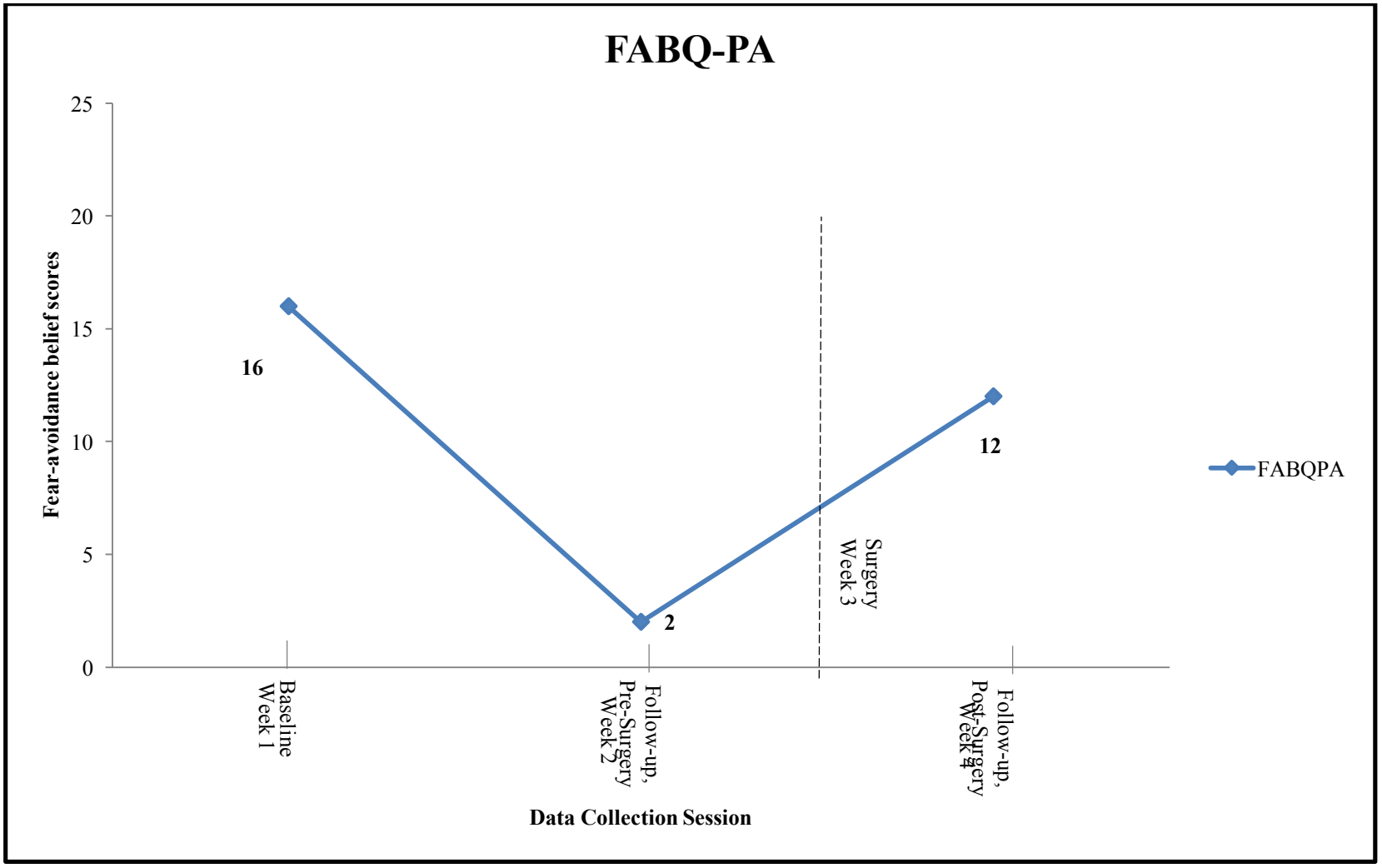

Figure 4.8 Participant scores from the Fear-Avoidance Beliefs Questionnaire Physical Activity Subscale (FABQ-PA) measured at three different points in time.

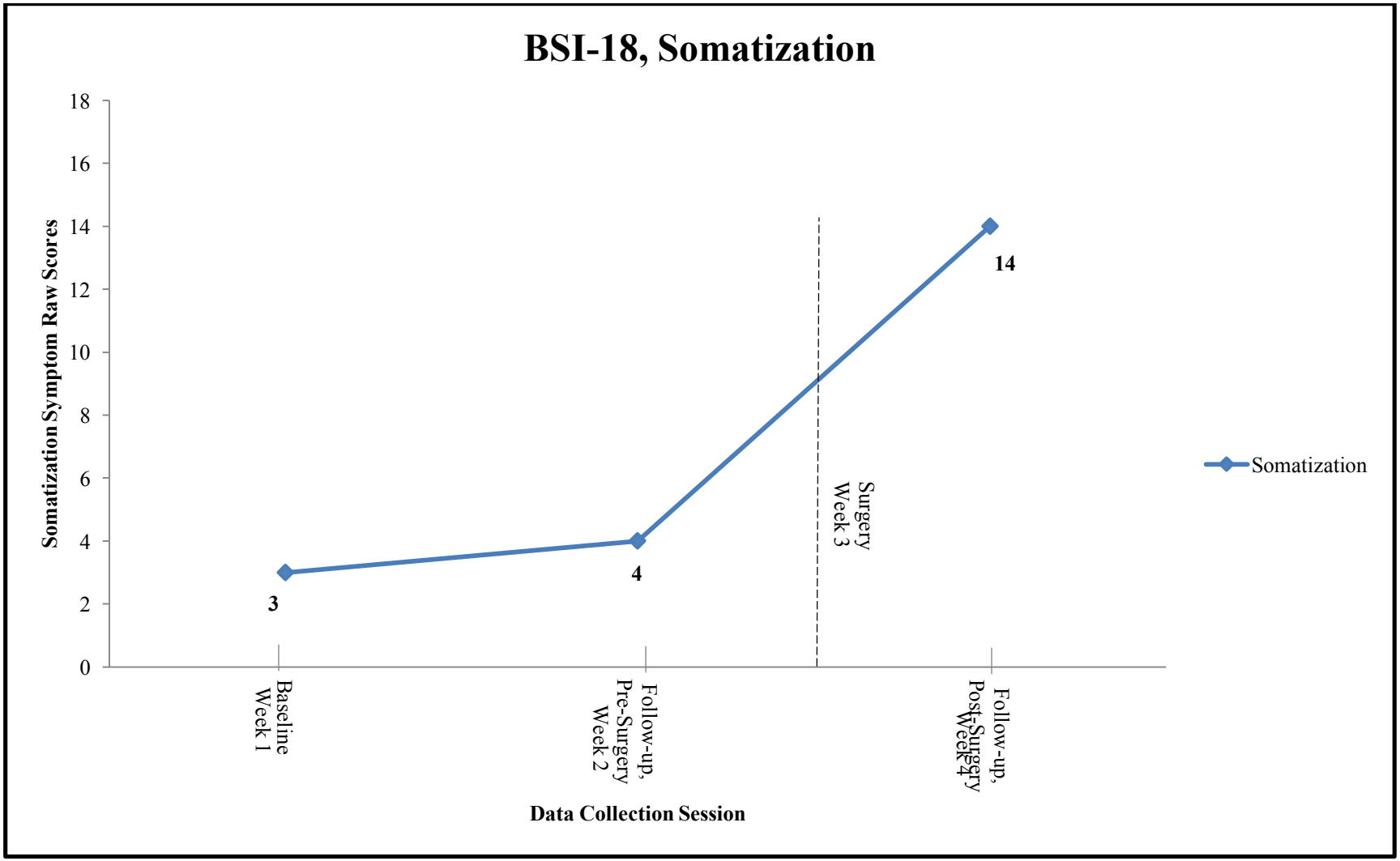

Figure 4.9 Participant scores on the somatization (SOM) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire

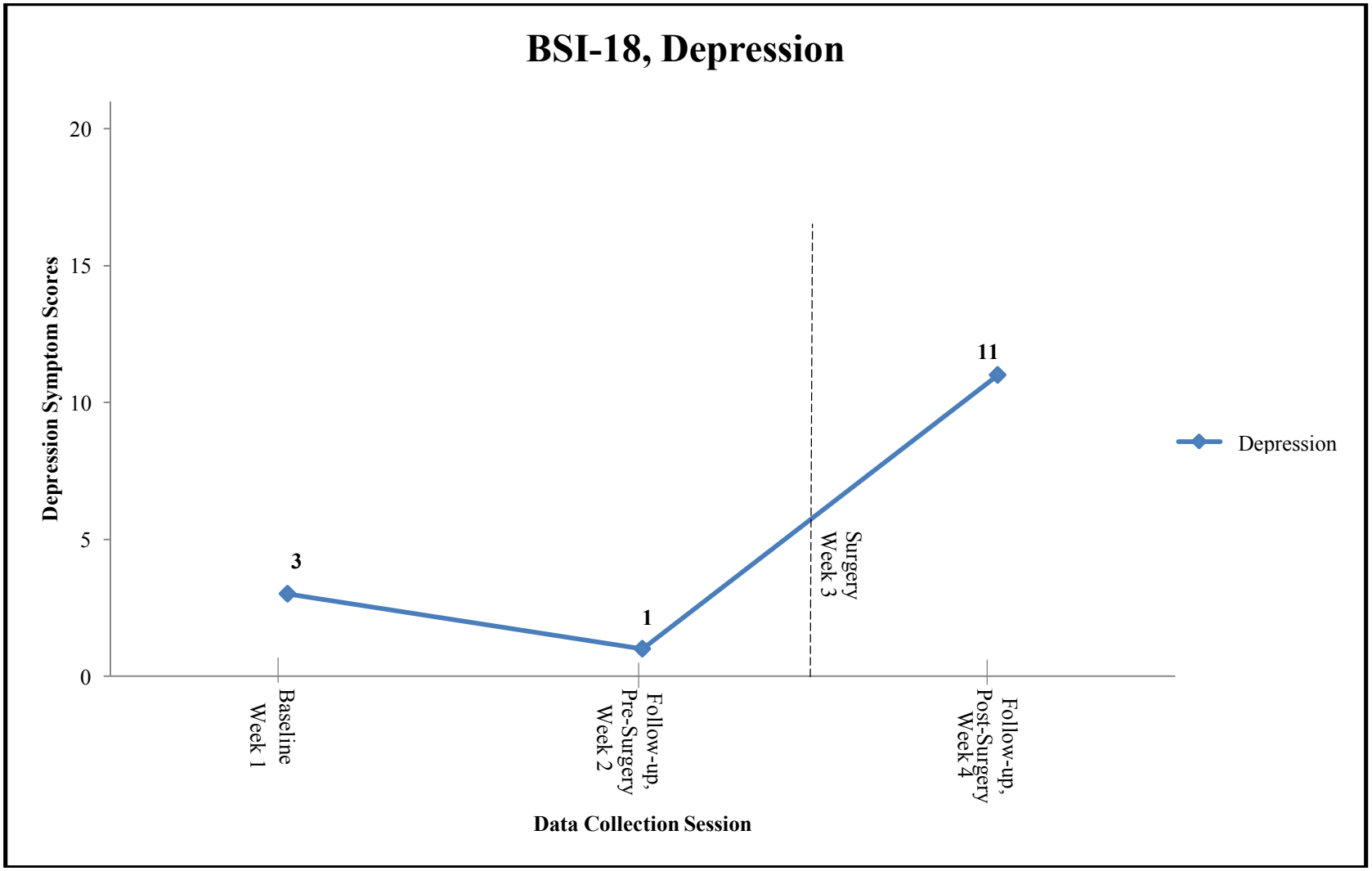

Figure 4.10 Participant scores on the depression (DEP) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire

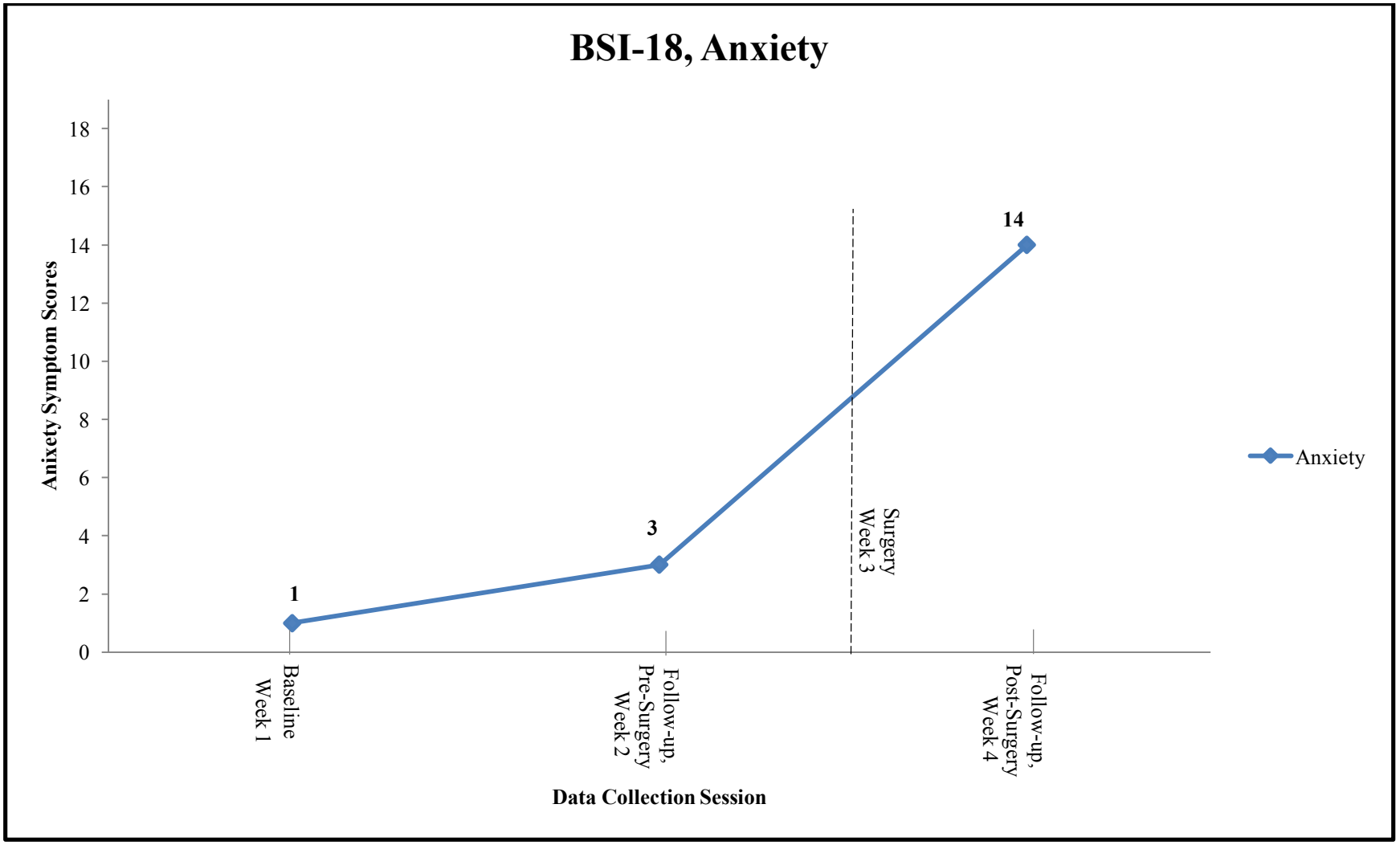

Figure 4.11 Participant scores on the anxiety (ANX) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire

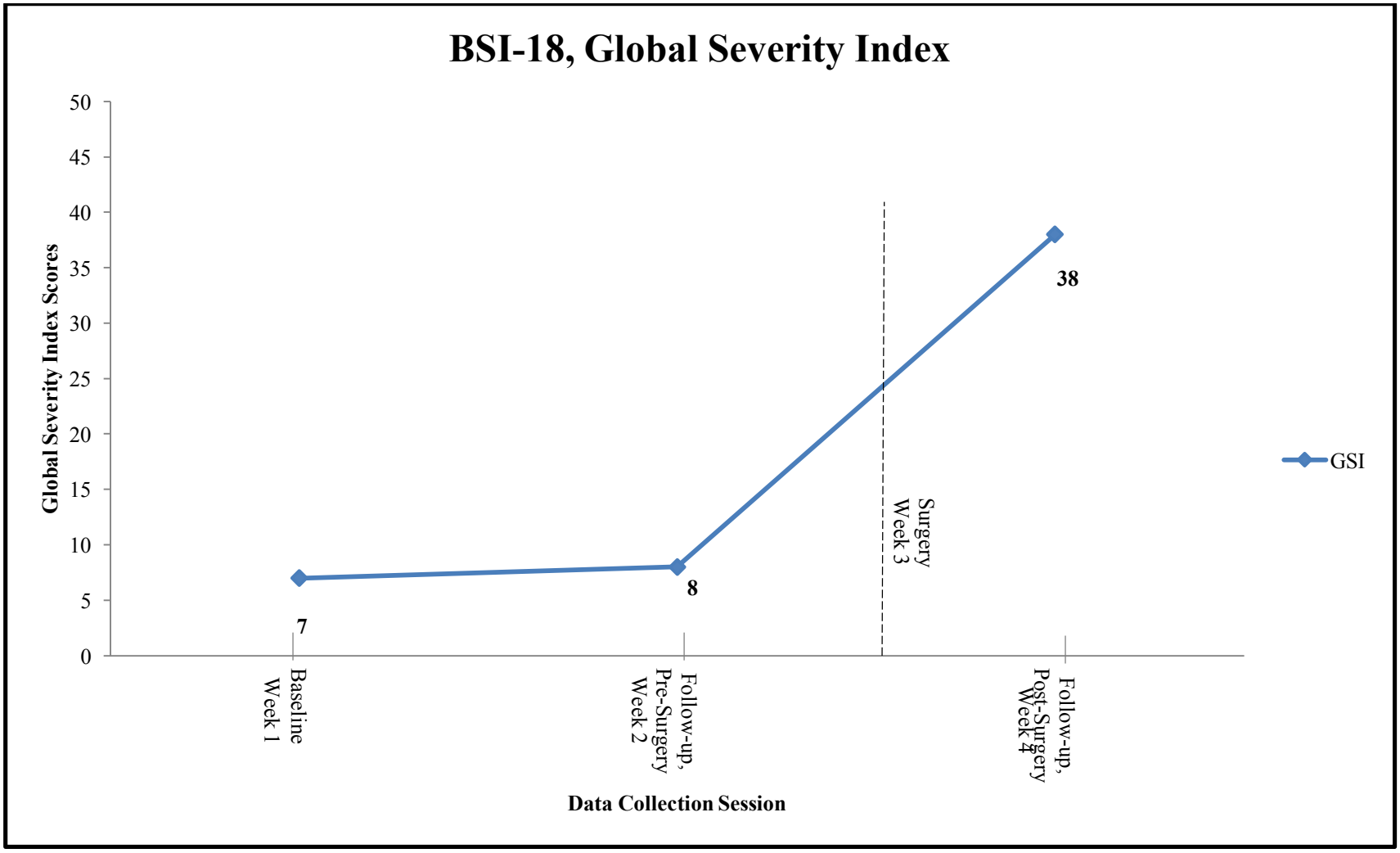

Figure 4.12 Participant scores on the global severity index (GSI) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire

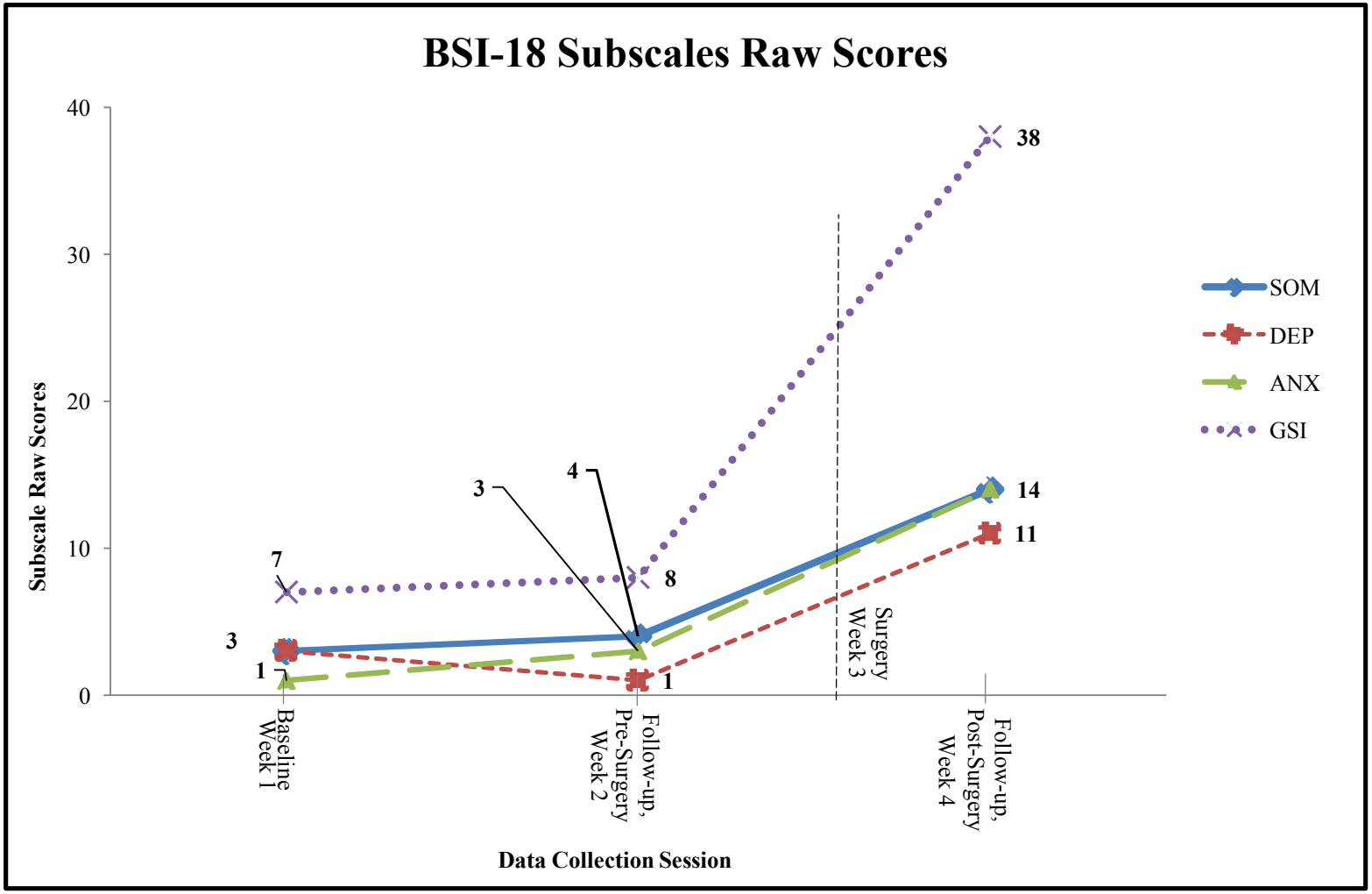

Figure 4.13 Compilation of raw scores of the somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire measured at three different points in time.

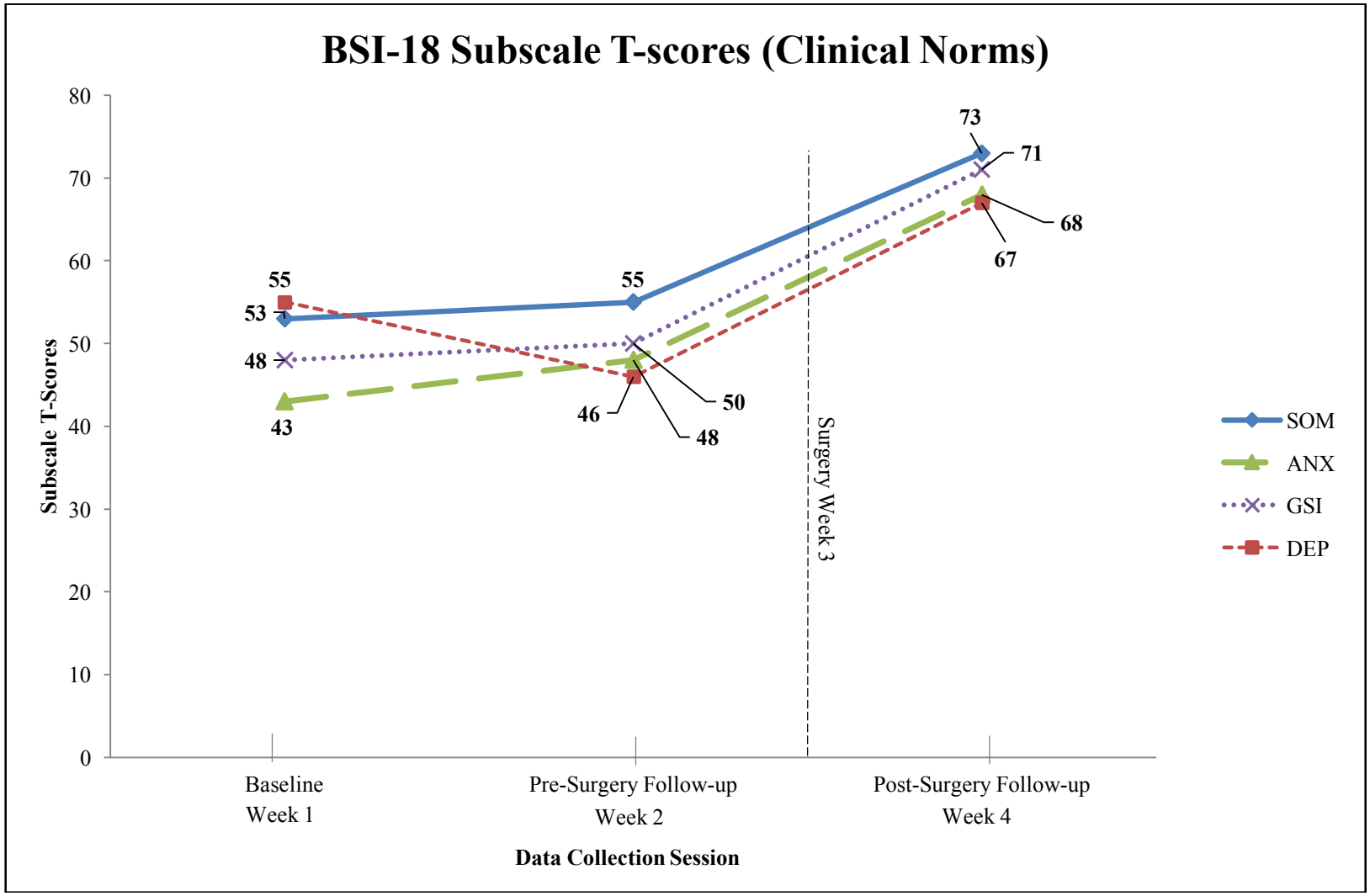

Figure 4.14 Compilation of t-scores of the somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire measured at three different points in time using clinical population norms

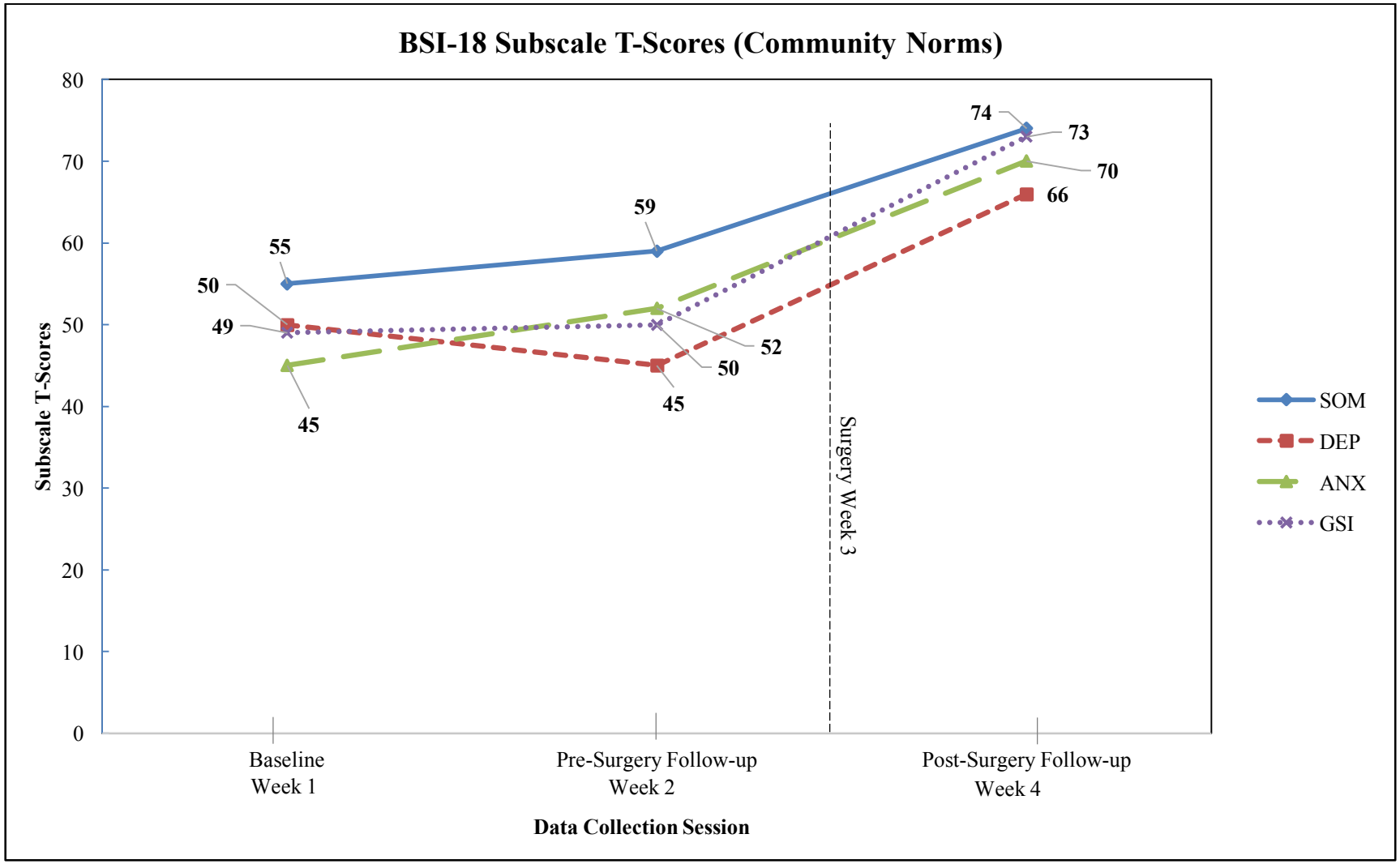

Figure 4.15 Compilation of t-scores of the somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire measured at three different points in time using community population norms

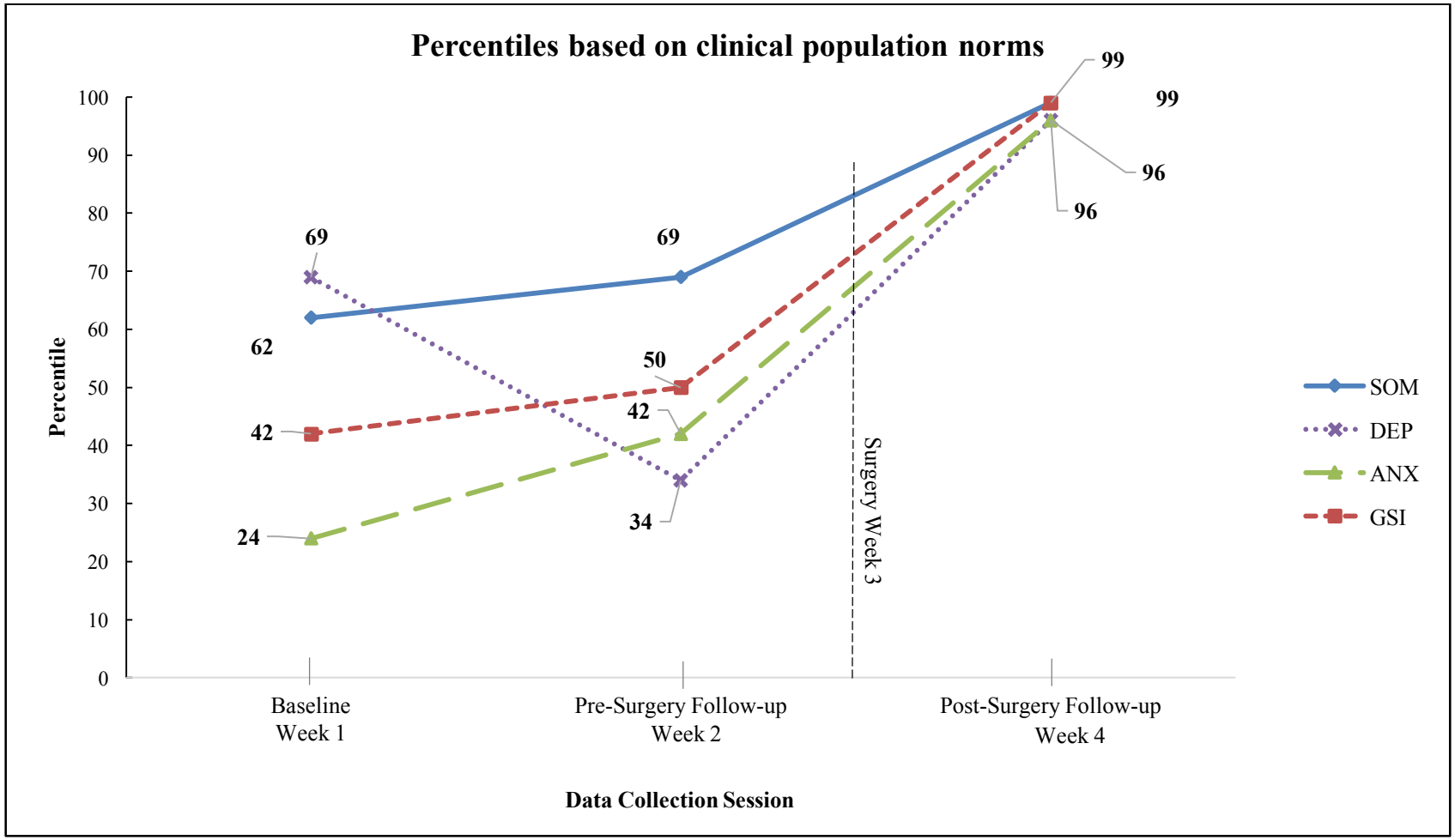

Figure 4.16 Participant percentiles for somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire

Chapter 5

Discussion

Currently, there is an extensive amount of evidence supporting the incorporation of mindfulness-based interventions in the treatment of various chronic conditions including chronic fatigue, fibromyalgia, chronic pain, depression, anxiety, cancer, diabetes, heart disease, coronary artery disease, obesity as well as binge eating disorders (Hofmann et al., 2010; Grossman et al., 2007). Mindfulness-based interventions have an impact on improvement in psychological well-being, cognitive functioning, and emotional regulation in healthy adult populations (Chiesa et al., 2011 & Van Gordon et al., 2013). In addition, mindfulness has assisted in improving an individual's coping mechanisms, quality of life, and reduces pain severity, as well as depressive and anxiety symptoms (Chiesa et al., 2011; Van Gordon et al., 2013; Grossman et al., 2004). Despite these findings, there continues to be a lack of evidence to support the use of mindfulness in individuals suffering from acute conditions such as musculoskeletal disorders including rotator cuff tears. Therefore, our study aimed to assess the feasibility of incorporating a new and innovative mindfulness-based intervention into the treatment of a rotator cuff repair. For the purpose of this study, one individual diagnosed with a single-tendon rotator cuff tear was recruited in order to assess participant satisfaction in regard to the study intervention Headspace, as well as for changes in mindfulness. The participant was assessed at three points in time, two weeks before surgery at baseline, one week before surgery at the pre-surgery follow-up, and one week post-operatively at the post-surgery follow-up. We hypothesized that an individual undergoing a rotator cuff tear would be satisfied in using Headspace as a mindfulness-based intervention and in addition, the individual would report an increase in mindfulness while using Headspace.

Main Findings

Research Question One-Participant Satisfaction

Participant satisfaction was used as our main outcome measure because patient satisfaction is a significant and frequently used measure in the assessment of quality of healthcare (Prakash, 2010). Four themes were found regarding patient satisfaction including 1) increased ability to concentrate and focus, 2) improved ability to manage pain, 3) improved ability to cope with life stressors, and 4) the ability to use the application at any time, anywhere as well as its affordable cost. To the best of our knowledge, identification of these themes are the first findings to be reported for the impact of Headspace in persons receiving surgical intervention for a rotator cuff repair.

The ability to concentrate and focus.

To the best of our knowledge, there is a lack of evidence examining the direct impact of mindfulness-based interventions on a person's ability to concentrate and focus. However, there is evidence that explores the relationship between attention and meditation as well as mindfulness.

The constructs of attention, focus, and concentration are intertwined within the concept of meditation based on Theravada Buddhism. Theravada Buddhism is the oldest of Buddhist traditions and defines meditation as mental development based on three practice types including ethical living, concentration practice through engagement of calming meditation, and wisdom practice by engaging in insight meditation (Rahula, 1959). Headspace uses a combination of both calming meditation (also known as focused attention meditation) and insight meditation (also known as open monitoring meditation) in all mindfulness training sessions. These two techniques are used to promote the optimum conditions for practicing the cognitive skill of mindfulness to direct an individual’s attention to a chosen object while continuously bringing the

attention back when the mind naturally wanders (Puddicombe, 2012). Specifically, calming meditation aims to train the user to concentrate on a particular object such as the breath, a mantra, visualization, physical objects or physical senses of the body. This type of meditation allows for a quieter, more peaceful state of mind and improved concentration (Kabat-Zinn, 1994). With regard to the application, Headspace incorporates calming meditation by cuing the user to continuously direct their focus on physical sensations of the body such as the sensation of the chest rising and falling while breathing. Simultaneously, the user is cued to direct their attention to be present in the moment with a focus on these different sensations when the mind wanders (Headspace, 2014). The ability to sustain attention fully on an object is due to concentration. In other words, mindfulness is the cognitive skill used to orient attention to an object as well as maintaining this attention on the object, while concentration is the cognitive skill that allows for fully focused attention. Therefore, mindfulness and concentration are considered to be separate cognitive skills but in combination are the two concepts that serve as the foundation of insight and calming meditation and result in a state of mindful attention (McGarvey et al., 2010).

Lutz et al. (2008) sought to provide theoretical frameworks for two meditation styles including focused attention meditation (calming) and open monitoring meditation (insight). Focused attention meditation is defined as the voluntary focus of attention on a specific object while open monitoring attention is monitoring the moment by moment experience of being present without judgement. Focused attention meditation is clearly in line with the concepts of calming meditation in that they both direct and maintain attention on a specific object. Lutz et al. (2008) further suggests that regulative skills such as concentration are used less frequently and

result in the ability to sustain focus effortlessly as an individual advances their meditation practice.

Despite the clear connection between meditation, mindfulness, attention and concentration in Theravada Buddhism, evidence has been found that suggests mindfulness training does not improve attentional control which is the self-regulation of attention. Anderson et al. (2007) assessed whether mindfulness impacts concepts related to attentional control including sustained attention, attention switching, inhibition of elaborative processes and non-directed attention in a healthy population of adults. Seventy-two participants were randomly assigned to either participate in the Mindfulness Based Stress Reduction program or participate in a wait-list control group. The authors found that participation in MBSR had a significant impact on mindfulness resulting in improved quality of awareness of the present moment but did not improve attention control. The authors ultimately concluded that the participants may have not had enough time to engage in mindfulness practice to have a direct impact on their ability to control attention.

We conclude that despite contrasting evidence regarding the impact of mindfulness on attention, we believe the mechanism that allowed for the participants improved ability to concentrate and focus was through the practice of calming meditation. The training in calming meditation used by Headspace should improve the ability to direct and maintain attention through concentration based on concepts in Theravada Buddhism (McGarvey et al., 2010).

Pain Management.

An individual experiencing a rotator cuff tear often presents with complaints of pain, decreased range of motion and loss of function. This in turn leads to decreased ability to participate in activities of daily living including self-cares and household chores (Plessis et al.,

2010). This was found to be true in our participant as she reported a combination of decreased range of motion and severe pain resulted in limitations with completing tasks such as washing her hair and laundry. Prior to the study intervention, the participant managed her pain by taking Ibuprofen and adapting her position while sleeping. These disruptions of her participation in meaningful occupations in her daily life due to pain and limited function resulted in the decision to seek surgical intervention to alleviate these limitations.

During the two weeks prior to surgery, the participants current pain scores remained stable with mild pain intensity slightly decreasing from baseline to the pre-surgery follow-up (40 mm to 30 mm). In contrast, average pain intensity scores increased from mild to moderate pain level between baseline and the pre-surgery follow-up (40 mm to 45 mm). The invasive nature of surgical repair of the rotator cuff inevitably results in high levels of persistent pain shortly after surgery (Armstrong, 2011) and was found to be true in our participant. She reported a moderate pain intensity for current pain (50 mm) and severe pain intensity for average pain (75 mm) one week after surgery. Overtime, these reports of high pain intensity will most likely dissipate as the surgical site heals in combination of physical therapy. Despite these increases in pain intensity scores from baseline to post-surgery, the participant reported that Headspace allowed for her to relax better by controlling her mindset to manage her pain.

Both brief and extensive training in mindfulness have been found to have a positive impact on an individual's ability to manage pain sensitivity and improve quality of life in persons with chronic pain (Grossman et al., 2007; Zeidan et al., 2010; Kingston et al., 2007).

Zeidan et al. (2010) investigated the impact of a brief 3-day mindfulness intervention of 20 minutes per day on ratings of painful electrical stimulation in a non-clinical population of students. Twenty-two students were delivered phasic pain using a device that delivered brief

electrical stimuli at 5 Hz. The authors found that three days of mindfulness training was effective in reducing pain ratings caused by increased pain stimuli as compared to baseline measurements. Additionally, pain sensitivity measured by changes in stimulus intensity thresholds, decreased after the brief training. Kingston et al. (2007) also assessed the impact of a brief mindfulness intervention on pain. They assessed a nonclinical population of 42 students who either completed three mindfulness sessions lasting 2 hours or two visual guided imagery sessions of for one hour each. Pain tolerance related to compression of cold packs was found to be significantly increased in persons who participated in the mindfulness sessions. These findings support that brief mindfulness training can have a positive impact on pain-related factors, while other evidence supports that prolonged mindfulness training is needed for significant impacts on pain.

Kabat-Zinn specifically designed the Mindfulness Based Stress Reduction (MBSR) program for patients experiencing chronic pain. The ten-week program was provided to individuals suffering from chronic low back pain, neck pain, shoulder pain and headaches. By the tenth week of the program, 65% of the patients showed a 33% or greater reduction in a total rating index of pain and demonstrated MBSR was an effective program for self-regulation of chronic pain (Kabat-Zinn, 1982). Another study conducted in 1985 resulted in significant reductions observed in measures of present moment pain and pain related drug utilization after participating in MBSR (Kabat-Zinn, 1985). Grossman (2007) assessed 58 females with fibromyalgia in a quasi-experimental study where participants either participated in the MBSR program or an active social support group. The authors found that pre-post analysis resulted in significantly greater benefits in the participants who completed the MBSR group in relation to the control group. In addition, MBSR resulted in sustained benefits 3 years after participating in the program.

The mechanism behind why Headspace and other mindfulness-based interventions improve pain management in persons receiving a rotator cuff repair may lie within the concept of fear-avoidance beliefs related to pain. Fear-avoidance beliefs are present among individuals with upper extremity disorders with elevated scores leading to higher pain and disability scores (Waddell et al., 1993; George et al., 2010; Hart et al., 2009). Fear of pain has the potential to reduce an individual's functional recovery, lead to avoidance of physical activity and can even result in depression, disability and chronic pain (Vlaeyan & Unton, 2000; Sindhu et al., 2012'; Leeuw et al., 2006). Our participant's fear-avoidance beliefs related to pain towards physical activity decreased in score from baseline to the post-surgery follow-up (from 16 to 12). We believe the decrease in the participant's fear-avoidance beliefs is due to the theory that mindfulness modulates the relationship between pain intensity and pain catastrophizing within the fear-avoidance model (Schutze et al., 2009). The involvement in mindfulness training may reduce the engagement in pain catastrophizing and further reduce fears related to pain, leading to an improved ability to manage pain.

Coping with Life Stressors.

There are five proposed mechanisms of mindfulness-based interventions that may account for increased ability to cope with stress. These mechanisms include, 1) change in perception leading to greater tolerance and acceptance of somatic pain and/or poor cognitive or emotional processes, 2) increased exposure to thoughts and feelings leading to reduced fear as well as anxiety responses, 3) increased self-awareness and self-motivation resulting in improved psychosocial coping strategies, 4) decreased autonomic arousal leading to increased levels of relaxation, and 5) enhancement of immune and neuroendocrine system biological pathways (Baer, 2003: Ludwig and Kabat Zinn, 2008; Compare et al., 2012). The combination of these

mechanisms appear to be incorporated into the Headspace application and allow for the improved ability to cope with life stressors leading to patient satisfaction. Coping can be classified into the two strategy types including avoidance and approach. Avoidant coping is characterized by ignoring, distorting, or escaping a negative stimulus. In contrast, approach coping aims to reduce a negative stimulus such as stress, through actions and behaviors that solve the problem directly (Roth & Cohen, 1986). Individual's with higher mindfulness have lower use of avoidance coping and higher uses of approach coping with daily experiences of stress. In addition, the reduction in stress in more mindful individuals led to higher daily well-being (Weinstein et al., 2009). Other mindfulness-based interventions enhance the ability to cope with distress associated with disability in everyday life leading to enhanced well-being (Grossman, 2004; Reiner et al., 2013; Shennan et al., 2011; Chiesa & Seretti, 2009).

Psychological distress has been found to be among individuals receiving rotator cuff repairs both before and after surgery and can lead to reduced function and greater pain in 3 months post-operatively (Nickinson, 2008; Craig et al., 2013). Therefore, we assessed the participant's psychological health status for the duration of the study using the Brief Symptom Inventory 18 questionnaire. Prior to surgery, the participants scores related to anxiety and somatization symptoms slightly increased while the participant's depression scores had a decrease. Similar findings related to a decrease in depression were also found in a study using Headspace. Howells et al. Conducted a randomized control study to assess the feasibility of using Headspace as a psychological intervention in a non-clinical population. Participants were randomly assigned to either the mindfulness intervention group (n=57) or a control intervention (n=64) for 10 days. The results of repeated measure ANOVAs yielded statistically significant increases in positive affect with a medium effect size and a small effect size with reduced

depressive symptoms in the intervention group. These findings demonstrate that Headspace has a positive impact on depressive symptoms and positive affect in just 10 days.

Following surgery, the participants scores for anxiety, depression, and somatization had a large increase which demonstrated an increase in psychological distress following surgery. The explanation for these results are likely due to a family life emergency experienced by the participant. She reported that two days following surgery, a close family member was in the intensive care unit and had only two more days to live. Despite the psychological toll this may have caused for the participant, she still completed one last mindfulness session the day of learning this news as she recognized mindfulness as an important coping skill to have. She also reported that she was able to be mindful in various stressful situations in her daily life throughout the duration of the study. She specifically reported that using Headspace allowed for her to regulate her thoughts and emotions better and may reflect the findings found by Weinstein et al. (2009) in that the participant may have addressed this life emergency using approach coping as she increased her experience with mindfulness.

Therefore, we believe the participants improved ability to cope with life stressors was due to the mindfulness training provided by Headspace and that if given more time, scores in psychological distress would have decreased overtime.

Anytime, anywhere accessibility & affordable cost.

Headspace is a mobile application and can be accessed at any time of day and anywhere. The program is also accessible on desktop computers and requires access to Wi-Fi or data in order to download the training sessions. A benefit of accessing the application by means of a smartphone or tablet provides the user the freedom to select the most appropriate time and place to participate in the mindfulness training sessions. Each session lasts between 10 to 20 minutes

depending on the level the user is on within the application. The participant reported that Headspace sessions were easy to complete each day and that it was not too consuming for her life. She reported that the Headspace experience could be improved to allow for further practice in mindfulness training. Our findings are in contrast of a study conducted by Laurie & Blandford (2016) in which participants reported the main barrier in using the Headspace application was the difficulty with incorporating mindfulness practice into their daily lives. The participants did however report the application was well designed and helped facilitate meditation practice.

The theme of any time accessibility cannot be applied to other mindfulness-based interventions such as the Mindfulness Based Stress Reduction (MBSR) and the Mindfulness Based Cognitive Therapy (MBCT) programs. These interventions are time intensive with MBSR requiring weekly attendance for eight to ten weeks with meeting lengths between 2.5 to 3 hours. In addition, participants are required to attend a six hour mindfulness retreat on the weekend resulting in an approximate time requirement of 36 hours (Grossman et al., 2004 & Khoury et al., 2015). MBCT was derived from MBSR and follows a similar eight week structured program with weekly meetings lasting two hours in length. MBCT has additional time requirements for the participant to complete homework assignments one time per day, six days a week along with attending an all-day retreat. The structure of these programs are time intensive and lead us to believe they are not feasible in the treatment of individuals suffering from a rotator cuff repair in addition to attending weekly physical therapy sessions, follow-up appointments with the surgeon, as well as completing a home exercise program. MBSR requires the physical ability to participate in yoga practice as a component of mindfulness and is a limitation for individual's receiving a rotator cuff repair. An additional limitation for both MBCT and MBSR is the requirement for the individual to leave their home in order to attend the program meetings. This

is seen as a limitation as individuals who have undergone a rotator cuff repair are given the recommendation to wait a minimum of six weeks post-operatively to drive. The individual can drive at an earlier date once they feel comfortable and in control of the vehicle (University of SouthHampton, 2016). Additionally, the participant reported Headspace is affordable with a one-year subscription costing $95 in comparison to a cost range of $275-$575 for MBSR and a cost of $400 for MBCT (Headspace, 2016; Sound, 2015; Shonin et al., 2013). The participant reported she would pay for a subscription to Headspace to continue her journey in mindfulness practice. The themes of any time, anywhere accessibility and affordable cost are important characteristics resulting in overall patient satisfaction with Headspace.

Research Question Two: Mindfulness using Headspace

We hypothesized that an individual undergoing a rotator cuff repair would report an increase in mindfulness after using Headspace. Mindfulness was assessed using two different methods including global rating change self-report questions as well as the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF). There were conflicting findings with the two methods in regard to changes in mindfulness while using Headspace. Up until recently, studies using Headspace have not focused on whether the application specifically impacts a person's mindfulness in a clinical population. Rosen (2016) found that post-hoc analysis revealed a detectable change in mindfulness in women with breast cancer who participated in Headspace as compared to a wait-list control group. Overall, changes in mindfulness while using Headspace in our study were inconclusive based on our findings using the global rating of change self-report and the FFMQ-SF.

The global rating of change assessment included three questions created for this specific project were not validated but were used to assess the participants self-report on changes in

mindfulness due to Headspace. The participant ranked each statement on a scale from 1 to 5, with 1 being false, and 5 being true. Two of the statements were considered to be positive while the third statement was considered to be negative. The two positive statements included, "I found the Headspace application was helpful and effective in my everyday mindfulness" and "I feel I can now be mindful without use of the application" and were found to be somewhat true with a score of 4 by the participant. The negative statement was "I feel that the Headspace application had no effect on my mindfulness" and was given a score of 5 and was seen as false by the participant. We interpret these findings that mindfulness was increased in a short duration of three weeks by Headspace based on global rating of change. The response of 'somewhat true' to the statement of being mindful without the use of the application indicates the participant is not an expert in mindfulness. Continued use of the application may result in more mindfulness overtime. These findings are similar to those reported by Rosen (2016) who conducted a randomized control trial to evaluate the use of Headspace on quality of life and mindfulness among women with breast cancer for eight weeks. A total of 95 women were recruited and were randomly assigned to either the intervention group (n=48), or wait-list control group (n=47). The intervention group was instructed to complete a minimum of the first ten sessions of Headspace but were given no other encouragements to participate in the intervention throughout the study duration. The wait-list control group was provided access four weeks into the study. Web-based assessments were collected at four points in time including baseline, week 5, week 9 and at 4-week follow-up. Overall, the authors found that the intervention group had higher quality of life over time as compared to the waitlist control group from baseline to the 4-week follow-up. Independent sample t-tests were used to in assessing changes in mindfulness using the Mindfulness Attention Awareness Scale (MAAS) and found no significant group differences in

regard to mindfulness. The authors performed a post-hoc analysis by examining the observation by group interaction term at week 5 revealed the Headspace intervention group had a higher MAAS score when compared to the wait-list control group, $t(252)=2.40$ $p=0.02$. Higher MAAS scores were found in the intervention group at week 9 compared to the wait-list control group, $t(252)=2.61$, $p=0.01$. This trend continued into the 4-week follow-up assessment where the intervention group demonstrated higher MAAS scores than the wait-list control group $t(252)=2.818$, $p=0.0004$. This post-hoc analysis revealed that the use of Headspace has a detectable change in mindfulness scores in a clinical population.

The FFMQ-SF evaluates five different facet scores found to make up mindfulness including acting with awareness, observing, describing, nonjudgement of inner experiences, and non-reaction to inner experiences. The participant was found to have an increase in mindfulness scores within the non-reaction facet and a decrease in mindfulness in the other four facets. Non-reaction to inner experiences can be defined as allowing thoughts and feelings to come and go without getting caught up in them (Bohlmeijer et al., 2011) In other words, an individual is able to perceive these thoughts and feelings without having to react to them. As humans, we develop habits of automatic reactions that we are unaware of towards emotional impulses that can negatively impact our health including poor dietary choices, smoking, drinking, and others (McGarvey, 2010). Therefore, the positive change in mindfulness scores towards the non-react facet may demonstrate that the participant's ability to not react to negative stimuli may be due to the use Headspace.

However, the other four facets of acting with awareness, describing, observing and non-judgement of inner experiences did not result in increases between baseline and post-surgery measures. Acting with awareness (act aware) is defined as attending to one's activities within the

moment and resulted in increased scores from baseline to the pre-surgery follow-up with a decrease in scores by the post-surgery follow-up (Bohlmeijer et al., 2011). These results may demonstrate the participant was able to attend her thoughts towards the engagement in her daily activities more mindfully prior to surgery due to Headspace. The decrease in scores though may be due to the fact that increases in pain from surgery limited her ability to attend to the present moment while engaging in her daily activities. Observing is defined as noticing or attending to internal and external experiences and resulted in decreased scores from baseline to the post-surgery follow-up. This may demonstrate Headspace did not have an impact on the participant's ability to pay attention or notice things such as her thoughts as well as attending to things within her environment. Describing is defined as labeling internal experiences with words and followed the same pattern as the observe facet and may demonstrate Headspace did not allow for the participant to recognize her thoughts or feelings were related to a specific label such as sadness, happiness, confusion, pain and others. Nonjudgement of inner experiences (non-judge) is defined as taking a nonevaluative stance toward thoughts and feelings and resulted in an initial increase in scores form baseline to pre-surgery with a decrease by the post-surgery follow-up. Headspace had a slight impact on the participant's ability to be a witness to her thoughts and feelings prior to surgery.

Overall, we were unable to conclude that using Headspace results in increases of mindfulness in combining the results of the global rating of change questions as well as the findings of the FFMQ-SF. There are four reasons as to why our findings are inconclusive.

First, there may be discrepancies with how mindful someone perceives themselves to be and how mindful they actually are (Grossman, 2008). Our participant reported that Headspace allowed for her to be more mindful in her daily life while standardized assessment scores

demonstrated a lack of change in mindfulness. Therefore, our participant may have perceived herself to be more mindful than she actually was based on the standardized assessment results.

Second, a well-known researcher in mindfulness and meditation research, Paul Grossman has proposed five critical issues with the psychometric assessments of mindfulness that are currently used in research including the FFMQ-SF. Issues include that there are differences in the common understanding of mindfulness even amongst experts and therefore results in the development of assessments caters to a developer's definition of mindfulness. In addition, these individuals who develop and construct mindfulness questionnaires lack the experience in Buddhist meditation practice and have not consulted with traditional mindfulness meditation experts. Research has been found that underlying measurement differs so much between mindfulness outcome measures, that different scales are frequently uncorrelated with each other (Baer et al., 2004; Thompson & Waltz, 2007). Another issue is found with the neglect of potential differences in understanding and interpreting scale items among individuals completing the questionnaires. For example, novice and advanced meditators may interpret a scale item such as, "I notice how foods and drinks affect my thoughts, bodily sensations and emotions" differently. The advanced meditator may interpret the act of noticing as intentionally attending to the comment of drinking and eating with a non-judgmental mindset where as a novice meditator may interpret the scale as noticing the impact of food and drink consumption has on physical and mental consequences. Grossman further supports this issue with results from two studies using the Freiburg Mindfulness Inventory (FMI) questionnaire. The first study assessed differences in mindfulness scores between students with binge drinking and smoking behaviors and students without these behaviors. The binge drinking and smoking students were found to have significantly higher levels of mindfulness (Leigh et al., 2005). These findings were compared to

the results of a separate study that assessed mindfulness scores in experienced meditations following an intensive mindfulness retreat. The students scored higher than the experienced meditations demonstrating scales can be interpreted in various ways and therefore may not be accurate in assessing mindfulness (Walach et al., 2006). Two additional issues proposed by Grossman include that developers who have had exposure to mindfulness-based interventions including MBSR and MBCT result in biases in the development of questionnaires and problems with questionnaire validity as most measures were developed using college students as the main criterion population.

Third, the duration of time given to the participant to engage in using Headspace may have limited changes in mindfulness scores using the FFMQ-SF. Our findings suggest that three weeks may not be enough time to have an impact on mindfulness scores whereas nine weeks may be a more appropriate duration to assess for changes in mindfulness based on findings by Rosen (2016). The FFMQ-SF may be more sensitive to changes in mindfulness that may not be seen using global assessments.

Finally, after the second assessment at the pre-surgery follow-up session, two significant events happened in the life of the participant including surgery and a personal life event. It appears the participant was prepared for surgery based on stable scores of the FFMQ-SF and scores may have increased if the participant had continued to use the application overtime. The decrease in FFMQ-SF scores may have been impacted due to the personal life event experienced by the participant resulting in decreased use of the application with completion of only two sessions. Overall, we do not know the exact reason why there were not increases in mindfulness using the standardized assessment and lead us to suggest for the use of multiple mindfulness questionnaires in the assessment of mindfulness changes in future studies.

Limitations & Future Studies

This study has four major limitations including short duration, the study population size, methods for assessing patient satisfaction and mindfulness, and the use of the Amazon Fire tablet.

First, our study was limited by the short duration of three weeks between baseline and follow-up. This limited the assessment of patient satisfaction throughout the time before surgery and after rehabilitation with using Headspace in the treatment of rotator cuff repairs. The short duration did not allow the participant enough time to engage in mindfulness practice that may have impacted the results of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF). Additionally, our findings related to psychological health may have been impacted by stressors within the participant's life and thus we were unable to assess the impact of Headspace on these factors.

Second, the recruitment of one participant is a limitation as our findings cannot be generalized to the clinical population of individuals a receiving rotator cuff repair. Our findings may not account for other types of rotator cuff tears other than a single-tendon tear. We also were unable to compare the impact of other mindfulness-based interventions such as the Mindfulness Based Stress Reduction (MBSR) and the Mindfulness Based Cognitive Therapy (MBCT) programs in this clinical population due to a sample size of 1.

Third, the methods for assessing patient satisfaction and mindfulness may be seen as a limitation. We did not use a standardized assessment tool for assessing patient satisfaction and results were interpreted without statistical analysis. The use of global rating of change questions were not asked on a +10 to -10 scale and did not provide information on what scores would be better. Further the absence of the questions validity and sensitivity results in a lack of

understanding the impact of the measures. In addition, the lack of using a total score for changes in mindfulness while using the FFMQ-SF presents difficulties with drawing conclusions on the impact Headspace had on mindfulness. In addition, the FFMQ-SF has been proposed to not accurately assess mindfulness and may suggest for using a different method for measuring mindfulness.

Fourth, the use of the Amazon Fire tablet can be viewed as a limitation as the device was not previously used by the participant prior to the study. This is seen as a limitation as the participant was unable to trouble shoot an issue with the application and resulted in completing mindfulness training sessions out of sequence.

Future studies should aim to assess our protocol in larger populations in individuals receiving rotator cuff repairs as well as in other orthopaedic conditions. These studies should follow the participants from pre-surgery to the end of rehabilitation, and assess for physical function by collecting measurements on range of motion and manual muscle testing. In addition, evaluating if Headspace improves psychological health within this population, similar to MBSR and MBCT. We do not recommend the use of the FFMQ-SF as the five separate facet scores make it difficult to draw conclusions on changes in mindfulness and lead us to recommend the use of a combination of a few mindfulness questionnaires including the Mindfulness Attention Awareness Scale (MAAS). Assessing whether Headspace directly impacts an individual's quality of life can further support patient satisfaction scores. Finally, we recommend that participants use their own smartphone, tablet or computer in order to participate in Headspace to reduce training on a device that may be foreign to the individual as well as to reduce study costs.

Significance to Occupational Therapy

Our study is significant to the profession of occupational therapy as they are often involved in the post-surgical rehabilitation process of rotator cuff repairs within the scope of hand therapy practice. Occupational therapists account for 85% of certified hand therapists in the U.S, Canada, Australia and New Zealand combined, while physical therapists only account for 14% (HTCC, 2016). Additionally, occupational therapists are distinguished from physical therapists due to the training with a value directed towards the mind-body connection between the physical, mental and emotional health of a patient (Hardison & Roll, 2016). Our study findings in addition to previous evidence, support that psychological distress and fear-avoidance beliefs related to pain are present in individuals who have undergone rotator cuff repairs, (Waddell et al., 1993; George et al., 2010; Hart et al., 2009) and thus calls for implementing biopsychosocial approaches to treatment. Occupational therapists are able to incorporate the biopsychosocial approach to treatment as they are equipped with the skills to assist patients in understanding, accepting and adjusting to a physical illness and disability. The restoration of physical function externally in addition to addressing internal experiences such as psychological distress, can increase a patient's participation in meaningful occupations.

One way occupational therapists can address psychological distress related to a physical conditions or disability, is by incorporating interventions that provide mindfulness meditation training. Mindfulness meditation training integrates the physical, cognitive, psychological and spiritual components of an individual and is in line with occupational therapy's value of addressing an individual's physical, mental and emotional health. Within the realm of occupational science, there is a concept similar to mindfulness known as occupational presence. Occupational presence is defined as a psychological state of consciousness of being aware of the

self while engaging in an occupation, in a specific place and contributes to a person's well-being (Reid, 1995). Mindfulness meditation can help to improve a client's engagement in occupational presence by training the user to apply mindfulness in daily activities.

Occupational therapists should seek to engage in mindfulness-based interventions in their own lives prior to implementing in a client population in order to understand how an intervention works as well as the mechanisms that allow for mindfulness to impact a client's health. The use of Headspace allows for clinicians to refrain from seeking training in other mindfulness-based interventions such as MBSR for implementation and allows for patients to complete these sessions outside of treatment sessions in their own environment. Additionally, occupational therapists should regularly assess a client's psychological health in regard to anxiety, depression, somatization as well as fear-avoidance beliefs related to pain as high levels of distress can lead to pain catastrophizing and result in the development of disability and chronic pain. Assessment can assist occupational therapists in identifying individuals with high levels of psychological distress in order to provide interventions to address these factors or to refer to another specialist if Headspace is not considered to be an appropriate intervention. The use of Headspace as a mindfulness-based intervention, has the potential to be incorporated in all areas of practice within the profession of occupational therapy as it addresses the physical, mental and emotional health of an individual. Headspace may help a patient with the ability to manage pain, cope with life stressors, reduce psychological distress and lead to improved quality of life and therefore should be considered an effective intervention for use in occupational therapy practice.

Conclusion

Our study findings suggest that Headspace is an appropriate mindfulness-based intervention to be included in the treatment of individuals receiving a single-tendon rotator cuff

repair. These findings are based on participant satisfaction as the use of Headspace improved the ability to concentrate, focus, manage pain, and cope with life stressors, as reported by the participant. Findings related to the impact of Headspace on mindfulness were inconclusive. In addition, Headspace was found to be an affordable intervention that was easy to use due to being able to access the application at anytime and anywhere. A major limitation of the present study is that results were based on one individual and the short duration of three weeks. We recommend that future studies assess a similar protocol in a larger study population from pre-surgery to the end of rehabilitation in individual's receiving rotator cuff repair

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Appendices

Appendix A: The Five Facets of Mindfulness Questionnaire-Short Form (FFMQ-SF)

5 facet questionnaire: short form (ffmq-sf)

Below is a collection of statements about your everyday experience. Using the 1–5 scale below, please indicate, in the box to the right of each statement, how frequently or infrequently you have had each experience in the last month (or other agreed time period). Please answer according to what really reflects your experience rather than what you think your experience should be.

never or very rarely true 1	*not often true* 2	*sometimes true sometimes not true* 3	*often true* 4	*very often or always true* 5

1	I'm good at finding the words to describe my feelings	*DS*	
2	I can easily put my beliefs, opinions, and expectations into words	*DS*	
3	I watch my feelings without getting carried away by them	*NR*	
4	I tell myself that I shouldn't be feeling the way I'm feeling	*/NJ*	
5	it's hard for me to find the words to describe what I'm thinking	*/DS*	
6	I pay attention to physical experiences, such as the wind in my hair or sun on my face	*OB*	
7	I make judgments about whether my thoughts are good or bad.	*/NJ*	
8	I find it difficult to stay focused on what's happening in the present moment	*/AA*	
9	when I have distressing thoughts or images, I don't let myself be carried away by them	*NR*	
10	generally, I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing	*OB*	
11	when I feel something in my body, it's hard for me to find the right words to describe it	*/DS*	
12	it seems I am "running on automatic" without much awareness of what I'm doing	*/AA*	
13	when I have distressing thoughts or images, I feel calm soon after	*NR*	
14	I tell myself I shouldn't be thinking the way I'm thinking	*/NJ*	
15	I notice the smells and aromas of things	*OB*	
16	even when I'm feeling terribly upset, I can find a way to put it into words	*DS*	
17	I rush through activities without being really attentive to them	*/AA*	
18	usually when I have distressing thoughts or images I can just notice them without reacting	*NR*	

PTO.

never or very rarely true 1	not often true 2	sometimes true sometimes not true 3	often true 4	very often or always true 5

19	I think some of my emotions are bad or inappropriate and I shouldn't feel them	/NJ	
20	I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow	OB	
21	when I have distressing thoughts or images, I just notice them and let them go	NR	
22	I do jobs or tasks automatically without being aware of what I'm doing	/AA	
23	I find myself doing things without paying attention	/AA	
24	I disapprove of myself when I have illogical ideas	/NJ	

correct scores for items preceded by a slash (/NJ, /AA, etc) by subtracting from 6

non react = ; observe = ; act aware = ; describe = ; non judge =

In the research study where the short form of the FFMQ was developed (see Bohlmeijer et al. below), most of the 376 participants were educated women with "clinically relevant symptoms of depression and anxiety". They were randomized to a nine week clinical intervention involving an *Acceptance & Commitment Therapy (ACT)* self-help book *"Living life to the full"*, plus 10 to 15 minutes per day of *Mindfulness-Based Stress Reduction* meditation exercises, plus some email support. Mean (and Standard Deviation) scores pre- and post- intervention were:

	non react	***observe***	***act aware***	***describe***	***non judge***
pre- mean (sd)	*13.47 (3.07)*	*13.86 (3.21)*	*13.19 (3.32)*	*16.28 (3.91)*	*14.09 (3.63)*
~70%	*10.4–16.5*	*10.6–17.0*	*9.9–16.6*	*12.4–20.2*	*10.5–17.7*
~95%	*7.3–19.6*	*7.4–20.3*	*6.5–19.8*	*8.5–24.1*	*6.8–21.3*
post- intervention	*16.90*	*15.22*	*15.98*	*18.46*	*18.14*

Bohlmeijer, E., P. M. ten Klooster, et al. (2011). *"Psychometric properties of the five facet mindfulness questionnaire in depressed adults and development of a short form."* Assessment 18(3): 308-320. In recent years, there has been a growing interest in therapies that include the learning of mindfulness skills. The 39-item Five Facet Mindfulness Questionnaire (FFMQ) has been developed as a reliable and valid comprehensive instrument for assessing different aspects of mindfulness in community and student samples. In this study, the psychometric properties of the Dutch FFMQ were assessed in a sample of 376 adults with clinically relevant symptoms of depression and anxiety. Construct validity was examined with confirmatory factor analyses and by relating the FFMQ to measures of psychological symptoms, well-being, experiential avoidance, and the personality factors neuroticism and openness to experience. In addition, a 24-item short form of the FFMQ (FFMQ-SF) was developed and assessed in the same sample and cross-validated in an independent sample of patients with fibromyalgia. Confirmatory factor analyses showed acceptable model fit for a correlated five-factor structure of the FFMQ and good model fit for the structure of the FFMQ-SF. The replicability of the five-factor structure of the FFMQ-SF was confirmed in the fibromyalgia sample. Both instruments proved highly sensitive to change. It is concluded that both the FFMQ and the FFMQ-SF are reliable and valid instruments for use in adults with clinically relevant symptoms of depression and anxiety.

Appendix B: Participant Information Questionnaire

University of Wisconsin-Milwaukee
Department of Occupational Sciences & Technology,

Demographic Questionnaire (Initial Session)

Participant ID#: _____ Date Completed:_____ Time:_____

DEMOGRAPHIC INFORMATION

1. Please fill out or circle the correct answer(s) for the following questions about yourself.

Year of birth? _____ Height? ___ft ___inches Dominant hand/arm? R L

Gender? M F

MINDFULNESS-RELATED INFORMATION (Introductory Session only)

2. What is your experience with mindfulness?

_____

_____

_____

_____

3. At this time, would you feel comfortable practicing mindfulness on your own?

YES or NO

INJURY-RELATED INFORMATION

4. How long have you had this condition (in years and months)? ____Years ____Months

_____

5. Have you had a previous injury to either arm previous to this injury? YES NO

If so, please describe the injury and which of your arms it occurred.

_____

6. Do you experience any sleep disturbances due to your condition?

If so, how often? _____Times per week

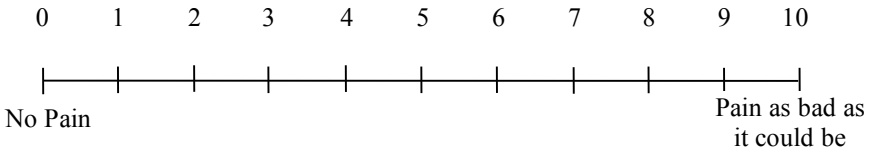
If so, please describe the kind of sleep disturbances.

_____

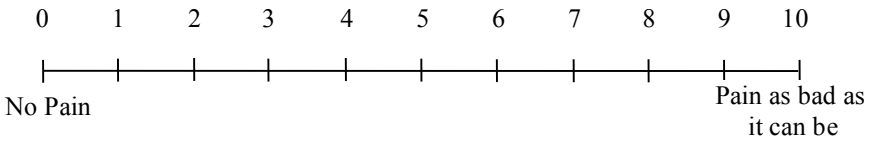
_____

7. Are you taking any pain medications? YES NO

8. What was the average range of pain over the last week on a scale of 0 to 10? (please cross the line below at the most appropriate point)



9. What is the level of your current pain on a scale of 0 to 10? Mark separate lines for left and right shoulder, labeled L or R. (please cross the line below at the most appropriate point)



10 . Do you experience increased pain during a specific time of the day?

OTHER HEALTH-RELATED INFORMATION

11. Have you been diagnosed with type I or type II Diabetes?

If so, circle which type: Type I or Type II

Please circle if your diabetes is controlled or uncontrolled Controlled Uncontrolled

12. Do you smoke?

If so, how many packs per day ____ Packs/Day

For how many years? ____ Years

Appendix C: Debriefing Follow-up Questionnaire

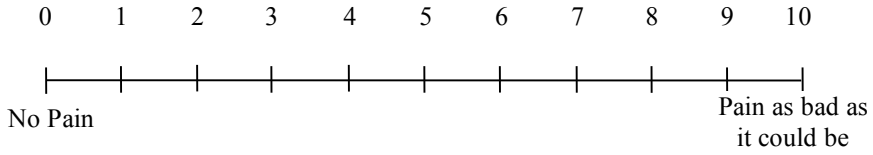
University of Wisconsin-Milwaukee
Department of Occupational Sciences & Technology,

Demographic Questionnaire (Follow-up Session)

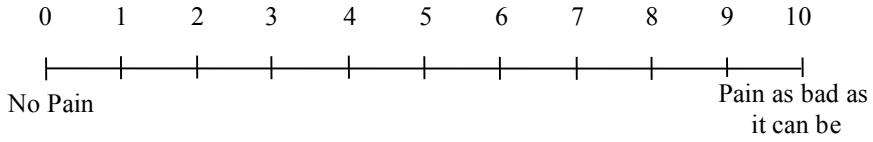
Participant ID#: _____ Date Completed:_____ Time:_____

How many sessions have you completed to this date? _____

1. What was the average range of pain over the last week on a scale of 0 to 10? (please cross the line below at the most appropriate point)



2. What is the level of your current pain on a scale of 0 to 10? Mark separate lines for left and right shoulder, labeled L or R. (please cross the line below at the most appropriate point)



3 . Do you experience increased pain during a specific time of the day?

If so, when? _____

4. Please answer the questions below to the best of your ability in regards to your experience with the Headspace application that you have been using for the previous 12 weeks.

Please circle the most appropriate answer using the key below:

1- False
2- Somewhat False
3- Neither True nor False
4- Somewhat True
5- True

Question:					
1. The application was easy to use.	1	2	3	4	5
2. I enjoyed the Headspace Application.	1	2	3	4	5
3. I found the Headspace Application was helpful and effective in my everyday mindfulness.	1	2	3	4	5
4. I would purchase a subscription to this application to continue mindfulness exercise.	1	2	3	4	5
5. I feel I can now be mindful without use of the application.	1	2	3	4	5
6. I feel that the Headspace Application had no effect on my mindfulness.	1	2	3	4	5
7. I would recommend use of the Headspace Application to a peer.	1	2	3	4	5
8. Headspace helped improve my overall mood.	1	2	3	4	5
9. Headspace was easy to do each day.	1	2	3	4	5
10. Headspace was too time consuming for my life.	1	2	3	4	5

Please answer the below questions with short answers.

What benefits do you think you've gained from your experience with Headspace?

_____

_____

_____

_____

What barriers, if any, did you experience while using the Headspace application?

_____
_____
_____
_____

How do you think your experience with Headspace or mindfulness in general could be improved?

_____
_____
_____
_____

What changes, if any, having you noticed in your life since participating in the mindfulness intervention?

_____
_____
_____

Appendix D: The Fear-Avoidance Beliefs Questionnaire

FEAR AVOIDANCE BELIEFS QUESTIONNAIRE (FABQ)

Purpose: The FABQ was developed by Waddell to investigate fear-avoidance beliefs among LBP patients in the clinical setting.[3] This survey can help predict those that have a high pain avoidance behavior. Clinically, these people may need to be supervised more than those that confront their pain.

Scoring: The FABQ consists of 2 subscales, which are reflected in the division of the outcome form into 2 separate sections. The first subscale (items 1-5) is the Physical Activity subscale (FABQPA), and the second subscale (items 6-16) is the Work subscale (FABQW). Interestingly, not all items contribute to the score for each subscale; however the patient should still complete all items as these items were included when the reliability and validity of the scale was initially established. A low FABQW score (less than 19) was one of 5 variables in a clinical prediction rule that increased the probability of success from SI region manipulation in individuals with low back pain.[1] Each subscale is graded separately by summing the responses respective scale items (0 – 6 for each item); for scoring purposes, only 4 of the physical activity scale items are scored (24 possible points) and only 7 of the work items (42 possible points). The method to score each subscale is outlined below. (Note: It is extremely important to ensure all items are completed, as there is no procedure to adjust for incomplete items.)

Scoring the Physical Activity subscale (FABQPA)
Sum items 2, 3, 4, and 5 (the score circled by the patient for these items).

Scoring the Work subscale (FABQW)
Sum items 6, 7, 9, 10, 11, 12, and 15.

Measurement Characteristics: The FABQ has been demonstrated to be valid and reliable in a chronic LBP population[3] and appears to be a useful screening tool for identifying acute LBP patients who will not return to work by 4wks.[2]

References:

1. Flynn T, Fritz J, Whitman J, Wainner R, et al. Clinical Prediction Rule for Classifying Patients with Low Back Pain Likely to Respond to a Manipulation Technique. Spine (In Press) 2002.
2. Fritz JM, George SZ, Delitto A. The role of fear-avoidance beliefs in acute low back pain: relationships with current and future disability and work status. Pain 2001; 94:7-15.
3. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993; 52:157-168

Name: _____ Date: _____

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

	COMPLETELY DISAGREE			UNSURE			COMPLETELY AGREE
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain.

	COMPLETELY DISAGREE			UNSURE			COMPLETELY AGREE
6. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6
7. My work aggravated my pain	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain	0	1	2	3	4	5	6
9. My work is too heavy for me	0	1	2	3	4	5	6
10. My work makes or would make my pain worse	0	1	2	3	4	5	6
11. My work might harm my back	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain	0	1	2	3	4	5	6
14. I cannot do my normal work until my pain is treated	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6
16. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6

Appendix E: Release of Contact Information Authorization Form

Release of Contact Information Authorization Form

I give permission to either A.B. and D.M., to provide the contact information listed below to H.P. for the purposes of setting up an introductory session to participate in the study under the supervision of Dr. S.G. I understand this form will be destroyed once the introductory session has been scheduled.

Date: _____

First Name (Print) : _____ Last Name: _____

Email: _____

Phone: _____

Contact preference (circle one): Phone or Email

Best time to contact me is: _____

Participant Signature_____

Appendix F: Informed Consent Form

Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

A feasibility study to determine the effect of a mindfulness-based intervention on psychological health among individuals undergoing surgical repair of the rotator cuff

Steven Grindel
Department of Orthopaedic Surgery
(414) 805-7437
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, possible risks and benefits to you, your choices, and other important information. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are invited to participate in this research study because you have met the following criteria: You are between the ages of 18-65 years old, English speaking, experienced shoulder pain for a year or less, have been scheduled for surgery within the next month, are not receiving treatment for a mental disorder at this time, have no history of a previous shoulder muscle tear in either of your arms, had not had an injury in the past 5 years to the limb undergoing surgery, do not have a systemic illness such as RA, no history of diabetes or neurological disorders, no cognitive impairments, are a non-smoker, visual and hearing abilities sufficient to use a mobile application and are currently not pregnant. Because you have met the above criteria you have been deemed eligible to receive an additional therapeutic intervention on top of your surgery and rehabilitation therapy.

Our study will implement a mindfulness-based intervention called *Headspace*. *Headspace* is a mobile application that provides short sessions including meditation and mindfulness training to its user through audio/video recordings. The meditation will require the individual to concentrate on a particular object, such as your breath, a mantra, visualization, physical objects, or physical senses within your body. Additionally you will focus your concentration on bodily sensations with the intention of gaining insight into reality. You will be required to complete a minimum of 12 sessions during the duration of the study. You will attend a total of 3 meetings throughout the duration of the study. Once today during the introductory session, once next week (one week prior to your surgery) and one week after your surgery.

One person will be recruited to participate in the study intervention.

The Director of the study is Dr. Steven Grindel from the Department of Orthopaedic Surgery at Froedtert Hospital. A team comprising of individuals from MCW and the University of Wisconsin-Milwaukee will be working with Dr. Steven Grindel. You can ask who these people are at any point during the study.

The Department of Occupational Science & Technology in the College of Health Sciences at the University of Wisconsin-Milwaukee is funding this study.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A research study is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to understand how to improve recovery for individuals who have undergone surgery for a tear in a shoulder muscle. In particular, we are interested in understanding how using a Smartphone application to assist with guided medication can improve recovery with rehabilitation.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

One individual will be recruited to participate in using the *Headspace* intervention in order to assess the influence of the intervention on your mental health.

After you have been screened for the study and deemed eligible by Dr. Grindel's Team, you will then make an appointment to attend an introductory session run by the graduate student investigator 2 weeks before your surgery. At this session you will be informed about the study and the study intervention, *Headspace* and be provided training and education on using an Amazon Fire Tablet to participate in the study. You will be provided a Tablet as well as educational materials regarding your role in the study. Additionally, a total of four surveys will be administered to you and require for you to fill these out prior to the end of the session. These surveys assess various psychological factors you may be experiencing during your recovery process. The introductory session will require about 45-60 minutes of your time and will occur at least one week prior to your surgery.

You will then attend a second data collection session one week before your surgery. You will complete the same survey questionnaires completed at the introductory session. This will last approximately 20-30 minutes.

You will participate in the experimental intervention for approximately 3 weeks. This intervention is in addition to the usual care provided by Dr. Grindel and rehabilitation team. You will be asked to complete a total of 5 sessions on the

Headspace app per week. These sessions last about 10-15 minutes and some sessions include brief introductory video sessions.

Following your one-week follow-up appointment after surgery where you will receive your usual care, you will then attend the third and final data collection session with the research team to fill out the same surveys during the introductory session as well as an additional follow-up questionnaire. This session should take approximately 60 minutes. You will return the Amazon Fire Tablet distributed to you at the introductory session.

You will receive payment for attending all three sessions totaling $60 in gift cards if the tablet is returned in appropriate condition. You will receive $10 during the introductory session, $20 during the 2nd data collection session, and $30 during the 1 week follow up session. You may not receive the full $30 during the final session if the tablet is not returned

B2. HOW LONG WILL I BE IN THE STUDY?
You will be involved in the study for approximately 3 weeks including the introductory session, second data collection session, and one-week follow up. You will participate in the study intervention for at least 3 weeks. We will not require you to participate in the study after the final follow-up session.

B3. CAN I STOP BEING IN THE STUDY?
You are free to withdraw from the study at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please inform Dr. Steve Grindel. You will be asked to return the Amazon Fire Tablet upon the need to leave the study prior to completion.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE STUDY?
We ask that you do not participate in additional services outside of your rehabilitation care including your physical therapy and check-up appointments with Dr. Grindel. Participating in additional services such as acupuncture or massage could impact the results of the study.

C1. WHAT RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?
We watch everyone in the study for unexpected problems (side effects). You need to tell Dr. Steven Grindel, or a member of the study team immediately if you experience any problems. The risks associated with this study are as follows:

Questionnaires: Questions asked during study will be personal in nature, in regards to your physical and mental health, and require full disclosure for the best possible study results. Answering these questions may invoke some emotions in some individuals. Note, all surveys and data collected during the study will be kept confidential and separate from any identifying information pertaining to your medicals records and health information related to your direct care. This information collected in this study will be kept separate from your medical health records.

Experimental Intervention: There are risks the intervention may not help you or your condition and may trigger unexpected emotions. Additionally, the intervention could result in increased stress with the time required to participate in the study intervention.

Another risk may be loss of confidentiality. Every effort will be made to keep your study records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your study information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?
This study may or may not help you, but we hope the information from this study will help us develop a better treatment procedure following surgical repair of your shoulder muscles. Potential benefits include improved health, decreased stress, and slightly increased rate of healing as well as overall improved quality of life.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?
There are no costs to you for any of the visits or services you receive in this study. If you have questions regarding study costs, please contact Dr. Grindel.

D2. WILL I BE PAID FOR BEING IN THE STUDY?
You will be paid $60 total in gift cards for your participation in this study. You will receive a $10 gift card after the introductory visit, a $20 gift card at the second data collection session and a $30 gift card after the 1 week follow up appointment. The gift cards serve as compensation for your time in attending the three study related sessions for the cost of parking and traveling expenses.

D3. WHAT OTHER CHOICES DO I HAVE?
You do not have to join this study. You are free to say yes or no. Whether or not you join this study, your usual medical services will not change.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?
If we learn any important new information related to the study that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study. After the study has been completed, we will notify you of the results if you are interested.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
- If you have more questions about this study at any time, you can call Dr. Steven Grindel's office at (414) 805-7437 or Dr. Bhagwant Sindhu at 414-229-1180.
- If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input you can call the Medical College of Wisconsin/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?
To be in this research study, the study team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, as described below. We will only collect and use information needed for the study.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); any Froedtert Health Affiliate- Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC. Due to UWM policy and IRS regulations, we are required to obtain the participants name, address, and signature in order to issue gift cards. This information will be kept separate from the deidentified information.

The health information we will collect and use for this study is:

- Personal information such as age, gender, hand dominance, height, and injury-related information.
- Your responses to four health related questionnaires including the Fear-Avoidance Belief Questionnaire (FABQ), Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF), Brief Symptom Inventory 18 (BSI-18) as well as an initial and follow-up questionnaire.
- Information on the time you spend using the intervention.

E2. Who will see the health information collected for this study?
The only people allowed to handle your health information are those on the study team at MCW/Froedtert Hospital, the University of Wisconsin-Milwaukee, and those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

The study team may share your information with people who are not part of the study team because they planned, pay for, or work with us on this study. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this study, we plan to share information with those doctors, researchers or government representatives working with us on this study at the institutions or companies listed here:

Research Team Members (Dr. Bhagwant Sindhu, Dr. Brooke Slavens, Ms. Hanna Paul) at the Department of Occupational Science & Technology in the College of Health

Sciences at the University of Wisconsin- Milwaukee, located at 2400 E Hartford Ave, Milwaukee, WI 53211.

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your health information for a different study without your permission, or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?
One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

E4. How long will you keep the health information for this study?
If you sign this form, we plan to keep your information for approximately 5 years after the research study is completed, in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Steven Grindel at 9200 W. Wisconsin Avenue, Milwaukee WI, 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.

- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**

*** Name of person discussing/ obtaining consent** *(if applicable)*	**Signature of person discussing/obtaining consent**	**Date**

Appendix G: Research Participant Privacy Acknowledgement Form

Exhibit A: Research Participant Data Privacy Acknowledgment

I, _____ (name), am a participant in research activities conducted by _____ (name of research organization). The research conducted will include data collection and analysis regarding my use of the Headspace Application. Such data will not include personal or financial information. I hereby authorize Headspace to furnish _____ (organization) with data regarding my use of the Headspace Application.

By: _____

(signature)

Name and title: _____

Date:_____

Appendix H: Headspace/Mindfulness Description Sheet

Thank you for your interest in taking part in a research study. Here is some information on mindfulness and the Headspace app to help get you started.

What is Mindfulness?

Mindfulness simply means paying attention to the present moment in a non-judgemental way. Modern mindfulness is a non-religious practice with its roots in Buddhist tradition. Anyone can practice mindfulness; all it takes is regular practice.

The Headspace App:

Headspace has created an app that helps you learn mindfulness by guiding you through short meditations. Headspace makes meditating accessible by combining technology and simple techniques that anyone can learn. You can access Headspace on your smartphone, tablet or computer, any time you want. The app offers straightforward, guided, bite-sized mindfulness training that is non-religious. You don't need to sit cross-legged on the floor to meditate either - a chair is fine!

What to expect when participating in research:

If you choose to take part is this research study, you will be asked to complete a brief survey before beginning your Headspace journey, and again after a period of time specified by the researcher. Where possible, questionnaires will be administered online. All your responses will remain anonymous. You are free to withdraw from the study at any time, in which case you will continue to receive access to Headspace. Following completion of the study, you will be provided with three months free access as a token of our appreciation.

Getting started:

You will be given a unique code allowing you to register at **www.headspace.com**. Once you have activated your code on the website, you can start using the app or website straight away. But do check what, if anything, you need to do for the researcher before you begin your first meditation. Headspace is available on Apple and Android platforms so simply visit the App Store or Google Play, download it to your smartphone and away you go.

Thanks for your interest and welcome to Headspace!

For more information visit: www.headspace.com

Appendix I: Tablet Use Disclaimer Form

Tablet Use Disclaimer Form

For the purpose of this study, you as a study participant will be provided a tablet which is property of the University of Wisconsin-Milwaukee Department of Occupational Science and Technology. The tablet will be used by you to access the intervention. Upon receiving this tablet, we ask you to read the following and sign below. Also with receiving this tablet recognize that any accidental damage will not be held against you, **however you will not receive the last $20 payment for failure to return the tablet.**

In receiving this tablet, I will try to the best of my ability to:

a) prevent unavoidable damage to the tablet
b) protect the tablet from liquid damage
c) treat the tablet with respect, so as not to damage it, and
d) report any accidental damage to project investigators.

Print name: _____ Sign name:_____

Date:_____

For researcher use only:

Witness of participant signature: _____

Appendix J: Participant Duties

Participant Duties

Your duties as a study participant include the following:

- Complete a minimum of 12 sessions of Headspace while you are in the study
    - Complete 5 sessions before our second meeting (8/29-9/5)
    - Complete 5 sessions 1 week prior to your surgery date (9/6-9/11)
    - Complete 5 sessions during the week of your surgery (9/12-19)
- Attend the second baseline measure meeting on **September 6th at 10:00 a.m.**
    - Complete the provided surveys
- Attend your 1-week follow-up appointment with Dr. G **September 19th at 8:20 a.m.**
    - Attend the debriefing session after appointment with Dr. G **September 19th, around 9 a.m.**
    - Return the tablet
    - Complete the provided surveys
- You are allowed to complete as many sessions of Headspace as you like but we ask you only do a maximum of one per day.
- You will receive an additional 6 month subscription code as compensation for your time. All you need to do is set up your own personal account with Headspace.
- Contact H.P if there are any issues or questions you may have

Appendix K: Gift Card Receipt

Gift Card Receipt

Thank you for your participation in the following session (circle one):

- Introductory session, $10
- Second Follow-up Session , $20
- Debriefing session, $30

Upon completion of this session I, _____, have received the
Please print name above.
appropriate amount, noted above, for my participation and completion. In relation to the 4 week follow-up, I am receiving compensation because I have returned the tablet provided to me during the study.

Signature (participant):_____ Date:_____

Signature (Student Investigator): _____ Date:_____

Appendix L: UWM Gift Card Disbursement Log

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Gift Card/Cash Disbursement Log

PC Name	
IRB Protocol #	
Level of confidentiality	
Purpose of Study	

INFORMATION ABOUT GIFT CARDS
Gift Card Vendor:
Gift Cards Ordered By:
Total Cards Ordered:
Date Received:

	Name of Recipient or Recipient Identifier *	Amount	* Recipient Contact Information (or On File)	Date Disbursed	Gift Card Number	Issued By (Person who disbursed)
	REQUIRED	REQUIRED	OPTIONAL	REQUIRED	REQUIRED	REQUIRED
EX	Suzy Somebody	$50	Address	6/1/2011	XYZ125687	Brian Anybody
GR	Participant ID-1	$25	on file with PI	6/1/2011	XYZ125687	Brian Anybody
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						

Total Disbursed	$

The disbursement log kept on file with the payment receipt must be updated as cards are disbursed.

*NOTE: A unique ID/Identifying No. may only be used when the research protocol submitted to the Institutional Review Board requires a Level 3 confidentiality of research subjects. A separate log is kept by the PI with the ID/Identifying No., participant's initials, and date card was disbursed to the participant. This form requires the participant's ID/Identifying No., "on file" in place of contact information, and remaining fields completed as outlined on the form. It is the responsibility of the PI and the department to keep these records on file for periodic review by the Office of Internal Audit.

Attach all required Backup paperwork, including signatures of receipt, to this Log. See Procedure 2.4.6 for requirements.

Appendix M: Definition of Terms

Definition of Terms

This section further defines the various terms used through this research project.

1. **Musculoskeletal System:** This system consists of the skeletal system encompassed by bones and joints as well as the skeletal muscle system including the peripheral nerves innervating skeletal muscles. This system functions to protect internal organs, posture maintenance, assistance in movement, formation of blood cells as well as storage of fats and minerals (Salter, 1999).
2. **Musculoskeletal Disorders:** Musculoskeletal disorders include a wide range of inflammatory and degenerative conditions affecting the muscles, tendons, ligaments, joints, peripheral nerves, and supporting blood vessels in the body. Anatomical regions commonly involved are the low back, neck, shoulder, forearm and hand (Devi & Kiran, 2015). Different causes range from acute onset and short duration disorders to lifelong disorders. Disorders most commonly manifest as rheumatoid arthritis, osteoarthritis, osteoporosis, spinal disorders, peripheral nerve injuries, major limb trauma, fibromyalgia, gout, as well as sprains and strains (Lidgren, 2003).
3. **Rotator Cuff:** The rotator cuff functions to position and control the upper extremity by allowing elevation and rotation about the glenohumeral joint located in the shoulder. It has a significant role in the static and dynamic stability of the glenohumeral joint. The RC is a group of four muscles and tendons that create a hood over the glenohumeral joint and its capsule. The tendons originate on the scapula and insert on either the greater or lesser tubercle of the humerus.

The muscles include the subscapularis, the supraspinatus, the infraspinatus and the teres minor (Malcarney & Murrell, 2003).

4. **Rotator cuff disorders:** Disorders of the rotator cuff are the most common cause of shoulder pain in primary care. The use of "rotator cuff disease" serves as an umbrella term allowing for categorization of all symptomatic disorders of the rotator cuff regardless of mechanism or anatomical location. Rotator cuff disease includes rotator cuff tendinopathy or tendinitis, tears of the cuff muscles, impingement syndrome, calcific tendinitis, subacromial bursitis (Whittle & Buchbinder, 2015).

5. **Rotator cuff tears:** A tear in the tendon of any of the SITS muscles, most often the tendon of the supraspinatus. These injuries are caused by strenuous circumduction of the upper extremity, shoulder dislocation, hard falls or blows to the shoulder, or repetitive use of the arm at a raised position. Recurrent inflammation of one of the SITS tendons can cause the tendon to degenerate and further rupturing in response to moderate stress (Saladin, 2011).

6. **Rotator Cuff Repairs:** Repairs of the rotator cuff for rotator cuff tears are performed surgically. The trends for repair have become less invasive procedures due to the advancements in surgical techniques. The ultimate goal of a rotator cuff repair is to reattach the tendon for healing (AAOS, 2011).

7. **Range of Motion:** An aspect of joint performance and a physical evaluation of an individual's joint flexibility is range of motion (ROM). ROM is the degrees through which a joint is able to move. The ROM of a joint is determined by the structure of the articular surfaces of bones, action of the muscles and tendons as well as the strength and tautness of ligaments and joints (Saladin, 2011).

8. **Psychological health:** The term psychological health for this project is in relation to psychological factors that may impact an individual's progress in therapy including anxiety, depression, fear-avoidance beliefs and somatization.

9. **Somatization:** Reflects distress arising from perceptions of bodily dysfunction. Complaints focus on cardiovascular, GI, respiratory, neurological and other systems with strong autonomic meditation. Pain and discomfort of the gross musculature and other somatic equivalents of anxiety are also possible components of somatization (Boothyard, 2003).

10. **Mindfulness:** Mindfulness is the key ingredient of most meditation techniques and goes far beyond the formal aspect of sitting down with your eyes closed. Meditation is the technique to provide an individual with the perfect conditions to practice the skill of mindfulness. It means to be present, in the moment, undistracted while experiencing life directly as it unfolds rather than being distracted, caught up and lost in thought. It implies resting the mind in its natural state of awareness, which is free of any bias or judgment" (Puddicombe, 2012, p. 18-19).

Appendix N: Equivalent Text Descriptions

Table 1.1

Brief Description: A rehabilitaiton protocol for rotator cuff repair.

Summary Description: The rehabilitation protocol is a protocol for rotator cuff repair rehabilitation instructions that are divided into increments between 0 to 10 weeks this given to both the patient and treating physical therapist.

Detailed Description: The protocol is divided into four phases including 0 to 6 weeks, 6 to 8 weeks, 8 to 10 weeks, and week 10. During the 0 to 6 week phase, the patient is to wear their sling or immoblizer at all times with ice pack to the shoulder for 20 minutes on and 20 minutes off. The sling is to be removed 4 or 5 times per day and the patient is to perform gentle Codman exercises by moving the body and not the arm. The therapist is to provide active range of motion to the scapula, elbow, forearm, wrist, and hand starting 1 week postoperatively. Passive range of motion in all planes are to meet the following goals by week 6: Shoulder flexion of 90 to 100 degrees, abduction of 90 to 100 degrees, internal rotation of 60 to 75 degrees, external rotation of 60 to 75 degrees. In addition, the protocol includes instructions for edema control, postural education, soft tissue mobilization, monitorying or range of motion in uninvolved joints including the scapula, elbow, forearm, the wrist and hand. Finally, the patient is to complete a home exercise program of codman and pendulum exercises, active range of motion to the uninvolved joints, passive range of motion to the shoulder by a family member. The week 6 to 8 phase includes instructions to continue passive range of motion with the goal of full range of motion in all planes by week 8. The patient is to begin active range of motion with pulleys, canes, and wall walks. The therapist can use high-voltage pulsed current or transcutaneous electrical nerve stimulation of needed. The week 8 to 10 phase includes gentle submaximal

isometrics to the affected shoulder within a pain-free range. The patient will participate in active range of motion of the affected shoulder and continue the use of modalities and soft tissue mobilization as needed. The week 10 and plus phase includes the continued use of modalities and soft tissue mobilization as needed, progressive resistance exercises with a goal to meet preinjury status, perform stretching as needed and the therapist is to monitor scapula mobility.

Table 3.1

Brief Description: Assessments administered by data collection session and gift card disbursements.

Summary Description: This table includes a layout of the three data collection sessions including the introductory, pre-surgery follow-up, and post-surgery follow-up session. Each session includes bullet points for the assessments administered as well as a separate column for the disbursement of gift cards.

Detailed Description: There are total of three columns and three rows for this table. The top row includes the following titles, data collection session, assessments administered, and gift card disbursement amounts. The data collection sessions include three separate rows for the introductory, pre-surgery follow-up and post-surgery follow-up sessions. The introductory session in row 2 included the following assessments, the initial demographic questionnaire, the FFMQ-SF, FABQ, and the BSI-18. The third column of the second row displays that ten dollars was administered during this session. The third row includes the pre-surgery follow-up and the following assessments of the follow-up questionnaire, the FFMQ-SF, FABQ, and the BSI-18. The third column in the third row displays that 20 dollars was distributed during this session. The fourth row for the post-surgery follow-up session includes the assessments administered in the

second column including the follow-up questionnaire, FFMQ-SF, FABQ, and the BSI-18. The third column in the fourth row displays that 30 dollars was distributed during this session.

Table 3.2

Brief Description: Step by step guide for redeeming Headspace subscription code for full access to the application for a six-month period.

Summary Description: The following table is divided into two columns with the header of step or procedure. The step column includes a total of fourteen steps and each step is paired with a specific procedure that must be completed in order to redeem the subscription code provided by Headspace.

Detailed Description: The steps to redeem the Headspace description codes will be described step by step. Step one, the individual will have to go to Headspace.com. Step two, the individual will click the words, redeem code which are located in the top right menu bar on the website next to the word login. Step three requires the individual to enter the provided subscription code by the student investigator in the provided text box. Step four is to click the word continue. Step seven includes having the study participant to log out of the Headspace account on the computer. Step eight directs the individual to grab the Amazon Fire Table which includes powering on the device for step nine. Step ten describes how you can power on the device by pressing the power button located on the top right corner of the tablet for 1 to 3 seconds. Step eleven includes pressing the home button on the tablet and is followed by step twelve to open the Headspace app on the tablet. Step thirteen states that an image will appear asking the user to create an account. Look below this to see where it says, ‘already have an account? Log in’. Click the log in link. Step fourteen instructs the individual to enter the pre-existing email address and password created on the computer and click the log in button.

Table 4.1

Brief Description: A table including demographic characteristics of 1 study participation with single-tendon rotator cuff tear

Summary Description: Table 4.1 includes a table listing various demographic information including age, gender, height, race, marriage status, hand dominance, injured extremity, work status, and primary language

Detailed Description: The table includes information about general characteristics of the participant. A population characteristics and be seen in the top right corner above the characteristics including the word ‘woman’ and a population size of N equaling one. The participants age in years was 56, gender was female, height in inches was 61 inches, race was African-American, marriage status was divorced, hand dominance was right hand, injured extremity was the right hand, the current work status was retired and the primary language was English.

Table 4.2

Brief Description: Results from the follow-up questionnaire regarding participant satisfaction in the use of Headspace during the post-surgery follow-up session evaluation

Summary Description: Table 4.2 provides results of a survey regarding 10 questions that were asked in the follow-up questionnaire.

Detailed Description: These questions include, 1) the application was easy to use, 2) I enjoyed the Headspace application, 3) I found the Headspace application was helpful and effective in my everyday mindfulness, 4) I would purchase a subscription to this application to continue my mindfulness exercise, 5) I feel I can now be mindful without the use of the application, 6) I feel that the Headspace application had no effect on my mindfulness, 7) I would

recommend use of the Headspace application to a peer, 8) Headspace helped improve my overall mood, 9) Headspace was easy to do each day and 10) Headspace was too time consuming for my life. The questions are separated into different rows and are rated on a scale from 1 to 5. The scale items include 5 additional columns for each question including the following headers, 1-False, 2-Somewhat False, 3-Neither True nor False, 4-Somewhat True, and 5-True. Each question has a space to select one of the five headers using the letter X. Question one, two, seven, and eight have an X in the 5-True column. Question three, four, five, and nine have an X in the 4-Somewhat True Column. Questions six and ten have an X in the 1-False column.

Table 4.3

Brief Description: Descriptive participant data usage when participating in meditation sessions in the Foundation Series of the Headspace application

Summary Description: The following table includes a layout of the completed sessions of the Headspace divided into four columns including Foundation Series Level, Session Number, Date and Time.

Detailed Description: The table includes a total of four columns with the headings as listed above and 13 additional rows for each session completed. Row 1 includes the headings of Foundation Series Level, Session Number, Date and Time. Row two includes level 1, session 1, date of August 30th, 2016 at 4:12 p.m. Row three includes level 1, session 2, date of August 31st, 2016 at 4:47 p.m. Row four includes level 1, session 3, date of September 1st, 2016 at 4:48 p.m., Row five includes level 1, session 4, date of September 2nd, 2016 at 3:47 p.m. Row six includes level 1, session 5, date of September 3rd, 2016 at 4:09 p.m. Row seven includes level 1, session 6, date of September 4th, 2016 at 4:45 p.m. Row eight includes level 1, session 7, date of September 5th, 2016 at 4:27 p.m. Row nine includes level 1, session 8, date of September 6th,

2016 at 4:30 p.m. Row ten includes level 1, session 10, date of September 9th, 2016 at 3:41 p.m. Row eleven includes level 1, session 9, date of September 9th, 2016 at 4:08 p.m. Row twelve includes level 2, session 11, date of September 11th, 2016, at 5:17 p.m. Row thirteen includes level 3, session 12, date of September 13th, 2016, at 2:56 p.m. Row fourteen includes level 3, session 13, date of September 15th, 2016 at 3:48 p.m.

Figure 3.1

Brief Description: Materials provided to the participant including one Amazon Fire Tablet, a power cord, & plug-in.

Summary Description: Figure 3.1 provides a picture of the front and back of the Amazon Fire Tablet, the power cord and the plug-in.

Detailed Description: The picture includes the front and back of the Amazon Fire Tablet. The back of the tablet includes a label on the back, "UWM OST&T Dept. Tablet 1". The tablet, power cord, and plug-in are all labeled with an individual textbox. The tablet includes additional labels for labeling the power button, volume button and camera.

Figure 3.2

Brief Description: A timeline of completing various procedures related to the current study.

Summary Description: This timeline outlines important time points between December 2016 and November 2016 in relation to tasks completed for this study.

Detailed Description: The timeline depicts 8 specific time points in relation to completing tasks for this study. The thesis was proposed in December of 2015. The IRB approval process occurred between the months of April to June of 2016. Both participant recruitment and the introductory session took place in August 2016. The pre-surgery and post-surgery follow-up

sessions took place in September 2016. Data analysis occurred in October 2016 and the thesis was defended in November 2016. In addition, the intervention period was between August and September of 2016.

Figure 4.1

Brief Description: Participant scores for the nonreactivity to inner experiences (non-react) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

Summary Description: Figure 4.1 provides a line graph of three data points in relation to the participants scores on the non-react facet of the FFMQ-SF questionnaire. The non-react facet mindfulness scores are on the y-axis and the three data collection sessions are on the x-axis.

Detailed Description: This line graph has both a Y and an x-axis with the title of FFMQ-SF, Non React Facet. The Y-axis includes the non-react facet mindfulness score range with tick marks for scores between 0 to 25 in 5 point increments (For example, 0, 5, 10, 15, 20, 25). The X-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The graph contains a key denoting that the line represents the non-react facet. The first data point at baseline is marked with a diamond at a score of 14. The pre-surgery follow-up data point is also marked with a diamond at a score of 14. The post-surgery follow-up data point is marked at a score of 19. All three data points are connected by a solid line. The line is stable between baseline and the pre-surgery-follow-up and has a positive trend by the post-surgery-follow-up

Figure 4.2

Brief Description: Participant scores for the observing (observe) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

Summary Description: Figure 4.2 provides a line graph of three data points in relation to the participants scores on the observe facet of the FFMQ-SF questionnaire. The observe facet mindfulness scores are on the Y-axis and the three data collection sessions are on the X-axis.

Detailed Description: This line graph has both a Y and an X axis with the title of FFMQ-SF, Observe Facet. The Y-axis includes the observe facet mindfulness score range with tick marks for scores between 5 to 20 in 2.5 point increments (For example, 5, 7.5, 10, 12.5, 15, 17.5, 20). The X-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The graph contains a key denoting that the line represents the observe facet. The first data point at baseline is marked with a diamond at a score of 15. The pre-surgery follow-up data point is also marked with a diamond at a score of 14. The post-surgery follow-up data point is marked at a score of 14. All three data points are connected by a solid line. The line has a negative trend with a decrease from baseline to the pre-surgery follow-up and is stable between the pre and post-surgery follow-up tick marks.

Figure 4.3

Brief Description: Participant scores for the acting with awareness (Act Aware) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

Summary Description: Figure 4.3 provides a line graph of three data points in relation to the participants scores on the act aware facet of the FFMQ-SF questionnaire. The act aware facet mindfulness scores are on the y-axis and the three data collection sessions are on the x-axis.

Detailed Description: This line graph has both a Y and an x-axis with the title of FFMQ-SF, Act Aware Facet. The y-axis includes the observe facet mindfulness score range with tick marks for scores between 5 to 25 in 2 point increments (For example, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25). The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The graph contains a key denoting that the line represents the act aware facet. The first data point at baseline is marked with a diamond at a score of 18. The pre-surgery follow-up data point is also marked with a diamond at a score of 19. The post-surgery follow-up data point is marked at a score of 14. All three data points are connected by a solid line. The line has a positive trend with an increase from baseline to the pre-surgery follow-up and negative trend with a decrease between the pre and post-surgery follow-up tick marks.

Figure 4.4

Brief Description: Participant scores for the describing (describe) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time

Summary Description: Figure 4.4 provides a line graph of three data points in relation to the participants scores on the describe facet of the FFMQ-SF questionnaire. The describe facet mindfulness scores are on the y-axis and the three data collection sessions are on the x-axis.

Detailed Description: This line graph has both a Y and an x-axis with the title of FFMQ-SF, Describe Facet. The y-axis includes the observe facet mindfulness score range with tick

marks for scores between 5 to 25 in 2 point increments (For example, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25). The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The graph contains a key denoting that the line represents the describe facet. The first data point at baseline is marked with a diamond at a score of 20. The pre-surgery follow-up data point is also marked with a diamond at a score of 19. The post-surgery follow-up data point is marked at a score of 19. All three data points are connected by a solid line. The line has a negative trend with a decrease from baseline to the pre-surgery follow-up and is stable with no change in scores between the pre and post-surgery follow-up tick marks.

Figure 4.5

Brief Description: Participant scores for the non-judgement of inner experiences (non-judge) facet of the Five Facets of Mindfulness Questionnaire Short Form (FFMQ-SF) measured at three different points in time.

Summary Description: Figure 4.5 provides a line graph of three data points in relation to the participants scores on the non-judge facet of the FFMQ-SF questionnaire. The non-judge facet mindfulness scores are on the y-axis and the three data collection sessions are on the x-axis.

Detailed Description: This line graph has both a Y and an x-axis with the title of FFMQ-SF, Non-Judge Facet. The y-axis includes the observe facet mindfulness score range with tick marks for scores between 5 to 25 in 2 point increments (For example, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25). The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks

denoting the time of surgery (week 3). The graph contains a key denoting that the line represents the describe facet. The first data point at baseline is marked with a diamond at a score of 17. The pre-surgery follow-up data point is also marked with a diamond at a score of 19. The post-surgery follow-up data point is marked at a score of 16. All three data points are connected by a solid line. The line has a positive trend with an increase from baseline to the pre-surgery follow-up and a negative trend with a decrease in scores between the pre-surgery and post-surgery follow-up tick marks.

Figure 4.6

Brief Description: A comparative bar graph of the five facets scores from the Five Facets of Mindfulness Questionnaire Short-Form measured at three different points in time.

Summary Description: Figure 4.6 includes a bar graph that has both an Y and an x-axis. The Y-axis includes the scores for all five facets of the FFMQ-SF facet scores. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). Each facet is represented across the three data collection points as a bar.

Detailed Description: The bar graph is titled the FFMQ-SF Five Facets and has both an x and a y-axis. The y-axis includes tick marks for scores ranging from 5 to 25 to represent the range of mindfulness scores for the five facets in 2 point increments. For example, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, and 25. Each tick mark has a corresponding line that spans across the three tick marks on the x-axis. Each of the tick marks on the x-axis contains 5 bars each for the 5 facets. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-

axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The baseline tick mark includes a bar for the non-react facet with a score of 14, a score of 15 for the observe facet, a score of 18 for the act aware facet, a score of 20 for the describe facet, and a score of 17 for the non-judge facet. The pre-surgery follow-up tick mark includes a bar for the non-react facet with a score of 14, a score of 14 for the observe facet, a score of 19 for the act aware facet, a score of 19 for the describe facet, and a score of 19 for the non-judge facet. The post-surgery follow-up tick mark includes a bar for the non-react facet with a score of 19, a score of 14 for the observe facet, a score of 14 for the act aware facet, a score of 19 for the describe facet and a score of 16 for the non-judge facet. All bars are categorized by different shading and designs that fill the bar in order to discern between which facet the bar represents. The non-react facet is characterized by a dark gray solid filling, the observe facet is characterized by diagonal black lines, the act aware facet is characterized by a light gray solid filling, the describe facet is characterized by a diagonal brick design and the non-judge facet is characterized by a black gray solid filling.

Figure 4.7

Brief Description: Participant's current pain intensity and average pain intensity over the last week scores collected at three different points in time using a Visual Analogue Scale (VAS).

Summary Description: The following graph depicts the participants pain intensity scores for average pain over the last week as well as their current pain. The average pain over the last week scores are depicted by a broken line in blue and the current pain scores are depicted by a solid line in red. The y-axis includes score ranging from 0 to 100 in 10 point increments for pain intensity scores in millimeters while the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery

follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: The figure is titled Pain Intensity, and has both a y and an x-axis. In addition, there are two different lines on the graph for both average pain over the last week depicted by a broken line in blue and a current pain score depicted by a solid line in red. The y-axis includes score ranging from 0 to 100 in 10 point increments for pain intensity scores in millimeters. For example, 0, 10, 20, 30, 40, 50, 60, 70, 80, 90, and 100. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The graph also includes four solid lines horizontally at the 4 millimeter, 45 millimeters, 75 millimeters, and 100 millimeter tick marks to help categorize pain scores into no pain, mild pain, moderate pain, and severe pain categories. The no pain category is given a denotation of being between 0 to 4 millimeters. The mild pain category is given a denotation of being between 4 to 44 millimeters. The moderate pain category is given a denotation of being between 45 to 74 millimeters. Finally, the severe pain category is given a denotation of being between 75 to 100 millimeters. The current pain data line has a data point at 40 for baseline, 30 for the pre-surgery follow-up, and a score of 50 at the post-surgery follow-up. The average pain score has a data point at 40 for baseline, 45 for the pre-surgery follow-up and a score of 75 at the post-surgery follow-up.

Figure 4.8

Brief Description: Participant scores from the Fear-Avoidance Beliefs Questionnaire Physical Activity Subscale (FABQ-PA) measured at three different points in time.

Summary Description: Figure 4.8 is a line graph containing both y and an x-axis. The y-axis includes tick marks for fear-avoidance belief scores and the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: The line graph is titled the FABQ-PA and includes both an x and a y-axis. The y-axis includes tick marks ranging from 0 to 25 in 5 point increments for fear-avoidance belief scores. For example, 0, 5, 10, 15, 20, and 25. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The baseline data point is placed at a score of 16, a score of 2 for the pre-surgery follow-up and a score of 12 at the post-surgery follow-up in comparison to the Y-axis. The line has a large decrease between the baseline and pre-surgery follow-up tick marks, and a large increase between the pre-surgery and post-surgery follow-up sessions. However, there is a general decrease in the line between baseline and the post-surgery follow-up. A key is located to the right of the line graph denoting the line represents FABQ-PA scores.

Figure 4.9

Brief Description: Participant scores on the somatization (SOM) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire.

Summary Description: This line graph provides a visual depiction of the data points for scores on the BSI-18 questionnaire in regard to the somatization subscale. The y-axis includes scores related to somatization symptom raw-scores and an x-axis with three tick marks

representing the three data collection sessions of baseline, the pre-surgery follow-up and the post-surgery follow-up.

Detailed Description: This line graph is titled the BSI-18, Somatization and has both y and an x-axis. The y-axis includes tick marks for scores ranging between 0 to 18 in 2 point increments. For example, 0, 2, 4, 6, 8, 10, 12, 14, 16, and 18. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The baseline data point has a score of 3, the pre-surgery follow-up has a score of 4 and the post-surgery follow-up has a score of 14. The line follows a positive trend with a slight increase between baseline and the pre-surgery follow-up and a large increase to the post-surgery follow-up. A key is located to the right of the line graph denoting the line represents somatization scores.

Figure 4.10

Brief Description: Participant scores on the depression (DEP) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire.

Summary Description: This line graph provides a visual depiction of the data points for scores on the BSI-18 questionnaire in regard to the depression subscale. The y-axis includes scores related to depression symptom raw-scores and he x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: This line graph is titled the BSI-18, Depression and has both Y and an x-axis. The y-axis includes tick marks for scores ranging between 0 to 20 in 5 point increments. For example, 0, 5, 10, 15, and 20. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The baseline data point has a score of 3, the pre-surgery follow-up has a score of 1 and the post-surgery follow-up has a score of 11. The line has a negative trend with a decrease between baseline and the pre-surgery follow-up and a positive trend with a large increase to the post-surgery follow-up. A key is located to the right of the line graph denoting the line represents depression scores.

Figure 4.11

Brief Description: Participant scores on the anxiety (ANX) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire.

Summary Description: This line graph provides a visual depiction of the data points for scores on the BSI-18 questionnaire in regard to the anxiety subscale. The y-axis includes scores related to anxiety symptom raw-scores and the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: This line graph is titled the BSI-18, Anxiety and has both y and an x-axis. The y-axis includes tick marks for scores ranging between 0 to 18 in 2 point increments. For example, 0, 2, 4, 6, 8, 10, 12, 14, 16, and 18. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the

post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The baseline data point has a score of 1, the pre-surgery follow-up has a score of 3 and the post-surgery follow-up has a score of 14. The line follows a positive trend with a slight increase between baseline and the pre-surgery follow-up and a large increase to the post-surgery follow-up. A key is located to the right of the line graph denoting the line represents anxiety scores.

Figure 4.12

Brief Description: Participant scores on the global severity index (GSI) subscale of the Brief Symptom Inventory 18 (BSI-18) questionnaire.

Summary Description: This line graph provides a visual depiction of the data points for scores on the BSI-18 questionnaire in regard to the GSI subscale. The Y-axis includes scores related to GSI raw-scores and the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3), the pre-surgery follow-up and the post-surgery follow-up.

Detailed Description: This line graph is titled the BSI-18, Global Severity Index and has both y and an x-axis. The y-axis includes tick marks for scores ranging between 0 to 50 in 5 point increments. For example, 0, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The baseline data point has a score of 7, the pre-surgery follow-up has a score of 8 and

the post-surgery follow-up has a score of 38. The line follows a positive trend with a slight increase between baseline and the pre-surgery follow-up and a large increase to the post-surgery follow-up. A key is located to the right of the line graph denoting the line represents GSI scores.

Figure 4.13

Brief Description: Compilation of raw scores of the somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire measured at three different points in time.

Summary Description: This graph provides 4 separate lines depicting the data points across three time points for somatization, depression, anxiety, and the global severity index in regards to the raw scores of the subscales. The y-axis includes raw scores ranging from 0 to 40 in 10 point increments while the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: The line graph is titled the BSI-18 Subscales Raw Scores and provides a comparison of the four subscales of the BSI-18 including somatization, depression, anxiety and the global-severity index with four separate line graphs of the raw scores. The y-axis includes raw scores ranging from 0 to 40 in 10 point increments. For example, 0, 10, 20, 30, and 40. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The somatization data is represented by a solid blue line with a score of 3 at baseline, 8 at the pre-surgery follow-up and a score of 14 at the post-surgery

follow-up. Depression data is represented by a broken red line with a score of 3 at baseline, 1 at the pre-surgery follow-up and a score of 11 at the post-surgery follow-up. Anxiety data is represented by a broken green line with a score of 1 at baseline, 3 at the pre-surgery follow-up and a score of 14 at the post-surgery follow-up. The GSI data is represented by a broken purple line with a score of 7 at baseline, 8 at the pre-surgery follow-up and a score of 38 at the post-surgery follow-up.

Figure 4.14

Brief Description: Compilation of t-scores of the somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire measured at three different points in time using clinical population norms.

Summary Description: This graph provides 4 separate lines depicting the data points across three time points for somatization, depression, anxiety, and the global severity index in regards to clinical norm T-scores of the subscales. The y-axis includes t-scores ranging from 0 to 80 in 10 point increments while the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: The line graph is titled the BSI-18 Subscales T-Scores (Clinical Norms) and provides a comparison of the four subscales of the BSI-18 including somatization, depression, anxiety and the global-severity index with four separate line graphs of the t-scores. The y-axis includes raw scores ranging from 0 to 80 in 10 point increments. For example, 0, 10, 20, 30, 40, 50, 60, 70, and 80. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery

follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The somatization data is represented by a solid blue line with a score of 53 at baseline, 55 at the pre-surgery follow-up and a score of 73 at the post-surgery follow-up. Depression data is represented by a broken red line with a score of 55 at baseline, 46 at the pre-surgery follow-up and a score of 67 at the post-surgery follow-up. Anxiety data is represented by a broken green line with a score of 43 at baseline, 48 at the pre-surgery follow-up and a score of 68 at the post-surgery follow-up. The GSI data is represented by a broken purple line with a score of 48 at baseline, 50 at the pre-surgery follow-up and a score of 71 at the post-surgery follow-up.

Figure 4.15

Brief Description: Compilation of t-scores of the somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire measured at three different points in time using community population norms.

Summary Description: This graph provides 4 separate lines depicting the data points across three time points for somatization, depression, anxiety, and the global severity index in regards to community norm T-scores of the subscales. The y-axis includes t-scores ranging from 0 to 80 in 10 point increments while the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: The line graph is titled the BSI-18 Subscales T-Scores (Community Norms) and provides a comparison of the four subscales of the BSI-18 including somatization, depression, anxiety and the global-severity index with four separate line graphs of the t-scores.

The y-axis includes raw scores ranging from 0 to 80 in 10 point increments. For example, 0, 10, 20, 30, 40, 50, 60, 70, and 80. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The somatization data is represented by a solid blue line with a score of 55 at baseline, 59 at the pre-surgery follow-up and a score of 74 at the post-surgery follow-up. Depression data is represented by a broken red line with a score of 50 at baseline, 45 at the pre-surgery follow-up and a score of 66 at the post-surgery follow-up. Anxiety data is represented by a broken green line with a score of 45 at baseline, 52 at the pre-surgery follow-up and a score of 70 at the post-surgery follow-up. The GSI data is represented by a broken purple line with a score of 49 at baseline, 50 at the pre-surgery follow-up and a score of 73 at the post-surgery follow-up.

Figure 4.16

Brief Description: Participant percentiles for somatization, depression (DEP), anxiety (ANX), and global severity index scores (GSI) of the Brief Symptom Inventory (BSI-18) questionnaire.

Summary Description: This graph provides 4 separate lines depicting the data points across three time points for somatization, depression, anxiety, and the global severity index in regards to percentiles based on the clinical norms. The y-axis includes t-scores ranging from 0 to 100 in 10 point increments while the x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3).

Detailed Description: The line graph is titled the Percentiles based on clinical population norms and provides a comparison of the four subscales of the BSI-18 including somatization, depression, anxiety and the global-severity index with four separate line graphs of the percentiles. The y-axis includes raw scores ranging from 0 to 100 in 10 point increments. For example, 0, 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100. The x-axis has three tick marks representing the three data collection sessions of baseline (week 1), the pre-surgery follow-up (week 2) and the post-surgery follow-up (week 4). The x-axis also has a dotted line between the pre-surgery and post-surgery follow-up tick marks denoting the time of surgery (week 3). The somatization data is represented by a solid blue line with a score of 62 at baseline, 69 at the pre-surgery follow-up and a score of 99 at the post-surgery follow-up. Depression data is represented by a broken purple line with a score of 69 at baseline, 34 at the pre-surgery follow-up and a score of 96 at the post-surgery follow-up. Anxiety data is represented by a broken green line with a score of 24 at baseline, 42 at the pre-surgery follow-up and a score of 96 at the post-surgery follow-up. The GSI data is represented by a broken red line with a score of 42 at baseline, 50 at the pre-surgery follow-up and a score of 96 at the post-surgery follow-up.