The Influence of Mindfulness on Patient-Reported Outcomes Following Hip Preservation Surgery

By

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CHAPTER ONE - INTRODUCTION

THE INFLUENCE OF MINDFULNESS ON PATIENT-REPORTED OUTCOMES FOLLOWING HIP PRESERVATION SURGERY

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Hip arthroscopy surgery is an increasingly common procedure that can help relieve pain, increase hip function and delay the onset of osteoarthritis (Spiker, 2021). While hip arthroscopy generally delays the need for a hip replacement, patients may nonetheless face potentially long-lasting effects such as muscle weakness, diminished joint function, hip pain and fear (Filbay et al., 2016). These effects can be related to both the precipitating injury and surgery itself, but may also be influenced by pre-existing psychological co-morbidities (Jacobs et al., 2020). Pre-operative anxiety and depression, for example, can negatively influence hip arthroscopy outcomes such as hip function and patient-reported outcomes (Cheng et al., 2020). Mindfulness meditation has been shown to be as effective as other cognitive and pharmaceutical therapies in treating a number of different mental health conditions (Goldberg et al., 2018). Remote delivery of mindfulness allows the intervention to be scalable, and its content to be standardized (Goldberg et al., 2020; Hirshberg, Flook, et al., 2022). Although psychological factors influence outcomes in hip arthroscopy patients, we are aware of no prior research that has evaluated the influence of behavioral interventions on post-surgical outcomes in this population. In this study, we will use a single-blind, randomized clinical trial design to evaluate the effects of a smartphone-based mindfulness program on patient-reported outcomes following hip arthroscopy surgery.

MUSCULOSKELETAL CONDITIONS

Musculoskeletal conditions are common, have a significant cost to society, and can lead to long-lasting psychosocial and physical detriments to patients. In 2009-2011, the average annual total direct costs of care for musculoskeletal disease were estimated at $796.3 billion, and the associated indirect costs, such as time lost from work, are estimated to be far higher (Filbay et al., 2016; Gupta et al., 2005; Lawrence et al., 2008). In 2011, 33.2% of the US population reported musculoskeletal conditions, and in a 2013 National Health Interview Survey, it was found that approximately 136 million adults reported having a disabling musculoskeletal condition (*CDC - NIOSH Worker Health Charts*, 2020; Yelin et al., 2016). Among the treatments for musculoskeletal conditions involving the hip joint, hip arthroscopy is an increasingly common procedure. Between 2004 and 2009 the annual incidence of hip arthroscopy increased 365% from 1.2 to 5.6 cases per 10,000 patients seeking care for musculoskeletal conditions, with the majority of patients between 20-39 years old (Filbay et al., 2016; Montgomery et al., 2013).

HIP ARTHROSCOPY SURGERY

Hip arthroscopy surgery primarily entails repair of the cartilaginous hip labrum, and is intended to prevent or delay the onset of osteoarthritis. Long-term studies have demonstrated reliable physical outcomes at up to 10 years following surgery, with 86% of hip arthroscopy patients delaying total hip replacement by ten or more years (Zimmerer et al., 2021). Despite these favorable outcomes, hip arthroscopy patients often have psychological co-morbidities. Hip arthroscopy patients have significantly lower post-operative quality of life (QoL) scores than age-matched controls, including reduced physical activity, and poorer physical and mental health (Filbay et al., 2016). In addition, higher preoperative levels of anxiety and depression in hip arthroscopy patients are associated with worse physical functional status at baseline, which can adversely affect surgical outcomes (Kaveeshwar et al., 2022).

While the main emphasis on outcomes from hip arthroscopy is on pain and physical function, psychological factors have been shown to significantly impact surgical outcomes. Hip arthroscopy patients have a high prevalence of anxiety and depression, which has been found to negatively impact a number of surgical outcomes (Beleckas et al., 2018; Ghoneim & O'Hara, 2016; Jacobs et al., 2020; Lansdown et al., 2018). For example, one in five new orthopedic patients reports anxiety scores that exceed the threshold warranting investigation, treatment and intervention (Beleckas et al., 2018). In hip arthroscopy patients, anxiety and depression are more predictive of preoperative pain and symptoms than the tissue pathology, such as the size of the labral tear or the magnitude of bony deformity (Jacobs et al., 2017). This relationship persists after surgery, as hip arthroscopy patients with comorbid mental health disorders incur greater health care costs than patients without comorbid mental health disorders (Jacobs et al., 2020). With respect to depression, evidence suggests that postoperative pain can cause depression, but that depression also lowers the threshold for pain (Ghoneim & O'Hara, 2016). Furthermore, pre-operative levels of depression may be predictive of worse outcomes following surgery, such as greater postoperative pain and increased morbidity & mortality (Ghoneim & O'Hara, 2016; Hall et al., 2022). Interventions that can potentially alleviate pain and/or depression may improve a range of patient outcomes following surgery.

PATIENT REPORTED OUTCOMES

Patient reported outcomes (PROs) are an important measure of health conditions as reported by the patient. Since PROs are, by definition, independent of clinician or researcher interpretation, they can provide insight into various elements of patients' health. Some PROs, however, are limited by floor and ceiling effects and a skewed response distribution, and may not be directly applicable a particular patient population. In response to these challenges, PROs specifically developed for certain conditions have been developed, such as hip-related pain, function, and quality of life. In addition, programs such as the Patient-Reported Outcomes Measurement Information System (PROMIS) were created to address the need for a rigorously tested patient reported outcome measurement tool. PROMIS measures use recent advances in information technology, psychometrics, and qualitative, cognitive and health survey research to measure factors that have a major impact on health such as pain, fatigue, physical functioning, emotional distress, and social role participation (*PROMIS*, 2013).

MINDFULNESS

Mindfulness has been shown to reduce anxiety and depression in a variety of clinical populations and are being increasingly used to improve psychosocial outcomes in a variety of medical settings (Goldberg et al., 2018; Hirshberg et al., 2021). In a small pilot study of 20 patients presenting to an orthopedics surgical practice, patients were offered a 60-second mindfulness program intended to reduce pain and negative emotions (Chad-Friedman et al., 2017). Patients who viewed the mindfulness video showed statistically significant and clinically meaningful reductions in state anxiety, pain intensity, distress, anxiety, depression and anger (Chad-Friedman et al., 2017).

Mindfulness has also been shown to improve PROs in a number of clinical populations, including patients with musculoskeletal pain, cancer patients, and patients who recently underwent surgery for spontaneous subarachnoid hemorrhage (Carlson, 2016; Chad-Friedman et al., 2017; Joo et al., 2010; Würtzen et al., 2013).

Until relatively recently, access to mindfulness training has generally been limited to in-person sessions. However, smartphone-based software applications that deliver mindfulness training are becoming increasingly common, and as a result, remote delivery of mindfulness can reduce the barriers to access, such as lack of available providers, cost and logistical challenges (Goldberg et al., 2020; Hirshberg et al., 2021). Together, these findings suggest remotely delivered mindfulness holds the potential to undermine the deleterious influence of psychological factors on outcomes following hip arthroscopy surgery.

FEAR AVOIDANCE MODEL

The Fear Avoidance Model (FAM) of musculoskeletal pain suggests that cycles of rumination (pain catastrophizing, avoidance and disuse) can lead to reduced function and greater pain (Lethem et al., 1983; Vlaeyen & Linton, 2000). On the other hand, individuals who are able to avoid this ruminative cycle are better able to engage in the rehabilitation process and return to activity (see Figure 1).

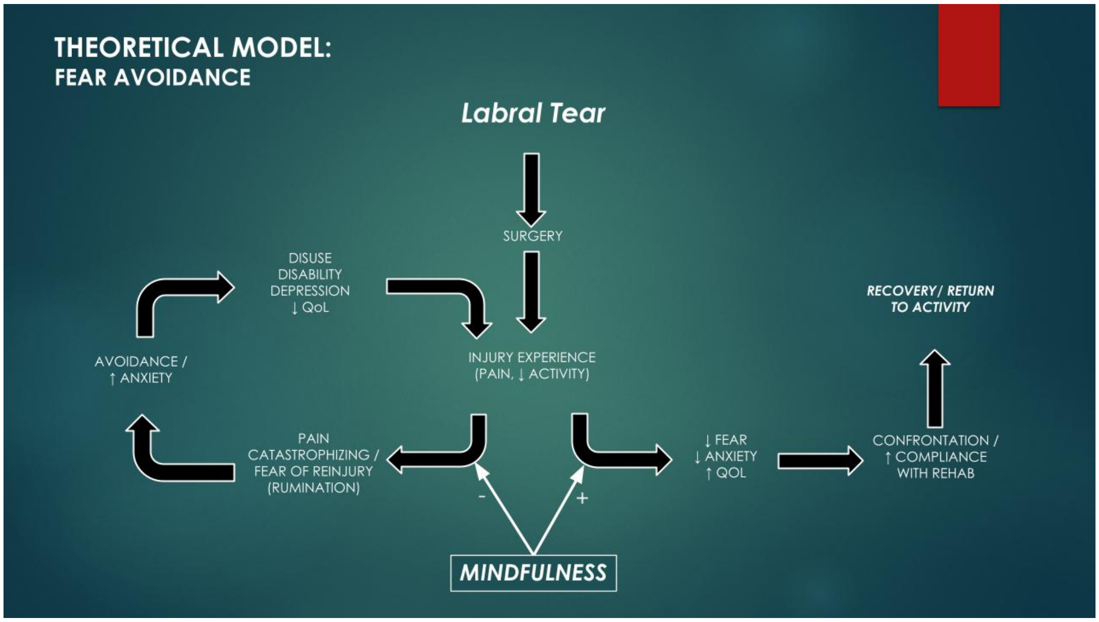


Figure 1 - Fear Avoidance Model (adapted for hip arthroscopy patients from an ACL injury model)

The reduction of rumination is a key component of mindfulness, related to dereification. Procedurally, mindfulness involves four steps; task set retention, non-aversive awareness, meta-awareness and dereification (Kabat-Zinn, 2009). In mindfulness practice, by recognizing thoughts as thoughts (meta-awareness), and not inherently possessing solidity or representing an objective reality, the power of those thoughts is reduced (dereification) (Dunne et al., 2019; Kabat-Zinn, 2009). Contrary to a common misconception, mindfulness is not about changing the thoughts that occur, but rather about changing the relationship to the thoughts that naturally arise (Kabat-Zinn, 2009). We propose that the post-surgical introduction of mindfulness practice dereifies the experiences of pain and concerns about the future that may occur during rehabilitation from hip arthroscopy. By changing the relationship to these thoughts and experiences, and interrupting the tendency toward rumination, the self-reported experience of pain is reduced.

RESEARCH SIGNIFICANCE

The incidence of hip arthroscopy has grown significantly over the past decade, and although psychosocial factors continue to influence outcomes, very little research has been conducted to evaluate the role of addressing these factors in the post-surgical period. Hip arthroscopy patients have significantly lower post-operative quality of life (QoL) scores than age-matched controls, including reduced physical activity, and poorer physical and mental health (Filbay et al., 2016). While orthopedic surgeries significantly improve PRO scores in post-operative surveys compared to pre-operative surveys, post-operative results often do not improve to the level of healthy age- and sex-matched population samples (Jansson & Granath, 2011).

By using a blinded, randomized clinical trial, we explored the influence of a scalable, low-risk, low-cost mindfulness program on PROs after hip arthroscopy, in addition to the standard of care. Delivering mindfulness via a software application with a robust body of supporting scientific evidence facilitates delivery to a large group of participants, and ensures that each participant receives standardized content (Goldberg et al., 2020; Hirshberg, Frye, et al., 2022). This can help overcome the limitations of prior investigations that have been hampered by the resources needed to deliver in-person psychological interventions. The intervention evaluated here is scalable to large groups with minimal resource use and minimal risk (Matthew J Hirshberg et al., 2020). If found to be impactful, the delivery method could allow for rapid and widespread utilization within different clinical settings.

RESEARCH AIMS AND HYPOTHESES

Study 1: The effect of mindfulness on patient-reported hip pain and function, global mental and physical health, and well-being following hip arthroscopy

Aim 1: To evaluate the effect of remotely delivered mindfulness on hip pain and function, global health and well-being following hip arthroscopy surgery.

Hypothesis 1: Among 18-50 year old patients, remote mindfulness training will be associated with improved patient-reported hip pain and function, global physical and mental health and well-being 3 months following hip arthroscopy surgery.

Primary Variables of Interest

- International Hip Outcome Tool (iHOT)
    - Total score
        - Pain
        - Symptoms & functional limitations subscale
        - Sports & recreational activities subscale
        - Job-related concerns subscale
        - Social/emotional & lifestyle subscale
- PROMIS Global Health Questionnaire
    - PROMIS Global Health Mental
    - PROMIS Global Health Physical

Study 2: Factors that influence the efficacy of remote mindfulness in patient-reported outcomes following hip arthroscopy.

Aim 2: To determine the patient characteristics that influence the effect of mindfulness on hip pain, function and well-being following hip preservation surgery.

Hypothesis 2: The influence of mindfulness on hip pain, hip function and global physical and mental well-being 3-months following hip arthroscopy surgery will be greater among participants with higher preoperative anxiety, such as women and people with hypermobility.

Primary Variables of Interest

- International Hip Outcome Tool (iHOT)
- PROMIS Global Health Questionnaire (GHQ)
- PROMIS – Anxiety
- PROMIS - Depression
- Demographic information (sex, age, race)
- Beighton score
- Body Mass Index (BMI)
- Mindfulness app usage: User actions data (activity ID and information, date completed, elapsed time spent on activity, open/close the app, daily reminders enabled/disabled)

OPERATIONAL DEFINITIONS

Mindfulness: The practice of paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally.

Healthy Minds App: A smartphone-based meditation app that includes four modules, with practices aimed at developing skills supportive of well-being.

Hip Arthroscopy Surgery: Surgery performed to treat severe and restrictive hip pain, often related to hip chondropathy and may involve labral debridement or repair, femoral and/or acetabular osteochondroplasty, loose body removal and/or synovectomy.

Hip Function: Self-reported hip-function as related to gait and functional activities.

Hip Pain: Self-reported pain as related to its impact on physical activity.

Beighton score: The Beighton score is a measure of joint mobility, ranging from 0-9, with higher being indicative of greater mobility. A Beighton score ≥ 5 is considered indicative of joint hypermobility.

ASSUMPTIONS AND LIMITATIONS

1. Participants will actively engage with the app's content during its use.
2. Participants will accurately and honestly complete the PROs.

CHAPTER TWO – REVIEW OF THE LITERATURE

MUSCULOSKELETAL CONDITIONS

Aging is among the four sufferings of conditioned existence, and one of the challenges of aging is the pain and debility that can result from orthopedic conditions (Gethin, 1998). Musculoskeletal conditions, particularly osteoarthritis (OA), are common. OA alone impacts almost 10% of US adults over the age of 45 years old (Filbay et al., 2016; Lawrence et al., 2008). From 1996 – 1998, the incidence of musculoskeletal conditions was 28% and increased by 21% in 2012-2014 to impact 34% of the US population (*CDC - NIOSH Worker Health Charts*, 2020; Yelin et al., 2019). The associated costs have increased at an even greater rate, as in these same time periods, medical expenditures on orthopedic conditions increased by 134% (Yelin et al., 2019).

While a disproportionate amount of this increase is among older adults, an increasing number of younger adults live with hip pain related to intra-articular pathology. This intra-articular pathology is often a precursor to the development of OA, and a recent study showed that approximately one in three people with OA are under 55 years of age (Filbay et al., 2016). Degeneration of hip labrum cartilage is a common intra-articular pathology that can lead to OA (Filbay et al., 2016). An increasing number of young adults aged 20 – 39 years experience pain related to hip cartilage degeneration, and hip arthroscopy is thought to delay the progression of this intra-articular damage that can be a precursor to OA (Zimmerer et al., 2021).

HIP ARTHROSCOPY

The hip is a ball and socket joint, where the femoral head is the ball and the acetabulum is the socket. (Figure 2) The cartilage lining the rim of the acetabulum, the labrum, deepens the hip socket, aids with joint stability, and helps the femoral head move smoothly within the socket.

The labrum can be damaged due to predisposing anatomical conditions such as femoroacetabular impingement (FAI), injury or as part of a degenerative process, resulting in pain, stiffness, and/or mechanical symptoms such as clicking, catching or locking (*Hip Labral Tear*, 2018; Kapandji, 1990). Labral injuries are often initially treated with activity modification, over-the-counter pain relievers, corticosteroid injections and/or physical therapy. Individuals with more severe damage to the labrum, or those with persistent symptoms despite conservative management, are often treated surgically with hip arthroscopy (*Hip Labral Tear*, 2018).

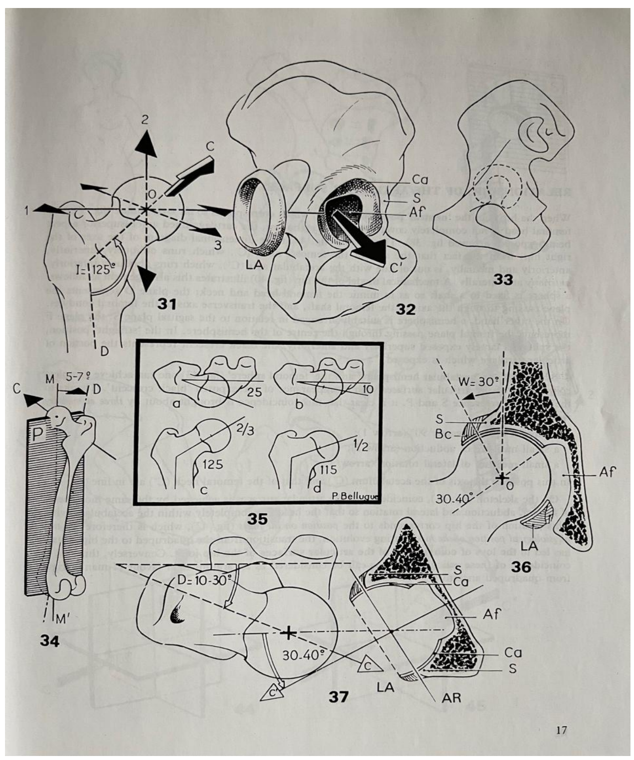


Figure 2 – Labrum labelled LA in 32, 36 and 37 (from Kapandji, 1990)

Hip arthroscopy is a relatively new procedure, though its utilization has grown rapidly in the past two decades (Filbay et al., 2016). The incidence of hip arthroscopy has increased by 365% from 2004 – 2009, with the vast majority of the surgeries performed among young adults (Filbay et al., 2016). In the past, many patients with hip pain were misdiagnosed with muscle strains, or told that their hips appeared normal on a radiograph and thus there was nothing that could be done to treat their pain and reduced function (Spiker, 2021). Due to improvements in imaging technology, greater exposure to this procedure in resident and fellow training programs, and improvements in the surgical tools, hip preservation surgery (arthroscopy) is now more commonplace (Spiker, 2021). Advanced medical imaging, particularly magnetic resonance imaging (MRI) and 3-dimensional computed tomography (CT), allows for a more detailed view of hip anatomy and pathology. Improved tools and implants have also contributed to increasingly successful outcomes (Spiker, 2021).

Hip arthroscopy is a minimally invasive surgical intervention that can include a number of different procedures, including labral debridement or repair, femoral or acetabular osteochondroplasty, loose body removal and/or synovectomy. In addition to the goals of reducing pain and improving function, hip arthroscopy surgery is also intended to delay the development or progression of OA and the need for a hip replacement (total hip arthroplasty, or THA) (Spiker, 2021; Westermann et al., 2019). As such, one of the measures of successful hip arthroscopy is the avoidance of THA, or increased hip survival (Zimmerer et al., 2021). Among the variables associated with reduced hip survival are advanced age, Tönnis grade > 1 (evidence of OA from radiographs) and female gender (Zimmerer et al., 2021). In addition, hip hypermobility and anxiety are risk factors for poorer rates of hip survival (Atwell et al., 2021; Spiker, 2021).

PATIENT REPORTED OUTCOMES

PROs are an important measure of a patient’s health status. Because they are independent of clinician or researcher interpretation, PROs can provide insight into the patient’s lived experience of their own health. There are many PROs used in clinical practice and research settings, covering a wide range of conditions. Unfortunately, many PROs have important shortcomings, such as floor and ceiling effects, high response burden, and limitations in form (*PROMIS*, 2013).

HIP PAIN AND FUNCTION

In recent years, PROs have become an important element of the care of individuals with musculoskeletal conditions, and an increasingly valuable measure of post-surgical outcomes. There are several hip-specific PROs, such as the International Hip Outcome Tool (iHOT), modified Harris Hip Score (mHHS) and the Hip Outcome Score (HOS, daily activities and sport specific). Each of the aforementioned hip outcome instruments are intended for specific populations. The mHHS and HOS are primarily intended for patients with a hip fracture or undergoing total hip arthroscopy, whereas the iHOT was designed for use with the typically younger, more active population that often undergoes hip arthroscopy. The iHOT is more useful in evaluating outcomes in hip arthroscopy due to reducing the ceiling effects that are often found in other hip-specific PRO instruments (Mohtadi et al., 2012).

The iHOT was developed for active patients ages 18 – 60 years. The original iHOT contained 33-questions, and was found to be reliable, showing face, content and construct validity. In addition, the IHOT-33 was found to be highly responsive to clinical change (Mohtadi et al., 2012). A 2015 review by Ramisetty and colleagues stated that “Critical appraisal of the development, measurement properties and head-to-head comparison studies suggest that the IHOT-33 is the recommended PRO tool for future use in hip preservation surgery.” (Ramisetty et al., 2015).

Unfortunately, the length of the iHOT-33 can be an impediment for clinical use, and a shorter, 12-question version was developed (see Figure 3). The iHOT-12 is similarly internally consistent, valid, reliable and responsive to change (Griffin et al., 2012). The iHOT-12 consists of 12-items, scored on a 0-100 scale, with higher scores representing better hip-related QoL (Griffin et al., 2012). Both the iHOT-12 and the iHOT-33 report pain level and four functional domains. In the iHOT-12 (see Figure 3), participants self-report pain in question 1. The four domains of the iHOT representing different elements of hip function include symptoms & functional limitations, sports & recreational activities, job-related concerns and social/emotional & lifestyle (Griffin et al., 2012). Symptoms and functional limitations are self-reported in questions 1, 2, 3, and 4. Sports and recreational activities are reported in questions 6, 7 and 11. Job-related concerns are reported in question 5. Social and emotional & lifestyle concerns are reported in questions 8, 9, 10 and 12 (Griffin et al., 2012). The threshold values to achieve a minimal clinically important difference (MCID) with the iHOT is 15.1 (Nwachukwu et al., 2020).

iHOT12

INTERNATIONAL HIP OUTCOME TOOL

NAME

DATE OF BIRTH

TODAY'S DATE

WHICH HIP IS THIS SURVEY ABOUT?

If we've asked you to tell us about one hip in particular, tick that. Otherwise, tick the one which causes most trouble.

◯ Left

◯ Right

QUALITY OF LIFE QUESTIONNAIRE FOR YOUNG, ACTIVE PEOPLE WITH HIP PROBLEMS

INSTRUCTIONS

- These questions ask about the problems you may be experiencing in your hip, how these problems affect your life, and the emotions you may feel because of these problems.
- Please indicate the severity by marking the line below each question with a slash.
  - If you put a mark on the far **left** it means that you **feel you are significantly impaired**. For example:

    SIGNIFICANTLY IMPAIRED /________________________________ NO PROBLEMS AT ALL

  - If you put a mark on the far **right**, it means that you **do not think that you have any problems** with your hip. For example:

    SIGNIFICANTLY IMPAIRED ________________________________/ NO PROBLEMS AT ALL

  - If the mark is placed in the middle of the line, this indicates that you are moderately disabled, or in other words, between the extremes of 'significantly impaired' and 'no problems at all'. It is important to put your mark at either end of the line if the extreme descriptions accurately reflect your situation.

TIP If you don't do an activity, imagine how your hip would feel if you had to try it.

- Please let your answers describe the typical situation in the last **month**.

Q1 Overall, how much pain do you have in your hip/groin?

EXTREME PAIN ________________________________ NO PAIN AT ALL

Q2 How difficult is it for you to get up and down off the floor/ground?

EXTREMELY DIFFICULT ________________________________ NOT DIFFICULT AT ALL

Q3 How difficult is it for you to walk long distances?

EXTREMELY DIFFICULT ________________________________ NOT DIFFICULT AT ALL

Q4 How much trouble do you have with grinding, catching or clicking in your hip?

SEVERE TROUBLE ____ NO TROUBLE AT ALL

Q5 How much trouble do you have pushing, pulling, lifting or carrying heavy objects?

SEVERE TROUBLE ____ NO TROUBLE AT ALL

Q6 How concerned are you about cutting/changing directions during your sport or recreational activities?

EXTREMELY CONCERNED ____ NOT CONCERNED AT ALL

Q7 How much pain do you experience in your hip *after* activity?

EXTREME PAIN ____ NO PAIN AT ALL

Q8 How concerned are you about picking up or carrying children because of your hip?

EXTREMELY CONCERNED ____ NOT CONCERNED AT ALL

Q9 How much trouble do you have with sexual activity because of your hip?

☐ This is not relevant to me

SEVERE TROUBLE ____ NO TROUBLE AT ALL

Q10 How much of the time are you aware of the disability in your hip?

CONSTANTLY AWARE ____ NOT AWARE AT ALL

Q11 How concerned are you about your ability to maintain your desired fitness level?

EXTREMELY CONCERNED ____ NOT CONCERNED AT ALL

Q12 How much of a distraction is your hip problem?

EXTREME DISTRACTION ____ NO DISTRACTION AT ALL

Figure 3 - iHOT-12 questionnaire (from Griffin, 2012)

GLOBAL PHYSICAL AND MENTAL HEALTH AND WELL-BEING

To explore global mental and physical well-being, the PROMIS Global Health Questionnaire (GHQ) was developed. The PROMIS measures come from the Common Fund of the National Institutes of Health, who developed the Patient Reported Outcomes Measurement

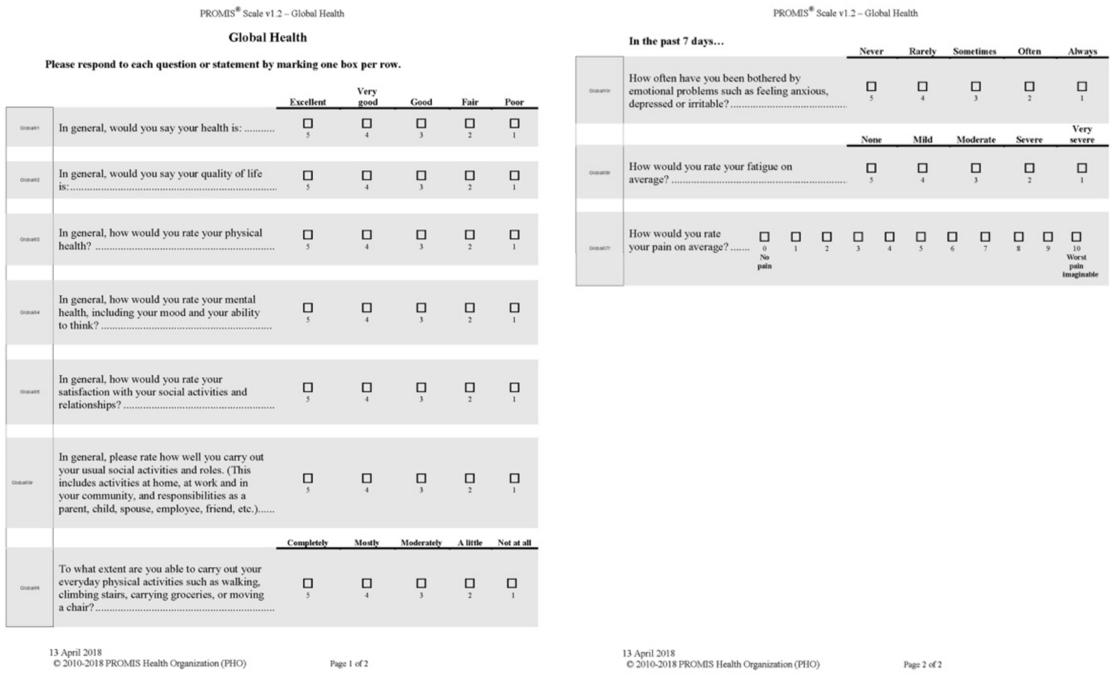
Information Systems (PROMIS) program in 2004 to develop new paradigms for how clinical research information is collected, used, and reported. In the intervening years, over three-hundred measures of well-being (physical, mental and social health) have been developed for use with the general population and those living with chronic conditions (*PROMIS*, 2013). PROMIS is built upon item response theory and was extensively tested and validated in large and varied populations. PROMIS measures multiple domains within an overall structure that are divided into physical, mental and social components, in both variable and fixed input formats. These formats are designed to reduce the time required for patients to complete (Jones & Stukenborg, 2017).

A common characteristic among the many PROMIS instruments is their concise form. Whereas many PROs may have dozens of questions and a high response burden, PROMIS instruments are more concise, often consisting of 4 – 6 questions. In addition, the PROMIS instruments have been translated into many languages, thus increasing the diversity of sample pools. To further facilitate accessibility, PROMIS measures are administrable in various forms, such as paper, with an app on a mobile device, or with a computer (*PROMIS*, 2013).

PROMIS measures also have greater precision than many legacy instruments and a common metric. The T-score for all PROMIS measures have a mean of 50 and standard deviation of 10. They have a larger range of measure than many legacy PROs, which decreases floor and ceiling effects. The greater precision (with less error) allows studies to be sufficiently powered with smaller sample sizes than was possible with legacy PROs, and PROMIS scores can be compared regardless of form (paper, app or computer). PROMIS measures have also been linked to many other PROs, facilitating comparability across studies (*PROMIS*, 2013).

The PROMIS Global Health Questionnaire consists of ten questions that assess general domains of health and functioning (see Figure 4). These domains include overall physical health, overall perceived quality of life, mental health, fatigue, social health, and pain. Each individual question can be examined separately to provide specific information about the aforementioned domains, and the PROMIS GHQ also offers Global Physical Health (GPH) and Global Mental Health (GMH) subscales.

Scores in the PROMIS GHQ range from 0 – 100, with higher scores indicating greater QoL (*PROMIS*, 2013) The threshold value to achieve an MCID in the Mental Component score is 3.0 (Bido et al., 2021; Jensen et al., 2017). The threshold value to achieve MCID in the Physical Component score is 2.3 (Bido et al., 2021; Darrith et al., 2021). The PROMIS mental health scores have been found to be highly correlated with both pain and physical function. As shown in Figure 5, greater anxiety is associated with reduced physical function (a), and greater pain interference (b) (Beleckas et al., 2018).



PROMIS® Scale v1.2 – Global Health

Global Health

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

	Excellent	Very good	Good	Fair	Poor
In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

	Completely	Mostly	Moderately	A little	Not at all
To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

13 April 2018
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PROMIS® Scale v1.2 – Global Health

In the past 7 days…

	Never	Rarely	Sometimes	Often	Always
How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

	None	Mild	Moderate	Severe	Very severe
How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

How would you rate your pain on average?	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst pain imaginable

13 April 2018
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Figure 4 – GHQ (from PROMIS, 2013)

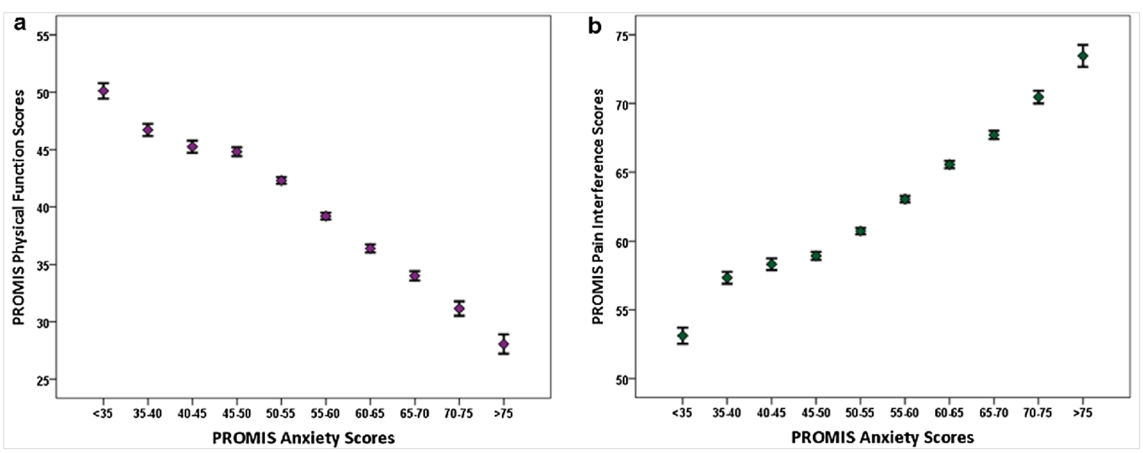

Figure 5 - Relationship between PROMIS anxiety scores and PROMIS (a) physical function and (b) pain interference (from Beleckas, 2018)

PATIENT REPORTED ANXIETY AND DEPRESSION

To explore anxiety and depression, the PROMIS Anxiety and PROMIS Depression instruments were developed. As described above, the PROMIS measures come from the Common Fund of the National Institutes of Health, who developed the Patient Reported Outcomes Measurement Information Systems (PROMIS) program in 2004 to develop new paradigms for how clinical research information is collected, used, and reported (*PROMIS*, 2013).

The PROMIS Anxiety (v.1.0) is designed to capture the trait of anxiety, rather than a temporary state of anxiety. The 8 item instrument captures the patient's emotional distress caused by stress, fear, hyperarousal and related somatic symptoms. Scores in the PROMIS Anxiety range from 0 – 100, with higher scores indicating greater anxiety (Beleckas et al., 2018)

Similarly, the PROMIS Depression (v.1.0) is designed to capture the trait of depression and is an 8 item instrument. The PROMIS Depression instrument measures negative mood, self-image, social interaction and affect. Scores in the PROMIS Depression range from 0 – 100, with higher scores indicating greater depression (Beleckas et al., 2018).

ANXIETY AND DEPRESSION

Musculoskeletal surgeries are a case-study of the bidirectional relationship of body and mind, as the degree of tissue pathology may be less predictive of symptom severity than psychological factors. For example, among patients with rotator cuff tears and OA of the shoulder, the severity of the degeneration or tear is less predictive of pre-operative pain than depression and anxiety (Jacobs et al., 2017). Both pre-operatively and post-operatively, the influence of mental health on outcomes is significant. Patients seeing orthopedic surgeons have a high prevalence of anxiety, and this heightened anxiety is associated with worse patient-reported function (Beleckas et al., 2018). In addition, anxiety is also associated with higher levels of pain and less satisfaction with the treatment of their musculoskeletal conditions (Beleckas et al., 2018). Because anxiety is a modifiable condition, addressing the anxiety can directly improve surgical outcomes (Beleckas et al., 2018).

In the case of hip arthroscopy to address FAI, patients with a history of anxiety or depression have consistently reported lower patient-reported outcomes than patients without anxiety or depression both before and after the surgical intervention (Beleckas et al., 2018; Ghoneim & O'Hara, 2016; Hall et al., 2022; Jacobs et al., 2020; Lansdown et al., 2018). In a 2020 review, Cheng and colleagues reported that baseline psychological impairments were associated with clinically significantly worse outcomes following hip arthroscopy surgery. This meta-analysis of 12 studies representing more than 5000 patients found that patients with baseline anxiety or depression scored 20.2 points (95% Confidence Interval, 7.5 to 32.9 points) worse on a composite of hip-related PROs post-operatively than did patients without baseline impairment, which significantly exceeds the MCIDs of the various PROs included in this review. Among their conclusions was "The next step is to identify feasible interventions that effectively optimize psychological health…" (Cheng et al., 2020). In a more recent (2022) review, Hall and colleagues reported that uncontrolled mental illness in hip arthroscopy patients was associated with poorer outcomes before and after hip arthroscopy surgery, including lower rates of achieving MCID in PROs such as the iHOT and mHHS (Hall et al., 2022).

While the causal pathways remain unclear, psychological comorbidities such as depression lead to an upregulation of inflammatory pathways. Whether an injury precipitates greater depression, or the presence of depression worsens the experience of an injury remains unclear, but the relationship between mental health conditions and increased levels of inflammatory markers such as IL-1, IL-4, IL-6, interferon alpha, tumor necrosis factor α and other inflammatory cytokines have been reported (Sochacki et al., 2018). Because these inflammatory cytokines are able to cross the blood-brain barrier and act upon neural centers, this inflammatory cascade may increase the patient's perception of pain due to the synergistic interplay of pain and depression (Sochacki et al., 2018).

JOINT HYPERMOBILITY

Joint hypermobility (JH) refers to increased passive or active movement of a joint beyond the normal range of motion. In an orthopedic clinical setting, joint range of motion can be determined through physical examination and the Beighton hypermobility score (Table 1) is often employed to identify patients with generalized JH (Atwell et al., 2021; Beighton, 2012).

Table 1 - Beighton hypermobility score (from Atwell et al., 2021)

Can place hands flat on the floor without bending the knees	1 point	
	Right	Left
Can passively dorsiflex the fifth metacarpophalangeal joint to 90° or greater	1 point	1 point
Can oppose the thumb to volar aspect of forearm	1 point	1 point
Can hyperextend the elbow 10° or more	1 point	1 point
Can hyperextend the knee 10° or more	1 point	1 point

Criterion 1—generalized joint hypermobility
Beighton score __/9 - ≥ 6 for prepubertal children and adolescents - ≥ 5 for pubertal men and woman to age 50 - ≥ 4 for men and women over age 50 *If Beighton score is 1 point below age-specific cutoff, affirmative answer to 2 of the following questions will meet criterion 1.* - Can you now (or could you ever) place your hands flat on the floor without bending your knees? - Can you now (or could you ever) bend your thumb to touch your forearm? - As a child, did you amuse your friends by contorting your body into strange shapes or could you do the splits? - As a child or teenager did your shoulder or kneecap dislocate on more than one occasion? - Do you consider yourself "double jointed"?

People with generalized JH may also be at an increased risk of concomitant conditions, such as chronic joint pain, skin manifestations, anxiety, depression, dysautonomia and exercise intolerance (Atwell et al., 2021). In a 2016 review, Mallorquí-Bagué et al. proposed a model of how the non-orthopedic symptoms of generalized JH, such as dysautonomia, interoceptive sensitivity and anxiety are interrelated (Mallorquí-Bagué et al., 2016; Mallorquí-Bagué et al., 2014). In a brain imaging study, Mallorquí-Bagué et al. showed a significant relationship between generalized JH (Beighton score) and state anxiety that was mediated by interoceptive sensitivity. In addition, when compared to participants without generalized JH, participants with generalized JH displayed heightened neural reactivity to sad and angry scenes within brain regions implicated in anxious feeling states, notably the insular cortex (Mallorquí-Bagué et al., 2016; Mallorquí-Bagué et al., 2014).

Generalized JH is also associated with an increased risk of joint injury, and damage to the hip labrum is disproportionately found in people with generalized JH (Clapp et al., 2021). People with generalized JH are often drawn to activities where flexibility and extreme ranges of motion, such as dance, gymnastics & yoga, confers an advantage. Unfortunately, the biomechanics and repetitive loading related to these extreme ranges of motion can damage the hip labrum and result in instability of the joint (Clapp et al., 2021).

MINDFULNESS

Mindfulness meditation has become increasingly popular in the United States and many other countries in the last two decades. Between 2012 and 2017, the number of US adults who reported meditating more than tripled from 4.1% to 14.2% (Clarke et al., 2018). The term "mindfulness" derives from the Sanskrit word *smrti*. The cultivation of *smrti* is a common thread across Buddhist traditions, and is defined as "that which prevents distraction" (Dunne, 2015;

Dunne et al., 2019; Harrington & Dunne, 2015; Wielgosz et al., 2019). In modern, common utilization, mindfulness can refer to many things, and the scientific literature has variously defined mindfulness as a spiritual path for cultivating well-being and relieving suffering, a term used to reference a mental trait, or a trainable cognitive trait (S. Goldberg et al., 2021). Frequently, the operational definition offered by the founder of Mindfulness-Based Stress Reduction, Jon Kabat-Zinn, is utilized: task-set retention, non-aversive awareness, meta-awareness and dereification (Kabat-Zinn, 2009). This definition is often accompanied by the procedural definition; pay attention, on purpose, in the present moment, non-judgmentally (Kabat-Zinn, 2009).

Mindfulness has been studied in a wide variety of pain-related disorders, such as irritable bowel syndrome, chronic pelvic pain, fibromyalgia, lower-back pain and other conditions. In a pioneering study 40+ years ago, Dr. Jon Kabat-Zinn and colleagues demonstrated how the Mindfulness-Based Stress Reduction program reduced chronic pain symptomology and improved QoL not only upon the completion of the 8-week program, but also at a 3-year follow up (Grossman et al., 2007; Kabat-Zinn et al., 1985; Zeidan & Vago, 2016). Since this study, the scientific inquiry into mindfulness has proliferated, and various mechanisms have been described. Among the many clinical indications for the use of mindfulness meditation are the management of anxiety, depression and pain (Chad-Friedman et al., 2017; Goldberg et al., 2020; S. B. Goldberg et al., 2021).

The benefits of mindfulness meditation practice may include structural changes in the brain (Davidson & McEwen, 2012; Kral et al., 2022). In expert meditators (those with > 10,000 hours of lifetime practice), neural habituation to pain and its anticipation were found to be significantly faster than age-matched controls. In addition, these expert meditators had less anxiety-related activity in regions of the brain associated with pain perception and the amygdala during anticipated pain (Lutz et al., 2013). In subsequent studies, it has been found that mindfulness meditation engages multiple brain mechanisms that reduce the subjective experience of pain (Wielgosz et al., 2022; Zeidan & Vago, 2016).

Pain is a constructed experience that is moderated by a combination of sensory, cognitive, and affective factors. These factors include prior pain cognitive states, such as anxiety and depression, making pain a complex and subjective conscious experience. The changing perception and meaning assigned to pain arises through activation of higher-order brain regions, such as the anterior cingulate cortex (ACC) and prefrontal cortex (PFC). Because of these perceptual interpretations of pain, the subjective experience of pain is highly influenced by the context in which it occurs. Previous experiences, expectations, conditioning, sensitization/habituation, mood, desires, and other cognitive factors can dramatically amplify or attenuate pain (Zeidan & Vago, 2016).

In a 2012 study by Grant and colleagues, meditators were found to have greater activity in brain regions associated with affective and sensory pain processing while they experienced pain. The brain regions associated with emotion, memory and appraisal of pain had the largest effects and were accompanied by reduced reports of pain intensity. Meditators had reduced connectivity between the dorsolateral prefrontal cortex (DLPFC) and dorsal anterior cingulate cortex (dACC), and the degree of this connectively correlated with their baseline pain sensitivity in comparison to the age and gender matched controls (see Figure 6). Meditators had stronger pain-related activation of spinothalamic nociceptive tract targets (dACC, thalamus and insula cortex), though the temperatures required to elicit a moderate-pain level (defined as the temperature required to elicit a pain intensity rating between 6–7 on an 11-point, visual analogue scale) were significantly higher than in the controls (Grant et al., 2011).

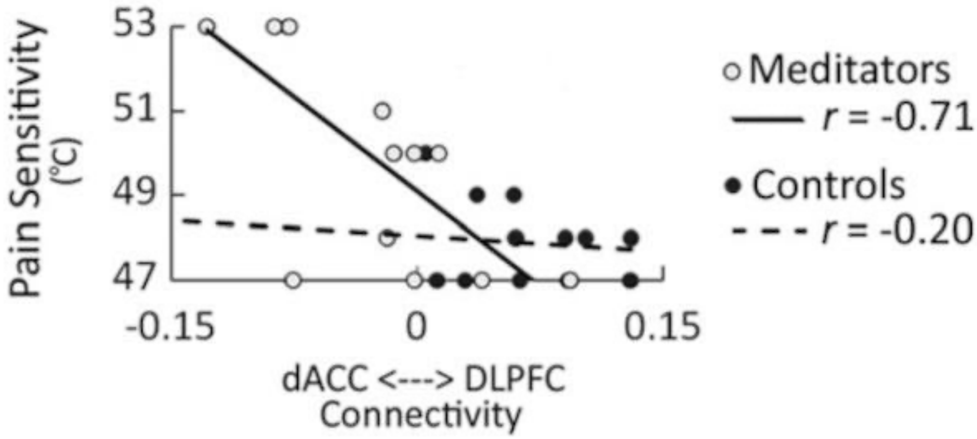

Figure 6 - Expert meditators showed reduced dACC and DLPFC connectivity (from Grant et al., 2012)

In another brain imaging study, Gard and colleagues found that mindfulness practitioners were able to reduce pain anticipatory anxiety by 29% and pain unpleasantness by 22% in comparison to age, gender, handedness and education matched controls. These reductions were associated with increased rostral anterior cingulate cortex activation during the anticipation of pain, and during the pain stimulation, increased activation in the right posterior insula and decreased activation in the lateral prefrontal cortex (Gard et al., 2012).

Mindfulness meditation is associated with greater activation in the orbitofrontal, subgenual anterior cingulate and anterior insular cortices. This brain region activity is distinct from placebo-induced analgesia and sham meditation; believing that one is meditating and practicing breathing exercises has distinctly different neural activation in the brain regions involved with the facilitation and modulation of pain than does mindfulness meditation. Mindfulness meditation reduces pain anticipation and reported pain unpleasantness through mechanisms that are distinctly different than those arising from reducing respiratory rate or initiating the "relaxation response." (Zeidan et al., 2015).

Further supporting the notion that mindfulness is more than simply relaxation training, Creswell *et al.* compared the effects of mindfulness training and relaxation training on inflammatory markers both at the end of the 3-day intervention, and at a 4-month follow-up in a sample of stressed adults. Levels of IL-6 were reduced in the mindfulness meditation group, whereas levels of IL-6 increased in the relaxation training control group over the same time periods (Creswell et al., 2016).

In a 2018 review and meta-analysis, Goldberg and colleagues found that treatments based on mindfulness performed similarly to other psychological and psychiatric interventions for psychiatric disorders, and when compared to other no-treatment controls, were superior in the treatment of pain (Goldberg et al., 2018). In addition, this review found that treatments based on mindfulness were as effective in the treatments of conditions such as anxiety and depression as first-line psychiatric and psychological interventions, and superior to other control conditions (Goldberg et al., 2018). Interventions based on mindfulness hold promise for both adolescent and adult samples, and may be particularly promising in addressing psychiatric disorders and symptoms. Unfortunately, the availability of mindfulness instruction remains limited, and accessibility barriers include logistical challenges, cost, lack of available providers and time constraints (Goldberg et al., 2020).

Smartphone-based meditation applications have the potential to overcome a number of the existing limitations of in-person delivery. Over the past five years there has been a significant increase in randomized control trials testing smartphone-based meditation interventions, and preliminary evidence suggests that remote delivery may provide psychological benefits that are similar to in-person programs (e.g., increased positive functioning, decreased psychological symptoms), albeit with a smaller magnitude (Goldberg et al., 2020). Meditation delivered by smartphone-based apps are less bound by physical constraints, making mindfulness more accessible at scale and for substantially lower cost than in-person alternatives (Hirshberg et al., 2021).

In a 4-week, smartphone-based mindfulness training, school system employees had immediate small-to-moderate magnitude benefits on measures of psychological distress, and these benefits persisted for three months following the intervention (Hirshberg, Frye, et al., 2022). . As shown in Figure 7, the z-score aggregate of the NIH Perceived Stress Scale and the PROMIS anxiety and depression scale scores dropped throughout the period of the app-based delivery, and the results persisted over the following three months (Hirshberg et al., 2021).

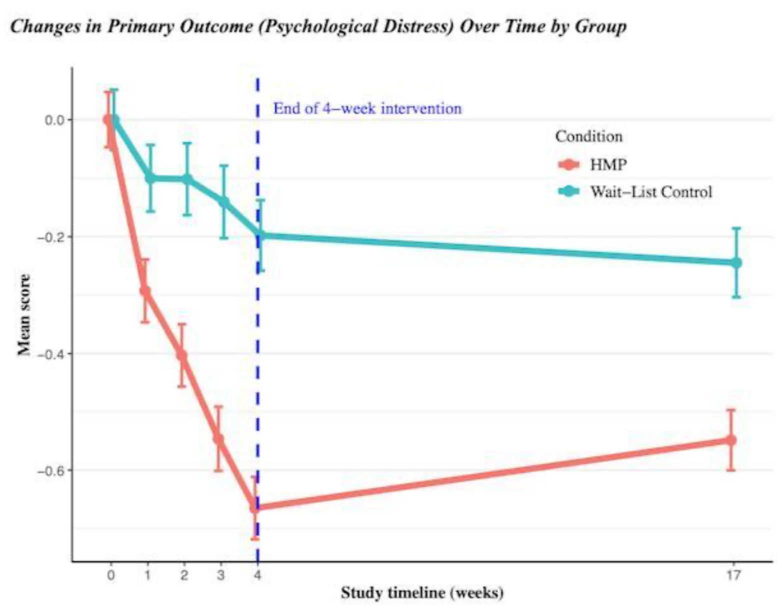

Figure 7 - Reductions in measure of psychological distress, including the antecedents of anxiety and depression, through the use of a mindfulness-based, well-being app (from Hirshberg et al., 2021)

The mindfulness meditation program of this study was a smartphone-based app, Healthy Minds Program (HMP). The HMP contents and practice durations are easily modified, and the architecture of the app is designed to be highly adaptable for research. The app design was refined through multiple user experience studies, including with school system employees, a highly diverse sample of college students, and general population adults (Hirshberg et al., 2021). In comparison to programs like Mindfulness-Based Stress Reduction (Kabat-Zinn, 2009) that require hours of participant time over multiple months, the HMP asks participants for just minutes a day of engagement (Hirshberg et al., 2021). The HMP has a very low risk of harm to participants (Matthew J. Hirshberg et al., 2020; Hirshberg et al., 2021), effectiveness for participants even with elevated baseline symptoms of anxiety and depression (Hirshberg et al., 2021) and requires minimal time investment (Hirshberg et al., 2021).

CHAPTER THREE - METHODS

Experimental Design

The overall study design for this project is mixed methods, with a single-blind, randomized clinical trial and qualitative interviews. The data utilized for this study are from the years 2021 – 2022.

Participants

The Health Sciences Institutional Review Board at the University of Wisconsin-Madison approved this study. Participants were identified through pre-operative clinical visits prior to hip arthroscopy surgery. Inclusion criteria were being 18-50 years old at the time of the pre-operative visit, having access to a mobile device compatible with the free Healthy Minds Program app (Android or iOS) and concurrent participation in the Sports Medicine Patient Reported Outcomes Clinical Database. Exclusion criteria included significant experience with meditation or mindfulness, defined as greater than 30 minutes in a month during the past year, and prior diagnosis of schizophrenia or bipolar disorder.

Procedures

During the pre-operative visit prior to surgery, interest and eligibility was determined. Following the provision of informed consent, participants were randomly assigned to the control or intervention groups in a 1:1 ratio using a random number generator. Participants in the control group received the typical, post-surgical standard of care, while participants randomized to the intervention group received 8 weeks of remote mindfulness training post-operatively, in addition to the same typical standard of care. Participants in the intervention group were provided with instructions to download the HMP app prior to their surgery date. All individuals involved in participants' care, including surgeons, physician's assistants, nurses, physical therapists, and administrative staff were blinded to the participant's group assignment. Age, surgery date, surgical side, gender, height and weight were collected directly from patient records. The study flow is shown in Figure 8.

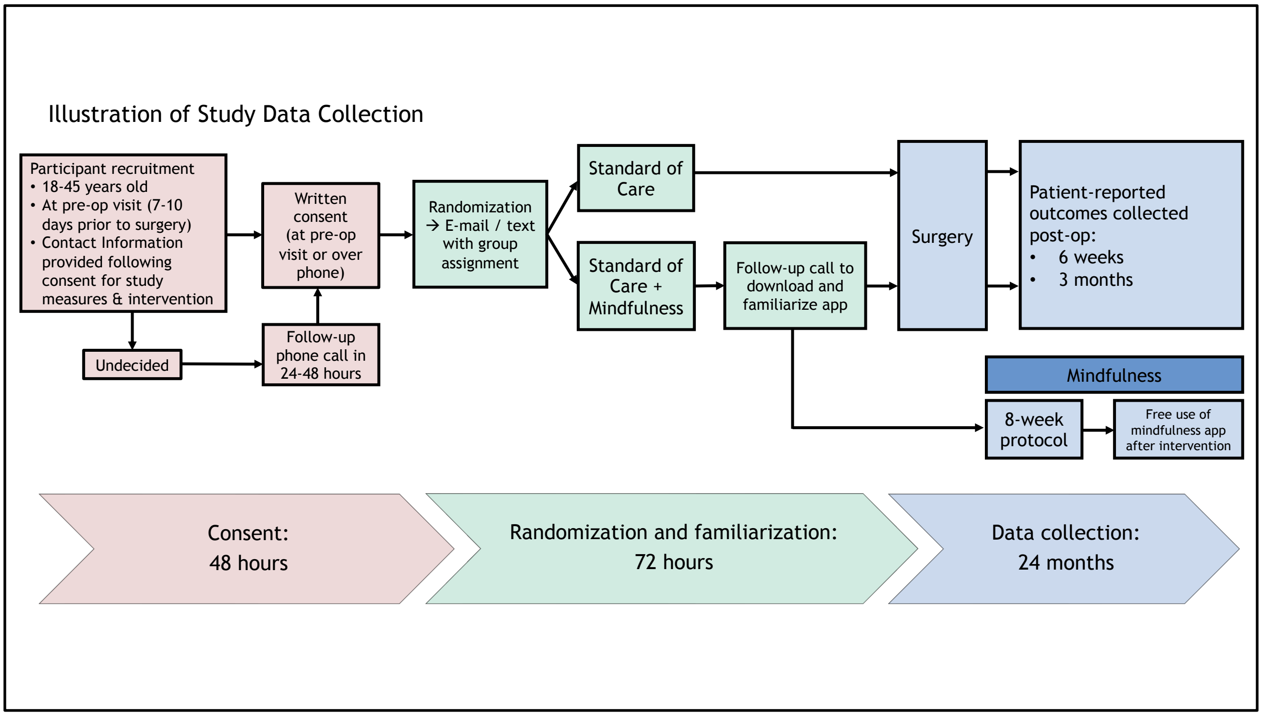

Figure 8 - Illustration of Study Flow

Remote Mindfulness Program

The full HMP app includes five modules with practices designed to cultivate categories of mental and emotional skills linked to both hedonic and eudemonic well-being (Goldberg et al., 2020). These include the cultivation of mindful attention (Awareness), positive relationships with self and others (Connection), insight into the nature of self and internal experience (Insight), and purpose, values, and meaning in life (Purpose), as well as an initial module which includes abbreviated introductions to the topics and lessons in all four areas (Foundations) (Goldberg et al., 2020). For this study, the active intervention included four weeks of training using the Foundations module followed by four weeks of training using the Awareness module.

The Foundations module includes a brief, optional self-assessment regarding each of the four categories. Each module includes brief didactic material and guided meditation practices. Didactic content includes discussion of the scientific context of the practices and the guided practices can be delivered at a self-selected length of 5-30 minutes. Participants were instructed to follow a pre-specified sequence within each module. The Foundations and Awareness modules require a minimum of 133 and 253 minutes, equating to less than 5 and less than 10 minutes per day on average, respectively. Date, duration, and content of usage were recorded for each participant through the app. Participants had access to the entire contents of the app for the full duration of the study.

To improve participant compliance with the mindfulness program, the study team encouraged study participants to consistently utilize the app. The app developer created a report of study participants' app usage that the study team downloaded twice a week through a password protected Amazon S3 server. On each of those days, participants who had not used the app in the past 3 to 5 days were sent a text message reminder, and those who had not used the app in the past 6 to 7 days received a phone call reminder. Participants were paid $25 for baseline and 3-month surveys, irrespective of group assignment.

Patient-Reported Outcomes

Prior to hip preservation surgery, and at 3-months following surgery, participants were asked to complete PRO surveys that provide information regarding pain, overall function and activity level, hip function, QoL, and hip-related QoL (see Table 2). These validated instruments have been used extensively in prior research regarding orthopedic and hip surgery to identify meaningful outcomes for patients following surgical intervention. The iHOT hip-related quality of life and function instrument is designed for active patients ages 18-60 and has demonstrated internal consistency, validity, reliability and responsiveness to change (Griffin et al., 2012).

The iHOT-12 consists of 12-items, scored on a 0-100 scale, with higher scores representing better hip-related QoL (Griffin et al., 2012). The iHOT-12 reports pain level and four functional domains. In the iHOT-12, participants self-report pain in question 1. The four domains of the iHOT include symptoms & functional limitations, sports & recreational activities, job-related concerns and social/emotional & lifestyle, each representing different elements of hip function (Griffin et al., 2012). Sports and recreational activities are reported in questions 6, 7 and 11. Job-related concerns are reported in question 5. Symptoms and functional limitations are self-reported in questions 1, 2, 3, and 4. Social and emotional & lifestyle concerns are reported in questions 8, 9, 10 and 12 (Griffin et al., 2012). The threshold values to achieve MCID with the iHOT is 15.1 (Nwachukwu et al., 2020).

The PROMIS – GHQ is a validated and concise instrument that is intended for the general population and is available in a variety of forms (*PROMIS*, 2013). The PROMIS Global Health Questionnaire consists of ten questions that assess general domains of health and functioning. These domains include overall physical health, overall perceived quality of life, mental health, fatigue, social health, and pain. Each individual question can be examined separately to provide specific information about the aforementioned domains, and the PROMIS GHQ also offers Global Physical Health (GPH) and Global Mental Health (GMH) subscales.

Scores in the PROMIS GHQ range from 0 – 100, with higher scores indicating greater QoL. (*PROMIS*, 2013) The threshold value to achieve a minimal clinically important difference (MCID) in the Mental Component score is 3.0 (Bido et al., 2021; Jensen et al., 2017). The threshold value to achieve MCID in the Physical Component score is 2.3 (Bido et al., 2021; Darrith et al., 2021).

The PROMIS Anxiety and PROMIS Depression instruments each consist of 8 questions, scored on a 0-100 scale, with higher scores representing higher levels of anxiety and depression, respectively (Beleckas et al., 2018). The PROMIS instruments are validated, concise in form, are intended for the general population and are available in multiple delivery methods (*PROMIS*, 2013).

Table 2 - Patient Reported Outcome Measures

CONSTRUCT	INVENTORY	CHARACTERISTICS	SUBSCALES / FACTORS	INTERPRETATION
Hip-related quality of life and function	International Hip Outcome Tool	● 12 items, 0-100 scale	Pain, job-related concerns, social/emotional, symptoms & functional limitations, sports & recreational activities	Higher score represents better hip-related quality of life or function
Global Health and Well-being	PROMIS Global Health Questionnaire 7+2, v1.1	● 9 items, 0-100 scale	Overall quality of life, pain interference, fatigue	Higher score represents better QOL, pain interference and fatigue
Anxiety and depression	PROMIS anxiety and depression questionnaires, v1.0	● 8 items, 0-100 scale	Emotional distress - anxiety, depression	Higher score represents greater anxiety, depression

Qualitative Participant Interviews

In addition to the quantitative measures, the present study included a qualitative component. Through the use of a four question discovery interview, selected participants who were randomized into the mindfulness group described their experience with mindfulness and the app by answering the following questions:

1. How did (or would) you describe the meditation to your friends?
2. How would you describe your experience with meditation?
3. How would you describe the impact of meditation on your recovery?
4. What suggestions do you have for the app developer regarding content, user experience, etc.?

Following the initial data collection, the four highest duration users of the app, and the four lowest (non-zero) duration users of the app were contacted to complete the interview. These eight participants were first sent an email request, and if a reply was not received within five-days, a second email request was sent. If after an additional five days a reply to the second email request was not received, these participants were then sent the same request via text message.

Data Processing

Paper questionnaires and consents that included identifiers were stored in a locked file cabinet accessible only to the study team. Data that were collected and stored through the usage of the HMP were transferred to password-protected Orthopedics & Rehabilitation departmental servers. PRO data that were collected and stored by collaborators in the Hip Arthroscopy clinic were forwarded to study personnel and transferred to password-protected Orthopedics & Rehabilitation departmental servers. Information from medical records, such as height and weight, were retrieved by authorized study personnel and transferred to password-protected

Orthopedics & Rehabilitation departmental servers. Data were managed by the primary investigators and available only to study team members.

Statistical Analysis

Univariate and bivariate summary statistics and distributional plots were examined for all variables to assess modeling and hypothesis testing assumptions. Associations between variables of interest were explored with the use of smooth scatter plots for continuous variables and cross-tabulations for discrete variables. Missing data were rare (out of a total of 396 data points, missing 3 data points in mindfulness group, and 4 data points in control group); baseline variable measurements were compared with those that did and did not supply follow-up data and no association was identified with study outcomes. As a result, missing data were treated as missing at random and were ignored in the analysis. All analyses were performed with an intent-to-treat model.

In Study 1, PRO scores and subscales were compared between groups at the 3 month follow-up timepoint using an intention-to-treat analysis with an ANCOVA model, including the baseline value of the variable, sex, age, BMI and treatment group as covariates. In the final ANCOVA models, individuals with complete data were included. Sample size was derived in R based on a two-tailed ANCOVA model to evaluate the influence of mindfulness on the continuous outcomes of iHOT. Utilizing MCID (SD) values of 15.1 (15.5) for iHOT, an estimate of 0.5 for within-subject correlation for repeated measures, required a minimum of 26 participants (13 per group) to achieve a statistical power of 0.80 at a significance level of 0.05 (Computing, 2018; Nwachukwu et al., 2020; Walters et al., 2019). For the PROMIS – GHQ, sample size was derived in R based on a two-tailed ANCOVA model to evaluate the influence of mindfulness on the continuous outcomes. Utilizing MCID (SD) values of 3.0 (2.7) for PROMIS

GHQ - Mental and 2.3 (2.3) for GHQ - Physical, an estimate of 0.5 for within-subject correlation for repeated measures, required a minimum of 20 participants (10 per group) and 24 participants (12 per group), respectively, to achieve a statistical power of 0.80 at a significance level of 0.05 (Bido et al., 2021; Darrith et al., 2021; Walters et al., 2019) Results included Cohen's d, which was interpreted using the effect size definition of small, medium and large as d=0.2, d=0.5 and d=0.8, respectively (Cohen, 1992). To evaluate any underlying relationships between missing data and study variables, baseline values of the study variables were compared between individuals with and without complete follow up data using Wilcoxon rank sum tests.

In Study 2, the influence of various moderator variables on the effect of mindfulness on patient-reported outcomes were evaluated through separate linear regressions to predict each outcome at 3 months including the baseline value of the variable and the interaction between group assignment and each moderator variable (gender, age, BMI and joint mobility). Univariate and bivariate summary statistics and distributional plots were examined for all variables to assess modeling and hypothesis testing assumptions.

Linear models were used to evaluate the relationship between minutes of app usage and the change in each outcome from baseline to 3 months, calculated as the 3 month value minus the baseline value. This was done separately for total minutes of usage as well as minutes of practice and minutes of didactic usage.

Pearson correlations were used to evaluate the relationship between the changes in anxiety and the changes in outcomes from baseline to 3 months (calculated as 3 month value minus baseline value for both). Based on the scoring of the measures, a more negative value would represent an improvement in anxiety from baseline to 3 months, while it would represent a worsening of each of the iHOT and PROMIS measures. As a result, a negative correlation would suggest that improvements in anxiety post-operatively are associated with improvements in the specific outcome.

For all components of studies 1 and 2, statistical significance was determined *a priori* at the 0.05 level, and all analyses were performed in R (Computing, 2018; Halekoh & Højsgaard, 2014).

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CHAPTER FOUR - MANUSCRIPTS

THE EFFECT OF REMOTE MINDFULNESS ON PATIENT-REPORTED HIP PAIN AND FUNCTION, GLOBAL MENTAL AND PHYSICAL HEALTH, AND WELL-BEING FOLLOWING HIP ARTHROSCOPY

ABSTRACT

Introduction: Hip arthroscopy is an increasingly common procedure that can improve hip pain and function, and delay the need for hip arthroplasty. Worse surgical outcomes are associated with baseline psychological co-morbidities, however, suggesting that the incorporation of a post-operative behavioral intervention, such as mindfulness meditation, may improve outcomes.

Purpose: To evaluate the influence of an 8-week, remotely-delivered mindfulness program on hip pain and function, and mental and physical well-being following hip preservation surgery.

Methods: Thirty-six hip arthroscopy patients ages 18-50 years were randomly assigned to two groups; standard of care, or standard of care plus mindfulness. The 8-week mindfulness program was delivered remotely via the Healthy Minds smartphone-based training. One week before surgery and three months after surgery, participants in both groups completed the International Hip Outcome Tool (iHOT) with its embedded subdomains(range 0 – 100, with higher scores representing higher function or less hip pain); symptoms & functional limitations, sports & recreational activities, job-related concerns and social/emotional & lifestyle, and PROMIS Global Health Questionnaire Mental and Physical. Additionally participants provided demographic information (age, sex, and race) and height & weight. ANCOVA models were used to compare 3-month outcomes between groups while adjusting for the baseline value, age, sex and BMI.

Results: In the mindfulness group, 9 (50%) were female, with mean (95% CI) age and BMI of 32.9 (8.7) years and 26.6 (4.4) kg/m^2, respectively. In the Control group, 13 (72%) were female

and had an age and BMI of 32.6 (8.8) years and 27.0 (5.3) kg/m^2, respectively. The mindfulness group engaged with the app 3.73 (3.5) minutes per day. The mindfulness group reported less hip pain 3-months post-surgery than the Control group, although the results were not statistically significant [mindfulness 83.63 (7.53) and control 73.89 (7.89), 95% CI, p=0.076, d=0.644]. Similarly, the mindfulness group demonstrated a non-significant trend toward less hip-related job-related concerns at 3-months post-surgery than the control group [79.66 (10.22) v. 65.95 (10.95), 95% CI, p=0.066, d=0.674]. No statistically significant differences were found in the iHOT total score or its other domains (p>0.05 for all), nor did PROMIS Global Physical [mindfulness 48.32 (3.29) and Control 48.65 (3.29), 95% CI, p=0.886, d=0.051] and Global Mental [mindfulness 50.57 (2.70) and Control 50.13 (2.70), 95% CI, p=0.822, d=0.084] scores show a statistical difference between the mindfulness and control group.

Conclusion: This pilot study suggests that remotely delivered mindfulness may be associated with reduced hip pain and hip-related job-related concerns after hip arthroscopy surgery, though may not be associated with improvements in patient-reported global physical and mental well-being indices. Further research is needed to determine the short and long-term post-operative effects of remote mindfulness.

INTRODUCTION

Hip arthroscopy surgery is an increasingly common procedure that generally delays the need for a hip replacement, though some patients may face potentially long-lasting effects that impact quality of life (Filbay et al., 2016; Spiker, 2021). These effects can be related to both the precipitating injury and surgery itself, but may also be related to pre-existing psychological co-morbidities (Jacobs et al., 2017). Pre-operative anxiety and depression, for example, can negatively influence measures of post-surgical quality of life (Cheng et al., 2020; Filbay et al., 2016).

Mindfulness meditation has been shown to be as effective as other cognitive and pharmaceutical therapies in treating mental health conditions (Goldberg et al., 2018). In the context of orthopedic surgery, a recent study showed that mindfulness was associated with statistically significant and clinically meaningful reductions in state anxiety, pain intensity, distress, anxiety, depression and anger (Chad-Friedman et al., 2017). Remote delivery of mindfulness allows the intervention to be scalable, and its content to be standardized (Goldberg et al., 2020; Hirshberg et al., 2022).

Although psychological factors are associated with worse outcomes following hip arthroscopy, we are aware of no prior research that has evaluated the influence of post-operative behavioral interventions on outcomes in population. This is likely at least partly due to the cost and logistical difficulties that accompany in-person delivery of behavioral interventions in a timely manner during the perioperative period. Therefore, the purpose of this study is to evaluate the effect of remotely delivered mindfulness on hip-related patient-reported outcomes following hip arthroscopy. We hypothesize that mindfulness training will be associated with improved hip pain and function, and quality of life 3 months following hip preservation surgery.

METHODS

Participants

This study was approved by the Health Sciences Institutional Review Board at the University of Wisconsin-Madison. Study participants were identified through pre-operative clinical visits prior to hip preservation surgery (hip arthroscopy) between January 2021 and December 2022. Inclusion criteria were being 18-50 years old at the time of the pre-operative visit, concurrent participation in the Sports Medicine Patient Reported Outcomes Clinical Database, and having access to a mobile device compatible with the free Healthy Minds Program app (Android or iOS). Exclusion criteria included significant experience with meditation or mindfulness, defined as greater than 30 minutes in a month during the past year, and prior diagnosis of schizophrenia or bipolar disorder.

Procedures

During the pre-operative visit, prior to hip preservation surgery, interest and eligibility was determined. Following the provision of informed consent, participants were randomly assigned to the control or intervention groups in a 1:1 ratio using a random number generator. Participants in the control group received the typical, post-surgical standard of care, while participants randomized to the intervention group received 8 weeks of remote mindfulness training post-operatively, in addition to the same typical standard of care. Participants in the intervention group were provided with instructions to download the HMP app prior to their surgery date. All individuals involved in participants' care, including surgeons, physician's assistants, nurses, physical therapists, and administrative staff were blinded to the participant's group assignment. Age, surgery date, surgical side, gender, height and weight were collected directly from patient records.

Remote Mindfulness Program

The full HMP app includes five modules with practices designed to cultivate categories of mental and emotional skills linked to both hedonic and eudemonic well-being (Goldberg et al., 2020). These include the cultivation of mindful attention (Awareness), positive relationships with self and others (Connection), insight into the nature of self and internal experience (Insight), and purpose, values, and meaning in life (Purpose), as well as an initial module which includes abbreviated introductions to the topics and lessons in all four areas (Foundations) (Goldberg et al., 2020). For this study, the active intervention included four weeks of training using the Foundations module followed by four weeks of training using the Awareness module.

The Foundations module includes a brief, optional self-assessment regarding each of the four categories. Each module includes brief didactic material and guided meditation practices. Didactic content includes discussion of the scientific context of the practices and the guided practices can be delivered at a self-selected length of 5-30 minutes. Participants were instructed to follow a pre-specified sequence within each module. The Foundations and Awareness modules require a minimum of 133 and 253 minutes, equating to less than 5 and less than 10 minutes per day on average, respectively. Date, duration, and content of usage were recorded for each participant through the app. Participants had access to the entire contents of the app for the full duration of the study.

To improve participant compliance with the mindfulness program, the study team encouraged study participants to consistently utilize the app. The app developer created a report of study participants' app usage that the study team downloaded twice a week through a password protected Amazon S3 server. On each of those days, participants who had not used the app in the past 3 to 5 days were sent a text message reminder, and those who had not used the app in the past 6 to 7 days received a phone call reminder. Participants were paid $25 for baseline and 3-month surveys, irrespective of group assignment.

Patient-Reported Outcomes

Prior to hip preservation surgery, and at 3-months following surgery, participants were asked to provide information regarding hip function and hip-related QoL via the iHOT survey and PROMIS Global Health Questionnaire (GHQ). The iHOT-12 is a 12 item instrument that is designed for active patients ages 18-60 to self-report their hip-related quality of life and function (Griffin et al., 2012) The iHOT instrument has demonstrated internal consistency, validity, reliability and responsiveness to change (Griffin et al., 2012). The iHOT-12 consists of 12-items, scored on a 0-100 scale, with higher scores representing better hip-related QoL (Griffin et al., 2012). The iHOT-12 reports pain level and four functional domains, including symptoms & functional limitations, sports & recreational activities, job-related concerns and social/emotional & lifestyle (Griffin et al., 2012). Symptoms and functional limitations are self-reported in questions 1, 2, 3, and 4. Sports and recreational activities are reported in questions 6, 7 and 11. Job-related concerns are reported in question 5. Social and emotional & lifestyle concerns are reported in questions 8, 9, 10 and 12 (Griffin et al., 2012). The threshold values to achieve MCID with the iHOT is 15.1 (Nwachukwu et al., 2020). The PROMIS GHQ is a well validated measure of well-being, developed for use with the general population and those living with chronic conditions (*PROMIS*, 2013). The PROMIS Global Health Questionnaire consists of ten questions that assess general domains of health and functioning. These domains include overall physical health, overall perceived quality of life, mental health, fatigue, social health, and pain. Each individual question can be examined separately to provide specific information about the aforementioned domains, and the PROMIS GHQ also offers Global Physical Health (GPH) and

Global Mental Health (GMH) subscales. Scores in the PROMIS GHQ range from 0 – 100, with higher scores indicating greater QoL. (*PROMIS*, 2013) The threshold value to achieve a minimal clinically important difference (MCID) in the Mental Component score is 3.0 (Bido et al., 2021; Jensen et al., 2017). The threshold value to achieve MCID in the Physical Component score is 2.3 (Bido et al., 2021; Darrith et al., 2021).

Statistical Analysis

Summary statistics and distributional plots were examined for all variables to assess modeling and hypothesis testing assumptions. Associations between variables of interest were explored with the use of smooth scatter plots for continuous variables and cross-tabulations for discrete variables. Missing data were rare (out of a total of 396 data points, missing 3 data points in mindfulness group, and 4 data points in control group) and appeared to be independent of study outcomes. As a result, missing data were treated as missing at random and were ignored in the analysis. Unadjusted baseline and 3-month values for iHOT total and domain scores, and PROMIS – GHQ scores were visualized to evaluate changes over time for both groups and each individual. ANCOVA models including the baseline value of the variable, sex, age, BMI and treatment group as covariates were used to evaluate the associations between covariates and each iHOT total and domain score separately, as well as to compare iHOT total and domain scores between groups at the 3 month follow-up timepoint. Similarly, ANCOVA models including the baseline value of the variable, sex, age, BMI and treatment group as covariates were used to evaluate the associations between covariates and PROMIS – GHQ mental and physical scores separately, as well as to compare PROMIS – GHQ mental and physical scores between groups at the 3 month follow-up timepoint. To evaluate any underlying relationships between missing data and study variables, baseline values of the study variables were compared between individuals with and without complete follow up data using Wilcoxon rank sum tests. All analyses were conducted using an intention-to-treat approach and covariates were modeled at the individual level to account for repeated measures at multiple timepoints.

Sample size was derived in R based on a two-tailed ANCOVA model to evaluate the influence of mindfulness on the continuous outcomes of iHOT, and PROMIS – GHQ Mental and Physical. Utilizing MCID (SD) values of 15.1 (15.5) for iHOT, 3.0 (2.7) for PROMIS GHQ - Mental and 2.3 (2.3) for GHQ – Physical, an estimate of 0.5 for within-subject correlation for repeated measures, required a minimum of 26 participants (13 per group), 20 participants (10 per group) and 24 participants (12 per group), respectively, to achieve a statistical power of 0.80 at a significance level of 0.05 (Bido et al., 2021; Computing, 2018; Darrith et al., 2021; Nwachukwu et al., 2020; Walters et al., 2019). Results included Cohen's d, which was interpreted using the effect size definition of small, medium and large as d=0.2, d=0.5 and d=0.8, respectively (Cohen, 1992).

RESULTS

Participant characteristics prior to surgery are shown in Table 1.

Table 1 - Participant Baseline Characteristics

Variable	Mindfulness	Control
Side (L)	7 (38.9%)	10 (55.6%)
Sex (F)	9 (50%)	13 (72.2%)
Age	32.9 ± 4.33	32.6 ± 4.36
Race (White)	18 (100%)	17 (94%)
Beighton Score (Units)	2.28 ± 1.06	4.53 ± 1.75
BMI (kg/m^2)	26.6 ± 2.16	27.0 ± 2.62
iHOT Total	42.5 ± 10.3	37.8 ± 8.92
Hip Pain (iHOT)	46.2 ± 11.9	47.2 ± 13.1
Symptoms and Functional Limitations (iHOT)	50.8 ± 11.3	43.4 ± 12.6
Sports and Recreational Activities (iHOT)	35.1 ± 12.3	28.4 ± 8.57
Job Related Concerns (iHOT)	46.5 ± 13.6	39.7 ± 12.1
Social, Emotional and Lifestyle Concerns (iHOT)	38.8 ± 10	38.7 ± 9.36
PROMIS – GHQ: Physical	45.8 ± 3.54	42.7 ± 4.3
PROMIS - GHQ: Mental	50 ± 3.8	43.2 ± 5.01

BMI = body mass index, iHOT = International Hip Outcome Tool, PROMIS = patient reported outcome measurement information systems

No significant differences in the baseline values of the study variables were identified between individuals with complete or incomplete follow up data (shown in Appendix 1). The different model assumptions for each outcome are shown in Appendix I.

The mindfulness group engaged with the app 3.73 (3.5) minutes per day on average. The unadjusted pre-surgery and 3 month values for iHOT total and domain scores are shown in Figure 1. The unadjusted pre-surgery and 3 month values for PROMIS – GHQ Physical and Mental are shown in Figure 2. The differences in iHOT total and domain scores at 3 months, after adjusting for sex, age, BMI, and baseline values are shown in Table 2 (Cohen, 1992). The differences in PROMIS – GHQ Mental and Physical scores at 3 months, after adjusting for sex, age, BMI, and baseline values are shown in Table 3 (Cohen, 1992). The association of treatment group (mindfulness, control) on iHOT scores and other model covariates 3 months after hip arthroscopy can be seen in Table 4. The association of treatment group (mindfulness, control) on PROMIS – GHQ mental and physical scores 3 months after hip arthroscopy can be seen in Table 5. The mindfulness group reported less hip pain 3-months post-surgery than the Control group, although the results were not statistically significant [mindfulness 83.63 (7.53) and control 73.89 (7.89), 95% CI, $p=0.076$, $d=0.644$]. Similarly, the mindfulness group demonstrated a non-significant trend toward less hip-related job-related concerns at 3-months post-surgery than the control group [79.66 (10.22) v. 65.95 (10.95), 95% CI, $p=0.066$, $d=0.674$]. No statistically significant differences were found in the iHOT total score or its other domains ($p>0.05$ for all), nor did PROMIS Global Physical [mindfulness 48.32 (3.29) and Control 48.65 (3.29), 95% CI, $p=0.886$, $d=0.051$] and Global Mental [mindfulness 50.57 (2.70) and Control 50.13 (2.70), 95% CI, $p=0.822$, $d=0.084$] scores show a statistical difference between the mindfulness and control group.

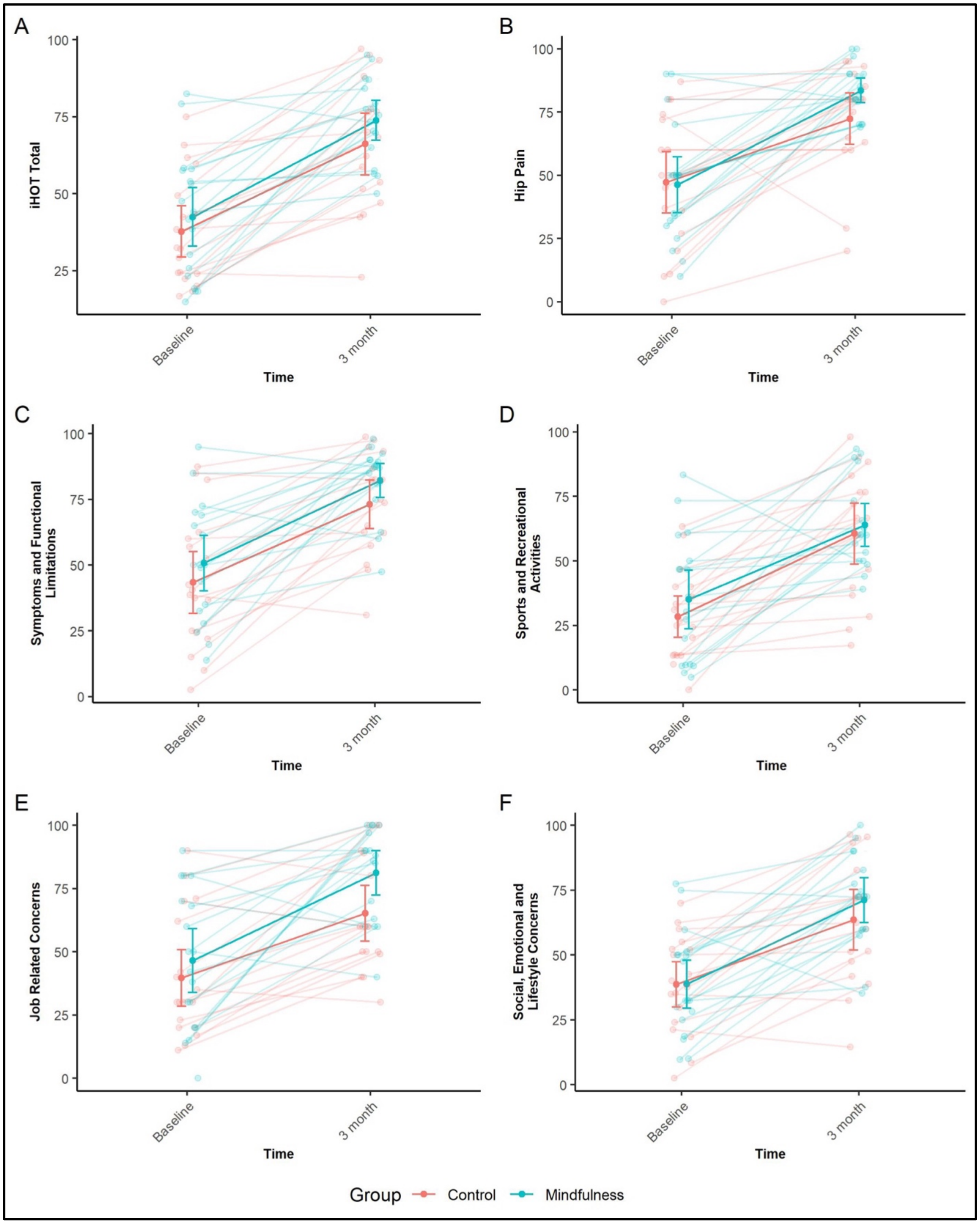

Figure 1 - Unadjusted hip pain, function and quality of life values prior to hip arthroscopy and at 3-month follow-up between mindfulness and control groups.

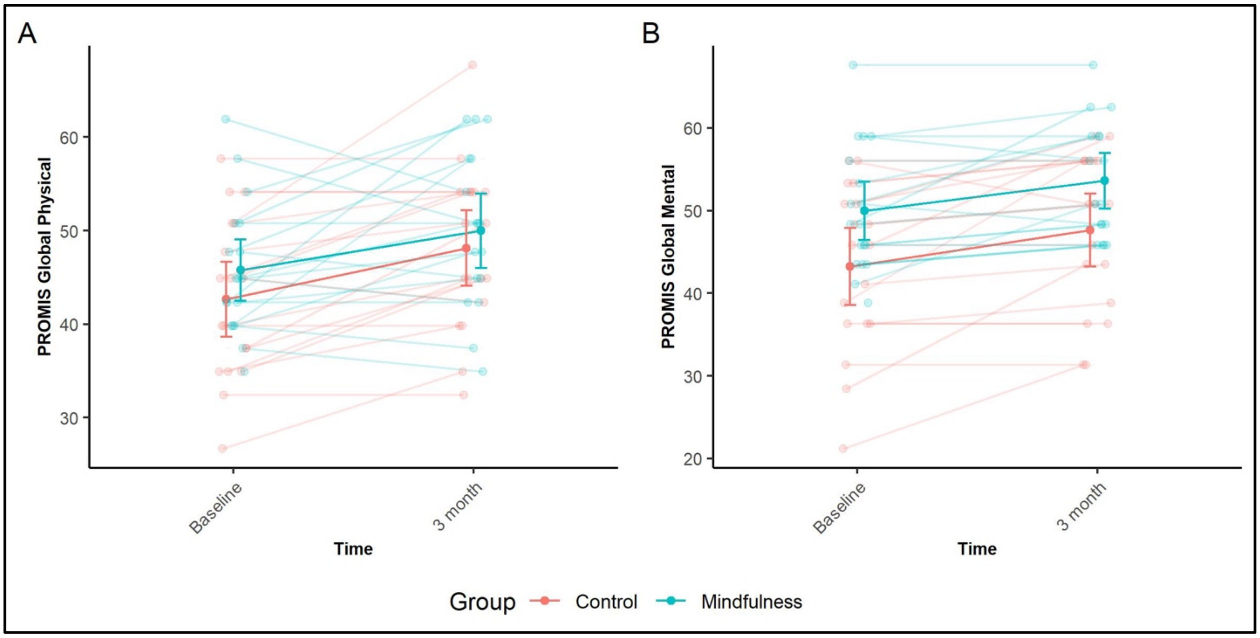

Figure 2 – Unadjusted PROMIS – GHQ mental and physical values prior to hip arthroscopy and at 3 month follow-up between mindfulness and control groups.

Table 2 - Hip pain, function and quality of life scores 3 months after hip arthroscopy, adjusted for age, sex, BMI and baseline values. Data shown as mean (95% confidence interval)

	Mindfulness	Control	p	d
iHOT Total	67.36 (8.58)	72.79 (8.27)	0.358	0.329
Hip Pain	83.63 (7.53)	73.89 (7.89)	0.076	0.644
Symptoms and Functional Limitations	81.36 (7.48)	75.44 (7.74)	0.269	0.398
Sports and Recreational Activities	63.08 (11.01)	61.34 (11.48)	0.825	0.079
Job Related Concerns	79.66 (10.22)	65.95 (10.95)	0.066	0.674
Social, Emotional and Lifestyle Concerns	70.97 (9.97)	63.36 (10.44)	0.286	0.380

iHOT = International Hip Outcome Tool; d=effect size

Table 3 - PROMIS - GHQ scores 3 months after hip arthroscopy, adjusted for age, sex, BMI and baseline values. Data shown as mean (95% confidence interval)

	Mindfulness	Control	p	d
PROMIS - GHQ				
Physical	48.32 (3.29)	48.65 (3.29)	0.797	0.051
Mental	50.57 (2.70)	50.13 (2.70)	0.839	0.084

PROMIS – GHQ = patient reported outcome measurement information system - global health questionnaire

Table 4 - The relationships between treatment group (mindfulness, control) and model covariates and hip pain, function and quality of life among hip arthroscopy patients.

	Estimate	SE	p
Total Score			
Group (mindfulness)	5.420	5.800	0.358
Time (pre)	0.403	0.165	0.021
Age (years)	-0.460	0.394	0.253
Sex (male)	0.593	6.160	0.924
BMI	-0.535	0.641	0.411
Pain			
Group (mindfulness)	9.740	5.290	0.076
Time (pre)	0.109	0.111	0.332
Age (years)	-0.221	0.343	0.526
Sex (male)	6.930	5.660	0.231
BMI	-1.390	0.578	0.023
Job-related concerns			
Group (mindfulness)	13.700	7.170	0.066
Time (pre)	0.347	0.157	0.035
Age (years)	-0.735	0.487	0.143
Sex (male)	-2.870	7.630	0.710
BMI	-0.027	0.784	0.973
Symptoms and functional limitations			
Group (mindfulness)	5.920	5.250	0.269
Time (pre)	0.225	0.122	0.075
Age (years)	-0.350	0.358	0.336
Sex (male)	6.080	5.600	0.287
BMI	-0.966	0.593	0.115
Sport and recreational activities			
Group (mindfulness)	1.730	7.770	0.825
Time (pre)	0.243	0.208	0.251
Age (years)	-0.178	0.556	0.752
Sex (male)	-0.483	7.920	0.952
BMI	-0.609	0.857	0.484

BMI = body mass index, SE = standard error

Table 5 - ANCOVA results – PROMIS Global Health Questionnaire

	Estimate	SE	p
Physical			
Group (mindfulness)	-0.326	2.260	0.886
Time (pre)	0.822	0.174	<0.001
Age (years)	-0.090	0.138	0.521
Sex (male)	-4.210	2.710	0.131
BMI	-0.144	0.254	0.573
Mental			
Group (mindfulness)	0.436	1.920	0.822
Time (pre)	0.787	0.103	<0.001
Age (years)	-0.018	0.110	0.87
Sex (male)	-1.420	1.870	0.454
BMI	0.052	0.196	0.791

Participation in the mindfulness group resulted in non-significant trends toward improvements with medium effect sizes in hip pain (d = 0.644) and job-related concerns (d = 0.674) at 3 months after surgery. Mindfulness was associated with non-significant increases with small to moderate effect sizes in iHOT total score, symptoms and functional limitations, and sport and recreational activities scores at 3 months after surgery. In the PROMIS – GHQ Mental and Physical well-being instrument, there was no difference between the mindfulness and control groups.

DISCUSSION

In contrast to our hypothesis, we found that hip arthroscopy patients randomized to remote mindfulness training in addition to the standard of care did not report statistically significant improvements in iHOT total scores than the patients who received the typical standard of care. Both the control and mindfulness groups saw significant improvement in iHOT scores at 3 months postoperatively. While this improvement provides supporting evidence for the efficacy of hip arthroscopy in improving hip-related QoL, the magnitude of the improved iHOT scores in both groups may make it more difficult to fully evaluate the efficacy of an intervention that complements the standard of care. In both groups the iHOT scores improved more than twice the magnitude of the MCID (Nwachukwu et al., 2019). Due to the unexpected magnitude of these improvements in iHOT scores, a statistically significant result associated with the mindfulness program would require iHOT scores reflecting nearly unimpaired hip-related QoL at 3 months post-operatively.

Nonetheless, we found that hip arthroscopy patients who practiced mindfulness in addition to the standard of care reported greater improvements in pain and hip function scores than patients who only received the standard of care post-operatively. In particular, the mindfulness group reported less overall pain and job-related concerns than did the control group. While the results of this study were not statistically significant, nonetheless the medium effect size of the differences with respect to pain and job-related concerns suggest that this effect may be more evident with larger groups and longer follow-up.

The present study presents non-statistically significant evidence that the participants in the mindfulness group experienced less pain at 3-months post-surgery than the control group. There is a robust body of evidence that supports the role of anxiety in the experience of pain, and that mindfulness can reduce the symptoms of anxiety (Goldberg et al., 2018; Leeuw et al., 2007; Lethem et al., 1983). Mindfulness has also been shown to reduce pain in other populations, particularly pain anticipatory anxiety and reported pain unpleasantness (Gard et al., 2012). The fear of future pain that arises for some people, especially those who have symptoms of anxiety, can negatively impact recovery from adverse events, such as surgery. In the fields of physical rehabilitation and orthopedics, the Fear Avoidance Model (FAM) of chronic pain has attracted attention and may provide the theoretical foundation for the results reported in this pilot study (Leeuw et al., 2007; Lethem et al., 1983; Vlaeyen & Linton, 2000). The FAM suggests that pain catastrophizing and fear of re-injury leads to avoidance, which in turn leads to greater debility related to inactivity. The meta-awareness of mindfulness leads to dereification, and is associated with reductions in the rumination that can interrupt the pain catastrophizing and fear of reinjury described in the FAM (Dunne et al., 2019; Kabat-Zinn, 2009; Lethem et al., 1983). Given the relatively short-term follow-up in this present study, these effects of mindfulness may be more visible over longer follow-up timelines.

In addition to the reductions in pain anticipatory anxiety and self-reported pain unpleasantness that have been associated with mindfulness practice, recent evidence suggests that the increased activity of the parasympathetic branch of the autonomic nervous system that accompanies mindfulness is also associated with pain relief (Adler-Neal et al., 2020; Jinich-Diamant et al., 2020).

We also found that participants in the mindfulness group trended toward having lower job-related concerns than participants in the control group. While not statistically significant, the overall magnitude and direction of this result is encouraging and further research is needed to better define this influence. Even a modest improvement in job-related concerns has the potential to yield many downstream benefits in workforce engagement and productivity. The direct and indirect costs of hip pain are substantial and among the many indirect costs of hip pain is time lost from work. In the working age population, nearly one in five people in the United States report lower-extremity joint symptoms in any 30-day period (*CDC - NIOSH Worker Health Charts*, 2020; Filbay et al., 2016; Gupta et al., 2005; Lawrence et al., 2008). While not all of these symptoms are hip-related, reducing the incidence of hip pain and loss of function over the long-term has the potential to greatly reduce care costs and increase workforce engagement.

In the PROMIS – GHQ Mental and Physical scores, hip arthroscopy patients who practiced mindfulness in addition to the standard of care reported mental and physical health scores at 3 months after surgery similar to the patients who only received the hip arthroscopy standard of care, which did not support our hypothesis. There are a few possible explanations for this result.

Firstly, it may be that mindfulness does not meaningfully improve self-reported well-being measures in hip arthroscopy surgery patients. While mindfulness programs have been shown to improve indices of well-being in multiple domains, it may be that in this particular sample of young, relatively active participants, mindfulness does not move the proverbial needle with regards to indices of overall well-being.

The other possible explanation relates to the use of the PROMIS – GHQ instrument with the relatively young and active population that undergoes hip arthroscopy. From the present evidence, it appears as though the improvements in hip pain and function do not significantly impact overall mental and physical as health reported by PROMIS – GHQ scores. The PROMIS instruments are all designed to have population-based t-scores of 50, with an SD of 10. In the present study, both the control and mindfulness groups had baseline t-scores that were within 1-SD of the population mean, suggesting that even with their reduced hip pain and function, their global mental and physical health as measured by the PROMIS – GHQ was within the normal range. Upon follow-up, both groups saw improved PROMIS – GHQ scores, though both groups' scores ended up very near the population mean score of 50 at 3 months (mindfulness t-score = 49.98, control t-score = 48.13). The PROMIS – GHQ may not be sufficiently sensitive to detect changes in global mental and physical health in this sample of relatively young and active hip arthroscopy patients.

In the mindfulness literature, a 2020 study of veterans with chronic back pain found that a mindful approach to movement (Yoga), in comparison to a stretching control, reported improvements in PROMIS – GHQ scores of similar magnitude to the present study (Rae et al., 2020). Taken together, the PROMIS – GHQ may not be sufficiently sensitive to detect changes in global mental and physical health in the present sample of hip arthroscopy patients, and that mindfulness does not significantly impact PROMIS – GHQ scores.

LIMITATIONS

This study has several limitations. This study may be vulnerable to response bias due to its reliance on self-reporting. Nonetheless, patient-reported outcomes are increasingly recognized as valuable primary endpoints following orthopedic surgery, especially those that are specifically indicated in order to reduce pain and improve quality of life. Due to its single-blind design, participants in the mindfulness group know they are in the experimental group, and as such, may be at greater risk of exhibiting social desirability in their responses. This social desirability bias could skew the results in favor of those in the mindfulness group. We also did not include any objective measures of function, mobility or physical activity, and consequently we are not able to compare these outcomes between groups. Consequently, it is unknown whether patient-reported improvements in pain and function are truly representative of objective increases in physical activity, for example. The addition of these functional measures in future research would support the construct validity of applying these self-report measures in the context of hip-arthroscopy and mindfulness programs. Lack of participant diversity is another limitation of this study. Of the thirty-six participants in the present study, 97% identified as white. Consequently, the present results may not be generalizable to more diverse populations. Finally, this study only includes results over the relative short term following hip arthroscopy. While more than 70% of the improvements in self-reported measures occur within 3-months of hip arthroscopy, the remaining improvements in PROs at timepoints greater than 3-months may not be equally distributed between the mindfulness and control group (Dippmann et al., 2014). Future research is needed to identify that long-term influence of mindfulness on patient-reported outcomes following hip arthroscopy.

CONCLUSIONS

Remotely-delivered mindfulness is a low-cost, low-risk, cost effective, scalable and safe intervention. The present study suggests that mindfulness meditation holds promise in improving hip-related quality of life and function after hip arthroscopy surgery. While not statistically significant, these results suggest that remote mindfulness may nonetheless specifically improve pain and job-related concerns in the short-term after hip arthroscopy, and further study with longer follow-up is needed. Despite the preliminary nature of these results, clinicians should consider remote mindfulness meditation as a low-cost, low-risk addition to the post-operative standard of care.

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EVALUATION OF FACTORS THAT INFLUENCE MINDFULNESS EFFICACY IN PATIENT-REPORTED OUTCOMES FOLLOWING HIP ARTHROSCOPY

ABSTRACT

Introduction: Hip arthroscopy can improve hip pain and function, and delay the need for hip arthroplasty. As a result, hip arthroscopy has become increasingly common procedure. However, worse surgical outcomes are associated with baseline psychological co-morbidities, suggesting that the incorporation of a post-operative behavioral intervention, such as mindfulness meditation, may improve outcomes.

Purpose: To evaluate the factors that influence the efficacy of remote mindfulness in patient-reported out comes following hip arthroscopy.

Methods: Thirty-six hip arthroscopy patients ages 18-50 years were randomly assigned to two groups; standard of care, or standard of care plus mindfulness. The 8-week mindfulness program was delivered remotely via the Healthy Minds smartphone-based training. One week before surgery and three months after surgery, participants in both groups completed the International Hip Outcome Tool (iHOT), Patient Reported Outcomes Measurement Information Systems (PROMIS) Global Health Questionnaire, PROMIS – Anxiety and PROMIS – Depression measures, along with providing demographic information (age, sex, and race) and height & weight. The influence of various moderator variables on the effect of mindfulness on patient-reported outcomes were compared between groups at 3 months using an intention-to-treat analysis with linear regressions, including the baseline value of the variable, sex, age, Beighton score, BMI and treatment group as covariates.

Results: : The average usage of the remote training in the mindfulness group was 3.73 (3.5) minutes per day. Although not statistically significant, participants in the mindfulness group

with higher baseline PROMIS – Anxiety scores reported greater reductions in hip pain than participants with lower baseline PROMIS – Anxiety scores [2.02 (1.14), $p = 0.087$], and those with lower baseline BMI reported greater improvements in PROMIS Physical and Mental scores than those with higher BMI [-0.77 (0.49), $p = 0.131$] and [-0.577 (0.388), $p = 0.147$], respectively. Time engaged with app practice sessions was negatively correlated with improvements in iHOT Job-Related Concerns [-0.12 (0.054), $p = 0.052$]. Sex and joint hypermobility did not seem to influence the effect of mindfulness on iHOT scores, global mental or global physical health.

Conclusion: This pilot study suggests that remotely delivered mindfulness may be associated with improved physical well-being and less pain in patients with lower BMI and higher baseline anxiety, respectively.

INTRODUCTION

Hip arthroscopy surgery is a surgical procedure that can help relieve pain, increase hip function and delay the onset of osteoarthritis (Spiker, 2021). Since hip arthroscopy generally delays the need for a hip replacement, it has become an increasingly common surgery (Spiker, 2021). Unfortunately, some hip arthroscopy patients may face potentially long-lasting effects such as muscle weakness, diminished joint function, hip pain and fear (Filbay et al., 2016). These effects can be related to both the precipitating injury and surgery itself, but may also be related to pre-existing psychological co-morbidities (Jacobs et al., 2017). Pre-operative anxiety and depression, for example, can negatively influence surgical outcomes such as hip function and patient-reported outcomes (Cheng et al., 2020).

Mindfulness meditation has been shown to be as effective as other cognitive and pharmaceutical therapies in treating mental health conditions (Goldberg et al., 2018). Remote delivery of mindfulness allows the intervention to be scalable, and its content to be standardized (Goldberg et al., 2020; Hirshberg et al., 2022). However, mindfulness may have differential impacts on different groups of people. For example, a prior study of college students found that women had a greater improvements in affect, mindfulness and compassion following meditation training (Rojiani et al., 2017). In addition, mindfulness has a greater benefit for those with higher baseline levels of anxiety (Brown et al., 2021). Taken together, mindfulness may be reasonably expected to benefit groups who tend to have higher levels of anxiety, such as females, or individuals with joint hyper mobility or higher body mass index (BMI)

Given the prevalence of psychological comorbidities that can influence outcomes following hip arthroscopy, the identification of individuals who would potentially benefit the most from a post-operative behavioral intervention is necessary to facilitate selective, cost-effective utilization of the intervention. We are aware of no prior research, however, that has evaluated whether the influence of a post-operative behavioral intervention varies between different groups of patients.

Therefore, the purpose of this study is to determine whether factors like age, sex, body composition, joint hypermobility, or mental health influence the efficacy of mindfulness on patient-reported outcomes following hip arthroscopy. We hypothesize that the influence of mindfulness on mental and physical well-being and hip-related pain, quality of life and function in the 3-months following hip preservation surgery would be greater among participants with higher baseline anxiety, female participants and those with joint hypermobility.

METHODS

Participants

This study was approved by the Health Sciences Institutional Review Board at the University of Wisconsin-Madison. At the pre-operative clinical visits prior to hip arthroscopy surgery, potential participants were identified. Inclusion criteria included being 18-50 years old at the time of the pre-operative visit, having access to a mobile device compatible with the free Healthy Minds Program app (Android or iOS) and concurrent participation in the Sports Medicine Patient Reported Outcomes Clinical Database. Exclusion criteria included prior diagnoses of schizophrenia or bipolar disorder or significant experience with meditation or mindfulness, as defined as greater than 30 minutes in a month during the past year.

Procedures

Participant interest and eligibility was determined during the pre-operative visit prior to hip preservation surgery. Following the provision of informed consent, participants were randomly assigned to the control or intervention groups in a 1:1 ratio using a random number generator. Participants in the control group received the typical, post-surgical standard of care. Participants who were randomized to the intervention group, in addition to the same typical standard of care, received 8 weeks of remote mindfulness training post-operatively. Participants in the intervention group were provided with instructions to download the HMP app prior to their surgery date.

All individuals involved in participants' care, including surgeons, physician's assistants, nurses, physical therapists, and administrative staff were blinded to the participant's group assignment. Height and weight, age, and sex were collected directly from patient records. Body mass index was calculated using the equation BMI = weight/height^2 (kg/m^2).

Remote Mindfulness Program

The HMP app includes five modules with practices designed to cultivate categories of mental and emotional skills that are linked to well-being (Goldberg et al., 2020). These mental and emotional skills include the cultivation of mindful attention (Awareness), positive relationships with self and others (Connection), insight into the nature of self and internal experience (Insight), and purpose, values, and meaning in life (Purpose), or taken together. As a prelude to exploring Awareness, Connection, Insight and Purpose, there is an initial module which includes abbreviated introductions to the topics and lessons in all four areas (Foundations) (Dahl et al., 2020; Goldberg et al., 2020). For this study, the active intervention included four weeks of training using the Foundations module followed by four weeks of training using the Awareness module.

Each module includes brief didactic material and guided meditation practices. Didactic content includes discussion of the scientific context of the practices and the guided practices can be delivered at a self-selected length of 5-30 minutes. The Foundations module includes a brief, optional self-assessment regarding each of the four categories. Participants were instructed to follow a pre-specified sequence within each module. The Foundations and Awareness modules require a minimum of 133 and 253 minutes, which equates to less than 5 and less than 10 minutes per day on average, respectively. Through the app, usage was recorded for each participant, including date, duration, and content. For the full duration of the study, participants had access to the entire contents of the app.

With the mindfulness program, the study team actively encouraged study participants to consistently utilize the app. The app developer created a report of study participants' app usage that the study team downloaded twice a week through a password protected Amazon S3 server. For participants who had not used the app in the past 3 to 5 days, study personnel sent a text message reminder. For participants who had not used the app in the past 6 to 7 days, study personnel sent a phone call reminder. Participants were paid $25 for baseline and 3-month surveys, irrespective of group assignment.

Patient-Reported Outcomes

Prior to hip preservation surgery, and again at 3 months following surgery, participants were asked to provide information regarding mental and physical well-being, hip function and hip-related QoL, and anxiety and depression via the PROMIS – GHQ, iHOT-12, PROMIS - Anxiety and PROMIS Depression surveys, respectively. The iHOT-12 hip-related quality of life and function instrument is designed for active patients ages 18-60 and has demonstrated internal consistency, validity, reliability and responsiveness to change (Griffin et al., 2012). In the iHOT-12, participants self-report pain in question 1. In addition to pain, the four domains of the iHOT representing different elements of hip function include symptoms & functional limitations, sports & recreational activities, job-related concerns and social/emotional & lifestyle (Griffin et al., 2012). Symptoms and functional limitations are self-reported in questions 1, 2, 3, and 4. Sports and recreational activities are reported in questions 6, 7 and 11. Job-related concerns are reported in question 5. Social and emotional & lifestyle concerns are reported in questions 8, 9, 10 and 12 (Griffin et al., 2012). The threshold values to achieve MCID with the iHOT is 15.1 (Nwachukwu et al., 2020).

The PROMIS GHQ is a well validated measure of well-being, developed for use with the general population and those living with chronic conditions (*PROMIS*, 2013). These validated instruments have been used extensively in prior research regarding orthopedic and hip surgery to identify meaningful outcomes for patients following surgical intervention. Scores in the PROMIS GHQ range from 0 – 100, with higher scores indicating greater QoL. (*PROMIS*, 2013) The threshold value to achieve a minimal clinically important difference (MCID) in the Mental Component score is 3.0 (Bido et al., 2021; Jensen et al., 2017). The threshold value to achieve MCID in the Physical Component score is 2.3 (Bido et al., 2021; Darrith et al., 2021).

The PROMIS Anxiety and PROMIS Depression instruments each consist of 8 questions, scored on a 0-100 scale, with higher scores representing higher levels of anxiety and depression, respectively (Beleckas et al., 2018). The PROMIS instruments are validated, concise in form, are intended for the general population and are available in multiple delivery methods (*PROMIS*, 2013).

In addition to the quantitative measures, the present study included a qualitative component. Through the use of a four question discovery interview, selected participants who were randomized into the mindfulness group described their experience with mindfulness and the app by answering the following questions:

1. How did (or would) you describe the meditation to your friends?

2. How would you describe your experience with meditation?
3. How would you describe the impact of meditation on your recovery?
4. What suggestions do you have for the app developer regarding content, user experience, etc.?

Eight participants were asked to complete the interview: the four highest duration users of the app, and the four lowest (non-zero) duration users of the app. These eight participants were first sent an email request, and if a reply was not received within five-days, a second email request was sent. If after an additional five days a reply to the second email request was not received, these participants were then sent the same request via text message.

Statistical Analysis

Baseline variables for each group were evaluated using descriptive statistics. For each moderator variable (sex, age, BMI, joint mobility, anxiety and depression), the influence of the moderator on the effect of mindfulness on patient-reported outcomes was evaluated through separate linear regressions to evaluate the association between the change in each outcome from baseline to 3 months and the interaction between group assignment and the moderator.

Among those 14 participants in the mindfulness group who engaged in the mindfulness program, separate linear models were used to evaluate whether minutes of app usage could predict the change in each outcome from baseline to 3 months, calculated as the 3 month value minus the baseline value. This was done separately for total minutes of usage as well as minutes of practice and minutes of didactic usage. In addition, the correlations between the changes in anxiety and the changes in outcomes from baseline to 3 months (calculated as 3 month value minus baseline value for both) were evaluated. Based on the scoring of the measures, a more negative change would represent an improvement in anxiety from baseline to 3 months, while it would represent a worsening of each of the iHOT and PROMIS measures. As a result, a negative correlation would suggest that improvements in anxiety post-operatively are associated with improvements in the specific outcome. Qualitative interview data were presented descriptively. Significance was determined a priori at the 0.05 level and all analyses were conducted in R (Computing, 2018).

RESULTS

Participant characteristics can be seen in Table 1.

Table 1 - Participant characteristics

Variable	Mindfulness	Control
Sex (F)	9 (50%)	13 (72.2%)
Age	32.9 ± 4.33	32.6 ± 4.36
Beighton Score	2.28 ± 1.06	4.53 ± 1.75
BMI (kg/m^2)	26.6 ± 2.16	27 ± 2.62
PROMIS Global Physical Health	45.8 ± 3.54	42.7 ± 4.3
PROMIS Global Mental Health	50 ± 3.8	43.2 ± 5.01
PROMIS Anxiety	54.1 ± 3.95	58.6 ± 4.72
PROMIS Depression	50.8 ± 3.99	53.2 ± 4.95
iHOT Total	42.5 ± 10.3	37.8 ± 8.92
Hip Pain	46.2 ± 11.9	47.2 ± 13.1
Symptoms and Functional Limitations	50.8 ± 11.3	43.4 ± 12.6
Sports and Recreational Activities	35.1 ± 12.3	28.4 ± 8.57
Job Related Concerns	46.5 ± 13.6	39.7 ± 12.1
Social, Emotional and Lifestyle Concerns	38.8 ± 10	38.7 ± 9.36

Data presented as mean ± 95% confidence interval; iHOT = International Hip Outcome Tool-12

The interaction between group and moderators can be seen in Tables 2 and 3. Plots of the interactions of baseline BMI, Anxiety, Depression and Age be seen in Figures 1 - 4. The distribution of practice and didactic time for each participant can be seen in Figure 5. The relationships between minutes of total app usage and outcomes can be seen in Figure 6, while the relationships with minutes of practice and didactic time are shown in Figures 7 and 8, respectively. Finally, the associations between the change in anxiety scores and the changes in outcomes from baseline to 3 months can be seen in Figure 9.

Although not statistically significant, participants in the mindfulness group with higher baseline PROMIS – Anxiety scores reported greater reductions in hip pain than participants with lower baseline PROMIS – Anxiety scores [2.02 (1.14), p = 0.087], and those with lower baseline

BMI reported greater improvements in PROMIS Physical and Mental scores than those with higher BMI [-0.77 (0.49), $p = 0.131$] and [-0.577 (0.388), $p = 0.147$], respectively. Time engaged with app practice sessions was negatively correlated with improvements in iHOT Job-Related Concerns [-0.12 (0.054), $p = 0.052$]. Sex and joint hypermobility did not seem to influence the effect of mindfulness on iHOT scores, global mental or global physical health.

Table 2 - Linear regression interaction results between group (mindfulness, control) and sex, BMI, age and Beighton score

	Interaction Estimate	SE	p
Sex			
PROMIS Global Physical	1.05	4.58	0.821
PROMIS Global Mental	0.996	3.84	0.797
iHOT Total Score	-4.16	15.2	0.787
Pain	0.775	20.5	0.97
SFL	10.9	17.7	0.541
Sports and Recreational Activities	-8.85	19.8	0.658
Job Related Concerns	9.25	20	0.646
Social, Emotional and Lifestyle Concerns	-19.1	15.8	0.237
BMI			
PROMIS Global Physical	-0.766	0.494	0.131
PROMIS Global Mental	-0.577	0.388	0.147
iHOT Total Score	-1.25	1.5	0.412
Pain	-0.188	1.97	0.925
SFL	-1.11	1.76	0.534
Sports and Recreational Activities	-2.53	1.93	0.199
Job Related Concerns	-2.43	1.99	0.232
Social, Emotional and Lifestyle Concerns	-0.126	1.61	0.938
Age			
PROMIS Global Physical	0.155	0.281	0.586
PROMIS Global Mental	-0.225	0.217	0.309
iHOT Total Score	-0.864	0.799	0.288
Pain	-0.282	1.14	0.807
SFL	-1.48	0.903	0.112
Sports and Recreational Activities	-0.497	1.07	0.646
Job Related Concerns	-1.51	1.04	0.157
Social, Emotional and Lifestyle Concerns	-0.365	0.921	0.695
Beighton Score			
PROMIS Global Physical	0.292	0.944	0.760

PROMIS Global Mental	-0.705	0.718	0.334
iHOT Total Score	1.73	3	0.568
Pain	0.274	3.77	0.943
SFL	0.626	3.37	0.854
Sports and Recreational Activities	5.3	3.71	0.163
Job Related Concerns	2.01	4.03	0.621
Social, Emotional and Lifestyle Concerns	0.0839	3.21	0.979

BMI = body mass index, SE = standard error, PROMIS = patient reported outcome measurement information system, iHOT = international hip outcome tool, SFL = symptoms and functional limitations

Table 3 - Linear regression interaction results between group (mindfulness, control) and baseline PROMIS Anxiety and Depression

	Interaction Estimate	SD	p
Anxiety			
PROMIS Global Physical	0.311	0.290	0.291
PROMIS Global Mental	-0.018	0.228	0.936
iHOT Total	1.27	0.861	0.152
Pain	2.02	1.14	0.0865
SFL	1.43	0.996	0.161
Sports and Recreational Activities	1.04	1.14	0.371
Job Related Concerns	1.11	1.08	0.311
Social, Emotional and Lifestyle Concerns	1.31	0.923	0.166
Depression			
PROMIS Global Physical	0.20	0.279	0.478
PROMIS Global Mental	0.033	0.221	0.884
iHOT Total	0.621	0.837	0.464
Pain	0.603	1.12	0.593
SFL	0.581	0.974	0.555
Sports and Recreational Activities	1.34	1.07	0.219
Job Related Concerns	1.2	1.04	0.26
Social, Emotional and Lifestyle Concerns	-0.0259	0.904	0.977

BMI = body mass index, SD = standard deviation, PROMIS = patient reported outcome measurement information system, iHOT = international hip outcome tool, SFL = symptoms and functional limitations

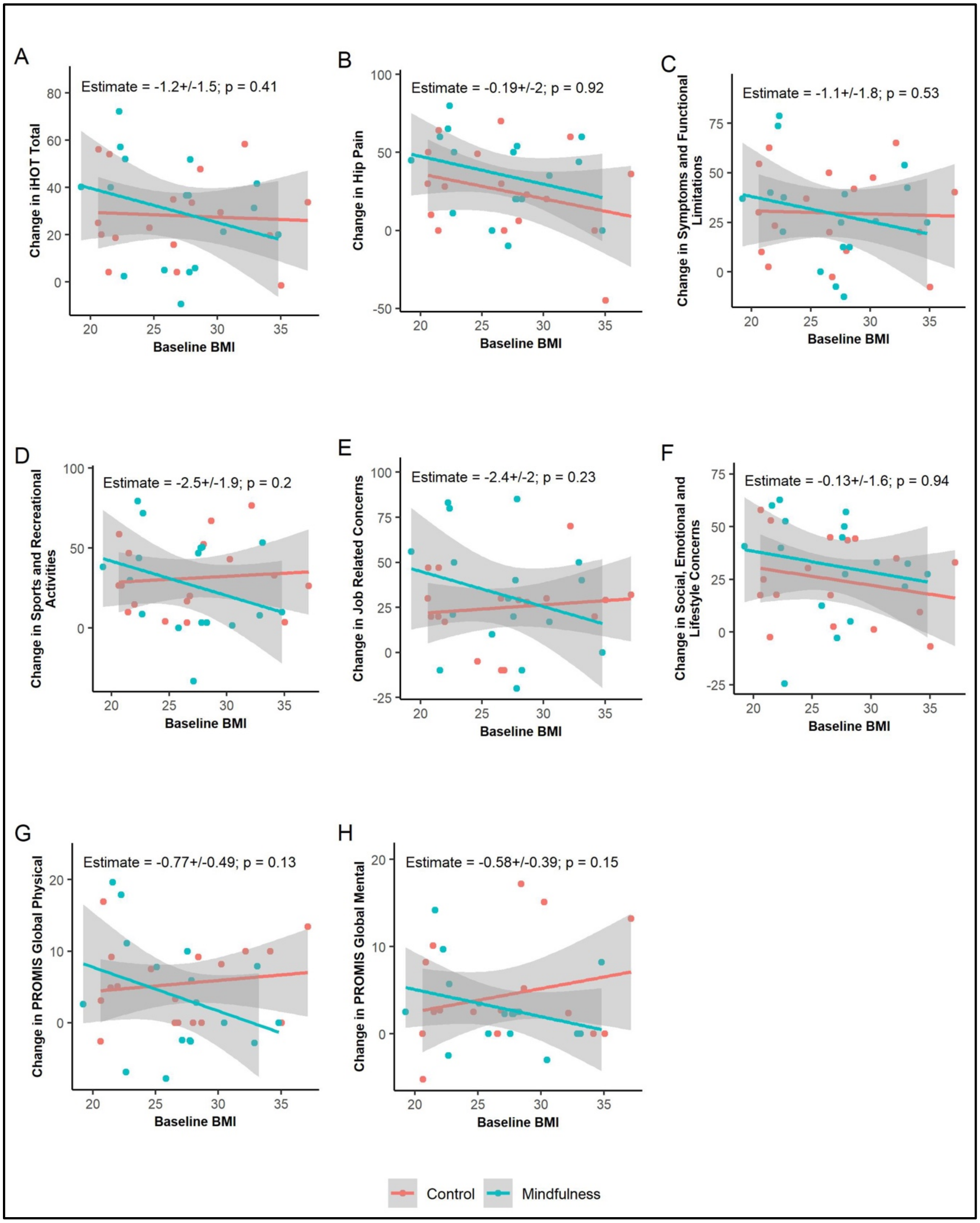


Figure 1 – Interaction of baseline BMI with outcome variables

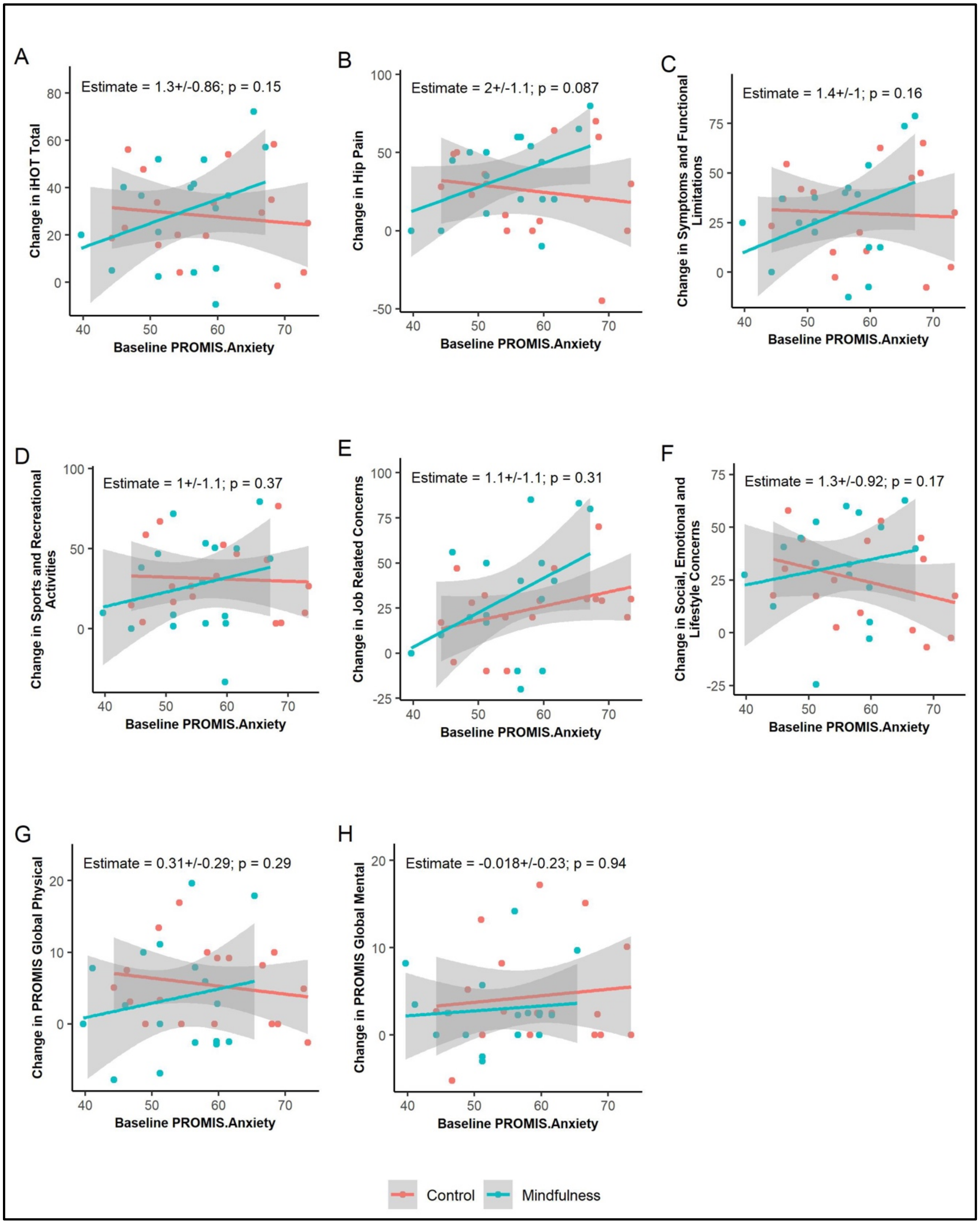


Figure 2 – Interaction of baseline PROMIS – Anxiety with outcome variables

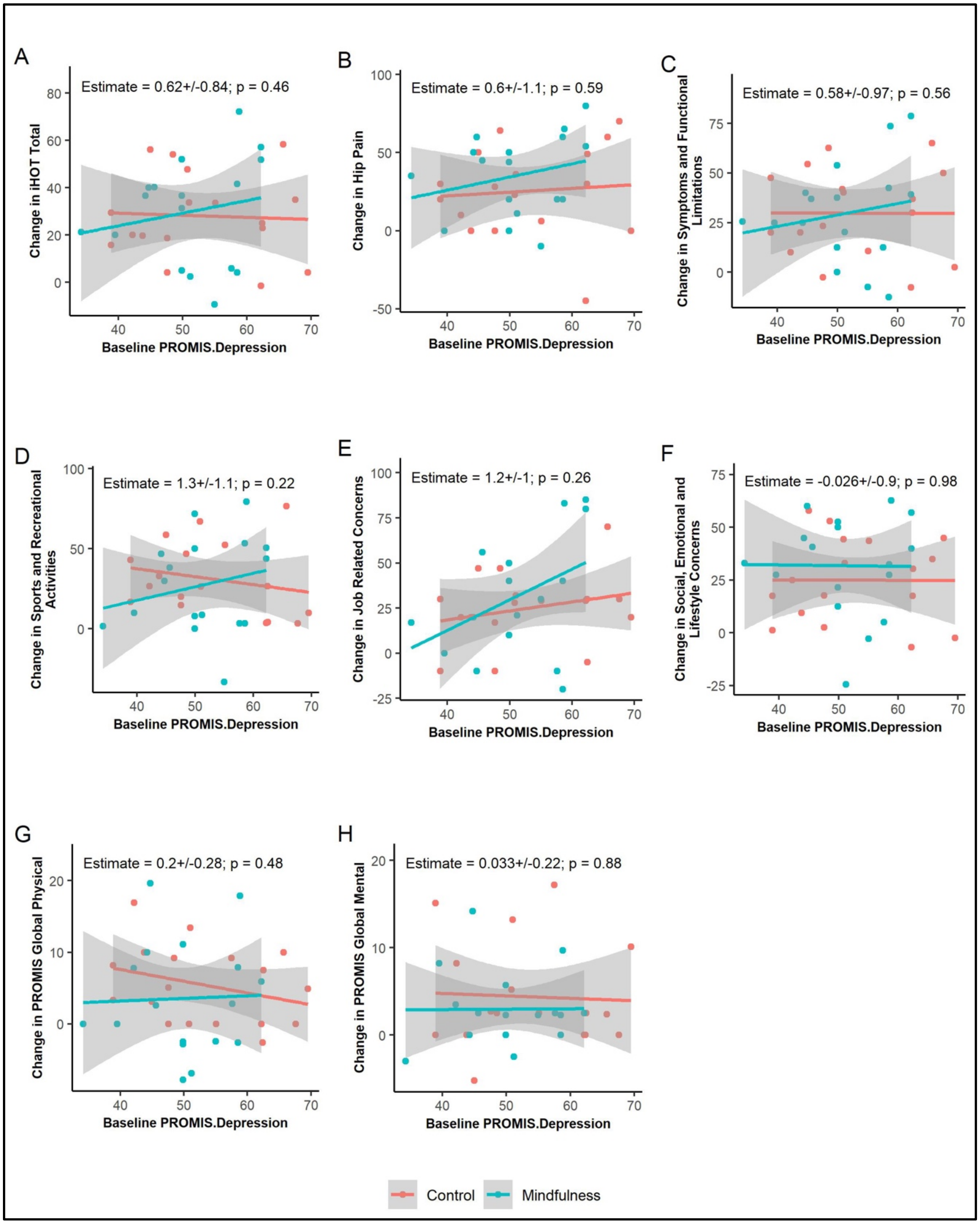


Figure 3 – Interaction of baseline PROMIS – Depression with outcome variables

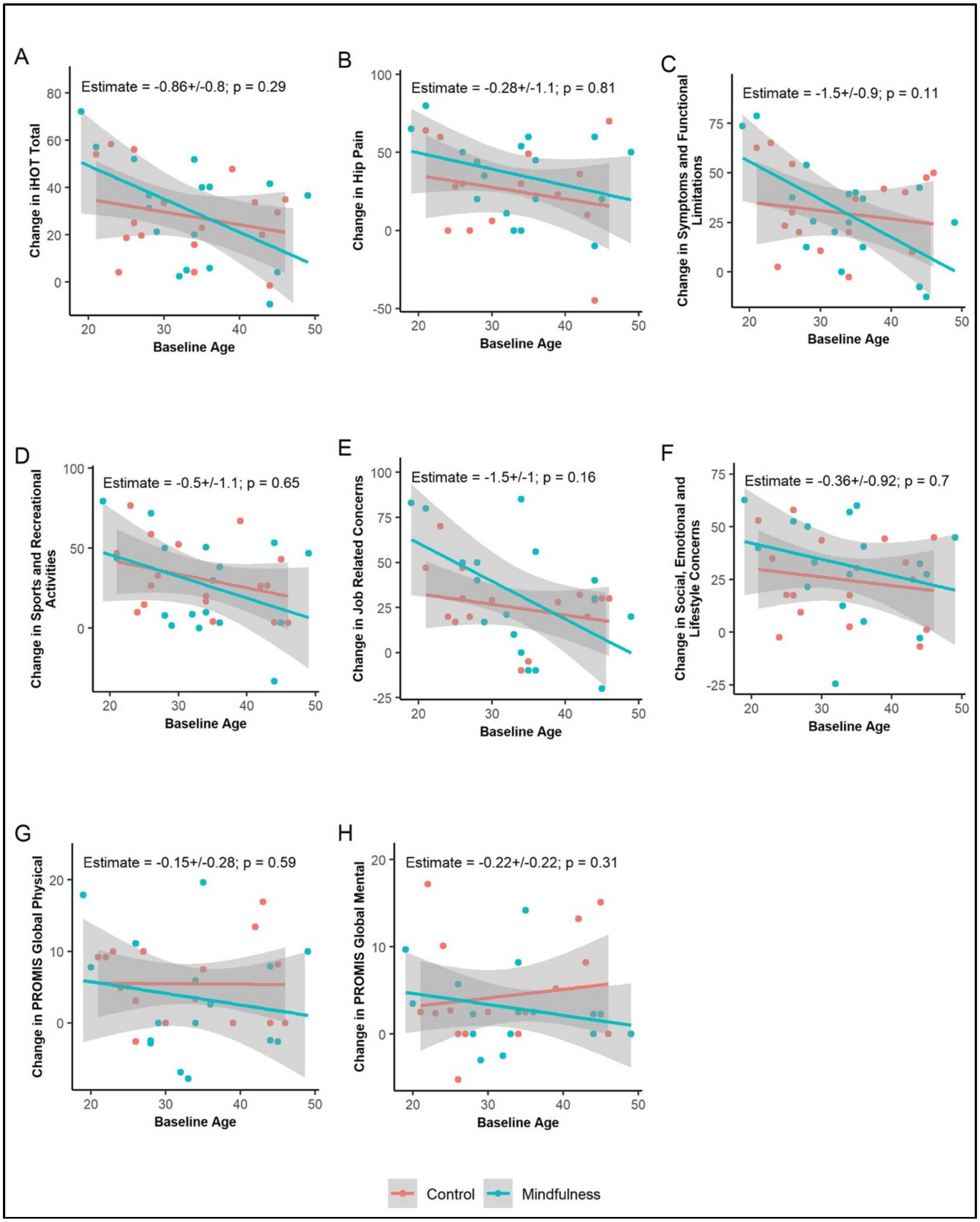


Figure 4 – Interaction of baseline age with outcome variables

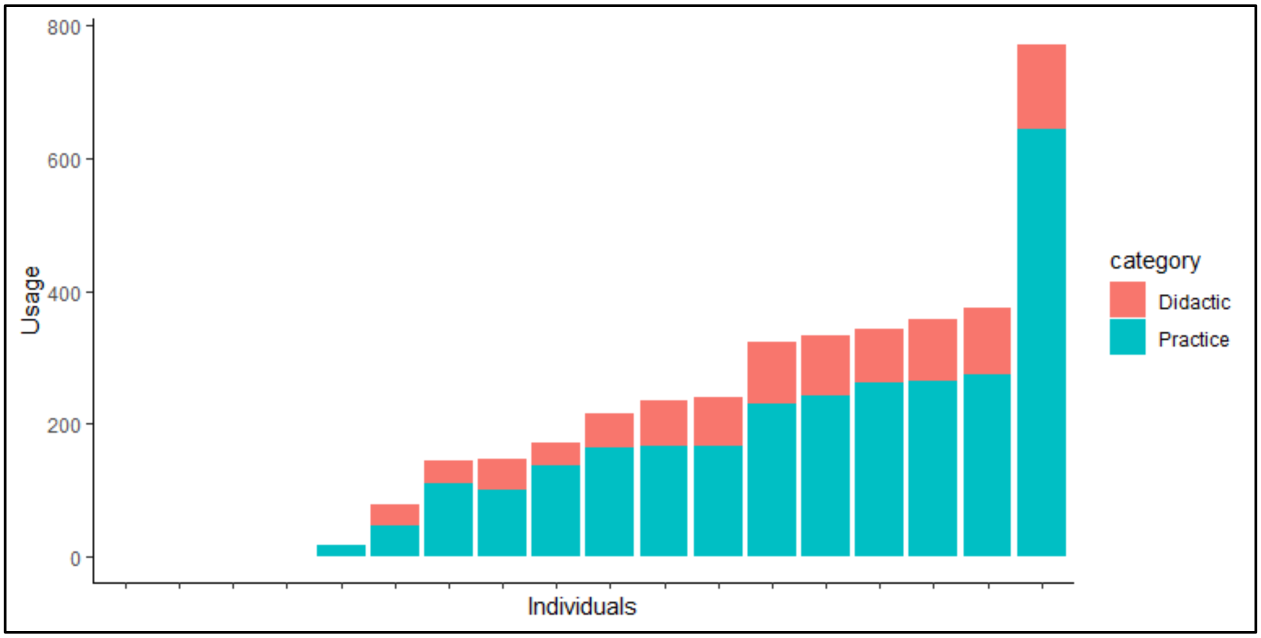


Figure 5 – Total minutes of mindfulness app usage within the mindfulness group by practice type. Practice Usage (minutes) Mean (SD): 157 (158) Median (range): 151 (0-643); Didactic Usage (minutes) Mean (SD): 51.3 (41.4) Median (range): 47.5 (0-129)

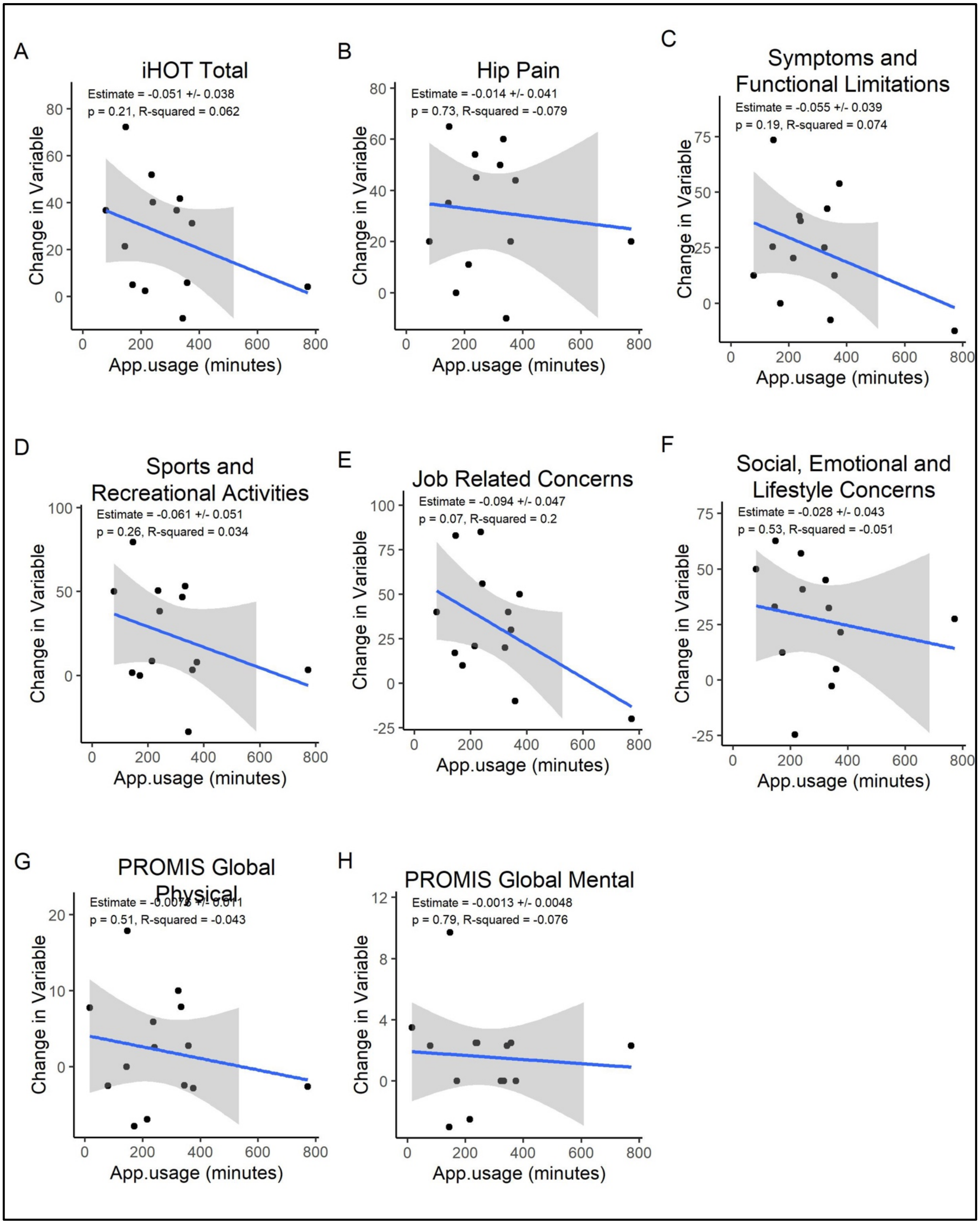


Figure 6 – Relationship between total app usage and outcome variables

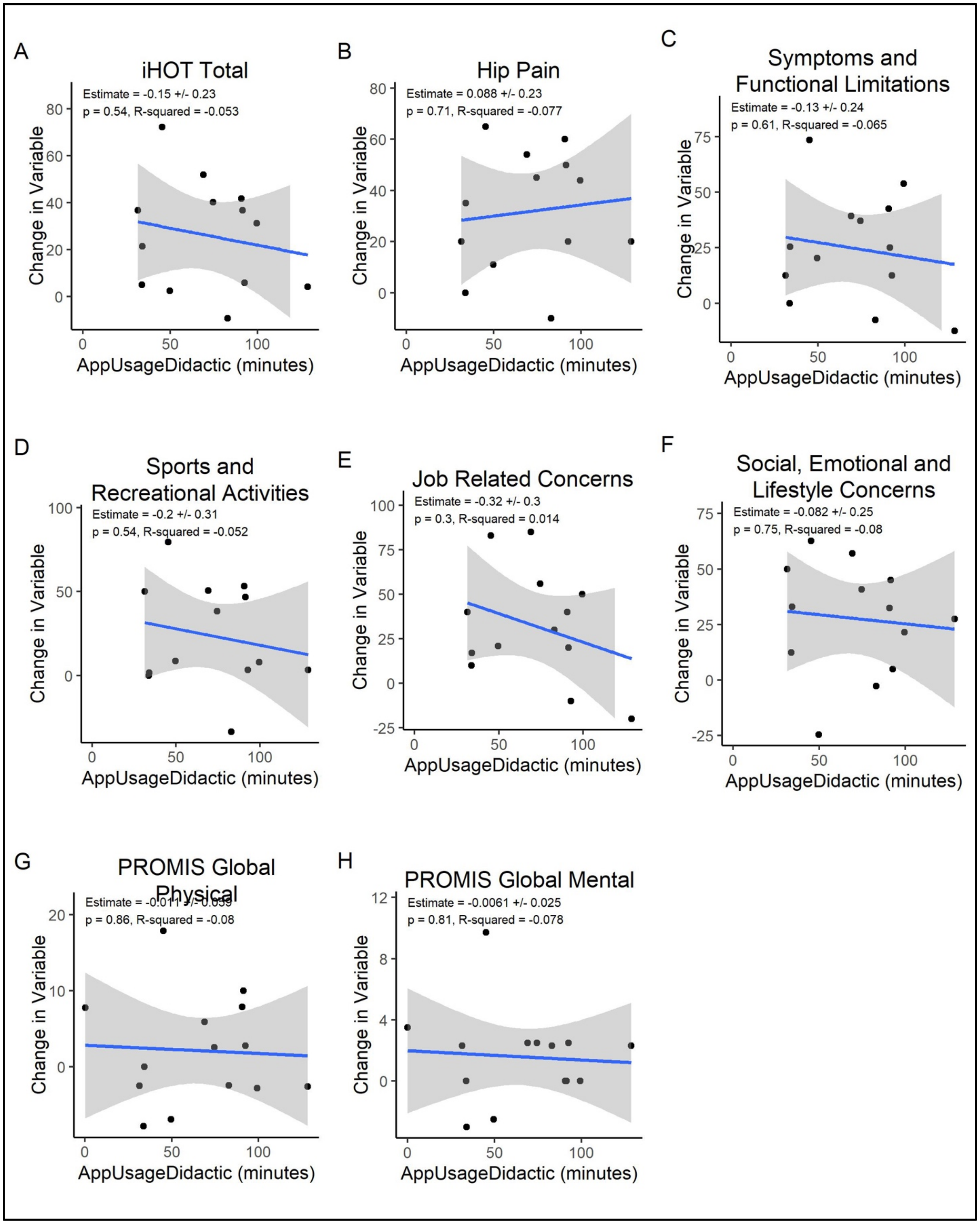


Figure 7 – Relationship between didactic app usage and outcome variables

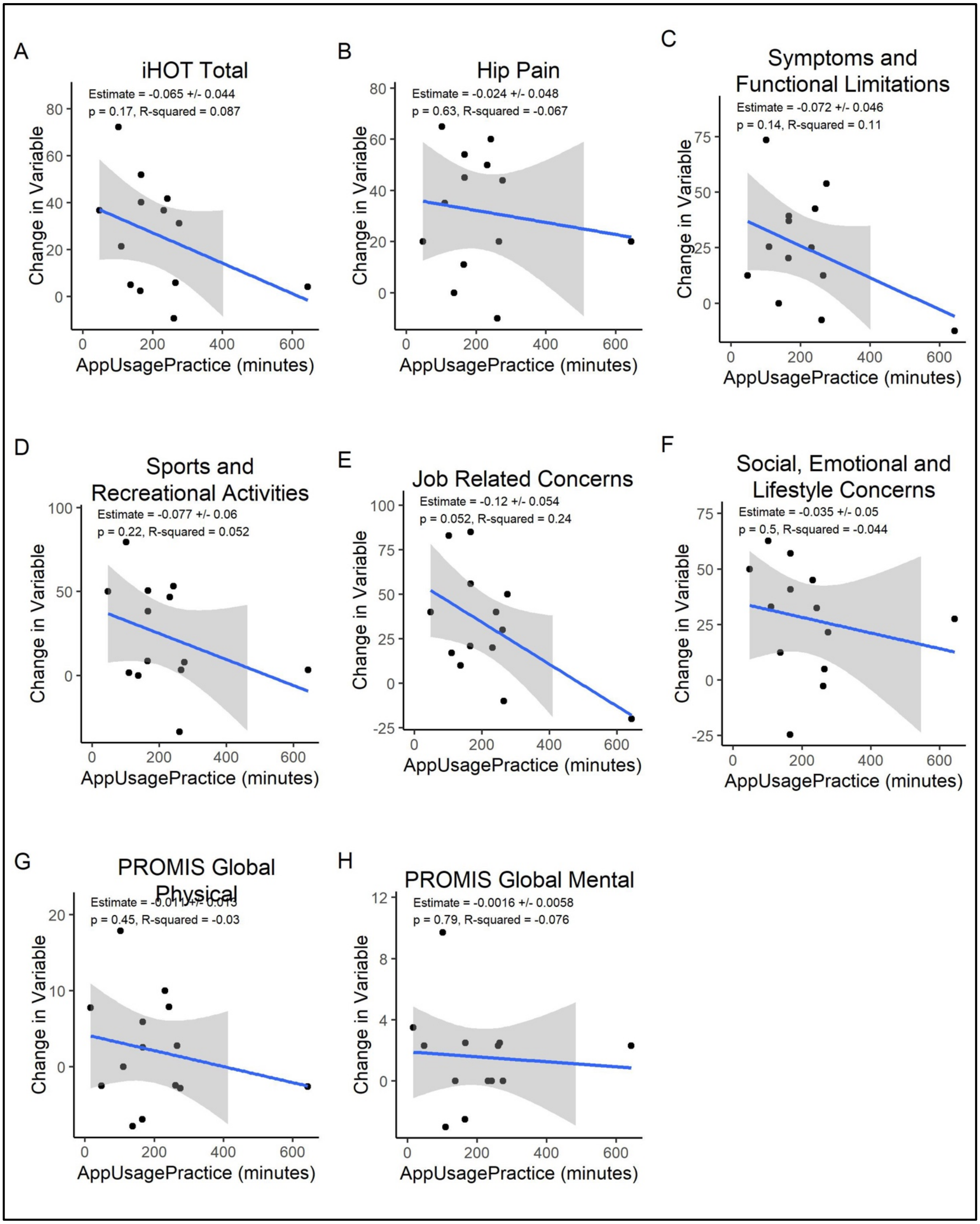


Figure 8 – Relationship between practice app usage and outcome variables

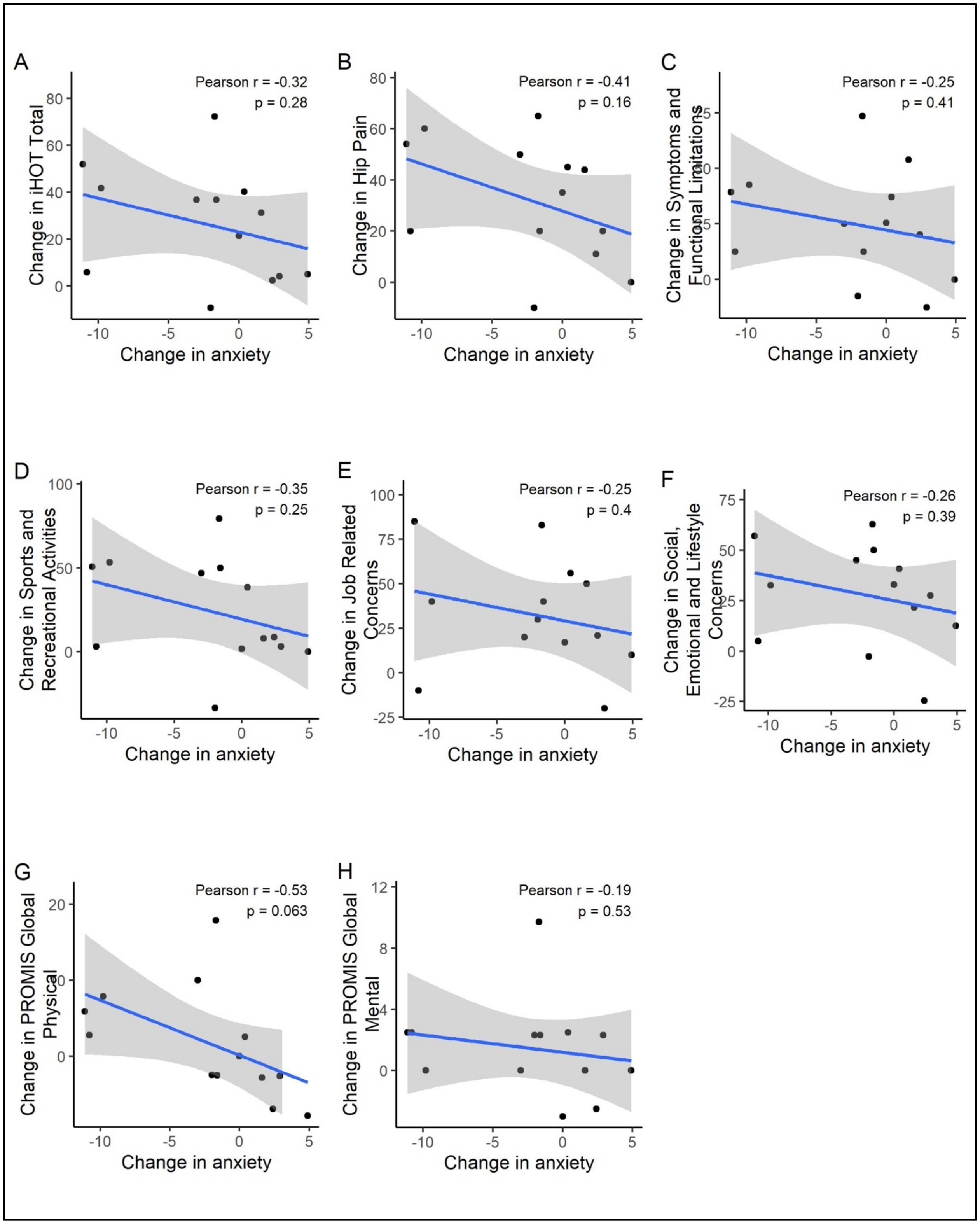


Figure 9 – Interaction of change in PROMIS – Anxiety scores with outcome variables

Qualitative – Mindfulness Participant Interviews

Following the 3 month data collection, selected participants in the mindfulness group completed discovery interviews. Of the four lowest duration app users, two did not reply to any of the requests, one participant refused and one agreed to be interviewed (participant #16). Of the four highest duration app users in the mindfulness group, two did not reply to any of the requests, one agreed to the virtual interview (participant #30), and one agreed to submit written answers to the interview questions (participant #32).

Participants in the mindfulness group overall spoke positively about their experience with the practices and the HMP app. Mindfulness participants reported that the practices were beneficial and supportive of mental health with statements as:

- "…initially it was really helpful."
- "I think it's very positive."
- "It was good to have something that was for my mental health."

Participants in the mindfulness group also spoke positive about the HMP app and its usability. Mindfulness participants reported that the HMP app was:

- "I think that it was pretty accessible, it wasn't hard to use or figure out."
- "I found it amazing - that you could choose a voice and length of time that you wanted to do it for."

DISCUSSION

Hip arthroscopy patients who experience poorer outcomes often have comorbid anxiety or depression, and investigating the interaction between mental health and surgical outcomes has the potential to improve clinical outcomes (Beleckas et al., 2018; Cheng et al., 2020; Ghoneim & O'Hara, 2016; Hall et al., 2022; Jacobs et al., 2020; Lansdown et al., 2018). In the present study, our results suggest that mindfulness may have a greater influence on post-operative pain improvements for individuals with greater baseline anxiety. Participants in the mindfulness group with higher levels of baseline PROMIS Anxiety scores trended toward greater reductions in iHOT Pain scores at 3 months post-operatively. This result suggests that the effect of mindfulness varies based on the level of baseline anxiety, such that individuals with higher levels of anxiety may have a greater benefit of mindfulness. Prior evidence has shown that hip arthroscopy patients with higher levels of baseline anxiety report more pain than hip arthroscopy patients with lower levels of baseline anxiety (Hall et al., 2022). Similarly, prior studies show that mindfulness meditation reduces symptoms of both anxiety and pain (Goldberg, 2015; Kabat-Zinn et al., 1985). As one of the mindfulness group's highest duration app users (participant #30) stated in their interview, "… (you can) bear your pain more easily by using a technique where you observe the pain rather than getting stuck in how awful it is." Prior studies have shown that mindfulness is associated with greater activity in brain regions associated with affective and sensory pain processing while experiencing pain, along with reductions in the inflammatory biomarkers that are associated with pain (Creswell et al., 2016; Grant et al., 2011). In addition, mindfulness practitioners have been found to experience reductions in pain unpleasantness in comparison to age, gender, handedness and education matched controls. (Gard et al., 2012).

In the orthopedics literature, there is extensive evidence that patients with greater baseline anxiety report having more pain after surgical procedures. Patients seeing orthopedic surgeons have a high prevalence of anxiety, and this anxiety is associated with higher levels of pain (Beleckas et al., 2018). In the specific case of hip arthroscopy, patients with a history of anxiety consistently report lower patient-reported outcomes, including pain levels, than patients without anxiety both before and after the surgical intervention (Beleckas et al., 2018; Hall et al., 2022;

Jacobs et al., 2020; Lansdown et al., 2018) Mindfulness meditation has been shown to reduce anxiety in a variety of populations (Goldberg et al., 2018). As a participant in the mindfulness group who was on the lower end of app usage (participant #30) mentioned in an interview, "There were some days where I thought that it was really helping, and like, I wasn't doing extremely well, like, mental health wise."

On the other hand, an individual in the mindfulness group who was among the longest duration users of the app (participant #32) reported in a qualitative interview that "…in general I felt pretty calm and at ease throughout the recovery. To contrast, I didn't do meditation in a more recent surgery (same procedure, other side) and generally felt more anxious and restless during that recovery compared to the one where I did do meditation." While preliminary, these results suggest that mindfulness may have a greater benefit for post-operative pain among individuals with higher levels of co-morbid psychological conditions.

To a lesser extent, a similar result was seen in the interaction of outcome variables with baseline PROMIS – Depression. While not a statistically significant interaction, higher baseline depression is associated with greater improvements in outcome measures among participants who practices mindfulness.

We also found that, although not statistically significant, participant BMI may moderate the influence of mindfulness on both PROMIS Global Physical and Global Mental scores 3 months post-operatively. Participants in the mindfulness group with lower BMI (less overweight or obese) trended toward greater reductions in all of the outcome measures at 3 months post-operatively. This result suggests that the effect of mindfulness varies based on the BMI, such that individuals with lower BMI may have a greater benefit of mindfulness. In prior studies of hip arthroscopy outcomes, overweight or obese patients demonstrate lower scores on hip-related

PROs before surgery, show similar improvement to non-overweight or obese patients, but still have with lower scores on hip-related PROs post-operatively. (Bech et al., 2015; Kuroda et al., 2021). .

Similarly, the interaction of age with outcome measures was not statistically significant, though showed a trend toward greater improvements in hip arthroscopy outcomes among younger patients who practiced mindfulness. While hip arthroscopy outcomes are overall better among younger patients, this trend toward greater improvements in outcomes for younger mindfulness practitioners may inform future studies' exploration into the populations most likely to benefit from a mindfulness adjunct to their hip arthroscopy standard of care. In the present study, neither sex nor Beighton score were associated with differences in outcome variables. While both female sex and higher Beighton score have been associated with higher levels of anxiety in previous studies, the present study did not corroborate that result (Bulbena et al., 1993; Iglinski-Benjamin et al., 2019).

The quantity of App utilization in the mindfulness group (minutes per day) did not demonstrate a dose-dependent relationship in PRO measures with the exception of the iHOT Job Related Concerns measure. Total time engaged with the app, time engaged with didactic sessions and time engaged with practice sessions were negatively associated with 3 month changes in the iHOT Job-Related concerns measure, although not statistically significant. While not statistically significant, these unexpected results suggest that in the present study, the dose-response relationship is minimal in the various PROs, and that less usage of the app may be associated with greater improvements in the domain of iHOT Job-Related Concerns.While this inverse dose-response relationship in iHOT Job-Related Concerns was an unexpected result, the decoupling of time spent engaging with mindfulness and outcome measures is not without precedent. In a 2020 meta-regression of dose-response in mindfulness-based RCTs, Strohmaier reported that several outcome measures showed a similar inverse relationship as the present study (Strohmaier, 2020). While the effect size was small, this meta-regression of RCTs showed that "being asked to practice mindfulness for longer predicted *increased* depression compared with inactive controls…" This same relationship held true for outcome variables related to anxiety and stress (Strohmaier, 2020). It may be that engaging with mindfulness for shorter durations delivers the intended benefits and perhaps it may be that less is more for some people when it comes to mindfulness practice and PRO scores. Further inquiry into the dose-response of mindfulness is indicated.

We did not find a statistically significant association between changes in anxiety and outcome measures. While all outcome measures were associated with reduced anxiety as measured by the PROMIS – Anxiety instrument to a non-statistically significant degree, only the iHOT – Pain and PROMIS – GHQ Physical trended toward significance ($p = 0.16$ and 0.063, respectively). In partial confirmation of our hypotheses, we find that a trend toward reducing baseline anxiety is associated with improved scores on some physical outcome measures. It seems likely that this may be limited by the relatively small sample size, and further research in this area is warranted within this population to better identify these relationships.

The role of anxiety in the experience of pain has been well described and mindfulness has been shown to reduce the symptoms of anxiety (Goldberg et al., 2018; Leeuw et al., 2007; Lethem et al., 1983). Mindfulness has also been shown to reduce pain in multiple postulations, particularly pain anticipatory anxiety and reported pain unpleasantness (Gard et al., 2012). Particularly for people who have symptoms of anxiety, fear of future pain can negatively impact recovery from adverse events, such as surgery. The Fear Avoidance Model (FAM) of chronic pain, from the fields physical rehabilitation and orthopedics, has attracted attention and may provide the theoretical foundation for the results reported in this pilot study (Leeuw et al., 2007; Lethem et al., 1983; Vlaeyen & Linton, 2000). According to the FAM, pain catastrophizing and fear of re-injury lead to avoidance, and avoidance leads to greater debility related to inactivity. Dereification, related to the meta-awareness of mindfulness, is associated with reductions in rumination. We hypothesize that reducing rumination can interrupt the pain catastrophizing and fear of reinjury described in the FAM (Dunne et al., 2019; Kabat-Zinn, 2009; Lethem et al., 1983). While the present study does not directly measure pain catastrophizing, the reductions in measures of anxiety that are non-statistically significantly associated with improvements in self-reported global physical health and hip-related pain suggest that further exploration into the treatment of anxiety through mindfulness and its role in surgical outcomes is merited.

In contrast to our hypotheses, we did not find that sex or joint mobility influenced the effect of mindfulness of patient-reported outcomes. In the general population, both people with higher Beighton scores (more joint mobility) and females tend to report higher levels of anxiety, and we hypothesized that hip arthroscopy patients who are more likely to experience anxiety would be more likely to benefit from the mindfulness program. It may, therefore, be the case that while anxiety may influence post-operative outcomes, as well as the influence of post-operative behavioral interventions, there may not be any independent influence of sex or joint hypermobility.

LIMITATIONS

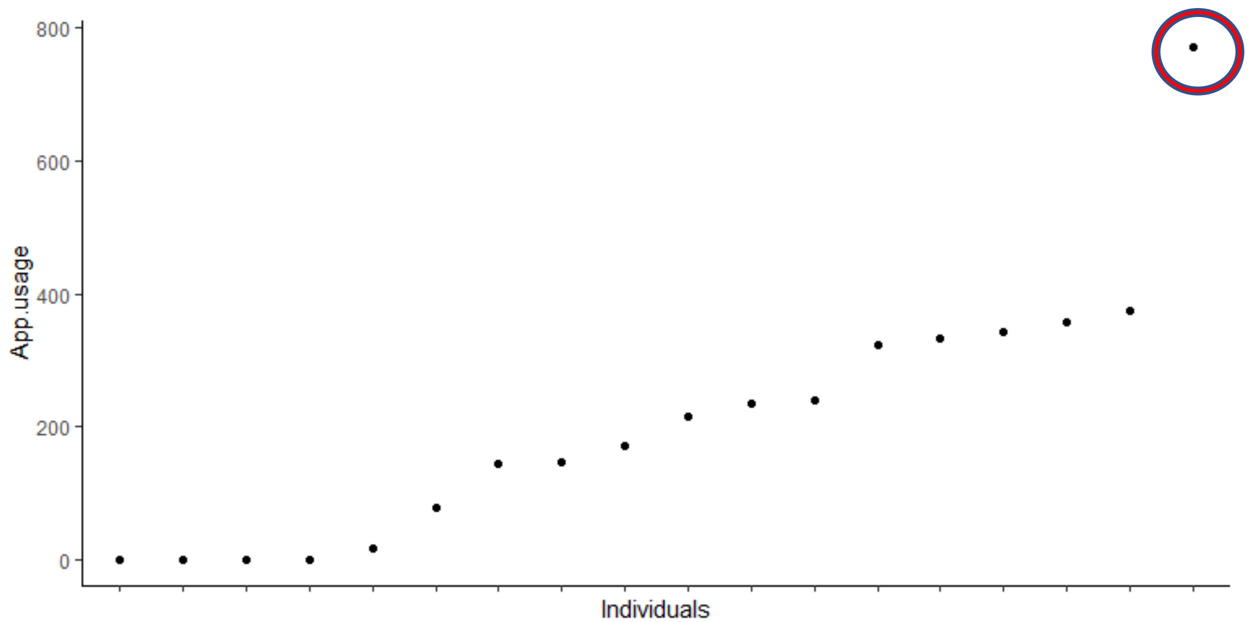
This study has several limitations. It may be susceptible to response bias due to its reliance on self-reporting. While functional measures are not strongly indicative of physical function or perception of surgical outcomes, their addition would strengthen the evidence provided by the PROs of the present study. In addition, the relatively small sample size may have precluded the identification of statistically significant relationships that may be identified with a larger sample of patients. In addition, we only investigated a narrow set of moderators and other patient characteristics not included here may better help identify those individuals that would benefit the most from post-operative mindfulness. Future studies can build upon this pilot study to more fully interrogate the influence of mindfulness on patient-reported outcomes following hip arthroscopy surgery.

CONCLUSIONS

The present study presents preliminary evidence that individuals with higher baseline anxiety may see a greater benefit of mindfulness with respect to improvements in pain post-operatively. On the other hand, individuals with higher BMI may be less likely to benefit from a remote mindfulness program with respect to global physical mental and physical health. With regards to duration of practice time, reduced job-related concerns are inversely associated with practice length, suggesting that short practice intervals may be beneficial. In follow-up interviews, individuals who participated in remote mindfulness reported significant perceived benefits with respect to affect, pain, and stress. Further study is needed to better identify the individual characteristics that may predispose some individuals to greater post-operative benefits from remote mindfulness training.

QUALITATIVE STUDY – MINDFULNESS PARTICIPANT INTERVIEWS

Participant #30 – highly engaged with app (772 minutes)



Question: How did (or would) you describe the meditation to your friends?

Well, I would say that every day I would use the app and it alternated back and forth between meditative practices and, umm, information and stories that backed up the practices that we were doing every other day. And it was between ten and twenty minutes long and you could select the times. The practices were very different, but very cool. There was one I remember very well was thinking kindly about someone you see every day but you don't have any relationship with somebody that you do have a strong relationship with and feel loving towards… and, umm, there was practices a bit like you had recommended earlier where you feel your feet and various mindfulness strategies.

Question: How would you describe your experience with meditation?

It's just like you were talking about - I think it's very positive. It is, it's a chance for me to feel the wonder of my existence… it's a chance for me to…. (long pause) umm, I guess just be in awe of the fact that I am.

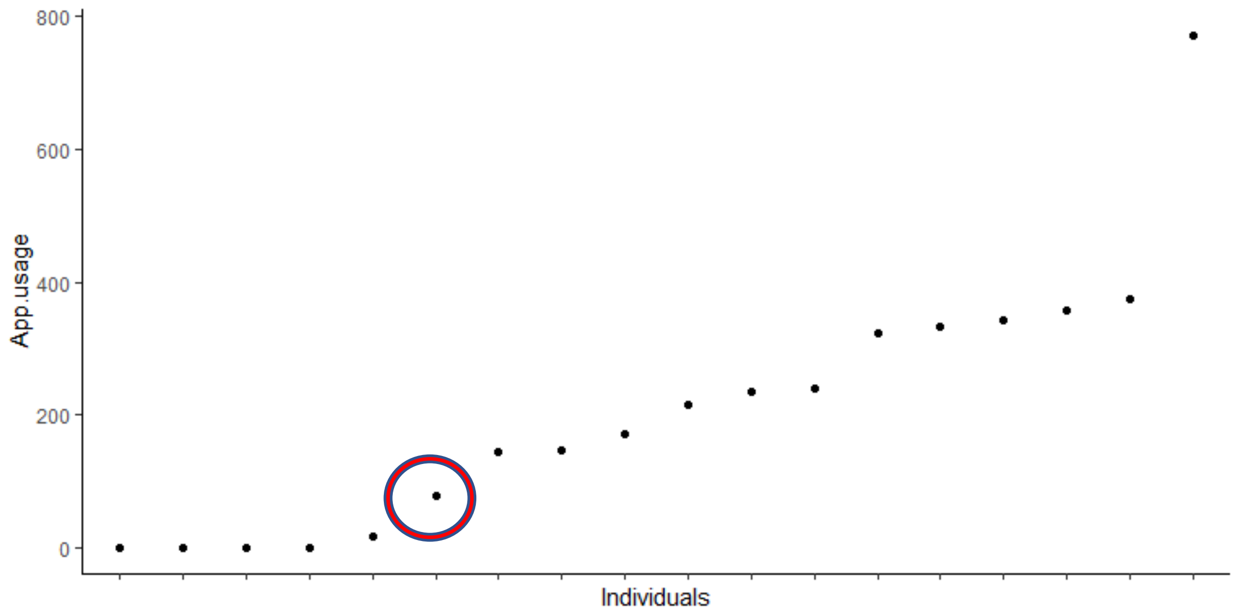
Question: How would you describe the impact of meditation on your recovery?

I think it was immensely positive - that would be my guess. I think, in part because (talks to people in background) and, I think, it was really nice at that moment… not only did you have the ability… you could see the connection between being mindful of your pain and being able to sort of bear your pain more easily by using a technique where you observe the pain rather than getting stuck in how awful it is. But it also gave me, like a structure to my day at that point, which actually was really helpful. And it gave me a routine, that much like the physical therapy exercises that I had to do, it felt really complementary to the PT.

Question: What suggestions do you have for the app developer regarding content, user experience, etc?

I wish there was… I wasn't sure when it ended. I wasn't… wait - what now? Is this over, do I keep going? That wasn't that clear to me - there was no goodbye at the end… you've done it… I don't believe it even suggested what to do at that point. So I wasn't sure… I even started just repeating… I kept going anyway and I would just repeat the sessions that I found spoke the most to me and meditating with those. Otherwise, I found it amazing - that you could choose a voice and length of time that you wanted to do it for (questioner speaks) You know what, come to think of it, that's something I found amazing - active practice like washing the dishes… meditating while doing the dishes was something that I always thought was true and wanted to be true really badly, and then that felt validating.

<u>Participant #16 – low engagement with app (147 minutes)</u>



Question: How did (or would) you describe the meditation to your friends?

Over a year ago, now… they were definitely relaxing, but there was also something, that like, I kind of felt like I had to do on top of, just like, existing after getting surgery. But like, the recordings themselves were nice and like I have a lot of friends that are into mindfulness and I would recommend it to them.

Question: How would you describe your experience with meditation?

In the beginning it was helpful, just to, like have something to do that I felt that, like, would work. But like, as I recovered it was harder to make time for it, just 'cuz I also went back to school not long after getting surgery, so it wasn't, like, as easy to build into my schedule as I think it would be for most people. Just cuz, like here we have 10-week terms and a lot of lab classes, so like, it was harder to continue doing, but initially it was really helpful.

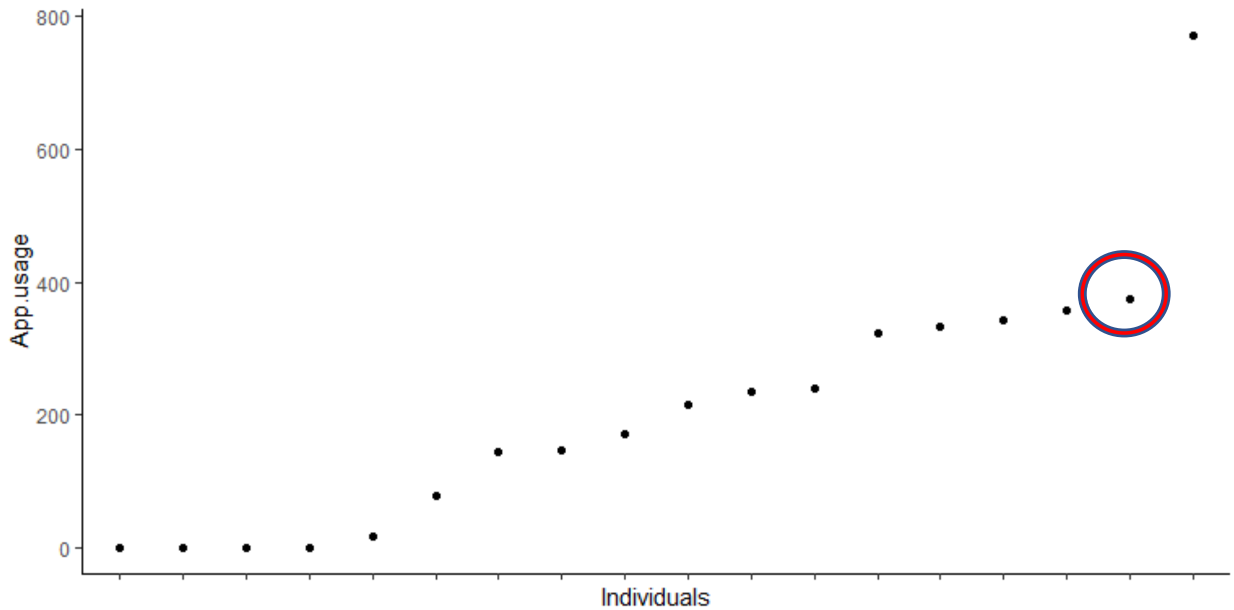
Question: How would you describe the impact of meditation on your recovery?

There were some days where I thought that it was really helping, and like, I wasn't doing extremely well, like, mental health wise. Just like, I had not been able to anything that I wanted to do for, like, a year at that point, and then I got home and had surgery and spent, like, about a month alone in the basement, so I think it was good that it was good to have something that was for my mental health during that time, but, like, in some ways it was also, like, I was doing it and then if I wasn't feeling the best, like, if I was kind of sad or feeling depressed, and like, I didn't feel like doing anything… is it worth continuing? I stuck with it until I left, but then school…

Question: What suggestions do you have for the app developer regarding content, user experience, etc?

I found that it was a pretty intuitively designed app… like, I never really had a hard time knowing what I was supposed to do… and, like, the reminders were helpful. I don't know… like, I guess especially, like, for someone that has more experience with meditation, like, that is something that that type of person would really want to incorporate into their surgery recovery. I know, I still feel like, general public perception sometimes is like… like my Dad was like "why are you doing these things?" Like anything else, but, like I don't think that it's something that he would use, but I think that my sister would use them. But I think that it was pretty accessible, it wasn't hard to use or figure out.

<u>Participant #32 – high engagement with app (374 minutes)</u>



Note: responses submitted via writing – participant was unwilling to meet synchronously

Question: How did (or would) you describe the meditation to your friends?

I don't think I would explain the actual meditation to people, but I would explain that I was participating in a study about meditation during my recovery.

Question: How would you describe your experience with meditation?

It was nice in general. It's not something I had really done before. I didn't like taking the time to calm my brain and thoughts in the same way that I did through this meditation. Now that I'm thinking about it, I might try to find a way to get back into it.

Question: How would you describe the impact of meditation on your recovery?

I don't know if I realized the impact during my recovery, but in general I felt pretty calm and at ease throughout the recovery. To contrast, I didn't do meditation in a more recent surgery (same procedure, other side) and generally felt more anxious and restless during that recovery compared to the one where I did do meditation.

Question: What suggestions do you have for the app developer regarding content, user experience, etc?

It was a bit unclear what I was supposed to do each day. I think it was supposed to be daily meditation, but there were only 5 days within each week in the app. I wanted the weeks to be full or more clear instructions on which ones to do multiple times.

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APPENDIX I – DATA AND SUPPLEMENTAL ANALYSES

iHOT – Total

Unadjusted Baseline and 3 month Values by Group for iHOT Total

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	37.77	29.48	46.05
Mindfulness	Baseline	18	42.49	32.96	52.01
Control	3 month	17	66.15	56.11	76.19
Mindfulness	3 month	17	73.86	67.42	80.31

Adjusted 3 month Values by Group for iHOT Total

Group	Time	mean	lower.CL	upper.CL
Control	3 month	67.36	58.78	75.95
Mindfulness	3 month	72.79	64.52	81.06

iHOT – Symptoms and Functional Limitations

Unadjusted Baseline and 3 month Values by Group for Symptoms and Functional Limitations (iHOT)

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	43.43	31.69	55.17
Mindfulness	Baseline	18	50.78	40.26	61.29
Control	3 month	17	73.18	63.93	82.43
Mindfulness	3 month	17	82.19	75.73	88.65

Adjusted 3 month Values by Group for Symptoms and Functional Limitations (iHOT)

Group	Time	mean	lower.CL	upper.CL
Control	3 month	75.44	67.70	83.18
Mindfulness	3 month	81.36	73.88	88.84

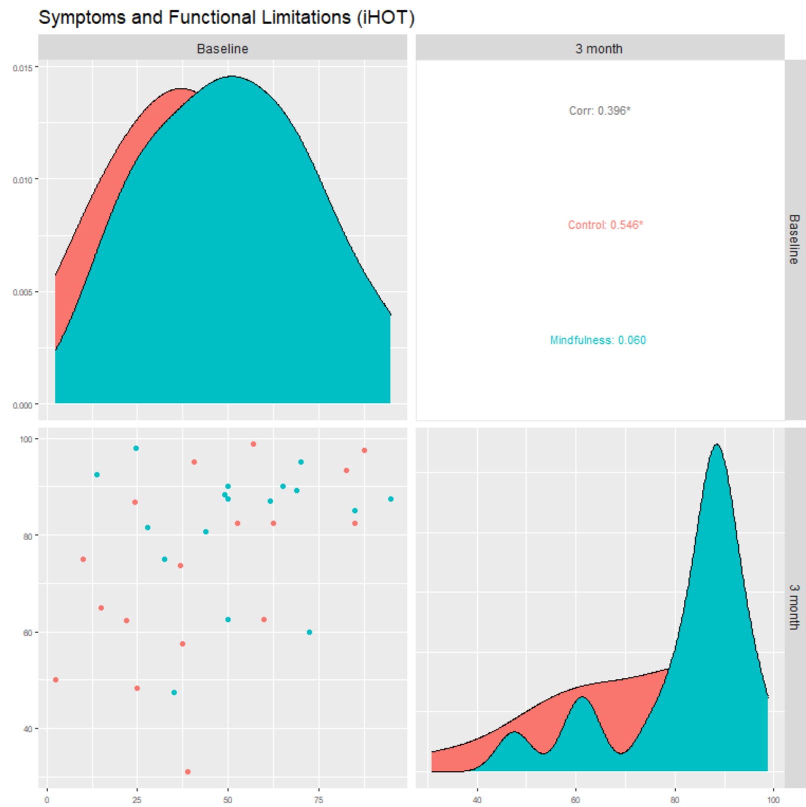
iHOT Sports and Recreational Activities

Unadjusted and Unadjusted 3 month Values by Group for Sports and Recreational Activities (iHOT)

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	28.35	20.39	36.31
Mindfulness	Baseline	18	35.07	23.68	46.46
Control	3 month	17	60.57	48.83	72.31
Mindfulness	3 month	17	63.96	55.67	72.25

Adjusted 3 month Values by Group for Sports and Recreational Activities (iHOT)

Group	Time	mean	lower.CL	upper.CL
Control	3 month	61.34	49.86	72.82
Mindfulness	3 month	63.08	52.07	74.08



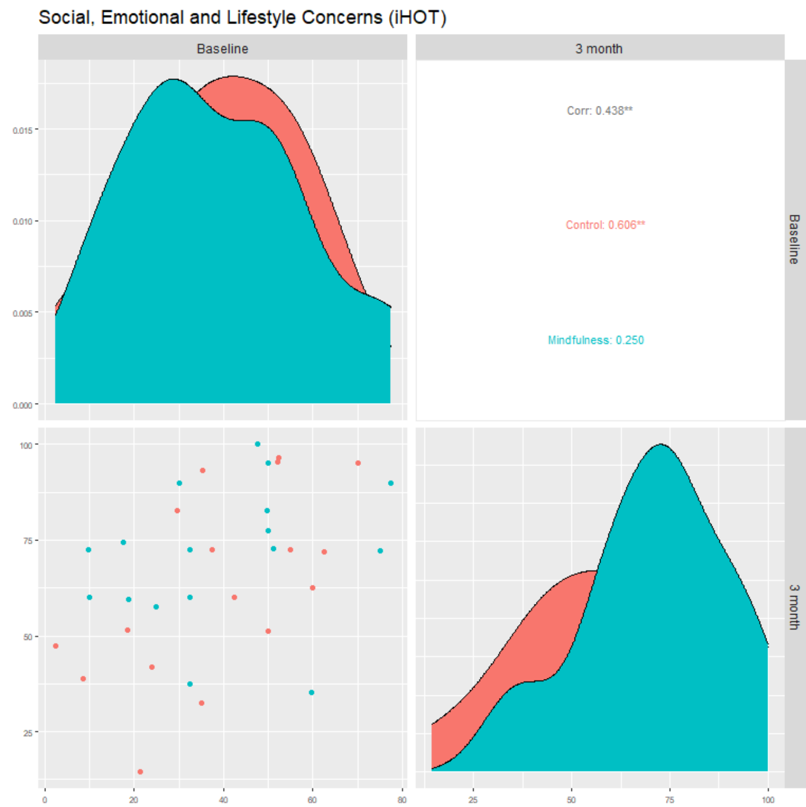
iHOT – social, emotional and lifestyle concerns

Unadjusted Baseline and 3 month Values by Group for Social, Emotional and Lifestyle Concerns (iHOT)

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	38.69	30.00	47.39
Mindfulness	Baseline	18	38.75	29.46	48.04
Control	3 month	17	63.54	51.90	75.19
Mindfulness	3 month	17	71.15	62.50	79.80

Adjusted 3 month Values by Group for Social, Emotional and Lifestyle Concerns (iHOT)

Group	Time	mean	lower.CL	upper.CL
Control	3 month	63.36	52.92	73.79
Mindfulness	3 month	70.97	61.00	80.93



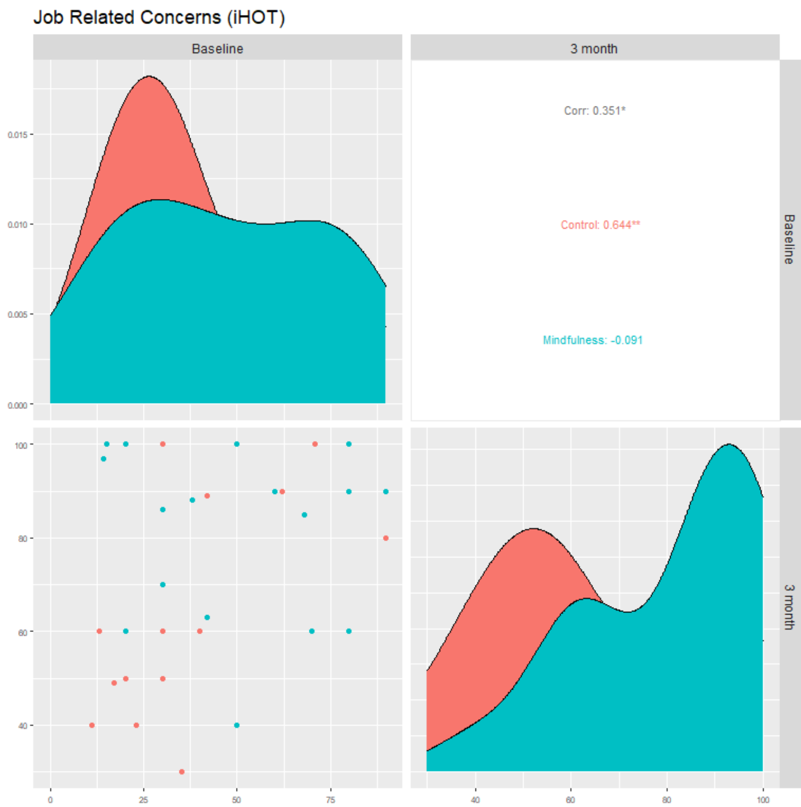
iHOT – job related concerns

Unadjusted Baseline and 3 month Values by Group for Job Related Concerns (iHOT)

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	39.67	28.43	50.90
Mindfulness	Baseline	18	46.50	33.86	59.14
Control	3 month	17	65.18	54.15	76.20
Mindfulness	3 month	17	81.12	72.32	89.92

Adjusted 3 month Values by Group for Job Related Concerns (iHOT)

	Group	Time	mean	lower.CL	upper.CL
3	Control	3 month	65.95	55.36	76.55
4	Mindfulness	3 month	79.66	69.44	89.89



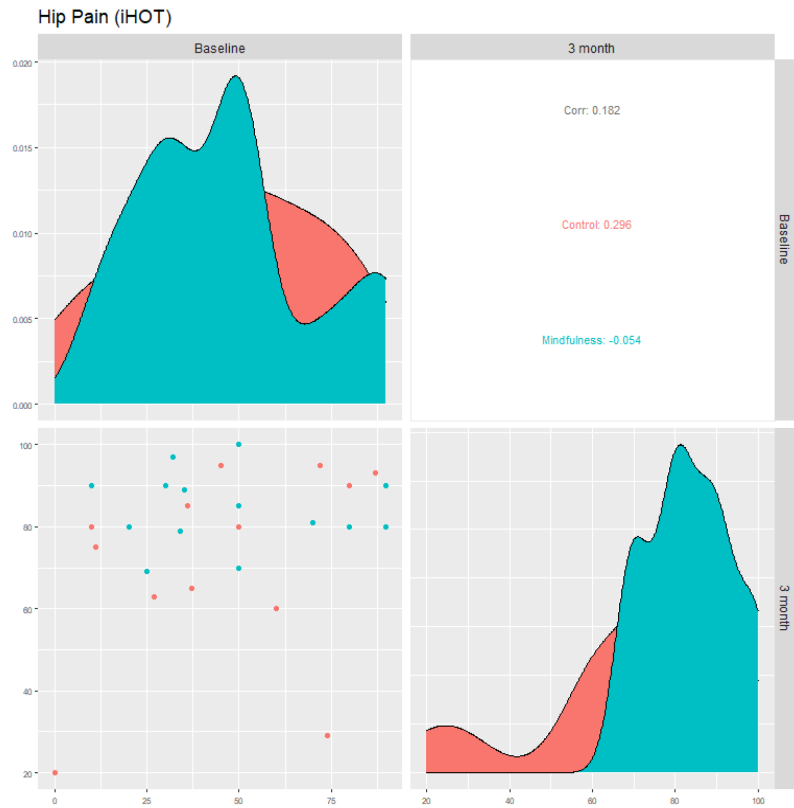
iHOT – pain

Unadjusted Baseline and 3 month Values by Group for Hip Pain (iHOT)

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	47.17	35.03	59.30
Mindfulness	Baseline	18	46.22	35.17	57.27
Control	3 month	17	72.35	62.21	82.50
Mindfulness	3 month	17	83.53	78.62	88.44

Adjusted 3 month Values by Group for Hip Pain (iHOT)

	Group	Time	mean	lower.CL	upper.CL
3	Control	3 month	73.89	66.0	81.78
4	Mindfulness	3 month	83.63	76.1	91.16



PROMIS Global Physical

Unadjusted Baseline and 3 month Values by Group for PROMIS Global Physical

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	42.67	38.67	46.67
Mindfulness	Baseline	18	45.78	42.49	49.07
Control	3 month	18	48.13	44.08	52.17
Mindfulness	3 month	17	49.98	45.99	53.98

Adjusted 3 month Values by Group for PROMIS Global Physical

	Group	Time	mean	lower.CL	upper.CL
3	Control	3 month	48.65	45.36	51.93
4	Mindfulness	3 month	48.32	45.03	51.61

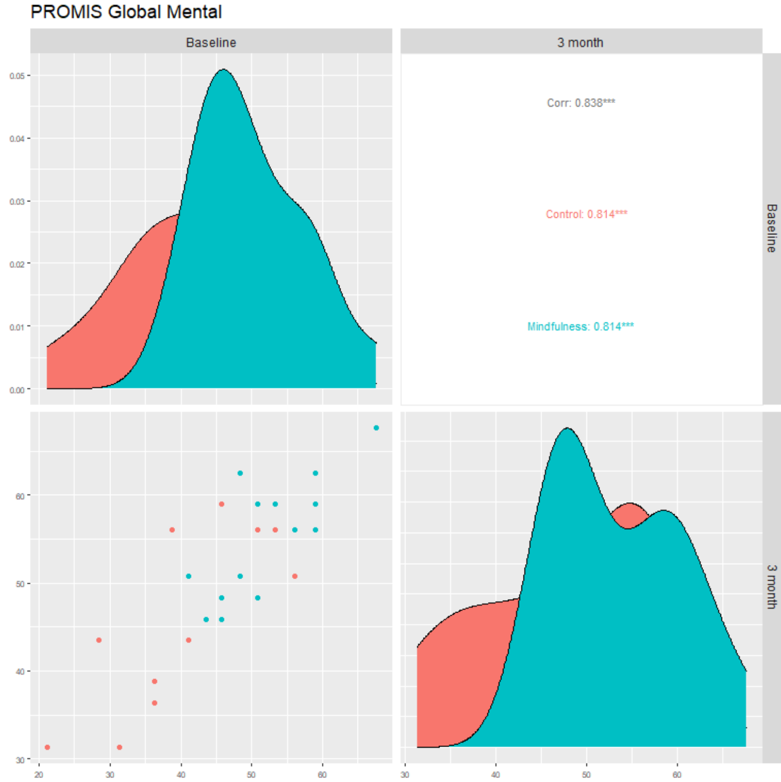
PROMIS Global Mental

Unadjusted Baseline and 3 month Values by Group for PROMIS Global Mental

Group	Time	N	mean	lower.CL	upper.CL
Control	Baseline	18	43.23	38.58	47.88
Mindfulness	Baseline	18	49.99	46.47	53.52
Control	3 month	18	47.62	43.22	52.03
Mindfulness	3 month	17	53.61	50.25	56.96

Adjusted 3 month Values by Group for PROMIS Global Mental

	Group	Time	mean	lower.CL	upper.CL
3	Control	3 month	50.13	47.43	52.84
4	Mindfulness	3 month	50.57	47.87	53.27



Mindfulness in Hip Arthroscopy by Compliance

Variable	Compliant	Non.compliant	p
Age	21 ± 12.7	33.4 ± 2.92	0.04
Beighton Score	4.5 ± 57.2	3.3 ± 1.02	0.86
BMI (kg/m2)	26.7 ± 21.2	26.8 ± 1.71	0.86
iHOT Total	25.4 ± 90	41 ± 6.75	0.28
mHHS Total	54.5 ± 19.1	63.8 ± 4.45	0.27
PROMIS Physical	49.5 ± 58.4	43.9 ± 2.8	0.30
PROMIS Mental	48.9 ± 128	46.5 ± 3.28	0.78
PROMIS Anxiety	50.4 ± 119	56.7 ± 3.06	0.53
PROMIS Depression	49.8 ± 97.8	52.1 ± 3.16	0.60
Hip Pain (iHOT)	33 ± 216	47.5 ± 8.69	0.47
Symptoms and Functional Limitations (iHOT)	31.1 ± 145	48 ± 8.48	0.32
Sports and Recreational Activities (iHOT)	9.67 ± 4.24	33 ± 7.38	0.09
Job Related Concerns (iHOT)	15 ± 191	44.7 ± 8.82	0.14
Social, Emotional and Lifestyle Concerns (iHOT)	34.1 ± 74.6	39 ± 6.87	0.70

APPENDIX II – PROMIS GHQ RECODING PROTOCOL

PROMIS Patient-Reported Outcomes Measurement Information System

Dynamic Tools to Measure Health Outcomes From the Patient Perspective

Table 2: Required Re-coding of Response Options for PROMIS Scale v1.0/v1.1 – Global Health

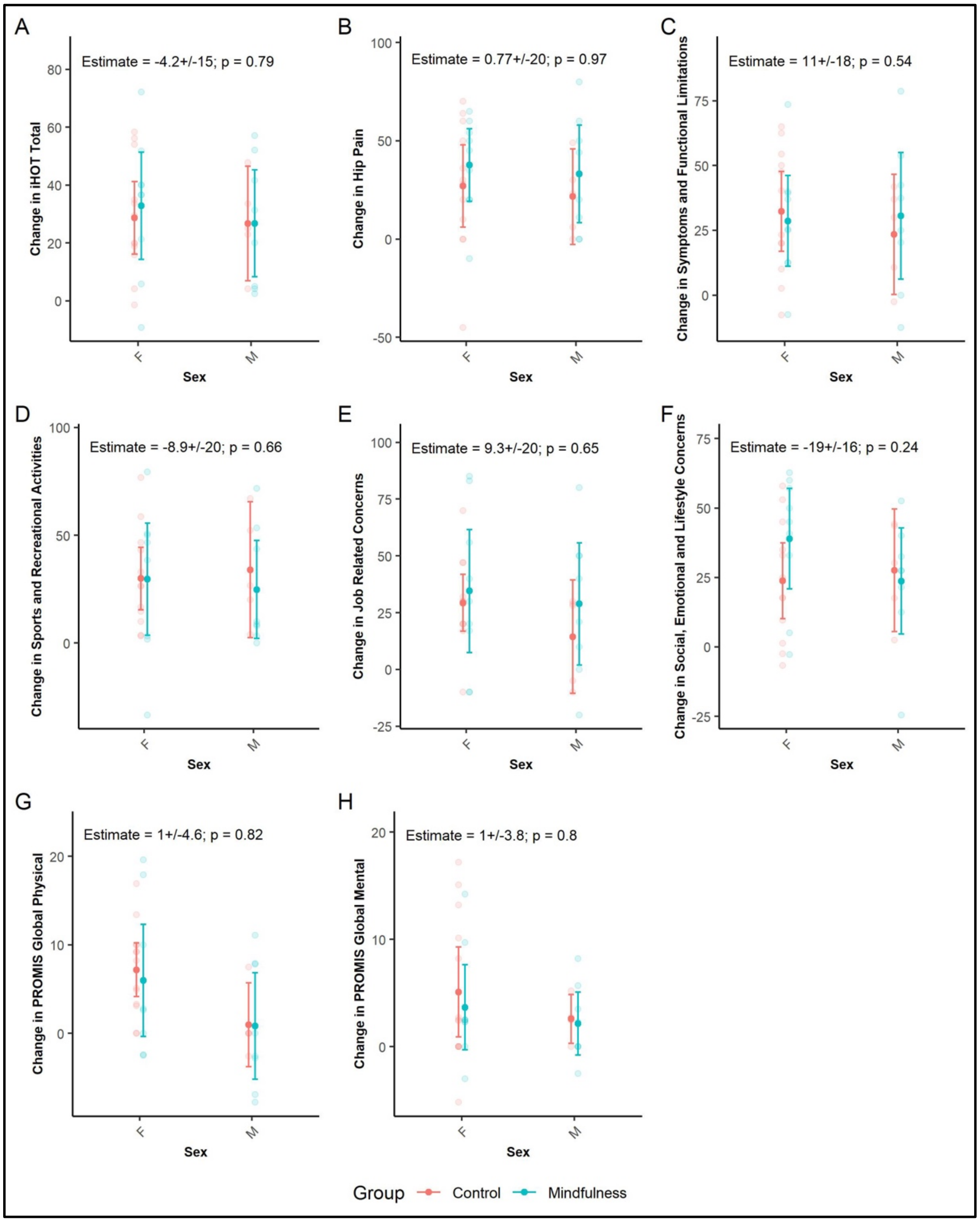
Original Item ID	Item Stem	New Item ID	Recoded Response Scores
Global07	How would you rate your pain on average?	Global07r	New Score = Response Text 5 = 0 - No pain 4 = 1 4 = 2 4 = 3 3 = 4 3 = 5 3 = 6 2 = 7 2 = 8 2 = 9 1 = 10 - Worst pain imaginable
Global08	How would you rate your fatigue on average?	Global08r	5 = None 4 = Mild 3 = Moderate 2 = Severe 1 = Very severe
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	Global10r	5 = Never 4 = Rarely 3 = Sometimes 2 = Often 1 = Always

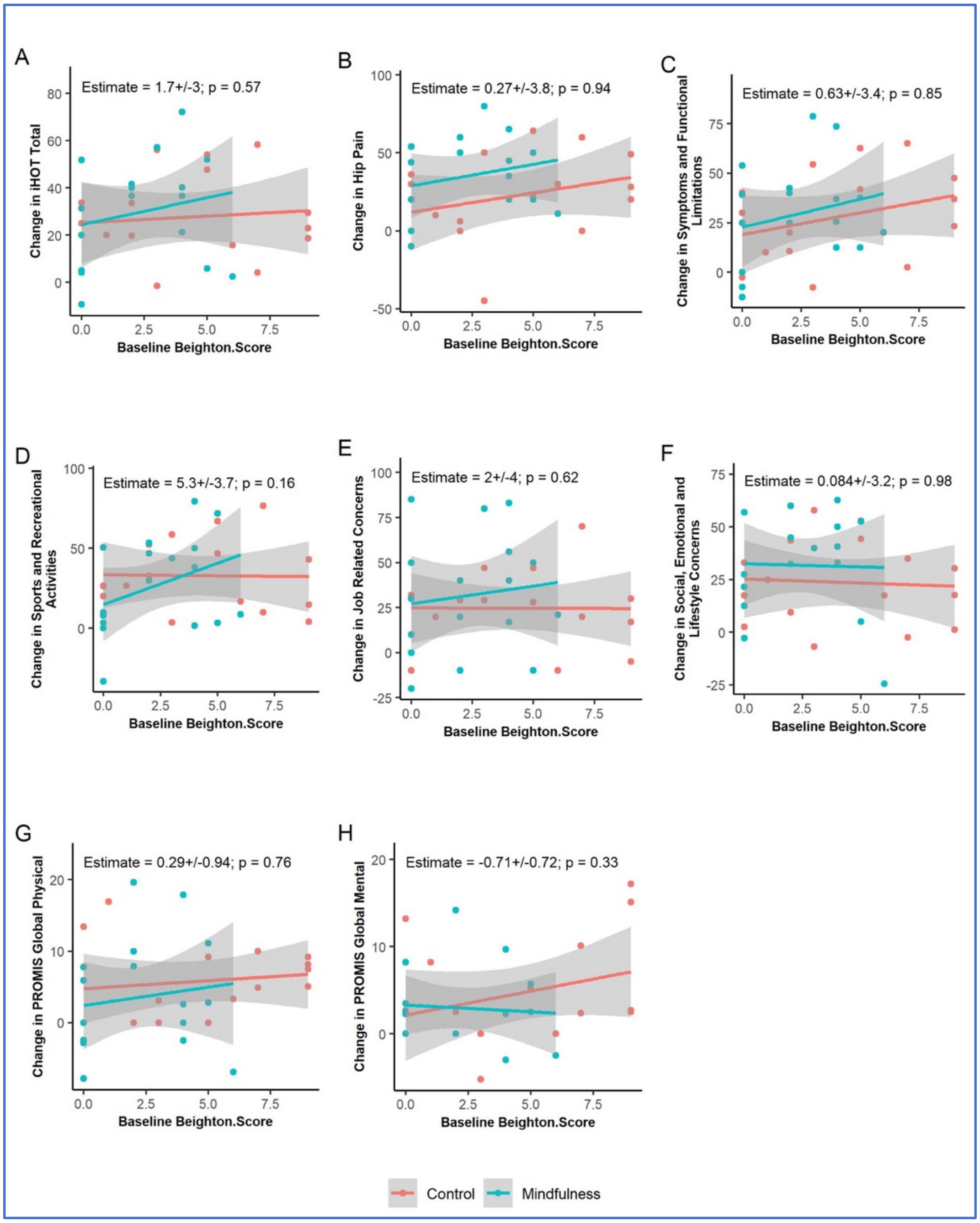
APPENDIX III - DATA

Baseline Variables by Group

Variable	Mindfulness	Control	p
Side (L)	7 (38.9%)	10 (55.6%)	0.50
Sex (F)	9 (50%)	13 (72.2%)	0.30
Age	32.9 ± 4.33	32.6 ± 4.36	0.90
Race	White (100%)	White (94%)	
Beighton Score	2.28 ± 1.06	4.53 ± 1.75	0.03
BMI (kg/m2)	26.6 ± 2.16	27 ± 2.62	0.84
iHOT Total	42.5 ± 10.3	37.8 ± 8.92	0.47
mHHS Total	65.4 ± 5.99	61.2 ± 6.5	0.33
PROMIS Physical	45.8 ± 3.54	42.7 ± 4.3	0.25
PROMIS Mental	50 ± 3.8	43.2 ± 5.01	0.03
PROMIS Anxiety	54.1 ± 3.95	58.6 ± 4.72	0.14
PROMIS Depression	50.8 ± 3.99	53.2 ± 4.95	0.44
Hip Pain (iHOT)	46.2 ± 11.9	47.2 ± 13.1	0.91
Symptoms and Functional Limitations (iHOT)	50.8 ± 11.3	43.4 ± 12.6	0.37
Sports and Recreational Activities (iHOT)	35.1 ± 12.3	28.4 ± 8.57	0.35
Job Related Concerns (iHOT)	46.5 ± 13.6	39.7 ± 12.1	0.43
Social, Emotional and Lifestyle Concerns (iHOT)	38.8 ± 10	38.7 ± 9.36	0.99

APPENDIX IV – INTERACTIONS OF SEX, AND BEIGHTON SCORES WITH DEPENDENT VARIABLES




A
Estimate = 1.7+/-3; p = 0.57
Change in iHOT Total
Baseline Beighton.Score
B
Estimate = 0.27+/-3.8; p = 0.94
Change in Hip Pain
Baseline Beighton.Score
C
Estimate = 0.63+/-3.4; p = 0.85
Change in Symptoms and Functional Limitations
Baseline Beighton.Score
D
Estimate = 5.3+/-3.7; p = 0.16
Change in Sports and Recreational Activities
Baseline Beighton.Score
E
Estimate = 2+/-4; p = 0.62
Change in Job Related Concerns
Baseline Beighton.Score
F
Estimate = 0.084+/-3.2; p = 0.98
Change in Social, Emotional and Lifestyle Concerns
Baseline Beighton.Score
G
Estimate = 0.29+/-0.94; p = 0.76
Change in PROMIS Global Physical
Baseline Beighton.Score
H
Estimate = -0.71+/-0.72; p = 0.33
Change in PROMIS Global Mental
Baseline Beighton.Score
Control
Mindfulness