

**Group therapy for fibromyalgia: a randomized controlled trial testing
the effectiveness of mindfulness-based therapy versus cognitive-
behavioral therapy**

Ph.D. Thesis

Submitted by:
Lee Frumer

Submitted to the Senate of Bar-Ilan University

Ramat-Gan, Israel

September 2023

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This work was carried out under the dedicated supervision of
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List of Abbreviations

ANOVA- Analysis of Variance

CBT- Cognitive behavioral therapy

FM- Fibromyalgia

MANOVA- Multivariate Analysis of Variance

MANCOVA- Multivariate Analysis of Covariance

MBSR - Mindfulness-Based Stress-Reduction

MDD- Major Depressive Disorder

NIH- The National Institutes of Health

PHQ-9 – Patient Health Questionnaire- 9

PIPS- Psychological Inflexibility in Pain

QOL- quality of Life

RCT- Randomized Controlled Trial

WL- Wait List Control Group

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Abstract

Background: Fibromyalgia (FM) is a rheumatic condition and pain disorder that primarily affects women. It is characterized by chronic and widespread spontaneous musculoskeletal pain and is highly comorbid with other functional somatic disorders, negative physical sensations in various organs and physiological systems, chronic fatigue, and impaired functioning. FM patients also report relatively high rates of psychiatric disorders, especially stress and mood disorders, as well as cognitive impairments and a general decline in their quality of life. Up to date, no optimal drug or psychological treatment has been found for FM patients. Cognitive behavioral therapy (CBT) and mindfulness-based therapy are the two recommended and popular psychological treatments for these patients. The present study compares the effectiveness of these interventions in a randomized controlled trial.

CBT is based on the theory that a person's basic belief system about oneself, and the world produces dysfunctional thoughts, which in turn contribute to negative feelings and maladaptive behaviors. The intervention thus includes an attempt to change cognitions and behaviors in order to reduce maladaptive emotional responses. When applied to chronic pain, CBT offers mental and physical practices that focus on thought patterns like catastrophizing and negative thoughts about one's ability or future, as well as on behaviors like avoidance. The therapist will also teach the patients to perform exercises (e.g., muscle relaxation) to calm negative emotions and reduce anxiety . Mindfulness involves "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally". It refers to awareness and attention on a moment-to-moment basis. The quality of awareness that this intervention tries to promote includes openness, curiosity, and a non-judgmental attitude, with an emphasis on seeing and accepting things as they are without trying to change them. Our study examined mindfulness-based stress reduction (MBSR) – a mindfulness protocol that focuses on stress and has been found to be effective for patients suffering from chronic pain. The essential difference between the treatments can be summarized as follows: while CBT promotes *change* in one's pain perception, Mindfulness promotes *acceptance* of the pain experience. Studies regarding the effectiveness of these approaches for FM patients indicate mixed results, and meta-analysis studies that compared the approaches showed an advantage for cognitive behavioral therapies.

To the best of our knowledge, there is no study that compares the two treatment methods directly. Moreover, most studies solely examined the outcomes (and not the process) of these interventions, focusing on general changes from pre- to post-intervention. Therefore, not much is known regarding how CBT and MBSR operate for this condition and what mechanisms are responsible for the changes in patient-reported symptoms following treatments. Finally, most of the previous studies used the generic protocols of CBT and MBSR that do not consider the vast cognitive and functional difficulties that FM patients cope with.

Objectives: The current study was designed to bridge these gaps in research through an extensive examination of the effectiveness of CBT and MBSR among FM patients using newly adapted treatment protocols designed for FM, and based on a variety of symptomatic, psychological, and cognitive measures. We expected that the interventions would be beneficial for FM patients, improving symptomatic aspects of FM, as well as the psychological aspects that accompany them, such as depression, perceived stress, and quality of life. As mentioned before, our study was conducted during COVID-19 pandemic, a situation that forced us to adapt the therapeutic interventions to a remote, online platform (using the Zoom app). This transition allowed us to compare the effect of treatments (CBT, MBSR) when delivered face-to-face and online by video conferencing. Another objective of the current study was to examine the processes underlying CBT and MBSR and identifying the mechanisms responsible for change in patient symptoms. We focused on the following potential mechanisms of change: 1) Difficulties in emotion regulation, 2) Psychological inflexibility related to pain, and 3) Pain catastrophizing. We generally hypothesized that the change in emotion regulation ability, as well the change in pain-related cognitions, would be associated with the change in the outcome variables.

Methods: The study we performed was a randomized controlled trial (RCT) that included 93 FM patients recruited through a large Israeli healthcare provider ('Maccabi healthcare). The criteria for study inclusion were: 1) a documented clinical diagnosis of FM given by an expert rheumatologist and/or clinical immunologist, 2) age 18 years or older, 3) Hebrew speakers, 4) physical ability to attend MBSR sessions, 5) no serious cognitive impairments, 6) no psychosis, 7) no active suicidality, 8) no substance abuse, 9) no concurrent participation in another clinical study, 10) no concurrent participation in another mindfulness-based/cognitive behavioral group

therapy, 11) insured by 'Maccabi' health care. Our study examined specific adjustments to the basic protocols of CBT and MBSR in accordance with the specific needs and characteristics of FM. Thus, we carefully adapted the standard protocols to address the symptoms of this condition more appropriately (e.g., emphasis on chronic pain, sleep, female gender-related characteristics, physical appearance, and movement), as well as patients' abilities (e.g., shorter exercises, more gradual processes). Our protocol included 10 (1.5 hour) group sessions. The CBT treatment protocol includes psychoeducation, work on maladaptive thinking schemes regulation techniques, and active daily activities planning to relieve pain and overcome avoidance. The MBSR treatment protocol includes psychoeducation and discussions about pain, stress and its effects and the application of mindfulness in everyday situations, in addition to mindfulness practices such as body scanning, conscious communication and focus on breathing. In both treatments, homework was given between the meetings. Following a comprehensive screening process, the participants were randomized into 3 groups – CBT, MBSR, and a waitlist control group (with delayed allocation to treatment post-waitlist). The study included these three measurements: pre-intervention, post-intervention, and 4-month follow up. The participants completed self-report questionnaires assessing the following primary outcome measures: FM, health-related quality of life, perceived stress, and major depression. Additionally, we assessed factors hypothesized to serve as change mechanisms in treatment: : psychological inflexibility in pain, pain catastrophizing, and difficulties in emotion regulation.

Results: In general, our findings reflect the therapeutic potential of MBSR and CBT for FM patients. In addition, MBSR was found to be more effective in comparison to CBT. Patients who received MBSR reported significant improvement in FM symptoms, depression, perceived stress, and health-related quality of life, compared to patients in the WL control group. Regarding CBT, improvements were observed in FM symptoms and the physical aspect of quality of life, compared to patients in the WL control group. These improvements occurred after a 10-week intervention and were stable after 4 months, except for HRQOL in the MBSR group. Moreover, while the comparison between CBT delivered face-to-face, CBT delivered by ZOOM, and the WL control group showed slightly higher therapeutic potential for face-to-face therapy, MBSR delivered by ZOOM was found to be more effective than both MBSR delivered

face-to-face, and the WL control group. It is important to note that when examining the trend of the follow-up results of the two MBSR groups, we found that while in the group that underwent face-to-face treatment, the relief of symptoms continued after 4 months, while in the group that underwent online treatment, the symptoms stabilized and even worsened. Additionally, the results of the study indicate a differential role for the change mechanisms examined in relation to both treatments and the various outcome measures. Our findings show that the change in psychological inflexibility in pain was most strongly associated with CBT outcome, while the change in pain catastrophizing was most strongly associated with MBSR outcome. The results of this study indicate that difficulty in emotional regulation played a less significant role in relation to the two treatments. Finally, the results show that the outcome measure most strongly associated with our chosen mechanisms of change was perceived stress.

Discussion: The current study is the first to compare two psychological interventions, with different therapeutic rationales, for FM patients. This study highlights the potential of MBSR (face-to-face and online) to treat conditions that are characterized by dominant mind-body aspects. This study also contributes to a deeper understanding of the effectiveness of CBT and MBSR for FM patients by creating an adequate protocol for this condition, and by examining a wide variety of symptomatic, psychological, and cognitive aspects. In addition, the study sheds light on the therapeutic components that may play a role in treatment outcome. It appears that the capacity to accept one's distress, rather than fight it, is highly important for FM. Moreover, it seems that when the patient manages to show greater flexibility in the face of pain, and especially when she manages to relate to it in a less catastrophic or reactive manner, the more her mental health improves following treatment.

Introduction

FM is a condition characterized by a complex clinical picture that includes physical and mental aspects that cause great distress (Häuser et al., 2015). This study will try to expand the knowledge about the condition, its common treatment methods effectiveness and, their mechanisms of action.

Over the years, a variety of treatments for FM have been offered by both pharmacology and psychotherapy. Nevertheless, an effective long-term treatment that fully addresses the spectrum of symptoms associated with FM has still not been found (Calandre, Rico-Villademoros, & Slim, 2015; Glombiewski et al., 2010). Furthermore, despite the scope of literature concerning the effects of individual interventions such as CBT and mindfulness-based interventions (MBI) on FM patients, there are few studies comparing the two in this regard. Thus, to fill these gaps in research knowledge and provide data to help determine the most suitable treatment method for FM patients, we performed an RCT (randomized control trail) comparing the two treatments. In addition, our study had the opportunity to compare videoconference and face-to-face therapy in both of the therapeutic approaches.

Additionally, research is lacking regarding the underlying mechanisms of change by which psychological treatments operate among rheumatic patients. In our study, we will explore the mechanisms of change of MBSR and CBT. We will focus particularly on pain-related cognition (Psychological Inflexibility in Pain, Pain Catastrophizing) and emotion regulation strategies which studies have linked to coping with FM (Angarita-Osorio et al., 2020; Geenen et al., 2012; Maurel Calvo, Sáez-Francàs, Alegre, & Castro-Marrero, 2020; van Middendorp et al., 2008; Sayer, Gulec, & Topbas, 2004).

For the present study, we have created newly amended treatment protocols for MBSR and CBT that are designed to suit the unique characteristics and difficulties of FM. We hope this study will enable the vast examination of MBSR and CBT effectiveness and the subsequent creation of a suitable protocol for these patients.

1. Fibromyalgia

FM is a rheumatic condition, characterized by chronic and widespread spontaneous musculoskeletal pain, as well as chronic headaches, sore throats, visceral pain, sensory hyper-responsiveness, and a wide variety of symptoms with no obvious tissue pathology. The American College of Rheumatology (ACR, 1990) criteria also included a demonstration of tenderness. Recently revised diagnostic criteria have delegated the symptom of tenderness to a list of frequent symptoms that include fatigue, lack of refreshing sleep, cognitive impairments, memory deficits, abdominal discomfort, and headache (Clauw, 2014; Glass, 2009; Wolfe & Hawley, 1998; Wolfe et al., 2011). FM is a common pain disorder that primarily affects women. It is highly comorbid with other functional somatic disorders, stress, and depression (Wolfe, Ross, Anderson, Russell, & Hebert, 1995). Unfortunately, at this time, there is no highly effective medical treatment for this condition (Häuser et al., 2015; Thieme, Mathys, & Turk, 2017).

The definition of FM as an autoimmune condition is controversial (Buskila & Sarzi-Puttini, 2008). FM is prevalent in autoimmune diseases, and some FM patients display autoimmunity dysfunction; thus, there is speculation that FM is, in fact, an autoimmune disorder (Buskila & Sarzi-Puttini, 2008). However, reports on immunological markers in FM are inconsistent, and there is no evidence regarding the inflammatory mechanisms in this syndrome. Currently, an FM diagnosis is mostly based on exclusion – meaning that other disorders are ruled out before FM is suggested (Sabik, 2012). While a distinct cause or pathology has not been identified, recent research has indicated that FM patients experience pain differently from the general population because of dysfunctional pain processing in the central nervous system (Abeles, Pillinger, Solitar, & Abeles, 2007). Furthermore, being diagnosed with FM is not an easy task. From the first time a patient presents their FM symptoms to a physician, the mean time to receiving an actual diagnosis of FM is 2.3 years. The average number of physicians to whom patients presented their symptoms before receiving a diagnosis of FM is 3.7, with 38% of patients having presented to more than three physicians (Choy et al., 2010).

Pharmacological treatment of the disorder has proved difficult, but central nervous agents such as tricyclic antidepressants (Heymann, Helfenstein, & Feldman, 2001) and selective serotonin/norepinephrine reuptake inhibitors (Arnold et al., 2005; Russell et al., 2008) have been found to be moderately successful for relatively short periods of time (Crofford, 2001). Only a

few non-pharmacological interventions have appeared to confer moderate benefits, including cardiovascular exercise, CBT, patient psychoeducation (Goldenberg, Burckhardt, & Crofford, 2004), or a combination of these (Häuser, Bernardy, Arnold, Offenbächer, & Schiltenswolf, 2009).

2. Stress, Stress-Related Medical Conditions, and Psychological Interventions

FM is known to be a stress-related condition. Stressful events are thought to influence the pathogenesis of physical diseases by prompting negative affective states (e.g., feelings of anxiety and depression), which affect biological processes or behavioral patterns that, in turn, influence disease risk (Cohen, Kessler, & Gordon, 1995). Exposure to chronic stress is deemed especially toxic since it has the highest likelihood of resulting in long-term or even permanent changes in the emotional, physiological, and behavioral responses that influence the course of the physical disease (Cohen, Janicki-Deverts, & Miller, 2007; Cohen, Kessler, & Gordon, 1995; Marin et al., 2011; McEwen, 1998).

An important pathway between stressors and disease risk is created by the behavioral changes that develop as adaptations or coping responses to stressors (i.e., sleep disruptions, worse adherence to medical regimens, and decreased exercise) (Cohen, Kessler, & Gordon, 1995; McEwen, 1998). Stressor-elicited endocrine response provides another key pathway. Two endocrine response systems are particularly reactive to psychological stress: the hypothalamic-pituitary-adrenocortical axis (HPA) and the sympathetic-adrenal-medullary (SAM) system. Prolonged or repeated activation of the HPA and SAM systems can interfere with their control of other physiological systems, resulting in an increased risk for physical and psychiatric disorders (Cohen, Kessler, & Gordon, 1995; McEwen, 1998). Additionally, the impact of stress on the regulation of immune and inflammatory processes can influence depression, anxiety, pain, and both infectious and autoimmune diseases (Kiecolt-Glaser et al., 2002).

2.1. Stress and Rheumatic Diseases

Rheumatic conditions such as FM are commonly referred to as stress-related conditions. They are painful and often disabling conditions that are enhanced and maintained by stress (Conversano et al., 2019; Hassett & Clauw, 2010; Sangha, 2000). Several studies have reported an increased risk of developing an anxiety disorder among patients with arthritis (Watad et al.,

2017), FM (Buskila & Cohen, 2007), Systemic Lupus Erythematosus (Roberts et al., 2017), and more. Additionally, patients with rheumatic illnesses have shown alterations in the stress-response and dysfunction in the immune system (Kojima et al., 2009). Rheumatic patients frequently note the occurrence of stressful or traumatic life events either prior to the onset of their illness or in relation to the onset (Hassett & Clauw, 2010). This is especially true for FM, where studies have shown a high incidence of traumatic events prior to the condition's onset (Cohen et al., 2002; Häuser et al., 2019). However, the question of whether stress is the cause or outcome of rheumatic conditions (or both) has yet to be fully answered. The presumed underlying mechanisms of these associations among rheumatic diseases include stress-related changes in functioning of the autonomic, neuroendocrine, and/or immune systems (Hassett & Clauw, 2010), as well as psychological factors such as anxiety, depression and catastrophizing (Pinto et al, 2023).

2.2. Stress and Chronic Pain Conditions

Since chronic pain is a central feature of FM, we will now address its general association with stress. Chronic pain has been particularly associated with high levels of stress. An estimated one in three people suffer from chronic pain, a condition frequently associated with decreased health-related quality of life and increased levels of psychological distress (Abdallah, & Geha, 2017; National Center for Health Statistics, 2006; Timmers et al., 2019).

Conventional treatments manage to help only a portion of chronic pain patients, unfortunately, almost half of the patients report that their pain is not under control, reflecting the complexity of these conditions (Rosenzweig et al., 2010). Limitations of drug therapy for chronic pain also indicate the complex pathophysiology of these conditions and the profound contribution of psychosocial factors to the perpetuation of pain and suffering (Keefe et al., 2004).

There is abundant evidence supporting the implication of psychological treatments for chronic pain conditions (Morley, Williams, & Eccleston, 2013). Psychological treatments are also used for autoimmune diseases (Glombiewski et al., 2010; Fiest et al., 2016). These psychological interventions include hypnosis (Torem et al., 2007), bio-feedback training (Buckelew et al., 1998), and cognitive behavioral therapies, which have received the most impressive empirical support (Hadley & Novitch, 2021; Morley, Eccleston, & Williams, 1999).

A significant development in the field of cognitive behavioral therapies includes the "third wave", a mind-body interventions, which appear to be very useful with stress-related conditions such as rheumatic conditions and chronic pain (Astin, 2004; Broderick, 2000). Mindfulness meditation, one of the predominant mind-body interventions practiced today, has gained momentum as an accepted form of "third wave" psychotherapy (Chiesa & Serretti, 2011). Mindfulness research and the clinical use of mindfulness as a therapeutic intervention have increased in recent years, and the results have been promising in a range of medical populations (Henke & Chur-Hansen, 2014; Horesh, Glick, Taub, Agmon-Levin, & Shoenfeld, 2017).

In our study we chose to compare CBT and MBSR, the two popular and promising psychological treatments for FM patients. The next section discuss the various treatments, their development and studies that examined its effectiveness among the population of patients with chronic pain and FM.

3. Cognitive Behavioral Therapy

The history of CBT can be divided into three different "waves" (Hayes, 2004). According to this conceptualization, each of the waves refers to different aspects of the fields of cognition and behavior in psychological therapy.

The "first wave" of CBT included the behavioral treatment approach (behavioristic). Behavioral therapy developed from the traditions of the learning theory developed by Pavlov (1927), Thorndike (1931) and Skinner (1953). These researchers generated and studied models of learning among animals in order to expand the understanding of the developmental processes of psychopathology. The early behavioral theorists believed that associations between stimuli and responses lead to the acquisition of maladaptive behaviors that underlie psychopathology (Watson & Rayner, 1920). The clinical treatment according to this approach includes the use of classical and operant conditioning techniques, behavioral training, and exposure therapy (Newman, LaFreniere, & Shin, 2017).

The "second wave" includes interventions derived from Aron Beck's theory (Beck, 1979). This approach was developed in the 1960-1970s and is based on principles of the behavioral approach that came before it. The innovations of cognitive theory went beyond behavioral theory to place great emphasis on the attempt to identify and change maladaptive cognitions.

This theory assumes that a person's basic belief system about himself and the world can produce dysfunctional thoughts, which in turn contribute to negative feelings and maladaptive behaviors (Beck, 1979).

The therapy includes an attempt to identify maladaptive thoughts and beliefs and to understand their effect on various symptoms. Beck hypothesized that cognitive change would lead to the relief of emotional distress and the change of maladaptive behaviors (Beck, 1979). The central technique in the treatment works through two channels: first, by identifying and monitoring negative and maladaptive thought patterns and their reconstruction, and second, through behavioral interventions – such as exposure, response prevention, etc. – aimed at interrupting the vicious circle between negative cognitive biases and the behavioral consequences (Bennett & David Nelson, 2006). A central part of the treatment focuses on identifying the thoughts, predictions, beliefs, behavioral reactions, physical sensations, and emotions experienced by the patient in moments of distress, with the aim of characterizing the patient's reactions to such situations. In fact, this method tries to promote new learning experiences. The common techniques used in this treatment to do so include psychoeducation, self-monitoring, cognitive re-construction, exposure in imagination/reality, relaxation, reduction of maladaptive behaviors and avoidance, behavioral activation, and more. The general features of these principles are maintained when applied in the context of group therapy (the subject of the present study), with the addition of important elements like sharing with other group members, providing mutual feedback after experiences of exposure and symptom monitoring, and mutual encouragement/motivation from the group. Beck's hypothesis (1979) asserts that each form of psychopathology can be characterized by negative cognitive schemas. As a result, different cognitive-behavioral-based models were developed for different psychopathologies. Each of these models attempts to explain the salient symptoms of specific disorders through the identification of cognitions, behaviors, and physiological responses that influence each other and are maintained through cognitive processes (i.e., attention, interpretations, memory, and evaluation).

Various and extensive studies have shown the effectiveness of CBT for different disorders, including depression, post-traumatic stress disorder, social anxiety, generalized anxiety,

obsessive-compulsive disorder, panic disorder, and more (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012).

The “third wave” of cognitive behavioral therapy presents a more contextual approach compared to previous waves. This approach attempts to elicit acceptance of the psychological experience rather than change or adjust how patients perceive it, as second wave therapists try to do. In recent years, methods associated with the “third wave” of CBT (e.g., Acceptance and Commitment Therapy, Dialectical behavior therapy, mindfulness) have been empirically tested. These methods began to develop mainly in the 1990s and include therapeutic models and theories that emphasize the principles of non-judgmental acceptance of thoughts and the overall experience, without attempting to resist or change them (Herbert & Forman, 2011). These methods will be explained in detail in the section describing the mindfulness approach.

3.1 CBT Studies among FM Patients

CBT for pain is based on the gate control theory of pain and the principles of operant conditioning treatment (Bennett & Nelson, 2006). The gate control theory of pain, published in 1965 (Melzack, 1996), states that when a stimulus gets sent to the brain, it must first travel to three locations within the spinal cord. These include the cells within the substantia gelatinosa in the dorsal horn, the fibers in the dorsal column, and the transmission cells in the dorsal horn (Ropero Peláez & Taniguchi, 2016). The substantia gelatinosa of the spinal cord's dorsal horn serves to modulate the signals that get through, acting like a “gate” for information traveling to the brain (Trachsel, Munakomi, & Cascella, 2022). The sensation of pain that an individual feels is the result of an interaction of these three components of the spinal cord. Simply stated, when the “gate” closes, the brain does not receive the information that is coming from the periphery to the spinal cord. However, when the signal traveling to the spinal cord reaches a certain level of intensity, the “gate” opens and a signal can travel to the brain where it is processed, and as a result, the individual feels pain. The information mentioned above accounts for the physical component of pain, but the Gate Control Theory acknowledges that psychological factors contributed to pain as well. Thus, in addition to the control provided by the substantia gelatinosa, there is an additional control mechanism located in cortical regions of the brain that are responsible for the effects of cognitive and emotional factors on the pain experienced (Ropero

Peláez & Taniguchi, 2016). Therefore, negative feelings and thoughts can amplify the intensity of the signals sent to the brain as well (Garland, 2012). For example, somebody who is anxious has a “gate” that is open more often, allowing more signals to get through, increasing the probability that an individual will experience pain from an otherwise normal stimulus. Accordingly, the CBT model for pain assumes that a recognition of emotion, behavior, cognition, as well as the physical and sensory aspects of pain is significant in understanding the patient’s experience of pain. The model states that this understanding is necessary when analyzing the impact of the patient’s personal beliefs regarding pain on their own distress. The goal of pain-focused CBT is to reduce maladaptive emotional responses to pain and its accompanying symptoms through cognitive and behavioral change techniques (Bradley & Albers, 1999; Keefe et al., 2005). Common techniques in this treatment include increasing the patient’s belief in their control over the pain, reducing maladaptive thoughts in relation to the pain, and improving the daily function that was undermined by the pain experience (Bennett & Nelson, 2006).

CBT for chronic pain has been applied and studied for many years (Bennett & Nelson, 2006). Therefore, this treatment is one of the two most common non-pharmacological treatments for FM (Goldenberg, Burckhardt, & Crofford, 2004). In a meta-analysis study that examined 23 RCT studies for FM, it was reported that CBT leads to the best results in reducing the intensity of pain in the short term and in alleviating sleep difficulties associated with FM. In addition, CBT has been proven to reduce negative mood or depression symptoms associated with the FM, improving patients’ daily functioning, ability to cope with pain, overall well-being, immune system functioning, increase brain efficiency and biological mechanisms that produce pain as well as increasing their general hope for improvement in their health (Bennett & Nelson, 2006; Lazaridou et al., 2017; Seminowicz et al., 2017; Thieme, Flor, & Turk, 2006). A recent systematic review conducted by Heller and colleagues (2021) showed CBT for FM improved pain processing and daily activities by decreasing patient’s limitations, such as morning stiffness. When CBT was compared to conventional pharmacological therapy, a certain superiority of CBT was observed concerning the quality of life, catastrophizing, and acceptance of pain. Furthermore, CBT found to help to normalize pain-related brain responses in FM (Lazaridou et al., 2017).

In the current study, a unique protocol of group CBT for FM was constructed. The protocol is based on the conclusions of studies that show the effectiveness of CBT for chronic pain and FM (Bernardy, Füber, Köllner, & Häuser, 2010; Glombiewski et al., 2010; Thorn & Kuhajda, 2006; Vallejo, Ortega, Rivera, Comeche, & Vallejo-Slocker, 2015).

4. Mindfulness

Mindfulness involves “paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally” (Kabat-Zinn, 1994, p.4). It refers to the cultivation of conscious awareness and attention on a moment-to-moment basis. The awareness sought by mindfulness practice includes openness or receptiveness, curiosity, and a non-judgmental attitude with an emphasis placed on seeing and accepting things as they are without trying to change them.

Mindfulness originated in ancient eastern and Buddhist philosophies and dates back about 2,500 years. Mindfulness meditation is one of the most important elements of the Buddha’s “noble eightfold path” to end suffering and instill wisdom. Principally, mindfulness in Buddhist teaching is viewed as a fundamental pathway to becoming aware of the causes and sources of suffering and to attain enlightenment or an awakening. As a result, individuals can become less egoistical and to obtain insight into the state of “non-self.” According to Buddhism, when an individual has truly acquired complete enlightenment or insight into the “non-self,” they will have achieved full freedom of the mind (Xiao, Yue, He, & Yu, 2017).

The Buddhist concept “sati” was first translated in 1881 from Pali as “mindfulness” by a British scholar of the Pali language, Thomas William Rhys Davids, based on his understanding of the *Mahasatipatthana Sutta*, and especially on the practice of watching how things “come to be” and how they “pass away” (Gethin, 2011). Through the process of mindfulness, one is able to dissociate from the contents of consciousness (i.e., one’s thoughts) and view one’s moment-by-moment experience with greater clarity and objectivity. Such a shift in perspective is labeled as “re-perceiving” by Shapiro and colleagues (2006), who found that this is the predominant methodology of mindfulness in therapy.

Mindfulness practice has been found to be effective in treating a variety of medical conditions, where patients’ distress stems from the intrusive nature of their pain and their subsequent difficulties in daily functioning (Kabat-Zinn, 1982; Kabat-Zinn, Lipworth, Burney,

& Sellers, 1986; Morone, Greco, & Weiner, 2008). A meta-analysis conducted by Astin (2004) on mind-body therapies categorized mindfulness meditation as a “promising MBT for heterogeneous pain but [one that] has yet to be adequately tested with randomized controlled trials” (Astin, 2004, p.30). In later sections of this dissertation, we will elaborate further on mindfulness and its specific clinical applications among our study population.

The field of mindfulness includes a variety of mindfulness-based interventions (MBIs), the most well-known and evidence-based of which are mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT). MBCT was originally designed to treat depression (Teasdale et al., 2000), but has been applied to a variety of medical populations (Fitzpatrick, Simpson, & Smith, 2010) and psychiatric disorders (Chiesa, & Serretti, 2011). MBSR is of particular interest for treating FM since it has been primarily recognized for reducing stress (Grossman, Niemann, Schmidt, & Walach, 2004). Considering that FM is defined as a stress-related disorder, MBSR seems more suitable for treatment of this disease than MBCT, which is less focused on stress reduction per-se.

4.1 Mindfulness-Based Stress Reduction (MBSR)

Mindfulness-Based Stress Reduction (MBSR) was developed at the University of Massachusetts Medical Center in 1979 by Jon Kabat-Zinn as an intervention to relieve stress and better cope with illness (Kabat-Zinn, 2003). MBSR is now being offered at many health care institutions in the U.S. and Europe (Santorelli, 1999). In its original version, MBSR is an eight-week program in mindfulness training. The standard program has weekly group sessions for 2–2.5 hours and one full-day session after six or seven weeks (Kabat-Zinn, 1990). Weekly sessions have standardized core elements consisting of different mental and physical mindfulness exercises: 1) body-scan exercises (paying close attention to all body parts from the feet to the head), 2) mental exercises (focusing one’s attention on breathing), 3) physical exercises (being aware of bodily sensations and one’s own limits during the exercises), and 4) practicing being fully aware during everyday activities by using breathing as an anchor for attention. Developing an accepting, non-reactive attitude is essential to all parts of the program. The intervention derives its roots from ancient Buddhist practices of Vipassana (insight) meditation and Yoga exercises; however, it has been adapted using Western terminology and is free of any religious

affiliation (Kabat-Zinn, 1990). In addition to the exercises, there are information sessions and discussions on stress, stress management, and how to apply mindfulness to interpersonal communication. In each session, group members are provided with time to discuss and reflect together on their experiences when practicing mindfulness. In between sessions, participants are strongly encouraged to practice the exercises daily for 30-45 minutes by listening to audiotapes with guided exercises on body-scanning, sitting mindfulness, breathing, and yoga stretching. MBSR is deemed effective once patients develop increased awareness to what is occurring in each moment with an accepting attitude (i.e., without getting caught up in automatic and habitual thoughts, emotions, and behavior patterns). This increased awareness allows for new coping mechanisms and healthier ways of responding to personal and environmental situations.

MBSR has been widely studied (Grossman et al., 2004). This intervention has been used to treat populations with a variety of mental disorders (e.g., anxiety, depression, attention deficit disorder; Haller, Breilmann, Schröter, Dobos, & Cramer, 2021; Lee et al., 2020; Oliva et al., 2021) as well as chronic physical illnesses (e.g., heart disease, cancer, epilepsy; Tedder, Shi, Si, Franco, & Chen, 2015; Walker, Obolensky, Dini, & Thompson, 2010; Würtzen et al., 2013). It was found to have extensive effects on biological processes as well, as it was associated with reduced cortisol levels and blood pressure, as well as with an increased number of white blood cells (Matousek, Dobkin, & Pruessner, 2010). All these factors are stress-related indicators (Carlson, Speca, Faris, & Patel, 2007).

4.2 MBSR Studies among FM Patients

There is conflicting evidence regarding whether MBSR is effective in treating FM-associated symptoms (Astin et al., 2003; Fjorback et al., 2013; Grossman et al., 2007). A recent review detected inadequate evidence for MBSR in FM patients (Lauche, Cramer, Dobos, Langhorst, & Schmidt, 2013). On the one hand, studies have examined MBSR among FM patients and have pointed to its effectiveness in improving physical symptoms, depression, pain, quality of life, and fatigue (Astin et al., 2003; Fjorback et al., 2013; Goldenberg et al., 1994; Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; Pérez-Aranda et al., 2019; Schmidt et al., 2011; Sephton et al., 2007). On the other hand, the effects that were found were inconsistent

in follow-up measurements (Lauche, Cramer, Dobos, Langhorst, & Schmidt, 2013), and there are studies that found non-significant effects to the reported measures (Fjorback et al., 2013; Schmidt et al., 2011). It is important to notice that the control groups of these studies differed widely, some studies used a wait-list (WL) or treatment as usual control group (Fjorback et al., 2013; Goldenberg et al., 1994; Schmidt et al., 2011; Sephton et al., 2007), while others applied an educational support group (Astin et al., 2003), or an active control procedure (Grossman et al., 2007; Schmidt et al., 2011). In addition to the differentiation in control group, there were also issues with reporting the results. Only a few of the RCTs reported adequate randomization and allocation concealment (Astin et al., 2003; Fjorback et al., 2013; Schmidt et al., 2011). Importantly, only one study examined the mechanisms of change of MBSR (Pérez-Aranda et al., 2019). In addition, most of the studies reported here examined the short-term effectiveness of MBSR (examining the changes from pre- to post-intervention). Few studies examined long-term effectiveness 6 months (Goldenberg et al., 1994) or 15 months after the intervention (Fjorback et al., 2013).

5. Comparison between CBT and MBSR for FM

In recent years, researchers have become interested in comparing psychological treatments for FM. There is currently no RCT studies that compare second wave cognitive behavioral treatment methods to those from the third wave regarding effectivity for FM directly. To date, this comparison has involved conducting meta-analysis studies comparing effect sizes found for the different treatment approaches in separate studies. The results of these studies indicate a preference for cognitive behavioral treatments from the second wave over relaxation interventions, educational interventions, behavioral treatments (including mainly operant interventions), and mindfulness-based treatments (Glombiewski et al., 2010). Furthermore, the authors point to methodological difficulties in studies that examined mindfulness-based approaches for the treatment of FM (Lami, Martinez, & Sanchez, 2013). In addition, these studies emphasize the need to examine and compare the therapeutic mechanisms and their suitability for FM patients to formulate interventions that can properly address the psychological and physiological complexity of this disorder (Glombiewski et al. 2010). Although it is currently impossible to find information on a direct comparison of the approaches, it is possible to find

information regarding their respective effectiveness in treating the main symptoms and difficulties from which FM patients suffer. Thus, for example, studies that compared the effectiveness of CBT and mindfulness-based therapy found that both approaches are equally effective for treating depression (Omid, Mohammadkhani, Mohammadi, & Zargar, 2013), pain (Cherkin et al., 2016), and anxiety (Arch et al., 2013).

This comparison is particularly interesting considering how different these two treatment modules are in terms of their philosophy. While one actively encourages modifying thoughts and correcting cognitions categorized as erroneous and irrational, the other, in almost paradoxically, emphasizes acceptance of negative feelings and thoughts without any attempt to change or fight them. The current study will be, to our knowledge, the first to conduct such a direct comparison.

6. Internet Based Psychological Therapy for FM

As mentioned before, our study was conducted during COVID-19 pandemic, a situation that forced us to adapt the therapeutic interventions to a remote, online platform (using the Zoom app). This transition allowed us to compare the effect of treatments (CBT, MBSR) when delivered face-to-face and online by video conferencing.

Although nonpharmacologic approaches have been shown to be efficacious in the treatment of FM patients, they are less likely to be used in clinical settings. These treatments are limited by inadequate access to qualified therapists, difficulty paying for treatments, a lack of physician awareness, or time constraints in implementing nonpharmacologic approaches. The patient burden associated with traveling to and from therapy may be another barrier (Menga et al., 2014).

Web-based therapies avoid many of these issues. The appeal of this approach lies in (1) reduced wait-list times and subsequent ease and speed of accessibility, (2) flexibility for individual schedules, (3) the ability for participants to work at their own pace in the comfort of their own homes, and (4) reduced cost (Andersson & Titov, 2014).

Online groups can be divided into two categories: synchronic groups (in which every participant is online at the same time) and asynchronic groups (in which participants can connect to the group at different times). Although the synchronic groups can be based on text alone, usually they are video conferences, using platforms that allow for both audio and video

communication (e.g., Zoom, Vsee, Doxy). The asynchronous groups usually use Internet forums (e.g., Google groups), although they can also use instant message platforms (e.g., WhatsApp), and are based on text messages only (Weinberg, 2020). There is evidence that the quality of the research on asynchronous therapy is not high, whereas quality of research for synchronously provided therapy is good (Varker, Brand, Ward, Terhaag, & Phelps, 2019).

Different studies have examined the effect of internet-based treatment for chronic pain. In a review conducted by Macea, Gajos, Calil, & Fregni (2010), 11 randomized control studies were assessed to quantify the efficacy of internet-based CBT (iCBT) with a specific focus on chronic pain. This meta-analysis found small reductions in pain compared to wait-list control groups. In another review (Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011) 17 articles that evaluated iCBT for chronic pain were evaluated. The total sample analyzed consisted of 2503 individuals with different chronic pain syndromes. Results showed that iCBT was associated with improvements in pain, activity limitation, and costs associated with treatment. The effects on depression and anxiety were less consistent. A meta-analysis aimed at evaluating the efficacy of different types of internet-based cognitive behavioral (iCBT) therapies in FM demonstrated that ICBTs provide a clinically relevant effect over control interventions in reducing negative mood and disability at the end of treatment (Bernardy, Klose, Welsch & Häuser, 2019).

Preliminary evidence suggests that Web-based MBIs may be helpful in alleviating the symptom burden that those with physical health conditions can experience, particularly when these interventions are tailored for specific symptoms (Toivonen, Zernicke & Carlson, 2017). Furthermore, a literature review on mindfulness-based online therapy for FM patients highlighted two studies conducted on the subject. Both studies indicate a therapeutic potential for this method (Davis & Zatura, 2013; Garrido-Torres et al., 2016).

It is important to note that these studies examined therapeutic intervention through recorded modules and not a direct therapeutic approach. Videoconference-delivered therapy is bidirectional such that it allows patients and their therapists to hear and see each other in real time, which may help to provide a greater sense of connection between the therapist and the patient (Stamm, 1998; Stefan et al., 2021). To our knowledge, only a few studies examined cognitive-behavioral group protocol for chronic pain patients by videoconferencing (Connolly et al., 2018; Palyo, Schopmeyer, & McQuaid, 2012; Taguchi et al., 2021) and mindfulness

videoconferencing for chronic pain patients (Gardner-Nix, Barbati, Grummitt, Pukal, & Raponi Newton, 2014; Gardner-Nix, Backman, Barbati, & Grummitt, 2018). These studies showed that videoconferencing is an effective mode of delivery for CBT and Mindfulness interventions for chronic pain and may represent a new way of helping chronic pain patients manage their suffering. To our knowledge no study examined the effectiveness of CBT or mindfulness videoconferencing therapies for FM patients. For this reason, in addition to the general absence of sufficient studies and therapeutic tools examined in them, it is important to examine online CBT and mindfulness interventions for this population.

7. Adapting Generic Treatment Protocols for FM Patients

Recent years have seen a surge in research supporting personalized treatment, tailored to specific disorders (Barlow, Allen, & Choate, 2020). Numerous studies have pointed to the problems with using the same generic protocol for different conditions (i.e., a “one-size fits all” approach; Purgato, Singh, Acarturk, & Cuijpers, 2021). Following this, many studies were carried out on disorder-adapted treatments in the cognitive-behavioral approach (Goldin et al., 2014; Lahad & Doron, 2010; Weeks et al., 2020) and in mindfulness-based treatments (Cairncross & Miller, 2020; Schroevers et al., 2015; Taub et al., 2021). Nonetheless, most research on CBT and mindfulness-based interventions among FM patients has used a generic treatment protocol (Lauche et al., 2013). This is understandable, considering the vast research that indicates the effectiveness of these protocols for a wide variety of populations (Hofmann et al., 2012; Praissman, 2008).

Our study examined specific adjustments to the basic protocols of CBT and MBSR in accordance with the specific needs and characteristics of FM. Thus, we carefully adapted the standard protocols to address the symptoms of this condition more appropriately (e.g., emphasis on chronic pain, sleep, female gender-related characteristics, physical appearance, and movement), as well as patients’ abilities (e.g., shorter exercises, more gradual processes). A detailed explanation of each of the protocols can be found in the method section, and the protocols of the interventions are attached as an appendix (see appendix 1 and 2). We hope this

study will help to establish adequate protocols for treating FM –protocols which are currently sorely missing in this field.

8. Mechanisms of Change in FM Psychotherapy

After decades of psychotherapy research, there is no evidence-based explanation of how or why the most well-studied interventions produce change, that is, the mechanisms through which treatments operate (Kazdin, 2009). There are several reasons why it is important to discover mechanisms of change: First, finding a link between a mechanism and an improvement in the outcome measures will strengthen the understanding of the treatment's effectiveness. Second, this endeavor will indicate which mechanisms are the most significant, thus improving the effectiveness of treatment by highlighting to therapists what are the most important treatment targets. And, finally, information about significant mechanisms and their relationship with specific symptoms will expand our understanding regarding both mental and biological processes associated with a disorder (Jensen, Turner, & Romano, 2007).

In this context it is necessary to mention "The Dodo bird verdict", a term first introduced by Luborsky, Singer and Luborsky (1975). The term refers to the issue of change factors in psychotherapy and, specifically, to different treatment approaches that bring the same results. For this reason, researchers tried to identify shared and different mechanisms for different treatments. Many times, scholars have concluded that there are generic mechanisms present in all types of treatment (Laska, Gurman, & Wampold, 2014; Wampold, 2010). An important paper in this field (Norcross, 1995) claims that beyond these common factors, it is important to identify the specific mechanisms through which each treatment works. This notion is based on the facts that not all types of psychological treatment have been tested, that a reduction in the same symptoms does not reflect the same long-term process and/or result, and that the appearance of identical components cannot indicate that the entire treatment process is the same. Various studies have examined the importance of cognitive processes for improvement in main outcome measures (depression, stress, anxiety, physical pain) following both CBT and MBSR (Alsubaie et al., 2017; Burns et al., 2023; Burns, Day & Thorn, 2012; Burns, Van Dyke, Newman, Morais, & Thorn, 2020; Teachma, Beadel, & Steinman, 2014).

In conclusion, up to date, there are not enough studies on the mechanisms of psychological treatments for FM patients, and specifically, there are no studies that compare the mechanisms of two different treatment approaches. In this study, we will try to bridge these gaps, by examining different mechanisms in CBT and MBSR for FM patients.

The next section will address potential mechanisms of change that will be examined in the present study, including two pain cognition (psychological inflexibility in pain and pain catastrophizing) and one general mechanism- difficulties in emotion regulation. We chose these mechanisms because we believe that the connection to pain is critical in FM and as will be detailed later, these mechanisms were also found to be significant in the development and maintenance of the disease. Along with this, we chose the emotional regulation mechanism that is found to be at the basis of the development of various psychopathologies and includes reference to different and more general cognitive and emotional components.

8.1 Psychological Inflexibility in Pain as a Mechanism of Change

Psychological flexibility is defined as the ability to behave adaptively in response to life events while accepting unpleasant thoughts, feelings, or physical symptoms. In our study, two mechanisms that make up psychological flexibility will be examined: avoidance and cognitive fusion (Hayes et al., 2006). In this context, cognitive ‘fusion’ describes the ability to treat thoughts as ‘thoughts’ rather than as necessary facts that one is bound to act upon. High cognitive fusion will describe focusing our attention on the contents of our mind (our thoughts, memories, assumptions, beliefs) rather than what we are experiencing. Psychological flexibility, specifically pain acceptance, has been shown to be related to psychological and physiological functioning among chronic pain patients (McCracken & Morley, 2014).

Despite the research evidence for the importance of these processes in pain disorders, there is little evidence presenting that these processes are involved in the development of FM. Relevant research shows that cognitive fusion, avoidance, and acceptance in relation to pain are related to functional abilities among FM patients (Trainor, Baranoff, Henke, & Winefield, 2018). Moreover, studies showed that an improvement in these processes may contribute to patients’ sense of self-efficacy (Trainor, Baranoff, Henke, & Winefield, 2018) and that psychological

flexibility may modulate the relation between the severity and impact of FM symptoms (Vallejo et al., 2021).

Regarding CBT, although it does not focus directly on the development of psychological flexibility, it seems that the two are connected in different aspects. The importance that CBT assigns to the separation between emotion and behavior and to the reduction of avoidance hints at its possible contribution to the development of this ability (Espejo, Gorlick, & Castriotta, 2017; Yasinski et al., 2020). Currently, there is no sufficient research on this aspect of CBT in FM. However, there is significant evidence that CBT contributes to the development of psychological flexibility among people diagnosed with panic disorder and social anxiety (Gloster, Klotsche, Chaker, Hummel, & Hoyer, 2011). Akerblom and colleagues (2021) demonstrated that pre-treatment scores on the psychological inflexibility scale predicted CBT outcomes (pain, depression) in chronic pain patients and that change scores on each of the psychological flexibility measures separately mediated outcomes.

Within the third wave theories of CBT, a willingness to maintain contact with negative experiences (such as fear and pain), as well as the ability to observe thoughts and feelings and not react to them, are seen as important factors in preventing emotional difficulties and reduction in subjective well-being (Hayes et al., 2006; Kabat-Zinn, 1994). In addition, avoiding unpleasant experiences is seen as having the potential to alleviate symptoms in the short term, but leading to inflexibility and a narrowing of the potential range of emotional experiences in the long term, thereby harming daily functioning and mental well-being. Avoidance of pain is an example of a process in which the thought or fear of the formation of pain leads to dysfunction. Thus, the avoidance resulting from thought leads to maladaptive behavior in response to life events that have the potential to cause development and growth (Hayes et al., 2006). Only two studies examined the role of psychological inflexibility in pain as a potential mechanism of change in treatments based on third wave theories. The first conducted an Acceptance and Commitment Therapy treatment (ACT) on chronic pain patients and found that psychological inflexibility in pain mediates the relationship between therapy and pain interference (Lin, Klatt, McCracken, & Baumeister, 2018). A recent study conducted by Pérez-Aranda et al. (2019) examined explored mindfulness and psychological inflexibility in pain as mechanisms of change in MBSR among FM patients. The results indicated that the changes

produced by MBSR on the impact of the disease were mediated by psychological inflexibility in pain and the mindfulness facet of “acting with awareness”. However, it is still limited since FM Impact is only one of the three subscales of the FM measure (FM Impact Questionnaire Revised; FIQR).

8.2 Pain Catastrophizing as a Mechanism of Change

The term catastrophizing was formally introduced by Albert Ellis (1962) and subsequently adapted by Aaron Beck (1979) to describe a maladaptive cognitive style employed by patients with anxiety and depressive disorders. At the core of their definitions, “catastrophizing” was deemed the concept of an irrationally negative forecast of future events. Similarly, pain-related catastrophizing is broadly conceived as a set of exaggerated and negative cognitive and emotional schema brought to bear during actual or anticipated painful stimulation. It is defined as “a cognitive and emotional state where patients magnify the threat value of a pain stimulus in the context of pain and are unable to inhibit intrusive pain-related thoughts” (Sullivan & Bishop, 1995).

Pain catastrophizing has been studied as a potential treatment mechanism among general chronic pain conditions (Burns, Johnson, Mahoney, Devine, & Pawl, 1998; Jensen, Turner, & Romano, 2001; Turner, Holtzman, & Mancl, 2007) such as lower back pain (Spinhoven et al., 2004) and chronic headaches (Thorn et al., 2007).

Among FM patients, the maladaptive coping strategy of pain catastrophizing is believed to play a key role (Baastrup et al., 2016; Gracely et al., 2004), and was found to be positively associated with pain intensity (Paschali, Lazaridou, Paschalis, Napadow, & Edwards, 2021). An important review describes the growing body of literature that links catastrophizing and depression to the experience of pain across several rheumatic diseases (Edwards, Cahalan, Mensing, Smith, & Haythornthwaite, 2011). It describes the way that depression and catastrophizing are consistently correlated with each other, and how they are both associated with reported severity of pain, sensitivity to pain, physical disability, poor treatment outcomes, inflammatory disease activity, and even potentially early mortality (Edwards et al., 2011).

Relate to CBT, the evidence that a change in pain catastrophizing represents a therapeutic mechanism in CBT for chronic pain comes mostly from longitudinal designs using

correlation methods (Burns, Day & Thorn, 2012). Few studies showed that reductions in pain catastrophizing were significantly related to outcome improvements of CBT for chronic pain (Burns, Day, & Thorn, 2012; Gilliam et al., 2021). One study examined the role of pain catastrophizing in CBT for FM patients and showed that reductions in pain catastrophizing mediated pain improvement (Lee et al., 2023).

To the best of our knowledge, no study examined pain catastrophizing as a change mechanism in MBSR treatment for chronic pain patients (Adler-Neal, Zeidan, 2017). Despite the role that pain catastrophizing plays in pain-related conditions, it has been examined only once in a study of the effect of MBSR on FM patients (Pérez-Aranda et al., 2019) but only as an outcome and not as a mechanism of change. Nevertheless, there are studies that showed a connection between mindfulness therapy and catastrophizing (Kearson et al., 2019; Turner et al., 2016).

8.3 Emotion regulation as a Mechanism of Change

Different researchers attribute different abilities and processes to the concept of emotional regulation. From the overview of the various models, emotional regulation can be characterized as a concept that involves emotional diversity and flexibility, awareness and understanding of emotions, acceptance of emotion, the ability to control impulsive behaviors in response to negative emotions, and the ability to use emotional regulation strategies in a flexible manner that matches the emotional state and the functional goal (Grazt & Roemer, 2004).

In accordance with the cognitive behavioral theories of psychopathology, which emphasize the importance of the cognitive and emotional mechanisms that underlie the distress in contrast to the importance of the symptoms accompanying it (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996), various studies have begun to consider the role of emotional regulation processes as having the potential to constitute a mechanism that leads to the development of various symptoms and inadaptability behaviors (Gross & Munoz, 1995).

Despite the high emotional distress among FM patients, few studies have addressed the processes of emotional regulation among this population. Studies that referred to emotional regulation showed that the emotional world of FM patients is characterized by high emotional intensity. Accordingly, they identified a high level of negative emotion and a low level of

positive emotion in FM patients. Moreover, difficulty identifying and expressing emotions, as well as the use of emotional avoidance have been found in FM patients (Middendorp et al., 2008; Sayar, Gulec, & Topbas, 2004). Another study shows that the ability to express emotions is linked to a decrease in the level of symptoms among FM patients (Geenen, Ooijen-van der Linden, Lumley, Bijlsma, & Middendorp, 2012). Moreover, another study showed that FM patients did not diverge from the healthy group in the amount of attention or awareness allotted to their mood states. However, they did differ in the acceptance of mood states, the ability to concentrate or perform tasks while experiencing negative mood states, the experience of becoming overwhelmed by emotional intensity and its persistence, as well as in their understanding and clarity of the emotions they experience (Trucharte et al., 2020).

A novel proposed model of FM suggests that an imbalance in emotion regulation, reflected by an overactive threat system and underactive soothing system, might keep the ‘salience network’ (also known as the midcingulo-insular network) in continuous alert mode and that this hyperactivation, in conjunction with other mechanisms, contributes to FM (Pinto et al., 2022).

Various studies have referred to the emotional regulation process as a therapeutic mechanism among a variety of populations. In relation to CBT, studies comparing the presence of emotional processing in CBT with other therapeutic modalities have revealed conflicting findings. While some researchers have reported no difference in emotional processing outcome between psychodynamic therapy and CBT (Coombs, Coleman, & Jones, 2002; Jones & Pulos, 1993), others have reported that experiential and psychodynamic therapies facilitate emotional processing more effectively than CBT (Rudkin, Llewelyn, Hardy, Stiles, & Barkham, 2007; Watson & Bedard, 2006). Along with this, there are studies suggesting that emphasizing emotional regulation strategies in cognitive-behavioral therapy promotes the effectiveness of the treatment (Berking et al., 2008). To summarize, the place of the emotional regulation process as a change mechanism in cognitive-behavioral therapy has not yet been clarified.

In relation to the ‘third wave’ treatments of the cognitive-behavioral approach, mindfulness-based meditation has been found to promote processes of emotional regulation (Kabat-zinn, 1994; Kabat-Zinn, 1990; Teper, Segal, & Inzlicht, 2013). In addition, studies show a relationship between high levels of mindfulness and the ability to regulate emotions (Gratz &

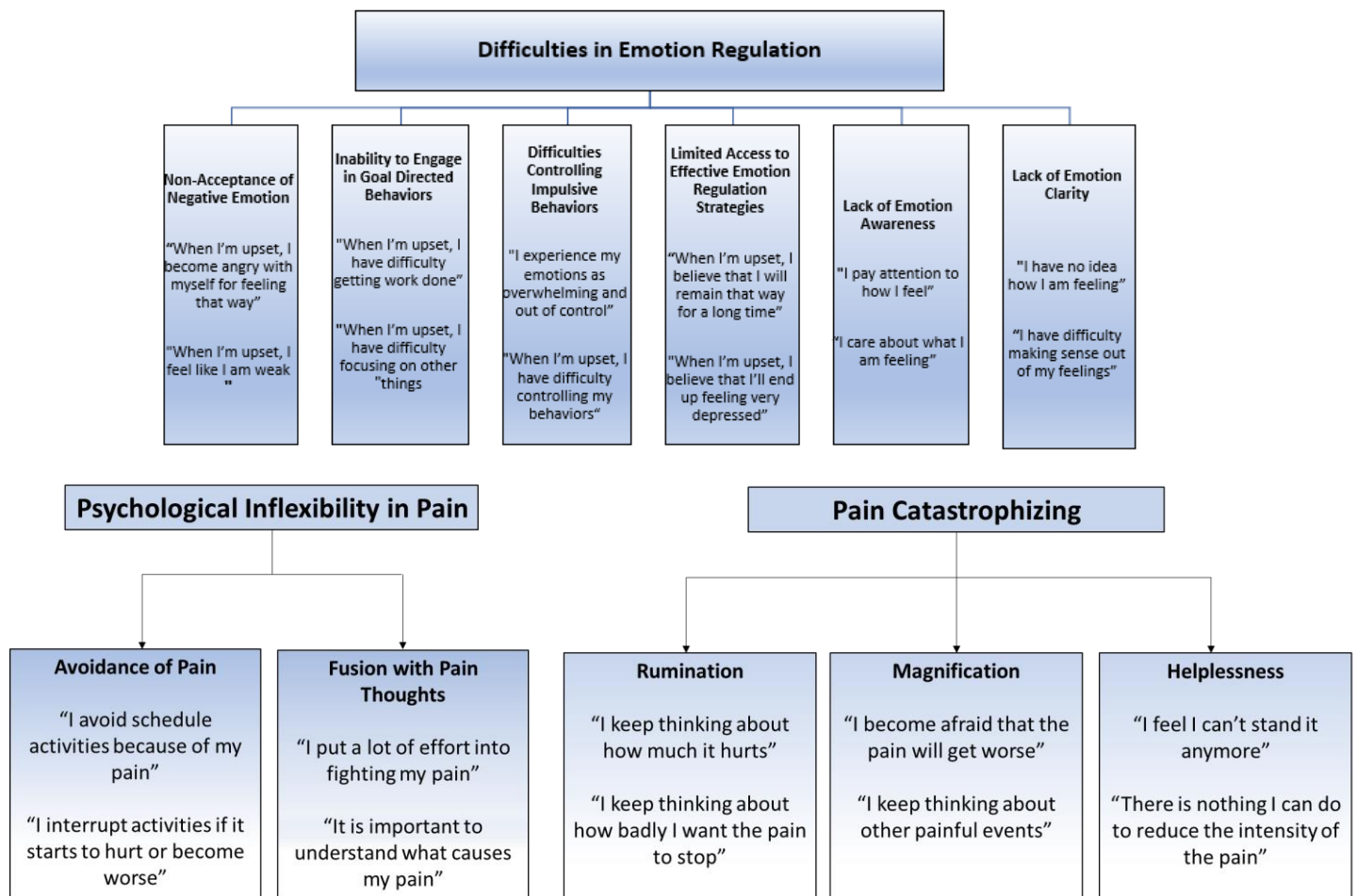
Roemer, 2004; Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2007). These results were maintained even when the effects of stress, anxiety and depression were neutralized. In contrast, the research of Chamber, Gullone, & Allen (2009) refers to aspects of mindfulness-based treatment that may hinder the effective use of emotional regulation processes and points to the importance of research to develop an understanding of whether the treatment promotes these processes with an emphasis on understanding the interaction between the various components of mindfulness and emotional regulation. To the best of our knowledge, there is no study that examined emotional regulation as a mechanism in CBT and mindfulness-based therapy for patients diagnosed with chronic pain or FM.

In conclusion, there is a significant research gap in understanding the involvement of the emotional regulation processes in the treatment processes - both in CBT and in mindfulness - and there is a need for more studies that examine the role of this emotional regulation within different treatment methods.

As can be seen, in general the mechanisms we will focus on - flexibility, catastrophizing and emotional regulation - were found to be important for FM and specifically were also found to be related to the effectiveness of both CBT and MBSR. However, they have been studied very little in these contexts, and their role in the treatment of FM in different approaches is not clear enough. Therefore, the current study will examine the role of these mechanisms in the two treatment methods, and will try to understand whether they play a role there, and if yes - whether they have a differential role in the two treatment methods, and against different outcome measures (for example, stress, quality of life)

Figure 1 illustrates the suggested mechanisms, their components, and examples that reflect their different aspects.

Figure 1. *Emotion regulation, psychological inflexibility in pain and pain catastrophizing as potential mechanisms of change in CBT and MBSR*



Research Questions and Hypotheses

In our study, we will examine a variety of outcome measures in FM therapy, covering FM symptoms, depression, perceived stress, and health related quality of life. We believe that these measures comprehensively represent the expected changes following our proposed interventions, and most importantly, cover both physical and psychological aspects of the disorder. In addition, we will examine three potential mechanisms of change in MBSR and CBT: difficulties in emotion regulation, pain catastrophizing, and psychological inflexibility in pain.

The current study presents three major research questions: 1. Are CBT and MBSR effective for treating FM patients, and if so – are they differentially effective? 2. Is psychotherapy delivered by video conferencing effective for treating FM patients? 3. What are the mechanisms of change that are associated with CBT and MBSR for FM? Based on these questions, we will focus on the following research hypotheses:

hypothesis #1: FM patients receiving CBT or MBSR will show greater improvements in FM symptoms, depression, perceived stress and health-related quality of life between pre- to post-intervention, compared to the waitlist (WL) control group.

hypothesis #2: All expected changes of CBT and MBSR between pre- and post-intervention will remain stable over a 4-month follow-up period. There will be a decrease between pre- and post-intervention, then no change between post-intervention and the follow-up measurement.

hypothesis #3: FM patients receiving CBT or MBSR by ZOOM will show greater improvements in FM symptoms, depression, perceived stress, and health-related quality of life between pre- to post-intervention, compared to waitlist (WL) control group and a similar effectiveness to face to face CBT and MBSR.

hypothesis #4: All expected changes of CBT and MBSR by ZOOM between pre- and post-intervention will remain stable over a 4-month follow-up period. There will be a decrease between pre- and post-intervention, then no change between post-intervention and the follow-up measurement.

hypothesis #5: Psychological inflexibility in pain will be used as a change mechanism in both MBSR and CBT. Thus, the degree of change in psychological inflexibility in pain will be positively correlated with the degree of change in fibromyalgia, major depression and perceived stress, and in a negative correlation with a health-related quality of life.

hypothesis #6: Pain catastrophizing will be used as a change mechanism in both MBSR and CBT. Thus, the degree of change in Pain catastrophizing will be positively correlated with the degree of change in fibromyalgia, major depression and perceived stress, and in a negative correlation with a health-related quality of life.

hypothesis #7: Difficulties in emotion Regulation will be used as a change mechanism in both MBSR and CBT. Thus, the degree of change in difficulties in emotion Regulation will be

positively correlated with the degree of change in fibromyalgia, major depression and perceived stress, and in a negative correlation with a health-related quality of life

Hypothesis #8: Although we hypothesize that flexibility, catastrophizing, and emotional regulation will play a role in the change due to the two treatment methods, in light of the essential difference in the two methods, and in light of preliminary findings from the little research that exists in the field, we hypothesize that differential effects will nevertheless be found for the two methods. Thus, we hypothesize in an exploratory way that the relationships between the mechanisms and the degree of change due to CBT and MBSR will not be the same, and there will be differences in the strength of the relationships and their actual existence in certain cases.

****Because the mechanisms of change include different subscales (eg, fusion, magnification), we hypothesize that different aspects of the mechanisms will play different roles as mechanisms of change in treatment. There is not enough literature to lead us to hypothesize in a directional manner about a certain sub-index, but we hypothesize that there will be different differential effects.**

Materials and Methods

1. Participants and Procedure

The participants in the study were fibromyalgia patients, insured by the 'Maccabi' health care in Israel. Participants were recruited from two major sources: 1. Advertisements on 'Maccabi' health care, 2. advertisements posted on social media (online groups and forums of FM patients) and sent to organizations supporting FM patients. The study included 93 FM patients that were randomly assigned to either the CBT group (n=32), MBSR group (n=28), or the WL control group (n=33). The sample ranged in age from 20 to 74 years (mean±SD: 47.53±12.69 years).

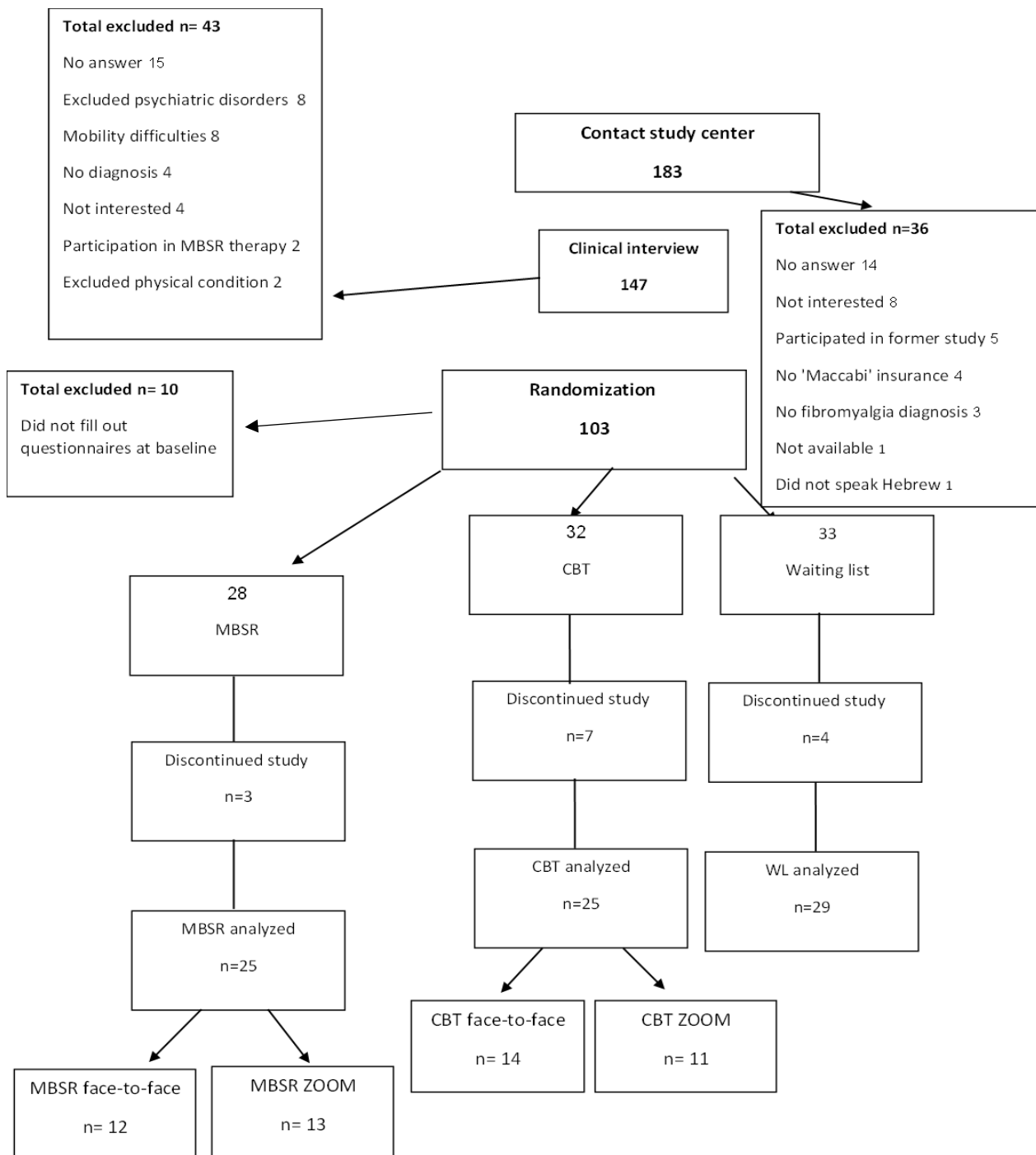
The criteria for study inclusion were: 1) a documented clinical diagnosis of FM given by an expert rheumatologist and/or clinical immunologist, 2) age 18 years or older, 3) Hebrew speakers, 4) physical ability to attend MBSR sessions, 5) no serious cognitive impairments, 6) no psychosis, 7) no active suicidality, 8) no substance abuse, 9) no concurrent participation in

another clinical study, 10) no concurrent participation in another mindfulness-based/cognitive behavioral group therapy, 11) insured by 'Maccabi' health care.

Our study was made under the supervision of the Ethics Committee of Maccabi Healthcare (ASMC-0111118). The screening process was comprised of several steps. First, an introductory phone call was conducted with all individuals who showed an interest in participation. The introductory conversation included a general explanation regarding group therapy and study participation, explanation of participation in online therapy for the relevant groups, as well as an initial screening. In this step we excluded those who were either not interested after hearing the details, not available (due to distance, busy schedule, etc.), not members of 'Maccabi' health care, or lacked a formal FM diagnosis (individuals in the process of being diagnosed were invited to call the study center upon completion of the process). Following the initial screening, we conducted clinical interviews that collected several types of information: 1) medical information, such as medical and pharmacological treatment, FM chronicity, and other known medical conditions, 2) cognitive functioning, including serious head injury and concentration capacity including potential attention deficit hyperactivity disorder (ADHD) diagnoses. Cognitive impairment was assessed to ensure a basic capacity to exercise mindfulness. 3) psychiatric and psychological information: individuals answered several questionnaires from the Paykel suicide scale (Paykel, Myers, Lindenthal, & Tanner, 1974), the alcohol use disorders identification test (AUDIT) (Babor, Higgins-Biddle, Saunders., Monteiro, & World Health Organization, 2001), and the Yale university PRIME screening test (Miller, 2004) for probable psychosis. Appendix 3 presents the clinical interview as described.

A detailed description of study procedures can be found in Figure 2 (PRISMA chart). All participants provided informed consent prior to their inclusion in the study. After screening process, patients were randomly assigned to either an CBT group, MBSR group or a wait-list control group. Patients assigned to the WL control group received no active treatment during their waiting period; upon completion of this time, they received CBT/MBSR. Due to the outbreak of the corona virus and with the approval of the ethics committee, it was decided to move the treatment online by videoconferencing using the Zoom application. Therefore, as you can see, about half of the subjects in each treatment methods underwent remote online treatment.

Figure 2. *PRISMA Flow-Chart for Screening and Allocation Process*



To ensure that there were no significant differences between groups following randomization, all the variables in this study were compared at baseline. Following randomization, paired-sample t-tests and chi-squared/Fisher tests were performed to compare the MBSR and WL groups on baseline measures. Table 1 presents patient demographic characteristics. Appendix 4 presents Comparison of Baseline Demographic and Physical Characteristics between the face-to-face and ZOOM interventions.

Table 1. *Comparison of Baseline Demographic and Physical Characteristics between the CBT, MBSR and the WL Groups*

Characteristic		CBT Mean (\pm SD) or n (%)	MBSR Mean (\pm SD) or n (%)	WL Mean (\pm SD) or n (%)	P _{diff}
Gender	Female	n=31 (96.9%)	n= 23 (82.1%)	n=33 (100%)	0.01**
	Male	n=1 (3.1%)	n=5 (17.9%)	n=0 (0%)	
Age		50.71 (12.78)	43.71 (12.18)	47.69 (12.5)	0.10(n.s)
Marital status	Married	n=20 (62.5%)	n=11 (39.3%)	n=14 (43.8%)	0.59(n.s)
	Single	n=5 (15.6%))	n=9 (32.1%)	n=10 (31.3%)	
	Divorced	n=4 (12.6%)	n=4 (14.3%)	n=7 (21.9%)	
	Widowed	n=1 (3.1%)	n=1 (3.6%)	n=0 (0%)	
	Re-married	n=1 (3.1%)	n=2 (7.1%)	n=0 (0%)	
	In a relationship	n=1 (3.1%)	n=1 (3.6%)	n=1 (3.0%)	
Place of birth	Israel	n=25 (83.3%)	n=21 (77.8%)	n=25 (78.1%)	0.83(n.s)
	Other	n=5 (16.7%)	n=6 (22.2%)	n=7 (21.9%)	
Education level	Grade school	n=3 (9.3%)	n=0 (0%)	n=0 (0%)	0.10(n.s)
	High school	n=7 (21.9%)	n=9 (32.1%)	n=11 (33.3%)	
	Currently student	n=7 (21.9%)	n=3 (10.7%)	n=2 (6.1%)	
	College graduate	n=15 (46.9%)	n=16 (57.2%)	n=20 (60.6%)	
Employed		n=18 (56.3%)	n=20 (71.4%)	n=19 (57.6%)	0.40(n.s)
Income	Below average	n=5 (15.6%)	n=7 (25%)	n=11 (33.3%)	0.59(n.s)
	Average	n=13 (40.6%)	n=10 (35.7%)	n= 11 (33.3%)	
	Above average	n=14 (43.8%)	n=11 (39.3%)	n=11 (33.3%)	
Years since diagnosis		5.25 (4.80)	6 (3.62)	6.2 (5.84)	0.77(n.s)

NOTE: **p < .01

As presented in Table 1, one way Anova and chi-square/Fisher tests for independence demonstrated that there were no significant differences between the CBT, MBSR and the WL groups on demographic measures, expect for Gender. In addition, there were no significant differences between the groups in baseline clinical measures FM (FIQR) [$F(93)=0.35$, n.s], perceived stress [$F(93)=2.30$ n.s], and major depression (PHQ) [$F(93)=0.30$ n.s], quality of life (HRQOL) [$F(93)=0.05$, n.s], except for quality of sleep (PSQI) [$F(93)=10.37$ p<0.05].

2. Randomization and Measurement

Patients were randomized using the SPSS 23.0 statistical software package randomization algorithm. Patients in the WL were blinded from their allocation to the control group and were told they were waiting for the next group opening. Participants were given an anonymous code at the beginning of the study and were asked to use the code to conceal any personal details (i.e., names or ID) that could reveal their identity. The study coordinator was the only one who had access to the code-name matrix. All participants signed an informed consent form prior to participation and were informed that they could withdraw from the study at any point. When switching to treatment through the Zoom application, the consent form was updated to refer to online treatment and questionnaires were sent to participants via email. Half of the patients were recruited after the outbreak of COVID-19 and were blinded allocated to 3 groups (CBT, MBSR and WL).

Data was collected at three time points: baseline (before the first treatment session), the end of the intervention (immediately after the final treatment session), and 4 months after treatment as a follow-up assessment. The follow-up assessment was only conducted for the MBSR/CBT groups. We employed an intention-to-treat (ITT) approach for our analysis, i.e., all randomized participants were contacted post-treatment to fill out questionnaires, regardless of whether they attended the entire therapy or had dropped out (Fisher et al., 1990). This was intended to provide a complete, reliable, and externally valid picture of our patients.

3. Treatment protocols

3.1 MBSR protocol

The MBSR protocol includes an adaptation of the classic MBSR treatment (Kabat-Zinn, 1990), meant to specifically suit the needs of fibromyalgia patients. The protocol was successfully implemented and validated in a previous study from our group (Taub et al., 2021). The weekly sessions include different mental and physical mindfulness exercises (e.g., body-scan, focusing one's attention on breathing, being fully aware during everyday activities), as well as information sessions and discussions on stress, stress management, and how to apply mindfulness to interpersonal communication. The changes made to the protocol included the extension of the basic protocol to 10 weeks (instead of 8), in order to include an in-depth

psychoeducation phase, as well as to allow more gradual practice. In addition, the duration of the meetings was shortened to an hour and a half so that there is no overload on the patients. Also, exercises were adapted to focus on typical difficulties of fibromyalgia patients, including chronic pain and fatigue. The groups were led by qualified and experienced mindfulness teachers. Each meeting began with a joint discussion by group members about the homework they completed during the week and in some meetings there were discussions and exercises conducted in pairs, that were followed by group conversations. In addition, in the middle part of the treatment there was a long practice day where the group spent several straight hours practicing.

3.2 CBT protocol

This treatment was constructed based on various protocols of cognitive-behavioral treatment for chronic pain patients (Bernardy et al., 2010; Glombiewski et al., 2010; Thorn & Kuhajda 2006; Vallejo et al., 2015). The treatment was conducted over 10 weeks, with weekly meetings lasting an hour and a half each. The protocol includes three main parts: first, psychoeducation (the “thoughts-feelings-beahvior” cycle, as well as information on pain and stress). Second, identifying and monitoring negative and maladaptive thought patterns (e.g., cognitive reconstruction, work on maladaptive thinking schemes), and third, behavioral interventions (e.g., exposure to situations posing functioning challenges, active planning, response prevention). Moreover, emotion regulation techniques were learned in most of the sessions. Specific issues, such as sleep difficulties, were also allocated specific time in sessions. Between the meetings assignments were given as homework and a review was conducted at the next meeting. The treatment was guided by a qualified and experienced CBT therapist, who is a licensed clinical psychologist. Similar to the mindfulness protocol, we have added couple and group practices, and each session began with a joint conversation about homework. In addition, we have added exercises during which a member of the group presents daily difficulties and thus enables group feedback.

Measures

Demographic background: Prior to the intervention (or waiting period for the WL group), participants were asked about their age, gender, ethnic background, income, family status, daily

habits, and employment situation. Moreover, we asked questions regarding the chronicity of the disorder, the date of its diagnosis, medication use, medical follow-up and compliance with it, psychiatric treatment, and pregnancy history.

The FM Impact Questionnaire Revised (FIQR; Bennett et al., 2009): The FIQR is a 21-item self-report instrument developed by Bennett et al. (2009) in order to assess primary FM symptoms, physical function deficits, and quality of life. This is an updated version of the FIQ, an extensively validated measure with comparable scoring. In addition to a total score, the FIQR also assesses scores of three individual subscales: Function, Impact, and Symptoms. Higher scores indicate a more negative impact of FM symptoms. In this study, the FIQR demonstrated very good internal consistency with a Cronbach's alpha of 0.93.

The Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001): This measure is a self-administered questionnaire used to assess Major Depressive Disorder symptoms, which scores each of the 9 DSM-IV criteria on a scale of 0 ("not at all") to 3 ("nearly every day"). It can yield either a continuous score or a probable Major Depressive Disorder diagnosis. Recent validation studies have suggested that the accuracy of the measures in predicting Major Depressive Disorder could be improved by using a rather conservative cut-off scores between 8 and 11 (Manea, Gilbody, & McMillan, 2012). Based on these studies, we used a cut-off score of 10 for a Major Depressive Disorder probable diagnosis. Thus, 0-9- indicates no depressive symptoms or mild depressive symptoms, 10-14 indicates moderate depressive symptoms, and 15-27 indicates moderately-severe depressive symptoms ; (Kroenke, Spitzer, & Williams, 2001). In the current study, PHQ-9 demonstrated very good internal consistency with a Cronbach's alpha of 0.84.

The Perceived Stress Scale (PSS; Cohen, & Williamson 1988): This measure is a widely used and well-validated 10-item scale that measures the degree to which situations in one's life over the previous month are considered unpredictable, uncontrollable, and overwhelming. It posits that people appraise potentially threatening or challenging events in relation to their available coping resources. Items are rated on a Likert scale ranging from 0 ("never") to 4 ("very often"). A higher score indicates a greater degree of perceived stress. The PSS is often found to possess

very good psychometric properties. In this study, the PSS showed very good reliability with a Cronbach's alpha of 0.88.

The World Health Organization Quality of Life Questionnaire-Brief Version (WHOQOL-BRIEF: The Whoqol Group, 1998): This measure was developed based on the original 100-item WHQOL questionnaire. It is a 26-item scale with each item rated on a scale from 1 (not at all) to 5 (extremely). It comprises five subscales that represent several quality of life domains: general, physical, psychological, social, and environmental quality of life. In the present study, WHOQOL-BRIEF had a Cronbach's alpha of 0.79.

Psychological Inflexibility in Pain Scale (PIPS; Wicksell, Lekander, Sorjonen, & Olsson, 2010): This is a 12-item measure based on a Likert scale of 1 (never true) to 7 (always true) per item, developed to assess psychological inflexibility towards pain (i.e., one's ability or inability to manage pain in a flexible manner while not avoiding it altogether or being inundated by it). The PIPS includes 2 subscales: Pain Avoidance and Cognitive Fusion. The total score ranges from 12-84. PIPS showed very good reliability in the present study with a Cronbach's alpha of 0.90.

Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995): This measure consists of 13 items evaluating different thoughts and feelings that individuals may experience when they are in pain. The PCS instructions ask participants to reflect on their past painful experiences and to indicate on a 5-point scale the degree to which they experienced each of 13 thoughts and feelings when experiencing pain (0="not at all" and 4="all the time"). The PCS yields one total score and three subscale scores assessing rumination (eg, "I can't stop thinking about how much it hurts"), magnification (eg, "I worry that something serious may happen"), and helplessness (eg, "There is nothing I can do to reduce the intensity of the pain"). PCS showed very good internal consistency in the current study at 0.91 in Study.

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) is a self-report questionnaire assessing emotion regulation difficulties. It comprises 36 items assessing six domains: non-acceptance of negative emotions, inability to engage in goal-directed behaviors, difficulties controlling impulsive behaviors, limited access to effective emotion regulation strategies, lack of emotional awareness, and lack of emotional clarity. Responses are given on a 5-point Likert scale from 1 (almost never) to 5 (almost always). The questionnaire was found to

have good psychometric properties (Gratz & Roemer, 2004)**Error! Reference source not found..** In the current study, the DERS demonstrated very good internal consistency, with a Cronbach's alpha of 0.87.

Pittsburgh Sleep Quality Index (PSQI; Buysse et al.,1989) measures self-reported sleep quality and disturbances during the previous 4 weeks. It has 19 items and measures 7 components of sleep: sleep quality, sleep latency, sleep duration, sleep disturbances, use of sleeping medication, habitual sleep efficiency, and daytime dysfunction. The component scores have each a range of 0–3 points and are added to yield one global PSQI score (range of 0–21 points) which distinguishes good sleep (PSQI total score <5) from poor sleep (PSQI total score >5). The questionnaire was found to have good psychometric properties (Buysse et al.,1989). This measure was tested only in the background data but not as an outcome measure.

Results

1. Pre- to Post-treatment Differences Between the CBT, MBSR and WL groups

In order to examine changes in outcome measures among CBT and MBSR participants in comparison to WL controls, we conducted a repeated measures Multivariate Analysis of Variance (MANOVA) and Univariate analyses (ANOVA) for Group X Time interactions. The variables intervention type (face-to-face or zoom), gender, and sleep quality were considered as covariates due to initial differences found between the groups. The analysis was conducted using Group (MBSR, CBT, WL) as a between-subject independent variable and Time (pre-intervention compared to post-intervention) as a within-subjects independent variable. A series of dependent variables were examined: FM, health-related quality of life, depression and perceived stress. Additionally, we conducted MANOVA to examine changes in the subscales of FM and health-related quality of life. A subsequent Univariate analysis was conducted for all for the measures that were comprised of subscales even if the MANOVA was not significant. We chose to conduct these tests due to the small number of subjects and the amount of comparisons made. To establish the source of the interaction, every MANOVA and ANOVA followed by subsequent pairwise comparisons. Table 2 presents the Multivariate and Univariate

effects and descriptive statistics for Group X Time comparisons. For the tests that came out significant, we performed effect size calculations.

Table 2. *MBSR vs. CBT vs. WL effects and descriptive statistics*

		CBT (n=28)		MBSR (n= 32)		WL (n=33)		Pre- to Post- Intervention Group Comparison	
		Pre	Post	Pre	Post	Pre	Post	F Time X Group	Cohen's d
		Mean (SD)							
FM	Total	61.92 (3.45)	58.94 (3.76)	70.69 (3.72)	60.48 (4.04)	62.29 (3.57)	61.06 (3.89)	3.57*	0.62
	Function	17.94 (7.40)	18.25 (7.46)	18.25 (7.46)	16.34 (7.88)	17.34 (5.64)	17.73 (6.20)	1.29	-
	Impact	12.56 (5.43)	12.36 (5.83)	13.76 (5.23)	10.04 (5.84)	14.32 (4.15)	13.52 (5.46)	3.32*	0.58
	Symptoms	33.00 (8.47)	29.88 (9.73)	33.24 (10.57)	28.76 (10.44)	34.42 (8.62)	33.60 (9.37)	1.94	-
Health Related Quality of Life	General	9.37 (0.56)	10.76 (0.67)	8.14 (0.60)	9.80 (0.72)	9.86 (0.57)	9.80 (0.67)	1.98	-
	Physical	9.67 (2.67)	11.55 (1.56)	9.24 (2.79)	12.00 (1.65)	9.71 (2.23)	11.24 (1.22)	4.52*	0.67
	Psychological	11.77 (1.94)	12.40 (2.00)	11.27 (3.67)	11.75 (2.52)	11.06 (2.88)	11.54 (1.76)	0.07	-
	Social	10.96 (3.81)	11.45 (3.28)	10.37 (4.80)	14.69 (16.16)	10.40 (3.64)	10.18 (3.33)	0.17	-
	Environmental	13.59 (2.50)	13.97 (2.59)	12.84 (3.05)	13.52 (3.05)	13.04 (2.87)	13.37 (3.13)	0.01	-
Major Depression		15.01 (1.09)	13.25 (1.10)	18.36 (1.15)	15.55 (1.16)	16.36 (1.11)	15.16 (1.11)	0.52	-
Perceived Stress		21.41 (1.40)	19.40 (1.59)	25.68 (1.50)	22.36 (1.71)	23.60 (1.40)	22.39 (1.65)	0.48	-

NOTE: *p < .05; **p < .01; ***p<0.001

As presented in Table 2, the Univariate analysis for FM total score showed a significant effect for Group X Time interaction with a medium effect size, a non-significant effect for Time [$F(1,69)=0.2$, n.s], and a non-significant effect for Group [$F(1,69)=0.6$, n.s]. A pairwise comparison revealed a significant improvement in the MBSR group ($i-j=10.21$, $SE=2.41$, $p<0.01$, Cohen's $d=1.71$), compared to non-significant change in the CBT group ($i-j=2.97$, $SE=2.24$, n.s) and the WL group ($i-j=1.22$, $SE=2.32$, n.s).

When all subscales of FM were tested together, FM yielded non-significant interaction of Group X Time [$F(6,134)=1.65$, n.s], and non-significant effect for Time [$F(3,67)=0.72$, n.s], or Group [$F(6,134)=1.54$, n.s]. In relation to the different FM subscales (FIQR), we found a significant effect for impact subscale for Group X Time interaction with a medium effect size, non-significant effect for Time [$F(1,69)=0.66$, n.s], and a non-significant effect for Group [$F(2,69)=0.38$, n.s]. A pairwise comparison revealed a significant improvement in the MBSR group for Impact ($i-j=4.03$, $SE=1.14$, $p<0.01$, Cohen's $d=1.35$) and Symptoms ($i-j=4.40$, $SE=1.26$, $p<0.01$, Cohen's $d=0.94$) subscales, and a significant improvement in the CBT group for symptoms ($i-j=3.14$, $SE=1.17$, $p<0.01$, Cohen's $d=1.72$) subscale, compared to non-significant change in the WL group in all subscales.

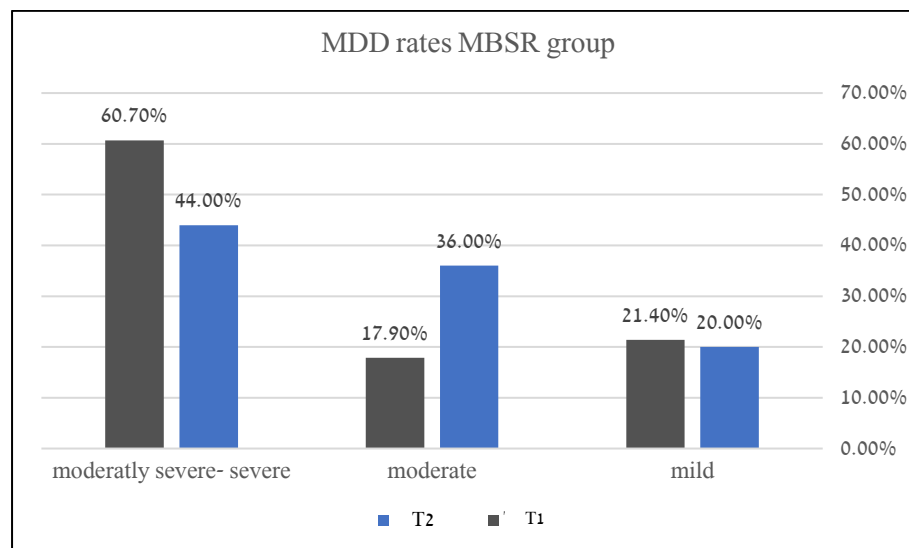
A Univariate analysis for health-related quality of life total score (HRQOL) showed non-significant effect for Group X Time interaction [$F(2,66)=1.98$, n.s], non-significant effect for Time [$F(1,66)=0.13$, n.s], and a non-significant effect for Group [$F(2,66)=1.18$, n.s]. A pairwise comparison revealed a significant improvement in the MBSR group ($i-j=-1.62$, $SE=0.60$, $p<0.01$, Cohen's $d=-1.16$), compared to non-significant change in the CBT group ($i-j=-1.02$, $SE=0.56$, n.s) and the WL group ($i-j=0.05$, $SE=0.57$, n.s). A Multivariate Analysis for health-related quality of life (HRQOL) subscales showed a non-significant interaction of Group X Time [$F(8,122)=1.27$, n.s], and non-significant effect for Time [$F(4,61)=0.30$, n.s], or Group [$F(8,122)=0.51$, n.s]. In relation to the different HRQOL subscales, significant effect only for physical health subscale for Group X Time with a medium effect size, non-significant effect for Time [$F(1,64)=0.00$, n.s], and for Group [$F(2,64)=0.18$, n.s]. A pairwise comparison revealed a significant improvement in the Physical health subscale for MBSR group ($i-j=-3.29$, $SE=0.50$,

$p < 0.01$, Cohen's $d = -2.08$), CBT group ($i-j = -1.81$, $SE = 0.47$, $p < 0.01$, Cohen's $d = 1.81$), and WL group ($i-j = -1.10$, $SE = 0.47$, $p < 0.05$, Cohen's $d = 0.90$).

A Univariate analysis for major depression (PHQ-9) showed non-significant effect for Group X Time interaction, a significant effect for Time [$F(1,68) = 4.78$, $p < 0.05$], and a non-significant effect for Group [$F(2,68) = 1.99$, n.s]. A pairwise comparison revealed a significant improvement in the MBSR group ($i-j = 2.81$, $SE = 1.08$, $p < 0.01$, Cohen's $d = 0.97$), compared to non-significant change in the CBT group ($i-j = 1.76$, $SE = 1.02$, n.s) and the WL group ($i-j = 1.19$, $SE = 1.04$, n.s).

Figure 3 presents the change in the diagnosis levels of Major depression between the beginning and end of the MBSR treatment.

Figure 3- Pre- to Post-treatment Differences in MBSR - Major Depression

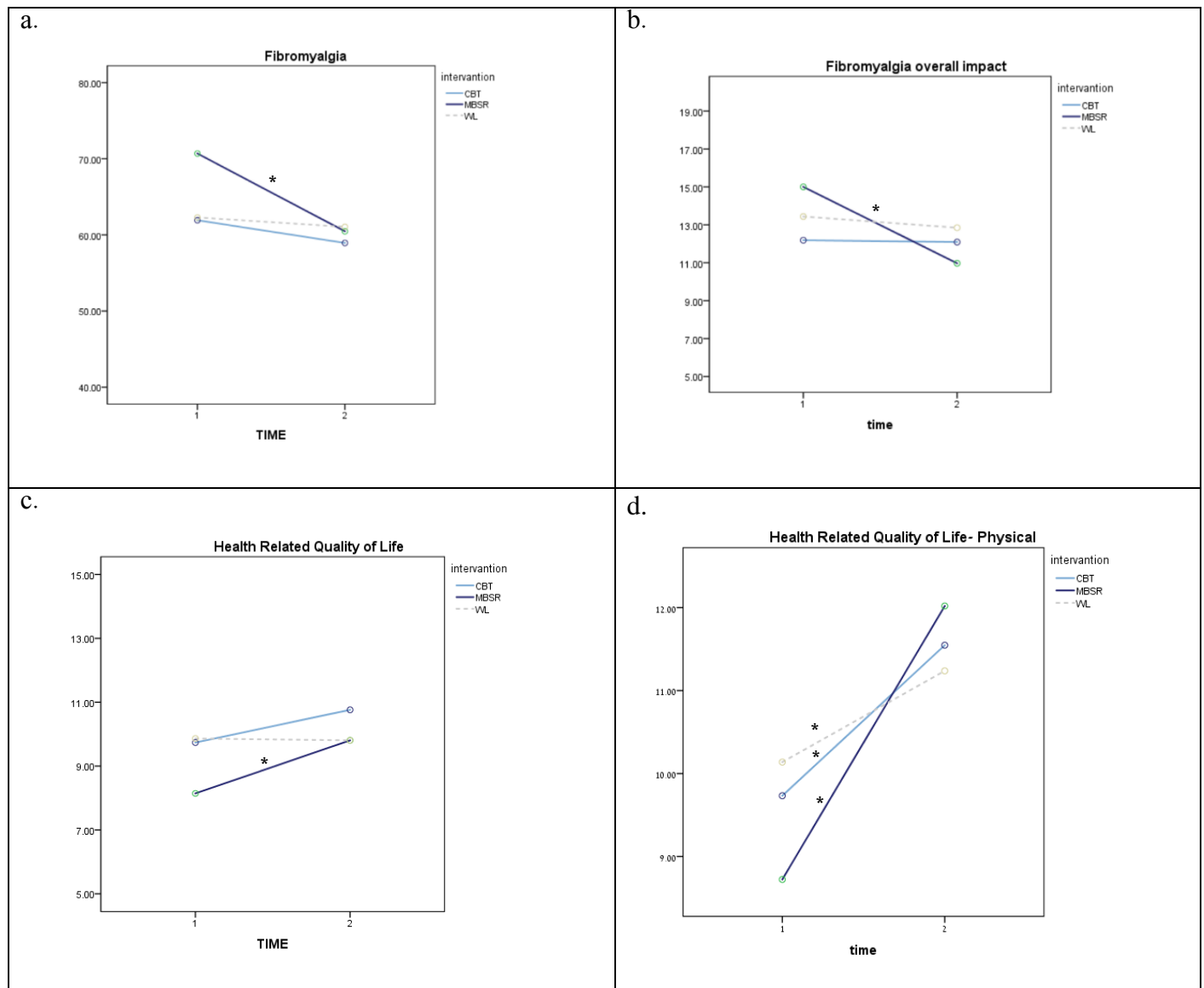


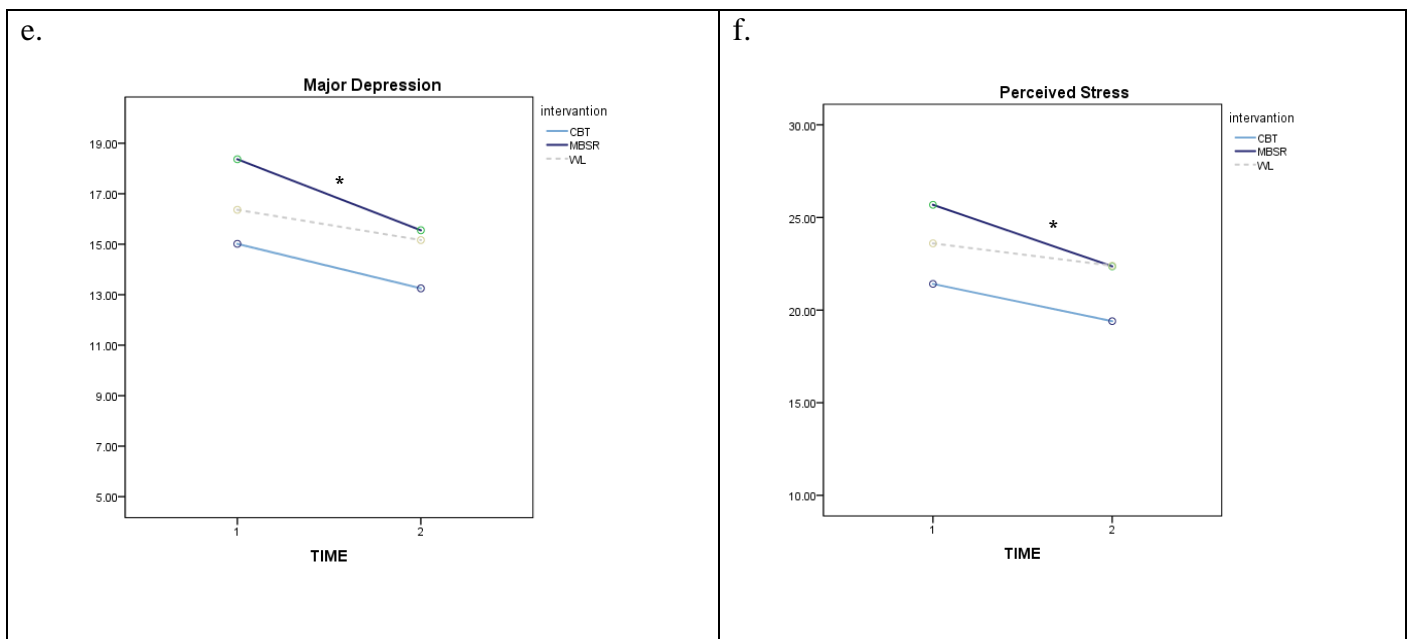
As you can see, some of the patients who suffered from depression at a severe level improved and therefore at the end of the treatment their distress corresponded to the diagnosis of moderate major depression.

A Univariate analysis for perceived stress (PSS) showed non-significant effect for Group X Time interaction, non-significant effect for Time [$F(1,69) = 3.56$, n.s], and a non-significant effect for Group [$F(2,69) = 1.86$, n.s]. A pairwise comparison revealed a significant improvement in the MBSR group ($i-j = 3.23$, $SE = 1.47$, $p < 0.05$, Cohen's $d = 0.68$), compared to non-significant change in the CBT group ($i-j = 2.01$, $SE = 1.47$, n.s) and the WL group ($i-j = 1.20$, $SE = 1.41$, n.s).

Figure 4 present the significant interaction effects of pre- to post-intervention measurements for the MBSR, CBT groups versus the WL control group on several outcome measures.

Figure 4. *Pre-Intervention to Post-Intervention Differences between CBT, MBSR and WL*





Note: Pre-intervention (1); post-intervention (2). (a) Fibromyalgia group X time interaction of CBT, MBSR compared to WL, (b) Fibromyalgia impact group X time interaction of CBT, MBSR compared to WL, (c) Quality of life group X time interaction of CBT, MBSR compared to WL, (d) Quality of life physical group X time interaction of CBT, MBSR compared to WL, (e) Major Depression group X time interaction of CBT, MBSR compared to WL, (f) Perceived Stress group X time interaction of CBT, MBSR compared to WL

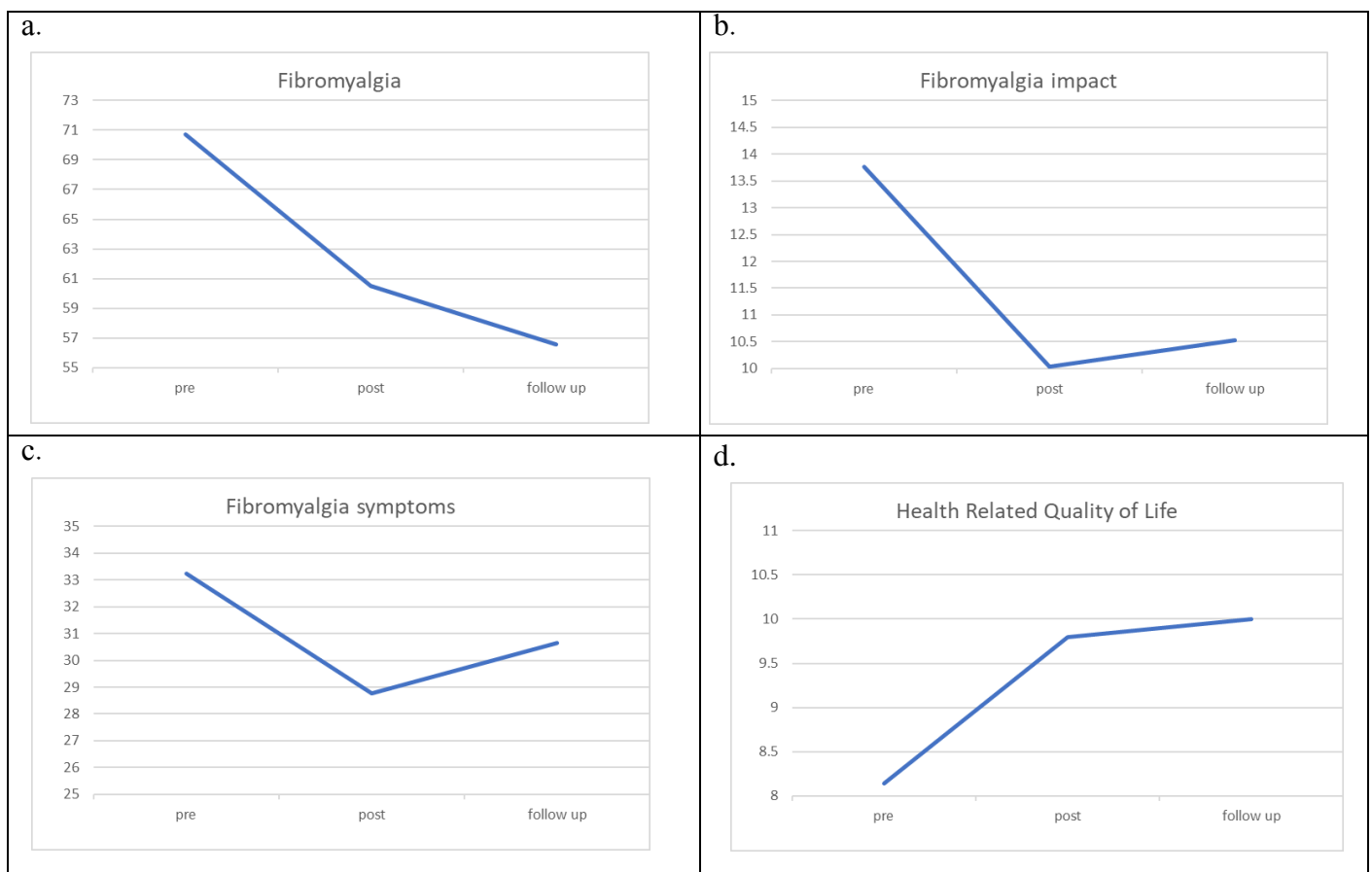
Univariate analyses, which included the follow-up assessment 4 months after the last session. We based this analysis on the CBT and MBSR groups alone, as the WL group did not go through a follow-up assessment. The second step of the analysis included contrasts between the effect of pre-treatment to post-treatment versus post-treatment to follow-up in order to detect the source of the effect. When performing these tests, we noticed that effects found to be significant between the first and second time point (pre and post treatment) appear in the joint comparison as non-significant. This change occurred because in a repeated measurements type test, the test is performed only on the subjects who filled out the three questionnaires, a limitation that reduces the number of subjects. Following this discovery, we separated the tests so that the results of the follow-up tests refer to a comparison of the post treatment point to the follow-up point alone, to test for stability over time (i.e., to see whether there was no change between the 2nd and 3rd assessment). Thus, the subjects included in the test are those who filled out the questionnaires at the time point at the end of the treatment and at the follow-up measurement. In addition, we will present graphs that show the three points together so that the change trend along the measurement points can be seen. The follow-up tests were performed only for the variables that were found to be significant in comparisons of pre and post treatment.

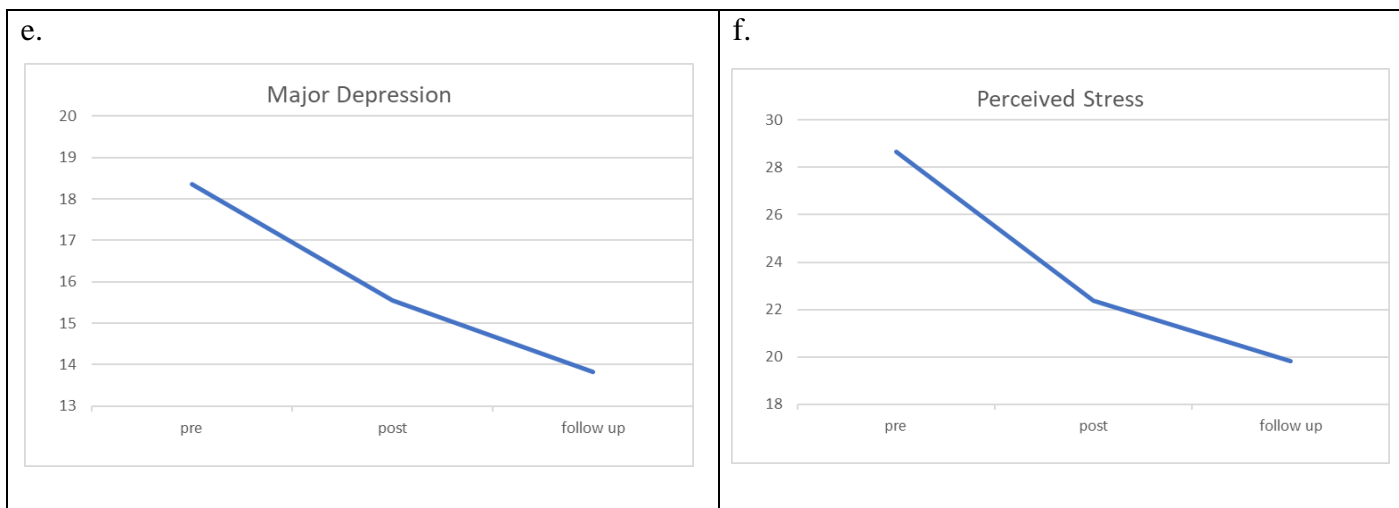
2.1 Long-Term Effectiveness of MBSR

To assess the long-term effects of MBSR, we conducted Multivariate analysis and Univariate analyses to compare post treatment to follow-up measure, with the follow-up assessment 4 months after the last session.

Figure 5 present the significant effects of pre- to post-intervention measurements and the non-significant of post- intervention to follow-up for the MBSR on several outcome measures.

Figure 5. *Pre-Intervention to Post-Intervention and follow-up Differences in MBSR*





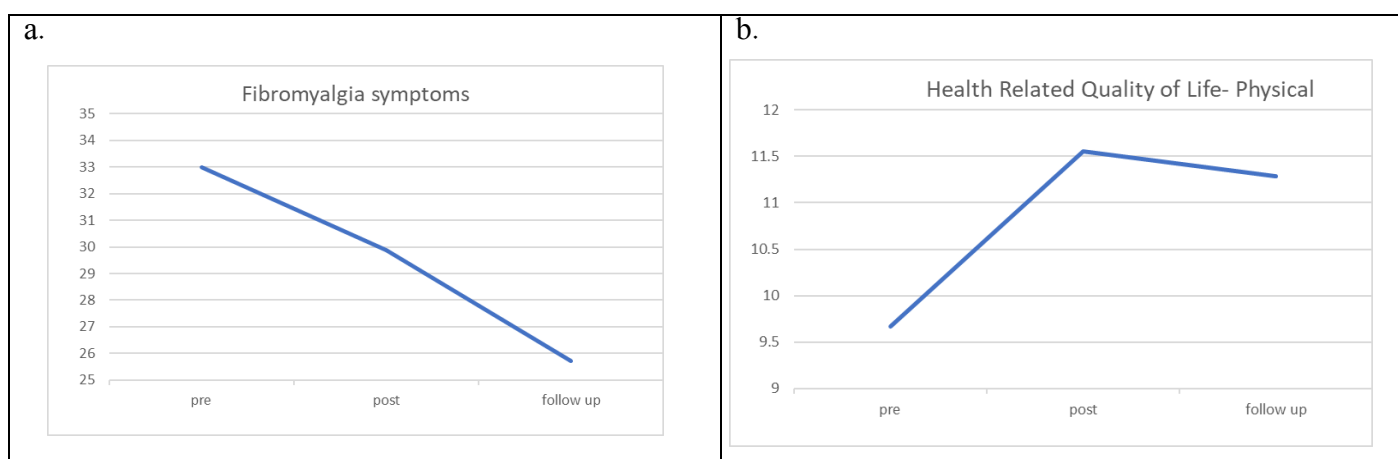
Note: Pre-intervention (1); post-intervention (2); follow-up (3). (a) Fibromyalgia time effect in MBSR (b) Fibromyalgia impact time effect in MBSR, (c) Fibromyalgia symptoms time effect in MBSR, (d) Quality of life time effect in MBSR, (e) Major Depression time effect in MBSR, (f) Perceived Stress time effect in MBSR.

As you can see, the Multivariate and Univariate Analysis for post treatment to follow-up in FM, FM impact and symptoms subscales, health-related quality of life, major depression, and perceived stress were non-significant [respectively ($(1,16)=0.29$, n.s), ($F(1,16)=0.10$, n.s), ($F(1,16)=0.26$, n.s), ($F(1,15)=0.06$, n.s), ($F(1,16)=1.67$, n.s), ($F(1,16)=1.12$, n.s)]. In conclusion, the only significant improvement following the MBSR that was not maintained in the follow up measurement is the change in physical subscale of health-related quality of life.

2.2 Long-Term Effectiveness of CBT

To assess the long-term effects of CBT, we conducted Multivariate Analysis to compare post-treatment to follow-up measure, with the follow-up assessment 4 months after the last session. Figure 6 present the significant effects of pre- to post-intervention measurements and the non-significant of post- intervention to follow-up for the CBT on several outcome measures.

Figure 6. *Pre-Intervention to Post-Intervention and follow-up Differences in CBT*



Note: Pre-intervention (1); post-intervention (2); follow-up (3). (a) Fibromyalgia symptoms time effect in CBT (b) Quality of life physical subscale time effect in CBT.

As you can see, the Multivariate Analysis for post treatment to follow-up in CBT group, the FM symptoms subscale and health-related quality of life physical subscale were non-significant [respectively ($F(1,13)=0.01$, n.s), ($F(1,13)=0.55$, n.s)].

3. Pre to Post-treatment Differences Between face-to-face and online therapy

In order to compare face-to-face treatment and treatment delivered by video conference (Zoom) in both treatment approaches, we conducted a repeated measures Multivariate Analysis of Variance (MANOVA) and Univariate Analysis (ANOVA) for Group X Time interactions. The analysis was conducted using Group (CBT, CBT ZOOM, WL and MBSR, MBSR ZOOM, WL) as a between-subject independent variable and Time (pre-intervention compared to post-intervention) as a within-subjects independent variable. A series of dependent variables were examined: FM, depression, perceived stress, and health-related quality of life. Additionally, we conducted MANOVA to examine changes in the subscales of FM and health-related quality of life. A subsequent Univariate analysis was conducted for all for the measures that were comprised of subscales even if the MANOVA was not significant. We chose to conduct these tests due to the small number of subjects and the number of comparisons made. To establish the source of the interaction, every MANOVA and ANOVA followed by subsequent pairwise comparisons.

3.1 Pre- to Post-treatment Differences Between the MBSR, MBSR ZOOM and WL groups

Table 3 presents the Univariate effects and descriptive statistics for Group X Time comparisons.

Table 3. *MBSR vs. MBSR ZOOM vs. WL effects and descriptive statistics*

		MBSR (n=13)		MBSR ZOOM (n= 15)		WL (n=33)		Pre- to Post- Intervention Group Comparison	
		Pre	Post	Pre	Post	Pre	Post	F Time X Group	Cohen's d
		Mean (SD)							
FM	Total	68.60 (5.73)	61.56 (6.13)	68.50 (5.72)	54.72 (6.12)	62.82 (3.83)	63.05 (4.10)	5.29**	0.90
	Function	19.97 (1.93)	19.28 (2.08)	19.41 (1.93)	16.04 (2.07)	16.02 (1.29)	17.09 (1.39)	3.55*	0.73
	Impact	14.95 (1.40)	11.21 (1.70)	14.15 (1.39)	9.52 (1.70)	13.63 (0.93)	13.36 (1.13)	2.66	--
	Symptoms	33.67 (2.93)	31.06 (3.00)	34.93 (2.92)	29.16 (2.99)	33.16 (1.96)	32.59 (2.00)	3.49*	0.70
Health Related Quality of Life	General	7.83 (1.00)	8.34 (0.93)	8.89 (0.94)	11.82 (0.87)	9.28 (0.63)	9.45 (0.59)	4.79*	0.86
	Physical	8.81 (0.81)	11.60 (0.47)	9.36 (0.80)	12.36 (0.46)	10.03 (0.52)	11.14 (0.30)	2.34	-
	Psychological	10.77 (1.04)	11.20 (0.68)	11.41 (1.02)	11.98 (0.67)	11.44 (0.67)	11.83 (0.44)	0.02	-
	Social	9.56 (1.32)	10.13 (3.33)	10.51 (1.30)	14.82 (3.23)	10.78 (0.85)	11.97 (2.15)	0.53	-
	Environmental	12.66 (0.95)	12.35 (0.99)	12.24 (0.93)	13.60 (0.97)	13.35 (0.61)	13.74 (0.64)	2.25	-

Major Depression		17.46 (1.78)	15.11 (1.88)	17.81 (1.78)	13.82 (1.88)	16.19 (1.19)	15.10 (1.26)	1.05	-
Perceived Stress		25.35 (2.15)	21.69 (2.29)	24.95 (2.14)	21.04 (2.29)	23.65 (1.43)	22.56 (1.53)	0.40	-

As can be seen in Table 3, a Univariate analysis for FM (FIQR) showed a significant effect for Group X Time interaction with a large effect size, but not for Time [$F(1,49)=0.25$, n.s] nor for Group [$F(2,49) = 0.10$, n.s]. A pairwise comparison of the MBSR, MBSR ZOOM groups versus the WL group in revealed a significant improvement in the MBSR ZOOM group ($i-j=13.77$, $SE=3.4$, $p<0.01$, Cohen's $d=2.28$), a significant improvement in the MBSR group ($i-j=7.04$, $SE=3.4$, $p<0.05$, Cohen's $d=1.27$), compared to non-significant change in the WL group ($i-j=-0.22$, $SE=2.28$, n.s).

Next, we conducted Multivariate analysis for the FM subscales (i.e. Function, Impact, and Symptoms). This test showed a non-significant interaction of Group X Time [$F(6,94)=1.80$, n.s], non-significant effect for Time [$F(3,47)=0.91$, n.s], or Group [$F(6,94)=1.65$, n.s]. In relation to the different FM subscales, Function and Symptom subscales yielded a significant interaction of Group X Time with medium effect size. A pairwise comparison of the MBSR and MBSR ZOOM groups versus the WL group in revealed a significant improvement in the MBSR group only for the impact subscale ($i-j=3.74$, $SE=1.62$, $p<0.05$, Cohen's $d=1.32$), and a significant improvement with large effect sizes in the MBSR ZOOM group for all subscales Function ($i-j=3.37$, $SE=1.31$, $p<0.05$, Cohen's $d=2.07$), Impact ($i-j=4.46$, $SE=1.62$, $p<0.01$, Cohen's $d=1.40$) and Symptoms ($i-j=5.57$, $SE=1.54$, $p<0.01$, Cohen's $d=2.43$), and non a significant improvement in the WL group.

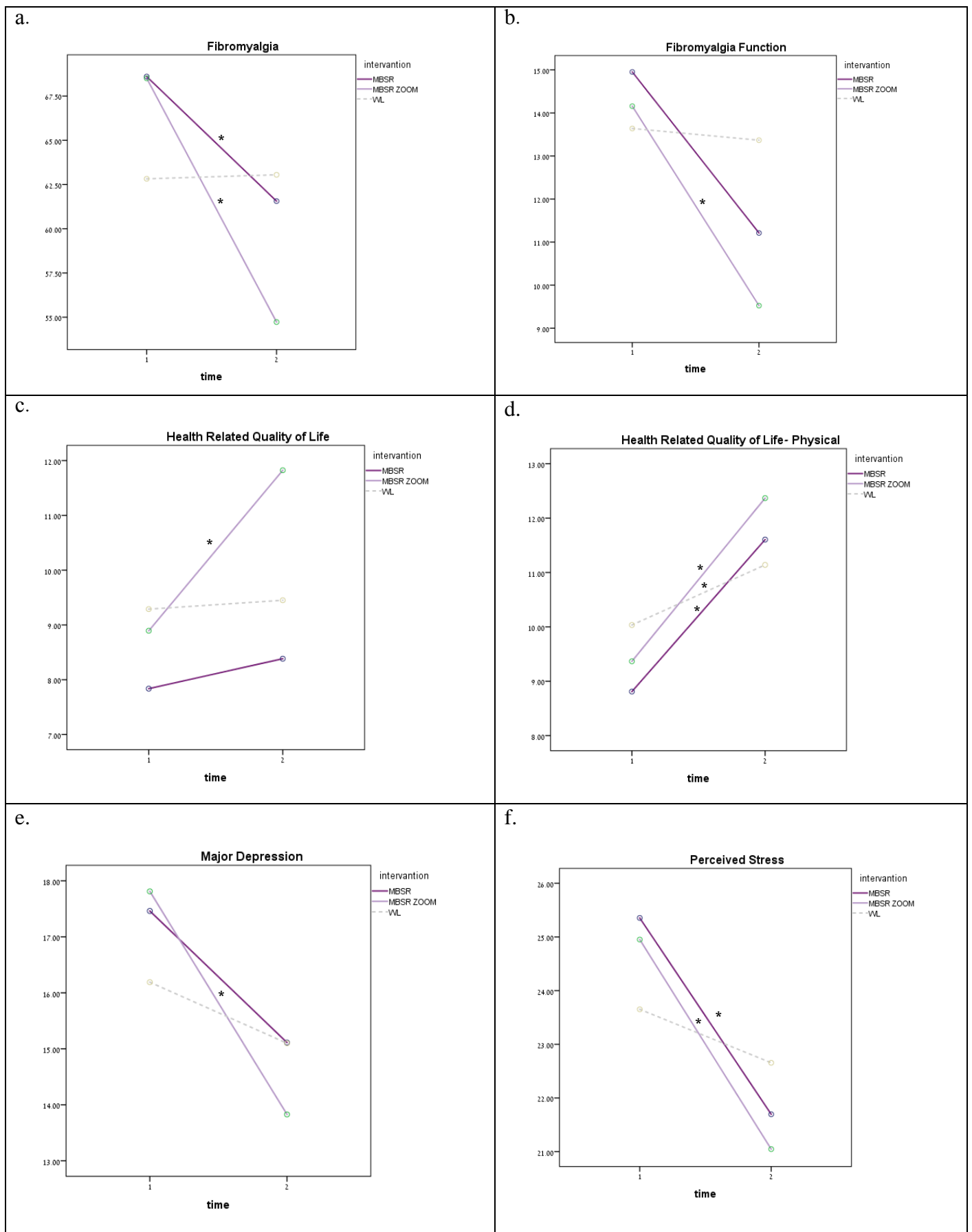
A Univariate analysis for health-related quality of life (HRQOL) showed a significant effect for Group X Time interaction with large effect size, but not for Time [$F(1,48)=0.31$, n.s] nor for Group [$F(2,48) = 1.84$, n.s]. A pairwise comparison revealed a significant improvement in the MBSR ZOOM group ($i-j=-2.93$, $SE=0.73$, $p<0.01$, Cohen's $d=-1.97$), compared to non-significant change in the MBSR group ($i-j=-0.54$, $SE=0.77$, n.s), and in the WL group ($i-j=-0.16$, $SE=0.49$, n.s).

Next, we conducted Multivariate analysis for the quality of life subscales (i.e. physical, psychological, social, and environmental). This test showed a non-significant interaction of Group X Time [$F(8,86)=1.23$, n.s], non-significant effect for Time [$F(4,43)=0.43$, n.s], or Group [$F(8,86)=0.30$, n.s]. In relation to the different HRQOL subscales, we found non-significant interactions. A pairwise comparison of the MBSR, MBSR ZOOM groups versus the WL group in Physical subscale revealed a significant improvement in the MBSR group ($i-j=-2.79$, $SE=0.80$, $p<0.01$, Cohen's $d=-1.81$), MBSR ZOOM group ($i-j=-3.00$, $SE=0.78$, $p<0.01$, Cohen's $d=-2.04$) and the WL group ($i-j=-1.10$, $SE=0.51$, $p<0.05$). A pairwise comparison of the MBSR, MBSR ZOOM groups versus the WL group in Environment subscale revealed a significant improvement in the MBSR ZOOM group ($i-j=-1.36$, $SE=0.57$, $p<0.05$, Cohen's $d=-1.71$), compared to non-significant change in the MBSR group ($i-j=0.31$, $SE=0.58$, n.s) and the WL group ($i-j=-0.38$, $SE=0.37$, n.s). We did not find significant change in any of the other scales (psychological, social).

A Univariate analysis for major depression (PHQ-9) showed a significant effect for Time [$F(1,49)=4.26$, $P<0.05$], but not for Group X Time interaction, or Group [$F(2,49)=0.04$, n.s]. A pairwise comparison of the MBSR group versus the WL group in revealed a significant improvement in the MBSR ZOOM group ($i-j=3.98$, $SE=1.56$, $p<0.05$, Cohen's $d=0.92$), compared to non-significant change in the MBSR ($i-j=2.35$, $SE=1.57$, n.s) and the WL group ($i-j=0.56$, $SE=1.09$, n.s).

A Univariate analysis for Perceived Stress (PSS) showed non-significant effects. A pairwise comparison of the MBSR group versus the WL group in revealed a significant improvement in the MBSR ZOOM group ($i-j=3.90$, $SE=1.94$, $p<0.05$, Cohen's $d=1.11$), a marginally significant improvement in the MBSR group ($i-j=3.65$, $SE=1.95$, $p=0.06$, Cohen's $d=0.89$), compared to non-significant change in the WL group ($i-j=0.99$, $SE=1.30$, n.s). Figure 7 present the effects of pre- to post-intervention measurements for the MBSR, MBSR ZOOM groups versus the WL control group on several outcome measures.

Figure 7. Pre-Intervention to Post-Intervention Differences between MBSR, MBSR ZOOM and WL



Note: Pre-intervention (1); post-intervention (2). (a) Fibromyalgia group X time interaction of MBSR, MBSR ZOOM compared to WL, (b) Fibromyalgia Function group X time interaction of MBSR, MBSR ZOOM compared to WL, (c) Quality of life group X time interaction of MBSR, MBSR ZOOM compared to WL, (d)) Quality of life physical group X time interaction of MBSR, MBSR ZOOM compared to WL, (e) Major Depression group X time interaction of MBSR, MBSR ZOOM compared to WL, (f) Perceived Stress group X time interaction of MBSR, MBSR ZOOM compared to WL

Note: Pre-intervention (1); post-intervention (2). (a) Fibromyalgia group X time interaction of MBSR, MBSR ZOOM compared to WL, (b) Fibromyalgia Function group X time interaction of MBSR, MBSR ZOOM compared to WL, (c) Quality of life group X time interaction of MBSR, MBSR ZOOM compared to WL, (d)) Quality of life physical group X time interaction of MBSR, MBSR ZOOM compared to WL, (e) Major Depression group X time interaction of MBSR, MBSR ZOOM compared to WL, (f) Perceived Stress group X time interaction of MBSR, MBSR ZOOM compared to WL

3.2 Long-Term Effectiveness of MBSR and MBSR ZOOM

In the next section I will present the results of the follow-up measurements for the variables that came out significant in the comparison between pre and post treatment in the face-to-face and zoom intervention groups separately. These results will be shown in averages and their corresponding graphs. Due to the small number of subjects in these groups, we did not perform statistical tests for the comparison between post and follow-up measurements.

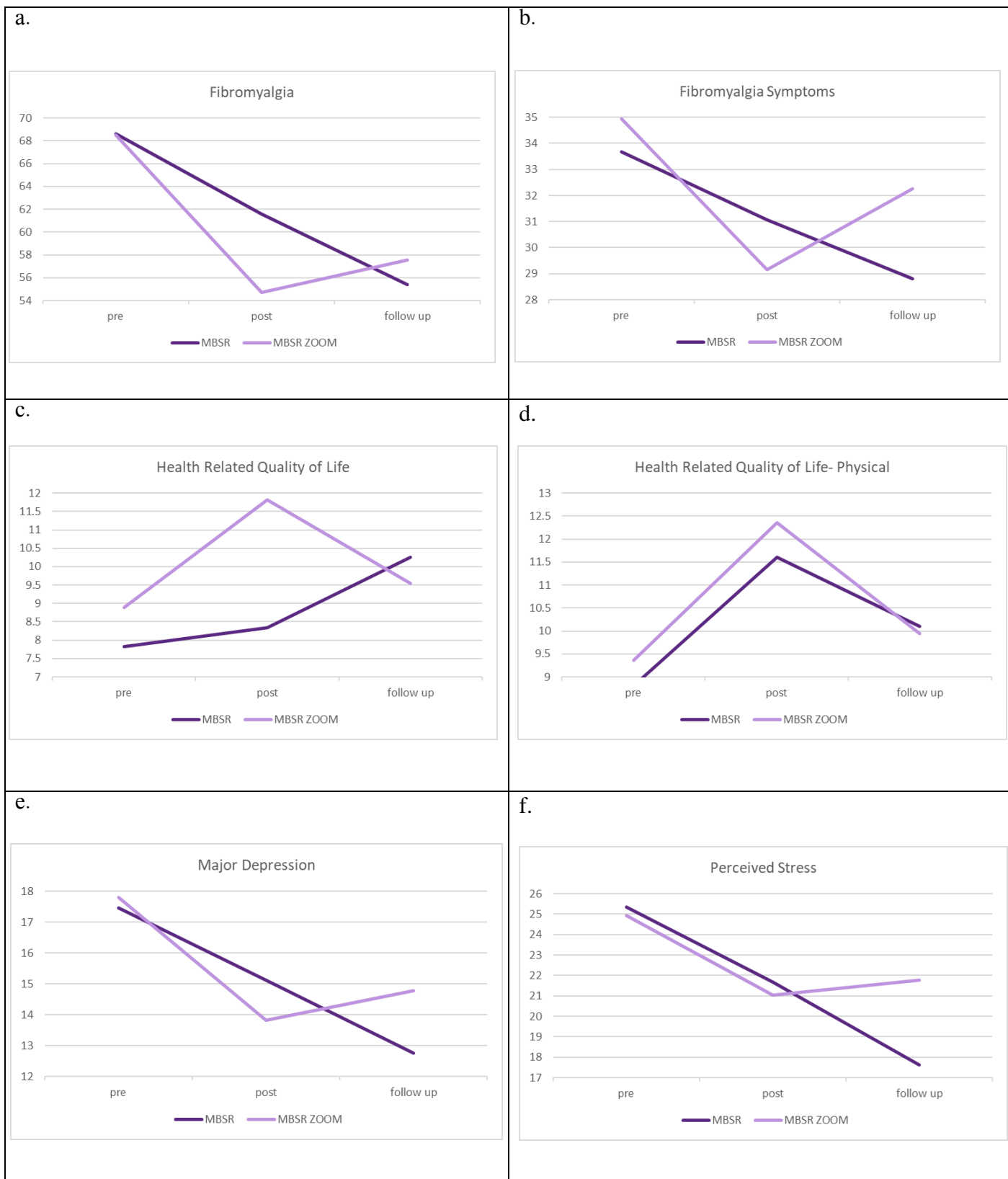
Table 4 and figure 8 presents the descriptive statistics of pre, post intervention and follow up measurements for the MBSR, MBSR ZOOM groups on several outcome measures.

Table 4. Long-Term Effectiveness of MBSR and MBSR ZOOM descriptive statistics

		MBSR (n=13)			MBSR ZOOM (n= 15)		
		Pre	Post	Follow-up	Post	Pre	Follow-up
		Mean (SD)					
FM	Total	68.60 (5.73)	61.56 (6.13)	55.39 (24.70)	68.50 (5.72)	54.72 (6.12)	57.57 (23.59)

	Function	19.97 (1.93)	19.28 (2.08)	15.83 (7.69)	19.41 (1.93)	16.04 (2.07)	14.96 (8.90)
	Impact	14.95 (1.40)	11.21 (1.70)	10.75 (6.60)	14.15 (1.39)	9.52 (1.70)	10.33 (5.19)
	Symptoms	33.67 (2.93)	31.06 (3.00)	28.81 (11.44)	34.93 (2.92)	29.16 (2.99)	32.27 (11.02)
Health Related Quality of Life	General	7.83 (1.00)	8.34 (0.93)	10.25 (3.10)	8.89 (0.94)	11.82 (0.87)	9.55 (2.78)
	Physical	8.81 (0.81)	11.60 (0.47)	10.10 (3.28)	9.36 (0.80)	12.36 (0.46)	9.95 (2.93)
	Environmental	12.66 (0.95)	12.35 (0.99)	13.14 (2.97)	12.24 (0.93)	13.60 (0.97)	13.05 (3.46)
Major Depression		17.46 (1.78)	15.11 (1.88)	12.75 (7.18)	17.81 (1.78)	13.82 (1.88)	14.77 (5.65)
Perceived Stress		25.35 (2.15)	21.69 (2.29)	17.62 (7.89)	24.95 (2.14)	21.04 (2.29)	21.77 (7.85)

Figure 8. *Pre-Intervention to Post-Intervention and follow-up Differences in MBSR and MBSR ZOOM*



Note: Pre-intervention (1); post-intervention (2); follow-up (3) of MBSR, MBSR ZOOM. (a) FM time effect (b) FM symptoms subscale time effect (c) Quality of life time effect, (d) Quality of life physical subscale time effect, (e) Major Depression time effect, (f) Perceived Stress time effect

As you can see in the table and in the graphs, in all the measures expect for health-related quality of life physical and function subscales, the measurements in the MBSR group at the follow-up

point indicate a continued improvement in the measured symptoms, while in the MBSR group delivered by Zoom there was an increase in symptoms over time.

3.3 Pre- to Post-treatment Differences Between the CBT, CBT ZOOM and WL groups

Table 5 presents the effects and descriptive statistics for Group X Time comparisons. The variable perceived stress was considered as a covariate due to initial differences found between the groups.

Table 5. *CBT vs. CBT ZOOM vs. WL effects and descriptive statistics*

		CBT (n=16)		CBT ZOOM (n= 16)		WL (n=33)		Pre- to Post- Intervention Group Comparison	
		Pre	Post	Pre	Post	Pre	Post	F Time X Group	Cohen's d
		Mean							
		(SD)							
FM	Total	65.85 (3.65)	62.82 (4.79)	66.50 (4.37)	62.85 (5.74)	63.34 (2.55)	63.49 (3.34)	0.63	-
	Function	18.35 (1.66)	19.14 (1.85)	18.95 (1.98)	18.19 (2.22)	16.61 (1.16)	17.76 (1.29)	0.54	-
	Impact	13.44 (1.08)	13.79 (1.29)	12.82 (1.30)	11.93 (1.55)	13.78 (0.76)	13.09 (0.90)	0.25	-
	Symptoms	34.05 (1.74)	29.88 (2.21)	34.72 (2.08)	32.72 (2.65)	32.94 (1.21)	32.64 (1.55)	1.93	-
Health Related Quality of Life	General	9.27 (0.67)	10.64 (0.83)	8.89 (0.84)	9.44 (1.03)	9.30 (0.46)	9.68 (0.56)	0.54	-
	Physical	9.30 (0.63)	11.52 (0.42)	9.12 (0.75)	11.30 (0.50)	10.27 (0.42)	11.24 (0.28)	1.99	-
	Psychological	11.78 (0.61)	12.01 (0.52)	10.66 (0.72)	12.50 (0.62)	11.70 (0.41)	11.84 (0.35)	2.95~	0.54

	Social	11.48 (1.00)	11.83 (0.86)	9.38 (1.20)	9.91 (1.03)	10.86 (0.67)	10.62 (0.57)	0.53	-
	Environmental	13.72 (0.70)	13.86 (0.75)	12.27 (0.84)	12.81 (0.89)	13.43 (0.47)	13.77 (0.50)	0.12	-
Major Depression		16.63 (1.12)	14.97 (1.28)	16.25 (1.44)	14.27 (1.65)	16.07 (0.78)	14.50 (0.90)	0.02	-
Perceived Stress		24.85 (1.71)	21.57 (2.27)	18.27 (1.93)	17.54 (2.57)	24.77 (1.19)	22.93 (1.58)	0.56	-

NOTE: *p < .05; **p < .01; ***p<0.001; ~ marginally significant

As can be seen in Table 5, A Univariate analysis and a pairwise comparison for FM total score (FIQR) did not reveal significant effects. A Multivariate analysis for FM subscales did not reveal significant effects (Group X Time interaction, Group, Time). A pairwise comparison of the CBT and CBT ZOOM groups versus the WL group revealed a significant improvement in the CBT group only for the Symptoms subscale ($i-j=4.16$, $SE=1.63$, $p<0.05$, Cohen's $d=1.25$), compared to non-significant change in the CBT ZOOM group ($i-j=1.99$, $SE=1.95$, n.s), and in the WL group ($i-j=0.30$, $SE=1.14$, n.s).

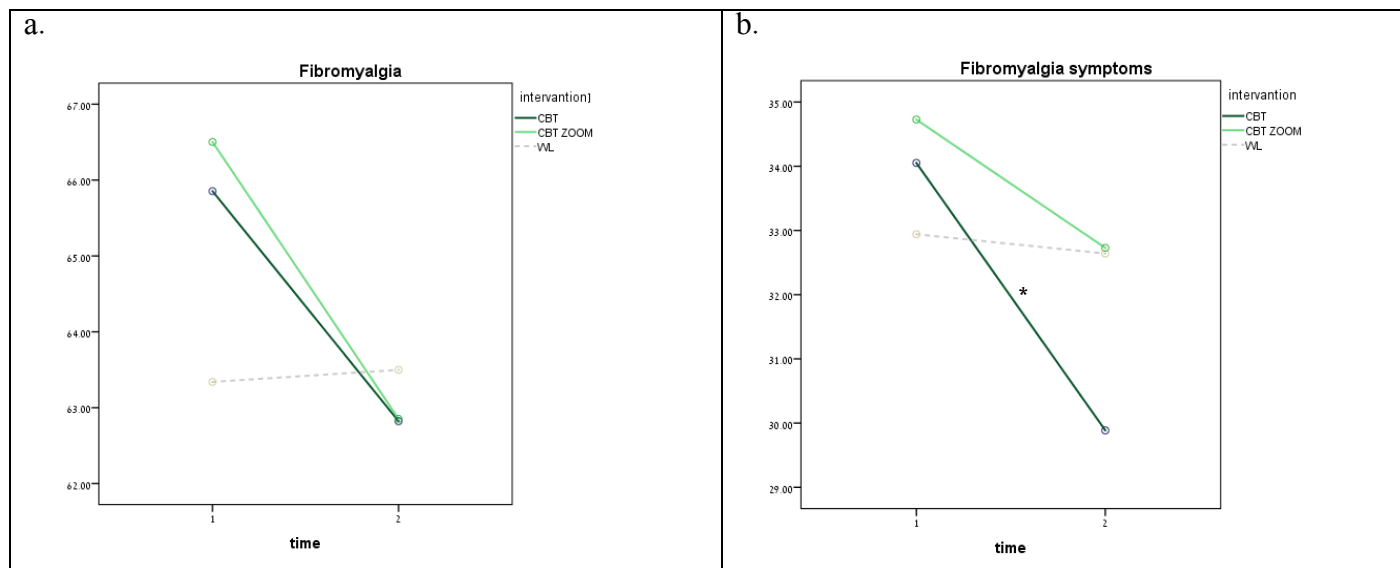
Next, we conducted Multivariate analysis for the quality-of-life subscales (i.e. physical, psychological, social, and environmental). This test showed a non-significant interaction of Group X Time [$F(8,86)=1.24$, n.s], a significant effect for Time [$F(4,43)=3.15$, $p<0.05$], or Group [$F(8,86)=0.52$, n.s]. In relation to the different HRQOL subscales, we found a marginally significant interaction of Group X Time with medium effect size in the psychological subscale. A pairwise comparison of the CBT and CBT ZOOM groups versus the WL group revealed a significant improvement in the CBT group in the physical subscale ($i-j=-2.21$, $SE=0.59$, $p<0.01$, Cohen's $d=-2.40$), the CBT ZOOM group ($i-j=-2.18$, $SE=0.71$, $p<0.01$, Cohen's $d=-1.54$) and the WL group ($i-j=-1.83$, $SE=0.60$, $p<0.05$). In the psychological subscale we found a significant improvement in the CBT ZOOM group ($i-j=-1.83$, $SE=0.60$, $p<0.01$, Cohen's $d=-1.08$), compared to non-significant change in the CBT ($i-j=-0.22$, $SE=0.50$, n.s) and WL group ($i-j=-0.14$, $SE=0.33$, n.s).

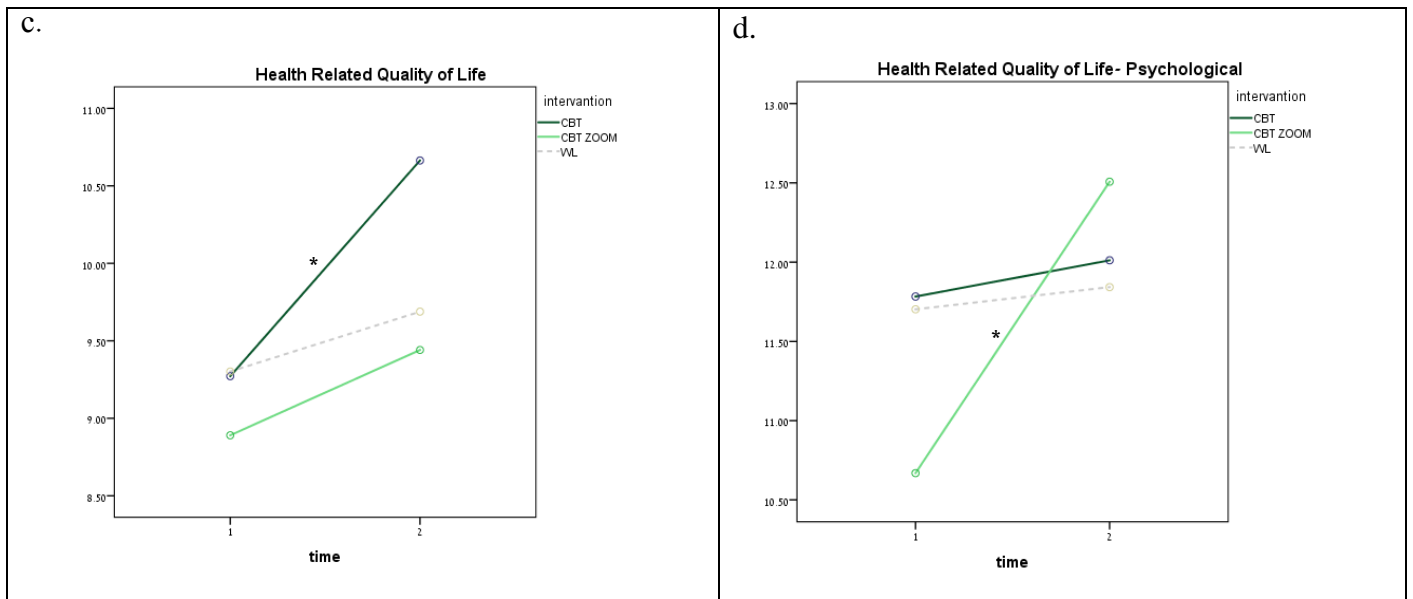
A Univariate analysis of variance and pairwise comparison for major depression (PHQ-9) did not reveal significant effects.

A Univariate analysis for Perceived Stress (PSS) showed non-significant effects for Group X Time interaction or group, in comparison to significant effect for time [$F(1,51) = 4.75, P < 0.05$]. A pairwise comparison of the CBT, CBT ZOOM groups versus the WL group in revealed a significant improvement in the CBT group ($i-j=3.28, SE=1.62, p<0.05, \text{Cohen's } d=1.05$), compared to marginally significant change in the CBT ZOOM group ($i-j=0.72, SE=1.82, p=0.06, \text{Cohen's } d=0.18$) and non-significant WL group ($i-j=1.84, SE=1.12, n.s$).

Figure 9 present the effects of pre- to post-intervention measurements for the CBT, CBT ZOOM groups versus the WL control group on several outcome measures.

Figure 9. *Pre-Intervention to Post-Intervention Differences between CBT, CBT ZOOM and WL*





Note: Pre-intervention (1); post-intervention (2). (a) Fibromyalgia group X time interaction of CBT, CBT ZOOM compared to WL, (b) Fibromyalgia symptoms subscale group X time interaction of CBT, , CBT ZOOM compared to WL, (c) Quality of life group X time interaction of CBT, , CBT ZOOM compared to WL, (d)) Quality of life psychological group X time interaction of CBT, , CBT ZOOM compared to WL

3.4 Long-Term Effectiveness of CBT and CBT ZOOM

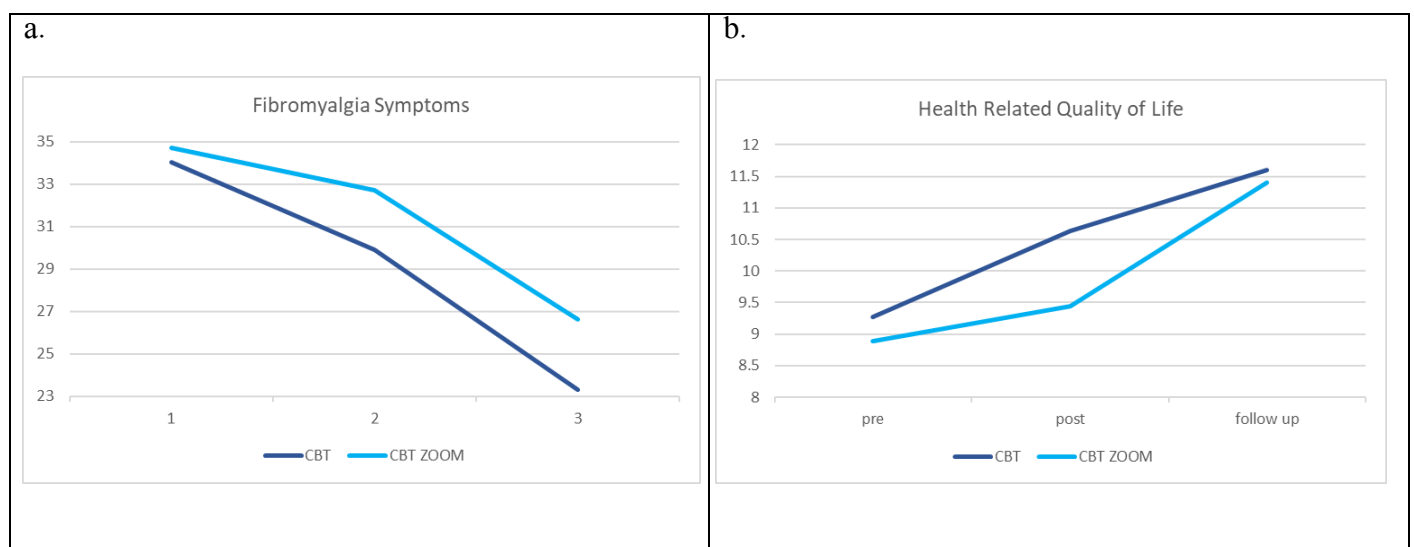
In the next section I will present the results of the follow-up measurements for the variables that came out significant in the comparison between pre and post treatment in the face-to-face and zoom intervention groups separately. These results will be shown in averages and their corresponding graphs. Due to the small number of subjects in these groups, we did not perform statistical tests for the comparison between post and follow-up measurements.

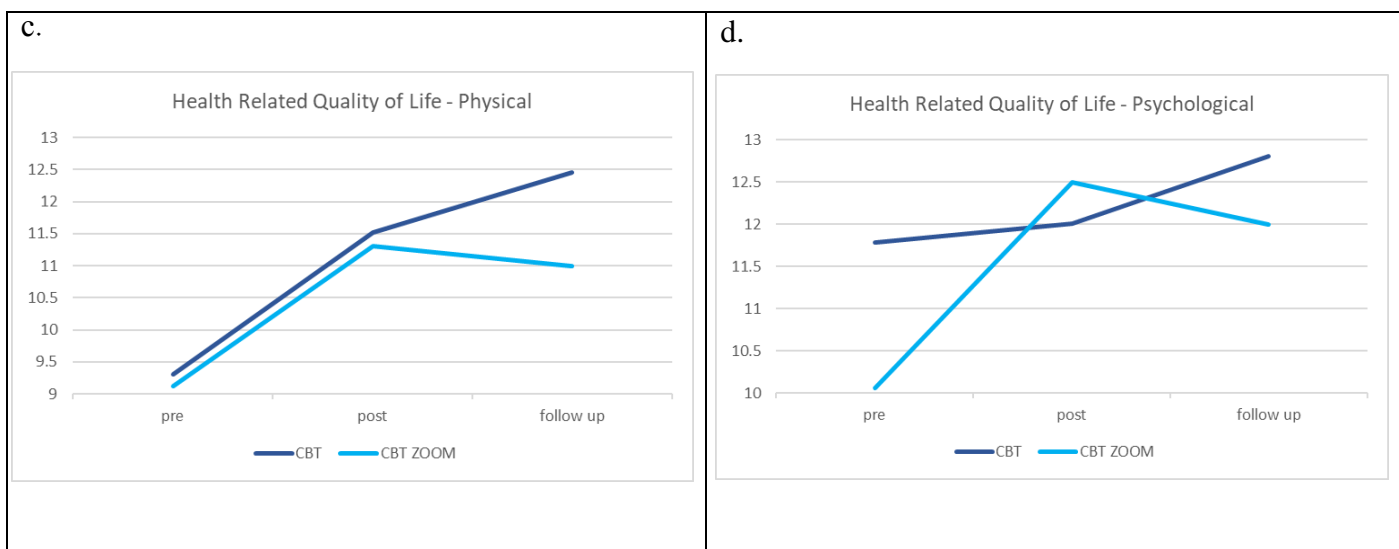
Table 6 and Figure 10 presents the descriptive statistics for pre, post and follow up measurements in CBT face-to-face and CBT by ZOOM groups.

Table 6. Long-Term Effectiveness of CBT and CBT ZOOM descriptive statistics

	CBT (n=16)			CBT ZOOM (n= 16)		
	Pre	Post	Follow-up	pre	Post	Follow-up
	Mean					
	(SD)					
FM Symptoms	34.05 (1.74)	29.88 (2.21)	23.30 (4.95)	34.72 (2.08)	32.72 (2.65)	26.63 (7.07)
Health Related Quality of Life	9.27 (0.67)	10.64 (0.83)	11.60 (2.19)	8.89 (0.84)	9.44 (1.03)	11.40 (2.67)
Health Related Quality of Life - Physical	9.30 (0.63)	11.52 (0.42)	12.45 (0.93)	9.12 (0.75)	11.30 (0.50)	10.99 (2.67)
Health Related Quality of Life - Psychological	11.78 (0.61)	12.01 (0.52)	12.80 (1.65)	10.66 (0.72)	12.50 (0.62)	12.00 (2.17)
Perceived Stress	24.85 (1.71)	21.57 (2.27)	18.50 (5.80)	18.27 (1.93)	17.54 (2.57)	18.45 (7.97)

Figure 10. Pre-Intervention to Post-Intervention and follow-up Differences in CBT and CBT ZOOM





Note: Pre-intervention (1); post-intervention (2); follow-up (3) of CBT, CBT ZOOM. (a) Fibromyalgia time effect (b) Fibromyalgia symptoms subscale time effect (c) Quality of life time effect , (d)) Quality of life physical subscale time effect

As you can see in the table and in the graphs, in the CBT group, the measurements at the follow-up point indicate a continued improvement in the measured symptoms. In the CBT delivered by ZOOM, the results are mixed. While the descriptive of FM symptoms and HRQOL indicates a continued improvement after treatment, the results of HRQOL subscales (physical and psychological) shows increase in symptoms.

4. Potentials Mechanisms of Change

The purpose of this section is to establish the relevance of different mechanisms to the physical and psychological aspects of FM and its treatment. In order to find the relevant mechanisms, we examined the correlations of the change that occurred at the levels of various presumed mechanisms, with the change that occurred in outcome measures follows the different interventions. In other words, we try to find whether there are psychological variables whose change in them related to a greater change in the outcome measures (FM, HRQOL, depression and perceived stress) following treatment (CBT/MBSR). The mechanisms we chose to focus on are difficulties in emotional regulation, pain catastrophizing and psychological inflexibility in pain. Examining these mechanisms will allow us to examine the significance of specific processes for dealing with FM and pain.

First, a score of the change in mechanisms and outcomes was calculated by subtracting the pre-intervention score from the post-intervention score or vice versa (depending on the measure – for example, QOL vs. perceived stress), yielding a score that represent the change in the measure throughout the intervention (This score will be marked by the sign- Δ). Subsequently, we have conducted Pearson correlations between all variables. The results were calculated separately for the change that occurred in the CBT group and the MBSR group.

It is important to note that in all the indices, except for health-related quality of life, the change that occurred was in the form of a decrease, that is, an improvement, therefore a positive relationship indicated a match in the improvement in the indices.

Table 7 presents Pearson correlations among change levels of FM, major depression, perceived stress, quality of life, difficulties in emotion regulation, pain catastrophizing and psychological inflexibility in pain in the CBT group.

Table 7. *Pearson correlations of change levels of pain cognition and its facets with change levels of FM and psychological factors following CBT*

	Δ FM	Δ FM Function	Δ FM Impact	Δ FM Symptoms	Δ PHQ	Δ PSS	Δ QOL	Δ QOL Physical	Δ QOL Psych	Δ QOL Social	Δ QOL Environ
Δ Pain Catastrophizing	.32	.12	.28	.21	.31	.41*	-.19	.23	-.23	.10	-.16
Δ Pain Catastrophizing - Rumination	.23	.20	.16	.10	.09	.19	-.09	.12	.09	.49*	.12
Δ Pain Catastrophizing - Magnification	.13	-.01	.21	.08	.22	.14	-.15	.28	-.29	-.14	-.28
Δ Pain Catastrophizing - Helplessness	.31	.06	.26	.25	.36	.52**	-.17	.14	-.31	-.11	-.22
Δ Psychological Inflexibility in Pain	.61**	.19	.40	.49**	.23	.47*	-.43*	.05	-.31	.19	.14
Δ Psychological Inflexibility in Pain - Avoidance	.65**	.29	.42*	.47**	.28	.36	-.37	.08	-.37	.21	.21
Δ Psychological Inflexibility in Pain - Fusion	.39	-.11	.21	.40	.06	.61**	-.44*	.03	-.05	.09	-.04
Δ Difficulties in Emotion Regulation	.27	-.04	.24	.29	.26	.36	-.12	-.00	.05	-.04	-.20
Δ DERS- Non-acceptance of negative emotions	.29	.14	.20	.21	.24	.43*	-.04	.168	.10	.09	-.18
Δ DERS- Inability to engage in goal directed behaviors	.31	-.07	.29	.34	.24	.43*	-.21	.02	-.19	-.06	-.31
Δ DERS- Difficulties controlling impulsive behaviors	.34	-.07	.22	.44*	.15	.32	-.24	.05	.11	.16	-.02
Δ DERS- Limited access to effective emotion regulation strategies	.10	.21	-.11	.06	.29	.05	.15	-.20	-.09	-.26	-.01
Δ DERS- Lack of emotional awareness	.18	-.20	.20	.29	.28	.59**	-.25	.18	.04	-.13	-.29
Δ DERS- Lack of emotional clarity	-.06	-.19	.13	-.05	-.18	-.13	.12	-.00	.15	.19	-.16

NOTE: PHQ=Depression; PSS=Perceived Stress; QOL=Quality of Life; QOL Psych=Psychological Quality of Life; QOL Environ=Environmental QOL; DERS= Difficulties controlling impulsive behaviors

Significance levels: * $p < 0.05$. ** $p < 0.01$.

As presented in Table 7, following CBT, significant positive correlations were found between change in pain cognitions and part of DERS subscales and change in perceived stress. Moreover, we found strong and positive correlation between change in FM and change in Psychological Inflexibility in Pain and a moderate negative correlation between health-related quality of life and Psychological Inflexibility in Pain changes.

Contrary to hypotheses, a positive relationship was found between a change in psychological inflexibility in relation to pain and a change in health-related quality of life and no correlations to change in major depression were found.

Table 8 presents Pearson's correlations among change levels of FM, major depression, perceived stress, quality of life, difficulties in emotion regulation, pain catastrophizing and psychological inflexibility in pain in the MBSR group.

Table 8. *Pearson correlations of change levels of pain cognition and its facets with change levels of FM and psychological factors following MBSR*

	Δ FM	Δ FM Function	Δ FM Impact	Δ FM Symptoms	Δ PHQ	Δ PSS	Δ QOL	Δ QOL Physical	Δ QOL Psych	Δ QOL Social	Δ QOL Environ
Δ Pain Catastrophizing	.16	-.21	.48*	.04	.26	.29	-.21	-.20	-.25	-.28	-.26
Δ Pain Catastrophizing - Rumination	.09	-.23	.29	.09	.48*	.43*	-.25	-.24	-.50**	-.33	-.28
Δ Pain Catastrophizing - Magnification	.17	.01	.33	.03	-.24	-.29	-.06	.11	.30	-.32	-.15
Δ Pain Catastrophizing - Helplessness	.12	-.19	.43*	-.01	.21	.32	-.13	-.23	-.21	-.06	-.16
Δ Psychological Inflexibility in Pain	.27	.04	.40	.16	.20	.33	-.11	-.07	-.05	-.27	-.20
Δ Psychological Inflexibility in Pain - Avoidance	.16	.01	.24	.11	.27	.44*	.02	-.07	-.08	-.13	-.11
Δ Psychological Inflexibility in Pain - Fusion	.30	.05	.45*	.16	.01	.03	-.24	-.04	-.22	-.34	-.24
Δ Difficulties in Emotion Regulation	.16	-.06	.31	.09	.08	.11	-.02	.04	.17	.09	-.35
Δ DERS- Non-acceptance of negative emotions	.18	-.07	.27	.18	.19	.15	.01	.02	-.01	.35	-.20
Δ DERS- Inability to engage in goal directed behaviors	.00	-.17	.03	.10	.12	-.02	-.10	.17	-.02	.13	-.43*
Δ DERS- Difficulties controlling impulsive behaviors	.12	.02	.14	.11	.04	.02	-.02	.05	.18	.14	-.21
Δ DERS- Limited access to effective emotion regulation strategies	.01	-.13	.34	-.21	-.16	-.02	.06	.01	.40*	-.07	-.16
Δ DERS- Lack of emotional awareness	.25	.00	.28	.26	.10	.11	-.05	.09	.20	-.01	-.40
Δ DERS- Lack of emotional clarity	.20	.05	.35	.03	.15	.28	-.08	-.07	.05	-.09	-.41*

NOTE: PHQ=Depression; PSS=Perceived Stress; QOL=Quality of Life; QOL Psych=Psychological Quality of Life; QOL Environ=Environmental QOL; DERS= Difficulties controlling impulsive behaviors

Significance levels: * $p < 0.05$. ** $p < 0.01$.

As presented in Table 8, following MBSR, the change rumination index (Pain Catastrophizing subscale) stands out with significant moderate relationships to depression, perceived stress and psychological health-related quality of life. Additionally, positive moderate correlations were found between change in FM overall impact subscale and changes in pain catastrophizing (total score and helplessness) and fusion (Psychological Inflexibility in Pain subscale).

Relate to difficulties in emotion regulation, significant negative correlations were found between changes in difficulties in emotion regulation (Inability to engage in goal directed behaviors and lack of emotional clarity) and changes in health-related quality of life environmental subscale. Contrary to hypotheses, a positive relationship was found between a change in difficulties in emotion regulation Limited access to effective emotion regulation strategies subscale and a change in psychological health related quality of life subscale.

General Discussion

In the present study, we conducted a randomized controlled trial to examine the effects of CBT and MBSR group therapies for patients with FM, employing a wide variety of measures covering disease-related characteristics, psychopathology, emotion regulation, and pain-related cognitions. For this study, we developed adapted CBT and MBSR protocols specifically suited to meet the unique characteristics, needs, and symptoms of FM. The present study aimed to examine four main research questions:

1. Are CBT and MBSR effective for treating FM patients, as measured by various psychological (depression, perceived stress, and quality of life) and physical (FM symptoms) outcome measures, compared to a wait-list control group?
2. Are the changes associated with CBT and MBSR stable over time after the end of the intervention?
3. Are CBT and MBSR treatments that are delivered online effective for treating FM patients, as measured by various psychological (depression, perceived stress, and quality of life) and physical (FM symptoms) outcome measures, compared to a wait-list control group?
4. What are the potential mechanisms for the changes that occur during the intervention?

In general, our findings reflect the therapeutic potential of MBSR and CBT for FM patients. In addition, MBSR was found to be more effective in comparison to CBT. Moreover, our research indicates that the two treatments have different therapeutic mechanisms and that these affect different symptoms. Our findings highlight the complex connection between the mind and body as well as the extensive and complex distress that FM causes.

1. The Effectiveness of CBT and MBSR for FM Patients

In our first hypothesis, we predicted that, in comparison to waitlist control participants, FM patients receiving CBT or MBSR would show a greater reduction between pre- and post-treatment assessments in different physical and emotional aspects. Concerning MBSR, this hypothesis was confirmed, indicating that mindfulness-based therapy was highly effective for FM patients. Patients who received MBSR significantly improved in FM, depression, perceived stress, and health-related quality of life, compared to patients in the WL control group. Regarding CBT, improvements were observed in fewer indices (FM symptoms and the physical aspect of quality of life). These results are in line with a growing body of studies supporting the effectiveness of MBSR in improving the well-being of FM patients (Astin et al., 2003; Fjorback et al., 2013; Goldenberg et al., 1994; Grossman et al., 2007; Schmidt et al., 2011; Sephton et al., 2007).

1.1 The Effectiveness of MBSR for FM Patients

The results of our study indicated an improvement in a variety of aspects following MBSR. FM was found to have a significantly greater improvement in the MBSR group compared to the WL group with large effect sizes. It is important to notice that these improvements happened after a 10-week intervention and were stable after 4 months.

Perceived stress also significantly improved from pre- to post-MBSR. Stress reduction is one of the main goals of MBSR, and a variety of therapeutic components focus on dealing with stress. Stress has a key role in FM and often plays a significant part in the vicious cycle in which stressful conditions often lead to a worsening of symptoms, and worsening symptoms often lead to more stress (Van Houdenhove & Egle, 2004). Consequently, an intervention that focuses on

stress, such as MBSR, could help patients slow down and even prevent this cycle. Moreover, such an intervention can help patients avoid being controlled and affected by feelings of stress.

Another important finding of our study was a significant improvement in depression following MBSR compared to WL controls. In previous studies, there have been mixed results regarding the effectiveness of MBSR on alleviating depression, from studies that did find MBSR helpful for depression (Astin et al., 2003) to other studies that did not find such an effect (Fjorback et al., 2013). Although MBSR is not specifically designed to reduce depression (as opposed to MBCT, another variant of mindfulness-based interventions), it nevertheless does so effectively, as can be seen in the present study. MBSR's effectiveness in reducing depression can likely be explained by the idea that mindfulness allows one to prevent a negative mental and emotional “drift” and to halt the escalation of negative thoughts and feelings, which is characteristic of depression (Clark et al., 2000). Additionally, mindfulness teaches one to shift mental gears, from the mode of a mind dominated by critical and judgmental thinking patterns (which are highly associated with depression as they are likely to provoke and accelerate downward mood spirals), to another mode of mind in which one can experience the world directly, non-judgmentally, and with a more compassionate point of view. Finally, these findings are especially important due to the high comorbidity of FM with depression, which has even been found to be a risk factor for suicidality among FM patients (Aguilera, Paz, Compañ, Medina, & Feixas, 2019; Raphael, Janal, Nayak, Schwartz, & Gallagher, 2006; Wolfe et al., 1995). In fact, it is becoming clear that suicidality itself is a risk factor for this population (Levine & Horesh, 2020); thus, these findings again highlight the importance of holistic interventions like MBSR for treating FM – interventions that do not focus solely on pain, but also affect mood and affective regulation, which could contribute to the well-being of FM patients.

An additional outcome of our study is the effectiveness of MBSR on increasing quality of life. It has been demonstrated that FM patients suffer from greater disability than patients with other chronic pain disorders (Fernández, 2000; Martínez et al., 2003). Our results suggest that MBSR improves health-related quality of life and its physical aspect compared to WL control. Our results support the studies that have found increased quality of life of FM patients following MBSR (Grossmann, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007), rather than studies that did not find this effect (Goldenberg et al., 1994). The physical quality of life relates to the following

symptoms: pain, energy, sleep, mobility, activities, medication, and work. The improvement that occurred following MBSR in quality of life is a very important outcome of our study since this result refers to significant aspects of the patient's daily functioning and thus represents the most direct effect of the disease on the patient's life.

1.2 The Effectiveness of CBT for FM Patients

As mentioned before, our study found that CBT led to improvement in FM symptoms and the physical aspect of health-related quality of life. These results are related to many studies that examined CBT for FM patients and showed improvements in pain, quality of life, disability, sleep difficulties, and fatigue associated with the disorder (Bernardy, Klose, Welsch & Häuser, 2019; Glombiewski et al., 2010). It is possible that these improvements stem from CBT's emphasis on behavior, psychoeducation, and practice of gradual behavior change. CBT addresses FM as the result of a vicious cycle created by behaviors of avoidance and withdrawal from the appearance of pain and emotional distress (Bradley & Alberts, 1999; Keefe et al., 2005). Thus, it is possible that CBT's behavioral practice led to an improvement in their physical sensations as patients developed the feeling that their bodies were strong and capable.

On the other hand, our results did not find that CBT leads to improvements in the emotional distress of the patients. This contradicts with the studies that show that CBT reduces the negative mood or depression symptoms associated with FM (Bernardy, Füßer, Köllner, & Häuser, 2010, Falcão et al., 2008).

1.3 The Comparison between CBT and MBSR

When examining our results, it is important to pay attention to the comparison between the approaches. As can be seen, MBSR led to more improvements compared to CBT, which reflects the significant therapeutic potential of this approach for FM patients above and beyond CBT. These results are not compatible with the meta-analysis studies that compare these interventions and indicate a preference for cognitive-behavioral treatments from the second wave (Albajes & Moix, 2021; Glombiewski et al., 2010; Kozasa et al., 2012). However, it should be mentioned that these studies did not compare the different treatments directly, and that this type of study has not been done to date.

The difference in results may derive from the fact that the reviews performed examined studies on treatments that were not adjusted for the specific difficulties of FM patients (Glombiewski et al., 2010). In contrast, our findings regarding the effectiveness of MBSR can possibly be explained by its specific suitability for FM as a result of its inherent mind-body emphasis. In many cases, FM has led to patients' attention and language passing through, or even beginning with, a description of the body. Thus, we speculate that talking through the body, focusing on it, and trying to explore it constitutes a significant starting point for change for these patients. In this regard, it is possible that working through cognition as part of CBT is important, but perhaps not the most effective way to address these patients.

Furthermore, it is possible that the non-judgmental component of mindfulness-based therapy is particularly significant. This population faces a substantial amount of stigma and a common sense of loneliness (Sabik, 2010). The theoretical model of the third wave approaches claims that acceptance must be promoted before change (Herbert & Forman, 2011). This understanding in combination with our results may indicate that, in order to help FM patients, it is necessary to focus on the promotion of an accepting and non-judgmental attitude towards the experience *before* behavioral or cognitive change. It is important to note that CBT does not address these facets of these patients' experience.

Another explanation for the partial results found regarding CBT could be the fact that we used CBT in isolation, rather than as part of a multidisciplinary approach. Previous studies have found the latter to be more effective for FM patients (Bennett & Nelson, 2006). Moreover, our results could be related to certain characteristics of the patients in our specific study (i.e., chronic illness, strength of symptoms, intensity of various emotional difficulties, age, etc.). It is possible that if we divide the patients in our study according to these characteristics, it may be found that some patients benefit more from CBT compared to MBSR. This assumption is based on studies that showed the correlation between patients' characteristics and effectiveness of psychological interventions (Ghaderi, 2006; Sil et al., 2014; Turk, 2005),

Our finding might point to the strength of the adapted protocol used in our study, which gave significant attention to FM symptoms through psychoeducation and practice. This contrasts with the generic protocol used in former studies that applied MBSR to FM patients without modifications that address FM issues specifically; rather, they solely addressed them if brought

up by the patients by chance. The differences between the generic and adapted protocols may also explain the mixed evidence regarding MBSR research with FM patients (Lauche et al., 2013). In general, there has been a trend of transitioning from generic protocols to population-specific protocols of MBSR. Upon implementation for other conditions (e.g., breast cancer; Cramer, Lauche, Paul, & Dobod, 2012), this shift has shown great success.

2. Differences Between Face-to-Face and Online Therapy

Our study was the first to compare face-to-face and online videoconferencing group treatments for FM patients. As mentioned in the introduction, research exists regarding online video treatments for chronic pain patients including research specifically evaluating CBT (Connolly et al., 2018; Palyo, Schopmeyer, & McQuaid, 2012; Taguchi et al., 2021), and mindfulness-based (Gardner-Nix, Barbati, Grummitt, Pukal, & Raponi Newton, 2014; Gardner-Nix, Backman, Barbati, & Grummitt, 2018). However, this research has included treatments that are self-guided and not adapted to the unique needs of the patients.

In this section, given the small number of subjects in each group, we performed separate comparisons for CBT and MBSR. Based on previous studies described in the introduction section, we hypothesized that FM patients receiving CBT or MBSR by ZOOM will show greater improvements in FM symptoms, depression, perceived stress, and health-related quality of life between pre- to post-intervention, compared to waitlist (WL) control group.

When we divided the group of MBSR participants between those who participated in therapy online and those who received it face-to-face, we saw that face-to-face therapy led to fewer short-term improvements. Patients who participated in MBSR by ZOOM significantly improved in FM, depression, perceived stress, and health-related quality of life, compared to patients in the WL control group. However, patients who participated in MBSR face-to-face showed improvements only in FM and its overall impact, as well as a marginally significant improvement in perceived stress. Regarding quality of life, improvement was detected only in the physical health-related quality of life. Thus, the MBSR delivered by videoconferencing was found to be more effective in the short term than both the MBSR delivered face-to-face and the WL control group. These results are particularly innovative since only a few studies have been conducted so far on online mindfulness-based therapy for FM patients, the majority of which

solely examined recorded and non-group therapies (Davis & Zatura, 2013; Garrido-Torres et al., 2016).

When examining these results, it is important to refer to the follow-up measurement. In those measurement, we did not perform statistical tests due to the small number of subjects; nevertheless, the trend of change between the time points demonstrates that there is a substantial difference between the stability of symptom intensity following online and face-to-face treatment. Although most indices (except for the QOL subscale) show a more significant decrease in symptoms between the beginning and end of treatment for the ZOOM group, improvements between the end of treatment and the follow-up continued only for the group that met face-to-face. This trend may be related to the functional aspect of face-to-face care that requires patients to leave the house. It can be assumed that compliance with this requirement contributes to patients' sense of competence and continued improvement after treatment. This reflects the findings of a study examining pain-related activity management patterns by Mélanie et al. (2018) which also presents less pain interference and better psychological function of the study's participants as significantly associated with the functionality-focused practice of pacing. This practice is a behavioral strategy used to help individuals schedule their activities based on time or quotas (rather than pain) to maximize their functionality despite persistent pain (Kerns, Sellinger, & Goodin, 2011).

In general, the comparison between CBT conducted face-to-face, over ZOOM, and WL control group showed slightly higher therapeutic potential for face-to-face therapy over the latter groups; patients in the face-to-face group showed more improvement in their FM symptoms than the online treatment and WL control group did. Nevertheless, improvements in health-related quality of life and perceived stress were observed in both treatment groups and follow-up trend results did not find significant differences between the treatments either. These results are consistent with other studies that show the effectiveness of CBT delivered through videoconferencing for pain patients (e.g., Connolly et al., 2018; Taguchi et al., 2021), and studies that showed the effectiveness of recorded online CBT therapy. For example, Vallejo et al. (2015) compared CBT and iCBT for FM patients and found an improvement in FM only for the participants in the CBT face-to-face group. Moreover, the CBT and iCBT groups both demonstrated improvement in psychological distress, depression, catastrophizing, and utilizing

relaxation as a coping strategy. Although this study did not use a real time video therapy, it shows the therapeutic potential of online psychological interventions for FM patients.

In conclusion. Our results show mixed evidence regarding the effectiveness of online videoconferencing psychotherapy, while in MBSR there was a clear preference for online treatment, in CBT there was a slight advantage for face-to-face treatment. It is important to note the trend of the follow-up results that indicate an advantage for the group that underwent face-to-face MBSR treatment.

A possible explanation for these results could be the adaptation of online treatment to a popular method of communication today. Results from a web-based survey suggest that people may prefer mindfulness internet interventions to in-person therapy: the internet was found to be the first-choice format for 42% of the participants, suggesting that, for many individuals, online MBIs may be an acceptable alternative to face-to-face formats (Wahbeh, Svalina, & Oken, 2014).

On the other hand, there are many writers who emphasize the importance of mutual regulation based on physical presence (Cozolino, 2006; Siegel, 2020). The affective, relational, and regulation mechanisms of change are central to psychotherapy, and they may be lost when treatment shifts online (Weinberg, 2020). Eye contact as well as the pheromones that affect our feelings of intimacy and attachment are lost as well (Cozolino, 2006). The absence of the former aspect is highly relevant for group therapists as it affects therapists' work with group coleaders as well (Weinberg, 2020). Eye contact is related to attachment and the parasympathetic nervous system, reducing distress and fight–flight reactions (Jarick & Bencic, 2019). It is possible that mindfulness therapy overcomes these challenges of virtual treatment as a result of the joint attention to the body that it manifests and its use of recordings that increase the feeling of physical togetherness of the participants in the therapy.

Therapeutic presence is defined as bringing one's whole self to the engagement with the client and being fully in the moment with and for the client, with little self-centered purpose or goal in mind (Craig, 1986). Therapists' presence involves a "being with" the client, rather than a "doing to" the client. Although there are many distractions when therapy is conducted online, and the barrier of the screen might decrease and dilute the therapist's presence, therapeutic

presence can still be achieved (Craig, 1986). A significant part of mindfulness therapy includes working on the patient's ability to be present. The practice of this presence takes place with the cooperation of both the patient and the therapist. It is possible that this situation allows the therapist's presence to increase and thus, contributes to the treatment and is also suitable for remote treatment.

A possible explanation for the fact that only a slight difference was observed between face-to-face and ZOOM CBT could be the challenge that both face in addressing exposure and behavioral tasks. As mentioned before, for the most part, online treatment allows for more gradual exposure and participation in treatment without functional change. However, since CBT includes behavioral tasks and a requirement for functional change, it is more difficult for the patient participating in the treatment to avoid functioning even if the treatment takes place remotely. To test this explanation, future research should be carried out regarding the effect of behavioral change and the tendency to avoid as mediators or moderators of various treatments' effect.

It is important to remember the possible advantages of online treatment that allow ease and speed of accessibility, the convenience of availability for individual schedules, anonymity, the ability for patients to work at their own pace in the comfort of their own homes, and reduced cost (Andersson & Titov, 2014). On the other hand, it is also important to understand that online group therapy is a vast open space with loose boundaries. Group therapists cannot assume that the confidentiality that is strictly kept in the consulting office will be kept online; therefore, therapists must be much more cautious and take more measures to ensure client confidentiality (Weinberg , 2020). Moreover, since little research has been done in the field of online group therapy, there are many aspects that have not yet been explored. In this context, there is not enough information about the development of the therapeutic alliance in this type of treatment (Weinberg , 2020). There is substantial evidence that the quality of the therapeutic alliance is the best predictor of positive client outcome for all psychotherapies (Martin, Garske, & Davis, 2000; Flückiger, Del Re, Wampold, & Horvath, 2018). The therapeutic alliance has three components: (a) collaborative agreement on the goals of therapy, (b) collaborative agreement on the tasks of therapy, and (c) the emotional bond between the therapist and client (Horvath & Symonds, 1991). Two of the ingredients of the therapeutic alliance, agreeing on the goals and tasks, can easily be

achieved in online groups. However, it is questionable whether the third component, the quality of the relationship, remains at an equivalent level when conducted online. The absence of body-to-body interaction in online groups can be a significant, if not the main, obstacle (Weinberg, 2020). On the other hand, there have been studies that found that a therapeutic alliance can develop in video-conference psychotherapy (e.g., Dunn, 2014; Norwood, Moghaddam, Malins, & Sabin-Farrell, 2018; Preschl, Maercker, & Wagner, 2011; Simpson & Reid, 2014). In the study we carried out, the therapeutic alliance was not tested, and it is possible that it was damaged due to the sudden change in the therapeutic plan from face-to-face to online.

In conclusion, considering that previous studies show a preference for CBT for FM patients and given the possible benefits of online treatment (Connolly et al., 2018; Gardner-Nix, Backman, Barbati, & Grummitt, 2018; Taguchi et al., 2021), we recommend conducting future studies that compare the effectiveness of videoconferencing treatments with an active control group, rather than only with control groups that do not receive treatment – as has been done in most studies so far (Bender et al., 2011).

3. Potentials Mechanisms of Change in MBSR and CBT

A central goal of this research was to find a psychological treatment that will be tailor-made for FM patients. For this purpose, we adjusted for the complex difficulties of FM patients in the treatment protocol and examined potential change mechanisms for the treatments.

Using an important article by Jensen, Turner, and Romano (2017), we attempted to see the role of the potential change mechanisms in treatments in two aspects: what is the most significant mechanism in each treatment? and is there a link between specific mechanisms and an improvement in specific symptoms? First, we examined difficulties in emotion regulation as a general mechanism of change in CBT and MBSR. Additionally, we examined the role of two other potential mechanisms that are related to pain-related cognitions: psychological inflexibility in pain and pain catastrophizing. In this examination we assessed the association between the change in the mechanism (pre- to post-treatment) and the change in several outcome measures: FM, depression, perceived stress, and health-related quality of life.

This study shows that different cognitive and emotional mechanisms have different roles in promoting improvement following mindfulness and CBT and in relation to different

symptoms. Our findings show that the most significant change mechanism for CBT was psychological inflexibility in pain, while the most significant mechanism for MBSR was pain catastrophizing. Difficulty in emotion regulation was found to play a less significant role in relation to the two treatments. In addition, the results show that perceived stress has the largest number of connections to the various mechanisms.

1.1 The Relationship between Potential Therapeutic Mechanisms and Outcome Measures

When examining the joint results of the correlation tests for the two groups (CBT and MBSR) in relation to the various physiological and emotional indices tested, it can be recognized that the variable that stands out in relation to the proposed mechanisms is perceived stress, while the variable to which the fewest relations were found is depression. These results reinforce the studies that claim that FM is a stress-related disorder (Cohen, Kessler, & Gordon, 1995; Sangha, 2000; Staud, 2007) and point to the importance of emphasizing the mechanisms we proposed – specifically, the pain-related mechanisms – for the treatment of the emotional distress accompanying pain among FM patients. Considering the many studies that show the prevalence of depression among FM patients (e.g., Aguglia, Salvi, Maina, Rossetto, & Aguglia, 2011; Arnold et al., 2006), the lack of results for associations between the change in the proposed therapeutic mechanisms to depression in this study indicates the importance of conducting future research on the mechanism that will lead to an improvement in mood difficulties.

Furthermore, our study had few results showing correlations between the improvement seen in the outcomes measures after patients received MBSR or CBT and difficulties in emotional regulation. This suggests that emotional regulation is not a therapeutic mechanism in our study. However, it is possible that the change in emotional regulation caused a change in another mechanism and that the latter led to a change in the results. In addition, it is possible that a change in emotional regulation that focuses on emotional processes and is not expressed through the body or the pain itself is not compatible with the mind-body connection that the patients suffer from.

1.2 Potential Therapeutic Mechanisms in MBSR

In relation to MBSR, our study shows the important relationship between the change that happened in pain catastrophizing and the reduction in distress. Moreover, we found

relationships between specific aspects of psychological inflexibility to pain and difficulties in emotion regulation to different outcomes. Compared to the CBT group, few connections were found between pain cognitions and emotion regulation and outcomes measures among the participants in the MBSR group. Considering the significant improvements observed in the MBSR group, it can be assumed that the proposed mechanisms are not significant change mechanisms in mindfulness-based therapy. It is possible that the difficulty in finding a mechanism is related to the complexity of this treatment that works simultaneously on the body and mind. We will now address the results of the associations found in relation to the proposed mechanisms.

Pain Catastrophizing

In our study we found associations between the change that occurred in pain catastrophizing (total score and helplessness) and FM impact. Moreover, we found associations between the change that occurred in rumination and the changes that occurred in depression, perceived stress, and psychological health-related quality of life. These results consisted with studies that showed the connection between pain catastrophizing and mindfulness (Day, Smitherman, Ward, & Thorn, 2015; Elvery, Jensen, Ehde, & Day, 2017).

Turner and Aaron (2001) suggested that when an individual experiences pain, he/she might switch into an "autopilot" mode and fall into a vicious cycle that amplifies the pain. This "autopilot" mode usually includes automatic catastrophic scenarios that can come into mind when experiencing unavoidable pain. According to our findings, the ability to stop this cycle through reduction in rumination is related to different physical and emotional symptoms. It seems that mindfulness practice may help in doing so by allowing one to return to the present moment and avoid being caught up in imaginary future disastrous events (Kabat-Zinn, 1994).

In addition, the questionnaire we used places significant emphasis on the individual's reactivity to stimuli and, specifically, to pain. Considering this, our results concluded that change in reactivity was significantly related to change in the effect of the disorder. This result is consistent with the theory underlying mindfulness-based treatments, in which there is an attempt to promote the ability to accept things as they are without trying to change them (Kabat-Zinn, 1994).

Psychological Inflexibility in Pain

Psychological flexibility in pain refers to the capacity to observe pain from a more neutral perspective, with the ability to recognize and accept pain (as opposed to avoiding it) without being caught up with it (Sullivan, Bishop, & Pivik, 1995).

We found that following MBSR, the change in cognitive fusion with pain was related to the change in FM impact, and the change in avoidance was related to the change in perceived stress. These results are important considering studies have found a highly common tendency among FM patients to develop an avoidance from pain sensations and attempt to exert control over pain (Van Koulil et al., 2008). The finding regarding avoidance supports the theory underlying mindfulness therapy, which claims that deliberate attempts to suppress thoughts and feelings can increase their occurrence and behavioral impact (Cioffi & Holloway, 1993; Clark, Ball, & Pape, 1991; Wegner, Schneider, Carter, & White, 1987) as well as the attempt of this theory to promote acceptance. In addition, it acknowledges the uncontrollable nature of certain stressors and focuses on the aspects that can be controlled such as viewing psychological reactions to external events as understandable and transient rather than as unbearable conditions that must be avoided (Casale et al., 2019).

The paucity of associations found in our study between the change in psychological flexibility in pain and actual change in outcome measures following mindfulness-based treatment points to a gap between the third wave theory that emphasizes the place of psychological flexibility in treatment and its actual effect for FM patients after MBSR. This gap reflects the need for additional studies that examine the place of psychological flexibility in third wave treatments and the possibility that MBSR works through a change in other mechanisms.

Difficulties in Emotion Regulation

We found significant associations between changes that occurred in the environmental health-related quality of life and part of these aspects of difficulties in emotion regulation: changes in inability to engage in goal-directed behaviors, and lack of emotional clarity. In our study, the tests conducted among the MBSR participants showed non-significant associations

between the total score of difficulties in emotion regulation and the physical and emotional outcomes.

Environmental health-related quality of life refers to financial resources, physical safety, health, and social care. Thus, most of the actions described under this variable relate to external components of patients' lifestyle. Fibromyalgia symptoms cause significant distress and discomfort that influence daily life considerably, including habits and routines (Henriksson, Gundmark, Bengtsson, & Ek, 1992). Therefore, finding a therapeutic process that will contribute to a change in their external living environment, such as emotional regulation in this study, is extremely significant. In addition, this type of therapeutic process includes cooperation or dependence on another individual, meaning that it requires the ability to communicate with another. It is possible that an improvement in emotional regulation contributes to the ability to communicate with another. This relates to the studies that show that emotion regulation influences the ability to communicate with others (Galvez-Sánchez, Reyes del Paso, & Montoro, 2022; Klein, Renshaw, & Curby, 2016; Martínez-González, Cervin, & Piqueras, 2022). Furthermore, it is possible that an improvement in emotional regulation contributes to the motivation to communicate with another for self-advancement.

Potential Therapeutic Mechanisms in CBT

As mentioned earlier, the most prominent mechanism found in CBT for FM patients was psychological inflexibility in pain. We will now address the results of the associations found in relation to the proposed mechanisms.

Psychological Inflexibility in Pain

In our study we found that among patients who participated in CBT, the most significant mechanism was psychological inflexibility in pain. The change in psychological inflexibility in pain was related to the change in FM, FM symptoms, perceived stress, and health-related quality of life. These results are consistent with the growing evidence that psychological flexibility modulates the relation between severity of the disease and the impact of FM symptoms (Vallejo et al., 2021). Considering the above, these results are particularly innovative and important as they indicate the significance of a change in psychological flexibility in pain.

This results can be explained in relation to the behavioral change emphasized as a therapeutic goal. Thus, the practice of behavioral change as well as the learning and practice of separating emotion, thought, and behavior included in CBT correspond to psychological flexibility. The essence of psychological flexibility represents one's ability to directly and openly get in touch with experiences in the present moment as well as the maintenance or changing of behavior according to what the situation affords and according to one's personal goals and values (Bond, Flaxman, & Bunce, 2008; Hayes et al., 2006).

Moreover, we found that the change in pain avoidance was related to the change in FM and FM symptoms, while the change in pain fusion was related to the change in perceived stress, and health-related quality of life. These results support studies that show that avoidance behavior is related to symptom severity and disability in the FM population (Nijs et al., 2013). In addition, the significance of pain fusion to perceived stress and quality of life points out the importance of separating the sense of self from the sense of pain in order to reduce anxiety and improve the effects of disease and health interventions on the individual's quality of life. This result might be explained by a metacognitive capacity called "Decentering". This term refers to the ability to observe one's thoughts and feelings as temporary, subjective events in the mind, as opposed to objective reflections of the self that are necessarily true (Safran & Segal, 1990). Thus, working on more flexible cognitive patterns that create a separation between "me and the pain" might be more beneficial for patients with initial higher cognitive fusion with pain.

Casale and colleagues (2019) claims that cognitive flexibility plays a central role in the ability to prevent stress-induced depressive and anxiety disorders. The authors link cognitive flexibility and resilience to positive explanatory style which is exhibited by people who do not automatically blame themselves or others for a difficulty. Instead, they see it as a temporary problem that only affects limited areas of their life and possess the ability to reframe experiences in a more positive light. CBT emphasizes the ability to reframe experiences, which may thereby promote cognitive flexibility, an ability that is so important for patients who suffer from various cognitive difficulties (Bertolucci & de Oliveira, 2013).

Pain Catastrophizing

Pain catastrophizing is defined as "a cognitive and emotional state where patients magnify the threat value of a pain stimulus in the context of pain and are unable to inhibit intrusive pain-related thoughts" (Sullivan & Bishop, 1995).

In our study, the associations found among CBT participants showed relationships between the change that occurred in pain catastrophizing during therapy and perceived stress. These results are in line with studies that show that the links between pain and emotional distress (depression and anxiety) were mediated by catastrophizing (Lami, Martínez, Miró, Sánchez, & Guzmán, 2018; Neves et al., 2023). On the other hand, in our study we did not find that pain catastrophizing was correlated with the change in depression. This contrasts with studies that indicate that depression and catastrophizing are constructs that exert their detrimental effects via multiple, overlapping pathways (Edwards et al., 2011) and, that reductions in pain catastrophizing after receiving CBT are related to reductions in depressive symptoms (Burns, Day, & Thorn, 2012).

In addition, we found that in the CBT group, the change in helplessness was related to the change in perceived stress. Previous research has demonstrated the significance of feelings of helplessness in FM. For example, one study found that helplessness partially mediated the effects of pain on coping and depression (Nicassio, Radojevic, Schoenfeld-Smith, & Dwyer, 1995). Furthermore, Nicassio and colleagues (1999) reported that helplessness partially mediated the effects of both pain and disability on depressive symptoms. In addition, there are studies that show the connection between a feeling of helplessness and stress among patients with rheumatic diseases (Mills, Azizoddin, Gholizadeh, Racaza, & Nicassio, 2018). CBT treatment includes the practice of behavioral change and thus, allows a gradual return to function, promoting the sense of competence that has been lost for patients with FM.

Combining these studies together with the results of our study, one may notice the importance of conducting future research regarding the role of pain catastrophizing in CBT for FM patients. Since the studies carried out so far mainly refer to depression as an outcome measure, while our study notes the importance of catastrophizing to improve perceived stress instead, we recommend that future studies examine the effect of CBT on various emotional and cognitive measures.

Difficulties in Emotion Regulation

As can be seen, emotional regulation showed the fewest relationships to changes in outcome measures following CBT compared to the other mechanisms tested in the study. The tests among the CBT participants showed non-significant associations between the changes in the total score of difficulties in emotion regulation and the physical and emotional outcomes. Nevertheless, we found significant associations between changes in perceived stress and changes in part of these aspects of difficulties in emotion regulation: non-acceptance of negative emotions, inability to engage in goal-directed behaviors, and lack of emotional awareness. These results support studies that show the different role of specific abilities that characterize emotional regulation among FM patients (Frumer, Marom Harel, & Horesh, 2023; Molinari et al., 2020; Trucharte et al., 2020).

Research comparing the presence of emotional processing in CBT with other therapeutic modalities has revealed conflicting findings. While some researchers have reported no difference in emotional processing outcome between CBT and other approaches (Coombs, Coleman and Jones, 2002; Jones and Pulos, 1993), others have reported that experiential and psychodynamic therapies facilitate emotional processing more effectively than CBT (Rudkin, Llewelyn, Hardy, Stiles and Barkham, 2007; Watson and Bedard, 2006). There are writers that suggested that a shortcoming of CBT may be the tendency to “intellectualize” the emotional experience by adopting a more instructional, as opposed to explorative approach (Mackay, Barkham, Stiles and Goldfried, 2002). This is supported by evidence from studies revealing that long verbal interventions and therapist interactions infused with a high incidence of cognitive speech were found to be negatively related to emotional processing and treatment outcome (Anderson, Bein, Pinnell and Strupp, 1999; Wiser and Goldfried, 1998). This explanation can be particularly relevant for fibromyalgia patients who suffer from various cognitive difficulties (Bell et al., 2018).

Another explanation can be related to the tool we chose to measure emotional regulation. As mentioned earlier, emotional regulation is a broad concept that has different references and definitions among different researchers (Gratz & Roemer, 2004). It is possible that if we had chosen to measure emotional regulation techniques, we would have seen different results.

Importance and Contribution of the Study, Limitations, and Future Directions

This study conducted a broad examination of CBT and MBSR using a variety of physical, psychological, and cognitive measures to examine the effectiveness and the mechanisms of change of the interventions among FM patients. This study has several potential limitations, one of them being the administration of self-report questionnaires, which may have been subject to reporting and memory biases. Another limitation of this study is the combination of a modest sample size and a considerable number of outcomes. Thus, this study may have been somewhat underpowered to detect some important effects. Additionally, most of the participants in the study were women, according to our population statistics. Still, it will be interesting to examine whether CBT and MBSR have a different impact on men than women with FM. In the current study there were not enough male participants to conduct this kind of examination. Moreover, when examining medical conditions, the addition of physiological data may be highly important. No physiological measures (such as heart rate, skin conductance, or blood tests) were collected in this study. Such a study could be carried out in the future. Finally, our research was carried out during the outbreak of COVID-19. This period has been studied and proven to have a negative psychological impact on individuals (Talevi et al., 2020) and that female gender was related to higher levels of psychological distress in this time (Horesh, Kapel, & Hasson-Ohayon, 2020). Thus, it is possible that the subjects in the study experienced higher levels of mental distress than usual due to the timing of the measurements and treatment, which may be difficult to distinguish from the results of the study. Furthermore, since the recruitment for the groups that participated in online treatment was carried out after the outbreak of the Corona virus while the recruitment for the face-to-face groups was carried out before the outbreak of the epidemic, the lack of findings in the comparison of the groups in the baseline indices partially answers the question of whether there is a difference in the level of distress, but it is possible that the difference is expressed in indices that were not tested. In addition, in this study, we examined mechanisms of change by measuring the change between pre- and post-treatment. This examination did not enable us to establish a timeline for cause and effect. This is a known problem in the research field of therapeutic mechanisms (Kazdin, 2009). Furthermore, the control group is of the waiting group type and does not include treatment as usual or other patient populations. Moreover, we recommend that future studies will examine the question of ‘what works for whom’, That is, an attempt to examine whether there are characteristics of illness, emotional distress or practice abilities, which are related to a greater benefit following cognitive behavioral therapy or mindfulness-based therapy.

Despite these limitations, our study was the first to conduct a direct comparison between approaches with different therapeutic philosophies for FM patients. Our findings have clinical importance. They point to the unique potential of CBT and MBSR to alleviate the distress of FM patients using a group intervention characterized by high cost-effective value (i.e., group setting, short period, online intervention). The results reveal the significant therapeutic potential of MBSR for FM (face-to-face and online) above and beyond CBT and thus, the importance of a psychological intervention with a holistic approach to body and mind for FM patients. The most innovative and significant results concern the effectiveness of MBSR delivered online (using the ZOOM application). Due to the small number of subjects, the trend of follow-up results, and the results showing better outcomes among the group that received CBT, further research is required to understand the effectiveness of this method.

While there is growing evidence for the effectiveness of psychological interventions in stress-related, pain-inducing physical illnesses, most studies in this area are still quite basic in their design, methodology, and measures. Considering the scarcity of studies examining the mechanisms underlying CBT and MBSR for FM patients, the present study concentrated on bridging these gaps, focusing on the understanding of mechanisms of change which have been hypothesized to play a role in relieving the symptoms associated with the disorder. Our research points to differences in the role of cognitive and emotional processes in the different treatments and in relation to different symptoms. This indicates that the treatments do not work in the same way and that it is important in further research to understand the way the treatments and therapists work in the different approaches. This study revealed that there are two important therapeutic components which are pain-related cognitions. Psychological inflexibility in pain and pain catastrophizing are both well-known and important cognitive processes in FM patients (Baastrup et al., 2016; Gracely et al., 2004). Our results suggest that psychological inflexibility in pain serves as a key mechanism in CBT, while pain catastrophizing serves as a key mechanism underlying MBSR, affecting relief in FM symptoms and its accompanying mental distress. Moreover, our study indicates that difficulties in emotion regulation did not serve as an important mechanism. This information points to significant therapeutic targets for those treating FM, allowing professionals to focus on the most significant aspects, as opposed to the less significant ones.

Furthermore, the attempt to create "tailor-made" treatments for FM patients has important implications concerning the therapeutic and management options offered to this population. Chronic patients often feel powerless or too exhausted to take a part in long and extensive therapeutic programs (Brintz, Roth, Faurot, Rao, & Gaylord, 2020). They often withdraw from therapy, which might result in only short-term improvement or no improvements whatsoever (Glombiewski et al., 2010). Thus, those who suffer from FM are in great need of therapeutic programs that are as short and efficient as possible and enable cooperation and adherence.

Finally, our research focuses on FM: the "invisible illness", the disorder for which no causality or cure has yet been found. Referring to various physical, cognitive, and emotional indicators, as well as comparing the two most popular psychological treatments for this disorder, our research expands the knowledge regarding the phenomenon that many researchers and clinicians deny. We hope that many will be exposed to this research and that it will contribute to the validation of this disorder's existence as well as the inspiration of further research that reduces the related stigma and helps alleviate the distress of FM patients.

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Appendix 1: CBT Treatment Protocol

CBT פרוטוקול

שלב א' - פסיכואדוקיה והיכרות עם המודל

שלב זה יכלול היכרות עם העקרונות של טיפול קבוצתי כמו גם פיתוח הבנה של חשיבות המעגל

סטרס-הערכה-התמודדות בדגש על התמודדות עם כאב.

1. מפגש 1- מפגש מקדים-

א. שאלונים

ב. מפגש עם צוות המחקר

ג. הסבר על הטיפול והמחקר

ד. הסבר על חשיבות ההגעה למפגשים והתרגול בבית

2. מפגש 2- פסיכואדוקציה, הכרות עם המודל הקוגניטיבי-התנהגותי

א. הכרות – דגש על מה הביא את המטופל למחקר/לטיפול

ב. מבוא CBT- מודל קוגניטיבי- מחשבה, רגש, התנהגות, פיזי

ג. מוקדי טיפול

i. השלכה רגשית

ii. התמודדות גופנית

iii. איכות שינה

iv. עבודה מול סדר יום

ד. תרגול- הרפיה- דמיון מודרך/ג'ייקובסון

ה. הסבר על מושג הכאב (מוסבר על ידי שינוי בתפקוד ולא תחושה פיזית, ישמש למפגשים הבאים).

ו. שיעורי בית- טבלת ניטור עצמי- אירועים במהלך השבוע- דיווח על אירועים פיזיים ורגשיים- מה קרה, כמה מצוקה, איך התמודדת, עזר/לא עזר.

3. מפגש 3- רלקסציה, מודל אפרת

א. מעבר על שיעורי בית

ב. תרגול רלקסציה בקבוצה וזמן דיון על התרגול

ג. הסבר על מודל אפר"ת- אירוע, פרשנות, רגש, תגובה.

ד. מטרה מרכזית: פיתוח הבנה כי הכאב מייצר מתח, המתח מגביר את הכאב וניהול המתח יגרום להפחתת כאב.

- ה. מעגל שיח על אירועים יומיומיים שמתאימים למודל אפר"ת
- ו. שיעורי בית- טבלת ניטור עצמי של אירועים המערבים מחשבה-רגש-התנהגות ויישום רלקסציה (להוסיף לטבלה האם השתמשתי ברלקסציה).

שלב ב'-

זיהוי, אתגור ושינוי מחשבות מעוותות. למידה של זיהוי, אתגור ושיקום, במידת הצורך, של מחשבות לא הסתגלותיות. המטרה היא לא לגרום לשינוי תוכן המחשבה, אלא ללמד את המטופלים להפריד בין הרגש והמחשבה.

4. מפגש 4- זיהוי עיוותי חשיבה

- א. מעבר על שיעורי בית
- ב. זיהוי עיוותי חשיבה- תרגול סוקרטי בקבוצה ודיון
- ג. תרגול קלפי COP- כניסה לאימון מחשבות אלטרנטיביות
- ד. הסבר על הבדל בין-
 - i. מחשבות אוטומטיות/מידיות- מחשבות שעולות במצבים שהרווחה שלי מדרדרת לרעה וחולפות. דגש על רגש, מחשבה והתנהגות ברגעים האלה.
 - ii. 'אמונות core' - אמונות שיש לי לגבי עצמי, המסוגלות שלי, אחרים, העולם (מטרה מרכזית- להבין כמה אני מזהה את עצמי כאדם כואב או אדם עם כאב).
- ה. דיון על החשיבות של מחשבות להתמודדות עם כאב.
 - ו. שיעורי בית- ניטור עצמי של מחשבות שעולות במהלך השבוע ודרך ההתמודדות עמן.

5. מפגש 5- זיהוי עיוותי חשיבה

- א. מעבר על שיעורי בית ודיון
- ב. תרגול קלפי COP
- ג. דיון על עיוותי חשיבה ואתגור חשיבה בהקשרי כאב- כיצד ניתן להתמודד עם המחשבות שזיהינו? לא מנסים לבטל מחשבות אלא להפריד רגש והתנהגות מהמחשבות.
- ד. שיעורי בית- טבלת ניטור עצמי של אתגור חשיבה בדגש על כאב.

שלב ג'- עבודה התנהגותית

6. מפגש 6- היגיינת שינה-

- א. מעבר על שיעורי בית- אתגור חשיבה ודיון
- ב. הסבר על חשיבות השינה להתמודדות עם סטרס וכאב
- ג. זיהוי אמונות שגויות ביחס לשינה

- ד. תרגול רלקסציה לפני שינה
- ה. הסבר על שיעורי בית- ניטור עצמי של שינה במהלך השבוע.

7. מפגש 7- שינה ותפקוד יומיומי

- א. מעבר על שיעורי בית- טבלת שינה ואתגור חשיבה
- ב. תרגול רלקסציה
- ג. הסבר על "היגיינת שינה"
- ד. עבודה בזוגות על טיוב "היגיינת שינה" בטבלה
- ה. דיון על 'מה השתנה בתפקוד שלי בעקבות המחלה?'
- ו. הסבר על שיעורי בית- ניטור עצמי שינה ותפקוד בעקבות שינוי השינה, בדגש על התמודדות עם כאב.

8. מפגש 8- Pacing (פסיעות) ועבודה התנהגותית

- א. מעבר על שיעורי בית- טבלת שינה ודיון
- ב. הסבר על PACING (פסיעות)- כיצד מכוונים את העבודה ההתנהגותית לקצב שמתאים לי ויאזן בין שמירה על מוטיבציה להתקדמות במטרותיי.
- ג. דיון בקורס- כל אחת אומרת מה המשימה שהכי מקשה עליה בתפקוד היומיומי וכיצד היא מתמודדת איתה.
- ד. דוגמא לחשיפה בדמיון- מה הכי כואב, מה את מרגישה/חושבת ברגעים האלה, מה את רוצה לעשות, איך אפשר להתנהג אחרת.
- ה. דיון על שילוב של בנאדם קרוב לסיוע בחשיפה ובמטרות PACING (פסיעות).
- ו. הסבר על שילוב במטלות יומיומיות
- ז. הסבר על שיעורי הבית- ניטור עצמי PACING (פסיעות).

9. מפגש 9- Pacing ועבודה התנהגותית

- א. מעבר על שיעורי בית- PACING.
- ב. התייחסות להתנהגות ביומיום ודגש על יחסים בינאישיים- בין הימנעות לתלות מוחלטת
- באחר, איך אפשר לשלב את מה שלמדנו בהתנהגויות יומיומיות ולקדם חזרה את העצמאות שלי בנפרד מהמחלה.
- ג. תרגול חשיפה בזוגות.
- ד. תרגול בזוגות- מטרות PACING חדשות.
- ה. הסבר על שיעורי בית- טבלת ניטור עצמי PACING בהתנהגות יומיומית.

מפגשים 10+11 – סיכום ומניעת הישנות

10. מפגש 10- סיכום

- א. מעבר על מודל אפר"ת
- ב. סיכום התרגולים בקורס
- ג. מטרות עתידיות- איך משתמשים בקורס ביומיום.
- ד. שיעורי בית- ניטור עצמי אינטגרטיבי של כל התחומים- שינה, עיוותי חשיבה, פעולות יומיומיות- כמה הפריע, איך יישמו, איך הרגישו אחרי שיישמו.

11. מפגש 11- סיכום בדגש על מניעת הישנות

- א. משוב על הקורס
- ב. איך נמנעים מלחזור להרגלים הישנים? איך שומרים על הפרוטוקול?
- ג. דיון בקבוצה- מה יותר קשה/קל לי ליישם, על מה חשוב שאשים דגש.
- ד. מטרות עתידיות
- ה. סיום בתרגול רלקסציה

Appendix 2: MBSR Treatment Protocol

פרוטוקול הטיפול

1. מפגש מקדים-

- א. שאלונים
- ב. מפגש עם צוות המחקר
- ג. הסבר על הטיפול והמחקר
- ד. הסבר על חשיבות ההגעה למפגשים והתרגול בבית

2. מפגש 1

- א. הכרות – מה הביא אותך לפה
- ב. ישיבה קצרה (דגש על טבען של המחשבות שבורחות)/צימוק (דגש על חוויה חושית ועל נוכחות מלאה)
- ג. נושא: טייס אוטומטי- המחשבות אוטומטיות שעולות
- ד. תרגול: סריקת הגוף – 5-10 דקות – לכוון לאזורים יותר ניטרלים – הנחייה איך להתייחס לכאב שאולי עולה מאזור אחר בגוף. התמודדות עם כאב/ תחושה חזקה – הטיית תשומת הלב חזרה לאזור שעליו אנחנו מתמקדים (מבלי להתנגד אלא לתת לתחושה/כאב להיות ברקע) או להישאר לרגע עם התחושות החזקות, לשים לב למחשבות שעולות ולהביא תשומת לב רכה ומתעניינת לאזור, לשים לב לרגע למאפיינים של התחושות, להרחיב מסביב, לחזור לאזור שממנו התחלנו.
- ה. שיחה על התרגול
- ו. שיעורי בית – תרגול – סריקת הגוף – עם קובץ, 7-10 דק * 6 (צריך להחליט איזה אזור בגוף) פעולה שגרתית – כל יום.

3. מפגש 2

- א. תרגול: סריקה – 10-12 – צריך לחשוב איזה אזורים בגוף
- ב. שיחה – על התרגול ועל ש.ב.
- ג. שיחה – איך יוצרים הרגל – זמן ומקום קבוע. זה אימון כמו כל אימון, לקבוע מראש מתי לתרגל ולא לחכות שיתפנה הזמן
- ד. תרגול: מדיטציה בישיבה – 10 דקות, מה שקורה בתרגול הוא רק דוגמאות למה שקורה בחיי היום יום – התרגול הוא המעבדה. לסיים עם דקה של ישיבה – להניח למה שהיה היום ומה שהיה בשעור, להניח למה שיהיה, להיות לרגע עם הנשימה
- ה. שיחה: האורחים – הצמדות, והימנעות, אי שקט, הרדמות, ספק/בלבול/התנגדות
- ו. נושא: תפיסה ואיך היא משפיעה על החוויה

ז. שיעורי בית-

- i. סריקה 10-12 דקות – 6* ביום
- ii. תשומת לב לנשימה – 5-10 דק' - יותר חשוב פעמים מאשר משך הזמן – כל יום אם אפשר
- iii. לוח אירועים נעימים
- iv. אופציה – פעולה שגרתית בתשומת לב אם רוצים

4. **מפגש 3**

- א. תרגול: מדיטציה בישיבה 10-15 דקות
- ב. שאלה – מה היא רמת הכאב? האם להדגיש את תנוחת התרגול? להציג כאופציה ולבחור להתאים תנוחה לפי בחירה של כל משתתף/ת ולפי הגבולות של הגוף באותו הרגע.
- ג. שיחה על התרגול ועל ש.ב., לוח אירועים נעימים
- ד. נושא: חוויית הנאה בנוכחות מלאה- אפשר למצוא רגעים נעימים אפילו באמצע אירועים לא נעימים (כמו כאב), ורגעים לא נעימים באמצע אירועים נעימים.
- ה. תרגול: הליכה 10 דקות, דגש על רכות, סקרנות, אי שיפוטיות, לכבד את הגבולות הפיזיים הנוכחים.
- ו. שיחה, תשומת לב להתניות שלנו לתייג אירועים כנעימים (ואז להיצמד אליהם) או לא נעימים (ולהתנגד) וכיצד זה משפיע על החוויה.

ז. תרגול לסיום- ישיבה של דקה

ח. **ש.ב.**

- i. סריקה/הליכה כל יום
- ii. ישיבה 10-15 עם תשומת לב לנשימה
- iii. לוח אירועים לא נעימים (לכוון לכתוב גם על הכאב/מחלה)

5. **מפגש 4**

- א. תרגול: מדיטציה בישיבה – 10 - 15 דקות, לפי יכולת הקבוצה. (נשימה, תחושות הגוף, הגוף כשלם, צלילים אם יש זמן)
- ב. תרגול- יוגה - מתיחות בעמידה 10 דקות.
- ג. שיחה: על התרגול ועל ש.ב., לוח אירועים לא נעימים
- ד. נושא: חזרה על איך התניות ותפיסה משפיעים על החוויה שלנו. הזמנה לזהות וללמוד את הדפוסים הריאקטיביים שלנו. תגובתיות למתח- מה האינטראקציה בין לחץ לפיברומיאלגיה/לופוס (שקף על מתח)

ה. תרגול: הליכה מודעת.

ו. **ש.ב.**

- i. סריקה/הליכה/מתיחות כל יום

- ii. ישיבה 10-15 עם תשומת לב לנשימה, ותחושות הגוף, צלילים אם תרגלנו
- iii. תשומת לתגובות ללחץ במשך השבוע מבלי לנסות לשנות
- iv. תשומת לב למקומות בהם אנחנו מרגישים מנותקים מהחיות/תחושה/חווייה שלנו – שוב בלי לנסות לשנות דבר.

6. מפגש 5

- א. שיחה: אנחנו בנקודת אמצע הקורס – שיחה בזוגות/קבוצות קטנות ואז בקבוצה הגדולה – איפה אתם עכשיו – איך הולך עם התרגול, מה השתנה, להזכר במוטיבציה להשתתפות בקורס ואם צריך לחדש תרגול.
- ב. תרגול: ישיבה 20 דקות (נשימה, גוף, צלילים, מחשבות, קשב פתוח)
- ג. שיחה על התרגול, ש.ב.
- ד. נושא: reacting vs. Responding, החופש לבחור את התגובה שלנו - דגש על התמודדות עם כאב/קושי/מחלה (כאב פיזי מול תפיסת הכאב, סיפור על הכאב והתנגדות לו, השפעה על העצמי ובהמשך על חיי היום יום)
- ה. ש.ב.

- i. סריקה/הליכה כל יום
- ii. ישיבה 10-20
- iii. תשומת לב לראקטיביות ללחץ, להשתמש בנשימה בכדי להאט את השתלשלות האירועים ולבחון/להתבונן במתרחש.
- iv. לשים לב לדו שיח מאתגר/קשה לאורך השבוע – מחשבות רגשות התנהגות

7. מפגש 6

- א. תרגול: ישיבה 20 – 25 דק' או הליכה בהתאם לקבוצה
- ב. שיחה על התרגול, ש.ב.
- ג. נושא: תקשורת – לראות את הרגשות בבירור ותבניות תקשורת, התקרבות והמנעות בקשרים, גם מחשבתית וגם התנהגותית, בכדי שיהיה אפשר לבטא אותם בבהירות.
- ד. נושא: מינדפולנס בקשרים בין אישיים-(לבחון דוגמא של mindful communication מול mindless communication)
- ה. נושא: חמלה – כתגובה לקושי – לקבל את עצמי ואת הקשיים
- i. תרגול קצר של חמלה – affectionate breathing ומרחב נשימה
- ו. הסבר על יום התרגול הקרב – עניינים לוגיסטיים, חששות, שאלות, התנהלות
- ז. ש.ב. תרגול בתנועה לסירוגין עם תרגול בישיבה, לתרגל מרחב נשימה או תרגול קצר של חמלה פעם ביום וברגעים של קושי.

8. יום תרגול

הסבר על היום – מה יהיה

הסבר על השתיקה

גם ההפסקה היא זמן לתרגול

לוח זמני תרגול

ארוחה – 60 דק

יוגה - 10

(שוטטות – 20 דק)

ישיבה - 25-30

ישיבה – 25 דק

הפסקה 10 דק

שיחה 30

סריקת גוף – 30 דק

חמלה – 5 דק

הליכה – 25 דק'

•

9. מפגש 7

א. תרגול: מתיחות עם אופציה להליכה/ישיבה למי שבחר זאת 15 דק

ב. שיחה: על התרגול שעשינו

ג. שיחה על יום התרגול

ד. זמן שאלות - תקשורת/תרגול חמלה/מרחב נשימה

ה. נושא: מיינדפולנס בחיי היום יום- איפה אנחנו שמים לב שמיינדפולנס כבר נכנס לחיינו ואיפה זה

עדיין אתגר? איך אנחנו עם הילדים, בני זוג, עבודה, קשיים? בחיי היום יום מה ממלא ומה מרוקן

אותנו? מה הבחירות שאנחנו עושים ביום יום?

ו. ש.ב.

i. תרגול חופשי, ללא ההקלטות, או תרגול עם הקלטות לסירוגין עם תרגול חופשי.

ii. תרגול לא פורמאלי – ערנות לאורך היום.

10. מפגש 8

א. תרגול: סריקת הגוף

ב. שיחה: תרגול ללא הקלטות

ג. לעבור על מה שלמדנו בקורס – תרגולים ונושאים.

ד. סיכום: מה אנחנו לוקחים איתנו, מה השתנה, מה לא השתנה, מטרות לעתיד – קודם בזוגות ואח"כ

בקבוצה.

ה. שיחה- מכאן הלאה – המשך תירגול – קבוצות תרגול, ספרים,

ו. סבב פרידה

ז. תרגול אחרון

Appendix 3: Clinical interview

1. גיל _____
2. שפת אם _____ שפה נוספת _____
3. האם קיימת נכות/מגבלה פיזית? כן/לא
a. אם כן איזה? _____
4. האם חווית חבלת ראש כלשהי במהלך חייד?
a. אם כן, פרטי (איזו פגיעה, מה הייתה ההשפעה, מה ההשלכות כיום) _____
5. האם אובחנת בעבר בהפרעה פסיכיאטרית? כן/לא
a. במידה שכן, איזו הפרעה? _____
6. האם אובחנת בעבר בהפרעת קשב וריכוז (ADHD) כן/לא
a. במידה שכן, האם מטופל תרופתית? כן/לא
b. במידה שמטופל תרופתית, מה סוג ומינון התרופה שנוטל/ת? _____
7. האם הינך מאובחן במחלת פיברומיאלגיה כן/לא
a. במידה שכן, על ידי מי ניתנה האבחנה? _____
b. במידה שכן, מתי ניתנה האבחנה? _____
8. **בשלב מאוחר יותר במחקר יידרש אישור לאבחנת פיברומיאלגיה מראומטולוג מומחה
שימוש בחומרים (סמן את התשובה שמתאימה לך בצורה המדויקת והכנה ביותר)

אף פעם	פעם בחודש או פחות	2-4 פעמים בחודש	2-3 פעמים בשבוע	4/ יותר פעמים בשבוע	
					במהלך השנה האחרונה, באיזו תדירות אתה שותה 6/ יותר משקאות באותו אירוע?
					במהלך השנה האחרונה, באיזו

					תדירות גילית שמהרגע שהתחלת לשתות, לא הצלחת להפסיק?
					כמה פעמים בשנה האחרונה לא זכרת מה קרה בלילה שעבר בגלל ששתית?

השאלות הבאות מתייחסות לתקופה של השנה האחרונה (12 חודשים)

לא	כן	האם עשית שימוש בסם כלשהו, חוץ מהתרופות הנדרשות לשימוש רפואי
לא	כן	האם תמיד הצלחת להפסיק להשתמש בסם כאשר רצית בכך?
לא	כן	האם אי פעם חווית אפקטי גמילה (חשת חולה) כאשר הפסקת להשתמש בסם?
לא	כן	האם חווית בעיות רפואיות כתוצאה מהשימוש בסם (לדוגמא, איבוד זיכרון, דימום, צהבת, עיוותים)?

9. האם הינך נוטל משככי כאבים? כן/לא

a. האם קרה שחרגת מהמינון? כן/לא

b. אם כן, באיזו מידה הייתה החריגה? _____

10. האם נוטל תרופות מקבוצת בנזודיאזפינים (ואבן, קלונקס, קסנס, לוריון...)? כן/לא

a. האם קרה שחרגת מהמינון? כן/לא

b. אם כן, באיזו מידה הייתה החריגה? _____

11. במידה שענה בשלילה על שתי השאלות הקודמות- האם אתה משתמש בתרופות קבועות כלשהן?

a. אם כן, איזה? _____

12. אובדנות

לעולם לא	לעיתים נדירות	לפעמים	לעיתים קרובות	לעיתים קרובות מאוד	כל הזמן
0	1	2	3	4	5
1.	האם במהלך השבועיים האחרונים, הרגשת שלא שווה לחיות?				
0	1	2	3	4	5
2.	האם במהלך השבועיים האחרונים, רצית למות? - לדוגמא, שתלך לישון ולא תתעורר?				
0	1	2	3	4	5
3.	האם במהלך השבועיים האחרונים, חשבת להתאבד, אפילו אם לא באמת תעשה את זה?				
0	1	2	3	4	5
4.	האם במהלך השבועיים האחרונים, הגעת לנקודה בה חשבת ברצינות להתאבד או תכננת תוכניות כיצד תעשה זאת?				

13. האם אי פעם ניסית להתאבד? כן/לא

a. במידה שכן, מתי? _____

14. פסיכוזה- אנא ענה על השאלות הבאות בכנות מוחלטת, הקף את התשובה הנכונה ביותר לגבייך (למעביר השאלון- בקש דירוג מ-1 להיגדים הבאים 1- לא מסכים בכלל 7- מסכים מאוד)

a. קורה לי שאני חושב שייתכן שלאנשים אחרים יכולת לקרוא את המחשבות שלי, או את

המחשבות של אחרים

i. לא מסכים לחלוטין

ii. לא מסכים במקצת

iii. לא מסכים במידה מתונה

iv. לא בטוח

v. מסכים במידה מתונה

vi. מסכים במקצת

vii. מסכים בהחלט

b. קורה לי שאני חושב האם אנשים מתכננים לפגוע בי או אפילו עומדים לפגוע בי

i. לא מסכים לחלוטין

ii. לא מסכים במקצת

iii. לא מסכים במידה מתונה

iv. לא בטוח

v. מסכים במידה מתונה

vi. מסכים במקצת

vii. מסכים בהחלט

c. לפעמים אני מאמין שיש לי כוחות מיוחדים, מעבר לאדם הרגיל

i. לא מסכים לחלוטין

ii. לא מסכים במקצת

iii. לא מסכים במידה מתונה

iv. לא בטוח

v. מסכים במידה מתונה

vi. מסכים במקצת

vii. מסכים בהחלט

d. היו לי חוויות של שמיעת קולות עמומים או ברורים או מלמולים או דיבורים של אנשים

כשלא היה אף אחד בקרבת

i. לא מסכים לחלוטין

ii. לא מסכים במקצת

iii. לא מסכים במידה מתונה

iv. לא בטוח

v. מסכים במידה מתונה

vi. מסכים במקצת

vii. מסכים בהחלט

15. האם השתתפת בעבר בטיפול פסיכולוגי/קבוצתי? _____

a. אם כן, באיזה סוג ולמשך כמה זמן? _____

16. עד כמה אני מעוניין להשתתף בסדנת טיפול קבוצתי? (1-10) (למעביר השאלון- במידה שעונים 5 ומטה, לנסות לתחקר למה)

17. מדוע אני מעוניין בהשתתפות בטיפול בסדנת קבוצתי? _____

18. הסדנא שתעבור תדרוש תרגול יומיומי בבית. הצלחתו של הטיפול ויעילותו של המחקר תלויים במידה רבה בתרגול שלך מעבר לפגישה הקבוצתית. עד כמה אני חושב שאוכל להתמיד בתרגולים בבית במהלך השבוע (1-10) אם פחות מ-5, לתחקר.

19. האם יש מגבלה כלשהי (פיזית, נפשית, לוגיסטית) שיכולה למנוע ממני להגיע לטיפול? _____

20. האם יש לי העדפה/הגבלות בזמני ההגעה לסדנא (לנסות לברר מהלך שבוע, אזור מגורים, ניידות תחבורתית, מגבלות...)? _____

Appendix 4 - Comparison of Baseline Demographic and Physical Characteristics between the face-to-face and ZOOM interventions

The second comparison we made included 63 FM patients that were randomly assigned to either the CBT group (n=15), CBT Zoom group (n=16), or the WL control group (n=32). The sample ranged in age from 20 to 74 years (mean \pm SD: 49.18 \pm 12.63 years). To ensure that there were no significant differences between groups following randomization, all the variables in this study were compared at baseline. Table 2 presents patient demographic characteristics.

Table 2. Comparison of Baseline Demographic, and Physical Characteristics between the CBT, CBT zoom and the WL Groups

Characteristic		CBT Mean (\pm SD) or n (%)	CBT ZOOM Mean (\pm SD) or n (%)	WL Mean (\pm SD) or n (%)	P _{diff}
Gender	Female	n=15 (93.8%)	n= 16 (100%)	n=33 (100%)	0.21(n.s)
	Male	n=1 (6.3%)	n=0 (0%)	n=0 (0%)	
Age		48.47 (14)	53.06 (11.4)	47.69 (12.5)	0.38(n.s)
Marital status	Married	n=10 (62.5%)	n=10 (62.5%)	n=14 (43.8%)	0.19(n.s)
	Single	n=2 (12.5%)	n=3 (18.8%)	n=10 (31.3%)	
	Divorced	n=4 (15.4%)	n=0 (0%)	n=7 (21.9%)	
	Widowed	n=1 (25%)	n=1 (6.3%)	n=0 (0%)	
	Re-married	n=0 (0)	n=1 (6.3%)	n=0 (0%)	
	In a relationship	n=0 (0%)	n=1 (6.3%)	n=1 (3.1%)	
Place of birth	Israel	n=12 (75%)	n=13 (92.9%)	n=25 (78.1%)	0.40(n.s)
	Other	n=4 (25%)	n= 1(7.1%)	n=7 (21.9%)	
Education level	Grade school	n=1 (6.3%)	n=2 (12.5%)	n=0 (0%)	0.20(n.s)
	High school	n=24(25%)	n=3 (18.8%)	n=11 (33.3%)	
	Currently student	n=4 (25%)	n=3 (18.8%)	n=2 (6.1%)	
	College graduate	n=7 (43.8%)	n=8 (50%)	n=20 (60.6%)	
Employed		n=11 (68.8%)	n=7 (43.8%)	n=19 (57.6%)	0.35(n.s)
Income	Below average	n=3 (18.8%)	n=2 (12.5%)	n=11 (33.3%)	0.50(n.s)
	Average	n=7 (43.8%)	n=6 (37.5%)	n= 11 (33.3%)	
	Above average	n=6 (37.5%)	n=8 (50%)	n=11 (33.3%)	
Years since diagnosis		5.33 (4.79)	5.2 (4.98)	6.2 (5.84)	0.81(n.s)

NOTE: *p < .05; **p < .01

As presented in Table 2, One way Anova and chi-square/Fisher tests for independence demonstrated that there were no significant differences between the CBT, CBT ZOOM and the WL groups on demographic measures. In addition, there were no significant differences

between the groups in baseline clinical measures FM (FIQR) [$F(64)=1.31$, n.s], major depression (PHQ) [$F(64)=1.15$ n.s], health related quality of life (HRQOL) [$F(64)=0.36$, n.s], expect for perceived stress (PSS) [$F(64)=5.05$ $p<0.01$].

The second comparison we made included 62 FM patients that were randomly assigned to either the MBSR group (n=13), MBSR Zoom group (n=17), or the WL control group (n=33). The sample ranged in age from 20 to 74 years (mean \pm SD: 45.86 ± 12.41 years). To ensure that there were no significant differences between groups following randomization, all the variables in this study were compared at baseline. Table 3 presents patient demographic characteristics.

Table 3. *Comparison of Baseline Demographic, Psychological, and Physical Characteristics between the MBSR, MBSR zoom and the WL Groups*

Characteristic		MBSR Mean (\pm SD) or n (%)	MBSR ZOOM Mean (\pm SD) or n (%)	WL Mean (\pm SD) or n (%)	P _{diff}
Gender	Female	n=12 (92.3%)	n= 11 (73.3%)	n=33 (100%)	0.00**
	Male	n=1 (7.7%)	n=4 (26.7%)	n=0 (0%)	
Age		45.38 (10.5)	42.26 (13.6)	47.69 (12.5)	0.37(n.s)
Marital status	Married	n=4 (30.8%)	n=7 (46.7%)	n=14 (43.8%)	0.27(n.s)
	Single	n=5 (38.5%))	n=4 (26.7%)	n=10 (31.3%)	
	Divorced	n=2 (15.4%)	n=2 (13.3%)	n=7 (21.9%)	
	Widowed	n=1 (7.7%)	n=0 (0%)	n=0 (0%)	
	Re-married	n=0 (0)	n=2 (13.3%)	n=0 (0%)	
	In a relationship	n=1 (7.7%)	n=0 (0%)	n=1 (3.1%)	
Place of birth	Israel	n=10 (83.3%)	n=11 (73.3%)	n=25 (78.1%)	0.82(n.s)
	Other	n=2 (16.7%)	n=4 (26.7%)	n=7 (21.9%)	
Education level	Grade school	n=0 (0%)	n=0 (0%)	n=0 (0%)	0.35(n.s)
	High school	n=2 (15.4%)	n=7 (46.7%)	n=11 (33.3%)	
	Currently student	n=1 (7.7%)	n=2 (13.3%)	n=2 (6.1%)	
	College graduate	n=10 (76.9%)	n=6 (40.0%)	n=20 (60.6%)	
Employed		n=9 (69.2%)	n=11 (73.3%)	n=19 (57.6%)	0.51(n.s)
Income	Below average	n=6 (60.0%)	n=6 (54.4%)	n=11 (33.3%)	0.72(n.s)
	Average	n=3 (30.0%)	n=3 (27.3%)	n= 11 (33.3%)	
	Above average	n=1 (10.0%)	n=2 (18.2%)	n=11 (33.3%)	
Years since diagnosis		6.22 (3.15)	5.75 (4.30)	6.20 (5.84)	0.97(n.s)
NOTE: **p < .01					

As presented in Table 3, one way Anova and chi-square/Fisher tests for independence demonstrated that there were no significant differences between the MBSR, MBSR ZOOM and

the WL groups on demographic measures, except for Gender. In addition, there were no significant differences between the groups in baseline clinical measures- FM (FIQR) [$F(60)=0.07$, n.s], perceived stress (PSS) [$F(60)=1.04$ n.s], major depression (PHQ) [$F(60)=0.35$ n.s], quality of life (HRQOL) [$F(60)=0.35$, n.s].

מבוא: פיברומיאלגיה היא מחלה ראומטית, הפרעת כאב הפוגעת בעיקר בנשים. פיברומיאלגיה מאופיינת בכאבי שרירים ושלד ספונטניים כרוניים ונרחבים, והיא נלווית להפרעות סומטיות תפקודיות אחרות, תחושות גופניות שליליות באיברים ובמערכות פיזיולוגיות שונות, עייפות כרונית ותפקוד לקוי. חולי פיברומיאלגיה מדווחים על שיעורים גבוהים יחסית של הפרעות פסיכיאטריות, במיוחד הפרעות מתח ומצב רוח, כמו גם ליקויים קוגניטיביים וירידה כללית באיכות חייהם. עד היום לא נמצא טיפול תרופתי או רגשי מיטבי לחולי פיברומיאלגיה. טיפול קוגניטיבי התנהגותי וטיפול מבוסס מיינדפולנס הם שני הטיפולים הפסיכולוגיים המומלצים והפופולאריים בקרב מטופלים אלו. טיפול קוגניטיבי התנהגותי מבוסס על התיאוריה שמערכת האמונות הבסיסית של האדם לגבי עצמו והעולם מייצרת מחשבות לא תפקודיות, שבתורן תורמות לרגשות שליליים ולהתנהגויות לא אדפטיביות. התערבות זו כוללת ניסיון לשנות קוגניציות והתנהגויות על מנת להפחית תגובות רגשיות לא הסתגלותיות. בכאב כרוני, CBT יציע פרקטיקות נפשיות ופיזיות המתמקדות במחשבות כמו קטסטרופיזציה ומחשבות שליליות על היכולת או העתיד, ובהתנהגויות כמו הימנעות. בנוסף, המטפל ילמד את המטופלים לבצע תרגילים להרגעת רגשות שליליים כמו הרפיית שרירים להפחתת חרדה. מיינדפולנס כרוך ב"תשומת לב בדרך מסוימת: בכוונה, ברגע הנוכחי, וללא שיפוטיות". השיטה מנסה לקדם מודעות ותשומת לב על בסיס מרגע לרגע. איכות המודעות שהתערבות זו מנסה לקדם כוללת פתיחות, סקרנות ויחס לא שיפוטי עם דגש על ראייה וקבלת דברים כפי שהם מבלי לנסות לשנותם. המחקר שלנו כלל התערבות מסוג MBSR, פרוטוקול מיינדפולנס המתמקד במתח ונמצא כיעיל לחולי כאב. ניתן לסכם את ההבדל המהותי בין הטיפולים כך - בעוד שטיפול קוגניטיבי התנהגותי מקדם שינוי בתפיסת הכאב, מיינדפולנס יקדם קבלה של חווית הכאב. מחקרים לגבי יעילות הגישות לחולי פיברומיאלגיה הצביעו על תוצאות מעורבות ומחקרי מטה-אנליזה שהשוו בין הגישות הראו יתרון לטיפולים התנהגותיים קוגניטיביים. בנוסף, רוב המחקרים בחנו רק את התוצאות (ולא את התהליך) של ההתערבויות, תוך התמקדות בשינויים כלליים שחלו בין תחילת וסוף ההתערבות. לכן, לא הרבה ידוע על איך הטיפולים פועלים ואילו מנגנונים אחראים לשינויים בתסמינים המדווחים על ידי מטופלים בעקבות טיפולים. לבסוף, רוב המחקרים הקודמים השתמשו בפרוטוקול הגנריים של הטיפולים, שאינם מתחשבים בקשיים הקוגניטיביים והתפקודיים העצומים שיש לחולי פיברומיאלגיה.

מטרות המחקר: המחקר הנוכחי נועד לגשר על פערים במחקר בנוגע לטיפולים השונים באמצעות בחינה מקיפה של יעילות ההתערבויות, תוך שימוש בפרוטוקול טיפול חדש ומותאם המיועד לחולי פיברומיאלגיה, יחד עם מגוון של סימפטומטיים, פסיכולוגיים, ומדדים קוגניטיביים. ציפינו שההתערבויות יהיו מועילות עבור חולי פיברומיאלגיה בכך שישפרו היבטים סימפטומטיים, כמו גם היבטים פסיכולוגיים, כגון דיכאון,

מתח נתפס כללי ואיכות חיים. מטרה נוספת של המחקר הנוכחי הייתה לבחון את התהליכים שבבסיס הטיפולים השונים על ידי זיהוי המנגנונים האחראים לשינוי בתסמיני המטופל. התמקדנו במנגנונים קוגניטיביים פוטנציאליים של שינוי: (1) קשיים בוויסות רגשות (2) חוסר גמישות פסיכולוגית הקשורה לכאב (3) קטסטרופיזציה של כאב. שיערנו כי יכולת וויסות רגשי, כמו גם השינוי בקוגניציות הקשורות לכאב, יהיו אחראים לשינוי במשתני התוצאה.

שיטה: המחקר הנוכחי הינו מחקר קליני מבוקר עם רנדומיזציה (Randomized-Controlled Trial), שכלל 93 חולי פיברומיאלגיה שחולקו ל-3 קבוצות – טיפול קוגניטיבי התנהגותי, טיפול מבוסס מיינדפולנס ורשימת המתנה (עם הקצאה מאוחרת לטיפול) שהיוותה קבוצת ביקורת. המחקר שלנו נערך במהלך התפרצות מגפת הקורונה COVID-19, מצב שאילץ להתאים את ההתערבויות הטיפוליות לפלטפורמה מקוונת (באמצעות אפליקציית זום). המעבר הזה אפשר לנו להשוות את ההשפעה של טיפולים (CBT, MBSR) כאשר הם מועברים פנים אל פנים ובאופן מקוון על ידי ועידת וידאו. המחקר כלל שלוש מדידות: טרום התערבות, לאחר התערבות ומדידת מעקב של 4 חודשים. המשתתפים מילאו שאלוני דיווח עצמי שהעריכו פיברומיאלגיה, איכות חיים הקשורה לבריאות, מתח נתפס ודיכאון מגוררי. בנוסף, גורמים קוגניטיביים הוערכו, לרבות חוסר גמישות פסיכולוגית בכאב, קטסטרופה של כאב וקשיים בוויסות רגשות. **תוצאות:** הממצאים שלנו משקפים את הפוטנציאל הטיפולי של טיפול מבוסס מיינדפולנס וטיפול קוגניטיבי התנהגותי עבור חולי פיברומיאלגיה. בהשוואת הגישות, טיפול מבוסס מיינדפולנס נמצא יעיל יותר עבור חולים אלו. מטופלים שקיבלו התערבות מבוססת מיינדפולנס השתפרו משמעותית בפיברומיאלגיה, דיכאון, מתח נתפס ואיכות חיים הקשורה לבריאות, בהשוואה לחולים בקבוצת הביקורת הביקורת. מצד שני, בקרב המשתתפים בטיפול קוגניטיבי התנהגותי, נצפו שיפורים רק במדדים בודדים (תסמיני פיברומיאלגיה וההיבט הפיזי של איכות החיים). שיפורים אלו התרחשו לאחר התערבות של 10 שבועות והיו יציבים לאחר 4 חודשים, פרט למדד איכות חיים בעקבות טיפול מבוסס מיינדפולנס. יתרה מכך, ההשוואה בין טיפול קוגניטיבי התנהגותי הניתן פנים אל פנים, טיפול קוגניטיבי התנהגותי המועבר באפליקציית זום וקבוצת הביקורת הראתה פוטנציאל טיפולי גבוה יותר לטיפול פנים אל פנים, בעוד שהתערבות מבוססת מיינדפולנס המועברת אונליין נמצאה יעילה יותר מה התערבות המועברת פנים אל פנים ומקבוצת ביקורת. בנוסף, תוצאות המחקר מצביעות על קיומה של דיפרנציאציה בתפקידם של המנגנונים שנבדקו ביחס לטיפולים ולמדדי תוצאה השונים. הממצאים שלנו מראים שמנגנון השינוי המשמעותי ביותר בטיפול קוגניטיבי התנהגותי היה חוסר גמישות פסיכולוגית בכאב, בעוד שהמנגנון המשמעותי ביותר לטיפול מבוסס מיינדפולנס היה קטסטרופיזציה של כאב. לעומת זאת, תוצאות המחקר מצביעות על כך שלקושי בוויסות רגשי היה תפקיד פחות משמעותי ביחס לשני הטיפולים. בנוסף, התוצאות מראות שמדד התוצאה הבולט ביחס למנגנוני השינוי שנבדקו הוא לחץ נתפס.

מסקנות ודיון: המחקר הנוכחי הוא הראשון שהשווה בין שתי התערבויות פסיכולוגיות עם פילוסופיות טיפוליות שונות עבור חולי פיברומיאלגיה. מחקר זה מדגיש את הפוטנציאל של טיפול מבוסס מיינדפולנס (המועבר פנים אל פנים ובאופן מקוון) לטיפול במחלות המאופיינות בהיבטים דומיננטיים של גוף-נפש, מעל ומעבר לטיפול קוגניטיבי התנהגותי. מחקר זה תורם להבנה מעמיקה יותר של הטיפולים הפסיכולוגיים השונים עבור חולי פיברומיאלגיה על ידי יצירת פרוטוקול הולם, ועל ידי בחינת מגוון רחב של היבטים סימפטומטיים, פסיכולוגיים וקוגניטיביים. מחקר זה סייע לשפוך אור נוסף על המרכיבים הטיפוליים החשובים, שעשויים לשמש כמנגנונים האחראים לשינוי, במהלך הטיפול ובעקבותיו. נראה שהיכולת לקבל את המצוקה של האדם, במקום להילחם בה, חשובה מאוד עבור חולי פיברומיאלגיה. יתרה מכך, נראה שכאשר המטופל מצליח לגלות גמישות רבה יותר מול הכאב, ובמיוחד כאשר הוא מצליח להתייחס אליו בצורה פחות קטסטרופלית או תגובתית, כך בריאותו הנפשית משתפרת בעקבות הטיפול.

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עבודה זו בוצעה בהנחייתו המסורה של פרופ' דני חורש

חיבור לשם קבלת התואר "דוקטור בפילוסופיה"

טיפול פסיכולוגי בפיברומיאלגיה:

מחקר קליני עם הקצאה רנדומלית לבדיקת יעילותו של טיפול מבוסס-מיינדפולנס

(קשיבות) אל מול טיפול קוגניטיבי-התנהגותי קבוצתי

מאת : לי פרומר

המחלקה לפסיכולוגיה

הוגש לסנט של אוניברסיטת בר-אילן