

# Music Medicine: An Alternative Approach for Managing Symptoms of Temporomandibular Disorder

by

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A thesis submitted in conformity with the requirements  
for the degree of Doctorate of Philosophy in Music Education  
Graduate Department Faculty of Music  
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2017

## Abstract

Temporomandibular disorders are one of the most common musculoligamentous disorders that cause chronic moderate to severe orofacial pain. To date there are many treatment options, but none have been demonstrated to be superior to one or the other. Regardless, generally non-invasive and reversible treatment modalities are preferred. This study examines the effectiveness of *music as medicine* for patients with temporomandibular disorder (TMD) characterized largely by pain of muscular origin. The rationale for the use of music as a complementary treatment for TMD is that TMD is a multi-factorial disease, which affects mood, depression, and pain levels of the patient and previous studies have demonstrated the effectiveness of music for managing these types of symptoms in other conditions. Twenty-five patients with TMD were recruited for this 12-week study. Patients were recruited from an out-patient dental clinic. All patients participating in this study received two Music Medicine treatments (vibroacoustic therapy and listening to a 25-preferred song playlist) as self-administered in-home treatments. This study used a cross-over design with a 4-week washout period. The results showed no statistically significant treatment effects for pain, depression, or

quality of life, but a statistically significant decrease in anxious and depressed mood was observed. Unexpectedly, TMD symptoms did not increase during the washout period, which makes the other results difficult to interpret. A post-treatment interview showed positive responses by patients to the use of music. The main reported benefit was that music helped managing chronic pain. Overall, the results suggest that music medicine can be an effective complementary treatment for TMD patients, but future research with a control group and a larger sample is needed to provide stronger evidence of treatment effectiveness.

## Acknowledgments

I would like to acknowledge the vital support and the expertise of my committee members, Dr. Michael Goldberg, Dr. Alan Gordon, and Dr. Howard Tenenbaum. Thank you to my thesis supervisor, Prof. Lee Bartel, who provided me with an exceptionally extraordinary research opportunity. I am extremely fortunate to have had the opportunity to learn and grow with such a wonderful, diverse and dynamic team. I can't thank all of you enough. And to Dr. Bruce Freeman, I am extremely grateful for your support and kindness throughout my study recruitment. I would also like to thank the team from the Wasser Pain Management Centre: Kethmini Amarasinghe, Marylin Galonski, Karina Gurbaxani, Leah Pink, and Denise Paneduro for your support. Thank you to Prof. Ulrich Schimmack for lending your support and expert skills in statistics. Lastly, I would like to thank my small circle of family and friends who have supported me during this life transitioning process: My daughter, Leila Rose, my brother, Lon Haber, my grandmother, Lucille Pleasant Washington, my mother, Geneva Washington Howard and of course "my music."

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# Chapter 1: Explanation of Research Question

Pain is described as an unpleasant feeling involving sensory and emotional experiences associated with actual or potential tissue damage (Woessner, 2006). Pain can be characterized according to duration (chronic & acute), medical diagnoses (myofascial, cancer pain, phantom pain, & fibromyalgia), and in anatomical terms (facial pain, limb pain, & lower back pain) (Woessner, 2006). Pain experiences are influenced by various biological, psychological, and social factors (Hauck, Metzner, Rohlffs, Lorenz, & Engel, 2012; Moayedi & Davis, 2012). Culture, personality, psychosocial stressors, and other disease states can greatly influence the experience of pain. Pain can be acute or chronic. Chronic pain lasts for prolonged periods of three to six months or longer.

Temporomandibular joint disorder (TMD) is a chronic oral facial pain disorder that affects 3.6% to 7% of adults, causing them to seek treatment (American Academy of Orofacial Pain, 2008; Okeson, 2008). TMD is more prevalent among women and young adults (Tenenbaum et al., 2001). The causes of TMD are poorly understood, but research suggests that TMD symptoms are caused by the interplay of multiple factors. The biopsychosocial model recognizes that TMD symptoms are caused by biological factors (genetic, biochemical) psychological factors (mood), and social factors (socioeconomic, cultural and familial) (Meurman et al., 2012.). The consequences of TMD are pain, depression, mood fluctuation, and poor quality of life (Dworkin & Massoth, 1994; Moreno et al., 2009).

Currently, the most common approaches for managing TMD are pharmacotherapy (muscle relaxants, anti-anxiety medications), cortisone injections, and surgery (Steinmetz et al, 2009). Some of these treatments are costly, invasive, and not always effective. Thus, it is valuable to explore alternative approaches to the treatment and management of TMD. One alternative approach for managing pain is music medicine (Hauck et al., 2012).

## 1.1 Statement of Problem

In an unpublished literature review of Howard (2014), two theories were examined that may explain the effectiveness of music as an intervention in pain management. The neuromatrix theory suggests that music can reallocate attention from chronic pain sensations and displace the negative feelings associated with pain with pleasant feelings accompanied by music. Studies have shown that when an individual's attention is occupied by a distracting task, activation to the brain areas associated with pain is reduced (Windich-Biermeier, 2007). Secondly, the gate-control theory is based on the finding that some forms of music elicit vibrations that are felt in the body and that the processing of this information can block the transmission of information from pain sensors in the body to the brain. Thus, the gate-control theory predicts that music with strong vibrations is more effective for the treatment of patients with chronic pain than music listening (Guétin et al. 2012).

Levitin (2007) found that music, when used in medical settings, can be effective for regulating mood and arousal and promoting physical and psychological health. Additional studies demonstrated that music is effective for the reduction of stress, depression, pain, and quality of life in patients (Cepeda et al., 2010; Siedliecki, 2009). These studies suggest that music medicine can be effective for the management of pain (Guétin et al., 2012). Music medicine has been used with fibromyalgia patients (Guétin et al., 2011; Naghdi et al., 2015) and chronic fatigue patients (Müller-Busch & Hoffmann, 1997), but not with TMD patients. However, Cepeda et al. (2010), add that the magnitude of these positive effects is small; the clinical relevance of music for pain relief in clinical practice requires further investigation.

## 1.2 Aims and Research Question

The purpose of this study will be to examine the effectiveness of the use of music as an intervention (Music Medicine) for patients with TMD, more specifically, those who have predominantly myofascial pain. The present study is based on previous research that

demonstrated music interventions to be effective on pain and mood levels with chronic pain patients (Roy et al., 2008; Villemure & Bushnell, 1998).

Music and rhythmic vibrations can alter the neurological processes underlying pain sensations (Melzack & Wall, 1965; Wigram & Dileo, 1997). Music vibrations also can block neurological pathways that transmit pain sensations and thereby, reduce pain (Boyd-Brewer, 2003). Music and vibrations are relaxing, reduce stress and depression levels, and thereby reduce sensitivity to pain (Melzack, 2001). The planned study will examine the effectiveness of two interventions: 1) vibroacoustic chair device, Sound Oasis VTS1000 set to Energize Track and 2) listening to 25-self selected songs of any style and/or genre.

The question to be investigated: What are the effects of music medicine as a complementary treatment on TMD Symptoms?

### 1.3 Hypotheses

The effectiveness of two Music Medicine treatments will be examined in this study. One treatment is vibroacoustic therapy (VAT-1000 Sound Oasis, which combines vibrations with music on the Energized Therapy Track) and the second treatment is 25 self-selected songs of any style and genre. The primary outcome measure is pain and the secondary outcome measures are depression, quality of life, and mood.

H1- Music medicine treatments will produce lower pain levels, lower depression levels, and improved mood and quality of life.

H2- VAT treatment will produce stronger effects than the self-selected music on pain levels, depression levels, and improved mood and quality of life because it combines vibration and music.

## 1.4 Definition of Key Terms

**Acute Pain-** A pain that results from the stimulation of a normally functioning pain detection system and serves as an indicator to avoid or minimize tissue damage (Woessner, 2006). Acute pain is characterized by pain limited to less than 3 to 6 months (Thienhaus & Cole, 2002).

**Biopsychosocial Model-** A model that attempts to integrate both physical factors, i.e., biological or biomedical factors, as well as other so-called non-biological factors related to illness including, but not limited to psychological and social factors (Suvinen et al., 2005).

**Chronic Pain-** A pain that is perceived lasting more than 6 months and influenced by a complex mix of pathologies (Thienhaus & Cole, 2002; Woessner, 2006).

**Depression-** A mood disorder associated with reduced social functioning, impaired quality of life, and a persistent feeling of sadness and loss of interest (Maratos et al., 2008).

**Entrainment-** Entrainment can be described as the process of two entities in synchrony. There are several types of entrainment: Brainwave Entrainment, Heart Rate Entrainment, and Psychological Entrainment.

Brainwave entrainment- Brainwave entrainment happens when brain waves synchronize with regular pulsating music resulting from neural excitation. “In Music Therapy the entrainment target is usually in the common brainwave states” (Bartel, 2013, p.42).

Heart Rate Entrainment- “Heart rate entrainment (HRE) refers to the phenomenon of the heart slowing its pulse when a person listens to music with a beat slower than the heart rate” (Fujioka et al., 2009).

Psychological Entrainment- “Entrainment, or phase locking is literally “getting on the same wavelength.” Metaphorically “getting on the same wavelength” refers to what can be described as psychological entrainment – two individuals or an individual and a group

arriving at a consonance and acceptance manifest through qualities such as agreement of ideas, matched energy levels, or talking speed” (Colgin et al., 2009).

**Gate Control Theory of Pain** - The Gate Control Theory is a pain theory developed in the 1960s by Ronald Melzack and Patrick Wall (Giummarra et al., 2007). The Gate Control Theory is based on the premise that information from pain receptors has to be transmitted to the brain along a pathway of interconnected nerves (Kirby et al., 2010). Thus, physical pain is not a result directly related to the activation of pain receptor neurons, but rather the result of sensory stimulation that is modified by interactions between different neurons (Dickenson, 2002). Central to GCT is the idea that along the pathway of nerves that transmit pain information are a series of gates. When these gates are open, pain information is passed on to the brain, resulting in the experience of a high level of pain. If these gates are closed, fewer pain signals are transmitted to the brain and the experience of pain is less intense (Dickenson, 2002).

**Health-Related Quality of Life**- The functional effect of a medical condition and/or its consequent therapy upon the patient. HRQOL is therefore “subjective and multidimensional, encompassing physical and occupational function, psychological state, social interaction and somatic sensation” (Cella, 1995; Schipper, Clinch, & Olweny, 1996).

**Hyperacusis** – A relatively rare condition where a patient, with or without hearing loss, experiences severe loudness discomfort to everyday environmental sound levels. Hyperacusis is a dominant acoustic shock (AS) symptom; and a common symptom of Hyperacusis is TMD pain at 25.1% (Westcott et al., 2013).

**Main Effect**- The overall treatment effect of both treatments combined (self-selected music and vibroacoustic therapy). In other words, the mean difference between pre-treatment and post-treatment scores (McBurney & White, 2004).

**Mood** – A fluctuating background state that impacts our experiences (Schimmack & Crites, 2004).

**Music Medicine** – The prescription of music to reduce anxiety, pain, and autonomic reactivity and improve the condition and well being of the medical patient (Dileo, 2013).

**Music Therapy**- “Music therapy is the skillful use of music and musical elements by an accredited music therapist to promote, maintain, and restore mental, physical, emotional, and spiritual health. These are used in the therapeutic relationship to facilitate contact, interaction, self-awareness, learning, self-expression, communication, and personal development” (Canadian Association for Music Therapy / Association de Musicothérapie du Canada Annual General Meeting, Vancouver, British Columbia, May 6, 1994).

**Myofascial Pain** – “A psychophysiological disorder involving central nervous system (CNS) pain-regulatory systems, which results in maladaptive emotional, physiological and neuroendocrine responses to emotional and physical stressors” (Maixner et al., 1995).

**Neuromatrix Theory of Pain**- A pain theory that states pain is a multidimensional experience produced when nerve impulses are generated by a widely distributed neural network – the “body-self neuromatrix”- in the brain rather than directly by sensory input evoked by injury, inflammation, or other pathology, as described by Melzack (2001).

**Pain** – An unpleasant, individual occurrence involving sensory and emotional experiences associated with an actual or potential damage to tissue (Moayedi et al., 2013). Pain is classified by anatomic location, body system, duration, severity, frequency, and etiology (Cole, 2002).

**Suffering**- Defined as a state of severe distress with events that threaten the intactness of the person (Cassell, 1982)

**Temporomandibular Joint Disorder** - Temporomandibular disorder (TMD) is a chronic facial disorder. It has been reported that about 3.6% to 7% of adult Canadians suffer from TMD symptoms that cause them to seek treatment (Wright &North, 2009).

**Vibroacoustic Therapy** –The use of low frequency vibrations between 30 and 120hz with emphasis placed on 40, 52, 68, and 86hz for therapeutic purposes (Naghdi, Ahonen,

Marcario, & Bartel, 2015; Skille & Wigram, 1995; Wigram, 1996). “Treatment involves application of a single frequency that is modulated with a steady rise and fall of amplitude at a rate of about 6 to 8 seconds from peak to peak” (Kirkland, 2013).



## Chapter 2: TMD and Music

The previous chapter presented a brief overview of music as an alternative approach for managing symptoms of Temporomandibular Joint Disorder (TMD). In this chapter, a review of literature of TMD (population, biopsychosocial factors and treatment strategies), theoretical perspectives of pain and music, and the various ways that music might affect pain perception will be presented.

### 2.1 Introduction to TMD

Temporomandibular joint disorder (TMD) is a chronic orofacial pain condition. It is considered to be a chronic musculoligamentous pain disorder of the head and neck region that involves largely the masticatory muscles as well as the temporomandibular joints (TMJs) themselves (Hapak et al., 1994; Maixner et al., 1995; Weissman-Fogel et al., 2010; Wright and North, 2009).

Figure 2.1 The temporomandibular joint and related structures.

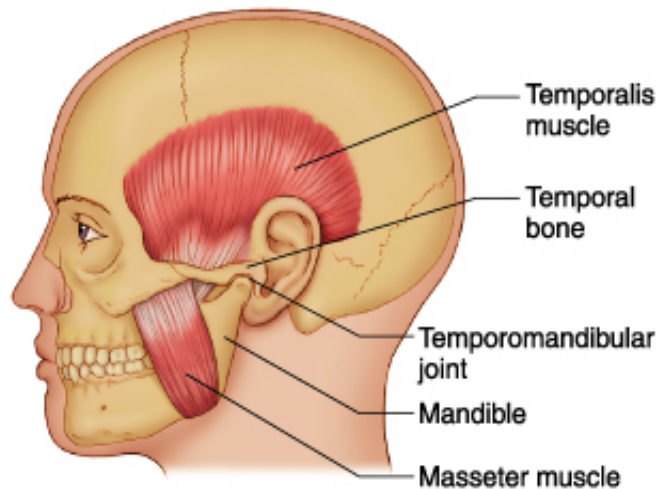


Image from YOUR SMILE, the Dental Patients Magazine (2016)

Epidemiologic and experimental intervention studies indicate that TMD is a chronic pain condition that shares major characteristics with other chronic pain conditions, including

but not limited to headache, irritable bowel syndrome (IBS) and low back pain (Dworkin, 1994; Grossi et al., 2008). These chronic pain conditions are also similar in regards to intensity, chronicity, frequency and associated pain-related disability (Dworkin, 1994). Furthermore, the data from selected affective behavioral variables indicate that TMD has the same, if not greater, impact on psychological functioning as headache, irritable bowel syndrome (IBS), and back pain (Dworkin, 1994; Grossi, 2008).

TMD is recognized as the most common cause of persistent pain in the head, neck and shoulders, and is frequently associated with limited range of mandibular motion, joint pain, joint noises (clicking, popping, crepitus), jaw locking, muscular tenderness in the face, neck, and shoulders, and ear complaints (ranging from ear pain to tinnitus) (Durham, 2008; Lam, Lawrence, & Tenenbaum, 2001; Maixner, Fillingim, Booker, & Sigurdsson, 1995; Romanelli, Mock & Tenenbaum, 1992). Romanelli et al. add that patients who suffer from TMD can have a history of clicking in one or both TMJs. This is related to malpositioning of the intra-articular disk or meniscus. Although popping or crepitus can progress to a closed lock of the mandible (Romanelli et al., 1992), others also indicate that most joint noises are stable and do not necessarily progress to closed lock (Könönen, Waltimo, & Nyström, 1996).

Depending on the specific sub-diagnosis, fundamental features of TMDs include various muscle and/or joint pain, joint sounds and masticatory dysfunction (Sharav & Benoliel, 2008). Romanelli et al. (1992) have subclassified TMD based on physical findings as myofascial pain, internal derangement, degenerative joint disorder diseases, and any combination of those conditions that contribute to the orofacial pain associated with this condition. Previous research has shown that patients who present with both myofascial pain and joint problems are very similar to those with strictly myofascial pain in their pain distribution, functional limitations, and even responses to treatment (Hapak et al. 1994; Romanelli et al. 1992).

Researchers generally agree that TMD falls into the following categories: 1) myofascial alone and myofascial with joint symptoms 2) joint symptoms alone 3) degenerative joint disease or other arthropathies ranging from gout, Rheumatoid Arthritis (RA), to

pseudogout (H. Tenenbaum, personal communication, December 14, 2015). When patients present with primarily joint-related problems including joint or joint-associated tissue inflammation, treatment might consist of the use of medication (steroids, non-steroidal anti-inflammatory medication), but if there are actual mechanical problems with the joint (i.e. locking), surgical interventions might be considered, ranging from arthrocentesis and arthroscopic surgery to arthrotomy. However, experts suggest that surgery should be avoided where possible. Surgical treatment is not always successful, can cause worsening of symptoms, and is an irreversible treatment modality (National Institute of Dental and Craniofacial Research, 2013). Given the associations between TMD and related muscle pain, most researchers agree that the treatment should be multidisciplinary and whenever possible should be reversible and non-invasive (McNeil, 1996).

Psychological studies have shown that patients with TMD pain have psychological profiles and mental health problems that are similar to those of patients with chronic musculoskeletal pain. The psychological factors include stress-related muscle pain, stress and depression (Anderson et al., 2009; Hapak et al. 1994; Muir et al., 2014; Oral, Küçük, Ebeoğlu, & Dinçer, 2009; Romanelli et al. 1992). This study will focus on patients with TMD characterized predominantly by the presence of pain in the muscles of mastication (myofascial in nature) because these patients are similar to patients with other chronic pain disorders who have demonstrated responsiveness to music medicine treatments.

### 2.1.1 Population Statistics of TMD

TMD is a common problem. Studies suggest that approximately 12% of adults are affected by TMD-related pain (Murray et al., 1996; National Institute of Dental and Craniofacial Research, 2013). In the general population, clicking or popping joints are very common and may occur during opening and/or closing, but often require no need for treatment unless it causes complication and/or pain to the patient (Sharav & Benoiel, 2007). It has been shown that more than 90% of cases where joint clicking or some other sound is present either stay the same or improve over time (Magnusson, Carlsson, & Egermark, 1993). On the other hand, 33% of the population presents with at least one

TMD symptom and 3.6% to 7% of the population have distressing symptoms, which cause them to seek treatment (Wright & North, 2009). Women are more prevalent TMD sufferers than men (Tenenbaum et al., 2001). The ratio of female to male prevalence is generally found to be 2:1, while the ratio in patients seeking care is 3.8:1 (LeResche, 1997). These findings suggest that many men who probably suffer from TMD related symptoms do not seek treatment. Males suffering from TMD appear to present predominantly with pain in their TMJs or with other strictly joint-related complaints including closed lock. In contrast, most females have muscular pain with or without joint symptoms (Schmid-Schwab et al., 2013). Additional populations with higher than average prevalence rates are orchestral musicians, people between the ages of 20 and 40, and those experiencing stress and sleep deprivation (Meurman et al., 2012). Though studies vary in their estimates of prevalence rates, Turk et al. (1995) suggested that the number of people suffering from TMD has not increased over the years, while the number of patients *seeking* treatment for TMD has increased dramatically.

## 2.1.2 Biopsychosocial Factors of TMD

TMD is a complex disorder caused by physical (disease), psychological (depression & stress), and social factors (Dworkin, 1994). The biopsychosocial model of TMD suggests that treatment of TMD requires a multimodal, interdisciplinary approach (Suvinen et al., 2005).

The biopsychosocial model of health and illness was first proposed by Engel (1977) and implied that behaviors, thoughts and feelings may influence a physical state. The development of the biopsychosocial model for understanding disease and illness was a result of limitations from the biomedical model, which had a single-cause focus to illness and focused on pathophysiology and other biological approaches in treatment. In contrast, the biopsychosocial model emphasized integrating both physical factors (i.e., biological or biomedical factors) and non-biological factors related to illness such as psychological factors (e.g., mood) and social factors (e.g., culture, familial, socioeconomics factors) (Borrell-Carrió et al., 2004; Suvinen et al., 2005). Today it is widely recognized that biological, social and psychological factors contribute to the

etiology of TMD (Oral et al., 2009; Sharma et al., 2011; Visscher & Lobbezoo, 2015). It is probable that these factors contribute also to progression of TMD as well as response to treatment (see below).

The etiological factors are classified further into predisposing, initiating, and perpetuating factors (McNeill, 1993; Oral et al., 2009; Sharma et al., 2011).

- Predisposing factors (structural, metabolic and/or psychological conditions) are those that increase the risk for development of TMD. An example of predisposing factors could include stress-related habits such as clenching and grinding of the teeth (Sharma et al., 2011; Tenenbaum et al., 2001).
- Initiating factors (trauma or repetitive adverse loading of the masticatory system) are thought to contribute to the onset of (acute) TMD. Common initiating factors of TMD are injury and adverse loading of the masticatory system (Sharma et al., 2011).
- Perpetuating factors (parafunctions, hormonal, or psychosocial factors) are factors that indicate their role in the progression of the TMD symptom. Perpetuating factors include behavioral factors, social factors (learned response to pain), emotional factors (depression & anxiety), and cognitive factors (negative thoughts and attitudes which could affect illness and treatment) (Sharma et al., 2011).

Osteoarthritis (OA) is often observed in patients with TMD (Krisjane et al., 2012), but in most cases OA is neither the cause of their overall TMD, nor even necessarily a source of actual pain in the affected joint (Kurita et al., 2014). Osteoarthritis is a degenerative joint disease that is characterized by cartilage degradation, subchondral bone remodeling and stiffening (Grynpas et al., 1991), synovitis, and chronic pain (Zarb & Carlsson, 1999). Studies also show that psychological and social factors like stress, tension, anxiety-depression, sleep routine, and non-ergonomic working conditions contribute further to TMD (Donovan et al., 2007; Durham, 2008, Kindler et al., 2007; Meurman et al., 2012; Romanelli et al., 1992).

The aspects of TMD most associated to psychological stress are clenching, grinding, and muscle pain, while the occurrence of depression is associated with bruxism, chronic widespread pain, and TMD associated persistent orofacial muscle pain (Marcus & Baehrisch, 2013). Buljan (2010) adds that anxious-depressive disorder is found in 50% of patients with TMD, while depression is found in 32.1% of patients. Moreover, patients with psychiatric problems are 4.5 times more prone to TMD than individuals without psychiatric problems and vice versa (Buljan, 2010).

These findings demonstrate that it is not yet possible to establish a direct cause and effect relationship between the presence and/or development of psychopathological disorders and TMD. It seems likely, however, that psychosocial problems and TMD pain influence each other. Thus, it is possible that biological, psychological, and social factors contribute to TMD symptoms. Given the multifactorial nature of TMD, approaches to treatment of this group of disorders need to take into account the complex nature of this condition.

### 2.1.3 Consequences of TMD

TMD affects various aspects of patients' lives. The primary feature of TMD is chronic pain. Chronic pain is comprised of three major components: a sensory-discriminative component, a motivational-affective component, and a cognitive-evaluative component (Hauck et al., 2012; Kirby, Oliva, & Sahler, 2010; Moayedi & Davis, 2012).

The sensory-discriminative components of TMD are joint pain, joint noises, jaw locking, muscular tenderness in the face, neck, and shoulders, and ear complaints (Durham, 2008; Lam, Lawrence, & Tenenbaum, 2001; Maixner et al., 1995; Romanelli et al., 1992). The motivational-affective component of TMD is the unpleasant feeling that is associated with the sensory component of pain and the desire for it to stop (Auvray, Myin, & Spence, 2010). The cognitive-evaluative component of pain refers to individuals' attitudes and beliefs about pain and the social component reflecting how they present themselves when interacting with peers, family, and physicians (Gustin, Wilcox, & Henderson, 2012).

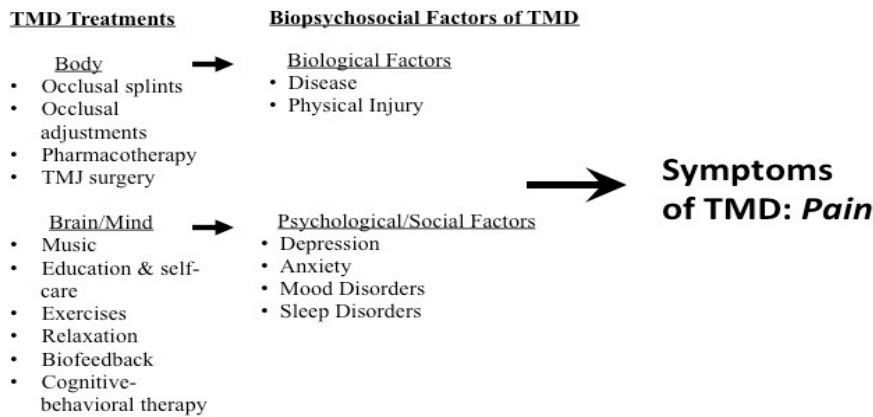
TMD also has negative effects on mood, a reduction in quality of life, and may trigger clinical levels of depression (Dworkin & Massoth, 1994; Moreno et al., 2009). Thus, the consequences of TMD can be emotionally and physically debilitating and can have a negative impact on various areas of patients' lives. Reisine and Weber (1989) showed that the quality of sleep is impaired in patients with TMD. Fifty-three percent of patients reported dysfunction in sleep and rest, which often resulted in fatigue and reduced mental capacity. It has also been estimated that TMD, when it becomes 'disabling', can lead to about 18 lost workdays annually for every 100 working adults in the US (Dworkin & LeResche, 1993). Murray et al. (1996) administered the Oral Health Impact Profile (OHIP) to 121 patients with TMD to assess the impact of this condition on their quality of life. They found that TMD influenced patients' moods, social relationships, and impaired their ability to work.

## 2.2 Treatments for TMD Myofascial Pain

As discussed above, TMDs are multifactorial in nature, which makes this condition difficult to treat (McNeil, 1996). Consequently, treatment approaches for TMD vary.

Figure 2.2 shows the various treatment options. Under the heading *TMD Treatments* are both music and non-music interventions. Medical interventions primarily influence biological factors (body), whereas alternative treatments, including music medicine, primarily influence psychosocial factors. The diagram illustrates the key assumption of the biopsychosocial model that core TMD symptoms are influenced by multiple biological and psychosocial causes and that biological and psychological interventions are needed for optimal treatment outcomes.

Figure 2.2. Illustration of TMD Treatment Options from a biopsychosocial perspective.



In previous studies, music was successfully shown to produce positive outcomes for music in the reduction of stress, depression, pain, and sleep disturbances; all factors that have been noted to affect TMD patients.

The figure distinguishes traditional treatments that target biological factors and complementary treatments that target psychological and social factors.

## 2.2.1 Traditional Treatments

On average, 75-80% of traditional treatments have some positive outcomes (Romanelli et al., 1992). The most common traditional treatment is splints (see Figure 2.3). The treatment aim is to protect the TMJ discs from dysfunctional forces that may lead to perforations or permanent displacements. Other goals of treatment are to improve jaw-muscle function and to relieve associated pain by creating a stable balanced occlusion (Yadav & Karani, 2011). Studies have demonstrated long-term benefits of this treatment (Ekberg & Nilner, 2004). However, studies investigating the effectiveness of splints in providing pain relief have stated that they should be used as an adjunct to pain management, rather than as a definitive treatment (Dao & Lavigne, 1998). Another



treatment uses biofeedback. In a meta-analysis of EMG (electromyography) biofeedback treatments, Crider and Glaros (1999) found that 69% of patients who received EMG biofeedback treatments were rated as symptom-free or significantly improved compared to 35% of patients treated with a variety of placebo interventions. The researchers added that the follow-up outcomes for EMG biofeedback treatments indicated no deterioration from posttreatment levels.

Figure 2.3. Illustration of Stabilizing Splint



Trigger point injection therapy, when combined with splint therapy, have been show to be effective in the management of myofascial TMD pain (Ozkan, Cakir, and Erkorkmaz, 2011).

Traditional methods of pain management rely heavily on pharmacological interventions. Studies suggest that 90% of patients are treated with some sort of pharmacological agent, usually an analgesic of the non-steroidal anti-inflammatory class. Other agents that have been used include corticosteroids, muscle relaxants, anxiolytics, opiates, and tricyclic

antidepressants. However, strong evidence in support of the effectiveness of these drugs is lacking (Cairns, 2010; Sharav & Benoliel, 2008).

In the case of refractory TMD, studies indicate that opiate analgesics are considered medically necessary in long-term pain management (Brennan & Ilankovan, 2006). However, the importance for achieving a balance between the benefits of opioid use and the potential harm that they present should be emphasized when prescribed (Ballantyne & Sullivan, 2015).

In general, recommendations regarding the initial management of TMD include an array of options including counseling, behavioral modification, cognitive behavioural therapy, physical therapy, pharmacotherapy, and interocclusal appliances. More invasive treatment approaches, including occlusal (bite) adjustments, are generally to be avoided or at least used with extreme care (Hagag, Yoshida, & Miura, 2000; National Institute of Dental and Craniofacial Research, 2013).

It is suggested that attention should be given to the stress factors of TMD in treatment, and therefore implement medications that address both pain and emotional stressors (Scott et al., 2008, p. 567). Although opioids are often prescribed to patients as a means for achieving rapid pain relief, opioids have undesirable consequences such as addiction, overdose, and death, and may produce no discernible reduction in the burden of chronic pain. Therefore, it is highly suggested that when using opioid therapy in the treatment of chronic non-cancer pain, patients should be carefully monitored.

## 2.2.2 Evaluation of Traditional Treatments

Anastassaki and Magnusson (2004) examined the effectiveness of traditional treatments and found that traditional treatments were effective for many patients. However, traditional treatments are costly. During the 1990's, it was calculated that approximately 3.6 million acrylic splints were constructed yearly in the US to treat TMDs and bruxism, accounting for an annual cost of \$990 million: 3% of the total US dental healthcare expenditure (Pierce et al., 1995; Sharav and Benoliel, 2008). Today, it is reported that the annual treatment cost is \$4 billion for the 10 to 15 percent of TMD patients in the US

(Gatchel et al., 2006). In a study, which examined healthcare services utilized by TMD patients, it was revealed that TMD subjects used significantly more healthcare services than controls with about 50% more mean costs in drug utilization, outpatient visits, and specialist services (White et al., 2001; Sharav and Benoliel, 2008). It has also been reported that patients with TMD generate approximately twice the amount of medical insurance claims as a comparison group (Shimshak & Defuria, 1998; Glaros, 2008). Overall, research suggests that the direct cost for the care of individuals with TMD and facial pain ranges between two to four billion dollars annually in the US (Drandsholt and LeResche, 1999; Stowell et al., 2007).

Anastassaki and Magnusson (2004) also reported that about 10% of TMD patients do not benefit from traditional treatments and experience chronic pain. Chronic TMD can lead to significant costs because patients require multiple treatments from a variety of health care providers and from lost wages. Anastassaki and Magnusson (2004) estimate that these patients account for 40% of the health care costs due to TMD. For this reason, suggests Gatchel et al. (2006), cost-effective interventions are necessary in order to cut the enormous costs of this disorder, as well as to decrease prolonged suffering in patients with TMD.

Anastassaki and Magnusson (2004) noticed that TMD patients with orofacial pain without unknown origin have a poorer prognosis than other TMD patients. Given the poor treatment outcomes of traditional treatments, these patients would benefit the most from complementary treatments that have been shown to be effective with other chronic pain disorders.

### **2.2.3 Music Medicine as a Complementary Treatment**

The National Pain Strategy (2015) emphasizes the importance of interdisciplinary treatments and recognizes that pharmaceutical interventions alone have limited effectiveness when it comes to managing chronic pain. It is suggested that the management of pain should be holistic, incorporating the sensory, affective and cognitive components of pain in treatment (Berman & Kozier, 2008, p. 740).

The following is a list of Complementary Treatments of TMD:

- Acupuncture – A complementary form of medicine in which thin needles are inserted into the body to relieve pain (Smith et al., 2007).
- Biofeedback – The use of biofeedback teaches the patient how to reduce muscle tension through relaxation and visualization techniques (Crider and Glaros, 1999).
- Cognitive Behavioral Therapy (CBT) - a short-term, goal-oriented psychotherapy treatment. The goal of CBT is to change patterns of thinking or behavior (Martin, 2016).
- Massage – The use of massage has been found to reduce muscle spasms and provide pain relief (Prilutsky, 2004).
- Mindfulness – a psychological process of focusing on internal and external experiences occurring in the present moment (i.e. anxiety and pain) (Kabat-Zinn, 2013; Meyers et al., 2002).
- Physiotherapy – a holistic therapy that aims to relieve pain, minimize stiffness, and to help restore normal function and mobility (Jackson & Kholia, 2012; Michelotti et al., 2004).

Music could also be an effective non-pharmacological complementary treatment for chronic pain. A meta-analysis of intervention studies of music for pain relief shows a moderate treatment effect for the use of music listening on chronic pain management (Cepeda et al., 2010). However, the authors caution that the evidence is not conclusive and further research is needed. Furthermore, to date, no studies have been found indicating the effectiveness of self-selected music and VAT in the management of TMD-related pain. Thus, it is relevant to demonstrate through concise research, the effectiveness of music as a complementary treatment for managing the painful symptoms of TMD. There are a variety of theories that explain how non-traditional, psychological interventions can be effective in the treatment of chronic pain disorders such as TMD. Some theories suggest that complementary treatments can teach coping skills and

acceptance strategies that have been found to primarily reduce the suffering associated with pain and only secondarily reduce the intensity of pain (Ballantyne & Sullivan, 2015). It is possible that reductions in suffering associated with pain are the primary outcome of complementary treatments as opposed to ‘merely’ addressing the analgesic components of their conditions (Cassell, 1982; Fishbain et al., 2015; Ostermann et al., 1999).

Other theories suggest that music medicine could have two effects. On the one hand, it could help with alleviating pain-related suffering. The reason for this hypothesis is that music has been shown to influence mood (Roy et al., 2008) and mood has been shown to influence the affective component of pain (Villemure and Bushnell, 1998). On the other hand, some theories suggest that music may have analgesic properties.

One benefit of music as a complementary treatment for pain is that it is easy to integrate in diverse medical settings (Sammler et al., 2007). When used as therapy, music has been described as effective because it possesses three positive characteristics. First, it has the ability to effect the central nervous system, particularly the limbic system which is a complex system involving areas of the cortex that involve mood and basic emotions (Bernatzky et al., 2011; Roxo et al., 2011). Second, it can be used to reduce pharmaceuticals (opioids and analgesics), reducing the cost of medical care (Sammler et al., 2007). For example, Beaulieu-Boire et al. (2013) investigated the link between music and medicine with patients on a ventilation machine in an intensive care unit. The research revealed that patients required less medication and experienced lower levels of stress by listening to classical music. Third, it has fewer side effects and contraindications than pharmacological interventions. Additionally, music can be self-administered, is readily available, reduces stress, and has no to low side effects. The potential benefits of music medicine suggest that music medicine can complement traditional treatments of TMD patients.

## 2.3 Theories of Music Medicine and TMD

In the previous section, I suggested that music medicine could be an effective complementary treatment for patients with TMD. Bartel (2012) developed a multi-level model of music response and proposes a variety of mechanisms of how music can influence experiences at the basic physiological levels and at higher cognitive levels. This model can be fused with prominent theories of pain to build an integrated theory of the effects of music on the experience of pain. The Gate Control Theory (GCT) was developed in the 1960s by Ronald Melzack and Patrick Wall (Giummarra et al., 2007). GCT is based on the premise that information from pain receptors has to be transmitted to the brain along a pathway of interconnected nerves (Kirby et al., 2010). Thus, physical pain is not a result directly related to the activation of pain receptor neurons, but rather the result of sensory stimulation that is modified by interactions between different neurons (Dickenson, 2002). Central to GCT is the idea that along the pathway of nerves that transmit pain information are a series of gates. When these gates are open, pain information is passed on to the brain, resulting in the experience of a high level of pain. If these gates are closed, fewer pain signals are transmitted to the brain and the experience of pain is less intense (Dickenson, 2002). The second theory is the neuromatrix theory of pain (NMT). NMT recognizes that pain experiences are generated in the brain (Hargrove, 2011). The neuromatrix is conceptual as a widespread network of brain regions such as the thalamus, insula, and the anterior cingulate that underlies the experience of pain (Bantick et al., 2002; Melzack, 2001). The key assumption of the neuromatrix theory of pain is that it is possible to alter pain experiences by influencing the processing of pain information in the brain without changing peripheral pain signals.

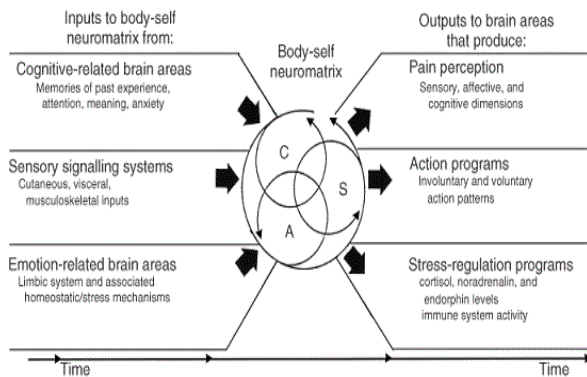
In my dissertation, I draw on this integrated model of music medicine and pain to examine the effectiveness of music medicine as a complementary treatment of TMD. Specifically, I will focus on three possible mediating processes that could contribute to an effect of music on pain experiences. These three mediators are (1) distraction, (2) vibration, and (3) mood.

### 2.3.1 Distraction as a Mediator for Managing Pain

Distraction has been proposed to be an effective strategy for pain management (Vessey, Carlson, & McGill, 1994; Hockenberry et al., 2003;). Distraction theories of pain management are based on the neuromatrix theory of pain (Melzack, 2001). According to NMT, when an injury occurs information is sent along ascending nociceptive pathways to a widespread network of brain regions such as the thalamus, insula, and the anterior cingulate (Bantick et al., 2002). The anterior cingulate cortex (ACC) is regarded as a key area for the affective component of pain, and activation of the ACC necessarily accompanies the experience of pain (Smale & Rayner, 2014). Importantly, the ACC is also influenced in the processing of other information. If other information is processed at the same time as the ACC receives information from nociceptive pathways, the experience of pain is reduced. In support of this hypothesis, brain-imaging studies have shown that pain-related activity in the ACC decreases when attention is directed towards other stimuli (Petrovic et al., 2000). In another study, patients with chronic temporomandibular pain were found to have slower reaction times to variants with emotional tasks. These emotional tasks also evoked fMRI responses in cortical areas associated with cognitive and emotion functions (Davis & Moayedi, 2013). Thus, stimulating the ACC with other information such as music could be beneficial in the management of pain (Smale & Rayner, 2014).

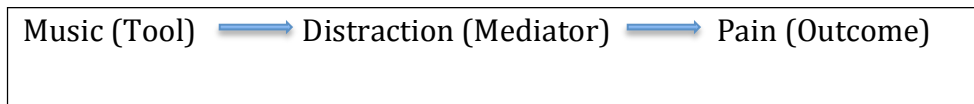
Figure 2.4 illustrates factors that contribute to the patterns of activity generated by the body-self neuromatrix, which are cognitive, sensory, and emotion related neuromodules. The output patterns from the neuromatrix produce the multiple dimensions of the pain experience, as well as action programs, and stress-related programs (Melzack, 2005). If music occurs at the same time pain is being processed, the occurrence of music acts as distractor, which consequently influences the experience of pain.

Figure 2.4 Neuromatrix Model (Melzack, 2005)



The use of music as a distractor to manage pain is illustrated in the distraction as a mediator model (Figure 2.5).

Figure 2.5 shows a mediator model of how music could influence pain by means of distraction.



In support of this model, some studies have demonstrated that music can reduce the experience of acute pain (Fowler-Kerry & Lander, 1987; Fanurik et al., 2000; Rusy & Weisman, 2000). For example, music has been successfully used to reduce pain (Anderson et al., 1991; Klassen et al., 2008; Bekhuis, 2009). Anderson et al. (1991) examined the effectiveness of music as an external distraction for pain management during dental procedures. Thirty-eight dental patients were assigned randomly to three groups. One group was assigned to incidental music during the procedure, a second group listened to music but this was also coupled with suggestions that music would help reduce stress, and a third group was not exposed to music and served as the control group. The patients in both music groups reported experiencing less pain, less discomfort, and more control than the patients in the no-treatment group. The researchers



concluded that distracting effects of music could be effective in management of pain caused by dental treatment procedures.

Although distraction might be useful for management of acute pain as noted above, its use for the management of chronic pain is less obvious since it is presumed that distraction is only effective as long as the distracting stimulus is present. Shortly after the distracting stimulus is removed, the experience of pain will resume because the ACC is still receiving input from nociceptive pathways. As a result, it might be concluded that music, when used as a distraction, might not be an effective treatment strategy for patients with chronic pain. Johnson (2005) suggested that music could even be counterproductive because distraction requires effort and using distraction, as a coping strategy would quickly exhaust patients with chronic pain who already have low levels of energy.

In support of this hypothesis, some studies of patients with chronic pain failed to demonstrate positive effects of music as distraction for management of pain symptoms. For example, Goubert et al. (2004) investigated the effects of distraction on chronic or recurring lower back pain on 60 patients during a pain inducing activity. They found that distraction had no effect on self-reported pain during the lifting task, and distraction had a paradoxical effect of more pain immediately following the lifting task.

In sum, based on the literature reviewed, the effectiveness of distraction on pain appears to depend on the type of pain being treated (i.e. acute vs. chronic). Acute pain associated with medical procedures is more likely to be reduced with music as a distraction than pain conditions classified as chronic.

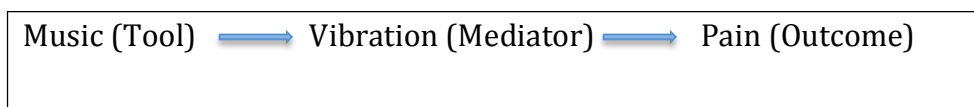
### **2.3.2 Vibration as a Mediator**

Viewed from a basic perspective, music is sound, and sound is transmitted by means of vibrations. These vibrations stimulate receptors in the ears that transmit this information to the brain to create the experience of music in the brain. However, this is not the only way sound vibrations can influence pain experiences. Sound vibrations can also penetrate the skin and stimulate receptors in the skin that primarily respond to touch, but can also

be ‘touched’ by music. Receptors that appear to be affected by vibrations associated with music are called mechanoreceptors (Purves et al., 2001). There are 4 major types of mechanoreceptors including Meissner's corpuscles, Pacinian corpuscles, Merkel's disks, and Ruffini's corpuscles (Purves et al., 2001). Mechanoreceptors are highly sensitive because even weak mechanical stimulation is sufficient to activate them and send information to the brain. Meissner’s corpuscles are the most common mechanoreceptors of the skin.

Melzack and Wall (1965) discovered that activation of mechanoreceptors reduces the experience of pain. This discovery explains why humans often experience pain relief from rubbing or scratching the skin near a pain stimulus (e.g., a wound or an insect bite). Melzack and Wall developed Gate Control Theory (GCT) to explain this phenomenon (Giummarra et al., 2007). GCT is based on the premise that painful stimuli need to be transmitted to the brain along nociceptive pathways (Kirby et al., 2010). Central to GCT is the premise that along this nociceptive pathway are a series of gates where messages about pain arrive and are sent forward to the next segment of the ascending neural pathway. When these gates are open, pain messages go on through to the brain, resulting in the experience of a pain. However, when these gates are closed, pain information is blocked from reaching the central nervous system (Dickenson, 2002). Melzack and Wall discovered that activation of mechanoreceptors closes the gates for the transmission of pain. As music has the ability to activate mechanoreceptors, the gate control theory provides another potential mechanism for the use of music medicine in the management of pain.

Figure 2.6 illustrates vibration as a mediator model.



An advantage of vibrations would be that the effect of music on pain does not require active listening and attention control because the activation of mechanoreceptors is an

automatic process. As a result, patients with chronic pain can use their limited energy to engage in purposeful activities and do not have to exert effort on attending to the music.

The vibration as a mediator model provides the foundation for the use of vibroacoustic therapy (VAT) in the management of pain. Vibroacoustic therapy is a process whereby low frequency vibrations are used to stimulate the body (Skille and Wigram, 1995; Bartel, 2012). This effect can be experienced, for example, by boosting the bass setting on a stereo. Low frequencies are useful because they are more effective than high-frequency sounds in stimulating mechanoreceptors such as Pacinian corpuscles, which play a key role in the perception of pain (Boyd-Brewer, 2003).

It has been suggested that vibroacoustic therapy is effective in the management of chronic pain, such as fibromyalgia (Wigram and Dileo, 1997). For example, findings from a 5-week study that investigated the effects of low frequency sound stimulation (delivered with a vibrating chair device) on patients with fibromyalgia, showed a significant improvement in sleep and pain levels (Naghdi et al., 2015). Significant improvements were observed in pain, a reduction in medication dosage, and sleep.

In sum, VAT may actually benefit patients with TMD since vibrations provide low-frequency stimulation, thereby closing the pain gates and providing immediate pain relief. The vibration as a mediator model suggests that music that does not provide low-frequency stimulation (e.g., classical music vs. percussion music) would be less effective as a treatment for chronic pain than vibroacoustic therapy with specially designed music to produce low-frequency vibrations.

### 2.3.3 Mood as a Mediator

Music's influence on mood could provide another avenue for the management of chronic pain. The mood as a mediator model assumes that music influences mood and mood influences pain experiences (Figure 2.7)

Figure 2.7. Mood as mediator of music effects on pain



There is ample evidence for effects of music on mood. Different music styles or harmonic patterns are capable of generating different mood states (Hauck et al., 2012). Composers and performers draw upon basic psychological cues in music to relay mood in music. In turn, listeners' mood states may be influenced by these specific psychological cues (Balkwill and Thompson, 1999). Converging evidence shows that acoustic features in music, such as melody and tempo are relevant in determining the happy and sad mood responses to music (Hunter, Schellenberg, & Schimmack, 2008). Happy music is usually characterized by fast tempo and major mode, while sadness in music is expressed by slow tempo and minor mode. Three examples of musical styles created to evoke specific moods are lullabies, which are used to evoke a soothing and relaxing mood state, soundtracks to horror films (e.g. *Jaws*) that are designed to evoke feelings of tension, and the traditional celebration song Happy Birthday, which is performed to elicit a happy mood.

Research shows that the effects of music on mood are quick, do not require musical training, and can occur outside of awareness. For example, Peretz et al. (1998) showed that non-musician listeners were able to distinguish happy from sad music within the first second of a song. Even infants have the ability to process mood in music. Infants from 2 to 4 months old exhibit a preference for consonant-pleasant over dissonant-unpleasant music (Trainor, Tsang, & Cheung, 2002).

Listeners typically prefer happy to sad sounding music (Husain et al., 2001). This preference is consistent across musical genres (Hunter et al., 2011). However, people's mood response to music also depends on music preferences. Music preferences and responses to music vary across different age groups and cultures (North, Hargreaves, & O'Neil, 2000; Tarrant et al., 2000). This suggests that it is important to take music preferences into account when music is used therapeutically.

One important factor that influences music preference is familiarity (Peretz, Gaudreau, and Bonnel, 1998; Dalla et al., 2001; Vieillard et al., 2008). An fMRI study showed that familiar music elicited stronger brain activity than unfamiliar music (Pereira et al., 2011). People may prefer familiar music due to the mere exposure effect. Mere exposure theory states that the liking of stimuli increases with familiarity. Zajonc (1980) showed that people tend to develop a preference for unfamiliar neutral objects with repeated exposure to these stimuli. For example, a person listening to a piece of music for the first time may not enjoy the music selection; however, after listening to the music selection a few times, the listener begins to enjoy the music due to familiarity. The mere exposure effect has also been demonstrated with music (Szpunar, Schellenberg, and Pliner, 2004). The more listeners were exposed to a piece of music, the more they preferred that piece of music.

Individuals' identities also influence music preferences, especially preferences of musical genres. Listeners who identify with the social/cultural aspects of a particular genre of music can have a strong preference for that music (Hargreaves, 1999). In addition, personality shapes music preferences (Renfrow & Gosling, 2003; Miranda & Claes, 2008). Extraverts tend to prefer energetic and rhythmic music such as Rap and Hip-Hop and people who are high in openness (people who are open-minded) prefer music that is reflective and complex like Jazz (Renfrow & Gosling, 2003).

There is also some evidence that people prefer music that matches their mood. Individuals with higher scores on a depression scale showed less preference for cheerful pop music than participants with low depression scores (Renfrow & Gosling, 2003). Hunter et al. (2011) directly manipulated mood states and found that inducing a sad mood increased liking of sad music. Mood-matching may seem counter-productive because listening to sad music could prolong and intensify the experience of sadness. However, it is important to distinguish the specific emotional quality (sadness) from the overall mood state of individuals. Although sad music elicits or amplifies sadness, it can be experienced as pleasant and enjoyable at the same time (Hunter et al., 2008; Zhao & Chen, 2009). Listening to sad music may help individuals in a sad mood to accept their sadness and acceptance of negative feelings can be more effective than trying to replace sadness with happiness. This mood-matching hypothesis suggests that it could be

detrimental to prescribe happy and cheerful music to depressed patients and that patients may benefit more from listening to self-selected music that matches their preferences. In support of this idea, self-selected music was effective in improving mood in a study with stroke patients (Sarkamo et al., 2008). In contrast, Garrido et al. (2016) found that experimenter-selected music with healthy participants had no significant effect on mood following treatment. This suggests that self-selected music enhances the effects of music on mood.

There is also support for the second assumption of the mood as mediator model that mood influences pain experiences. Several studies found that positive mood inductions dampen pain experiences (Villemure & Bushnell, 1998; Weisenberg, Raz, & Hener, 1998). However, mood may have different effects on the sensory and affective components of pain. For example, Villemure & Bushnell (1998) manipulated mood states with pleasant and unpleasant odors, while participants rated the intensity and unpleasantness of painful heat stimulation. Pleasant odors reduced the unpleasantness of pain, but did not alter the perceived intensity of pain. This finding suggests that mood effects of music can help pain patients to manage their pain better without necessarily lowering the intensity of pain. Possible explanations for the effect of mood on pain experiences are Beck's theory of cognitive distortion of experience (Beck et al., 1979) and Bower's network model of emotion and cognition (Bower, 1987). According to these theories, mood states distort thinking and influence judgment of events and situations. In a bad or depressed mood, pain may activate negative self-schemas that undermine optimal functioning, whereas individuals in a good mood may be better able to keep a positive sense of self that is not defined by the experience of pain.

Although there is strong evidence for the effect of music on mood and the effect of music on experiences of pain, few studies have directly tested mood as a mediator (McCraty, 1998; Weisenberg, Raz, and Hener, 1998; Kirby et al., 2010; McCraty; Sachs et al., 2015). Burrai et al. (2014) examined the effects of music on mood and pain in patients undergoing hemodialysis. The results indicated that listening to music produced more intense feelings of positive mood and decreased pain levels. The results of this study are in accordance with the Cochrane systematic review (Bradt et al., 2011), which reports

that music interventions effectively assists in the reduction of pain and helps improve mood.

## 2.4 Conclusion

In conclusion, previous research suggests that music can influence the experience of pain in a variety of ways. Experiences of acute pain may be altered by distraction from the pain stimulus, but is unlikely to explain effects of music on experiences of chronic pain. Gate control theory suggests that musical vibrations can activate receptors and dampen the transmission of pain signals to the brain. Finally, the neuromatrix theory suggests that music can alter mood states and modulate the processing of pain information in the brain. At present it is not known how music influences pain perceptions. The intervention studies in this thesis examine this question by comparing the effectiveness of two different music medicine treatments. One treatment uses vibroacoustic therapy with a chair device. The other music medicine treatment uses 25-self selected songs with preferred music. According to the vibration as a mediator model, vibroacoustic therapy should be particularly effective in reducing pain experiences. According to the mood as mediator model, merely listening to mood-enhancing music would have beneficial treatment effects.

Based on the literature, I hypothesize that the music treatment will produce lower pain levels, lower depression levels, and improved mood and quality of life. I also hypothesize that the VAT treatment will produce stronger effects than the music treatment on pain levels, depression levels, and improved mood and quality of life because it combines vibration and music.

## Chapter 3

### 3 Methodology

To date there are several complementary treatment options for TMD, but the effectiveness of them remains unknown. It is also unknown whether some treatments are more effective than others. This study examines the effectiveness of music as medicine for patients with temporomandibular joint disorder (TMD) characterized largely by pain of muscular origin. The study focuses on music medicine as a complementary treatment and compares the effectiveness of two music medicine interventions on a number of outcome measures. The primary outcome measure is subjective experience of pain. Secondary outcome measures are depression, quality of life, and mood.

#### 3.1 Research Design

##### 3.1.1 Power Analysis

Cohen (1988) recommended planning studies so that they have an 80% chance of avoiding a type-II error; that is, coming to the false conclusion that a treatment is not effective when it is actually effective. To ensure that the study has sufficient statistical power, the following power analysis was conducted using the free program GPower.

The design is a within-subject design with four repeated measures, (1) pre-treatment 1, (2) post-treatment 1, (3) pre-treatment 2, and (4) post-treatment 2. I assume a conservative estimate of retest stability of dependent measures of .70. It was assumed that the chair would have a strong effect on pain (Naghdi et al., 2015). Accordingly, I used an effect size of  $d = .8$  for the standardized difference between pre- and post-treatment scores for the chair treatment (Naghdi et al., 2015). I assumed that self-selected music would also have an influence on pain, but that the effect would be weaker than the chair treatment. For the power analysis I assumed a moderate effect size of  $d = .5$ . Power analysis showed that a sample of  $N = 20$  is sufficient to achieve 80% power to detect an effect size of  $d = .5$  in a within-subject comparison with a pre-post treatment correlation



of  $r = .70$ . Power to demonstrate differences in effectiveness of the two treatments is lower. Power to detect differences in effectiveness of the two treatments is weaker. With a predicted difference in effect sizes of  $d = .8 - .5 = .3$ . This implies a small difference between treatments,  $d = .8 - .5 = .3$ . With  $N = 25$ , the study has 60% power to demonstrate a difference in effect sizes of  $d = .3$  using planned comparisons (equivalent to one-tailed t-test at the .10 level). To achieve 80% power, the significance criterion would have to be set at  $p < .15$  (one-tailed). Balancing the need for statistical power and the difficulty of recruiting patients, I decided to test 25 patients. This sample size provides good power to detect treatment effects of the two music medicine interventions if these effects are moderate to large.

### 3.1.2 Patients

Patients with on-going myofascial chronic pain of at least 6-months, were recruited from a hospital dental unit to participate in the study. Inclusion and exclusion criteria were based on the patient being able to hear because listening to music is required as part of treatment. Additionally, a list of contraindications of Vibroacoustic Therapy (VAT) were provided: 1) Acute Inflammatory Conditions - an inflammation having a rapid onset, with a clear and distinct termination. (e.g. Rheumatoid arthritis and Osteoarthritis) 2) Clients presenting with psychoses 3) Pregnancy 4) Hemorrhaging or Active Bleeding 5) Thrombosis 6) Hypotension and 7) Pacemakers. Patients were informed that if they presented with these conditions, they would be excluded from the study. One patient was excluded from the study due to Hyperacusis.

The first patient for this study was assessed on August 2015 and the final patient assessment occurred in July 2016. Data collection continued until the criterion for study completion of 25 patients was reached. A total of 30 patients started the study, but 5 dropped out due to conflict with scheduling. There were 19 female and 6 male patients. The higher number of female patients is consistent with the overrepresentation of women in patients seeking treatment for TMD. The age of patients with TMD ranged from 21 to 63 years, while the average age was 36 years. The number of years a patient has lived with a TMD diagnosis ranged from 1 to 38 years. The average year a patient has lived with a TMD diagnosis was 7.4 years. Ten out of twenty-five patients reported that trauma

before the onset of their TMD. Two patients out of twenty-five reported a previous issue with substance abuse. Seventeen out of twenty-five patients previously used complementary treatments for managing TMD. The patient group reflected the ethnic diversity of the community. Patients self-identified as the following ethnicities:

Table 3.1

Asian 20%	Filipino, Vietnamese-Chinese, Korean, Chinese
Black 12%	African, Afro-Caribbean Black-Canadian
Middle Eastern 8%	Middle Eastern, Persian, Turkish
South Asian 8%	Indian, Indian- Canadian
White 52%	Italian-Canadian, Jewish, Portuguese, Canadian

### 3.1.3 Procedure

The study examined the effectiveness of two interventions: 1) vibroacoustic therapy chair, Sound Oasis VTS1000 and 2) sessions of listening to self-selected music. A blind-randomized control crossover design was used to test the effects of self-selected music vs. VAT on TMD symptoms. For the first treatment, the music medicine treatments were randomly assigned. Randomization procedures were followed using a computerized random generator by one of the investigators not involved with recruitment or data. Randomization was done prior to the consent form and data collection forms were completed. Patients' treatment order was not disclosed until all patients in the study were assessed. Twelve patients started with vibroacoustic therapy and 13 patients started with self-selected music.

The study consisted of 4 assessments and 2 treatments with a 4-week washout period between treatments. Assessment 1 (served as pre-test for treatment time 1) occurred before 1st treatment and lasted 1 hour. Assessment 2 (served as post-test for treatment

time 1) and lasted between 30- 45 minutes. Assessment 3 (served as pre-test for treatment 2) followed the washout period and also lasted between 30-45 minutes. Assessment 4 (served as post-test for treatment 2), which was a 1-hour session, included a patient treatment review interview. Pre/post assessments were utilized as a means to examine change in pain, mood levels, depression and the perception of quality of life at the level of each patient.

During the treatment time, patients received 1 treatment compliance call per week. The purpose of the compliance call was to answer general questions regarding treatment. Patients were advised not to disclose treatment. Complications and questions regarding the specific treatment were addressed to the Wasser Pain Management Centre Research Coordinator as I was blinded. No data were collected to calculate compliance rate.

Both music medicine treatments were prescribed for self-administered in-home sessions for 3-weeks, 7 days (recommended) but at least a minimum of 5 days per week for 30 minutes a day. Patients were provided with written instructions for the VTS-1000 Sound Oasis. The instructions were (1) use the vibroacoustic chair device in the morning on energize setting for 30 minutes, (2) set the vibration intensity level to 15 and the volume to 1 or 2, and (3) the unit will automatically turn off after 30-minutes.

Patients were asked to keep a record of the type of medication taken, a pill count, and frequency of medication during their treatment time. It was suggested that medication be taken as needed during the music medicine treatment times.

#### **3.1.4 Intervention**

Patients were randomly assigned to 2 groups: (a) vibroacoustic therapy (Sound Oasis VTS-1000) and (b) self-selected music. The VTS-1000 Sound Oasis is a vibroacoustic therapy system that provides music and low pitch frequencies. Patients were asked to use the Energize Track during treatment in the ‘morning’. Patients were also advised to adjust the vibration intensity to 15 and the volume to 1 or 2. The Energize Track was comprised of 3 tracks: 1) Energize Track 1- [total track length 5:18] Guitar, piano, digital keyboards, bass Low pitch 41 Hz - 73 Hz with 41 Hz dominant 2) Energize Track 2- [total track

length: 4:40] Guitar, piano, digital keyboards, bass Low pitch 36 Hz - 61 Hz with 41 Hz dominant mono and binaural high alpha and beta entrainment mono and binaural high alpha and beta entrainment Energize and 3) Energize Track 3- [total track length: 5:55] Guitar, piano, digital keyboards, bass Low pitch 36 Hz - 65 Hz mono and binaural high alpha and beta entrainment. The unit is programmed to loop all three Energize tracks until the 30-minute session is complete.

### 3.1.5 Ethical Issues/Concerns

Patients were offered the option of participating in the study and informed participation would not affect their standard of care. Patients were contacted by the researcher who explained the study in detail and were permitted as much time as need to decide if they would like to participate.

Only I, and my supervisory team had access to patient information. No other persons had access to these data.

In case of any personal health information inappropriately released, embarrassment could arise. The REB and the MSH privacy office would be notified immediately so that patients may be informed and deal with any adverse consequences as soon as possible. However, any personal health information collected for this study would not be connected to any personal names as all Patients were assigned an ID number that was used throughout the duration of the study.

There were no limits on withdrawal. All patients had the option to withdraw from the study at any point during the study. Data was only analyzed for those who completed the study. Confidentiality was maintained throughout the research process.

All patients were presented with a consent form (see Appendix A) providing a clear description of the study and their rights of participation, withdrawal and confidentiality.

Dr. Lee Bartel, who is the dissertation supervisor of the PhD candidate Alicia Howard, serves as a paid consultant for the scientific design of music recordings to the Somerset Group that supplied the music on the Sound Oasis VTS1000. He is not a composer or

performer on these Somerset Group recordings but receives limited (non-composer, non-performer) royalties for the Somerset Group Sonic Aid series and for the sound on the VTS1000. Dr. Bartel consulted with Headwaters Corporation on the design development of the Sound Oasis VTS1000, his image and words are used as endorsement for the product, and he receives royalties on the sale of the devices.

## 3.2 Measures

The following primary and secondary outcome measures were administered at all study visits for all patients to examine change in pain, mood levels, depression and the perception of the quality of life at the level of each patient. Total scores for each standardized measure were used for analyses.

### 3.2.1 Pain Intensity

The Visual Analog Scale for Pain (VAS-Pain) is a one-dimensional measure of pain intensity that has been widely used in various adult pain populations (Williamson and Hoggart, 2005; Kushner et al., 2008; Moreno et al., 2009), including those with Temporomandibular Joint Disorders (Moreno et al., 2009). Patients were required to complete a VAS-Pain scale rating during the 4-assessment times of the study (T1, T2, T3, T4). The VAS uses a 100-cm line with a written description of “no pain” on the left and “worst possible pain” on the right (see Appendix I for VAS used in study). Instructions, verbal descriptor anchors, and time period for reporting vary depending on intended use of the scale (Burckhardt, & Jones, 2003). Using a ruler, the score is determined by measuring the distance (mm) on the 100-cm line between the “no pain” anchor and the patient’s mark, providing a score range of 0 –100 (Jensen, Karoly, & Braver, 1986). Patients were asked to mark on the line in relation to the amount of pain they were feeling within the past 7 days. A higher score indicates greater pain intensity. Test-retest reliability has shown to be good (Ferraz et al., 1990). The VAS-Pain has demonstrated sensitivity to changes in pain assessed hourly for a maximum of 4 hours and weekly up to 4 weeks following analgesic therapy for patients with chronic inflammatory or degenerative joint pain (Joyce et al., 1975).

The daily VAS-Pain measure (see Appendix K for VAS daily) is similar to the VAS Pain scale. It also is a one-dimensional measure of pain intensity that was used to measure pain following patients' 3-week, in-home music medicine treatment. The VAS uses a 100-cm line with a written description of "no pain" on the left and "worst possible pain" on the right (see Appendix G for VAS). The VAS-Pain is a scale comprised of horizontal or vertical line, usually 100 cm in length, anchored by 2 verbal descriptors, one for each symptom extreme (Hawker et al., 2011). Patients were asked to mark on the line in relation to the amount of pain they were feeling in that moment, following their in-home music medicine treatment. Reliability for the VAS-Pain has shown to be good (Ferraz et al., 1990). The VAS-Pain has also demonstrated to be sensitive to change in pain (Hawker et al., 2011).

Before the VAS-Pain Scale was administered, patients were given two VAS practice scales (see Appendix F and G) to familiarize them with the response format for the VAS-Pain Scale. The first scale asked patients to indicate with an 'X' how they would feel wearing a parker in the middle of July/August and how they would feel wearing a t-shirt in the middle of November/December. The second scale asked patients indicate the darkness of a black square. Three out of 25 patients expressed slight difficulty in completing the VAS practice measure.

### 3.2.2 Depression

The Center for the Epidemiological Studies of Depression Short Form (CES-D; Radloff, 1977) is a 10-item scale widely used to screen for depression (see Appendix J for CES-D scale used in study). A 4-point ordinal scale is used for this measure: (less than 1 day), (1-2 days), (3-4 days), and (5-7 days). The total score is calculated by finding the sum of 10 items. If more than 2 items are missing from a form, it is not to be scored. A score equal to or above 10 is considered depressed (Miller et al., 2008). The 10-item measure has demonstrated strong predictive accuracy and high correlations with the original 20-item version, as well as high internal consistency and demonstrates both convergent validity and divergent validity, and excellent sensitivity (Björgvinsson et al., 2013). These data suggest that although the CES-D has strong psychometric properties in a

psychiatric sample, the measure should be used to primarily assess the severity of depression symptoms rather than as a diagnostic screening tool (Björgvinsson et al., 2013).

### 3.2.3 Mood

Mood was measured with the Multidimensional Mood Questionnaire (MMQ) (see Appendix H) (Zou, Schimmack, & Gere, 2013). The MMQ is a 27-item questionnaire that distinguishes four primary qualities of mood that are also recognized as basic emotions, namely happiness/cheerfulness (HAP), anxiety/tension (ANX), sadness/depression (SAD), and anger/irritation (ANG) (see Appendix III for MMQ). The MMQ has been shown to be a valid measure due to convergent validity with ratings by well-acquainted informants (Zou et al., 2013; Schneider and Schimmack, 2009).

### 3.2.4 Quality of Life

The Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (see Appendix I) (Q-LES-Q-SF; Endicott, 2008) is a self-reported QOL measure that assesses the physical health, subjective feelings, leisure activities, social relationships, general activities, satisfaction with medications and life satisfaction domains (Stevanovic, 2014) (see Appendix IV for Q-LES-Q-SF used in study). Q-LES-Q-SF shows sound internal consistency, stability of test-retest reliability, and convergent and criterion validity, with 80% sensitivity and 100% specificity (Ritsner, 2005; Stevanovic, 2011). The findings suggest that the Q-LES-Q SF could produce reliable, valid, and sensitive assessments of QOL when used with patients with mood disorders (Ritsner, 2005; Stevanovic, 2011).

### 3.2.5 Self-Perceived Benefits

The Glasgow Benefit Inventory (GBI) (see Appendix L) is a generic patient-recorded post-intervention health-related measure (GBI; Robinson, Gatehouse, & Browning, 1996; Hendry et al., 2016). The GBI has been translated into eight languages. The GBI questionnaire contains 18 questions that can be completed as an interview or filled-in by the patient. The potential GBI score ranges from -100 (maximal harm) to 0 (no change) to

+100 (maximal benefits) (see Appendix V for GBI used in study). The GBI has been used as a measure with various medical populations. The GBI shows sensitivity to different interventions (Hendry et al., 2016).

### 3.2.6 Post-Treatment Interview

The post-treatment interview questionnaire was developed by the researcher (see Appendix M).

The first questionnaire was administered during patients' first study visit prior to receiving treatment (T1). Patients were asked to report demographic information, first TMD diagnosis, current pain management, alternative pain management approaches, 25 favorite songs, and device used to listen to music.

The second questionnaire was administered during the final assessment (T4). This 4-item questionnaire asked patients to report on their experiences with music medicine: challenges encountered, feelings during the music medicine treatments (VAT and music treatment), other pains experienced during treatment, and treatment preferred.

The third questionnaire was completed during both music medicine treatment times. Patients were asked the amount medication (including name) and the days that medication was used during their treatment times. This journal was used to explore the association between the effectiveness of music medicine treatments and medication.

### 3.2.7 Administration of Measures During Study

Table 3.1 gives an overview of the design and at which occasions the various measures were completed.



Table 3.2. Table of Repeated Measurements

	N	Pre- Test 1 Assessment	Treatment 1 (3 weeks)	Post- Test 1 Assessment	Washout (4 weeks)	Pre- Test 2 Assessment	Treatment 2 (3 weeks)	Follow-up Assessment 4/ Interview
<b>1 Group</b>	12		Self-Select Music				Sound Oasis VT	
<b>2 Group</b>	13		Sound Oasis VAT				Self-Select Music	
VAS-Pain		X		X		X		X
CES-Depression		X		X		X		X
MMS		X		X		X		X
Q-LES-Q-SF		X		X		X		X
VAS-Pain (Daily)			X				X	
Treatment Compliance Call			X3				X3	
Glasgow Benefit Inventory (GBI)								X

Note: Music Medicine group: (T1) = pre-treatment 1, Treatment= 3 weeks, (T2) = post-treatment 1, Washout= 4 weeks, (T3) = pre-treatment 2, Treatment= 3 weeks, (T4) = post-treatment 2

### 3.3 Data Analysis

Data was analyzed with reference given only to an assigned ID number. All information collected has been used for this study to investigate the effects of music medicine on the management of TMD symptoms. Furthermore, all patients were informed that all information that has been disclosed has remained confidential, unless the disclosed information will cause harm to self or others.

The data was analyzed with a mixed-model ANOVA with treatment group as between subject factor (VAT and Music vs. Music and VAT) and assessment time (pre, post treatment 1, post washout, post-treatment 2) as within-subject factor. The analysis was repeated for various outcome measures. The main hypothesis is an interaction effect between time of assessment and treatment group. Post-hoc tests probed the interaction by comparing post-music pain levels to post-chair music levels. I expected that pain would be significantly lower after treatment with the chair than after treatment with self-selected music.

## Chapter 4

### 4 Results

All analyses were carried out using R ‘stats’ program (R Core Team, 2012). The ez- package was used to conduct Analyses of Variance (ANOVA). The pre-registered hypotheses were tested first, followed by exploratory analysis. The results for the primary outcome, pain intensity, are presented first, followed by the results for the pre-registered secondary outcomes, depression and quality of life. Afterwards, the effects of music on mood are examined to test the mood as mediator hypothesis. In the end, quantitative and qualitative results are presented from a patient exit interview.

#### 4.1 Visual Analog Scale-Pain (VAS)

The effects of music treatments on VAS scores were tested with an Analysis of Variance (ANOVA) with Order (self-selected music vs. VAT) first, Time of Treatment (First Treatment vs. Second Treatment), and Pre-Post (Pre-Treatment vs. Post-Treatment) as factors. Order was manipulated between patients and the other factors were manipulated within patients. The ANOVA for the VAS pain measure did not produce statistically significant results with the conventional  $p < .05$  criterion (see Table 4.1).

**Table 4.1**

Results from the ANOVA of VAS Pain scores.

Effect	F	P
Order	3.42	.078
Time of Treatment	3.62	.070
Pre-Post	0.94	.343
Order X Time of Treatment	0.27	.612
Order X Pre-Post	0.01	.904
Time of Treatment X Pre- Post	0.34	.566
3-way interaction	0.07	.788

The results provided no statistically significant support for the first hypothesis that predicted a pre-post main effect. A follow-up analysis with a paired t-test showed that the difference between pre and post treatment means was 2.64% (95%CI = -2.86 to 8.14). Although this effect is in the predicted direction, it is weaker than the effect size that was used for the power analysis ( $d = .65 * 26 \text{ SD} = 17$  percentage points). Thus, the non-significant result cannot be interpreted as evidence that music medicine has absolutely no effect. It is also possible that it has a statistically small effect ( $d = .2$  or 3.4 percentage points on the VAS scale) and that the sample size was too small to provide empirical support for it.

The ANOVA produced two unexpected marginally significant main effects ( $p < .10$ ) for order and time of treatment. The following exploratory analyses examined which pattern in the means produced these effects. Table 4.2 shows the means for all eight cells of the design.

**Table 4.2.** Standard Deviation and Means of Pain Intensity (VAS scores 0-100mm)

Order	SD	Treatment 1		Treatment 2	
		$\bar{X}$ -Pre	$\bar{X}$ -Post	$\bar{X}$ -Pre	$\bar{X}$ -Post
VAT/SSM	22	29	27	26	22
SSM/VAT	29	46	46	41	36
Combined	26	38	37	34	29

Note. Pre = assessment before treatment, Post = assessment after treatment, VAT/SSM – treatment 1 = vibroacoustic therapy; treatment 2 = self-selected music, SSM/VAT – treatment 1 = self-selected music; treatment 2 = vibroacoustic therapy, Combined = VAT/SSM and SSM/VAT mean scores combined

The marginal order effect is due to higher pain scores in the SSM/VAT group than in the VAT/SSM group. These differences are already visible at the first assessment before the occurrence of any treatment. This shows that the random assignment did not fully match the two groups in terms of pre-existing pain levels. The means in both groups also show a continuous decline from the first assessment to the last assessment. Even during the washout period, means stayed the same or decreased. This unexpected finding makes it harder to detect potential treatment effects during the second treatment. However, even during the first treatment, the means show little evidence for a change in pain intensity. Nevertheless, pain scores decreased from the first measurement to the final measurement (see Table 4.2) and this effect was marginally significant,  $t(24) = 2.04$ ,  $p = .052$ .

Seventeen patients (8 chair first, 9 self-selected music first) completed daily pain ratings during both treatment periods. Pain levels were highly stable from the first to the second

treatment period,  $r = .95$  with some patients reporting consistently low levels of pain ( $< 10$ ) and others reporting high levels of pain ( $> 80$ ). Average pain intensity was slightly lower after the self-selected music treatment ( $\bar{X} = 33$ ,  $SD = 28$ ) than after the chair ( $\bar{X} = 36$ ,  $SD = 28$ ), but the difference was not significant,  $t(16) = 1.50$ ,  $p = .15$ .

In conclusion, the results for pain intensity differed from the predicted results in several ways. There was no statistically significant treatment effect and there was no increase in pain intensity during the washout period. Possible explanations for these results are discussed in Chapter 5.

## 4.2 Depression

Depression was one of the secondary outcome measures and was measured with the CES-D scale. The ANOVA did not show a significant main effect for pre-post treatment comparisons (Table 4.3). However, the time of treatment X pre-post interaction approached significance, as did the main effect for time of treatment.

Table 4.3

ANOVA results for CES-D scores

Effect	F	P
Order	1.03	.322
Time of Treatment	3.53	.073
Pre-Post	0.35	.561
Order X Time of Treatment	0.13	.726
Order X Pre-Post	0.36	.561

Time of Treatment X Pre	3.00	.097
Post		
3-way interaction	0.41	.530

---

The table of means (Table 4.4) shows a general decrease in depression over time. This decrease was more pronounced during the first treatment. As for pain intensity, depression did not increase again during the washout period. This could be an explanation as to why depression scores did not decrease during the second treatment. However, both groups showed the expected decrease in depression during the first treatment, although this difference was not statistically significant in a paired t-test of depression scores before and after the first treatment,  $d = .16 / .69 = .23$ , 95%CI =  $-.06$  to  $.54$ ,  $t(24) = 1.66$ ,  $p = .109$ . As for pain intensity, there was a marginally significant decrease in depression from the first to the final assessment,  $t(24) = 1.92$ ,  $p = .07$ .

Table 4.4. Standard Deviations and Means of CES-D scores.

Order	SD	Treatment 1		Treatment 2	
		$\bar{X}$ -Pre	$\bar{X}$ -Post	$\bar{X}$ -Pre	$\bar{X}$ -Post
VAT/SSM	0.64	2.31	2.05	2.00	2.08
SSM/VAT	0.73	2.49	2.42	2.21	2.28
Combined	0.69	2.40	2.24	2.11	2.18

Note. Pre = assessment before treatment, Post = assessment after treatment, VAT/SSM – treatment 1 = vibroacoustic therapy; treatment 2 = self-selected music, SSM/VAT – treatment 1 = self-selected music; treatment 2 = vibroacoustic therapy, Combined = VAT/SSM and SSM/VAT mean scores combined

To summarize, the ANOVA also failed to provide evidence for the second hypothesis that music medicine produces a pre-post main effect. However, as seen in pain intensity, depression did not increase during the washout period, which makes it difficult to interpret results for the second treatment. A comparison of depression scores before and after the first treatment showed a statistically small decrease in depression that was not significant. Once more, the sample size was too small to test effects of this magnitude.

### 4.3 Quality of Life Enjoyment & Satisfaction Questionnaire-Short Form (QoL)

The first analysis used the sum of the 14 Quality of Life items of the QoL as the dependent variable. The pre-post main effect was not significant, but once more the pre-post interaction with time of treatment was marginally significant.

Table 4.5

ANOVA results for Quality of Life

Effect	F	P
Order	1.69	.207
Time	1.79	.194
Pre-Post	1.47	.237
Order X Time	0.03	.864
Order X Pre-Post	0.86	.365
Time X Pre-Post	3.87	.061



3-way interaction                      0.43                      .521

---

Once more the washout period produced no decrease in quality of life (Table 4.6). This makes it difficult to interpret the lack of a treatment effect during the second treatment and a separate analysis for the first treatment was conducted. A paired t-test for quality of life scores before and after the first treatment showed a marginally significant increase in quality of life,  $t(24) = 2.05, p = .051$ . The standardized effect size was small,  $(46.34 - 43.75) / 11.81 = .22, 95\%CI = .00 \text{ to } .41$ . There was also a marginally significant increase in quality of life from the first to the final assessment,  $t(24) = 1.84, p = .08$ .

Table 4.6.

Standard Deviations and Means of Quality of Life scale.

Order	SD	Treatment 1		Treatment 2	
		$\bar{X}$ -Pre	$\bar{X}$ -Post	$\bar{X}$ -Pre	$\bar{X}$ -Post
VAT/SSM	10.20	45.89	49.98	49.06	49.66
SSM/VAT	12.89	41.79	42.98	43.76	43.20
Combined	11.81	43.75	46.34	46.30	46.30

Note. Pre = assessment before treatment, Post = assessment after treatment, VAT/SSM – treatment 1 = vibroacoustic therapy; treatment 2 = self-selected music, SSM/VAT – treatment 1 = self-selected music; treatment 2 = vibroacoustic therapy, Combined = VAT/SSM and SSM/VAT mean scores combined

Quality of Life has an objective and a subjective component. It is likely that music medicine has a stronger impact on the subjective component of quality of life that is commonly called subjective well-being (SWB, Diener, 1984). Subjective well-being has

an affective (mood) and a cognitive (life-evaluations) component (Diener, 1984). The QoL has two items that ask for an overall evaluation of life quality. The items are 1) “Reflecting on everything which has happened in the past week, how satisfied have you been with your overall sense of well-being” and 2) “How would you rate your overall life satisfaction and contentment during the past week”. It has one item that measures affective well-being. The item is 3) “Reflecting on everything which has happened in the past week, how satisfied have you been with mood”. The three items were averaged into a single SWB scale. The scale had acceptable internal consistency ( $\alpha = .85$ ). The SWB scores were analyzed with the same ANOVA that was used for the QoL scale.

Table 4.7 ANOVA results for the Subjective Well-Being Scale of the Quality of Life Questionnaire.

Effect	F	P
Order	1.00	.328
Time	14.95	.001
Pre-Post	1.92	.179
Order X Time	0.26	.616
Order X Pre-Post	0.99	.331
Time X Pre-Post	1.83	.190
3-way interaction	0.02	.878

The SWB measure did not show main effects or interaction effects for pre-post treatment differences. However, it did show a highly significant time of treatment effect. The

pattern of means showed again an improvement over time and an increase in SWB during the first treatment. A paired t-test for the first treatment showed that increase was only marginally significant,  $t(24) = 1.74, p = .095$ . A comparison of SWB at the beginning of the study and at the end of the study showed a significant increase,  $t(24) = 3.30, p = .003$ .

Table 4.8 Standard Deviations and Means of the SWB scale

Order	SD	Treatment 1		Treatment 2	
		$\bar{X}$ -Pre	$\bar{X}$ -Post	$\bar{X}$ -Pre	$\bar{X}$ -Post
VAT/SSM	0.90	3.06	3.42	3.47	3.63
SSM/VAT	0.85	2.79	2.97	3.33	3.25
Combined	0.87	2.92	3.18	3.40	3.43

Note. Pre = assessment before treatment, Post = assessment after treatment, VAT/SSM – treatment 1 = vibroacoustic therapy; treatment 2 = self-selected music, SSM/VAT – treatment 1 = self-selected music; treatment 2 = vibroacoustic therapy, Combined = VAT/SSM and SSM/VAT mean scores combined

#### 4.4 Multidimensional Mood Questionnaire

Mood was measured with the Multidimensional Mood Questionnaire (MMQ). The MMQ distinguishes four primary qualities of mood that are also recognized as basic emotions, namely happiness/cheerfulness (HAP), anxiety/tension (ANX), sadness/depression (SAD), and anger/irritation (ANG). Although these mood qualities are not independent, they can show unique relationships with other variables. Given the high level of depression and anxiety among patients with TMD, the music intervention was expected to have the strongest effect on the anxiety (ANX) and depression (DEP) scales of the MMQ. Each mood scale was analyzed with an ANOVA (Table 4.9).

Table 4.9 ANOVA results for the four MMQ scales

Effect	ANX	DEP	ANG	HAP
Order	2.58	0.15	0.01	1.69
Time of Treatment	10.88*	8.94*	0.63	3.16
Pre-Post	2.72	2.45	4.10	0.06
Order X Time of Treatment	3.97	0.68	0.08	0.67
Order X Pre-Post	0.49	2.23	2.05	1.11
Time of Treatment X Pre-Post	6.17*	4.29*	1.62	0.03
3-way interaction	0.90	1.98	0.11	0.66

\*  $p < .05$

The results do not show a main pre-post effect for any of the four mood scales of the MMQ. However, the pre-post X time of treatment interaction was significant for anxiety and depression, but not for anger and happiness. This pattern of results confirms that the four mood scales measure different mood qualities and that music medicine influenced anxiety and depression more than other mood qualities. The parallel patterns of effects for anxiety and depression are to be expected because these two mood qualities are highly correlated. Controlling for depression eliminated the effects on anxiety and vice versa. Therefore, a follow-up analysis was conducted by combining both mood scales (ANX & DEP) into a single measure of suffering. Table 4.10 shows the means of suffering for the 8 cells of the design.

Table 4.10 Standard Deviations and Means of Suffering (Anxiety/Depression)

Order	SD	Treatment 1		Treatment 2	
		$\bar{X}$ -Pre	$\bar{X}$ -Post	$\bar{X}$ -Pre	$\bar{X}$ -Post
VAT/SSM	1.17	4.21	3.38	3.50	3.35
SSM/VAT	1.33	4.73	4.38	3.42	3.59
Combined	1.26	4.48	3.90	3.46	3.47

Note. Pre = assessment before treatment, Post = assessment after treatment, VAT/SSM – treatment 1 = vibroacoustic therapy; treatment 2 = self-selected music, SSM/VAT – treatment 1 = self-selected music; treatment 2 = vibroacoustic therapy, Combined = VAT/SSM and SSM/VAT mean scores combined

The pattern of means shows a decrease in suffering scores before and after the first treatment, no increase in suffering during the washout period, and no changes during the second treatment. Once more the lack of a washout effect makes it difficult to interpret the lack of a treatment effect during the second treatment. A paired t-test that compared suffering before and after the first treatment showed a significant decrease,  $t(24) = 3.49, p = .002$ , with a moderate effect size of  $d = (4.48 - 3.90)/1.26 = 0.46$ . Suffering also decreased from the beginning to the end of the study,  $t(24) = 3.54, p = .002$ .

In conclusion, this finding supports the first part of the mood as mechanism hypothesis that music medicine improves mood. The effect size is moderate. As effects of mood on pain are likely to be moderate as well, the mood as mechanism hypothesis predicts only a small decrease in pain intensity. This prediction is consistent with the results for pain in this study but larger samples are needed to provide stronger evidence for the mood as mechanism model.

## 4.5 Patient Exit Interview

The patient exit interview had a quantitative and a qualitative component. The quantitative component assessed patients' evaluations of the music interventions with the Glasgow Benefit Inventory (GBI). The qualitative part was a semi-structured interview with questions about patients' experiences during the two different types of treatments.

### 4.5.1 Glasgow Benefit Inventory

The GBI is scored so that scores range from -100 to +100 and 0 means participants reported that things did not get better or worse. Accordingly, I compared the average GBI score to a score of 0 with a one-sample t-test. The mean GBI score was 22.78 (95%CI = 12.51 to 33.04), which is significantly above 0,  $t(24) = 4.58$ ,  $p = .0001$ . In addition, 23 patients reported some improvement and only 2 reported that things got worse. Table 4.11 shows the results for individual items. Items that showed clear evidence of benefits were items 1 (daily activities), 2 (overall life), 3 (optimism), 5 (pain management), and 8 (interest in more treatment), but all items showed more improvement than negative effects (Table 4.11).

Table 4.11  
Responses to Glasgow Benefit Inventory Items

Item	Worse	Same	Better
1	1	6	18
2	1	5	19
3	3	8	16
4	2	15	10
5	1	13	11
6	1	13	11
7	4	16	5
8	4	6	15
9	1	12	12
10	1	15	9
11	1	13	11
12	1	18	6
13	0	13	12
14	2	18	5
15	2	11	12
16	2	16	7

## 4.5.2 TMD Treatment Review Interview

The study concluded with a structured TMD Treatment Review Interview. In this Interview patients were asked four questions about their treatment experiences and they were asked to reflect and share their overall experiences with both music medicine treatments. The following are examples of responses provided by patients regarding their music medicine experiences.

When patients were asked to reflect on treatment adherence and challenges in music medicine prescription, several patients found complications with the morning time for both treatments. Many patients said that mornings were the busiest time of the day for them and being required to begin treatment during this time actually made them feel more stressed. Some patients reported that they adapted the treatment scheduling to a time that was better suited for them. Some patients noted complications with the set-up of the VAT device and that it was uncomfortable. Lastly, a few patients stated difficulties with the music. One patient suggested adding more songs because the playlist of 25 songs became repetitive over the course of the 3-week treatment period. Other patients stated that they found the 30-minute music treatment prescription difficult to follow due to a lack of attention span.

Patients were asked how they felt during the vibroacoustic therapy treatment. A few patients liked the tactile experience from the chair and found the vibrations beneficial for relieving pain. One female patient stated that the VAT device was effective in easing her lower-back pain and menstrual cramps. However, other patients complained of an increase in pain during the VAT treatment.

Finally, patients were asked to describe their experience with music medicine for managing TMD. The majority of patients stated that self-selected music had a positive effect on their mood. Fewer patients reported the same benefits for the VAT treatment. Patients also reported that neither music medicine treatment had a strong effect on pain, but that music improved their mood, which helped them to better manage their pain.

The patient exit interview not only provides an insight into patients' experiences of music medicine treatments, it also provides another means to examine the effectiveness of music medicine through the lens of patients' subjective experiences. The following are the results from this analysis.

Eighty-percent of patients reported that both music medicine treatments had positive effects on mood, whereas 16% of patients found both music medicine treatments to be effective on pain. Thirty-two percent of patients reported a lingering mood effect after the treatment with self-selected music, whereas only 8% of patients reported a similar effect for the vibroacoustic therapy. Additionally, 60% of patients preferred the self-selected music treatment as opposed to 24% of patients who preferred the vibroacoustic treatment. The remaining patients liked both treatments equally.

Lastly, patients' medication usage was measured during both music medicine treatments using a medication diary. The medication diary allowed patients to record the amount of medication required during both music medicine treatment times. The results indicated that medication was required for an average of 20% of days during the self-selected music treatment as compared to 26% of days for the vibroacoustic treatment. These results are consistent with other findings in this study that music medicine treatments may improve mood and have only a weaker effect on pain and that there were no major differences between the two types of music medicine treatments. Furthermore, these findings are consistent with Freeman et al. (1998), who found no significant treatment effects in objective measures of mandibular opening, while subjective perceptions of quality of life improved significantly. These findings demonstrate that diseases are multidimensional and should be approached as such.



## Chapter 5

### 5 Discussion

The primary goal of this study was to evaluate the effectiveness of music medicine (vibroacoustic therapy-VTS and self-selected music) in reducing pain, depression, mood and quality of life on patients suffering from Temporomandibular Joint Disorder (TMD). Effectiveness was evaluated in a randomized cross-over design with a washout period. For the primary outcome measure, pain ratings, no statistically significant treatment effect was observed, but pain scores decreased as expected over the course of the study. Secondary outcome measures showed stronger effects and the effect for mood, suffering, was statistically significant.

#### 5.1 Summary of Main Results

The effect of music medicine on the VAS-Pain scores did not produce statistically significant results with the conventional criterion for statistical significance of  $p < .05$ . A comparison of the means showed the expected decrease in pain intensity, but the decrease was much smaller than anticipated. Pain scores dropped by a mere 2.64 points on the 0 to 100 scale. Although this effect is in the predicted direction, it is weaker than the effect size that was used for the power analysis. Therefore, the non-significant result cannot be interpreted as evidence that music medicine has no effect. It is also possible that it has a statistically small effect, but that the sample size was too small to provide empirical support for it.

The results also showed no indication that treatment effects varied due to time of treatment or type of treatment. This finding is not surprising. In the absence of a clear treatment effect, it is statistically impossible to demonstrate that one treatment is significantly better than another.

The ANOVA did not show a significant main effect on depression for pre-post treatment comparisons. However, the time X pre-post interaction approached significance, as did the main effect for time. Unexpectedly, depression did not increase during the washout period. This may explain why there was no decrease in depression during the second treatment, though both groups showed the expected decrease in depression during the first treatment.

The pre-post main effect for quality of life was not significant, but once more the pre-post interaction with time was marginally significant. An examination of means showed a trend that quality of life improved over the course of the study, especially from Time 1 to Time 2. Once more there was no change in quality of life during the washout period. This makes it difficult to interpret the lack of treatment effects. Also noticed was a marginally significant increase in quality of life when a paired t-test was performed.

I also examined treatment effects for subjective evaluations of life overall using three global subjective well-being items of the Quality of Life measure. Once more, the results showed improvement during the first treatment and over the whole period, but no changes during the washout period and less changes during the second treatment.

Statistically significant results were obtained for two of the four mood scales of the MMQ, namely anxiety and depression. Anger and happiness showed weaker and non-significant trends. The two scales were combined into a suffering scale. Suffering decreased significantly during the first treatment and from the first to the last assessment.

## 5.2 Evaluation of Statistical Results

The pattern of results for the primary and secondary outcomes shows some positive changes over the course of the two treatments with stronger effects for the first treatment. However, effect sizes were often small and not statistically significant. Stronger and significant results were obtained only for the anxiety and sadness scales of the multi-dimensional mood questionnaire, which were combined to create a measure of psychological suffering. There are several reasons why the results for mood were stronger than those for pain intensity. One possible explanation is that the mood measure

may have better psychometric properties than the other measures. Another possible explanation is that music has the strongest direct effect on mood and effects on pain were weaker than effects on depression and quality of life. From the perspective of the biopsychosocial model of TMD, the results suggest that music mainly influences psychological symptoms of TMD with weak effects on physical symptoms like pain and social factors like patients' social relationships and functioning in daily life. The statistically significant effect on suffering is encouraging and consistent with positive results in studies with other chronic pain patients. These results are consistent with the suggestion that treatment of TMD requires a trans-disciplinary approach and that the main benefit of music medicine is to help patients with psychological symptoms of anxiety and depression, which are very common in TMD patients and other chronic pain patients.

### 5.3 Limitations and Future Directions

There were several challenges encountered in this study. Given the small sample size, the study had insufficient power to rule out sampling error as a possible explanation for the decrease in pain. Non-significant trends in this study might have shown positive evidence for treatment effects in a study with a larger sample. Nevertheless, the results of this study provide valuable information. Future studies should include the same measures as this study so that data from this study can be combined with other studies to examine the effectiveness of music medicine in a meta-analysis that combines results from different studies. The multi-dimensional mood scale is particularly promising because it showed significant results and can be used to test the mood as mediator model. Future studies might also benefit from a more extensive assessment of pain that distinguishes the sensory and affective component of pain.

Another shortcoming was the ineffective washout period. I purposefully selected a crossover design to increase power by administering the same treatment to each patient. A cross-over design is also efficient if it is difficult to recruit patients. However, a crossover design is only more efficient if treatment effects are short-lived and TMD symptoms intensify again during the washout period. This did not happen in this study.

As a result, there were no benefits in conducting a second treatment session after the washout period and it was not possible to use patients as their own controls or to compare the two treatments with each other. As a result, the second treatment extended the study without producing meaningful results. Future studies should use a more efficient design with a single treatment and if possible follow-up assessments to examine long-term benefits of implementing music medicine as a complementary treatment in patients' self-care management of TMD.

Moreover, without a washout effect it is difficult to interpret improvements during the first treatment period as evidence for a treatment effect. To obtain more conclusive evidence of treatment effects, it would be necessary to compare the changes in the treatment group to changes in a randomized control group without treatment. Few intervention studies have compared treatment groups to a treatment as usual group as a control group and none of these studies included mood measures. Dworkin, Huggins, Wilson et al (2002) found no changes in depression scores in the treatment as usual group. This result suggests that the marginally significant effect for depression and the significant result for suffering in this study are treatment effects. However, a follow up study needs to compare music medicine to treatment as usual in a randomized controlled study.

## 5.4 Comparison of the Two Music Medicine Treatments

The Sound Oasis VTS-1000 was predicted to produce a stronger effect than the self-selected music treatment. However, neither the quantitative analyses nor the qualitative analysis of post-treatment interviews suggested that vibroacoustic therapy was more effective than self-selected music.

The primary reason given by the patients for the preference of the self-selected music over the vibroacoustic treatment was the sense of actively participating in their treatment. Patients also reported that it was more difficult to incorporate the vibroacoustic treatment in their schedule. In addition, the finding that self-select music had the most notable effect on mood is more consistent with the mood as mediator model than with the

vibration as mediator model. Self-selected music is also more cost-effective than vibroacoustic therapy, which requires purchasing special equipment. Vibroacoustic therapy may have additional benefits for other disorders such as fibromyalgia (Naghdi et al., 2015), but facial pain may not respond to vibrations in the lower body. Given the low costs, ease of implementation, and promising mood effects in this study, a follow-up study should compare the effectiveness of self-selected music in a randomized controlled study with a treatment as usual control group.

## 5.5 Follow-Up Proposal

Developing proficient, effective, and valid complementary patient-focused treatments with direct benefits to patients who suffer from chronic pain is imperative. To establish the effectiveness of music medicine as a complementary treatment, more solid evidenced-based research is needed (Hillecke, Nickel, & Bolay, 2005). There are a vast number of studies that have examined music in medical settings, but the evidence is comprised by studies with small sample sizes, lack of statistical power to show effect, non-experimental study designs and methods of interventions, and variation in the type and intensity of treatment. As a result, the evidence is mixed and inconclusive (Bradt et al., 2011). The present study added to the existing literature, but also had a number of limitations. These limitations can be addressed in a follow-up study that builds on the results obtained in this groundbreaking study of music medicine as a complementary treatment for TMD.

The most important goal of a follow-up study is to provide stronger evidence that music medicine is an effective treatment by demonstrating a significant difference to a control group with usual care. To examine effectiveness for outcome measures that only showed marginally significant trends in this study, I recommend increasing sample sizes from a total of  $N = 25$  to  $N = 50$ .

I also suggest increasing the number of songs. A few patients complained that the list of 25 songs became repetitive over time. This could also be a problem with the vibroacoustic treatment. Several patients complained that the music was not engaging and repetitive. This could also explain the lack of mood effects in a study by Garrido et al.

(2016) that used a prescribed playlist of 7 songs and participants complained that 7 songs were not enough. Therefore, I suggest to increase the number of songs from 25 to 50 songs.

I propose the following study design for a follow up study.

**Table 5.1**

Proposed Study Design

	N	Pre-Treatment Assessment	Treatment 1	Post-Treatment Assessment	Treatment 2	Follow-up Assessment
<b>1a Group</b>	25		Care as usual (waitlist control)		Self-Select Music	
<b>1b Group</b>	25		Self-Select Music			
VAS		X		X		X
MMS		X		X		X
QoL		X		X		X
Depression		X		X		X
Daily Pain Rating			Daily		Daily	

The expected outcome of the new study design would produce the same improvement in the treatment group and no change in the control group. Furthermore, increasing the number from 25 to 50 would increase power. Lastly, the VAS-daily scale would be used immediately following each treatment and would be required at the end of day. This would be used to measure the effectiveness of the treatment for managing pain throughout the course of the day. Additionally, patients would also be asked to complete an end-of-day medication journal to measure the amount of medication required during treatment.

## 5.6 Final Conclusions

This study examined for the first time the effectiveness of music medicine as a complementary treatment for TMD. The results suggest that music medicine can be an effective complementary treatment as 23 out of 25 patients responded on the Glasgow Benefit Inventory found music medicine beneficial, especially for the psychological symptoms associated with TMD and the suffering associated with chronic pain. Self-selected music was as effective as vibroacoustic therapy, which is consistent with the mood as mediator model. Based on these results, it is possible to recommend self-selected music to manage chronic pain. The key advantage over medical interventions is that there are no-to-low side effects to the use of music as medicine. Thus, even small benefits have direct benefits for patients' well being. Additionally, music can be self-administered, is readily available, reduces stress, low-cost to institute into an existing pain management program, and has low-to-no side effects. The use of music medicine may also help some patients to reduce the amount of medication required to manage pain. Patients with TMD also share symptoms that are similar to other chronic pain disorders, suggesting that self-selected music could easily be integrated into other chronic pain treatment programs.

The results of this study suggests that music medicine may help patients to manage the suffering associated with TMD, but does not reduce the experience of pain. This could be critically important since, regardless of the algesic characteristics of TMD (and perhaps other chronic pain conditions), patients undergoing music therapy report better pain management. This might suggest that management and other outcomes apart from pain alone should be considered as important outcomes for the management of chronic pain conditions; perhaps this is more important than assessment of pain levels themselves and certainly assessment only of pain.

Future research is needed to provide more conclusive evidence for the effectiveness of music to manage pain, to estimate how effective music is, and how it influences pain. It will also be interesting to examine whether music with specific properties has stronger medicinal properties to maximize the effectiveness of music medicine.

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# Appendices

## **Appendix A:** Invitation Letter

**Study Title:** What are the Effects of Music on Temporomandibular Joint Disorder (TMD) Symptoms?

**Investigator/Study Doctor:** Dr. Allan Gordon, Director of Wasser Pain Management Centre at Mt. Sinai Hospital

Alicia Howard, PhD Candidate at the University of Toronto (supervision under Dr. Allan Gordon)

**Contact Information:** 905-617-0386

### **Introduction**

I am Alicia Howard, PhD Candidate at the University of Toronto, Faculty of Music, and I am seeking TMD patients to participate in a research study.

### **Purpose:**

The purpose of the study will be to examine the effectiveness of an innovative use of music medicine on TMD. Music and rhythmic vibrations can alter the basic processes related to sensation of pain in the brain. As well, music can block the neurological pathways that transmit pain sensations and thereby reduce pain. Music and vibrations are relaxing, reduce stress, and thereby reduce sensitivity to pain.

### **Main criteria to participate:**

For this study, it is a requirement that you are hearing able as listening to music is required as part of treatment and your main source of pain is myofascial pain (muscle pain due to inflammation in the body's soft tissues).

### **Location:**

Mount Sinai Hospital's Wasser Pain Clinic, 600 University Ave, Toronto, ON

### **Participation:**

Participation in this study is voluntary and will involve 4 visits to the Mount Sinai Hospital Wasser Pain Clinic. The study will last for 3 months. All music treatments are self-administered in-home and will be required for 30 minutes per day, 5 days per week. Reimbursement for study related to parking will be available.

If you are interested in participating or would like more information, please contact the study coordinator: Alicia Howard, PhD Candidate [alicia.howard@mail.utoronto.ca](mailto:alicia.howard@mail.utoronto.ca).

**Appendix B:** Consent to Participate in Research Study Form

**Study Title:** What are the Effects of Music on Temporomandibular Joint Disorder (TMD) Symptoms?

**Principal Investigator:** Dr. Allan Gordon, Director of Wasser Pain Management Centre at Mt. Sinai Hospital

**Investigator/Study Doctor:** Alicia Howard, PhD Candidate at the University of Toronto (supervision under Dr. Allan Gordon)

**Contact Information:** 905-617-0386

**Introduction:**

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

**Background/Purpose:**

The purpose of the study will be to examine the effectiveness of an innovative use of music on TMD. Music and rhythmic vibrations can alter the basic processes related to sensation of pain in the brain. As well, music can block the neurological pathways that transmit pain sensations and thereby reduce pain. Music and vibrations are relaxing, reduce stress, and thereby reduce sensitivity to pain.

**Study Visits and Procedures:**

You will be asked to participate in a 12-week study where you will be randomly assigned to receive 2 therapeutic music treatments: vibroacoustic therapy in the form of the Sound Oasis-VTS1000 vibrating chair and preferred music playlist. Both music treatments will take place in the comfort of your own home.

Your first study visit will include completing a variety of self-report questionnaires: demographics, pain experience, a short depression scale, mood questionnaire, and quality of life questionnaire.

You will be randomized to begin with either the Sound Oasis-VTS1000 vibrating chair or self-select music intervention. Whether you begin the Sound Oasis-VTS1000 vibrating chair first followed by the self-selected music intervention second or vice versa will be decided randomly (by chance) like flipping a coin or rolling dice. The first self-



administered in-home music intervention will be for 3 weeks, 7 days per week (recommended) but at least a minimum of 5 days per week. During each 3-week music intervention period, you will receive 1 phone call per week from the music therapist arranged at your convenience to see whether you have any questions or difficulty with the treatment each week.

You will continue with your regular pain management regimes, as per your standard care. There will be a 4-week wash-out period between therapeutic music treatments 1 and 2. You will receive no music treatment during this time. The 2 different music therapies will be in addition to standard care. You will be asked to keep a record of the type of medication taken, a pill count, and frequency of medication during this time.

Following the 4-week wash-out period, the second intervention period will begin. If your first intervention was self-selected music, you will then receive Sound Oasis VTS1000. If your first intervention was Sound Oasis VTS100, you will then take part in self-selected music.

During both music treatments (Sound Oasis VTS-1000 and Self-Select Music) and treatment as usual periods you will be asked to keep a daily record of your pain levels.

In order to monitor changes in your pain and mood levels throughout the study, there will be 4 assessment meetings (which will take place at the Wasser Pain Clinic) where you will be asked to complete the following measurement forms: 1) Therapeutic Music and TMD Participant Demographic Form 2) Visual Analog Scale 3) Short Inventory Depression Scale 4) Multi-Dimensional Mood Questionnaire and 5) Quality of Life Enjoyment and Satisfaction Questionnaire 6) Glasgow Benefit Inventory which will be used to evaluate your experience with the therapeutic music intervention and 7) TMD Treatment Review Interview 8) Pain Medication Diary.

The first three assessments will be a total of 30 minutes each. The final and 4th assessment, which will also include an interview, will be approximately 60 minutes in duration.

You will be required to supply a list of music that you enjoy listening to. This song list will be used to create one of your music treatments.

The Sound Oasis VTS-1000 chair is a vibrating cushion that can fit easily on an upright or reclining chair. Sound Oasis VTS-1000 will be available for pick up, following the first assessment meeting, from the Mount Sinai Hospital's Wasser Pain Management Clinic.

**Risks:**

There are low risks with therapeutic music treatments. There may be risks related to using the vibroacoustic therapy system, for example some patients may find the vibration uncomfortable, however, they will be able to adjust the vibration frequency to an intensity that is comfortable for them should they choose.

**Benefits:**

The direct benefit of therapeutic music is that it may provide an alternative for managing your pain related to TMD. Additionally, music can be self-administered, is readily available, reduces stress, and has no to low side-effects. Music interventions have also been shown to decrease the amount of medication required to manage pain.

Information learned from this study may help provide management for sufferers of chronic pain in other illnesses. Music can be effective for the management of chronic pain in other illnesses.

**Confidentiality:**

**Personal Health Information**

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- address,
- date of birth,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 25 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- The study sponsor or its representatives/partner companies.
- Representatives of the Mount Sinai Hospital Research Ethics Board.
- Representatives of Health Canada, or other regulatory bodies (groups of people who oversee research studies), outside of Canada, such as the United States Food and Drug Administration.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

**Voluntary Participation:**

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

**Withdrawal from the Study:**

Your participation is entirely voluntary and you may withdraw at any time by indicating this desire to the researcher (or by withholding your survey document). You, as a participant in this study, have the right to withdraw from this study if so needed.

If you decide to withdraw or refuse to participate in the study, data collected from your participation will be destroyed- papers will be shredded and electronic files will be deleted.

**Costs and Reimbursement:**

Participation in this study is solely on a voluntary basis. The cost for parking will be reimbursed with submission of receipts.

**In Case You Are Harmed in the Study:**

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

**Conflict of Interest:**

As a participant in this study, you state that you are not related to members of the research team, and/or not part of the research team.

Dr. Lee Bartel, who is the dissertation supervisor of the PhD candidate Alicia Howard, serves as a paid consultant for the scientific design of music recordings to the Somerset Group that supplied the music on the Sound Oasis VTS1000. He is not a composer or performer on these Somerset Group recordings but receives limited (non-composer, non-performer) royalties for the Somerset Group Sonic Aid series and for the sound on the VTS1000. Dr. Bartel consulted with Headwaters Corporation on the design development of the Sound Oasis VTS1000, his image and words are used as endorsement for the product, and he receives royalties on the sale of the devices.

**Questions about the Study:**

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Alicia Howard at 905-617-0386, Dr. Allan Gordon at 416-586-5181, or alternatively contact the dissertation supervisor, Prof. Lee Bartel on 416-978-3750.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph. D., Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

**Consent:**

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

<b>Print Study Participant's Name</b>	<b>Signature</b>	<b>Date</b>
My signature means that I have explained the study to the participant named above. I have answered all questions.		

<b>Print Name of Person Obtaining Consent</b>	<b>Signature</b>	<b>Date</b>
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*(continue if applicable)*

Was the participant assisted during the consent process?   **NO**  
If **YES**, please check the relevant box and complete the signature space below:

The person signing below acted as an interpreter for the participant during the consent process and attests that the study as set out in this form was accurately interpreted has had any questions answered.

\_\_\_\_\_  
**Print Name of Interpreter**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Relationship to Participant**

\_\_\_\_\_  
**Language**

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

\_\_\_\_\_  
Print Name of Witness

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Participant

**Appendix C: Instructions: Sound Oasis VTS1000**

In the morning, select “energize” and use for 30 minutes.

a) Press the Power Button to turn the unit on. The unit will automatically start playing the ENERGIZE THERAPY SESSION.

The Remote Control Display will show:

ENERGIZE THERAPY SESSION

b) Adjust the vibration intensity to 15 and the volume to 1 or 2.

The unit will play all three (3) ENERGIZE tracks and then continue looping all three (3) tracks unless you press the ENERGIZE BUTTON. Pressing the ENERGIZE BUTTON will play and loop ENERGIZE THERAPY TRACK 1.

The unit will automatically turn off after 30 minutes.

**Appendix D: Music Medicine and TMD: Participant Demographic**

Please do not write your name on this form. This information will be added to other information you provide and will become part of your file during this study.

1. **Gender:** Male \_\_\_ Female \_\_\_ Other \_\_\_
2. **Age:** \_\_\_\_\_
3. **Ethnicity:** \_\_\_\_\_
4. **When you were first diagnosed with TMD?**
5. **How do you currently manage your pain?**
  - **Medication**
  - **Relaxation**
  - **Other (please describe)**
6. **Have you tried alternative approaches to managing your pain?**
  - **(If yes, please describe)**
7. **Please list your 25 favorite songs?**
8. **What type of device will you use to listen to you favorite songs?**

**Appendix E:** Tenenbaum-Visual Analog Scale (VAS)-Practice (Park/T-Shirt)

Please indicate how you would feel wearing a winter coat with a parka in the middle of a hot day in July/August:

Much Worse \_\_\_\_\_ Much Better

Please indicate how you would feel wearing only a t-shirt in the middle of a cold day in December/November:

Much Worse \_\_\_\_\_ Much Better



**Appendix F: Tenenbaum-Visual Analog Scale (VAS)-Practice (Black Square)**

1) How black/dark is this square?



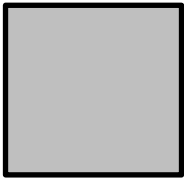
Not at all \_\_\_\_\_ Extremely

2) How black/dark is this square?



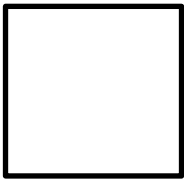
Not at all \_\_\_\_\_ Extremely

3) How black/dark is this square?



Not at all \_\_\_\_\_ Extremely

4) How black/dark is this square?

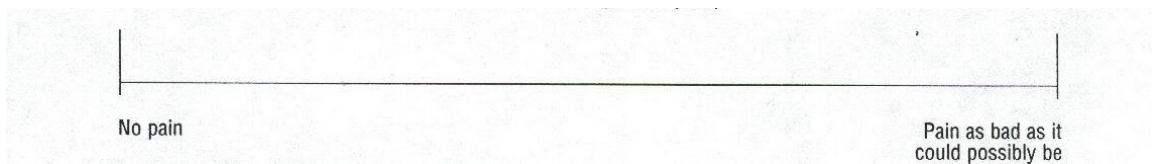


Not at all \_\_\_\_\_ Extremely

**Appendix G: Visual Analog Scale (VAS)**

Date: \_\_\_\_\_

How intense is your pain today? Place a vertical mark or “x” on the line below to indicate how you feel your pain today.



A horizontal line representing the Visual Analog Scale. The line is flanked by two vertical tick marks. Below the left tick mark is the text "No pain". Below the right tick mark is the text "Pain as bad as it could possibly be".

**Appendix H: Multi-Dimensional Mood Questionnaire**

Date: \_\_\_\_\_

The following questions are about your feelings IN THE PAST 7 DAYS (not at this moment).

On a typical day, how much did you experience the following feelings?

1	2	3	4	5	6	7
<b>almost almost never always</b>	<b>very rarely</b>	<b>rarely</b>	<b>sometimes</b>	<b>often</b>	<b>very</b>	<b>often</b>

[Please check or circle numbers, **do not** check between numbers]

	1	2	3	4	5	6	7
	Almost Never			Almost Always			
1. I felt <b>bad</b>	-----	-----	-----	-----	-----	-----	-----
2. I felt <b>tired</b>	-----	-----	-----	-----	-----	-----	-----
3. I felt <b>angry</b>	-----	-----	-----	-----	-----	-----	-----
4. I felt <b>positive</b>	-----	-----	-----	-----	-----	-----	-----
5. I felt <b>alert</b>	-----	-----	-----	-----	-----	-----	-----
6. I felt <b>pleasant</b>	-----	-----	-----	-----	-----	-----	-----
7. I felt <b>cheerful</b>	-----	-----	-----	-----	-----	-----	-----
8. I felt <b>sad</b>	-----	-----	-----	-----	-----	-----	-----
9. I felt <b>anxious</b>	-----	-----	-----	-----	-----	-----	-----
10. I felt <b>relaxed</b>	-----	-----	-----	-----	-----	-----	-----
11. I felt <b>sluggish</b>	-----	-----	-----	-----	-----	-----	-----
12. I felt <b>happy</b>	-----	-----	-----	-----	-----	-----	-----
13. I felt <b>energetic</b>	-----	-----	-----	-----	-----	-----	-----
14. I felt <b>negative</b>	-----	-----	-----	-----	-----	-----	-----
15. I felt <b>good</b>	-----	-----	-----	-----	-----	-----	-----
16. I felt <b>afraid</b>	-----	-----	-----	-----	-----	-----	-----
17. I felt <b>calm</b>	-----	-----	-----	-----	-----	-----	-----
18. I felt <b>unpleasant</b>	-----	-----	-----	-----	-----	-----	-----
19. I felt <b>irritated</b>	-----	-----	-----	-----	-----	-----	-----
20. I felt <b>lively</b>	-----	-----	-----	-----	-----	-----	-----
21. I felt <b>depressed</b>	-----	-----	-----	-----	-----	-----	-----

22. I felt **sleepy** ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
23. I felt **joyful**----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
24. I felt **worried** ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
25. I felt **blue**----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
26. I felt **annoyed** ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7
27. I felt **peaceful**----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7

**Appendix I:** Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF)

Date: \_\_\_\_\_

Reflecting on everything which has happened in the past week, how satisfied have you with....

	Very Poor	Poor	Fair	Good	Very Good
.....physical health?	1	2	3	4	5
.....mood?	1	2	3	4	5
.....work?	1	2	3	4	5
.....household activities?	1	2	3	4	5
.....social relationships?	1	2	3	4	5
.....family relationships?	1	2	3	4	5
.....leisure time activities?	1	2	3	4	5
.....ability to function in daily life?	1	2	3	4	5
.....sexual drive, interest and/or performance?*	1	2	3	4	5
.....economic status?	1	2	3	4	5
.....living/housing situation?*	1	2	3	4	5
.....ability to get around physically without feeling dizzy or unsteady or falling?*	1	2	3	4	5
.....your vision in terms of ability to do work or hobbies?*	1	2	3	4	5
.....overall sense of well-being?	1	2	3	4	5
.....medication? (If not taking any, check here _____ and leave item blank.)	1	2	3	4	5
.....How would you rate your overall life satisfaction and contentment during the past week?	1	2	3	4	5

\*If satisfaction is very poor, poor or fair on these items, please UNDERLINE the factor(s) associated with a lack of satisfaction.

**Appendix J: Short Depression Inventory**

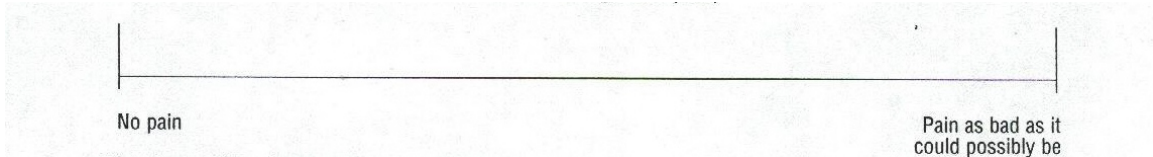
Date: \_\_\_\_\_

<b>Items</b>	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)
1. I was bothered by things that usually don't bother me.				
2. I had trouble keeping my mind on what I was doing.				
3. I felt depressed.				
4. I felt that everything that I do takes effort.				
5. I felt hopeful about the future.				
6. I felt fearful.				
7. My sleep was restless.				
8. I was happy.				
9. I felt lonely.				
10. I could not "get going".				

**Appendix K:** Daily Pain Rating Scale (VAS)

Date: \_\_\_\_\_

How intense is your pain today? Place a vertical mark or “x” on the line below to indicate how you feel your pain today.



No pain

Pain as bad as it could possibly be

**Appendix L: The Glasgow Benefit Inventory (GBI) questionnaire- TMD (all-purpose)**

Date: \_\_\_\_\_

**1. Has the result of the Music Medicine Intervention affected the things you do?**

Much worse	A little or somewhat	No change worse	A little or somewhat	Much better better
1	2	3	4	5

**2. Have the results of the Music Medicine Intervention made your overall life better or worse?**

Much better	A little or somewhat	No change better	A little or somewhat	Much worse worse
5	4	3	2	1

**3. Since your Music Medicine Intervention, have you felt more or less optimistic about the future?**

Much more optimistic	More optimistic	No change	Less optimistic	Much less optimistic
5	4	3	2	1

**4. Since your Music Medicine Intervention, do you have more or less self-confidence?**

Much more self-confidence	More self-confidence	No change	Less self-confidence	Much less self-confidence
5	4	3	2	1

**5. Since your Music Medicine Intervention, have you found it easier or harder to manage the pain levels associated with your TMD?**

Much easier	Easier	No change	Harder	Much harder
5	4	3	2	1

**6. Since your Music Medicine Intervention, do you feel that your mood has improved or worsen?**



Much better	A little or somewhat	No change better	A little or somewhat	Much worse worse
5	4	3	2	1

**7. Have you been to your family doctor, for any reason, more or less often, since your Music Medicine Intervention?**

Much more often	More often	No change	Less often	Much less often
1	2	3	4	5

**8. Would you feel confident to receive Music Medicine treatment in the future?**

Much more confident	More confident	No change	Less confident	Much less
5	4	3	2	1

**9. Since your Music Medicine Intervention, do you feel more or less stress?**

Much more stress	More stress	No change	Less stress	Much less stress
1	2	3	4	5

**10. Since your Music Medicine Intervention do you feel more or less productive in your daily activities?**

Much more productive	More productive	No change	Less productive	Much less productive
5	4	3	2	1

**11. Since you had the Music Medicine Intervention, do you feel pain more or less often?**

Much more often	More often	No change	Less often	Much less often
1	2	3	4	5

**12. Have you had to take more or less medicine for any reason, since your Music Medicine Intervention?**

Much more medicine 1	More medicine 2	No change 3	Less medicine 4	Much less medicine 5
----------------------------	-----------------------	-------------------	-----------------------	----------------------------

**13. Since your Music Medicine Intervention, do you feel better or worse about yourself?**

Much better 5	Better 4	No change 3	Worse 2	Much worse 1
---------------------	-------------	-------------------	------------	--------------------

**14. Since your Music Medicine Intervention, do you feel that you have had more or less support from your friends and/or family?**

Much more support 5	More support 4	No change 3	Less support 2	Much less support 1
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**15. Since your Music Medicine Intervention, are you more or less inconvenienced by your TMD symptoms?**

Much more inconvenienced 1	More inconvenienced 2	No change 3	Less inconvenienced 4	Much less inconvenienced 5
----------------------------------	-----------------------------	-------------------	-----------------------------	----------------------------------

**16. Since your Music Medicine Intervention, have you been able to participate in more or fewer social activities?**

Many more activities 5	More activities 4	No change 3	Fewer activities 2	Many fewer activities 1
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**17. Since your Music Medicine Intervention, have you been more or less inclined to withdraw from social situations?**

Much more inclined 1	More inclined 2	No change 3	Less inclined 4	Much less inclined 5
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**Appendix M:** TMD Treatment Review (Interview Questions)

Date: \_\_\_\_\_

TMD Treatment Review

1. How was it to follow the music medicine prescription? Were there any challenges?
2. How did you feel during the vibroacoustic therapy treatment? Did you fall asleep during the VAT interventions?
3. If you experienced other pains which were minor compared to your TMD, how were they affected by the music treatments?
4. How would you describe your experience with music medicine for managing TMD? Would you use music medicine treatments again to manage your TMD pain? If yes, which one would you use?

**Appendix N: Pain Medication Journal**

Instructions- Please list each medication and the amount taken at that time.

Date	Time	Medicine Used and Amount	Other things I tried	Comments:

**Appendix O: Music Medicine Treatment Response**

1) Music Medicine Treatment Preference	Patient felt that music treatment was much easier to follow, no difficulty. Vibroacoustic device was a bit more difficult for set up.
2) Music Medicine Treatment Response	Patient stated that the vibroacoustic device was hard on her body during the first day of treatment. She found that it was helpful with tension and pain temporarily.
3) Music Medicine Treatment Response	Patient stated that the vibroacoustic device was a bit stressful.
4) Music Medicine Treatment Response	Patient said the intensity level 15 of the vibroacoustic device was a bit too strong and made her feel nauseated. She added that intensity level 10 was OK, but if she was a bit tired, it would make her feel sick as well. During the VAT treatment, patient stated that she experienced motion sickness. Patient also was a bit worried about continuing treatment due to her prior negative response to treatment.
5) Music Medicine Treatment Response	Patient said the vibration of the chair was not pleasant. She found the intensity level to strong, even after lowering the level. When comparing the VAT to the music treatment, she said that she was not limited as to where she could use the music. She also stated that using the chair in the evening, instead of in the morning, was better and helped with sleeping.
6) Music Medicine Treatment Response	Patient said that she felt that the chair was ineffective. She added that the chair did not match her lifestyle. Patient stated that it was difficult to get comfortable when using the vibroacoustic device. The ergonomics of the VAT device did not work for her.

7) Music Medicine Treatment Response	Patient said that the vibroacoustic device put her in a bad mood. However, when she was using her own music during the music treatment, it was great. Patient said her music made her feel mellower. She added that the music improved mood, making her feel happier and calmer. Her own music helped her to feel that she was in her own space.
8) Music Medicine Treatment Response	<p>Patient said that she did not like being restricted to a 25-song playlist. She would have preferred to select the music based on her mood for that moment.</p> <p>Patient added that she did not like the vibroacoustic device. She found the intermittence in the rhythm very distracting.</p>
9) Music Medicine Treatment Response	Patient said that she had difficulty using the vibroacoustic device. She reported that the beginning of the treatment was painful because it was vibrating her jaw, but then it became a bit more relaxing. Patient had to lower the frequency to reduce the pain, but towards end of the study, she was able to return to the recommended number of 15.
10) Music Medicine Treatment Response	Patient said he found the chair painful.
11) Music Medicine Treatment Preference	Patient suggested that the he was not comfortable selecting his music for treatment because he could select the wrong music. He also added that the vibroacoustic device had more positive effect for him but the difficulty was following through. The patient concluded that he experienced a mood boosting effect and pain relief experienced from VAT.
12) Music Medicine Treatment Response	Patient said that one of the main issues for her regarding treatment was making the time, especially in the morning. She also added that VAT helped with lower back menstrual pain.
13) Music Medicine Treatment Response	Patient said that he liked the VAT device. It was like having a massage. He felt that the VAT energized him.

14) Music Medicine Treatment Response	Patient said that he had a lot of challenges with the music component. He said that he found it difficult to stay focused for the required amount of time of 30 minutes. Patient also added that he felt that VAT had a more tangible impact. Both treatments had some impact on mood, but did not feel much change in pain.
15) Music Medicine Treatment Response	Patient said that is was difficult to stay in the chair because it was painful and uncomfortable.
16) Music Medicine Treatment Response	Patient said that is was difficult to stay in the chair because it was painful. She added that she found it hard to sit down for a long time and that the chair was disruptive to her schedule. The music was easier because she could still function.
17) Music Medicine Treatment Response	Patient said that she found no challenges with the music medicine treatments. However, the music portion was most rewarding.
18) Music Medicine Treatment Response	Patient said that she found the frequency level 15 of the VAT device made her nervous and gave her pain, so she lowered the frequency to 1.
19) Music Medicine Treatment Response	Patient said that the VAT device made her light pain more intense.
20) Music Medicine Treatment Response	Patient stated that the chair device gave him more pain. He changed the setting of the chair and found it more tolerable. However, he could not continue using the chair for the entire treatment time because it was too painful. He also said that he initially thought that he was not able to tolerate the chair because he had pain problems but realized later that the complication was with the chair.

21) Music Medicine Treatment Response	Patient stated that she found it difficult to sit for 30 minutes for the music treatment because her mind was always thinking of things she might not be doing. To adjust to this issue, she used the music treatment while she walked to home from work. She said that the music treatment was more effective this way.
22) Music Medicine Treatment Response	Patient stated that the VAT device gave her motion sickness and that the vibrations were a bit too strong.
23) Music Medicine Treatment Response	Patient stated that she found VAT relieved lower back tension. It also helped with neck tension.
24) Music Medicine Treatment Response	Patient stated that the first VAT treatment was initially good but the next day the VAT treatment hurt her body. She said that the pain she received put her in a bad mood.
25) Music Medicine Treatment Response	Patient said that she found the music of the vibroacoustic device good but did not like the vibrations. She found the vibrations too strong.