Should Individualized Music Therapy be Considered as an "Essential Medicine" to Treat Elderly with Dementia as Defined by the World Health Organization?

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I intend to submit a copy of my Health Science Scholars thesis to the Texas ScholarWorks (TSW) Repository. For more information on the TSW, please visit https://repositories.lib.utexas.edu/.

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Table of Contents

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Abstract

The World Health Organization (WHO) biennially maintains a list of essential medicines that countries and organizations use to establish internal pharmaceutical supplies and to develop healthcare policies. Despite its effort to provide a comprehensive list, the essential medicines list lacks many other potentially beneficial treatments, such as individualized music therapy. The prevalence of dementia increases each year in many developed and developing countries. Individualized music therapy has been shown to be an effective form of treatment for dementia. Unfortunately, many still lack access to this treatment due to unpopular views regarding complementary medicines and a lack of insurance coverage for such therapies. However, this could potentially be altered if individualized music therapy is added to the essential medicine list. This thesis aims to provide evidence showing the current state of individualized music therapy as a treatment for dementia. It considers the six criteria used by the WHO to determine essential medicine status and details the deficits in the current peer-reviewed research of music therapy that would need further attention in order to be considered by the WHO as an essential medicine in the adults list for dementia. Based on extensive literature review and personal data collection, it was concluded that criteria 1 and 2 have been met, criteria 4 and 5 may need further data, and criteria 3a and 3b definitely need more evidence. This thesis shows that existing evidence to date does not objectively meet criteria 3a, 3b, 4, and 5. Future studies should focus on further developing evidence in these categories before individualized music therapy can be considered to be a core essential medicine for the adults list in treating dementia.

Introduction

The World Health Organization (WHO) released in 1977 the first list of 208 essential medicines (WHO, 1977). These medicines were chosen because of their ability to "provide safe, effective treatment for the majority of communicable and non-communicable diseases" (WHO, 2016, para. 8). This list has been important due to the immense impact pharmaceuticals have in the health and economy of countries. According to a 2020 report by the WHO, in many developing countries, pharmaceuticals have become the second largest public health expenditure and largest household health expenditure. Furthermore, expenses stemming from treating a serious illness is one of the major causes that leads to household impoverishment (WHO, 2020). Even in developed countries, pharmaceuticals encompass around one-fifth of total public and private health spending. Thus, by providing a list of essential medicines, the WHO can guide the process of acquisition, production, and donation of medicines as well as reimbursement for medical costs in public and private sectors. In fact, many international organizations, nongovernmental organizations, and international non-profit organizations as well as other countries have adapted or used this list as a basis for determining the supply and acquisition of medicines for individual countries, and to help guide policy regarding the use of medicines (WHO, 2020).

The definition of essential medicine has evolved throughout the years. The original 1977 concept was to define and develop a list of medicines that were "of the utmost importance, and are basic, indispensable and necessary for the health needs of the population" (WHO, 1977, p. 9). Since then, the definition has been updated to include medicines "that satisfy the priority health care needs of the population" (WHO, 2002, p. 1), thus allowing the list to become more

comprehensive. The list of essential medicines is also separated into a core list and a complementary list. According to the WHO (2007), the core list consists of:

> Minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. (p. 3)

The complementary list "presents essential medicines for priority diseases which are efficacious, safe and cost-effective but not necessarily affordable, or for which specialized health care facilities or services may be needed" (WHO, 2007, p. 3). For example, under the category of "Non-opioids and non-steroidal anti-inflammatory medicines (NSAIMs)," ibuprofen is considered as a core essential medicine while acetylsalicylic acid (Aspirin) is considered as a complementary essential medicine (WHO, 2007, p. 5). Acetylsalicylic acid is considered as a complementary essential medicine since it is only specifically used for rheumatic fever, juvenile arthritis, and Kawasaki disease. In addition, a separate list of essential medicines was created for children in 2007 (WHO, 2007).

Since 1977, a new list of essential medicines has been released every two years. Despite the constant effort by the WHO to provide a comprehensive list of essential medicines, the list still needs to be elaborated further to include more diverse forms of treatments. One prime example is the use of individualized music therapy for dementia. Many developed countries, such as the United States, have an aging population (Kinsella & Phillips, 2005). Due to the sudden increase in life expectancy in these countries over the past few decades, it is projected that the median age of the population will increase dramatically in the next few decades (WHO, 2010). With an aging population and rise in non-communicable diseases, it is also anticipated

that the illnesses associated with age, such as dementia, will increase as well (WHO, 2017). The incidence of dementia has been shown to be increasing in developing countries such as Nigeria and China as well (Zhu et al., 2019; Skaalum et al. 2019). There has been extensive research that individualized music therapy shows promise in treating patients with dementia. If added to the list of essential medicines, individualized music therapy could be more easily accessible to treat many patients in the future.

This thesis seeks to establish a roadmap of how to optimize the opportunity for the World Health Organization (WHO) to consider individualized music therapy as an adult core essential medicine to treat dementia. Through literature review and personal data collection, this thesis offers a definition of individualized music therapy, details the reasons regarding our culture's skepticism toward alternative and complementary medicines as an essential part of treatment, outlines the criteria for a treatment to become an essential medicine, and offers evidence of which criteria are met and which need further research for individualized music therapy to become an essential medicine within the WHO.

Definition: Individualized Music Therapy

According to the American Music Therapy Association (n.d.), the official definition of music therapy is "the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program" (para. 1). By successfully completing a Bachelor's degree in music therapy and passing the national certification exam, an individual can obtain the credential Music Therapist-Board Certified (MT-BC) (American Music Therapy Association, n.d.). Thus, music therapy is not simply listening to songs (i.e. from a radio, an

electronic device, or record player) and can be adjusted depending on the patient's illnesses and situation. While there are broad forms and applications of music therapy, this thesis focuses only on one-on-one interventions, which will be called individualized music therapy, and its use in treating elderly patients with dementia. According to Mckhann (1984), "dementia is the decline of memory and other cognitive functions in comparison with the patient's previous level of function as determined by a history of decline in performance and by abnormalities noted from clinical examination and neuropsychological tests" (p. 939). As defined by the United Nations, elderly will refer to anyone who is 60 years or older (WHO, 2002).

Background: The Evolution of Music Therapy

Music has been integrated into medical practices across several cultures since ancient times, and its role in medicine has continuously changed throughout time. This thesis briefly describes the history and evolution of music therapy.

Root of Music Therapy

Prior to development of civilizations, music played an important role in healing rituals (Sonke, 2011). Prime examples were healing rituals found in Greek temples of Asclepius, the god of medicine. Individuals were put to sleep with music to enter a spiritual state where Asclepius would bring a diagnosis and treatment for the illness (Sonke, 2011). During the Renaissance (14^{th} to the 17^{th} century), music continued to play a role in medicine. Due to its emotive powers, music was thought to help balance the soul and treat sadness (Lippi et al, 2010). Music therapy gained further interest during the 18^{th}-19^{th} century. This was because it was believed to serve as a useful adjunct to improve other therapies as well as to help induce a trance-like state (i.e. mesmerism or animal magnetism) treatments that were popular at that time (Lippi

et al., 2010). In 1789, the term music therapy was first used in an article in Columbian Magazine (1789). During the mid 1800s, the first recording of music therapy in an institutional setting occurred in hospitals located in Blackwell's Island, New York (Kingsbury, 1847). Furthermore, the first recorded systematic study of music therapy was published in the late 1800s (Corning, 1899). This increasing evidence in support of the therapeutic effects of music allowed music therapy to rise in popularity with medical providers and the public. However, sometime after this period, modern medicine evolved, and the medical culture shifted to an emphasis on science and evidence-based medicine over potential treatments that mainly dealt with aspects that cannot necessarily be objectively measured such as increased quality of life. Thus, music as a form of therapy lost its popularity with the lack of science supporting its use (Lippi et al., 2010).

The Flexner Report

In the early 20th century, there was an immense reduction in health care professionals' understanding and need to treat the psychological aspect of patients alongside the physical components (Lippi et al., 2010). One prominent reason for this was due to the Flexner Report. This 1910 study was commissioned by the Council on Medical Education to improve the standards of medical school and quality of the medical students (Brown 2017). Consequently, this report called for a substantial change in the medical education system. It recommended that medical schools train physicians to treat patients in a more scientific manner, control clinical instruction within hospitals, and engage medical school faculty members to participate in research (Flexner, 1910). The report also ridiculed complementary medicines such as music therapy. Flexner doubted these forms of treatment since they lacked significant scientific backings compared to modern medicine, and required qualitative measures as opposed to quantitative measures that were much easier to substantiate. Medical schools that incorporated

alternative medicine approaches were instructed to cease teaching these or lose their accreditation (Flexner, 1910). Although few resisted, eventually all medical schools either stopped teaching alternative medical approaches that lacked scientific evidence, or were forced to shut down (Ballweg et al., 2008). Furthermore, doctors participating in these forms of treatments were derided (Flexner, 1910). Although the quality of an average physician significantly increased, this consequently diminished doctor-patient relationships (Ballweg et al, 2008). Medicine had shifted from relieving the suffering of the patient to treating the diseases and prolonging patient life. This had marked the end of many forms of alternative medicines, including music therapy. Thus, when the WHO began releasing a list of essential medicines in the late 1900s, it was nearly impossible for alternative and complementary medicines to become part of these lists.

Rise of Music Therapy since the Flexner Report

With the rapid advances of medical technology in the 20th century, the most commonly diagnosed diseases shifted from being acute and infectious to chronic and degenerative as the natural history of many diseases began to be altered due to the extension of life expectancy as people began living longer with diseases that would otherwise have taken their lives (Lippi et L., 2010). The Flexner Report led to medical education having a much greater focus on science and technology and much less on the psychosocial aspects of a person's illness. The failure to treat all aspects of an illness (physical and psychosocial), and the training of students who were more scientifically motivated and who cared less about the emotional wellbeing of their patients, caused the American public to begin to lose trust in many aspects of modern medicine (Lippi et al., 2010). This loss of trust, particularly in various ethnic groups, made it difficult for health care professionals to effectively treat their patients (Lippi et al., 2010). More medical consumers

began looking toward and considering alternative therapies again, one of which was music therapy (Lippi et al., 2010; McMasters, 2015).

Music therapy gained popularity as it called for a deeper doctor-patient relationship and seemed to have a more "human and caring therapist" (Lippi et al., 2010, p. 137). The WHO became aware of this new perspective to treating patients and redefined health as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity" (WHO, 1948, para. 1). The pendulum of medicine began to gradually swing from "curing the disease" to "caring for the sick." (Zannini, 2008, p. 4). Despite gaining more popularity in the 20th century, music therapy, as with most alternative and complementary therapies and medicines, still lack widespread support. Some of this can be accredited to the lack of evidence-based scientific study within this field due to lingering effects of the Flexner Report (Lippi et al., 2010). Fortunately, the numbers of peer-reviewed studies within the field of music therapy are slowly increasing, and should contribute to the overall knowledge that we be critical for consideration of becoming an essential medicine for the treatment of dementia.

Methods

A proposed medicine must meet several criteria before being considered an essential medicine. First, an application must be submitted by an institution or a company with a deep understanding of the treatment to the secretary of the Expert Committee. From there a systematic review is performed by relevant committees within the WHO. The specific criteria that must be evaluated by the committee(s) for a medicine to be considered essential are as follows according to the WHO (2001):

1. Information supporting the public health relevance (epidemiological information on disease burden, assessment of current use, target population)
2. Treatment details (dosage regimen, duration; reference to existing WHO and other clinical guidelines; need for special diagnostic or treatment facilities and skills)
3. Summary of comparative effectiveness in a variety of clinical settings
4. Summary of comparative evidence on safety
5. Summary of available data on comparative cost and cost-effectiveness within the pharmacological class or therapeutic group (p. 7)

All other criteria such as "name of the organization(s) consulted and/or supporting the application," " summary of regulatory status of the medicine," etc. (p. 7) were beyond the scope of the thesis. These criteria are applicable to whoever submits a formal application to the WHO for individualized music therapy to be considered as an essential medicine in the future. This thesis seeks to aid such a submission by providing evidence in a multi-methods study and details for a future application as well as calling into light what aspect of the application requires further evidence.

Criteria 3 was split into 3a and 3b, which will be explained below. Data supporting criteria 2, 3a, part of 4, and 5 were gathered from personal data collection. The treatment details and proposed aims (criterion 2) and comparative safety of individualized music therapy (criterion 4) were generated from an interview with a licensed music therapist at the Center for Music Therapy in Austin, Texas. Data concerning the effectiveness of individualized music therapy on the proposed aims from the interview (criterion 3a) were gathered through personal observations of individualized music therapy sessions. The cost and comparative cost-effectiveness of individualized music therapy to Donepezil (a common treatment for mild to moderate dementia)

was obtained by calling different music therapy centers in Austin, Texas for their rate per session as well as searching online for the retail price of Donepezil. Data for criteria 1, 3b, and part of 4 were generated from a general literature review by Google Scholar and other online information from the WHO's website.

Criterion 1 - The Public Health Relevance

The public health relevance of individualized music therapy (criterion 1) was answered using articles and documents published by the WHO as well as articles generated from a Google Scholar search. Articles and documents within the WHO's website discussing dementia prevalence were reviewed. In Google Scholar, the key term "dementia prevalence" was searched. The search was further filtered to only include articles since 2019 and sorted by relevance. There were 21600 articles that fit these criteria. Only the articles in the first three pages (10 articles per page) were considered since they would be the most relevant articles. Of these 30, only those that discussed the trend and prevalence of dementia were selected for the literature review of criterion 1. Furthermore, articles that discussed the effects of a person with dementia on family caregivers and loved ones were selected out of these 30 articles for review.

Eight of the identified articles discussed the trend of dementia. Of the eight articles, five articles discussed the trend of dementia for developed countries, two articles discussed developing countries, and one discussed a self-governing nation under Denmark. Furthermore, two more articles discussing the effects of dementia on the caregivers/loved ones were identified and analyzed.

Criterion 2 - Treatment Details and Its Aims

In the interview with the music therapist, the following open-ended question was asked: "How do you determine the frequency of treatment sessions for the elderly with dementia?"

Other questions asked were based upon the WHO's "Risk reduction of cognitive decline and dementia" guideline. This guideline categorizes different recommendations that alleviate the symptoms/effects of dementia as either strong or conditional. According to the WHO, "strong recommendations imply that most individuals would want the intervention and should receive [them], while conditional recommendations imply that different choices may be appropriate for individual patients and they may require assistance at arriving at management decisions." (WHO, 2017, p. 3). The recommendations were categorized according to their quality of evidence: insufficient, very low, low, moderate, or high. For instance, the WHO indicates that there is moderately strong evidence that tobacco causes further cognitive decline, and therefore strongly recommend that patients with dementia receive tobacco cessation interventions. Only the recommendations with quality of evidence of low or above were taken into consideration and asked during the interview. If the quality of evidence had a range that included either insufficient or very low, it was also excluded to simplify the interview. Lastly, if the intervention did not apply to the elderly, it was excluded. The questions asked were:

- What are the main aspects of dementia that individualized music therapy is seeking to alleviate? Specifically, does it aim to help patients:
    - Recover motor and cognitive functions to the point that they can participate in increased amount of physical activities?
    - Reduce their tobacco intake?
    - Increase their appetite to eat a more healthy and well-balanced diet?
    - Reduce their alcohol intake?
    - Manage their weight?
    - Manage their pre-existing hypertension?

Continuing with the example of tobacco cessation intervention, if the goal of individualized music therapy is to aid in decreasing tobacco intake of the patient and proves to be effective, it can be considered a strong recommendation for patients with dementia. Throughout the music therapist interview, only questions concerning what individualized music therapy aims to improve were asked. Subsequently, the effect of individualized music therapy on these proposed aims were observed during individualized music therapy sessions.

Criterion 3a - Effectiveness of Treatment on Proposed Aims

This thesis intended to perform a limited observational study of the effects of individualized music therapy on the proposed aims from criterion 2, but Austin's Shelter-in-Place order from the Coronavirus pandemic precluded any more than a one-time observation of an individualized music therapy session for three patients. Therefore, the observations described are anecdotal, but are included to address criterion 3a in this thesis. These observational results need validated evidence to see if the assumptions are correct. This should be done through randomized and controlled clinical trials using individualized music therapy as an intervention.

Based on the interview with the music therapist, individualized music therapy seeks to improve a patients' motor and cognitive functions to the point that the patient can participate in physical activities, reduce addictive behaviors such as tobacco and alcohol, increase appetite, and manage pre-existing hypertension. However, enhancing appetite and managing hypertension involve the use of individualized music therapy along with other forms of treatment, and was therefore not observed or included in this report. Unfortunately, due to the aforementioned circumstances, the observation was only a single 1-hour session for each patient, and any reduction in addictive behaviors could not be observed over time. Thus, only the effects of individualized music therapy in treating the elderly with dementia to improve patients' motor and

cognitive functions during and immediately following the intervention were observed and discussed.

One patient was observed at a one-on-one (one patient and one therapist) individualized music therapy session (Client 1). The other two patients were given a two-on-one session, (two patients and one therapist; Clients 2 and 3). Although the two-on-one session does not meet the definition of individualized music therapy, the results are included because the two patients did not conflict with one another during the session and were given full attention by the therapist throughout the session. Because Client 3 was < 60 years of age, they were excluded from the results. Both Clients 1and 2 carried the diagnosis of dementia with underlying Parkinson disease. Observed patients were deemed by their physicians to be decisional, and appropriate informed consent to observe was obtained from each subject as required by the University of Texas Institutional Review Board.

Criterion 3b - Comparative Effectiveness

To understand the comparative effectiveness of individualized music therapy (criterion 3b), articles referenced by a Cochran Library meta-analysis article were used for literature review (van der Steen et al., 2018). The Cochrane Library article discusses the effects of music therapy interventions on dementia. It chose 22 articles out of 1809 screened articles based on several criteria. Some important criteria to mention are that the patients were formally diagnosed with dementia based on an accepted diagnostic criterion such as DSM-5, a minimum of five intervention sessions were delivered to patients, and primary and secondary outcomes such as emotional well-being and cognition, respectively, were measured and reported. Of the 22 articles, 19 articles were not included in our review because the studies included patients who were <60 years of age. Therefore, three articles were chosen for the literature review of the

comparative effectiveness of individualized music therapy. All three articles were composed of a >60-year-old population that were taking medication for dementia prior to and during the research. If any changes in medication intake occurred, it was reported. Patients on a dementia medication were then compared to patients on a dementia medication who also received individualized music therapy.

Criterion 4 - Comparative Safety

The comparative safety of individualized music therapy (criterion 4) was answered using personally collected data based from an interview with the music therapist at the Center for Music Therapy and using some of the articles chosen for criterion 3b. The question, "What is/are side effects and/or risks associated with individualized music therapy?" was asked.

Criterion 5 - Comparative Cost and Cost Effectiveness

The comparative cost and cost-effectiveness of individualized music therapy (criterion 5) within Austin, Texas was analyzed and compared with the cost of a common Alzheimer's medication called Donepezil (Aricept) for elderly patients with mild to moderate dementia. The cost of 30 tablets of 10 mg Donepezil was calculated to provide a monthly cost. For both individualized music therapy and Donepezil, the retail prices were compared. There were three websites, ConsumerReport, GoodRX, and SingleCare that discussed the monthly retail price of 10 mg dosage of Donepezil. The three retail prices were averaged and compared to the price of individualized music therapy. The five music therapy centers in Austin, Texas were asked to provide their respective hourly rates for an individualized music therapy session and the frequency of the patient visits. Of the five music therapy centers, two were excluded from analysis because the patient population seen were exclusively children at one center, and because dementia was not treated at the second center. The remaining clinics were named Clinic 1, 2, and

3. The monthly costs were then averaged. Since the price for Clinic 1 was an outlier, the median prices of the three music therapy clinics were reported and used to compare to the average price of Donepezil.

Table 1 shows a summary of each criteria and the methods used.

Table 1

The WHO's Criteria to Determine an Essential Medicine and the Methods Used to Address Each for Individualized Music Therapy

Criteria	Method
1 – The Public Health Relevance	Google Scholar Literature Review
2 – Treatment Details and its Aims	Personal Data Collection - Interview
3a – Effectiveness of Treatment on Proposed Aims	Personal Data Collection - Observation
3b – Comparative Effectiveness	Cochrane Library Literature Review
4 – Comparative Safety	Cochrane Library Literature Review & Personal Data Collection - Interview
5 – Comparative Cost and Cost-effectiveness	Personal Data Collection - Interviews and Google

Results

The results indicate that individualized music therapy needs further studies and evidence before completely meeting the criteria as an essential medicine. This thesis describes which criteria are met and which require further evidence.

Criterion 1 - The Public Health Relevance

The WHO predicted in 2004 that there would be around 35.6 million people with dementia by 2010 and 65.7 million by 2030 (WHO, 2013). However, in 2017, dementia was affecting almost 50 million people around the world according to the WHO, far exceeding the original prediction. This number is predicted to further increase to 82 million by 2030 and 152 million by 2050 (WHO, 2017). In fact, many studies indicate an upward trend of cases of dementia as shown below.

Many developed countries have an aging population. Due to a continuous decline in fertility rate but increase in life expectancy, the average age of their populations increases each year (WHO, 2010). With older age, there is a coincident increased risk for chronic illnesses such as dementia. A 2019 study observed the trend of dementia for those aged 80 and older in Ontario, Canada from 2003-04 to 2012-13. It concluded that the prevalence of dementia will "approximately double every 20 years" (Cerasuolo et al., 2019, p. 2-3). A U.S. study analyzed 2794 individuals from Chicago for the prevalence and incidence of dementia between 1994 and 2012 and standardized it to the 2010 U.S. census population. When the Chicago population was extrapolated to the U.S. population, dementia within the U.S. had a prevalence of approximately 4.9 million in 1996, which increased to 6.1 million by 2011. Thus, the incidence of dementia was approximately 80,000 new diagnoses per year nationwide before correcting for deaths from patients with dementia (Rajan et al., 2019). A study from Germany determined that the incidence of new dementia cases for people 65 years or older decreased by 1.2% per year between 2009-2012, but the overall prevalence of dementia within the German population still increased (Nerius et al., 2019). A meta-analysis of four published articles by Pierse et al. (2019) determined that approximately between 7752 and 13,733 new cases of dementia appear annually

for those aged 60 and older in Ireland. Finally, a 2019 study comprised of eight developed European countries indicates that the prevalence of non-specified dementia is on average 16% for patients living at home and 21% living in a nursing home (Lethin et al., 2019). Overall, every study shows a persistent increase in the incidence and/or prevalence of dementia in developed countries.

Even in developing countries and a small self-governing archipelago, the prevalence of dementia increases each year. A 2019 meta-analysis in Nigeria estimated that the number of dementia cases increased by 400% from 1990 to 2018 (Adeloye et al., 2019). Although no specific statistics are given, a 2019 meta-analysis study in China also indicates an increase in cases of dementia over the past 30 years (Zhu et al., 2019). Furthermore, a study in the Faroe Islands determined that although the Faroe Islands have a lower prevalence of dementia when compared to other Western European countries, the prevalence of the disease still continued to increase from 2010 to 2017 (Petersen et al., 2019). These studies all strongly indicate that the incidence and prevalence of dementia in society will continue to dramatically increase, and a nontoxic but effective treatment to optimize the quality of life for this population is sorely needed.

Discovering a cost-effective treatment for dementia is further needed due to the unique and difficult challenges that dementia brings. Patients affected by dementia sometimes forget their family members or revert back to child-like behaviors. Patients can also lose their ability to function independently and require constant assistance. As a result, family members must either care for the patient themselves or spend great amounts of money to hire a caregiver, greatly impacting them emotionally, physically, and financially (WHO, 2019). In fact, a 2019 meta-analysis determined that family caregivers, such as a spouse or other family member who care

for a loved one with dementia have a 31.24% prevalence of depression and 49.26% prevalence of burden of depression, such as cognitive impairment or suicidal thoughts (Collins & Kishita, 2019). Furthermore, many professional caregivers of dementia patients at nursing homes feel low to moderate burnout in their profession (Costello, 2018). Thus, if individualized music therapy can effectively treat elderly with dementia and consequently lessen stress and burden of their caretakers, it could be concluded that it meets criterion 1.

Criterion 2 - Treatment Details and Its Aims

Based on the interview with the music therapist, it was determined that the frequency and duration of the individualized music therapy session for the elderly depends on the severity of the dementia. For patients with a mild dementia, there is typically one 30 to 60-minute session per week. During these sessions, caregivers and/or family members have the option to sit in on the session to learn the appropriate treatment strategies for when the music therapist is not present. These strategies focus on relaxing and reducing sundowning for the patient. For patients with moderate dementia, the music therapist described in the interview that the recommended frequency is two 30 to 60-minute sessions per week. For these sessions, the caregiver/loved ones are highly encouraged to attend to learn the appropriate strategies. Furthermore, the music therapist begins to track indicators and metrics for dementia. After each session, the music therapist notes the progress. The music therapist stated that for patients with severe dementia, denoted by constant aggressive behavior, severe anxiety, etc., the frequency increases to 30-minute sessions daily. The caregiver/loved ones are still trained for the times music therapists are not present. Furthermore, the music for the sessions become highly personalized, which has been shown to be more effective. For instance, a composer sits in and writes a piece personalized for the patient.

Based on the interview with the music therapist, individualized music therapy aims to alleviate many symptom burdens for patients with dementia. It seeks to improve patients' motor and cognitive functions to the point that patients can participate in physical activities, reduce addictive behaviors such as tobacco and alcohol, increase appetite, and manage pre-existing hypertension. Based on the interview, individualized music therapy does not specifically aim to help patients manage their weight aside from the secondary effects that may come from increasing the patient's participation in physical activity. Individualized music therapy has definite treatment details and aims based on a single interview. However, the WHO would certainly require more peer-reviewed and evidence based studies to confirm these anecdotal findings. Thus, criterion 2 is provisionally met but requires further research.

Criterion 3a - Effectiveness of Treatment on Proposed Aims

Data attempting to show efficacy of individualized music therapy on the proposed aims detailed in the section on criterion 2 above were gathered through personal observations of individualized music therapy sessions. Through this observation, the proposed aim of individualized music therapy in treating the elderly with dementia to improve patients' motor and cognitive functions was observed and analyzed. Although a pilot study had been planned, due to the 2020 coronavirus and the ensuing mandated national quarantine efforts, it had to be terminated after one session. However, the anecdotal observational data after one session per patient are presented. Even within one session, there were clear and apparent potential benefits of individualized music therapy that were noted.

For Client 1, the following was the outline of the 1-hour session:

- Vocalizing/warming up
- Singing a song the patient enjoys

- Assessing pain levels of patient
- Singing a song the patient enjoys
- Assessing the memory recall ability of patient
- Singing four songs the patient enjoys
- Allowing the patient to interact with the nurses and loved ones and taking medications
- Singing a song for loved one

Before the session, Client 1 was cognitively responsive but at a slow rate. Furthermore, the patient had trouble with motor function and had poor enunciation and projection of voice when speaking, all common symptoms of Parkinson's dementia. As soon as the patient began vocalizing, there was an increase in volume of voice as well as better enunciation. However, these positive effects disappeared as soon as the patient stopped vocalizing. After singing each song, there was an increase and improvement in motor function and a longer positive effect on volume of voice and enunciation. For instance, Client 1, who could not move at all prior to the session, began to tap their foot to the rhythm after a few songs. Furthermore, even after singing, Client 1 maintained good volume and enunciation when speaking. When the patient's loved one came, they were amazed at how the patient was singing the lyrics to a song from memory and was able to remember memory from their past when asked. From this one-time observation, there was a noticeable improvement in motor and cognitive functions of Client 1, although it was not a long-term improvement (longer than 10 minutes).

The observed session for Client 2 was their first session of a series of sessions. Thus, it followed a different outline than usual:

- Therapist introducing themself and explaining the sessions
- Breathing exercise with therapist playing guitar and singing

- Stretching neck with therapist playing guitar and singing
- Singing
- Making a repertoire of songs to sing in future sessions

Client 2 was very cognitively responsive and had fairly good motor function even prior to the session. The patient did suffer from short term memory loss as indicated by asking the same questions repeatedly. Furthermore, the patient's speech was labored and slightly unclear. During the stretching section, Client 2 began to move their neck much better and fluidly once the therapist began singing and playing the guitar. The patient moved their neck in sync with the rhythm. While singing, Client 2 showed improved memory and was eventually able to sing the song without looking at the lyrics. There were no significant improvements in speech. It could be concluded that individualized music therapy showed potential signs of motor and short term memory improvements in the patient. Furthermore, it aided in the patient's ability to recall memory. However, follow up sessions must be observed in order to assess any definite improvements.

From these initial impressions, it appears that individualized music therapy may hold some potential to meet criterion 3a. Although there is a suggestion of improvement in cognitive and physical function for the two observed patients toward meeting the proposed aims, the data is completely anecdotal and requires further evidence and study in a formal manner. Thus, these observational data were supplemented with literatures and discussed below in Criterion 3b.

Criterion 3b - Comparative Effectiveness

The three articles chosen to analyze the comparative effectiveness of individualized music therapy, as explained in the Methods, were by Raglio (2010), Raglio (2015), and Ridder (2013).

Raglio (2010) was a randomized control trial, parallel study. In this study, 20 individuals were selected from a nursing home in Italy who met the criteria discussed in this thesis's Methods and who had no prior musical knowledge. These 20 individuals were randomly categorized into either the experimental or control group. The experimental group received two 30-minute individualized music therapy sessions per week for 15 weeks while the control group received other educational and occupational activities such as a bath, reading a newspaper, personal care, etc. It was determined that clinical depression was significantly reduced in the experimental group and 50% of individuals in the experimental group had increased heart rate variability, which translates to decreased stress and increased relaxation. However, there was no reported difference in cognition levels between the groups (Raglio, 2010).

Raglio (2015) also reported a second randomized controlled parallel trial. In this study, 120 participants were chosen from nine different institutions in Italy. These participants were chosen for meeting the criteria in this thesis's Methods as well as other factors such as: agitation, mood or behavioral problems, no major psychiatric diagnosis or major depression, and no form of music therapy treatment in the past year. These 120 individuals were randomly categorized into the experimental, control 1, or control 2 group. The experimental group received a 30-minute individualized music therapy session twice a week for 10 weeks. The control 1 group listened to an individualized playlist made based on interviews with the patient and caregivers for 30-minutes, twice a week for 10 weeks. The control 2 group received usual care with no exposure to music. Assessment of these individuals were done prior to study initiation, at the completion of the study, and again two months following completion. Interestingly, this study determined that there was a significant improvement in behavioral and psychological symptoms of dementia for all 3 groups. Furthermore, all 3 groups had an improvement of quality of life and

decrease in depression. However, the study explained that their stringent outcome measures may be the cause of little observed difference between the different groups. Furthermore, since the participants came from nine different institutions, there was no consistency for usual care (control 2 group), which may have resulted in the lack of difference between the groups (Raglio, 2015).

Ridder (2013) reported a randomized control, crossover trial. In this study, individuals were randomly grouped into either the experimental group receiving individualized music therapy or the control group with usual care. After 6 weeks, the groups were given a week break before crossing over into the other arm of the study. The entire study period was 15-weeks. This 15-week study was repeated three times in Fall 2010, Fall 2011, and Spring 2011 for a total of 42 participants from 14 different nursing homes in Denmark and Norway. All participants had agitation and met the criteria discussed in this thesis's Methods. It is important to note that a few nursing homes provided group singing sessions as part of their usual care, causing certain individuals in the control group to have similar musical sessions as the individualized music therapy sessions. This study determined that receiving individualized music therapy significantly reduced agitation and improved quality of life in comparison to those receiving standard care. Furthermore, it was determined that individuals receiving standard care had a significant increase in medication intake compared to those receiving individualized music therapy. This study showed overwhelming evidence in favor of individualized music therapy. It is important to note that there may be bias involved since the funding for this study was provided by someone with a potential interest in the effectiveness of music therapy. However, this was a peer-reviewed study with the methods and data clearly outlined, which improves the credibility and validity of the study (Ridder, 2013).

Due to inconsistent results among the three articles, no conclusions can be drawn regarding the efficacy of individualized music therapy, and further research in this area is necessary to support that individualized music therapy meets criterion 3b.

Criterion 4 - Comparative Safety

Based upon personal experience, the music therapist indicated in the interview that there are a few potential risks associated with individualized music therapy. For example, music can bring back unintended, negative memories. When the current elderly population was in their childhood, it was a time where sexual abuse was not well reported but was certainly occurring. A common location for these crimes were in a religious setting. Thus, playing church hymns could conceivably bring back painful memories for the patient and cause negative consequences. The patient and their caregiver/loved ones must be carefully interviewed in order to avoid these negative consequences. However, some patients refuse to share their story or cannot speak, which can make it difficult for the therapist to choose the appropriate songs. In this case, the music therapist stated that they must observe and measure the patient's blood pressure, heart rate, and behavioral indicators to determine which songs are safe.

The music therapist indicated that another potential risk of individualized music therapy is that it can too quickly activate the motor system of patients. Especially for people who have severe motor and cognitive disabilities, their executive function may not be able to keep up with their sudden increase in motor function. This can result in patient's wandering into potentially dangerous areas with little sense of pain. The music therapist stated in the interview that a patient in this state may break through a glass window, or wander aimlessly outside their residence. Therefore, music therapists and/or others must be present before stimulating the patient to prevent these behaviors.

The patients can also become too dependent on individualized music therapy according to the music therapist in the interview. In some cases, the patients begin to replace human interaction with the music. This can cause the patients to feel neglected and abandoned when there is no music present. Thus, it is crucial that a music therapist assesses the patient in an ongoing and frequent interval.

The music therapist concluded the interview by stating that the risks associated with individualized music therapy can be reduced by ensuring a music therapist stay with the patient and take appropriate measures to ensure their safety. Thus, this thesis concluded that individualized music therapy is safe provided that precautions noted above are attended to. Furthermore, the interview strongly suggests that the safety profile of individualized music therapy compares favorably to the safety profile of anti-dementia pharmaceuticals with various side effects that cannot be controlled. In fact, if individualized music therapy is used with a medication, one study indicates that it can decrease psychotropic medication intake, which could further reduce risks to the patient (Raglio, 2015). However, further evidence must be given to confirm that individualized music therapy meets criterion 4. For instance, an interview with multiple music therapists and a scientific study looking into the safety of the treatment is warranted.

Criterion 5 - Comparative Cost and Cost Effectiveness

Through the interview with the music therapist at the Center for Music Therapy in Austin, TX, it was identified that the most common frequency of visits for patients with mild to moderate dementia was one hour per week, as noted in the section on criterion 2 above. The frequency for severe dementia was not considered since Donepezil is only indicated for mild to moderate dementia. If clients with severe dementia are excluded, the mean frequency of music

therapy sessions was 4.29 hours per month. This was multiplied by the private pay hourly rate for each music therapy center to determine the monthly cost. The monthly costs were averaged, and showed that an individual spends on average $429.00 per month for individualized music therapy. The cost per session at Clinic 1 was an outlier (See Table 2). Therefore, the median cost per session of the three music therapy clinics ($386.10) was used and compared to the price of a monthly prescription for Donepezil. Table 2 shows a visual representation summarizing the information for the cost of individualized music therapy.

Table 2

Information Regarding the Cost of Individualized Music Therapy for 3 Clinics in Austin, Texas

Music Therapy Clinics	Clinic 1	Clinic 2	Clinic 3	Average
Hourly Rate for Individualized Sessions ($)	140	70	90	
Estimated Frequency of Patient Visits (hours per month)	4.29	4.29	4.29	
Estimated Monthly Cost ($)	600.60 (outlier)	300.30	386.10 (median)	429.00

On average, a daily dosage of 10 mg of Donepezil is taken to treat dementia. Although dementia patients start with 5 mg per day for the first four weeks and can increase up to 23 mg per day, 10 mg is the most common dosage and was used for comparison (Birks & Harvey, 2018). Using the three websites that discussed the monthly retail price of a 10 mg/day dosage of Donepezil, (ConsumerReport, GoodRX, and SingleCare), the three retail prices were averaged. Table 3 shows a visual representation summarizing the information for cost of Donepezil.

Table 3

Monthly Cost of a Daily Dosage of 10 mg Donepezil

Name of Website	ConsumerReport	GoodRX	SingleCare	Average
Monthly Cost (Retail Price) ($)	367.00	94.31	236.99	232.77

Receiving individualized music therapy sessions in central Texas will cost a client approximately $386.10 per month (range: $300.30 – $600.60) compared to taking Donepezil, which costs on average $232.77 (range: $94.31 – $367.00) per month (Difference: $153.33). This underscores the importance of individualized music therapy being in the essential medicine list as that would be a huge step toward allowing it to be covered by insurance companies due to the relatively low risk and potential benefits of individualized music therapy, based on the preliminary information in this thesis.

Donepezil, unlike individualized music therapy, has many coupons and insurance coverage opportunities that allow the price to significantly drop. Not being part of essential

medicine, individualized music therapy does not get the blanket insurance coverage for services. Private insurance companies cover music therapy on a case-by-case basis. Furthermore, music therapists have to undergo very specific methods to receive reimbursements from Medicare and Medicaid (Simpson & Burns, 2004). Some require the therapists to receive extra training or require that the treatment is part of a partial hospitalization program providing psychiatric care (Simpson & Burns, 2004). In fact, there are entire courses and books regarding how music therapists can receive reimbursements from insurance. The difficulty in receiving reimbursements prompts some music therapists to opt out of allowing their patient to use insurance. Therefore, if individualized music therapy was considered as an essential medicine, its cost would likely decrease, making it similar in price to Donepezil with coupons significantly. Furthermore, in most cases of mild and moderate dementia, once the patient is on a stable program, his or her caretaker could likely administer the therapy, allowing the frequency of follow-up visits for routine check-ins to likely decrease and making individualized music therapy further affordable.

For severe dementia, both the cost of medications and individualized music therapy increases due to the increase in dosage and sessions of the treatments. However, medications for severe dementia often include psychoactive drugs with serious side effects, so it is commonly recommended that non-drug management first be attempted (Lindsey, 2009). Furthermore, patients with severe dementia are likely on more than one psychoactive medications, which dries the cost per month up considerably (Lindsey, 2009). This gives a further reason for individualized music therapy to be considered, especially with similar costs to the medications and a potential for the cost to be decreased if covered by insurance.

The key results for each criterion were summarized in Table 4.

Table 4

Key Results for Each Criterion

Criteria	Key Results
1 – The Public Health Relevance	- Increase in Dementia Cases Globally - Dementia has Many Consequences for Patient and their Caregiver/Loved Ones
2 – Treatment Details and its Aims	Hour of Treatment Per Week Seeks to Improve: - Motor and Cognitive Functions - Reduce Addictive Behaviors - Increase Appetite - Manage Pre-existing Hypertension
3a – Effectiveness of Treatment on Proposed Aims	- Shows Potential Success in Improving Patient's Motor and Cognitive Functions
3b – Comparative Effectiveness	- No Conclusions can be Drawn - Shows Potential for Individualized Music Therapy
4 – Comparative Safety	- Few Risks that Can Be Accounted For - Relatively Safer than Psychotropic Medications
5 – Comparative Cost and Cost-effectiveness	- Cost of Individualized Music Therapy is Similar to Donepezil and Could be Further Decreased

Conclusion

This thesis provides an evidence-based roadmap that may be used to enable interested investigators an opportunity to get individualized music on the WHO list of essential medicines. There were six criteria discussed: 1) public health relevance, 2) treatment details and its proposed aims, 3a) effectiveness of treatment on proposed aims, 3b) comparative effectiveness, 4) comparative safety, and 5) comparative cost and cost-effectiveness. Arguably, it can be concluded that criteria 1 was met and 2 was provisionally met. There is ample evidence that supports the public health relevance as well as the treatment details and aims of individualized music therapy. Criteria 4 and 5 were partially met. Although, there is evidence to support individualized music therapy as comparatively safe and not out of the cost range of current pharmaceutical medications to treat dementia, more extensive research should be done to decisively conclude that these criteria were met. Furthermore, the comparative cost-effectiveness of individualized music therapy was only for patients with mild to moderate dementia. This was because Donepezil is not used for patients with severe dementia, and the medication and cost for severe dementia differ by the patient, depending on the doctor's recommendations. Criteria 3a and 3b need more evidence before satisfying the rigorous criteria set by the WHO. There are numerous studies on the effects of music therapy. However, when broken down into specific types of music therapy (i.e. individualized music therapy as defined by the thesis) and specific types of illness it aims to treat (i.e. dementia), it can be seen that there needs to be more research done on establishing the effectiveness of individualized music therapy on its proposed aims (criterion 3a) as well as its overall comparative effectiveness (criterion 3b). Once further studies establish that individualized music therapy meets the 6 different criteria completely, it could be

submitted to the WHO for consideration as a core essential medicine for the adults list in treating dementia for the elderly.

Limitations

For literature reviews, the main limitation was the number of articles that met the criteria and were used to answer criteria 3b and 4. Although over 1800 articles were filtered, only three met the criteria for this thesis. Therefore, it shows the need for further studies discussing the effects of individualized music therapy on elderly with dementia.

For personal data collection, there exist several limitations. Due to the 2020 COVID-19 (Novel Coronavirus) outbreak, the thesis was limited in the number of observations for the patients; safety and health. The observations therefore do not account for the variabilities that can occur day by day, such as the patient's mood. For instance, Client 1 in the study had lacked sleep the night prior to his session and was in an unpleasant mood during the individualized music therapy session. There was sampling bias as well because all patients were patients from one music therapy clinic in Austin, Texas. The clinic's patient base could be patients from a similar socioeconomic status as well as from similar backgrounds, and culture, making the results potentially skewed. Also, there was a very small sample size in the number of patients observed, and the observations were somewhat subjected and certainly not controlled. There was only one music therapist interviewed for the thesis. Although the music therapist has an extensive number of years of practice and experience, the data cannot account for potential biases the music therapist may have had. The numbers gathered for the cost of individualized music therapy was limited to Austin, Texas and may not be representative in other parts of the world.

Future Studies

This thesis shows that individualized music therapy has the potential to become an essential medicine according to the WHO criteria, assuming that the aspects of study that need further research are successfully completed. As mentioned in the conclusion, there needs to be further research specifically on the effects and comparative effects of individualized music therapy, as defined by this thesis, in the elderly with dementia. Furthermore, there needs to be an extensive study on the cost and safety of individualized music therapy.

To better understand, access, and disseminate the growing body of research on individualized music therapy, the music therapy research community ought to consider specialized forums, such as specialized journals within the domain, for the publication of future research. For instance, separating articles based on the type of music therapy and/or the illness it aims to treat may be beneficial. Furthermore, perhaps outlining priorities of research for the community might also benefit the effort for more widespread acceptance and adoption of the individualized music therapy practices.

This thesis provides preliminary evidence of the beneficial and side effects of music in dementia, and can be used as a roadmap of how professionals within the field should proceed in an attempt to have this complementary therapy added as an essential medicine of the WHO.

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Author Biography

My name is Sung-Hoon Park. I was born in Seoul, South Korea and was raised in Mobile, Alabama where I attended the Alabama School of Mathematics and Science for my high school. Being a huge science person and having a strong interest in medicine, I entered The University of Texas at Austin (UT Austin) as a Chemistry BSA major in the Health Sciences Scholars honors program. A few years ago, a series of fortuitous events led me to embark my journey into the world of singing, and I love every moment of it! The aspect of singing I enjoy the most is that I have the power to help others smile and feel better. My singing activities enable me to express my creativity in the arts while my science courses enable me to engage in critical thinking - a perfect medium for me! My other hobbies include exploring different places to eat within Austin and sometimes the world, playing soccer, singing at a karaoke (because singing at school isn't enough for me!), and volunteering to help the community. After graduating from UT Austin, I will be attending McGovern Medical School in Houston, Texas. Sometime after medical school, I hope to earn a Masters in Music in order to pursue my goal of becoming a physician who uses music therapy as a tool to treat patients both physically and psychically.