THE FLORIDA STATE UNIVERSITY

COLLEGE OF MUSIC

THE EFFECT OF CHORAL SINGING ON INDIVIDUALS WITH PARKINSON'S DISEASE AS MEASURED BY BLOOD PRESSURE AND OXYGEN SATURATION

By

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“It is only with the heart that one can see rightly; what is essential is invisible to the eye.”
– Antoine de Saint-Exupery

This thesis is dedicated to the sculptors of my life.

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ABSTRACT

The purpose of this study was to determine the effect of choral singing on the blood pressure and oxygen saturation of individuals with Parkinson's disease. The study followed a pre-post test ABA^1B reversal design across 4 days, in which adult participants (N=15) enrolled in the Parkinson's choir outpatient program at Tallahassee Memorial Rehabilitation Center served as their own control. The Friedman Two-Way Analysis of Variance found that there was no significant difference in the pre/post daily changes of blood pressure and oxygen saturation, however, trends for blood pressure to move toward a normal or healthy blood pressure level did occur with the addition of singing.

CHAPTER ONE: INTRODUCTION

There are a multitude of studies in which the results consistently point toward music having an effect on individuals. When one looks at the data collected on mental or physical measures, there is no question as to the efficacy of the positive effect that music has on humanity. However, there is a question as to the extent or magnitude of music's effect on differing types of individuals or groups. In regard to individuals with Parkinson's disease, there is still much to be explored when researching the effect of music.

Parkinson's disease (PD) is a degenerative disorder in the nervous system where the nerve cells in the brain decrease in the production of dopamine. Typically found late in middle age adults with an average onset age of 60, Parkinson's disease produces a number of symptoms such as resting tremors, bradykinesia, rigidity, and postural instability (Parkinson's Disease Foundation, 2012). In 2012, the National Institute of Neurological Disorders and Stroke stated that about 50,000 Americans are diagnosed with PD every year, and men are 50% more likely to acquire PD then women. Some research suggests that because of the loss of nerve endings caused by PD, blood pressure and other autonomic functions in the sympathetic nervous system do not regulate correctly. Orthostatic hypotension, getting dizzy from standing up due to a drop in blood pressure, is much more prevalent in individuals with PD. In order to combat the symptoms of Parkinson's disease, individuals take numerous medications in addition to other medications commonly taken in that age bracket.

It is estimated that one in every three adults has high blood pressure, and the probability to have high blood pressure increases in conjunction with age (American Heart Association, 2008). Healthy blood pressure and oxygen saturation are imperative to one's health. A lack of oxygen in the blood can lead to cell damage and organ dysfunction. High blood pressure is one of the leading precursors to cardio vascular disease. Some Parkinson's medications also affect blood pressure, which can be beneficial or harmful to the patient, depending on their blood pressure predicament.

Because choral singing requires one to breathe differently from everyday activities, awareness of the effect singing has on oxygen saturation is important. There are currently conflicting studies that suggest blood pressure is either raised or lowered when singing is implemented. In individuals with Parkinson's disease lower blood pressure is more prevalent

due to certain medications. Knowing the effect of choral singing on blood pressure and oxygen saturation may help music therapists provide better interventions. Therefore, the purpose of this study is to determine the effect of choral singing on the blood pressure and oxygen saturation of individuals with Parkinson's disease.

CHAPTER TWO: REVIEW OF LITERATURE

This chapter is organized into the following sections: (a) why humanity sings, (b) the effect of singing on individuals and groups, and (c) Parkinson's disease and music. A simple measure of the value of something is to propose the age-old question: "Has it stood the test of time?" By that definition of value, singing is extremely prevalent across the history of humanity, and, therefore, invaluable. Although there are numerous studies containing knowledge about choral singing, the number of studies that measure the physiological effects that choral singing has on individuals are quite finite. Also, literature using music with Parkinson's clients is relatively rare. This literature review provides a summary of the aforementioned topics.

Why Humanity Sings.

The confluence of humanity and song continues to impact the world. Some of the most remarkable aspects of singing that science still considers are why, how, and what it does for humanity. Some theories surrounding the birth of song suggest that singing may have been one of the first forms of communication; along with many different species, Gibbons in particular, a lesser ape primate, use vocal songlike phrases to communicate. In *The Origins of Music*, Geissmann authored a chapter on a comparison of Gibbon songs and human music. The recorded and observed vocal duets that occur between male and female Gibbons, along with shared codas at the end of different phrases, incites the hypothesis that humanity may have shared a similar beginning. Research has shown that certain Gibbon calls actually elicit an emotional response in humans (Geissmann, 2000).

One of the goals of this study is to explore the physiological effects that singing has on the human body. The thought that song and the act of singing can have physical effects on individuals is not a novel idea. Many ancient civilizations, such as the Greeks, used music in combination with dancing and herbal remedies in healing practices (Legeros, 1937). To the Australian Aboriginals, music, along with other art forms, was and still is something that everyone participates in daily. Music was present in numerous situations such as births, healing, rituals, story telling, and providing comfort for the grieving. In most cultures today and in the past, the voice is used as the main instrument (Bartlett, 2002). Native Americans also have a history of music being a large part of a multifaceted healing approach. However, the definition

of healing is also slightly different, in that true healing does not consist of just curing a disease, but it encompasses one to attain a balance, or wholeness with the community and world (Cohen, 1999). Not only have different cultures around the world used music in healing practices, but music has also been documented as causing physiological state changes. Monks at the Tibetan Gyuto Tantric College, founded in 1475, learn overtone singing in order to attain an enlightened state (Deuson, 2004). This form of singing has been practiced for hundreds of years; one overtone composition by Rin-chen-bzang-po dates back to between 958-1055 (Yonnetti, 2011).

Throughout history, the effects of singing on both mental and physical characteristics have been discussed. Singing can increase heart rate or lower it depending on multiple factors; tempo especially plays a large role. Using music to guide the mood of a group or individual is a prominent recurring theme in different cultures (Roseman, 1991). Music directed toward changing one's state, whether mental or physical, is presently used in therapeutic settings. The Iso-principle, used by music therapists, is a technique in which a Board Certified Music Therapist manipulates a song in order to bring a patient or client to a goal-oriented physiological and or mental state (Podolsky, 1954).

Studies of Singing By Discipline

Research on singing and listening to songs appears in several different disciplines such as education, medicine, communication, anthropology, psychology, biology, neurology, marketing, and, of course music therapy. The study of singing continues to build a knowledge base because it has such a profound effect on humanity. Of the listed disciplines, the effect of singing on individuals and groups can be sectioned into the following: (a) educational, (b) psychological, and (c) physical. Although there are crossovers between the abovementioned sections, clear differentiation and distinctions are also apparent. The subsequent paragraphs provide a brief review as to what effects singing has on individuals and why it is studied by multiple disciplines.

Educational

In education, singing is not just beneficial in a choral setting. Singing has been shown to be effective in teaching phrasing and other musical techniques during band rehearsal. To aid in the development of aural skills, singing is an efficient way to address intonation, pitch discrimination, and correction skills during rehearsal (Wolbers, 2002). Because singing is an effective tool for learning and retaining different concepts, it is also prevalent in many subjects outside of the typical musical setting. Mnemonic devices are quite common in the field of

education. In 2000, an interesting article written by Hughes focused on the cross-cultural use of melodic mnemonic devices. Hughes found that acoustic-phonetic patterns emerge in vowel and consonant use that create an intrinsic pitch, intensity, and duration. The study gives insight to the nature of how the use of singing certain melodic progressions aid in the acquisition of new information for people from different cultures. Writing songs to teach different chains of information, such as a foreign language or complex concepts are also used in educational situations.

When learning new material, singing is a useful tool. A study that consisted of 60 first graders, compared learning vocabulary words with singing and gestures to just using gestures. The group that received the combined singing-gesture learning approach showed a significant difference when compared to the group that learned with just gestures and the control group (Madsen, 1991). In teaching children how to read, singing is used to enhance understanding of literature concepts, sight vocabulary, reading comprehension, and fluency. Song picture books are commonly used when teaching new readers for the abovementioned reasons and that it also brings attention to the subject matter (Kolb, 1996).

Psychological

Psychological effects of singing provide a variety of information, from how to create more effective therapy treatments to marketing's goal to increase revenue. Clift and Hancox (2001) conducted a study that looked at the perceived or psychological benefits of singing in a choral setting. The study compared two previous surveys of the choral experience of multiple participants. In the first survey with 84 participants, results revealed that 87% benefitted socially, 75% benefitted emotionally, and 58% benefitted physically. Of the two studies they compared, consisting of 175 participants combined, six principle benefits were found: well-being and relaxation, breathing and posture, social benefits, spiritual benefits, emotional benefits, and benefits for the heart and immune system. Without taking quantitative measurements of physical responses to music, over half of the participants of the first reviewed study perceived choral singing as having a positive physical effect.

A study published in 2010 conducted by Clift, Hancox, Morrison, Hess, Kreutz, and Stewart, employed the WHOQOL-BREF questionnaire (World Health Organization Quality of Life) to assess the psychological wellbeing of 633 choral singers. Again, the results revealed that the majority of singers perceived positive benefits from singing and high psychological

wellbeing. About 10% of the participants scored low on the psychological wellbeing scale but still cited positive benefits from choral singing; extenuating circumstances such as mental, physical, and the loss of loved ones emerged as common causes for low psychological wellbeing.

In Israel, a study led by Anshel and Kipper (1988) investigated the influence group singing had on trust and cooperation. A comparison was made between four groups consisting of group singing, listening to music, reading, and film viewing. Each group contained 24 adult Israeli males, and out of the four groups, the group singing showed the highest scores in trust and cooperation.

Hillman (2002) sent out a questionnaire to participants in the community arts project, Call that Singing, to determine the perceived benefit of the program. The 75 participants consisted of women over the age of 60 and men over 65 in Scotland. The results of the questionnaire showed that the participants enjoyed participatory singing and that the lives of the participants were perceived to be improving in areas such as self-confidence, social life, positive perspective of health, and emotional wellbeing. Some participants also reported an improvement in physical health when breathing and walking.

Physical

A study by Kreutz, Bongard, Rohrmann, Hodapp, and Grebe (2004), researched how singing can have an effect on a choir and audience. Immunoglobulin-A, a primary mucosal antibody response, is one physiological measurement used to determine the health of the immune system, or rather a measurement to expose immunodeficiency (Dixon, 1987). By using measurements of Secretory Immunoglobulin A (S-IgA), Cortisol levels were collected from both the choir and listeners, as were emotional states via questionnaire. The results revealed that singing had a significant effect on S-IgA levels and positive affect. One of the most curious aspects to the study is that listening had a very different effect than singing, in that listening pointed toward a negative affect and lower Cortisol levels.

A study published in 2000 by Beck, Cesario, Yousefi, and Enamoto, in which S-IgA measurements were taken using a pre-post test design, found that S-IgA levels increased 150% during rehearsals and 240% during a performance. An increase in S-IgA levels implies that a chemical reaction is occurring in the body and strengthening the immune system during the action of singing. Though the mindset that music has an effect on individuals is commonplace, the above research reveals evidence that something physical is happening on a chemical level.

Although there are studies that measure specific physiological effects that singing can have on both singers and listeners, different studies point to what appears to be contradictory data for measures of blood pressure. In one case study an individual was scheduled to receive total joint replacement surgery. However, due to extremely high blood pressure, 240/120 mm Hg, the surgery was postponed. After several attempts by the medical staff to lower the patient's blood pressure with medication, the patient's systolic pressure blood pressure remained at around 200 mm Hg. The patient then asked permission to sing, and after singing two songs, the patient's blood pressure dropped to 180/90 mm Hg allowing for the surgery to proceed (Niu, Perez, and Katz, 2011). However, another study, consisting of four participants, revealed that blood pressure rose when professional vocalists sang. Blood pressure measurements showed a significant increase in diastolic pressure and variable change in systolic pressure when singing (Broadwater, 2002). Although blood pressure results were contradictory the sample sizes were too small to draw a definitive conclusion.

Oxygen saturation is an instantaneous measurement of the amount of oxygen in the blood measured by an oximeter (Lynn-McHale, 2001). One of the benefits of an oximeter is that it is a non-invasive measurement for oxygen saturation, making it an ideal tool to use in research. Because neonates are connected to a pulse oximeter, constant real-time readings of oxygen saturation can be measured. While there are no studies of oxygen saturation affected by participants singing, there are studies using music listening. A study by Cassidy and Standley (1995) compared two groups of premature infants. One group received a brief period of recorded music and another did not receive music. The group that listened to recorded music showed a significant increase in oxygen saturation on the first day of data collection and the O2 levels remained high throughout the subsequent days of recorded O2 measures. In another study both male and female singing was shown to not only lower heart rate but also increase oxygen in listening infants. Premature infants were divided into two groups of 33, one group received singing/speaking and the other did not. The group that received singing not only significantly increased in oxygen saturation but also in caloric weight gain, a desired outcome for premature infants. Both physiological and behavioral data revealed the benefits of just listening to someone singing (Coleman, Pratt, Stoddard, Gerstmann, Hans-Henning, 1997).

Because research points to a direct correlation between music and an increase in oxygen saturation in premature infants, questions arise concerning how oxygen saturation is affected by

music in other age groups. Recently, a study was published that randomly assigned 66 adult patients receiving a C-clamp procedure after percutaneous coronary interventions into two groups. One group was exposed to 45 minutes of recorded music and the other received 45 minutes of an uninterrupted rest period. The results of the study concluded that the music group showed statistically significant reductions in heart rate, respiratory rate, and oxygen saturation when compared to the control group (Chan, 2007). An interesting point is that Chan's study showed a decrease in oxygen saturation for adults exposed to recorded music, whereas premature infants showed an increase.

Parkinson's Disease

In order to understand the effect that music or rather singing can have on individuals with Parkinson's disease, one must first have an understanding of Parkinson's. PD is a disorder in the nervous system in which the nerve cells in the brain that produce dopamine slowly decay. Without the appropriate production a dopamine, signals sent from the brain are incomplete or broken (A.D.A.M., 2011). The resulting effect is a progressive decrease in muscle control. The symptoms of Parkinson's can be grouped into three areas: primary motor, secondary motor, and non-motor. The common primary motor symptoms include: resting tremor – shaking typically found in a resting appendage, bradykinesia – slow movement, rigidity – stiffness and inflexibility in trunk or limbs, and postural instability – balance instability when standing upright. Common secondary motor symptoms consist of freezing – hesitation when walking or rather random pauses in gait, micrographia – an increase in time spent writing equals a decrease in the size of the handwriting, mask-like expression – flat affect, or a lack of facial expression, and unwanted accelerations – in increase in speed whether in speech or everyday movement. Some of the non-motor symptoms are orthostatic hypotension – low blood pressure upon standing up, mood disorders, difficulty sleeping, and a decrease in sense of smell (P.D.F., 2012).

Music Related Studies

A study conducted on elderly individuals with moderate to severe dementia over a 2-year period revealed that the systolic blood pressure significantly decreased for 24 participants that received music therapy. The systolic blood pressure for the 19 participants in the control group rose significantly (Takahashi, Marsushita, 2006). One study, compared music therapy with physical therapy for 3-months. The Unified Parkinson's Disease Rating Scale showed that music therapy had an initial significant effect on decreasing bradykinesia, whereas physical therapy had

benefits on rigidity and motor ability (Pacchetti, C., Mancini, F., Aglieri, R., Fundarò, C., Martignoni, E., and Nappi, G., 2000). Rhythmic auditory-motor stimulation (RAS) was used in a study with 31 Parkinson's patients to improve gait. Gate velocity, cadence, and stride length all showed a significant improvement. The data supported the already documented benefit of RAS on the gait of individuals with PD (McIntosh, Brown, Rice, and Thaut, 1997). In 2009, Di Benedetto, Cavazzon, Mondolo, Rugiu, Peratoner, Biasutti, conducted a study in which voice and choral singing treatment (VCST) was adapted for 20 individuals with Parkinson's. The PD patients received both 20 hours of speech therapy and 26 hours of choral singing. The study found that lung strength, and the duration of a sustained note increased significantly with VCST.

Rationale for Study

Many studies point toward physiological effects from the act of singing. Blood pressure is a measurement that has been used in multiple studies and significant changes have been documented when music is present. However, the direction of the change is not consistent. Singing requires one to consume and use more oxygen, and some studies have shown changes in oxygen saturation levels due to singing. However, no studies have measured these two variables for PD patients who have difficulty with blood pressure due to age and medication side effects.

CHAPTER THREE: METHODS

Participants

This study used adult participants (N=15) enrolled in the Parkinson's choir outpatient program at Tallahassee Memorial Rehabilitation Center. The age range was between 61-87, and the average age was 73.5. After signing the FSU and TMH IRB approved consent form (Appendix B), a short demographic survey (Appendix C) was completed. Table 1 shows demographic data for participants.

Table 1. Participant Demographics

Participant Demographics							
	Year born	*Diagnoses*	*Gender*	*Length in choir*	*Attendance*	*Medication use for Parkinson's*	*Medication taken that may effect BP*
100	1946	1990	M	4	1	Y	Y
101	1926	2006	M	3	1	Y	Y
102	1940	2002	M	3	1	Y	Y
103	1930	1996	M	1	2	Y	Y
104	1943	2005	M	2	1	Y	Y
105	1931	1999	M	3	1	Y	Y
106	1942	2006	M	3	1	Y	Y
107	1924	1994	M	1	1	Y	Y
108	1934	*I/C*	M	*I/C*	1	Y	Y
109	1931	1998	F	4	1	Y	Y
110	1935	2008	M	1	4	Y	Y
111	1944	2002	M	2	1	Y	Y
112	1950	2004	M	1	4	Y	Y
113	1943	2011	F	1	1	Y	Y
114	1943	1987	M	1	4	Y	*I/C*

*Length in choir**: (1) = less than 1 year, (2) = 1-2 years, (3) = 3-4 years, (4) = 5 or more years

*Attendance***: (1) = almost every rehearsal, (2) = 1-2 times per month, (3) = less than 12 times per year, (4) = just started to attend

I/C = Incomplete form

Yellow = 8 Participants in data analysis

Settings

The data collection took place in the cafeteria at Tallahassee Memorial Rehabilitation Center during regular choir rehearsal hours. The cafeteria was arranged for filling out the demographic questionnaire at a table, followed by two rows of chairs set up for a seated choir rehearsal.

Design

The study followed a pre-post test ABA^1B reversal design across 4 days, in which the participants served as their own control. A was continuous singing, whereas A^1 was spaced-singing, or singing with a 1-2 minute period of time to enable the choir to pick a song from a short selection. B consisted of group discussion. The dependent variables were blood pressure and oxygen saturation taken pre and post.

Medications

One of the problems found for measuring blood pressure in this study is its volatility. Not only can blood pressure fluctuate +/-10 to 20 mmHg with activities, such as walking, but it is also affected by different medications (Netea-Maier, Thien, 2004). In 2008, the American Heart Association estimated that one third of the population of adults in the United States has high blood pressure. Blood pressure is also a typical problem in individuals with PD due to the effect of medications taken to treat PD symptoms, and the effect that PD can have on the monitoring of the Sympathetic nervous system (N.I.N.D.S., 2012). Some common medications used to treat PD symptoms cause blood pressure to drop. The combination of PD symptoms and medications lead to orthostatic hypotension, dizziness when standing up from a seated position. The medications that the participants used during this study are listed in Appendix A.

Equipment

Measurements were acquired through the use of two Jobar International wrist blood pressure monitors and two Devon Medical 100-A fingertip pulse oximeters. To minimize human error, both the monitors and oximeters used in the study were automatic, one button start, in order to acquire a reading. One wrist blood pressure monitor and oximeter were marked in order to ensure that the same equipment was consistently used to take the participant's measurements. A key code (Appendix D) was used in order to ensure participants received their assigned wrist cuff and oximeter. After the completion of the study the key code was destroyed, to maintain

participant confidentiality. The measurements were recorded on a data collection form (Appendix E) and filled out by the research assistants.

Data collection Training

Six research assistants (RAs) were trained during in the course of this study. The RAs were first educated about the purpose of the study and the correct use of the wrist cuff and oximeter. For blood pressure, the RAs received explanation of the ideal placement of the wrist cuff and proper elevation of the hand (to hold hand at heart level with arm and hand relaxed). After the explanation of correct use, the RAs were shown a designated/marked wrist cuff and oximeter and were informed to only use with the corresponding participant number. Once the RAs demonstrated competence on correct usage of the oximeter and wrist cuff, they were assigned a wrist cuff, oximeter, and corresponding list of participants. Because of the possibility of false BP readings, RAs were taught that if they measured a BP change greater than or equal to +/-25 mm Hg, the BP should be re-measured immediately and the second reading used.

Procedure

The purpose of the study was explained to participants in the Parkinson's choir at TMH. They were then asked if they would like to participate. Once members of the choir volunteered to participate, they were asked to sit at the arranged tables and were handed a FSU/TMH approved consent form, which was then explained by the principle investigator (PI). Of the 14 participants, 8 individuals participated in all 8 pre and posttest measurements that occurred over the course of 4 days. On day 1 and 3 the experimental singing condition was applied, and day 2 and 4 consisted of the control condition, group discussion. Once consent was given, the PI and RAs handed out a short demographic survey with the first page to be filled out one time, and the second page, which asked what medications were taken that day, to be filled out on all experimental and control days. After participants filled out the survey at the table area, they stood up and walked over to the chair area and sat down. There the participants waited about 5 minutes before having their BP and O_2 measurements recorded by the RAs. BP and O_2 measures were recorded for all 4 days of the study immediately before and after the music or discussion session.

The experimental condition on day 1 consisted of a 5-minute vocal warm-up and 25-minutes of continuous singing of popular songs. On the second day, a control day, the Parkinson's choir interacted in a 30-minute group discussion about fond Christmas memories.

On day 3, the music content consisted of a 5-minute vocal warm-up and then 25 minutes of spaced-singing with about 1-2 minutes between each song. Within the 1-2 minute space the choir chose the next song to sing from a list presented at the beginning of the rehearsal. The control session, on day 4, was again a group discussion with non-music related topics.

Hypotheses

(1) There will be no significant difference in systolic blood pressure pre-post different scores across four days.

(2) There will be no significant difference in diastolic blood pressure pre-post different scores across four days.

(3) There will be no significant difference in oxygen saturation pre-post different scores across four days.

(4) There will be no difference between pre-posttest systolic blood pressure medical chart level changes on any day.

(5) There will be no difference between pre-posttest diastolic blood pressure medical chart level changes on any day.

CHAPTER FOUR: RESULTS

Data Analysis

The Friedman Two-Way Analysis of Variance was used to answer the first three hypotheses. Data from the 8 participants present for all four days of data collection were used in the analysis as per Table 1.

Hypothesis 1: *There will be no significant difference in systolic blood pressure pre-post different scores across four days.*

There was no significant difference in systolic blood pressure (.3632) pre-post scores across four days. ($x^2 = 3.19$ $p > .3632$ fail to reject H_o)

Table 2 shows the means of systolic BP, diastolic BP, and oxygen saturation for the four days of data collection.

Table 2. Mean Scores for Friedman Two-Way Analysis of Variance

	Mean Scores			
	Day 1	*Day 2*	*Day 3*	*Day 4*
Systolic BP	1.9	2.6	2.4	3.1
Diastolic BP	2.2	2.6	3.1	2.1
O_2 Saturation	2.4	2	2.9	2.6

Hypothesis 2: *There will be no significant difference in diastolic blood pressure pre-post different scores across four days.*

There was no significant difference in diastolic blood pressure (.3421) pre-post scores across four days. ($x^2 = 3.34$ $p > .3421$ fail to reject H_o)

Hypothesis 3: *There will be no significant difference in oxygen saturation pre-post different scores across four days.*

There was no significant difference in oxygen saturation (.53) pre-post scores across four

days. ($x^2 = 2.21$ $p > .53$ fail to reject H_o)

The results to address the following two hypotheses are graphed according to medical chart health ranges and show systolic and diastolic changes for participants each day. The subsequent charts consist of a background that shows a medically relevant blood pressure scale and multiple lines that signify the direction of blood pressure change for each participant from pre to post measures each day. The blood pressure scale measures in millimeters of mercury (mm Hg). The chart used to create the graphs (Rose, 1998) can be found in Appendix F.

Hypothesis 4: *There will be no difference between pre-posttest systolic blood pressure medical chart level changes on any day.*

Figure 1 reveals that on day 1, a singing day (n=10), 4 participants moved in the direction toward normal systolic blood pressure. After singing for 30-minutes, 3 participants moved from stage 1 hypertension BP down to the high-normal range. Two participants increased BP pre/post into a more dangerous in the more dangerous hypertension range.

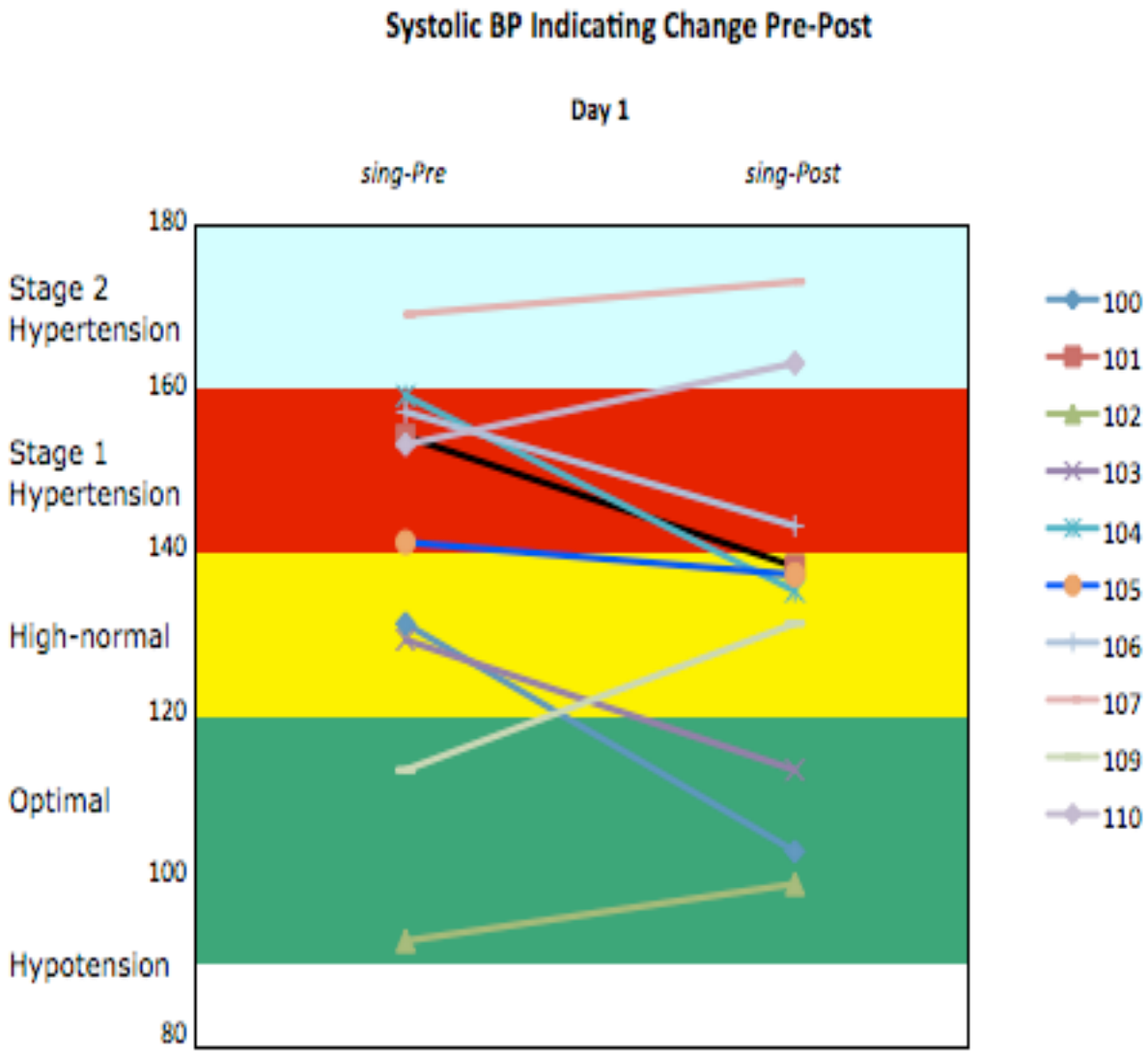


Figure 1. Systolic BP Indicating Change Day 1 – Singing

On day 2 (n=11), a discussion day, Figure 2 shows that 4 participants moved in the direction toward normal systolic BP and 2 increased in the hypertension levels.

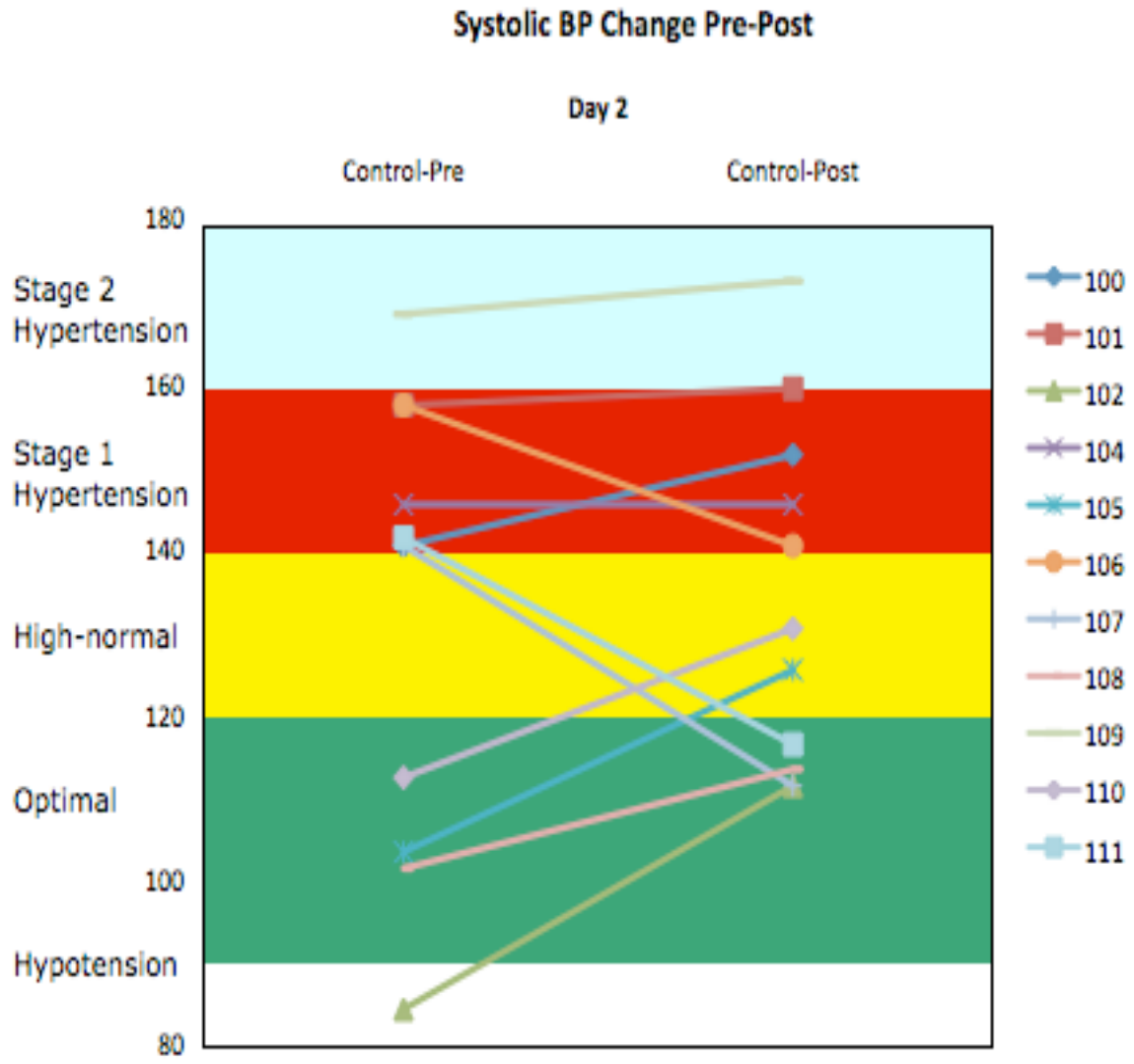


Figure 2. Systolic BP Indicating Change Day 2 – Control

Figure 3, day 3 (n=11), a singing day, shows that 4 participants with dangerous BP did move in the direction toward normal BP after singing, however, 1 participant moved out of the normal BP range. All others stayed in the normal range.

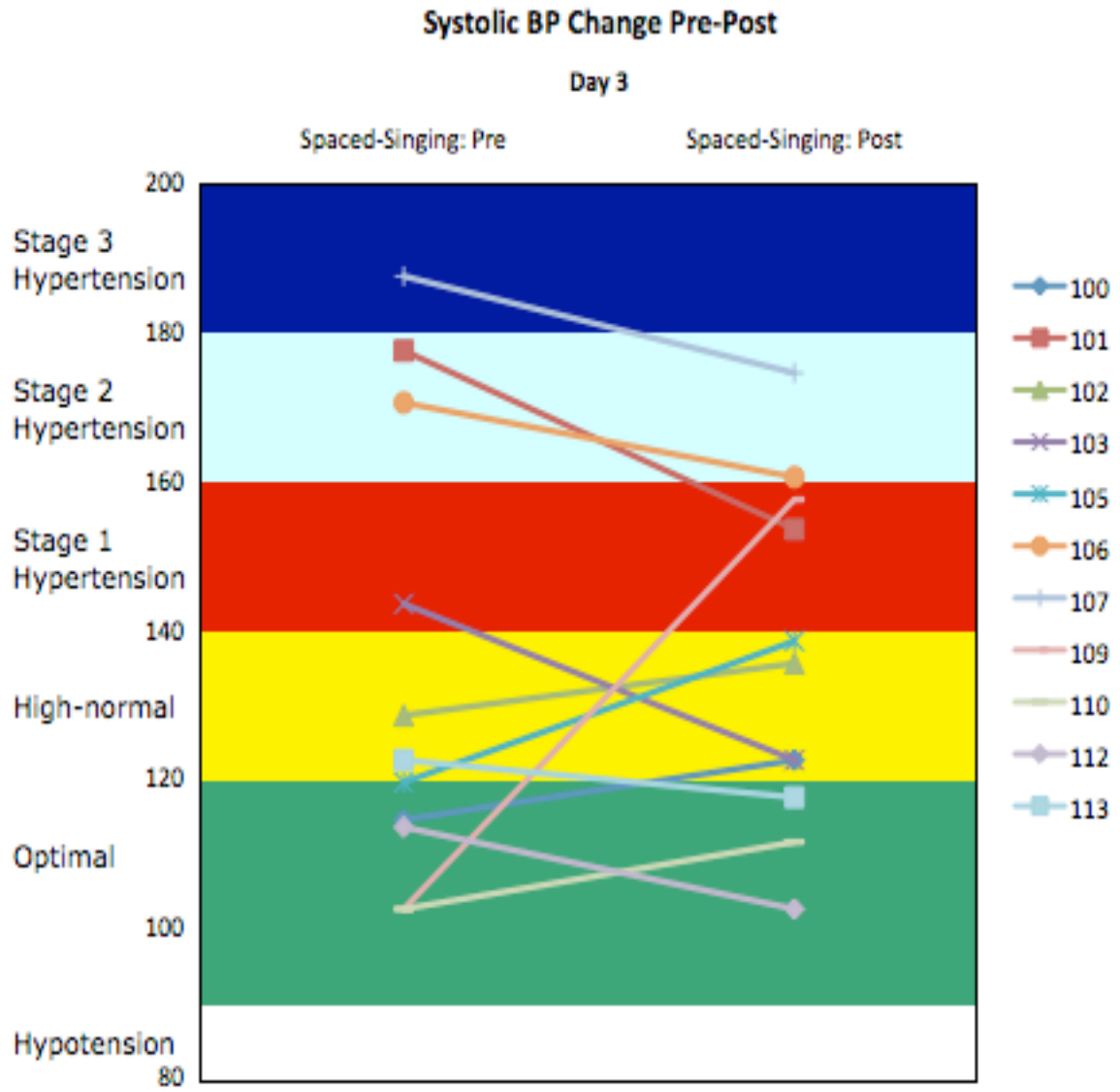


Figure 3. Systolic BP Indicating Change Day 3 – Spaced-Singing

Day 4 (n=12), chart 4, shows that 7 participants were outside of the normal range of systolic BP, and after group discussion 6 individuals had unhealthy systolic BP.

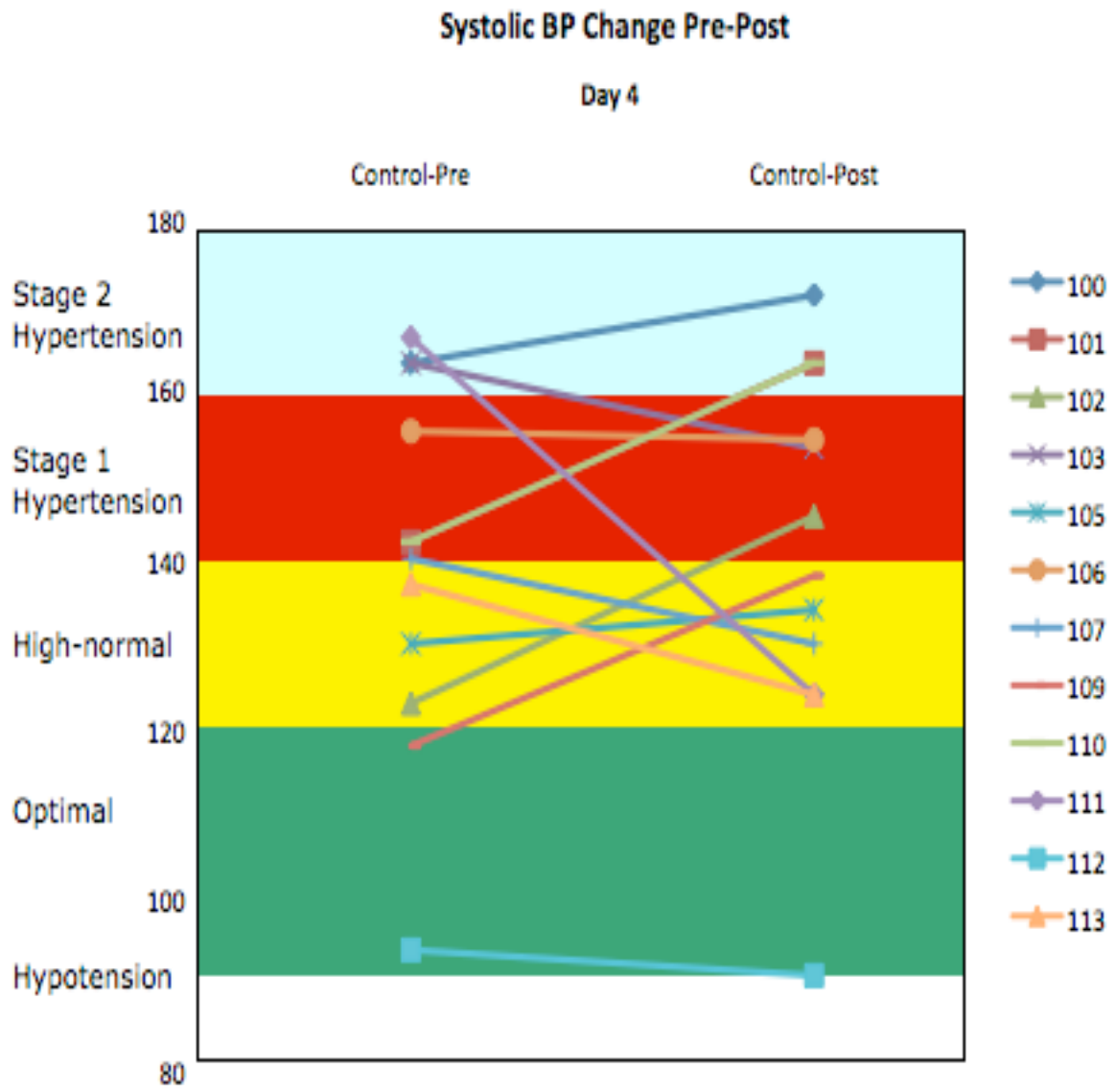


Figure 4. Systolic BP Indicating Change Day 4 – Control

Hypothesis 5: *There will be no difference between pre-posttest diastolic blood pressure medical chart level changes on any day.*

Figure 5 reveals that 3 participants moved to normal diastolic pressure and 1 moved into Stage 1 hypertension.

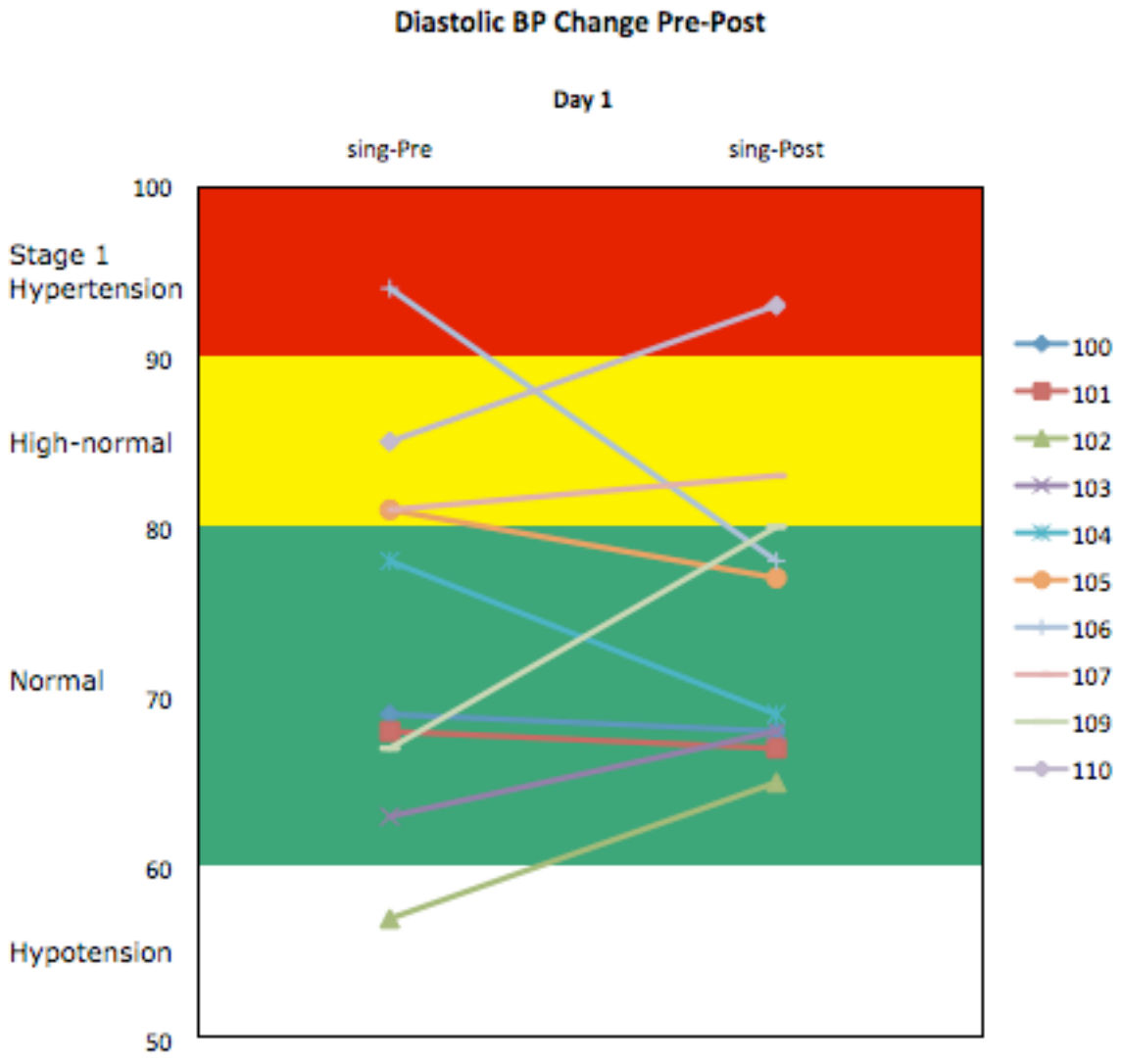


Figure 5. Diastolic BP Indicating Change Day 1 – Singing

Figure 6, day 2 (n=11), showed that two individuals moved away from dangerous diastolic levels and one participant dropped into hypotension.

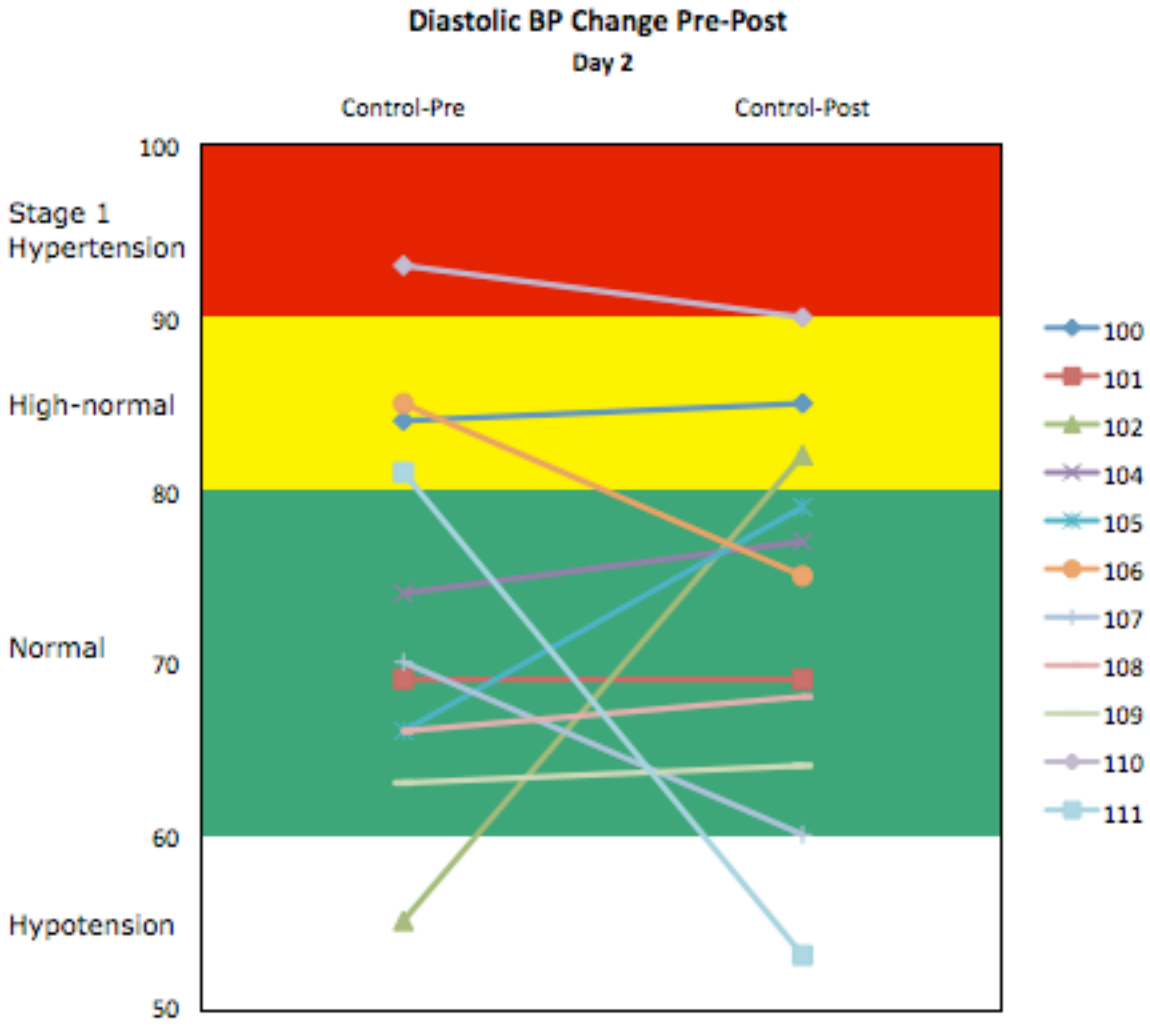


Figure 6. Diastolic BP Indicating Change Day 2 – Control

Day 3 (n=11), a singing day, the majority of participants had normal diastolic pressure and a participant in the hypertension category moved toward a high-normal range. One participant almost dropped into hypotension (60 mm Hg).

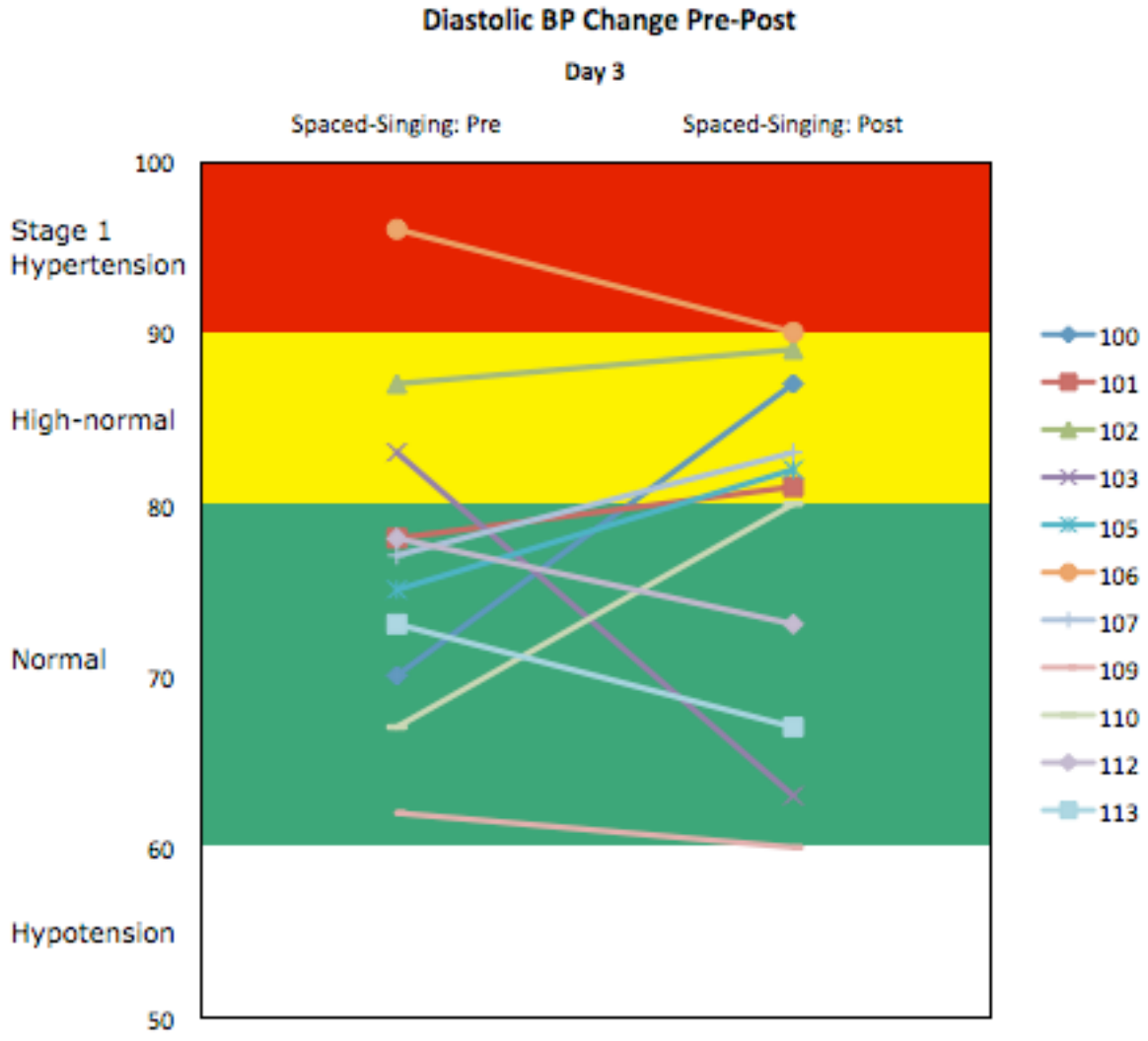


Figure 7. Diastolic BP Indicating Change Day 3 – Spaced-Singing

Day 4 (n=12), a control day, showed two participants moved into stage 2 hypertension and 3 participants moved toward a normal diastolic BP.

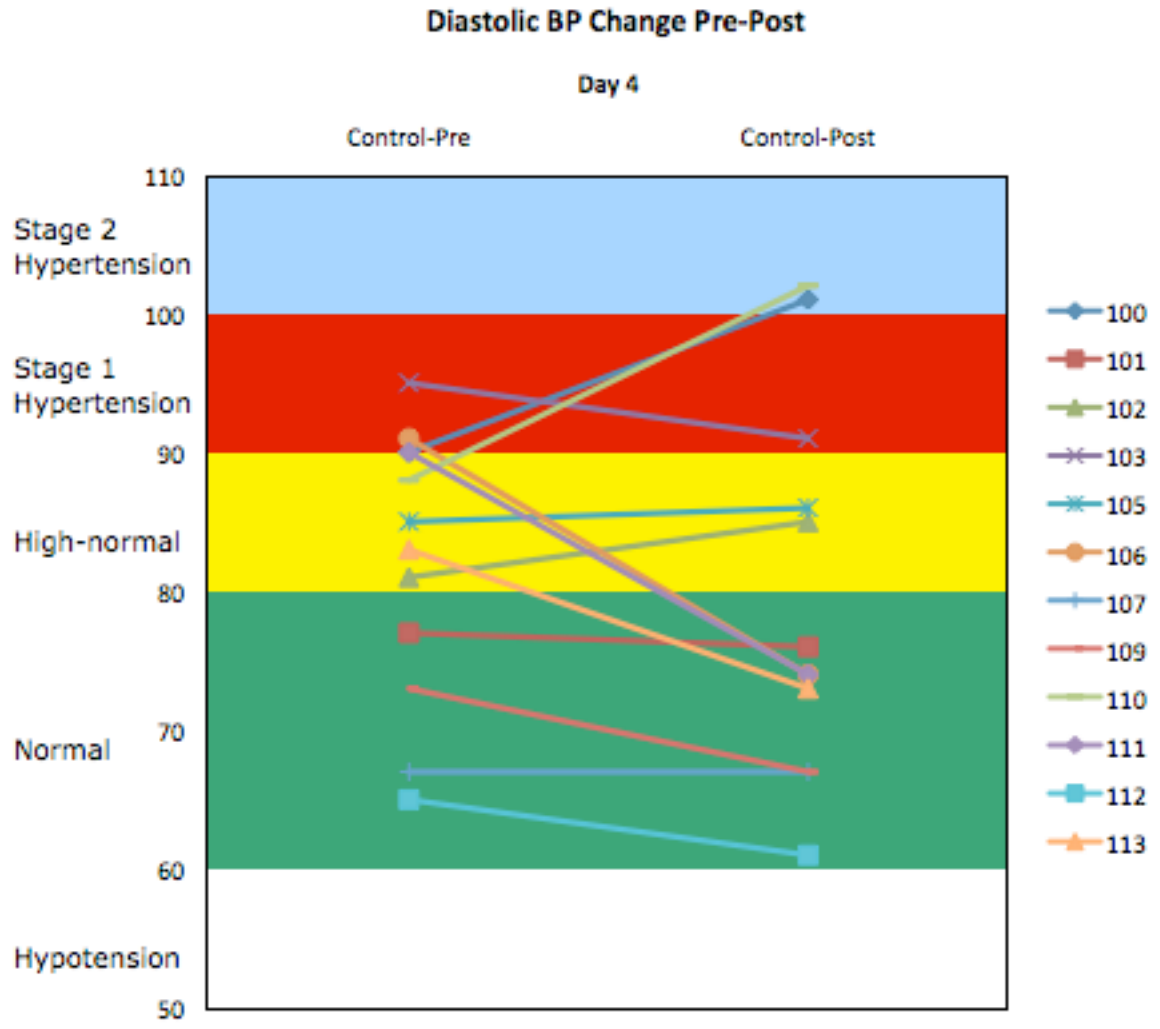


Figure 8. Diastolic BP Indicated Change Day 4 – Control

These graphs show the volatility and variability of BP measures with both increases and decreases being medically important. Table 3 shows the number of participants that experienced either a positive or negative change in BP during singing and discussion conditions.

Definitions of positive and negative change for Table 3.

Positive change = movement within or toward normal/optimal and normal-high BP range.

Negative change = movement from normal to hypo or hypertension range, movement in hypo or hypertension range away from the normal range, or no movement.

Table 3. Positive/Negative Change in Blood Pressure

Positive/Negative change in Blood Pressure

		Day 1 Singing	Day 3 Spaced-Singing	Day 2 Group Discussion	Day 4 Group Discussion
Systolic BP	Positive	8	10	7	8
	Negative	2	1	4	4
Diastolic BP	Positive	9	11	10	10
	Negative	1	0	1	2

Table 3 reveals a higher positive change in systolic BP with choral singing when compared to group discussion. However, the positive and negative change in diastolic pressure did not show a difference between the two conditions.

The graphs above use two different colors, green for normal/optimal, and yellow for high-normal/pre-hypertension, to describe a normal range for blood pressure. Although both the optimal and high-normal ranges are considered healthy, the optimal range, in green, is the medical ideal range for blood pressure. Table 4 shows the number of the participants that either moved toward or away from the optimal blood pressure range.

Definitions for toward or away from optimal BP in Table 4.

Toward optimal = pre-post blood pressure readings that move toward or within the optimal range.

Away from optimal = pre-post blood pressure readings that move away from the optimal range or have no movement in BP.

Table 4. Movement Toward or Away from Optimal Blood Pressure

Movement toward or away from optimal Blood Pressure					
		Day 1 Singing	Day 3 Spaced-Singing	Day 2 Group Discussion	Day 4 Group Discussion
Systolic BP	Toward optimal	7	7	5	6
	Away from optimal	3	4	6	6
Diastolic BP	Toward optimal	7	5	8	8
	Away from optimal	3	6	3	4

Table 4 reveals more movement toward optimal systolic blood pressure on the days where the singing condition was applied. Whereas, the days that had group discussion moved more toward optimal diastolic BP when compared to the singing condition days.

CHAPTER FIVE: DISCUSSION

The purpose of this study was to determine the effect of choral singing on the blood pressure and oxygen saturation of individuals with Parkinson's disease. The Friedman Two-Way Analysis of Variance showed that there was no significant difference in blood pressure and oxygen saturation when comparing choral singing to group discussion. However, change in systolic blood pressure did occur on an individual basis and the general direction was toward normal BP for both singing conditions

Relationship to Literature

Previous studies posit contradictory data on how singing effects blood pressure and oxygen saturation. This study shares similar conflicting results, in that blood pressure both increased and decreased after 30-minutes of singing. However, the studies that pointed toward an increase in blood pressure typically started at a relatively low to normal blood pressure. Studies that show that singing aids in lowering blood pressure tended to have participants that started with a particularly high blood pressure. Although the data appear contradictory, they are consistent and point to a hypothesis that the act of singing may induce or aid in bringing blood pressure to a healthy homeostasis. Knowing if music causes blood pressure to increase or decrease is important, but awareness of the direction of blood pressure may be a more pertinent medical question.

It is common for individuals with Parkinson's disease to have low blood pressure due to the side effects of both Parkinson's and medications taken to maintain PD symptoms. The majority of medications to treat PD lower blood pressure but some also increase BP (see Appendix A). Because of the multiple variables that effect BP, individuals with PD tend to have irregular blood pressure. The Friedman test did not show a significant difference after the choir sang. Conversely, it does demonstrate that singing is not dangerous for individuals with PD.

Limitations of Study

The sample size was quite small and a little over half of the participants were present all four days of data collection. Blood pressure, although a simple measurement to take, is a difficult measurement to control because it is influenced by multiple factors. There are also a couple of confounding variables that may have affected the data collected. Five out of the six

research assistants were female, and some male participants commented that having such pretty girls take their BP was having the adverse effect of raising their BP. However comical the manner in which the statement was made, it does expose an unexpected variable. Another confounding variable is that on the spaced singing day, two participants briefly stood up and walked a short distance about 19-minutes into the 25-minute spaced-singing experimental condition, which may have affected their BP reading about 6-minutes later.

In training the research assistants were instructed to repeat a BP measurement if there was a change > +/-25 mm Hg. On day 3, one reading of systolic pressure rose 55 mm Hg, and on day 4, a reading consisted of -42 mm Hg. Because the data collection form had no place to show if a second reading was for a faulty first reading, it is difficult to know if the above readings were faulty or checked twice. Since the sample size is quite small, these large outlier systolic BP measurements had an effect on the overall average amount of change.

Suggestions for Future Research

One of the top questions to address in future research is does singing affect the release of Cortisol in PD patients? Because singing has been shown to significantly strengthen the immune system through the use of S-IgA measurements, it would be interesting to research what effect singing has on Immunoglobulin A in individuals with Parkinson's disease. A comparison could be made between individuals with PD that do or do not sing in a choir, in order to measure if there are any long or short-term physiological effects related to singing.

Conclusions

This study set out to determine the effect that choral singing has on individuals with Parkinson's disease. Though the review of literature reports that singing has physiological effects on individuals; the measure of oxygen saturation and blood pressure in this study were not significant. Further, this study reveals that music does not change blood pressure in a manner that endangers the health of the individual's with PD. In looking at different graphs of individual change, a pattern emerges for systolic blood pressure and less so for diastolic BP. When looking at diastolic pressure, on day 1 and day 3 the participants with either very high or low blood pressure moved toward a normal BP. Whereas for day 2, the overall movement of BP was minimal, and day 4 had several increases. Though the amount of change was not significant, these patterns of change create new questions.

APPENDIX A.

MEDICATIONS TAKEN BY PARTICIPANTS

Participant-Medication use															
	Participant #														
Medications	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114
Amantadine						Y							Y		
Aspirin								Y		Y					
Azilect					Y			Y			Y	Y	Y		
Carbidopa/ Levodopa	Y		Y			Y			Y				Y		
Ciprofloxacin															
Clonidine						Y									
Colace			Y												
Comtan	Y		Y			Y									
Diltiazem								Y							
Donepezil								Y							
Fexofenadine								Y							
Fludrocortisone											Y				
HCTZ														Y	
Ibprofen								Y							
Levetiracetam					Y										
Lodosyn														Y	
Lopressor						Y									
Melatonin								Y							
Metformin							Y								
Mirapex	Y					Y				Y		Y	Y		
Namenda								Y							
Pramipexole					Y										
Pravastatin								Y		Y					
Prevacid														Y	
Prilosec							Y								
Requip								Y			Y				
Selegiline			Y												
Simvastatin			Y												
Sinemet	Y	Y	Y	Y						Y					
Stalevo				Y	Y		Y	Y				Y	Y	Y	
Symmetrel															
Synthroid										Y					
Tamsulosin								Y							
Tramadol														Y	
Valerian								Y							

Key	
Yellow	May lower BP
Orange	May raise BP

APPENDIX B.

CONSENT FOR RESEARCH

Consent for Research

Title of Project: *The effect of choral singing on individuals with Parkinson's disease as measured by blood pressure and oxygen saturation.*

Principal Investigator: Thomas Hayden

Participant's Printed Name: _____

This is a research study. Research studies include only people who want to take part. This form gives you information about this research, which will be discussed with you. It may contain words or procedures that you do not understand. Please ask questions about anything that is unclear to you. Discuss it with your family and friends and take your time to make your decision.

1. **Purpose of the Research**

   The purpose of this study is to learn more about the effect of choral singing on individuals with Parkinson's disease as measured pre and posttest by oxygen saturation and blood pressure. Individuals with Parkinson's disease are being offered the opportunity to take part in this research because this study requires participants to both sing in a choir and be diagnosed with Parkinson's disease. The study will take place during two regular rehearsal times at the common rehearsal location, the dining room at Tallahassee Memorial Rehabilitation Center (TMRC).

2. **Procedures to Be Followed**

   You will be asked to fill out a demographic questionnaire, have your blood pressure and oxygen saturation measured before and after singing and before and after reading/socializing. The demographic questionnaire will only ask questions that are anonymous and basic information such as: gender, year of birth, diagnosis of Parkinson's and the specific medications that you are currently taking. The oximeter will be used to measure the oxygen in your blood, also known as oxygen saturation, and works by pulsing a small light on a fingertip clip. Your participation is voluntary, and you can stop the questionnaire, blood pressure, and oxygen saturation measurement at any time without any penalty to you.

3. **Discomforts and Risks:**

   Your blood pressure will be taken in a manner similar to how it is taken at a Doctor's office and you may feel a slight squeeze when blood pressure is measured. This study has minimum risk and any possible risk is comparable to risks you would have with or without this research. Both the blood pressure monitor and oximeter are FDA approved.

4. **Possible Benefits:**

   You will not benefit from taking part in this research study.
   The results of this study may guide the future treatments or interventions that music therapists use with individuals with Parkinson's disease and other populations.

5. **Other Options that Could be Used Instead of this Research:**

   You may decline to participate in this study at any time.

Approved

FSU Human Subjects Committee Approved on 11/30/2011. Void after 11/28/2012. HSC# 2011.7077

Research measures cannot be obtained without enrolling in the research.
You do not have to participate in this study.
The therapy offered to you is available to you without taking part in this research study.

6. **Time Duration of the Procedures and Study:**

The first rehearsal will consist of obtaining informed consent, completing the demographic questionnaire, a blood pressure and oximeter reading which should take approximately 20 minutes depending on how many you may have. The choral rehearsal will take a minimum of 30 minutes of singing, followed by another blood pressure and oximeter reading which should take no more than 10 minutes.

The second rehearsal (one week later) will consist of a blood pressure and oximeter reading (approximately 10 minutes), a minimum of 30 minutes of socializing/reading time, followed by another blood pressure and oximeter reading (approximately 10 minutes).

7. **Statement of Confidentiality:**

Privacy and confidentiality measures

Your research records that are reviewed, stored, and analyzed will be kept in a secure locked cabinet before transferred to a password secured encrypted computer in a locked office. All data collected will have a numerical and alphabetical code; names will not be used. Neither video nor audio devices will be used to record participants in this study.

The list that matches your name with the code number will be kept in a locked file in the PI's office and destroyed after research data is analyzed. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Write to Thomas Hayden and let me know that you are withdrawing from the research study. My mailing address is 2566 West Tennessee St. Apt. 12131A Tallahassee, FL 32304.

If you withdraw your permission:

- We will no longer use or share information about you or this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The principal investigator, Thomas Hayden, may use your health information and share it with other specific groups in connection with this research study.

The principal investigator may share your health information with the following people/groups for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original records.

Approved

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The Institutional Review Board at Tallahassee Memorial HealthCare, Inc.
- The Human Subjects Protection Office at Florida State University

We will do our best to make sure that the personal information in your record will be kept private. However, because of the need to release information to the above parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released, it may be redisclosed and no longer protected by federal privacy regulations. Your personal information may also be given out if required by law and in rare circumstances may be subpoenaed by a court.

8. **Costs for Participation:**
   It will not cost you anything to participate in this study.
   You will not lose any legal rights by signing this form.

9. **Compensation for Participation:**
   You will not receive any compensation for being in this research study.

10. **Research Funding:**
    The researcher is not receiving any funds to support this research study.

11. **Voluntary Participation:**
    Taking part in this research study is voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are entitled.

12. **Contact Information for Questions or Concerns:**
    You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns related to this research, contact Thomas Hayden at (901) 481-0137.

    If you have questions regarding your rights as a research participant or you have concerns or general questions about the research, contact the research protection advocate Cynthia Blair, Administrative Liaison/IRB, Tallahassee Memorial Health Care, 850-431-5676 or the Human Subjects Office at Florida State University, 850-431-5676. You may also call either number if you cannot reach the research investigator or wish to talk to someone else.

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Approved

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

Signature of Participant	Date	Time	Printed Name

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators/research coordinators and those trained in obtaining research informed consent and familiar with this research may explain the research and obtain informed consent.)
A witness or witness/translator is required when the participant cannot read the consent document; so it was read or translated.

Approved

INSTITUTIONAL REVIEW BOARD
OCT 24 2011
APPROVED AT TMH

APPENDIX C.
DEMOGRAPHIC SURVEY

#_____

Demographic Survey

What year were you born?_____

What year were you diagnosed with Parkinson's?_____

What is your gender: Male____ Female____

How long have you sung in the Parkinson's choir?

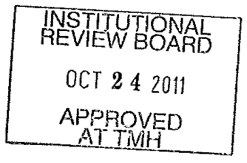
___ Less than 1 year ___ 1 - 2 years

___ 3 - 4 years ___ 5 or more years

How often do you go to choir rehearsal?

___ Almost every rehearsal ___ 1 - 2 times per month

___ Less than 12 times per year ___ Just started to attend



#_____

Did you take any medications today to manage symptoms related to Parkinson Disease? ___ Yes ___ No

Please list any medications that you took today, their dosage, and what time you took them.

Medication	Dosage	Time taken

Thank you for participating in this study!

APPENDIX D.

CODE KEY

Code Key

Name	Code

INSTITUTIONAL REVIEW BOARD
OCT 24 2011
APPROVED AT TMH

APPENDIX E.

DATA COLLECTION FORM

Participant #_____

Data Collection Form

With Singing	Oxygen Saturation	Blood Pressure
PreTest		Systolic = Diastolic=
Posttest		Systolic = Diastolic=
Control	**Oxygen Saturation**	**Blood Pressure**
PreTest		Systolic = Diastolic=
Posttest		Systolic = Diastolic=

APPENDIX F.

BLOOD PRESSURE CHARTS

Categories for Blood Pressure levels in Adults (Ages 18 Years and Older)

Category	Systolic (mm Hg)		Diastolic (mm Hg)
Optimal	<120	and	<80
Normal	<130	and	<85
High-normal	130 to 139	or	85 to 89
Hypertension			
Stage 1	140 to 159	or	90 to 99
Stage 2	160 to 179	or	100 to 109
Stage 3	≥180	or	≥110

APPENDIX G

PRE-POST DAY 1, 2, 3, AND 4

DAY 1	**With Continuous Singing**								
	pre	*post*	***CH***	pre	*post*	***CH***	pre	*post*	***CH***
participant #	O2 sat	O2 sat		bp (sys)	bp (sys)		bp (dia)	bp (Dia)	
100	96	96	**0**	130	102	**-28**	69	68	**-1**
101	99	98	**-1**	153	137	**-16**	68	67	**-1**
102	98	97	**-1**	91	98	**7**	57	65	**8**
103	99	99	**0**	128	112	**-16**	63	68	**5**
104	98	97	**-1**	158	134	**-24**	78	69	**-9**
105	98	98	**0**	140	136	**-4**	81	77	**-4**
106	97	97	**0**	156	142	**-14**	94	78	**-16**
107	99	92	**-7**	168	172	**4**	81	83	**2**
108									
109	99	91	**-8**	112	130	**18**	67	80	**13**
110	93	95	**2**	152	162	**10**	85	93	**8**

	sys	dia
hypo	< 90	< 60
normal	90-119	<60-79
pre-hyper	120-139	80-89
stage 1	140-159	90-99
stage 2	160 +	100 +

DAY 2	**Control (No Singing)**								
	pre	*post*	***CH***	pre	*post*	***CH***	pre	*post*	***CH***
participant #	O2 sat	O2 sat		bp (sys)	bp (sys)		bp (dia)	bp (Dia)	
100	98	91	**-7**	140	151	**11**	84	85	**1**
101	99	96	**-3**	157	159	**2**	69	69	**0**
102	96	99	**3**	84	111	**27**	55	82	**27**
103									
104	99	99	**0**	145	145	**0**	74	77	**3**
105	98	98	**0**	103	125	**22**	66	79	**13**
106	99	96	**-3**	157	140	**-17**	85	75	**-10**
107	95	94	**-1**	140	111	**-29**	70	60	**-10**
108	91	91	**0**	101	113	**12**	66	68	**2**
109	97	91	**-6**	92	114	**22**	63	64	**1**
110	99	99	**0**	163	153	**-10**	93	90	**-3**
111	93	90	**-3**	141	116	**-25**	81	53	**-28**

	sys	dia
hypo	< 90	< 60
normal	90-119	<60-79
pre-hyper	120-139	80-89
stage 1	140-159	90-99
stage 2	160 +	100 +

DAY 3	**With Spaced Singing**								
	pre	*post*	***CH***	pre	*post*	***CH***	pre	*post*	***CH***
participant #	O2 sat	O2 sat		bp (sys)	bp (sys)		bp (dia)	bp (Dia)	
100	99	96	**-3**	114	122	**8**	70	87	**17**
101	97	97	**0**	177	153	**-24**	78	81	**3**
102	99	99	**0**	128	135	**7**	87	89	**2**
103	99	96	**-3**	143	122	**-21**	83	63	**-20**
104									
105	98	98	**0**	119	138	**19**	75	82	**7**
106	97	96	**-1**	170	160	**-10**	96	90	**-6**
107	99	99	**0**	187	174	**-13**	77	83	**6**
108									
109	98	99	**1**	102	157	**55**	62	60	**-2**
110	95	95	**0**	102	111	**9**	67	80	**13**
111									
112	99	99	**0**	113	102	**-11**	78	73	**-5**
113	95	99	**4**	122	117	**-5**	73	67	**-6**
114	98			98			56		

	sys	dia
hypo	< 90	< 60
normal	90-119	<60-79
pre-hyper	120-139	80-89
stage 1	140-159	90-99
stage 2	160 +	100 +

DAY 4	**Control (No Singing)**								
	pre	*post*	***CH***	pre	*post*	***CH***	pre	*post*	***CH***
participant #	O2 sat	O2 sat		bp (sys)	bp (sys)		bp (dia)	bp (Dia)	
100	99	99	**0**	163	171	**8**	90	101	**11**
101	99	98	**-1**	142	163	**21**	77	76	**-1**
102	99	99	**0**	123	145	**22**	81	85	**4**
103	99	99	**0**	163	153	**-10**	95	91	**-4**
104									
105	98	98	**0**	130	134	**4**	85	86	**1**
106	99	98	**-1**	155	154	**-1**	91	74	**-17**
107	96	95	**-1**	140	130	**-10**	67	67	**0**
108									
109	99	99	**0**	118	138	**20**	73	67	**-6**
110	99	99	**0**	142	163	**21**	88	102	**14**
111	95	95	**0**	166	124	**-42**	90	74	**-16**
112	99	99	**0**	94	91	**-3**	65	61	**-4**
113	99	99	**0**	137	124	**-13**	83	73	**-10**

	sys	dia
hypo	< 90	< 60
normal	90-119	<60-79
pre-hyper	120-139	80-89
stage 1	140-159	90-99
stage 2	160 +	100 +

APPENDIX H.

DATA FROM FRIEDMAN TWO-WAY ANALYSIS OF VARIANCE

Change in Systolic Blood Pressure

Participants	**Change in systolic blood pressure RANKS**			
	Day 1	*Day 2*	*Day 3*	*Day 4*
100	1	4	2.5	2.5
101	2	3	1	4
102	1.5	4	1.5	3
105	1	4	3	2
106	2	1	3	4
107	4	1	2	3
109	1	3	4	2
110	3	1	2	4
	15.5	**21**	**19**	**24.5**
mean	1.9	2.6	2.4	3.1
csq$_r$	3.19			
df	3			
p	0.3632			

Change in Diastolic Blood Pressure

Participants	**Change in diastolic blood pressure RANKS**			
	Day 1	*Day 2*	*Day 3*	*Day 4*
100	1	2	4	3
101	1.5	3	4	1.5
102	3	4	1	2
105	1	4	3	2
106	2	3	4	1
107	3	1	4	2
109	4	3	2	1
110	2	1	3	4
	17.5	**21**	**25**	**16.5**
mean	2.2	2.6	3.1	2.1
csq$_r$	3.34			
df	3			
p	0.3421			

Change in Oxygen Saturation

Participants	**Change in oxygen saturation RANKS**			
	Day 1	*Day 2*	*Day 3*	*Day 4*
100	3.5	1	2	3.5
101	2.5	1	4	2.5
102	1	4	2.5	2.5
105	2.5	2.5	2.5	2.5
106	4	1	2.5	2.5
107	1	2.5	4	2.5
109	1	2	4	3
110	4	1.66	1.66	1.66
	19.5	**15.66**	**23.16**	**20.66**
mean	2.4	2	2.9	2.6
csq$_r$	2.21			
df	3			
p	0.53			

APPENDIX I.

TALLAHASSEE MEMORIAL IRB APPROVAL LETTER

Tallahassee Memorial HealthCare

Office of Research
Institutional Review Board
[redacted]

November 4, 2011

Thomas Hayden
[redacted]

Dear Mr. Hayden:

Your study IRB # 2011-37 Titled: The effect of choral singing on individuals with Parkinson's disease as measured by blood pressure and oxygen saturation met the criteria for review using the expedited review guidelines. [redacted] Chairperson, Institutional Review Board (IRB) at Tallahassee Memorial HealthCare, Inc. (TMH) reviewed the study, the supporting documentation and approved the study on October 24, 2011 for one year. The expiration date of this approval is October 23, 2012.

IRB # 2011-37	The effect of choral singing on individuals with Parkinson's disease as measured by blood pressure and oxygen saturation
Principal Investigator:	Thomas Hayden
Informed Consent:	Date 10/14/11 Approved as is.
Protocol:	Version 10/5/11 Approved as is.

List other appropriate materials reviewed by the Reviewer:
Reporting Requirements:

- Report to the IRB any planned change in the study or informed consent and do not implement any change without receiving prior approval, except to eliminate immediate hazard;
- Report to the IRB any unanticipated problems involving risks to subjects;
- Report to the IRB any new information on the project that adversely influences the risk/benefit ratio;
- Report to the IRB any serious or unexpected adverse events;

FWA #00006166
Tallahassee Memorial HealthCare, Inc. Institutional Review Board is organized and operates according ICH-GCP standards and applicable laws and regulations.

- Report to the IRB any major protocol violations with in ten days. Minor protocol deviations may be reported at the time of the Study Progress Report (Application for Renewal). Maintain a log throughout the year and establish a plan of correction to minimize the deviations.
- Report to the IRB when the study is terminated or completed and submit a summary of the study findings.

Please request approval for advertising copy, recruitment flyers, publications, that appear in any medium prior to use.

Supplemental Reporting Requirements: None
Expiration Date: October 23, 2012
Continuation Review Date: October 23, 2012
Continuation Review Requirements:
At the time of renewal please check the Office of Research/IRB intranet site to ensure that you have the most current edition of the IRB Forms. The investigator must submit a completed Study Progress Report Application and supporting documentation packet to the Office of Research/IRB one month prior to the approval expiration date. Please note the expiration date to ensure timely review and processing of the study file prior to the study's approval expiring. If you have any questions about the forms or submitting them, please contact Mary Sandell, Regulatory Readiness Coordinator at (850) 431-5676.

As the principal investigator you are responsible for ensuring compliance with the study protocol, the applicable IRB at TMH Guidelines and Code of Federal Regulations set forth by the Department of Health and Human Services. The IRB Guidelines and forms required to comply with reporting requirements are available on the TMH Intranet.

Enclosed are copies of the informed consent and other materials which were reviewed and approved by the Chairperson and have the IRB approval stamp for this year.

Sincerely,

[redacted]

Administrative Liaison/IRB

APPENDIX J.

FLORIDA STATE UNIVERSITY IRB APPROVAL LETTER

Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2742
[redacted]

APPROVAL MEMORANDUM

Date: 11/30/2011

To: Thomas Hayden

Address: [redacted]
Dept.: MUSIC SCHOOL

From: [redacted]

Re: Use of Human Subjects in Research
Effect of singing on individuals with Parkinson's disease.

The application that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Secretary, the Chair, and one member of the Human Subjects Committee. Your project is determined to be Expedited per per 45 CFR § 46.110(7) and has been approved by an expedited review process.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals, which may be required.

If you submitted a proposed consent form with your application, the approved stamped consent form is attached to this approval notice. Only the stamped version of the consent form may be used in recruiting research subjects.

If the project has not been completed by 11/28/2012 you must request a renewal of approval for continuation of the project. As a courtesy, a renewal notice will be sent to you prior to your expiration date; however, it is your responsibility as the Principal Investigator to timely request renewal of your approval from the Committee.

You are advised that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report, in writing any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chair of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Human Research Protection. The Assurance Number is FWA00000168/IRB number IRB00000446.

Cc: [redacted], Advisor
HSC No. 2011.7077

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BIOGRAPHICAL SKETCH

Education

September 2002 to May 2007	**Bachelor of Science in Psychology, University of Tennessee at Chattanooga**, Chattanooga, Tennessee
September 2004 to May 2005	**University of Hawaii at Hilo** Hilo, Hawaii
September 2006 to December 2006	**Kangnung National University** Gangneung, South Korea

Professional Experience

November 2011 to March 2012	**Graduate Research Assistant, Tallahassee Memorial Hospital** Tallahassee, Florida
September 2010 to May 2011	**Music Therapy Intern, Connecticut Hospice** New Haven, Connecticut
September 2010 to May 2011	**Music Therapy Intern, Yale-New Haven Children's Hospital** New Haven, Connecticut
October 2006 to December 2006	**English Teacher, Dong-Do Church Language Academy** Gangneung, South Korea

Certifications and Training

December 2011	**Board Certification in Music Therapy**
August 2009	**NICU Music Therapist**