Title: The Influence Of Relaxation Music On Physiological Responses In Patients Receiving Osteopathic Interventions

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November 2004

Submitted as part fulfilment of the requirements for the degree-
Master of Health Science (Osteopathy)

ABSTRACT

This study examined the effects of music on physiological and psychological responses in Osteopathic patients who listened to relaxation music. Fifty subjects, twenty-six females and twenty-four males ranging in age from 18-51, were randomly assigned to one of two environmental settings. Participants in the control group were treated in the absence of relaxation music. The participants allocated to the experimental group received their normal Osteopathic treatment whilst relaxation music played in the background. The specific music selected was shown in previous research to decrease State anxiety. Physiological data collected before and after treatment included heart rate, respiration, diastolic blood pressure, and systolic blood pressure. Psychometric data was assessed using a Visual Analogue Scale for self-perceived relaxation. Significant differences ($p<.05$) were found from pre-test to post-test in the music group for heart rate, blood pressure and respiration. There were no significant differences in self-perceived tension ratings between the two groups.

INTRODUCTION

Research indicates that music has been successfully used to reduce anxiety and facilitate relaxation in conventional medical settings (Augustin & Hains, 1996; Good, 1996; White, 1992). Researchers have also discovered that when music is playing in the background it induces mental and physical relaxation in patients, making treatments more effective and less painful. Although general inferences can be made from published data, at present minimal research has been conducted investigating the effects of music within a healthcare system such as Osteopathy.

Anxiety

Anxiety is usually divided into two types: State anxiety, which refers to an individual's anxiety at a particular point in time, and Trait anxiety which is an overall prevailing condition of anxiety unbounded by time and determined by personality (Aldridge, 1996). Researchers agree that the degree of anxiety can be monitored via observable changes in the sympathetic nervous system (Steelman, 1990; Hanser, 1985). These physiological responses can include an increase in heart rate, blood pressure, respiration rate, metabolism, and peripheral vasoconstriction (Biley, 1992; Spintge & Droh, 1992; Steelman, 1990; Stevens, 1990; Zimmerman, Pierson & Marker, 1988).

Long Term Affects Of Anxiety

Psychological stress has been associated with a variety of physical and psychological disorders. In fact research indicates that up to seventy five percent of all medical disorders can be directly attributed to stress (Hughes, Pearson & Reinhart, 1984). Typically these disorders include gastrointestinal problems such as peptic ulcers and ulcerative colitis (Khorana, 1983), skin disorders such as eczema (Pillsbury, Shelley & Kligman, 1956), female reproductive dysfunction (O'Moore, 1983), headaches (Kutash & Schlesinger, 1980), respiratory ailments such as asthma (Bieliauskas, 1982), and other serious diseases (Rose & Levin, 1979).

Research has also recognized that stress is associated with reductions in lymphocyte levels, a strong risk factor for cancer (Paterson & Neufeld, 1989; Everly & Sbelman, 1987; Charlesworth & Nathan, 1984; Grossarth-Maticek, Kanazir, Vetter, & Schmidt, 1983), sodium and fluid retention that predisposes to hypertension (Light, Koepke, Obrist & Willis, 1983), and obesity (Lowe & Fisher, 1983), which in turn may contribute to cardiovascular disease (Rozanski, Blumenthal & Kaplan, 1999; Krantz & Manuck, 1984). A number of studies have also linked anxiety and subsequent somatic stress responses to delays in wound healing: standardised wounds took 24% to 40% longer to heal in anxious, stressed subjects than in control subjects. (Marucha, Kielcolt-Glaser, Favegehi, 1998; Padgett, Marucha & Sheridan, 1998; Kiecolt-Glaser, Marucha, Malarkey, Mercado & Glaser, 1995).

Studies suggest that subjective and physiological indices of anxiety may not always be correlated (Davies & Thaut, 1989; Iwanaga, Ikeda & Iwaki, 1996). Conclusions drawn by Davies and Thaut (1989) suggest that each individual may have a unique biological system that reacts to a given stimulus with an idiosyncratic but consistent physiological response and perceived psychological experience. Methodological problems including small sample sizes or absence of adequate controls or baselines may also be partly responsible for this inconsistency (Bartlett, 1996; Biley, 2000; Dainow, 1977).

Music and Medicine

Methods other than pharmacological interventions are being sought to reduce stress and produce a sense of relaxation and tranquillity (Davis & Thaut, 1989). Music has been found to increase parasympathetic activity (McCraty, Atkinson, Tiller, Rein & Watkins, 1995), and increase humoral immunity (McCraty, et.al 1996). Therefore, it is effective in decreasing stress-induced autonomic and neuroendocrine arousal and facilitating physiological relaxation responses (Kibler & Rider, 1983; Scartelli, 1984; McCraty, Barrios-Choplin, Atkinson & Tomasino, 1998).

Music therapy has been widely used in a variety of cultures for centuries to decrease patients' perception of pain, anxiety and depression, and boost their feelings of relaxation (Gonzalez, 1989; Barger, 1979). Schorr (1993) explored the effect of music on the chronic pain of 30 female patients with rheumatoid arthritis. This study revealed that listening to self-selected music for 20 minutes a day resulted in a highly significant reduction in McGill pain questionnaire scores. Like Schorr, other studies have also demonstrated that music can decrease pain perception through distraction or dissociation (Gardner, Licklider & Weisz, 1978; Wolfe, 1978). Several studies conducted in clinical settings have demonstrated that when music is playing in the background, patients experience less pain from treatment. Patients who listened to music before ambulatory surgery showed a reduction in blood pressure, respiratory rates and anxiety levels, compared to the control group (McGreevy-Steelman, 1990; Augustin & Hains, 1996). Good (1996) showed that the use of music as an audio-analgesic in chronic and acute pain had a positive and significant effect on pain control.

Music therapy, heart rate, respiration and blood pressure.

The influence of music on physiological processes has been investigated by many studies but has produced variable results. As anxiety impacts an individual physiologically and emotionally, it is necessary to have tools to measure both of these outcomes (Spintge & Droh, 1992). Davis & Thaut (1989) have stated that outcome measures must be selected carefully. The most reliable markers used to detect changes of physiological stress include changes in heart rate, blood pressure and respiratory rate (Chetta, 1981; Kaempf & Amodei, 1989; Meltzler & Berman, 1991; Moss, 1988; Steelman, 1990; Updike, 1990; White, 1992; Zimmerman, Pierson & Marker, 1988). In these studies, the most common methods for measuring changes in psychological stress include the State-Trait Anxiety Inventory, and subjective reporting of tension levels such as a Likert-Scale or Visual Analogue Scale.

Preferred Music Style

Researchers have studied the effectiveness of preferred music on anxiety with varied results. Stratton and Zalanowski (1984) found that state anxiety decreased consistently while the participants listened to their preferred music. In a later study by Davis & Thaut (1989), the effect of subject-selected and experimenter-chosen music did not have a significant effect on anxiety and relaxation. Abeles and Chung (1996) believe the potential of music to reduce anxiety and increase relaxation in an individual depends on factors such as familiarity and preference with respect to the music being listened to, as well as their current mood, and previous music training. Despite the inconsistencies in the literature, research has generally supported the idea that musical stimuli, when perceived as pleasant and relaxing, can increase the psychological relaxation in wellness programs and in a diversity of clinical populations (Davis & Thaut, 1989; Gonzalez, Snyderman & Colket 1996, Hanser, 1985; O'Connell, 1983; Scartelli, 1994; Thaut, 1989).

Osteopathy-Music And Manual Therapy

In formulating the principles of Osteopathy, Still placed importance on treating the body as a unit with interrelated components. He proposed that the body has an ability to regulate itself toward health, given an appropriate physical and mental environment and adequate nutrition (De Giovanna & Schiowitz, 1991). A properly formulated and applied Osteopathic treatment should successfully treat the presenting complaint, but should also have the additional benefits of improving the overall psychological and physiological functioning of the patient. Based on previous studies (McCaffrey & Freeman, 2003; Miller & Redmond, 1999; Watson, 1997) there is strong circumstantial evidence that music could form a useful adjunct to normal Osteopathic treatment, particularly if one considers conditions that are commonly seen by Osteopaths such as tension headaches or low back pain, which may be caused or aggravated by underlying anxiety and stress (Abrams & Ellis, 1994).

Two studies (Augustin & Hains, 1996; Davis, 1992) have been conducted concerning the use of music therapy within conventional medical settings as a tool for relaxation, or to reduce pain perception through distraction. In a review of literature concerning the use music in an alternative healthcare system only two studies were found. The earliest of these studies was conducted by Strauser (1997) who examined the effects of music versus silence on measures of State anxiety, perceived relaxation, and physiological responses of Chiropractic patients prior to and immediately following Chiropractic treatment. Even though this study did not examine continuous background music during treatment, significant differences were found from pre-test to post-test for State anxiety and tension. Blood pressure was not found to be significant.

A recent, unpublished, study conducted by Sherriff, (2002) focused on State anxiety and self perceived tension levels on Osteopathic students. These students listen to three different relaxation compact discs but did not receive any Osteopathic treatment. A significant difference was found between post-test group means for both State anxiety and self- perceived tension. The instrumental style of relaxation music followed by Natural "Ocean sounds" were found to be the most successful in decreasing State anxiety and self-perceived tension. This data however was collected from healthy subjects, further research is required to investigate the effects of relaxation music on symptomatic patients as they often suffer from a higher level of anxiety than Osteopathic students due to pain or chronic illness (Mulooly, Levin & Feldman, 1988; Pilowsky & Spence, 1975).

The present study is aimed to provide evidence to support the use of music in Osteopathic health-care. This study was performed on Osteopathic patients scheduled for treatments at the Victoria University Osteopathic Medicine Clinic. It was hypothesised that environmental relaxation music would have a positive effect on the participants, thus establishing a more effective and holistic Osteopathic treatment approach in which the practitioner provides a combination of manual therapy to treat the patient's symptoms and music therapy to assist in enhancing patient relaxation and reducing anxiety levels.

METHODS

Subjects

Fifty Osteopathic patients participated in this study (26 female, 24 male) ranging in age from 18-51 years old (control: 26.8 ± SD 6.38, music: 27.5 ± SD 7.86) Participants who were attending their scheduled treatment times at the Victoria University Student Osteopathic Medicine Clinic in Melbourne were invited to participate on a voluntary basis. Each patient was given an information sheet detailing the study and procedures. The information sheets did not however include words which may have led the patient to believe that they would be listening to relaxation music or alternatively that they were being deprived of relaxing music. Additionally, participants were not told that the device worn around their chest would be measuring their respiration. This served to minimise the chance they would change their breathing pattern. A standard approved Victoria University of Technology consent form was signed by each participant, which outlined their right to withdraw from the study at any time without prejudice or alteration of their treatment. The Faculty of Human Development Human Research Ethics Committee of Victoria University approved the study.

Participants were excluded from this study if they had been diagnosed with a clinical anxiety state, had been taking medications that affects their nervous system, had consumed a beverage other than water in the past two hours, had consumed food, alcohol, nicotine in the last two hours, had been diagnosed with significant hearing loss, suffered from a condition that affects their normal breathing other than asthma, had a formal background in music (higher than Grade 5 Australian Music Examinations board or equivalent), as individuals with extensive music training may respond differently than non-musicians to musical stimuli (Hodges 1980).

Facilities and apparatus

All testing was undertaken at the Victoria University Student Osteopathic Medicine Clinic located at the City-Flinders campus of Victoria University, Melbourne.

Physiological data was collected using non-invasive procedures with the following equipment: (a) ADI instruments plethysmographic sensor (MLT1020) to measure heart rate (b) Piezo ADI instruments respiratory belt transducer (MLT1132) to measure respiration rate (c) Omron M4 electronic sphygmomanometer to measure blood pressure. Data from the plethysmograph and the respiration transducer were gathered on a multi-channel recorder and monitored using Power Lab v 3.6 chart software computer program. Other equipment included a portable compact disc player and a stopwatch. Self perceived anxiety was assessed using a Visual Analogue Scale (VAS) which consisted of a horizontal line ranging from 0, labelled "not tense at all" at one end, to 10, labelled "extremely tense" at the opposite end (see Appendix C). This scale is a useful and commonly used technique for rating subjective phenomena such as tension (Hersen & Bellack, 1988). The compact disc used in this study was Natural Sounds with music "Ocean Sounds" New World Music Limited 1998, it has been marketed as an environmental style of relaxation music. This disc has demonstrated to be effective in decreasing State anxiety (Sherriff, 2002).

Treatment

Treatments were conducted by fourth and fifth year students at Victoria University under the supervision of a qualified Osteopathic practitioner. Treatments ran for approximately 20 minutes. The methods of treatment employed are diverse and dependent on the presenting complaint but may include combinations of soft tissue techniques, stretching and manipulation.

Procedure

Subjects were tested individually. Before entering the testing area, participants completed a consent form and indicated whether they had any of the exclusion criteria apply to them. Participants were randomly allocated to an intervention group (treatment in a room with background music) or a control group (treatment in a room without music). After the practitioner had taken the patient's history (5 mins) they asked the patient to disrobe. The researcher then entered the room to attach the measuring devices. The plethysmographic sensor was strapped to the pad of

participant's left index finger, the respiration transducer was strapped around the patient's chest and the blood pressure cuff was applied to the patient's right arm.

The researcher left the testing area and participants rested quietly for four minutes to achieve resting baseline measures, and reduce the chance of significant parameter overestimation (Bakx, Netea, van den Hoogen, Oerlemans, van Dijk, van den Bosch; 1999). At the end of this period the participant's indicated their current level of self-perceived tension (SPT) by placing the appropriate mark on the supplied VAS. The researcher then re-entered the room to obtain base line measures of blood pressure, heart rate and respiration rate. All sensors and transducers were removed before the practitioner re-entered the treatment room to commence the scheduled treatment. Participants in the intervention group were treated whilst music played continuously in the background for the length of the treatment (approximately 20 minutes) participants in the control group were treated in the absence of music.

On completion of the treatment, the researcher entered to refit the transducers. After resting quietly for four minutes the participant was required to complete a second VAS. Post-treatment measurements of blood pressure, heart rate and respiratory rate were then taken. (See Appendix D). Practitioners were required to fill out a table outlining which treatment techniques they used during the treatment and to what areas they applied them (See Appendix E). These checklists were evaluated to ensure that patients in the intervention group did not receive substantially different treatment from the control group.

Independent t-tests were performed on all five parameters using the SPSS 11.0 computer package. The change that occurred from pre-treatment to post-treatment was calculated and these scores were compared between groups. Thus five t-tests were completed. Because of this large amount, a Bonferonni adjustment (0.05/5)=0.01 was used to assess significance.

RESULTS

The current research evaluated the physiological effects of listening to music. Recordings of heart rate, respiratory rate, systolic and diastolic blood pressure measured this physiological effect. Subjective tension levels were measured using a Visual Analogue Scale.

As depicted in Figures 1-5 the group means for HR, diastolic pressure, systolic pressure and respiration decreased consistently from pre-test to post-test in the intervention group. Paired analysis for differences in the means of these physiological measures revealed a significance decrease (<0.05) between pre-test and post-test scores in the music group (Refer to Appendix F).

The mean heart rate for the control group dropped from 61.44 to 58.92 (pre-test= SD ± 9.57, post-test= SD ± 8.16) beats per minute post treatment. However the experimental groups' mean heart rate dropped from 65.72 to 58.92 (pre-test = SD ± 9.01, post-test = SD ± 8.56) beats per minute after the music intervention (t=3.554, p= 0.001). (Refer to Figure 1).

The mean respiration rate for the control group increased from 14.82 to 15.18 (pre-test = SD ± 4.06, post- test = SD ± 4.22) breaths per minute post treatment compared to a significant change of 13.32 to 11.10 breaths per minute (pre-test = SD ± 2.42, post- test = SD ± 1.62) (t=3.187, p=0.003) in subjects in the music group (Refer to Figure 2).

Systolic blood pressure showed a significant decrease in the music group from 119.60 mmHg pre-test to 114.32 mmHg post-test (pre-test = SD ± 11.86, post- test = SD ± 13.40). The mean systolic blood pressure of the control group elevated slightly from 111.96 mmHg pre-test to 112.80 mmHg post-test (pre-test = SD ± 11.86, post- test = SD ± 16.11). This was also found to show significance (t=2.834, p=0.007) (Refer to Figure 3).

Mean diastolic blood pressure in the control group increased slightly by an average of 3.32 mmHg from 67.24 to 70.56 mmHg (pre-test = SD ± 8.26, post- test = SD ± 9.43). Diastolic blood pressure in the music group decreased on average by -0.56mmHg from 72.68 pre-test to 72.12 mmHg post-test (pre-test = SD ± 8.71, post- test = SD ± 11.34). This slight decrease still expressed significance (t=0.932, p=0.004) (Refer to Figure 4).

Initial observation of both groups' means for self-perceived tension levels suggested considerable decreases pre and post testing. Those in the control group experienced a mean reduction in perceived anxiety of 5%, (pre-test = SD ± 20.96, post- test = SD ± 16.94), compared to 10% (pre-test = SD ± 14.39, post- test = SD ± 7.49) in those patients who listened to music during Osteopathic treatment. The reduction in perceived anxiety post treatment was not significant for either group (t=1.832, p=0.073). (Refer to Figure 5).

DISCUSSION

It was hypothesized that individuals who listened to the relaxation music during their treatment would perceive themselves to be more relaxed than those who were deprived from listening to the music. Although the results of the physiological data from this study supports this hypothesis, the perceived anxiety data does not.

These results are consistent with Iwanaga, Ikeda & Iwaki (1996) and Davies & Thaut (1989), who suggest that subjective and physiological indices of anxiety may not always be correlated. The present study reinforces conclusions drawn by Thaut (1989) that each individual may have a unique biological system that reacts to a given stimulus with an idiosyncratic but consistent physiological response and perceived psychological experience.

Given that perceived anxiety is a subjective measure, a larger standard deviation is expected. The control group in the present study had a large standard deviation and therefore may have contributed to the "insignificant" results. With Thaut's conclusions in mind, the magnitude of the changes in the physiological scores may be the best indicator of reliable differences in the relaxation of the participants.

The physiological findings of this study are consistent with other research that supports the efficacy of music to enhance relaxation (Greenburg & Fisher, 1971; Hanser, Larson & O'Connell, 1983; Jellison, 1975; Rohner & Miller, 1980; Scartelli, 1984). In this study, patients who listened to music during their Osteopathic treatment experienced a larger decrease in heart rate, respiration, systolic and diastolic blood pressure compared to the control group.

A curious observation pertains to the mean heart rate scores. The mean heart rate for the control group dropped from 61.4 to 58.92 beats per minute post treatment. Whereas the experimental groups' mean heart rate dropped from 65.72 to 58.92 beats per minute after the music intervention. It was extraordinary to find that the control and experimental groups had identical mean scores post-treatment (58.92). These scores were rechecked to detect the possibility of errors in data analysis. Results support the original findings.

Previous studies in this area of music research have yielded many inconsistencies, particularly with regard to blood pressure and heart rate indices (Bartlett, 1996). These inconsistencies have in the most part been due to inadequate study designs. Several factors may account for the more significant findings observed in the current study. First a moderate sample size was used and baseline measures were obtained. This would have reduced variability considerably. Secondly, the piece of music chosen had been demonstrated to be generally liked by participants in a previous study (Sherriff, 2002). It is not possible from the current study to evaluate the influence of familiarity or preference of the piece used, since the participants were not asked to indicate this.

While individual physiological responses to musical stimuli will likely vary, musical stimuli perceived by the individual as pleasant and relaxing may best enhance the physiological and psychological processes of relaxation (Davis & Thaut, 1989; Iwanaga & Moroki, 1999; Stratton & Zalanowski, 1984). At the same time, however, the client's preferred relaxation music may not elicit the best physiological response (Saperston, 1989).

It is plausible that relaxation music contributed to the physiological changes evident in this study. However, it is necessary to consider that these changes were facilitated with the treatment techniques applied to these patients. Research indicates that manipulation has reduced hypertension in patients undergoing Osteopathic and Chiropractic treatment (Knutson, 2001& Morgan, 1985). In addition gentle touch has also been found to produce measurable effects on finger blood flow. Purdy, Frank and Oliver (1996) demonstrated that gentle, soft tissue manipulation in the suboccipital region resulted in significant changes in blood flow to the fingers, mediated by the sympathetic nervous system.

In the current study practitioners we required to complete a treatment checklist and indicate the techniques that were employed during the consultation. This served to control variability and ensure that treatments received by both groups were similar. Evaluation of these checklists demonstrated that the control group received similar treatment to the music group. It is therefore unlikely that the physiological changes detected post treatment in the music group were attributed to the treatment techniques administered to them.

The current findings provide clear experimental evidence that background music can be used to prevent significant increases in heart rate, respiration, diastolic and systolic blood pressure. The additional health benefits of reducing stress, particularly in individuals whose health is already compromised, are considerable.

A number of limitations were identified in the current study. The following issues will need to be addressed by future researchers. As this study was conducted at a student Osteopathic clinic, many different practitioners were used to treat the participants. In

this situation, apart from the background music, it is impossible to control many of the variables that could affect the patients' state of relaxation. One of these variables includes the amount of conversation or its content occurring between practitioners and participants. In addition, the ability of the patient to relax may have also been impaired if they were not being treated by their usual practitioner that day. Other patients may have found it easier to relax as they may have developed a good rapport with their practitioner. Future research should aim to eliminate many of these problems by collecting data from patients treated by the same practitioner. This research can be conducted at a private Osteopathic practice, with a sole practitioner administering treatment to all the participants, or alternatively using a single student practitioner. This would not eliminate the variability of personal interaction entirely, but would serve to eliminate the variables associated with the use of multiple practitioners.

A further minor limitation was the use of such a specific sample comprising predominantly of young Caucasian participants makes any extrapolation of the results beyond this population somewhat tenuous. Because of this, the results are not entirely representative of all Osteopathic clientele. An obvious point is that many suburban Osteopathic clinics would be expected to attract patients who are on average older than the subjects in this study, as the Victoria University Osteopathic Clinic is significantly patronised by the student population. Ethnicity or socio-economic status would also differ according to region. Future research conducted that pools community samples from a number of local Osteopathic practices would better reflect the age, ethnicity and socio-economic status of the general population.

An important strength of this study is the use of a control group that were treated in the absence of music. Many of the variables relating to the atmosphere of the consulting rooms were difficult to control for. The use of the control group who were subjected to a similar environment provided stronger evidence that the outcomes were achieved through the presence of music. To further improve studies in this area, future research may also compare an additional group who would listen to self-selected relaxing music. This would help to control for the differences in preferences about what type of music is relaxing.

In future, studies can measure the cognitive-verbal behavioural component to anxiety using the State-Trait Anxiety Inventory (STAI) in conjunction with the Visual Analogue Scale. The self perceived tension scores obtained from a Visual Analogue Scale together with the STAI which can measure transient mood states, will provide greater reliability in detecting changes in anxiety levels.

CONCLUSION

The results of this study strongly indicate that patients who listened to relaxation music during their Osteopathic consultation, had significantly greater decreases in heart rate, respiration and blood pressure, compared with the control group. This is extremely encouraging for health professionals who may be able to implement this type of music intervention during the consultation or in the waiting room in order to reduce the anxiety of patients before, and during treatment.

Additional research is warranted involving the use of music within an Osteopathic clinic. Data should be collected from various Osteopathic clinics around the country to gain a broader understanding of the effect of music over the general population.

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Appendix A

Information to Participants

Participants Name:

Title of Project

"Physiological Responses In Patients Receiving Osteopathic Treatment".

Investigators

Dr. Jim Kiatos and Miss Angela Speranza, (student researcher)

Location

Osteopathic Medicine Clinic, 4th Floor, 301 Flinders Lane, Melbourne.

Purpose and Plan of the Study

You are invited to participate in a study to examine the effect of Osteopathic treatment on various body functions. The aim of this study is to identify whether Osteopathic treatment can produce a measurable change in these normal functions. The study will basically involve having your blood pressure and a number of other simple measurements made both before and after your scheduled Osteopathic treatment. Your Osteopathic treatment will not be altered for this study, as your practitioner will still provide an individually tailored treatment.

Exclusion Conditions

Unfortunately you will not be eligible to participate if any of the following conditions apply to you. Please notify the researcher's if you fall under any of these categories. Please ask the researcher's if you need further assistance.

- I cannot provide informed written consent.
- I have been diagnosed with a clinical anxiety state.
- I am taking medication(s) that affects my nervous system, heart or lungs.

For example- Sleeping tablets (*Librium, Valium*). Antidepressants (*Tryptanol, Tryptine, Prozac, Lovan*). Anti-histamines (*Actifed, Benadryl, Sudafed*). Antiepileptic drugs (*Epilim, Valpro, Dilantin*). Medication for high blood pressure and heart conditions (eg *Lasix*, *Aprinox*, *Aldactone*, Inder*a*l, *Tenormin*, *Renitec*, *Adalat* etc), Asthma medication (*Ventolin less than 4hrs ago, Serevent*) etc.

- I have consumed a beverage other than water in the last two hours eg coffee, fruit juice, tea or coke-cola.
- I have consumed food in the last two hours.
- I have consumed alcohol in the last two hours.
- I have consumed nicotine in the last two hours.
- I have been diagnosed with significant hearing loss.
- I have a formal background in music (higher than Grade 5 Australian Music Examinations board or equivalent).
- I suffer from a condition that affects my normal breathing, other than asthma.

Please note: If you are taking any medication and you are unsure about how it may be affecting your nervous system, please notify the researcher. The researcher will help to determine whether you are eligible to participate in this study.

Procedures

On entering the treatment room, your student Osteopathic practitioner will commence the consultation. Before leaving the room to consult the supervising clinician, they will instruct you to disrobe to the appropriate underwear and put on the gown provided for your privacy. You will have a small device strapped to your finger and an elastic strap placed around your chest. You are then required to lay quietly for four minutes before the researcher enters the room to take three measurements. Your blood pressure will be measured in a similar way to that used by your doctor. The researcher will also give you a piece of paper with a diagram on it and explain how to complete it. Please indicate the level of tension you feel at the time by marking a point along

the scale with a pen. When all measurements have been completed, the student Osteopathic practitioner will then commence Osteopathic treatment. Upon completion of the treatment you required to lay quietly for four minutes, after which the researcher will return to repeat each of the measurements made earlier. After these measurements are taken you will then be free to get dressed and leave the treatment room.

Risks, inconveniences and discomforts

Testing will take place in a normal treatment room with the door closed. If your student Osteopath requires you to disrobe, a gown will be provided so that you don't feel uncomfortable.

Safety

All measurements will take place in the Osteopathic Medicine clinic by a trained investigator. You will be encouraged to report any problems you may experience during or after the testing procedure. In the rare event the researcher finds that your blood pressure is elevated and in need of attention, he/she will notify your practitioner who will provide the attention you require.

Potential Benefits to Participants

To date there are no studies to indicate that Osteopathic treatment causes a change in blood pressure and heart rate. The information gained in this study may open up avenues for further research into how Osteopathy can be used to provide a more effective and holistic treatment.

Voluntary participation

Your participation in this study is entirely voluntary. You are free to withdraw from the study at any time and for any reason. Your decision to not participate or to withdraw from the study at any time WILL NOT jeopardise or affect your Osteopathic treatment in any way.

Appendix A (continued)

You will be asked to provide your name to the researcher to ensure that we only test you once. Neither your name or any other identifying data will be published.

Confidentiality

Only the investigators will have access to confidential data that identifies you by name. On completion of the measurements, your name will be removed from the research records thus maintaining confidentiality. You will not be named in any published research reports.

Questions

At any time before or during the study, you will be free to discuss any questions regarding the study, and will be encouraged to do so with the principle investigator or any of the co-investigators. If you have any questions related to ethical issues or issues regarding your rights please contact the investigators at the numbers below.

Contact phone numbers:

Dr. Jim Kiatos	Principal Investigator	(03) 9248 1191
Miss Angela Speranza	Student Investigator	(03) 9248 1111

Please read the consent form carefully and complete it if you wish to participate in this study. You are under no obligation to continue and may withdraw from the study at any time. I understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Victoria University. Individual results will remain confidential.

Any queries about your participation in this project may be directed to the researcher (Dr. Jim Kiatos ph (03) 9248 1191 or if you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MC, Melbourne, 8001 (Telephone no: (03) 9688 4710).

Appendix B

Consent Form for Participants Involved in Research

INFORMATION TO PARTICIPANTS:

We would like to invite you to be a part of a study to examine the influence of Osteopathic treatment on physiological responses. The study will involve having your blood pressure and a number of other simple measurements made both before and after your scheduled Osteopathic treatment. You will have a small device strapped to your finger and an elastic strap placed around your chest. Your blood pressure will be measured in a similar way to that used by your doctor. Your Osteopathic treatment will not be altered for this study. Your practitioner will provide an individually tailored treatment based on your current complaint(s).

CERTIFICATION BY PARTICIPANT

I, _____

Of _____

certify that I am over 18 years old and that I am voluntarily giving my consent to participate in the experiment entitled: "Physiological responses in patients receiving Osteopathic treatment", being conducted at Victoria University of Technology, Level four, 301 Flinders Lane by : Dr Jim Kiatos and Miss Angela Speranza

I certify that the objectives of the experiment, together with any risks to me associated with the procedures listed hereunder to be carried out in the experiment, have been fully explained to me by Dr Jim Kiatos or Angela Speranza and that I freely consent to participation involving the use on me of these procedures.

Appendix B (continued)

Procedures

On entering the treatment room, my student Osteopathic practitioner will commence the consultation. Before leaving the room to consult the supervising clinician, they may instruct me to disrobe to the appropriate underwear and put on the gown provided for my privacy. The researcher will then enter the room to fit the measuring devices. I will then lay quietly for four minutes before the researcher will re-enter the room to take three measurements. The researcher will ask me to place a mark on a self-perceived tension scale. My student Osteopathic practitioner will commence the Osteopathic treatment. Upon completion of the treatment I will lay quietly for four minutes, after which the researcher will return to take my measurements again.

The following risks, inconveniences and discomforts have been explained to me:

1. In the event the researcher finds that my blood pressure is elevated and in need of attention. He/she will notify my practitioner who will provide the attention I require.

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Victoria University.

I have been informed that the information I provide will be kept confidential.

Signed: _____

Witness other than the experimenter: _____Date _____/_____/____

Any queries about your participation in this project may be directed to the researcher Dr. Jim Kiatos ph (03) 9248 1191 or If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MC, Melbourne, 8001 (Telephone no: (03) 9688 4710).

Appendix C

Self-Perceived Tension Scale

Please indicate your current level of tension by marking a point along this scale with a pen.

Not Tense **Extremely Tense**

Appendix D

Data Recording sheet

			PRE-TREATMENT				POST-TREATMENT			
Patient No.	**Age**	**Sex**	**Heart Rate**	**Respir. Rate**	**Blood Pressure**	**SPT (mm)**	**Heart Rate**	**Respir. Rate**	**Blood Pressure**	**SPT (mm)**

Appendix E

Treatment Techniques

Please indicate which techniques were used during the consultation and to which area they were applied.

	Technique	Details
☐	HVLA	
☐	MET	
☐	COUNTER STRAIN	
☐	POSITIONAL RELEASE	
☐	STRETCHES	
☐	INHIBITION	
☐	SOFT TISSSUE	
☐	VISCERAL	
☐	CRANIAL	
☐	MYOFASCIAL	
☐	ARTICULATION	
☐	FUNCTIONAL	
☐	OTHER	

Figure 1. Heart Rate Mean Scores

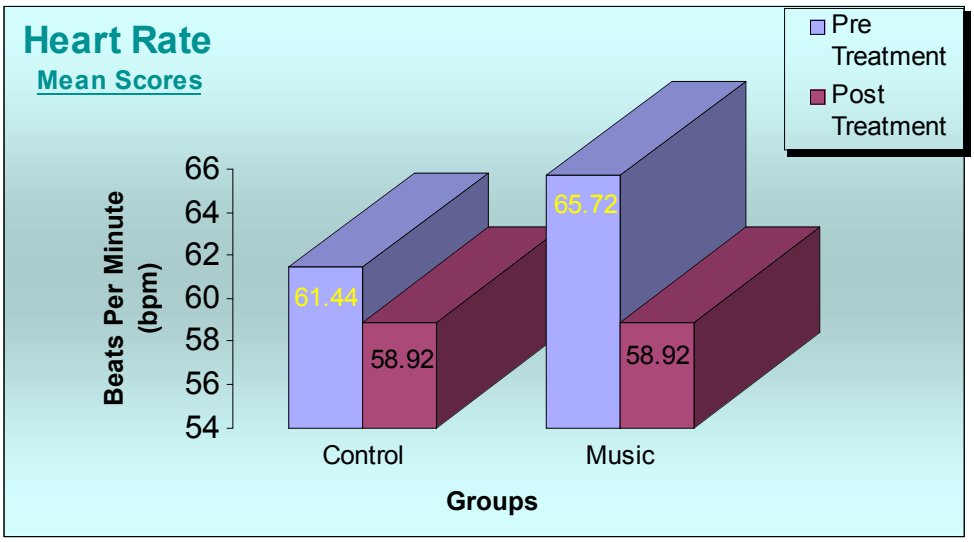

Figure 2. Respiration Rate Mean Scores

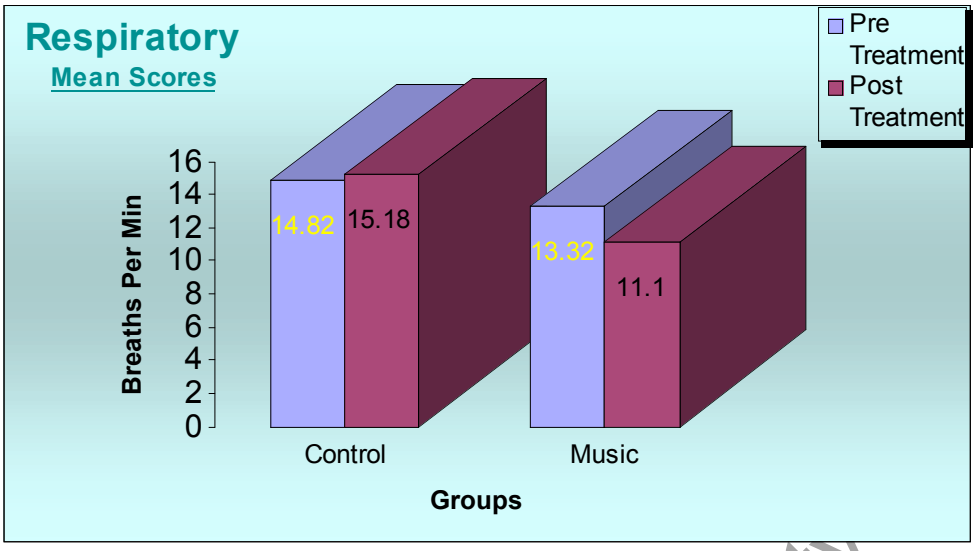

Figure 3. Systolic Blood Pressure Mean Scores

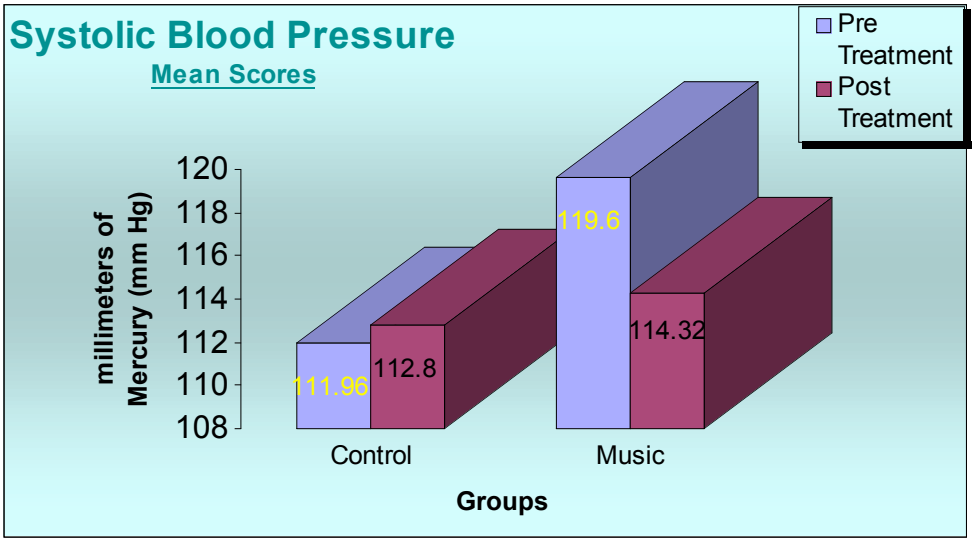

Figure 4. Diastolic Blood Pressure Mean Scores

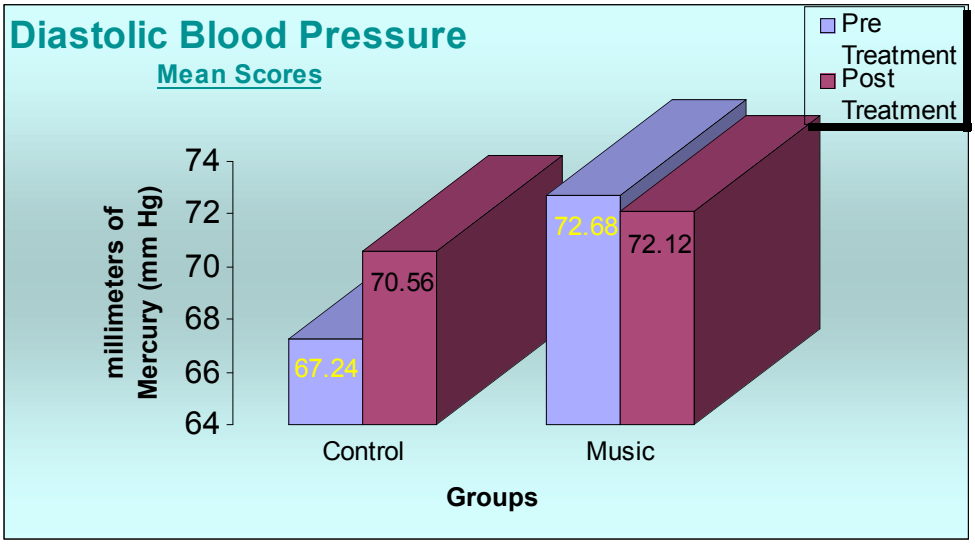

Figure 5. Self-Perceived Tension Mean Scores