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**Does Music Therapy Reduce Anxiety Levels in End-Stage Renal Disease Patients
Undergoing Hemodialysis?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements for

The Degree of Master of Science

In

Health Science - Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not music therapy reduces anxiety levels in end-stage renal disease patients undergoing hemodialysis.

STUDY DESIGN: Systematic Review of two randomized controlled trials and one crossover study published in English in 2008, 2012 and 2013, respectively.

DATA SOURCES: Two non-blind randomized controlled trials and one cross-over study were found via PubMed and EBSCOhost databases.

OUTCOMES MEASURED: Subjective Anxiety Levels were measured in ESRD patients undergoing hemodialysis pre and posttest via patient self-reporting. An anxiety level survey graded on a scale of 1-10 was used in the study by Binson et al. The State-Trait Anxiety Index was utilized in the studies by Pothoulaki et al and Cantekin et al.

RESULTS: All three studies demonstrated a statistically significant change in post-test anxiety levels in the ESRD patients who were surveyed following music therapy which was during their dialysis sessions.

CONCLUSIONS: Music therapy seems to be effective in ESRD patients undergoing hemodialysis treatments, however the effects of repeated, non-novel music therapy interventions over the course of time are not known.

KEYWORDS: Music Therapy, Anxiety, Renal Dialysis

INTRODUCTION

End Stage Renal Disease (ESRD) is a manifestation of long standing chronic kidney dysfunction, where the glomerular filtration rate (GFR) is reduced and nitrogenous wastes are retained.¹ The most common causes of ESRD in the developed world are diabetes and hypertension.² In 2012, incidence of ESRD in the United States due to these disorders were 43,922 and 29,911 persons, respectively.³

End stage renal disease is a costly disease process. In the United States, ESRD costs totaled approximately \$42.5 billion in 2009⁴, and Medicare spent upwards of \$33 billion in 2010 alone.⁵ Estimates from 2012 indicate a per person Medicare cost of \$87,561 when the patient was treated with the use of hemodialysis.⁵ The United States Renal Data System estimated that 449,342 patients in the U.S. were treated by either hemo or peritoneal dialysis in the year 2012.³

There are 5 stages of Chronic Kidney Disease, each representing a progressive decline in kidney function. The earliest stages are asymptomatic; with nonspecific symptoms developing as the disease worsens and different stages are experienced. It is only when the glomerular filtration rate is substantially lowered that the uremic toxins and metabolic waste byproducts give the patient with symptoms including weakness, fatigue, anorexia, nausea, vomiting, and a metallic taste in the mouth.¹

Treatment for stages 1 through 3 (GFR greater than 30 mL/min/1.73 m²) revolve around the stabilization of causative etiologies, comorbidities and careful monitoring of relevant laboratory values including the GFR, blood urea nitrogen (BUN) and blood creatinine.¹ Lifestyle modifications include restrictions of protein, potassium, phosphorus, sodium and water.¹ Stage 4 (GFR < 30 mL/min/1.73 m²) treatment includes preparatory steps for an impending end stage failure with the addition of relevant medical disciplines that can aid the patient and family.¹

Stage 5 renal failure is end stage, and is diagnosed when the patient's GFR is reduced to 5-10 mL/min/1.73 m².¹ The treatment options for stage 5 status include dialysis, transplant or palliative care, Renal transplant requires participation on a donor list. Transplants from living donors provides 1 and 5 year survival rates of 95% and 80% respectively, and from deceased donors, 89% and 66% respectively.¹ These survival rates are much better than that of hemodialysis in isolation, which is approximately 40% survival at 5 years.¹

Hemodialysis administered at a treatment facility is typically a 3 day per week commitment to treatment, with sessions lasting as long as 5 hours depending on factors which are specific to the individual patient.¹ It is recognized how the transition from subclinical illness to an intensively treated ESRD state requiring hemodialysis can be psychologically and socially problematic for patients - with anxiety being one of the most common traits being seen in experimental studies.⁶ The majority of benzodiazepines are hepatically excreted and are therefore used in this population⁷, but such medications threaten symptoms which may imitate dementia and or a worse prognosis.⁸ The purpose of this selective evidence based medicine review is to evaluate the effectiveness of music therapy as a means of decreasing anxiety levels in ESRD patients who are undergoing hemodialysis treatment.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not music therapy reduces anxiety levels in end-stage renal disease patients undergoing hemodialysis.

METHODS

Two randomized controlled trials and 1 cross-over study were selected for this evidence based medicine review. Each one included a population consisting of ESRD patients who were

actively undergoing hemodialysis during the time period of the study. The intervention in each study was music therapy during hemodialysis sessions and the comparison groups were patients also undergoing hemodialysis, but without music therapy . Outcomes were recorded as baseline changes of anxiety levels during the process of hemodialysis.

The keywords utilized in the search for the studies were “hemodialysis”, “anxiety” and “music therapy”. Each study was written in the English language and published in peer-reviewed journals. This author performed the research for the included studies on PubMed and EBSCOhost databases and articles were selected based on their relevance to the clinical question. Inclusion criteria included RCT or cross-over studies in the English language with subjective measurements of anxiety. Exclusion criteria included the absence of subjective anxiety measurements and studies in non-English language. Statistics reported in the chosen studies include: change in mean (Wilcoxon Signed Rank Test), F-score, one way anova and T-test.

OUTCOMES MEASURED

The outcomes measured in the selected studies were subjective changes in anxiety levels experienced by voluntary hemodialysis patients during dialysis sessions, as measured by the patients with the use of self-report surveys and the State-Trait Anxiety Inventory.

Binson et al utilized an anxiety level survey which allowed patients to rate their own anxiety levels on a 1-10 scale. Each patient was tested with either pre-recorded music or live music which included interaction with musical instruments. Pre-recorded music was chosen by the patient from a provided catalog of songs. These sessions (either pre-recorded or live music) were pre-empted with a 5 minute relaxation-breathing session and then patients were given the music therapy intervention for a 7 minute period. Anxiety scores were recorded both pre and post musical therapy intervention during a 3 minute feedback session which concluded the test.

There were 2 sessions per patient with a 1 week “washout period” and random allocation of treatment order. The mean change of anxiety levels was calculated and P-values were assigned by use of the Wilcoxon Signed Rank Test.⁹

Table 1: Demographics & Characteristics of included studies

| Study | Type | # Pts | Age (yrs) | Inclusion Criteria | Exclusion Criteria | W /D | Interventions |
|--------------------------------|-----------------|-------|---|---|--|------|---|
| Binson ⁷ (2013) | Crossover Study | 54 | 18 - 70 years old Avg age 69.7 years old | 18-70 year old able to sufficiently care for selves ability to hear music out-pt at Bangkok Metro Admin Hospitals. | Pulse/BP abnormalities non communicating hearing disorders medically unstable | 0 | 15 minutes / 3 stage process with breathing exercise, followed by 7 minutes of live or recorded music. 3 minute oral followup |
| Cantekin ⁸ (2012) | RCT | 100 | > 18 years old | no hearing or visual problems. voluntary, over age 18 HD for at least 6 months, 3 times per week | hearing or visual problems non voluntary | 0 | music therapy (Turkish art songs) during HD |
| Pothoulaki ⁹ (2008) | RCT | 60 | 22 - 84 years old | voluntary patients HD on regular basis Patients of Laiko Gen. Hosp. of Athens | non voluntary | 0 | pt preference of music via CD |

Pothoulaki et al used a State-Trait Anxiety Index questionnaire which was supplied to all experiment participants to fill out. Patients that were provided the music therapy intervention were given a choice of preference from a predetermined CD collection which was supplied to them. Control group participants were allowed to do their normal activities. The State Anxiety score was recorded for the control and experimental group, both pre and post the hemodialysis session. Scoring of State Anxiety depends on the total value of the answers given to questions that pertain to anxiety. Possible answers are valued as follows: (1) Not at all, (2) Some, (3) A lot, (4) Completely. After a tally of the responses to the questionnaire, higher numbered scores indicate higher levels of anxiety, whereas lower scores indicate lower levels of anxiety.¹⁰ Change of the mean was reported as well. One-way Anova was used to compare pre and post-test State Anxiety scores between the experimental (music therapy) group, control group (no music therapy) and within groups using a paired t-test. P values were assigned to indicate any significant differences that were found.¹¹

Cantekin et al utilized the State-Trait Anxiety Index questionnaire, as well. Data was acquired by face to face meetings between the researchers and patients undergoing hemodialysis. Pre and post-test State Anxiety scores were tallied and then analyzed with SPSS 15.00 and furthermore compared by a dependent sample t-test.

RESULTS

Binson et al ⁹ utilized a crossover design study which measured pre and posttest levels of anxiety of 54 patients (N = 54) receiving hemodialysis treatment. Allocation to either live or recorded music was randomized for the first trial, with the opposite treatment following in suite after the one week washout period previously described. Patients were aged between 18 to 70

years, able to hear satisfactorily and were able to care for themselves. Exclusion criteria included unstable medical conditions, inability to communicate and any hearing dysfunction. There were no losses to follow-up. The study concluded that pre and post-test anxiety levels were significantly different ($P < .001$ for both recorded and live music), indicating a reduction in anxiety levels. The study also found the difference of mean change of the anxiety levels associated with either recorded or live music were not significant ($P=.678$) indicating that effects of either type of music therapy are comparable. Pre and post anxiety score, mean change comparison between types of music therapy and associated P-values are reflected in Table 2 and Table 3, respectively.

Table 2 - Pre and Post Anxiety Score, Recorded and Live Music Therapy⁹

| Type of Music Therapy | Pre-Test Anxiety (1 - 10) | Post-Test Anxiety (1 - 10) | P Value |
|-----------------------|---------------------------|----------------------------|---------|
| Recorded Music | 2.83 | 1.33 | <.001 |
| Live Music | 2.44 | 1.06 | <.001 |

Table 3 - Mean Change of Anxiety Score, Recorded and Live Music Therapy⁹

| | Type of Intervention | |
|------------------------|----------------------|------|
| | Recorded | Live |
| Anxiety Score (1 - 10) | 1.39 | 1.50 |

Pothoulaki et al¹¹ utilized a randomized control trial design with a total of 60 patients (N=60), with 30 patients (N=30) assigned to a music therapy treatment group and the other 30 patients (N=30) assigned to a control (no music therapy) group. Block randomization was used to randomly assign the patients. Each patient was diagnosed ESRD and on an established hemodialysis treatment regimen. There was no loss to follow-up. The study found that there were significant differences of State-Anxiety scores between experimental and control groups

both pretest ($F(1,58)=5.61, P < .05$) and post-test ($F(1,58)=35.88, P < .05$). These results indicate higher levels of anxiety in the control group pretest and posttest. Within each group, significant differences were found between pre and posttest State-Anxiety Scores within the experimental group ($t(29)=3.42, P < .005$) and within the control group ($t(29)=-2.17, P < .05$). The experimental group experiences significant reduction in anxiety, whereas anxiety levels were found to increase in the control group which was allowed to conduct their normal activities as opposed to being exposed to music therapy. Refer to Table 4 for representation intergroup study statistics and P values. Refer to Table 5 for Intragroup Statistics and P values.

Table 4 - Mean State-Anxiety Scores, Comparing Experimental and Control Groups¹¹

| Group | Mean State Anxiety Score (SD) | P Value |
|---------------------|-------------------------------|---------|
| Pretest | | |
| Experimental | 36.17 (14.41) | 0.021 |
| Control | 45.13 (14.91) | |
| Posttest | | |
| Experimental | 30.57 (10.06) | .0000 |
| Control | 48.17 (12.56) | |

Table 5 - Intragroup Pre/Posttest State-Anxiety Scores¹¹

| Group | Mean State Anxiety Change | P Value |
|---------------------|---------------------------|----------|
| Experimental | $t(29) = 3.42$ | $< .005$ |
| Control | $t(29) = -2.17$ | $< .05$ |

Cantekin et al¹⁰ conducted a randomized control trial with a total of 100 patients (N=100), with 50 patients making an experimental (music therapy) group (N=50) and the other 50 forming a control group (N=50) without music therapy. Randomization was assigned depending on which of 2 schedules the patients were on individually. Patients were voluntary, over the age of 18, received hemodialysis for at least 6 months, and lacked any hearing or visual disabilities.

The study did not indicate any loss to follow-up. The study reports a significant difference in mean State-Anxiety scores pre and posttest within the experimental group ($t = 22.4$), $P < 0.01$. The study found non-significant change in mean of State-Anxiety scores within the control group, pretest and posttest, $P > 0.05$. Non-significant pre-test State Anxiety score differences were found between the experimental (music) and control (no music) groups, $P = 0.058$, but significant differences were found in the post-op State Anxiety scores between the two groups, $P = 0.000$. These findings indicate a significant reduction in State Anxiety with music therapy. Refer to Table 6 for relevant scores and P values.

Table 6 - Mean State-Anxiety Scores Compared, Experimental and Control¹⁰

| Group | Pretest X +/- SD | Posttest X +/- SD | T Score / P Value |
|--------------|--------------------------|--------------------|---------------------|
| Experimental | 54.6 +/- 6.6 | 50.2 +/- 6.1 | $t = 22.4 / P=0.00$ |
| Control | 53.2 +/- 3.7 | 52.4 +/- 3.7 | $t= 0.26 / P=0.80$ |
| | T Score / P Value | | |
| | $t = 6.8 / P=0.058$ | $t= 5.7 / P=0.000$ | |

None of the studies indicated any concerns for safety in the use of musical therapy for ESRD patients receiving hemodialysis.

DISCUSSION

Music therapy is considered to be a non-pharmacological and complementary therapy which can be useful in the management of severe illness.¹² An article in a 1789 issue of *Columbian Magazine* is regarded as the first published work referencing music as a form of therapy. It became a treatment utilized in U.S. veteran hospitals after both World Wars, and was seen as a benefit to the point where healthcare facilities hired musicians for the specific purpose of exposing hospital patients to music as a form of alternative treatment.¹³ In the United States

music therapists sit for a board examination after their respective training and are awarded a Music Therapist Board Certified credential (MT-BC).¹⁴

No contraindications of music therapy for ESRD patients have been described in the research for this paper. Limitations of the studies used for this selective evidence based review include the availability of studies relevant to the ESRD patient population and music therapy. Each study that has been referenced was conducted outside of the United States and focused on patients who were established consumers of the facilities where the studies were conducted. None of the studies had researcher blinding and the sample sizes were small - the largest was 100 patients.¹⁰ Study duration is also a factor that limits the generalizability of the studies. Cantekin¹⁰ and Pothoulaki¹¹ both conducted studies which lasted the length of single episode of hemodialysis. Binson et al⁹ used a second hemodialysis session after a one week washout period with results similar to their first trial, but this is the only study available to compare the effects of two specific time periods. It is unknown how longer time and further repetition of music therapy would affect the subjective anxiety levels of ESRD patients during hemodialysis treatment. It should also be noted that all subjects in each study were volunteers who were approached on the same day as the study/studies.⁹⁻¹¹

CONCLUSIONS

The evidence shows that music therapy is effective at reducing anxiety levels in ESRD patients undergoing hemodialysis treatment, but further research is needed that can cover more episodes of treatment to observe any changes to the efficacy of music therapy's anti anxiolytic effects. Further studies should be constructed so they can account for music therapy's diminishing novelty and the influences of repetition over time - if they even exist.

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