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Abstract

Objective: This study was intended to examine the effect of selective soothing music on fistula puncture-related pain in hemodialysis patients.

Methods: This is a randomized clinical trial in which 114 participants were selected from two hemodialysis units by means of a non-random, convenience sampling method. The participants were then allocated in three groups of music (N=38), headphone (N=38), and control (N=38). The fistula puncture-related pain was measured one minute after venipuncture procedure in all three groups. The music group listened to their self-selected and preferred music 6 minutes before needle insertion into a fistula until the end of procedure. The headphone group wore a headphone alone without listening to music 6 minutes before needle insertion into a fistula until the end of procedure. The control group did not receive any intervention from the research team during needle insertion into a fistula. The pain intensity was measured immediately after the intervention in all three groups.

Results: This study showed a significant difference between the music and control groups, and the music and headphone groups in terms of the mean pain score after the intervention. However,
the analysis did not indicate any significant difference between the headphone and control groups with regard to the mean pain score after the intervention.

**Conclusion:** It is concluded that music can be used effectively for pain related to needle insertion into a fistula in hemodialysis patients. Future research should investigate the comparative effects of pharmacological and non-pharmacological interventions on fistula puncture-related pain.

**Keywords:** Hemodialysis, pain related to needle insertion into a fistula, soothing music

1. **Introduction**

End-stage renal disease (ESRD) is one of the most common life-threatening conditions. A kidney transplant is the treatment of choice for patients with ESRD. However, patients are on dialysis before they get a kidney transplant. Hemodialysis is the most common treatment for ESRD. Over two million patients with chronic renal failure in the world are undergoing hemodialysis, with an annual increase of 15%. The expected number of patients with ESRD in the United States will be almost 2240000 by 2030.

Regular long-term hemodialysis requires a permanent vascular access, preferably arteriovenous fistulas. In hemodialysis, patient’s blood is taken to a dialysis machine through a needle inserted into an arterial vessel and the blood is filtered to remove wastes and extra fluid and then the filtered blood is pumped back into the body through another tube connected to a second needle placed in a vein. Most patients undergo hemodialysis two or three times per week with 3-to-4 hour session. They repeatedly experience stress and pain related to needle insertion into a fistula, estimated 320 times in total per year. The pain perceived by hemodialysis patients is
mostly associated with fistula puncture\textsuperscript{10} and these pain episodes can bring about depression and reduced quality of life in these patients.\textsuperscript{11} On average, 48\% of patients have fear of fistula puncture-related pain\textsuperscript{12}, and more than one-fifth of them find the pain intolerable.\textsuperscript{13} Therefore, the relief of pain might increase patients’ acceptance of procedure as well as their quality of life.\textsuperscript{14} Although the pain is decreased after the first three months, there is no significant decline in the reported pain.\textsuperscript{15} The management of fistula puncture-related pain should therefore be an integral part of patients’ treatment plan.

A review of literature revealed that several pharmacological and non-pharmacological options can help relieve fistula puncture-related pain. The pharmacological options include EMLA topical cream\textsuperscript{16}, vapocoolant spray\textsuperscript{14} and lidocaine spray.\textsuperscript{17} Non-pharmacological approaches encompass rhythmic breathing\textsuperscript{11}, local cryotherapy\textsuperscript{18}, Shiatsu massage\textsuperscript{19}, transcutaneous electrical nerve stimulation\textsuperscript{20} and lavender aromatherapy.\textsuperscript{21} Pharmacological interventions have unpleasant side effects and incur costs to clients. The possible vasoconstrictive effects of vapocoolant can cause obstruction in the arteriovenous fistula.\textsuperscript{14} The adverse effects of lidocaine include allergic reactions, systemic toxicity, and cardiac dysrhythmias.\textsuperscript{22} The anesthetic effect of eutectic mixture of EMLA is achieved after approximately 60 minutes.\textsuperscript{23} As inappropriate pain management gives rise to physiological, psychological, social and financial consequences for patients, family and society\textsuperscript{24}, simple, non-invasive and low-cost interventions with fewer side effects than pharmacological methods\textsuperscript{19} should be sought for patients’ comfort.\textsuperscript{25} Research studies show that distraction is an effective way of relieving pain following needle insertion into a fistula.\textsuperscript{11,26} Attention is directed away from a painful
stimulus when a person is distracted, thereby reducing fear, stress, and pain related to medical procedures.\textsuperscript{27} Listening to music is an effective tool in distraction.\textsuperscript{28} A pleasant distraction can lead to the release of endorphins.\textsuperscript{29} Furthermore, listening to music can engender hemodynamic changes (including decreased heart rate and blood pressure)\textsuperscript{30}, the release of endorphins, and the activation of dopaminergic system\textsuperscript{31} and autonomic nervous system (parasympathetic nervous system).\textsuperscript{32} Soothing music has 60-80 beats per minute or less.\textsuperscript{33} Soothing music enhances parasympathetic activities that results in a reduction in the respiration rate and heart rate, while exciting music stimulates the sympathetic nervous system with an increase in the heart rate and respiration rate.\textsuperscript{34} A review of literature revealed that music therapy is effective for patients with painful muscle cramps induced by hemodialysis\textsuperscript{35}, cancer pain\textsuperscript{36}, breast biopsy pain\textsuperscript{37}, musculoskeletal pain\textsuperscript{38} and postoperative pain following open heart surgery.\textsuperscript{39}

To the best of our knowledge, no published study has explored the effect of self-selected soothing music on pain following needle insertion into a fistula in hemodialysis patients. Therefore, this study was intended to examine the effect of selective soothing music on fistula puncture-related pain in hemodialysis patients.

2. Materials and methods

2.1 Sample and sampling method

This is a randomized clinical trial in which recruitment was limited to patients with end-stage renal disease admitted to the dialysis units of two academic hospitals affiliated to the Mazandaran University of Medical Sciences, Sari, Iran. The sample size was
calculated as, at least, 35 patients per group according to a difference above one unit on the pain scale as a significant change and standard deviation of 1.5 found in the study conducted by Esmaeili et al.\textsuperscript{29} With consideration of the likelihood of patient exclusion during the study, the final sample consisted of 38 patients in each group. A convenience sampling method was used to recruit participants.

Inclusion criteria for participation in this study were as follows: a desire to listen to the music, age of 18 years and older, not diagnosed with neuropathic disorders\textsuperscript{11}, no history of depression\textsuperscript{40}, treated with hemodialysis for at least 3 months\textsuperscript{15}, not administered tranquilizers, analgesics and sedatives 3 hours before the study, not recently taken antipsychotic medications and tranquilizers, not being cognitively impaired\textsuperscript{41}, no hearing and visual impairments (for marking the VAS-pain), and not habitually listening to music during hemodialysis. Exclusion criteria were acute pain in other parts of the body\textsuperscript{17}, more than one attempt for fistula puncturing, any changes in the physical status during the study (occurrence of such acute conditions as hypertension and vomiting)\textsuperscript{33}, withdrawal from the study, and death (See CONSORT diagram).
CONSORT diagram

Assessed for eligibility
(N = 203)

Excluded
(N = 89)

Visual impairment (N=19)
Drug addiction (N=11)
Administered analgesics (N=4)
Administered antidepressants (N=4)
Administered lidocaine for fistula puncture-related pain (N=1)
Habitual listening to music during hemodialysis (N=5)
Catheterized with Shaldon and Percath (N=17)
Arteriovenous graft (N=6)
Intellectually impaired (N=2)
Hearing impairment (N=4)
Arteriovenous fistula < 3 months (N=12)
Refused to participate in the study (N=4)

Randomized
(N=114)

Control group
(N=38)

Headphone group
(N = 38)

Music group
(N= 38)

Completed study
(N = 37)

Completed study
(N = 35)

Completed study
(N = 36)

Withdraw (N=1)
More than one attempt for fistula puncturing (1)

Withdrew (N=3)
More than one attempt for fistula puncturing (1)
Abdominal pain (1)
Administered analgesics before hemodialysis (1)

Withdrew (N=2)
More than one attempt for fistula puncturing (1)
Fractured leg with severe pain (1)
2.2. Measurement instruments

The data were collected using two instruments of measure: a sociodemographic/medical questionnaire and a Visual Analogue Scale (VAS) pain intensity. The demographic/medical questionnaire recorded information on participants' age, gender, marital status, level of education, occupation, place of residence, duration of kidney failure, history of hemodialysis, length with a fistula, and underlying diseases. The needle insertion-related pain was measured using VAS pain intensity, which consists of a 10-cm straight line with two endpoints as the extremes ('no pain' and 'worst possible pain'). The scale was presented as a 10-cm horizontal ruler in this study. The reverse side of the ruler was numbered from 0 (no pain) to 10 (worst possible pain). Patients were asked to rate the intensity of pain on the ruler. The experimenter then read the number on the back of the ruler and recorded it. A number of studies have used VAS pain intensity to measure fistula puncture-related pain in hemodialysis patients.¹⁷ ²¹

2.3. Ethical considerations

The study protocol was approved by the Medical Research and Ethical Committee of Mazandaran University of Medical Sciences (project approval number: IR.MAZUMS.REC.95.2435). The study was also registered in the Iranian Registry of Clinical Trials (www.irct.ir) with the registration number: IRCT201607297494N20. The additional approvals were also obtained from the two recruiting hospitals. Each participant was informed of the confidential nature of the data. All participants also signed a consent form in which the study procedures were explained.
2.4. Procedure

The participants were selected from the hemodialysis units of two academic hospitals in Mazandaran province (Iran) by means of a non-random, convenience sampling method. They were recruited between October and December 2016 according to their order of entry to the hospitals. The participants were then allocated in three groups of music, headphone, and control using Excel's RANDBETWEEN function. Each group was identified by a letter: A to music group, B to headphone group, and C to control group. Fifty seven envelopes were sequentially numbered from 1 to 57 for each hospital. Each opaque and sealed envelope contained a letter (A, B, or C) randomly selected using RANDBETWEEN function of Excel. This procedure was carried out by someone not involved in the project. The first eligible patient was designated as number one, and the envelope numbered one was then opened and the patient was allocated to one of the three groups (music group, headphone group, and control group) based on the letter contained in the envelope.

The demographic/medical data and the intensity of pain related to needle insertion into a fistula were recorded at baseline. The fistula puncture-related pain was measured one minute after venipuncture procedure and fixation of the needle onto the fistula in all three groups. A few pieces of familiar Persian folklore/traditional/soothing music were initially selected by the experimenter on the basis of patients’ social and cultural background, and were then offered to the music group during a session before the intervention. The music group listened to their self-selected and preferred music using an MP4 DOLPH player through an XP-H828 headphone 6 minutes before needle insertion.
into a fistula until the end of venipuncture procedure. Each participant was asked to concentrate on the music and ignore everything else. The headphone group wore a headphone alone without listening to music 6 minutes before needle insertion into a fistula until the end of venipuncture procedure. The control group did not receive any intervention from the research team during needle insertion into a fistula. The pain intensity was measured immediately after the intervention in all three groups.

2.5. Data analysis
Data were analyzed with SPSS-13.0 (Statistical Package for Social Science, Chicago, Illinois, USA) using descriptive (mean, standard deviation and percentage) and analytical statistics. Qualitative variables were compared with use of the Chi-square test. The analysis of variance (ANOVA) was also used to compare quantitative variables between all the groups. Furthermore, pairwise comparisons were made by the Tukey’s test, and changes in pain score before and after intervention were analyzed using the dependent t-test in each group. Data were examined for normal distribution by the Kolmogorov-Smirnov test. Since the length with a fistula was not distributed normally, the non-parametric Kruskal-Wallis test was used to find differences.

3. Results
No significant differences were observed between the groups for age, gender and length with a fistula (Table 1). The music and control groups predominantly had a high school education or less (music group=50%, control group=59.5%), while most of the patients in the headphone group were illiterate (60%). The Chi-square test revealed no statistically
significant difference between the groups for educational level ($p = 0.29$, df = 2, & $\chi^2 = 2.45$). Hypertension was the leading cause of renal failure in the music group (47.2%), while diabetes mellitus and hypertension were the primary cause of renal failure in the headphone (37.1%) and control groups (51.4%). According to our results, there were no statistically significant differences between the three groups for demographic/medical characteristics, which are consistent with the findings of others that explored no relationship between gender and pain intensity as well as age and pain intensity.\(^{14; 21}\) A two-way analysis of covariance was used to estimate the effect of patients’ group, gender, age, and the length with a fistula on pain score after the intervention. The analysis revealed that only the effect of patients’ group was statistically significant ($p < 0.001$) after the elimination of the effect of other variables. It also showed that 44% of changes in the pain score was related to the patients’ group ($R^2 = 0.44$).
Table 1
Demographic/medical characteristics of hemodialysis patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Test &amp; P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Music</td>
<td>Headphone</td>
</tr>
<tr>
<td>Age (mean±SD)</td>
<td>56.22 ± 2.37</td>
<td>61.91 ± 2.38</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>% 63.9</td>
<td>% 54.3</td>
</tr>
<tr>
<td>Female</td>
<td>% 36.1</td>
<td>% 45.7</td>
</tr>
<tr>
<td>Length with a fistula (Months) (mean±SD)</td>
<td>64.4 ± 84.8</td>
<td>38.4 ± 34.23</td>
</tr>
<tr>
<td>Cause of ESRD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>% 47.2</td>
<td>% 25.7</td>
</tr>
<tr>
<td>Diabetes</td>
<td>% 25</td>
<td>% 22.9</td>
</tr>
<tr>
<td>Diabetes &amp; Hypertension</td>
<td>% 13.9</td>
<td>% 37.1</td>
</tr>
</tbody>
</table>

The results of this study showed that the mean (± standard deviation) pain score before the intervention in the music, headphone, and control groups was 5.58 ± 1.71, 5.17 ± 1.50, and 5.41 ± 2.32, respectively. According to the ANOVA, no significant difference was found between the groups in respect to the mean pain score before the intervention (f = 0.42, p= 0.65) (Table 2). The Tukey’s test did not show any significant difference
between the music and control groups \((p = 0.91)\), the music and headphone groups \((p=0.63)\), and the headphone and control groups \((p = 0.85)\) in terms of the mean pain score before the intervention. The ANOVA also demonstrated a significant difference between the three groups with respect to the mean pain score after the intervention (Table 2). In addition, the Tukey’s test showed a significant difference between the music and control groups \((p < 0.001)\), and the music and headphone groups \((p = 0.002)\) in terms of the mean pain score after the intervention. However, the Tukey’s test did not show any significant difference between the headphone and control groups with regard to the mean pain score after the intervention \((p = 0.72)\).

Table 2
Pain measurements before and after intervention in music, headphone and control groups

<table>
<thead>
<tr>
<th>pain</th>
<th>Group</th>
<th>ANOVA &amp; (P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before intervention</td>
<td>Music</td>
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<tr>
<td>(mean ± SD)</td>
<td>5.58 ± 1.71</td>
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</tr>
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<td>(f = 0.42)</td>
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</tr>
<tr>
<td>After intervention</td>
<td>Music</td>
<td>Headphone</td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td>3.28 ± 2.09</td>
<td>4.91 ± 1.7</td>
</tr>
<tr>
<td></td>
<td>(f = 10.74)</td>
<td>(p &lt; 0.001)</td>
</tr>
<tr>
<td>Pain score difference</td>
<td>Music</td>
<td>Headphone</td>
</tr>
<tr>
<td>before &amp; after intervention</td>
<td>2.3 ± 1.16</td>
<td>0.25 ± 0.88</td>
</tr>
<tr>
<td>Confidence interval(CI)</td>
<td>CI = (-1.91) – (-2.7)</td>
<td>CI = (-0.56) – (+0.04)</td>
</tr>
<tr>
<td>Paired t-test</td>
<td>(p &lt; 0.001)</td>
<td>(p = 0.09)</td>
</tr>
<tr>
<td>(mean±SD)</td>
<td>(df = 35)</td>
<td>(df = 34)</td>
</tr>
<tr>
<td></td>
<td>(t=11.85)</td>
<td>(t=1.71)</td>
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</table>
4. Discussion

This study revealed that the music group had less mean pain score than the headphone and control groups. Therefore, the hypothesis of this study was confirmed in that self-selected soothing music can alleviate pain following needle insertion into a fistula in the music group in comparison to that in the headphone and control groups. To the best of our knowledge, there has been no previous report on the effect of self-selected soothing music on pain related to needle insertion into a fistula in hemodialysis patients. In our study, the mean pain score significantly decreased from $5.58 \pm 1.71$ before the intervention to $3.28 \pm 2.09$ after the intervention in the music group. A study by Zengin et al. found that music therapy significantly reduces acute procedural pain in oncology patients undergoing port catheter placement procedure.$^{30}$ In addition, Hartling et al. concluded that music leads to a reduction in pain in children undergoing intravenous placement.$^{43}$ Two studies on thalassemic patients also found that music can be effective for pain relief during venipuncture procedure.$^{29,44}$ A review of current research demonstrates that music has a positive impact on pain related to medical procedures, such as phlebotomy$^{45}$, venipuncture$^{46}$, injections for vaccination$^{47}$, intravenous injections$^{48}$ and heel-stick capillary blood sampling in newborns.$^{49}$ Listening to preferred music promotes muscle relaxation, distraction from pain$^{50}$, and the release of endorphins that counteract pain.$^{27}$

The results of the present study indicate that the mean pain score did not differ significantly from pre- to post intervention for the headphone group. Correspondingly, another study revealed no apparent effect on pain perception with the use of headphone alone, and decreases of pain scores were only observed in the music headphones group.$^{51}$
Our findings also revealed that the mean pain score did not differ significantly from pre-to post intervention in the control group. Likewise, the results of a study on the effect of music on the pain caused by venipuncture in patients with thalassemia showed a statistically significant lower pain in the music and EMLA ointment groups in comparison to the routine care group\textsuperscript{44}, which might imply the necessity of providing pain relief interventions during painful medical procedures, such as venipuncture and needling of hemodialysis arteriovenous fistulas. Based on our findings and the results of comparable studies, music can reduce pain following needle insertion into a fistula in hemodialysis patients. As a result, it is recommended to use selective soothing music as a non-pharmacological method to relieve fistula puncture-related pain in hemodialysis patients, which yields to an increase in the acceptance of hemodialysis treatment and an enhancement in quality of life in hemodialysis patients.

The present study has several potential limitations. First, it was not feasible to control the impact of participants' anxiety and stress on their pain intensity. Second, there was no possibility to have the same nurses for all needle insertion procedures, which may have affected the study results. Finally, our participants may have had various perceptions of the emotional content of music preferred to listen and reacted to it differently. It is recommended to examine the effects of music combined with viewing nature images and photographs on pain related to needle insertion into a fistula in hemodialysis patients. Future research should also investigate the comparative effects of pharmacological (e.g. lidocaine spray and EMLA cream) and non-pharmacological interventions (e.g.
aromatherapy, Shiatsu massage, and transcutaneous electrical nerve stimulation) on fistula puncture-related pain.

Conflicts of interest
The authors have no conflict of interest to declare.

Acknowledgments
This study is part of a master thesis of Hosniyeh Shabandokht-Zarmi (Critical Care Nursing, School of Nursing & Midwifery, Mazandaran University of Medical Sciences), approved by the Medical Research and Ethical Committee of Mazandaran University of Medical Sciences. Funding for this study was provided by the Mazandaran University of Medical Sciences.

References


34. Cheng TH, Tsai CG. Female listeners' autonomic responses to dramatic shifts between loud and soft music/sound passages: a study of heavy metal songs. Front Psychol. 2016;7:182-93.


40. Rakhshekhorshid M, Foadoddini M, Saadatjoo AR. Comparison between the effects of applying massage and ice massage to SP6(SPLEEN6) point on severity and length of primary dysmenorrhea. Journal of Birjand University of Medical Sciences. 2013;20:11-9. [Persian]


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<td></td>
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<td>Control</td>
<td>5.41± 2.32</td>
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</table>
CONSORT diagram

Assessed for eligibility
(N = 203)

Excluded
(N = 89)
Visual impairment (N=19)
Drug addiction (N=11)
Administered analgesics (N=4)
Administered antidepressants (N=4)
Administered lidocaine for fistula puncture-related pain (N=1)
Habitual listening to music during hemodialysis (N=5)
Catheterized with Shaldon and Permcat (N=17)
Arteriovenous graft (N=6)
Intellectually impaired (N=2)
Hearing impairment (N=4)
Arteriovenous fistula < 3 months (N=12)
Refused to participate in the study (N=4)

Randomized
(N=114)

Control group
(N=38)

Withdraw (N=1)
More than one attempt for fistula puncturing (1)
Completed study (N=37)

Headphone group
(N = 38)

Withdraw (N=3)
More than one attempt for fistula puncturing (1)
Abdominal pain (1)
Administered analgesics before hemodialysis (1)
Completed study (N=35)

Music group
(N= 38)

Withdraw (N=2)
More than one attempt for fistula puncturing (1)
Fractured leg with severe pain (1)
Completed study (N=36)
This is a randomized clinical trial in which 114 participants were selected from two hemodialysis units by means of a non-random, convenience sampling method. The participants were then allocated in three groups of music (N=38), headphone (N=38), and control (N=38). The fistula puncture-related pain was measured one minute after venipuncture procedure in all three groups. The pain intensity was measured immediately after the intervention in all three groups.

This study showed a significant difference between the music and control groups, and the music and headphone groups in terms of the mean pain score after the intervention. However, the analysis did not indicate any significant difference between the headphone and control groups with regard to the mean pain score after the intervention.

It is concluded that music can be used effectively for pain related to needle insertion into a fistula in hemodialysis patients. Future research should investigate the comparative effects of pharmacological and non-pharmacological interventions on fistula puncture-related pain.
\[ n = \frac{\left( Z_{1-\alpha} + Z_{1-\beta} \right)^2 \left( \sigma_1^2 + \sigma_2^2 \right)}{(\mu_1 - \mu_2)^2} = \frac{[0.85 + 1/96]^2[1/5^2 + 1/5^2]}{1} = 35 \]