





Live music during haemodialysis: A multiple methods randomised controlled pilot study

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Abstract

Background: Fatigue is an immense problem among patients undergoing haemodialysis and is associated with anxiety and depression. Live music used in different hospital settings has shown promising effects, but the feasibility and potential effectiveness of live music during haemodialysis are unknown.

Objectives: To evaluate the feasibility, the participants' musical experience and potential effectiveness of live music on patients' levels of fatigue, relaxation, anxiety, depression, treatment satisfaction and work engagement among nurses.

Design: A pilot randomised controlled trial evaluated with a multiple methods design.

Participants: Two clusters of 12 patients were each randomised to receive either 30 min of live music once a week during haemodialysis or usual care over a period of 6 weeks.

Measurements: The primary outcome was patients' immediate fatigue. Other outcomes were patients' long-term and post-dialysis fatigue, relaxation, anxiety, depression, treatment satisfaction and work engagement among nurses. Observations and semi-structured interviews with patients, nurses and musicians were

conducted to gain an in-depth understanding of the musical experience as well as feasibility.

Results: The study was feasible and detected significant differences on immediate fatigue ($p < 0.001$) and anxiety ($p < 0.012$) in the intervention group compared to controls. Among 17 nurses, a significant difference was found in Dedication ($p < 0.024$). Furthermore, live music gave patients an uplifting experience, bringing joy and relaxation and the nurses experienced a sense of quietness in a stressful day.

Conclusions: Providing live music performed by professional musicians in a haemodialysis setting is feasible and showed a significant effect on immediate fatigue and anxiety compared to controls.

KEYWORDS

fatigue, haemodialysis, music intervention, multiple methods design

INTRODUCTION

Patients diagnosed with kidney failure face numerous psychological problems and changes that impact profoundly on life expectancy and quality of life (Monfared et al., 2009; Moreiras-Plaza et al., 2011; Simic-Ogrizovic et al., 2009). Patients have consistently indicated fatigue as the most persistent and commonly occurring symptom (Almutary et al., 2016). Fatigue affects 60%–97% of patients undergoing haemodialysis (HD) and is associated with impaired health-related quality of life (HRQoL) (Artom et al., 2014; Jhamb et al., 2013; Maruyama et al., 2021). Patients undergoing HD treatment describe fatigue solely as a biomedical condition affecting their functioning, together with low mood, frustration, anger and lack of self-motivation (Picariello et al., 2018). Furthermore, 'debilitation and exhausting burden', 'bodily exhaustion' and 'restricted life participation' were themes identified in a systematic review including 65 studies among patients receiving HD treatment (Jacobson et al., 2019). A linear association has also been found between anxiety, depression, stress and HRQoL among patients undergoing HD treatment (Bujang et al., 2015; Farragher et al., 2017; Marthoenis et al., 2021; Raj et al., 2017; Vasilopoulou et al., 2015).

LITERATURE REVIEW

There is promising evidence for music as a nonpharmacological intervention to reduce fatigue in other patient groups, for example, cancer (Alcântara-Silva et al., 2018; Bradt et al., 2021) and multiple sclerosis (Moumdjian et al., 2019). Recently, music therapy in the form of 30 min of patient-tailored live music reduced levels of fatigue and pain among hospitalised patients with cancer compared to controls (Reimnitz & Silverman, 2020). In patients undergoing HD, a quasi-experimental study has shown a significant decrease in fatigue and anxiety through experiencing 30 min of recorded classical and modern music three times a week over one month (Haghi et al., 2019).

In a systematic review of 32 studies, mind-body therapies (music therapy, relaxation therapy and spiritual therapy) showed consistent efficacy for anxiety, pain and depression across multiple studies in patients with kidney failure; however, no studies looked at fatigue as an outcome (Chu et al., 2021). Nine out of 10 randomised controlled trials (RCTs) applying intradialytic music interventions have found significant effects on anxiety, pain, depression, stress, sleep and relaxation compared to controls (Burrai et al., 2014; Burrai et al., 2019; Cantekin & Tan, 2013; Koca Kutlu & Eren, 2014; Lin et al., 2012; Melo et al., 2018; Momennasab et al., 2018; Pothoulaki et al., 2008; Schuster, 1985; Shabandokht-Zarmi et al., 2017). However, as fatigue is found to be a persistent and debilitating symptom without a total medical solution and is linked to impaired HRQoL, anxiety, sleep problems and increased levels of depression (Almutary et al., 2016), there is a need to investigate whether a music intervention might decrease levels of fatigue among patients undergoing HD and to explore the mechanisms behind any effect. To the best of our knowledge, no studies have investigated the effect of live music performed by highly skilled professional musicians during HD. Musicians trained to perform in the health care environment are attuned to this social situation, resulting in the ability to tailor their music, adjusting tempo, intensity and repertoire, according to individual patients' reactions (Bro et al., 2019; Smilde et al., 2019). Recent research has also found that patient-tailored live music in the healthcare environment can lead to a new conscious understanding of patient-tailored care and affect work engagement among nurses (De Wit, 2020; Smilde et al., 2019). This might counteract the moderate to high levels of burnout found among nurses working in an HD setting (Hayes et al., 2015; Moisoglou et al., 2021). However, the question of whether live music interventions are feasible in an HD setting, for the benefit of both patients and staff, remains to be investigated.

The aims of this study were threefold. First, to evaluate the feasibility and acceptability among patients, nurses and musicians of conducting a randomised controlled pilot trial in the HD setting.

Second, to examine the potential effectiveness of patient-tailored live music interventions among patients undergoing HD compared to controls on levels of fatigue, relaxation, anxiety, depression and treatment satisfaction. Third, to explore the musical experience among patients and nurses and to examine work engagement among nurses.

Hypothesis and assumptions

- We hypothesise that patient-tailored live music will be feasible and decrease fatigue, anxiety, depression and relaxation and improve treatment satisfaction among patients undergoing HD compared to patients undergoing a control condition.
- We hypothesise that patient-tailored live music may improve work engagement among staff.
- We assume that patient-tailored live music will positively affect patients, nurses and musicians in an HD setting.

MATERIALS AND METHODS

Study design

This study was a pilot cluster RCT combined with a qualitative interview study and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT04959682). To address the research hypothesis and assumption, a multimethod design was used. Even though it concerns only one study and qualitative and quantitative data were collected simultaneously, each part had various foci, that is, patient outcomes and nurses/musicians' outcomes. Quantitative data were collected using questionnaires to evaluate patients' levels of immediate, long-term and post-dialysis fatigue, relaxation, anxiety, depression and treatment satisfaction and nurses' levels of work engagement. Qualitative data were collected using first-hand observations, semi-structured individual interviews with patients and staff and a semi-structured group interview with staff and musicians. Additionally, reflective journals were completed by the musicians. An overview of the qualitative and quantitative measurements is found in the supplemental material.

The CONSORT 2010 statement: extension to randomised pilot and feasibility trials was used to qualify the trial as a future definitive RCT and the Reporting Guidelines for Music-based Interventions were used to ensure transparency (Eldridge et al., 2016; Robb et al., 2011).

Participants

We recruited participants on HD treatment at one satellite unit at a regional hospital in Denmark, from 22 April 2021 to 7 July 2021. Eligible patients were aged 18 or over. We excluded patients with mental illness or deafness and those not able to understand or speak Danish.

Two weeks before the start of the study, a research nurse gave eligible patients oral and written information about the study. The patients were informed that participation was voluntary and that they could withdraw from the study at any time.

Randomisation

Randomisation was conducted using two sealed envelopes with treatment allocation inside. To ensure the primary investigator (PI) remained blinded to the allocation, an administrator was responsible for forwarding the treatment allocation to the PI responsible for delivering the intervention. The patients were divided into two treatment clusters in advance; one cluster received HD treatment on Mondays, Wednesdays and Fridays, and the other on Tuesdays, Thursdays and Saturdays. The two clusters were randomised (1:1) either to receive the intervention one day a week for 6 weeks plus usual care (intervention group) or only usual care (control group).

Intervention: patient-tailored live music and usual care

The intervention was provided by four professional acoustic guitarists (one duo, two soloists) from the organisation 'Live Music in Schools' (<https://lms.dk>). They all participated in a 3-day introductory course, dealing with choice of repertoire, patient information, the hospital environment and how to fine-tune the music to the individual patient and to the patient group as a whole. An advance meeting of musicians and nurses was also held in the HD unit to facilitate cooperation and discuss the logistics and potential challenges, as well as to give the musicians the opportunity to test the acoustics in the clinic. Published guidelines ensured the reporting of formal music characteristics based on musical parameters like tempo, melody/harmony and instrumentation in relation to targeted fatigue management. The musicians prepared a varied high-quality basis repertoire containing both familiar and unknown music to meet the patient's preferences and needs. They performed 3 × 30 min of patient-tailored instrumental music to a group of 4 patients each with a combination of relaxing (on average 60–80 bpm) and lively, slightly more upbeat tempos to regulate arousal levels. The patients were passively listening and were informed that this was not an ordinary concert, instead a musical experience based on their own and the group's common needs. At the first music intervention, the musician received feedback and guidance from the HCM and the musical content was adjusted along every music session and throughout the study period based on the feedback of the patients. To ensure equal communication across groups, a guideline for nurses and physicians was developed, recommending only talk related to the treatment procedures. Nurses were presented in the room throughout the intervention. The control group was asked not to listen to music during HD until data collection was complete. Once the data collection was completed, the control group received the same music interventions as the intervention group for a period of 6 weeks.

Quantitative data collection

Before randomisation at baseline, all participants completed a questionnaire covering age, gender, height, body weight, marital

and social status and years/months on HD. They then filled out validated questionnaires on the following outcome variables: long-term fatigue (Multidimensional Fatigue Inventory, MFI-20) (Smets et al., 1995), anxiety and depression (Hospital Anxiety and Depression Scale, HADS) (Zigmond & Snaith, 1983) and treatment satisfaction (visual analogue scale, VAS) (Singer & Thode, 1998). The primary outcome of interest was immediate fatigue, measured by VAS immediately before the commencement of each HD session (pre-intervention) and after the 30-min music intervention (post-intervention) at the first to sixth treatments. Furthermore, the patients rated levels of relaxation (VAS) pre- and post-intervention, as well as registering fatigue levels in a fatigue diary (VAS) (between 8:00 am and 10:00 am, and between 8:00 pm and 10:00 pm) the day after each intervention. One week after the intervention period, the patients filled out the same questionnaires on outcome variables as at baseline. The patients in the intervention group were asked whether they would prefer live music during future HD sessions. To determine the staff's perception of the music interventions on work engagement, they filled out the validated Utrecht Work Engagement Scale (UWES) questionnaire before and after the project period (Schaufeli & Bakker, 2004).

Qualitative data collection

Qualitative data were collected in the intervention group only, and included first-hand observations and semi-structured interviews with patients and nurses, based on the methods developed by Spradley (Spradley, 2016). A further semi-structured group interview with the nurses and musicians was conducted after the project period to discuss their experiences and the inter-professional cooperation across disciplines. For each music intervention, interviews with patients were conducted immediately after collecting post-dialysis fatigue and relaxation scores. The interviews and the following analysis were conducted in the native language whereafter a throughout careful translation of themes, subthemes and quotes were made in cooperation between the authors and an English translator. The nurse interviews were conducted at a convenient time on music intervention days. The semi-structured interview guides were developed based on Kvale and Brinkmann's methods (Kvale & Brinkmann, 2014). An in-depth analysis of the qualitative data is published separately (Bro et al., 2022).

Sample size

Because this was a pilot trial, a sample size calculation was not performed. We estimated that 24 participants would ensure the objectives of feasibility (Eldridge et al., 2016). Feasibility was illuminated by the collected qualitative data, together with quantitative data on attendance rates among patients and nurses and the acceptability of implementing music interventions in the HD setting.

The acceptability of outcome measures was assessed by completion rates of the questionnaires and missing data.

Data analysis

A concurrent multiple-method design was used, meaning that data collection and data analysis was conducted separately, but the results were compared, to complement, and contrast the quantitative and qualitative findings (Driessnack et al., 2007). Data were given equal priority to bring forward new perspectives and to answer research hypotheses and assumptions.

The statistical analyses of the quantitative data were performed using the program Stata16 (StataCorp UC, n.d.). All descriptive statistics and tests were reported in accordance with the CONSORT statement for RCTs (Eldridge et al., 2016). Baseline demographic and clinical characteristics were reported descriptively for all patients in the full data analysis set. Differences in baseline and demographic measures between groups were tested using analysis of variance (ANOVA) for continuous data and the chi-square test for categorical data. To assess between-group effects in immediate fatigue and relaxation, a linear mixed model was applied, with a time factor (before treatment one and after treatment six) and between-group factor (intervention vs. control), and the interaction between intervention and visit. Assumptions underlying the model were checked using residual plots in case the data would need to be transformed (e.g., using a logarithmic transformation). Missing values were treated as 'missing at random'.

Within a phenomenological-hermeneutic tradition, the qualitative data were analysed using a method inspired by the French philosopher Paul Ricoeur developed by Dreyer and Pedersen (Dreyer & Pedersen, 2009). In this method, analysis consists of three levels: (1) naïve reading, (2) structural analysis and (3) critical interpretation (Dreyer & Pedersen, 2009). The first level involves an open-minded, intuitive and naïve reading of the text, focusing on whichever elements strike the interpreter. At level two, the interpreter re-reads the text to uncover the structure and the underlying dependencies within the text. At level three, the critical interpretation involves a dialectic process, moving from understanding to explanation of the text, forming the basis of a new understanding of being in the world, in this case as a patient or health care professional in an HD unit (Dreyer & Pedersen, 2009). Data were managed using the software programme NVivo (<https://www.qsrinternational.com>, n.d.).

Ethical considerations

The Central Denmark Region Committee on Health Research Ethics did not consider the study to be a health research study; therefore, it was not notifiable (File no. 1-10-72-1-21). However, data management was approved by the Department of Data Security, Central Denmark Region (File no 1-52-81-142-21). We obtained written consent from all participants before participation.

RESULTS

Patient characteristics

The average age of the patients was 63 years, average time on HD was 54 months, and the gender distribution was 15 men and nine women. No differences were found comparing the two groups at baseline (see Table 1).

Feasibility

Of the total number of eligible patients ($n = 26$), 24 were included (92%). There was no mixing of the two groups, and all patients remained in their allocated group. Figure 1 shows the flow chart of the study. After the first treatment day, two patients left the project due to lack of surplus to participate and cognitive impairment, respectively. The main reasons for the patients being absent on treatment days were hospitalisation, Covid symptoms, undergoing an operation, medical examinations at other hospitals, or unknown reasons for changing treatment day.

At follow-up, 100% of the patients in the intervention group expressed a wish for future music interventions in the outpatient clinic. Furthermore, there were possibilities for establishing new routines among the staff, possibly allowing music interventions in clinical settings. The participation rate for the nurses was 94%.

Feasibility of the intervention experienced by patients, nurses and musicians

Overall, the patients were grateful for and satisfied with the music experiences. No complaints were mentioned as to acoustics, repertoire, musicians' approach, or appearance.

The nurses pointed out several logistical aspects important for conducting music interventions in the HD setting. First, to ensure a calm and quiet environment for the patients, nurses and musicians, the intervention took place in the morning immediately after commencement of HD treatment. According to the nurses, at this point in the treatment, the patients were at their best, and nurses could spare time to share the music with the patients. Occasionally, the observations recorded, that sudden alarms and critical situations requiring nurses' attention disrupted elements of the music experience for both nurses and patients. To minimise interruptions from outside, the door to the intervention rooms was closed, with a sign placed on it requesting no unnecessary disturbances. Secondly, the 30-minute duration of the live music was estimated to be suitable to fit in with the clinical routines of the clinic. For space reasons, it was noted that a maximum of two musicians was suitable for this setting. The volume of the music was appropriate for listening and working at the same time: *'It's fantastic that it's acoustic music... because you can relax to it [the music] in another way. Both the musical level, in terms of volume, level of intensity, is very suitable, I think'* (ID 61). However, some nurses mentioned a certain tension between being at work and responsible for the patients, and at the same time being engrossed in the music. They found it distracting, and worried that they might overlook important signals from the patients. Finally, some nurses mentioned the importance of having a nurse in charge of planning and organising the entire set-up, including communicating with the musicians, patients and staff before the session, and helping the musicians adjust to the individual patient rooms. From the musicians' perspective, the setting, logistics, acoustics and timing of the interventions were well planned. The staff's supportive and cooperative attitude was mentioned as being very important to them: *'It means a lot that the nurses help to stabilize the situation, or give support'* (ID DUO). The musicians' diverse choices of format and repertoire seemed to match the patients' different needs, as there were no comments critical of the content, length and tempo of the music in the interviews. Some musicians told stories about the music

TABLE 1 Baseline demographic data and characteristics of the study population

Characteristics	Intervention group ($n = 12$)	Control group ($n = 12$)	p value	Total ($n = 24$)	Range
Age (years)	65 (20)	61 (14)	0.489	63 (17)	24–86
Gender (male/female)	6/6	9/3	0.206	15/9	
Body weight (kg)	86.0 (22.1)	85.0 (16.1)	0.907	85.5 (18.9)	49–138
Height (cm)	172.8 (12.8)	177.2 (8.2)	0.324	85.5 (18.9)	174–196
BMI (kg/m^2)	28 (5)	28 (6)	1.000	28 (5)	16–36
Marital status (cohabiting/single)	7/5	7/5	1.000	14/10	
Employment status (employed/unemployed)	0/12	2/10	0.140	2/22	
Length of HD treatment (months)	39.7 (24.5)	68.5 (53.3)	0.200	54.0 (43.3)	8–192

Note: Data are shown as mean (SD) and numbers. Differences were tested using analysis of variance (ANOVA) for continuous data and chi-square test for categorical data.

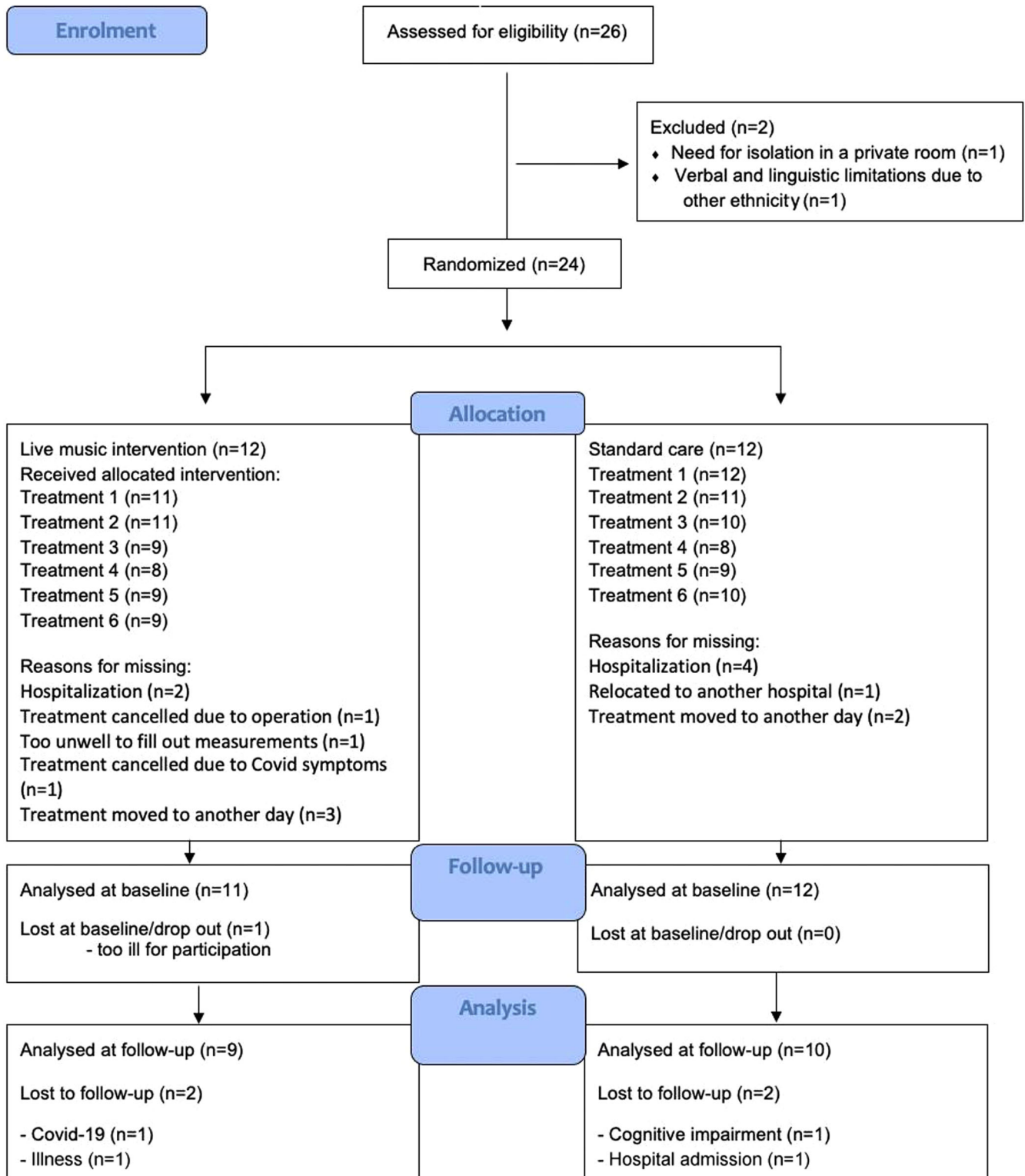


FIGURE 1 Flow chart of the study. The analysis refers to primary outcome collected pre-/post-treatments 1–6.

beforehand and initiated a relational dialogue with the patients. This interactive approach was positive for many patients, bringing new perspectives on the musical experience. On occasions when the musicians chose not to introduce the music, a more reflective, calming and introspective experience was achieved. However, the

musicians felt that it was sometimes difficult to read the patients' reactions when they listened with their eyes closed. It was also a challenge to choose music to suit all patients when some wanted to interact with the musicians and others preferred not to engage verbally.

Effect size estimates

Primary outcome

When testing the treatment effect of pre- and post-fatigue measurements for all six treatments, the linear mixed model showed a significant reduction in fatigue in the intervention group compared to the control group (Δ : -15.0 (3.8); $p < 0.001$) (Table 2).

There was no detectable change in long-term fatigue, measured 1 week before the intervention and 1 week afterwards (Δ : -24.1 (15.6); $p < 0.142$).

Secondary outcomes

An increase in anxiety and depression scores was found in the control group, whereas a decrease in anxiety levels was found in

the intervention group at follow-up. The between-group analysis showed a significant decrease in anxiety in the intervention group ($p < 0.012$) but no significant difference for depression ($p < 0.407$) (Table 3). The mean levels were similar across groups, and no significant differences were found (Table 3). Additionally, there were no significant differences found between groups on the subscales in MFI-20, relaxation, or treatment satisfaction post-dialysis.

Patients' experiences of the intervention

Seventeen informal interviews with patients in the intervention group were conducted. Eight patients were interviewed once and four patients more than once (ID 13 = 2, ID 16 = 2, ID 15 = 2, ID 22 = 3) about how the musicians' approach, musical format and content affected their experience. Analysing the interviews and semi-structured interviews,

TABLE 2 Mean pre-/post-intervention values for immediate fatigue

Fatigue (VAS) Treatment	Intervention			Control		
	Pre-Mean (SD)	Post-Mean (SD)	Diff	Pre-Mean (SD)	Post-Mean (SD)	Diff
1	24.5 (22.7)	11.4 (19.7)	-13.1 (22.2)	38.7 (22.5)	46.8 (25.3)	8.2 (12.6) ^a
2	32.6 (31.9)	23.0 (27.4)	-9.6 (25.9)	45.6 (27.8)	61.6 (28.8)	16.0 (34.0)
3	34.0 (27.4)	23.3(29.0)	-10.7 (12.2) ^a	29.8 (31.6)	46.9 (31.8)	17.1 (24.6)
4	17.9 (20.2)	20.4 (28.6)	2.5 (14.7)	45.4 (22.7)	46.8 (35.9)	1.4 (22.8)
5	39.9 (35.6)	37.8 (33.8)	-2.1 (10.1)	35.4 (29.8)	40.3 (32.1)	4.9 (16.9)
6	19.6 (19.3)	14.0 (23.3)	-5.6 (20.9)	45.4 (32.1)	43.4 (33.0)	-2.0 (14.6)

Note: Data are means and standard deviations. The calculated difference is based on paired t-test.

^aSignificant change: $p \leq 0.05$.

TABLE 3 Mean baseline values, follow-up values and between-group differences on HADS and MFI-20

	Intervention baseline mean (SD)	Intervention follow-up mean (SD)	Control baseline mean (SD)	Control follow- up mean (SD)	Intervention versus control mean (SE)	95% CI	p value
HADS							
Anxiety	4.3 (2.9)	2.6 (2.0)	5.75 (4.5)	7.6 (4.9)	-2.9 (1.0)	-5.0;-0.8	0.011 ^a
Depression	2.9 (2.5)	2.7 (2.3)	3.7 (2.4)	4.0 (2.7)	-0.7 (0.9)	-2.6;1.1	0.406
MFI							
General fatigue	12.5 (4.0)	12.2 (3.9)	13.1 (2.3)	14.4 (3.2)	-1.3 (1.5)	-4.5;1.9	0.388
Physical fatigue	15.7 (4.5)	15.7 (4.3)	14.2 (2.8)	15.4 (3.1)	1.0 (1.5)	-2.1;4.1	0.503
Mental fatigue	9.5 (4.3)	8.4 (3.3)	10.3 (3.3)	10.3 (3.2)	-0.8 (1.1)	-3.2;1.6	0.475
Reduced activity	15.3 (5.6)	14.1 (5.7)	13.8 (1.7)	12.8 (3.8)	0.7 (1.5)	-2.4;3.8	0.649
Reduced motivation	8.3 (4.3)	8.5 (3.3)	9.0 (3.2)	7.3 (3.0)	0.4 (1.1)	-1.8;2.7	0.687

Note: Differences are estimated as the difference between means with 95% confidence intervals (95% CI), based on the one-factor analysis of covariance (ANCOVA) with the level at baseline applied as a covariate. Values are least squares means with standard deviation and standard errors presented for each group. Abbreviations: HADS, Hospital Anxiety and Depression Scale; MFI-20, Multidimensional Fatigue Inventory.

^aSignificant change: $p \leq 0.05$.

the theme: 'An uplifting experience bringing joy and relaxation into life' emerged.

The music affected both the physical and mental state of the patients. Refreshing, calming, relaxing and uplifting were some of the words the patients used when describing the immediate effect of the music. Two patients described this as follows: 'My body relaxes a bit more' (ID 18). 'You feel more comfortable' (ID 19). For some, the good physical feeling continued after they had returned home from the hospital. It seemed important that the patients were informed that the music interventions were not traditional concerts, but that they could choose to close their eyes and enjoy the music on their own terms or be more participatory. One patient described it in this way: 'It's allowed to just be yourself when you hear the music, and that's relaxing in itself' (ID 15). It appeared that the music allowed the patients to enter an individual inner space where they could relax on their own terms and be themselves. For many, it was an emotional and distracting experience, a musical journey that evoked memories of the past; some imagined different natural scenes, such as waves, according to the tempo, intensity and musical expression: 'When it was so quiet and so calm, I thought of the sea. The waves that came rushing just as quietly and so calmly. You can imagine some pictures' (ID 23). Some of the patients were impressed by the musicians' skills, enjoyed having a dialogue with the musicians and thought that the music created a positive atmosphere in the patient rooms.

Nurses' experiences of the interventions

Of the 18 nurses invited to take part in the study, 17 agreed to participate. Of these 17, one did not experience the music interventions and was excluded from the analysis. Mean baseline and follow-up levels on the UWES subscales were categorised as average according to norm data for the UWES-17. When testing the difference between baseline and follow-up data, we found a significant improvement in the subscale Dedication. No significant difference was found in the other subscales, nor the overall score (Table 4).

TABLE 4 Summary results of changes in work engagement (UWES) for nurses after 6-week intervention

Variable	Work engagement among nurses (n = 16)		
	Post- versus pre-intervention		
UWES	Coefficient (SE)	95% CI	p value
Vigour	-0.17 (0.14)	-0.47;0.14	0.261
Dedication	0.52 (0.12)	0.08;0.95	0.023^a
Absorption	-0.16 (0.13)	-0.44;0.12	0.245
Overall score	0.04 (0.20)	-0.39;0.47	0.855

Note: Differences are estimated as the difference between means with 95% confidence intervals (95% CI), based on the one-factor analysis of covariance (ANCOVA) with the level at baseline applied as a covariate. Abbreviation: UWES, Utrecht Work Engagement Scale.

^aSignificant change: $p \leq 0.05$.

Nine informal interviews were conducted with the nurses, and the following theme: 'A sense of quietness in a stressful day' emerged through the analysis.

Although the nurses still needed to focus on treating the patients during the music, the observations and interviews revealed that they experienced the music as a calming, de-stressing and relaxing interlude. Compared to their normal work situation, there was a new sense of quietness, despite continuing work and the alarms of the machines—as if time stood still. Furthermore, the nurses stated that the music gave them a feeling of capturing the moment, entering an inner space with personal thoughts, having a physical sensation of calm and breathing more deeply: 'It was just getting out of stress, and just letting go and breathing ... I was just in that moment' (ID 61). Overall, it seemed the nurses felt that the musicians made a positive difference for both patients and staff. One noted that it gave her professional satisfaction to see the patients enjoying the music: 'I think it does something for one's nursing professionalism, because you can see that here is something that the patients like' (ID 63).

The musical content

The classical duo and solo musician performed a wide range of classical guitar music, from Tarrega, Vivaldi, Sor, Walton, Bach and Albeniz to film music by Stanley Myers and arrangements of well-known Danish songs. The remaining guitarist performed a mix of film music and arrangements of popular Beatles, Eric Clapton and Danish songs combined with improvisations in bossa nova and blues styles.

DISCUSSION

This multiple methods evaluation of a pilot cluster RCT showed that patient-tailored live music performed by professional musicians was feasible, with acceptability and adherence among patients, nurses and musicians. The levels of immediate fatigue were significantly reduced in the intervention group compared to the controls. For patients in the intervention group, the experience created a joyful, comfortable and relaxing moment during treatment, and the nurses experienced a sense of quietness during a stressful workday.

Overall, we found that conducting this multisession intervention study was feasible in an HD setting. Data showed that the logistical challenges related to the music interventions were minor, and there was acceptability across groups in terms of attendance rates and wishes for future implementation of the intervention in the clinic. Conducting a music intervention in a clinical setting requires careful planning, with advance meetings and trust-based collaboration between musicians and staff. Not all the patients were able to participate in the intervention each time, and in one instance, four out of 12 participants were missing (30%), which revealed that the study population was a fragile group of patients. However, a lack of rigour in the set-up—with nurses allowing patients to move their treatment for reasons other than their disease—may have caused

additional absences and thus missing data. As a result, tightening the inclusion criteria may be worth considering, and the importance of thorough training in conducting research in a clinical setting cannot be stressed enough.

Given the impact of fatigue on the burden of treatment and QoL, this study's key finding is that patient-tailored live music performed by professional musicians has the potential to reduce immediate fatigue. Our results are in line with a study showing a significant decrease in fatigue by offering a single 30-min session of patient-preferred live music therapy to oncology patients undergoing bone-marrow transplantation compared to controls (Reimnitz & Silverman, 2020). Reimnitz and colleagues argue that a trained music therapist is needed to play at an aesthetically pleasing level and to use verbal interaction skills to augment the therapy to influence results. However, we found that highly trained professional musicians, who underwent a competency boost and supervision process to tailor music to patients in the HD environment, was a satisfying way to run the music intervention. Jacobson et al. (2019) argue that, for patients undergoing HD, fatigue means bodily exhaustion and lack of energy, strength and motivation, with eroded self-esteem and identity as a serious consequence. In our study, interviews, observations and higher post-intervention mean scores for immediate fatigue in the control group—from low to moderate—indicate that this sample of patients was facing similar experiences of fatigue. Our findings suggest that live music might counteract some of the negative feelings related to fatigue. The minimally important difference for fatigue in an HD population is unknown (Ju et al., 2018) but in a patient population with Rheumatoid Arthritis they found a minimally important difference for the VAS-fatigue score less than the difference we identified, which may strengthen our statistical findings on our primary endpoint (Khanna et al., 2008).

The literature presents no consensus on the content of music interventions to reduce fatigue (Qi et al., 2021). In this study, a mix of relaxing (slow), lively (up-tempo), familiar and unfamiliar music was selected to meet the patients' needs, both individually and as a group. Familiar music can allow latent feelings to emerge (Pereira et al., 2011), whereas unfamiliar music, chosen to fit the cultural context, may open up new perspectives (Vuust & Kringelbach, 2010). These mechanisms were reflected in the qualitative interviews where the patients stated that the music was both reflective and uplifting, and relaxing and enjoyable. Most RCTs investigating the effect of music in the HD setting use prerecorded music (Cantekin & Tan, 2013; Koca Kutlu & Eren, 2014; Lin et al., 2012; Melo et al., 2018; Momennasab et al., 2018; Pothoulaki et al., 2008; Shabandokht-Zarmi et al., 2017). However, interventions offering live music are not comparable to those using prerecorded music, often played via headphones. The musicians in this study could adapt the music in the moment according to patients' feedback.

Although the patients described music as a bodily and mentally relaxing experience in the interviews, this was not found in the quantitative analysis of the pre-/post- relaxation measurements. We argue that there may be a subtle linguistic difference between rating a bodily sense of relaxation and describing a musical experience as

relaxing for body and soul, making it impossible for one to verify the other. It may be possible to use physical/biochemical indicators as supplementary measures of relaxation, e.g., respiratory rates (Melo et al., 2018). As to anxiety, there was some agreement between the results from the qualitative and quantitative data in our study; the music was described as an uplifting experience, bringing joy and relaxation into life and there was a significant decrease in anxiety compared to controls. Our results are in line with a meta-analysis showing a medium effect size for anxiety data in seven studies offering prerecorded music during HD (Kim et al., 2015).

For the nurses, our results show that live music might counteract feelings of burnout and improve work engagement in the HD setting. Although the qualitative data indicated that the music interventions altered mental resilience and engagement while working, this was not shown in the Vigour and Absorption UWES subscales. As Absorption is characterised as giving full concentration and Vigour as having high levels of energy and mental resilience while working, it is possible that the tension some nurses mentioned, between enjoying the music and still having responsibility for the patients' treatment, may have affected the UWES results. However, one UWES subscale—Dedication—showed interesting results, emphasising that the music enabled the nurses to be involved in their work in new ways, discover new sides to the patients, and find meaning, inspiration, enthusiasm and joy in a stressful workday.

Study limitations

Our study has several limitations. First, a pilot trial is not meant to detect statistically significant differences between groups, and therefore the efficacy results should be interpreted with caution, although we found our primary outcome and one of the secondary outcomes to be statistically significant. Second, no blinding was used among participants and researchers, and this might have affected the validity of the design and interpretation of the findings. The nurses' behaviour might have affected the patients and thus the results. Third, the choice of self-reported measurements might have affected the reliability of the results. Further, as there was no control condition among the nurse, the interpretation of the UWES scale might be a random finding.

Finally, as this study was conducted at a satellite HD unit, some logistical aspects may not be adaptable to other settings, although the intervention was tested beforehand at a large HD unit at a university hospital.

Implications for clinical practice

This study suggests that patient-tailored music interventions in an HD setting are acceptable and feasible from the patients', nurses and musicians' perspectives. Live music, performed by qualified, professional musicians may help to reduce immediate fatigue in patients undergoing HD. However, as this was a pilot study involving

24 patients, the intervention's effectiveness must be tested further on a larger scale, preferable in a multicentre design. The nurses in this study suggest that 30-min music sessions would be suitable to adapt the clinical routines. Further, we suggest a work distribution, that is, only a part of the nurses should be able to participate in the music at a time. This work distribution will secure that there always will be nurse(s) not being distracted by the music.

CONCLUSIONS

This study has shown that patient-tailored live music interventions in an HD setting are acceptable for patients, nurses and musicians. Conducting patient-tailored live music interventions performed by highly skilled musicians is feasible within a future cluster RCT with some modifications. We found significant reductions in levels of immediate fatigue and anxiety among a small sample of patients undergoing HD compared to controls. Qualitative data showed that the music was an uplifting and meaningful experience for the patients, as well as a de-stressing experience for the nurses at work. A definitive cluster RCT should maintain the intervention design to measure immediate fatigue pre- and post-intervention in a two-armed design, strengthen the methodological rigour and include more centres to illuminate differences across different outpatient settings.

AUTHOR CONTRIBUTIONS

All authors have substantially contributed to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work. All authors have drafted or revised the paper critically for important intellectual content. All authors have given final approval of the version to be published. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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