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ORIGINAL RESEARCH

A pilot trial exploring the use of music in the emergency department and its association with delirium and other clinical outcomes

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Abstract

Objective: To assess potential feasibility of a targeted music intervention trial in older ED patients and association with clinical outcomes.

Methods: Prospective pragmatic trial of adults aged ≥65 years in the ED, with prevalent delirium or increased risk of incident delirium, receiving either 2-h music intervention via headphones or usual care. The primary outcomes were (i) feasibility as assessed by actual use of the intervention (target 70% of offered patients) and (ii) incident delirium in delirium-free patients.

Results: Among 211 initially screened patients, 44 were included. The initially planned randomised controlled trial proved difficult due to poor intervention adherence, resulting in a move to patient self-selection to routine care or 2-h music intervention. There were 19 control (13 prevalent delirium) and 25 intervention participants (20 prevalent delirium); 2-h target intervention duration was achieved in 17/25 (68%) patients (8/25 achieving <2 h). Among those without prevalent delirium, incident delirium occurred in 1/6 of control and 4/5 of intervention ($P = 0.08$). There were no between-group differences in terms of improved or resolved delirium, pain scores or agitation/sedation scores (all $P > 0.1$).

Conclusions: Self-selected use of a targeted music intervention was feasible in a cohort of older ED patients. While we were likely underpowered to detect associations between intervention and outcome, collection of selected outcome measures proved feasible; these may be helpful in larger scale studies. Exploration of barriers and facilitators to use, as well as preferred delivery methods, are likely to be helpful in wider investigations of music therapy in this high-risk cohort.

Key findings

- In this pilot trial, the use of headphone-delivered receptive music in the ED proved feasible with patient self-selection.
- Our study was underpowered to assess the association between intervention and clinical outcomes.
- Larger, better funded studies are needed to assess clinical outcomes, and to address patient risk and experiences in the complex ED setting.

Key words: *aged, delirium, emergency service, hospital, music, patient outcome assessment.*

Introduction

Delirium is a potentially life-threatening neuropsychiatric syndrome, that is commonly found in patients in the ED, especially older people.[1] It is associated with poor patient outcomes and numerous downstream complications, including chronic cognitive decline and increased mortality.[2] The Australian Commission on Safety and Quality in Healthcare clinical care standards[3] highlight the importance of delirium management for patients.

Sensory overload is a key environmental stressor linked with delirium, with excessive noise thought to adversely affect patient outcomes and

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contribute to sleep disruption.[4,5] This is particularly relevant to ED contexts where consistent and high noise levels have been widely documented.[6,7] Despite this, existing literature investigating delirium interventions in EDs is scarce, likely hindered by logistical and methodological limitations.[8] Receptive listening to calm, slow-tempo music has a potential role in delirium prevention and management,[9] with benefits conceivably mediated through inflammatory inhibition, and altered autonomic and sympathetic nervous system activity.[4,10] Nonetheless, data regarding the potential use of music therapy in the ED are scarce.[11] As a result of logistical and methodological limitations, researching delirium in the ED setting is difficult and published literature is scant. Studies are commonly performed in community or residential aged care settings, the results of which may not be validly generalised to emergency settings.[12] There is some evidence that music therapy in the acute setting may be feasible[13] and may reduce delirium in specific cohorts such as those undergoing orthopaedic surgery.[14] Outside of the acute hospital setting, hypothesis-generating studies have found associations between music therapy and either reduced pain or improved agitation.[15,16]

In this context, our aim was to investigate the feasibility of a controlled trial, and explore potential efficacy of a targeted music intervention in preventing delirium, and improving patient outcomes for older ED patients presenting with prevalent delirium or at increased risk of incident delirium.

Methods

Setting

This prospective pragmatic controlled trial was conducted at a tertiary metropolitan hospital ED in Liverpool, New South Wales, Australia, August 2018.

Design

In order to allow real-world assessment of feasibility, we allowed for dynamic change to design based on emerging experiences. The initial plan included a randomised clinical trial design, but allowed for change (patient self-selection) if this was difficult to institute.

Randomisation was made according to random number generator. Allocation sequence was concealed from the recruiting researchers in opaque, sealed and stapled envelopes until participants have consented to participate and undergone baseline assessment.

Intervention

The present study followed a previously reported 2-h recorded receptive music intervention methodology that was developed in accordance with the tenets of professional music therapy.[11] Three instrumental playlists were available, selected for music with appropriate elements (tempo, dynamics, texture, timbre, etc.) across three different musical genres: classical, ambient and world music.[11,17] Patients in the intervention arm were provided with MP3 players and good quality over-ear headphones, which were not actively noise-cancelling, but likely had some degree of passive noise cancellation. Infection control issues were addressed by placing the players in small press-seal plastic bags and using disposable headphone covers, which were provided by an unrestricted donation from Haines Medical Australia.

Participant eligibility criteria

Eligible participants were patients aged ≥65 years, classified as categories 2–5 on the Australasian Triage Scale,[18] presenting with prevalent delirium or who were identified as at increased risk of incident delirium. To minimise bias, we utilised a stratified sample, where recruitment occurred over a pre-agreed set of different times/days within the ED, matched with capacity of the research team.

As one of the researchers is bilingual, patients who spoke English or Mandarin were eligible for inclusion. Prevalent delirium was defined as a positive baseline 3-minute diagnostic Confusion Assessment Method (3D-CAM): presence of acute onset or fluctuating course, inattention and either disordered thinking, or altered level of consciousness.[19] Increased delirium risk was defined as a Delirium Risk Assessment Tool score of ≥2 based on pre-morbid risk factors (one being age ≥70).[20] Patients were excluded if they had a significant hearing impairment, did not speak English or Mandarin, were likely to leave the ED within 2 h, or declined eligibility assessment or participation. We did not have sufficient resources to provide interpretive services for non-English non-Mandarin speakers.

Outcome measures

The primary outcomes were (i) feasibility as assessed by actual use of the intervention (target 70% of offered patients) and (ii) incident delirium in delirium-free patients. Outcomes measures were assessed by a single researcher (SW).

We primarily wished to identify if a controlled trial could be conducted in this setting and patient group. Beyond this, the primary outcome of interest was occurrence of incident delirium (newly CAM positive at 2 h and delirious on assessment by the treating team). Secondary outcomes included 'resolution' of prevalent delirium at 2 h (CAM negative, and not actively delirious on clinician assessment), improved delirium severity (decrease in CAM-based Delirium Severity Measure [CAM-S] ≥1 point),[21] improved pain (decrease in Faces Pain Scale Revised [FPS-R] score ≥1 point),[22] improved agitation/sedation (decrease in Richmond Agitation-Sedation Score [RASS] ≥1 point)[23] and total hospital length of stay (LOS).

Statistical analysis

We utilised descriptive statistics and simple statistical significance tests for comparisons of outcomes. Where groups (total or comparison) were small ($n < 20$), percentages are not reported, but rather numerator over denominator.

Ethics committee approval

The present study was approved by the South Western Sydney Local Health District Human Research Ethics Committee (ETH2018/00167) and granted a waiver of written informed consent. Patients provided verbal consent to participation, and use of data for research purposes, including publication.

Results

Overall, 211 patients were screened during the 4-week study period in August 2018. Of these, 132 did not meet eligibility criteria, 23 patients declined eligibility assessment, and seven patients were unavailable for assessment (e.g. undergoing radiological assessment or discharged but not removed from the record-keeping system). Five patients were included in an initial randomisation process, but discarded from the final analyses, which was based on patient self-selection groups only. In total, 44 patients were included, mean age 80.5 (standard deviation 8.3, range 65–97), and 57% (25/44) were female. Nineteen patients received standard care alone, and 25 received music therapy intervention.

Baseline characteristics

Baseline characteristics are presented in Table 1. There were no differences in the distribution of baseline demographic characteristics between the control and intervention groups.

Feasibility

After an initial attempt at randomisation of the five patients, we noted that those randomised to the study intervention were poorly compliant, and quickly removed headphones. In line with our allowance for flexibility in design, we decided to permit patient self-selection, and data collection was restarted, excluding the initial five patients. Of the 25 who then received study intervention, 17 (68%) received the planned 2-h music intervention and eight adhered to the music intervention for <2 h. This was less than our specified ≥70% target rate for 2-h adherence.

Incident delirium in previously delirium-free patients

Only 11 patients did not have prevalent delirium based on use of the 3-minute CAM (3D-CAM) tool. Among those without prevalent delirium, incident delirium occurred in 1/6 of control and 4/5 of intervention (Fisher's exact test, $P = 0.08$) (Table 2).

Secondary outcomes

In the wider group ($n = 44$), there were no differences in terms of improved pain (2/19 control *vs* 4/25 intervention group, $P = 0.68$) or agitation/sedation scores (1/19 *vs* 5/25, $P = 0.21$).

In those with prevalent delirium ($n = 33$), there were no differences in terms of delirium resolution (4/13 *vs* 12/20, $P = 0.16$) nor improved delirium severity (4/13 *vs* 3/20, $P = 0.39$). No LOS differences were identified (median 5 *vs* 8, $P = 0.3$).

Discussion

While randomisation proved challenging and was abandoned, an alternative trial model of patient-self-selection to the receptive music intervention arm proved feasible in a select cohort of older ED patients with prevalent delirium or at high risk of developing incident delirium, with some important caveats, detailed below.

This was a feasibility study, and was under-powered to detect anything but very large treatment effects. Many participants with prevalent delirium who self-selected the music intervention adhered to this, despite the fact that in theory

TABLE 1. *Baseline characteristics according to treatment arm (total,* n = *44)*

Characteristic	Control group ($n = 19$)	Music group ($n = 25$)	*P*-value
Age, mean (SD)	81.9 (9.3)	79.5 (7.6)	0.4
Female, *n* (%)	10 (53)	15 (60)	0.8
Residing in a RACF, *n* (%)	11 (58)	18 (72)	0.4
Existing sensory impairment, *n* (%)	7 (37)	6 (24)	0.5
Existing cognitive impairment, *n* (%)	9 (47)	17 (68)	0.2
CAM positive, *n* (%)	13 (68)	20 (80)	0.5
FPS-R score ≥ 1, *n* (%)	6 (32)	9 (36)	>0.9
RASS score ≠ 0, *n* (%)	8 (42)	9 (36)	>0.9
Principal diagnosis			
Delirium, *n* (%)	1 (5)	4 (16)	0.4
Falls, *n* (%)	5 (26)	2 (8)	0.2
COPD, *n* (%)	2 (11)	1 (4)	0.6
UTI, *n* (%)	1 (5)	2 (8)	>0.9
Pneumonia, *n* (%)	1 (5)	2 (8)	>0.9
Stroke, *n* (%)	2 (11)	1 (4)	0.6
Acute coronary syndrome, *n* (%)	0 (0)	2 (8)	0.5
Other, *n* (%)	7 (37)	10 (40)	>0.9

CAM, confusion assessment method; FPS-R, Faces Pain Score Revised; RACF, residential aged care facility; RASS, Richmond Agitation and Sedation Score; SD, standard deviation.

TABLE 2. *Exploration of potential association between treatment arm and pre-specified outcomes*

Participants without prevalent delirium	Control ($n = 6$)	Music ($n = 5$)	*P*-value
Occurrence of incident delirium	1/6 (17%)	4/5 (80%)	0.08
Participants with prevalent delirium	**Control ($n = 13$)**	**Music ($n = 20$)**	***P*-value**
Possibly 'resolved' prevalent delirium at 2 h†	4/13 (31%)	3/20 (15%)	0.39
Improved delirium severity at 2 h	4/13 (31%)	12/20 (60%)	0.16
Secondary outcomes	**Control ($n = 19$)**	**Music ($n = 25$)**	***P*-value**
Improved pain	2/19 (11%)	4/25 (16%)	0.68
Improved agitation/sedation	1/19 (5%)	5/25 (20%)	0.21
Length of stay (days), median	5	8	0.3

†Possible 'resolution' of delirium by 2 h is defined as CAM negative, and not presenting as actively delirious at 2 h assessment. CI, confidence interval.

delirium might impact on decision-making and adherence. Rates of prevalent delirium were high, limiting our ability to explore incident delirium in delirium-free individuals but highlighting the vulnerability of older persons presenting to the ED. We did not observe any differences between control and intervention groups in our primary outcome measure of incident delirium at 2 h, or secondary outcomes, but these outcome measures proved usable in the ED setting.

While the evidence for use of music therapy interventions in the acute setting is limited, our data add to the burgeoning cohort of acutely focused studies,[11,13–15,24] and highlight the need for large, well-funded studies which can identify potential benefits or harms, in terms of delirium risk reduction, pain, agitation and other patient experiences. ED may be a distressing and frightening place for some older people.[25] We did not ask patients about acceptability, or whether they enjoyed the experience, but with increasing focus on the patient experience during hospitalisation,[26,27] this would be important to assess in future studies.

Limitations

Our study was exploratory, and its findings should be interpreted in light of its strengths and limitations. Enrolment was poorer than anticipated, with high ineligibility rates (65%). There was difficulty maintaining consistent application of the intervention as some participants removed headphones. Moreover, some participants declined the intervention because they did not like the available music. Introduction of patient self-selection to either intervention or control meant unavoidable selection bias, but this allowed us to assess the feasibility and potential outcomes in those who chose to undertake the intervention. Even with the introduction of patient self-selection, not all patients listened to the music for the prescribed 2 h. We did not capture reasons for why some patients terminated early, nor whether cessation was patient or staff/care driven, and acknowledge this limitation.

The discontinuation of randomisation may be considered a significant limitation in terms of assessing efficacy, but our adoption of a pragmatic dynamic approach allowed us to respond to real-life obstacles and still address feasibility. We did not blind participants to intervention status, which almost certainly lead to its own biases. The use of headphones allowed intervention delivery with less interruption by the noise of ED, but lack of awareness of surrounds may have had its own negative impact. On the other hand, virtual reality devices are being increasingly explored in settings such as the ED and to reduce delirium in other cohorts,[28,29] and the benefits and disadvantages of reduced situational awareness *versus* augmented experiences in such settings are as yet not well defined; further research to explore this is needed. The use of personalised music interventions and/or alternative methods of delivery (e.g. via less bulky headphones or speakers) might also be more tolerable to participants. We did not account for other characteristics, such as illness severity, and while we believe that application of headphones may not be ideal for patients with the most severe presentations (triage category 1), these patients are at even higher risk of delirium. We also acknowledge that delirium is dynamic and can develop rapidly and fluctuate; absence of delirium at 2 h does not preclude its emergence shortly thereafter and longer follow up may have been helpful.

Conclusions

In a pilot trial of a music intervention, patient self-selection proved feasible, although not associated with outcomes assessed. Given the paucity of existing evidence examining receptive music interventions in

the ED, we believe that the present study represents a valuable addition to the literature in this area, and is hypothesis-generating. Larger trials of receptive music interventions in the ED for delirium, investigating different types of music applied therapy interventions as well as barriers to and facilitators of adherence and potential benefit, will enable us to better understand the application of music therapy for older patients in this acute setting.

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Competing interests

Disposable headphone covers were kindly provided by an unrestricted donation from Haines Medical Australia. The authors have no other conflicts of interest to declare.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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