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Individualized Music Playlist Based on Iso-Principle for De-Escalating Agitation of People With Dementia: A Randomized Controlled Feasibility Study

Daphne Sze Ki Cheung[1,2,3] | Hau Yi Jodie Tse[3] | Paul Hong Lee[4] | Ken Hok Man Ho[5] | Xue Bai[6] | Claudia Kam Yuk Lai[3]

[1]School of Nursing and Midwifery, Faculty of Health, Deakin University, Melbourne, Australia | [2]Centre for Quality and Patient Safety Research/Alfred Health Partnership, Institute for Health Transformation, Deakin University, Melbourne, Australia | [3]School of Nursing, The Hong Kong Polytechnic University, Kowloon, Hong Kong | [4]Southampton Clinical Trials Unit, University of Southampton, Southampton, UK | [5]School of Nursing and Midwifery, La Trobe University, Bundoora, Australia | [6]Department of Applied Social Sciences, The Hong Kong Polytechnic University, Kowloon, Hong Kong

Correspondence: Daphne Sze Ki Cheung (d.cheung@deakin.edu.au)

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ABSTRACT

Objectives: To evaluate the feasibility of the Individualized Music Playlist based on Iso-Principle for de-escalating agitation of people with dementia and provide preliminary evidence about its efficacy.

Methods: The randomized participants listened to either a 30-min music playlist or a book-reading audio script twice weekly for six weeks, and when agitation occurred. Their agitation level was observed every 5 min from the beginning of an agitation episode for an hour to monitor its trajectory over a 2-week period. Multilevel models with maximum likelihood analysis was conducted. The frequency of agitation and other behavioural symptoms was assessed at baseline and the 6th week and analysed with Generalized Estimating Equations.

Results: Twenty-four participants were recruited, and 10 presented 36 agitation episodes during the first two weeks of observation. The recruitment and retention rates were 85.7% and 83.3%, respectively. A total of 97.2% of the intervention and control conditions were delivered as planned. The intervention was not more effective than the control condition in de-escalating agitation or reducing agitation and other behavioural symptoms. Overall, agitation symptoms were apparently alleviated in the first 10 min, with a decelerated pace observed thereafter.

Conclusions: The intervention was feasible, and its efficacy in de-escalating agitation is yet to be confirmed.

1 | Introduction

Agitation is common among people with dementia, with a prevalence of over 80% [1]. It includes a range of behaviours, such as restlessness, pacing, repetitive vocalisations, and verbally or physically aggressive behaviour, that are accompanied by emotional distress and excessive disability [2]. Agitation has detrimental consequences for the person with dementia and caregivers. It has been found to be associated with a higher use of psychotropic medication [3], and physical restraints [4]. In addition, agitation has been identified as one of the most burdensome symptoms for family caregivers [5, 6], as well as formal caregivers in the residential care home setting [7]. Alzheimer's Disease-related healthcare costs among the agitation

Summary

- The Iso-Principle music playlist intervention showed good feasibility with 85.7% recruitment and 83.3% retention rates, using well-accepted neckband speaker delivery.
- Both music and control groups showed agitation reduction within 10 min.
- Six-week regular listening to the music showed no significant advantage over control in reducing agitation frequency, possibly due to small sample size.
- This study provides insight into behavioural symptoms management using neckband-delivered music intervention. Larger trials are needed.

cohort were approximately 57% higher compared to the no agitation cohort [8].

Music intervention has been consistently found effective in reducing the agitation occurrence frequency among people with dementia in meta-analyses and the Cochrane Review, suggesting its robust clinical relevance [9–11]. Particularly, listening to preferred music could enhance the perceived sense of personal control and divert attention away from negative stimuli [12], and hence achieve a calming effect. However, the literature informs us that the preferred music listening intervention was usually delivered regularly, and the effect of music listening for de-escalating agitation in dementia is unknown. There is only some preliminary evidence showing that music listening intervention (e.g., caregivers' singing and listening to background music) may reduce resistance to care [13, 14]. In addition, it has been anecdotally reported that music therapists would apply the Iso-Principle during music therapy when playing live music to manipulate the mood of their clients to a preferred state successfully [15]. An experimental study by Starcke and von Georgi [16] on healthy participants showed that listening to music using the Iso-Principle is effective in modulating their affect [20].

The Iso-Principle is a system of musical prescription used to manipulate clients' moods by gradually shifting the musical elements (rhythm, tempo, melody, harmony, and mood of the music) [17]. The sequencing of music used in this system is as follows: (a) music that can capture the client's attention for fostering therapeutic music listening; (b) music with a rhythm that matches the client's emotional state (slower rhythms for depressed clients or faster rhythm for people experiencing manic states); and (c) gradually shifting the client's internal state to a more positive direction by manipulating the musical elements. However, playing live music and manipulating the features of music by a music therapist or musician to de-escalate an agitated person with dementia is not practical because they would not be onsite round the clock and able to provide the intervention immediately when needed. Therefore, by playing pre-recorded preferred music with the genres sequenced based on the Iso-Principle, it may be possible to exert similar results at a lower cost and overcome the implementation barriers.

The aim of this study is to evaluate the feasibility of the individualized music playlist based on the Iso-Principle for de-escalating agitation among nursing home residents living with dementia. We seek to answer the following three research questions: (1) what is the feasibility of the intervention in terms of recruitment, retention, and acceptability? (2) what are the effects of the intervention on participants' agitation intensity and emotion during the agitation episode as compared to the control group; and (3) what are the effects of the intervention on the frequency of agitated behaviours and other behavioural symptoms before and after the 6 weeks of intervention as compared to the control group?

2 | Methods

This was a randomized controlled trial with two parallel arms. This study was registered at ClinicalTrial.gov (NCT04236557) and approved by the Ethical Review Committee of the University (HSEARS20190731001). Due to social restrictions in the residential care setting during the COVID-19 pandemic, the study setting was changed to daycare services after protocol registration. Heart rate was not measured as planned due to the shortage of suitable devices as shipping was also affected by the pandemic. The report of this trial followed the CONSORT statement for randomized pilot and feasibility trials.

2.1 | Participants

An invitation letter was sent to all 93 Day Care Centres for the Elderly in Hong Kong. These services aim at helping the service users maintain an optimal level of functioning and improve their quality of life. The responsible staff (either a registered nurse or registered social worker) screened the eligibility of their members and referred them to the research team for verifying the eligibility after getting the initial consent from the proxies of potential participants.

Eligible participants were older adults diagnosed with any type of dementia who presented with significant agitation in the past 2 weeks before recruitment (i.e., Cohen-Mansfield Agitation Inventory total score > 39, the cut-off score for defining clinically significant agitation adopted in a previously published relevant local study [18]. During the study period, the participants were expected to attend the Centre at least 3 days per week.

Older adults newly admitted to the Centre within 3 months were excluded due to the expected increase in agitation induced by an unfamiliar environment and routine. Participants who were involved in other experimental trials; had uncorrectable hearing impairments that prevent them from receiving the music listening intervention; or had comorbid psychiatric illnesses, such as depression or schizophrenia, were also excluded. However, concurrent psychotropic medications prescribed during the study period were allowed, but any changes in these prescriptions were monitored and analysed.

2.2 | Intervention and Control Condition

When a participant presented with agitation that required de-escalation (i.e., Behavioural Activity Rating Scale (BARS)

scored five or above [19], after eliminating potential known physical and environmental triggers of agitation, they received the intervention or control condition according to the group assignment, provided by a trained research assistant in the first 2 weeks, followed by trained staff for the remaining 4 weeks of the 6-week study period. A BARS score of 5 refers to signs of over-activity in terms of physical or verbal behaviour but able to calm down with instruction; while the highest possible score of 7 means violent behaviour requiring restraint. Both groups continued to receive the treatment as usual, for instance, calming or distraction offered by the staff.

Participants of the intervention group were prescribed a 30-min individualized playlist with preferred music genres sequenced by a music therapist according to the Iso-Principle, considering the music's tempo, mood, rhythm, melody, etc. A registered music therapist selected 50 music pieces favoured by most older adults in Hong Kong, primarily songs from 1940 to 1980, along with some instrumental and religious music. Participants, family members, and staff were invited to identify 10–12 pieces of music selected from the list or to suggest additional preferred tracks. The therapist then organized these selections into a 30-min playlist based on arousal properties (e.g., from stimulating to relaxing), emotional quality (e.g., uplifting to peaceful), and structural features (e.g., from fast tempo to slow tempo).

To ensure the participants were familiar with the music listening practice and to reduce resistance to the intervention, they listened to the prescribed music playlist in the morning twice weekly for 6 weeks. A Sony Wireless Neckband Speaker (SRS-NS7) was used, which weighted approximately 318 g and connected to an iPod touch by Bluetooth. Music playlists were created with YouTube Premium, and the participants could enjoy the music offline and ad-free. The music selected was screened by the music therapist to ensure its quality. In case the participants refused to use headphones, a desktop speaker was provided. A trained research assistant observed the participants on-site in the first week and reported to the music therapist to ensure the playlists were suitable or modified if necessary.

The control group participants listened to a 30-min audio script of a book reading in Cantonese instead of music twice weekly and, when agitated, using the same devices as the intervention group. The book was about the benefits of physical exercises, which should not arouse any emotional reactions. This design was aimed to control the possible distraction caused by sound from distressing situations that may trigger agitation. Participants in the control group were offered the music playlist sequenced by the registered music therapist after follow-up assessments were completed in the study.

2.3 | Outcomes

The outcomes assessment plan is depicted in Figure 1.

2.3.1 | Feasibility Assessment

The feasibility outcomes of this study included recruitment, retention, and acceptability. The research coordinator documented the number of potential participants screened and recruited, the reasons for exclusion or decline, as well as the reasons for attrition. Recruitment rate = (randomized/eligible) x 100%; retention rate = (retained by providing the outcomes at follow-up/enrolled) x 100%. To assess the acceptability of the intervention by the participant, the number of refusals was documented, and field notes on exhibited behaviours were taken. A description of agitated behaviours exhibited, the potential triggers and other events around the participant at that time were recorded using pen and paper. Any adverse reactions observed while listening were also recorded and reported to the first author.

2.3.2 | Preliminary Efficacy

To address research question 2 about the effects of the intervention in de-escalating agitation, all episodes of agitation observed

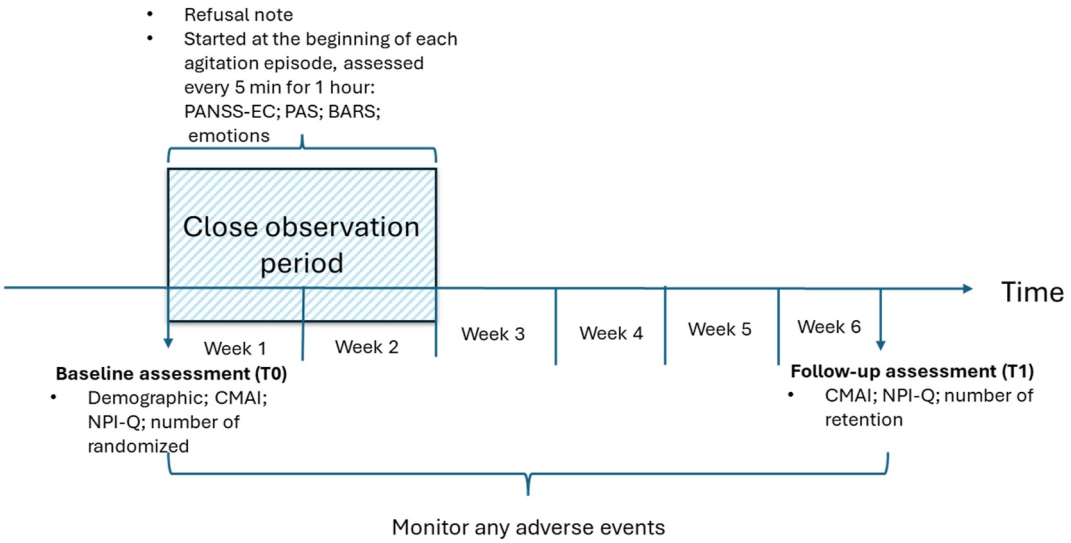

FIGURE 1 | Outcomes assessment timeframe.

within the first 2 weeks were rated every 5 minutes for 1 hour from the beginning of the agitation episode. We employed Qualtrics to record the scores and the observation time. Since there is no universally accepted gold standard in assessing the level of agitation intensity, the following common validated tools were used in this feasibility trial:

The Positive and Negative Syndrome Scale Excited Component (PANSS-EC) is a five-item scale with seven points indicating the severity of physical manifestations [20]. The internal consistency reliability was good ($\alpha = 0.86$) [21].

The Pittsburgh Agitation Scale (PAS) is a 4-item scale with five points measuring the intensity of agitation behaviours [22]. The internal consistency was good ($\alpha = 0.84$) [23].

The Behavioural Activity Rating Scale (BARS) is a single-item question indicating the agitation severity of the participant on a seven-point Likert-scale ranging from 1—difficult or unable to rouse to 7—violent, requires restraint. The inter-rater reliability was almost perfect ($\alpha = 0.999$), and it has been found sensitive in capturing the change of agitation after medication [19].

An emotion assessment scale, derived from DSM-V by another similar study assessing emotion during individualized music listening intervention among older adults with cognitive impairment was used [24]. It is a 16-item scale (8 items for negative mood and positive mood, respectively) with 0–3 point rating of mood severity.

To address research question 3 about the efficacy of the six-week intervention programme in reducing the occurrence of agitation and other behavioural symptoms, we evaluated participants using the Cohen-Mansfield Agitation Inventory (CMAI) and the Neuropsychiatric Inventory Questionnaire (NPI-Q), measured at baseline (T0) and post-intervention (at the 6th week, T1). Six weeks of the programme was designed according to a relevant study indicating that the frequency of agitation was significantly reduced after 6 weeks of twice-weekly music listening [25]. Qualtrics was employed to record the findings.

The CMAI is a 29-item scale with a 7-point rating of agitation frequency ranging from 1–7, with acceptable internal consistency ($\alpha = 0.75$) and inter-rater reliability ($r = 0.88$–0.92) [26]. The NPI-Q is a 12-item scale with a 1–3 point rating of severity of 12 behavioural and psychological symptoms such as delusions, depression, appetite, etc., with acceptable internal consistency (alpha = 0.756) and test–retest coefficient of 0.990 [27].

2.4 | Sample Size

A sample size of 30 per arm is commonly recommended as the rule of thumb for a pilot or feasibility study [28]. Given that the intervention was to be given during an agitation episode, it was likely to have a higher refusal rate. To be conservative, we assumed to have 40% of drop-out, a total sample of 84 participants was the estimated sample size.

2.5 | Randomization

Participant were randomly assigned to either an intervention or control group using simple randomization by an independent research assistant who did not participate in any stage of this trial, using computer-generated random numbers.

2.6 | Blinding

There were no observable indicators on the playlist showing that the audio script was either music or book-reading. The first 30 s of the audio script was to inform the participants they were going to listen to the audio for approximately 30 min. This design aimed to facilitate the research assistant or staff in adjusting the volume without knowing the group assignment. The same research assistant was responsible for data collection through observation in the first 2 weeks.

2.7 | Analysis

Descriptive statistics were presented as percentages, or as means ± SD, or median (interquartile range). Differences in demographic variables and the occurrence of agitation and other behavioural symptoms between groups were compared using the Chi-square test for categorical variables; and the Mann-Whitney *U* test for continuous variables.

The mean scores of the four outcome measures (PANSS-EC, PAS, BARS and DSM-V Negative mood) measured every 5 minutes over an hour (i.e., Time = 0, 1, 2, ..., 12) at each agitation episode between groups were compared. A series of multilevel growth models with restricted maximum likelihood was employed to examine the individual change over time, determine the shape of the growth curve, investigate the systematic differences in change, and evaluate the effects of covariates on group differences in the initial state and growth rate. The overall fit of the models was evaluated by the -2 log likelihood (-2LL), Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) on a smaller-is-better basis. Four models (M1–4) were tested in the study according to Singer and Willett [29]. These included an unconditional model (M1) that was tested to examine any mean differences in the outcome variables across individuals and the Intraclass coefficient (ICC). A random effect model (M2), comprising time growth trajectories, group, and interaction between group and time with random intercept was used as a baseline model to explore any group differences in change over time with an assumption that the intercept may vary across individuals. The M3 model was expanded from the M2 model by including the number of agitation episodes observed throughout the observation period. The M4 model was the extension of the M3 model, factoring the demographic profiles and health-related variables (i.e., age, gender, stage of cognitive impairment and the number of co-morbidity diseases).

To evaluate the efficacy of the intervention as compared to the control condition in reducing the frequency of agitation and

other behavioural symptoms of dementia, the scores of CMAI and NPI-Q at baseline and post-intervention (i.e., after 6 weeks) between two groups were analysed with the generalized estimating equations (GEE) with random effect for individual subjects. The adjusted GEE analyses were performed with covariates selected a priori—age, gender, and severity of dementia.

The missing values were imputed using the Last Observation Carried Forward method. A p-value < 0.05 was regarded as statistically significant in all analyses. Data were analysed using IBM SPSS statistics, version 26.

2.8 | Ethical Considerations

Ethics approval was obtained from the University and the participating sites. All experimental procedures were performed in accordance with the Declaration of Helsinki. We obtained the written informed consent from the proxy and verbal consent from the participant after discussing the study, its risks, and their rights. Procedural consent was also sought from the participants to ensure they were willing to receive the assigned condition throughout the entire study.

3 | Results

In this feasibility study, 24 participants were recruited from six participating centres during the period from December 2022 to April 2023. Among them, 15 were randomized to the intervention group, while 9 were randomized to the control group (see Figure 2 for details). They were at moderate to severe stages of dementia according to the Global Deterioration Scale (Stage 4 to 7).

3.1 | Baseline Data

The sample was mainly female (66.67%), with a mean age of 83.13 ± 10.20. They presented with frequent agitation and an average total CMAI score of 50.79 ± 14.18 at baseline. There was no statistically significant difference in demographic characteristics between the two groups at baseline (Table 1).

3.2 | Recruitment

The six participating centres served 438 older adults. The majority of them did not fit the selection criteria. The major reasons were, they: (1) had not received a formal medical diagnosis of dementia; (2) did not present with clinically significant agitation; or (3) did not return to the centre three times or more a week. There were 28 potential participants eligible, with 24 of them consenting to participate and being randomized in this study. The recruitment rate was 85.7%.

3.3 | Retention

The overall retention rate was 83.3%, with rates of 80% and 88.9% for the intervention and control groups, respectively.

3.4 | Acceptability

During the regular listening session, three out of 23 participants (excluding the participant deceased before the start of the intervention period) always refused to wear the neckband. They were given a speaker to play the audio and tolerated it well. There were 36 episodes of agitation observed in 10 participants

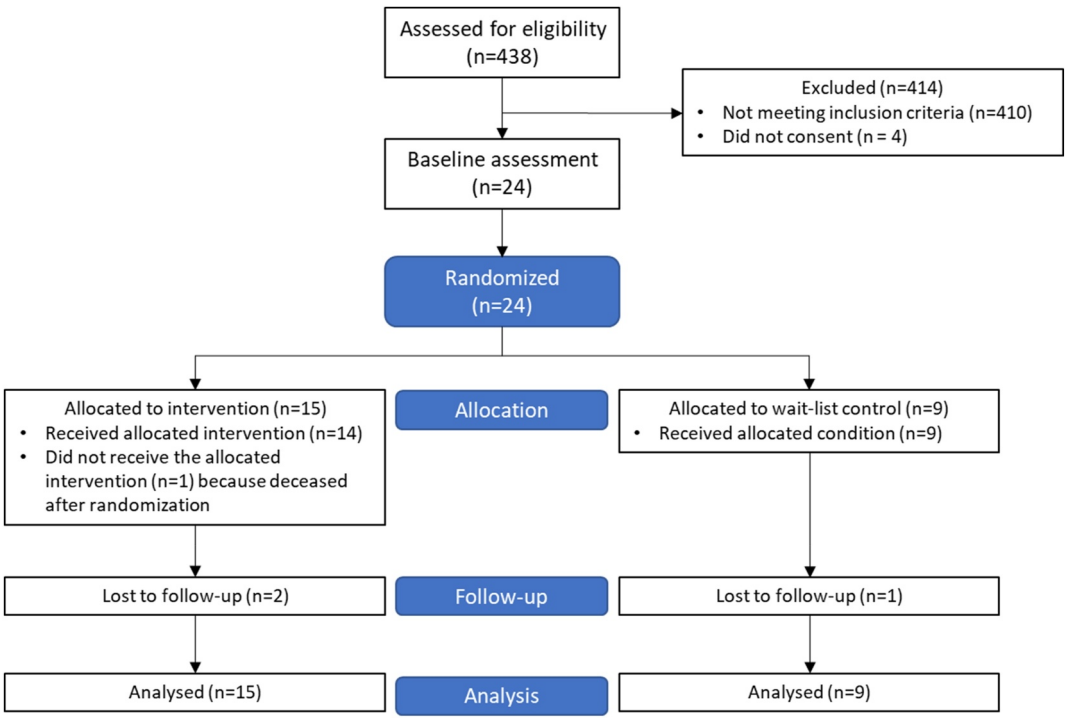

FIGURE 2 | CONSORT flow diagram.

TABLE 1 | Participants characteristics at baseline.

	Intervention group ($n = 15$)		Control group ($n = 9$)		Total ($n = 24$)		
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	***p***
Age	81.80	10.65	85.33	3.19	83.13	10.20	0.446[a]
Number of co-morbidities	1.73	0.96	1.22	1.30	1.54	1.103	0.194[a]
Baseline CMAI total score	53.20	12.16	46.78	17.03	50.79	14.18	0.138[a]
	N	**%**	***N***	**%**	***N***	**%**	
Gender							0.371[b]
Male	4	26.67	4	44.44	8	33.33	
Female	11	73.33	5	55.56	16	66.67	
Marital status							0.563[b]
Single	0	0	1	11.11	1	4.17	
Married	7	46.67	3	33.33	10	41.67	
Divorced/Widowed	8	53.33	5	55.56	13	54.17	
Educational level							0.340[b]
Junior secondary or below	10	66.67	4	44.44	14	58.33	
Senior secondary	4	26.67	2	22.22	6	25.00	
Tertiary or above	1	6.67	3	33.33	4	16.67	
Stage of dementia							0.242[b]
GDS 4	1	6.67	0	0.00	1	4.17	
GDS 5	9	60.00	4	44.44	13	54.17	
GDS 6	5	33.33	3	33.33	8	33.33	
GDS 7	0	0.00	2	22.22	2	8.33	

Abbreviation: CMAI = Cohen-Mansfield Agitation Inventory.
[a]Mann-Whitney *U* Test.
[b]Chi-square test.

($n = 6$ from the intervention group). Among these episodes, only one episode from the intervention group involved a participant who refused the neckband speaker but received the intervention with a portable speaker.

Based on the observation log recorded by the research assistant, participants were attracted to listen to the audio immediately once the neckband devices were applied. The agitated behaviours gradually diminished after application.

3.5 | Adverse Event

No adverse event was observed throughout the study. The participant who deceased after random allocation got pneumonia and had a sudden deterioration of health without receiving the intervention.

3.6 | Agitation Escalation Effect

Six participants in the intervention group presented 24 episodes of agitation, and four participants in the control group presented 12 episodes during the two-week observation period that were analysed (See Table 2). None of them had any changes in the medication regime during the period.

3.6.1 | Changes in the PANSS-EC Score Between Groups

The best-fit model M3 indicated that time ($p < 0.001$), time^2 ($p < 0.001$) and time^3 ($p < 0.001$) had a significant contribution to the model. There was no significant effect between two groups ($p = 0.053$), and the interaction effects ($p = 0.782$).

3.6.2 | Changes in the PAS Score Between Groups

The best-fit model M3 indicated that time ($p < 0.001$), time^2 ($p < 0.001$) and time^3 ($p < 0.001$) had a significant contribution to the model. There were no significant effects between two groups ($p = 0.382$) and the interaction of ($p = 0.408$).

3.6.3 | Changes in the BARS Score Between Groups

The best-fit model M2 showed that time ($p < 0.001$), time^2 ($p < 0.001$) and time^3 ($p < 0.001$) had a significant contribution

TABLE 2 | Result of multilevel growth model.

	Model 1				Model 2				Model 3[#]				Model 4			
PANSS-EC	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**
Intercept	12.02	0.67	< 0.001	[10.71, 13.33]	23.30	1.38	< 0.001	[20.58, 26.01]	22.22	1.43	< 0.001	[19.43, 25.01]	21.10	12.23	0.085	[−2.88, 45.08]
Time (linear)					−5.85	0.66	< 0.001	[−7.14, −4.57]	−5.84	0.65	< 0.001	[−7.12, −4.57]	−5.83	0.65	< 0.001	[−7.10, −4.56]
Time^2 (quadratic)					0.86	0.13	< 0.001	[0.60, 1.11]	0.86	0.13	< 0.001	[0.61, 1.11]	0.86	0.13	< 0.001	[0.61, 1.11]
Time^3 (cubic)					−0.04	0.01	< 0.001	[−0.05, −0.02]	−0.04	0.01	< 0.001	[−0.05, −0.02]	−0.04	0.01	< 0.001	[−0.05, −0.02]
Group					−2.41	1.55	0.120	[−5.45, 0.63]	−2.92	1.51	0.053	[−5.88, 0.04]	−3.12	2.61	0.231	[−8.23, 1.99]
Time x group					−0.05	0.19	0.787	[−0.43, 0.32]	−0.05	0.19	0.782	[−0.42, 0.32]	−0.05	0.19	0.780	[−0.42, 0.31]
Number of agitation episode by the individual									0.51	0.22	0.019	[0.08, 0.94]	0.51	0.24	0.032	[0.04, 0.98]
Age													−0.01	0.11	0.944	[−0.22, 0.20]
Gender													1.11	2.13	0.604	[−3.07, 5.28]
GDS (moderate or above)													0.86	1.55	0.580	[−2.17, 3.88]
Number of comorbidities													−0.38	0.55	0.491	[−1.47, 0.70]
σ^2	45.14	4.22	< 0.001		29.89	2.43	< 0.001		29.32	2.36	< 0 .001		29.11	2.29	< 0.001	
ρ	0.52	0.05	< 0.001		0.39	0.05	< 0.001		0.38	0.05	< 0.001		0.37	0.05	< 0.001	
σ_τ^2	1.52	2.07	0.462		1.02	1.63	0.533		0.81	1.42	0.566		3.00	3.63	0.408	
Model Information Criteria																
-2 log likelihood		2979.73				2861.55				2857.28				2854.11		
AIC		2985.73				2867.55				2863.28				2860.11		
BIC		2998.17				2879.95				2875.68				2872.48		

(Continues)

TABLE 2 (Continued)

	Model 1				Model 2				Model 3#				Model 4			
PAS	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**
Intercept	1.18	0.17	< 0.001	[0.85, 1.51]	3.22	0.42	< 0.001	[2.40, 4.04]	2.88	0.42	< 0.001	[2.06, 3.70]	0.25	1.92	0.899	[−3.53, 4.02]
Time (linear)					−1.15	0.20	< 0.001	[−1.54, −0.77]	−1.15	0.20	< 0.001	[−1.53, −0.76]	−1.15	0.20	< 0.001	[−1.53, −0.76]
$Time^2$ (quadratic)					0.17	0.04	< 0.001	[0.10, 0.25]	0.17	0.04	< 0.001	[0.10, 0.25]	0.17	0.04	< 0.001	[0.10, 0.25]
$Time^3$ (cubic)					−0.01	0.00	< 0.001	[−0.01, 0.00]	−0.01	0.00	< 0.001	[−0.01 0.00]	−0.01	0.00	< 0.001	[−0.01, 0.00]
Group					−0.21	0.47	0.656	[−1.12, 0.71]	−0.38	0.44	0.382	[−1.24, 0.47]	−0.27	0.50	0.581	[−1.25, 0.70]
Time x group					−0.05	0.06	0.412	[−0.16, 0.07]	−0.05	0.06	0.408	[−0.16, 0.06]	−0.05	0.06	0.406	[−0.16, 0.06]
Number of agitation episode by the individual									0.17	0.06	0.008	[0.04, 0.29]	0.14	0.07	0.040	[0.01, 0.27]
Age													0.02	0.02	0.338	[−0.02, 0.05]
Gender													0.54	0.32	0.099	[−0.10, 1.17]
GDS (moderate or above)													0.51	0.26	0.049	[0.00, 1.01]
Number of comorbidities													0.05	0.09	0.533	[−0.12, 0.23]
σ^2	3.10	0.25	< 0.001		2.67	0.21	< 0.001		2.63	0.21	< 0.001		2.61	0.20	< 0.001	
ρ	0.40	0.05	< 0.001		0.37	0.05	< 0.001		0.37	0.05	< 0.001		0.36	0.05	< 0.001	
σ_τ^2	0.12	0.13	0.356		0.11	0.12	0.382		0.05	0.09	0.569		< 0.001	< 0.001	1.000	
Model Information Criteria																
2 log likelihood	1788.42				1752.61				1749.55				1752.54			
AIC		1794.42			1758.61				1755.55				1758.54			
BIC		1806.86			1771.02				1767.95				1770.91			

TABLE 2 (Continued)

	Model 1				Model 2#				Model 3				Model 4			
BARS	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**
Intercept	4.35	0.08	< 0.001	[4.20, 4.51]	5.17	0.18	< 0.001	[4.81, 5.52]	5.17	0.19	< 0.001	[4.80, 5.54]	4.01	1.28	0.002	[1.49, 6.53]
Time (linear)					−0.43	0.09	< 0.001	[−0.61, −0.25]	−0.43	0.09	< 0.001	[−0.61, −0.25]	−0.43	0.09	< 0.001	[−0.61, −0.25]
$Time^2$ (quadratic)					0.07	0.02	< 0.001	[0.03, 0.10]	0.07	0.02	< 0.001	[0.03 0.10]	0.07	0.02	< 0.001	[0.03, 0.10]
$Time^3$ (cubic)					−0.003	0.001	0.002	[−0.01, −0.001]	−0.003	0.001	0.002	[−0.01, −0.001]	−0.003	0.001	0.002	[−0.01, −0.001]
Group					−0.03	0.20	0.890	[−0.41, 0.36]	−0.02	0.20	0.904	[−0.41, 0.36]	0.07	0.29	0.819	[−0.49, 0.62]
Time x group					−0.04	0.02	0.122	[−0.09, 0.01]	−0.04	0.02	0.122	[−0.09, 0.01]	−0.04	0.02	0.122	[−0.09, 0.01]
Number of agitation episode by the individual									0.00	0.03	0.935	[−0.06, 0.05]	0.00	0.03	0.950	[−0.06, 0.06]
Age													0.01	0.01	0.547	[−0.02, 0.03]
Gender													0.32	0.22	0.149	[−0.11, 0.76]
GDS (moderate or above)													0.08	0.17	0.631	[−0.25, 0.41]
Number of comorbidities													−0.04	0.06	0.446	[−0.16, 0.07]
σ^2	0.69	0.05	< 0.001		0.60	0.05	< 0.001		0.60	0.05	< 0.001		0.60	0.05	< 0.001	
ρ	0.27	0.05	< 0.001		0.22	0.05	< 0.001		0.23	0.05	< 0.001		0.22	0.05	< 0.001	
σ_τ^2	0.03	0.03	0.243		0.02	0.02	0.399		0.02	0.02	0.393		0.03	0.05	0.582	
Model Information Criteria																
2 log likelihood		1129.25				1108.36				1113.71				1126.04		
AIC		1135.25				1114.36				1119.71				1132.04		
BIC		1147.69				1126.77				1132.11				1144.41		

(Continues)

TABLE 2 (Continued)

	Model 1				Model 2				Model 3#				Model 4			
Negative mood	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**	**Estimate**	**SE**	***p***	**95% CI**
Intercept	5.35	0.38	< 0.001	[4.61, 6.08]	10.29	1.00	< 0.001	[8.33, 12.24]	9.58	1.00	< 0.001	[7.61, 11.54]	9.71	9.54	0.309	[−8.99, 28.41]
Time (linear)					−2.92	0.45	< 0.001	[−3.80, −2.04]	−2.92	0.45	< 0.001	[−3.79, −2.04]	−2.91	0.44	< 0.001	[−3.78, −2.04]
$Time^2$ (quadratic)					0.44	0.09	< 0.001	[0.27, 0.61]	0.44	0.09	< 0.001	[0.27, 0.61]	0.44	0.09	< 0.001	[0.27, 0.61]
$Time^3$ (cubic)					−0.02	0.005	< 0.001	[−0.03, −0.01]	−0.02	0.005	< 0.001	[−0.03–0.01]	−0.02	0.00	< 0.001	[−0.03, −0.01]
Group					0.32	1.14	0.783	[−1.93, 2.56]	−0.18	1.06	0.867	[−2.26, 1.90]	−0.17	2.01	0.934	[−4.11, 3.77]
Time x group					−0.16	0.14	0.258	[−0.44, 0.12]	−0.16	0.14	0.256	[−0.44, 0.12]	−0.16	0.14	0.250	[−0.43, 0.11]
Number of agitation episode by the individual									0.38	0.17	0.022	[0.05, 0.71]	0.34	0.19	0.079	[−0.04, 0.71]
Age													0.00	0.08	0.959	[−0.17, 0.16]
Gender													0.15	1.66	0.929	[−3.11, 3.40]
GDS (moderate or above)													0.64	1.21	0.597	[−1.73, 3.00]
Number of comorbidities													−0.20	0.43	0.637	[−1.05, 0.65]
σ^2	19.35	1.84	< 0.001		14.37	1.32	< 0.001		14.26	1.28	< 0.001		13.99	1.24	< 0.001	
ρ	0.60	0.04	< 0.001		0.53	0.04	< 0.001		0.52	0.04	< 0.001		0.51	0.04	< 0.001	
σ_τ^2	< 0.001	< 0.001	1.000		0.42	0.90	0.644		0.003	0.47	0.995		1.77	2.35	0.450	
Model Information Criteria																
-2 log likelihood		2518.17				2452.51				2449.38				2449.42		
AIC		2524.17				2458.51				2455.38				2455.42		
BIC		2536.61				2470.92				2467.78				2467.79		

Abbreviations: AIC = Akaike's Information Criterion, BIC = Schwarz's Bayesian Criterion, CI = Confidence interval, GDS = Global Deterioration Scale, SE = Standard error, σ^2 = Within−individual variance, ρ = First order autocorrelation, σ_τ^2 = Between individual variance, # = Best model.

TABLE 3 | Mean and standard deviation of outcomes in 1 hour.

	PANSS-EC						PAS						BARS						DSM-V negative mood					
	Intervention group			Control group			Intervention group			Control group			Intervention group			Control group			Intervention group			Control group		
Min	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI	M	SD	95% CI
0	22.08	1.61	[21.40, 22.76]	23.58	2.97	[21.7, 25.47]	3.58	2.21	[2.65, 4.51]	3.25	1.67	[2.2, 4.3]	5.29	0.46	[5.10, 5.49]	5.08	0.29	[4.90, 5.27]	11.29	2.90	[10.07, 12.51]	9.83	1.85	[8.66, 11.01]
5	14.79	5.29	[12.56, 17.03]	18.5	6.10	[14.63, 22.37]	1.33	2.12	[0.44, 2.23]	1.75	1.42	[0.85, 2.65]	4.58	0.65	[4.31, 4.86]	4.75	0.45	[4.46, 5.04]	7.17	4.27	[5.36, 8.97]	7.92	3.78	[5.52, 10.32]
10	10.58	5.73	[8.17, 13.00]	13.67	8.69	[8.15, 19.19]	1.00	1.96	[0.17, 1.83]	1.08	1.38	[0.21, 1.96]	4.29	0.96	[3.89, 4.69]	4.50	0.52	[4.17, 4.83]	5.25	4.95	[3.16, 7.34]	5.83	4.45	[3.01, 8.66]
15	10.79	6.67	[7.97, 13.61]	13.25	6.00	[9.44, 17.06]	0.83	1.92	[0.02, 1.65]	1.25	1.55	[0.27, 2.23]	4.33	0.82	[3.99, 4.48]	4.50	0.52	[4.17, 4.83]	5.33	5.36	[3.07, 7.60]	5.58	3.73	[3.21, 7.95]
20	9.67	6.30	[7.01, 12.32]	13.25	7.00	[8.81, 17.69]	0.71	1.60	[0.03, 1.38]	1.33	1.56	[0.34, 2.32]	4.17	0.76	[3.85, 4.49]	4.42	0.52	[4.09, 4.74]	4.71	4.52	[2.80, 6.62]	6.08	3.70	[3.73, 8.44]
25	9.21	5.70	[6.90, 11.52]	14.17	7.61	[9.33, 19.00]	0.63	1.58	[−0.04, 1.29]	2.25	2.7	[0.53, 3.97]	4.08	0.97	[3.67, 4.49]	4.67	0.65	[4.25, 5.08]	4.00	3.81	[2.39, 5.61]	5.83	3.46	[3.64, 8.03]
30	8.67	5.95	[6.15, 11.18]	14.25	7.76	[9.32, 19.18]	0.54	1.25	[0.01, 1.07]	2.42	3.26	[0.35, 4.49]	3.88	0.95	[3.48, 4.27]	4.67	0.78	[4.17, 5.16]	4.21	3.70	[2.65, 5.77]	5.92	3.75	[3.53, 8.30]
35	8.13	5.38	[5.86, 10.39]	10.25	7.09	[5.75, 14.75]	0.38	1.01	[−0.05, 0.80]	0.92	1.62	[−0.11, 1.95]	4.00	0.72	[3.69, 4.31]	4.33	0.89	[3.77, 4.90]	2.83	2.85	[1.63, 4.04]	4.08	4.23	[1.40, 6.77]
40	8.29	5.54	[5.95, 10.63]	15.25	6.97	[10.82, 19.68]	0.21	0.51	[−0.01, 0.42]	1.67	1.61	[0.64, 2.69]	3.96	0.81	[3.62, 4.30]	4.67	0.78	[4.17, 5.16]	3.04	3.07	[1.74, 4.34]	6.50	4.98	[3.33, 9.67]
45	7.63	5.08	[5.48, 9.77]	14.42	7.28	[9.79, 19.04]	0.42	1.21	[−0.10, 0.93]	1.58	1.62	[0.55, 2.61]	4.00	0.66	[3.72, 4.28]	4.67	0.88	[4.10, 5.23]	3.33	3.42	[1.89, 4.78]	6.50	4.76	[3.48, 9.52]
50	8.67	5.58	[6.31, 11.02]	11.75	7.09	[7.25, 16.25]	0.54	1.22	[0.03, 1.05]	1.33	1.72	[0.24, 2.43]	4.13	0.80	[3.79, 4.46]	4.50	0.80	[3.99, 5.01]	3.33	4.11	[1.60, 5.07]	4.58	5.04	[1.38, 7.78]
55	8.96	5.85	[6.49, 11.43]	11.92	7.32	[7.27, 16.57]	0.67	1.20	[0.16, 1.18]	1.42	1.78	[0.28, 2.55]	4.13	0.99	[3.71, 4.54]	4.42	0.67	[3.99, 4.84]	3.92	4.22	[2.13, 5.70]	4.33	4.66	[1.37, 7.29]
60	9.21	5.59	[6.85, 11.57]	11.42	6.92	[7.02, 15.81]	0.71	1.52	[0.07, 1.35]	1.5	1.78	[0.37, 2.63]	4.08	0.78	[3.76, 4.41]	4.42	0.67	[3.99, 4.84]	3.58	3.99	[1.90, 5.27]	4.42	4.42	[1.61, 7.23]

Abbreviations: BARS = Behavioural Activity Rating Scale, CI = Confidence interval, DSM-V-Negative Mood = Negative mood sub-scores of the Emotional Assessment Scale, EXP = Intervention group, M = Mean, PANSS-EC = Positive and Negative Syndrome Scale - Excitatory Component (PANSS-EC), PAS = Pittsburgh Agitation Scale, SD = Standard deviation.

to the model. There were no significant effects between two groups ($p = 0.890$) and the interaction ($p = 0.122$).

3.6.4 | Changes in Negative Emotion Between Groups

The best-fit model M3 indicated that time ($p < 0.001$), time^2 ($p < 0.001$) and time^3 ($p < 0.001$) had a significant contribution to the model. There were no significant effects between two groups ($p = 0.867$) and the interaction ($p = 0.256$).

3.7 | Trajectory of the Outcomes

The mean score of each outcome was tabulated to show the changes with 5-min intervals over an hour (Table 3, Figure 3). In general, there was an apparent reduction in all outcomes during the first 10 min, with a deceleration pace onwards.

3.8 | Effects on Agitation Frequency and Other Behavioural and Psychological Symptoms of Dementia

There were no significant group, time and interaction effects on agitation frequency and behavioural and psychological symptoms, measured with CMAI and NPI-Q, respectively (Table 4).

4 | Discussion

The results demonstrated that the individualized music playlist based on the Iso-Principle is feasible and acceptable, although the effectiveness for de-escalating the agitation of nursing home residents with dementia is yet to be confirmed.

Our study revealed that the recruitment and retention of participants were feasible in the daycare service sectors. Over 85%

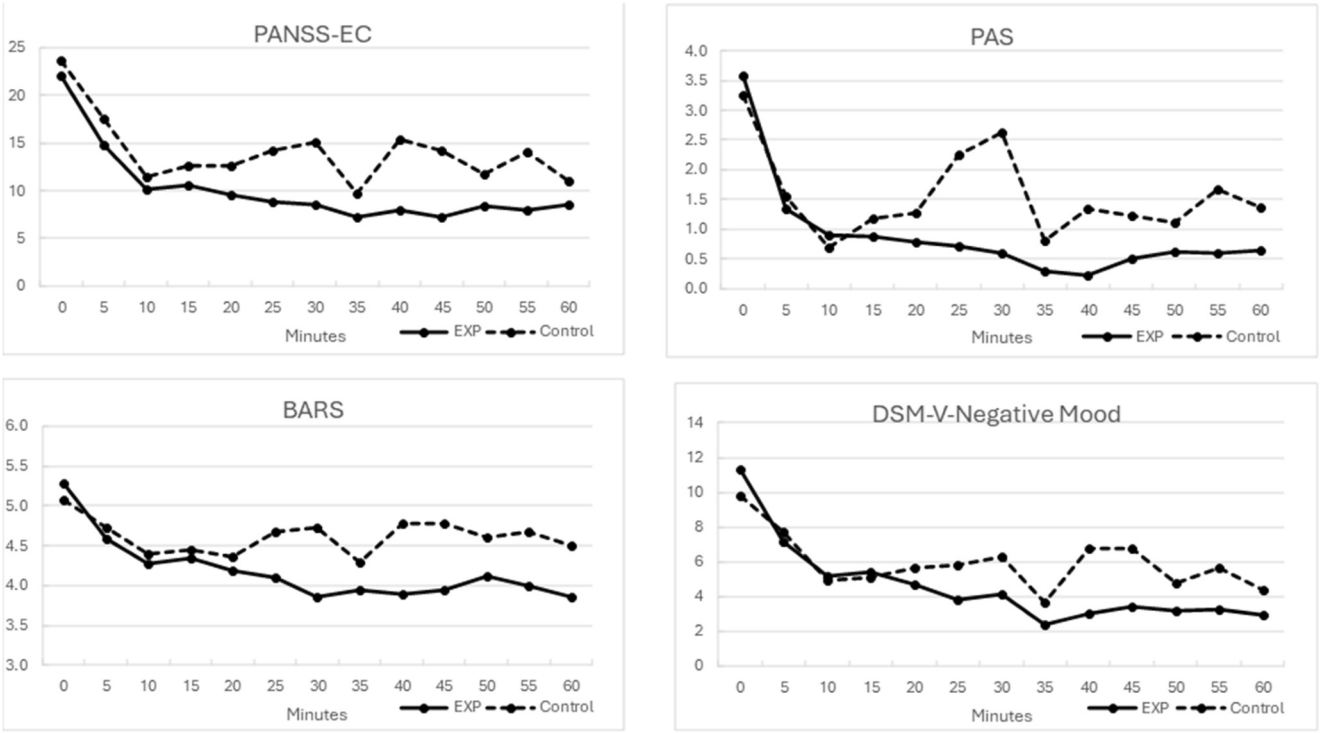

FIGURE 3 | Changes in outcomes in 1 hour observation period.

TABLE 4 | Group x time GEE analysis results adjusted the effects of age, gender and stage of dementia.

	Intervention group ($n = 15$)	Control group ($n = 9$)	Group x time GEE analysis results		
	Mean ± SD		β (SE)	95% Wald CI [lower, upper]	p
CMAI—Total score			0.10 (0.01)	0.04, −0.02	0.424
Baseline	53.20 ± 12.16	46.78 ± 17.03			
Follow-up	50.53 ± 9.75	35.67 ± 5.66			
NPI-Q—Total score			0.0 (0.01)	0.01, −0.01	0.821
Baseline	9.00 ± 4.94	5.56 ± 6.06			
Follow-up	7.00 ± 4.41	5.33 ± 4.18			

Abbreviations: CMAI = Cohen-Mansfield Agitation Inventory, NPI-Q = Neuropsychiatry Inventory Questionnaire.

of eligible participants' proxies provided consent, and over 80% of participants completed the intervention and the follow-up assessment. We recruited 24 participants, with 15 of them were randomly allocated to the intervention group, and fulfilled the rule-of-thumb sample size of 12 participants for a feasibility study [30].

Listening to music through headphones is advocated because it provides an immersive experience that helps people with dementia focus better and minimize distractions [31]. Yet, the literature commonly reports rejections because of discomfort [32, 33]. We applied a lightweight wireless neckband speaker to the participants' shoulders instead of putting the headphones on their heads to create an immersive music-listening experience. In this study, the overall acceptance of the neckband speaker by the participants for regular audio listening was as high as 87%, while 97% of agitation episodes were treated with the neckband speaker. The findings indicated that the neckband was accepted by older adults with dementia, even in a state of agitation.

Although assessing the efficacy of the intervention was not the primary objective of this trial, the findings provided preliminary evidence of its effects. No significant group x time interaction de-escalating effect was detected on all outcomes (PANSS-EC, PAS, BAR and negative mood). However, the agitation symptoms and negative emotions observed were apparently reduced within 10 minutes. According to the Consensus Statement of the American Association for Emergency Psychiatry Project BETA De-escalation Workgroup, 5-10 min would be enough for successful de-escalation [34], so our intervention may be a useful technique to be implemented. The findings align with two other studies on the Iso-Principle music intervention's effects on emotion, which also found no significant difference between groups, though the intervention group exhibited a larger effect size among healthy adults and patients undergoing haematopoietic stem cell transplant [35, 36]. Given the small sample size of this study, it is worth investigating the effects of the intervention with a larger sample size in future research to determine its potential to address a substantial clinical problem.

Using preferred music provides a sense of familiarity to the person with dementia and offers additional soothing effects [25, 37]. However, it is unclear if listening to an Iso-Principle-based music playlist is superior to listening to preferred music played in random sequences. In future research, we can compare the effects between the two approaches. Contrary to the existing knowledge, no significant results were found by comparing two groups at two time-points in terms of the agitation and other behavioural symptoms occurrence frequency. The results may have been affected by the small sample size of the study.

Our study is not without limitations. Although we attempted to blind the research assistant who rated the intensity of agitation from the group assignment, the assignment might have been known because some participants sang, clapped or tapped their feet while listening; or possibly could hear the sound played with the neckband. In addition, we did not anticipate the occurrence of agitation in more than one participant at the same time when preparing the devices for the intervention, which actually happened. A slight delay in applying the intervention was noted. Lastly, the project was heavily delayed due to the pandemic and ultimately closed without achieving the target sample size, primarily because the depletion of financial resources during the waiting period. As a result, the study may have had reduced statistical power and increased variability in its results, making interpretation more difficult.

5 | Conclusion

This study demonstrated that the individualized music playlist sequenced according to the Iso-Principle was feasible and acceptable to persons with dementia in their agitated state. Group x Time interaction effects on all preliminary de-escalation outcomes did not reach statistical significance. Both groups of participants demonstrated an apparent reduction in agitation in the first 10 minutes. The clinical effectiveness of de-escalating agitation is yet to be confirmed.

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Conflicts of Interest

The authors declare no conflicts 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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