

## RESEARCH ARTICLE

# An aromatherapy massage intervention on sleep in the ICU: A randomized controlled feasibility study

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## Abstract

We conducted a feasibility randomized controlled trial exploring the effect of aromatherapy massage on sleep in critically ill patients. Patients were randomized to receive aromatherapy massage or usual care, and feasibility of recruitment and outcome data completion was captured. Sleep (depth) was assessed through Bispectral Index monitoring and self/nurse-reported Richards-Campbell Sleep Questionnaires, and the Sleep in the ICU Questionnaire. Thirty-four patients participated: 17 were randomized to aromatherapy massage and 17 to control. Five participants who received the intervention completed outcomes for analysis (alongside eight controls). A larger study was deemed unfeasible in this population, highlighting the value of testing feasibility of complex interventions, such as massage for sleep in ICU.

## 1 | INTRODUCTION

Many patients experience significant issues with sleep in the ICU, which can lead to adverse consequences, including delirium, cognitive impairment and protracted recovery. The causes for this are multifactorial and the effects are deleterious, impacting on patients' recovery from ICU from intra-ICU to post-discharge.<sup>1-4</sup> Massage to enhance onset and quality of sleep is one solution put forward in the literature, although little evidence on efficacy exists.<sup>1,5,6</sup> Several small studies indicate aromatherapy Inhalation or massage improved self-reported sleep quality in patients being treated for heart disease, cardiac ICU or percutaneous coronary interventions in ICU.<sup>5-9</sup> Moreover, anxiety is also reportedly reduced with massage interventions<sup>10,11</sup>; however, massage had no effect on delirium in one study conducted in a cardiac ICU.<sup>12</sup> Polysomnography is the gold standard for sleep

studies; however, this is not practical in routine care for ICU. Electro-encephalography (EEG) bispectral index monitoring (BIS) is part of usual care in anaesthesia. It is easily accessible and can also be used to measure physiological sleep. It also correlates well with stages of sleep in ICU patients.<sup>13-15</sup> Studies have found that BIS matches natural sleep stages, shifting from low voltage, high-frequency EEG patterns (alpha, beta) of wakefulness to the high voltage, low-frequency component (theta, delta) of slow wave stage (SWS) of deep non-rapid eye movement (NREM) sleep.<sup>13-16</sup> BIS values  $\leq 74$  have been found to correspond well to SWS (deep NREM sleep, stage A), BIS values of 75-89 correspond to light sleep and rapid eye movement (REM) sleep (sleep stage B) and BIS values  $\geq 90$  equate to the awake state (sleep stage C).<sup>16,17</sup> It has been recognized as a good method of objectively evaluating sleep in ICU patients, without the need for invasive and expensive polysomnography.<sup>16</sup>

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## 2 | METHOD

### 2.1 | Aim

We aimed to assess the feasibility of conducting a randomized clinical trial to explore the effect of aromatherapy massage on sleep in critically ill patients.

### 2.2 | Research design/methods

We conducted a randomized feasibility trial in the ICU of a large cancer hospital in the United Kingdom. A feasibility approach was adopted to assess whether a larger trial could be done.<sup>18</sup> A favourable ethical opinion was given by a national research ethics committee (Reference: IRAS ID 166974, Health Research Authority: 15/LO/1014: NCT 02623686). Written informed consent was taken from all participants. Recruitment took place via the pre-assessment unit and in the critical care unit. Patients were randomized (using telephone randomization at the Institute of Clinical Research Clinical Trials Unit) to receive aromatherapy massage using a blended oil and aroma-inhalation patches, or usual care.

### 2.3 | Sample

Critically ill patients who were likely to stay in ICU for  $\geq 4$  (subsequently reduced to 3, as described later) days were included. The suggested sample sizes for feasibility studies range from 24 to 50<sup>19-21</sup> in order to provide adequate power information for a future trial.

We aimed for a feasibility sample of 35–50 patients, stratified into good/bad sleepers pre-randomization (using the self-report screening question of the Sleep in ICU questionnaire establishing normal sleep prior to ICU). Inclusion/exclusion criteria are outlined below in Table 1:

### 2.4 | Randomization

Patients recruited in the pre-assessment appointment were asked about their current sleeping habits and use of sleeping pills. In addition, patients recruited when admitted directly to CCU were asked about their usual sleeping habits and use of sleeping pills. Stratification was used to ensure that patients with pre-existing poor sleep quality were equally represented in both groups. This was measured by answers to the first question of the sleep in the intensive care unit (ICU)<sup>22</sup> questionnaire: 'Rate the overall quality of your sleep at home' on a scale of 1–10 where 1 = poor, 10 = excellent. A score of  $\leq 5$  will form the 'poor' sleep group; a score of  $\geq 6$  will form the 'good' sleep group.

### 2.5 | Intervention

Aromatherapy massage (20 min) was performed on the hands/feet/back as per patient preference and clinical indication (taking place

#### What is known about the topic

- Massage has been shown to improve sleep in several intervention studies, but no clear evidence is available for effectiveness in critical care.
- Moreover, robust objective assessment of sleep, particularly in critical care settings, remains contentious.

#### What this paper adds

- This study identified that trying to use a pragmatic alternative (bispectral index) to known gold standards of sleep assessment was not feasible in a critical care setting.
- This study also identified that delivering a complex intervention such as massage to improve sleep was not feasible in this cohort of patients.

**TABLE 1** Inclusion criteria

Inclusion criteria: Any NHS patient with cancer admitted to the CCU during the period of the study

- Aged 18 years or over
- Who wishes to take part in the study and has capacity to consent

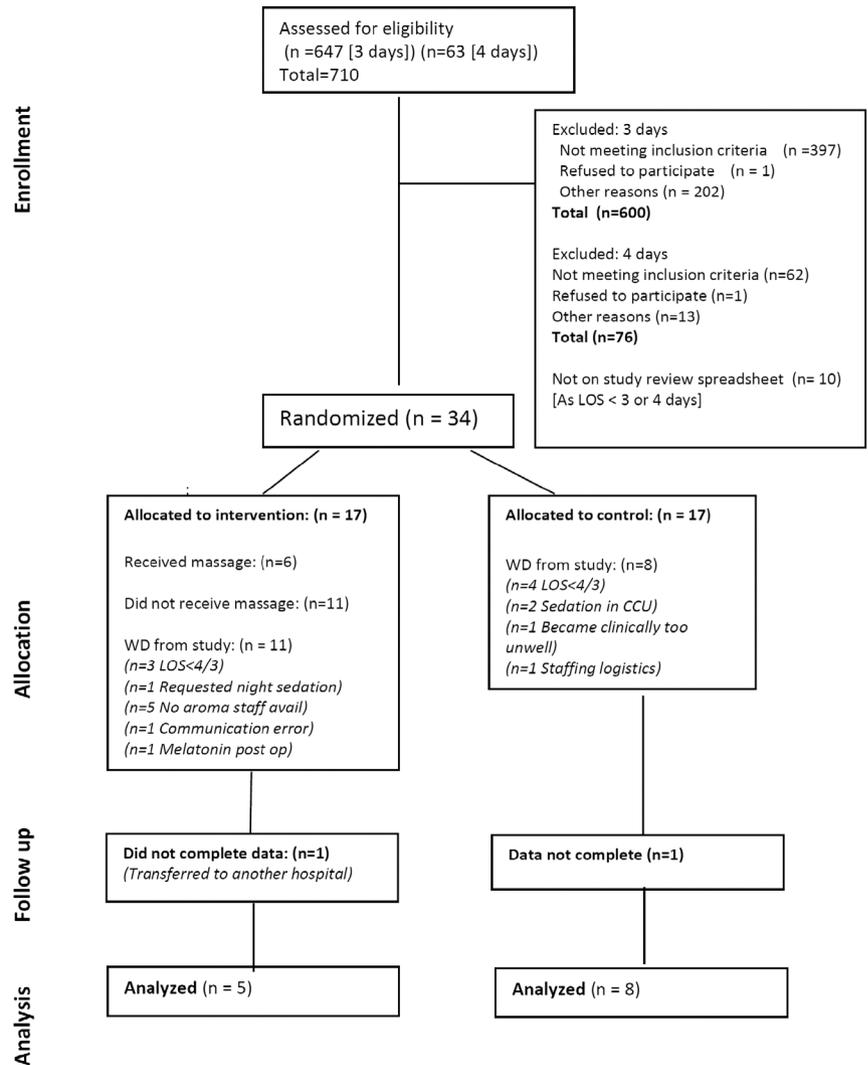
Exclusion criteria, patients with

- Expected length of stay  $\leq 3$  days<sup>a</sup>
- Habitual use of sleep medication more than three times per week
- Sleep meds/hypnotics during the study period
- Sedation during intervention period (propofol; clonidine; midazolam)
- Extensive brain metastases/hypoxic or traumatic brain injury
- Sleep apnoea
- Delirium/impaired capacity to consent
- Excessive alcohol consumption  $>50$  units/week (ascertained via notes)
- Extensive wound/skin damage that precludes massage (e.g., drug-related bullae/skin desquamation)
- Neuromuscular blockade
- Any normal massage contraindications including: severe respiratory or hemodynamic instability, GCS  $<7^{**}$ , ICP  $<20^{**}$  mmHg, contraindication for changing in body position (including active significant bleeding, etc)
- Allergies to the use of essential oils, either on the skin or inhaled, precluding the use of both of the study blends
- Allergy to base (grapeseed) oil

\*\*Glasgow Coma Scale (GCS) less than 7 indicating significantly reduced level of consciousness; Intracranial pressure (where recorded) of  $<20$  mmHg also indicating reduced consciousness.<sup>a</sup>This was subsequently reduced to 3 days.

after 2 pm). Patients were offered a choice of two blends (Blend A: Bergamot FCF [*Citrus bergamia*], Sandalwood [*Santalum austrocaladonicum*]); Blend B: Mandarin (*Citrus reticulata*) Frankincense (*Boswellia carterii*) Lavender (*Lavandula angustifolia*). These blends have been previously reported on with no safety concerns.<sup>23</sup> Interventions took place in late afternoon (due to massage therapist availability and a

**FIGURE 1** CONSORT. LOS, length of stay; WD, withdrawn.



high volume of clinical interventions in the morning) and massages were administered by qualified massage therapists working across the ICU. Bioesse™ inhalation patches are applied overnight with patient choice of blend (see Figure 1).

## 2.6 | Measures

The primary outcome measure was the Richards Campbell Sleep Questionnaire (RCSQ), score 0–100 (best possible sleep) on a visual analogue scale and a total sleep score (sum of all 5 scores/5).<sup>24</sup> Sleep in the ICU Questionnaire was also collected at Day 10 and 3 months.<sup>22,25</sup> Baseline measures of RCSQ were collected at least 24 h post-anaesthesia and counted as night 0 (N0), whereas the remaining nights counted as N1, N2. RCSQ data were collected in the morning (for both nurse and patient reports of a persons' sleep; the RCSQ is validated for both nurse and patient reports<sup>25</sup>). A substantial amendment was approved via the sponsor and research ethics

committee to reduce the length of stay from 4 to 3 days (thereby reducing the number of massages received in the intervention). We also attempted to monitor depth of sleep using bispectral index score (BIS) monitoring, with a view to reporting the BIS ranges (downloaded into bedside Phillips Intellivue monitoring system [ICCA]). We collected the following feasibility data: completeness of outcome data and ability to collect outcomes, achievement of recruitment targets (n = 35–50), attrition/drop-out rates. Secondary exploratory outcomes included the self-reports of sleep. Patients also reported on their experience of the massage with a simple open-ended question (asked and completed by bedside nurse) to provide a qualitative perspective and enhance information from the feasibility study.<sup>26</sup>

## 3 | RESULTS

In the study period (Dec 2015–August 2017) of 710 patients, 106 were screened as eligible; two declined; 34 patients consented to

TABLE 2 Exploratory clinical outcome data

Stratification question (how would you rate your overall sleep at home?) from Sleep in the ICU questionnaire: <5 poor sleep >6 good sleep; block randomization	BASELINE		Day 1 RCSQ		Day 1 RCSQ Patient Score		Day 1 RCSQ Nurse Score		Day 2 RCSQ Nurse Score		Sleep in the ICU Day 7-10 (overall quality of sleep in the ICU, score 0-10)		Sleep in the ICU Day 90 (3 months) (overall quality of sleep in the ICU, score 0-10)		Bispectral Index Score (BIS) ranges (BL-baseline; N = night)	
	RCSQ Patient Score Total Sum sleep score	RCSQ Nurse Score Total Sum sleep score	Day 1 RCSQ Patient Score Total Sum sleep score	Day 1 RCSQ Nurse Score Total Sum sleep score	Day 2 RCSQ Patient Score Total Sum sleep score	Day 2 RCSQ Nurse Score Total Sum sleep score	Day 7-10 (overall quality of sleep in the ICU, score 0-10)	Day 90 (3 months) (overall quality of sleep in the ICU, score 0-10)	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data	BL = 79-94 until 2 am. N1 + 2, no data
Intervention 6	59.2	56.6	55.6	44.2	Missing (discharged)	Missing (discharged)	3	3	Missing (discharged)	3	3	3	3	3	3	Not tolerated. BL = 79-94 until 2 am. N1 + 2, no data
Intervention 5	77.2	41.4	52.2	Missing	40.6	52.6	6	6	52.6	6	6	6	6	6	6	Not tolerated. BL = 44-97 until 3 am. N1 = no data
Intervention 4	86	64.2	66	67.2	Missing (discharged)	Missing (discharged)	1	1	Missing (discharged)	1	1	1	1	1	1	Not tolerated. No data
Intervention 5	15.6	23.8	23	22.6	60.2	Missing (discharged)	2	2	Missing (discharged)	2	2	2	2	2	2	BL = 47-72. N1 = 59-92
Intervention 6	0.2	0.2	43	22.8	Missing (discharged)	45.2	3	3	45.2	3	3	3	3	3	3	BL = No data. N1 = 38-82. N2 = 33-96
(Mean)	Mean 47.6 (SD: 37.9)	Mean 31.2 (SD 25.8)	Mean 47.9 (14.5)	Mean 39.2 (SD: 21.2)	Mean 50.4 (SD 13.8)	Mean 48.9 (SD 5.2)	Mean 3 (range 1-6, SD 1.9)	Mean 4 (range 1-6, SD 2)	Mean 48.9 (SD 5.2)	Mean 3 (range 1-6, SD 1.9)	Mean 3 (range 1-6, SD 1.9)	Mean 3 (range 1-6, SD 1.9)	Mean 3 (range 1-6, SD 1.9)	Mean 3 (range 1-6, SD 1.9)	Mean 3 (range 1-6, SD 1.9)	Mean 3 (range 1-6, SD 1.9)
Control 8	89.4	74.6	78.8	80.2	32	47.2	6	6	47.2	6	6	6	6	6	6	No data
Control 1	88.2	79.2	86.2	88.2	84.7	78	9	9	78	9	9	9	9	9	9	BL = 76-92 but poor contact
Control 6	8.4	9.4	82.2	Missing	Missing (discharged)	Missing (discharged)	6	6	Missing (discharged)	6	6	6	6	6	6	BL = 82-97. No other BIS data
Control 5	76.2	75.4	90.6	83.8	Missing (discharged)	Missing (discharged)	3	3	Missing (discharged)	3	3	3	3	3	3	BL = 57-78. N1 = 55, only one hour captured
Control 5	6.8	39.6	51	33.6	49.8	68	5	5	68	5	5	5	5	5	5	Poor contact for BL = 57-88. Good contact N1 = 63-96 and N2 = 54-98

TABLE 2 (Continued)

Stratification question (how would you rate your overall sleep at home?) from Sleep in the ICU questionnaire: <5 poor sleep >6 good sleep; block randomization	BASELINE		Day 1 RCSQ		Day 1 RCSQ Patient Score		Day 1 RCSQ Nurse Score		Day 2 RCSQ Patient Score		Day 2 RCSQ Nurse Score		Sleep in the ICU Day 7-10 (overall quality of sleep in the ICU, score 0-10)		Sleep in the ICU Day 90 (3 months) (overall quality of sleep in the ICU, score 0-10)		Bispectral Index Score (BIS) ranges (BL-baseline; N = night)	
	RCSQ Patient Score Total Sum sleep score	RCSQ Nurse Score Total Sum sleep score	Day 1 RCSQ Patient Score Total Sum sleep score	Day 1 RCSQ Nurse Score Total Sum sleep score	Day 1 RCSQ Patient Score Total Sum sleep score	Day 1 RCSQ Nurse Score Total Sum sleep score	Day 2 RCSQ Patient Score Total Sum sleep score	Day 2 RCSQ Nurse Score Total Sum sleep score	Day 7-10 (overall quality of sleep in the ICU, score 0-10)	Day 90 (3 months) (overall quality of sleep in the ICU, score 0-10)	BL	N	BL	N	BL	N	BL	N
Control	76.8	67.6	59.4	52.6	71.8	61.4	3	Missing	BL = 44-96. N1 = 55-98. N2 = 51-97									
Control	84	64.8	96.8	77.4	93.5	71	8	7	BL = 45-98. N1 = 93-97. N2 = 44-97									
Control	64.2	62.4	82.8	72.6	44.8	32.6	2	Missing	BL = 62-98. N1 = 61-98. N2 = 55-97									
(Mean)	Mean 61.7 (SD: 34.4)	Mean 59.1 (SD 23.5)	Mean 78.4 (SD: 15.6)	Mean 69.7 (SD: 19.6)	Mean 62.8 (SD: 24.3)	Mean 59.7 (SD: 16.8)	Mean 5.2 (SD: 2.5)	Mean 7 (SD: 1.4)										

Abbreviations: BL, baseline; BIS, bispectral index; N, night; RCSQ, Richards Campbell Sleep Questionnaire; SD, standard deviation.

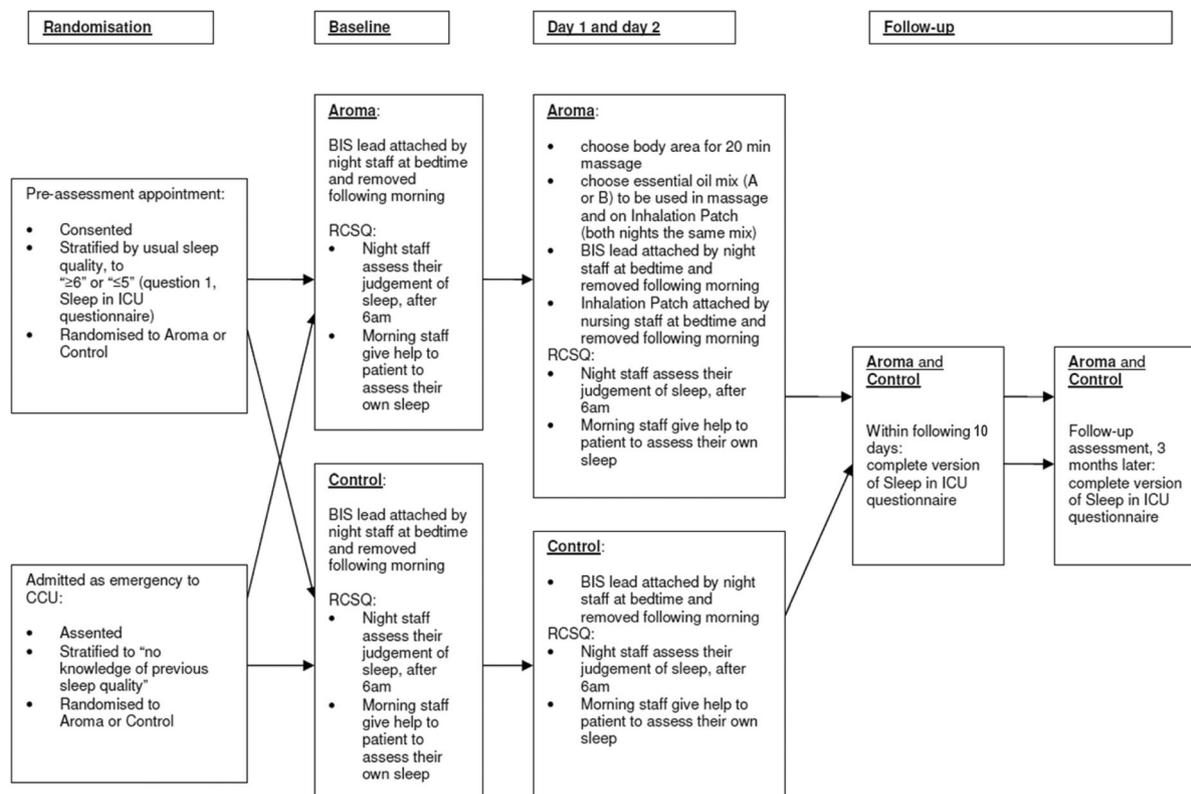


FIGURE 2 Study procedures.

participate (see Figure 1 for CONSORT, which includes eligible patients when inclusion criteria were 4 days, and at 3 days, when reduced, following a study amendment). We randomized (as per procedures outlined above) 17 (50%) participants to the intervention arm (aromatherapy massage) and 17 to the control arm (usual care). Seven/17 (41%) received the intervention, 12 (35%) were withdrawn overall because of changes in clinical condition or early discharge, and nine (52.9%) completed all questionnaire data (baseline to 3 months). Of the 34 patients who consented, 10 (29.4%) in total tolerated BIS. Two patients died before the final follow-up (at 90 days). Table S1 (supplemental file) compares the baseline characteristics between the intervention and control groups.

Patient-level data are reported in Table 2. Mean scores for RCSQ (sum score for sleep<sup>22,24</sup>) were 47.6 (SD 37.9) (baseline); 47.96 (SD 14.5) (day 1); 50.4 (SD 13.8) (day 2) in the intervention and 61.7 (SD 34.4) (baseline), 78.48 (SD 15.5) (day 1), 62.8 (SD 24.3) (day 2) in control group respectively. Sleep in the ICU (overall score for sleep<sup>22</sup>) mean scores were 3 (SD 1.9) at day 10 and 4 (SD:2) at 3 months in the intervention groups and 5.3 (SD 2.5) and 7 (SD:1.4) in the control. BIS range data proved difficult to capture with high levels of artefact and missing data, and low levels of patient tolerance. Managing and downloading the large volumes of data from BIS was also problematic, rendering this largely unusable (Figure 2).

The intervention was reported as an enjoyable experience. Inclusion criteria presented challenges, and feasibility outcomes

demonstrated that it would not be feasible to conduct a full-scale powered RCT in this population.

While outcome measures on the questionnaires were completed by participants and bedside nurses, it was found that BIS was not feasible are part of a clinical trial because of frequent missing values and poor patient tolerance, with some patients reporting a 'pricking sensation' from BIS, or not liking being connected. The massage therapy team availability changed during the study, reducing opportunities for recruitment and participation.

## 4 | DISCUSSION

Despite the in-principle value of an RCT to explore massage use to support sleep, and measurement of sleep quality, this feasibility RCT demonstrated it would not be feasible to carry out a full-scale, powered RCT because of outcome data collection and recruitment challenges. BIS was not deemed acceptable, and the data yielded was poor. EEG remains the gold standard for sleep studies, but actigraphy has an increasing potential.<sup>27,28</sup> Limitations include this being a single-centre study in a specialist ICU population, where usual care involved massage intervention, and the study was not powered to detect and effect (in line with feasibility methods). Baseline characteristics were not equal, and data completion poor. Massage intervention delivery was limited by the therapist availability (given the consecutive days intervention required), meaning patients could only be recruited on

certain days of the week and occasionally different massage therapists delivered the intervention on different days. Moreover, the massage therapy team changed (reduction in hours) during the study, meaning it was harder for available staff to deliver the intervention. Nursing staff also struggled with the BIS, and the questionnaire completions, therefore requiring significant study staff oversight, further limiting feasibility. Measurements for immediate and longer-term self-assessment of sleep were not completed by all participants (as per table), suggesting this was an additional burden. Recruitment took a long time, again indicating this was not a feasible study, despite a substantial amendment to reduce the number of days eligibility (and thus massages). Completion of the questionnaires was reasonable, but there was a high withdrawal rate following the intervention (35%). Systematic reviews of studies of interventions around sleep in the ICU have indicated the poor evidence quality base, as have studies of massage in the ICU.<sup>1,5,29,30</sup> However, this research has confirmed how these studies are complex and difficult to complete, with gaps around measurements of quality of sleep requiring large populations from which to draw (and multi-centre research), high adherence to outcome measurements, to provide high-quality evidence. This study was conducted prior to COVID-19 and therefore implementation of this kind of massage intervention now may be very different and challenged because of increasing staffing constraints.

## 5 | CONCLUSION

This study identified important limitations in conducting a complex intervention study around sleep in the ICU, and emphasized the value of testing feasibility of complex interventions and how it would be unfeasible to conduct a full RCT.

### FUNDING INFORMATION

This work was supported through infrastructure provided through the Royal Marsden NIHR Biomedical Research Centre and the materials funded through the Royal Marsden Charity.

### CONFLICT OF INTEREST STATEMENT

The authors declare they have 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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## SUPPORTING INFORMATION

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

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