

Research Q2 Evidence Profile (Quantitative)

Recommendation question 2: Should sensory-minimizing strategies that address noise and light (used to facilitate people-centred care) be recommended or not?

Recommendation: The expert panel suggests that people are provided with eye masks and/or earplugs as a sensory-minimising strategy according to the needs and preferences of the person.

Population: Health providers at all levels of health-service organizations or people receiving care

Intervention: Sensory-minimizing strategies that address noise/lighting to facilitate people-centred care

Comparison: Usual care or no sensory-minimizing strategy

Outcomes: Physiologic measures; Length of stay; Satisfaction with overall care; Provider knowledge [not measured]; Re-admission rates [not measured]; Adoption and sustainability (of sensory-minimizing strategies) [not measured], Provider burden [not measured]; Provider satisfaction [not measured]

Setting: all healthcare settings

Bibliography: 1-7

Table 1 – Quality details

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Physiologic measures: Sleep time (measured by actigraphy. Actigraphy is a type of tool used to measure various sleep outcomes. A wristband device is worn by the study participant and measures activity levels such as periods of rest/sleep and awake times.)											
2 ^a	Cochrane review	Serious ^b	Not serious	Not serious	Very serious ^c	Undetected	N=62 Le Guen: Mean hours (standard deviation [SD]) =6.6(2.6) Xie: Mean hours (SD) = 7.8(0.8)	N=54 Le Guen: Mean hours (SD) =5.5(2.6) Xie: Mean hours (SD) =4.9(1.0)	Total sleep time (hours) was greater in the intervention group compared with the control group when adults were provided with earplugs and eye mask in the adult intensive care unit (ICU) setting. (Mean difference (MD): 2.19 hours, 95% confidence interval (CI) (0.41 to 3.96) I ² statistic: 67%	⊕○○○ Very low	(1)
Physiologic measures: Delirium rate(measured by multiple tools - Neelon and Champagne Confusion Scale; occurrence of early delirium (yes/no))											
2	Cochrane review	Serious ^d	Serious ^e	Not serious	Not serious ^f	Undetected	# of people: 89 Events = 24 Le Guen: 0 events in 20 participants	# of people: 88 Events = 43 Le Guen: 3 events in 21 participants	A meta-analysis of these two studies showed that use of earplugs or eye masks or both for adults in the ICU decreased the risk of delirium or confusion (risk ratio (RR) 0.55, 95%	⊕⊕○○ Low	(1)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
							Van Rompaey: 24 events in 69 participants	Van Rompaey: 40 events in 67 participants	CI 0.38 to 0.80) (Le Guen, 2014; Van Rompaey, 2012). For every 100 people who receive eye masks or ear plugs to mitigate light or sound in the ICU setting to facilitate people-centred care, 22 fewer people will experience delirium in the ICU (ranges from 30 fewer to 10 fewer).		
Physiologic measures: Vital signs [heart rate (beats per minute)]											
2	RCTs	Serious ^a	Very serious ^b	Not serious	Serious ⁱ	Undetected	Total participants: 77 Avudaiappan: post-heart rate 99.04 (14.01) Turan: post-intervention heart rate 91.40 (10.87)	Total participants: 77 Avudaiappan: post-heart rate 93.38 (18.29) Turan: post-heart rate 102.45 (12.83)	In one study, adults in the ICU who used eye masks and earplugs during sleep had a slightly higher heart rate compared to the adults who did not use eye masks or ear plugs: mean difference (MD): 5.66, 95%CI (-1.88 to 13.20) (2). In another study, adults in the CICU who used eye masks and earplugs during sleep had a lower heart rate, compared to adults who did not use eye masks or ear plugs: mean difference (MD): -11.05, 95%CI (-16.72 to -5.38) (3)	⊕○○○ Very low	(2,3)
Physiologic measures: Vital signs [systolic blood pressure (mmHg)]											
2	RCTs	Serious ^a	Not serious	Not serious	Serious ⁱ	Undetected	Total participants: 77 Avudaiappan: post-intervention	Total participants: 77 Avudaiappan: post-SBP rate 131.66 (19.98)	In both studies, diastolic blood pressure was lower (moderate to large effect) in adults who wore eye masks and ear plugs while sleeping in the ICU and CICU, compared to those who did not wear them: Mean	⊕⊕○○ Low	(2,3)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
							SBP 119.76 (8.11) Turan: post-intervention SBP 125.14 (9.50)	Turan: post-SBP 135.14 (11.97)	difference (MD): -11.90, 95%CI (-18.52 to -5.28) (2) and Mean difference (MD): -10.00, 95%CI (-15.15 to -4.84) (3).		
Physiologic measures: Vital signs [diastolic blood pressure (mmHg)]											
2	RCTs	Serious ^f	Very serious ⁱ	Not serious	Serious ⁱ	Undetected	Total participants: 77 Avudaiappan: post-intervention DBP 85 (14.01) Turan: post-intervention DBP 68.42 (8.64)	Total participants: 77 Avudaiappan: post-DBP rate 80 (14.01) Turan: post-DBP 74.11 (11.16)	In one study, adults who used eye masks and ear plugs had a slightly higher diastolic blood pressure, compared to those who did not wear eye masks and ear plugs: Mean difference (MD): 5.00, 95%CI (-1.08 to 11.08) (2) In another study, adults who used eye masks and ear plugs had a moderately lower diastolic blood pressure compared to those who did not wear eye masks and ear plugs: Mean difference (MD): -5.69, 95%CI (-10.45 to -0.93)	⊕○○○ Very low	(2,3)
Physiologic measures: Height and weight (Preterm or very low birth weight infant (< 1500 mg) height was measured at 34 weeks post menstrual age and weight was measured at 34 weeks post menstrual age and corrected for 18-22 months of age)											
1 ^k	Cochrane review	Not serious ^l	Not serious	Not serious	Extremely serious ^m	Undetected	To manage sound in the neonatal intensive care unit (NICU) setting (reduce sound to 45 decibels or less), silicone	Newborns in the control group received standard care.	For preterm or very low birth weight infants in the NICU when earplugs were used to reduce sound, there was a small difference in infant height at 18 to 22 months corrected age; favoring infants managed with silicone earplugs versus infants	⊕○○○ Very low	(4)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
							earplugs were used in the NICU and during transport. Earplugs were positioned at the time of randomization and worn continuously until the infants were 35 weeks postmenstrual age or discharged (whichever came first). Earplugs were removed for medical or social reasons (e.g. parental visits). Height (cm) at 18 to 22 months corrected age N= 7 Mean cm (SD) = 79.9 (6)		receiving usual care (MD 2.7 cm, 95% CI -3.1 cm to 8.5 cm).		
1 ^k	Cochrane review	Not serious ^l	Not serious	Not serious	Extremely serious ⁿ	Undetected	Weight (g) at 34 weeks	Weight (g) at 34 weeks	Weight at 34 weeks post menstrual age: For preterm or very low birth weight infants in the NICU when earplugs were used to reduce	⊕○○○ Very low	(4)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
							postmenstrual age N= 10 Mean grams (SD) = 1,932.5 (377) Weight (kg) at 18-22 months corrected age N= 7 Mean kg (SD) = 11.1 (1.8)	postmenstrual age N= 13 Mean grams (SD) = 1,821.4 (220) Weight (kg) at 18-22 months corrected age N= 7 Mean kg (SD) = 10.8 (1.8)	sound), there was a small difference in this outcome favoring infants managed with earplugs versus infants who received usual care (MD 111 g, 95% CI -151 g to 374 g) Weight at 18-22 months corrected age: For preterm or very low birth weight infants in the NICU when earplugs were used to reduce sound), there was a small difference in this outcome favoring infants managed with earplugs versus infants who received usual care (MD 0.31 kg, 95% CI -1.53 kg to 2.16 kg).		
Physiologic measures: Vital signs of preterm babies in NICU [Heart rate (beats per minute)]											
1	Non-randomized study	Serious ^o	Not applicable	Not serious	Extremely serious ^p	Undetected	N = 20 141.55 (2.42)	N = 20 157.55 (2.52)	When the preterm babies wore ear plugs, they had a moderately lower mean heart rate compared to when they did not wear ear plugs: MD: -16.00, 95% CI (-17.58 to -14.42)	⊕○○○ Very low	(5)
Physiologic measures: Vital signs of preterm babies in NICU [systolic blood pressure (mmHg)]											
1	Non-randomized study	Serious ^o	Not applicable	Not serious	Extremely serious ^p	Undetected	N = 20 60.1 (11.58)	N = 20 61.85 (1.6)	There was little to no difference in systolic blood pressure when preterm babies wore ear plugs compared to when they did not wear ear plugs: MD: -1.75, 95% CI (-7.04 to 3.54)	⊕○○○ Very low	(5)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Physiologic measures: Vital signs of preterm babies in NICU [diastolic blood pressure (mmHg)]											
1	Non-randomized study	Serious ^o	Not applicable	Not serious	Extremely ^p	Undetected	N = 20 35.55 (3.41)	N = 20 39.45 (2.86)	The use of ear plugs may reduce the diastolic blood pressure of newborn babies: MD: -3.9, 95% CI (-5.91 to -1.89)	⊕○○○ Very low	(5)
Length of hospital or intensive care unit stay in days or hours (measured from chart data)											
1 ^a	Cochrane review	Not serious ^r	Not serious	Not serious	Extremely serious ^s	Undetected	N=11 Mean days (SD) = 90.4 (43.1)	N=13 Mean days (SD) = 89 (36.9)	For preterm or very low birth weight infants in the NICU when earplugs were used to reduce sound, there was a small difference in length of stay (LOS) that favoured the infants who received standard care compared to infants who received earplugs to reduce sound (MD 1.4 days, 95% CI -31.0 days to 33.8 days).	⊕○○○ Very low	(4)
1	RCT	Serious ^t	Not serious	Not serious	Extremely serious ^u	Undetected	N=27 LOS (days) mean [SD] = 10±6	N=36 LOS (days) mean [SD] = 12±17	For patients who received earplugs in the cardiothoracic post anesthesia care unit (C-PACU), the duration of hospital stay (days) following surgery was shorter compared to those who did not receive earplugs. MD -2.0 days, 95% CI (-8.85 days to 4.85 days).	⊕○○○ Very low	(6)
1	RCT	Serious ^t	Not serious	Not serious	Extremely serious ^v	Undetected	N=8 Median hours (interquartile	N=9 Median hours (IQR) = 65(20)	For adults in an adult ICU who were given earplugs and cloth eye mask to sleep at night, their length of stay	⊕○○○ Very low	(7)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
							range [IQR] = 96 (66.5)		in the ICU was longer compared to those who received usual care.		
Satisfaction with overall care (measured by a Likert scale – 1 = excellent, 5 = very poor; measured using the RAND-36 tool [0-100 higher scores indicating higher levels of functioning/well-being])											
1	RCT	Serious ^t	Not serious	Not serious	Extremely serious ^w	Undetected	N=27 Median satisfaction score = 2, IQR of 1-2, range of 1-4	N=36 Median satisfaction score = 2, IQR of 2-3, range of 1-5	When people who underwent fast-track cardiothoracic surgery wore earplugs their first night in the cardiothoracic post-anesthetic care unit (C-PACU) following their surgical procedure, there was no difference in their overall satisfaction with their C-PACU experience compared to those who did not wear earplugs.	⊕○○○ Very low	(6)
Provider knowledge (not measured)											
N/A											
Re-admission rates (not measured)											
N/A											
Adoption and sustainability (of sensory-minimizing strategies) (not measured)											
N/A											
Provider burden (not measured)											
N/A											
Provider satisfaction (not measured)											

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
N/A											

Acronyms

- CI = confidence interval
- C-PACU = cardiothoracic post-anesthetic care unit
- ICU = intensive care unit
- IQR = interquartile range
- LOS = length of stay
- MD = mean difference
- NICU = neonatal intensive care unit
- PACU = post anesthesia care unit
- RCT= randomized control trial
- RR= relative risk
- SD = standard deviation
- SMD = standardized mean difference
- SR = systematic review

Table 2 – Individual Study Details

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias of included study
Physiologic measures: Sleep quality						
(1)	Cochrane Review (2 RCTs)	France & Belgium	<p>1st study (Le Guen): Use of earplugs and eye mask during 1 night (from about 10 p.m. to 6 a.m.) Study duration: 1 night of using earplugs, 1 night without earplugs</p> <p>N= 20</p> <p>Ear plugs/ eye mask: mean (SD) =6.6 hours (2.6)</p> <p>Mean difference, Random, 95% CI (hours) = 1.10 [0.49,2.69]</p> <p>2nd study (Xie): Participants sleeping with earplugs during the night Study duration: 4 days</p> <p>N = 42</p> <p>Ear plugs/ eye mask: mean (SD) =7.8 hours (0.8)</p> <p>Mean difference, Random, 95% CI (hours) = 2.94[2.51,3.37]</p>	<p>Usual care without earplugs and eye mask</p> <p>1st study: N=21</p> <p>Usual care: mean (SD) = 5.5 hours (2.6)</p> <p>2nd study: N= 33</p> <p>Usual care: mean (SD) = 4.9 hours (1.0)</p>	<p>A meta-analysis of these 2 studies showed that total sleep time was greater in the intervention group compared with the control group.</p> <p>Meta-analysis: N=116</p> <p>MD 2.19 hours, 95% CI 0.41 to 3.96, Chi2=4.78, I2=79.09%</p>	<p>LOW</p> <p>Based on ROBIS tool</p>
Physiologic measures: Delirium rate						
(1)	Cochrane Review (2 RCTs)	France & Belgium	<p>1st study: Use of earplugs and eye mask during 1 night (from about 10 p.m. to 6 a.m.) Study duration: 1 night of using earplugs, 1 night without earplugs</p> <p>2nd study: Participants sleeping with earplugs during the night Study duration: 4 days</p> <p>1st study:</p> <p>Ear plugs/ eye mask (n/N), Events = 0</p> <p>N = 20, RR = 0.15 [0.01, 2.73]</p> <p>2nd study:</p>	<p>Usual care without earplugs and eye mask</p>	<p>A meta-analysis of these two studies showed that use of earplugs or eye masks or both decreased the risk of delirium or confusion.</p> <p>Meta-analysis: N = 89, Total events = 24</p> <p>RR = 0.55 [0.38,0.80], Chi2=0.87, I2=0%</p>	<p>LOW</p> <p>Based on ROBIS tool</p>

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias of included study
			Ear plugs/ eye mask (n/N), Events = 24 N = 69, RR = 0.59 [0.40,0.85]			
Physiologic measures: Vital signs (heart rate, systolic blood pressure, diastolic blood pressure)						
2	RCT	India	ICU patients in the study group were given ear plugs and eye masks after their first 24 hours of admission, and asked to wear them from 1030pm to 0630. Patients could remove their eye masks/ear plugs if they had any discomfort or needed something from staff. This information was repeated for 3 days. N = 42 Avg. HR in study at posttest was 99.04 ± 16.38 compared to pretest 84.95 ± 15.08 Avg. systolic blood pressure at posttest was 119.76±8.11, compared with the pretest 128.33±18.59 Avg. diastolic BP in at posttest was 85.00 ± 14.01 compared to pretest was 77.61 ± 10.54	Usual care – no ear plugs or eye masks worn N = 42 Avg. HR in control group the same at posttest 93.38 ± 18.29 compared to pretest 93.66 ± 21.10 Avg systolic blood pressure in the control group was 125.95±20.48 at pretest and 131.66±19.98 at posttest Avg. diastolic BP in study group was the same at posttest 80.00 ± 14.01 compared to pretest 80.00 ± 113.25	In one study, adults in the ICU who used eye masks and earplugs during sleep had a slightly higher heart rate compared to the adults who did not use eye masks or ear plugs: mean difference (MD): 5.66, 95%CI (-1.88 to 13.20). Systolic blood pressure was lower in adults who wore eye masks and ear plugs while sleeping in the ICU compared to those who did not wear them: Mean difference (MD): -11.90, 95%CI (-18.52 to -5.28). In one study, adults who used eye masks and ear plugs had a slightly higher diastolic blood pressure, compared to those who did not wear eye masks and ear plugs: Mean difference (MD): 5.00, 95%CI (-1.08 to 11.08).	SOME CONCERNS Based on Cochrane ROB 2.0 tool
3	1 RCT	Turkey	Patients in the CICU who were in the study group wore ear plugs and eye masks from 1030 pm to 0630 for three nights. They were allowed to remove their ear plugs and eye masks for a short time when intervention or communication was required. N = 35 Mean heart rate: pre-intervention: 94.45 (14.06) and post intervention: 91.40 (10.87) Mean diastolic blood pressure pre-intervention: 74.28 (10.08) and post-intervention: 68.42 (8.64) Mean systolic blood pressure: pre-intervention: 133.14 (14.50) and post-intervention: 125.14 (9.50)	Usual care – no ear plugs or eye masks were worn N = 35 Mean heart rate: pre-intervention: 101.00 (14.15) and post-intervention: 102.45 (12.83) Mean diastolic blood pressure: pre-intervention: 71.42 (12.16) and post-intervention: 74.11 (11.16) Mean systolic blood pressure: pre-intervention: 131.71 (15.62) and post-intervention: 135.14 (11.97)	Adults in the CICU who used eye masks and earplugs during sleep had a lower heart rate, compared to adults who did not use eye masks or ear plugs: mean difference (MD): -11.05, 95%CI (-16.72 to -5.38). Systolic blood pressure was lower in adults who wore eye masks and ear plugs while sleeping in the CICU, compared to those who did not wear them: Mean difference (MD): -10.00, 95%CI (-15.15 to -4.84) Adults who used eye masks and ear plugs had a moderately lower diastolic blood pressure compared to those who did not wear eye masks and ear plugs: Mean difference (MD): -5.69, 95%CI (-10.45 to -0.93).	SOME CONCERNS Based on Cochrane ROB 2.0 tool
Physiologic measures: Height (cm) and weight (g or kg)						

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias of included study
(4)	Cochrane Review (1 RCT)	USA	<p>To manage sound in the NICU setting (reduce sound to 45 decibels or less), silicone earplugs were used in the neonatal intensive care unit (NICU) and during transport. Earplugs were positioned at the time of randomization and worn continuously until the infants were 35 weeks postmenstrual age or discharged (whichever came first). Earplugs were removed for medical or social reasons (e.g. parental visits).</p> <p>Height (cm) at 18 to 22 months corrected age N= 7 Mean (SD)= 82.6 (5.1) Mean difference fixed, 95% CI = 2.7 (-3.13, 8.53)</p> <p>Weight (g) at 34 weeks postmenstrual age N= 10 Mean (SD) = 1932.5 (377) Mean difference fixed (95%CI) = 111.1 (-151.39, 373.59)</p> <p>Weight (kg) at 18-22 months corrected age N= 7 Mean (SD) = 11.1 (1.8)</p> <p>Mean difference fixed (95%CI) = 0.31 (-1.53, 2.16)</p>	<p>Newborns in the control group received standard care.</p> <p>Height (cm) at 18 to 22 months corrected age N= 7 Mean (SD)= 79.9 (6)</p> <p>Weight (g) at 34 weeks postmenstrual age N= 13 Mean (SD) = 1821.4 (220)</p> <p>Weight (kg) at 18-22 months corrected age N= 7 Mean (SD) = 10.8 (1.8)</p>	<p>For preterm or very low birth weight infants in the neonatal intensive care unit (NICU) when earplugs were used to reduce sound, there was a small difference in infant height at 18 to 22 months corrected age; favoring infants managed with silicone earplugs versus infants receiving usual care (MD 2.7 cm, 95% CI -3.1 cm to 8.5 cm).</p> <p>Weight at 34 weeks post menstrual age: There was a small difference in this outcome favoring infants managed with silicone earplugs versus infants who received usual care (MD 111 g, 95% CI -151 g to 374 g)</p> <p>Weight at 18-22 months corrected age: There was a small difference in this outcome favoring infants managed with silicone earplugs versus infants who received usual care (MD 0.31 kg, 95% CI -1.53 kg to 2.16 kg).</p>	<p>LOW</p> <p>Based on ROBIS tool</p>
Physiologic measures: Vital signs (heart rate, systolic blood pressure, diastolic blood pressure)						
(5)	Non-randomized control trial	India	<p>Silicone ear plugs that were mouldable and hypoallergenic were used to decrease the noise in the ICU to 32 decibels (minimum noise reduction was 16 decibels less than the environmental noise). The ear plugs were placed in the babies ears one hour before admission to the NICU. The babies were studied on days 1 and 3 with ear plugs inserted and the same babies were studied on day 2 and 4 without the ear plugs. Data was collected every two hours for four days.</p> <p>N = 20</p> <p>Mean heart rate: 141.55±2.42 Mean systolic blood pressure: 60.1±11.58</p>	<p>The same babies served as both test subjects (days 1 and 3) and controls (days 2 and 4)</p> <p>N = 20</p> <p>Mean heart rate: 157.55±2.52 Mean systolic blood pressure: 61.85±1.6 Mean diastolic blood pressure: 39.45 ±2.86</p>	<p>When the preterm babies wore ear plugs, they had a moderately lower mean heart rate compared to when they did not wear ear plugs: MD: -16.00, 95% CI (-17.58 to -14.42)</p> <p>There was little to no difference in systolic blood pressure when preterm babies wore ear plugs compared to when they did not wear ear plugs: MD: -1.75, 95% CI (-7.04 to 3.54)</p> <p>The use of ear plugs may reduce the diastolic blood pressure of newborn babies: MD: -3.9, 95% CI (-5.91 to -1.89)</p>	<p>Moderate</p> <p>Based on ROBINS-1, version 2</p>

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias of included study
			Mean diastolic blood pressure: 35.55 ± 3.41			
Length of stay (NICU, or hospital) measured in days or hours						
(4)	Cochrane Review (1 RCT)	USA	To manage sound in the NICU setting (reduce sound to 45 decibels or less), silicone earplugs were used in the neonatal intensive care unit (NICU) and during transport. Earplugs were positioned at the time of randomization and worn continuously until the infants were 35 weeks postmenstrual age or discharged (whichever came first). Earplugs were removed for medical or social reasons (e.g. parental visits). N = 11 Mean days (SD) = 90.4 (43.1)	Newborns in the control group received standard care. N = 13 Mean days (SD) = 89 (36.9)	There was no difference in this outcome between infants managed with silicone earplugs versus infants receiving usual care (MD 1.4 days, 95% CI -31.0 days to 33.8 days).	LOW based on ROBIS tool
(6)	RCT	Austria	People randomized into the intervention for their first postoperative night following cardiothoracic surgery staying in the cardiothoracic post anesthetic care unit (C-PACU) received earplugs from the nursing staff at around 10 p.m. and advised to wear them until the following morning. The single-use earplugs were made of paraffin wax, petroleum jelly and cotton wool. This type of earplug offers a SNR (single number rating) value of 27 decibels (dB). N=27 LOS (days) mean [SD] = 10±6	The participants in the control group received usual care N=36 LOS (days) mean [SD] = 12±17	For participants who received earplugs the first night in a fast-track cardiothoracic post anesthesia care unit (PACU), the duration of hospital stay (days) following cardiothoracic surgery was shorter compared to those who did not receive earplugs.	SOME CONCERNS Based on Cochrane ROB 2.0 tool
(7)	RCT	Thailand	In the intervention group, the patients were given earplugs (noise reduction rating of 32 dB) and cloth eye masks by physician or nurse during sleep at nighttime according to their habitual home bedtime but not after 22:00 hours, during their first five nights in ICU. Earplugs and eye masks were removed at 07:00 hours on the following morning. Earplugs and eye masks were allowed to be removed for no longer than 10 minutes for communication if needed. The patients were informed to use earplugs and eye masks every night during the ICU stay	The participants in the control group received usual care N=9 Median hours (IQR) = 65(20)	For adults in an adult ICU who were given earplugs and cloth eye mask to sleep at night, their length of stay in the ICU was longer compared to those who received usual care.	SOME CONCERNS Based on Cochrane ROB 2.0 tool

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias of included study
			N=8 Median hours (IQR) = 96 (66.5)			
Satisfaction with overall care						
(6)	RCT	Austria	People randomized into the intervention for their first postoperative night following cardiothoracic surgery staying in the cardiothoracic post anesthetic care unit (C-PACU) received earplugs from the nursing staff at around 10 p.m. and advised to wear them until the following morning. The single-use ear plugs were made of paraffin wax, petroleum jelly and cotton wool. This type of earplug offers a SNR (single number rating) value of 27 decibels (dB). N=27 Median score = 2, IQR of 1-2, range of 1-4	People randomized into the control group spending their first night following cardiothoracic surgery in the C-PACU were offered no noise reduction strategy. N=36 Median score = 2, IQR of 2-3, range of 1-5	When people who underwent fast-track cardiothoracic surgery wore earplugs their first night in the post-anesthetic care unit following their surgical procedure, there was higher overall satisfaction with their C-PACU experience by patients who wore earplugs compared to those who did not wear earplugs. Median score = 2, IQR of 1-2, range of 1-4.	HIGH Based on Cochrane ROB 2.0 tool

References:

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Explanations:

^a The number reported in this column reflects the number of primary studies reporting each outcome from the primary studies captured in the systematic review and meta-analysis results. There were two randomized control trials in this Cochrane review pertaining to this outcome (Hu et al., 2018).

^b The review was assessed using the ROBIS tool for systematic reviews and had low risk of bias (ROB). Studies included in the review were assessed by the authors using the Cochrane ROB tool for RCTs; the authors downgraded in multiple domains across the RCTs. We downgraded by 1.

^c The total number of participants was far less than the optimal number of 800 (n=116). We downgraded by 2.

^d The review was assessed using the ROBIS tool for systematic reviews and had low risk of bias (ROB). Studies included in the review were assessed by the authors using the Cochrane ROB tool for RCTs; the authors downgraded in multiple domains across the 3 RCTs for lack of blinding of outcome assessors, and risk of selection bias. We downgraded by 1.

^e There was variability in the direction of effect shown in the studies; the studies demonstrated mixed results in delirium rates. We downgraded by 1.

^f The 2 Cochrane Reviews had 1 primary study that were identical (Van Rompaey et al., 2012). This was taken into consideration and the number of events was accounted for when calculating imprecision. The total number of events was still above the rule of thumb of 300; therefore, we did not downgrade.

^g The two studies were assessed using the Cochrane risk-of-bias tool for randomized trials (RoB-2). Both studies had some concerns with ROB due to lack of a pre-specified analysis plan. We downgraded by 0.5.

^h One study showed an increase in heart rate and a second study showed a decrease in heart rate; therefore downgraded by 1 for inconsistency.

ⁱ The total number of participants was far less than the optimal number of 800 (n=77). We downgraded by 3 due to small sample size and wide confidence intervals.

^j One study showed an increase in diastolic blood pressure, while a second study showed a decrease in diastolic blood pressure; therefore, downgraded by 1 for inconsistency.

^k The number reported in this column reflects the number of primary studies reporting each outcome from the primary studies captured in the systematic review and meta-analysis results. There was one randomized control trial in this Cochrane review pertaining to this outcome (Almadhoob et al., 2020).

^l The review was assessed using the ROBIS tool for systematic reviews and had low risk of bias (ROB). Studies included in the review were assessed by the authors using the Cochrane ROB tool for RCTs; the authors also rated the RCT as overall low risk of bias. We did not downgrade.

^m The total number of participants was far less than the optimal number of 800 (n=14). We downgraded by 3.

ⁿ The total number of participants was far less than the optimal number of 800 (n=23). We downgraded by 3.

^o The study was assessed using the ROBINS-1, version 2 risk-of-bias tool. The study had some concerns with ROB due to lack of a pre-specified analysis plan. We downgraded by 0.5.

^p The total number of participants was far less than the optimal number of 800 (n=20). Therefore, despite the narrow confidence intervals, downgraded by 3.

^q The number reported in this column reflects the number of primary studies reporting each outcome from the primary studies captured in the systematic review and meta-analysis results. There was one randomized control trial in this Cochrane review pertaining to this outcome (Almadhoob et al., 2020).

^r The review was assessed using the ROBIS tool for systematic reviews and had low risk of bias (ROB). Studies included in the review were assessed by the authors using the Cochrane ROB tool for RCTs; the authors also rated the RCT as overall low risk of bias. We did not downgrade.

^s The total number of participants was far less than the optimal number of 800 (n= 24). We downgraded by 3.

^t The RCT was assessed using the ROB 2.0 tool for randomized control trials. The study had several domains of some concerns. We downgraded by 1.

^u The total number of participants was far less than the optimal number of 800 (n=63). We downgraded by 3.

^v The total number of participants was far less than the optimal number of 800 (n=17). We downgraded by 3.

^w The total number of participants was far less than the optimal number of 800 (n=63). We downgraded by 3.