ISRCTN13528343 https://doi.org/10.1186/ISRCTN13528343

A study of silent alarm delivery versus standard audible alarm delivery

Submission date	Recruitment status	[X] Prospectively registered
03/01/2026	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/01/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/02/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at registration.

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Does eliminating alarm noise cacophony for intensive care staff and patients improve burnout and encephalopathy levels

Acronym
DECIBEL

Study objectives
Determine the contribution of audible alarms to patient delirium, staff burnout and alarm fatigue in high dependency and intensive care units.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/10/2025, Cachar Cancer Hospital and Research Centre (Meherpur Road, Meherpur, Silchar, ASSAM, 788 015, India; +91 7005538196; admin@cacharcancerhospital.org), ref: ECR/925 /I n stl AS I 2017 / RR-21

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Prevention of delirium in adults receiving inpatient high dependency or intensive care.

Interventions
The intervention will consist of implementing a silent alarm delivery system that will communicate alarms to staff wirelessly using a bone conduction headset, which verifies human presence. This intervention falls back to normal audible alarm delivery if alarm delivery cannot be verified by electronic presence confirmation and manual response from the staff receiving the alarm notification. This intervention is designed to reduce auditory stimulation currently present in the high dependency and intensive care environments.

Brief Name: Silent Alarm Delivery System

Why: Alarm noise generated by medical devices is ubiquitous in the ICU environment. The ICU audible environment contains the sum of many overlapping individual alarms, which often leads to a high noise level and a nonspecific alarm signal for staff to interpret. High noise levels are linked to ICU delirium in critically ill patients, and frequent non-specific audible alarm signals are

thought to lead to staff alarm fatigue and to degrade staff response times to all alarms. The hypothesis is that a silent alarm system that delivers specific alarms to individually responsible staff will improve staff alarm response time and reduce patient delirium incidence and severity.

What: The intervention consists of the implementation of a silent alarm system in an ICU environment. The silent alarm system consists of a self-locating interface device, which is interposed between an alarm-generating device and its audio output. This device contains communication, locating, motion, logic, and relay chips, which enable the interface device to identify its location and staff responsible for that location, as well as to detect audio output from the alarm-generating device, and to control the audible state of that output. The Interface device can communicate with separate bone conduction headsets worn by staff, which contain sensors that confirm staff presence at the headset, and buttons for response to an alarm announcement. The interface device then delivers alarms silently to those staff specifically responsible for its location when a responsible staff member can be identified, confirmed to be present, and accepts responsibility for the alarm through button action on their headset. One touch screen kiosk per unit allows staff to manage their responsibility assignments. One Beacon is fixed at the head of each bed and provides a location reference for Interface Devices to use in self-locating, and also provides a screen for displaying staff responsibility for that location.

MindWave Medical is the provider of the silent alarm system. More details about the silent alarm system are available at http://www.mindwavemedical.com.

Who and How:
This intervention is provided at the ICU system level to mitigate noise for all staff and patients in the ICU within the intervention group. This is a systematic technical intervention provided through an engineering method. The silent alarm system is applied to cardiac monitors, IV pumps, and ventilators.

Where:
The study groups consist of Intensive and High Dependency Care units in India. These units are of open architecture with curtain separation of individual beds.

When and How Much:
The intervention will be applied continuously throughout the intervention period.

Tailoring, Modifications: N/A

How Well:
Alarm incidence and response data, as well as silent/audible alarm time and decibel monitoring, will assess the quality of the intervention.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Silent alarm delivery system using a wireless bone conduction headset, audible alarm delivery

Primary outcome(s)

1. Alarm fatigue, assessed from the response time from alarm initiation to staff response (headset button response) or alarm audio termination, measured using data collection on every alarm occurring on every participating device during the study and control periods, each lasting 4 weeks at one time point

2. Delirium severity measured using the Confusion Assessment Method (CAM) at every 12 hours

3. Global noise level, assessed by Decibel Level Monitoring (LAeq integrated at 10-second intervals and LCpeak for the same 10-second intervals), measured using the SoftDB Piccolo-II integrating decibel meter (SoftDB.com) at a continuous sampling rate through the intervention and control periods

Previous primary outcome(s):

1. Alarm fatigue, assessed from the response time from alarm initiation to staff response (headset button response) or alarm audio termination, measured using data collection on every alarm occurring on every participating device during the study and control periods, each lasting 4 weeks at one time point
2. Staff burnout measured using the Maslach Burnout Survery at days 0, 7, 14, 21, and 28 of the study and intervention periods
3. Delirium severity measured using the Confusion Assessment Method (CAM) at a daily assessment
4. Global noise level, assessed by Decibel Level Monitoring (LAeq integrated at 10-second intervals and LCpeak for the same 10-second intervals), measured using the SoftDB Piccolo-II integrating decibel meter (SoftDB.com) at a continuous sampling rate through the intervention and control periods

Key secondary outcome(s))
1. Nursing work measured using pedometer measurements at each nursing shift (adjusted for hours worked)

2. Total alarm time measured using data collected from continuous electronic monitoring at one time point

3. Proportion or silent to audible alarm time measured using data collected from continuous electronic monitoring at one time point

Completion date
28/04/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 06/02/2026:

1. Admission to an intensive care or high dependency care unit
2. Age greater than 18 years

Previous key inclusion criteria:

1. Admission to an intensive care or high dependency or intensive care unit
2. Age greater than 18 years

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 06/02/2026:

1. Patients with a previous diagnosis of dementia
2. Patients with a diagnosis of CNS trauma, infection, or malignancy as the reason for admission.
3. Patients currently requiring endotracheal intubation

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Previous key exclusion criteria:

1. Patients with a previous diagnosis of dementia
2. Patients with a diagnosis of brain injury leading to this admission
3. Patients currently requiring endotracheal intubation

Date of first enrolment
03/02/2026

Date of final enrolment
28/04/2026

Locations

Countries of recruitment
India

Sponsor information

Organisation
MindWave Medical Inc

Funder(s)

Funder type

Funder Name
MindWave Medical Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date