ISRCTN86243044 https://doi.org/10.1186/ISRCTN86243044

Sleep after intensive care study

Submission date
08/09/2025

Recruitment status
No longer recruiting

Registration date
11/09/2025

Overall study status
Completed

Last Edited
12/11/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people who have been in intensive care (ICU) experience unusual sleep problems after they go home. These can include panic on waking, strange dreams, or broken sleep. This study explores whether these symptoms could be linked to memories formed while patients were sedated and on a ventilator. The researchers aim to understand how these experiences affect sleep and will explore how sleep patterns differ between patients who were sedated and those who were not.

Who can participate?
Adults aged 18 years or over who spent at least 72 hours in ICU and are now well enough to leave critical care. Participants must be English-speaking and able to give informed consent. Some will have received sedation and ventilation during their ICU stay, and some will not. Those that were sedated and ventilated must have been so for at least 24 hours and must have been extubated in the ICU. Patients in the non-sedated group must not have received continuous sedation or mechanical ventilation for any part of their admission.

What does the study involve?
Participants will complete three short questionnaires at home, 2 weeks after discharge. These ask about sleep quality, ICU memories, and trauma symptoms. A small number of participants (8–10) with high sleep disturbance scores will be invited to take part in a one-off interview to explore their ICU experiences and sleep symptoms in more detail.

What are the possible benefits and risks of participating?
There is no direct benefit, but the study may help improve future support for ICU survivors and some participants may find it helpful to reflect on their experiences. There is a risk of emotional distress when discussing ICU memories. Support will be available throughout the study, and participation is entirely voluntary.

Where is the study run from?
The study is run from County Durham and Darlington NHS Foundation Trust, with recruitment taking place at both Durham and Darlington Hospitals (UK)

When is the study starting and how long is it expected to run for?
August 2025 to February 2026

Who is funding the study?
The study is funded by the NIHR via the Sheffield Hallam University Internship program (UK)

Who is the main contact?
Sally Horsley, sally.horsley@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Sally Horsley

ORCID ID
https://orcid.org/0009-0006-6253-1802

Contact details
3 Malkiln Cottages
Staindrop
United Kingdom
DL2 3AG
+44 (0)7985281075
sally.horsley@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
357332

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Sedation, memory and sleep disturbances after intensive care: a mixed-methods study

Study objectives
1. To explore the nature and prevalence of sleep symptoms in ICU survivors following discharge, including poor sleep quality, nightmares, and unusual sleep-related experiences.
2. To investigate whether these sleep symptoms are associated with memories of sedation and mechanical ventilation, including both explicit and implicit memory re-experiencing.

3. To compare sleep symptom profiles between ventilated and non-ventilated ICU patients, identifying any differences in memory-related sleep disturbances.
4. To qualitatively examine patient narratives about their ICU experiences and sleep symptoms, using semi-structured interviews to identify themes related to memory and recovery.
5. To inform future clinical support and rehabilitation strategies by identifying specific memory-linked sleep symptoms that may benefit from targeted psychological or therapeutic interventions.

Rationale:
This study is being conducted to explore whether sleep symptoms experienced by ICU survivors are linked to memories of sedation and mechanical ventilation, including implicit and explicit memory re-experiencing. The rationale is based on clinical observations that some patients report persistent sleep issues that improve when these symptoms are understood as memory-related rather than general sleep disturbance.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Single-centre mixed-methods observational cross-sectional study

Primary study design
Observational

Study type(s)
Other, Quality of life, Treatment

Health condition(s) or problem(s) studied
Post-intensive care syndrome (PICS), sleep disturbance, trauma symptoms, memory re-experiencing

Interventions
Current methodology as of 12/11/2025:
ICU patients will be invited to complete three questionnaires 4 weeks after discharge home. Questionnaires will ask about their ICU memories (ITQ - International Trauma Questionnaire), current sleep experiences (PSQI - Pittsburgh Sleep Quality Index) and symptoms of trauma /emotional distress (ICUMT ICU-Memory Types). 10-12 of the participants with high sleep scores will be invited for an hour-long semi-structured interview. Questionnaires and interviews will include both sedated/ventilated and non-sedated/ventilated patient groups. Questionnaire results will be analysed using descriptive statistics and Pearson's correlation; the sedated/no-sedated sub-groups will be compared using t-tests or non-parametric equivalents. Interviews will undergo reflexive thematic analysis to identify patterns in how patients describe their sleep experiences and ICU memories.

Previous methodology:
ICU patients will be invited to complete three questionnaires 2 weeks after discharge home. Questionnaires will ask about their ICU memories (ITQ - International Trauma Questionnaire), current sleep experiences (PSQI - Pittsburgh Sleep Quality Index) and symptoms of trauma

/emotional distress (ICUMT ICU-Memory Types). 8-10 of the participants with high sleep scores will be invited for an hour-long semi-structured interview and interviews will include both sedated/ventilated and non-sedated/ventilated patient groups. Questionnaire results will be analysed using descriptive statistics and Pearson's correlation; the sedated/no-sedated sub-groups will be compared using t-tests or non-parametric equivalents. Interviews will undergo reflexive thematic analysis to identify patterns in how patients describe their sleep experiences and ICU memories.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 12/11/2025:
Sleep experience/symptoms identified using the Pittsburgh Sleep Quality Index (PSQI), at least 4 weeks post-ICU discharge, completed once

Previous primary outcome measure:
Sleep experience/symptoms identified using the Pittsburgh Sleep Quality Index (PSQI), at least 2 weeks post-ICU discharge, completed once

Key secondary outcome(s))
1. Trauma/distress symptoms identified using the International Trauma Questionnaire (ITQ) at least 2 weeks post-ICU discharge, completed once
2. ICU memories identified using the ICU- Memory Tool (ICUMT) at least 2 weeks post-ICU discharge, completed once

Completion date
01/02/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. English-speaking (to ensure language accuracy of data collection)
3. Admitted to ICU for a minimum of 72 hours (to ensure sufficient exposure to the ICU environment relevant to the study aims)
4. No longer requiring critical care (downgraded to ward-level care)
5. Expected to be discharged home within the next 7 days
6. Able to provide informed consent
7. Score negative on a CAM-ICU assessment
8. Score 15/15 on a GCS assessment

For ventilated participants:
9. Must have received continuous sedation for ≥24 hours during ICU admission
10. Sedation depth must be confirmed by a RASS score of -3 or deeper (as documented in clinical records)
11. Must have been extubated within the ICU setting

For non-sedated participants:
12. Must not have received sedation or ventilation at any point during their hospital admission.

A subset of participants may be invited to take part in a one-off interview. Selection will be based on sleep symptom profiles, although matching across sedation groups may be limited due to timing and sample availability.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Documented diagnosis of severe cognitive impairment that would affect their ability to participate meaningfully (assessed via clinical records and/or clinician judgement)
2. Currently receiving end-of-life care
3. Non-English speaking
4. Transferring to another hospital

Date of first enrolment
01/01/2026

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road

Darlington
England
DL3 6HX

Sponsor information

Organisation
County Durham and Darlington NHS Foundation Trust

ROR
https://ror.org/03vamsh08

Funder(s)

Funder type
University/education

Funder Name
Sheffield Hallam University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The questionnaire datasets generated during the current study will be stored in a publicly available repository (e.g. Zenodo or Figshare). Anonymised excerpts from interview transcripts will be published with the results and may be made available upon request from Sally Horsley (sally.horsley@nhs.net).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes