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

Sleep after intensive care study

Submission date
08/09/2025

Recruitment status
Not yet recruiting

Registration date
11/09/2025

Overall study status
Ongoing

Last Edited
11/09/2025

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 that 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 have not 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?
Sheffield Hallam University (UK)

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

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
357332

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Sedation, memory and sleep disturbances in ICU survivors: 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)
Not yet submitted 29/08/2025, North East Newcastle and North Tyneside (tbc) (Address not provided, City not provided, Zip/postal code not provided, United Kingdom; Telephone number not provided; Email not provided), ref: Reference number not provided

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

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home, Hospital, Medical and other records, Telephone

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

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
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 participants with high sleep scores will

be invited for an hour long semi-structued interview. Questionnaires and interviews will include both sedated/ventilated and non-sedated/ventilated patient groups. Questionnaire results will be analysed using descriptive statistics and Pearsons correlation, the sedated/no-sedated sub-groups will be compared using t-tests or non-parametric equivelants. Interviews will undergo reflexive thematic analysis to identify patterns in how patients describe their sleep experiences and ICU memories.

Intervention Type
Not Specified

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

Secondary outcome measures
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

Overall study start date
29/08/2025

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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
01/11/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Sponsor information

Organisation
County Durham and Darlington NHS Foundation Trust

Sponsor details
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
United Kingdom
DL3 6HX

Sponsor type
Hospital/treatment centre

Website
https://www.cddft.nhs.uk/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

01/11/2025

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