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Does in-bed cycling, started within the first 2 days of an admission to ICU, reduce delirium in adults receiving mechanical ventilation?

Submission date
13/05/2024

Recruitment status
Recruiting

Registration date
23/05/2024

Overall study status
Ongoing

Last Edited
16/09/2024

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
Delirium is a state of severe confusion and can be a frightening experience; frequently it can cause patients to see or hear things that are not really there. This state can fluctuate throughout the day leaving patients confused about what is real or unreal. It occurs in up to 4 out of 5 patients who need support from an artificial breathing machine on ICU (mechanical ventilation - MV) and its effects may continue long after discharge from hospital, leading to a reduced quality of life and additional financial and social burdens on patients, families and health services. The causes of delirium are unclear but previous research has shown that delirium can be reduced if patients are more active. Therefore, it is possible that exercise could reduce delirium in ICU patients, but no evidence exists to answer this question. In-bed cycling may be the solution to exercise in severely unwell patients and this study is designed to assess if in-bed cycling for ICU patients receiving MV is possible. This study aims to investigate if in-bed cycling, started within the first 2 days of an admission to ICU, reduces delirium in adults receiving mechanical ventilation.

Who can participate?
Patients over the age of 18 years, who need a mechanical ventilator (artificial breathing machine) to breathe in the intensive care unit

What does the study involve?
The project is made up of three parts that will generate vital information for future researchers:
1. A small trial conducted at two hospitals in which patients receiving mechanical ventilation are randomly allocated to receive either in-bed cycling for up to 14 days in addition to usual care or usual care alone. The study will be designed to test how achievable it is to undertake in-bed cycling, how well it is tolerated by patients and if high-quality data can be collected. A number of patient-focused short and long-term (90-day) outcomes will be collected to help evaluate the study's success.
2. A sub-study will be undertaken at one of the hospitals to look at mechanisms that may cause delirium and whether in-bed cycling affects these mechanisms. The study will focus on how much oxygen there is in the brain and the level of inflammation in the body. Brain oxygen levels

will be measured using sensors placed on the patient’s forehead. Blood samples will be collected from lines already in place as part of usual ICU care. Information will be used to help gauge the level of exercise required in future studies and understand more about how delirium can be prevented.
3. A second sub-study will focus on interviewing study participants, family members and/or carers involved in the main study to evaluate their views on the study and their experience of in-bed cycling. This will help us understand how the research process worked and how it might be improved in the future.

What are the possible benefits and risks of participating?
All participants will continue to receive the care that they need and be monitored throughout their ICU stay. Participants in the in-bed cycle group may be at risk of increased stress on their bodies. This may include a high heart rate, breathing work, or increased agitation. However, the researcher with the ICU medical team will decide each day if the patient's participation in the research is appropriate. A safety assessment each day will be completed and the patient's observations will be monitored before, during and after in-bed cycling. The medical team and research team will be made aware of any concerns about potential increased stress on the patient's body. This will help to avoid any of the risks explained above. The in-bed cycling protocol will not be repeatedly carried out where participants demonstrate clear signs of distress.
There is no guarantee that patients will benefit from taking part in this study. Both groups may experience relief of symptoms or an improvement in their condition. However, information collected as part of their participation in this study may benefit patients with ICU delirium in the future.

Where is the study run from?
1. University Hospitals Plymouth NHS Trust (UK)
2. Torbay and South Devon NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2023 to April 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Jacqueline Bennion, Jacqueline.Bennion@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
337629

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 337629, NIHR 303338, CPMS 61574

Study information

Scientific Title
Does in-bed Cycling delivered within 48 hours of mechanical ventilation, rEduce the occurrence of Delirium in critically ill patients (FRECycl-D): a mixed-methods feasibility randomised controlled trial

Acronym

FRECycl-D

Study objectives
Feasibility of in-bed cycling to reduce ICU-delirium in mechanically ventilated patients

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/05/2024, South Central - Oxford C Research Ethics Committee (Health Research Authority 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8144; oxfordc.rec@hra.nhs.uk), ref: 24/SC/0096

Study design
Dual-site feasibility randomized controlled trial including a mechanistic sub-study and an embedded qualitative interview study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format. To request a PIS please contact the Chief Investigator: Jacqueline Bennion, Jacqueline.Bennion@nhs.net

Health condition(s) or problem(s) studied
Delirium in critically ill patients

Interventions
Participants will be stratified to site and randomised 1:1 using permuted block randomisation to receive either early (within ≤48 hours following invasive mechanical ventilation) in-bed cycling in addition to usual care vs usual care alone for 5 days per week across 14 days or until out-of-bed mobilisation begins (whichever comes first).

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability of early (within ≤48 hours following invasive mechanical ventilation) in-bed cycling to reduce ICU delirium in mechanically ventilated patients. The following measures will be collected to determine trial feasibility:
1. Recruitment rate (% of participants enrolled vs participants eligible)
2. Retention rate (% of enrolled participants who completed the intervention protocol in full

excluding deaths)
3. Intervention fidelity (% intervention sessions completed)
4. The acceptability of the intervention will be evaluated by the key stakeholders (assessed by qualitative interviews)
There will be no interim analysis therefore these measures will be collected up until the end of the study period. The end of the study period is defined as the date of the last follow-up visit of the last participant undergoing the study (via telephone or in-person).

Secondary outcome measures
1. Occurrence of ICU delirium measured using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) on days 0-14 and up to day 30
2. Delirium-free days (CAM-ICU) day-0-14, and up to day 30
3. Duration (days) of ICU-Delirium (CAM-ICU) days 0-14, and up to day 30
4. Severity of ICU-Delirium using the Confusion Assessment Method for the Intensive Care Unit 7 (CAM-ICU-7), delirium severity scale on days 0-14
5. Physical function measured using the Functional Status Score for the Intensive Care Unit (FSS-ICU) on day-14 or out-of-bed mobilisation (whichever comes first)
6. Quality of life measured using the EQ-5D-5L questionnaire and the SF-36 questionnaire at day 90. The quality of life of participants will also be measured from the perspective of their relative or carer using the proxy EQ-5D-5L questionnaire at day 90.
7. Pain measured using the SF-36 questionnaire at day 90
8. Cognition after ICU discharge assessed using the Montreal Cognitive Assessment (MoCA) on day 90
9. Presence of delirium after ICU discharge measured using the Family Confusion Assessment Method (FAM-CAM) at day 90
10. Time to delirium resolution (days) measured using time from delirium diagnosis to time delirium resolved in days/ patient health records
11. ICU and hospital length of stay (days) measured using days of ICU admission to discharge and days of hospital admission to discharge/patient electronic health records
12. Ventilator-free days (days) on days 0-30 measured using days spontaneously breathing i.e., nil invasive ventilator support required between day 0 and day 30 from randomisation/patient electronic health records
13. Sedation-free days (days) on days 0-30 measured using days nil sedation administered between day 0 and day 30 from randomisation/patient electronic health records
14. [Severity of sedation] measured using the Daily Richmond Agitation Sedation Scale (RASS) at day 0 to day 14 from randomisation or out-of-bed mobilisation commences (whichever comes first)
15. Adverse events measured using [adverse events related to the trial procedures and serious adverse events/electronic Case Report Form] at from day 0 to day 90 from randomisation
16. Deaths measured using eCRF and patient electronic health records at from day 0 to day 90 from randomisation

Overall study start date
01/10/2023

Completion date
30/04/2026

Eligibility

Key inclusion criteria

1. Adults (aged 18 years and above)
2. Unplanned ICU admissions
3. MV initiated within ≤48 hours of ICU admission
4. Expected to remain on MV >72 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
84

Key exclusion criteria
1. Contra-indications to mobilisation
2. Known or suspected cognitive impairment and/or learning difficulties
3. Plan is for palliation/withdrawal of treatment
4. Immobile prior to ICU admission
5. Body weight over the device safety limit (≥135 kg)
6. BMI <18.5 kg/m2
7. Planned ICU admission
8. Pregnancy
9. Prisoners

Date of first enrolment
30/07/2024

Date of final enrolment
30/01/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University Hospitals Plymouth NHS Trust
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PL6 8DH

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
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Sponsor type
Government

Website
http://www.plymouthhospitals.nhs.uk/home

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This programme of research is part of an NIHR Doctoral Fellowship (NIHR303338). Planned expected outputs of this research are detailed below:
A subsequent multi-centre RCT will inform best practice guidelines for the prevention and management of ICU delirium.
Findings will be shared with the research, healthcare and public communities by:
Publication in peer-reviewed, open-access journals:
Study protocol
Findings from the research
Presentations
Submissions of the research findings to relevant medical conferences.
Other
Collaboration with Southampton BRC, ICUsteps support groups, the Intensive Care Foundation, the South West Clinical Schools network, the South West Critical Care Community network, ACPRC, ICS, named local and international collaborators on the NIHR award, and associated public networks.
Publicising outputs through relevant professional networks, social media networks, and industry collaborators.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Jacqueline Bennion (Jacqueline.Bennion@nhs.net)

IPD sharing plan summary

Available on request