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Using brain wave recordings to detect and monitor delirium in older hospitalised patients

Submission date
20/07/2026

Recruitment status
Recruiting

Registration date
09/11/2026

Overall study status
Ongoing

Last Edited
09/11/2026

Condition category
Mental and Behavioural Disorders

[ ] 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 condition of sudden confusion and changes in awareness, affecting around 1 in 4 older patients in hospital at any given time, usually when someone is unwell for another reason. Delirium is very serious. It is linked to longer hospital stays, long-term memory problems, and an increased risk of death. However, it often goes unrecognised by healthcare professionals. At present, doctors and nurses assess delirium using bedside behavioural tests. These can be subjective and hard to interpret, particularly in patients who already have conditions such as dementia.
Electroencephalography (EEG) safely records the brain's electrical activity through the scalp, and could help detect delirium. However, traditional EEG needs expensive equipment, along with specialists to record and then interpret the signals. In the NHS, EEG is poorly available and there are not enough specialists. Newer portable EEG equipment is much easier to use, and can be fitted at the bedside by non-specialist staff.
This study aims to combine portable EEG with computer analysis to develop an automated, objective bedside measure of delirium. The goal is provide simple numbers describing brain function, similar to how a blood pressure reading gives a simple number describing the circulation.

Who can participate?
The study is open to:
1. Adults aged 65 years and over who are currently in hospital, expected to stay longer than 24 hours, who may or may not have delirium
2. Healthy adults aged 65 years and over living in the community, with no history of delirium, dementia, or other significant neurological or psychiatric conditions.
Delirium can affect a person's ability to make decisions about taking part. Patients in this situation can still join the study, provided a consultee – usually a relative or close friend who knows them well – agrees that taking part is in keeping with their wishes and feelings.
Participants may also be asked to name an informant: a partner, relative or close friend, ideally someone who has known them for 10 years or more, who can answer some questions about them. Having an informant is helpful but is not required to take part.

People cannot take part if they are on a ventilator, if their confusion is due to alcohol withdrawal, if they have severe scalp skin problems that would prevent an EEG recording, or if they are unable to consent and no consultee is available.

What does the study involve?
Participants take part in up to four types of assessment over about a year.
1. Baseline assessment (during the hospital admission, or at Imperial College London for healthy volunteers): a brain wave recording using a portable EEG headset, computerised memory and thinking tests done on a tablet or computer, a blood sample, and a clinical interview and examination. Hospitalised participants are also asked to wear a smartwatch, and to have a sleep sensor placed under the mattress and a small environmental sensor placed nearby.
2. Repeat assessments (hospitalised participants only): up to five shorter visits, about every 1 to 3 days during the hospital stay, including a portable EEG recording, a clinical examination, and thinking tests.
3. Follow-up assessment (about 6 months after discharge, or after the baseline visit for healthy volunteers): similar to the baseline assessment but without the standard clinical EEG. This can take place at the hospital, at Imperial College London, or at the participant's home.
4. Remote follow-up (about 12 months after discharge or baseline): by telephone or video call, including a short interview and computerised thinking tests.
The blood samples are taken in the same way as a routine hospital blood test. They are tested for markers of inflammation, of injury to nerve cells, and of neurodegeneration, and for genes involved in brain function, repair and neurodegeneration.
All assessments are carried out by trained members of the research team. Taking part is entirely voluntary, and it does not affect a participant's clinical care in any way.

What are the possible benefits and risks of participating?
Participants will not receive any direct medical benefit from taking part. The study may, however, lead to better tools for detecting and monitoring delirium in older hospital patients in future, which could benefit a great many people.
The risks of taking part are minimal. The portable EEG headset is non-invasive and painless, although the electrodes can occasionally feel slightly uncomfortable. The blood sample involves a small needle prick and can cause minor bruising.

Where is the study run from?
The study is sponsored by Imperial College London. It takes place across three Imperial College Healthcare NHS Trust hospitals: Charing Cross Hospital, Hammersmith Hospital, and St Mary's Hospital, all in London, UK.

When is the study starting and how long is it expected to run for?
September 2026 to April 2030

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

Who is the main contact?
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Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
350632

Central Portfolio Management System (CPMS)
72204

National Institute for Health and Care Research (NIHR)
302971

Protocol number
EDGE ref 181924

Study information

Scientific Title
The Delirium Electroencephalography and Phenotyping with Endpoints (DEPEND) study

Acronym
DEPEND

Study objectives
The primary study objective is to develop automated pEEG-based delirium classification and severity measures that detect and grade delirium in older acutely hospitalised patients.

The secondary objective is to examine inter-relationships between these pEEG-derived measures and multi-modal data, including clinical, behavioural, cognitive, blood, and outcome data.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/02/2026, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; cambridgecentral.rec@hra.nhs.uk), ref: 26/EE/0010

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Delirium

Interventions
This is a longitudinal observational study that involves assessing participants at multiple time points. It does not involve any invasive procedures and it will not interfere with the clinical care of participants.

The study is in people ≥65 years old, also called older people.

The following groups and numbers of participants will be recruited:
1. Older acutely hospitalised patients with possible delirium (n≈135)
2. Older acutely hospitalised patients without possible delirium (n≈70)
3. Healthy older people (n≈30)
Please note that the labels a-c are used hereafter for the three groups of participants.

The study additionally involves:
Informants: someone, e.g. a partner, relative, or close friend, ideally who has known the participant for 10 years or more, who can provide additional information about a participant, which is required for some data collection, and
Consultees: only required if a participant does not have capacity, this is someone who has known the participant well when they had capacity and is willing to be consulted specifically on what the patient’s wishes and feelings would be towards participating in the study.

It may be that the same person, e.g., a participant's marital partner, has the role of both Informant and Consultee, e.g., if that participant is unable to consent, and therefore a consultee is needed.

The duration of involvement of individual participants is expected to be just over 1 year.

The details of what happens to each participant will depend on which group (a-c) they are in. No study procedures will take place without appropriate consent.

The descriptions of the study procedures are based on our expectations of what will be possible in the ideal case. However, because of the possible impairments present in participants, particularly in hospitalised patients, the full range and form of procedures listed may not always be feasible or appropriate in each individual. Furthermore, some variation in the duration of procedures is expected, on account of clinical factors (e.g., the level of concentration of each participant) and technical factors (e.g., the time taken to attach equipment in an individual).

Relatedly, given the involvement of hospitalised patients, it may be that clinical factors (e.g., the need to undergo clinical procedures, medical deterioration) arise at times when study procedures were planned to take place, or as study procedures are under way. In all such cases, priority will be given to the clinical care of the participant.

The study from a participant's perspective is summarised in the following list, and then more description is provided afterwards.

Study overview for hospitalised patients (groups a & b):
×1 Screening
×1 Initial approach
×1 Consent
×1 Baseline assessment (during hospital admission) – involving Clinical interview, Clinical examination, portable EEG (pEEG) + Clinical-grade EEG (subset of participants), Cognitive battery, Blood test, Smartwatch (attached), Sleep mat (deployed), Environmental sensor (deployed)
×≈1-5 Rapid assessment/s (in hospital admission, ≈1-21 days post-baseline) – involving Clinical examination, pEEG, Cognitive battery
Once the participant (groups a & b) has been discharged:
×1 Follow-up assessment (≈6 months post-discharge, at Imperial College Healthcare NHS Trust, Imperial College London, or home) – involving Clinical interview, Clinical examination, pEEG, Cognitive battery, Blood test
×1 Remote follow-up assessment (at home, ≈12 months post-discharge) – involving a Remote clinical interview, Remote cognitive battery

Study overview for healthy controls (group c):
×1 Screening
×1 Initial approach
×1 Consent
×1 Baseline assessment (at Imperial College London) – involving Clinical interview, Clinical examination, portable EEG (pEEG) + Clinical-grade EEG, Cognitive battery, Blood test
×1 Follow-up assessment (at Imperial College London, ≈6 months post-baseline) – involving Clinical interview, Clinical examination, portable EEG (pEEG), Cognitive battery, Blood test
×1 Remote follow-up assessment (at home, ≈12 months post-baseline) – involving a Remote

clinical interview, Remote cognitive battery
Screening, initial approach, and consenting procedures are described in later, dedicated, sections.

Screening:
Potential hospitalised participants (groups a & b) will be identified by the following two routes:
1. Direct contact between the research team and ICHT clinicians (e.g., doctors, nurses, therapists) who are caring for hospitalised patients admitted at these ICHT hospitals (and would therefore have knowledge of potential participants)
2. Screening of the ICHT electronic health records (EHR) system for patients admitted at these ICHT hospitals by a member of the research team who (1) also has clinical responsibilities (e.g., as part of paid employment or an honorary clinical contract), and (2) could conceivably have clinical responsibility for the care of the hospitalised participants screened (including input as a clinical specialist), but need not be the lead clinician for these participants, and (3) already has clinical access to the EHR system as part of these responsibilities.

Potential healthy participants (group c) will be recruited from the following four routes:
1. Existing healthy volunteer databases held at Imperial College London (ICL),
2. By inviting friends or family members of patient participants, including their informants or consultees,
3. Existing healthy volunteer databases held at the NIHR Imperial Clinical Research Facility (ICRF), and
4. Existing healthy volunteer databases held at Join Dementia Research (JDR).

Initial approach and consent:
The approach and consent procedures are described in detail in A29 and B7; the following is a summary.
All participants are assumed to have the capacity to consent unless it is evident that they have difficulties with understanding information and making choices. The capacity of a patient to consent to research participation will be initially assessed during screening.

If this assessment, or the impression during the initial approach to a patient, concludes that the patient does not have capacity, the clinical care team will identify a suitable consultee, i.e., a person who has known the patient well when they had capacity and is willing to be consulted on what the patient's wishes and feelings would be towards participating in the project.

If no consultee can be identified, the patient will not be involved in the research.

Assessments:
This section, to be read in conjunction with summaries above, describes the details of assessments from the perspective of participants, including the types and locations of assessments, and what procedures will take place.

The four types of assessment are:

Baseline assessment (groups a-c):
A more detailed assessment carried out once in all participants, and similar for all participants (but not identical, e.g., since some aspects do not apply to healthy controls)

Rapid assessment/s (groups a & b only):
A shorter assessment carried out up to about five times, in hospitalised participants only, intended to be done periodically (every 1-3 days) during their stay.

Follow-up assessment (groups a-c):
A detailed assessment, similar to the baseline assessment, carried out once in all participants, and similar for all participants (but not identical)

Remote follow-up assessment (groups a-c):
A shorter assessment carried out once remotely (e.g., over the telephone from the participant's home or usual place of residence) in all participants, and similar for all participants (but not identical).

Locations:
There are several types of location for assessments:
In hospital admission (groups a-b only)
This location applies to Baseline and Rapid assessments. The assessments at this location will take place in the hospital where the patient is admitted, i.e., a hospital ward within Imperial College Healthcare NHS Trust (ICHT).

The research team will 'come to the patient' and carry out all the research procedures. The research team will work with the clinical care team to ensure that the research procedures do not interfere with the patient's care. The participant will be in their usual hospital bed. Baseline assessments at this location additionally involve attaching a smartwatch sensor, deploying a sleep mat under the bed mattress, and placing an environmental sensor nearby, but these activities require minimal or no action from the participant.

Imperial College London (groups a-c):
This location applies to Baseline (for group c) and Follow-up assessments (groups a-c). The assessment will take place at the UK Dementia Research Institute Care Research & Technology Centre (CR&T), 9th Floor, Sir Michael Uren Hub, Imperial College London, White City Campus, 86 Wood Lane, London, W12 0BZ. Participants and any carer will travel to/from this site. Participants will be reimbursed for their travel costs. They will be greeted upon arrival at reception by a member of the research team. A member of the research team will be with the participant throughout the visit/assessment. The research procedures will take place with the participant sitting in a private room at the CR&T.

Imperial College Healthcare NHS Trust (groups a-b only):
This location applies to Follow-up assessments, as an alternative to an assessment at Imperial College London (above), if (1) the participant is being seen in a clinic, which the clinical team may have referred to for clinical reasons, and (2) this is both convenient for the participant and possible for the research team, in terms of practicalities, and suitability for the timing of the assessment ~6 months post-discharge from hospital. In this case, the research team will have confirmed in advance that there is time and a suitable place at the site, e.g. in or nearby the clinic, to complete the assessment at the same hospital site as the participant's clinic appointment. A member of the research team will be with the participant throughout the visit /assessment. The research procedures will take place with the participant sitting in a private room.

At home (groups a-b only):
Given some of the participants in groups a & b may not be able to leave their homes on account of their medical problems, a member of the research team may be able to visit the participant at home, i.e., their place of residence, which could include a care home.

In the scenario where participants are living not at home but in, e.g., supported accommodation, care homes or nursing homes, no such residence would be considered a research site (i.e., no active staff involvement or record access), but rather the "place of residence" of the participant. In these cases, the research team will obtain local permission from the manager of the site (e.g. care home manager) in order to conduct the follow up visit on the premises. The sponsor's insurance covers researcher activities in these non-NHS premises.

Remote follow-up assessment at home (groups a-c):
This location applies to Follow-up assessments. The assessment will be carried out remotely by the research team, i.e., over the telephone, Teams, or Zoom, whichever the participant or consultee prefers. The participant will be based in their home, i.e., their place of residence, which could include a care home.

For the Follow-up and Remote assessments, arrangements will be made over the telephone or email with participants, their next-of-kin, or their consultees, and they will be reminded in advance of future assessments, by telephone, and optionally email.

Procedures:
From a participant's perspective, the following procedures will take place as part of the assessments. These procedures often involve collection of multiple items of data but are here described in terms of a participant's experience of the procedures. The number of procedures is shown in the summary above.

Clinical interview:
The participant will answer a range of questions from a research team member, including about their medical history, medications, social circumstances, and current problems. This will be similar to a consultation with a doctor. Some questions are from standardised questionnaires. The informant will also be asked questions, which complement
the information provided by the participant, e.g. in cases where the participant is not able to provide details because of memory impairment, and there will be some standardised questionnaires specifically meant for informants to provide a perspective on the participant.

A version of this interview will be performed remotely for the final (remote) assessment.

Clinical examination:
The participant will be examined by a research team member from a neurological perspective using standardised behavioural tests. This will include observation of the participant at rest, asking the participant questions (such as their name and address, the current date and location), asking the participant to follow commands, (such as opening the
eyes), and asking them to perform some tests, such as repeating back a sequence of numbers. For some hospitalised participants who have a low level of consciousness, this examination may require administering a brief painful stimulus like that used in standard clinical care to assess level of consciousness, e.g., a sternal rub (pressure over the breastbone); this is a standard procedure to grade consciousness in patients who are not already responsive and who do not respond to voice.

Portable EEG (pEEG):
The participant will have a portable electroencephalogram (pEEG), attached and recorded by a research team member. EEG is an entirely non-invasive recording technique, monitoring the brain's electrical activity from the scalp. pEEG involves the placement of ~20 'dry' electrodes within a cap placed on the scalp. This form of EEG is simpler and requires less preparation time compared to clinical-grade EEG (below). We will be using pEEG equipment that is specialised for

research purposes. The participant is not required to do anything for us to record an EEG, but they may be asked, e.g., to open/close their eyes for periods. There are no side effects from a pEEG. The electrodes and cap are not painful. They may occasionally feel slightly uncomfortable or leave a temporary red mark on the skin. Localised allergic reactions to any material on the skin are possible, but this is thought to be extremely unlikely.

In a subset of participants, a clinical-grade EEG will be performed near the time of pEEG, and once only, to allow direct comparison of signal quality. The participant is not required to do anything for us to record a clinical-grade EEG, but they may be asked, e.g., to open/close their eyes for periods. Clinical-grade EEG is the form of EEG already used in routine clinical care. It is similar to pEEG, but uses about 20 'wet' electrodes, attached individually to the scalp using a gel /paste. The set-up time is therefore longer. Two electrodes are attached to the shoulders to provide a simultaneous heart tracing. The electrodes are not painful. The material used to attach electrodes can leave some minor residue on the skin or hair afterwards which can be wiped away with wet cotton wool, and can leave a sticky feeling that comes out during normal washing.

Cognitive battery:
The participant will have cognitive tests, i.e., assessments of thinking, memory, etc., administered using a computer tablet (e.g. an iPad) or their own computer. This is carried out using an online platform called Cognitron, that involves a battery of up to 12 tests (including object memory, digit span, and verbal analogies). This is similar to playing simple computer games or puzzles. For in-person assessments (Baseline, Rapid, Follow-up), this will be supervised by a research team member. For remote assessments, this can be done by the participant from home using their own device. They will be sent a link to a website via their email address. If they do not have a device to complete the remote assessments, they will not have to complete them.

The cognitive tasks used have been previously used extensively in different research settings including in people with a range of medical and psychiatric problems. The cognitive tasks that the participant completes will vary according to their level of impairment, from no tasks at all (e. g. in those who have a low level of consciousness), to a range of tasks that tests different aspects of cognition. Participants will be able to take breaks in between tasks if needed.

Blood tests:
The participant will have a blood test, performed by a research team member. The blood will be taken in the same way as a routine blood test. The blood sample (up to about 25ml or two tablespoons of venous blood) will be used to test for inflammatory, neuronal injury, and neurodegenerative blood markers. We will also use this sample to look for genes involved in brain function, repair, and neurodegeneration. The blood samples will be stored and then processed in large batches. The technology for analysing the blood tests is called a "panel", which measures a large number (>100) of different molecules at the same time to provide a detailed characterisation.

Smart watch, sleep mat, and environmental sensor:
For patients in hospital (groups a-b), the participant will be given a "smart watch", attached by the research team, to wear continuously for up to thirty days during their hospital stay. This is like a normal watch, but it additionally continuously captures information about movement, heart rate, and some other physiological information. The research team will retrieve the data from the watch about once a week, which does not require any action from the participant. The watch will be removed before hospital discharge.

The research team will also place an environmental sensor near the patient but out of the way of any clinical equipment or belongings. This is like the device a parent might use to monitor their

baby's bedroom environment. This sensor records the room temperature and light levels. It is thought that the hospital environment can sometimes contribute to the development of delirium. This sensor could therefore provide some useful additional information about this possibility as well as information about the range of environmental conditions in all patients studied.

In addition, the research team will place a pressure sensor under the hospital bed mattress. This 'sleep mat' continuously senses a participant's movement and aspects of their heart rate and breathing rate when they are in bed.

It also contains a microphone to identify snoring, but no sound recordings are saved. Some people use these devices to track their health at home.

The research team will retrieve the devices when the patient is discharged or after thirty days of hospital stay, whichever is sooner, which does not require any action from the participant.

Sleep mat installation at home:
Additionally, following discharge, in addition to use of the sleep mat in hospital, for patients in hospital (groups a-b), and with the participant's (or consultee's) permission, if the participant has a home internet connection, the same 'sleep mat' device will be installed under the participant's own mattress in their home, i.e., place of residence, which
could include a care home. This is to gather the same information in the home setting, to compare it with the data from hospital and the other data collected. It plugs into the mains electricity but uses very little power. It connects to the internet either via a cellular data hub or via existing WiFi.

The device is easy to install, and it will either be (1) posted to the participant to self-install, or with the help of someone else in the residence, or (2) installed by the research team, with the appropriate permission. Installation usually takes up to half an hour. Having the device in the home does not require the participant to do anything. In the unlikely event that the device stops working (e.g., data is no longer being collected, something we will be able to detect remotely), we will contact the participant about this and arrange to fix or replace it. The research team will also arrange collection of the sleep mat at the time of the 6 month follow-up assessment, either asking the participant to bring it to the appointment or collecting it from the participant's place of residence.

End of study:
After the 12-month remote follow-up assessment, participation in the study will end for all participants (groups a-c).

Intervention Type
Other

Primary outcome(s)
Automated portable electroencephalography (pEEG)-based delirium classification (delirium present/absent) and delirium severity score, validated against DSM-5 delirium diagnosis. Severity grading is validated against the Memorial Delirium Assessment Scale (MDAS; range 0–30). This will be measured at baseline, up to five rapid assessments during hospital admission, and 6-month follow-up.

Key secondary outcome(s)

1. Delirium severity measured using Memorial Delirium Assessment Scale (MDAS; range 0–30) correlated with automated portable electroencephalography-based measures; Timepoint(s): Baseline, rapid assessments (days 2–21 of hospital admission), 6-month follow-up
2. Functional outcome measured using Extended Glasgow Outcome Scale (GOSE); Timepoint(s): 6-month follow-up
3. Normalisation of automated portable electroencephalography measures following delirium resolution measured using Automated machine learning analysis of portable electroencephalography signals recorded using the Zeto New Wave headset, compared between acute admission and follow-up; Timepoint(s): Baseline, 6-month follow-up
4. Inter-relationships between electroencephalography measures and multi-modal biomarker and outcome data measured using Correlation of automated portable electroencephalography measures with clinical assessments (Confusion Assessment Method, Montreal Cognitive Assessment), blood biomarkers (inflammatory, neuronal injury, and neurodegeneration markers), wearable sensor data (smartwatch, sleep mat), environmental sensor data, genetic data, and electronic health record data; Timepoint(s): Baseline, rapid assessments (days 2–21 of hospital admission), 6-month follow-up, 12-month follow-up

Completion date
30/04/2030

Eligibility

Key inclusion criteria
For hospitalised patients (groups a-b):
1. Age >=65 years
2. Clinically likely to be admitted for >24 hours
3. Able to consent or an available consultee

For healthy participants (group c):
1. Age >=65 years
2. No history of delirium, dementia, or other significant neurological or psychiatric disorder

Healthy volunteers allowed
Yes

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
For all participants (groups a-c):
1. Intubated
2. Delirium due to alcohol withdrawal
3. Unwillingness or anticipated inability to follow all the study procedures
4. Severe scalp skin lesions (e.g., extensive broken skin) that would preclude EEG
5. Lacking capacity to consent and no available consultee

6. Any other medical or psychiatric condition or any treatment which, in the opinion of the investigators, would interfere with the study or compromise patient safety

Date of first enrolment
14/09/2026

Date of final enrolment
31/01/2030

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
England
W6 8RF

Study participating centre
Hammersmith Hospital
Du Cane Road
London
England
W12 0HS

Study participating centre
St Mary's Hospital
Praed Street
London
England
W2 1NY

Study participating centre
NIHR Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
Shepherd's Bush
London

England
W12 0HS

Study participating centre
UK DRI Care Research & Technology Centre
Imperial College London, Sir Michael Uren Hub, 86 Wood Lane
London
England
W12 0BZ

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

ROR
https://ror.org/056ffv270

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

Individual participant data (IPD) sharing plan

Anonymised multi-modal data generated by this study, including EEG recordings, clinical, cognitive, and outcome data, will be made available via a publicly accessible data repository at study completion, subject to applicable ethical and data governance requirements. Analysis code will be made openly available (e.g., via GitHub).

IPD sharing plan summary

Stored in publicly available repository