ISRCTN98883107 https://doi.org/10.1186/ISRCTN98883107

Improving research and care for people with traumatic brain injury

Submission date
12/08/2026

Recruitment status
Recruiting

Registration date
15/09/2026

Overall study status
Ongoing

Last Edited
15/09/2026

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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
Traumatic brain injury (TBI) affects millions of people worldwide and can have long-lasting effects on physical health, thinking, emotions, and quality of life. However, doctors and researchers still do not fully understand why people recover differently after similar injuries. Better information is needed to improve diagnosis, predict recovery, and develop more effective treatments for future patients. The 3P Study is part of the UK TBI-REPORTER programme, a national research initiative designed to improve understanding of traumatic brain injury. The study aims to test whether researchers across hospitals in the UK can collect information in a consistent way from people with different types and severities of TBI. Researchers will collect information from medical records, brain scans, blood and other biological samples, brain activity recordings, and follow-up assessments of recovery. The information gathered will be used to create a national research resource that will support future studies and help improve the care and outcomes of people living with traumatic brain injury.

Who can participate?
Adults diagnosed with a traumatic brain injury who receive care at a participating hospital.

What does the study involve?
Participants will be asked to allow researchers to collect information about their injury and treatment, provide blood samples, take part in follow-up assessments, and may also be invited to have brain scans and brain activity tests.

What are the possible benefits and risks of participating?
Taking part is unlikely to benefit participants directly, but the information collected may help improve understanding, diagnosis and treatment of traumatic brain injury for future patients. Risks are low but may include discomfort or bruising from blood samples, inconvenience from study visits, and possible discomfort during MRI scans or other assessments.

Where is the study run from?
University of Cambridge, UK.

When is the study starting and how long is it expected to run for?
The study started in June 2025 and is expected to finish in March 2029.

Who is funding the study?
UK Research and Innovation (UKRI) Medical Research Council, UK.

Who is the main contact?
Joanne Outtrim, TBI-REPORTER@medschl.cam.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
None TBI-REPORTER Study team -

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Additional identifiers

Integrated Research Application System (IRAS)
351717

Central Portfolio Management System (CPMS)
66498

Medical Research Council (MRC) Grant Codes
MR/Y008502/1

Study information

Scientific Title
TBI-REPORTER prospective proof of principle study

Acronym
3P Study

Study objectives
The 3P TBI reporter study aims to:
1. Establish the feasibility of a standardised, national TBI (Traumatic Brain Injury, Head Injury) reporting network
2. Refine a core data and biosample collection protocol for acute and chronic TBI studies to be

further utilised across the TBI REPORTER platform
3. Evaluate the clinical feasibility of the TBI REPORTER data repository
4. Provide pilot data for sample size calculation in future EMN studies

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/05/2025, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; cambridgecentral.rec@hra.nhs.uk), ref: 25/EE/0055

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Injuries to the head

Interventions
The 3P study is a prospective observational study that will recruit up to 350 TBI patients across all severity levels at 7 sites over 24 months. Patients will be enrolled upon hospital presentation (ED, ward, ICU and clinic) and followed for up to 2 years to track their recovery from acute injury onward.

The 3P data collection will be divided into five groups based on clinical care pathways at enrolment:
- ED cohort: patients evaluated in the ED and discharged (n=100)
- Ward cohort: patients admitted to the hospital but not to ICU (n=100)
- ICU cohort: patients admitted directly from the ED or other hospital to the ICU (n=100)
- Chronic cohort: patients presenting more than 6 months after initial TBI (up to 50)
- Healthy volunteers: volunteer subjects at each centre for MR study (up to 100)

All patients will be screened for eligibility before informed consent is obtained. In the case of patients who are assessed as not having capacity, a consultee/proxy will be approached as set out in the Mental Capacity Act 2005/Adults with Incapacity (Scotland) Act 2000. There are core data modules to which patients can take part, although some parts of the study may not be available depending on local resources. The 3P baseline data clinical variables will be prospectively collected from all enrolled patients, through medical records and personal interviews, and will include, for example:
• Demographic information
• Socioeconomic information
• Medical history
• Mechanism of injury
• Pre-hospital clinical course variables
• Brain CT report

• Emergency department clinical course
• Hospital admission clinical course
• Hospital therapies, surgeries and neuromonitoring
• Admission and discharge information
• Acute care outcome evaluation
• Biomarker samples
• 12-lead ECG and rhythm strip

The 3P study will collect bodily fluid samples (blood, CSF, urine, and faeces) to identify substances that may influence the body's response to and recovery from TBI.

Centres in the MR data collection arm will use 3 Tesla scanners for MR brain scans. Some will perform ultra-early scans within 72 hours of TBI, while others will scan within 5 days, aiming to scan all patients within 2-3 weeks. Each participant will typically have two MRIs: one during the acute stage and one at follow-up (6, 12, or 24 months). Chronic cohort participants may have up to four MRIs over 24 months.

Patients may be invited for follow-up visits over 2 years, including blood sampling, neurocognitive tests, and quality-of-life questionnaires at various time points. At sites with MRI and EEG facilities, additional MRI scans and EEG tests may be done. The length of visits will vary, as some tasks, like questionnaires and cognitive tests, can be completed online or by phone.

Intervention Type
Other

Primary outcome(s)
1. Feasibility of recruitment and retention from enrolment to study completion (up to 24 months) measured using data collected from study records on participant recruitment and retention rates at the end of the study

2. Feasibility of standardised data collection up to 24 months measured using data collected from study records on the completion of clinical, biosample, MRI, EEG and outcome assessment datasets at recruitment and scheduled follow-up visits at the end of the study

Key secondary outcome(s)
1. Characterize TBI and identify endotypes for interventional studies measured using data on clinical features, neuroimaging, and blood biomarkers at ?

2. Functional outcome measured using the Glasgow Outcome Scale Extended (GOSE) at scheduled follow-up assessments [?]

3. Health-related quality of life measured using the EQ-5D and Quality of Life After Traumatic Brain Injury Overall Scale (QOLIBRI-OS) at scheduled follow-up assessments [?]

4. Cognitive function measured using the Cognitron cognitive assessment platform at ?

Completion date
01/03/2029

Eligibility

Key inclusion criteria
3P acute cohort inclusion criteria:
1. Clinical diagnosis of TBI
2. Consideration for CT scan based on NICE screening criteria
3. Presentation within 24 hours of injury
4. Informed consent/consultee agreement obtained according to local and national requirements
5. > = 18 years of age

3P chronic cohort inclusion criteria:
1. Clinical diagnosis of TBI
2. Consideration for CT scan based on NICE screening criteria
3. > = 6 months after TBI
4. Informed consent obtained according to local and national requirements
5. > = 18 years of age
6. Able to engage with biosample, MRI and outcome assessments

Healthy volunteer inclusion criteria:
1. > = 18 years of age
2. Informed consent agreement received

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
3P acute cohort exclusion criteria:
The following will be assessed on a case-by-case basis:
1. Severe pre-existing neurological disorder that would confound outcome assessments. In practical terms, this would exclude individuals who, because of a neurological disease, would be assessed as having pre-injury moderate disability (or worse) on the Glasgow Outcome Score (GOSE < 6).
2. Patients who may have difficulties in understanding written or verbal information in English that would limit their ability to consent and complete the outcome assessments.
3. Patients who have a catastrophic injury where death is expected within 24 hours of injury.

Chronic cohort exclusion criteria:
The following will be assessed on a case-by-case basis:

1. Severe pre-existing neurological disorder that would confound outcome assessments. In practical terms, this would exclude individuals who, because of a neurological disease, would be assessed as having pre-injury moderate disability (or worse) on the Glasgow Outcome Score (GOSE < 6).
2. Patients who have difficulties in understanding written or verbal information in English that would limit their ability to consent and complete the outcome assessments.

Healthy volunteer exclusion criteria:
1. Significant neurological or systemic disease (American Society of Anaesthesiologists Grade 1 or 2)
2. History of TBI requiring hospital attendance or medical input

Date of first enrolment
12/06/2025

Date of final enrolment
01/03/2029

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
St. Marys Hospital
Praed Street
London
England
W2 1NY

Study participating centre
Kings College Hospital
Denmark Hill
London

England
SE5 9RS

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
Scotland
EH16 4SA

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
Scotland
G51 4TF

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
De-identified data generated and/or analysed during this study will be made available through the Dementias Platform UK (DPUK) Data Portal (https://portal.dementiasplatform.uk/), subject to relevant approvals and governance requirements. Approved researchers from academic, healthcare, governmental, or commercial institutions will be able to access the data through the secure DPUK/TBI-REPORTER Trusted Research Environment for scientifically and ethically approved research purposes. Data will be made available following study completion and publication of primary findings and will remain available in accordance with repository policies. Only de-identified data will be shared, with access governed by participant consent, ethical approvals, data protection legislation, and applicable data access agreements.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			12/08/2026	No	No