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Using home monitoring technology to study the effects of traumatic brain injury on older multimorbid adults: protocol for a feasibility study

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To cite: Parkinson ME, Dani M, Fertleman M, *et al*. Using home monitoring technology to study the effects of traumatic brain injury on older multimorbid adults: protocol for a feasibility study. *BMJ Open* 2023;**13**:e068756. doi:10.1136/bmjopen-2022-068756

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-068756).

Received 12 October 2022
Accepted 03 May 2023

Check for updates

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ABSTRACT

Introduction The prevalence of traumatic brain injury (TBI) among older adults is increasing exponentially. The sequelae can be severe in older adults and interact with age-related conditions such as multimorbidity. Despite this, TBI research in older adults is sparse. Minder, an in-home monitoring system developed by the UK Dementia Research Institute Centre for Care Research and Technology, uses infrared sensors and a bed mat to passively collect sleep and activity data. Similar systems have been used to monitor the health of older adults living with dementia. We will assess the feasibility of using this system to study changes in the health status of older adults in the early period post-TBI.

Methods and analysis The study will recruit 15 inpatients (>60 years) with a moderate-severe TBI, who will have their daily activity and sleep patterns monitored using passive and wearable sensors over 6 months. Participants will report on their health during weekly calls, which will be used to validate sensor data. Physical, functional and cognitive assessments will be conducted across the duration of the study. Activity levels and sleep patterns derived from sensor data will be calculated and visualised using activity maps. Within-participant analysis will be performed to determine if participants are deviating from their own routines. We will apply machine learning approaches to activity and sleep data to assess whether the changes in these data can predict clinical events. Qualitative analysis of interviews conducted with participants, carers and clinical staff will assess acceptability and utility of the system.

Ethics and dissemination Ethical approval for this study has been granted by the London-Camberwell St Giles Research Ethics Committee (REC) (REC number: 17/LO/2066). Results will be submitted for publication in peer-reviewed journals, presented at conferences and inform the design of a larger trial assessing recovery after TBI.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Home monitoring systems can passively collect large amounts of high temporal-resolution activity and sleep data from a person's own environment. This technology allows for a unique, patient-centred approach to research, incorporating data collection around people's lives.
⇒ The study will recruit older adults with traumatic brain injury (TBI), a group which is underrepresented in current research.
⇒ The study builds on work done with community-dwelling people with dementia and focus groups with patients with TBI. The protocol has been designed using prior insights gained into what is practical and achievable.
⇒ As this is a feasibility study, we are recruiting small numbers of a specific population, for a limited duration. The extent to which trajectory of recovery in our cohort can be extrapolated to larger or different clinical populations may be limited. In addition, our study will not be able to assess longer-term outcome. A comparator group will not be included as this study aims to focus on the feasibility of assessing health at an individual level. However, this will limit understanding of potential issues arising in older adults with TBI, compared with healthy older adults or older adults with chronic neurological condition.
⇒ We are recruiting patients from a UK major trauma centre and tertiary neurosciences unit, which may not reflect the wider population with TBI.

INTRODUCTION

The prevalence of traumatic brain injury (TBI) among older adults is increasing faster than any other age group, primarily due to low-energy trauma from falls.[1] Despite the scope of the problem, post-TBI outcomes in older adults remain understudied.[2] There is a particular paucity of data on the early post-discharge period after TBI when older adults are vulnerable to complications such as repeated injuries.[3]

Survivors of TBI can suffer from long-term physical, cognitive and behavioural consequences.[4–6] These include sleep disorders,[7] autonomic dysfunction,[8–10] memory and attentional problems,[11 12] and mood and

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behavioural difficulties.[11 13] The sequelae can be severe in older adults[2] and can interact with age-related conditions such as multimorbidity. Traditionally, TBI studies have excluded people with prior health conditions,[2 14] therefore not reflecting real-world clinical populations. Consequently, little is known about the interaction between common comorbidities, such as dementia[15] and TBI. There is a need for greater inclusivity in TBI trials to study the effects of these interactions.

Inexpensive sensors, using wireless technology, can be used to unobtrusively monitor patients in their homes.[16] These systems capture millions of continuous observations of daily activity,[17] providing unprecedented insight into the 'real-world' effect of health conditions on patients' lives. The continuous monitoring of daily sleep and household activity patterns can offer a valuable insight into a patient's health status, cognition and functioning.[16 18–23] In previous work, we applied machine learning algorithms to large physiological and environmental datasets from sensor systems used to monitor people living with dementia.[16 18] We found that deviations from usual data patterns relate to clinically significant changes in an individual's health, such as agitation and urinary tract infections.[16]

Continuous home monitoring can capture information beyond that acquired during infrequent clinical or laboratory-based visits and has potential to provide more relevant outcome measures for studies of interventions in TBI. For example, using high-resolution data to detect changes in health status or predict clinical outcomes, rather than relying on an individual's deviation from group average features, could make it possible to use *n-of-1* statistical approaches to assess the efficacy of interventions, helping to mitigate the heterogeneity within populations with TBI.

TBI is a common cause of hospitalisation in an ageing population and will place increasing pressure on health services in years to come. Sensor systems enable real-time transfer of health data directly to clinicians, researchers, family and carers, allowing them to track the progression of health conditions, and better target support from health and social care teams.[21 22] For patients whose insight and recall are affected by impaired cognition, an episode of acute illness may be heralded by a reduction in activity, rather than traditional signs of illness.[24] Therefore, passive sensors offer an attractive solution, free of compliance issues, for detecting early health-related changes in vulnerable patient groups. These systems are gradually being introduced within the National Health Service to enhance clinical decision-making[25] in hospital at home settings and other community-based models of care, but there is an urgent need to develop these systems further, to meet the challenges facing acute services.[26]

To date, studies using home monitoring systems have focused on chronic neurological conditions, such as dementia.[16 18 21–23 27] We hope to assess the feasibility of using home sensing technology to monitor health status following acute events such as TBI. The results will inform the design of multicentre trials to fully explore the trajectory of TBI recovery and the suitability of these systems as tools for delivering care for older adults.

METHODS AND ANALYSIS

The aim

The study aims to assess the feasibility and acceptability of using sensor systems to study clinically relevant changes in older adults' health (through monitoring changes in activity and sleep patterns over time) following moderate to severe TBI.

The objectives

- To assess the feasibility of recruiting older adults with TBI from the inpatient setting.
- To assess if it is feasible to determine clinically relevant changes in the health of older adults post-TBI, by analysing sensor-derived measures of activity and sleep.
- To assess whether data acquired are of sufficient quantity and quality to be able to develop machine learning algorithms capable of detecting clinical events.
- To understand the acceptability of the study procedures, including installation, maintenance of the system and the ability of participants to adhere to repeated assessments.
- To evaluate patient and carer acceptability of home monitoring systems.

Study design

This is a feasibility study that has been developed by the primary researcher in collaboration with clinicians and patients. The design has been informed by the Imperial Neurotrauma Centre study of clinical outcomes after TBI and the UK Dementia Research Institute Care Research and Technology's (DRI CR&T) study into community populations living with dementia. We will perform qualitative analysis to understand any challenges around recruitment, data acquisition and acceptability to participants.

Study setting

Participants will have the sensor system installed in their homes. Other assessments will be conducted in the settings outlined in figure 1.

Participants

We will recruit 15 inpatients aged over 60 years with moderate-severe TBI.[28] We will include adults with multimorbidity including people living with dementia. Eligibility criteria are outlined in figure 1.

Recruitment

Participants will be recruited as inpatients from the acute medical units, major trauma centre and neurorehabilitation ward within a London Trust. Hospital-based contacts working with the patients will help identify participants, whom the research team will screen using electronic health records.

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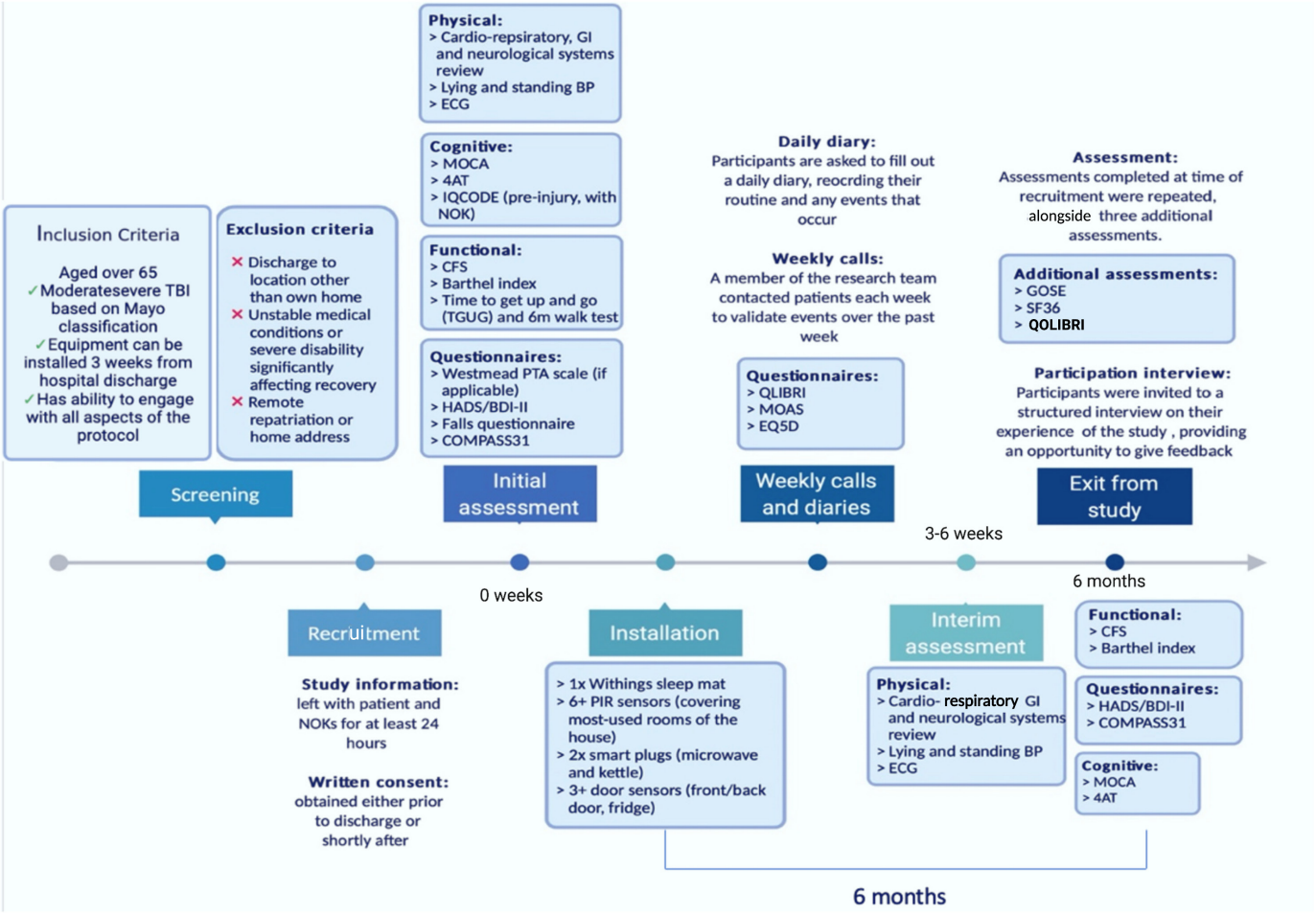


Figure 1 Schematic outlining study inclusion and exclusion criteria, study timeline, assessments and procedures. The Mayo criteria is chosen as it uses readily available positive clinical evidence of brain injury and impaired function, such as loss of consciousness and post-traumatic amnesia (PTA) and is felt to be a better predictor of long-term outcomes in comparison with pure imaging or GCS-based severity scoring criteria in TBI. Created with BioRender.com. BDI-II, Beck Depression Inventory; BP, blood pressure; CFS, Clinical Frailty Score; COMPASS31, Composite Autonomic Symptom Score-31; GCS, Glasgow Coma Scale; GI, gastrointestinal; GOSE, Extended Glasgow Outcome Scale; HADS, Hospital Anxiety and Depression Scale; IQCODE, Informant Questionnaire on Cognitive Decline in the Elderly; MOAS, Modified Overt Aggression Scale; MOCA, Montreal Cognitive Assessment; NOK, next of kin; PIR, passive infrared; QLIBRI, Quality of Life After Brain Injury; TBI, traumatic brain injury;4-AT, Alertness, Abbreviated Mental Test-4, Attention and Acute change or fluctuating course; EQ-5D, A standardised measure of health-related quality of life developed by the EuroQol Group to provide a simple, generic questionnaire for use in clinical and economic appraisal or population health status surveys;SF-36, 36-Item Short Form Survey.

The researchers will approach patients and carers on the ward, providing verbal and written study information, and invite them to participate. The hospital team and participants' carers will be involved in the decision-making process. Potential participants and carers will have at least 24 hours to consider participation and ask questions.

If a patient is unable to provide fully informed consent in an inpatient or outpatient setting, we will enrol them only if there is a favourable declaration of advice from next of kin or personal/nominated consultee. Should the patient regain capacity, retrospective patient consent will be sought.

If patients are agreeable, written consent will be taken from the participant or designated personal consultee and other household members. It will be made clear that participants may refuse participation or withdraw at any stage and it will not affect their usual medical care.

Sample size calculation

Similar studies applying machine learning approaches to in-house activity and sleep data to monitor patients' health have guided our sample size and monitoring period calculation.[18 23 27 29] For detecting within-participant deviations, numbers of participants may be less important than the length of monitoring period for each participant. For example, a previous study that collected data in 12 people with dementia over 3 months was able to train algorithms predicting episodes of agitation.[18] Our previous experience with recruitment in the larger Minder study suggests that 17% of patients approached to participate in this type of study consent to

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take part and the dropout rate is 13%. Consideration will be given to the potential challenges of recruiting from an acute setting and ongoing disruption to research access from COVID-19 measures. There are approximately three admissions per week at our recruitment centre fulfilling eligibility criteria. Therefore, we aim to identify 85 potential recruits over 28 weeks, and recruit 15 patients to account for dropout.

Trial status

The first participant was recruited in October 2021. We are still actively recruiting. We have screened 263 potential recruits and consented 12 patients. One patient was readmitted to hospital on the proposed day of installation. Eleven patients have been enrolled and installed. One of the main challenges has been as a result of our recruiting from a major trauma centre. Patients are transferred out as soon as specialist trauma care is no longer required and many potential recruits have been repatriated to local centres where we do not yet have access. Access to these centres will be sought for future studies. Enrolment is expected to last at least until May 2023.

Outline of study visits and procedures

Initial assessment

Baseline assessments (figure 1) will be carried out to determine the participant's premorbid function and early post-injury function. Information on medical history and medication will be obtained. The Informant Questionnaire on Cognitive Decline in the Elderly,[30 31] which has been used in previous studies to screen for pre-stroke cognitive impairment,[32] will be used to screen for pre-TBI cognitive impairment for patients without a formal dementia diagnosis.

Installing and briefing

The sensors we will install and an example of their placement are shown in figure 2. Sensor placement will be specific to each household dependent on the rooms they use most frequently. Participants will also be offered a Withings smartwatch to record person-specific activity.

Home monitoring

Household activity

The households in the study will have sensor systems installed consisting of passive infrared (PIR) movement

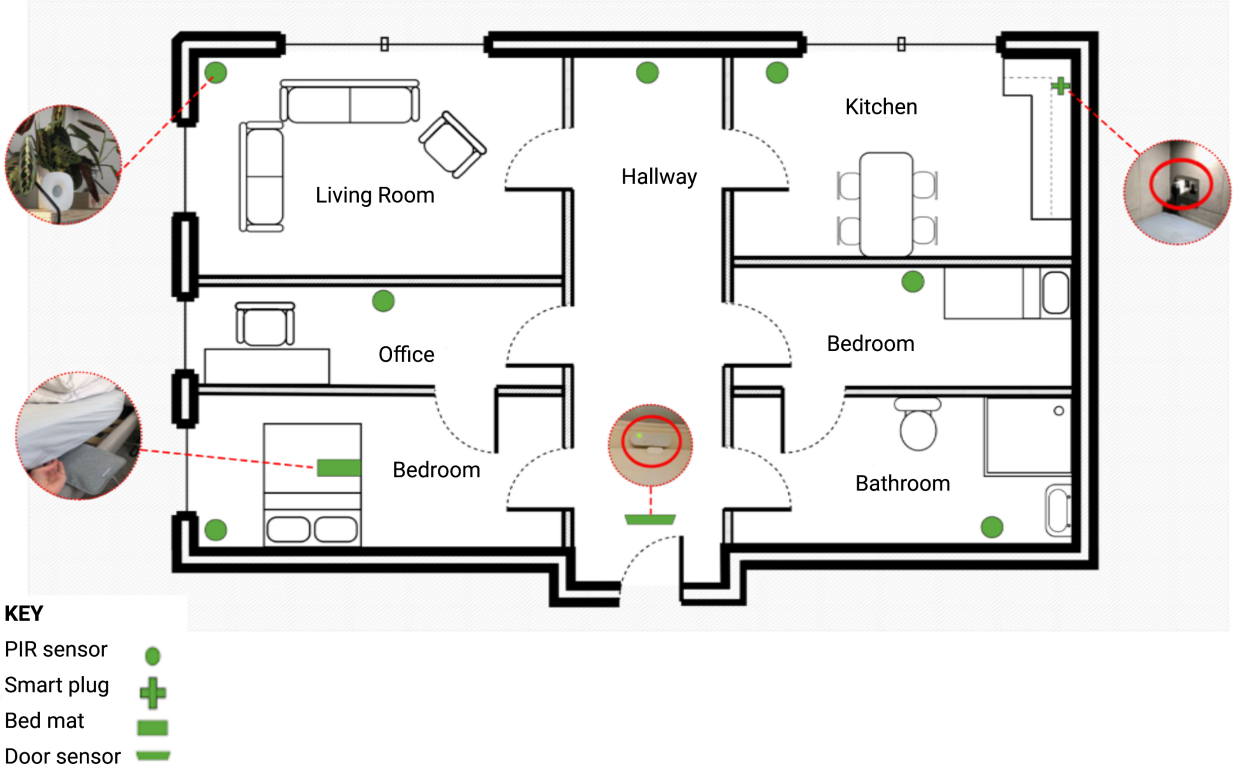


Figure 2 Diagram showing pictures of sensors to be used in study and schematic illustrating how sensors may be placed in the participant's home. The system will include five passive infrared (PIR) motion sensing units, four magnetic door sensors, two smart plugs and the Withings bed mat that communicates with a base unit. Door sensors record any opening or closing, and smart plugs record electrical use as a proxy for appliance use. The base unit receives binary data from the sensors via a wireless protocol and sends it to the cloud in real time. The PIR sensors measure light temperature and heat. They sense movement up to 9 m away from the sensor with a view angle of 45° up/down and left/right.[58] In our study, we obtain maximum sensitivity at around 3 m and have set the 'off-time' to 30 s (sensors detect the presence or absence of motion every 30 s). The Withings bed mat passively captures minute-by-minute heart rate, respiratory rate and movement using pneumatic sensors. The bed mat is waterproof and is placed out of sight underneath the mattress. The mat was developed in collaboration with sleep physicians at Hôpital Béclère and validated against polysomnography.[59]

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sensors which detect door opening, smart plugs which detect appliance usage and a bed mat that can determine when a person is in bed (figure 2). PIR sensors and door sensors will be placed in the rooms households use most often, to best capture the participant's routine. Data from the sensors will be used to derive metrics of activity as described in our outcomes.

Both single and multiple occupant households will be included in the study. Activity recorded by PIR sensors will reflect the entire home, accepting that occupants are interdependent, and that an individual's ill health is likely to have collateral effects on the activity patterns of the whole household.[33 34] Where possible, participant-specific activity will also be captured with an activity watch and bed mat.

Notes will be kept on all household participants' daily routines (including household pets) to enable labelling of the sensor data. In households with pets, sensors can be placed above head height to minimise possible interference.

The data will be reviewed weekly for anomalous activity, for example, night-time activity in multiple rooms. Participants and carers will be able to view data via an app. It will be made clear to participants and family during the consent process that the data will not be viewed live by researchers and that participants must continue to use usual care pathways.

Sleep activity and physiology

A bed mat that uses pneumatic sensors to detect heart rate, respiratory rate and movement in bed will be placed under the participant's mattress (figure 2). Data from the environmental sensors (PIR sensors) and the bed mat can be used to derive metrics of sleep, for example, the number of exits from bed, as well as the number of PIR activations that occur in different rooms throughout the house at night. If the participant's partner does not have a history of brain injury, they may be offered a mat to provide control data.

Weekly phone call and daily activity diary

We will collect information about participants' activities, sleep and clinical condition through weekly semistructured phone calls to participants or a proxy. Participants or proxy will also be encouraged to complete a daily diary. We will check for specific events (eg, falls, medication changes, issues with continence, unplanned seeking of medical advice, changes in the composition of the household or changes to care requirements) and collect quality of life questionnaire data.

Interim assessment

We will carry out an early functional assessment (figure 1). This visit will also be an opportunity to proactively address concerns and technical issues. To maximise participation and to be flexible to participants' needs, participants may decline the interim assessment without being excluded.

Exit assessment

All assessments highlighted in figure 1 will be repeated with the addition of TBI-specific outcome questionnaires. This will enable tracking of cognition, physical health and functional ability and will enable these more commonly used measures to be compared with continuously acquired data obtained from the sensors.

Qualitative assessment

When participants have exited the study, through completion or dropout, they will be asked to participate in a semistructured exit interview to seek feedback about their experience. Relevant clinical staff will also be interviewed about the acceptability and utility of the system.

Outcomes

Baseline clinical and demographic data will be gathered (table 1).

Sensor-derived metrics

Activity

Metrics of activity will be derived using data from the PIR sensors, door sensors and activity watch. We will measure the total daily PIR sensor activation per room, total daily room transitions, total daily step count and the total daily time spent outside the house. We will assess changes in quantity and sequences of activity over time to examine for correlations with changes in health and overall trajectory of recovery.

Sleep

The bed mat sensor detects movement (ie, whether the participant is in or out of bed or restless) as well as heart rate and respiratory rate, through activation of pneumatic pressure sensors (figure 2). We will assess the following variables using the Withings bed mat in conjunction with data from the environmental PIRs: total number of hours in bed and number of night-time exits from bed. Subjective measures of the quality and quantity of sleep will be collected through questionnaires, diary entries and phone calls.

Clinical assessments

Multiple clinical assessments will be repeatedly measured across the duration of the study. We will identify appropriate outcome measures for the larger trial.

Autonomic function

Autonomic dysfunction can occur in the chronic phase of TBI[8 35] and is linked to poor functional outcomes.[8 9 35] We will assess autonomic function with heart rate variability collected from the bed mat[8 10] and sit to stand blood pressure measurements. Autonomic symptoms will be assessed using the Composite Autonomic Symptom Score-31 questionnaire.[36]

Frailty

Frailty is defined as 'multidimensional syndrome of loss of reserves (energy, physical ability, cognition, health)

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Table 1 Summary of outcome measures detailing assessments to be carried out and the period over which they will be measured

Concept	Assessment	Administration
Activity	**Minder smart home monitoring equipment** *Household* Passive infrared sensors Door sensors Smart plug *Individual* Withings activity watch Sleep mat *Validation* Patient's diary Weekly questionnaire	0–6 months
Sleep	*Home monitoring equipment* Wearable Withings watch *Validation* Patient diary Weekly questionnaire	0–6 months
Autonomic function	Composite Autonomic Symptom Score Lying standing blood pressure Heart rate variability	0–3 weeks, 3–6 weeks, 6 months
Frailty	Rockwood Clinical Frailty Score	0–3 weeks, 3–6 weeks, 6 months
Motor performance	Timed up and go test 6-metre walk test	0–3 weeks, 3–6 weeks, 6 months
Quality of life	EQ-5D Quality of Life After Brain Injury	Weekly 0–6 months
Function	Barthel Index Timed up and go test 6-metre walk test Extended Glasgow Outcome Scale	0–3 weeks, 3–6 weeks, 6 months
Cognition	Montreal Cognitive Assessment Computerised cognitive battery	0–3 weeks, 3–6 weeks, 6 months
Neuropsychiatric complications	Hospital Anxiety and Depression Scale Beck Depression Inventory-II Modified Overt Aggression Scale	0–3 weeks, 3–6 weeks, 6 months

that give rise to vulnerability'.[37] We will assess frailty with the Rockwood Clinical Frailty Score (a 7-point measure of frailty based on clinical judgement).[37]

Motor performance

Standardised measures of gait speed, the timed up and go test and 6-metre walk test will be used to measure motor performance.[38 39]

Quality of life

Quality of life (QOL) will be assessed using the EQ-5D,[40] the SF-36 and the QOL After Brain Injury Scale.[41 42]

Functional outcome

Functional outcome will be assessed using the Barthel Index, which is commonly used in post-TBI studies.[43 44] In addition, the Extended Glasgow Outcome Scale, a TBI-specific questionnaire which assesses disability and social participation, will be used.[45]

Cognition and neuropsychiatric complications

Cognitive function will be tested using a computerised system developed for repeated testing of cognitive function post-TBI over time. Scores are reported compared with a normative cohort of >100 000 healthy individuals.[46] Cognitive impairment will also be assessed and tracked using the Montreal Cognitive Assessment.[47]

The Hospital Anxiety and Depression Scale is used as a screening tool for symptoms of anxiety and depression.[48] The Beck Depression Inventory-II is designed to measure the severity of depressive symptoms.[49] Both have been used in numerous studies post-TBI.[12 13 50]

The 4AT will be used as an initial screening tool for delirium.[51] To measure post-TBI aggression and irritability, we will use the Modified Overt Aggression Scale,[52] a scale that has been widely used in the population with TBI.[53]

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Table 2 Key steps in thematic analysis approach to reviewing qualitative data from patient interviews

Steps of framework analysis	Method
Familiarisation	The research team familiarise themselves with the data by repeatedly reading the interview transcripts and listening to recordings of the interviews.
Identification of a thematic framework	The research team will independently read and apply codes to key themes in the transcripts, then meet to discuss the key themes they have identified and think about how to build an initial framework. This process is repeated until no new themes are generated and a final framework is agreed.
Indexing	The thematic framework that has been developed is the one systematically applied to the interview transcripts using a qualitative data management package (QSR NVivo V.14). The codes that can be used to address the research question will then be organised into categories that reflect common themes in the data.
Charting	A matrix will be created for each theme by charting and summarising data from each participant and the codes within each theme.
Mapping and interpretation	Thematic analysis will then be carried out on the dataset. The matrices will be reviewed, and connections will be drawn between codes and for individual participants. This process will be informed by the original research objective and any new concepts derived during the process of data analysis.

Feasibility of trial design and procedures

- Recruitment strategy and rates (feasibility of recruitment from major trauma wards)—percentage of patients screened, eligible, approached, consented and excluded after screening.
- Compliance and adherence to weekly phone calls and repeated assessments.
- Completion rates—percentage of participants who complete the 28-week monitoring period (not dropping out or being withdrawn from the study).
- Acceptability and reasons for decline/withdrawal—number of participants who withdraw or decline the study and reasons why. Reasons will be recorded in the order of most common; this will help the researchers understand the reasons for dropout or declining to participate.
- Experience participating in the study—participants and carers will be invited to take part in a structured interview aimed at understanding their experience of the study. Clinical staff will be interviewed about the clinical utility of the system.

Data analysis

Quantitative data analysis

Sensor-derived metrics of sleep and activity

Activity

Data from the PIR sensors, smart plugs, door and bed mat sensors are accessed and preprocessed using DCARTE, a set of Python tools developed in-house.[54] Metrics for the assessment of activity during the day and night are the total number of PIR activations and the number of night-time PIR activations (sensor firings between 00:00 and 06:00) and daily step count. We will look at both absolute values and values normalised for the number of household members. The number of room transitions (ie, number of hourly transitions between bedroom and bathroom) is associated with well-being and cognition as well as motor function and will be calculated daily as described by Schutz *et al*.[23] Total time spent outside will be calculated using algorithms developed in previous work.[17] We will assess changes in activity by plotting aggregated data for each individual over time for each metric of activity, for example, the average number of PIR activations per week.

Sleep

The total number of hours in bed and number of night-time exits from bed will be calculated using data from the bed mat and PIR sensors and analysed as described above.

Mapping health status and trajectory of recovery post-TBI

In previous work, data from sensors have been mapped (visualised) over time to detect behaviour patterns accompanying a change in a patient's health status.[22] The mean number of daily PIR sensor activations per room over time will be plotted using Python to create maps of the data for each participant. This will be complemented by data from the bed mat to capture sleep and night-time behaviour patterns. A case-by-case descriptive analysis of the trajectory of recovery will be carried out, using data from the weekly calls in conjunction with the activity maps.

We will also seek to quantitatively detect anomalous within-participant activity with different detection approaches. For example, baseline night-time activity for each room will be calculated as the average overnight activity from week 1 to 4 of monitoring. A room will be deemed to have abnormally high night-time activity if its weekly average night-time activity is >2.5 SD above the baseline. This approach will also be used to detect weeks with abnormally low or high daytime activity and room transitions.

Exploratory analysis will be carried out to determine whether there are correlations between sensor-derived metrics and standard functional outcome assessments. For example, we will test for a correlation between 6-month Barthel score and the number of weeks with higher than baseline night-time activity in rooms other than the bedroom.

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Prediction of clinical events

We aim to evaluate the feasibility of developing algorithms capable of predicting clinical events, such as falls, with an accuracy of >80%. We will initially test similar machine learning algorithms used by Enshaeifar *et al*[16 18] that were able to detect urinary tract infections in community-dwelling adults living with dementia.

Machine learning algorithms will use continuously collected data from the sensors. Input predictors will consist of sensor-derived activity and sleep metrics as described above. Outcome measures will be the occurrence of a clinical event and its nature (eg, seizure, fall or hospital admission). Clinical events will be deduced from information collected from the daily diaries and weekly phone calls. This will create a set of labels to train and test the machine learning models.

We aim to develop models that can adapt to changes in the environment and be resilient to working with noisy and multivariate data. We will adopt semisupervised machine learning models to extract latent features and patterns from unlabelled data (episodes in the time series data where we are unaware of clinical events).

Then, a smaller set of labelled data will be used with the extracted patterns and latent features to train predictive and risk assessment models. We will also use entropy and change analysis methods to quantify activity and sleep pattern variations. The latter will allow us to conduct trend analysis and create risk scores associated with anomalies in sleep and movement patterns.

The training phase will use the combinational datasets from five participants' homes over 3 months. We will use a larger dataset from our dementia study to improve the training and will apply cross-validation and generalisation assessments. The training phase algorithms will then be used in data from 10 participants' homes over 6 months, to test their ability to detect clinical events.

Further details on how the machine learning methods will be developed and tested are included in online supplemental materials.

Qualitative data analysis

To assess the acceptability of system and perceived utility and benefit to our participants, we will conduct interviews using a predefined topic guide and aim to explore the impact of the system on the participant's and their carer's daily life as well as the system's ease of use, perceived effectiveness for detecting clinical events and any suggestions for improvement. Interview data will undergo thematic analysis by the research team, a method that is well suited to the analysis of interview data where it is necessary to identify themes by comparing individual cases.[55 56] Interview data will be entered into NVivo[57] line by line. Coding and analysis will be informed by Gale *et al*'s description of thematic framework analysis[55] (further details are included in table 2). Thematic analysis will be used to systematically determine key themes from the patient and healthcare interviews, for example, 'effect of the sensors on a patient's sense of independence' or 'practicalities of maintaining the system'. The key themes that have been identified will be used to guide improvements to the system, future trial design and clinical use of the system.

Patient and public involvement

No patient and public involvement (PPI) work was done for this specific study. However, the PPI work carried out by the UK DRI CR&T as a whole was used to inform the design of this study. This involved focus groups as well as individual interviews of the participants in the broader Minder study about their experience of different monitoring equipment and protocols, as well as discussions with 'Minder Champions', who are individuals involved in the Minder study and who have volunteered to test out and give feedback on changes to monitoring procedures.

ETHICS AND DISSEMINATION

The study follows the UK Policy Framework for Health and social care Research and General Data Protection Regulation (GDPR) 2018. The study has ethical approval granted by the London-Camberwell St Giles Research Ethics Committee (REC) (REC number: 17/LO/2066). The current approved protocol is version 6 dated 2021.

Data will be stored according to Imperial College London's information governance guidelines. The data from sensors and wearables are stored under a code on the Minder platform, operated by Imperial College London. The Minder platform is hosted within a privately managed Kubernetes cluster in Azure's UK South data centre; the Azure subscription lies with Imperial College London's information technology. Remotely collected data will be stored without any identifying information. The code will be paired with identifiable data in databases which are stored on the Imperial College London's Research Data Store service and hard copies in locked offices within the laboratory buildings. Imperial College London will act as the data controller for the study. Researchers will have patients' names, contact numbers, emails and home addresses for the purpose of arranging visits.

Participants can withdraw from the study at any time but information that has already been collected will be used, unless the participant requests that it not be.

Trial results will be submitted for publication in journals and presentation at conferences, such as neuroscience conferences, clinical neurology conferences, brain injury-specific conferences, neurotechnology and engineering conferences, machine learning conferences and geriatrics conferences. This study will also be presented at Imperial College London, DRI and relevant charity outreach events.

Acknowledgements The research was supported by the National Institute for Health and Care Research (NIHR) Brain Injury MedTech Co-operative based at Cambridge University Hospitals NHS Foundation Trust and University of Cambridge. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Collaborators Acknowledgement list for UK Dementia Research Institute (UK DRI) Care Research & Technology (CR&T) Centre publications using the MINDER core

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Funding Equipment and technology costs are covered by the NIHR Brain Injury Med Tech Co-operative 2019 Funding Round (award/grant number: NA). LL is funded by an NIHR Clinical Lectureship.

Disclaimer The views expressed are those of the author(s) and not necessarily those of the NIHR or UK DRI as a whole.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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Supplement 1

Machine learning algorithms will be developed by applying two approaches: classification methods and designing probabilistic state transition models to analyse the sequences of continuous combined sleep mat and environmental data. The input data will consist of sleep and household activity data, and the predicted events will be the verified clinical events ascertained from weekly phone calls.

The aim is to develop models that can adapt to changes in the environment and be resilient to work with noisy and multivariate data. For the classification, we will test a semi-supervised model by combining Convolutional Deep Neural Networks (for unsupervised feature extraction from large unlabelled data) and a probabilistic classification method such as the Gaussian Process Logistic Regression model (for training a supervised model using the extracted features and using a smaller set of labelled data consisting of events marked with the Withings event marker or diary and verified through phone interview). For the household activity sequence analysis and training the state transition model, we will use Hierarchical Hidden Markov Models.

The training phase will use the combinational datasets collected from 5 patients' homes over 3 months. To avoid overfitting, we will use a k-fold cross validation to test and validate the algorithms. The algorithms developed during the training phase will then be implemented in 15 patients' homes over 6 months, to test their ability to detect clinical events.