HRB Open Research

HRB Open Research 2022, 4:66 Last updated: 16 OCT 2023

STUDY PROTOCOL

REVISED Traumatic brain injury epidemiology and rehabilitation in Ireland: a protocol paper [version 2; peer review: 1 approved, 2 approved with reservations]

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v2 **First published:** 15 Jun 2021, **4**:66
https://doi.org/10.12688/hrbopenres.13209.1
Latest published: 22 Sep 2022, **4**:66
https://doi.org/10.12688/hrbopenres.13209.2

Abstract

Background: Traumatic brain injury (TBI) is a leading cause of death and disability worldwide. In Ireland, a dearth of research means that we neither know the number of people affected by TBI, nor have the required data to improve neuro-rehabilitation services. This is a study protocol to examine the epidemiology and pathways through rehabilitation for a cohort of TBI survivors in the Republic of Ireland.

Aims:

1. To document the epidemiological data of TBIs in Ireland.
2. To explore the pathway of TBI survivors through rehabilitation/health services.
3. To document the experiences of those providing care for TBI survivors in Ireland

Methods: This is a quantitative cohort study. Existing routine datasets will be used to report epidemiological data. Participants with moderate or severe TBI will be recruited through two brain injury service providers, two acute hospitals that provide neurosurgical services, and the National Rehabilitation Hospital. Participants with TBI will be surveyed on two separate occasions, to explore their use of health and rehabilitation services. Those providing care or support to TBI survivors will be surveyed, on one occasion. Additionally, data

Open Peer Review

Approval Status ? ✓ ?

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version 2 (revision) 22 Sep 2022		✓ view	? view
version 1 15 Jun 2021	? view	? view	

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from the medical records of TBI survivors will be extracted to capture key information about their TBI, such as mechanism of injury, severity, hospitalisation and follow-up. TBI survivors' use of health care will be followed prospectively for six months.

Expected outcomes: The epidemiological data of TBI in Ireland will be documented. Data on survivors' experiences of how rehabilitation services are accessed, and any barriers encountered with rehabilitation/health services will be reported. The experiences of those providing care or support for TBI survivors will be captured. It is expected that the outcomes of the study will support advocacy efforts toward the redevelopment of neuro-rehabilitation services in the Republic of Ireland.

Zurich, Switzerland

Any reports and responses or comments on the article can be found at the end of the article.

Keywords

Traumatic Brain Injury, TBI, Head Injury, Brain Injury, Rehabilitation, Epidemiology, Health Services, Health Priorities

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Competing interests: No competing interests were disclosed.

Grant information: Health Research Board [APA-2016-1880], under Applied Partnership Award Grant: Acquired Brain Injury Ireland and Headway.
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: O'Donnell K, Healy A, Burke T *et al.* **Traumatic brain injury epidemiology and rehabilitation in Ireland: a protocol paper [version 2; peer review: 1 approved, 2 approved with reservations]** HRB Open Research 2022, **4**:66 https://doi.org/10.12688/hrbopenres.13209.2

First published: 15 Jun 2021, **4**:66 https://doi.org/10.12688/hrbopenres.13209.1

REVISED **Amendments from Version 1**

Revisions made for this version include editing, correction of sources and additional details (supported by evidence) on items raised by the reviewers. 'Cohort study' is added to the title. The rationale, aims, and expected outcomes are clearly stated and aligned. This is an extensive quantitative cohort study with substantial outcomes expected. The study design has been clarified, and the methods are expounded on to allow replication. Details on existing routine datasets such as the Major Trauma Audit, Hospital In-Patient Enquiry, The National Physical and Sensory Disability Database and the Central Statistics Office are presented. We have clarified the 6-month follow-up re the TBI survivors' use of health and rehabilitation services. We appreciate that the study will not accurately reflect all service use and that is not our intention, rather we want to learn accessibility and appropriateness of service use by the TBI survivor. The level of severity is modified to 'moderate *or* severe' and we are predominately using the term 'carers' in lieu of 'family members' throughout the revised manuscript. LOC and PTA have been added to the classification of TBI and as well as a note on the extraction of CT and MRI results from the patients' medical records. Equity of access was replaced by 'inequity' and expounded upon as defined by WHO. Reasons for the choice of instruments (by experienced neuro researchers) are provided. We have provided additional data with new citations on the economic consequences of TBI. Effects of Covid-19 are also addressed, in particular, how the pandemic affected recruitment and data collection which has significantly delayed the progress of this study.

Any further responses from the reviewers can be found at the end of the article

Introduction

Traumatic brain injury (TBI) is the disruption to normal brain function caused by an exterior force or penetrating injury[1] and along with spinal cord injury, is the largest cause of death and disability of trauma-related injuries worldwide[2]. TBI can have long-term sequelae, including a wide range of cognitive, sensory, behavioural, emotional and physical impairments, and social and socio economic consequences for individuals, families, communities and societies[1–3]. A lack of formal surveillance or reporting systems for TBI has led to difficulties in establishing the magnitude of the problem in Ireland. In Europe, 7.7 million people and 5.3 million people in the United States (US) are living with disabilities related to TBI[2,3]. European incidence rates of TBI are estimated to be 262 per 100,000 population per year[4,5], while the United Kingdom incidence rates are estimated at 238 per 100,000[6] and more than 2.5 million TBIs are recorded in the US each year[1,3]. In Ireland the incidence and prevalence of TBI is unknown and there is no national mechanism for "capturing the incidence, management and outcome of TBI presenting" to the health care system[7] (p.9). Indeed, no unique ICD-10 code exists for TBI, making it difficult for epidemiologists to identify TBIs from routine data[8].

In Ireland, it is estimated that 40% of brain injury survivors will have a moderate or severe disability resulting in unmeasured personal, societal and economic consequences[7] and up to 150,000 people need neuro-rehabilitation on an ongoing basis[9]. The international evidence[10] is reflected in Ireland where survivors of TBIs are often discharged from acute care facilities to inappropriate placements, such as nursing homes, or to their own homes, where rehabilitation services may not be available locally[11]. There are considerable gaps in rehabilitation-service provision, as well as excessively long delays in accessing inappropriate services[11]. A lack of reliable data concerning patient groups that require neuro-rehabilitation undermines the planning of such services[9,12], for instance, there is disparity in service availability geographically[11]. Efforts to map this disparity have been complicated by the fact that referrals cannot be made to services that do not exist, creating difficulties in demonstrating demand[11]. Furthermore, Ireland has insufficient numbers of Physical Rehabilitation Medical Specialists with only 9 available of the recommended 27 PRMS for Ireland's population size[13]. All these challenges influence the rehabilitation pathways of individuals with TBI in Ireland.

Substantial economic consequences can be a major factor for brain injury survivors, their families and society. However, rehabilitation can improve the quality of life and reduce the hospital length of stay, therefore decreasing cost[14]. In adults with severe brain injury, specialised rehabilitation is highly cost-efficient[15] and promotes better health outcomes[16,17]. Health 'inequities' can have noteworthy social and economic costs for individuals and societies as well. The World Health Organization defines health inequities as "systematic differences in the health status of different population groups"[18(para 2)]. For example, in the context of TBI survivors, access to rehabilitation services is lower in rural areas, meaning that health inequities can occur because of inaccessibility[19]. The patient's geographical location, and health systems that require patients to self-advocate, also contributes to inequitable access to rehabilitation internationally[19].

Responsibility for the provision of care frequently falls to the families of TBI survivors, who report feeling unprepared for the task[20,21]. Individuals with a brain injury may be discharged home without an understanding by themselves or their family members, of the long-term consequences of their condition[22]. This can result in a significant burden to family members. The transition from acute care to the community presents challenges[20,21], for instance, delays in accessing rehabilitation may result in unnecessary disability[22] impacting rehabilitation potential and functional independence[23]. Losses in functional independence, loss of social networks, and occupational roles, can increase the survivor's reliance on family members[22], while changes in family roles can create tension and emotional difficulties[21]. Financial pressures associated with loss of earnings and extra costs, such as housing adaptations and transport, add to the family burden[21]. Findings from international studies indicate that family members often act as advocates and are vital to the long-term rehabilitation of individuals with TBI[19,20]. Furthermore, the availability of an advocate is a significant factor in successfully accessing rehabilitation services[20]. The role and wellbeing of families and family caregivers are, therefore, important considerations in the rehabilitation pathways of individuals with TBI.

Timely access to acute care services can limit the impact to the patient, of the primary head injury and its secondary complications, while access to ongoing rehabilitation can maximise functional recovery[19]. The British Society of Rehabilitation Medicine (BSRM) guidelines for the management of rehabilitation following serious injury, propose that the rehabilitation pathway begins in the acute care phase of treatment. At this point, rehabilitation medicine consultants should identify the rehabilitation needs of the TBI survivor and direct them to appropriate rehabilitation services, expediting such referrals where necessary. The treatment setting is based on the complexity of the identified needs, with low complexity cases being treated on a local level[24]. Difficulties in accessing rehabilitation arise however, where there is a reliance on acute care practitioners to discharge patients to the appropriate clinical services[10] and a lack of organisation and systematic follow-up in rehabilitative ensues[20].

Rehabilitation typically focuses on the restoration of motor and functional recovery to the same level of function as prior to the injury[25]. Rehabilitation can be non-specialised (motor and functional activities), or specialised, for instance a cognitive rehabilitation program[17]. Rehabilitation pathways provide a streamlined approach to the appropriate service, ideally involving an interdisciplinary team within a multi-service system. Integrated trauma systems (across services and multidisciplinary teams) are associated with decreases in trauma-related mortality, can facilitate clinical change[16] and contribute to the demand for effective rehabilitation pathways. Turner-Stokes and colleagues' review of multidisciplinary rehabilitation for adults with acquired brain injury (ABI)[23] suggested that the provision of rehabilitation services should be organised around need rather than diagnosis, and that the ongoing rehabilitation needs of an ABI survivor could be appropriately met in outpatient and community settings.

Ireland's Neuro-rehabilitation Strategy[26] and subsequent implementation framework[11] address deficits in rehabilitation provision through reconfiguring and integrating the systems that currently form the rehabilitation care pathway. An interdisciplinary approach to holistic rehabilitation, to be provided across the continuum of care, is proposed by the Health Service Executive (HSE)[11]. The strategy includes accessibility at four levels: primary care for lower level therapy needs; geographically based *Community Neuro-rehabilitation Teams*, providing specialist services to meet moderate therapy needs; regional neuro-rehabilitation services, accepting referrals from acute hospitals, specialist centres and community teams, to meet high level therapy needs, and national neuro-rehabilitation services, providing a high level of therapy for complex cases[9,11]. *Managed Clinical Rehabilitation Networks* will coordinate services to ensure timely and equitable access to rehabilitation[11]. Despite this vision, progress with the implementation of the strategy is slow and indeed, many concerns and challenges reflected in neuro-rehabilitation policy documents published since 2001 continue to be key challenges today[12]. These include a lack of epidemiological data and a lack of knowledge around the level of service need[11,12,26]. In Ireland, data is warranted to demonstrate the need for, and the effectiveness of, rehabilitation programmes for people with TBI[12].

It is expected that the findings from this research study will contribute to the literature on TBI in Ireland in a number of ways. The research team aims to document the epidemiological data of moderate or severe TBI, describe patterns of associated disability, and document the rehabilitation experiences of TBI survivors in Ireland. We will also assess the burden of TBI on family members, health services, and the Irish society, and translate the research findings into a workable knowledge translation plan for TBI stakeholders.

Providing epidemiological data of TBIs in Ireland and reporting on the individual, family, societal and economic consequences[1] of moderate or severe TBI, will help to advocate for effective systems of care and rehabilitation outlined in the Implementation Framework of the Health Service Executive (HSE are the national public health service in Ireland)[11]. The team will capture data on the mechanisms of injury in line with the classifications of the Phillips report[7] and outline the pathways through rehabilitation, experienced by adults with moderate or severe TBI. In line with previous research, we anticipate that the data will support findings of inequitable access to rehabilitation and variable outcomes for TBI survivors. We will also record the health service usage of individuals with TBI over a six-month period and capture individuals' views on the benefits of rehabilitation received, as well as the unmet requirements on their rehabilitation journey. In addition to investigating the experiences of individuals with TBI, and in recognition of the critical role played by families in influencing the rehabilitation pathways of TBI survivors, we will explore the experience of those providing care or support to individuals with TBI. We will refer to family caregivers and others providing support or care, simply as 'carers'.

This study is in process, in partnership with two leading Irish brain injury organisations, Acquired Brain Injury Ireland and Headway; two major trauma centres, Beaumont Hospital and Cork University Hospital; the National Rehabilitation Hospital and Dublin City University (DCU).

Protocol

Ethical approval

Ethical approval was obtained from the Research Ethics Committee in DCU (DCUREC/2018/123) and the ethics committees of all partner organisations: Acquired Brain Injury Ireland, Headway, Beaumont Hospital, Cork University Hospital, and the National Rehabilitation Hospital.

Primary and secondary aims

The primary aims of the study are:

- To describe the incidence, prevalence and patterns of disability associated with moderate or severe TBI survivors

- To improve the knowledge of rehabilitation pathways of TBI survivors
- To assess the burden on the carers, the health services, and the Irish society
- To translate the research findings into a workable Knowledge Translation Plan for TBI stakeholders.

Secondary aims of the study are to develop and deliver on the Knowledge Translation Plan and to disseminate the findings in conferences and publications globally.

Study design

This is a quantitative, cohort study involving survivors of moderate or severe TBI and those who provide, or have provided care for them. Cohort 1 will comprise TBI survivors that are at 3–12 months post injury; cohort 2 will comprise TBI survivors that are 12 months or longer post injury. A cohort of carers will be recruited to form dyads. Participants with TBI will be surveyed on two separate occasions six months apart and followed-up monthly regarding their health care service use. Some qualitative data may be derived from the monthly account of current health service usage which we will report if deemed useful in response to the aims of the study. Carers will be surveyed on one occasion. Surveys can be completed, a) in person in a suitable location proposed by the participants, b) over the phone, or c) online. We anticipate that TBI survivors will need assistance with the questionnaire which will be provided by the research team. Data in relation to mechanism of injury, initial and long-term management, follow-up and referrals for further treatment or rehabilitation will be retrieved from the medical records. The study, initially planned for a 30-month period, has already begun. Of note however, are the challenges in data collection brought on by Covid-19. It was difficult to identify participants as the research team were unable to access consent forms from the postal service which was the main method of participant identification. Lockdown in March 2020 coincided with hospital recruitment of participants. A project website was developed in an effort to promote recruitment with minimal benefit, nevertheless, the study continues with a sufficient number of respondents.

In addition to the study participant data, existing routine datasets will be accessed:

a) Major Trauma Audit (MTA)[16] records the rehabilitation recommendations for all trauma patients following the acute phase of their injury. We will collect data on the prevalence of TBI causalities, the number of TBI survivors who require rehabilitation and the level of rehabilitation recommended. A limitation is that MTA is only in existence since 2014 and their data capture is not 100% (currently estimated at 55–60%).

b) Hospital In-Patient Enquiry (HIPE) data captures demographics, clinical data and deaths from all the acute public hospitals in Ireland. HIPE reports over 1.5 million records annually. through Health Intelligence, HSE. We will collect data on discharges and morbidity and mortality TBI data. HIPE data is reported in aggregate format, meaning that linking it to the patients in the research study is not possible; however, we can use it in addition to the cohorts we intend to study to report our findings in context.

c) The National Physical and Sensory Disability Database (NPSDD) is a service-planning tool that provides a profile of people with physical or sensory disability (approx. 23,000 records created annually) and data on current service use regionally and nationally. Expected future service needs for people with physical or sensory disability are also recorded. NPSDD focuses on physical/sensory disability in general, meaning that data pertaining to TBI specifically is not retrievable. Registration on the database is voluntary, meaning that the numbers are not definitive; nevertheless, we will access the data for information on current service use in Ireland.

d) Central Statistics Office will be used to extract national mortality data. Specific TBI case fatality data are not available; age specific mortality data with relevant external causes of morbidity and mortality codes, along with data from this study will assist in estimating numbers.

Sampling plan

A purposive sampling method will be used to invite individuals with moderate or severe TBI to participate in the study. Clinicians at partner sites (Acquired Brain Injury Ireland, Headway, Beaumont Hospital, Cork University Hospital, National Rehabilitation Hospital,) will identify potential participants who fit the criteria and invite them to participate in the study. The first cohort will be recruited through the acute hospitals, Beaumont Hospital and Cork University Hospital; the second cohort will be recruited through the other partner sites. Individuals with TBI who are recruited to take part in the study will be asked to provide an invitation pack to a carer who provides care or support for them, to participate in the study.

Sample size calculation

Within the time and resources available for this project, we expect to recruit, and follow up, 100 TBI survivors in each cohort. This gives us sufficient power to estimate a true proportion of 0.5 within +/- 0.055, to estimate a mean to a precision of 0.07 standard deviations in each cohort, and to detect a difference between the means in the two cohorts of 0.35 standard deviations. Our judgement is that this is an adequate number of subjects to answer our key questions. We also aim to recruit one carer per TBI survivor recruited, who has provided, or provides, care or support to the person with TBI.

Inclusion criteria

Participants with TBI

- Individuals aged 18 years and above
- Individuals who have sustained a moderate or severe TBI
- Individuals who have capacity to give informed consent
- Individuals who resident in Ireland

Injury severity will be determined as follows: 'severe' where a participant had a Glasgow Coma Scale (GCS) score of <9, loss of consciousness (LOC) for > 24 hours or post traumatic amnesia (PTA) lasting >1 week; 'moderate' where the participant had a GCS score between 9 and 12, LOC between 30 minutes and 24 hours or PTA that lasted between 24 hours and 1 week[27]. If these measures of injury severity are not available, positive findings on computerised tomography (CT) or magnetic resonance imaging (MRI) will be used to determine injury severity.

Carer participants

- Individuals aged 18 years and above
- Non-professional caregivers who provide support to individuals with TBI

In order to be included in the study, participants will be required to have the capacity to give informed consent. In line with the principles of the Assisted Decision Making (Capacity) Act, 2015, participants will be assumed to have the capacity to give consent unless there is a reason to believe that they do not have the capacity to give consent[28]. If a participant's capacity to consent is in question, a clinician at the appropriate partner site will be asked to evaluate using the Functional Test for Capacity. This test of capacity is used to ascertain the participant's (a) ability to understand; (b) at the time the decision has to be made; (c) the nature and consequences of the decision to be made; (d) in the context of available choices at the time[28].

Exclusion criteria

Individuals with TBI

- TBI survivors with mild trauma (classified by GCS >12, LOC <30 min, and PTA lasting <24 hours)[27]
- TBI survivors who lack capacity to give informed consent at the time of recruitment.

Carers

- Professional caregivers

Data collection

Surveys will be administered to all participants, with options for completion in-person, by phone, online, or on paper. Individuals with TBI in each cohort will be surveyed at the point of inclusion into the study and approximately six months after the initial survey. As participants have moderate or severe brain injuries, we anticipate that many will opt to complete the survey with the support of a researcher in an interview format. Between the two surveys, participants will be asked to complete a monthly questionnaire about their use of health and rehabilitation services. In addition, the medical records of consenting TBI survivor participants will be accessed to collect key data relating to their injury such as, mechanism and severity, details of acute care and referrals for rehabilitation. Carers will be surveyed on one occasion.

Materials. Potential participants will be invited to participate in the study by the clinician, either in person, by telephone, or by written communication. An invitation pack comprising a letter of invitation, an information sheet and a consent form will be provided to those invited to participate (see extended data[29]). Potential participants will be encouraged to take time to decide if they wish to be included in the study, to discuss the research with someone they trust, and to contact the research team with questions if they wish, before making a decision.

A separate invitation pack for carers will be included in the TBI survivors' invitation pack. The TBI survivor will be asked to give this second pack to a person who provides, or has provided care or support for them.

The invitation packs to both the potential participant with TBI and their carer include a postage-paid envelope for the return of the consent forms directly to the DCU research team. This process complies with General Data Protection Regulation (GDPR) 2016/679[30] and will allow the research team to construct a database of participants. GDPR is a European Union (EU) data privacy and security law targeted at organisations collecting data relating to people in the EU. Dyads of participants with TBI and their carers will be matched from returned consent forms.

In addition, a plain-language brochure calling for volunteers will be distributed to the partner organisations. Flyers will also be distributed to professionals at relevant conferences and seminars, inviting their involvement in the project. Project information will be available on a research project website, and updates and news on the project will be shared regularly via Twitter. Participants may self-enrol through these avenues and will be included in the study if they meet the criteria.

Outcome measures

Four questionnaires will be used for this project. TBI survivors will be asked to complete a bespoke questionnaire to collect demographic data, and data pertaining to the circumstances of their injury, employment and rehabilitation. Three standard instruments the EQ-5D-3L, WHOQOL BREF, and the European Brain Injury questionnaire (EBIQ) will also be administered. The follow-up survey for participants with TBI will be administered approximately 6 months after the first survey. A shorter version of the bespoke questionnaire, designed to capture changes in living circumstances, employment and rehabilitation, and the three standard instruments will be repeated. Between the first and second surveys, TBI survivors will be asked to complete a short monthly survey to capture their ongoing use of health and rehabilitation services (see extended data[29]).

Carer participants will be asked to complete a bespoke questionnaire comprising questions that compliment those administered to the TBI survivor. The questions will include items relating to the TBI survivor, for example, general circumstances, employment and rehabilitation and items concerning the carer such as, general circumstances, employment, care or support provided, and health of the carer. In addition, carer participants will be asked to complete three standard tools: the Mayo-Portland Adaptability Inventory 4, WHOQOL BREF, and the Burden Scale for Family Caregivers.

Instruments

EQ-5D-3L. The EQ-5D-3L (3-level version) is a widely used measure of health-related quality of life[31]. It comprises a descriptive system and a visual analogue scale. The descriptive system outlines five dimensions (5D) of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression[31]. Respondents are asked to indicate what they are experiencing within 3-levels of difficulty (no problems, some problems, extreme, problems) represented numerically (1,2,3). The visual analogue scale displays a vertical measure from 0 to 100; where 0 is the 'worst imaginable health' and 100 is the 'best imaginable health' state. The respondent is asked to indicate the point on this scale that best represents their health state on the day of administration[31].

A description of the respondent's health status is derived by combining the values related to the level of problems experienced in each dimension. For example, the health status of a person indicating no problems under mobility, some problems under self-care, some problems with usual activities, and extreme problems with both pain/discomfort and anxiety/depression, would be represented as '12233'. The numbers assigned to the level of problem under a dimension have no arithmetic properties[31].

Comparison of the EQ-5D-3L and the EQ-5D-5L (more precise measurement with the 5L), suggests that the EQ-5D-3L is prone to ceiling effects and may not accurately discriminate problems experienced at the mild level, therefore demonstrating 'full health' where mild problems exist[32]. Other criticisms of both instruments are that they are not sufficiently sensitive in capturing psychological or social dimensions[33]. However, the EQ-5D-3L is widely used and is considered a credible basis for clinical decision making[34]. An advantage of the EQ-5D-3L over other measures for health-related quality of life (HRQoL), is its brevity, and therefore low burden for completion[33]. Permission to use this tool in this study was obtained from the Euroqol Research Foundation.

WHOQOL-BREF. The World Health Organisation (WHO) defines quality of life as an 'individual's perception of their life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns'[35] (p.1). Quality of life is 'a broad ranging concept which is affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment'[36] (p.1). The WHOQOL instruments may be used in particular cultural settings while allowing for cross-cultural comparisons[35]. It can also be used to provide insight into the effect of disease on subjective well-being[35]. The psychometric properties of the WHOQOL-BREF have demonstrated reliability and validity[36,37]. Although there is a lack of consensus on the suitability of this instrument in people with TBI, studies support the applicability of the WHOQOL-BREF in this population[38,39]. Permission to use the WHOQOL-BREF in this research was obtained from the World Health Organisation Press.

European Brain Injury Questionnaire (EBIQ). The European brain injury questionnaire (EBIQ) was developed specifically for use with both brain injured patients and their relatives by Teasdale and colleagues[40]. It comprises 63 questions regarding 'problems or difficulties that people sometimes experience in their lives'. Respondents are requested to indicate if they have experienced these problems 'not at all', 'a little' or 'a lot', over the previous month. Items can be grouped into nine domains or scales: somatic, cognitive, motivation, "impulsivity, depression, isolation, physical, communication and core, all of which demonstrated satisfactory levels of reliability with Cronbach's α value of near or above 0.5[40]. Sopena and colleagues[41] found that the EBIQ demonstrated robust test-retest reliability for persons with brain injury and relatives of persons with brain injury; Schonberger and colleagues[42] report r values of 0.47–0.66,with all p values <0.001 for all scales. The EBIQ was designed for use with brain injury survivors and their relatives, on the basis that close relatives' perspectives may balance lack of an awareness in the participant with TBI[40,41]. The EBIQ is freely available and specific permission is not required to use the instrument for research purposes.

Mayo-Portland Adaptability Inventory 4. The MPAI-4 provides meaningful documentation of cognitive, behavioural and social challenges experienced by those who have acquired a brain injury. The MPAI-4 includes 30 items covering limitations commonly experienced by ABI survivors. Items are rated on a five-point scale from 0–4, where 0 represents 'normal' function and 4 'severe limitations'. The instrument also comprises three subscales: the ability index, adjustment index and the participation index. The MPAI-4 demonstrates good levels of clinical utility and psychometric quality, with very good construct validity and internal consistency[43] in people with TBI. A recent study in an Irish sample with ABI reported very good internal consistency for the total scale score (0.91) as well as the three subscales: abilities (0.94), adjustment (0.82) and participation indices (0.85)[39]. The MPAI-4 is freely available and specific permission is not required to use the instrument for research purposes.

Burden Scale for Family Caregivers (BSFC). The BSFC measures subjective burden in informal caregivers. It is available in 20 European languages, allowing for comparison between European populations[44]. Subjective burden in those who provide care for the chronically ill has been found to significantly affect their emotional health, physical health and mortality as well as how the caregiver relates to the care receiver[45]. The BSFC is a 28 item self-reporting instrument, that uses a four-point Likert scale ranging from 'strongly agree' to 'strongly disagree'[45]. Split-half reliability test attained values of higher than 0.8[44]. The BSFC is freely available and specific permission is not required to use the instrument in research.

These instruments were chosen by experienced neuro researchers, to ascertain the quality of life, health states, effect of injury and difficulties experienced by the TBI survivor (EQ-5D-3L, WHOQOL-BREF, EBIQ). The MPAI-4 addresses cognitive, behavioural and social challenges. This data is essential to explore the state of health of TBI survivors in relation to the current state of neuro-rehabilitation in Ireland. The BSFC will provide date on the experiences of those who provide care or support the TBI survivor.

Data management

Two research assistants will maintain a database on their encrypted, password protected computers. Hardcopy consent forms and survey responses will be stored separately and securely in locked cabinets in the offices of the researchers. Names and other contact details will be stored separately from completed questionnaires, whether on paper, or electronic format. Unique identifiers will be used by the DCU research team who will have sole access to the raw data and no identifiable information will be published. The DCU Risk and Compliance Officer has reviewed a personal data security schedule (PDSS) that lists the categories of personal data being processed. Data is available in the Open Science Framework data repository. On completion of the study, the archived dataset will be anonymised and lodged with the Irish Social Science Data Archive (ISSDA). If a TBI registry is established, anonymised data from this study will be shared with registry developers.

Data analysis and statistical plan

An analysis of the data generated throughout the study will be reported to the Knowledge Users (Acquired Brain Injury Ireland and Headway). Consultation with a Patient and Public Involvement (PPI) advisory panel and a Research Advisory Group, set up as part of the wider team involved in this study, will also inform reports in collaboration with Knowledge Users and the research team.

Data points:

- Existing routing datasets
- Hospitals' and voluntary organisations' medical record data of TBI participants
- TBI participant surveys and six-month follow-up surveys
- Monthly accounts of the TBI survivors' health care service usage for 6 months
- Carer survey data

Descriptive statistics using a range of univariate and multivariate statistical analyses will be employed to explore the data obtained through the partner sites and from participant surveys. Data will be collected and analysed using Qualtrics software[46], R[47] and SPSS[48].

Reporting of results

The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) framework will be used[49,50]. We will report on eligibility; lack of participation, attrition numbers and reasons for same as well as those completing follow-up. The demographics, clinical condition on admission and discharge from acute care, rehabilitation and their use of health care on a continuum will be reported. Data from standardised instruments, participants' financial situations, material changes and care circumstances will be presented.

Bias

There are several potential sources of bias in this study. The first is that the criteria for entry into the study are imperfect as there are no uniform data collection systems for people with TBI in Ireland. While every effort will be made to identify people with moderate or severe brain injury correctly, and to exclude those with mild brain injury and those with very severe and profound brain injury, this is believed to be imperfect. There are no independent central sources of information on rehabilitation services that can be used to check reported use. To mitigate this, service use will be documented from participants prospectively, which should minimise error.

The potential for information bias exists, in particular because of the study participants. Respondents cognition may be less than optimal since injury, resulting in exaggeration or forgetfulness. The Covid-19 pandemic is another consideration where bias might occur as participants may not have been able to access rehabilitation or health care services because of lockdowns, resulting in alternative data compared to similar data collected under normal circumstances.

Dissemination and knowledge translation

A formal knowledge translation plan has been designed in direct response to the needs of the TBI population identified by ABI Ireland and Headway. The findings will be applicable to these needs. The research protocol was developed in partnership with the researchers, Knowledge Users, the Public and Patient Involvement advisory panel and the Research Advisory Group.

The Knowledge Users are very experienced in managing political and policy advocacy campaigns and raising awareness of brain injury. The findings of this study will be directly applicable to these actions. In consultation with the PPI advisory panel, a plain language narrative synthesis of the research findings will be prepared and shared with key stakeholders. The research findings will also be shared with other organisations that find the data useful, for example, St. Doolagh's Park Care and Rehabilitation Centre, Nua Healthcare, Redwood Extended Care Facility, The Irish Wheelchair Association, The Road Safety Authority and the Irish Medical Organisation. An open briefing will be held for members of the Irish Parliament (Teachta Dála), and senators in the Dáil.

The research team and the PPI panel will disseminate the final report. Members of the PPI panel are involved in this study to include the writing of the funding proposal. Advocacy efforts to influence health care pathways will be coordinated by ABI Ireland and Headway through the Neurological Alliance of Ireland (NAI). The NAI is instrumental in influencing health policy and practice on neuro-rehabilitation and has direct engagement with principal actors within the broader HSE clinical programme and the Department of Health.

Knowledge Users, the researcher team, the Research Advisory Panel and the PPI panel will collaborate to propose solutions from the findings.

Knowledge Users and the PPI advisory panel have made a number of recommendations to disseminate the findings of this research study:

- A social media strategy, with partner organisations to disseminate the findings to people with brain injuries, their families and the wider public
- A launch seminar with all key stakeholders and other interested parties (for example, the Road Safety Authority, Irish Medical Organisation) to share findings
- A Policy Briefing Paper to outline the policy issues that arise from the research conference dissemination

Presentations at Irish, European, and international conferences. Manuscripts will be submitted to appropriate peer reviewed journals, such as Brain Injury, Neuro-epidemiology, The Journal of Head Trauma and Rehabilitation, and BMC Neurology (an open access, peer-reviewed journal).

There will be potential for further projects within the DCU/ Knowledge Users/ PPI partnership team, in particular around implementation of strategies, and the evaluation of interventions.

Study status

This study is well underway with data collection complete and data analysis currently in progress. The expected completion data has been delayed because of barriers with data collection due to Covid-19.

Discussion

Advances in acute care have surpassed developments in rehabilitative care, resulting in increased demand for neuro-rehabilitation services[11], as more individuals who have experienced moderate or severe TBI are surviving. Increased demand, in turn, is contributing to longer waiting times for rehabilitation services, which are poorly configured to meet this demand[11]. Previous research demonstrates that delayed rehabilitation can result in loss of function and unnecessary disability of TBI survivors[11], as well as pose significant challenges for their family members[22]. The full scale of unmet needs in Ireland is unknown to date[7,20], and rehabilitation pathways for this population are essentially undocumented. This study will address the current epidemiological data of TBI in Ireland and data on rehabilitation pathways for adult TBI survivors.

Ireland's neuro-rehabilitation implementation plan outlines how rehabilitation services in Ireland might be reconfigured to achieve a flexible, responsive, accountable, rehabilitation service that can provide a standardised rehabilitation pathway[11]. The service should be structured to deliver individualised rehabilitation locally, where possible, and in a timely and integrated manner, to meet the needs of service users[11]. Through examining the rehabilitation pathways of individuals with moderate or severe TBI in Ireland, we expect that the current research findings will provide insight into the specific barriers to rehabilitation, and contribute valuable information to support the redevelopment of neuro-rehabilitation services. Additionally, acting on the knowledge of the current rehabilitation pathways has the potential to positively impact outcomes for TBI survivors currently navigating the system.

This study is the first in Ireland to examine how individuals use health care services following a TBI; it will provide a comprehensive view on health services usage and the rehabilitation services required of moderate or severe TBI survivors. The data derived from the study will help support efforts to maximise health service availability for TBI survivors locally and nationally. The research will explore the experiences of those providing care and support to an individual with TBI, many of whom are family members. Both international research and research within the Irish context demonstrate that is a considerable burden associated with providing care and support to TBI survivors[20–22]. Understanding the considerable role of informal carers in providing support to TBI survivors' access to rehabilitation is of particular importance[20].

A dearth of research in the area of TBI in Ireland means that we do not fully understand the difficulties faced by individuals with moderate or severe TBI in accessing rehabilitation services. Health policy documents dating back to 2001 have acknowledged the need to develop rehabilitation services and, more recently, a specific focus on neuro-rehabilitation services has found that services are inadequate and poorly configured to meet demand[11,12]. A key area of challenge identified is the lack of reliable data on the TBI population[9,12]. In this context, the current study is timely in its focus on the epidemiology of TBI in Ireland and on rehabilitation pathways for TBI survivors. It is anticipated that findings from of this study will inform the aforementioned organisations, contribute to advocacy efforts for the redevelopment of neuro-rehabilitation services and make a much-needed contribution to the Irish literature on TBI.

Data availability

Underlying data

No data are associated with this article.

Extended data

Open Science Framework: Traumatic Brain Injury - Pathways to rehabilitation. https://doi.org/10.17605/OSF.IO/2BAUF[29].

This project contains the following extended data:

- Carer-Family Member Questionnaire.pdf
- Participant materials HRB.pdf
- Person with TBI 1st interview Questionnaire.pdf
- Person with TBI 2nd Interview Questionnaire.pdf
- Person with TBI Health Care Usage.pdf

Acknowledgments

We acknowledge the support of many colleagues from ABI Ireland, Headway, the National Rehabilitation Hospital, Beaumont Hospital and Cork University Hospital who encouraged and supported us, and from DCU Research Support who helped us secure funding as well as Patrick Boylan, School of Psychology DCU, who provided much help and guidance with online survey support.

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Open Peer Review

Current Peer Review Status: ? ✓ ?

Version 2

Reviewer Report 16 October 2023

https://doi.org/10.21956/hrbopenres.14875.r35187

?

Katrin Rauen
University of Zurich, Zurich, Switzerland

Dear authors, thank you very much for your revision of your protocol. There is no doubt that TBI research is necessary in Ireland. I suggest to adopt your protocol for comparability as follows:

1. Please double check your clear aims 1-3 from the abstract and repeat those in the main text. In the current status there is a discrepancy, and thus the protocol would benefit from revising this section.

2. Why did the quthors did not incorporate the CENTER-TBI recommendation for assessing outcome with the current gold standard (GOSE) and generic (SF-36v2 or SF-12v2) and disease-specific HRQoL (QOLIBRI instrument). Please compare for TBI outcome assessments the citation below:

   https://www.center-tbi.eu/project/validated-translations-outcome-instruments

3. It would be of major interest how many TBI patients received in- and out-patient neurorehabiltion

4. It would be of interest to assess time from TBI to admission to neurorehabilitation.

5. Citing relevant TBI outcome publications on HRQoL would be beneficial.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Neurotrauma, Traumatic brain injury, HRQoL, neuropsychiatric outcome after TBI, sleep disorders, depression, sex- and gender-specific depression, post-concussion syndrome

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 03 October 2022

https://doi.org/10.21956/hrbopenres.14875.r32908

✓

Dominic Trepel
[1] School of Medicine, Trinity College Dublin, Dublin, Ireland
[2] Global Health Health Institute (TCD | UCSF), San Francisco, CA, USA

Thank you for considering the reviewers' suggestions and for the pithy rebuttals. Having reviewed the manuscript, comments on the protocol have been addressed as best possible (given that the project is now completed) and the work should be indexed.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health economics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 07 September 2021

https://doi.org/10.21956/hrbopenres.14361.r29933

? **Dominic Trepel**
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Summary:
Thanks you for inviting input to this intended work, it is admirable that the research group outlines their intentions in this open peer review process at the protocol stage.

The work is very much needed to improve the current state of research on rehabilitation services for brain injuries in Ireland and this draft provides a good summary of the intentions. However, in outlining multiple aims, the intended study became a little confusing to read and often less than clearly described. It is recommended one aim is stated (e.g. to establish a prospective cohort of survivor of a brain injury) and then state the research questions this will be answered (e.g. estimate prevalence/incidence). It might also be beneficial to present other questions in separate protocol papers as this would allow sufficient methodological detail to allow replication. Despite these methodological issues, overall this protocol is well received and sets out an exciting agenda.

Here are specific comments the paper should address (presented by section):

TITLE:
Specify the methods in the title (e.g. a protocol "for a prospective cohort study")

ABSTRACT
Background:
Move sentence in Aims (i.e."This is the protocol for a ["mixed methods" OR perhaps more accurately "prospective cohort"] study that will examine pathways through rehabilitation for survivors of TBI in the Republic of Ireland") to be last sentence of background.

Aims:
Clearly state Aims numerically:
Aim(s):
1. To explore the experiences of family members providing care or support to a person with TBI;

2. To estimate the incidence and prevalence of TBI in Ireland.
[But having read the paper, it was difficult to be clear on the aim and became confused if it was actually create a 'prospective cohort study'. Also, I am struggling to find relationship to "experiences of family members" (which was assumed indicated additional qualitative methods).]

Final sentence in Aims may not be a research aim. Considering as a aim if could be stated as:
3. To support advocacy efforts by providing epidemiological data and information on how people with TBI access rehabilitation and health services

... however, 'advocacy' is not research aim (i.e that you will specify a research method to achieve) but could rather be more a considered a conflict of interest. Consider either removing. Or, if the aim is integral to this proposed research, maybe consider reworking to indicate a 'translational research' aim.

Cross reference to ensure that aim(s) stated in body text are aligned with those stated at abstract level, and that any stated aim clearly links to the related methodology.

Also, as stated above, the protocol paper might be easier to follow describe one aim (e.g. the prevalence study) and other aims (e.g. qualitative study, or, assessment of resource use) might better be presented in a separate Protocol paper. This would allow more clear elaboration in describing methods (see below for more details).

Method:
Clearly describe methods that align with stated aims (above). For example, it is unclear to which stated aim the statement: "Questionnaires will be administered to participants with TBI on two separate occasions, six months apart, and to family members providing care or support to an individual with TBI, on one occasion."
relates - is this part of qualitative exploration or quantifying prevalence/incidence?

clarify statement "medical records of participants will be abstracted" - do you mean data will be 'extracted' from medical record to create a dataset? And, if so, be more explicit on what is "key information" and provide explicit detail on the process from identifiable patient record to a dataset fit for analysis that conforms with GDPR . As it currently stands, this method is vague and unclear how it relates to the aim.

It is unclear how the methods relates to stated aims: "TBI survivor participants’ use of health care will be followed prospectively for six months."

Expected outcomes:
Following statement suggest a new and additional aim (ie which is different to those stated above): "pathways through rehabilitation in Ireland, to understand how rehabilitation services are accessed". If this is related to qualitative interviewing, try to make more congruent and then indicate methodologically 'how' an expected outcome will be delivered (e.g. a grounded theory that indicates the pathway (etc.) and then adjust *Aim 1* to not solely reflect care partner(s) experience)

INTRODUCTION
Rubiano et al 2015 does not support statement that TBI 'is a leading cause of death and disability

worldwide".

Statement "*In Ireland the incidence and prevalence of TBI is unknown*" is central, as is *" there is no national mechanism for "capturing the incidence, management and outcome of TBI presenting" to the health care system".* However, to the latter statement greater elaboration on WHY 'incidence, management and outcomes" are such an unknown in Ireland would be helpful to a more international audience (e.g. for example, is is because both US and UK estimates benefit from more solid routinely collected administrative data, or because Ireland does not have unique patient identifiers?)

A clear and early definition of what is considered to constitute "rehabilitation' may be useful. Currently, the protocol makes an immediate assumption all readers should be aware what might constitute a "rehabilitation pathway" and also that rehabilitation does not vary.

Change statement "...intensive and early access to neuro-rehabilitation **[may be]** cost-effective[9,10] " (NB neither referenced papers by McGregor (1997) or Turner-Stokes (2019) are evidence ono cost-effectiveness) - consider referring the forthcoming review [1] which does more comprehensively support the assertions on cost effectiveness of rehabilitation for brain injury

RE - with respect to reference to Turner-Stokes editorial in 2004, this is not evidence on cost effectiveness but rather shows "long- term cost savings would outweigh short-term rehabilitation costs in a UK setting for those with serious brain injuries" (i.e. provides an opinion that rehabilitation is cost-minimising) - Again, recommend reference to Mitchell et al work which provides a critical appraisal of the health economic evidence base[1].

Query statement "estimated that 40% of brain injury survivors will have a moderate to severe disability". Does this assume that incidence of brain injury (ie. denominator of total brain injuries) was established by Philips? Given aims outlined in this protocol (ie. incidence), perhaps statement could be more tenuous.

"As is the case internationally, difficulty navigating the health system[17,20] and poorly configured, inefficient, funding streams have been shown to relate to these gaps and delays". Some caution is required in terms of the rigour of supporting evidence. For example, HSE report is more of an action plan rather than a source of evidence and therefore assertions (e.g. level of relative efficiency) may not grounded in fact (i.e. have academic rigour).

Statement (and subsequent paragraph)"It is expected that the findings of this research study will contribute to the literature on TBI in Ireland in a number of ways" is indicative that the protocol paper is too broad and may merits greater focus to explain any one well. Providing robust estimates of population level prevalence/incidence of TBIs in Ireland would be a solid and welcome contribution. The description of pathway through services (which I assume is qualitative in nature), experience of carers (not to mention more general resource use measurement) and formulation of knowledge translation plan are all also good aims but surely benefit separate protocol papers (so to allow sufficient detail for replication).

PROTOCOL
Ethical approval:
Attach ethics submission DCUREC/2018/123 as a supplement to this Protocol paper.

Primary and secondary aims:
As indicated above, recommend selection one primary aim:

RE "To describe the incidence, prevalence and patterns of disability associated with moderate to severe TBI survivors" - Reading further, as this is not a population prevalence, it is not (as stated in abstract) aiming to "estimate the incidence and prevalence of TBI in Ireland" but rather (I assume) prevalence of subtypes of TBIs.

I am also confused by aim on 'incidence' which would introduce temporal aspect to the study (i.e. rates of TBI going up or down over time). Over time, it might be of interest (and feasible) to explore relationships between incidence of disability types, service use and/or demand for informal care (e.g. by exploiting the 6-month follow up), but again, this could validly constitute a completely separate paper (although, it would be commendable of the formulated datasets were designed to allow such future questions to be answered).

Statement of aim to improve "knowledge of rehabilitation pathways for TBI survivors" is vague in terms of what it is aiming to show

Study design
Statement "This is a quantitative, descriptive cohort study involving survivors of moderate to severe TBI " suggest that the primary aim is qualitative, so perhaps consider indicate qualitative part of mixed methods as a secondary aim (also study design makes not references to the qualitative design as indicated in the abstract reference to "mixed method").

Sampling plan
Again, with earlier reference to "prevalence in Ireland", the limitation of sampling from hospitals only needs to clearly acknowledged throughout.

Sample size calculation
Clarify: What is the sample size detecting? This should be related to your primary aim (and an associated hypothesis test?)

Inclusion criteria:
Criteria for level of severity is a little confusing do participants need to have all three, or at least one of the criteria. Currently, I interpret as just one and, if that is correct, recommend rephrasing to "must satisfy at least one of the following" (NB: exclusion that "TBI survivors with mild trauma (classified by GCS >12)" should also indicate similar of LOC and PTA to exclude)
Elaborate on protocol for: "If these measures of injury severity are not available, positive findings on computerised tomography (CT) or magnetic resonance imaging (MRI) will be used to determine injury severity." May require cross reference to a supplement, if extensive?

Consider changing "family member" to "care partner" (or "non-professional care partner" to be exact) as: 1. assumes occurs in diads and; 2. refers to non-profession caregiver" (which may not be family).

Data collection
The "Extended data[26]" is well received and therein the "Questionnaires and materials" have been

inspected. However, content of suppository is greater than just and might better directly point reader to specific hyperlink for the "letter of invitation, a patient information leaflet and a patient consent form" (https://osf.io/nhbt8/). Authors need to better orientate read through these materials.

"Extended data" also provides three questionnaire to person with TBI and one for carer, and the deployment process for these could be explained (e.g. I note reference to "Qualtrics Survey Software" which could be explained)
- The survey questionnaires seem to expect quite a time commitment from participants, which raise concerns that, overall, data completeness will suffer (particularly when participants are asked at follow up timepoints to contribute their time again). Has the survey been piloted ahead of moving to collecting data from n=200? If so, to relay concerns that research does not overly burden on survey respondents, please report average time to complete survey (available from survey tool) for each of the following materials:

Carer_Family Member Questionnaire (70 pages - Ref: https://osf.io/bxjnw/)
Person with TBI 1st interview Questionnaire (36 pages -Ref: https://osf.io/n46ea/)
Person with TBI 2nd Interview Questionnaire (30 pages - Ref: https://osf.io/53hx9/)
- Person with TBI Health Care Usage (5 pages - Ref: https://osf.io/5cjpz/)
- furthermore, outcomes make reference to "EQ-5D-3L[28], WHOQOL BREF[29], European Brain Injury questionnaire (EBIQ)[30] "

RE "Surveys will be administered to all participants" - It should be assumed that some for people with severe TBI may have impaired ability to complete surveys, clarification required on what is the process will be in such situations (e.g. proxy report?)

Under "**Instruments**"
The addition of the quality of life measure such at EQ5D3L and WHOQOL, whilst welcomed, do not appear linked to any of the stated aims. Also, it is unclear what they contribute (recommend consulting with a trained health economist on quality of life and also for developing robustly designed '*bespoke*' resource use measurement tools).

Consider that the MPAI-4 is routinely collected in brain injury and therefore collecting primary data may add unduly to respondent burden.

The study appears to primarily be developing a 'prospective cohort' (with a good deal of rich data for each individual and carer) and this should be reflected under **Data analysis and statistical plan.** As part of outlining this plan, it would be very helpful if the authors would comment to providing empty tables to indicate what descriptive statistics will be reported in the final paper. Also, with respect to analysis (i.e. "univariate and multivariate statistical analyses ") further detail should be provided to explain what outputs this aims to provide (ie to answer salient research questions).

Bias
There are likely many more sources of bias that may, and should, be considered ahead of rolling out this research plan.

It would be helpful if the team could commit to documenting and reporting consideration of potential sources of bias and committing to conducting postdoc analyses to determine whether they are valid concerns.

Dissemination and knowledge translation
Strong dissemination plan with good involvement of PPI. One recommendation is to commit to seek peer review of outputs by people living with brain injuries (In terms of grant funding, there is likely a PPI review panel at funding application stage).

DISCUSSION
Reference to "increasing demand" and "poor configuration to meet demand" sets a policy agenda of HSE. However, it would be helpful if the group could ensure that economic aspects such as "supply" and "demand" are considered in design of the datasets - highly recommend the research group collaborating with a health economist.

The study purports to be the first study in Ireland to *"examine how individuals use healthcare services following a TB*I". However, having considered the study design and inspected the questionnaire design, the study is not population-based and focuses on survivors (so will not accurately reflect all service use). Also the "bespoke" resource questionnaire may likely have issues as may result in missing data due to not considering zero, and operationalising methods to deal with zero service users. Finally, this seems a deviation from the stated aims

Throughout the paper, there are several reference to equity of access (as it also mentioned in the discussion) however, equity (or indeed inequality) has not been defined anywhere to be operationalised and further detail on data collected and the associated analysis plan would be required.

Data availability
Underlying data: it is highly recommended that the study be initially piloted in a small number and some preliminary data be provided

Extended data: well received however further orientation to each questionnaire (and their merits) would be welcomed. At present, there data collection appears so extensive that, overall, overburdening respondence may compromise overall quality of the study.

Acknowledgments
Specify sources of funding which were received, providing grant numbers etc.

References
1. Mitchell E, Ahern E, Saha S, Trepel D: Neuropsychological rehabilitation interventions for people with an acquired brain injury. A protocol for a systematic review of economic evaluation.*HRB Open Res*. 2020; **3**: 83 PubMed Abstract | Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?
No

Are the datasets clearly presented in a useable and accessible format?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health economics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 17 Aug 2022

Catherine Corrigan

Thank you for your time to provide this valuable review. We have taken the steps to address each issue.

TITLE modified to reflect cohort study; it is not entirely prospective however, therefore 'prospective' was not added.

ABSTRACT
Background – last sentences added to background as recommended.
Aims are now clearly stated numerically. The abstract aims align with the aims in the body of the paper and link to the methodology. As this is an extensive study, substantial outcomes are expected. Thank you for the suggestion for separate protocol papers, however as the study is ending, we are focusing on reporting outcomes at this stage.
Method – additional information added to this section in the abstract to reflect the use of existing routine data as epidemiological sources. Key information is expounded on. See GDPR details under ‘data collection’ and ‘materials’ headings. Clarification for the 6-month follow-up re participants' use of health and rehabilitation services has been added.
Expected outcomes are clarified to align better with the aims of the study.

INTRODUCTION
Rubiano et al. article indicate ‘within the spectrum of trauma related injuries, TBI and SCI are the largest causes of death and disability’ – sentence modified to reflect trauma related.
Incidence and prevalence of TBI in Ireland is unknown - no unique ICD-10 code exists for TBI.
An explanation of rehabilitation is provided in the introduction with sources cited.
RE: “*neither referenced papers by McGregor (1997) or Turner-Stokes (2019) are evidence onto cost-effectiveness…”* McGregor is removed; however in the Turner Stokes (2019) study, findings indicate: “specialist rehabilitation proved highly cost-efficient for patients severely disabled by severe TBI”. Thank you for the Mitchell et al. source now cited.
RE: “*Turner-Stokes editorial in 2004, this is not evidence on cost effectiveness…”* The author indicates: “there is an increasingly strong evidence base for the effectiveness and cost-

effectiveness of rehabilitation following acquired brain injury"; however, we appreciate the update from Mitchell et al. (added) indicating the lack of evidence of cost-effectiveness of neuropsychological rehabilitation.
RE: *"estimated that 40% of brain injury survivors will have a moderate to severe disability"*
This incidence was established by the Traumatic Coma Databank; we were unable to locate the original source, nor find an updated source with that information, therefore the reference from the Phillips report had not been changed.
RE: *"As is the case internationally, difficulty navigating the health system·…"*
While we appreciate your comment on the rigour of the supporting evidence, HSE indicate that their document is a "scientific approach based on data". Additionally, we are aware of this work as Dr Jacinta McElligott (co-chair of the National Strategy Group on the HSE document) is a co-applicant and we have met with the HSE regarding the mapping of neuro-rehabilitation services in Ireland.
RE: *"It is expected that the findings of this research study will contribute to the literature on TBI in Ireland in a number of ways"…* As above, re separate protocol papers: the study is ending and we are focusing on reporting outcomes at this stage. This is an extensive study generously funded by HRB, ABII and Headway, that merits substantial outcomes.

PROTOCOL
Ethical approval:
RE: *"Attach ethics submission…"*
Attaching the ethics submissions is not a requirement.
Primary and secondary aims:
As above, this is an extensive study generously funded by HRB, ABII and Headway, that merits substantial outcomes with more than one primary aim.
RE: *"To describe the incidence, prevalence and patterns of disability associated with moderate to severe TBI survivors"…* 'incidence and prevalence' has been replaced with 'epidemiological data' in the context of the aims of the study. Existing routine datasets such as the Major Trauma Audit has been added to the manuscript and will assist with the epidemiological data for this study.
RE: *"I am also confused by aim on 'incidence' which would introduce temporal aspect to the study"…*
Incidence is the occurrence of new cases over a specific time period which we had hoped to capture from the cohort that sustained brain injury within 3-12 months; however, our recruitment of new cases (Cohort 1) was poor and we will likely not report on estimated incidence rates. The dataset is extensive and will be available for other papers on the Open Science framework.
RE: *"knowledge of rehabilitation pathways for TBI survivors"…* the wording of this aim has been modified to read 'document the rehabilitation experiences of TBI survivors in Ireland'.
Study design
RE: *"This is a quantitative, descriptive cohort study involving survivors of moderate to severe TBI "* …
The primary focus of the study is the epidemiological data; however, some qualitative data will likely be derived from monthly accounts of current health service usage, which we will report if deemed useful in response to the study objectives. We removed the mixed method error.
Sampling plan

RE: *“Again, with earlier reference to "prevalence in Ireland", the limitation of sampling* from hospitals only”… The “current study is undertaken in partnership between two leading Irish brain injury organisations, Acquired Brain Injury Ireland and Headway…” and is not limited to hospitals only.

Sample size calculation

RE: *“what is the sample size detecting?* Epidemiological data on TBI in Ireland.

Inclusion criteria:

RE: *“Criteria for level of severity is a little confusing…”* Level of severity is modified to moderate *or* severe throughout the revised manuscript. LOC and PTA are added to the mild TBI (exclusion criteria). CT, MRI results etc. added – thank you for this as we did extract that data from the medical records.

RE: *“Consider changing family members…”* Family members now changed to 'carers'.

Data collection

RE: *“The “Extended Data” is well received and therein…better directly point reader to specific hyperlink”*… We will take your recommendations on board and revisit the content in OSF.

RE: *“Extended data” also provides three questionnaires…”* Under Study design: “Surveys will be completed, a) in person in a suitable location proposed by the participants, b) over the phone, or c) online. Deployment process added. The Qualtrics reference is added.

RE: *“The survey questionnaires seem to expect quite a time commitment…has the study been piloted…”* Yes, we piloted the study with 5 TBI survivors. ABII and Headway were consulted regarding the length of the questionnaire and the potential for participant burden; members from the PPI panel reviewed the questionnaire as well; this resulted in a shorter questionnaire; the research assistants are experienced in communicating with brain injury survivors and are very sensitive to fatigue of difficulties with attention of the participants; participants can stop during the survey and take breaks to rest; survivors were willing participants and sometimes completed the survey over two sittings or more.

RE: *“Carer_family member questionnaire…report average times to complete the survey”*

We used Qualtrics for the carer_family member questionnaire. A participant could start and stop the survey at intervals, meaning complete it over days; there was no pressure to complete it within a specified time limit.

RE: *"Surveys will be administered to all participants"…*

“individuals who have capacity to give informed consent” is an inclusion criterion which excludes people with impaired ability. Capacity to give informed consent is also detailed. Proxy data is not permitted.

Instruments

RE: *“The addition of the quality of life measure such as EQ5D3L and WHOQOL…”* Additional information on the instruments to indicate alignment with stated aims has been provided.

RE: *“Also it is unclear what they contribute…”* Thank you for the recommendation to consult with a health economist which we will take on board.

RE: *“Consider that the MPAI-4 is routinely collected in brain injury…*” Please refer to the above response on how the burden on respondents was addressed. Additionally, data retrieved from the MPAI-4 that is commonly used in the field of brain injury studies allows other researchers to compare findings.

RE: *“The study appears to primarily be developing a ‘prospective cohort’…”* The study has two cohorts and is not considered primarily prospective. Populated tables will be provided when the data is ready for analysis. Details of data analysis in relation to the RQs and the aims of the study will be provided in a separate outputs paper.

Bias
RE: *"There are likely many more sources of bias…"* Information bias and potential bias as a result of the Covid-19 pandemic was added. Thank you for the post doc analysis suggestion.
Dissemination and knowledge translation
RE: *"Strong dissemination plan…"* A PPI panel is involved in this study to include the writing of the proposal for funding.
DISCUSSION
RE: *"Reference to "increasing demand" and "poor configuration to meet demand" sets a policy…"* Thank you again for the recommendation to consult with a health economist which we will take on board.
RE: *"The study purports to be the first study in Ireland…"* We appreciate that the study will not accurately reflect all service use and that is not the intention, rather we want to learn accessibility and appropriateness of services being uses by the TBI survivor. This relates to the aims where TBI survivors may be using, have access to or not, services not appropriate for the best chance of optimizing their quality of life, e.g. frequent GP visits c/o pain when adequate mobility/exercise regime could mitigate this complaint.
RE: *"Throughout the paper, there are several references to equity of access…"*
Inequity is defined (WHO) and equity has been removed from the discussion section as per your recommendation.
Data availability
RE: Underlying data: *"it is highly recommended that the study be initially piloted…"*
We piloted the study with 5 TBI participants and modified accordingly.
RE: Extended data: *"The extended data is well received however further orientation to each questionnaire…"* Reasons for the choice of instruments (by experienced neuro researchers) are provided. We appreciate the extensive data collection and have closely considered the potential burden on the respondents. Both research assistants have experience in working with people with brain injury and are well educated on brain injury awareness. Respondents will be assisted to complete the questionnaire and will be informed they can take breaks to rest.
RE: *"Extended data also provides three questionnaires…"* The use of the questionnaires and the deployment process are explained.

Thank you.

Competing Interests: No competing interests were disclosed.

Reviewer Report 12 August 2021

https://doi.org/10.21956/hrbopenres.14361.r29835

Laraine Winter

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This ms describes the protocol for an on-going study that will examine incidence and prevalence of moderate to severe TBI in Ireland, identify pathways through rehabilitation for survivors, and document the experience of family caregivers. The ms is clearly written and extremely interesting, and the study protocol seems compelling and likely to result in valuable contributions.

A limitation of the ms is that it is only a description of the study protocol, with no findings. It strikes me as a very strong grant proposal, more than a journal publication. The journal editors will have to determine whether it fits within their journal's purview to present a study protocol only.

The most likely limitation of the eventual study seems to be that its findings will be limited to Ireland and perhaps not relevant to other countries. Even so, the fact that is will be a nation-wide study helps to argue in favor of the generalization of its findings.

The fact that it will include a focus on family caregivers, using a good measure of burden, will be an important strength of the study.

The exclusion of individuals with mild TBI (mTBI) strikes me as unfortunate. Worldwide, the large majority of persons with TBI have a mTBI, as the authors point out, and many of them will continue to experience TBI-related symptoms for years after the injury. It seems like a missed opportunity to follow many individuals some of whom will not completely recover.

Some points of clarification are needed. Some individuals with TBI may not have a family caregiver or whose caregiver will not be willing to participate in the study. It was not clear whether individuals without a willing family member will still be eligible for the study. If they are excluded, this may very well bias the sample. If they are included, the sample size for caregivers will be smaller and statistical power weaker.

Outcome measures for persons with TBI include three measures of quality of life. It wasn't clear why three such measures (which cover much of the same territory) were selected or how distinct findings will be interpreted.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: TBI, family caregiving, rehabilitaiton

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 13 Aug 2021

Anthony Staines

We thank the reviewer for her helpful comments.
This paper is precisely a study protocol, as the title announces, and hence has no results.
It is indeed unfortunate that we are not able to include mild head injury in our work, but our resources are very limited, and moderate to severe head injury is the main driver of needs for rehabilitation, and the main focus of our charity co-funders.
The comment about outcome measures is well taken, and indeed our final choice of measures was the product of much discussion - we are partly motivated by what is achievable, and partly by a desire for consistency with the existing literature. We accept that there were many other possible choices, and were we doing the study again, we might make other choices.

Competing Interests: PI on the study Funded by HRB ABI and Headway