TITLE PAGE

LIFE THREADS – TBI

FULL TITLE OF THE STUDY

Working with the 'Life Threads' approach to support families after traumatic brain injury.

SHORT STUDY TITLE

Life Threads – TBI

RESEARCH REFERENCE NUMBERS

IRAS Number:	329362
SPONSORS Number:	23NS011
FUNDERS Number:	NIHR204092 Research for Patient Benefit Competition 46

SPONSOR: Nottingham University Hospitals Trust

PROTOCOL VERSION NUMBER AND DATE:

Version 3 20-11-23

This protocol has been designed to ensure regard for the HRA guidance.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

.....to be added post-HRA review..... ...../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: .... Date: ...../...../.....

Name: (please print):.. Dr Charlotte Jane Whiffin.....

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Chief Investigator	Dr Charlotte Whiffin c.whiffin@derby.ac.uk 07800664853
Study Co-ordinator	N/A
Sponsor	Nottingham University Hospitals NHS Trust researchsponsor@nuh.nhs.uk 0115 924 9924
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	National Institute for Health and Care Research (NIHR) Research for Patient Benefit.
Key Protocol Contributors	Dr Fergus Gracey (Joint lead applicant) f.gracey@uea.ac.uk Dr Caroline Ellis-Hill (Co-applicant) cehill@bournemouth.ac.uk Dr Alyson Norman (Co-applicant) alyson.norman@plymouth.ac.uk Morag Lee (PPI co-applicant) moglee@sky.com Pam Singh (PPI co-applicant) pam_singh@hotmail.co.uk
Committees	N/A

STUDY SUMMARY

Study Title	Working with the 'Life Threads' approach to support families after traumatic brain injury.
Internal ref. no. (or short title)	Life Threads - TBI
Study Design	A qualitative study situated within an interpretivist paradigm
Study Participants	Family members of relatives who have sustained TBI in the last 2 years from the East and West Midlands of England
Planned Size of Sample	50 (stage 1) 20 (stages 2-6)
Follow up duration	One month
Study end definition	Study end is defined as completion of the final data collection period. For this study completion of focus group II by all participants will determine study end
Study end date	31st May 2024
Research Question/Aim(s)	Qu. Does narrative storytelling through the 'Life Threads' approach support processes of family well-being and adjustment post-TBI? Aim: To understand the clinical potential of storytelling through the 'Life Threads' approach and gather the information required to plan a feasibility randomised control trial. Objectives: 1. Explore if family members' find storytelling through the 'Life Threads' approach useful as a strategy to support their individual subjective wellbeing and adjustment post-TBI. 2. Assess uncertainties in relation to the 'Life Threads' approach including: acceptability; adherence; and level of facilitation required.

	3. Identify appropriate methods for a feasibility study including: representative recruitment; choice of primary outcomes; mode of delivery; and comparator arm(s). 4. Understand how family members use the 'Life Threads' approach to understand the impact of TBI on themselves and their family. 5. Explore if the four domains of subjective experience post-TBI (Displacing and Anchoring; Rupturing and Stabilising; Isolating and Connecting; Harming and Healing) are representative of family member experiences.

FUNDING AND SUPPORT IN KIND

<table>
<tr><th>FUNDER(S)
(Names and contact details of ALL organisations providing funding and/or support in kind for this study)</th><th>DETAILS OF FINANCIAL AND NON FINANCIAL SUPPORT GIVEN</th></tr>
<tr><td>National Institute for Health and Care Research (NIHR) Research for Patient Benefit.
Nicolas Sillett (nicholas.sillett@nihr.ac.uk)</td><td>£141,778.00
<table>
<tr><th>Cost</th><th>Year 1</th><th>Year 2</th></tr>
<tr><td>1. ANNUAL COSTS OF POSTS</td><td>£54,437.42</td><td>£27,765.90</td></tr>
<tr><td>2. TRAVEL, SUBSISTENCE & CONFERENCES</td><td>£6,662.20</td><td>£7,341.00</td></tr>
<tr><td>4. CONSUMABLES</td><td>£503.74</td><td></td></tr>
<tr><td>5. PATIENT & PUBLIC INVOLVEMENT</td><td>£2,967.00</td><td>£3,418.50</td></tr>
<tr><td>6. OTHER DIRECT COSTS</td><td>£5,432.46</td><td>£6,461.23</td></tr>
<tr><td>7. INDIRECT COSTS - HIGHER EDUCATION INSTITUTION (HEI) INDIRECT COSTS</td><td>£39,252.64</td><td>£19,607.75</td></tr>
<tr><td></td><td>£109,255.46*</td><td>£64,594.38*</td></tr>
</table>
*HEI costs at 80%</td></tr>
</table>

ROLE OF STUDY SPONSOR AND FUNDER

For the avoidance of doubt, **Nottingham University Hospitals NHS Trust** shall act as Sponsor under the UK Policy Framework for Health and Social Care Research. Nottingham University Hospitals NHS Trust shall have overall responsibility for the conduct of the Project.
The study is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR204092). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

The study sponsor will monitor the study conduct against applicable regulatory standards. The study sponsor and study funder will have no role in the design, data analysis, interpretation, manuscript writing and dissemination of the results. The sponsor and funders will be consulted for the final decision/s regarding any aspects of this study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Independent steering committee
To provide overall independent supervision of the Life Thread-TBI project.

To monitor the timely progress of the Life Thread-TBI project, adherence to the protocol and participant wellbeing.

To monitor spending against the project costing forecast.

Project management group
All operational matters relating to the Project shall be decided upon by the Project Management Group which shall also put in place a suitable structure to manage the Project that it agrees.

PPI Advisory Group
To ensure that the views of family members are integrated to the design and conduct of the research.

Protocol contributors

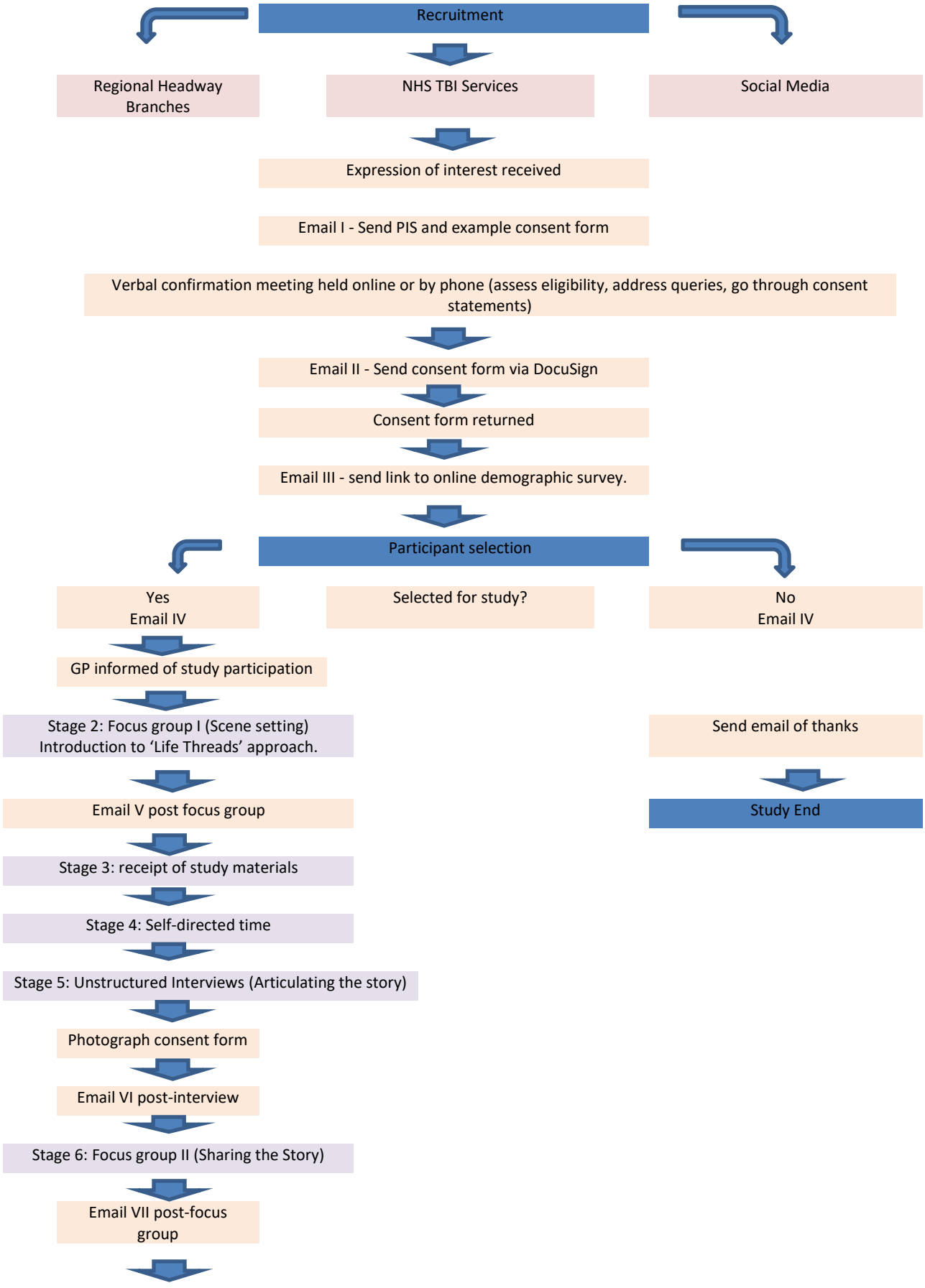
Dr Charlotte Whiffin (Chief investigator) Associate Professor in Nursing, University of Derby	Overall responsibility for the proposed research.
Dr Fergus Gracey (Joint lead applicant) Associate Professor in Clinical Psychology, University of East Anglia	Mentoring lead applicant and advising on study methods and dissemination.
Dr Caroline Ellis-Hill (Co-applicant) Senior Lecturer in qualitative research, University of Bournemouth	Advising lead applicant on study methods and dissemination.
Dr Alyson Norman (Co-applicant) Associate Professor in Psychology, University of Plymouth	Lead for PPI advising lead applicant on study methods and dissemination.
Mrs Morag Lee (PPI co-applicant)	Advising the steering committee and keeping the study grounded in the lived experience of family members.
Ms Parmjeet Singh (PPI co-applicant)	Advising the steering committee and keeping the study grounded in the lived experience of family members.
Dr Mark Holloway (Collaborator) Brain Injury case manager and expert witness	Will support the PPI and data analysis/interpretation workstreams.
Dr Natasha Yasmin Felles (Collaborator) Clinical psychologist and lecturer in psychology, University of Derby.	Will support the methodology workstream with CW.
Sara Rose (Collaborator) Dance and movement psychotherapist, PhD candidate University of Derby	Will work alongside CW in recruitment, consent and data collection.
Dr Audrey Daisley (Collaborator) Consultant clinical neuropsychologist independent practice.	Will support data analysis/interpretation and dissemination/impact workstreams.

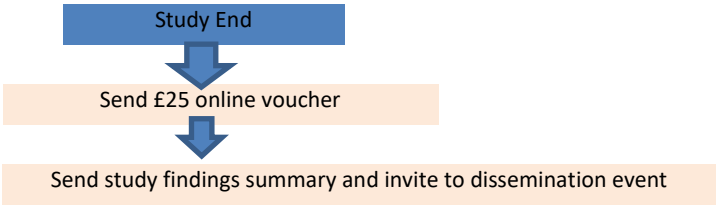
Jo Clark Wilson (Collaborator) Occupational therapist/case manager Head First and chair of Brains Matter.	Will support data analysis/interpretation and dissemination/impact workstreams.
Sponsor / Funder	For the avoidance of doubt, **Nottingham University Hospitals NHS Trust** shall act as Sponsor under the UK Policy Framework for Health and Social Care Research. Nottingham University Hospitals NHS Trust shall have overall responsibility for the conduct of the Project. The study is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR204092). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

KEY PHRASES: Brain Injuries, Traumatic; Family; Qualitative Research; Adaptation, Psychological; Focus groups.

Table of Contents

STUDY FLOW CHART




Study End
Send £25 online voucher
Send study findings summary and invite to dissemination event

STUDY PROTOCOL

Title: Working with the 'Life Threads' approach to support families after traumatic brain injury (Life Threads – TBI).

1. BACKGROUND

This is a preparatory study to identify the promise of the 'Life Threads' approach in supporting family member well-being and adjustment post-injury. When a traumatic brain injury (TBI) is sustained by a close relative, families are pulled into a frightening world of trauma, loss and negative change. Family members describe grieving for a person who is still physically present but is different to before (1). Many family members adopt caring responsibilities, lose employment and become socially isolated. Futures within this context are perceived to be of less value, tainted with the knowledge that hopes and dreams as a family may be lost forever. These losses are felt acutely, and families suffer within their wake. Family members have little to relieve their trauma, resolve their grief or prevent their suffering. Left unchallenged, without support, such changes pose a substantial risk to their physical, psychological and emotional well-being. This study is important because it aims to explore ways family members can reduce problematic responses post-TBI. This study may be of value to both family members and their injured relative while also possibly benefiting healthcare delivery and wider society.

2. RATIONALE

For those under 40 years of age TBI is the leading cause of disability in the UK (2–4). Recovery is commonly incomplete and those who survive are often left with a complex range of physical, psychological, cognitive, behavioural and emotional deficits. Survivors rarely return to their pre-injury life, without consequence, and families are braced for change. Family members are considered vulnerable and are known to exhibit symptoms of depression, anxiety, stress, and reduced life satisfaction (5–9). TBI has a significant negative effect on family relationships, lifestyles and quality of life (10). Brain injury damages the stability of the family system and negatively affects family functioning. It is not the physical demands of caring that cause the greatest burden but trying to live with changes in personality, behaviour and cognition (9,11–16). Poor family functioning has been associated with emotional distress including anxiety, depression and increased strain (15,17–20) and is also linked to poorer outcomes for the injured person (20). Despite the evidence showing the importance of positive family functioning, and repeated calls for comprehensive services to support families to adjust post brain-injury (21) support for families is inconsistent at best, and what is available often inadequate for their needs (1). While formal psychological therapy is essential for complex psychological issues, this is not available, nor appropriate, for many family members.

The impact of TBI on the family is inevitable, enduring, and there is increasing recognition that family members are changing post-TBI in response to a major life event. Studies have shown the importance of subjective changes experienced by family members in understanding recovery and rehabilitation (22–26). In response to this increasing evidence base we (CW, FG, CEH) conducted a meta-synthesis of thirty qualitative studies that aimed to examine the family experience of adult TBI (27). We identified four domains of subjective experience each of which had two inter-related parts: Displacing and Anchoring; Rupturing and Stabilising; Isolating and Connecting; Harming and Healing. The interpretation of these parts revealed the substantial existential work involved for families negotiating lives, maintaining family system equilibrium and moving forward. We concluded that family members have their own unique subjective needs and recommended more research that explored the conditions which maximise opportunities to develop richer accounts post-injury not saturated by trauma and loss. We also suggested that storytelling approaches with uninjured family members was an emerging area that warranted further evaluation.

Traditional rehabilitation models typically focus on "functional status and psychological distress, rather than changes in self-understanding in response to trauma and rehabilitation"(28, p.2). This holds as true for family members as it does for person with brain injury (29) but the deficit in support is vaster. Storytelling (i.e. narrative) approaches are becoming an established part of the neurorehabilitation landscape for those with TBI (30,31) and studies have demonstrated their use in building a strengths-based identity (32). However, despite some useful discussion of practice examples that illustrate the potential of narrative approaches to help family members (32–34) there is a lack of empirical evidence of effectiveness.

Narratives are an expression of how we see ourselves and our presentation to others (35). Attending to the narrative changes felt and experienced by family members and helping them to make sense of what they themselves have been through may create opportunities to work in more positive ways with family members post-injury. There are lots of examples of family members sharing their stories as books, blogs, conference presentations and this provides some evidence that this storytelling is valued and facilitating storytelling may make it accessible for more people.

Storytelling is a highly accessible modality, that transcends cultural, literacy and gender barriers. Momentum for such approaches continues to grow and these are increasingly seen as central to person-centred provision (36). Similarly arts-based research is increasingly popular as a therapeutic intervention and is used often where thoughts are not as easy to express in words (37). In this research we are combining storytelling with an arts-based approach. Together, and individually, these methods have potential for creating 'shared, embodied understanding' (37).

The 'Life Threads' approach as a specific narrative storytelling method may be useful post-TBI due to its origins with stroke survivors (38). The Life Thread Model was devised by CEH following interviews with 20 people and their partners following a stroke. The Life Thread Model provides a visual representation of the narrative threads that we use to create a sense of coherence and identity through life (See Figures 1-4).

The four stages describe:

i. The Life Threads (or life stories) as coherent, creating continuity with past present and future self.
ii. How these Life Threads (or identities) are created in relation with others and wider society.
iii. The fraying which occurs with a sudden life disruption such as ABI.
iv. How life threads can be reconnected, developed or safely tied off through physical and discursive interventions.

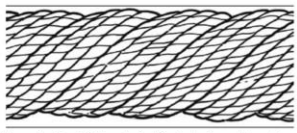


Figure 1: The life threads (or life stories) as coherent, creating continuity with past present and future self

Figure 2: How these life threads (or identities) are created in relation with others and wider society

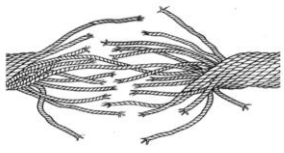


Figure 3: The fraying which occurs with a sudden life disruption such as ABI

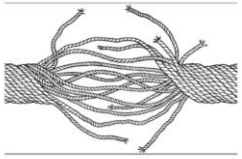


Figure 4: How life threads can be reconnected, developed or safely tied off

The model suggests that positive emotional responses can be supported through:

1. Endorsing a positive view of self.

2. 'Being' with somebody as well as 'doing' things for them.
3. Seeing acquired disability as a time of transition rather than simply of loss.

Whilst firmly grounded in qualitative analyses of people's everyday experience, use of the Life Thread Model as a clinical tool to help people with their processes of adjustment has not been empirically investigated. We will apply the principles of the Life Thread Model to a method of storytelling that we call the 'Life Threads' approach. Given the emerging evidence base advocating the use of narrative approaches with people who have sustained TBIs we predict that attending to the narrative changes felt and experienced by family members and empowering families to find hope and new meaning in their lives will create opportunities to work in more positive ways to support family well-being and adjustment. However, we do not yet know the best way to deliver the 'Life Threads' approach or the extent to which it requires facilitation. The answers to these questions are key outcomes of the study.

Therefore, our research question is: Does narrative storytelling through the 'Life Threads' approach support processes of family well-being and adjustment post-TBI?

3. THEORETICAL FRAMEWORK

This is a qualitative study that will allow us to explore the value and acceptability of using the 'Life Threads' approach with family members post-TBI. Qualitative research attempts to interpret the meaning people bring to their experiences (39). This study is situated within an interpretivist paradigm with a relativist ontology and constructivist epistemology. Work with subjectivity and honouring multiple realities (40) will facilitate an in-depth and exploratory approach. This commitment to qualitative philosophy will strengthen understanding of the perceived benefits of using the 'Life Threads' approach from the participant's perspective.

4. RESEARCH AIM

To understand the clinical potential of storytelling through the 'Life Threads' approach and gather the information required to plan a feasibility randomised control trial.

1.1. Objectives

1.2. Primary Objective

A. Explore if family members' find storytelling through the 'Life Threads' approach useful as a strategy to support their individual subjective wellbeing and adjustment post-TBI.

1.3. Secondary Objectives

B. Assess uncertainties in relation to the clinical application of 'Life Threads' approach including: acceptability; adherence; and level of facilitation required.
C. Identify appropriate methods for a feasibility study including: representative recruitment; choice of primary outcomes; mode of delivery; and comparator arm(s).
D. Understand how family members use the 'Life Threads' approach to understand the impact of TBI on themselves and their family.
E. Explore if the four domains of subjective experience post-TBI (Displacing and Anchoring; Rupturing and Stabilising; Isolating and Connecting; Harming and Healing) are representative of family member experiences.

1.4. Outcome

We will know if the 'Life-Threads' approach is useful through the interpretation of what people tell us during interviews and focus group, what people show us during individual interviews, adopting a critically reflexive approach to analysis and the discussion of these interpretations with both co-researchers and the PPI representatives.

This study will tell us about the clinical potential of families who are supported to tell their story through the 'Life Threads' approach and if this is beneficial for their wellbeing and adjustment post-injury. This is of importance to both the brain injury community and the professionals who support them and following this study we will be able to explore whether the 'Life Threads' approach can be integrated into professional practice. The significant mental health issues that can arise after a family member sustains a TBI are rarely addressed by neurorehabilitation services or indeed GP/ community based mental health and wellbeing services. Finding ways to support these complex processes provides: 1) support to family members whose injured relative is accessing NHS services; 2) reduces the need for specialist intervention from NHS mental health services.

If this study shows the 'Life Threads' approach is of benefit to family members, then this may also lead to positive outcomes for the person with brain injury who will benefit from more stable family support networks.

Impact is also achieved through the generation of new knowledge as this research will be amongst the first to provide empirical evidence for whether narrative storytelling approaches with family members post-TBI are acceptable and offer promise. This evidence is crucial for services that want to support families post-TBI through mobilising the talents within the existing neurological workforce rather than relying on those of a specialist.

5. STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

5.1 Data collection

The study is conducted in six stages after informed consent has been provided:

1. Collection of demographic data.
2. Focus group I: Scene setting.
3. Receipt of study materials.
4. Self-directed time.
5. Unstructured interviews: Articulating the story.
6. Focus group II: Sharing the story.

5.1.1. Collection of demographic data:

In this study we aim to be inclusive and recruit people from a diverse range of backgrounds. However, in a study with a small sample size there is a risk of not recruiting people from under-served groups. Therefore, we will collect demographic data after formal consent to prioritise recruitment from specific groups including LGBTQ+ communities and Black, Asian and mixed ethnic groups.

After informed consent [see Informed Consent Form (ICF)] has been given, participants will be provided with a random four-digit study ID and will be asked to provide the following information [see demographic survey]: Age; gender; sexual orientation; ethnicity; first language; marital status; disability; religion; and contact with NHS/third sector organisations. These data will allow us to invite participants from a wider range of diverse backgrounds to participate in the focus groups and

interviews reflective of the local population and heterogeneity within the brain injury community. These data will be recorded by the CI and added to an excel spreadsheet.

We will also ask the family member to provide data pertaining to the injured person to provide contextual understanding of the nature and severity of brain injury. These data include: age; time since injury; severity of injury, gender, sexual orientation; ethnicity; first language, marital status; disability; and living arrangements.

Family members will be written to via email by the CI and informed if they have, or have not, been selected to participate in the next phase of the study [see Email IV]. Once the study sample has been recruited the demographic data for those who have not been recruited will be fully anonymised and summarised so these data can be reported on as a comparator to the sample recruited.

Those who have not been selected will be asked if they would like to receive updates on the study and if they wish to be invited to participate in future research. Email addresses for those who wish to stay informed will be retained so we can write to them with a summary of the study findings.

5.1.2. Focus group one: Scene setting.

Focus groups are a popular method in health services research for their ability to determine views and perspectives on healthcare interventions and initiatives (41). We will hold focus groups with approximately four – six participants in each. Typical size for a focus group is 6–12 participants, (42) although other researchers suggest 4 to 8 (43). Smaller groups are better for more complex or sensitive topics where participants feel they need more time to share their experiences. To ensure study methods are inclusive we will offer focus groups in both face-to-face and online formats. Participants can then choose which mode of participation they would prefer for the focus groups. Online focus groups will be held using Microsoft Teams and recorded using the desktop application. For face-to-face focus groups we will use an encrypted audio recording device. At each focus group we will aim to have at least three members of the research team. This will enable one researcher to follow-up any participant who leaves the focus group, by choice (for example if they become upset), or through connectivity issues and need help to re-join. Focus groups will last approximately 60-90 minutes.

The first focus group (scene setting) has two main aims. The first is to provide an opportunity for participants to share their experiences. Our PPI group reminded us of how important, and meaningful, it was for them to share their individual story with others. We will then use these data to determine the broader social context of each family system. The second part of the first focus group will be used as an introduction to the 'Life Threads' approach [see Focus group schedule].

Once participants have completed the first focus group, they will be sent an email thanking them for their participation and details on what happens next [see Email II]. Participants will be informed that they are being invited to complete a follow-up interview and how to make the necessary arrangements with the lead researcher.

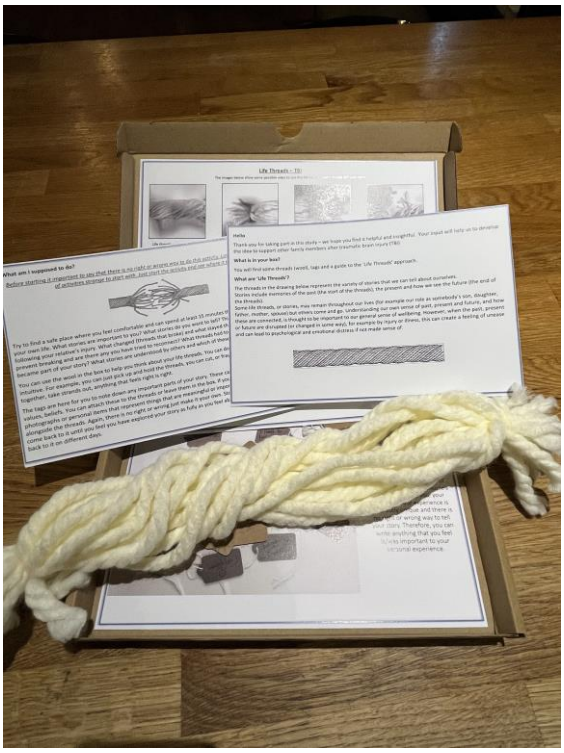
In this study the focus groups are primarily a means of data collection and not a specific part of the 'Life Threads' approach. However, we will need to carefully evaluate the additional value, if any, of sharing Life Threads with a wider community of family members.

5.1.3. Receipt of study materials.

Each family member will be sent the 'Life Threads' approach through the post in a 'large letter cardboard postal mailing box'. The items depicted in Figure 5 will be sent to participants in this study

together with an explanation of the 'Life Threads' approach [see: 'Life Threads' approach boxes and instructional text].

Figure 5: 'Life Threads' approach materials to be sent to family members.



5.1.4. Self-directed time.

Participants will be asked to engage with the Life-Thread approach using the study materials provided for approximately one month. We will not limit the ways participants can do this but will suggest possibilities such as writing down meaningful events/ experiences, adding photographs, or using artifacts as representations of things that are meaningful to their story. Photographs and drawings are commonly used in arts-based health methods (37). Participants will be asked to think and reflect on these choices prior to the unstructured interview.

5.1.5. Unstructured interviews: Articulating the story.

In contrast to the focus groups which emphasise a collective experience, we will use unstructured follow-up interviews to examine the individual experience [see Unstructured interview schedule]. Interviews will be conducted by CW, in a location chosen by the participants. This location may be their home or workplace, alternatively we will be able to use a room at the University of Derby or a regional Headway centre. An online interview may be conducted where requested or required.

It is possible that engagement with the 'Life Threads' approach will vary from comprehensive and creative usage to no usage at all and we will need to explore this variation in use. Participants who have engaged will be asked about their choices of artifacts/photographs and what they mean to them and their story. Participants who have not used the materials in their own time will be supported to work with the materials in a co-created way with the researcher during the interview itself. These experiences may help us to understand the benefits of a more, or less, facilitated approach to using the 'Life Threads' approach. At the end of the individual interview the researcher will take photographs of the participant's creation and seek consent to share this with other participants in focus group II [see: Photograph consent form]. Once participants have completed the

unstructured interviews, they will receive another thank you email and details of focus group II [see Email III].

5.1.6. Focus group II: Sharing the story.
In the second focus group we will aim for participants to meet with the same family members from focus group I and we will share the images of the creations if consent is provided. We will ask participants what worked well, what did not, what improvements could be made and if this would be helpful for others. We will talk about their experience of working with the materials on their own versus working with the materials with the researcher. We will ask what, if anything, they feel they have gained from the storytelling using the 'Life Threads' approach, over and above talking with us in the focus groups and individually. We will ask if they have continued to work with the materials since the interview or if they have shared them with anyone else outside of the research. These questions will guide our understanding of whether the materials could be used in a self-guided way or if facilitation is required [see Focus group II schedule].

Once the second focus group has been completed an email to participants will explain that their commitment to the study has now ended but that they will be invited to an event where the findings will be shared with them [see Email IV]. As a small token of gratitude, we will provide participants with a £25 amazon voucher on completion of the study (an alternative online voucher be requested if preferable).

5.2 Analysis
This study will use thematic analysis to analysis data from focus groups and interviews. Thematic analysis is a widely used method to analyse qualitative data by searching for patterns of meaning. We will use a specific TA approach, namely, 'reflexive Thematic Analysis' (rTA) which involves six stages (Table 3) (44–47).

Table 3: The six stages of reflexive Thematic Analysis (Ref)	
1.	Data familiarisation and writing familiarisation notes
2.	Systemic data coding
3.	Generating initial themes from coded and collated data
4.	Developing and reviewing themes
5.	Refining, defining and naming themes
6.	Writing the report.

Analysis of the focus group and interview data will address the objectives as identified in Table 2. All data will be analysed using thematic analysis. Given that the research question is broad and exploratory we will not decide what is important in the data a priori. We will use established qualitative techniques to analyse the data for what is common and particular and where engagement with the 'Life Threads' approach has worked well or failed to work as expected. Therefore, whilst we do have certain areas of interest, we will be open and curious about the data and prioritise an inductive approach to analysis.

Table 2: How the analysis of data sources contributes to specific research objectives.			
		Focus groups I & II	Interviews
	Primary objective		
A	Explore if family members' find storytelling through the 'Life Threads' approach useful as a strategy to support their individual subjective wellbeing and adjustment post-TBI.	x	x

	Secondary objectives		
B	Assess uncertainties in relation to the 'Life Threads' approach including: acceptability; adherence; and level of facilitation required.	x	
C	Identify appropriate methods for a feasibility study including: representative recruitment; choice of primary outcomes; mode of delivery; and comparator arm(s).	x	
D	Understand how family members use the 'Life Threads' approach to understand the impact of TBI on themselves and their family.		x
E	Explore if the four domains of subjective experience post-TBI (Displacing and Anchoring; Rupturing and Stabilising; Isolating and Connecting; Harming and Healing) are representative of family member experiences.		x

MP4 video files will be converted to MP3 audio files and sent via an encrypted file transfer system to an NHS-approved supplier for transcription. Pseudonymised files will then be returned via email to the lead researcher to be checked against the audio and video files for accuracy and anonymisation.

Stages one to three of rTA will be followed for focus group and interview data separately. Stages four to six will then be completed with the full data set to find patterns and meaning across the data set. The research team are experienced qualitative researchers and are familiar with the proposed approach to thematic analysis. Data collection and analysis will occur in parallel so that early analysis can inform later data collection. A team approach will be adopted where an anonymised summary is shared with co-researchers and the PPI advisory group to challenge and advance interpretation reached.

Analysis will be supported by the use of NVivo software allowing researchers to organise the data, share coding decisions, discuss generation of themes and confirm the origins of interpretation.

6. STUDY SETTING

The study setting is the East and West Midlands regions which includes rural and urban locations and has a diverse socioeconomic and ethnic population. We are specifically targeting these areas so that we can work with the regional Headway branches and groups, and specifically target under researched groups.

7. SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Any family member, or close friend, can take part (e.g. spouse, partner, sibling, grandparent, significant other) and more than one person per family can take part. We will use an inclusive definition of family as 'the family is who they say they are'(48) so that any person who identifies as a member of the injured person's family, including a close friend, is eligible. Furthermore, the current evidence base regarding the experiences of families post-TBI is formed predominantly by respondents who are white, female, and in heterosexual relationships (27,49). We will make sustained efforts to recruit from other under-researched groups including male relatives and families with same-sex couples. We will recruit and collect data from family members and not the injured person (Table 1). This focus is important because so little is focused on resources to help families with their unique needs. We have carefully explored the inclusion criteria for this study with our PPI group. We decided on these criteria to recruit family members who would be less likely to be within the traumatic and distressing period of their response to TBI. This will allow us to use the 'Life Threads' approach with fewer risks of psychological/emotional distress. Our PPI group felt it was

important to allow participants the opportunity to have another family member or friend present during data collection. However, they were divided on whether this should include the injured person. This has been a difficult issue to resolve. One difficulty we know about from our work with family members is that it can be difficult to take time away from their caring responsibilities therefore we have made provision and budgeted for community support via regional Headway branches during data collection to allow the family member to participate on their own. We will carefully evaluate this decision during the study.

7.1.1 Inclusion criteria

- Identifies as a family member or close friend of a person with: Any severity traumatic brain injury, sustained at least two years prior, age at injury 18 years or older.

The family member must be:

- Known to the injured person before injury.
- Age 16 years or above.
- Able to give informed consent.
- Residing within the East/West Midlands of England.
- Have access to a smart phone, tablet or computer that can access the internet.
- Willing to participate in a group.
- Fluent in English.

7.1.2 Exclusion criteria

Those with mental health issues of a nature or severity that jeopardise safe engagement in the study tasks.

We anticipate the study tasks might be naturally emotive for participants. Many family members will be familiar with their own understandable emotions about their situation, and some may be seeking more formal support, or have their own established ways of coping. We do not want to create barriers for participation as negative emotions are common amongst family members and the study aims relate to the emotional needs of this population. Therefore, we would only exclude those who feel their circumstances or mental health needs might make participation too distressing for them. Family members will be asked to verbally confirm at the pre-consent meeting prior to recruitment.

7.2 Sampling

7.2.1 Size of sample

Up to 50 people will be recruited in stage one of this study (completion of demographic questionnaire). However, only 20 of these will be invited to complete stages 2 – 6.

A sample size of 20 for qualitative data collection is within the parameters identified for data saturation within qualitative research (50,51). However, saturation is a contentious issue with those who have expressed concern about its overuse and lack of explanation for its application within the context of the study methods proposed (40,52–54). Data saturation is also not aligned to the proposed analytical framework for this study (55).
An alternative to data saturation is proposed by Dey (56) as data ‘sufficiency’ whereby the sample is good enough to address the research questions. In the context of this study the sample of 20 participants was identified based on what is considered sufficient to address the aims and objectives

of this study and feasible within the resource constraints of the projects. We will evaluate the sufficiency of the sample size during the data analysis phase.

7.2.2 Sampling technique

The study will use a non-random purposive variation sample (similar to quota sampling) whereby we will work collaboratively with gatekeepers to recruit people from a range of cultural backgrounds. We have reviewed the NIHR-INCLUDE guidance (57) and all those eligible will have equal opportunity to participate. Regional data suggests approximately 20 – 30% of the East/West Midlands identify as Black, Asian or Mixed ethnicity. We are committed to reflecting this diversity within the sample.
Given the sample size, collaborative study methods and exploratory nature of this study we feel it is reasonable to restrict the sample to those who speak English. Within the regions identified for study recruitment, 6.2% of the East Midlands (58) and 7.2% of the West Midlands (59) population speak a language other than English as their main language. However, we will recruit all those with sufficient English to engage with the study methods in a way that yields interpretable results.

7.3 Recruitment

We will use a three-pronged approach to recruitment: NHS; third sector and social media.

7.3.1 Sample identification

NHS: We will recruit through NHS TBI services at:

- QMC, Nottingham University Hospitals NHS Trust
- Royal Derby Hospital, University Hospitals of Derby and Burton NHS Foundation Trust
- Queen Elizabeth Hospital, University Hospitals Birmingham NHS foundation Trust

Each site will act as a participant identification centre. A member of the direct care team will review patient records for eligibility and identify the next of kin contact details.

The patient will be written to first [see Patient letter] informing them about the study and notifying them that their family member will be contacted directly by the research team approximately one week later. Patients, or people who normally support them, can contact the lead researcher if they have any questions. The recorded next of kin will then be written to with a study summary sheet and contact details to express their interest [see NoK letter and Study summary sheet]. Depending on local practice preferences the patient, and NoK, may be given this letter in person during a hospital visit or this letter may be sent in the post / via email.

Third sector: We will use our established relationships with the third sector organisation Headway. Managers of regional branches and groups in the East and West midlands will be given a general notice of study recruitment [see General notice of study recruitment for regional Headways] to be sent to members directly or to be included in newsletters or social media pages. We will also provide a family member letter [see Family member letter] and study summary sheet to be sent to directly to family members who are registered with the local branch/group. This email will be sent by a staff member at the local Headway. Family members can then contact the CI directly to express interest in taking part.

Social Media: An infographic [see Infographic for social media] will be posted on Social Media Channels including Twitter, LinkedIn and Facebook. We will tag relevant organisations such as

Headway UK, regional headway groups and branches, the United Kingdom Brain Injury Forum (UKABIF); Headfirst and Anchor Point. We will also ask UKABIF and Anchor Point to send the recruitment details to their mailing list. The infographic has a QR code leading to the study summary sheet providing additional detail prior to contacting the CI to express an interest in the study.

For all recruitment methods interested parties will be able to contact the CI to request further details at which stage they will be sent a participant information sheet and example consent form. If a family member wanted to pass on details of the study to someone else, they may do so. This person can then contact the CI in the same way to express an interest in joining the study.

Participants will be offered reimbursement for all reasonable travel expenses in addition to a £25 Amazon voucher on completion of the study (an alternative online voucher can be requested by the participant such as 'love to shop'). If the participant requires respite for their relative with brain injury to enable them to participate, we will pay for the cost of attending their local Headway for one full or half day.

7.3.2 Consent

All participants will provide electronic consent. Participants will first be sent a participant information sheet (PIS) [see PIS] and example consent form on expression of interest [see ICF]. The PIS will make all study procedures transparent. A telephone/online meeting will be arranged with the CI at least 48 hours later so that family members have the opportunity to ask any questions they may have and have these answered to their satisfaction so they can make an informed decision about their participation in the study. Consenting statements will be read out and participants asked to verbally confirm they understand and agree with these. The consent form will then be returned to participants via DocuSign for electronic signature. Participants will be asked to download a completed copy for themselves. We will also use the consent form to record GP details. These details are required so that we can inform the GP of their participation in the study.

While we recognise that the injured and un-injured family member's stories are intertwined it is important to give the family member the right to choose themselves if they wish to participate. Therefore, we will not seek formal consent from the injured person for their family member to take part. We will ask the family member to be open and honest with the injured person, and encourage dialogue between the family members about the study. If the injured person wishes to talk to the researcher we will ensure we make time to discuss the study with them and answer any questions they have. This transparent approach has shown to be effective in a prior study (60). We will then ask the participating family member, during the consenting process, to confirm that their injured relative does not object to their participation in the study.

A separate consent form will be used for the CI to take photographs of the 'Life Threads' approach during individual interviews.

7.3.3 Right to withdraw.

Participants are free to withdraw from the study at any time without reason and without penalty. However, withdrawal of research data will be subject to the following restrictions:

- Interview data – can be withdrawn up to seven days after completion of the research interview.
- Focus group data – can NOT be withdrawn from analysis; however, participants will have up to seven days to request their responses in the focus group (full or partial) are not included in publications.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk
The primary risk to participants associated with the study are psychological/emotional upset from telling their story (please see adverse events). Participants will be cautioned about this and told they do not have to answer any questions they find uncomfortable to answer. Participants will also be advised they can stop the recording at any time during the interview and either re-start after a short break or end at that point. Our experience would suggest emotional upset caused by retelling their story is within tolerable, and manageable limits.

All participants will be signposted to the Headway UK national support line and their regional branch after the interviews have been completed. We will also recommend the participant contacts their GP [see GP letter] or self-refers to the Improving Access to Psychological Therapies (IAPT) services (the NHS web address for IAPT will be provided in the PIS) where appropriate and we will follow-up participants over the phone 24-48 hours after the interviews.

In cases of more severe distress, we will provide a one-hour debrief with a psychologist. After this debrief the psychologist can then refer to appropriate ongoing services if necessary. Referral to a psychologist will be classed as an adverse event.

While we do not anticipate that any illegal activity or safeguarding concerns will become apparent during this research, we will inform participants of what we will do if such disclosure is made. Context depending, concerns will be discussed with the participant and the research programme team. If action is required, we will escalate our concerns to the appropriate authorities which may be the police, social services the referring NHS service, or the regional Headway branch/group.

Participants are given the choice for where their individual interviews will be held. If this is in a participant's home a safety protocol will be initiated where a member of the research team will be notified of the time and date and location of the interview taking place. An email or text will be sent to this person to state the interview has commenced. After the interview has been completed an email or text will be sent again to notify this person that interview has ended. If this communication is not sent within three hours the designated member of the research team will call. If there is cause for concern, a pre-agreed 'safeword' will be used and the member of the research team will then contact the police.

8.2 Research Ethics Committee (REC) review & reports
We will ensure all regulatory and ethical approvals are in place prior to commencing the proposed research.

We will submit a request for ethical review from the Health Research Authority/NHS Local Research Ethics Committee through the integrated research application system. During the research, we will safeguard confidentiality and anonymity, adhering closely to the Declaration of Helsinki and comply with the Data Protection Act (61) and GDPR. (62)

Furthermore, the CI and co-investigators are bound by their professional/regulatory codes of practice including those from the Nursing and Midwifery Council, the British Psychological Society, and the Health and Care Professions Council.

It is the responsibility of the CI to:

- Produce the annual reports as required.
- Notify the REC of the end of the study.

- Write and submit an annual progress report (APR) to the REC within 30 days of the anniversary date on which the favourable opinion was given.
- Notify the REC if the study is ended prematurely.
- Submit a final report with the results, including any publications/abstracts, to the REC within one year of the study ending.

8.3 Peer review

This protocol has been subject to independent and internal, expert and proportionate peer review by the funder (NIHR) [see Evidence of peer review and response].

8.4 Patient & Public Involvement

We met with six family members to develop this proposal. Family members told us the study was worthwhile and helped us to choose data collection and recruitment methods. We continue to work two members of this initial group as PPI co-applicants who regularly attend the project management group. Furthermore, we have a PPI advisory group to support the conduct of the study and who will be consulted about findings from the study, their interpretation and appropriate means of dissemination.

8.5 Regulatory Compliance

Before any site can enrol participants into the study, the Chief Investigator will apply for HRA approval for the study and will make contact with all potential site Principal Investigators, R&D departments and, if applicable, the local Clinical Research Network.

Prior to commencing recruitment, sites must confirm their capacity and capability to conduct the study, as per the HRA approval letter.

Any amendment to the protocol should be considered that it may potentially affect a site's capacity to continue in the study, the Chief Investigator/ Principal Investigator or designee will inform the Sponsor of the proposed amendment. The amendment will be submitted as per Section 8.4.

8.6 Protocol compliance

Accidental protocol deviations can happen at any time. These will be appropriately documented on the relevant forms and reported to the Sponsor immediately. In the unlikely event of a serious breach this will be reported to the HRA/LREC.

8.7 Amendments

Substantial amendments need to be reviewed and approved by the HRA/NHS local REC, following review by the Sponsor, and will not be implemented until relevant approvals are in place. Amendments will be undertaken and logged by the CI and tracked using good version control. Substantive changes will be communicated to relevant stakeholders by email from the CI.

8.8 Adverse Events

Where an adverse event (AE) arises from this study the CI will record the AE and report to the sponsor (see section 8.1 Assessment of Risk). In the unlikely event of a serious AE this will be reported directly the to Nottingham 1 Research Ethics committee where in the opinion of the Chief Investigator, the event was:

'related', ie resulted from the administration of any of the research procedures; and

'unexpected', ie an event that is not listed in the protocol as an expected occurrence

In this instance, RDSAE@nuh.nhs.uk will be copied into all correspondence with the REC. Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the TAFR01910 SAE form for non-IMP studies. The most recent copy of the form can be found via NUH intranet pages.

Sponsor Contact Details for SAEs:

I. Email (RDSAE@nuh.nhs.uk)

Email: researchsponsor@nuh.nhs.uk

8.9 Data protection and patient confidentiality

8.9.1 Safe storage

All personal data, raw audio files, and consent forms will be stored in a folder in a University of Derby Microsoft OneDrive accessed through a password protected computer. We are cognisant that we are collecting special category data to inform our purposive sampling strategy and will take particular care of this data. Personal data will only be accessible by the lead applicant and a representative of the sponsor where necessary.

At the end of the online focus groups and online interviews an MP4 file will be saved directly to the OneDrive. Audio files on an encrypted device will be immediately transferred to a folder in OneDrive and the data on the recording device destroyed. All personal data held by the CI will be destroyed one year after the study has been completed. However, personal data will be transferred to NUH for archiving purposes. A password protected data linkage file will also be saved in Microsoft One Drive in a different location to personal data.

The third-party transcription service is a University of Derby approved supplier.

Pseudonymised research data will be accessible to co-investigators to aid the analytical process also through the University of Derby OneDrive.

All study data will be archived by the NUH and destroyed a minimum of five years after completion of the study.

If there is any necessity for paper records these will be held in a lockable filing cabinet at the University of Derby in a location with restricted access.

8.9.2 Confidentiality

All information will be kept strictly confidential. Participants will be allocated a unique (random) four-digit study ID and this will be used to identify any pseudonymised data. A password protected data linkage file will be stored in OneDrive in a separate folder to the pseudonymised data. This file will contain names, contact details and unique study IDs. On completion of data analysis this data linkage file will be destroyed immediately. During analysis each participant will then be given a pseudonym by the research team in place of the four-digit ID.

Participants will be advised not to share any personal information in the online focus group because we cannot guarantee that other participants will keep this confidential. Participants will be told that anonymised quotes will be published in the findings of this study and that it is possible that despite these attempts to anonymise the data their contributions may be recognisable to others who know their story.

Confidentiality will be maintained unless there is a risk to self or others identified when we will initiate the safety protocol described in section 8.1.

8.9.3 Data custodian

Dr Charlotte Whiffin is the data custodian for this study.

8.9.4 Data controller

NUH and the University of Derby are joint data controllers.

8.9.5 Indemnity

As Nottingham University Hospitals NHS Trust is acting as sponsor for this study, NHS indemnity applies. NHS bodies are legally liable for the negligent acts and omissions of their employees. Non-negligent harm is not covered by the NHS indemnity scheme. The Nottingham University Hospitals NHS Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

8.9.6 Access to the final study dataset

The Chief investigator will have to access to the full data set. An anonymised data set may be used for secondary analysis where prior participant consent has been obtained. An anonymised data set will also be held by the sponsor.

9. DISSEMINATION

9.1 Dissemination policy

The study will be registered on the www.isrctn.org website and adopted into the NIHR portfolio. All dissemination/outputs will include the following statement:

"This project is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR204092). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care."

All dissemination/outputs will also acknowledge the NIHR Clinical Research Network.

On completion of the study, the data will be analysed and a final study report prepared by the CI. This report can be accessed on request.

Prior to any publication or presentation (oral or written) the Party intending to present or publish any outcomes of the Project shall provide a copy of the proposed publication or presentation to NUH and the Collaborators for review at the same time as submission for publication or at least five (5) days before the date intended for publication whichever is earlier. The Reviewing Party shall have a period of thirty (30) days from the date of posting of said text in which to intimate, in writing, to the Publishing Party that such text contains either Confidential Information or commercially sensitive information.

9.1.1 Local dissemination

On completion of this study, we will work with the PPI advisory group to develop an accessible summary of the results that will be shared with participants. Participants can also request an update on the study at any time prior to this.

We will invite participants, PPI advisory group members and the wider research team to a local post-project dissemination event at the University of Derby. We will invite participants to present at this event where we will be able to share verbal and written accounts as well as photographs and images of how the life-thread approach was used.

We will return to Headway branches/groups and share our findings with staff and members and discuss the practice implications of using the Life-Thread approach.

9.1.2 National dissemination

A summary of the study and its findings will be given to relevant stakeholders.

Findings will be shared with NHS acute and community head injury services.

We will actively engage with social media sharing our results through an infographic on Twitter, LinkedIn and Facebook.
We will continue our dialogue with our wider professional network and stakeholders to further develop these relationships and generate interest and support for our ongoing research.

9.1.3 International dissemination

The study protocol and final findings will be published in international open access journals such as 'Neuropsychological Rehabilitation' (impact factor 2.50) or 'BMJ Open' (impact factor 2.692).
We will present and/or deliver workshops at service user/professional conferences e.g. 'Ahead Together', the International Brain Injury Association (IBIA), and the Society for Research in Rehabilitation (SRR) and do this with our PPI co-applicants.

9.1.4 Authorship eligibility guidelines

9.1.5 CRediT author statement

Authorship for publications arising from this study will follow the CRediT author statement as follows:

- Charlotte Whiffin: *Conceptualization, Methodology, Investigation, Writing - Original Draft, Project administration, Funding acquisition*
- Fergus Gracey: *Conceptualization, Methodology, Writing - Original Draft, Supervision, Project administration, Funding acquisition*
- Caroline Ellis-Hill: *Conceptualization, Methodology, Writing - Original Draft, Project administration, Funding acquisition*
- Alyson Norman: *Conceptualization, Methodology, Writing - Original Draft, Project administration, Funding acquisition*
- Morag Lee: *Writing - Review & Editing, Project administration, Funding acquisition*
- Parmjeet Singh: *Writing - Review & Editing, Project administration, Funding acquisition*
- Mark Holloway: *Methodology, Writing - Review & Editing, Funding acquisition*
- Natasha Yasmin Felles: *Methodology, Writing - Review & Editing, Funding acquisition*
- Sara Rose: *Methodology, Investigation, Writing - Review & Editing, Funding acquisition*
- Audrey Daisley: *Methodology, Writing - Review & Editing, Funding acquisition*
- Jo Clark-Wilson: *Methodology, Writing - Review & Editing, Funding acquisition*

9.1.6 Manuscript authorship

Authorship on the manuscripts arising from this study is proposed as follows…

- Whiffin, CJ*., Ellis-Hill, C. Norman, A. Lee, M. Singh, P. Clark-Wilson, J. Daisley, A., Felles, N.Y., Holloway, M., Rose, S. & Gracey, F.

*Corresponding author

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11. APPENDICES

Appendix 1 - Required documentation

3_ Informed Consent Form (ICF)
4_Online Demographic Survey
5_Email I – On expression of interest
6_Focus group I schedule.
7_Email II - Consent form for signing
8_'Life Threads' approach boxes and instructional text
9_Unstructured interview schedule
10_Photograph consent form
11_Email III - Link to survey
12_Focus group II Schedule
13_Email IV - Participant selection/non selection
14_Patient letter
15_NoK letter
16_Study summary sheet
17_General notice of study recruitment for regional Headways
18_Family member letter
19_Infographic for social media
20_Participant Information Sheet (PIS)
21_GP letter
22_Evidence of peer review
23_Evidence of response to peer review
24_CVs of the research team
25_Risk Assessment
26_Letter from funder
27_OID
28_nCPIC

29_Email V Post-focus group I
30_Email VI - Post-interview
31_Email VII – Post-focus group II

Appendix 2 – Schedule of Procedures

Procedures	**Visits**				
	Screening	**0**	**1**	**Weeks 1-4**	**Week 4-6**
Informed consent	x				
Collection of demographic data		x			
Participants receive study materials		x			
Focus group I: Scene setting			x		
Time to engage with study materials				x	
Unstructured interviews					x
Focus group II					x

Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**