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

IRAS Reference: 329362

Participant Information Sheet; Version 3, [Dated 29-11-2023]

Principal Investigator: Dr Charlie Whiffin

LIFE THREADS – TBI

Contact details

Investigator 1 (Lead researcher)

Name: Dr Charlie Whiffin

Tel: 01332 593882

Email: c.whiffin@derby.ac.uk

Investigator 3

Name: Dr Caroline Ellis-Hill

Contact: cehill@bournemouth.ac.uk

Investigator 2

Name: Dr Fergus Gracey

Contact: f.gracey@uea.ac.uk

Investigator 4

Name: Dr Alyson Norman

Contact: alyson.norman@plymouth.ac.uk

1. What is the purpose of the study?

We would like to understand more about ways to support family members after traumatic brain injury. This is because family members can have increased levels of stress and reduced life satisfaction after a relative's traumatic brain injury. Family members may report loss of their own pre-injury lives and experience complex feelings of grief due to changes in the injured person. Family members are not always well supported to make sense of these complex feelings, and this can make adjustment to life after traumatic brain injury difficult for all the family.

There is evidence that suggests storytelling techniques can help people to understand and make sense of their lives. This research will explore if a specific approach to storytelling called the 'Life Threads' approach is helpful for family members after traumatic brain injury.

If you decide to take part in this research you will be invited to complete a short questionnaire, take part in two group interviews, one individual interview and will be given an activity to complete in your own time.

We aim to invite up to 50 people to complete the questionnaire and 20 people to take part in the interviews and study activity .

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, Nottingham 1 Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute for Health and Care Research has funded this research.

3. Why have I been asked to take part?

a) You have been asked to take part in this study because you are a family member, or close friend, of an adult with traumatic brain injury. To take part in this study the injury must have occurred when the person was an adult (aged 18 years or above) at least two years ago.

Furthermore, you 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.

If you meet these criteria but are concerned about your mental health in a way that may jeopardise safe engagement in the study tasks, it may be better for you not to take part in this study. The research team will speak to you about this before you make a final decision about taking part.

b) Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep, you will have the opportunity to ask questions and confirm you agree with the items on the consent form to show that you understand what is involved when taking part in this study. A copy of the consent form will be sent to you to sign via DocuSign. If you decide to take part, you are free to leave the study at any time and without giving a reason.

If you withdraw, we will still keep anonymised records relating to your participation in the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

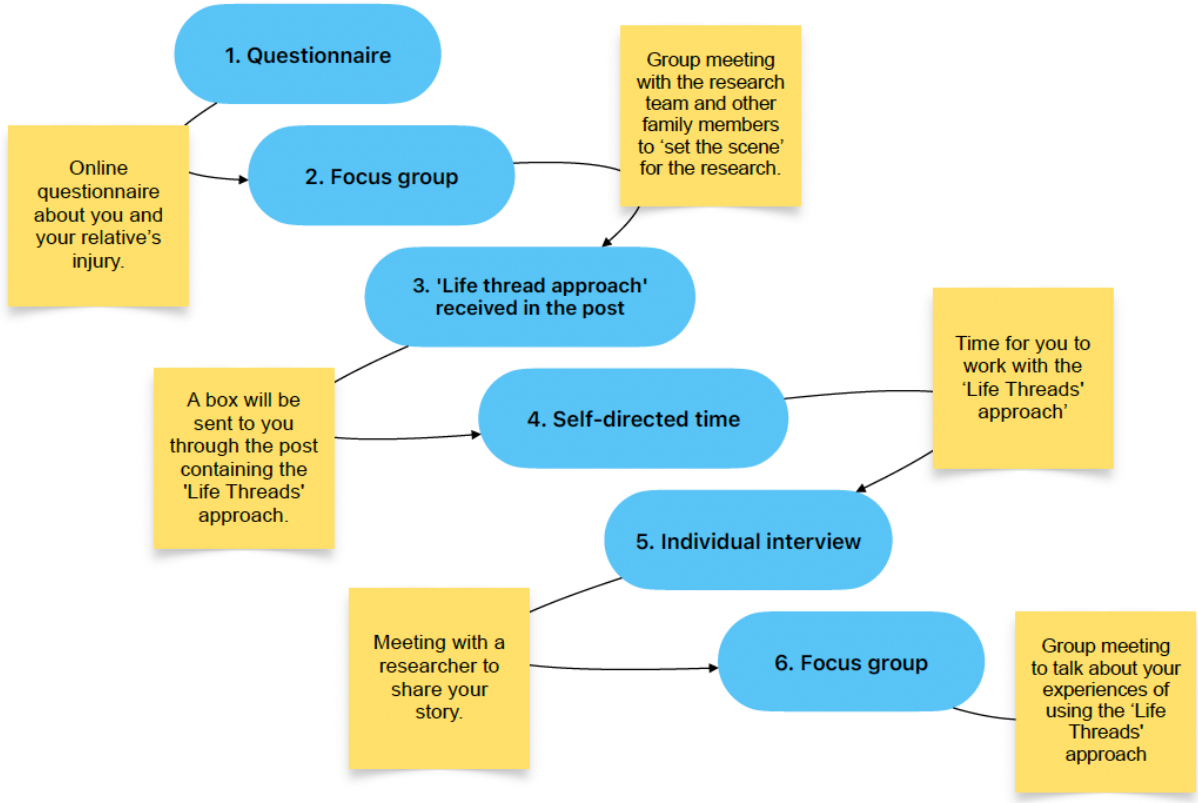
c) Can other family members take part?

Yes, other members of your family can take part, as well as or instead of you, if they meet the inclusion criteria. If you think they may be interested, please ask them to contact the lead researcher.

4. What do I have to do?

If you decide to take part, we will send you the consent form to sign using DocuSign. You will be able to review the consent statements and provide an electronic signature. Once complete this will be sent directly back to the lead researcher and you will be able to download a copy for your own records.

Once we have your consent the study is separated into six stages.



Stage 1 Questionnaire:

After you have provided consent, you will be sent a link to a short online survey. The survey should take no more than 10 minutes to complete. We will ask questions about your background and that of your injured relative. This will help us to understand the diversity of the people in the study.

We will use this information to invite people to take part in the interviews and study activity who are representative of the ethnic diversity of the East and West Midlands or are from groups that are not often included this type of research. We will write to you, within four weeks, via email to tell you if you have been invited to take part in the next stages of the research.

If you are not invited to take part any further, we will anonymise the information provided and combine it with the responses provided by other people so that you cannot be identified. Your involvement in the study will then end. If you would like to know what we find out in this research let the research team know that you would like your email to be added to our mailing list.

Stage 2 Focus group:

If you are invited to carry on with the study, you will be asked to attend a group interview called a 'focus group'. This first meeting is an opportunity to 'set the scene' both in terms of what the study is about and what you will do, and also to meet other family members in the study. We will explain the 'Life Threads' approach and show you the study activity. The 'Life Threads' approach is a creative arts-based method and this can initially feel quite strange for some. Therefore, at this first meeting we can explain the thinking behind the Life Thread approach and let you ask any questions so you feel more comfortable with the study task.

Stage 3 'Life Threads' approach received in the post:

We will send you the study activity in a post box sized parcel. This will include all the materials you need and a guide for what to do. Please let us know the best address to send this to. When you receive the box, have a look inside and familiarise yourself with the contents. If you have any questions, please contact the lead researcher using the details on the front page of this information sheet.

Stage 4 Self-directed time:

You will have approximately one month to engage in the activity in a self-directed way (this will be explained in more detail during the first focus group). There is no right way to do this activity i.e. you choose the best way of using it for your needs/experiences, just take your time. If and how you engage in the activity is part of the research aim, so do what comes naturally. We suggest you find a quiet place where you can spend at least 15 minutes on this task to start with. You can then continue to work with the 'Life Threads' approach or come back to it at another time.

Stage 5 Interview: You will be asked to identify a time and place for an individual meeting with the lead researcher where you can talk about your experiences using the 'Life Threads' approach. At the end of this meeting, we will ask to take a photograph of your 'Life Threads' and ask you to sign another consent form to show if, and how, you agree for us to share the picture we take.

Stage 6: Focus group

You will be invited to a second focus group to talk with the research team and other family members about how useful, or not, you found the 'Life Threads' activity to be, if you would recommend other family members engage in similar activities in the future and what recommendations you have to improve the approach. After the second focus group your participation in the study will end.

b) How long will the research take?

Each focus group will last 60 – 90 minutes. However, you should allow approximately two hours for this meeting. Individual interviews will last approximately 60 minutes but will depend on what you would like to share with the research team.

c) Where will the research take place?

We will ask you if you would prefer to take part in the group interview online or in person. We will provide you with several different dates and times and find one that is convenient for you. If you need to travel to any research meetings, you will be reimbursed reasonable out of pocket expenses.

For the individual interview, a researcher will meet you at a place that is most convenient. This could be at your home or workplace, a regional Headway, the University of Derby or another place of your choosing which is quiet and confidential. If you would prefer this meeting to be online, please tell us.

If you have carer responsibilities, we will pay for the cost of attending your local Headway for one full or half day.

5. What are the possible benefits?

We do not know if the 'Life Threads' approach can be used to support families after traumatic brain injury, therefore we cannot promise that participating in the research will be of any benefit to you

personally. However, we do anticipate this study will help advance supportive interventions for families after brain injury in the future.

If you complete the study, you will receive an online £25 Amazon voucher in recognition of your contribution to the study (an alternative online voucher can be requested such as 'love to shop' please just let the research team know).

6. What are the disadvantages?

You may find that telling your study is psychologically / emotionally upsetting. Our past experiences with families would suggest that sometimes this upset is a very normal response to a difficult time in their lives and they want to talk about this despite being upset. There are ways to reduce impact of this upset such as: taking your time, choosing not to answer a question, taking a break from the activities or the research interviews, or stopping altogether.

If during the research, you would like to speak with someone about how you feel we recommend calling the national helpline for Headway UK Tel: 0808 8002244 or speaking with your regional Headway branch/group (see below).

Headway Group/Branch	Contact Number	Headway Group/Branch	Contact Number
Birmingham	0121 457 7541	N Derbyshire	07940 729544
Black Country	01384 869961	North Staffordshire	01782 280952
Coventry and Warwickshire	07745525698	Northampton	01604 591045
Derby	01332 365270	Nottingham	0115 9679669
East Northants	01933 652311	Shropshire	01743 365565
Herefordshire	01432 761000	South Staffordshire	01785 257462
Leicester	0116 273 9763	Tamworth and Lichfield	07974 945028
Lincolnshire	07546592526	Worcestershire	01905 729729

You may also like to contact your GP for more formal support (we will ask you for your GP's contact details so they know about the study) or self-refer to Improving Access to Psychological Therapies (IAPT) services:

https://www.nhs.uk/service-search/mental-health/find-an-NHS-talking-therapies-service/

We will contact you approximately 24-48 hours after the research interviews if we feel it is necessary. In cases of severe distress, we can provide a one hour debrief with a psychologist. After this debrief the psychologist can then refer you to appropriate ongoing services if necessary.

We will also ask you for an emergency contact for someone who we can call if you leave an online interview, and we cannot contact you ourselves. Please let this person know that you are taking part in this research, that we have their contact number, and we may get in touch to ask them to contact you if necessary.

7. What will happen to my data?

a) What will you do with the research data?

Information from the questionnaire is pseudonymised prior to analysis and then fully anonymised once the analysis is complete. Interviews and focus groups held in person will be audio recorded using an encrypted digital recorder. Online interviews and focus groups will be video recorded using video conferencing software. Audio files for both the interviews and focus groups will be sent for transcription using a confidential approved 3rd party transcription service. All audio and video files will be deleted following the completion of analysis.

b) Will my taking part in this study be kept confidential?

All the information about your participation in this study will be kept confidential. We will keep all information about you safe and secure.

If you consent to take part in this study, the records obtained while you are in this study will remain strictly confidential at all times. The information will be held securely electronically on a University of Derby Microsoft One Drive account and, if necessary, on paper at the University of Derby under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the study. You will be allocated a study number, which will be used as a code to identify you on all study forms.

Study co-investigators will have access to pseudonymised data to aid with analysis, your names and personal details will have been removed before this is shared with them.

If you withdraw consent from this study, your data will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived by The University of Nottingham Hospitals NHS Trust for a minimum of five years. Arrangements for confidential destruction will then be made.

With your permission your GP will be notified that you are taking part in this study. We will ask you for their contact details so that we can write to them.

All will have a duty of confidentiality to you as a research participant.

While we do not anticipate that any illegal activity or safeguarding concerns will become apparent during this research, it is important that you know what we will do if such a disclosure is made. Depending on the circumstances this action may involve passing on our concerns to the police, social services, the referring NHS service, or a regional Headway branch/group. If appropriate we may be able to discuss this with you before raising these concerns with a third party.

c) Use of your personal data in research.

We will need to use information from you for this research project. This information will include your initials, name and contact details . People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will be asked to consent to future research using your data saved from this study.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk, or at the University of Derby at dpo@derby.ac.uk
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- by visiting www.nuh.nhs.uk/gdpr.

8. What will happen if I don't want to carry on with the study?

You can change your mind about taking part at any time after providing consent without giving a reason, this is called 'withdrawal'. If you withdraw, we will still keep anonymised records relating to your participation in the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive or your legal rights.

However, please note that while you can withdraw at any time you cannot withdraw information that you have provided after it has been anonymised. It is also difficult to withdraw information provided during a group discussion. Therefore, please make a note of the following conditions for withdrawal of…

- Interview data – up to SEVEN days after completion of the research interview.

- Focus group data – can NOT be withdrawn from analysis; however, you have up to SEVEN days to request your responses in the focus group (full or partial) are not included in publications.

9. What happens when the study is finished?

We will write to you after the study has completed with a summary of what we found out. We will also invite you to a follow-up event at the University of Derby. Twelve months after the study has completed, your personal details held by the lead researcher at the University of Derby will be destroyed. However, your personal details will be transferred to NUH for archiving purposes for a minimum of five years.

We will publish the findings in academic journals and at conferences. You will not be named in any publication arising from this study and any uniquely identifying features of you experience will be changed. However, it is important that you understand that despite this when we publish direct quotes, you and those close to you may be able to recognise your experience.

10. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question.
If you remain unhappy and wish to complain formally, you can do this through the sponsor team. Email researchsponsor@nuh.nhs.uk, or by phoning 0115 970 9049.
In the event that something does go wrong, and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation but you may have to pay your legal costs.
The normal NHS complaints mechanisms will still be available to you.

11. Further Information

You are encouraged to ask any questions you wish before, during or after your participation in the study. If you have any questions about the study, please speak to the research team. If you require any further information or have any concerns while taking part in the study, please contact us using the details on the front of this document.

If you decide you would like to take part, then please read and sign the consent form when it is sent to you via DocuSign. A copy of your consent form can then be downloaded for your own records. A copy of the consent form will be filed with the study records.

12. Patient and Public Involvement

All research participants should be offered the opportunity to feedback on their experiences of taking part in clinical research at NUH through the Participant in Research Excellence Survey (PRES). PRES is a requirement for all NIHR-adopted studies (although you are free to choose if you want to participate or not).

The web link is: *www.nuh.nhs.uk/ri-feedback*

13. What to do next

If you think you would like to take part, please contact the lead researcher Dr Charlie Whiffin who will answer any questions and talk you through the consent process. You will have at least 48 hours before we ask you to sign the consent form in case you would like to change your mind following this initial meeting. Before meeting the researcher, we would like to encourage you to talk about the study with your injured relative, where it is appropriate to do so. If your family member has any questions, we would be happy to speak with them. We will then ask you to confirm that your injured relative does not specifically object to you taking part.

Please take your time and think this over if you are at all unsure and talk to family members or friends if this would be helpful.

Thank you for taking the time to read this information sheet and to consider this study.

Lead researcher contact details:

Dr Charlie Whiffin

Te: 01332 593882

Email: c.whiffin@derby.ac.uk

Postal address:

Dr Charlie Whiffin, Associate Professor of Nursing

College of Health, Psychology and Social Care, University of Derby, Kedleston Road, Derby, DE22 1GB