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Life story telling in the process of adjustment for families after traumatic brain injury

Submission date
30/10/2023

Recruitment status
No longer recruiting

Registration date
22/12/2023

Overall study status
Completed

Last Edited
14/11/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
For those under 40 years of age, traumatic brain injury (TBI) is a leading cause of disability. TBI damages the stability of the family system and negatively affects family functioning. There is very little support to help families understand and come to terms with the substantial impact of TBI on themselves. Storytelling approaches are emerging to help the injured person after TBI. However, there is no empirical evidence for storytelling approaches with family members. This study will seek to understand if a specific approach to storytelling (the 'Life Threads' approach) can support processes of family well-being and adjustment post-TBI. Research question: Does narrative storytelling, through the 'Life Threads' approach, support processes of family well-being and adjustment post-Traumatic Brain Injury (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.

Who can participate?
A family member or close friend aged 16 years or above of a person with any severity traumatic brain injury, sustained at least two years prior, aged at injury 18 years or older

What does the study involve?
This a qualitative study that will recruit up to twenty family members in total. Participants will first complete a focus group to introduce the storytelling approach and related study materials. We will then ask participants to work with the study materials to construct their story of TBI and share this during an individual follow-up interview. We will evaluate the acceptability and perceived usefulness of this approach to storytelling in a second, and final focus group. We will use thematic analysis, to make sense of participant experiences and determine if and how engaging with storytelling has led to any perceived benefits.

What are the possible benefits and risks of participating?
Participants will be offered reimbursement for all reasonable travel expenses in addition to a £25 online shopping voucher as a token of gratitude. The primary risk to participants is psychological/emotional upset from telling their stories. Our experience would suggest emotional upset caused by retelling their story is within tolerable, and manageable limits. However, we have several strategies in place to reduce this risk.

Where is the study run from?
The University of Nottingham Hospitals NHS Trust is the sponsor. The Chief Investigator is from the University of Derby.

When is the study starting and how long is it expected to run for?
March 2023 to September 2024

Who is funding the study?
NIHR Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Charlie Whiffin, c.whiffin@derby.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
329362

Central Portfolio Management System (CPMS)
57707

Study information

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

Acronym

Life Threads – TBI

Study objectives
As an exploratory study, we do not have a hypothesis. Our research aim is to establish the acceptability of the intervention, determine initial feasibility parameters for future evaluation, and gain feedback to develop the intervention for future use.

Added 22/08/2024:
Study 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.

Study Objectives:

Primary Objective:
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.

Secondary Objectives
1. Assess uncertainties in relation to the clinical application of the 'Life Threads' approach including: acceptability; adherence; and level of facilitation required.
2. Identify appropriate methods for a feasibility study including: representative recruitment; choice of primary outcomes; mode of delivery; and comparator arm(s).
3. Understand how family members use the 'Life Threads' approach to understand the impact of TBI on themselves and their families.
4. 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/09/2023, East Midlands – Nottingham 1 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8115; E.Nottingham1.rec@hra.nhs.uk), ref: 23/EM/0185

Primary study design
Interventional

Study design
Non-randomized controlled study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions

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.

We will recruit up to 20 family members of people with traumatic brain injury sustained 2-5 years ago.

Updated 22/08/2024: We will consent up to 50 family members of people with traumatic brain injury sustained 2-5 years ago and from these purposively select up to 20 to take part in the 'Life Threads approach'.

Data collection 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.

1. After informed consent has been received participants will be provided with a random four-digit study ID and asked to complete a short survey administered by the CI. 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. Family members will be written to and informed if they have, or have not, been selected to participate in the next phase of the study.

2. 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.

3. Each family member will be sent the 'Life Threads' approach through the post.

4. Participants will be asked to engage with the 'Life Threads' 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 artefacts as representations of things that are meaningful to their story. Participants will be asked to think and reflect on their choices before the unstructured interview.

5. Interviews will be conducted 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. 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. Interviews will follow an unstructured interview style to allow participants to share the story they wish to tell.

6. 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. Data will be analysed using thematic approaches familiar to the researchers and will be conducted concurrently alongside data collection methods. We will take emerging findings to our PPI advisory group and collaborators to explore our early understanding of the data.

Intervention Type
Behavioural

Primary outcome(s)
Acceptability and feasibility measured using data gathered through qualitative interviews and focus groups to remain open to participants' views and experiences pertinent to the study aims during the study

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/09/2024

Eligibility

Key inclusion criteria
Identifies as a family member or close friend of a person with:
Any severity traumatic brain injury, sustained at least 2 years prior, age at injury 18 years or older

The family member must be:
1. Known to the injured person before injury
2. Age 16 years or above
3. Able to give informed consent
4. Residing within the East/West Midlands of England; Updated 22/08/2024: Residing within England
5. Have access to a smartphone, tablet or computer that can access the internet
6. Willing to participate in a group
7. Fluent in English

Participant type(s)
Carer, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
20

Key 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 consent meeting prior to verbal consent being requested.

Date of first enrolment
19/01/2024

Date of final enrolment
14/06/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Derby Royal Hospital
Uttoxeter Road
Derby

England
DE22 3NE

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
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Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Chief Investigator Dr Charlie Whiffin, c.whiffin@derby.ac.uk. The participants did consent to their anonymised data being used to support future research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/10/2024	21/10/2024	Yes	No
Basic results		14/11/2025	14/11/2025	No	No
Participant information sheet	version 3	29/11/2023	22/12/2023	No	Yes
Protocol file	version 3	29/11/2023	22/12/2023	No	No