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Managing uncertainty and post-traumatic stress symptoms in stroke survivors

Submission date
16/02/2026

Recruitment status
Recruiting

Registration date
24/02/2026

Overall study status
Ongoing

Last Edited
26/02/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is focused on improving the recognition and treatment of post-traumatic stress symptoms in stroke survivors.

Strokes are a sudden and life-threatening event, affecting more people at younger ages each year. The impacts of a stroke are often significant and long-term, including weakness or paralysis, and difficulties with thinking, memory, and speaking.

Many stroke survivors develop post-traumatic stress symptoms in the months following a stroke. This is where they are so deeply upset by what has happened that it affects their thoughts, feelings, and behaviours after a stroke. They might experience nightmares about the stroke and keep reliving it over and over again through flashbacks. They may avoid reminders of their stroke and develop thoughts and feelings about it, such as worry and sadness, that make it harder to manage their treatment and recovery after stroke.

Traumatic events, such as a stroke, can also create fear around what might happen next. This could make it harder for stroke survivors to tolerate all the new uncertainties they experience in daily life after a stroke. For example, not knowing how their recovery will go or if another stroke will happen. These impacts of a stroke are not always recognised and supported, making it harder for stroke survivors to manage their health and recovery, affecting their wellbeing and quality of life after stroke.

Talking therapies are often recommended for treating post-traumatic stress symptoms and involve helping individuals work through the upset of a traumatic experience. Although treatments of this kind are available through existing mental health services, they are not often tailored to the experiences of stroke survivors and can be hard to access and engage with over time. Online versions of these treatments could also help, but it is not clear if these are suited to the needs of stroke survivors.

The research aims to:
1. Develop a brief in-person/telephone intervention to help reduce post-traumatic stress symptoms in stroke survivors.

2. Examine the acceptability of the intervention to help inform further development, including possible digitisation, and future testing within routine stroke care.

Who can participate?
Adult patients aged 18 years or over with a confirmed diagnosis of a first-ever stroke. This might have been caused by a blockage or a bleed inside the brain. Adult unpaid stroke carers can also participate in aspects of the research.

What does the study involve?
There are three phases of the research (Work Packages (WP)). Stroke survivors and carers will be invited to take part whilst still in hospital or during rehabilitation.

In the first phase of the study (WP1), stroke survivors will fill in some questionnaires to understand how post-traumatic stress symptoms, uncertainty relating to stroke, intolerance of uncertainty, thoughts about stroke, and coping are related at 3, 6, and 12 months following stroke. Demographic, medical history, and clinical data will also be collected.

The second phase of the research (WP2) will develop a new intervention, involving discussions and feedback from stroke experts, including patients, carers, healthcare professionals/providers, and researchers.

In the final phase of the research (WP3), the intervention will be delivered to stroke survivors and further feedback will be gathered through interviews/discussions with a range of people, including stroke patients, carers, and healthcare professionals/providers. This is to find out what they think of the intervention and the different ways it could be improved. An embedded PhD study is also included within the research to help further inform the intervention plans.

What are the possible benefits and risks of participating?
The study could help improve the understanding and treatment of post-traumatic stress symptoms in stroke survivors.

No specific risks are expected from taking part in the study. There will be a time commitment involved. Participants will be offered gift vouchers, and they will be provided with help for any travel expenses. Participants may get tired during the research activities, but they can take breaks when needed. The research team will also support any participants who get upset when thinking or talking about their stroke during the research.

Where is the study run from?
The University of Leicester (UK).

When is the study starting and how long is it expected to run for?
September 2025 to August 2029.

Who is funding the study?
The National Institute for Health and Care Research (UK).

Who is the main contact?
Dr Navneet Aujla, na434@leicester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Central Portfolio Management System (CPMS)
62620

National Institute for Health and Care Research (NIHR)
305270

Integrated Research Application System (IRAS)
344411

Study information

Scientific Title
Managing uncertainty after a stroke: development and acceptability of a brief psychological trauma-informed intervention to help recognise and reduce post-traumatic stress symptoms in stroke survivors

Acronym
Uncertain-T

Study objectives
The research objectives are to:
1. Explore key factors related to post-traumatic stress symptoms in the 12 months following a stroke.
2. Develop a new intervention for reducing post-traumatic stress symptoms in stroke survivors.
3. Examine what people think about the intervention, including stroke patients, carers, and healthcare professionals/providers, to help inform future plans.

An embedded PhD study will contribute further evidence to the plans for the intervention, including reviewing relevant literature (Study 1), exploring experiences of stroke survivors

(Study 2), and examining further patterns relating to factors linked with post-traumatic stress symptoms in this population (Study 3).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/01/2026, East of England – Cambridge Central (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; cambridgecentral.rec@hra.nhs.uk), ref: 25/LO/0925

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Stroke, Primary sub-specialty: Acute Care; Health Category: Mental health, Stroke; Disease/Condition: Cerebrovascular diseases, Neurotic, stress-related and somatoform disorders

Interventions
The intervention will be developed through the research, following established guidance and the Intervention Mapping approach, and drawing on relevant evidence and expert feedback through discussions and workshops.

An Intervention Planning Group involving a range of stroke experts will be established and a series of workshops will help design and produce an intervention manual and materials. Think-Aloud approaches will help refine the intervention materials.

The intervention is expected to be brief, trauma-informed, and underpinned by relevant theory and therapeutic approaches. The exact components and techniques of the intervention will be confirmed during the study, though key topics are likely to include addressing intolerance of uncertainty and unhelpful perceptions of stroke. Key areas of consideration during intervention development will include: the scope, content, number, duration, and timing of sessions; eligibility; accessibility; carer involvement; additional features; and plans for digitisation.

The intervention evaluation is designed to address important uncertainties before moving to potential digitisation and further testing.

Intervention Type
Behavioural

Primary outcome(s)
1. Symptoms of post-traumatic stress disorder (PTSD) measured using the PTSD Checklist at 3, 6, and 12-months following stroke

2. Uncertainty in Illness measured using the Mishel Uncertainty in Illness Scale at 3, 6, and 12-months following stroke

3. Intolerance of Uncertainty measured using the Intolerance of Uncertainty Scale Short-Form at 3, 6, and 12-months following stroke

4. Illness Perceptions measured using the Brief Illness Perception Questionnaire at 3, 6, and 12-months following stroke

5. Coping measured using the Coping Strategies Inventory Short Form at 3, 6, and 12-months following stroke

6. Usability, acceptability, and engagement with the intervention materials measured using data collected using Think-Aloud approaches at intervention development

7. Acceptability of the intervention, staffing and training to deliver the intervention, the acceptability of digitisation, and the involvement of carers, measured using interviews/focus group discussions, at post-intervention

8. Preliminary feasibility, including eligibility, recruitment, and retention rates, measured using data collected from recruitment logs at recruitment and intervention delivery

9. Preliminary feasibility, including participant characteristics, measured using a study-specific questionnaire at pre-intervention

Key secondary outcome(s))
1. Experiences of post-traumatic stress symptoms amongst stroke survivors, measured using interviews at PhD Study 2 participation

Completion date
31/08/2029

Eligibility

Key inclusion criteria
The key inclusion criteria for stroke survivors in all WPs are:
1. Adults (≥18 years).
2. Confirmed diagnosis of first-ever stroke (ischaemic stroke or intracerebral haemorrhage).
3. Within 8-weeks of stroke onset.
4. Has capacity, comprehension, and ability to engage in study procedures/activities.

5. Deemed well enough by their clinician to participate.
6. Able to provide or witness informed consent.

The key inclusion criteria for carers in WP2 and WP3 include:
1. Adults (≥18 years).
2. Provides regular unpaid care for a stroke survivor who is participating in the study.
3. Spouse, partner, relative, or friend of the stroke survivor.
4. Able to provide written informed consent.

The key inclusion criteria for stroke survivors in Study 2 of the PhD research include:
1. Involved in WP1.
2. Agreed to further contact for involvement in future studies.
3. Have capacity, comprehension, and ability to engage in study procedures/activities.
4. Able to provide or witness informed consent.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
The key exclusion criteria for stroke survivors in all WPs are:
1. Diagnosis of subarachnoid haemorrhage.
2. Recurrent stroke or a history of stroke.
3. Involved in psychological intervention studies.
4. Serious mental illness currently under psychiatric care.
5. Receiving palliative care.
6. Lacking capacity to provide informed consent or requiring proxy consent.
7. Lives outside the research area.

The exclusion criteria for carers in WP2 and WP3 include:
1. Child or adolescent carer (<18-years).
2. Does not provide regular unpaid care for the stroke survivor.
3. Cares for a stroke survivor who is not participating in the study.
4. Paid carer.
5. Lacking the capacity to provide informed consent or requiring proxy consent.
6. Lives outside the research area.

The exclusion criteria for stroke survivors in Study 2 of the PhD research include:
1. Has experienced further strokes.
2. Involved in psychological intervention studies.
3. Serious mental illness currently under psychiatric care.
4. Receiving palliative care.
5. Lacking the capacity to provide informed consent or requiring proxy consent.

Date of first enrolment
30/03/2026

Date of final enrolment
31/05/2029

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
England
LE5 4PW

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
England
NN1 5BD

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre

Lincolnshire Community Health Services NHS Trust
Beech House
Witham Park
Waterside South
Lincoln
England
LN5 7JH

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

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
With permission from participants, the datasets generated during and/or analysed during the current study will be stored in a publicly available repository or will be available upon request from the Lead Investigator, Navneet Aujla, na434@leicester.ac.uk.

IPD sharing plan summary
Available on request