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Enhanced reviews of psychological changes after stroke

Submission date
26/07/2024

Recruitment status
Recruiting

Registration date
26/07/2024

Overall study status
Ongoing

Last Edited
03/03/2025

Condition category
Circulatory System

[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
A stroke can affect the way the brain understands, organises, and stores information. A stroke can also cause changes in mood, anxiety, and fatigue. These changes in thinking, mood, and fatigue can all have a negative impact on day-to-day lives. The ENRICH programme was co-designed with stroke survivors and their family members as a way to communicate personalised thinking, mood, and fatigue changes after stroke, and provide information about how stroke survivors can manage any changes after stroke. The ENRICH programme is meant to enhance standard stroke care and be delivered at 1, 3, and 6 months after stroke.
In Study 1, the aim is to find how if the ENRICH materials are helpful to stroke survivors, family members, and healthcare professionals when used in an NHS stroke care service in Oxfordshire. This will be done by training Oxfordshire health care professionals to deliver one single ENRICH review session.
In Study 2, the aim is to find out how best to run the full ENRICH programme (all three sessions) “in practice” in two NHS stroke care settings outside of Oxfordshire, and whether we can recruit enough people to take part in the study. The researchers also want to explore whether the ENRICH programme shows promise in improving the quality of life after stroke compared to standard stroke care.

Who can participate?
Stroke patients aged 18 years and older, their family members/carers, and healthcare professionals from included NHS sites

What does the study involve?
Study 1 involves one ENRICH review session (about 45 minutes to 1 hour) between a stroke survivor, a family member carer (if available), and their stroke healthcare professional. The ENRICH review includes assessments on thinking skills, mood, and fatigue, and structured education on stroke survivor’s personalised outcomes, and strategies for self-management. Afterwards, stroke survivors and family members will be invited to complete a survey and interview with the research team about their experiences receiving the review. Healthcare professionals will also be invited to complete an interview about their experiences delivering the ENRICH review session. The researchers will also look at stroke survivor medical records to get details on the type of stroke and how the stroke happened. All data will be made anonymous.

Study 2 will use a special type of study design, where included NHS stroke services will first have a “care-as-usual” period where they will only recruit participants to the study. At a certain point, the NHS stroke services will then “switch” to delivering the full ENRICH programme (three sessions at 1, 3 and 6 months after stroke). Each session will have the same structure as Study 1. Stroke survivors recruited to the study will be invited to complete questionnaires on quality of life will be taken both during the “care-as-usual” period and during the ENRICH programme period at 6-months post-stroke and at a 3-month follow-up. Stroke survivors, family members /carers, and healthcare professionals involved in the study will be invited to complete an interview about their experiences in the ENRICH programme. Data will be collected on recruitment numbers, completion rates of study questionnaires, and attendance at the ENRICH reviews. The researchers will also look at stroke survivors' medical records to get details on the type of stroke and how the stroke happened. All data will be made anonymous with names kept separately from research data.

What are the possible benefits and risks of taking part?
There are no major risks involved in taking part. Some stroke survivors may find it difficult to talk about their changes after their stroke. All healthcare professionals will be trained on the ENRICH materials, and to respond appropriately to sensitive conversations. Stroke participants are free to have a family member/carer present to support them if needed, and take breaks during study sessions as needed. There may be no direct benefits to participants, but taking part in the study can help improve the stroke care pathway.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2021 to April 2027

Who is funding the study?
National Institute of Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Nele Demeyere, nele.demeyere@ndcn.ox.ac.uk

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
336341

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61285, IRAS 336341

Study information

Scientific Title
ENhanced Reviews of psychologIcal CHanges after stroke (ENRICH): acceptability of the ENRICH reviews and feasibility of a non-randomised cluster trial

Acronym
ENRICH

Study objectives
There are no study hypotheses as the research is primarily qualitative or based on feasibility data.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2024, London – Brighton and Sussex Research Ethics Committee (2 Redman Place, London, E20 1JQ, UK; +44 (0)2071048202; brightonandsussex.rec@hra.nhs.uk), ref: LO/24/0341

Study design
Non-randomized cluster trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
Current interventions as of 03/03/2025:
Study 1: participants will receive one ENRICH review covering assessment, psychoeducation, and self-management of psychological changes after stroke. Consenting participants will be surveyed and interviewed on their feedback on receiving the ENRICH reviews.

Study 2 aims to establish the feasibility of (a) implementing the full ENRICH intervention – including enhanced reviews at 1-, 3-, and 6-months after discharge from inpatient services – within two NHS sites that are not within Oxfordshire (i.e., unknown) to inform the potential for the ENRICH intervention for a future definitive trial. The ENRICH review covers assessment, psychoeducation, and self-management of psychological changes after stroke. Outcome measures are collected from patients receiving standard NHS care during the control period and from patients receiving the ENRICH intervention during the intervention period.

Previous interventions:
Study 1: participants will receive one ENRICH review covering assessment, psychoeducation, and self-management of psychological changes after stroke. Consenting participants will be surveyed and interviewed on their feedback on receiving the ENRICH reviews.

Study 2 is a multicentre pragmatic feasibility study using a stepped-wedge cluster randomised trial (SWCRT) design. The design consists of a control period, where patients receive standard NHS care. Then, sites are exposed to the intervention in randomised sequences or “steps” so that the intervention is implemented across all sites by the end of the study timeline. The ENRICH review covers assessment, psychoeducation, and self-management of psychological changes after stroke. Outcome measures are collected from patients receiving standard NHS care during the control period and from patients receiving the ENRICH intervention during the intervention period.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Study 1: ENRICH review acceptability measured by a custom survey and qualitative data within approximately 1 week of receiving one ENRICH review

Study 2: Feasibility measured by descriptive statistics on recruitment, attendance, and completion of study measures over the course of the study

Key secondary outcome(s))
Study 2: Detailed quality of life measures at 6 months post-stroke as measured by the World Health Organisation-Quality of Life scale and the Quality of Life after Brain Injury Scale

Completion date
30/04/2027

Eligibility

Key inclusion criteria
STUDY 1
Healthcare professionals:
1. Currently conducting ENRICH reviews of stroke survivors within Oxford University Hospital (OUH) Early Supported Discharge (ESD) service
2. Able and willing to give informed consent to participate in the study

Stroke patients:
1. Confirmed clinical diagnosis of stroke by medical team
2. Aged 18 years or older
3. Ability to concentrate for 10 minutes, as judged by the clinical team
4. Able and willing to give informed consent to participate in the study, OR
5. Favourable consultee advice for adults lacking the capacity to consent

Family members/carers:
1. Aged 18 years or older
2. Cohabiting with stroke survivor
3. Able and willing to give informed consent to participate in the study

STUDY 2
NHS sites:
1. Existing early supported discharge (ESD) stroke service within NHS England
2. Existing 6-month reviews offered to all stroke patients within the service
3. Capacity for research activity within the clinical team (i.e., capacity for recruitment and to conduct enhanced reviews)

Healthcare professionals:
1. Currently working within eligible stroke pathway NHS sites
2. Currently deliver stroke reviews within eligible stroke pathway NHS sites
3. Are able and willing to provide informed consent

Stroke patients:
1. Aged 18 years or older
2. Within 4 weeks of confirmed clinical diagnosis of stroke (first-ever or recurrent)
3. Ability to concentrate for 10 minutes, as judged by the clinical team
4. Sufficient English fluency
5. Able and willing to provide informed consent, OR
6. Favourable consultee advice for adults lacking the capacity to consent

Family members/carers:
1. Aged 18 years or older
2. Cohabiting with stroke survivor
3. Able and willing to provide informed consent

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion will be based on not meeting the inclusion criteria above, as well as the below for Study 1 and Study 2:

Family members/carers:
1. They are a paid or professional carer

Date of first enrolment
29/07/2024

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Kent Community Health NHS Foundation Trust
Trinity House
110-120 Eureka Park
Eureka Business Park
Ashford
United Kingdom
TN25 4AZ

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Gloucester
United Kingdom
GL3 4AW

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: NIHR302224

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes