

Enhanced reviews of psychological changes after stroke

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|----------------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Submission date 26/07/2024 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/07/2024 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 03/03/2025 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Study website

<https://www.demeyerelab.org/research/psychological-care/enrich/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

336341

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 170; UK Sample Size: 170

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

England

United Kingdom

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

Sponsor details

Joint Research Office
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OX3 7GB

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RGEA.sponsor@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Government

Funder Name

NIHR Academy; Grant Codes: NIHR302224

Results and Publications**Publication and dissemination plan**

All findings will be published in peer-reviewed journals and disseminated to teams involved in study recruitment, to stroke survivors and family members, and to the general public. For each paper the researchers will create a plain language summary and look to publish these online for example through the blogs of stroke societies or key journals. Stroke survivors and their families will be informed through lay reports and knowledge exchange via the Stroke Association, Stroke Assembly and Stroke Forum outlets.

Intention to publish date

01/09/2027

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