

Shared decision making in the treatment of severe stroke

Submission date 21/12/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/12/2021	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Worldwide, stroke is the second leading cause of death, the third leading cause of disability and results in 6.5 million years being lived with disability. For most people, a stroke is a shock. With no prior experience of dealing with stroke they are not only unprepared; also they just don't know what options they have nor do they have a benchmark for supporting them to make the best decisions for themselves or their loved one. The objective of this study is to develop and embed a Shared Decision Making (SDM) process that will enable staff to be empowered confident to have difficult conversations with patients and families, including the communication of poor prognosis and uncertainty, and enabling patients and carers to be more effectively able to participate in these conversations. This should ensure that treatment decisions are more aligned with patient's values and beliefs.

Who can participate?

Stroke survivors, their family members, and healthcare professionals.

What does the study involve?

The SDM process will be developed through co-production workshops involving clinical staff who work with stroke patient as well as survivors of stroke and their relatives. Once the SDM process is adopted into practice we will explore how well it is implemented and whether it is associated with change in clinical processes and outcomes through an audit of stroke patients in the Royal Infirmary of Edinburgh and talking to participants at 6 months after their stroke. In order to understand the views of staff, patients and relatives of the SDM process, we will use questionnaires, interviews and focus groups. It will take 19 months to collect and analyse the data.

What are the possible benefits and risks of participating?

There are potential benefits to taking part as some people find it helpful to be able to provide feedback about the quality of care they have received. The information you provide will help us improve the way that the clinical team communicate with patients who have had a severe stroke, and their families.

There are no risks to your health by taking part but some people might find it difficult or upsetting to talk about the care they received after stroke. If you find that the questions are too difficult or upsetting, you will be referred to service and professionals to help and you can change your mind about participating.

Where is the study run from?

The Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?

November 2021 to July 2023

Who is funding the study?

Edinburgh and Lothians Health Foundation (UK)

Who is the main contact?

Prof Gillian Mead, gillian.e.mead@ed.ac.uk

Study website

<http://emergeresearch.org>

Contact information

Type(s)

Principal Investigator

Contact name

Prof Gillian Mead

ORCID ID

<https://orcid.org/0000-0001-7494-2023>

Contact details

Room S1642

Royal Infirmary

Little France Crescent

Edinburgh

United Kingdom

EH16 4SA

+44 131 242 6481

gillian.e.mead@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

294697

ClinicalTrials.gov number

Secondary identifying numbers

IRAS 294697

Study information

Scientific Title

Development and implementation of realistic medicine for severe stroke through shared decision making at the Royal Infirmary of Edinburgh (RIE)

Study objectives

The primary objective of this project is to develop and embed a process for Shared Decision Making (SDM) for severe stroke into the stroke service at Royal Infirmary, Edinburgh, starting at the point of admission to RIE, in either Medical Assessment Unit or the Emergency Department (ED). This process will incorporate Tailored Talks. The goal of the SDM process is to enable staff to be empowered and confident to have difficult conversations with patients and families, including the communication of poor prognosis and uncertainty, and enabling patients and carers to be more effectively able to participate in these conversations. This should ensure that treatment decisions are more aligned with patient's values and beliefs. The SDM process will be developed through co-production.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/11/2021, Scotland A Research Ethics Service (2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 7814609032; manx.neill@nhslothian.scot.nhs.uk), ref: 21/SS/0044

Study design

Observational mixed methods study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Stroke

Interventions

The outcome of the shared decision making process will be assessed by measuring how well it was implemented and whether it was associated with a change in clinical processes and outcomes. This will be measured through an audit of stroke patients in the Royal Infirmary of Edinburgh and talking to participants at 6 months after their stroke. In order to understand the views of staff, patients and relatives of the SDM process, we will use questionnaires, interviews and focus groups.

Intervention Type

Other

Primary outcome measure

The TIDIER checklist will be used to report on the shared decision making process and implementation over 18 months

Secondary outcome measures

1. To evaluate implementation, the number of time 'tailored talks' is recorded in the medical notes will be counted using the audit at monthly timepoints throughout the study; months 1 to 18.
2. To explore how the outcome of the shared decision-making process relates to clinical outcomes, the number of death, admissions to institutional care, discharge to another hospital, and use of feeding tubes will be counted using the audit at monthly timepoints throughout the study; month 1 to 18.
3. Patients', relatives' and staff's views of the shared decision-making process will be explored by collecting qualitative data (questionnaires) and qualitative data (interviews and focus groups) between months 3 to 18.
4. Comparison of actual outcome to the preferred outcome as stated at the time of stroke will be made using quantitative questionnaires at baseline (time of stroke) and 6 months later.

Overall study start date

17/11/2021

Completion date

01/07/2023

Eligibility

Key inclusion criteria

For the Coproduction workshop

1. Stroke survivors will be eligible for co-production workshops provided they:
 - 1.1. Are aged 16 years or over
 - 1.2. Have experienced a severe stroke within the last 18 months and are either currently receiving stroke related care or treatment in community based services, or have previously received care or treatment from a participating stroke service
 - 1.3. Are able to attend RIE co-production workshops on line
 - 1.4. Are able and willing to provide written informed consent
 - 1.5. Are English-speaking and have access to email
 - 1.6. Are able to attend the dates of at least three of the five workshop sessions (i.e. four co-production workshops and one pre-meeting)
 - 1.7. Are able to use online packages e.g. Microsoft Teams
2. Caregivers will be eligible for co-production provided they:
 - 2.1. Are aged 16 years or over

2.2. Are a family member/close friend of a stroke survivor who is either currently receiving stroke related care or treatment, or has previously received care or treatment from a participating stroke service; or bereaved in the past five years from stroke

2.3. Are able and willing to provide written informed consent

2.4. Are English-speaking and have access to email

2.5. Are able to attend the dates of at least three of the five workshop sessions

3. At least one older lay person who has no experience of stroke, who has capacity, access to the internet and able to attend at least three of the five workshops.

3.1. Are able and willing to provide written informed consent

3.2. Are English-speaking and have access to email

3.3. Are able to attend the dates of at least three of the five workshop sessions

4. Healthcare professionals will be eligible for co-production provided they:

4.1. Are health care professional working in a stroke service in Scotland or in an A&E department, or in acute medicine and have regular contact with stroke patients-and are regularly involved in conversations to make shared decisions about severe stroke ('regularly' means at least once a month)

4.2. Are able and willing to provide written informed consent

4.3. Are English-speaking and have access to email

4.4. Are able to attend the dates of at least three of the five workshop sessions

For the questionnaire, interview or focus group

1. Patient and Relative:

1.1. Patient (or next of kin/welfare guardian if patient does not have capacity) with severe stroke NIHSS of 15 or more

1.2. Aged 16 or more

1.3. Proficient in English

2. Staff: Staff will be eligible if they provide care in A&E, medical assessment or the integrated stroke unit at RIE, and are willing to provide informed consent.

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

116

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

17/01/2022

Date of final enrolment

28/02/2023

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Royal Infirmary of Edinburgh at Little France

51 Little France Crescent

Old Dalkeith Road

Edinburgh

Lothian

United Kingdom

EH16 4SA

Sponsor information

Organisation

University of Edinburgh

Sponsor details

The University of Edinburgh and Lothian Health Board ACCORD

The Queen's Medical Research Institute

47 Little France Crescent

Edinburgh

Scotland

United Kingdom

EH16 4TJ

+44 1312423330

accord@nhslothian.scot.nhs.uk

Sponsor type

University/education

Website

<http://accord.ed.ac.uk>

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Charity

Funder Name

Edinburgh and Lothians Health Foundation

Alternative Name(s)

ELHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/07/2024

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Coproduction version 2.0	13/04/2021	23/12/2021	No	Yes
Participant information sheet	Guardian version 5.0	16/11/2021	23/12/2021	No	Yes
Participant information sheet	Patient version 2.0	13/04/2021	23/12/2021	No	Yes

Participant information sheet	Patient easy access version 2.0	13/04/2021	23/12/2021	No	Yes
Participant information sheet	Patient representative version 2.0	16/11/2021	23/12/2021	No	Yes
Protocol file	version 2.0	13/04/2021	23/12/2021	No	No