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Outcomes and needs of stroke survivors after acute stroke and early supported discharge (ESD) in an Irish population

Submission date
29/07/2022

Recruitment status
No longer recruiting

Registration date
02/08/2022

Overall study status
Completed

Last Edited
11/04/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
An observational cohort study will explore the outcomes, needs, and healthcare utilisation of adult stroke survivors, as they transition from hospital to home, and in the first 6 months after stroke.

Who can participate?
Adults who have experienced a stroke will be recruited through Beaumont Hospital, University Hospital Galway, and Midlands Regional Hospital Mullingar stroke services, in partnership with the director of stroke services, stroke consultants, clinical nurse specialist, and multi-disciplinary team members in stroke care.

What does the study involve?
Within 7-10 days of hospital discharge validated questionnaires and survey instruments will be used to identify additional patient characteristics and disease-related data, and to explore participant outcomes and needs. Outcomes, needs and interim healthcare utilisation will be collected again at 3 and 6 months. The method of data collection (face-to-face, remote or postal) will be determined by participant preference and COVID-19 guidelines.

What are the possible benefits and risks of participating?
The study will help us to better understand the long-term outcomes and needs of stroke survivors. This understanding will help researchers and service providers to design services and evaluate ways to improve outcomes and meet the needs of stroke survivors in Ireland.
There are no immediate or obvious potential harms to participants taking part in the study. There is a small risk that participants may feel tired after the interview. We will try to minimise this as much as possible by allowing participants to decide where and when they take part in the interview, and allowing the interview to be split into 2 sessions if necessary. The study will make some small demands on participant time, which might be an inconvenience.
There is a slight risk that participants may feel a little upset when describing their health and

ongoing needs, or when answering questions about their general mood. The researcher, Geraldine O'Callaghan, will monitor for risks during the data collection timepoints, and offer support or signposting as indicated.

Where is the study run from?
Royal College of Surgeons in Ireland

When is the study starting and how long is it expected to run for?
January 2022 to July 2023

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Geraldine O'Callaghan, gocallaghan@rcsi.com

Contact information

Type(s)
Public

Contact name
Ms Geraldine O'Callaghan

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Outcomes and needs of stroke survivors after acute stroke and early supported discharge (ESD) in an Irish population, and at 3 and 6-months: a prospective cohort study.

Study objectives

This study aims to explore and describe the outcomes, needs and healthcare utilisation, at discharge, and at 3 and 6 months, of people with stroke who have transitioned from hospital to home. This study will allow us to better understand the needs of the stroke population at the care transition from hospital and ESD services to home, and how those needs change over time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/01/2022, Clinical Research Ethics Committee Galway University Hospitals (Main Administration Building, Merlin Park University Hospital, Galway, Ireland; +353 91 – 775022; colette.collins@hse.ie), ref: C.A. 2739
2. Approved 09/05/2022, Beaumont Hospital Research Ethics Committee (Beaumont Hospital, Beaumont Road, Dublin 9, Ireland; +353 1 809 2680; beaumontethics@rcsi.com), ref: 22/04
3. Approved 13/07/2022, Research Ethics Committee Midlands Area (Reference Research Ethics Committee Midlands Area and Corporate (Regional Health Area B), C/o Department of Public Health - Public Health Area B, HSE Area Office, Arden Road, Tullamore, Co. Offaly. R35 TY28, Ireland; no telephone number provided; REC.B.CorporateMidlands@hse.ie), ref: RRECB0622GOC

Study design
Longitudinal observational cohort study

Primary study design
Observational

Study type(s)
Other

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

Interventions
Study design:
An observational prospective cohort study of consecutive patients presenting with stroke will determine discharge, 3-month, and 6-month outcomes and needs of stroke survivors' post-thrombectomy, stroke rehabilitation and ESD. The Strengthening and the Reporting of Observational Studies and Epidemiology (STROBE) guidelines will be used to improve the quality of reporting (ensuring complete and adequate reporting) for my observational study.

Setting:
The study will take place in collaboration with the stroke service and ESD in Beaumont Hospital, the stroke service at Midlands Regional Hospital Mullingar, and the ESD team in University College Hospital, Galway.
Recruitment:
Consecutive acute stroke patients will be recruited, between March 2022-December 2022, from the stroke service at each site in partnership with the directors of stroke services, stroke consultants, clinical nurse specialists and multi-disciplinary team members in stroke inpatient, ESD and off-site rehabilitation.

Procedure:
Patients will be screened for inclusion in the study by a gatekeeper, members of the inpatient,

ESD or rehabilitation team at each site. Eligible participants will be given, by the gatekeeper, a participant information leaflet (PIL) about the proposed study and a consent form, with directions to complete the consent form and return to the gatekeeper. Those who consent can be supported by a family / carer to partake in the study. The gatekeeper will inform the researcher (GOC) when consent has been obtained, and provide contact details for the participant (and support person), and some disease-related data.

Data Collection:
Baseline participant characteristics, disease-related data, and self-reported outcomes and needs of consenting participants will be collected by the primary researcher (GOC) within 7-10 days of discharge to home (T0). GOC will contact the participant (or support person) via telephone to arrange a suitable day, time and method for data collection. The researcher (GOC) will determine patient (and support person) preference for data collection (visit the participant in their home, telephone interview, or use videoconferencing platforms (Zoom/Microsoft Teams)), while adhering to relevant Covid-19 guidelines.

Participant characteristics
Patients will complete self-reported questionnaires that will gather information on their date of birth, gender, previous stroke, co-habiting status, employment, and pre-stroke homecare.

Disease-related data
Disease-related data including; date and type of stroke, stroke severity, reperfusion, and level of communication will be gathered from the patient chart and reported by the gatekeeper on transfer of participant contact details. Stroke severity on admission is measured using the National Institute of Health Stroke Severity Scale (NIHSS), a validated and reliable tool, evaluating the level of consciousness, vision and gaze, facial palsy, extremity weakness, limb ataxia, sensory loss, language, dysarthria, and neglect.
Self-reported outcomes (global health, function, cognition, quality of life), and needs will be gathered from the standardised self-reported questionnaires and surveys. Self-reported healthcare utilisation will be gathered from participant completion of a healthcare diary.

Intervention Type
Other

Primary outcome(s)
At baseline (within 7-10 days of hospital discharge), 3 and 6 months:
1. Global Health - PROMIS-10
2. Function - Simplified Modified Rankin Scale (smRS)
3. Cognition - Telephone Montreal Cognitive Assessment Scale (T-MoCA)
4. Health-related quality of life - EQ5D-5L
5. Needs - UK Stroke Survivors Needs Assessment
6. Healthcare utilisation - Diary (Real time)

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

Completion date
01/07/2023

Eligibility

Key inclusion criteria
1. Consenting adults, over the age of 18 years
2. Hospitalised after an acute stroke
3. Identified as being discharged home
4. Cognitively competent to consent (as determined by clinical judgement)
5. Able to communicate or be supported to communicate
6. Able to sign/give verbal consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
75

Key exclusion criteria
1. Patients who present with subarachnoid haemorrhage (SAH)
2. Patients who present with transient ischemic attack (TIA)
3. Patients who decline to provide informed consent
4. Patients who are unwilling to be followed up

Date of first enrolment
01/04/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Ireland

Study participating centre
Beaumont Hospital
Beaumont Road
Dublin 9

Dublin
Ireland
D09 V2N0

Study participating centre
University Hospital Galway
Newcastle Rd
Galway
Ireland
H91 YR71

Study participating centre
Regional Hospital Mullingar
Longford Rd
Robinstown (Levinge)
Mullingar
Ireland
N91 NA43

Sponsor information

Organisation
Royal College of Surgeons in Ireland

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
At the end of the project, anonymised files will be deposited in the Zenodo data repository. Raw data is available upon request from Geraldine O'Callaghan (geraldineocallaghan@rcsi.com) or fhorgan@rcsi.ie. Data collection forms and patient consent forms are being held securely in the RCSI.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/04/2024	11/04/2024	Yes	No
Protocol file			14/03/2023	No	No