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What is the impact of large scale implementation of stroke Early Supported Discharge?

Submission date
16/07/2018

Recruitment status
No longer recruiting

Registration date
25/07/2018

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Early supported discharge (ESD) services provide early, home-based rehabilitation for stroke survivors. Research suggests that people who receive ESD spend less time in the hospital and have better recovery than patients who did not. Following recommendations in UK national policy documents and clinical guidelines a variety of ESD services have now been set up across England. However, the type of ESD service patients receive on the ground is variable and in some regions ESD is still not offered at all. This study is part of a bigger project aiming to assess the impact of implementing ESD in real world conditions and investigate which models of ESD are effective in practice. This study investigates three selected ESD teams from East Midlands, East of England and North of England respectively.

Who can participate?
Stroke patients aged between 16 and 100 who are admitted to ESD services, and NHS staff involved in delivery of the ESD service

What does the study involve?
NHS staff members are interviewed to gain a better understanding of how ESD services operate in practice, identify factors contributing to the adoption and implementation of ESD models as well as contextual influences to their effectiveness and sustainability. Stroke survivors are also asked about their experiences of ESD services and what matters to them the most.

What are the possible benefits and risks of participating?
The findings may lead to improvements in stroke services across England towards the provision of efficient, evidence based care and better patient recovery. This study does not involve direct medical treatment, only interviews, no potential physical risks or burdens are expected. Researchers involved with interviewing will ensure that interviews are conducted with due regard to respect and confidentiality. However, disclosure during interviews may result in participants becoming emotional, especially if they experience cognitive and language difficulties as a result of their stroke. As experienced qualitative interviewers, the researchers will be aware of this and will stop the interview should participants become distressed.

Questions will focus on the research aims in order to avoid addressing sensitive personal information. Sensitivity concerning the timing and length of research interviews will be applied, and the researcher will re-schedule an interview if necessary. Patients will be signposted and made aware of available services in the community should they require this. The patient may also disclose information that suggests they are ‘at risk’ or ‘vulnerable’. Should this occur, the researchers would be obliged to disclose further any serious concerns to appropriate authorities.

Where is the study run from?
1. Early Supported Discharge Service (ESDS)
2. Norfolk Early Supported Discharge
3. Newcastle Community Stroke Service (NCSS)

When is the study starting and how long is it expected to run for?
September 2017 to August 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
38455

Study information

Scientific Title
What is the impact of large scale implementation of stroke Early Supported Discharge?

Acronym
WISE

Study objectives
Early supported discharge (ESD) services provide early, home based rehabilitation for stroke survivors. Research suggests that people who receive ESD spend less time in the hospital and have better recovery than patients who did not. Following recommendations in UK national policy documents and clinical guidelines a variety of ESD services have now been set up across England. However, the type of ESD service patients receive on the ground is variable and in some regions ESD is still not offered at all.

This multi-site study is part of a bigger project aiming to assess the impact of implementing ESD in real world conditions and investigate which models of ESD are effective in practice.Under a realist evaluation framework a case study design will be used to investigate three purposively selected ESD teams from East Midlands, East of England and North of England respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 1, 23/07/2018, ref: 18/EM/0160

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
This study will follow an explanatory multiple case design to investigate qualitatively three purposively selected ESD teams from East Midlands, East of England and North of England respectively (regions corresponding to Clinical Network boundaries). The three sites have been selected based on the level to which evidence based ESD has been implemented (contrasting ESD models) and the influence of rurality on ESD effectiveness (urban vs rural sites).

Participants will be recruited from the following three ESD services (and host organisations)
1. North of England: Newcastle ESD team, Newcastle upon Tyne Hospitals NHS Foundation Trust
2. East of England: Norfolk ESD team, Norfolk Community Health and Care NHS Trust
3. East Midlands: Leicester ESD team, University Hospitals of Leicester NHS Trust

1. Staff participants
The setting for the data collection will predominantly be the administrative centres for the ESD services delivering rehabilitation and the CCGs involved in the commissioning of community stroke services. NHS staff stakeholders may be located in the administrative centres for the

Early Supported Discharge service. NHS staff who are commissioners may be located in the administrative centres for the acute provider and community provider, public health, strategic clinical networks and other administrative locations.
1. Individual semi structured interviews with up to eight NHS staff informants at senior management, service lead and commissioning level at each ESD site (up to 24 in total)
2. In each site, up to two group interview sessions will be conducted with a cross section of the multidisciplinary team including physicians, therapists, nurses, rehabilitation assistants, and administrators. Healthcare staff will be purposively sampled to attain a range of professions and grades.Two sessions will ensure a representative sample of the ESD team is included each time without disrupting provision of patient care. An information sheet will be provided in advance by the service lead/line manager and this will be reviewed by participants with the researcher when consent is taken, with the opportunity given to ask questions. We will also make it clear in the information sheet that their decision to participate is completely voluntary and that not taking part will not affect their employment or relationship with colleagues.

Stakeholders who consent to participate in the study will be interviewed at a time of their choice. Where possible, a quiet room will be requested where disturbances can be kept to a minimum and to ensure confidentiality.

2. Patient participants
Interviews with 5 purposively selected ESD patients from each research site (up to 15 in total). Sites with evidence based ESD models will be selected from one urban setting and one rural setting. Purposive sampling will be applied to ensure different stroke severity levels are represented in the sample. Patients will be first contacted by members of the ESD team who will introduce patients to the study and hand over the information sheets. If patients are happy to be contacted by the researchers, researchers will give them a phone call to arrange a home visit. The home visit will be arranged at least 24 hours after participants were given the information sheet.

During the home visit, researchers will go through the information sheet and offer patients and their relatives the opportunity to ask questions. Should patients wish to participate in the study, they will be asked to sign a consent form. The interview will take place once the consent form is signed. Patients with language and/or cognitive difficulties will be presented a simplified information sheet and will be given the option to have their relatives/ carers present to assist with discussion of the study, consent process and interview. Patients who lack the capacity to consent and patients who do not have English as a first language will not be included in the study.

The interviews will be conducted under a realist evaluation framework and will follow a semi-structured format. Interview schedules will be drafted to guide discussions and to ensure the following broad topics are covered (for examples of questions see attached interview schedules):

For patient interviews:
1. Patient’s experience of leaving hospital to return home
2. Patient’s experience of the ESD service
3. Perceived outcomes of the service
4. Life at home
5. Suggestions for improvement of the service

For staff interviews:
1. Role/involvement in the service
2. Factors influencing the adoption of ESD and model of operation

3. Perceived benefits of implementing ESD
4. Factors influencing the effectiveness of ESD in practice (i.e. patient/team/organisation/wider setting-geography factors)
5. Factors contributing to the sustainability of ESD services

All interviews will be carried out by the two research fellows from the WISE research team. The interviews will be digitally recorded. We will be using a transcribing agency who we have worked with on other occasions. They are reliable and accurate, and adhere to University of Nottingham' s strict guidelines on data security and confidentiality. All personal identifiers will be removed from transcriptions and each participant will be allocated identifying code and a pseudonym to be used in the report. Audio files will be stored securely on a password-protected computer and backed up to the University of Nottingham protected network. Electronic copies of transcripts will be stored in the same way.

Documents:
To investigate contextual factors that stakeholders may not readily articulate, the trialists will also gather documentary evidence. This will be in the form of service specifications, monthly and annual reports, meeting notes and paperwork used by the teams as part of their day-to-day operational activities. These will be used to inform and expand on interpretation of the interview data. Documents will be identified through formal and informal discussion with participants. Access will be requested once a document has been identified. Where possible and if appropriate, the author of the document will also be invited to interview. Documents will be stored in a locked filing cabinet at the School of Medicine, University of Nottingham.

Intervention Type
Other

Primary outcome(s)
Work package 1:
The selection of outcome measures reflects both evidence based metrics, as defined in national clinical guidelines, and outcomes that were used to measure effectiveness of ESD in original clinical trials. These include: a) length of hospital stay, b) responsiveness of the service, c) amount of rehabilitation delivered and d) changes in patient dependency as measured by the Modified Rankin Scale recorded before stroke, at hospital discharge and discharge from the ESD service. Data for these outcomes are routinely collected by stroke services and will be obtained by gaining access to historical prospective SSNAP clinical audit data from hospital and community providers across the East Midlands, West Midlands, East of England and Northern England.

Work package 2:
To assess perceived effectiveness and contextual influences on implementation, qualitative data will be collected through:
1. Staff interviews: Semi-structured one-to-one interviews will be conducted with up to ten NHS staff informants at senior management, service lead and commissioning levels at each ESD site (up to 48 in total). Participants will be identified through collaboration with the national audit team and clinical network cardiovascular leads and stroke clinical leads operating in each region. Two group interview sessions will also be conducted at each of the six sites with a representative cross-section of disciplines included in the ESD team (physicians, therapists, nurses, rehabilitation assistants, administrators).
2. Stroke survivor interviews: Interviews with 5 purposively selected ESD patients per site (30 patients in total) will also be conducted. Patients will be recruited by the ESD teams in

consultation with the research team. Purposive sampling will allow to ensure the sample includes patients with a variety of experiences.

Key secondary outcome(s))
Cost consequence analysis will be conducted to relate measures of effectiveness of different ESD models with estimated costs of service provision

Completion date
14/12/2020

Eligibility

Key inclusion criteria
1. Staff participants:
1.1. Adults (over the age of 18 years)
1.2. NHS staff participants involved in delivery of the ESD service (i.e. consultants, occupational therapists, rehabilitation assistants, physiotherapists, social workers, nursing staff, psychologists and administrators)
1.3. Stroke service commissioners (i.e. members of a Clinical Commissioning Group (CCG) involved in the commissioning of ESD services)

2. Patient participants:
2.1. All stroke patients who are admitted to ESD services and fit the eligibility criteria used by the hospital and community-based staff. Eligibility criteria are likely to include the patient wishing to return home, that they are medically stable and that they can transfer independently or with the assistance of one person. It is highly unlikely that stroke patients with mental capacity issues and those unable to consent, will be eligible or referred to an ESD service.
2.2. Having sustained first or recurrent stroke
2.3. Medically stable
2.4. Ability to give informed consent
2.5. Aged between 16 and 100 years old
2.6. In the services' caseload at the time of recruitment

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
147

Key exclusion criteria
1. Staff participants:
1.1. Communication problems (e.g.aphasia) that prevents participation in the interviews.

2. Patient participants:
2.1. Stroke patients who are not eligible for Early Supported Discharge (ESD)
2.2. Patients who do not have adequate understanding of the English language to participate in the interviews (translators may not be available in community-based services)

Date of first enrolment
01/09/2018

Date of final enrolment
13/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Early Supported Discharge Service (ESDS) (lead site)
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Norfolk Early Supported Discharge
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Newcastle Community Stroke Service (NCSS)
45 Scrogg Rd
Newcastle
United Kingdom
NE6 3EY

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/01/17

Results and Publications

Individual participant data (IPD) sharing plan
Due to the qualitative nature of the data the trialists are unable to share them with other researchers for confidentiality reasons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2020	20/07/2020	Yes	No
Results article	results	20/01/2021	22/01/2021	Yes	No
Results article		28/03/2023	29/03/2023	Yes	No
Results article		01/11/2021	06/08/2024	Yes	No
Protocol article	protocol	13/06/2019	17/06/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2	05/07/2018	26/07/2018	No	Yes
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