ISRCTN38920246 https://doi.org/10.1186/ISRCTN38920246

A longer-term care strategy for stroke – a feasibility study

Submission date
18/05/2016

Recruitment status
No longer recruiting

Registration date
22/06/2016

Overall study status
Completed

Last Edited
17/03/2023

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
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). This requires extensive care both in the short and long term. The early stages of the stroke care pathway are becoming more prescribed (treatment in acute and rehabilitation stroke units), but despite policy recommendations, strategies for longer-term care are not developed and stroke survivors and their families face a number of problems and challenges. This is looking at a new system (New Start) for longer-term stroke care which has been developed to help improve the mental and physical wellbeing of patients (and their carers) living at home following a stroke. The aim of this study is to find out whether undertaking a large-scale study investigating the effectiveness of this tool is feasible.

Who can participate?
Stroke services located in participating hospitals in the UK; stroke survivors who had a stroke four to six months ago who live at home and their carers.

What does the study involve?
Participating sites are randomly allocated to one of two groups. Those in the first group receive standard care as provided by their treating clinician. Those in the second group take part in the New Start program, a strategy based upon analyses of the needs of stroke survivors and what helped and hindered them to address these needs. It involves taking part in an initial face-to-face meeting with a trained facilitator to identify any unmet needs and then to work to address these needs over later sessions. At the meeting, these issues and needs are discussed and a supported self-management approach is introduced with the aim of addressing needs through individualised problem-solving. The process involves facilitated action-planning, goal-setting, and review, all of which are supported by a flexible document – the New Start Guide. Stroke survivors can have as many meetings with the facilitators as required, but it is thought that most need at least three visits and support may also be provided via the internet, phone or email. Participants in both groups complete a number of questionnaires at the start of the study and

then after three, six and 12 months about their mental and physical wellbeing. The acceptability of the program is then measured through interviews and specially designed questionnaires, and the number of participants who complete the follow up questionnaires is recorded.

Added 05/07/2017: A detailed Process Evaluation will also be conducted to understand the functioning of the intervention, examining its implementation, mechanisms of impact, and contextual factors.

What are the possible benefits and risks of participating?
There are no known benefits or risks involved with participating in this study.

Where is the study run from?
Edgeware Community Hospital and nine other NHS hospitals in England and Wales (UK)

When is the study starting and how long is it expected to run for?
June 2016 and September 2018

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

Who is the main contact?
Professor Anne Forster, Chief Investigator
a.forster@leeds.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Anne Forster

Contact details
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)113 343 0504
lots2care@leeds.ac.uk

Additional identifiers

Protocol serial number
30510

Study information

Scientific Title

A longer-term care strategy to support stroke survivors and their carers (LoTS2Care) – a feasibility study

Acronym
LoTS2Care

Study objectives
The aim of this study is to undertake a feasibility cluster randomised controlled trial (cRCT) of a purposely developed intervention 'New Start' to inform a future definitive cRCT to investigate the clinical and cost-effectiveness of the New Start intervention for stroke survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Feasibility Trial: Yorkshire & The Humber - Leeds East Research Ethics Committee, 26/04/2016, ref: 16/YH/0068

Added 05/07/2017:
Process Evaluation: Yorkshire & The Humber - Leeds West Research Ethics Committee, 23/09/2016, ref: 16/YH/0390

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Complex Intervention

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Stroke, Primary sub-specialty: Rehabilitation; UKCRC code/ Disease: Stroke/ Cerebrovascular diseases

Interventions
Participating sites will be randomised on a 1:1 basis to one of two study arms

Control arm: Participants receive standard care as provided by their treating clinician.

Intervention arm: Participants receive an initial face-to-face meeting with a trained facilitator approximately six months after stroke that seeks to help stroke survivors identify any unmet needs they may have and then work with them to address these needs. A priming tool /pamphlet, which also details the date and time of the meeting, is sent out in advance. This tool highlights some of the issues which may be covered, and prompts the survivor to note down which, if any, may be relevant to them. At the meeting, these issues and needs are discussed and a supported self-management approach is introduced with the aim of addressing needs through individualised problem-solving. The process involves facilitated action-planning, goal-setting, and review, all of which are supported by a flexible document – the New Start Guide. The intervention directly identifies and addresses unmet needs, and seeks to enhance participation

by providing usable information and assisting the participant to build and sustain a flexible support network. Stroke survivors can have as many meetings with the facilitators as required, it is anticipated that most stroke survivors will have at least three visits and support may also be provided via the internet, phone or email.

Trial participants will be followed up using postal questionnaires at 3, 6 and 9 months.

Intervention Type
Other

Primary outcome(s)
1. Acceptability of recruitment methods for sites is determined using site feasibility questionnaires and face to face/telephone discussions with site teams collected prior to trial opening
2. Acceptability of recruitment methods for participants is measured using screening data and face to face/telephone discussions with site teams throughout the recruitment period
3. Acceptability of implementation and delivery of the intervention is measured by collecting training records, collecting data on competency assessment, treatment records and data collected as part of a detailed process evaluation throughout the training recruitment and follow up period
4. Acceptability of collecting questionnaires at baseline, 3, 6 and 9 months is determined through number of patients who completed the questionnaires at baseline, 3, 6 and 9 months
5. Routinely offered services (usual care) is defined through feasibility questionnaires and face to face/telephone discussions with site teams, collected throughout the trial
6. Safety is measured by collecting adverse events continuously throughout the trial
7. Health economics analysis is conducted using the health economics resource use questionnaire, the EQ5D and the ICECAP-A at baseline, 3, 6 and 9 months

Key secondary outcome(s)
No secondary outcome measures

Completion date
28/07/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/07/2017:
Stroke Service Inclusion Criteria:
1. Encompasses primary and secondary care over a defined geographical area within the United Kingdom (UK)
2. Includes a stroke unit which fulfils the RCP guidelines definition of a stroke unit
3. Agree to try and establish a robust mechanism to identify all stroke survivors at four to six months post stroke.
4. Have the facilities and capacity to deliver the New Start intervention
5. Fully supportive of time required for New Start training, including two face to face away days and online training
6. Agreement to be involved via signed model Non-Commercial Agreement (mNCA) and local management approval

Stroke survivor inclusion criteria:
1. At least four months and not more than six months since confirmed primary diagnosis of new stroke
2. Are residing in the community (i.e. not in a nursing or residential care home
3. Provide informed consent or consultee assent

Carer inclusion criteria (participation optional):
1. Identified by the stroke survivor, as the main informal caregiver who provides the stroke survivor with support a minimum of once per week
2. Provided informed consent (i.e. implied via return of completed baseline questionnaire)

Previous inclusion criteria:
Stroke Service Inclusion Criteria:
1. Encompasses primary and secondary care over a defined geographical area within the United Kingdom (UK)
2. Includes a stroke unit which fulfils the RCP guidelines definition of a stroke unit
3. Agree to try and establish a robust mechanism to identify all stroke survivors at four to seven months post stroke.
4. Have the facilities and capacity to deliver the Moving Forward intervention
5. Fully supportive of time required for Moving Forward training, including two face to face away days and online training
6. Agreement to be involved via signed model Non-Commercial Agreement (mNCA) and local management approval

Stroke survivor inclusion criteria:
1. At least four months and not more than seven months since confirmed primary diagnosis of new stroke
2. Are residing in the community (i.e. not in a nursing or residential care home
3. Provide written informed consent or consultee assent

Carer inclusion criteria (participation optional):
1. Identified by the stroke survivor, as the main informal caregiver who provides the stroke survivor with support a minimum of once per week
2. Provided informed consent (i.e. implied via return of completed baseline questionnaire)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
269

Key exclusion criteria

Current inclusion criteria:
Stroke services exclusion criteria:
1. Previously participated in the development of the intervention; as part of this programme of research or are intending to implement the New Start intervention within the proposed duration of the study will not be eligible because these sites might be expected to have enhanced skills or knowledge about the New Start intervention
2. Stroke services that are currently delivering or planning to deliver a similar supported self-management intervention

Stroke survivors exclusion criteria:
It is unknown whether the Moving Forward intervention can be delivered to Stroke Survivors with other (specific) co-morbidities. Therefore, no exclusion criteria will be applied and reasons for not receiving care at 6 months post-stroke will be documented and used to inform eligibility criteria for a definitive trial.

Carer exclusion criteria:
Their stroke survivor does not consent for carer involvement.

Previous exclusion criteria:
Stroke services exclusion criteria:
1. Previously participated in the development of the intervention; as part of this programme of research or are intending to implement the Moving Forward intervention within the proposed duration of the study will not be eligible because these sites might be expected to have enhanced skills or knowledge about the Moving Forward intervention
2. Stroke services that are currently delivering or planning to deliver a similar supported self-management intervention

Stroke survivors exclusion criteria:
1. Main requirement is palliative care
2. Have concurrent major illness which is likely to predominately determine care (e.g. in receipt of consistent medical input from a specialist other than stroke/neurologist)
3. Stroke survivors not resident within the geographical area covered by the stroke service

Carer exclusion criteria:
Their stroke survivor does not consent for carer involvement.

Date of first enrolment
26/01/2017

Date of final enrolment
05/01/2018

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Edgware Community Hospital
Burnt Oak Broadway
Edgware
United Kingdom
HA8 0AD

Study participating centre
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Stroke Early Supported Discharge Team
Edward Jenner Court
Gloucestershire Care Services NHS Trust
Gloucester
United Kingdom
GL3 4AW

Study participating centre
Gorseinon Hospital
Abertawe Bro Morgannwg University Local Health Board
Brynawel Road
Gorseinon
Swansea
United Kingdom
SA4 4UU

Study participating centre

West Park Hospital
The Royal Wolverhampton NHS Trust
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Doncaster Royal Infirmary
Rotherham Doncaster and South Humber NHS Foundation Trust
Thorne Road
Yorkshire
Doncaster
United Kingdom
DN2 5LT

Study participating centre
South Petherton Community Hospital
Somerset Partnership NHS Foundation Trust
Bernard Way
Somerset
South Petherton
United Kingdom
TA13 5EF

Study participating centre
Bronglais General Hospital
Hywel Dda University Health Board
Caradoc Road
Aberystwyth
United Kingdom
SY23 1ER

Study participating centre
Darlington Memorial Hospital
County Durham and Darlington NHS Foundation Trust
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre

University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick Road
Hardwick
Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre
Sunderland Royal Hospital
City Hospitals Sunderland NHS Foundation Trust
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Newton Abbot Hospital
Torbay & South Devon NHS Foundation Trust
West Golds Road
Devon
Newton Abbot
United Kingdom
TQ12 2TS

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article		01/03/2021	21/04/2021	Yes	No
Results article	feasibility and acceptability outcomes	15/03/2023	17/03/2023	Yes	No
Protocol article	protocol	11/06/2018		Yes	No
Protocol article	protocol for the process evaluation	11/07/2018		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No