

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

<b>Submission date</b> 18/05/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/03/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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?

Edgware 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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Study design

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

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### 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

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 measure**

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

## **Secondary outcome measures**

No secondary outcome measures

## **Overall study start date**

01/06/2016

## **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

269; UK Sample Size: 269

**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**

England

United Kingdom

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

**Sponsor details**

Research Management & Support Office  
Bradford Institute for Health Research  
Bradford Royal Infirmary  
Duckworth Lane  
Bradford  
England  
United Kingdom  
BD9 6RJ

**Sponsor type**

Hospital/treatment centre

**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****Publication and dissemination plan**

1. Presentation of results at the UK Stroke Forum, at the Yorkshire Consumer Conference and at the annual conference of the Association of Directors of Social Services (ADSS)

2. All research participants will be made aware that results will be posted on the Programme website

### Intention to publish date

20/11/2020

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