

# Longer-term health and social care strategies for stroke survivors and their carers: the LoTS2Care research programme including cluster feasibility RCT

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**Declared competing interests of authors:** Anne Forster was a member of the National Institute for Health Research (NIHR) Health Services and Delivery Research Researcher-led Panel (2016–18) and a member of the NIHR Programme Grants for Applied Research (PGfAR) subpanel (2006–18). Allan House was a member of the NIHR PGfAR Expert Panel (2011–19), NIHR Career Development, Senior and Transitional Fellowships Panel (2015–19) and NIHR PGfAR subpanel A (2017–19) and chairperson of the Research for Patient Benefit Yorkshire and Humberside Regional Funding Committee (2012–16). Jenny Hewison was a member of the NIHR Clinical Trials Unit Standing Advisory Committee (2012–17). Claire Hulme was a member of the NIHR HTA Commissioning Board (2013–17). Robbie Foy reports being a member of the NIHR Dissemination Centre Advisory Group (2015–19) and member of a NIHR PGfAR subpanel (2017 to present). David Meads is a member of a NIHR PGfAR subpanel (2018 to present) and was a member of a NIHR HTA prioritisation panel (2013–17). Amanda Farrin was a member of the NIHR HTA Clinical Evaluation and Trials Board (2014–18) and of the HTA Commissioning Strategy Group (2014–18). Elaine Roberts was Director of Stroke Support (England) for the Stroke Association during this programme (2017–19); the Stroke Association provides commissioned services for people after stroke.

Published March 2021

DOI: [10.3310/pgfar09030](https://doi.org/10.3310/pgfar09030)

## Scientific summary

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Programme Grants for Applied Research 2021; Vol. 9: No. 3

DOI: [10.3310/pgfar09030](https://doi.org/10.3310/pgfar09030)

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# Scientific summary

## Background

Research on, and the care of, patients after stroke has been transformed in recent years. The recommended stroke care pathway in the first weeks after stroke is evidence based and becoming established. Despite this, longer-term outcomes remain poor for many, with unmet needs frequently identified by stroke survivors.

## Aims and objectives

The aims were to develop and test a longer-term integrated stroke care strategy focused on improving the quality of life of stroke survivors and their carers by addressing unmet needs, and maintenance and enhancement of participation (i.e. involvement in life situations).

The objectives were to:

- develop the content of the care strategy through qualitative exploration with stroke survivors and their carers and review the evidence relating to content and delivery
- inform feasible means of delivery through national survey and more detailed examination of exemplar services
- use an intervention mapping framework to develop a care strategy, supporting materials and training programmes (for stroke survivors, carers and staff)
- refine content and test implementation of the care strategy through case studies in three stroke services
- undertake a feasibility cluster randomised trial to refine procedures for a future large-scale trial.

## Setting

The intervention development work and feasibility trial were in stroke services (inclusive of primary, secondary, community and social care provision) across England and Wales.

## Participants

Participants were stroke survivors living in the community and their carers, and health and social care professionals in the included stroke services.

## Methods

### Workstream 1a

Semistructured interviews were undertaken with stroke survivors and their carers at 9–12 months post stroke and between 2 and 4 years post stroke to identify needs and to explore the barriers and enablers that affect unmet needs and restrict participation (i.e. involvement in life situations). Purposive sampling was undertaken to identify participants with diverse characteristics (socioeconomic, level of need and independence). Interviews were analysed via thematic analysis. In addition, literature and Stroke Association helpline data were scrutinised to gain a comprehensive picture of unmet needs after stroke.

**Workstream 1b**

A review of the evidence relating to interventions that may enhance longer-term outcomes for people after stroke was undertaken through an overview of Cochrane reviews and a review of individual studies. A scoping review of reviews addressing delivery mechanisms in chronic illness was also undertaken.

**Workstream 2**

A national survey was conducted to clarify current service models across England. Focus groups were undertaken in a range of identified service models to gain further insights and understanding from service deliverers about barriers to and enablers of development and implementation of our care strategy.

**Workstream 3**

Intervention development: building on the information and evidence gained in early workstreams, and working through structured engagement with a range of stakeholders and research colleagues, we developed the intervention plan (a component of our care strategy) using problem structuring and shared knowledge creation.

**Workstream 4**

Using a case study approach and working with specially convened action groups, the intervention was implemented and iteratively refined in three stroke services. Semistructured interviews were undertaken with participating staff and patients.

**Workstream 5**

A feasibility cluster randomised controlled trial was undertaken in 10 stroke services to develop procedures, including intervention implementation and process and economic evaluations, for a large-scale trial. The process evaluation, including observations of training and practice, interviews with staff and patients, and documentary analysis, was undertaken to gain an understanding of how New Start was implemented and received by stroke survivors, in order to inform the optimisation of its future design and evaluation. The health economic analysis evaluated the costs and benefits associated with the New Start intervention and developed an economic model to analyse future costs and benefits beyond the trial time horizon.

**Results****Workstream 1a**

Twenty-eight stroke survivors and 11 carers (eight wives and three husbands) were interviewed. Thirteen of the stroke survivors were between 9 and 12 months post stroke; the remainder were between 32 and 47 months post stroke. Stroke survivors (and, in some cases, their carers) reported 13 needs that they felt were important, with some identifying needs that were unaddressed, even up to 3 years post stroke. The factors that stopped people from addressing their needs (barriers) and the factors that enabled them to address their needs (facilitators) were also identified. Emotional needs and the importance of information and having support in the longer term after stroke were highlighted. Even though stroke survivors and their carers faced challenges, they developed ways of problem-solving. These interviews, the literature review and scrutiny of the Stroke Association helpline data identified 23 needs in all.

**Workstream 1b****Overview of Cochrane reviews**

A total of 28 reviews were included, encompassing 352 studies. Of these, 17 reviews met all quality criteria, and 11 met five of the six criteria. There was very little evidence of intervention effect on mood, participation, health status, quality of life or carer burden. This was primarily because few studies measured these outcomes.

## Review of individual studies

The majority of trials related to physical exercise, and there was a noticeable lack of trials evaluating other interventions for longer-term stroke survivors and their carers. Although many studies reported significant effects, trials were small and there were no consistent patterns to indicate effective types of intervention.

## Scoping review of delivery mechanisms

The majority of the primary evidence synthesised was focused on diabetes and the most convincing evidence was of supported self-management.

## Workstream 2

Fifty-seven per cent of Clinical Commissioning Group areas (116/203) responded to our survey.

The most common model of service provision, reported by 46 (40%) services, was a stroke-specific, neurorehabilitation community team service providing care up to 12 months post stroke. Thirty-five (30%) services provided care up to 6 months post stroke and 35 (30%) services provided care beyond 12 months post stroke. Eight focus groups were completed with staff and stakeholders from a range of service models in rural and urban areas. Five of the focus groups were with services using the common model of stroke service provision (up to 12 months). Key barriers to service provision included deficits of skills and resources, lack of availability of training, prevailing cultural systems and organisational processes in the NHS and failure of multiagency partnership working. Enablers included creative in-house approaches to training and educational enhancement, and flexible operational, managerial and cultural approaches.

## Workstream 3

Through work with a purposely convened reference group and our consumer group, the identified unmet needs were prioritised and principles of the care strategy were developed. These were that the intervention is relevant and accessible to all stroke survivors and their carers, is responsive to context, is feasible and sustainable, and can be developed in a context of existing health and social care resources. Delivery would be face to face at an individual level and, following the exploration of current services, we concluded that the 6-month review time point was an appropriate anchor point for our intervention. In brief, the intervention (New Start) included a priming tool to assist stroke survivors and their carers to identify needs; problem-solving self-management with survivors and carers; providing help with obtaining usable information; and helping survivors and their carers build sustainable flexible support networks.

## Workstream 4

Action groups were convened in three stroke services and facilitators were appointed to deliver the intervention. The intervention and associated materials and staff training plans were refined and clarified iteratively through regular meetings of the action groups with a member of the research team attending and recording actions. Feedback from staff and patients facilitated finalisation of the intervention.

The intervention (called New Start) was delivered face to face at 6 months post stroke by facilitators who have undertaken a purposely designed and comprehensive training programme. Intervention delivery was supported by a range of intervention materials, covering key components as described for workstream 3.

## Workstream 5

A cluster randomised controlled trial of the New Start intervention was undertaken in our target of 10 stroke services across England and Wales.

## Recruitment of stroke survivors

Of 1127 stroke survivors who received care across the 10 services and were screened for participation, 1034 (91.7%) were eligible, 367 were interested (35.5% of eligible; 32.6% of those screened) and 269 were registered to participate in the trial (26.0% of eligible; 23.9% of those screened).

More than half of sites had recruitment periods of > 6 months, but the overall average number of recruited stroke survivors per site, prorated to a 6-month period, was 24.1 (fulfilling green requirements on the recruitment criteria for progression to a main trial).

We were able to demonstrate that recruitment of longer-term stroke survivors by post is feasible and resource efficient.

### **Follow-up of stroke survivors**

Stroke survivors were assessed via postal questionnaires at 3, 6 and 9 months after registration to the trial. A total of 216 (80.3%) of registered stroke survivors returned follow-up questionnaires at 9 months: 84.1% in the intervention arm and 75.8% in the usual care arm (fulfilling green requirements on the follow-up progression criteria).

### **Intervention delivery**

According to site-reported data, overall, 95.2% of registered stroke survivors were offered at least one session of the intervention, with all sites offering the intervention to at least 75% of their registered stroke survivors (fulfilling green requirements on the intervention delivery progression criteria).

### **Intervention implementation**

All five intervention sites had at least two facilitators deemed competent in delivering the New Start intervention and providing it to stroke survivors (fulfilling green requirements on the intervention implementation progression criteria).

There were, however, concerns regarding the number of stroke survivors being offered, accepting and receiving the intervention at some sites. There was variable take-up of the offer of a 6-month review, with some stroke survivors choosing not to engage with stroke services. Uptake of a review across all services was 58.7%; however, it varied widely, from 9.7% to 100%.

Overall, 86 out of 145 (59.3%) of intervention trial participants had at least one intervention meeting.

No safety concerns were reported.

### **Process evaluation**

The procedures for the process evaluation were shown to be feasible. The evaluation found that, although training and implementation of New Start in sites were successful, fidelity was variable. Facilitators could find it hard to adopt a collaborative approach to problem-solving and goal-setting, and integration of this approach with the clinical data collection required for the national stroke audit was problematic. Some stroke survivors found it difficult to actively engage with the process. Most stroke survivors reported benefiting from the intervention because they felt supported and understood.

### **Health economics**

The primary within-trial cost-effectiveness analysis and long-term evaluation of lifetime costs and benefits in the economic model were both exploratory. The within-trial analyses indicated that, although the New Start intervention may be a cost-effective use of resources, the results were not robust to alternative assumptions explored in sensitivity analyses. The results obtained from the longer-term analysis of costs and benefits using the decision-analytic model indicated that New Start was unlikely to be cost-effective compared with usual care. As in the within-trial analysis, there was uncertainty in the results, which was driven by the small differences between the treatment options in terms of both costs and quality-adjusted life-years.

## Conclusions

For the first time, to our knowledge, the barriers to and facilitators of addressing needs in the longer term after stroke have been identified from the perspectives of stroke survivors and their carers and service providers. A national survey highlighted the wide variability of stroke services available. We report the relatively limited amount of research being conducted, relevant to the longer-term needs of people after stroke. A complex intervention that included problem-solving approaches was developed, with input from stroke survivors and health and social care professionals, and implemented in the context of a feasibility cluster randomised controlled trial in five varied stroke services across England and Wales. Detailed data on the take-up of an offered review 6 months after stroke are provided, which will inform future service delivery. We met the criteria to progress to a full trial evaluation; however, implementation of the intervention was not as intensive as we had anticipated. The detailed process evaluation captured the complexities of introducing service change in this environment.

## Future work

Researchers should develop and evaluate interventions relevant to the expressed needs of stroke survivors and their carers. Our work demonstrated the importance of having detailed conversations with as many stakeholders as feasibly possible, prior to service reconfiguration, to enhance communication and cohesion. The findings suggest that consideration should be given to the specification of a stroke care pathway beyond the first few weeks after stroke, recognising that stroke survivors will report a variable range of needs and some may choose not to re-engage with stroke services at the 6-month time point.

Refinement of the target population, possibly through assessment of unmet needs and optimisation of the intervention materials, through clarifying and streamlining is required prior to a full randomised controlled trial evaluation.

## Trial registration

This trial is registered as ISRCTN38920246.

## Funding

This project was funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research programme and will be published in full in *Programme Grants for Applied Research*; Vol. 9, No. 3. See the NIHR Journals Library website for further project information.





# Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

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## This report

The research reported in this issue of the journal was funded by the PGfAR programme as project number RP-PG-0611-20010 from route sheet. The contractual start date was in October 2013. The draft report began editorial review in May 2019 and was accepted for publication in June 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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