

Development and evaluation of tools and an intervention to improve patient- and carer-centred outcomes in Longer-Term Stroke care and exploration of adjustment post stroke: the LoTS care research programme

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Scientific summary

Interventions and tools for long-term stroke care

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Scientific summary

Background

It is important to ensure that the whole stroke care pathway is evidence based and interlinked; however, previous reports indicate that longer-term stroke problems are not appropriately addressed and post-hospital services are fragmented. Despite policy recommendations for the role of the stroke care co-ordinator (SCC) in supporting patients and carers in the community, this role remains ill-defined and evaluation equivocal. To address this we have previously developed a post-discharge system of care more clearly focused on the post-stroke problems of patients and their carers. The system of care consists of a structured assessment covering 16 problem areas, linked to evidence-based treatment algorithms and a goal and action planner. We had also developed a monitoring tool to identify longer-term unmet needs after stroke (LUNS).

Objectives

The twofold aim of this programme was to enhance the care of stroke survivors and their carers in the first year after stroke and to gain insights into the process of adjustment. This was undertaken through:

- the updating of evidenced-based treatment algorithms focused on problems identified by patients and carers
- the pragmatic evaluation by cluster randomised controlled trial (RCT) of the system of care, which uses the evidence-based algorithms, delivered to stroke patients after hospital discharge by SCCs
- finalising the development and robust psychometric evaluation of a monitoring tool for longer-term unmet needs after stroke (the LUNS questionnaire)
- in-depth qualitative exploration of barriers to, and facilitators of, post-stroke recovery and adjustment.

Methods

Update of evidenced-based treatment algorithms

A hierarchical comprehensive structured protocol for identifying evidence in each of the 16 problem areas [transfer of care, communication and information, medicines and general health, pain, mobility/falls, personal hygiene and dressing, shopping and meal preparation, house and home, cognition, driving and general transport, finances and benefits, continence, sexual functioning, patient mood, patient social needs (and employability) and carer social and emotional needs] was developed. This included identifying relevant stroke- and problem-specific guidelines, meta-analyses and systematic reviews and, if necessary, individual RCTs. Two researchers independently reviewed all outputs. Evidence identified for inclusion was assessed for quality using standard tools. Draft treatment algorithms were peer reviewed by external experts before compilation in the manual developed to support our newly developed system of care.

Cluster randomised controlled trial of the system of care

A pragmatic, multicentre, cluster RCT compared the system of care with usual practice, delivered to patients by a SCC within a stroke service that received referrals from a stroke unit. A SCC was eligible if he or she was a registered health-care professional with documented experience in stroke care, undertaking a community-based co-ordinating role for stroke patients. Services were randomised to the control (usual care) or the intervention, stratified by the quality of the stroke unit (*National Stroke Audit* score), the annual number of referrals, whether SCCs worked alone or within a community-based multidisciplinary team and by Strategic Health Authority. SCC(s) in services randomised to the intervention were trained in

the system of care and gained experience in delivery prior to trial recruitment commencing, after which they delivered it to all patients.

Patients with a new stroke, living at home and referred to a SCC were eligible; they were recruited before their first SCC assessment with the optional recruitment of informal carers. The primary objective was to determine whether the intervention improved patient psychological outcomes [General Health Questionnaire-12 (GHQ-12)] at 6 months; secondary objectives included further functional outcomes for patients and outcomes for carers (if registered), measured through self-completed postal questionnaires at 6 and 12 months.

Participants' use of health/social care services and informal care was measured by self-completed questionnaires at baseline and 6 and 12 months to estimate and compare individual-level total costs from health/social care and societal perspectives at 6 and 12 months and over 1 year. Costs were combined with the primary outcome (GHQ-12 score) and quality-adjusted life-years (QALYs; based on the European Quality of Life-5 Dimensions measure) to examine cost-effectiveness at 6 months. Cost-effectiveness acceptability curves based on the net benefit approach and bootstrapping techniques were used to estimate the probability of cost-effectiveness.

Initial sample size calculations based on the primary outcome measure indicated that recruitment of 800 patients from 40 services would provide 90% power at a 5% significance level to detect a clinically relevant difference of 2.5 GHQ-12 points (standard deviation 7). Statistical analyses were based on the intention-to-treat (ITT) population. All statistical testing was performed at a two-sided 5% significance level. Per-protocol analysis was also undertaken in which major protocol violators or patients not receiving care from a SCC were excluded. Outcome measures were compared between the intervention group and the control group using a two-level multilevel model, with patients nested within stroke services. Details of patient deaths and hospital readmissions, carer deaths and any serious adverse events are reported for each treatment group.

Development and psychometric evaluation of the Longer-term Unmet Needs after Stroke tool

A pilot study and semistructured interviews and focus groups with stroke patients were used to refine the draft LUNS tool. The final tool was then evaluated in a multicentre study. Patients with a primary diagnosis of stroke, being discharged to their own home or that of a carer, after a minimum 3-day hospital stay, were recruited from 40 stroke units across England. A questionnaire pack including the LUNS tool, the GHQ-12, the Frenchay Activities Index (FAI) and the Short Form questionnaire-12 items was posted to participants 3 or 6 months after stroke to assess LUNS acceptability and validity. The LUNS tool was re-sent 1 week after the first pack to assess test-retest reliability. The study was conducted in two phases. Phase 1 ($n=350$) was undertaken on English-speaking patients without communication or cognitive impairment. Interim analysis of phase 1 data was conducted to ensure adequate psychometric properties of the LUNS tool in this optimised group before proceeding to phase 2. In phase 2 ($n=500$) we recruited patients who had spent longer in hospital (likely to be more disabled) and included patients with cognitive and/or language impairment. Proxy responses were accepted.

Qualitative exploration of adjustment post stroke

Trial data were purposively sampled to identify stroke survivors with varying levels of social activity (FAI) in relation to their physical ability (Barthel Index) to include participants who seemed to be less or more socially active than anticipated and those who seemed to be 'as anticipated'. The sample was also purposively selected to ensure variation in relation to key characteristics that the evidence suggests may shape adjustment and social participation post stroke (age, socioeconomic status, living arrangements, gender).

A combination of qualitative methods was used to explore adjustment after stroke with stroke survivors (and their carers if available): initial semistructured interviews, limited observations and solicited diaries with a follow-up interview 3–4 months after the first interview. The initial interview addressed topics including life before stroke, the stroke event itself and being in hospital, life post-discharge home and life since (up to and including the present). The follow-up interview was informed by the initial interview and diaries. A grounded theory approach to data analysis was taken, which entailed simultaneous data collection and analysis. The interpretations made were tested by the use of 'constant comparison' both within and across cases to provide an understanding of similarities and differences in the process of recovery and adjustment over time for different participants.

Results

Update of evidenced-based treatment algorithms

Over 71,000 articles were identified by the searches (excluding titles identified for the Cochrane review, described in the following section). Robust guidelines were identified for three problem areas; for a fourth, information provision, we are the authors of the Cochrane review, which we updated. For the 12 remaining problem areas detailed searches were implemented. Following the review procedure the algorithms were updated in accordance with the identified evidence and, following external peer review, were incorporated into the system of care manual.

Update of the Cochrane review

For the most recent update we reviewed 28,110 titles including 134 full papers, resulting in the inclusion of four additional studies. The review now includes 21 trials from seven countries involving 2289 patients and 1290 carers.

Meta-analyses of reported outcomes showed a significant effect in favour of information provision on patient knowledge, carer knowledge and patient satisfaction with information provision. There was a small effect on reducing patient depression.

Cluster randomised controlled trial of the system of care

In total, 32 stroke services from across the UK were randomised. Three services did not participate because of changes in the service, the lack of a researcher or the lack of a SCC. A total of 800 patients (399 control, 401 intervention) and 208 carers (100 control, 108 intervention) were recruited.

Baseline characteristics were, on the whole, well balanced between the study arms, demonstrating a lack of selection bias in the recruitment of participants. In ITT analysis, the adjusted difference in patient GHQ-12 mean scores between the groups at 6 months was -0.6 points [95% confidence interval (CI) -1.8 to 0.7 points, $p=0.394$], indicating no evidence of a statistically significant difference between the treatment arms. There was no evidence of statistically significant differences in secondary end points or adverse events. Analyses of the per-protocol population were consistent with the ITT analyses. Our prespecified level of intervention compliance was achieved by 96% of the initial structured assessments, indicating that the assessment was delivered as expected. The use of a problem-solving, goal-setting approach appeared to be more variable and outcomes may be partially influenced by the availability of services to address problems, with psychological services and voluntary/community resources reported to be limited.

Costs of SCC inputs (mean difference £42; 95% CI $-\text{£}30$ to $\text{£}116$) and total health and social care costs at 6 months, 12 months and over 1 year were similar between groups. Societal costs were higher in the intervention group (mean difference at 6 months: $\text{£}1163$; 95% CI $\text{£}56$ to $\text{£}3271$). There were no differences in QALYs.

Development and psychometric evaluation of the Longer-term Unmet Needs after Stroke tool

A 22-item questionnaire was produced from the pilot study ($n=65$) and interviews ($n=18$), which was subsequently evaluated in the main study. In phase 1, 350 patients were recruited from 29 sites. In phase 2, 500 patients were recruited from 40 sites. All results are reported for the combined study population of 850 patients, including 199 (23%) with communication and/or cognitive impairment.

In total, 529 questionnaire packs were returned (69% of those sent), with 3.5% missing LUNS items on initial receipt, comparable to missing items for the concurrent measures. Test–retest reliability of the LUNS questionnaire ($n=326$) was moderate to good (individual item agreement 77.9–98.8%, kappa statistic 0.45–0.67). Identification of an unmet need was consistently associated with poorer outcomes on concurrent measures compared with those without the unmet need (Mann–Whitney U -test). The median number of unmet needs was four (range 0–19) and semistructured interviews with participants reporting low unmet need verified that they did not have unmet needs, either in areas covered by the LUNS questionnaire or in other areas not covered by the LUNS questionnaire. The LUNS questionnaire therefore demonstrated adequate acceptability, test–retest reliability and validity.

Qualitative exploration of adjustment post stroke

In total, 22 stroke survivors and 12 carers/significant others were recruited. Of the stroke survivors, 12 were from the more socially active than anticipated group, eight were from the less socially active than anticipated group and two were from the doing as expected group (based on Barthel Index and FAI scores).

As analysis progressed and the researchers explored individual and across-case recovery and adjustment after stroke, the concept of the recovery trajectory became particularly important. Analysis of participants' accounts led to the identification of four different recovery trajectories as well as the exploration of the processes and mechanisms that shaped these: (1) disruption followed by adjustment and acceptance; (2) cycles of disruption followed by adjustment and acceptance; (3) disruption without adjustment and acceptance; and (4) stroke as a continuation of ongoing decline. This work emphasised the importance of everyday tasks and activities not only for what they achieve in themselves but in enabling stroke survivors to maintain and enact (and sometimes establish) relationships that are important and meaningful to them.

Conclusions

We have updated 16 evidence-based treatment algorithms centred on patient- and carer-identified post-stroke problems. The Cochrane review on information provision has been updated and indicates that active information giving, including the opportunity for questions, is more effective than passive information provision in improving outcomes for patients and carers after stroke.

Since this programme grant was awarded in 2007 there have been considerable changes in stroke service provision across the UK. Our system of care is very much in keeping with current developments, with similar systems having been developed (e.g. Greater Manchester Stroke Assessment Tool for 6-month reviews). We are therefore presenting the first ever trial evaluation of this approach. The trial demonstrated no benefit for clinical effectiveness or cost-effectiveness outcomes from the system of care compared with usual SCC practice. However, compliance with the structured assessment was high and involved no additional SCC time, indicating that this is an appropriate approach to implement evidence into clinical practice, for example as a structured way of ensuring an evidence-based post-stroke review. The manual containing evidence-based treatment algorithms would support staff to form a broader professional base moving from multidisciplinary to interdisciplinary work. These tools may be of particular use for developing services in sites currently without organised long-term care for stroke.

To assist in the configuration of appropriate services in the future we have developed and robustly tested a simple tool (LUNS) suitable for assessing unmet needs in stroke survivors. The LUNS tool is now available for clinical use, to identify the unmet needs of individuals, for example during post-stroke reviews, or populations, for example to assist commissioners in service planning.

We have also identified, through in-depth qualitative work, a range of recovery trajectories post stroke and the factors that shape the different trajectories. Case studies illustrating different recovery trajectories may be a useful resource for stroke survivors/carers or for training health and social care professionals.

This programme of work has progressed the evidence base for longer-term post-stroke care. This includes completing one of the largest ever stroke rehabilitation trials, demonstrating that this method is feasible. Our work highlights that successfully addressing the needs of a heterogeneous post-stroke population remains problematic. In future work, consideration should be given to the stratification of patients following the initial post-discharge assessment to facilitate targeting of appropriate treatment. Some patient (and carer) needs may be so complex that they necessitate a tailored case management approach; for others the system of care as described may be appropriate; and other patients (and carers) might require minimum further involvement but could benefit from a programme of supported self-management. Our newly developed LUNS tool and the qualitative work will help inform such services.

Trial registration

This trial is registered as ISRCTN67932305.

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