

An extended stroke rehabilitation service for people who have had a stroke: the EXTRAS RCT

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Scientific summary

The EXTRAS RCT

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Scientific summary

Background

Around two-thirds of stroke survivors leave hospital with disability; some make a full recovery, whereas for others stroke is a long-term condition. Stroke is the most common cause of complex disability in the UK, affecting over 1.2 million people. Owing to an ageing population, the number of stroke survivors living with disability is expected to increase by one-third by 2035.

Stroke units and early supported discharge services have been shown to be both clinically effective and cost-effective and are the cornerstones of 'organised stroke care'. Their key features are multidisciplinary stroke specialist expertise, regular review, co-ordination of care, and active patient and carer involvement. However, after patients leave early supported discharge, there is limited evidence to guide rehabilitation to optimise recovery and meet the longer-term needs of stroke patients and their carers.

Rehabilitation is a broad term that encompasses focused interventions for specific impairments through to complex care processes that involve teams of health-care professionals delivering a package of interventions. Different types of interventions and services that seek to improve long-term outcomes post stroke have been evaluated (e.g. stroke support workers), but results have been mixed and have not provided sufficient evidence of clinical effectiveness or cost-effectiveness to support further investment in community stroke services.

This research project evaluated an extended stroke rehabilitation service (EXTRAS). EXTRAS sought to help individuals to maximise their recovery and/or adjust to residual disability in the context of their day-to-day activities through intermittent assessment, goal-setting and action-planning, with referral if required. Both stroke survivors and their carers were included in the study. EXTRAS did not include any assessment of carer needs or specific interventions for carers, but it was important to evaluate how a new service may affect carers. EXTRAS was delivered by early supported discharge teams and provided continuation of specialist stroke care beyond early supported discharge.

Aim and objectives

The aim of the EXTRAS trial was to determine the clinical effectiveness and cost-effectiveness of an extended stroke rehabilitation service.

The objectives were to:

- determine whether or not EXTRAS improved patient outcomes
- determine whether or not EXTRAS improved carer outcomes
- determine the cost-effectiveness of EXTRAS
- document how EXTRAS was implemented and delivered in different settings
- seek the views and experiences of patients, carers and rehabilitation staff about the community rehabilitation that they received or provided
- explore the impact of the severity of activity limitation, pre-stroke health status and comorbidity on the effectiveness of the intervention.

Methods

This study was a pragmatic, observer-blind, parallel-group, multicentre randomised controlled trial with health economic and process evaluations.

Setting

The study was conducted in 19 NHS study centres.

Participants

Adults with a new stroke (first ever or recurrent) were eligible to take part if they received early supported discharge care and were able to participate in a rehabilitation programme focusing on extended activities of daily living. We also sought to recruit informal carers (the main family member or friend) who provided support after the stroke.

Randomisation

Randomisation to a study group took place at discharge from early supported discharge services and was conducted by NHS staff at participating study centres using an online web-based service. Stratification was by study centre and permuted block sequences assigned participants to the intervention or control group in a 1 : 1 ratio.

Study intervention treatment

EXTRAS consisted of five rehabilitation reviews conducted at 1, 3, 6, 12 and 18 months post discharge from early supported discharge services. Reviews were conducted by a senior member of the early supported discharge team, usually by telephone, and covered issues identified in a national survey of patient needs and other literature, and by clinicians, patients and carers. These issues were mobility; personal care; mealtimes; domestic activities; work and volunteering; hobbies and interests; driving and transport; communication; memory and concentration; mood, anxiety and depression; medical issues; pain; and other issues. The patient's progress was assessed along with their current rehabilitation needs and service provision. Rehabilitation goals were agreed and an action plan was made at each review. Action plans could include verbal advice and encouragement; discussion with services currently involved in the patient's care; signposting to local activities, community services or voluntary services; and referral to stroke services, rehabilitation services or primary care.

Study control treatment

Patients randomised to the control group received usual NHS care. Following completion of early supported discharge, patients who had ongoing rehabilitation needs received standard care for that locality according to clinical judgement, including referral to a range of available services (e.g. neurorehabilitation teams, day hospital and community rehabilitation services).

Data collection and outcome measures

For patients, data concerning demography and stroke details were collected, and baseline measurements for (1) performance in extended activities of daily living (Nottingham Extended Activities of Daily Living Scale), (2) health status (Oxford Handicap Scale), (3) mood (Hospital Anxiety and Depression Scale) and (4) health-related quality of life [EuroQol-5 Dimensions, five-level version (EQ-5D-5L)] were obtained by face-to-face assessment prior to randomisation. Carers completed a baseline questionnaire that captured demographic data, carer stress (Caregiver Strain Index) and health-related quality of life (EQ-5D-5L).

Outcome data were collected at 12 and 24 months post randomisation. For patients, in addition to the measurement scales listed above, an experience of services survey (designed by Northumbria Healthcare NHS Foundation Trust based on Picker Institute questions), the resource utilisation data (adaption of the Client Service Receipt Inventory) and adverse events data were collected. A telephone interview was the intended method for outcome assessments but face-to-face visits and postal questionnaires could also be used. Carers completed a postal questionnaire that recorded carer stress (Caregiver Strain Index), health-related quality of life (EQ-5D-5L) and experiences of services using the survey described above.

Owing to the nature of the intervention, the patients, carers and staff providing EXTRAS could not be blinded to the study group. However, outcome data were intended to be collected by a blinded researcher and any unblinding (e.g. as a result of a participant revealing the study group) was recorded.

Sample size

The primary outcome was the Nottingham Extended Activities of Daily Living Scale. To provide 90% power to detect a clinically important difference of 6 points on the Nottingham Extended Activities of Daily Living Scale (scored 0–66, standard deviation 18), 382 patients split equally between the intervention and control groups were required. Based on other stroke rehabilitation studies, it was estimated that there could be up to 25% attrition between randomisation and 24 months. To allow for this, 510 patients were required to be randomised.

Statistical analysis

Mean scores on the Nottingham Extended Activities of Daily Living Scale (the primary outcome) were compared at 24 months between the intervention and control groups using multiple linear regression, including terms for centre, baseline Oxford Handicap Scale, age and sex. The Oxford Handicap Scale was analysed using ordinal regression, adjusting for the same covariates as the primary analysis. The Hospital Anxiety and Depression Scale and Caregiver Strain Index were analysed using multiple linear regression adjusting for appropriate covariates. For the experience of services survey, responses were dichotomised as 'in agreement or not' or 'satisfied or not', and differences in proportions were calculated with 95% confidence intervals.

Health economic analysis

Responses to the EQ-5D-5L were mapped to utility values and combined with observed mortality to create quality-adjusted life-years. NHS and social care resources used by participants in each study group were collected using an adaption of the Client Service Receipt Inventory, and costs of the intervention were based on the time spent with each participant. Cost and quality-adjusted life-year differences were estimated using appropriate generalised linear models and uncertainty quantified by random sampling with replacement.

Process evaluation

The process evaluation used quantitative and qualitative methods to (1) document how EXTRAS was implemented and delivered in different settings, (2) seek the views and experiences of patients and carers about the rehabilitation services they received, and (3) seek the views and experiences of early supported discharge teams and community rehabilitation staff about the services provided to intervention and control groups.

Results

A total of 573 patients with 194 carers were randomised to a study group between January 2013 and October 2015 (EXTRAS: patients, $n = 285$, carers, $n = 103$; usual care: patients, $n = 288$, carers, $n = 91$). Study groups were well matched at baseline. Most patients had suffered a first ischaemic stroke; the median time from stroke to randomisation was 72 days. The majority of carers were female and the spouse/partner of the patient. At 24 months, outcome data were available for 450 out of 573 (78%) patients and 153 out of 194 (79%) carers.

Primary outcome

There was no significant difference between the groups for the primary outcome. The mean Nottingham Extended Activities of Daily Living Scale score (range 0–66) at 24 months was 40.0 (standard deviation 18.1) in the intervention group and 37.2 (standard deviation 18.5) in the control group, an adjusted mean difference of 1.8 (95% confidence interval 0.7 to 4.2).

Secondary outcomes

The Nottingham Extended Activities of Daily Living Scale scores at 12 months were similar to those at 24 months, with no significant difference between study groups.

For health status, measured using the Oxford Handicap Scale at 24 months, the odds of the intervention group being in worse (instead of better) health was 0.7 times as high as that for control patients (95% confidence interval 0.5 to 1.0), which was not significantly different from equal odds in both groups. The comparison at 12 months was similar.

The mean anxiety and depression Hospital Anxiety and Depression Scale scores were lower for patients in the intervention group at 12 and 24 months, but the 95% confidence intervals for the difference in scores included zero.

No association was found between the effectiveness of the intervention and the pre-stroke Oxford Handicap Scale score, the baseline Nottingham Extended Activities of Daily Living Scale score and the time in organised stroke care (defined as time as an inpatient plus time in early supported discharge), which were prespecified exploratory analyses.

For 4 of the 19 aspects of care examined in the patients' experience of services survey at 24 months, the 95% confidence interval for the differences in the percentage of 'in agreement' or 'satisfied' between the groups did not cover the value zero. These were 'staff treated you with dignity and respect', 'staff met your needs', 'overall satisfaction' and 'help with mobility'.

Serious adverse events were reported for 125 out of 285 (44%) patients in the intervention group (total 250 events) and 130 out of 288 (45%) patients in the control group (total 254 events). These medical events were predominantly admissions to hospital and none were believed to be related to EXTRAS.

For carers, there were no significant differences between the groups for carer stress measured by the Caregiver Strain Index or for quality-adjusted life-years. For the experience of services survey with 19 aspects, at 24 months a significantly higher proportion of carers reported that they were 'in agreement' or 'satisfied' with 'overall satisfaction with services your friend/relative received' and 'help with mobility'.

Post hoc analysis

A post hoc analysis of the Hospital Anxiety and Depression Scale case versus non-case at standard clinical thresholds found that there were significantly fewer cases of depression at 12 months in the intervention group (29% intervention group vs. 40% control group; adjusted odds ratio 0.59, 95% confidence interval 0.39 to 0.90) and significantly fewer cases of anxiety at 24 months (28% intervention group vs. 38% control group; adjusted odds ratio 0.64, 95% confidence interval 0.41 to 0.99).

Health economic evaluation

Patients who were randomised to receive EXTRAS gained, on average, 0.07 additional quality-adjusted life-years (95% confidence interval 0.01 to 0.12). The mean cost of resource utilisation was lower in the intervention group at -£311 (95% confidence interval -£3292 to £2787), with a 68% chance of EXTRAS being cost saving. The changing resource use pattern suggests that it is likely that additional costs to health services were offset by savings in social care. At the current standard willingness to pay of £20,000 per quality-adjusted life-year, there is a 90% probability that EXTRAS is cost-effective for the NHS.

Process evaluation

Depending on time point, between 91% (1-month review) and 81% (12-month review) of the expected EXTRAS reviews were undertaken. Health-care professionals conducting the reviews included physiotherapists (56% of reviews), occupational therapists (28%) and nurses (8%). The majority of reviews were undertaken by telephone, as intended. Mobility and hobbies and interests were the most commonly selected topics for goals. Action plans predominantly featured telephone advice from the reviewer with related actions for the patient and/or carer to carry out. Very few new referrals were made to health or social services.

A total of 20 patients, 6 carers and 41 NHS staff took part in semistructured interviews. Patient and carer interviews were conducted after the 24-month outcome assessment was completed, that is 6 months after

the last EXTRAS review. Most patients and carers did not have a detailed recollection of EXTRAS reviews but those who did reported that they were helpful in terms of providing regular contact and the relevance of the advice given. Staff felt that the advice and approach to self-management was likely to improve patient confidence, well-being and emotional health, but they felt that the intervention was unlikely to have an impact on performance in extended activities of daily living as it did not involve direct supervision of the patient practising activities.

Conclusion

EXTRAS did not improve stroke survivors' performance in extended activities of daily living. The lack of effect on the primary outcome is likely to be a result of the concept of the intervention rather than the fidelity of the intervention. However, EXTRAS provided more quality-adjusted life-years and was associated with lower costs. In addition, patients and carers in the intervention group were more satisfied with aspects of their overall care. EXTRAS did not improve patients' health status or carers' quality of life or stress. A post hoc finding was that the intervention group had fewer cases of anxiety and depression than those who received usual care.

Given the impact on costs and quality-adjusted life-years, there is a high chance that EXTRAS could be considered cost-effective at conventional thresholds of the NHS/UK society's willingness to pay for a quality-adjusted life-year (currently £20,000 per quality-adjusted life-year), despite there being no difference in the primary outcome.

Implications for health care

The decision-makers will probably be most interested in the finding that, although there is no evidence of any treatment effect on the primary outcome, the estimated cost-effectiveness analysis is consistent with EXTRAS being associated with cost saving and quality-of-life gain. Another consideration for decision-makers is that cost savings were predominantly made in social care rather than health services. Our findings suggest that EXTRAS may be an affordable addition to improve stroke care.

Implications for research

The EXTRAS trial has demonstrated that a large multicentre trial to evaluate a new innovative community stroke service is achievable. Multicentre trials evaluating community stroke services are rare and there remains a need to develop and evaluate different approaches to addressing the wide range of long-term needs of stroke survivors and carers and improving physical, psychological and quality-of-life outcomes. In particular, further research is required to identify whether or not longer-term community-based interventions tailored to the individual needs of stroke survivors can improve performance of extended activities of daily living, and to understand the mechanisms by which health-related quality of life is improved and costs are reduced by provision of intermittent longer-term specialist review.

Trial registration

This trial is registered as ISRCTN45203373.

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This report

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