

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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Published PDF deposited in [Curve](#) February 2016

Original citation:

Forster, A. , Mellish, K. , Farrin, A. , Bhakta, B. , House, A. , Hewison, J. , Murray, J. , Patel, A. , Knapp, M. , Breen, R. , Chapman, K. , Holloway, I. , Hawkins, R. , Shannon, R. , Nixon, J. , Jowett, A. , Horton, M. , Alvarado, N. , Anwar, S. , Tennant, A. , Godfrey, M. and Young, J. (2014) 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. no. 6. Perth, Scotland:National Institute for Health Research.

DOI: 10.3310/pgfar02060

URL: <http://dx.doi.org/10.3310/pgfar02060>

Publisher: National Institute for Health Research

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**National Institute for
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Declared competing interests of authors: Bradford Teaching Hospitals NHS Foundation Trust received additional funding for the submitted work from The Stroke Association. AF received funding from the NIHR Stroke Research Network and The Stroke Association for activities outside of the submitted work. Funding was provided by a Stroke Association Junior Research Fellowship for NA to undertake a PhD - a realist evaluation of the LoTS care trial. JRTF 2009/03.

Published December 2014

DOI: [10.3310/pgfar02060](https://doi.org/10.3310/pgfar02060)

This report should be referenced as follows:

Forster A, Mellish K, Farrin A, Bhakta B, House A, Hewison J, *et al.* 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. *Programme Grants Appl Res* 2014;**2**(6).

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

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This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0606-1128. The contractual start date was in September 2007. The final report began editorial review February 2013 and was accepted for publication in November 2013. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, NETSCC, PGfAR or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PGfAR programme or the Department of Health.

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Abstract

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Background: Evidence-based care pathways are required to support stroke patients and their carers in the longer term.

Aims: The twofold aim of this programme of four interlinking projects was to enhance the care of stroke survivors and their carers in the first year after stroke and gain insights into the process of adjustment.

Methods and results: We updated and further refined a purposely developed system of care (project 1) predicated on a patient-centred structured assessment designed to address areas of importance to patients and carers. The structured assessment is linked to evidence-based treatment algorithms, which we updated using a structured protocol: reviewing available guidelines, Cochrane reviews and randomised trials. A pragmatic cluster randomised controlled trial evaluation of the clinical effectiveness and cost-effectiveness of this system of care was undertaken in 29 community-based UK stroke care co-ordinator services (project 2). In total, 15 services provided the system of care and 14 continued with usual practice. The primary objective was to determine whether the intervention improved patient psychological outcomes (General Health Questionnaire-12) at 6 months; secondary objectives included functional outcomes for patients, outcomes for carers and cost-effectiveness, as measured through

self-completed postal questionnaires at 6 and 12 months. A total of 800 patients and 208 carers were recruited; numbers of participants and their baseline characteristics were well balanced between intervention and control services. There was no evidence of statistically significant differences in primary or secondary end points or adverse events between the two groups, nor evidence of cost-effectiveness. Intervention compliance was high, indicating that this is an appropriate approach to implement evidence into clinical practice. A 22-item Longer-term Unmet Needs after Stroke (LUNS) questionnaire was developed and robustly tested (project 3). A pack including the LUNS questionnaire and outcome assessments of mood and social activity was posted to participants 3 or 6 months after stroke to assess acceptability and validity. The LUNS questionnaire was re-sent 1 week after return of the first pack to assess test–retest reliability. In total, 850 patients were recruited and the acceptability, validity and test–retest reliability of the LUNS questionnaire as a screening tool for post-stroke unmet need were confirmed. This tool is now available for clinical use. An in-depth qualitative investigation was undertaken with 22 patients (and carers) at least 1 year after stroke (project 4) to gain further insights into the experience of adjustment. This included initial semistructured interviews, limited observations and solicited diaries with a follow-up interview 3–4 months after the initial interview and highlighted a range of different trajectories for post-stroke recovery.

Conclusions: The programme has been completed as planned, including one of the largest ever stroke rehabilitation trials. This work highlights that successfully addressing the needs of a heterogeneous post-stroke population remains problematic. Future work could explore stratifying patients and targeting services towards patients (and carers) with specific needs, leading to a more specialised bespoke service. The newly developed LUNS questionnaire and the qualitative work will help inform such services.

Trial registration: Current Controlled Trials ISRCTN67932305.

Funding: The National Institute for Health Research (NIHR) Programme Grants for Applied Research programme. The Bradford Teaching Hospitals NHS Foundation Trust received additional funding for project 2 in the submitted work from the Stroke Association, reference number TSA 2006/15. The initial development work for the LUNS tool and the Longer-Term Stroke care (LoTS care) trial carried out before the start of the programme grant was funded by the Stroke Association, reference number TSADRC 2006/01.

Contents

List of tables	xiii
List of figures	xvii
Glossary	xix
List of abbreviations	xxv
Plain English summary	xxvii
Scientific summary	xxix
Chapter 1 Introduction	1
Development of the system of care	2
<i>Creation of problem-specific reference guides</i>	2
<i>Manual presentation</i>	2
<i>Clinical implementation</i>	3
<i>Pilot work: feasibility of the system for longer-term stroke care</i>	3
<i>Objectives</i>	3
Assessment of unmet needs after stroke	4
<i>Objectives</i>	4
'Failure to thrive' patients	4
<i>Objectives</i>	5
Programme management	5
<i>Clinical engagement</i>	5
<i>Patient and public involvement</i>	5
<i>Collaborations</i>	6
Chapter 2 Project 1: update of the system of care documentation	7
Abstract	7
<i>Background</i>	7
<i>Methods</i>	7
<i>Results</i>	7
<i>Conclusion</i>	7
Introduction	7
<i>The care plan</i>	8
<i>The manual</i>	8
Methods	8
<i>Updating the manual</i>	8
<i>The Cochrane review of information provision for stroke patients and carers</i>	11
Results	12
<i>Updating the manual</i>	12
<i>Review of the evidence</i>	14
<i>The Cochrane review of information provision for stroke patients and their carers</i>	14
Discussion	15

Chapter 3 Project 2: cluster randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of a system of longer-term stroke care	17
Abstract	17
<i>Trial design</i>	17
<i>Methods</i>	17
<i>Results</i>	17
<i>Conclusions</i>	17
<i>Trial registration</i>	17
Introduction	17
<i>Background</i>	17
<i>Objectives</i>	18
Methods	18
<i>Trial design</i>	18
<i>Eligibility</i>	19
<i>Randomisation</i>	20
<i>Blinding</i>	20
<i>Interventions</i>	20
<i>Assessments</i>	22
<i>Outcomes</i>	23
<i>Sample size</i>	23
<i>Statistical methods</i>	24
<i>Economic evaluation</i>	25
Results	29
<i>Participant flow</i>	29
<i>Recruitment</i>	31
<i>Baseline data</i>	34
<i>Numbers analysed</i>	41
<i>Outcomes and estimation</i>	41
<i>Ancillary analyses</i>	46
<i>Adverse events</i>	48
<i>Withdrawals</i>	51
<i>Process data: implementation of control and intervention services</i>	52
<i>Economic evaluation</i>	60
Discussion	71
<i>Key findings</i>	71
<i>Strengths and limitations of the study</i>	71
<i>Generalisability</i>	73
<i>Context</i>	75
Chapter 4 Project 3: Longer-term Unmet Needs after Stroke study	77
Abstract	77
<i>Aim</i>	77
<i>Methods</i>	77
<i>Results</i>	77
<i>Conclusions</i>	77
Introduction	77
<i>Background</i>	77
<i>Development of the Longer-term Unmet Needs after Stroke questionnaire</i>	78
<i>Objectives</i>	79

Methods	80
<i>Study design</i>	80
<i>Participants</i>	80
<i>Data collection</i>	81
<i>Sample size</i>	81
<i>Statistical methods</i>	82
<i>Qualitative evaluation of unmet needs</i>	82
Results	83
<i>Participant flow</i>	83
<i>Recruitment</i>	84
<i>Baseline data</i>	84
<i>Numbers analysed</i>	85
<i>Response to questionnaire packs</i>	86
<i>Primary analysis: evaluation of acceptability, validity and test-retest reliability</i>	88
<i>Ancillary analyses: evaluation of internal consistency and dimensionality</i>	91
<i>Qualitative evaluation of unmet needs</i>	92
Discussion	93
<i>Interpretation</i>	93
<i>Generalisability and limitations</i>	94
<i>Recommendations for research and implications for health care</i>	95
Chapter 5 Project 4: adjustment after stroke study	97
Abstract	97
<i>Aim</i>	97
<i>Study design</i>	97
<i>Methods</i>	97
<i>Results</i>	97
<i>Conclusions</i>	97
Introduction	97
<i>Background</i>	98
<i>Aims and objectives</i>	99
Methods	99
<i>Study design</i>	99
<i>Eligibility criteria</i>	100
<i>Sampling strategy</i>	100
<i>Data collection methods</i>	100
<i>Data analysis</i>	102
Results	103
<i>Recruitment</i>	103
<i>Recovery trajectories</i>	103
<i>Processes and mechanisms shaping recovery trajectories</i>	118
<i>What is a good (social) recovery post stroke?</i>	119
<i>Critical reflection on the eligibility criteria and sampling strategy (developing a better definition of poor adjustment post stroke)</i>	120
Discussion	120
<i>Summary and discussion of key findings</i>	120
<i>Strengths and weaknesses</i>	121
<i>Implications for health and social care</i>	121
<i>Recommendations for future research</i>	122

Chapter 6 Conclusions/recommendations	123
Recommendations for research	126
<i>Research methodology</i>	127
Implications for health care	127
Implications for commissioners	128
<i>Service provision</i>	128
<i>Training and education</i>	128
Acknowledgements	129
References	133
Appendix 1 Development of the system of care	143
Appendix 2 Programme management structure	147
Appendix 3 Project 1: sample (contact 1) of the care plan	149
Appendix 4 Project 1: example search strategies (pain)	157
Appendix 5 Project 1: example reference guide (pain)	165
Appendix 6 Project 2: evidence submitted to the Academy of Medical Sciences for the review on research governance	169
Appendix 7 Project 2: unit costs	177
Appendix 8 Project 2: additional results	187
Appendix 9 Project 2: implementation of control and intervention services	203
Appendix 10 Project 2: resource use	209
Appendix 11 Project 3: The Longer-term Unmet Needs after Stroke questionnaire	217
Appendix 12 Project 4: categories of social activity	219
Appendix 13 Dissemination activities	223

List of tables

TABLE 1 Summary of the search methods used for each reference guide	12
TABLE 2 Search results for each reference guide	13
TABLE 3 Summary of unit costs	27
TABLE 4 Characteristics of randomised services (clusters)	33
TABLE 5 Screening data: flow from screening to registration	33
TABLE 6 Screening data: gender, ethnicity, age and modified Rankin Scale score	34
TABLE 7 Screening data: modified Rankin Scale score – registered patients	34
TABLE 8 Patient baseline: language and living arrangements	35
TABLE 9 Patient baseline: education and employment	36
TABLE 10 Patient baseline: characteristics of current stroke and length of inpatient stay	37
TABLE 11 Patient baseline: current ability	38
TABLE 12 Carer baseline demographics and language ability	39
TABLE 13 Carer baseline: relationship with patient and place of residence	40
TABLE 14 Carer baseline: education and employment	40
TABLE 15 Patient baseline questionnaires: researcher completed	41
TABLE 16 Patient and carer populations	41
TABLE 17 Patient unadjusted questionnaire scores at different time points by arm	42
TABLE 18 Patient adjusted questionnaire scores at 6 and 12 months	42
TABLE 19 Longer-term Unmet Needs after Stroke questionnaire: number of unmet needs for patients at 6 months	43
TABLE 20 Longer-term Unmet Needs after Stroke questionnaire: number of unmet needs for patients at 12 months	44
TABLE 21 Carer unadjusted questionnaire scores at different time points by arm	46
TABLE 22 Carer adjusted questionnaire scores at 6 and 12 months	46
TABLE 23 Patient adjusted questionnaire scores at 6 and 12 months: per-protocol population	47

TABLE 24 Carer adjusted questionnaire scores at 6 and 12 months: per-protocol population	47
TABLE 25 Sensitivity analyses for the primary end point: patient adjusted GHQ-12 scores at 6 months	48
TABLE 26 Total patient deaths and place of death	49
TABLE 27 Six-month researcher-completed follow-up summary	50
TABLE 28 Twelve-month researcher-completed follow-up summary	51
TABLE 29 Patient withdrawals and types of withdrawal	52
TABLE 30 Carer withdrawals	52
TABLE 31 Completion of time logs	53
TABLE 32 Completion of care plans	54
TABLE 33 Compliance with completion of care plans	55
TABLE 34 Number of patient contacts	56
TABLE 35 Care plans: summary of problems and goals/actions	57
TABLE 36 Care plans: problem areas identified in the assessment	58
TABLE 37 Care plans: problem areas addressed in the goal and action planner	59
TABLE 38 Care plans: types of goals/actions	59
TABLE 39 Return/completion rates for the CSRI and EQ-5D	61
TABLE 40 Baseline characteristics of the full sample and subsamples included in the 6-month analyses	61
TABLE 41 Resource use at baseline (for previous 3 months)	62
TABLE 42 Resource use at 6 months (for previous 6 months)	63
TABLE 43 Resource use at 12 months (for previous 6 months)	64
TABLE 44 Costs of SCC inputs (£, 2010/11 prices)	66
TABLE 45 Mean costs by resource category at baseline (for the previous 3 months), 6 months (for the previous 6 months) and 12 months (for the previous 6 months) (£, 2010/11 prices)	67
TABLE 46 Mean total costs at baseline (for the previous 3 months), 6 months (for the previous 6 months), 12 months (for the previous 6 months) and over 1 year (£, 2010/11 prices)	68

TABLE 47 Patient utility scores and QALYs	68
TABLE 48 Sensitivity analyses	69
TABLE 49 Self-reported comorbidities at baseline for those recruited	84
TABLE 50 Baseline characteristics for all recruited patients	85
TABLE 51 Baseline characteristics of the no-impairment and impairment groups	86
TABLE 52 Manikin responses	88
TABLE 53 Acceptability: missing data	88
TABLE 54 Test–retest reliability	89
TABLE 55 Comparison of unmet need with concurrent measures: concurrent measures for which the group identifying an unmet need had significantly poorer health ($p < 0.05$) than the group with no unmet need	90
TABLE 56 Test–retest analysis in the no-impairment group	91
TABLE 57 Test–retest analysis in the impairment group	91
TABLE 58 Comparison with concurrent measures	91
TABLE 59 Definitions of the categories	99
TABLE 60 Numbers of stroke survivors and carers participating in each phase of data collection	103
TABLE 61 Summary of the characteristics of participating stroke survivors	104
TABLE 62 Summary of the formal and informal support received by participating stroke survivors (self-reported at second interview)	106
TABLE 63 Longer-Term Stroke care trial: summary of timelines to first patient recruited	170
TABLE 64a Longer-Term Stroke care trial: timelines for set-up and R&D approval (phase 1)	171
TABLE 64b Longer-Term Stroke care trial: timelines for set-up and R&D approval (phase 2)	173
TABLE 65 Pre-recruitment screening data summaries by treatment arm (age, gender and ethnicity)	187
TABLE 66 Pre-recruitment screening data summaries by treatment arm (modified Rankin Scale)	187
TABLE 67 Screening data: reasons not assessed	188

TABLE 68 Screening data: reasons not eligible	189
TABLE 69 Screening data: reasons not consented	191
TABLE 70 Screening data: reasons not registered	193
TABLE 71 Patients with carers: baseline demographics	194
TABLE 72 Patients with carers: baseline education and employment	195
TABLE 73 Patients with carers: baseline characteristics of current stroke	196
TABLE 74 Patients with carers: baseline patient current ability	197
TABLE 75 Patients with carers: baseline length of inpatient stay	198
TABLE 76 Patient follow-up at 6 months	198
TABLE 77 Patient follow-up at 12 months	199
TABLE 78 Carer follow-up at 6 months	199
TABLE 79 Carer follow-up at 12 months	200
TABLE 80 Intervention: number of patient contacts with the SCC per service within 12 months of registration	204
TABLE 81 Resource use at baseline (in the previous 3 months)	209
TABLE 82 Resource use at 6 months (in the previous 6 months)	211
TABLE 83 Resource use at 12 months (in the previous 6 months)	213
TABLE 84 Definitions of the categories	220
TABLE 85 Numbers of stroke survivors by category and recovery trajectory	220

List of figures

FIGURE 1 Protocol for identifying evidence-based interventions for stroke problem areas	9
FIGURE 2 Written search strategy used in stage 4	10
FIGURE 3 CONSORT flow diagram	30
FIGURE 4 Accrual into the trial	32
FIGURE 5 Prevalence of individual unmet needs	45
FIGURE 6 Time between registration and patient death	49
FIGURE 7 Adjusted differences of each service from adjusted control mean in GHQ-12 scores ordered by service completion of time logs: control	55
FIGURE 8 Adjusted differences of each service from adjusted intervention mean in GHQ-12 scores ordered by service compliance with care plans: intervention	56
FIGURE 9 Cost-effectiveness plane of incremental total health and social care costs and point changes on the GHQ-12 at 6 months	69
FIGURE 10 Cost-effectiveness plane of incremental total health and social care costs and QALYs at 6 months	70
FIGURE 11 Probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional point improvement on the GHQ-12	70
FIGURE 12 Probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional QALY	70
FIGURE 13 Tool development summary	78
FIGURE 14 Study flow chart	83
FIGURE 15 Total number of unmet needs reported by individuals	87
FIGURE 16 Types of unmet need in the impairment and no-impairment groups	87
FIGURE 17 The LUNS Rasch targeting plot, displaying the relative distributions of person and item logit locations on the underlying 'unmet need' continuum	92
FIGURE 18 Data collection procedure for adjustment after stroke study	100
FIGURE 19 Time between registration and receiving questionnaires: patients	200
FIGURE 20 Time between registration and receiving questionnaires: carers	201

FIGURE 21 Time between registration and patient withdrawal	201
FIGURE 22 Time between registration and carer withdrawal	202
FIGURE 23 Problem areas addressed in the goal and action planner at contact one in two example services compared with all patients	203
FIGURE 24 Reduction in Barthel Index and FAI scores from pre stroke to 12 months post stroke	219
FIGURE 25 Reduction in FAI and Barthel Index scores from pre stroke to 12 months post stroke for participating stroke survivors in the different recovery trajectories	221

Glossary

Activities of daily living Tasks that are carried out on a daily basis, such as dressing, eating, toileting and walking.

Analysis of variance (ANOVA) fit statistics (within Rasch analysis) A fit statistic used at the individual item level. The person sample is partitioned into a number of discrete ability groups and fit residual values are calculated for these discrete groups. The ANOVA fit statistics assess whether there is a difference in fit residuals between these discrete ability groups.

Aphasia Difficulty using or understanding spoken or written language. Mild forms of aphasia can be referred to as dysphasia.

Barthel Index An index measuring independent function in activities of daily living. The total score ranges from 0 to 20, with lower scores indicating increased disability.

Caregiver Burden Scale A 22-item scale measuring subjective carer burden. The overall score ranges from 22 to 88, with higher scores indicating a greater carer burden.

Carer A relative or friend who provides regular care to another person. Carers were eligible for the Longer-Term Stroke care trial if they were the main person providing practical support to the patient a minimum of once per week.

Cerebral infarction A stroke caused by deprivation of the blood supply to the brain, for example because of a clot, leading to death of part of the brain.

Chi-squared fit statistics Fit statistics based on whether the observed frequency distribution differs from the theoretical distribution of a particular model.

Client Service Receipt Inventory A measure of use of health, social care and informal resources. The Longer-Term Stroke care trial used an adapted version of this measure.

Clinically important difference A clinically important difference represents a change (e.g. the smallest change in outcome score) that would be considered meaningful and worthwhile by a patient or health care professional.

Cluster randomised controlled trial A type of randomised controlled trial in which clusters of individuals (such as services or geographical areas), as opposed to individual subjects, are randomly assigned to either the treatment or the control group.

Community based An activity that is organised and takes place locally, for example care and support provided to stroke survivors by their local stroke service in their own home or local community.

Confidence interval A confidence interval gives an estimated range of values that are likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment; a narrow confidence interval indicates a more precise estimate.

Confirmatory factor analysis A statistical analysis that confirms whether a set of items fall within a predefined number of factors/dimensions.

Consolidated Standards of Reporting Trials (CONSORT) The CONSORT statement is an evidence-based minimum set of recommendations for reporting randomised controlled trials.

Content validity The extent to which a measure represents all aspects of a given concept (such as the concept of unmet need).

Cost-effectiveness acceptability curve A method used to represent the uncertainty of cost-effectiveness results. A cost-effectiveness acceptability curve presents the probability that one treatment is more cost-effective than another treatment.

Cronbach's alpha A value used to rate the internal consistency or correlation of items in a test. A correlation coefficient is given between 0 and 1, with higher values representing higher levels of internal consistency.

Differential item functioning A form of item bias in which item difficulty changes depending on which group is responding. For example, men and women with the same level of anxiety may consistently respond differently to an item in an anxiety questionnaire.

Dimensionality The number of dimensions (also known as factors, components or constructs) that are being measured by a scale or set of items.

Dysarthria A motor speech disorder. Patients suffering from dysarthria have problems in controlling the muscles used for speaking.

Dysphasia Difficulty using or understanding spoken or written language. A mild form of aphasia.

Early supported discharge A service model that aims to bring forward hospital discharge and provide a more continuous rehabilitation process by transferring stroke patients from an inpatient setting to continue rehabilitation in primary care.

Edinburgh stroke case mix adjuster Predictive model that can be used to predict stroke outcomes using six factors (age, pre-stroke independence, pre-stroke living circumstances, verbal subsection of the Glasgow Coma Scale, ability to lift both arms off the bed, independent walking). The model used in the Longer-Term Stroke care trial predicts the probability of dependency-free survival at 6 months.

European Quality of Life-5 Dimensions health state measure A five-item scale to identify health state. The total score varies from -0.59 for worst health to 1.0 for perfect health, with a score of 0 representing the state of being dead.

Exploratory factor analysis A statistical analysis that explores how many factors/dimensions a set of items partition into.

Fit indices Indicators of the extent to which observed data agree with a particular statistical model. These can be reported at an overall scale level or on an individual item basis.

Fit residuals A fit statistic relating to the discrepancies between model-predicted expected data values and what is actually observed. The reported values are z-standardised.

Frenchay Activities Index A 15-item measure of activities of daily living for use with stroke survivors. The overall score ranges from 0 to 45, with lower scores indicating lower activity levels.

Frenchay Aphasia Screening Test A screening tool for identifying communication or language impairment. The test assesses comprehension and reading and uses written and pictorial stimuli.

General Health Questionnaire-12 A 12-item measure of emotional and mental health and well-being. The overall score ranges from 0 to 36, with higher scores indicating greater psychological distress.

Hemiparesis Weakness of one side of the body that may be caused by stroke and can be accompanied by sensory or other neurological deficits.

Intention-to-treat analysis An analysis conducted on participants based on the group that they were initially (and randomly) allocated to regardless of whether they dropped out, fully complied with the treatment or switched to an alternative treatment. Intention-to-treat analyses are used to assess clinical effectiveness because they mirror actual practice.

Internal consistency A type of reliability that reflects the extent to which items of a test measure aspects of the same characteristic (and nothing else) (see *Cronbach's alpha*).

Intracluster correlation coefficient The intracluster correlation coefficient is a measure of the relatedness of data within a cluster. It accounts for the relatedness of clustered data by comparing the variance within clusters with the variance between clusters. Values of the intracluster correlation coefficient range from 0 to 1.

Kappa A measure of (non-random) agreement between multiple measurements of the same variable.

Length of stay Duration of admission in hospital.

Longer-term Unmet Needs after Stroke A 22-item tool developed to assess unmet needs, in which a 'yes' response indicates unmet need.

Modified Rankin Scale A single-item measure of functional independence. The total score ranges from 0 (perfect health) to 6 (death).

Multidisciplinary team A team of professionals, including those from different disciplines such as nursing or physiotherapy, who work together to co-ordinate and provide patient care.

National Stroke Audit A report outlining where progress in stroke care has been made and providing recommendations for improving stroke outcomes and reducing costs. Produced by the National Audit Office.

National Stroke Strategy A report providing a national strategy for stroke services with the intention of making improvements in stroke care, providing guidance to commissioners and informing the expectations of patients and families. Produced by the Department of Health.

Per-protocol analysis Analysis that includes only participants who complete the trial according to the protocol are included in the final results (see *Intention-to-treat analysis*).

Person separation index Similar to the Cronbach's alpha statistic, this is a measure of reliability/internal consistency. However, the person separation index is also influenced by scale targeting. Again, the person separation index is given a value between 0 and 1, with higher values representing higher levels of internal consistency.

Primary intracerebral haemorrhage A stroke caused by the rupture of a blood vessel within the brain, usually an artery.

Primary objective The most important aim of a study, evaluated using primary outcomes or end points.

Psychometric properties How well a scale/test/set of items measures the construct of interest. These broadly consist of the reliability of the scale (how consistently the scale measures) and the validity of the scale (whether the scale is measuring what it is supposed to measure).

Quality-adjusted life-year A measure of disease burden, including quality and quantity of life lived, used in assessing the value for money of clinical interventions.

Rasch analysis A statistical method that allows evaluation of a scale measuring a particular latent attribute. Observed data are fitted within a Rasch unidimensional measurement model framework to assess the measurement characteristics of the scale.

Response dependency Response to one item (question) has a direct impact on the response to another item, over and above what is explained by the underlying trait.

Root-mean-square error of approximation A goodness-of-fit index used within confirmatory factor analysis and structural equation modelling. Values of <0.08 are widely regarded as acceptable and values of <0.05 are classed as good.

Secondary objectives Aims that are secondary to the primary objective, evaluated using secondary outcomes or end points.

Short Form questionnaire-12 items A 12-item tool measuring health-related quality of life. The total score ranges from 0 to 100, with a score of <50 indicating health worse than the norm and a score of >50 indicating health better than the norm.

Six-item Cognitive Impairment Test A screening tool for identifying cognitive impairment. The overall score ranges from 0 to 28, with a score of ≤ 7 indicating normal cognitive function and a score of >7 indicating cognitive impairment, with higher scores indicating greater cognitive impairment.

Standard deviation A measure that shows how much variation exists from the average (mean) or expected value.

Stroke Association A UK charity that campaigns for better care of people affected by stroke. Includes research and support services.

Stroke care co-ordinator Registered health professional with experience in stroke care, working in a community-based co-ordinating role for stroke patients.

Stroke Research Network Part of the National Institute for Health Research, the Stroke Research Network supports both quality and delivery of stroke research.

Stroke unit A specialised hospital unit with a dedicated stroke team and stroke resources (e.g. care pathway, educational material, monitored beds).

System of care A structured assessment linked to evidence-based treatment algorithms and reference guides contained in a manual.

Targeting A comparison of the distribution of item difficulty level within a scale relative to the distribution of person abilities within a particular sample.

Test-retest reliability The extent to which a scale or measure that is repeated in the same stable population yields the same result.

Transient ischaemic attack A stroke-like event that fully recovers within 24 hours of the start of symptoms.

List of abbreviations

6CIT	six-item Cognitive Impairment Test	LoTS care	Longer-Term Stroke care trial
A&E	accident and emergency	LUNS	Longer-term Unmet Needs after Stroke
ANOVA	analysis of variance		
AUECR	Academic Unit of Elderly Care and Rehabilitation	MCS	mental component score (of the SF-12)
CBS	Caregiver Burden Scale	MDT	multidisciplinary team
CEAC	cost-effectiveness acceptability curve	NEADL	Nottingham Extended Activities of Daily Living
CI	confidence interval	NICE	National Institute for Health and Care Excellence
CINAHL	Cumulative Index to Nursing and Allied Health Literature	NIHR	National Institute for Health Research
CONSORT	Consolidated Standards of Reporting Trials	NSA	<i>National Stroke Audit</i>
CRAG	Consumer Research Advisory Group	NSS	<i>National Stroke Strategy</i>
CSRI	Client Service Receipt Inventory	PCS	physical component score (of the SF-12)
CTRU	Clinical Trials Research Unit	PSI	person separation index
DIF	differential item functioning	QALY	quality-adjusted life-year
EQ-5D	European Quality of Life-5 Dimensions	R&D	research and development
FAI	Frenchay Activities Index	RCP	Royal College of Physicians
FAST	Frenchay Aphasia Screening Test	RCT	randomised controlled trial
GHQ-12	General Health Questionnaire-12	SCC	stroke care co-ordinator
GM-SAT	Greater Manchester Stroke Assessment Tool	SD	standard deviation
GP	general practitioner	SE	standard error
HADS	Hospital Anxiety and Depression Scale	SF-12	Short Form questionnaire-12 items
HRG	Healthcare Resource Group	SHA	Strategic Health Authority
ICC	intracluster correlation coefficient	SMG	study management group
ICER	incremental cost-effectiveness ratio	SRN	Stroke Research Network
ITT	intention to treat	TOTAL	Trial of Occupational Therapy and Leisure
		TRACS	Training Caregivers After Stroke
		YSRN	Yorkshire Stroke Research Network

Plain English summary

There have been important steps forward in the treatment of patients soon after a stroke. However, longer-term recovery can be challenging. Our research focused on the needs of patients and their carers after hospital discharge and in the longer term. We previously developed a system for longer-term stroke care that includes structured assessment questions. These are based on problems that are of importance to patients and their carers, linked to information about treatment options and action plans.

Our research included four interlinked projects:

1. Based on a comprehensive review of the evidence we provided clear treatment guidance for health professionals based around individual patient and carer problems.
2. We evaluated our new system for longer-term stroke care in 29 centres in the UK involving community-based health professionals. Stroke patients in half of these centres received the new system of care. Patients in the other centres received care as currently delivered. We found no differences between the two groups in a range of outcomes assessed for 800 stroke survivors and 208 carers 6 months after joining the study.
3. We demonstrated the robustness of a monitoring tool to identify unmet needs after stroke by testing it with 850 stroke survivors.
4. Through in-depth interviews we explored how stroke survivors and their carers adjust and adapt to the consequences of stroke.

We have developed systems of care and assessment tools and gained insights into patients' needs and experiences. All will inform improved care strategies after stroke.

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.

Funding

The National Institute for Health Research (NIHR) Programme Grants for Applied Research programme. The Bradford Teaching Hospitals NHS Foundation Trust received additional funding for project 2 in the submitted work from the Stroke Association, reference number TSA 2006/15. The initial development work for the LUNS tool and the Longer-Term Stroke care (LoTS care) trial carried out before the start of the programme grant was funded by the Stroke Association, reference number TSADRC 2006/01.

Chapter 1 Introduction

There are over 900,000 people in England who have had a stroke, of whom 300,000 live with moderate to severe disability.¹ As such, stroke generates considerable health and social care costs. Costs are estimated at £7B a year, which includes £2.8B in direct costs to the NHS, £2.4B in informal care costs and £1.8B in income lost to productivity and disability.¹ Unplanned general practitioner (GP) visits and hospital readmissions generate an economic burden to the NHS and cause stress and discomfort to the patient. Previously viewed in a nihilistic way, stroke care is now characterised by a more dynamic and positive approach supported by the development of stroke medicine as a clinical specialty, rigorous reviews of services and production of evidence-based guidelines.² Although successful preventative measures (e.g. carotid endarterectomy) and drug interventions (e.g. thrombolysis) have been identified, they are appropriate for only a minority of stroke patients, and rehabilitation remains the cornerstone of treatment for many.

The recommended stroke care pathway in the first weeks after stroke is becoming established. Well-described service components include neurovascular clinics, stroke units and early supported discharge schemes. Despite these service developments, approximately one-third of stroke survivors are left with some physical impairment,^{3,4} one-third of stroke survivors are depressed,⁵ inactivity is common, participation levels are low⁶ and health-related quality of life deteriorates post stroke.⁷

Community-based observational studies over three decades have left little doubt about the daily struggle for stroke survivors and their families as they come to terms with the longer-term consequences of a stroke illness.⁸⁻¹⁰ Many stroke survivors require assistance from informal carers, often family members, for activities of daily living, including bathing, dressing and toileting.^{11,12} This burden of care has an important effect on carers' physical and psychosocial well-being,^{13,14} with up to 48% of carers reporting health problems, two-thirds reporting a decline in their social life and high self-reported levels of strain.¹⁴

In recognition of the pressing need for a 'comprehensive revolution' in stroke care the *National Stroke Strategy* (NSS) was produced in 2007.¹⁵ This included an emphasis on longer-term stroke care.

Despite this recognition of the importance of longer-term stroke care, surveys undertaken demonstrate that current service responses are not appropriately developed as stroke survivors have a range of unmet needs 1–5 years after stroke. In one study including 1251 participants,⁴ half reported some unmet needs. These related to information provision (54%) mobility problems (25%), falls (21%), incontinence (21%), pain (15%) and fatigue (43%).

The *National Service Framework for Older People*¹⁶ and the NSS¹⁵ emphasised the need for post-discharge support, in particular the need for 'good-quality, appropriate, tailored and flexible rehabilitation' (p. 35).¹⁶ Previous service models for post-stroke care have been associated with equivocal,¹⁷⁻²¹ and sometimes adverse, outcomes.²⁰ There was a requirement therefore for innovative models of care to be developed, more closely tailored to the expressed needs of patients and their carers, and embedded in local stroke services.^{8,22} A primary care orientation to assess, support and co-ordinate services might be more helpful in minimising longer-term stroke morbidity.

To address this we developed (through previously funded work; see *Appendix 1*) a systematic approach (termed a system of care) to longer-term stroke care based on the expressed needs of patients and carers²³⁻²⁵ and a monitoring tool to identify longer-term unmet needs after stroke. The twofold aim of the current 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.

Development of the system of care

Previously no systematic approach has been developed for routine monitoring, problem identification and co-ordination of services to assist stroke patients and their families as they continue to recover from their stroke and make life adjustments to its consequences. The system of care is based on a systematic review and synthesis of the available qualitative literature reporting interviews with stroke patients and carers in which longer-term stroke-related issues were discussed. Approximately 500 patients and 180 carers had participated in the 23 studies included in the review.²⁵ The review identified 203 patient- and carer-centred problems, which were clustered into five domains (hospital experience, transfer of care, communication and information, service provision and social and emotional difficulties) encompassing 12 main problem areas. A complementary review of 27 quantitative stroke surveys including 6000 patients and 3000 carers assessed the prevalence of these problem areas.²⁴ A further two prevalent problem areas (falls and sexual problems) were identified. To confirm content validity, our emerging findings were checked and refined by stroke patients and carers in individual interviews and in focus groups, leading to the addition of two more problem areas.²⁶ This approach has ensured that the proposed new service model is targeted at the most common stroke-related problems of central importance to stroke patients and their carers. The final 16 problem areas were 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.

Validated assessment tools (e.g. *The Camberwell Assessment of Need for the Elderly*²⁷ and EASY-Care²⁸) were appraised to map relevant questions to the identified problem areas. A number of questions required modification to ensure that they accurately reflected the stroke-specific problem areas identified in the reviews. Additionally, some problem areas were not represented by the assessment tools and thus assessment questions were developed by the research team. From this process, patient and carer action plans were devised consisting of 15 questions (patient) and 12 questions (carer) representing the problem areas identified and an additional question to capture 'other' stroke-related problems.

Creation of problem-specific reference guides

Having identified the key problem areas and operationalised them through appropriate assessment questions, a range of literature, both within and beyond stroke, was reviewed to identify effective evidenced-based service interventions. The 16 problem-specific reference guides (relating to the 15 patient questions plus one carer-specific question) contain educational text with supporting assessment/treatment algorithms and checklists. The algorithms guide problem-solving as many apparently straightforward problems become multilayered on closer examination. For example, the activity of shopping might be impeded by physical barriers (mobility, lack of suitable transport), cognitive problems (poor comprehension, short-term memory loss) or psychological problems (fear, embarrassment). The final stage in this development phase was to obtain feedback from a range of local community and primary care professionals. This involved presenting and discussing the model during two workshops. Feedback from the workshops enabled us to frame our model into a product that was considered acceptable to primary care professionals. The resulting system of care is presented in a manual.

Manual presentation

Evidence on the implementation of clinical guidelines suggests that presentation can influence uptake into practice. The National Institute for Health and Care Excellence (NICE)²⁹ details five key principles – language and style, bulleted lists, tables and figures, abbreviations and algorithms – and these were used to structure the components of the system of care. The aim of these principles is to make the information clear, accessible to non-specialists, unambiguous, succinct and guiding, but not prescriptive.

The resulting manual comprises patient- and carer-structured assessments representing the identified problem areas linked to, a reference guide and treatment algorithm; patient and carer goal and action plans; a directory of service information; and a selection of validated assessment scales for specific areas such as depression³⁰ and cognitive impairment,³¹ included as appendices. Thus, we have created a manualised system for longer-term stroke care that is comprehensive (encompasses all areas of potential concern to patient and carer) but individualised (patient-specific action plans constructed).

Clinical implementation

The next stage in the development of the system for longer-term stroke care was to identify means of clinical implementation. Our previous work has identified a need for a service embedded in the community, where staff would have a greater awareness of locally available services.²² Other work has identified that nurse-delivered interventions have been effective.³² A survey of local district nurses demonstrated that nurses had relevant insights and skills but would appreciate additional training.³³

The *National Service Framework for Older People*¹⁶ identified a new role of 'stroke care co-ordinator' (SCC) to provide advice, arrange reassessment when necessary and co-ordinate long-term support. But who should be involved and how this role might be fulfilled are ill-defined. Through national presentations of our work, through links with the Stroke Association and through the National Stroke Nursing Forum, we were aware that a number of centres were developing SCC roles. To explore this further we undertook a national survey of all UK stroke services. For the purposes of this survey, a SCC was defined as 'a qualified health professional in regular contact with stroke patients in the community, co-ordinating care inputs on their behalf'.

Pilot work: feasibility of the system for longer-term stroke care

Pilot work was conducted to investigate the practical implementation and feasibility of the proposed system of care.²³ A training programme was provided to community-based staff recruited to use the system of care in clinical practice. In total, 47 stroke patients and 21 carers were assessed using the new system of care. Analysis of care plans, 3 months after the initial assessment, indicated that the process was successful in picking up patient and carer problems. Of 219 problems, 75% had been resolved 3 months after assessment. Patient and carer participants thought that the review process would be more valuable if conducted sooner after hospital discharge (undertaken 8 months after stroke in the pilot study). We were able to demonstrate that a systematic assessment approach incorporated in a disease-specific manual is feasible to implement and was successful in identifying problems and triggering interventions.

Objectives

Projects 1 and 2 of the programme grant described here continue this work:

- project 1 – an update of the evidence-based treatment algorithms using a structured protocol for searching and assessing the available literature (see *Chapter 2*)
- project 2 – a cluster randomised controlled trial (RCT) of the system of care as delivered by SCCs, evaluating its impact on patients' and carers' psychological and physical outcomes and its cost-effectiveness (see *Chapter 3*).

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. Similar approaches have been developed, for example the Greater Manchester Stroke Assessment Tool (GM-SAT) for 6-month reviews.³⁴ This indicates that our thinking is feasible, practical and appropriate for ongoing service development.

Assessment of unmet needs after stroke

In interlinked work we had undertaken preliminary development of a tool to assess and monitor patient longer-term unmet needs after stroke [the Longer-term Unmet Needs after Stroke (LUNS) tool].

We, and others, have demonstrated that the problems faced by stroke patients and their families in the longer term encompass physical, social and mental well-being.^{4,24,25} There is no currently available measure that provides a 'good fit' across all of these outcome domains in the special context of longer-term stroke care. The common compromise in research, in which greater insights are required, is to use a basket of measures, all addressing different components of the stroke experience, or to create and use one larger outcome tool (e.g. the Stroke Impact Scale³⁵). In clinical practice such approaches are impractical, expensive and time-consuming and there is a need for a short, easy to complete monitoring tool. We developed a comprehensive monitoring tool to measure unmet needs in stroke patients by converting the assessment questions (based on patient- and carer-identified problems) contained in our proposed system of care into statements of need. Preliminary psychometric testing was undertaken. The draft, 28-item version of the measure, was reviewed by experts in the field and refined in collaboration with our Consumer Research Advisory Group (CRAG), which contributed to various aspects of the measure, including layout, presentation and wording of questions. The monitoring tool therefore has face and content validity. We have undertaken preliminary work (through existing funding) to investigate the reliability of the measure. Patients ($n=29$) were assessed with the measure in their home on two occasions, approximately 1 week apart. Statistical analysis demonstrated poor reliability for 12 questions and, in the light of this, further work was undertaken with the CRAG, members of other local stroke groups and stroke physicians. All aspects of the measure, including layout, presentation and wording of questions, were reviewed. The number of items was reduced from 28 to 21 and the questions were grouped according to whether they addressed informational needs or practical needs.

Objectives

Project 3 in this programme continues this work:

- further development and psychometric testing of a measure to assess and monitor patient longer-term met/unmet stroke-related needs (the LUNS questionnaire) (see *Chapter 4*).

Identification of needs after stroke has become increasingly topical during the implementation of this programme grant. The Stroke Association commissioned a survey of post-stroke unmet needs and co-applicants of this grant (Forster and Young) contributed to the development of this survey,⁴ which included some questions from the LUNS tool.

'Failure to thrive' patients

A complementary approach to the described projects is to work with patients and their families to gain a greater understanding of the mechanisms of adjustment to stroke. It is reported in the literature, and often cited anecdotally, that many patients with good physical recovery are paradoxically socially inactive; however there is little information on the prevalence or cause of poor social recovery.

We were fortunate to have a number of data sets available to us from previous community stroke studies,^{18,36,37} on which we undertook some exploratory analysis. By comparing Barthel Index³⁸ scores at various time points with social activity scores [measured by the Frenchay Activities Index (FAI)³⁹] we have been able to identify statistically a small subgroup of patients who do not do as well as we would expect, that is, they are more socially restricted than would be expected for their level of disability. To investigate why there is such a variation in social recovery for patients with good physical recovery, this subgroup was investigated further. Unsurprisingly, previous activity level, age and living in institutional care were all related to poor social activity at 12 months after stroke, even when physical recovery is good. A review of a number of our previous

data sets indicates that approximately 10% of the patients in each of the samples had 'unexplained' poorer outcomes (i.e. more socially restricted than expected for their level of disability but not explained by age or living in institutional care or pre-stroke activity). Although this group of patients is small, it is possible that they have attributes that have impeded their recovery that are present to a lesser extent in the wider stroke population and therefore have been difficult to detect. A specific study of this smaller group may therefore provide insights of relevance to the wider stroke population and thereby inform future service development.

Objectives

Project 4 undertook further exploratory work:

- identify factors contributing to patients' poor adjustment after stroke through a qualitative and quantitative case-control study nested in the randomised trial (see *Chapter 5*) [it was clarified during the review of the grant application that the design is not in fact a nested case-control study but rather a qualitative substudy (with purposive sampling based on the quantitative trial data)].

Programme management

This programme grant has been undertaken and completed by a committed team of co-applicants. The management structure is summarised in *Appendix 2*. During implementation one of the co-applicants (Val Steele) retired and another (Joanna Powell) left clinical practice. The update of the system of care (project 1) and further development of the LUNS tool (first part of project 3) were completed before the system of care trial (project 2), which then ran until the end of the programme grant; the LUNS tool was included in the trial outcome measures. Psychometric evaluation of the LUNS tool (second part of project 3) was carried out in parallel with project 2. Exploration of poor adjustment (project 4) was carried out in parallel with the 12-month follow-up in project 2.

Clinical engagement

Clinical engagement has been sustained throughout the programme through:

- Yorkshire Stroke Research Network (YSRN) therapy meetings – held three times a year and open to all allied health professionals in Yorkshire
- the attendance of the chief investigator at the quarterly Clinical Stroke Network meetings, where research progress is reported as a regular agenda item
- the ongoing contact of the chief investigator, clinical lead for the YSRN, with all local stroke services and robust links with national colleagues.

Patient and public involvement

Terry Brady (co-applicant and stroke survivor) has been involved at all stages of programme development. He is a member of the CRAG, which has met bimonthly throughout the duration of the programme. The CRAG has been provided with regular updates on the progress of the programme and has contributed at all stages.

Terry Brady is also on the organising committee for the annual consumer conference, which is hosted by the YSRN and attracts over 70 stroke survivors and their carers each year. Updates on ongoing research are provided at the conference and this includes progress reports on this programme of research. In addition, advice and guidance were sought on specific components of the research through 'round table' discussions, for example outcome assessment for the cluster trial and layout of the outcome assessment booklet (project 2); considerable input into the development of the LUNS tool, both content and layout (project 3); and contribution to the adjustment after stroke study and consideration of the results (project 4).

Colleagues in the CRAG have become experienced in the review of stroke research. One of our members, Mick Speed, is now a member of the Stroke Association research panel.

Collaborations

Professors Anne Forster and John Young were members of the Stroke Association UK Stroke Survivor Needs Survey study team and this survey included some of the questions from the LUNS questionnaire.

Chapter 2 Project 1: update of the system of care documentation

Abstract

Background

Our purposely developed system of care was framed around patient- and carer-identified problems. To support treatment delivery a manual was created that included algorithms to assist SCCs in clarifying problems and directing patients to treatment options. To ensure that all of the treatment algorithms were up to date and evidence based, they were rigorously reviewed and updated.

Methods

In collaboration with information specialists at the University of Leeds, a hierarchical, comprehensive structured protocol for identifying evidence in each of the 16 problem areas was developed. This protocol included identifying relevant stroke- and problem-specific guidelines; meta-analyses and systematic reviews; and, if necessary, individual RCTs. Two researchers independently reviewed all outputs. Guidelines, reviews and papers identified for inclusion were assessed for quality using standard tools. Drafted treatment algorithms were peer reviewed by external experts.

Results

Over 71,000 articles were identified by the initial searches. Robust guidelines were identified for three problem areas; for one problem area, 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 algorithms were updated in accordance with the identified evidence and, following external peer review, they were incorporated into the system of care manual. Presentation of the manual was informed by expert opinion and feedback from clinical colleagues.

Conclusion

The system of care manual was created using robust methods to ensure that advice and guidance provided were up to date and evidence based.

Introduction

The system of care was formulated around the post-stroke problems identified by patients and their carers. These were translated into a series of assessment questions to elicit the problems and to enable the SCC to work with each patient and his or her carer to develop goals and action plans. Goal setting is considered an essential part of clinical rehabilitation,⁴⁰ and there has been growing emphasis on the need for interventions with patients to be goal orientated. Our intent was that the system of care would more appropriately address patient unmet needs. Documentation involved with the delivery of this system of care included:

- the care plan: assessment questions (formulated around problem areas) and goal and action planner
- the manual: providing information about the problem area (reference guide) linked to an evidence-based treatment algorithm and other supporting material
- national and local service information.

All required refining and updating before the planned trial to evaluate the system of care (see *Chapter 3*).

The care plan

The care plan included questions addressing all problem areas supported by additional prompts. It also included goal and action planners for the patient/carer, which aimed to encourage and support shared decision-making about goals and the prioritisation of goals according to patient (carer) preference and joint problem-solving approaches. The layout and presentation of the assessment questions for patients and their carers were initially reviewed by the study management group (SMG) and clinical colleagues. The care plan was further refined by SCCs taking part in the trial, before the start of the trial (see *Chapter 3, Intervention arm: system of care*).

Part of the care plan is shown in *Appendix 3*.

The manual

The manual associated with our system of care was created in 2003. The manual included introductory text, reference guides with associated detailed treatment algorithms, which are centred around the patient- and carer-identified problems, and general advice on patient assessment. On commencement of the programme grant the manual needed updating to ensure that it remained a relevant and reliable resource.

Methods

Updating the manual

To ensure that all of the treatment algorithms were up to date and evidence based, in collaboration with information specialists at the University of Leeds, a hierarchical, comprehensive, structured protocol for identifying evidence in each problem area was developed (*Figure 1*).

The reference guides linked to treatment algorithms addressed the following 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)
- carer social and emotional needs.

The protocol started (stage 1) with searches to identify all potentially relevant evidence-based stroke guidelines (e.g. the *National Clinical Guidelines for Stroke*^{2,41}). This progressed to the identification of guidelines for problem areas of relevance to stroke but that were not necessarily stroke specific (stage 2) and the identification of systematic reviews and meta-analyses (stage 3). If it was considered that the problem area had not been adequately addressed (e.g. through the availability of national guidelines) then a comprehensive electronic search strategy was developed and implemented to identify all RCTs of effective interventions evaluated for stroke and for other diseases with similar experiences to those of stroke (stage 4).

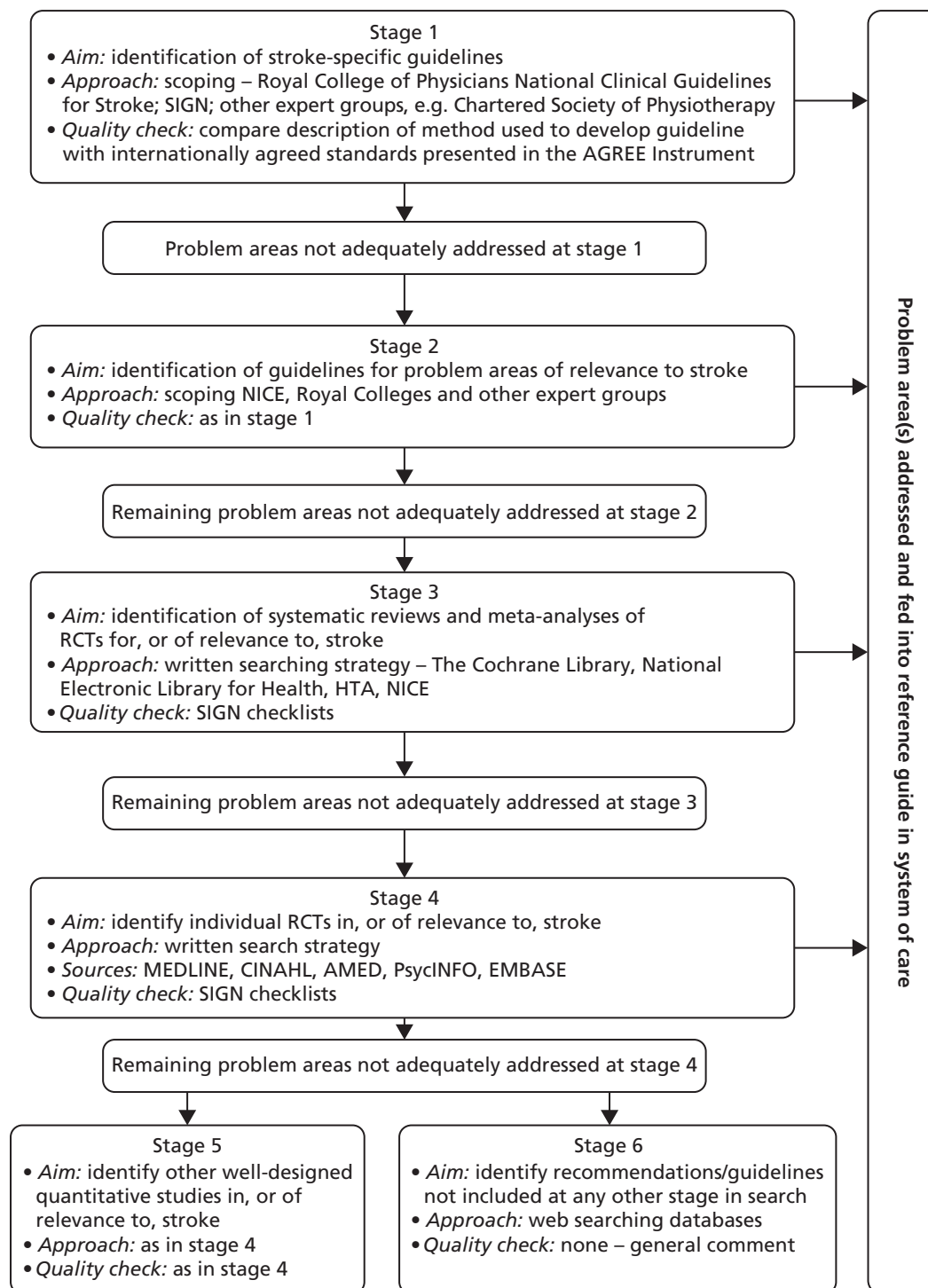


FIGURE 1 Protocol for identifying evidence-based interventions for stroke problem areas. AGREE, Appraisal of Guidelines Research and Evaluation; AMED, Applied and Complementary Medicine Database; CINAHL, Cumulative Index to Nursing and Allied Health Literature; HTA, Health Technology Assessment; SIGN, Scottish Intercollegiate Guidelines Network.

The search strategy was developed iteratively. Each problem area was discussed between the researchers (A Forster, J Murray and R Breen) and the information specialists and consensus agreement was reached about scope (e.g. age limits, key words, databases to be searched). When available, guidance on search terms was taken from existing reviews (e.g. the Cochrane review on the prevention and treatment of urinary incontinence after stroke in adults⁴²). Example search strategies for pain for MEDLINE and EMBASE are provided in *Appendix 4* and other search strategies are available on request from the authors. All searches were restricted to the English language only, with a date restriction from 1995 onwards, and included appropriate methodological filters for guidelines, consensus statements, systematic and other reviews and RCTs. The information specialists then conducted initial searches with the results reviewed by J Murray and A Forster to verify that appropriate titles were being identified. Following further amendments as necessary, the full search was undertaken, with the results downloaded into EndNote (version 5; Thomson Reuters, CA, USA). All searches were undertaken in MEDLINE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Evidence-based Medicine Reviews, PsycINFO and EMBASE. A member of the research team was designated as lead reviewer for each problem area.

The overall purpose was not to develop guidelines but to identify and present the evidence in a format that will aid the clinical application of the structured assessment system, triggering appropriate, evidenced-based interventions. These interventions had to be relevant to SCC practices; therefore, for example, in medicines management the focus was on knowledge rather than the SCC being an active prescriber of drugs. Similarly, when considering the problem area of mobility, interventions that require specialist equipment (such as a treadmill) were not considered as the SCC would refer to a physiotherapist for such specialist treatment.

The outputs from stages 1–3 were initially reviewed by one researcher (J Murray) and presented and discussed at regular SMG meetings (monthly then moving to fortnightly). For stage 4 (*Figure 2*),

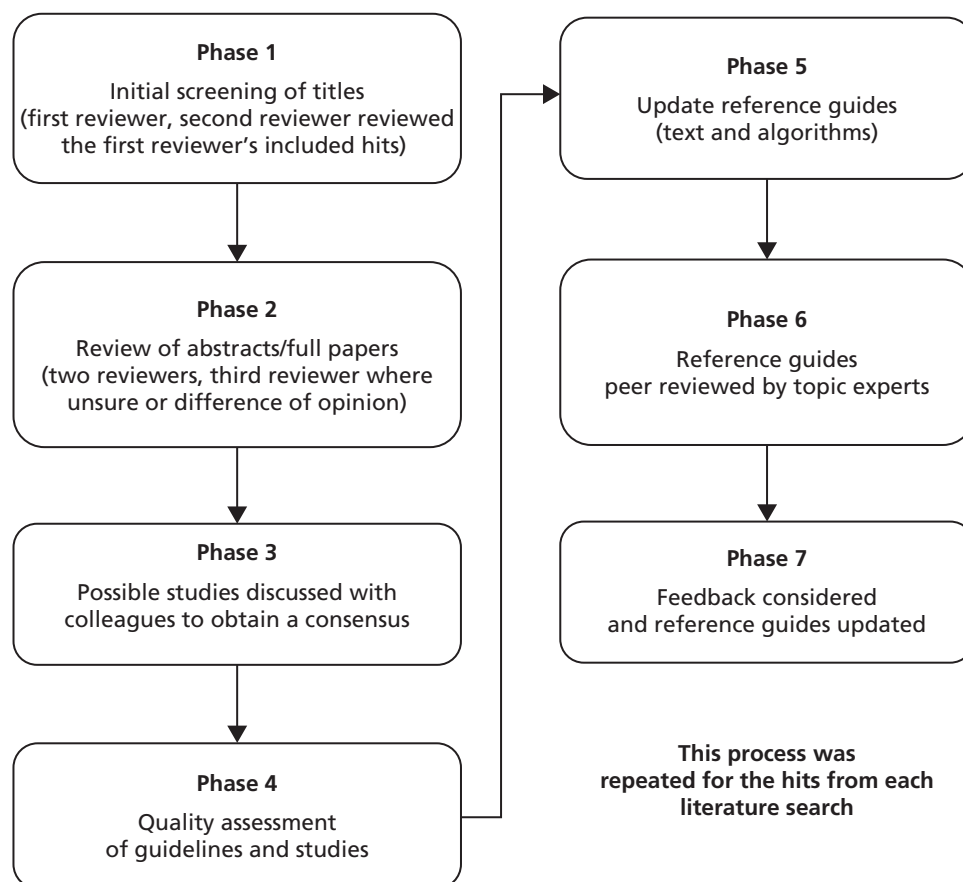


FIGURE 2 Written search strategy used in stage 4.

initial screening of the titles was conducted in two phases: the first reviewer carried out an initial screen to eliminate any obviously irrelevant papers and then the second reviewer screened all remaining papers. The abstracts/full papers were then considered by two reviewers independently using a standard proforma. A third reviewer was required when there was a conflicting opinion or both reviewers were unsure about study inclusion. Following discussions a consensus of studies for inclusion was reached.

Quality assessment

The quality of the guidelines was assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument (see www.agreetrust.org/about-the-agree-enterprise/agree-research-teams/agree-collaboration/). Quantitative studies were assessed using quality checklists developed by the Scottish Intercollegiate Guidelines Network (see www.sign.ac.uk).

Synthesis of papers

Evidence identified through the structured protocol was presented to the SMG by the lead reviewer for each problem area. The evidence (identified guidelines/studies, etc.) was used to inform development of the reference guide (supporting text) and treatment algorithm. Existing algorithms were reviewed and amended as necessary. A synthesis of study results through meta-analysis was not undertaken. Drafts of the reference guides and algorithms for each problem area were discussed and reviewed in SMG meetings.

Once agreement on content was reached by the SMG, the reference guides were then sent out for peer review to topic experts in the UK and their feedback was incorporated into the updated reference guides.

Presentation of the manual

Concurrent with content development, advice was sought regarding presentation, to facilitate ease of use. This was sought through a review of the relevant literature and from the Medical Illustration Department of Bradford Teaching Hospitals NHS Foundation Trust. In addition, the SMG considered what components were essential for delivery of the system of care.

The Cochrane review of information provision for stroke patients and carers

The Cochrane review of information provision for patients and their carers after stroke has been updated twice during the programme. The systematic review was conducted using The Cochrane Collaboration-recommended methodology for undertaking systematic reviews of RCTs and full details of the methods and outcomes have been published.^{43–45}

Studies were included if there was random assignment of participants (patients with a clinical diagnosis of stroke and/or their identified carers) to intervention groups (one of which involved the provision of information and/or education) and to a control group. In addition, studies using a matched pairs design and studies in which strict randomisation procedures were not adopted were also considered for inclusion.

We excluded trials in which information giving was only one component of a more complex rehabilitation intervention, for example family support worker trials (e.g. Forster and Young¹⁸ and Dennis *et al.*²⁰), which are the subject of a separate Cochrane review.⁴⁶

The primary outcomes used to assess the effectiveness of information provision were patient and carer knowledge about stroke and stroke services, and impact on health, especially mood. Secondary outcomes were activities of daily living; handicap; social activities; perceived health status; quality of life; satisfaction with information; hospital admissions, service contacts or health professional contacts; compliance with treatment/rehabilitation; death and/or institutionalisation; and cost to health and social services.

Relevant trials were identified in the Cochrane Stroke Group Specialised Trials Register. Additional intervention-based search strategies were developed for the Cochrane Central Register of Controlled Trials (CENTRAL/CCTR, formerly Cochrane Controlled Trials Register), MEDLINE, EMBASE, CINAHL, ISI Citation

Index, ISI Web of Science Service, ASLIB Index to Theses, Dissertation Abstracts International, Applied Social Sciences Index and Abstracts and PsychLIT/PsychINFO. We also searched registers of trials in progress and bibliographies of retrieved papers, articles and books.

Results

Updating the manual

Following a review of all problem areas it was agreed that each category of problem should be subjected to a separate search, with the approach and range of the search varying according to the problem. Broadly three approaches to the search strategy were undertaken:

1. an inclusive general search of the problem area
2. the search was restricted to 'stroke'
3. the search was restricted to stroke and other similar long-term conditions, which we termed a 'chronic illness filter'.

A summary of the search methods used is presented in *Table 1*.

TABLE 1 Summary of the search methods used for each reference guide

Reference guide	Search strategy
Transfer of care	It was felt that a full literature search of this area was outwith the scope of this model. A systematic review and guideline were available
Communication and information	A Cochrane review on information provision was conducted as part of this programme (see an update of the Cochrane review on information provision for stroke patients and carers ^{44,45})
Medicines and general health	The <i>National Clinical Guidelines for Stroke</i> ² had comprehensively covered this problem type
Pain	Stroke-specific search, specifically including shoulder pain and neuropathic pain
Mobility/falls	Mobility: stroke/exercise guidelines; excluded equipment-related therapy (treadmills/robots) as SCCs would not deliver this treatment Falls: stroke-specific search – for general falls a Cochrane review is available ⁴⁷
Driving and general transport	Search combined because of considerable overlap. General search then limited using terms (stroke, traumatic brain injury, disabled persons, chronic disease) supported by text word searches for physical disabilities
Continence	General search: aware that a Cochrane review of urinary incontinence is available ⁴²
Sexual functioning	General search then limited to stroke, chronic heart disease, traumatic brain injury, disabled persons
Shopping and meal preparation	Problem areas combined. General search excluding anorexia/bulimia/children, then limited to stroke, traumatic brain injury, disabled persons, chronic disease and text word searches for physical disabilities
House and home	General search (excluding children)
Finances and benefits	General search
Personal hygiene and dressing	General search then limited using chronic illness filter
Cognition	Search terms tailored based on existing Cochrane reviews; ⁴⁸⁻⁵⁰ additional search for compensation devices, e.g. aids/devices to compensate for memory loss
Patient mood	A recent systematic review and guidelines were available ⁵¹
Patient social needs (and employability search)	General search
Carer social and emotional needs	General search followed by stroke-specific search

Over 71,000 titles were identified by the individual searches, details are provided in *Table 2*. In total, 12 problem types required a review of evidence-based interventions from stage 3 (see *Figure 1*). Two problem areas, shopping and meal preparation and house and home, were addressed by a combined search and one problem area, patient social needs (and employability), was addressed by two separate searches.

Identified guidelines and papers were subject to appropriate quality assessment. Relevant evidence-based interventions from guidelines and studies found to be of high quality were then used to update treatment algorithms. Each was drafted by a lead reviewer and then reviewed by the SMG before external review. Final versions were further revised and formatted for inclusion in the manual.

The completed reference guides and treatment algorithms with supporting text are included in the manual; an example (for pain) is provided in *Appendix 5*.

Manual content and layout

In discussion with clinical colleagues and colleagues from the Medical Illustration Department of Bradford Teaching Hospitals NHS Foundation Trust, presentation of the manual was agreed. Introductory text was finalised and advice and guidance on use of the manual were provided. Each reference guide has a

TABLE 2 Search results for each reference guide

Reference guide	Guidelines/reviews/RCTs identified	Number of papers after first review	Number of papers after final review
Transfer of care	–	–	–
Communication and information	–	–	–
Medicines and general health	–	–	–
Pain	215 guidelines, 1619 reviews, 1565 RCTs	190	7
Mobility/falls	193 guidelines, 141 reviews, 109 RCTs	17	8
Driving and general transport	131 guidelines, 364 reviews, 1028 RCTs	49	49
Continence	867 guidelines, 5793 reviews, 12,139 RCTs	Guidelines sufficient	Guidelines sufficient
Sexual functioning	Not recorded	243	21
Shopping and meal preparation	313 guidelines, 1377 reviews, 4213 RCTs	40	16
House and home			
Finances and benefits	640 guidelines, 1296 reviews, 4101 RCTs	80	10
Personal hygiene and dressing	195 guidelines, 742 reviews, 830 RCTs	43	17
Cognition	Not recorded	83	13
Patient mood	–	–	–
Patient social needs (and employability)	94 guidelines, 489 reviews, 1757 RCTs	209 (395)	25 (21)
Carer social and emotional needs	3483 general, 485 stroke	420	52

number of sections ('The problem', 'The evidence' and 'Addressing the problem') followed by the algorithm. A frequency table was also provided for each of the problem areas (e.g. 88% of stroke patients have a fear of falling), to provide insight for SCCs and also assist them in informing/reassuring the patient. A list of screening tools that might be of use was included in the manual, with the tool reviewed to ensure that there were no copyright issues. All documentation was reviewed by members of the SMG before being finalised.

The essential components of the system of care were considered by the SMG. These were described as principles and were included in the manual. They were as follows:

- patient-centred comprehensive coverage of problems identified as important by patients and carers
- all assessment questions asked
- follow-up on actions and review goals.

In addition, national information about services available for patients after stroke was collated, with the intention that this would be used alongside information about local services.

Review of the evidence

Updating these treatment algorithms provided an opportunity to review evidence gaps. Available evidence was reviewed for each problem area. The results were tabulated and summarised to include available evidence and recommendations (if available) made in the *Evidence-Based Review of Stroke Rehabilitation* (see www.ebrsr.com), a relevant Cochrane review, Royal College of Physicians (RCP) guidelines,² Australian guidelines⁵² or Canadian guidelines⁵³ or identified through searches undertaken for the manual update. We also highlighted when a relevant RCT was ongoing. The resulting output is 85 pages long. Although the work was completed, we did not promote it as we were mindful that NICE was developing stroke rehabilitation guidelines (issued June 2013)⁵⁴ that could replicate the work and the RCP was similarly updating its guidelines (issued September 2012).⁵⁵

The Cochrane review of information provision for stroke patients and their carers

For the first update⁴⁴ we identified 228 abstracts, of which 63 studies were potentially relevant to the review. In total, 17 studies, involving 1773 patients and 1058 carers, were included (published 2009).

For the most recent update⁴⁵ we reviewed 28,110 titles including 134 full papers, resulting in the inclusion of four additional studies. The current review includes 21 trials from seven countries involving 2289 patients and 1290 carer participants.

Meta-analyses of reported outcomes showed a significant effect in favour of the intervention on patient knowledge, carer knowledge and patient satisfaction with information provision. There was also an effect on patient depression; however, the reduction was small and may not be clinically relevant. There was no effect on the number of cases of anxiety or depression or on patient mortality. Qualitative analyses found no strong evidence in favour of the intervention for other outcomes relevant to stroke recovery, including independence, participation in social activities, service use or modification of health-related behaviours.

Post hoc subgroup analyses demonstrated that, when information was provided in a format that more actively involved patients and carers, for example by offering repeated opportunities to ask questions, it had more effect on patient mood than information provided on one occasion only. However, as we saw no effect on the dichotomous end points of anxiety or depression (number of cases), the effects may be small. The specific component of the active information provision that may provide beneficial effects requires further investigation. There was no evidence that active information provision strategies were effective for other outcomes.

Discussion

The content and delivery of the developed system of care were comprehensively reviewed. Reviewing the literature for evidence-based treatment options focusing on patient-identified problems is a novel approach. This work focused on handicap rather than impairments and intended to create a more patient-centred service.

We took expert advice and guidance in the development of the treatment algorithms, using recognised methods to review the literature, and involved external peer review. The work was rigorous and comprehensive. However, some topic areas, for example house and home, are huge and may not be addressed in the more medical, impairment-focused literature. However detailed our searching, we may have missed some pertinent literature in less mainstream journals.

Information provision is reported as the most common unmet need and we undertook and published the Cochrane review relating to information provision for stroke patients twice during this programme.^{43,45}

Chapter 3 Project 2: cluster randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of a system of longer-term stroke care

Abstract

Trial design

A pragmatic, multicentre, cluster RCT compared a new system of care with usual practice delivered by SCCs.

Methods

Stroke services were randomised to the intervention or the control. Patients with new stroke living at home post stroke and referred to a SCC, and their informal carers, were eligible for recruitment before their first SCC assessment. 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, carer outcomes (if registered) and cost-effectiveness. Follow-up was through self-completed postal questionnaires at 6 and 12 months after registration.

Results

In total, 32 randomised stroke services (29 participated), including 800 patients (399 control, 401 intervention) and 208 carers (100 control, 108 intervention), were recruited. In intention-to-treat (ITT) analysis the adjusted difference in patient GHQ-12 mean scores 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 treatment arms; analyses of secondary end points and of the per-protocol population resulted in the same conclusion. The intervention involved no additional SCC time. Quality-adjusted life-years and total health and social care costs at 6 months, 12 months and over 1 year were similar between arms. Societal costs were higher for the intervention arm ($+\pounds 1163$ at 6 months, 95% CI $\pounds 56$ to $\pounds 3271$).

Conclusions

This robust trial demonstrated no benefit for clinical effectiveness or cost-effectiveness outcomes for the system of care compared with usual SCC practice.

Trial registration

This trial was registered as ISRCTN67932305.

Introduction

Background

The diversity of longer-term problems experienced by stroke patients and their carers has long been recognised,⁵⁶ but they remain poorly addressed by existing services.⁵⁷ There are persuasive arguments that a community-based orientation to post-stroke care delivered by primary care in the patient's local community, to assess, support and co-ordinate relevant services, might be more helpful in minimising longer-term stroke morbidity.^{22,58}

To address this we have developed an evidence-based system of care that aims to meet the longer-term needs of stroke survivors and their carers living at home in the community. The system of care incorporates structured assessment focused on patient- and carer-centred problems and associated evidenced-based treatment algorithms.

We aimed to evaluate the clinical effectiveness and cost effectiveness of the system of care when delivered by SCCs compared with usual practice in a cluster RCT [Longer-Term Stroke care (LoTS care) trial]. The methodology for the trial was informed by our survey of 39 SCCs.⁵⁹ The survey, undertaken in 2006, revealed that approximately 40% of SCCs reviewed the patient within 1 week of discharge from hospital. Most SCCs ($n=27$) saw patients more than twice after discharge from hospital, but the number of contact visits was often dependent on patient need (as opposed to defined time points). The majority of SCCs appeared to refer on to other services for carer assessments.

Objectives

Primary objective

The primary objective of the trial was to determine whether the system of care improved psychological outcomes for stroke patients living at home.

Secondary objectives

The secondary objectives were to:

- determine whether the provision of the system of care improved functional outcomes for stroke patients living at home
- determine whether the provision of the system of care improved psychological and functional outcomes for carers of stroke patients living at home
- assess whether the system of care was cost-effective based on patient outcomes from both health/social care and societal perspectives.

Methods

A summary of the protocol has been published.⁶⁰ The study was approved by Leeds West and Scotland A Research Ethics Committees.

Trial design

The trial has been designed as a pragmatic, multicentre, cluster RCT. The unit of randomisation was at the level of the stroke service, with SCCs (single practitioners or part of a community-based team) randomised to deliver the new system of care to all patients (and their carers, if appropriate) or to continue to deliver current practice as determined through local SCC policy and practices. Follow-up was through postal questionnaires at 6 and 12 months after recruitment.

A prospective cluster RCT design was used to reduce between-group contamination. The training component of the intervention was designed to impact on the skills, knowledge and clinical practice of SCCs and therefore the risk of contamination would be high if randomisation was at the individual patient level. If a service had more than one SCC it was likely that the SCCs would meet on a regular basis and work as a team, sharing caseloads. For these reasons the unit of randomisation was at the level of the service.

The system of care was evaluated as a whole to avoid a type III error,⁶¹ in which deconstruction of the component parts of a complex intervention may result in the loss of benefits of the interactions between components.

We recognised that the intervention may be effective on a number of domains. We therefore chose a range of outcome measures. The primary outcome measure was the General Health Questionnaire-12 (GHQ-12),⁶² to reflect patient mood, which would be influenced by a range of service inputs (including overall co-ordination of care). We aimed to capture psychosocial outcomes rather than just physical abilities as reflected in activities of daily living. The GHQ-12 has been used in previous stroke research and is sensitive to change.

Eligibility

Stroke services

The trial evaluated a complex intervention delivered to patients by a SCC within a stroke service; therefore, eligibility criteria were applied at three levels – the stroke service, the stroke unit and the SCC.

A stroke service encompasses primary and secondary care over a defined geographical area within the UK. As treatment in a stroke unit is the recommended care pathway for all patients after stroke,^{16,63} a stroke service was considered for inclusion in the trial only if it included a stroke unit that fulfilled the RCP's⁴¹ definition of a stroke unit, that is, it fulfilled four out of the five following criteria:

- it had a consultant physician with responsibility for stroke
- it had formal links with patient and carer organisations
- it had multidisciplinary meetings at least weekly to plan patient care
- it provided information to patients about stroke
- it provided continuing education programmes for staff.

A SCC was eligible if he or she fulfilled the following criteria:

- is a registered health-care professional with documented experience in stroke care
- undertakes a community-based/liaison or co-ordinating role for stroke patients (i.e. providing care for patients living in the community after discharge from hospital)
- is in contact with patients and co-ordinates a range of longer-term care inputs on their and their carers' behalf (e.g. signposting, carrying out assessments)
- works within a stroke service as above.

If SCCs worked as a team and shared caseloads then they were classed as one 'stroke service' for the purpose of the trial randomisation. A SCC was classified as working in a team if he or she attended regular (i.e. weekly/fortnightly) community multidisciplinary team (MDT) meetings.

Participants

In keeping with the pragmatic trial design, the patient eligibility criteria were broad to be inclusive of a clinically meaningful variety of stroke pathology and severity affecting patients and reflecting current clinical practice.

Patients were eligible for the trial if they:

- had a confirmed primary diagnosis of new stroke
- were referred to a SCC on discharge home from hospital or within 6 weeks of stroke and were still waiting for their first home or outpatient SCC assessment
- were able to provide written informed consent or consultee declaration.

Patients were excluded from the trial only if:

- they had a planned permanent admission to, or were already resident in, a nursing or residential care home
- their main requirement was palliative care
- they had been previously registered to the trial.

Patients involved in other Stroke Research Network (SRN)-adopted studies could be recruited into this trial unless they were first recruited into another study that was considered to overlap, as listed in the excluded studies list [Assessing Communication Therapy in the North West (ActNoW), LUNS, Oxford Vascular Study (OXVASC), Surgical Trial in Lobar Intracerebral Haemorrhage (STICH) II and Training Caregivers After Stroke (TRACS)].

Recruitment of carers was optional. Carers were eligible for the trial if:

- they were identified by the patient as the main informal carer who provides the patient with practical support a minimum of once per week.

Carers were excluded from the trial if their patient did not consent to the trial.

Randomisation

Randomisation was undertaken by the University of Leeds Clinical Trials Research Unit (CTRU). Stroke services were randomised on a 1:1 basis to either the intervention group or the control group. A detailed overview of the stroke services was obtained before randomisation to inform stratification.

Randomisation was stratified by the quality of the stroke unit [*National Stroke Audit* (NSA) score based on 2006 data⁶⁴], the annual number of referrals, whether SCCs work alone or within a community-based MDT and the Strategic Health Authority (SHA). When a SCC received referrals from more than one stroke unit, a weighted average of the NSA scores reflecting referral rates was used.

A method of obtaining a balanced design from the covariates available at the start of the trial, as proposed by Carter and Hood,⁶⁵ was used. This method uses an imbalance measure to compare the extent to which all possible designs balance important covariates between the arms of the trial and then randomly selects one member from the class of designs that achieves maximum balance. The advantage of the method is that it allows randomisation in multiple phases, conditioning on previous allocations. Because of the complexities of the current research approvals process, which created variable time delays (see *Appendix 6*), the services were randomised in two phases.

Blinding

As this was a cluster trial, all patients within the services randomised to the intervention received the new system of care and all patients within the services randomised to the control received usual care.

Recruitment of trial participants was by members of the independent research team and the SCCs were unaware which of their patients had consented to participate. Members of the research team were blinded to whether they were recruiting within an intervention service or a control service. This trial design has the advantage of reducing the potential for selection bias from differential recruitment, inherent if the SCCs were responsible for patient identification, and it minimises altering of SCCs' clinical activity for trial participants.

Interventions

All patients received the services of a SCC in a community stroke service. SCCs within the intervention arm provided care according to the new system of care. Control SCCs continued with usual practice.

Control arm

Patients who received care from the control SCCs received current community-based care as determined by local policy and practices.

Intervention arm: system of care

The development and description of the system of care is provided in *Chapter 1* and *Appendix 1*.

For implementation in the trial, the system of care comprised the following components:

- A care plan containing a structured assessment (assessment questions linked to reference guides in the manual) and a goal and action planner for each contact (patients and carers) (see *Appendix 3*). In discussion with the SCCs it was agreed that the assessment documentation should incorporate the patient details that they collected in delivery of their service, the intent being to create a single care plan that would replace currently used patient records, thus facilitating it becoming embedded in their service. The care plan was piloted by the SCCs (between the two training days; see below) before the final version was produced.
- An optional checklist detailing the content of the assessment to be given to patients before the SCC visit.
- A manual containing reference guides with evidence-based treatment algorithms, a frequency table of longer-term problems after stroke, a service directory and recommended assessment scales.
- National information about services available for patients after stroke was collated and provided to the SCCs at the first training day. Each SCC was given a large box file including leaflets of relevant services (e.g. Disabled Holiday Directory, Age Concern). The SCCs were asked to further develop a resource inventory of local services.

Training in the delivery of the system of care was provided for each of the SCC services randomised to the intervention before commencement of patient recruitment. Training was delivered through two centrally based Royal College of Nursing-accredited training days approximately 1 month apart and was supported by detailed documentation and a purposely produced CD. The first training day included details of the system of care [from the Academic Unit of Elderly Care and Rehabilitation (AUECR) research team, involved in its development, and clinicians involved in the pilot work], guidance on problem-solving techniques and the principles of the intervention, as described below:

- patient centred (comprehensive coverage of problems identified by patients and carers)
- provide assessment areas (checklist) before assessment whenever possible
- ask all assessment questions
- keep accurate records
- problem-solving approach with collaborative goal setting
- follow up on actions
- review goals
- non-prescriptive – individual creativity
- according to local services/resources
- within patient's own environment whenever possible
- timing/duration of intervention (according to national recommendations)
- cut-off time (problem-solving approach leads to reduced problems over time)
- flexible approach to carer assessment.

The SCCs then used the system of care with several patients in their service before the second training day, which reviewed the use of the system of care and problem solving and in addition provided training in specific areas such as pain and benefits. After the second training day SCCs began to use the system of care for all patients referred to their service. Recruitment was not opened until all parties were satisfied that the system of care was being delivered. This was assessed during site set-up visits at which a sample of care plans was reviewed to ensure that all assessment questions were asked and that identified problems were being addressed in the goal and action planner.

Documentation of interventions

Before randomisation, all SCC services completed a survey and a semistructured interview; these were used both to assess eligibility and inform stratification and to describe the services and the nature of their interactions with patients. Changes in service set-up and SCC practice were captured by semistructured interviews midway through recruitment and after the end of the 12-month follow-up and by a second survey after the end of follow-up. The second survey also requested estimates of typical SCC input times, to be used in the economic analysis. Interviews that took place during recruitment were designed and performed so that they did not influence SCC practice.

After randomisation, control SCCs were asked to complete time logs for all patients, documenting the number and duration of contacts and the time spent co-ordinating actions, note writing and discussing patients in MDT meetings. Time logs were collected for trial patients after the end of the 12-month follow-up so as not to unblind SCCs to trial patients during follow-up. Once trained in use of the system of care, intervention SCCs were asked to use the care plan for all contacts with all patients (and carers if carer assessments were performed). After the end of the 12-month follow-up, equivalent data to those contained in the time logs and additional information on the use of the structured assessment and goal and action planner were collected for trial patients by transcribing the appropriate information from the care plans at site. This was carried out by two researchers from AUECR who were familiar with the intervention, to ensure consistency.

Assessments

Recruitment

The trial reflected usual referral pathways of patients to SCCs, determined during site set-up visits, involving the SCCs and the hospital-based clinical team and clinical research team. Patients were referred to SCCs in three main ways: by in-hospital referral (the majority of patients), by referral post discharge or by referral of patients not admitted to local hospitals. The recruitment process was facilitated by close liaison between the clinical research team and the clinical team, but patients were recruited by independent members of the clinical research team.

Anonymous screening data (demographic data and modified Rankin Scale score⁶⁶) were collected for all patients referred to a participating SCC. Written informed consent for baseline and follow-up assessments was obtained from patients and carers (if appropriate) before any trial-specific procedures were carried out. In the event that a patient lacked the capacity to consent, the patient's family member, carer or friend was asked to act as the consultee and provide a consultee declaration.

The clinical research team collected baseline demographic data, which included assessment of cognition [six-item Cognitive Impairment Test (6CIT)],⁶⁷ language ability, pre-stroke disability (Barthel Index)^{38,68} and the six factors from the Edinburgh stroke case mix adjuster.⁶⁹

Patients and carers completed the baseline questionnaires predominantly before discharge from hospital. Patients completed the GHQ-12,⁶² the FAI,³⁹ the Barthel Index (post-stroke disability), the European Quality of Life-5 Dimensions (EQ-5D)⁷⁰⁻⁷² and the Client Service Receipt Inventory (CSRI).⁷³⁻⁷⁵ Carers completed the GHQ-12.

Follow-up

Patients and carers were followed up by the CTRU using postal questionnaires at 6 and 12 months post recruitment. These included the questionnaires completed at baseline and in addition the LUNS questionnaire (see *Chapter 4*) for patients and the Caregiver Burden Scale (CBS)⁷⁶ for carers. This was supported by postal and telephone reminders if questionnaires were not returned within 2 weeks. If necessary (following postal and telephone reminders), patients were contacted by telephone to complete the primary outcome measure (GHQ-12)⁶² at 6 months and at 12 months if no 6-month data had been

obtained. The clinical research team recorded deaths, emergency outpatient treatment and hospital admissions at 6 and 12 months.

Questionnaire scoring

- The GHQ-12 is measure of current mental health. It is a 12-item scale with a total score ranging from 0 to 36; higher scores are indicative of greater psychological distress.
- Modified Rankin Scale – 0, no symptoms; 1, no significant disability; 2, slight disability; 3, moderate disability; 4, moderately severe disability; 5, severe disability.
- The Barthel Index is a measure of daily functioning, specifically the activities of daily living and mobility. The total score ranges from 0 to 20, with lower scores indicating increased disability. Barthel Index (categorical):⁷⁷ independent 20, mild disability 15–19, moderate disability 10–14, severe disability 0–9.
- 6CIT – the total score ranges from 0 to 28; a score of ≤ 7 indicates normal cognitive function whereas a score of > 7 indicates cognitive impairment.
- The Edinburgh stroke case mix adjuster predicts the probability of survival free of dependency at 6 months.
- The EQ-5D is a five-item scale able to identify 243 unique health states. The EQ-5D index varies from –0.59 for the worst possible health status to 1.0 for perfect health, with 0 on the scale representing the state of being dead.
- The CBS is a 22-item scale measuring subjective burden score, with higher scores indicating greater carer distress. Each domain has a possible score of 1–4, with the overall score ranging from 22 to 88.
- The FAI is a measure of instrumental activities of daily living for use with patients recovering from stroke. It is a 15-item scale with the total score ranging from 0 to 45; a low score is indicative of a low level of activity.
- The LUNS questionnaire is a monitoring tool that has been developed to assess unmet needs consisting of 22 items, with a 'yes' response indicating unmet need.

The CSRI measures use of health, social care and informal resources (see *Resource use data*).

Outcomes

In common with other stroke rehabilitation trials^{78,79} the primary outcome point was at 6 months, with the final follow-up at 12 months to assess whether any intervention effect was sustained.

Primary outcome

The primary end point was the psychological outcome for stroke patients living at home as measured by the patient-reported GHQ-12 at 6 months after recruitment.

Secondary outcomes

Patients

The following patient-reported secondary outcomes were measured at 6 and 12 months after recruitment: social activity (FAI), disability (Barthel Index), health state (EQ-5D), unmet stroke-related needs (LUNS questionnaire; see *Chapter 4*), death, hospital readmission and institutionalisation. In addition, the psychological outcome for patients was measured using the GHQ-12 at 12 months after recruitment.

Carers

Secondary outcomes also included the following carer end points: carer self-reported GHQ-12 and CBS scores, death and institutionalisation, all measured at 6 and 12 months after recruitment.

Sample size

Initial sample size calculations, based on the primary outcome measure, GHQ-12 at 6 months, indicated that recruitment of 800 patients from 40 services would provide 90% power at the 5% significance level to detect a clinically relevant difference of 2.5 GHQ-12 points [standard deviation (SD) 7 points], as defined

in the Trial of Occupational Therapy and Leisure (TOTAL).⁷⁸ This sample size accounted for loss to follow-up and clustering; the inflation factor of 1.95 was derived from a maximum cluster size of 20 and an intracluster correlation coefficient (ICC) of no greater than 0.05.^{80,81} The TOTAL study achieved an 80% response rate to postal questionnaires at 6 months and a 71% response rate at 12 months. We therefore estimated the maximum loss to follow-up at 6 months as 25%. Losses to follow-up are likely to increase over time⁷⁸ and the interpretation and credibility of results are difficult if losses exceed 30%. Therefore, follow-up was limited to 12 months post recruitment and the primary outcome was defined as 6 months, when there will be a higher follow-up rate.

The SCCs indicated that they were likely to receive two or three new referrals per week, of which one or two were likely to consent to inclusion in the trial. The initial aim was to recruit 40 SCC services; if 40 services recruited an average of 20 patients, this would result in the required number of patients (800) and the trial having 90% power to detect the clinically relevant difference (2.5 GHQ-12 points). Overall, 32 services were randomised, each with the aim of recruiting 25 patients, providing a power of 88%. To minimise unequal recruitment, the maximum number of patients per service was capped at 45, maintaining 85% power.

Statistical methods

Statistical analyses were based on the ITT population. All statistical testing was performed at a two-sided 5% significance level.

The ITT population was defined as all patients registered for active follow-up regardless of non-compliance with the intervention. All patients within a stroke service were analysed according to the intervention that that stroke service was randomised to. The ITT population was used for both primary and secondary analyses.

Per-protocol analysis was also undertaken in which major protocol violators or patients not receiving care from a SCC were excluded from the ITT population. The following groups of patients were excluded from the per-protocol population:

- non-eligible patients
- patients registered but then not referred to the SCC
- patients referred to the SCC at baseline but who were not known to the SCC as a referred patient
- patients not receiving any care from the SCC for the following reasons: patient declined the SCC service, the SCC was unable to contact the patient and the patient was registered but died before the first SCC assessment.

As the trial was a cluster RCT, outcome measures at follow-up were compared between the intervention group and the control group using a two-level multilevel model, with patients nested within stroke services.

Both primary analysis and secondary analysis involved a two-level linear model. The models were adjusted for the patient-level covariates (level 1) [baseline Barthel Index score (pre and post stroke); gender; age; living circumstances (living alone vs. living with carer); stroke severity, reflected by speech and language impairment (normal/impaired) and baseline 6CIT score (normal/impaired), and patient baseline score for the outcome measure] and the following stroke unit-level covariates (level 2): quality of stroke unit (NSA score), referral rate and SCCs working alone compared with working within a community MDT.

Two-level linear models for analyses of carer outcomes were adjusted for carer covariates (level 1) (carer baseline score for the outcome measure, gender, carer education, patient baseline Barthel Index score) and stroke unit covariates (level 2) [quality of stroke unit (NSA score), referral rate and SCCs working alone vs. working within a community MDT].

No interim analyses were undertaken.

All losses to follow-up because of death, dropouts and loss of contact are fully reported.

Details of patient deaths and hospital readmissions, carer deaths, any serious adverse events and related and unexpected serious adverse events are reported for each treatment group.

Sensitivity analyses to examine the robustness of the conclusion of the primary analysis were employed. Each of these analyses was compared with the primary analysis separately. The following sensitivity analyses were performed:

- Including patients who died – patients who died were assumed to have a GHQ-12 score of 36 (worst possible outcome).
- Only including patients returning postal questionnaires at 6 months; patients who provided primary outcome data by telephone were excluded.
- Repeating analysis without proxy responses (the proxy response was when the whole questionnaire was completed on the patient's behalf without consulting him or her) to assess the impact of proxy responses on the analysis of the primary end point.
- Using data collected at 12 months for patients who did not send their questionnaires back at 6 months.
- Accounting for all participants in the ITT population assuming data missing at random using multiple imputation. Information based on Edinburgh stroke case mix adjuster, clinical classification of stroke, patient status in terms of response compared with non-response (alive, died, too poorly) and prespecified model covariates was used to impute the missing outcomes. The analysis with imputed values was repeated using the same model as the model in the primary analysis.

The relationship between the adjusted primary outcome and compliance with care plans and completion of time logs was explored graphically.

Economic evaluation

Study question

Is SCC care under the new system of care cost-effective compared with SCC care according to usual practice, from either a health and social care perspective or a societal perspective?

Selection of alternatives

The economic evaluation was embedded within the trial and incorporated the same comparators (system of care vs. usual care) as for the outcome evaluation and the same overall design (same sample size, participants, randomisation, recruitment, etc.).

Form of evaluation

The economic evaluation was based on individual-level data collected within the trial. It assessed cost-effectiveness based on the GHQ-12 and cost-utility based on quality-adjusted life-years (QALYs) derived from the EQ-5D.

Time horizon

In keeping with the outcome evaluation, the primary end point for the economic evaluation was 6 months. We also explored findings at 12 months and over 1 year to determine whether any advantages were sustained in the longer term. The 1-year costs were estimated as the sum of the costs from the 6-month and 12-month assessments and were linked with (1) GHQ-12 values at 12 months and (2) the sum of the QALYs from the 6-month and 12-month assessments.

Effectiveness data

The GHQ-12 scores were measured as described earlier. For the estimation of QALYs, health states were measured using the EQ-5D at baseline, 6 months and 12 months. Utility weights from a UK general population survey⁸² were attached to these. QALYs were estimated using linear interpolation to calculate the area under the QALY curve as follows:

$$\text{6-month QALYs} = ((\text{baseline utility} + \text{6-month utility})/2) \times 0.5 \quad (1)$$

$$\text{12-month QALYs} = ((\text{6-month utility} + \text{12-month utility})/2) \times 0.5 \quad (2)$$

$$\begin{aligned} \text{1-year QALYs} = & (((\text{baseline utility} + \text{6-month utility})/2) \times 0.5) \\ & + (((\text{6-month utility} + \text{12-month utility})/2) \times 0.5) \end{aligned} \quad (3)$$

Resource use data

Individual-level data on use of health and social care resources and informal care were collected using a CSRI specifically adapted for this study from versions used successfully in previous large stroke rehabilitation trials.⁷³⁻⁷⁵ It was administered retrospectively as a self-complete questionnaire alongside other measures, predominantly in hospital for the baseline assessment (which measured the previous 3 months) and as a postal questionnaire at 6 months and 12 months (each of which measured the previous 6 months).

We also prospectively measured the duration of SCC inputs (of both a contact and a non-contact nature) at the individual patient level in both the intervention group and the control group. In the intervention group, these inputs were measured as part of the care plan. In the control group, staff recorded equivalent inputs into a specifically designed time log. Staff were also asked to report their pay band to enable costs to be estimated by staff level.

We further conducted a general survey of SCCs at all services to gather information about typical inputs (e.g. typical duration of a patient assessment, typical duration spent discussing a patient in a MDT meeting) across all of their patients, not just trial participants, to obtain service-relevant imputation values in the event of missing trial data for trial participants because of non-completed/partially completed or misplaced care plans or time logs.

Unit costs

Unit cost estimates, their sources and any assumptions made for their estimation are detailed in *Appendix 7* and summarised in *Table 3*. Unit costs were standardised at 2010/11 levels and national estimates were used when possible to represent the geographical spread of the sites and facilitate the generalisability of the results.

Hospital admission costs were estimated by mapping participant-reported specialty or reason for the admission to Healthcare Resource Groups (HRGs) and then applying weighted average non-elective long-stay bed-day costs for each of those HRGs (or across HRGs when multiple specialties were reported for one admission). An average cost across all HRGs was applied when specialty and reason were missing or could not be readily allocated to a specific HRG. Outpatient costs were estimated using the same approach.

The CSRI included a question asking respondents to report the use of any other services not covered by the previous questions. Many responses to this question were for services already itemised in the instrument. We report these total 'other' costs separately rather than amalgamate them into the specific resource categories.

TABLE 3 Summary of unit costs

Category	Unit	Unit cost (£, 2010/11)
Residential care home stay	Night	75
Nursing home stay	Night	76
Inpatient services	Bed-day	Range 315–1213
Day hospital/day case services	Activity	Range 230–1190
Outpatient services	Visit	Range 3–772
Primary care/community-based services	Contact/hour/item	Range 9–152
Value of caregiver time – average wage	Hour	15
Value of caregiver time – leisure time	Hour	5
SCC	Hour	Range 19–78
Stroke MDT meeting	Hour	284

Informal care inputs were valued using the opportunity cost approach to represent the opportunities forgone by carers because of time spent caregiving. For patients with a carer enrolled in the trial, we distinguished opportunity costs as either lost employment or lost leisure on the basis of a carer's employment status at each assessment. When it was assumed that the carer could otherwise have been working (those working part-time or unemployed seeking work), we applied the national average wage. When it was assumed that the carer was unlikely to instead be working (those working full-time, at home not seeking work, retired, redundant/early retired, unable to work and students), we applied an estimate of the cost of leisure time. We applied the average of the two unit costs when carer employment status was 'other' or missing and for carers outside the trial. We assumed that, if the main carer lived with the patient, all reported live-in informal care inputs were by that carer and all live-out inputs were provided by others. Conversely, if the main carer did not live with the patient, we assumed that all live-out informal care inputs were provided by that person and that all live-in inputs were provided by others.

Costs and perspectives

Unit costs were multiplied by individual-level resource use quantities at each assessment point. The total costs for each individual were computed from (1) health and social care and (2) societal perspectives. Health and social care costs included the costs of nursing/residential care; hospital inpatient, hospital outpatient, day hospital and accident and emergency (A&E) services; and primary care/community-based health/social care services. Societal costs included all of these categories plus informal care costs. It was not necessary to discount costs or outcomes because the evaluation covered only 1 year.

Cost-effectiveness and cost-utility analyses

Given the two cost perspectives and the two outcomes of interest, we examined the following four cost-outcome combinations at the primary end point of 6 months: (1) GHQ-12 and health and social care costs, (2) GHQ-12 and societal costs, (3) QALYs and health and social care costs and (4) QALYs and societal costs. Considering cost-effectiveness and cost-utility at 12 months and over 1 year involved examining the same cost-outcome combination set twice more. There were thus a total of 12 cost-outcome combinations to consider.

We aimed to calculate incremental cost-effectiveness ratios (ICERs) only for any cost-outcome combinations for which there were statistically significant higher costs and greater benefits for one group compared with the other.

We further examined uncertainty around the cost-effectiveness and cost-utility of the system of care using cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs) based on the net benefit approach.⁸³

Cost-effectiveness planes plot between-group mean differences in total health and social care costs, GHQ-12 scores and QALYs at 6 months. Differences were calculated using bootstrapped regressions (5000 replications) with an adjustment for cluster and the same patient-level baseline covariates as used for other group comparisons (see *Statistical analyses*).

Net benefits provide a single summary monetary measure of costs and outcomes for each individual (removing the need to examine ICERs, which have limitations as they are based on point estimates and it is difficult to estimate CIs around them). Net benefits account for the value (λ) that a decision-maker would be willing to pay for a greater net benefit and are calculated as follows: net benefit = $(\lambda \times \text{outcome}) - \text{cost}$. For each cost-outcome combination, we calculated a series of net benefits for a range of relevant λ values (£0–2000 per point improvement on the GHQ-12 and £0–50,000 per QALY gain). Net benefits were then compared by randomisation group using bootstrapped regressions (5000 replications) of study group on net benefit, with an adjustment for cluster and the same patient-level baseline covariates as used for other group comparisons (see *Statistical analyses*). For each value of λ , the proportion of iterations indicating a higher net benefit for the intervention group was calculated and plotted as a CEAC. CEACs are an alternative to CIs around ICERs and show the probability of the system of care being cost-effective (or optimal) compared with usual care for a range of values that a decision-maker may be willing to pay for an additional unit gain in the GHQ-12 or QALYs.

Statistical analyses

All cost and QALY data are reported as mean values with SDs. To accommodate a cluster randomisation design, differences in costs and QALYs between groups were tested by multilevel modelling using the xtreg procedure in Stata 10.1 (StataCorp LP, College Station, TX, USA), from which we report 95% CIs and *p*-values for the differences in means. Relevant baseline patient characteristics were included as covariates for comparisons at follow-ups: Barthel Index (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility and GHQ-12 score (and total cost from the relevant cost perspective for the comparison of costs). Data were analysed using the same ITT approach as for the outcome evaluation, with individuals analysed according to the group to which they were randomised regardless of compliance with the intervention. Resource use differences were not compared statistically to avoid problems associated with multiple testing.

Missing data

As for the outcomes evaluation, the base-case economic evaluation was a completers analysis without imputation for loss to follow-up under the assumption that loss to follow-up was at random. We report CSRI and EQ-5D completion rates and describe baseline characteristics of those with and without these data at the primary end point, 6 months. We also report rates for the combined availability of CSRI/GHQ-12 and CSRI/EQ-5D data for the cost-effectiveness and cost-utility analyses respectively.

Missing GHQ-12 and EQ-5D data were not imputed. Resource use data from the CSRI formed the basis of the total cost calculations for each participant. Self-completed applications of such complex instruments inevitably include missing items on returned questionnaires and, to allow the computation of total costs that reflect variations in resource use rather than variations in data completeness, we imputed missing cost items. For returned questionnaires, if there was no report of use of a particular resource, we assumed that it was not used and thus imputed a zero cost. When use of a resource was reported without specifying quantity, we imputed the cost of that resource based on the mean cost for participants with data for that item at the same assessment point and in the same randomisation group (or the other randomisation group if there were no valid cases to impute from in the same group). In the case of hospital admissions, we used an average admission cost from NHS reference costs,⁸² rather than mean values from within the

sample. All such imputations were made to cost estimates, rather than to the resource use data, so any descriptions of resource use data include no imputations.

It was similarly necessary to impute missing data related to SCC inputs. Costs for each SCC input were imputed separately (rather than the total SCC cost) to make use of any input data that were present. For patients in both groups, we assumed a zero cost if a care plan or time log was not completed for the following reasons: referral not received by the SCC service, patient declined the SCC service, patient died before receiving the SCC service, SCC unable to contact the patient or patient withdrew from all follow-up. If a care plan/time log was completed and the duration of input was missing, we imputed values from the SCC survey when available (by service) or else used the within-group mean cost for those with care plans/time logs and data for the relevant component. If a patient received a SCC service but no care plan/time log was completed, we imputed the mean cost for those with data in the control group.

For carers in the intervention group, we assumed a zero cost if an assessment did not take place, if it was unknown whether one took place or if there was no consenting carer. If an assessment took place but the duration was missing, we allocated the mean cost for those with completed assessments and data for that component. Data for inputs to non-consenting carers were found to be complete across all components. We assumed a zero cost in the absence of any identified non-consenting carer.

Sensitivity analyses

We examined the effect of loss to follow-up by imputing missing health and social care costs and QALYs at the primary end point, 6 months, and comparing group differences with those in the base-case analyses. We report the same statistics around means and mean differences (using the same covariates for comparisons of means) as for the base-case analyses and recomputed alternative ICERs and CEACs based on the alternative values if group comparisons suggested different cost or QALY conclusions compared with the base-case analyses. For those who were lost to follow-up because of death, we computed QALY gains assuming a utility value of zero at 6 months and included costs of SCC inputs while assuming that all other health and social care costs were zero. For those lost to follow-up for any other reason, we imputed total costs and QALYs using the multiple imputation procedure in Stata 10.1. Imputations were based on key baseline variables expected to predict follow-up costs and QALYs. These were the same variables used as covariates for the comparisons of costs and QALYs for those with data, plus randomisation group and three service-level variables: at the patient level – baseline Barthel Index (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility and GHQ-12 score (and total cost from the relevant cost perspective for the prediction of costs); at the service level – quality of stroke unit (NSA score), referral rate and SCCs working alone compared with working within a community MDT.

Results

The trial was a pragmatic, multicentre, cluster RCT of 800 stroke patients requiring community-based longer-term stroke care and their carers if appropriate. The unit of randomisation was at the level of the stroke service.

Participant flow

The Consolidated Standards of Reporting Trials (CONSORT) flow diagram depicting the progress of participants and clusters through the phases of the trial, including assessment of eligibility of clusters, cluster randomisation, participant screening, recruitment and follow-up and the ITT populations, is provided in *Figure 3*, with additional detail given in *Appendix 8* (see *Tables 76–79*).

In total, 32 clusters were randomised and, of these, 29 participated (14 control clusters and 15 intervention).

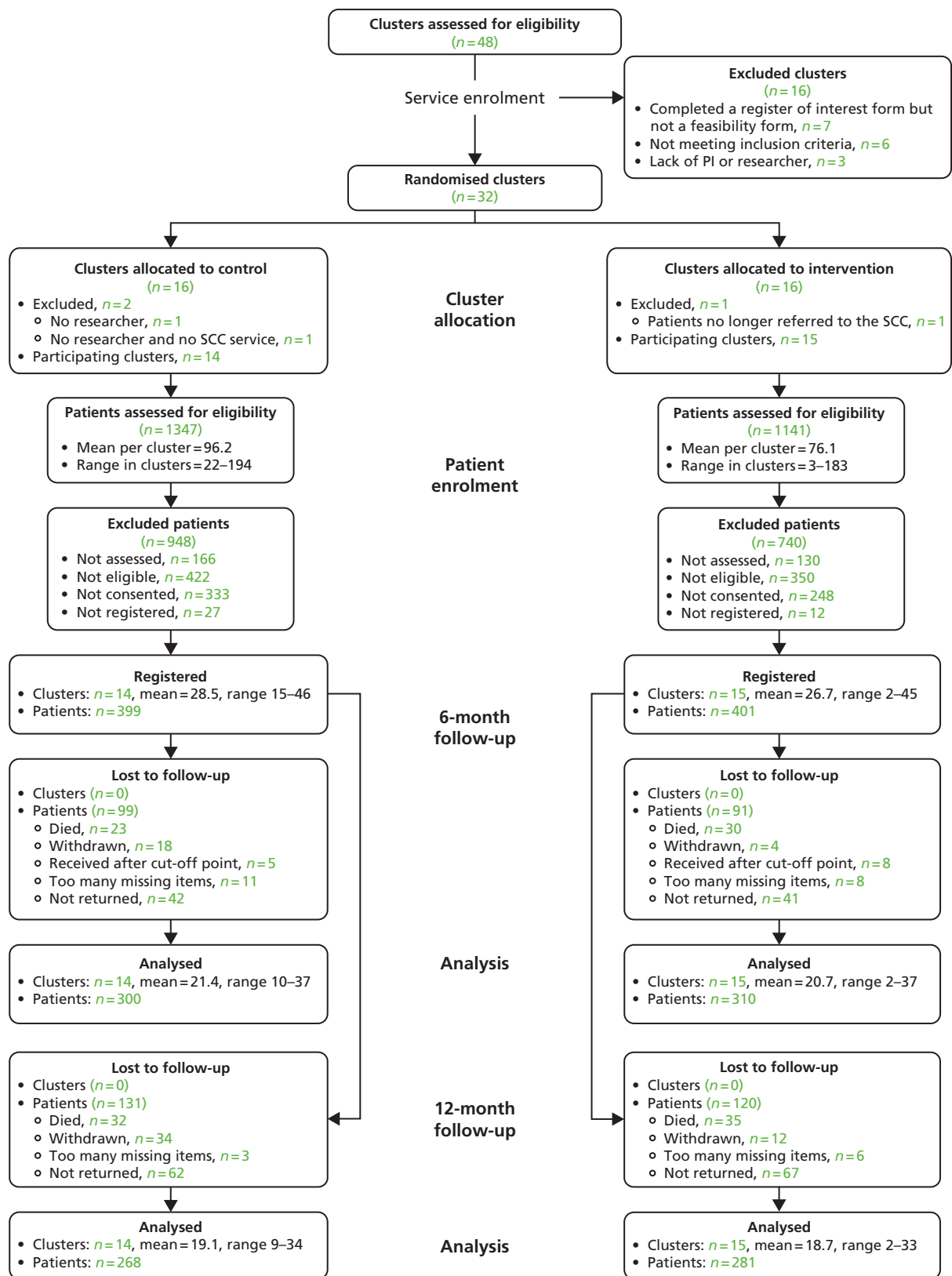


FIGURE 3 CONSORT flow diagram. PI, principal investigator.

During screening, 2488 participants were screened for eligibility, 1347 in the control group and 1141 in the intervention group.

The numbers of registered patients were balanced between the two arms (399 control, 401 intervention). At all time points the number of clusters remained the same (14 control, 15 intervention). The numbers of registered carers were also balanced (100 carers were recruited in the control group and 108 in the intervention group).

Response rates for patient-reported outcomes at 6 months were 75.2% (300 patients) in the control group and 77.3% (310 patients) in the intervention group; these dropped to 67.2% (268 patients) and 70% (281 patients), respectively, at 12 months' follow-up.

Response rates for carer-completed outcomes at 6 months were 88% (88 carers) in the control group and 82.4% (89 carers) in the intervention group; these dropped to 71% (71 carers) and 67.3% (73 carers), respectively, at 12 months' follow-up.

Recruitment

Service eligibility and randomisation were undertaken in two phases. Fourteen services were randomised in phase 1 in January 2009. In phase 2, in September 2009, an additional 18 services were randomised. Following the training and implementation period (intervention services), participant recruitment began in July 2009 in phase 1 and in March 2010 in phase 2, which is reflected in the steep increase in monthly accrual (*Figure 4*). Overall, 800 patients were registered from July 2009 to March 2011, 399 patients from 14 control services and 401 patients from 15 intervention services. Follow-up was completed in May 2012.

Randomised services

The characteristics of the randomised services are shown in *Table 4*. Both arms are balanced in terms of SCC teamworking, referral rate and NSA 2006 score. Balance based on SHA was difficult to achieve because of the requirement to randomise 32 services from 11 SHAs. Of 16 control services, two clusters dropped out post randomisation. One had no researcher and one had neither a researcher nor a SCC service. Of 16 intervention clusters, one cluster dropped out as patients were no longer referred to the SCC.

Patient screening

Anonymised information for each patient referral to the participating SCC was reported to the CTRU on a monthly basis. Each service screened patients for eligibility to participate in the trial, with 1347 patients screened in the control services and 1141 screened in the intervention services (*Table 5*). Details of participant non-registration were collected, including reasons for participants not being screened, assessed, eligible, consented and registered (see *Appendix 8, Tables 67–70*).

Of the screened patients, 399/1347 (29.6%) were registered in control services and 401/1141 (35.1%) were registered in intervention services. There were more patients screened and subsequently found not to be eligible in control services than in intervention services; three control sites (3, 14 and 15) screened large numbers of participants (see *Appendix 8, Table 67*) but a higher than average percentage of patients from these sites were not registered in the trial (see *Appendix 8, Tables 68–70*).

The demographics of screened patients including patient age, gender, ethnicity and modified Rankin Scale score were collected and are presented in *Tables 6 and 7*. These data show balance between the two treatment arms. Demographic screening data were also collected before the start of recruitment and are shown in *Appendix 8* (see *Tables 65 and 66*); there were no major differences between screening data pre and post recruitment.

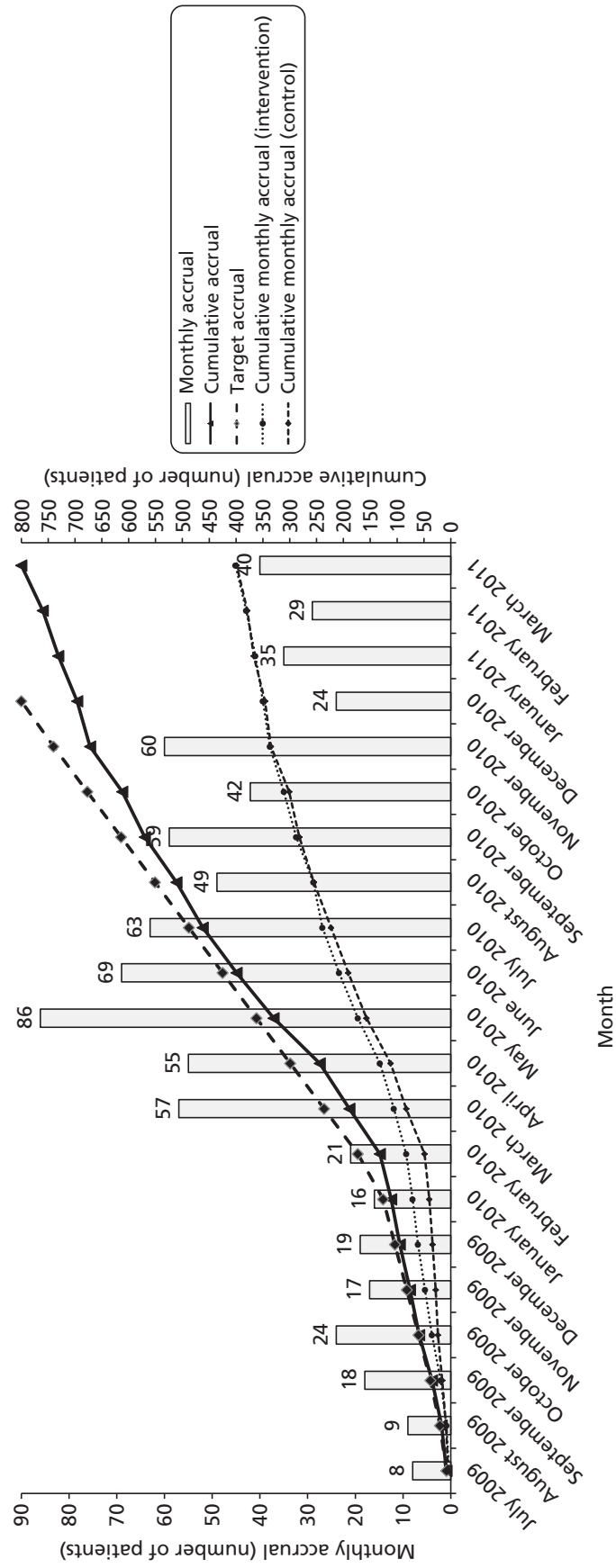


FIGURE 4 Accrual into the trial.

TABLE 4 Characteristics of randomised services (clusters)

Centre characteristic	Control (N=16), n (%)	Intervention (N=16), n (%)	Total (N=32), n (%)
SHA			
North East	1 (6.3)	2 (12.5)	3 (9.4)
North West	2 (12.5)	4 (25.0)	6 (18.8)
Northern Ireland	2 (12.5)	1 (6.3)	3 (9.4)
Wales	0 (0.0)	2 (12.5)	2 (6.3)
West Midlands	2 (12.5)	1 (6.3)	3 (9.4)
South East Coast	2 (12.5)	1 (6.3)	3 (9.4)
South Central	1 (6.3)	0 (0.0)	1 (3.1)
South West	3 (18.8)	3 (18.8)	6 (18.8)
East of England	1 (6.3)	1 (6.3)	2 (6.3)
Scotland	1 (6.3)	1 (6.3)	2 (6.3)
East Midlands	1 (6.3)	0 (0.0)	1 (3.1)
SCC			
Individual	4 (25.0)	4 (25.0)	8 (25.0)
Team	12 (75.0)	12 (75.0)	24 (75.0)
Referral rate			
Mean (SD)	190.3 (88.63)	178.9 (126.16)	184.6 (107.41)
Median (range)	185.0 (44.0–304.0)	148.5 (38.0–539.0)	161.5 (38.0–539.0)
NSA 2006 score			
Mean (SD)	63.8 (11.04)	62.4 (10.26)	63.1 (10.50)
Median (range)	64.0 (49.0–80.0)	65.0 (42.0–76.0)	64.5 (42.0–80.0)

TABLE 5 Screening data: flow from screening to registration

	Control (N=1347), n (%)	Intervention (N=1141), n (%)	Total (N=2488), n (%)
Assessed	1181 (87.7)	1011 (88.6)	2192 (88.1)
Eligible	759 (56.3)	661 (57.9)	1420 (57.1)
Consented	426 (31.6)	413 (36.2)	839 (33.7)
Registered	399 (29.6)	401 (35.1)	800 (32.2)

TABLE 6 Screening data: gender, ethnicity, age and modified Rankin Scale score

Characteristic	Control (N=1347), n (%)	Intervention (N=1141), n (%)	Total (N=2488), n (%)
Age (years)			
Mean (SD)	75.1 (12.77)	74.3 (13.17)	74.7 (12.95)
Median (range)	78.0 (23.0–100.0)	76.0 (22.0–100.0)	77.0 (22.0–100.0)
Missing	8	3	11
Gender			
Male	668 (49.6)	562 (49.3)	1230 (49.4)
Ethnicity			
White	1278 (94.9)	1101 (96.5)	2379 (95.6)
Modified Rankin Scale score			
0	44 (3.3)	41 (3.6)	85 (3.4)
1	233 (17.3)	167 (14.6)	400 (16.1)
2	203 (15.1)	140 (12.3)	343 (13.8)
3	250 (18.6)	221 (19.4)	471 (18.9)
4	352 (26.1)	380 (33.3)	732 (29.4)
5	170 (12.6)	156 (13.7)	326 (13.1)
Missing	95 (7.1)	36 (3.2)	131 (5.3)

TABLE 7 Screening data: modified Rankin Scale score – registered patients

Modified Rankin Scale score	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
0	24 (6.0)	13 (3.2)	37 (4.6)
1	99 (24.8)	81 (20.2)	180 (22.5)
2	76 (19.0)	81 (20.2)	157 (19.6)
3	90 (22.6)	92 (22.9)	182 (22.8)
4	82 (20.6)	102 (25.4)	184 (23.0)
5	4 (1.0)	21 (5.2)	25 (3.1)
Missing	24 (6.0)	11 (2.7)	35 (4.4)

Baseline data

Patients

The clinical research team recorded patients' baseline characteristics before registration. Patients' characteristics at baseline related to their demographic data, living circumstances, education, employment, characteristics of current stroke and current verbal, physical and cognitive ability, are shown in *Tables 8–11* (see also *Table 15*).

The mean patient age in control services was 72.5 years (SD 12.84 years) and in intervention services was 70.9 years (SD 13.18 years). The majority of patients were of white ethnic origin [389 (97.5%) control, 388 (96.8%) intervention]. The observed ethnic breakdown is comparable to the ethnic breakdown of the population aged ≥ 65 years in England in 2001.⁸⁵ There were more men than women registered to the trial

TABLE 8 Patient baseline: language and living arrangements

Characteristic	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Age (years)			
Mean (SD)	72.5 (12.84)	70.9 (13.18)	71.7 (13.03)
Median (range)	74.8 (23.2–98.8)	72.6 (22.9–95.7)	73.6 (22.9–98.8)
Missing	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Ethnicity			
White	389 (97.5)	388 (96.8)	777 (97.1)
Mixed – white and black Caribbean	0 (0.0)	2 (0.5)	2 (0.3)
Asian – Indian	3 (0.8)	4 (1.0)	7 (0.9)
Asian – Pakistani	2 (0.5)	0 (0.0)	2 (0.3)
Asian – Bangladeshi	0 (0.0)	1 (0.2)	1 (0.1)
Other Asian background	1 (0.3)	1 (0.2)	2 (0.3)
Black – Caribbean	2 (0.5)	3 (0.7)	5 (0.6)
Other black background	1 (0.3)	1 (0.2)	2 (0.3)
Other ethnic group	1 (0.3)	1 (0.2)	2 (0.3)
Gender			
Male	218 (54.6)	215 (53.6)	433 (54.1)
Female	181 (45.4)	186 (46.4)	367 (45.9)
Preferred language			
English	398 (99.7)	391 (97.5)	789 (98.6)
Other	1 (0.3)	10 (2.5)	11 (1.4)
If other, can read and understand English?			
Yes	0 (0.0)	7 (70.0)	7 (63.6)
No	1 (100.0)	3 (30.0)	4 (36.4)
Lived alone before stroke?			
Yes	149 (37.3)	132 (32.9)	281 (35.1)
No	249 (62.4)	269 (67.1)	518 (64.8)
Missing	1 (0.3)	0 (0.0)	1 (0.1)
What are living arrangements post stroke?			
Live alone	138 (34.6)	118 (29.4)	256 (32.0)
Cohabit with identified carer	105 (26.3)	114 (28.4)	219 (27.4)
Cohabit with other	153 (38.3)	169 (42.1)	322 (40.3)
Missing	3 (0.8)	0 (0.0)	3 (0.4)

TABLE 9 Patient baseline: education and employment

Characteristic	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Has the patient had any formal education?			
Yes	383 (96.0)	380 (94.8)	763 (95.4)
No	15 (3.8)	21 (5.2)	36 (4.5)
Missing	1 (0.3)	0 (0.0)	1 (0.1)
If yes, at what age did the patient leave education?			
≤16 years	282 (73.6)	319 (83.9)	601 (78.8)
17–20 years	83 (21.7)	48 (12.6)	131 (17.2)
≥21 years	14 (3.7)	12 (3.2)	26 (3.4)
Unknown	4 (1.0)	1 (0.3)	5 (0.7)
If yes, has the patient received more education since leaving school?			
Yes	107 (27.9)	131 (34.5)	238 (31.2)
No	264 (68.9)	245 (64.5)	509 (66.7)
Missing	12 (3.1)	4 (1.1)	16 (2.1)
Main employment before stroke			
Working full time (≥30 hours per week)	46 (11.5)	44 (11.0)	90 (11.3)
Working part time (<30 hours per week)	23 (5.8)	20 (5.0)	43 (5.4)
At home and not looking for work (e.g. looking after home/family)	15 (3.8)	15 (3.7)	30 (3.8)
Unemployed and looking for work	7 (1.8)	8 (2.0)	15 (1.9)
Retired	295 (73.9)	287 (71.6)	582 (72.8)
Made redundant/took early retirement	2 (0.5)	5 (1.2)	7 (0.9)
Unable to work (for medical and/or other reasons)	10 (2.5)	20 (5.0)	30 (3.8)
Other	1 (0.3)	2 (0.5)	3 (0.4)

[218 (54.6%) control, 215 (53.6%) in intervention]. In total, 383 (96.0%) in the control services and 380 (94.8%) in the intervention services had received formal education and 282 (73.6%) in the control services and 319 (83.9%) in the intervention services left education at the age of ≤16 years.

Before stroke, 149 (37.3%) patients in control services and 132 (32.9%) patients in intervention services lived alone; post stroke, 138 (34.6%) patients in control services and 118 (29.4%) patients in intervention services planned to live alone. The majority of patients in both treatment arms suffered a cerebral infarction [343 (86.0%) control, 341 (85.0%) intervention]. In control services, 179 (44.9%) patients had left hemiparesis and 165 (41.4%) patients had right hemiparesis; in intervention services, 178 (44.4%) patients had left hemiparesis and 164 (40.9%) patients had right hemiparesis. In total, 60 (15.0%) patients in control services and 84 (20.9%) patients in intervention services had had a previous stroke.

Patient language ability was classified as normal in 323 (81.0%) patients in control services and 295 (73.6%) patients in intervention services. Cognitive function was measured using the 6CIT, with 267 (66.9%) patients in control services and 229 (57.1%) patients in intervention services having normal cognitive function.

TABLE 10 Patient baseline: characteristics of current stroke and length of inpatient stay

Characteristic	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Source of referral to the SCC			
Prior to hospital discharge (including community hospital)	369 (92.5)	354 (88.3)	723 (90.4)
After discharge from hospital (including community hospital)	30 (7.5)	42 (10.5)	72 (9.0)
From the community	0 (0.0)	1 (0.2)	1 (0.1)
Missing	0 (0.0)	4 (1.0)	4 (0.5)
Pathological classification of current stroke			
Cerebral infarction	343 (86.0)	341 (85.0)	684 (85.5)
Primary intracerebral haemorrhage	39 (9.8)	50 (12.5)	89 (11.1)
Unclassified	17 (4.3)	10 (2.5)	27 (3.4)
Clinical classification of stroke symptoms			
Left hemiparesis	179 (44.9)	178 (44.4)	357 (44.6)
Right hemiparesis	165 (41.4)	164 (40.9)	329 (41.1)
Brain stem	9 (2.3)	11 (2.7)	20 (2.5)
Unclassified	46 (11.5)	48 (12.0)	94 (11.8)
Has the patient had a previous stroke?			
Yes	60 (15.0)	84 (20.9)	144 (18.0)
No	336 (84.2)	315 (78.6)	651 (81.4)
Missing	3 (0.8)	2 (0.5)	5 (0.6)
Overall time from admission to discharge for patients with a hospital stay related to this stroke incident (days)			
Mean (SD)	29.5 (34.9)	38.9 (44.4)	34.2 (40.2)
Median (range)	16 (1–305)	23 (1–306)	20 (1–306)
Missing	2 (0.5)	2 (0.5)	4 (0.5)
No. of patients with a hospital stay related to this stroke			
Hospital stay not related to this stroke	3 (0.8)	3 (0.7)	6 (0.8)
Hospital admission did not include a stay in a stroke unit	5 (1.3)	5 (1.3)	10 (1.3)

TABLE 11 Patient baseline: current ability

Characteristic	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Can the patient talk and is he or she orientated?			
Yes	387 (97.0)	378 (94.3)	765 (95.6)
No	12 (3.0)	22 (5.5)	34 (4.3)
Missing	0 (0.0)	1 (0.2)	1 (0.1)
Can the patient lift both arms off the bed?			
Yes	341 (85.5)	333 (83.0)	674 (84.3)
No	56 (14.0)	68 (17.0)	124 (15.5)
Missing	2 (0.5)	0 (0.0)	2 (0.3)
Can the patient walk without help from others?			
Yes	262 (65.7)	257 (64.1)	519 (64.9)
No	135 (33.8)	144 (35.9)	279 (34.9)
Missing	2 (0.5)	0 (0.0)	2 (0.3)
Is the patient's language ability normal?			
Yes	323 (81.0)	295 (73.6)	618 (77.3)
No	76 (19.0)	104 (25.9)	180 (22.5)
Missing	0 (0.0)	2 (0.5)	2 (0.3)
If not, does the patient have dysphasia?			
Yes	56 (73.7)	80 (76.9)	136 (75.6)
No	20 (26.3)	24 (23.1)	44 (24.4)
If the patient has dysphasia, what type of dysphasia?			
Receptive	3 (5.4)	1 (1.3)	4 (2.9)
Expressive	42 (75.0)	65 (81.3)	107 (78.7)
Global	5 (8.9)	4 (5.0)	9 (6.6)
Missing	6 (10.7)	10 (12.5)	16 (11.8)
If not, does the patient have dysarthria?			
Yes	29 (38.2)	30 (28.8)	59 (32.8)
No	47 (61.8)	74 (71.2)	121 (67.2)
Was the patient able to answer the 6CIT?			
Yes	366 (91.7)	361 (90.0)	727 (90.9)
No	33 (8.3)	40 (10.0)	73 (9.1)
If not, why not?			
Stroke-related communication problems	30 (90.9)	31 (77.5)	61 (83.6)
Other	3 (9.1)	9 (22.5)	12 (16.4)

Both treatment arms are balanced across the majority of baseline variables; differences in age when left education (see *Table 9*), language ability (see *Table 11*) and cognitive ability (see *Table 15*) are accounted for in statistical modelling of primary and secondary end points. Differences in the length of inpatient stay (see *Table 10*) could not be used as a covariate as not all patients had an inpatient stay.

The baseline demographic characteristics of patients with carers registered in the trial are shown in *Appendix 8* (see *Tables 71–75*).

Carers

In total, 208 carers consented to participate in the trial, 108 in the intervention group and 100 in the control group. Carer baseline demographics in terms of age, gender, ethnicity, relationship to patient and characteristics of carer education and employment are balanced between the two arms (*Tables 12–14*).

In general, carers were younger than patients, with a mean carer age of 61.4 years (SD 14.07 years) in the control group and 61.0 years (SD 15.02 years) in the intervention group (see *Table 12*).

Researcher-completed baseline questionnaires

The clinical research team completed additional baseline questionnaires with patients including the pre-stroke Barthel Index, the 6CIT and items necessary to derive the Edinburgh stroke case mix adjuster. Scores on these measures are summarised in *Table 15*. Differences in 6CIT scores are accounted for in the statistical modelling of primary and secondary end points.

TABLE 12 Carer baseline demographics and language ability

Characteristic	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Carer age (years)			
Mean (SD)	61.4 (14.07)	61.0 (15.02)	61.2 (14.54)
Median (range)	62.8 (19.4–87.4)	60.7 (23.6–89.6)	62.3 (19.4–89.6)
Missing	1.0 (1.0)	0.0 (0.0)	1.0 (0.5)
Ethnicity			
White	99 (99.0)	105 (97.2)	204 (98.1)
Asian – Indian	0 (0.0)	1 (0.9)	1 (0.5)
Asian – Pakistani	1 (1.0)	0 (0.0)	1 (0.5)
Asian – Bangladeshi	0 (0.0)	1 (0.9)	1 (0.5)
Other ethnic group	0 (0.0)	1 (0.9)	1 (0.5)
Gender			
Male	32 (32.0)	35 (32.4)	67 (32.2)
Female	68 (68.0)	73 (67.6)	141 (67.8)
Preferred language			
English	99 (99.0)	107 (99.1)	206 (99.0)
Other	1 (1.0)	1 (0.9)	2 (1.0)
If other, can read and understand English?			
Yes	1 (100.0)	0 (0.0)	1 (50.0)
No	0 (0.0)	1 (100.0)	1 (50.0)

TABLE 13 Carer baseline: relationship with patient and place of residence

Characteristic	Control (N= 100), n (%)	Intervention (N= 108), n (%)	Total (N=208), n (%)
Carer-patient relationship			
Partner (married/never married/ divorced/separated)	67 (67.0)	70 (64.8)	137 (65.9)
Daughter/son (including in-law, stepchild)	29 (29.0)	33 (30.6)	62 (29.8)
Grandchild	0 (0.0)	1 (0.9)	1 (0.5)
Other relative	3 (3.0)	3 (2.8)	6 (2.9)
Friend/neighbour	1 (1.0)	1 (0.9)	2 (1.0)
Carer place of residence			
Did the carer reside with the patient in the last 12 months?			
Yes	75 (75.0)	81 (75.0)	156 (75.0)
No	25 (25.0)	27 (25.0)	52 (25.0)
Is the planned residence of the carer with the patient?			
Yes	78 (78.0)	85 (78.7)	163 (78.4)
No	22 (22.0)	23 (21.3)	45 (21.6)

TABLE 14 Carer baseline: education and employment

Characteristic	Control (N= 100), n (%)	Intervention (N= 108), n (%)	Total (N=208), n (%)
Has the carer had any formal education?			
Yes	97 (97.0)	103 (95.4)	200 (96.2)
No	3 (3.0)	5 (4.6)	8 (3.8)
If yes, age that the carer left full-time education			
≤16 years	68 (70.1)	76 (73.8)	144 (72.0)
17–20 years	19 (19.6)	21 (20.4)	40 (20.0)
≥21 years	7 (7.2)	6 (5.8)	13 (6.5)
Unknown	3 (3.1)	0 (0.0)	3 (1.5)
If yes, has the carer received further education since?			
Yes	40 (41.2)	45 (43.7)	85 (42.5)
No	53 (54.6)	58 (56.3)	111 (55.5)
Missing	4 (4.1)	0 (0.0)	4 (2.0)
Carer main employment in the last 3 months before patient stroke			
Working full time (≥30 hours per week)	19 (19.0)	20 (18.5)	39 (18.8)
Working part time (≤30 hours per week)	11 (11.0)	13 (12.0)	24 (11.5)
At home and not looking for work (e.g. looking after home/family)	13 (13.0)	15 (13.9)	28 (13.5)
Unemployed and looking for work	3 (3.0)	2 (1.9)	5 (2.4)
Retired	48 (48.0)	47 (43.5)	95 (45.7)
Made redundant/took early retirement	2 (2.0)	2 (1.9)	4 (1.9)
Unable to work (for medical and other reasons)	4 (4.0)	9 (8.3)	13 (6.3)

TABLE 15 Patient baseline questionnaires: researcher completed

Measure	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Pre-stroke Barthel Index			
Mean (SD)	19.2 (1.98)	19.2 (2.22)	19.2 (2.10)
Median (range)	20.0 (7.0–20.0)	20.0 (3.0–20.0)	20.0 (3.0–20.0)
Missing	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Pre-stroke Barthel Index (categorical)			
Independent	311 (77.9)	317 (79.1)	628 (78.5)
Mild disability	70 (17.5)	67 (16.7)	137 (17.1)
Moderate disability	14 (3.5)	12 (3.0)	26 (3.3)
Severe disability	4 (1.0)	5 (1.2)	9 (1.1)
6CIT			
Normal cognitive function	267 (66.9)	229 (57.1)	496 (62.0)
Cognitive impairment	99 (24.8)	132 (32.9)	231 (28.9)
Communication problems	33 (8.3)	40 (10.0)	73 (9.1)
Edinburgh stroke case mix adjuster			
Mean (SD)	0.59 (0.277)	0.59 (0.295)	0.59 (0.286)
Median (range)	0.66 (0.00–0.98)	0.68 (0.00–0.98)	0.67 (0.00–0.98)
Missing	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)

Numbers analysed

All analyses and data summaries were carried out using the ITT population. Per-protocol analysis was undertaken for analyses of primary and secondary end points. Numbers of patients and carers in each population are shown in *Table 16*.

Outcomes and estimation

Patient-reported outcomes

Patient-reported outcomes were collected at three time points: baseline, 6 months and 12 months.

Unadjusted scores

Summaries of unadjusted scores for primary and secondary patient-reported outcomes at baseline and 6 and 12 months are shown in *Table 17*. Baseline unadjusted scores are balanced between treatment arms.

TABLE 16 Patient and carer populations

Population	Control, n	Intervention, n	Total, n
ITT – patients	399	401	800
Per protocol – patients	300	301	601
ITT – carers	100	108	208
Per protocol – carers	73	82	155

TABLE 17 Patient unadjusted questionnaire scores at different time points by arm

Questionnaire	Baseline, [mean (SD)]		6 months, [mean (SD)]		12 months, [mean (SD)]	
	Control	Intervention	Control	Intervention	Control	Intervention
Barthel Index <i>n</i>	15.2 (4.48) 398	14.4 (5.06) 401	16.2 (4.24) 296	15.5 (4.48) 307	16.3 (3.91) 266	15.7 (4.26) 282
GHQ-12 <i>n</i>	15.2 (7.26) 396	15.9 (7.03) 397	15.3 (7.32) 305	16.2 (7.17) 318	14.5 (6.78) 268	14.3 (6.87) 281
EQ-5D <i>n</i>	0.56 (0.340) 382	0.51 (0.378) 381	0.61 (0.339) 288	0.56 (0.322) 301	0.61 (0.316) 259	0.54 (0.318) 270
FAI <i>n</i>	28.1 (9.71) 398	27.8 (9.70) 399	20.3 (11.41) 293	18.4 (11.27) 304	21.5 (11.30) 266	18.8 (11.53) 281

Adjusted scores

Two-level hierarchical modelling was used to compare the intervention and control groups, with patient-level covariates (baseline Barthel Index score, baseline GHQ-12 score, gender, age, living circumstances, stroke severity and baseline 6CIT score) being level 1 and service-level covariates (quality of stroke unit, referral rate, SCC working alone or in a team) being level 2. In all models we allowed for different variances between the treatment arms.

A summary of the adjusted scores, differences in scores with 95% CIs, *p*-values and adjusted ICCs for each treatment arm for the primary and secondary end points at 6 and 12 months is provided in *Table 18*.

TABLE 18 Patient adjusted questionnaire scores at 6 and 12 months

Questionnaire	Control, mean (SE) <i>n</i>	Intervention, mean (SE) <i>n</i>	Difference (SE)	95% CI of the difference	<i>p</i> -value	Adjusted ICC	
						Control	Intervention
6 months							
GHQ-12	14.9 (0.60) 300	15.5 (0.60) 310	-0.6 (0.65)	-1.8 to 0.7	0.394	0.013	0.025
Barthel Index	15.8 (0.33) 296	15.3 (0.28) 307	0.5 (0.33)	-0.2 to 1.1	0.133	0.022	0.000
EQ-5D	0.58 (0.025) 288	0.55 (0.022) 301	0.03 (0.025)	-0.02 to 0.08	0.252	0.014	0.059
FAI	19.0 (0.76) 293	18.0 (0.76) 304	1.0 (0.80)	-0.6 to 2.5	0.229	0.000	0.014
12 months							
GHQ-12	14.4 (0.58) 268	13.9 (0.72) 281	0.5 (0.73)	-0.9 to 2.0	0.454	0.000	0.063
Barthel Index	15.6 (0.36) 266	15.4 (0.30) 282	0.2 (0.37)	-0.5 to 0.9	0.585	0.049	0.023
EQ-5D	0.56 (0.030) 259	0.51 (0.028) 270	0.05 (0.033)	-0.02 to 0.11	0.167	0.050	0.044
FAI	20.2 (0.78) 266	18.7 (0.84) 281	1.5 (0.87)	-0.2 to 3.2	0.078	0.000	0.025
SE, standard error.							

The primary and secondary analyses were based on a complete case analysis with no substitution for missing patient-level outcome data; numbers of patients analysed for each end point are shown in *Table 18*.

In the analysis of the primary end point, the adjusted GHQ-12 mean score at 6 months was 14.9 [standard error (SE) 0.6] in the control group and 15.5 (SE 0.6) in the intervention group, a difference of -0.6 points (95% CI -1.8 to 0.7 points), with a p -value of 0.394 and an adjusted ICC of 0.013 for the control group and 0.025 for the intervention group, indicating that there is no statistical evidence of a significant difference between the treatment groups in psychological outcomes for stroke patients living at home at 6 months, as measured by the GHQ-12.

Results for secondary end points (Barthel Index, EQ-5D and FAI at 6 and 12 months and GHQ-12 at 12 months; see *Table 18*) also indicate that there are no statistically significant differences between the treatment groups for any of the secondary end points.

Longer-term Unmet Needs after Stroke questionnaire

Summaries of the patient-completed LUNS questionnaire at 6 and 12 months, showing the number of unmet needs out of a possible 22, are provided in *Tables 19* and *20* respectively. The numbers and types of unmet needs reported were similar for the control group and the intervention group at 6 and

TABLE 19 Longer-term Unmet Needs after Stroke questionnaire: number of unmet needs for patients at 6 months

No. of unmet needs at 6 months	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
0	57 (14.3)	43 (10.7)	100 (12.5)
1	46 (11.5)	46 (11.5)	92 (11.5)
2	44 (11.0)	41 (10.2)	85 (10.6)
3	25 (6.3)	39 (9.7)	64 (8.0)
4	28 (7.0)	31 (7.7)	59 (7.4)
5	15 (3.8)	16 (4.0)	31 (3.9)
6	18 (4.5)	17 (4.2)	35 (4.4)
7	15 (3.8)	18 (4.5)	33 (4.1)
8	13 (3.3)	17 (4.2)	30 (3.8)
9	8 (2.0)	8 (2.0)	16 (2.0)
10	3 (0.8)	10 (2.5)	13 (1.6)
11	3 (0.8)	5 (1.2)	8 (1.0)
12	7 (1.8)	1 (0.2)	8 (1.0)
13	4 (1.0)	7 (1.7)	11 (1.4)
14	2 (0.5)	1 (0.2)	3 (0.4)
15	1 (0.3)	1 (0.2)	2 (0.3)
16	0 (0.0)	1 (0.2)	1 (0.1)
17	1 (0.3)	0 (0.0)	1 (0.1)
18	0 (0.0)	1 (0.2)	1 (0.1)
Missing	109 (27.3)	98 (24.4)	207 (25.9)

TABLE 20 Longer-term Unmet Needs after Stroke questionnaire: number of unmet needs for patients at 12 months

No. of unmet needs at 12 months	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
0	62 (15.5)	62 (15.5)	124 (15.5)
1	35 (8.8)	36 (9.0)	71 (8.9)
2	34 (8.5)	43 (10.7)	77 (9.6)
3	29 (7.3)	31 (7.7)	60 (7.5)
4	20 (5.0)	28 (7.0)	48 (6.0)
5	21 (5.3)	11 (2.7)	32 (4.0)
6	11 (2.8)	12 (3.0)	23 (2.9)
7	12 (3.0)	19 (4.7)	31 (3.9)
8	10 (2.5)	8 (2.0)	18 (2.3)
9	10 (2.5)	7 (1.7)	17 (2.1)
10	6 (1.5)	7 (1.7)	13 (1.6)
11	4 (1.0)	3 (0.7)	7 (0.9)
12	2 (0.5)	6 (1.5)	8 (1.0)
13	3 (0.8)	2 (0.5)	5 (0.6)
14	1 (0.3)	1 (0.2)	2 (0.3)
15	1 (0.3)	0 (0.0)	1 (0.1)
18	1 (0.3)	0 (0.0)	1 (0.1)
21	0 (0.0)	1 (0.2)	1 (0.1)
Missing	137 (34.3)	124 (30.9)	261 (32.6)

12 months. A median of 2.5 unmet needs were reported, and the prevalence of individual unmet needs ranged from 2% to 51% of those completing the questionnaire (*Figure 5*). The most commonly reported unmet need was for more information; this was followed by unmet needs in the areas of falls, memory/concentration, accessible holidays and pain, all reported by over one-fifth of responders.

Carer-reported outcomes

Unadjusted scores

Carer unadjusted outcome scores are shown in *Table 21*. The carer baseline GHQ-12 score is 1.7 points higher in the intervention group than in the control group. This difference is accounted for in the statistical modelling of the carer GHQ-12 end point.

Adjusted scores

Carer-reported outcomes were also assessed using two-level hierarchical models allowing for different variances between the treatment arms, with carer-level covariates (carer gender, education, patient baseline Barthel Index score) being level 1 and service-level covariates (quality of stroke unit, referral rate, SCC working alone or in a team) being level 2. A summary of the adjusted scores, differences between the scores, 95% CIs, *p*-values and adjusted ICCs for each treatment arm at 6 and 12 months is provided in *Table 22*.

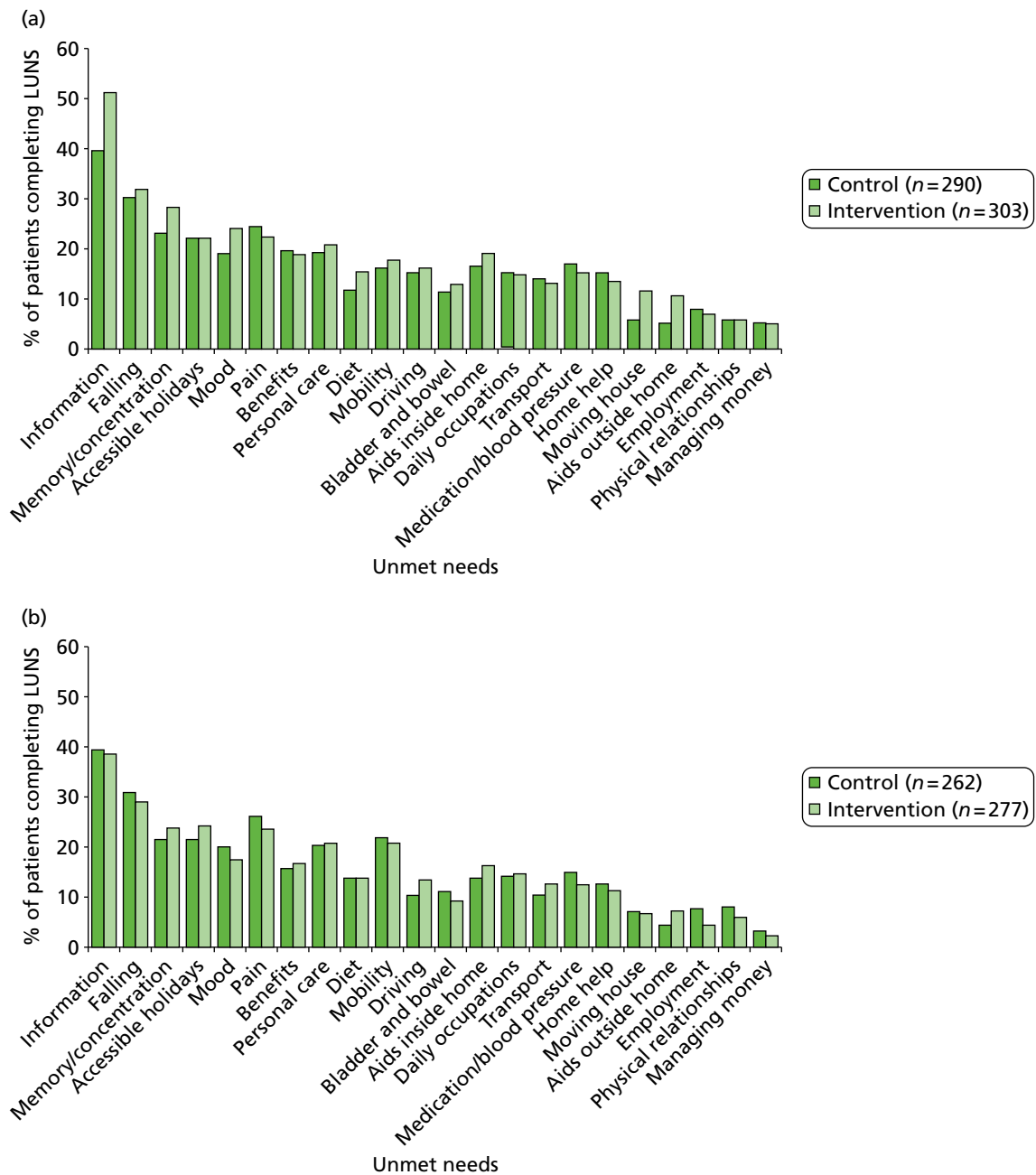


FIGURE 5 Prevalence of individual unmet needs: (a) 6 months; and (b) 12 months.

TABLE 21 Carer unadjusted questionnaire scores at different time points by arm

Questionnaire	Baseline, mean (SD) <i>n</i>		6 months, mean (SD) <i>n</i>		12 months, mean (SD) <i>n</i>	
	Control	Intervention	Control	Intervention	Control	Intervention
GHQ-12	14.0 (6.61) 100	15.7 (6.30) 108	12.8 (6.00) 82	15.3 (6.23) 80	13.0 (5.68) 71	14.3 (5.77) 73
CBS	N/A	N/A	44.8 (14.58) 81	48.7 (13.82) 80	44.3 (15.23) 71	48.2 (15.15) 72
General strain	N/A	N/A	2.23 (0.789) 82	2.48 (0.793) 80	2.19 (0.853) 71	2.45 (0.805) 72
Isolation	N/A	N/A	2.17 (0.808) 81	2.27 (0.772) 80	2.20 (0.768) 71	2.28 (0.840) 72
Disappointment	N/A	N/A	2.15 (0.790) 82	2.33 (0.812) 80	2.12 (0.886) 71	2.34 (0.807) 73
Emotional involvement	N/A	N/A	1.61 (0.625) 81	1.69 (0.632) 79	1.58 (0.585) 71	1.63 (0.638) 72
Environment	N/A	N/A	1.61 (0.640) 81	1.80 (0.688) 80	1.60 (0.686) 71	1.75 (0.725) 72

N/A, not applicable.

TABLE 22 Carer adjusted questionnaire scores at 6 and 12 months

Questionnaire	Control, mean (SE) <i>n</i>	Intervention, mean (SE) <i>n</i>	Difference (SE)	95% CI of the difference	<i>p</i> -value	Adjusted ICC	
						Control	Intervention
6 months							
GHQ-12	12.5 (0.69) 82	14.2 (0.79) 80	-1.7 (0.91)	-3.5 to 0.1	0.061	0.000	0.000
CBS	44.5 (2.19) 81	48.4 (1.80) 80	-3.9 (2.51)	-8.8 to 1.1	0.125	0.055	0.000
12 months							
GHQ-12	13.5 (1.11) 71	13.9 (0.85) 73	-0.4 (1.26)	-2.9 to 2.1	0.747	0.255	0.000
CBS	43.9 (2.85) 71	48.7 (2.12) 72	-4.8 (3.17)	-11.1 to 1.5	0.132	0.137	0.000

Comparison of adjusted scores for the carer-reported outcomes of GHQ-12 and CBS at 6 and 12 months indicates that there is no evidence of statistical differences in either of these outcomes between the intervention group and the control group.

Ancillary analyses

Per-protocol analyses

Per-protocol analyses were undertaken as there were a considerable number of protocol violators and patients not receiving care from SCCs. Per-protocol analyses were also undertaken for carers of patients from the per-protocol population.

Patients

In total, 601 patients were included in the per-protocol population, 300 in the control group and 301 in the intervention group (see *Table 16*).

Analyses on the per-protocol population were conducted for all end points and the results of these analyses are consistent with those of the ITT analyses, indicating that there is no evidence of a statistically significant difference in any patient-reported outcomes at 6 or 12 months between the treatment arms for this population of patients (Table 23).

Carers

In total, 155 carers were included in the per-protocol population, 73 in the control group and 82 in the intervention group. Results from the analyses of end points based on the per-protocol population indicate that, for this population of carers, there is no evidence of any statistically significant differences between the treatment arms (Table 24).

TABLE 23 Patient adjusted questionnaire scores at 6 and 12 months: per-protocol population

Questionnaire	Control, mean (SE) n	Intervention, mean (SE) n	Difference (SE)	95% CI of the difference	p-value	Adjusted ICC	
						Control	Intervention
6 months							
GHQ-12	14.0 (0.69) 228	14.8 (0.78) 248	-0.8 (0.76)	-2.3 to 0.7	0.280	0.000	0.058
Barthel Index	15.7 (0.35) 228	15.4 (0.34) 244	0.3 (0.33)	-0.3 to 1.0	0.310	0.000	0.000
EQ-5D	0.57 (0.028) 223	0.56 (0.025) 228	0.01 (0.026)	-0.04 to 0.07	0.602	0.007	0.000
FAI	18.9 (0.90) 225	17.9 (0.87) 467	1.0 (0.87)	-0.7 to 2.7	0.240	0.000	0.011
12 months							
GHQ-12	13.8 (0.70) 201	12.9 (0.85) 227	0.8 (0.85)	-0.9 to 2.5	0.336	0.000	0.097
Barthel Index	15.6 (0.35) 203	15.6 (0.36) 226	0.0 (0.37)	-0.8 to 0.7	0.933	0.000	0.036
EQ-5D	0.55 (0.033) 199	0.52 (0.032) 215	0.03 (0.034)	-0.03 to 0.1	0.328	0.034	0.046
FAI	20.0 (0.93) 201	18.2 (0.95) 225	1.7 (0.94)	-0.1 to 3.6	0.069	0.000	0.016

TABLE 24 Carer adjusted questionnaire scores at 6 and 12 months: per-protocol population

Questionnaire	Control, mean (SE) n	Intervention, mean (SE) n	Difference (SE)	95% CI of the difference	p-value	Adjusted ICC	
						Control	Intervention
6 months							
GHQ-12	12.6 (0.82) 58	14.0 (0.90) 67	-1.4 (1.04)	-3.5 to 0.7	0.181	0.000	0.000
CBS	45.5 (2.64) 57	49.7 (2.25) 67	-4.3 (3.02)	-10.2 to 1.7	0.162	0.073	0.037
12 months							
GHQ-12	13.7 (1.18) 51	14.2 (0.95) 61	-0.50 (1.34)	-3.2 to 2.1	0.707	0.145	0.000
CBS	45.1 (2.80) 51	50.1 (2.46) 60	-5.0 (3.22)	-11.4 to 1.3	0.120	0.054	0.025

Sensitivity analyses

Sensitivity analyses were undertaken to examine the robustness of the conclusions of the primary analysis. The results from these analyses are shown in *Table 25* and support the conclusions of the primary analysis, that is, that there is no evidence of any statistically significant differences between the control group and the intervention group in terms of GHQ-12 scores.

Adverse events

Deaths, hospital readmissions, institutionalisation and treatment on an emergency outpatient basis were reported at 6 and 12 months' follow-up by the clinical research team using health and social care records.

Deaths

Throughout the trial, no safety issues were highlighted. Overall, 67 patient deaths were reported, 32 in the control group and 35 in the intervention group; most of these occurred in hospital and within the first 6 months of registration, as shown in *Table 26* and *Figure 6*.

TABLE 25 Sensitivity analyses for the primary end point: patient adjusted GHQ-12 scores at 6 months

Analysis	Control, mean (SE) <i>n</i>	Intervention, mean (SE) <i>n</i>	Difference (SE)	95% CI of the difference	<i>p</i> -value	Adjusted ICC	
						Control	Intervention
Patients who died (GHQ-12 score assigned to be 36)	17.5 (0.67) 325	18.3 (0.61) 342	-0.8 (0.68)	-2.1 to 0.6	0.263	0.004	0.000
Excluding those who provided the primary end point by telephone	15.0 (0.62) 294	15.5 (0.60) 308	-0.5 (0.66)	-1.8 to 0.8	0.436	0.018	0.027
Excluding proxy responses	14.7 (0.62) 296	15.2 (0.63) 294	-0.5 (0.63)	-1.7 to 0.7	0.427	0.009	0.021
Data from 12 months used for patients who did not return their questionnaires at 6 months	14.9 (0.57) 319	15.7 (0.61) 331	-0.7 (0.64)	-2.0 to 0.5	0.251	0.007	0.031
Multiple imputation	15.4 (0.59) 399	15.9 (0.58) 401	-0.5 (0.59)	-1.7 to 0.6	0.370	N/A ^a	N/A ^a

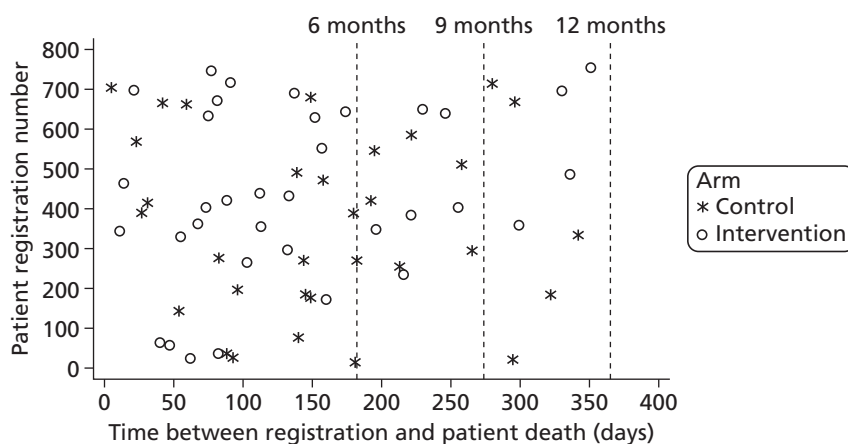
^a Not available – unable to obtain ICCs from multiple imputation as estimates in some of the imputations had an ICC of zero.

TABLE 26 Total patient deaths and place of death

Time/Location of death	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Deaths			
6 months ^a	27 (6.8)	31 (7.7)	58 (7.3)
12 months	5 (1.3)	4 (1.0)	9 (1.1)
After 12-month follow-up ^b	2 (0.5)	2 (0.5)	4 (0.5)
Total	32 (8.0)	35 (8.7)	67 (8.4)
Place of death			
Home	2 (0.5)	4 (1.0)	6 (0.8)
Hospital	23 (5.8)	19 (4.7)	42 (5.3)
Nursing home	3 (0.8)	3 (0.7)	6 (0.8)
Unknown	3 (0.8)	7 (1.7)	10 (1.3)
Other	1 (0.3)	2 (0.5)	3 (0.4)

a Summary of all deaths up to 9 months from registration (end of 6-month follow-up).

b These deaths are not included in the total death count or place of death as they were reported after the follow-up period.

**FIGURE 6** Time between registration and patient death.

One carer death was reported in the control group, which occurred 7 days after the carer was registered to the trial.

Treatment on an emergency outpatient basis and hospital admissions

Information on further treatment on an emergency outpatient basis and hospital admissions as reported by researchers at 6 and 12 months, is summarised in *Tables 27* and *28* respectively. In the first 6 months after registration, 105 (26.3%) patients in the control group and 113 (28.2%) patients in the intervention group visited an A&E department and 113 (28.3%) patients in the control group and 97 (24.2%) patients in the intervention group were admitted to hospital overnight. Between 6 and 12 months post registration, 71 (17.8%) patients in the control group and 77 (19.2%) patients in the intervention group visited an A&E department and 74 (18.5%) patients in the control group and 77 (19.2%) patients in the intervention group were admitted to hospital overnight.

TABLE 27 Six-month researcher-completed follow-up summary

6-month summary	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Follow-up form completed?			
Yes	395 (99.0)	400 (99.8)	795 (99.4)
Withdrawn	4 (1.0)	1 (0.2)	5 (0.6)
Patient visited A&E in the past 6 months?			
Yes	105 (26.3)	113 (28.2)	218 (27.3)
No	290 (72.7)	261 (65.1)	551 (68.9)
Missing	4 (1.0)	27 (6.7)	31 (3.9)
Number of A&E visits per patient			
Mean (SD)	0.4 (0.95)	0.4 (0.83)	0.4 (0.89)
Median (range)	0.0 (0.0–8.0)	0.0 (0.0–7.0)	0.0 (0.0–8.0)
Patient admitted to hospital overnight in the past 6 months?			
Yes	113 (28.3)	97 (24.2)	210 (26.3)
No	282 (70.7)	303 (75.6)	585 (73.1)
Missing	4 (1.0)	1 (0.2)	5 (0.6)
Number of hospital admissions			
Mean (SD)	0.4 (0.93)	0.3 (0.66)	0.4 (0.81)
Median (range)	0.0 (0.0–10.0)	0.0 (0.0–5.0)	0.0 (0.0–10.0)
Number of patients who died during hospital admission	13 (3.3)	10 (2.5)	23 (2.9)
Number of patients who spent time in a specialist care unit	8 (2.0)	4 (1.0)	12 (1.5)
Number of times admitted to a specialist care unit			
Mean (SD)	0.0 (0.20)	0.0 (0.13)	0.0 (0.17)
Median (range)	0.0 (0.0–3.0)	0.0 (0.0–2.0)	0.0 (0.0–3.0)
Time spent in a specialist care unit (days)			
Mean (SD)	0.2 (1.36)	0.0 (0.63)	0.1 (1.06)
Median (range)	0.0 (0.0–20.0)	0.0 (0.0–11.0)	0.0 (0.0–20.0)

TABLE 28 Twelve-month researcher-completed follow-up summary

12-month summary	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Follow-up form completed?			
Yes	374 (93.7)	374 (93.3)	748 (93.5)
Died	21 (5.3)	26 (6.5)	47 (5.9)
Withdrawn	4 (1.0)	1 (0.2)	5 (0.6)
Patient visited A&E in the past 6 months?			
Yes	71 (17.8)	77 (19.2)	148 (18.5)
No	303 (75.9)	275 (68.6)	578 (72.3)
Missing	25 (6.3)	49 (12.2)	74 (9.3)
Number of A&E visits per patient			
Mean (SD)	0.3 (1.17)	0.3 (0.66)	0.3 (0.95)
Median (range)	0.0 (0.0–19.0)	0.0 (0.0–4.0)	0.0 (0.0–19.0)
Patient admitted to hospital overnight in the past 6 months?			
Yes	74 (18.5)	77 (19.2)	151 (18.9)
No	300 (75.2)	297 (74.1)	597 (74.6)
Missing	25 (6.3)	27 (6.7)	52 (6.5)
Number of hospital admissions			
Mean (SD)	0.3 (0.73)	0.3 (0.68)	0.3 (0.71)
Median (range)	0.0 (0.0–5.0)	0.0 (0.0–4.0)	0.0 (0.0–5.0)
Number of patients who died during hospital admission	3 (0.8)	5 (1.2)	8 (1.0)
Number of patients who spent time in a specialist care unit	2 (0.5)	4 (1.0)	6 (0.8)
Number of times admitted to a specialist care unit			
Mean (SD)	0.0 (0.07)	0.0 (0.13)	0.0 (0.11)
Median (range)	0.0 (0.0–1.0)	0.0 (0.0–2.0)	0.0 (0.0–2.0)
Time spent in a specialist care unit (days)			
Mean (SD)	0.0 (0.29)	0.0 (0.56)	0.0 (0.45)
Median (range)	0.0 (0.0–5.0)	0.0 (0.0–10.0)	0.0 (0.0–10.0)

Related and unexpected serious adverse events

No related and unexpected serious adverse events were reported.

Withdrawals

Withdrawals of patients and carers from the trial are shown in *Tables 29* and *30* respectively. Overall, there were 49 withdrawals among the patients and more patients and carers withdrew in the control group than in the intervention group (35 patients and 8 carers in the control group and 14 patients and two carers in the intervention group).

TABLE 29 Patient withdrawals and types of withdrawal

	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Withdrawals			
6 months	21 (5.3)	6 (1.5)	27 (3.4)
12 months	14 (3.5)	8 (2.0)	22 (2.8)
After 12-month follow-up ^a	3 (0.8)	2 (0.5)	5 (0.6)
Total	35 (8.8)	14 (3.5)	49 (6.1)
Type of withdrawal			
Patient withdrew consent for postal follow-up	31 (7.8)	13 (3.2)	44 (5.5)
Patient withdrew consent for all follow-up	4 (1.0)	1 (0.2)	5 (0.6)

a Not included in the total withdrawals or types of withdrawal.

TABLE 30 Carer withdrawals

	Control (N= 100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
6 months	5 (5.0)	1 (0.9)	6 (2.9)
12 months	3 (3.0)	1 (0.9)	4 (1.9)
Total	8 (8.0)	2 (1.9)	10 (4.8)

Process data: implementation of control and intervention services

Completion of process data

Control services were asked to complete a time log for all patients summarising the contacts. Intervention services were asked to complete the care plan for all contacts with all patients. *Table 31* shows the completion of the time logs and *Table 32* shows the completion of the care plans. Of patients registered to the trial, 314 (78.7%) and 318 (79.3%) received the SCC service in the control and intervention arms respectively. Reasons for not receiving the service include the SCC not receiving a referral, the patient declining to receive the service, patient death or patient not contactable. SCCs completed time logs for 207 (51.9%) patients in the control arm and completed care plans for 283 (70.6%) patients in the intervention arm. Of the 283 completed care plans, three had all contacts completed > 12 months after patient registration to the trial.

For control services, the relationship between the adjusted mean primary outcome and the mean percentage of completed time logs (of registered patients) by service is shown in *Figure 7*. There is no linear trend between the percentage of completed time logs observed and services' adjusted means.

TABLE 31 Completion of time logs

Service	Registered, n (%)	Time log completed		Reasons not completed					Patient died before receiving SCC service, n (%)	SCC unable to contact patient, n (%)	Patient withdrew from all follow-up, n (%)	Received SCC service, no time log completed, n (%)
		Yes, n (%)	No, n (%)	Referral not received by SCC, n (%)	Patient declined SCC service, n (%)	Referral not received by SCC, n (%)	Patient died before receiving SCC service, n (%)	SCC unable to contact patient, n (%)				
Total	399 (100.0)	207 (51.9)	192 (48.1)	67 (34.9)	9 (4.7)	3 (1.6)	2 (1.0)	4 (2.1)	107 (55.7)			
S001	15 (3.8)	8 (53.3)	7 (46.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)			
S003	18 (4.5)	8 (44.4)	10 (55.6)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	5 (50.0)			
S004	32 (8.0)	20 (62.5)	12 (37.5)	1 (8.3)	1 (8.3)	1 (8.3)	0 (0.0)	1 (8.3)	8 (66.7)			
S008	25 (6.3)	22 (88.0)	3 (12.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)			
S010	17 (4.3)	13 (76.5)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	3 (75.0)			
S011	45 (11.3)	18 (40.0)	27 (60.0)	13 (48.1)	7 (25.9)	0 (0.0)	0 (0.0)	0 (0.0)	7 (25.9)			
S014	29 (7.3)	5 (17.2)	24 (82.8)	7 (29.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	17 (70.8)			
S015	46 (11.5)	35 (76.1)	11 (23.9)	1 (9.1)	0 (0.0)	1 (9.1)	1 (9.1)	0 (0.0)	8 (72.7)			
S018	35 (8.8)	4 (11.4)	31 (88.6)	14 (45.2)	1 (3.2)	0 (0.0)	1 (3.2)	0 (0.0)	15 (48.4)			
S019	45 (11.3)	33 (73.3)	12 (26.7)	4 (33.3)	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	7 (58.3)			
S022	19 (4.8)	3 (15.8)	16 (84.2)	13 (81.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (18.8)			
S025	18 (4.5)	7 (38.9)	11 (61.1)	4 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (63.6)			
S029	41 (10.3)	25 (61.0)	16 (39.0)	6 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (62.5)			
S032	14 (3.5)	6 (42.9)	8 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	7 (87.5)			

TABLE 32 Completion of care plans

Service	Registered, n (%)	Care plan completed		Reasons not completed						Patient withdrew from all follow-up, n (%)	Received SCC service, no care plan completed, n (%)
		Yes, n (%)	No, n (%)	Referral not received by SCC, n (%)	Patient declined SCC service, n (%)	Patient died before receiving SCC service, n (%)	SCC unable to contact patient, n (%)	SCC unable to contact patient, n (%)	SCC unable to contact patient, n (%)		
Total	401 (100.0)	283 (70.6)	118 (29.4)	45 (38.1)	21 (17.8)	14 (11.9)	2 (1.7)	1 (0.8)	35 (29.7)		
S002	27 (6.7)	20 (74.1)	7 (25.9)	0 (0.0)	0 (0.0)	2 (28.6)	0 (0.0)	1 (14.3)	4 (57.1)		
S005	19 (4.7)	15 (78.9)	4 (21.1)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (75.0)		
S006	30 (7.5)	26 (86.7)	4 (13.3)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)		
S007	31 (7.7)	28 (90.3)	3 (9.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)		
S009	17 (4.2)	16 (94.1)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)		
S012	45 (11.2)	25 ^a (55.6)	20 (44.4)	8 (40.0)	4 (20.0)	2 (10.0)	0 (0.0)	0 (0.0)	6 (30.0)		
S013	45 (11.2)	33 ^b (73.3)	12 (26.7)	8 (66.7)	1 (8.3)	2 (16.7)	0 (0.0)	0 (0.0)	1 (8.3)		
S016	27 (6.7)	19 (70.4)	8 (29.6)	2 (25.0)	1 (12.5)	4 (50.0)	1 (12.5)	0 (0.0)	0 (0.0)		
S020	2 (0.5)	1 (50.0)	1 (50.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
S023	13 (3.2)	11 (84.6)	2 (15.4)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)		
S024	27 (6.7)	10 (37.0)	17 (63.0)	4 (23.5)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	12 (70.6)		
S026	45 (11.2)	29 (64.4)	16 (35.6)	8 (50.0)	5 (31.3)	0 (0.0)	1 (6.3)	0 (0.0)	2 (12.5)		
S027	26 (6.5)	26 (100.0)	0 (0.0)	N/A	N/A	N/A	N/A	N/A	N/A		
S030	29 (7.2)	10 (34.5)	19 (65.5)	10 (52.6)	5 (26.3)	3 (15.8)	0 (0.0)	0 (0.0)	1 (5.3)		
S031	18 (4.5)	14 (77.8)	4 (22.2)	2 (50.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)		

N/A, not applicable.

a One care plan with all contacts completed > 12 months after registration.

b Two care plans with all contacts completed > 12 months after registration.

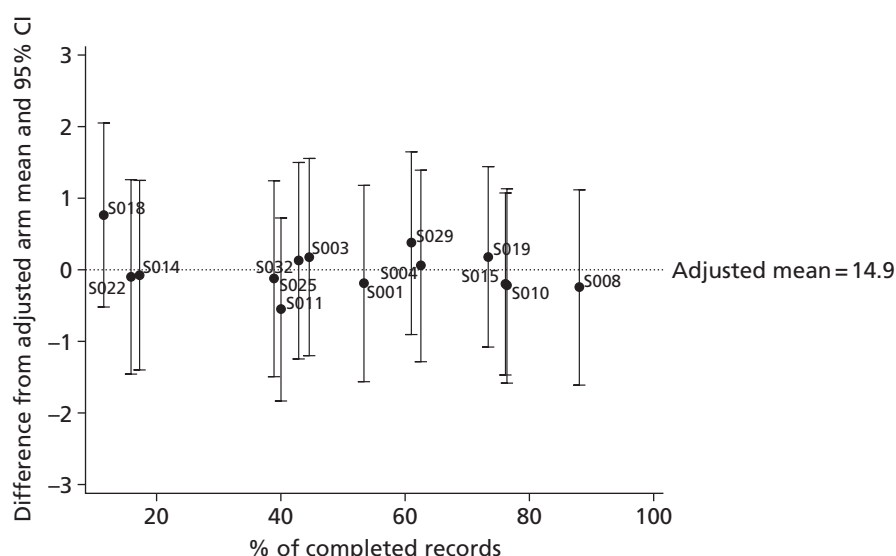


FIGURE 7 Adjusted differences of each service from adjusted control mean in GHQ-12 scores ordered by service completion of time logs: control.

Compliance with the intervention

Compliance with the intervention assessed from completed care plans is shown by service in *Table 33*. Compliance with the intervention was defined as at least 12 of 16 (75%) assessment areas (each linked to a reference guide in the manual) asked on patient contact 1 of the care plan (with at least one question in the assessment area being asked). In total, 10 care plans were not compliant and 269 (96.1%) met the definition of compliance.

TABLE 33 Compliance with completion of care plans

Service	Compliant record, n (%)	Non-compliant record, n (%)	Missing, n (%)	Care plan completed, n (%)
S002	19 (95.0)	0 (0.0)	1 ^a (5.0)	20 (7.1)
S005	15 (100.0)	0 (0.0)	0 (0.0)	15 (5.4)
S006	25 (96.2)	1 (3.8)	0 (0.0)	26 (9.3)
S007	28 (100.0)	0 (0.0)	0 (0.0)	28 (10.0)
S009	16 (100.0)	0 (0.0)	0 (0.0)	16 (5.7)
S012	24 (100.0)	0 (0.0)	0 (0.0)	24 (8.6)
S013	31 (100.0)	0 (0.0)	0 (0.0)	31 (11.1)
S016	18 (94.7)	1 (5.3)	0 (0.0)	19 (6.8)
S020	1 (100.0)	0 (0.0)	0 (0.0)	1 (0.4)
S023	11 (100.0)	0 (0.0)	0 (0.0)	11 (3.9)
S024	10 (100.0)	0 (0.0)	0 (0.0)	10 (3.6)
S026	28 (96.6)	1 (3.4)	0 (0.0)	29 (10.4)
S027	20 (76.9)	6 (23.1)	0 (0.0)	26 (9.3)
S030	9 (90.0)	1 (10.0)	0 (0.0)	10 (3.6)
S031	14 (100.0)	0 (0.0)	0 (0.0)	14 (5.0)
Total	269 (96.1)	10 (3.6)	1 (0.4)	280 (100.0)

^a Only the front page of the care plan was completed; no assessment contacts were used.

For intervention services, the relationship between the adjusted mean primary outcome and the mean percentage of compliant care plans (of registered patients) by service is shown in *Figure 8*. There is larger variation in adjusted scores for services with higher compliance, but no linear trend is observed between the percentage of compliant care plans and services' adjusted mean scores.

Number of patient contacts

The numbers of SCC contacts within 12 months of registration to the trial for patients with completed time logs or completed care plans are shown in *Table 34* (it should be noted that in some cases SCCs continued to see patients post 12 months; only data up to 12 months are included). Both control services and intervention services had a median of two SCC contacts with patients. The median number of contacts per service ranged from 1 to 4 for control services and from 1 to 4.5 for intervention services (see *Appendix 9*).

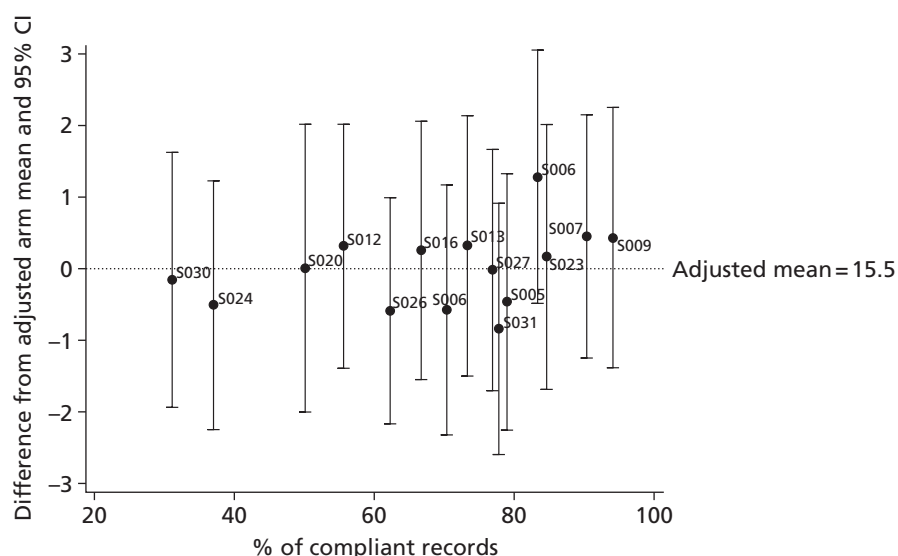


FIGURE 8 Adjusted differences of each service from adjusted intervention mean in GHQ-12 scores ordered by service compliance with care plans: intervention.

TABLE 34 Number of patient contacts

Patient contacts	Control (N=207)	Intervention (N=280)
Number of patient contacts within 12 months of registration		
Mean (SD)	2.3 (1.46)	2.1 (1.15)
Median (range)	2.0 (1.0–7.0)	2.0 (1.0–6.0)
Missing	3	1
Number of patient contacts within 12 months of registration, n (%)		
Missing	3 (1.4)	1 (0.4)
1	81 (39.1)	98 (35.0)
2	49 (23.7)	99 (35.4)
3	35 (16.9)	47 (16.8)
4	19 (9.2)	23 (8.2)
5	10 (4.8)	8 (2.9)
6	9 (4.3)	4 (1.4)
7	1 (0.5)	

The median duration from registration to the first/last contact was 14/57.5 days and 27/103 days in the control services and intervention services respectively. In total, 76% of control service contacts were face to face and 94% of intervention service contacts were face to face. In addition, 68% of intervention service contacts took place in the patient's home (these data were not collected for control services).

Delivery of the intervention

The overall proportion of assessment areas asked at contact 1 was 94% and ranged from 80% to 93% at subsequent contacts. A median of three problem areas were identified in the assessment at contact 1, dropping to one or fewer at subsequent contacts (*Table 35*); this is the same as the median number of problems addressed in the goal and action planner. A median of three goals/actions were set at contact 1, dropping to two at contact 2 and one or less at subsequent contacts; these comprise both SCC and patient goals/actions. Data were collected on the number of goals/actions achieved; however, this section of the care plan was poorly completed by SCCs and therefore has not been reported.

Apart from assessment area 13 (sexual functioning), at least 90% of patients were asked each of the assessment areas at contact 1. In total, 63% of patients were asked about sexual functioning at contact 1, increasing to 76–100% at subsequent contacts. At least 80% of patients were asked about the other assessment areas at contacts 2–4; this value was slightly lower for some of the assessment areas at contacts 5 and 6 because these areas had already been addressed. *Table 36* shows the assessment areas in which problems were identified. At contact 1, the most common problem areas, affecting at least one-third of patients, were medicines/general health, mobility/falls, personal hygiene/dressing, mood and 'other' problems (including speech and language, limb weakness/numbness, visual problems, swallowing, sleep/fatigue and employment). Apart from mood and sexual functioning, the prevalence of all problem areas had substantially reduced by contact 2 and generally continued to reduce at subsequent contacts. The prevalence of mood (and sexual functioning) problems remained similar until contact 3, after which a reduction was observed. After an initial reduction, the prevalence of social need problems remained constant from contact 2 to contact 5.

TABLE 35 Care plans: summary of problems and goals/actions

Care plan summary	Contact 1 (n=279)	Contact 2 (n=181)	Contact 3 (n=82)	Contact 4 (n=37)	Contact 5 (n=12)	Contact 6 (n=4)
Problem areas identified in the assessment						
Mean (SD)	3.9 (2.90)	1.8 (1.71)	1.4 (1.34)	0.9 (1.16)	0.5 (1.73)	0.5 (0.58)
Median (range)	3.0 (0.0–14.0)	1.0 (0.0–7.0)	1.0 (0.0–6.0)	0.0 (0.0–4.0)	0.0 (0.0–6.0)	0.5 (0.0–1.0)
Problems addressed in the goal planner						
Mean (SD)	3.3 (2.46)	1.6 (1.48)	1.4 (1.37)	0.8 (0.97)	0.7 (1.72)	0.5 (0.58)
Median (range)	3.0 (0.0–12.0)	1.0 (0.0–7.0)	1.0 (0.0–6.0)	0.0 (0.0–3.0)	0.0 (0.0–6.0)	0.5 (0.0–1.0)
Total goals/actions in the goal planner						
Mean (SD)	3.7 (2.73)	2.0 (2.14)	1.7 (1.60)	0.7 (0.87)	0.6 (1.44)	0.5 (0.58)
Median (range)	3.0 (0.0–12.0)	2.0 (0.0–10.0)	1.0 (0.0–8.0)	0.0 (0.0–3.0)	0.0 (0.0–5.0)	0.5 (0.0–1.0)
Patient goals/actions in the goal planner						
Mean (SD)	1.2 (1.84)	1.1 (1.80)	1.0 (1.29)	0.4 (0.63)	0.0 (0.00)	0.0 (0.00)
Median (range)	1.0 (0.0–8.0)	0.0 (0.0–9.0)	0.5 (0.0–6.0)	0.0 (0.0–2.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)

TABLE 36 Care plans: problem areas identified in the assessment

Assessment area (related reference guide)	Number (%) of patients with problem					
	Contact 1 (n=279)	Contact 2 (n=181)	Contact 3 (n=82)	Contact 4 (n=37)	Contact 5 (n=12)	Contact 6 (n=4)
1. Transfer of care	17 (6.1)	N/A	N/A	N/A	N/A	N/A
2. Communication and information	60 (21.5)	5 (2.8)	1 (1.2)	2 (5.4)	0 (0.0)	0 (0.0)
3. Medicines and general health	103 (36.9)	39 (21.5)	16 (19.5)	4 (10.8)	1 (8.3)	0 (0.0)
4. Pain	56 (20.1)	20 (11.1)	11 (13.4)	2 (5.4)	1 (8.3)	0 (0.0)
5. Mobility/falls	143 (51.3)	52 (28.7)	18 (22.0)	2 (5.4)	0 (0.0)	0 (0.0)
6. Personal hygiene and dressing	92 (33.0)	27 (15.0)	6 (7.3)	1 (2.7)	1 (8.3)	0 (0.0)
7. Shopping and meal preparation	74 (26.5)	19 (10.5)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
8. House and home	38 (13.6)	9 (5.0)	1 (1.2)	1 (2.7)	0 (0.0)	0 (0.0)
9. Cognition	64 (22.9)	19 (10.6)	4 (4.9)	1 (2.7)	0 (0.0)	0 (0.0)
10. Driving and general transport	73 (26.2)	21 (11.7)	9 (11.0)	3 (8.1)	0 (0.0)	0 (0.0)
11. Finances and benefits	66 (23.7)	15 (8.3)	3 (3.7)	1 (2.7)	0 (0.0)	0 (0.0)
12. Continence	27 (9.7)	4 (2.2)	1 (1.2)	2 (5.4)	1 (8.3)	0 (0.0)
13. Sexual functioning	7 (2.5)	4 (2.2)	3 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)
14. Patient mood	99 (35.5)	53 (29.3)	26 (31.7)	6 (16.2)	1 (8.3)	0 (0.0)
15. Patient social needs	53 (19.0)	11 (6.1)	5 (6.1)	3 (8.1)	1 (8.3)	0 (0.0)
16. Other	110 (39.4)	33 (18.3)	8 (9.8)	4 (10.8)	0 (0.0)	2 (50.0)

N/A, not applicable.

The problem areas that have been addressed in the goal and action planner are shown in *Table 37* (differences between services are discussed in *Appendix 9*). Apart from a few exceptions (contact 1 – transfer of care; contact 2 – continence, mood; contact 3 – cognition, finances/benefits, social needs; contact 4 – transport, other), at least 80% of problem areas identified in the assessment were subsequently addressed in the goal and action planner. In some cases, a problem area was addressed in the goal and action planner without having been documented in the assessment. The types of goals/actions used to address these problems are summarised in *Table 38*. At contact 1, the most common goals/actions were referral to physiotherapy, referral to occupational therapy or ‘other referral’, provision of information/advice or ‘other goals/actions’. ‘Other referrals’ include referrals to other health-care services (e.g. podiatry, psychology, stroke clinic, community rehabilitation team or smoking cessation) and local authority and third-sector services (e.g. the Stroke Association, benefits review, social services, exercise classes). ‘Other goals/actions’ include patient goals and SCC actions (e.g. discussing with colleague or chasing up appointment). The numbers of patients requiring referrals, information/advice or signposting were substantially reduced at subsequent contacts, whereas the number of ‘other goals/actions’ remained high and the number requiring GP appointments increased.

An optional component of the intervention was the provision to patients, before the assessment with the SCC, of a checklist of the assessment areas to be discussed. Data from the care plans showed that SCCs provided the checklist to patients in advance in 14% of contacts.

The intervention included an optional carer assessment. Of the 279 patients with a care plan, 178 (64%) had a carer and, of these, 58 (33%) had a carer assessment. The most common reasons for not completing a carer assessment were that the assessment was provided by another service, the carer was

TABLE 37 Care plans: problem areas addressed in the goal and action planner

Assessment area (related reference guide)	No. (%) of patients with problem addressed					
	Contact 1 (n=279)	Contact 2 (n=181)	Contact 3 (n=82)	Contact 4 (n=37)	Contact 5 (n=12)	Contact 6 (n=4)
1. Transfer of care	11 (3.9)	N/A	N/A	N/A	N/A	N/A
2. Communication and information	56 (20.1)	5 (2.8)	2 (2.4)	N/A	N/A	N/A
3. Medicines and general health	106 (38.0)	38 (21.0)	20 (24.4)	6 (16.2)	2 (16.7)	N/A
4. Pain	50 (17.9)	18 (9.9)	11 (13.4)	2 (5.4)	1 (8.3)	N/A
5. Mobility/falls	139 (49.8)	50 (27.6)	20 (24.4)	4 (10.8)	N/A	N/A
6. Personal hygiene and dressing	95 (34.1)	27 (14.9)	11 (13.4)	1 (2.7)	2 (16.7)	N/A
7. Shopping and meal preparation	78 (28.0)	23 (12.7)	6 (7.3)	N/A	N/A	N/A
8. House and home	38 (13.6)	11 (6.1)	1 (1.2)	1 (2.7)	N/A	N/A
9. Cognition	51 (18.3)	18 (9.9)	2 (2.4)	1 (2.7)	N/A	N/A
10. Driving and general transport	63 (22.6)	20 (11.0)	9 (11.0)	1 (2.7)	N/A	N/A
11. Finances and benefits	59 (21.1)	15 (8.3)	2 (2.4)	2 (5.4)	N/A	N/A
12. Continence	24 (8.6)	3 (1.7)	1 (1.2)	2 (5.4)	1 (8.3)	N/A
13. Sexual functioning	6 (2.2)	4 (2.2)	4 (4.9)	N/A	N/A	N/A
14. Patient mood	89 (31.9)	41 (22.7)	24 (29.3)	6 (16.2)	1 (8.3)	N/A
15. Patient social needs	53 (19.0)	18 (9.9)	7 (8.5)	3 (8.1)	1 (8.3)	N/A
16. Other	100 (35.8)	31 (17.1)	9 (11.0)	2 (5.4)	N/A	2 (50.0)

N/A, not applicable.

TABLE 38 Care plans: types of goals/actions

Goal/action	No. (%) of patients with individual goal/action					
	Contact 1 (n=279)	Contact 2 (n=181)	Contact 3 (n=82)	Contact 4 (n=37)	Contact 5 (n=12)	Contact 6 (n=4)
Referral to physiotherapist	95 (34.1)	16 (8.8)	3 (3.7)			
Referral to occupational therapy	78 (28.0)	14 (7.7)	1 (1.2)			
Referral to speech and language therapy	43 (15.4)	4 (2.2)	1 (1.2)	1 (2.7)		
Referral to dietitian	14 (5.0)	2 (1.1)				
Referral to community nurse	22 (7.9)	6 (3.3)				
Other referral ^a	115 (41.2)	31 (17.1)	14 (17.1)	4 (10.8)	1 (8.3)	
GP appointment	19 (6.8)	17 (9.4)	9 (11.0)	4 (10.8)		
Information and advice	87 (31.2)	22 (12.2)	10 (12.2)	2 (5.4)	2 (16.7)	
Signposting ^a	34 (12.2)	6 (3.3)	2 (2.4)	1 (2.7)		
Other goals/actions ^a	175 (62.7)	97 (53.6)	49 (59.8)	12 (32.4)	2 (16.7)	2 (50.0)

^a Patient may have one or more of these types of goals/actions at each contact.

not present or the carer declined. All of the carers who underwent an assessment had a single contact with the SCC except for one carer who had two contacts; 97% of contacts were face to face.

Of the carers registered to the trial, 26 (24%) had a carer assessment. For these carers, 90% of the assessment areas were asked at contact 1 and a median of one problem area was identified (range 0–6). As with patients, the sexual functioning assessment was asked less frequently (58% of carers) than other assessment areas (88–96% of carers). Problems were identified across the assessment areas, most commonly in the areas of communication/information, mood and social/emotional needs, all identified in 23% of carers. A median of one problem (range 0–5) was addressed in the goal and action planner, leading to a median of one (range 0–3) goal/action. These included the provision of information (11 carers), referrals to health-care/social care/third-sector services (three carers), a GP appointment (one carer) and other goals/actions (eight carers).

Overview of stroke care co-ordinator practice

A description of the control and intervention services based on surveys and semistructured interviews with SCCs is given in *Appendix 9*.

Overall, the intervention SCCs seem to feel that the trial or manual has not changed their practice. Specifically, four services said that the care plan did not change their assessment and five services said that the manual did not change their practice (no data for other services). However, 10 SCCs gave examples during interview of how their assessment or practice has changed (as a result of either the training day or using the system of care). These included more in-depth thinking about problem-solving; enabling patients to identify their resources or coping strategies; a more consistent and well-structured assessment; covering new areas such as sexual functioning; and delegating more responsibility for actions to the patient. Some services have subsequently adapted their documentation to include areas from the system of care.

The control and intervention arms are similar in that, generally, they aimed to assess all areas at initial assessment; actions rather than goals were recorded by SCCs; goals were reviewed in similar ways; the co-ordinator role was seen as giving information, secondary prevention and/or co-ordinating referrals; and responses to problems were largely informed by experience, local knowledge and discussions. Local services that were felt to be lacking were generally similar between the control arm and the intervention arm, with access to psychology being the most problematic. There was no difference in arms between involving the family in patient assessments and encouraging patients to carry out actions for themselves.

There are two clear differences between the control arm and the intervention arm. First, there were differences in the components of the assessment. Seven intervention SCCs provided patients with the LoTS care checklist before assessment, whereas no control SCCs mentioned an equivalent in their service. Control SCCs also did not report using an evidenced-based manual whereas 10 of the intervention SCCs used the LoTS care manual to at least some extent. Second, although control SCCs intended to provide a fully holistic initial assessment, it is not clear from interviews whether they actually did, and three services reported not covering all areas for all patients, whereas the intervention SCCs appeared to provide a holistic assessment more consistently.

Economic evaluation

Client Service Receipt Inventory return rate and European Quality of Life-5 Dimensions completion rate

Table 39 summarises the numbers of patients returning the CSRI and completing the EQ-5D at each assessment point. Both measures had similar rates of return/completion at each assessment point and rates were balanced between the intervention arm and the control arm. *Table 40* characterises those with and without the necessary cost and outcome data at 6 months for inclusion in the CEAC-based analyses at the primary end point. Although differences were not explored statistically, the baseline characteristics of

TABLE 39 Return/completion rates for the CSRI and EQ-5D

Group	CSRI, <i>n</i> (%)			EQ-5D, <i>n</i> (%)		
	Baseline	6 months	12 months	Baseline	6 months	12 months
Intervention (<i>N</i> =401)	401 (100)	307 (77)	283 (71)	381 (95)	301 (75)	270 (67)
Control (<i>N</i> =399)	398 (99)	295 (74)	268 (67)	382 (96)	288 (72)	259 (65)
Total (<i>N</i> =800)	799 (99)	602 (75)	551 (69)	763 (95)	589 (74)	529 (66)

TABLE 40 Baseline characteristics of the full sample and subsamples included in the 6-month analyses

Characteristic	Full sample (<i>N</i> =800)	Subsample with both cost and GHQ-12 data at 6 months (<i>N</i> =589)	Subsample with both costs and QALY data at 6 months (<i>N</i> =564)
Age (years, mean)	72	72	72
Male, <i>n</i> (%)	433 (54)	324 (55)	310 (55)
Mean baseline health and social care cost (£)	750 (valid <i>n</i> =799)	699	713
Mean baseline GHQ-12 total score	16 (valid <i>n</i> =793)	15 (valid <i>n</i> =585)	–
Mean baseline utility score	0.53 (valid <i>n</i> =763)	–	0.54

patients with the necessary data at 6 months appeared similar to those of the full sample. Therefore, the results based on those followed up are likely to generally be representative of the full sample.

Resource use

Tables 41–43 show resource use at each assessment point. For brevity, these tables are limited to all inpatient services and all informal care plus other health and social care resources used by at least 10% of responders in either trial arm at that time point. Full resource use data are provided in *Appendix 10*. Use of health and social care resources appeared broadly comparable between the two groups at baseline, 6 months and 12 months. As could be expected, use of inpatient services (following the index stroke admission), outpatient services, hospital-based physiotherapy and hospital-based occupational therapy increased during the post-stroke period compared with baseline. Greater numbers of people accessed a wider range of community-based services in the first 6 months after recruitment but numbers were reduced in the final 6 months of follow-up. In comparison with formal care inputs, use of informal care was very high, with care from non-resident informal carers increasing at each time point.

Costs and quality-adjusted life-years

The mean cost of SCC inputs was similar between the groups: £277 in the intervention group and £239 in the control group (mean difference £42; 95% CI –£30 to £116) (*Table 44*). This is the mean across the whole group, including zero costs when SCC inputs were not received. The system of care therefore did not substantially add to the average cost of SCC inputs. The majority of SCC costs were related to patient assessments and time spent discussing patients in MDT meetings. Non-contact activities (actions related to assessments and note writing) accounted for a substantial proportion of the total cost, at 66% of the cost of patient assessments in the intervention group and 58% of the cost of patient assessments in the control group. The costs of inputs to carers in the intervention group were minimal.

TABLE 41 Resource use at baseline (for previous 3 months)^a

Resource	Unit	Intervention (n=401)			Control (n=398)		
		Users (%)	Mean ^b	SD	Users (%)	Mean ^b	SD
Index stroke admission ^c	Bed-days	99	39	44	99	30	35
Inpatient services	Bed-days	7	11	24	10	7	6
A&E	Visit	7	11	24	10	7	6
Outpatient services	Visit	8	2	4	10	1	1
Community-based services							
GP							
Surgery visit	Visit	49	2	1	44	2	2
Home visit	Visit	9	2	1	11	2	2
Telephone call	Call	10	2	1	12	2	1
Repeat prescription	Occurrence	47	2	1	49	2	1
Practice nurse	Visit	26	2	1	23	2	2
Chiropodist	Contact	10	2	1	12	1	1
Dentist	Contact	12	1	1	12	1	1
Optician	Contact	12	1	<1	12	1	<1
Informal care from coresidents							
Personal care	Hour	3	47	43	3	219	320
Providing transport	Hour	3	78	205	6	37	56
Preparing meals	Hour	4	138	175	6	134	141
Housework/laundry	Hour	4	147	186	6	95	93
DIY	Hour	2	97	247	3	40	65
Gardening	Hour	3	94	207	4	31	44
Shopping	Hour	4	81	184	5	41	47
Outings	Hour	2	106	231	3	44	63
Socialising	Hour	3	415	604	3	202	428
Help managing finances	Hour	3	77	214	4	31	40
Informal care from non-residents							
Personal care	Hour	1	39	29	1	171	281
Providing transport	Hour	6	25	23	4	39	48
Preparing meals	Hour	3	66	72	2	48	65
Housework/laundry	Hour	4	43	39	4	24	20
DIY	Hour	3	19	19	2	10	7
Gardening	Hour	4	18	14	3	18	14
Shopping	Hour	5	24	15	4	28	21
Outings	Hour	5	28	56	3	23	16
Socialising	Hour	5	95	115	5	78	100
Help managing finances	Hour	2	19	14	2	12	7

a Inpatient services and informal care plus other resources used by at least 10% of either group.

b Mean for valid user values only.

c Not included in the evaluation.

TABLE 42 Resource use at 6 months (for previous 6 months)^a

Resource	Unit	Intervention (n=307)			Control (n=295)		
		Users (%)	Mean ^b	SD	Users (%)	Mean ^b	SD
Inpatient services	Bed-days	19	15	18	19	14	27
Day hospital/day cases	Activity	12	1	1	8	1	1
A&E	Visit	17	2	2	14	2	1
Outpatient services	Visit	44	3	3	40	3	5
Physiotherapist, hospital ^c	Visit	12	8	8	17	7	8
Community-based services							
GP							
Surgery visit	Visit	57	3	2	60	3	2
Home visit	Visit	24	2	2	22	2	1
Telephone call	Call	20	2	2	21	2	3
Repeat prescription	Occurrence	52	3	4	51	5	3
Practice nurse	Visit	33	3	3	40	3	3
Physiotherapist	Home visit	28	8	9	22	8	10
Occupational therapist	Visit	26	5	8	24	6	7
Speech and language therapist	Home visit	11	4	3	13	4	4
Social worker	Home visit	12	2	1	11	2	1
Community/district nurse	Contact	23	7	21	23	4	9
Chiropodist	Contact	18	2	2	16	2	1
Dentist	Contact	21	2	1	14	1	1
Optician	Contact	20	1	1	22	1	1
Informal care from coresidents							
Personal care	Hour	15	385	834	14	242	324
Providing transport	Hour	15	108	140	14	120	126
Preparing meals	Hour	19	249	234	14	249	200
Housework/laundry	Hour	18	244	305	14	204	163
DIY	Hour	9	87	224	4	49	51
Gardening	Hour	11	80	94	8	60	52
Shopping	Hour	16	115	122	15	95	113
Outings	Hour	14	116	142	9	93	87
Socialising	Hour	14	728	1125	9	489	488
Help managing finances	Hour	13	89	123	11	124	225

continued

TABLE 42 Resource use at 6 months (for previous 6 months)^a (continued)

Resource	Unit	Intervention (n=307)			Control (n=295)		
		Users (%)	Mean ^b	SD	Users (%)	Mean ^b	SD
Informal care from non-residents							
Personal care	Hour	8	110	96	6	110	102
Providing transport	Hour	14	63	82	14	58	58
Preparing meals	Hour	8	104	135	6	85	98
Housework/laundry	Hour	9	80	82	7	45	43
DIY	Hour	6	20	20	4	24	35
Gardening	Hour	9	26	36	7	32	37
Shopping	Hour	11	48	48	11	44	35
Outings	Hour	13	57	98	11	54	62
Socialising	Hour	13	156	163	9	146	218
Help managing finances	Hour	7	60	69	5	33	36

a Inpatient services and informal care plus other resources used by at least 10% of either group.

b Mean for valid user values only.

c Separate from other outpatient visits. Further visits to this service are also included in the broader outpatient visit numbers.

TABLE 43 Resource use at 12 months (for previous 6 months)^a

Resource	Unit	Intervention (n=283)			Control (n=268)		
		Users (%)	Mean ^b	SD	Users (%)	Mean ^b	SD
Inpatient services	Bed-days	16	9	15	15	8	9
Day hospital/day cases	Activity	8	2	1	10	1	<1
A&E	Visit	12	2	1	10	2	1
Outpatient services	Visit	36	3	3	37	3	5
Physiotherapist, hospital ^c	Visit	14	6	6	12	6	8
Community-based services							
GP							
Surgery visit	Visit	53	3	3	60	3	2
Home visit	Visit	15	3	4	13	3	6
Telephone call	Call	18	2	1	13	3	3
Repeat prescription	Occurrence	49	5	3	54	5	2
Practice nurse	Visit	35	3	4	44	3	4
Community/district nurse	Contact	15	8	27	14	4	5
Chiropodist	Contact	18	2	1	18	2	2
Dentist	Contact	27	2	1	22	2	1
Optician	Contact	21	1	<1	24	1	1
Other services	Occurrence	6	4	6	3	2	1

TABLE 43 Resource use at 12 months (for previous 6 months)^a (continued)

Resource	Unit	Intervention (n=283)			Control (n=268)		
		Users (%)	Mean ^b	SD	Users (%)	Mean ^b	SD
Informal care from coresidents							
Personal care	Hour	11	564	1695	6	460	1035
Providing transport	Hour	12	202	357	10	134	278
Preparing meals	Hour	14	317	336	9	213	203
Housework/laundry	Hour	14	339	769	11	210	235
DIY	Hour	7	157	455	4	67	83
Gardening	Hour	9	137	390	8	81	160
Shopping	Hour	11	175	349	10	80	141
Outings	Hour	11	173	378	7	123	176
Socialising	Hour	11	550	776	7	343	488
Help managing finances	Hour	9	169	403	8	63	117
Informal care from non-residents							
Personal care	Hour	5	209	356	3	186	349
Providing transport	Hour	12	53	66	11	42	40
Preparing meals	Hour	7	106	170	4	87	84
Housework/laundry	Hour	9	107	154	7	60	67
DIY	Hour	5	46	43	7	34	44
Gardening	Hour	6	38	37	6	31	36
Shopping	Hour	8	62	72	8	44	39
Outings	Hour	11	63	135	9	47	46
Socialising	Hour	12	222	356	8	116	140
Help managing finances	Hour	5	49	64	4	44	37

a Inpatient services and informal care plus other resources used by at least 10% of either group.

b Mean for valid user values only.

c Separate to other outpatient visits. Further visits to this service are also included in the broader outpatient visit numbers.

TABLE 44 Costs of SCC inputs (£, 2010/11 prices)

Input	Intervention (n=401)		Control (n=399)		Intervention-control ^a		
	Mean	SD	Mean	SD	Mean difference	95% CI	p-value
Patient inputs							
In-hospital contact	3	7	2	6			
Assessment	104	86	100	72			
Actions arising from assessment	33	34	36	30			
Note writing	36	29	22	19			
MDT meetings	90	104	78	41			
Consenting carer inputs ^b							
Assessment	3	8	–	–			
Actions arising from assessment	1	2	–	–			
Note writing	3	7	–	–			
Non-consenting carer inputs ^b							
Assessment	2	6	–	–			
Actions arising from assessment	1	4	–	–			
Note writing	1	3	–	–			
Total	277	207	239	146	42	–30 to 116	0.258

a Comparisons include covariates for baseline patient Barthel Index score (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility score and GHQ-12 score.

b Not recorded for the control group.

There were no differences in specific categories of health and social care costs (*Table 45*) or in total health and social care costs (*Table 46*). Informal care costs notably increased after baseline and were significantly higher in the intervention group at 6 months, 12 months and over 1 year. Although informal care costs fell between 6 months and 12 months in the control group, they increased over the same period in the intervention group. These costs overshadowed health and social care costs by a factor of 2.4 in the intervention group and 1.9 in the control group at 6 months. This pattern was reflected in total societal costs, with the intervention group having significantly higher societal costs at 6 months, 12 months and over 1 year. Higher informal care costs in the intervention group may suggest that these patients had ongoing care needs for a longer period of time or that they accessed more informal care because of the goal-setting element of the intervention.

There were no differences in QALYs between the two groups at any assessment point (*Table 47*).

Sensitivity analyses

Imputing missing health and social care costs and QALYs at 6 months did not alter the base-case conclusion of no difference in costs or QALYs between the groups (*Table 48*).

TABLE 45 Mean costs by resource category at baseline (for the previous 3 months), 6 months (for the previous 6 months) and 12 months (for the previous 6 months) (£, 2010/11 prices)

Resource category	Intervention (N=401)			Control (N=399)			Intervention-control ^a		
	Valid n	Mean	SD	Valid n	Mean	SD	Mean difference	95% CI	p-value
SCC inputs	401	277	207	399	239	146	42	-30 to 116	0.258
Institutionalisation									
Baseline	401	1	27	398	0	0	1	-1 to 4	0.319
6 months	307	294	1438	295	317	1462	-62	-287 to 164	0.590
12 months	283	351	1777	268	451	2333	-137	-473 to 200	0.426
Secondary care									
Baseline	401	504	2507	398	495	1486	9	-277 to 295	0.950
6 months	307	1599	3726	295	1608	4902	-18	-708 to 671	0.959
12 months	283	932	2529	268	820	1993	99	-286 to 484	0.614
Community-based services									
Baseline	401	188	400	398	286	705	-99	-181 to -18	0.016
6 months	307	1100	1557	295	953	1476	106	-142 to 353	0.404
12 months	283	1017	2031	268	692	1390	207	-67 to 481	0.139
Other health and social care services									
Baseline	401	20	298	398	6	80	14	-16 to 45	0.353
6 months	307	76	738	295	41	241	25	-69 to 118	0.605
12 months	283	109	1101	268	5	31	49	-50 to 147	0.334
Informal care									
Baseline	401	1937	3451	398	1508	3014	429	-20 to 878	0.061
6 months	307	8217	10,404	295	6176	6381	1586	-252 to 2918	0.020
12 months	283	11,152	21,493	268	5686	8786	3958	836 to 7081	0.013

a Comparisons of 6-month and 12-month costs include covariates for baseline patient Barthel Index score (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility score and GHQ-12 score (and the relevant cost category for comparisons of costs).

TABLE 46 Mean total costs at baseline (for the previous 3 months), 6 months (for the previous 6 months), 12 months (for the previous 6 months) and over 1 year (£, 2010/11 prices)

	Intervention (N=401)			Control (N=399)			Intervention-control ^a		
	Valid n	Mean	SD	Valid n	Mean	SD	Mean difference	95% CI	p-value
Total health and social care costs									
Baseline	401	713	2636	398	787	1709	-74	-382 to 234	0.639
6 months ^b	307	3369	4735	295	3171	5942	98	-721 to 917	0.814
12 months	283	2408	4161	268	1967	3726	291	-316 to 898	0.347
1 year ^b	263	5442	6837	252	4462	6415	706	-335 to 1748	0.184
Total societal costs									
Baseline	401	2651	4401	398	2296	3661	355	-206 to 917	0.215
6 months ^b	307	11,586	11,981	295	9347	9269	1663	56 to 3271	0.043
12 months	283	13,560	22,383	268	7653	9472	4135	618 to 7652	0.021
1 year ^b	263	24,450	28,055	252	16,359	15,034	5809	1884 to 9734	0.004

a Comparisons of 6-month, 12-month and 1-year costs include covariates for baseline patient Barthel Index score (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility score, GHQ-12 score and the relevant cost category.
 b Including the cost of SCC inputs.

TABLE 47 Patient utility scores and QALYs

	Intervention (N=401)			Control (N=399)			Intervention-control ^a		
	Valid n	Mean	SD	Valid n	Mean	SD	Mean difference	95% CI	p-value
Utility scores									
Baseline	381	0.51	0.38	382	0.56	0.34	-0.04	-0.12 to 0.03	0.246
6 months	301	0.56	0.32	288	0.61	0.34	-0.03	-0.07 to 0.02	0.206
12 months	270	0.54	0.32	259	0.61	0.32	-0.04	-0.10 to 0.01	0.140
QALYs									
6 months	289	0.27	0.15	276	0.29	0.15	-0.004	-0.02 to 0.01	0.436
12 months	247	0.28	0.14	238	0.31	0.15	-0.01	-0.03 to 0.01	0.233
1 year	239	0.56	0.28	228	0.61	0.28	-0.01	-0.04 to 0.02	0.492

a Comparisons of 6-month and 12-month QALYs include covariates for baseline patient Barthel Index score (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility score and GHQ-12 score.

TABLE 48 Sensitivity analyses

Sensitivity analysis	Intervention (N=401)			Control (N=399)			Intervention–control ^a		
	Valid n	Mean	SD	Valid n	Mean	SD	Mean difference	95% CI	p-value
Effect on total health and social care costs (£) at 6 months of imputing missing total costs at 6 months									
Base case	307	3369	4735	295	3171	5942	98	–721 to 917	0.814
Imputed data	401	3208	4324	399	2999	5215	70	–565 to 704	0.829
Effect on QALY gains at 6 months of imputing missing QALY gains at 6 months									
Base case	289	0.27	0.15	276	0.29	0.15	–0.004	–0.02 to 0.01	0.436
Imputed data	401	0.25	0.15	399	0.28	0.14	–0.005	–0.01 to 0.004	0.264

a Comparisons include covariates for baseline patient Barthel Index score (pre and post stroke), gender, age, living circumstances (living alone vs. living with carer), stroke severity as represented by speech and language impairment (normal/impaired) and 6CIT score (normal/impaired), utility score and GHQ-12 score (and the relevant cost category for comparisons of cost).

Cost-effectiveness and cost-utility

Of the 12 cost–outcome combinations examined for the cost-effectiveness and cost-utility analyses, none suggested that there were statistically significant between-group differences for both cost and outcome elements. Therefore, we have not calculated ICERs.

Cost-effectiveness planes (*Figures 9 and 10*) show that differences in health and social care costs between the groups at 6 months are fairly strongly centred around zero, that is, no difference, whereas outcome differences suggest a disadvantage for the intervention group in terms of less improvement on the GHQ-12 and QALY losses rather than gains. This conclusion is further represented in *Figures 11 and 12*, which show the probabilities that the intervention group is cost-effective compared with the control group. The probabilities of cost-effectiveness were low based on both outcome measures, not exceeding 30% for the threshold ranges examined. Probabilities based on the societal perspective were particularly low as these costs are dominated by informal care costs, which were significantly higher in the intervention group. Therefore, the intervention is unlikely to be cost-effective over a 6-month period at current policy thresholds of £20,000–30,000 per QALY gain. It is unclear what the willingness to pay for a GHQ-12 point improvement would be in practice.

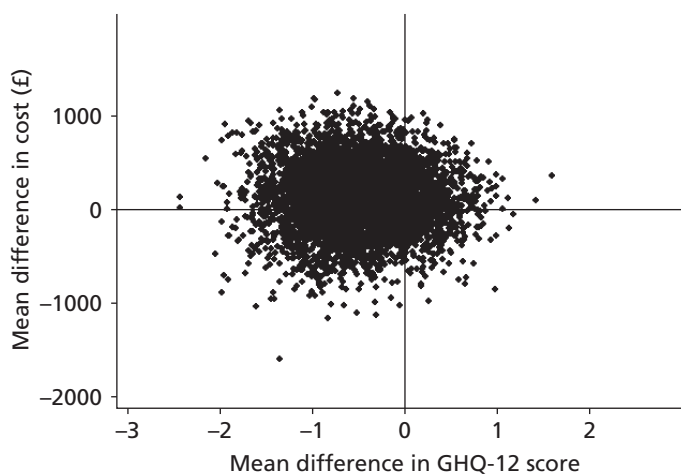


FIGURE 9 Cost-effectiveness plane of incremental total health and social care costs and point changes on the GHQ-12 at 6 months. Note: GHQ-12 scores have been reversed so that a positive difference is an improvement.

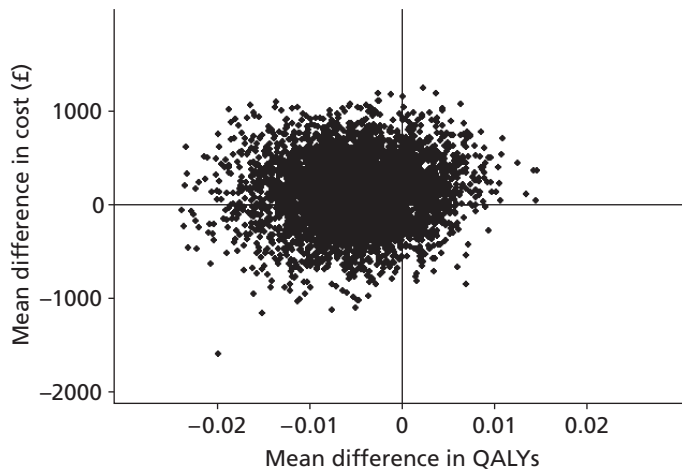


FIGURE 10 Cost-effectiveness plane of incremental total health and social care costs and QALYs at 6 months.

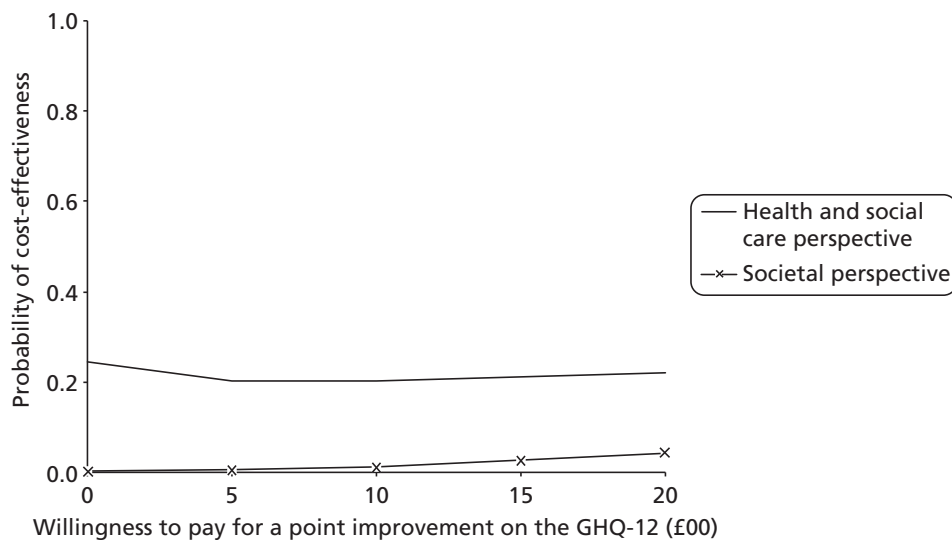


FIGURE 11 Probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional point improvement on the GHQ-12.

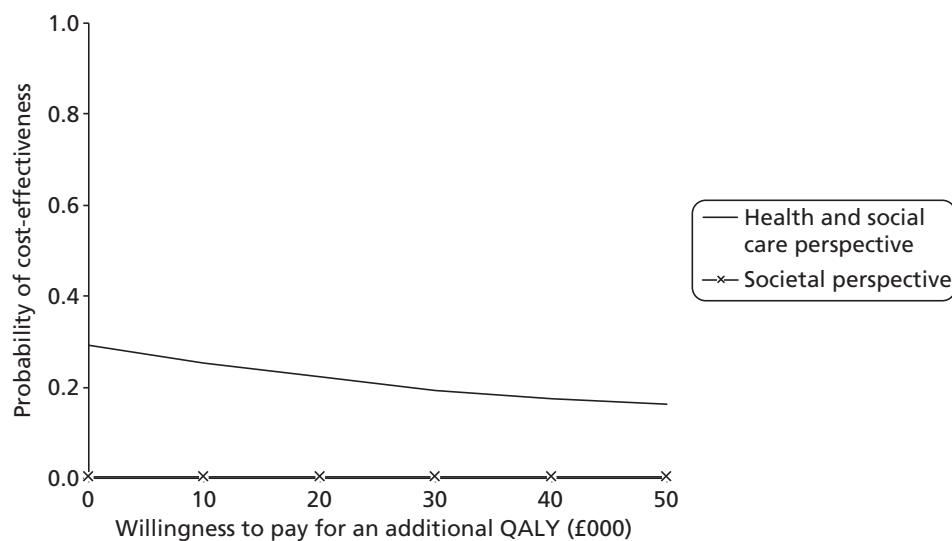


FIGURE 12 Probability that the intervention is cost-effective compared with the control at 6 months, from each cost perspective, for a range of willingness-to-pay values for an additional QALY.

Discussion

Key findings

This trial was a pragmatic multicentre cluster RCT of a complex intervention. The trial was designed to evaluate a newly developed system of care compared with usual practice when implemented by stroke services, specifically SCCs, across the UK. The system of care was predicated on patients' and carers' needs and was developed through systematic reviews and the views of patients and carers, with input from primary health-care providers. The intervention was manualised and the treatment algorithms were developed through robust, evidence-based methodologies.

Services randomised to the intervention were trained in using the system of care whereas control services continued with usual practice. Patients (and optionally carers) were recruited on referral to the service and patient and carer outcomes were assessed using postal questionnaires at 6 and 12 months post recruitment. The primary outcome was patient psychological health (GHQ-12) at 6 months and secondary outcomes included patient functional health, carer psychological and functional health, and cost-effectiveness.

In total, 800 patients and 208 carers were recruited from 29 stroke services in England, Scotland, Northern Ireland and Wales. SCCs in 14 services provided the intervention whereas those in 15 services continued with usual practice. Patient groups were well matched between the two arms in demographic and clinical characteristics. There was no evidence of statistically significant differences between the arms in primary or secondary outcomes using either ITT analysis or per-protocol analysis. There was no difference in adverse events between the two groups.

The costs of SCC inputs (mean difference £42; 95% CI –£30 to £116) and total health and social care costs at 6 months, 12 months and over 1 year were similar between the groups. Societal costs were higher in the intervention group (mean difference at 6 months £1163; 95% CI £56 to £3271) because of greater use of informal care. There was no difference in QALYs between the groups and the probability of the intervention being cost-effective at 6 months was low at the current policy threshold.

Strengths and limitations of the study

This trial is one of the largest stroke rehabilitation trials completed to date (worldwide). It successfully recruited to time and target and involved centres from a wide geographical area. Implementation was supported by the National Institute for Health Research (NIHR) SRN and demonstrates the importance of the network in facilitating set-up and recruitment.

Study design

The trial followed closely Medical Research Council guidance on the evaluation of a complex intervention.⁸⁶ A cluster RCT design was chosen as the most appropriate design for the evaluation of this service-level intervention; outcome measures were carefully considered; an economic evaluation was conducted; and process data were collected.

We elected to collect outcomes by post, in keeping with our patient- and carer-centred approach. This also helped mitigate against bias, particularly as unblinding of a researcher to one patient would inevitably result in unblinding of the whole cluster. Outcome assessments for stroke patients are challenging and postal assessments are no different in this regard. There are some missing data but sensitivity analysis suggests that this does not affect the trial outcome.

Internal validity

Clusters

A total of 32 clusters were randomised equally between the control arm and the intervention arm, stratified by quality of the stroke unit (NSA score), referral rate, SCCs working alone compared with

working within a community MDT, and SHA. This was fewer than the 40 services anticipated. In total, 48 services expressed an initial interest, with seven of these deciding not to pursue their involvement further and the remaining nine not being suitable to participate, either because the SCC service did not fulfil the eligibility criteria (six) or because we were unable to identify a principal investigator or researcher provision (three).

Three randomised clusters were unable to participate in the trial because of changes in SCC service or researcher provision, and some services struggled to achieve the target recruitment of 25 patients. However, low recruitment in some services was compensated for by increasing the recruitment target in services with high levels of recruitment, with only a small loss of power.

Recruitment

The cluster trial was rigorously implemented. Recruitment of patients and carers commenced after cluster randomisation of the services. The trial was carefully designed to avoid selection bias. The SRN researchers assisted with the successful minimisation of selection bias in the trial, allowing recruitment by research staff who were independent of the clinical MDTs. The SRN researchers were unaware of whether they were recruiting to an intervention cluster or a control cluster. Comprehensive screening and recruitment data were collected from all participating services and reviewed by the trial management group on a monthly basis to assess any potential bias in selection procedures.

Fewer carers were recruited to the trial than anticipated. Recruitment of carers is difficult as they may not be readily available to meet and talk through trial documentation and, when they are present, their focus will be on their relative. These lower than expected numbers are likely to be a reflection of these practical issues set in the context of SRN staff being performance managed only on number of patients recruited. These factors should be considered by researchers planning other similar studies.

Procedures were set in place to ensure that the SCCs were unaware of which patients had consented to provide trial data. The SCCs in the intervention arm delivered the system of care to all referrals regardless of trial participation. The intervention documentation (care plan) was designed so that it replaced the intervention SCCs' previous patient documentation and thus became embedded in their standard practice.

These design features proved successful. Pre- and post-recruitment screening data show no systematic bias in favour of 'better' patients. Among all patients, 22% had a modified Rankin Scale score of 0–1 and 7% had a modified Rankin Scale score of 5 in pre-recruitment screening, compared with 27% and 3%, respectively, in patients recruited to the trial. Both the numbers of participants recruited and their baseline characteristics were on the whole well balanced between the study arms, demonstrating a lack of selection bias in the recruitment of participants. In the control arm there were more people who had participated in higher education and fewer with language or cognitive impairments than in the intervention arm (accounted for in statistical modelling). There was also a difference in length of inpatient stay, which was shorter in the control arm, possibly influenced by the introduction of early supported discharge services. The follow-up rate for patients of 75% at 6 months required for the power calculation was achieved in the trial (actual follow-up rate 76%).

Outcomes

The selection of outcome measures is always problematic and was subject to considerable discussion within the trial team and trial steering committee. It may be that the GHQ-12 was not sufficiently sensitive to change to pick up outcome differences in our study population. We felt that this measure was consistent with a patient-centred model of stroke recovery in which adjustment to disability is seen as a critical issue, reflects the high prevalence of psychological symptoms after stroke,²⁵ and that psychological problems become more prevalent with time.⁸⁷ We also used a range of secondary outcomes, which similarly demonstrated little between-group differences.

Economic evaluation

It was necessary to rely on self-reported data (CSRI) in the context of factors that served as major strengths: large sample, broad evaluation perspective and spread of the sample across geographical areas/health regions. There was no feasible way to collect the same level of data by other means within the available time, staffing and monetary resources, as we lack nationally common electronic recording systems that cover different care sectors. Any limitations associated with this approach, because of inaccuracies in recollection of service use, can be assumed to apply equally to both the control group and the intervention group.

There were different patterns of informal care costs between the groups, with these costs rising over time in the intervention group but tending to fall in the control group. This may suggest that the intervention group had ongoing care needs for a longer period of time or that the intervention group may have accessed more informal care because of the goal-setting element of the intervention. However, caution must be exercised in interpreting the informal care data, which were based on retrospective self-reports. Questions about inputs were categorised to aid recall but it cannot be ruled out that responders double-counted or overestimated inputs. However, although this would affect the quantification of care inputs and their costs, any such bias could be expected to be equal across the groups. The size of the informal care costs in comparison to the formal care costs highlights the need for more attention to be paid to the development of appropriate and feasible methods for the measurement and valuation of such inputs.

Generalisability

Including a wide range of disparate geographical regions ensured a good representation of different health-care settings. The eligibility criteria were kept to a minimum, in keeping with the pragmatic trial design, to ensure that a stroke patient population representative of referrals to SCCs was recruited, including patients with language and cognitive impairments. Of those patients eligible for the trial, 56% were recruited. In total, 29% of patients recruited had a cognitive impairment and 9% were unable to complete the cognitive test as a result of communication difficulties.

Implementation of a complex intervention

As a pragmatic trial the intervention was implemented as any service initiative within the NHS would have been. The challenges of implementation were considered carefully in designing the delivery of the training and included choosing a method that would be acceptable and feasible to MDT staff and NHS management and which could easily be replicated across the UK at the end of the trial.

Training was provided at national training days, which SCCs from all intervention services attended. Because of the nature of a cluster trial the SCCs randomised to the intervention were unaware of what the new service model consisted of before these training days. The system of care was well received when presented by the trial team, demonstrating 'face validity' for the intervention. In the first training day the system of care was introduced and a workshop was led by Professor Allan House on assessment and problem-solving techniques. Practical issues of implementation were addressed, specifically the design of the care plans and manual. The content of subsequent training days was informed by the needs of the SCCs. Thus, a lecture on pain management was provided by Professor Tony Rudd and a discussion on benefits was led by a colleague from the Department for Work and Pensions. The format and layout of the care plan were further reviewed and refined following feedback from the SCCs. The intent was to ensure that the paperwork captured all of the information that SCCs might require to deliver their service and that it was therefore able to replace the current documentation.

The training was supported by a CD of the training day. The SCCs implemented the new system of care in their service over a period of months and when they were comfortable with implementation (demonstrated through a review of completed care plans) trial recruitment began. We feel that this process was thorough and comprehensive. Some SCCs left and were replaced during the trial and, in services that included MDTs, all SCCs did not necessarily attend the training. The intent was that the training would be cascaded down

to other staff in the team by staff who had attended the training days. It may be that this commonly used 'cascade' method was not as effective as we would have wished.

Trial procedures

Service engagement in the trial was preceded by completion of an extensive survey, individual interviews with SCCs and visits to every service. In addition, an 'organisational' visit took place at every service, which included all staff directly involved in the trial and post-discharge care pathway. This included the inpatient services trial principal investigator (often the stroke consultant), the community principal investigator, the SCC(s), SRN staff and researchers. At this meeting the practicalities of trial recruitment were discussed in relation to the patient flow and agreement was reached on the most efficient processes. At these meetings it was also emphasised that the SCCs should not be aware of which patients were trial participants and researchers should not know whether the service was an intervention service or a control service. Despite this, however, when visits were undertaken to collect process data after the end of follow-up, it emerged at some services that patients fulfilling the entry criteria of 'referred to stroke care co-ordinator' had not been seen by a SCC (approximately 20% of patients across all services). There were a range of reasons for this, which included patients never actually being referred or being referred but living outside the catchment area for the service and the referral therefore not being accepted. These glitches in the service caused those SCCs affected to review their referral pathways. Of patients seen by a SCC, 89% in the intervention arm had a completed care plan compared with 66% in the control arm with a completed time log (completed only for the purposes of the trial), illustrating the difficulty of ensuring completion of additional trial paperwork.

Intervention compliance

We set a high bar for intervention compliance, defined as at least 12 of 16 assessment areas (75%) (each linked to a reference guide in the manual) discussed at patient contact 1 of the care plan. Of all care plans completed, 96% were compliant according to this definition, with on average 94% of assessment areas discussed at contact 1, indicating that the assessment was delivered as expected and that this is an appropriate approach to implement evidence into practice.

Although it seems that the structured assessment was delivered to the majority of participants who received the SCC service, the basic tenet of the approach, what is more difficult to assess is whether this translated into a change of practice. In keeping with the pragmatic trial design, we collected limited data about processes of care. A process evaluation may have provided more in-depth information.

The number of intervention patient assessment contacts ranged from one to six, with the majority (70%) of patients having one or two (comparable to the number in control services). This reflects the pre-trial survey and service models, in which a SCC undertakes initial assessment before referral to other members of the MDT (75% of the services in the trial included team rather than individual SCCs). It may be that in this service model the notion of comprehensive holistic assessment becomes dissipated by individual allied health professionals delivering their single discipline input, for example therapists prioritising mobility problems. Although the number of assessment contacts was not prescribed, a key principle of the intervention is that goals are reviewed at subsequent contacts, which will necessarily be limited if the number of contacts is limited.

It was observed that, in some services, care plans were clearly different from patient to patient and gave an impression of a patient's personality, overall situation and priorities. In other services, care plans were more uniform, being difficult to distinguish from one patient to another, and it appeared that the SCCs were focusing the assessment on certain areas for all patients, despite asking questions in all of the assessment areas. These observations might have several interpretations (see *Appendix 9*): they may reflect wider service pressure, for example a service-level focus on secondary prevention and medical management could mean (however unintentionally) prioritising that aspect of the assessment, but may also represent the extent to which the assessment was patient led and holistic and based on a collaborative

discussion with the patient. This highlights the challenge of implementing interventions in rehabilitation that are a complex interaction between context, patient and professional.

Despite regular MDT meetings the original care plan assessments were not always revisited to check that actions had been undertaken and goals reached. It does appear from the LUNS monitoring tool that needs remain unmet at 6 and 12 months. A proportion of these may be intractable difficulties for which there is no solution available, or needs that have emerged after the end of SCC service provision, whereas others may reflect a lack of access to appropriate services to address the need. No service will necessarily be able to successfully address all problem areas or predict what difficulties may occur in the future.

The SCCs gave examples during interview of how their assessment or practice has changed (as a result of either the training day or using the system of care). These included more in-depth thinking about problem-solving; enabling patients to identify their resources or coping strategies; a more consistent and well-structured assessment; covering new areas such as sexual functioning; and delegating more responsibility for actions to the patient. It is possible that delegated responsibility may move from the patient into additional burden for the carer, contributing to the observed increase in informal care costs discussed earlier. SCCs used the care manual to at least some extent. There were a number of similarities between the practice of control SCCs and the practice of intervention SCCs; however, although control SCCs intended to provide a fully holistic initial assessment, it is not clear from interviews whether they actually did, and three services reported not covering all areas for all patients, whereas the intervention SCCs appeared to provide a holistic assessment more consistently. Although elements of evidence-based practice were evident across all settings, the intervention ensures that all key issues are covered. The lack of effectiveness of the intervention may be in part because there were not big enough differences in the work of SCCs between the control setting and the intervention setting.

Improving outcomes following comprehensive assessment can be successful only if appropriate care and treatment are available for the problems identified. Although all of the reference guides are evidence based, the evidence points to more effective interventions for certain problems than for others. This may be particularly relevant in relation to psychological problems. Interviews with the SCCs after the trial indicated that access to psychological care was particularly patchy, with 12 services across control and intervention services reporting extremely limited psychological services. This in turn impinges on our main outcome measure, which assessed mood. Access to other services was generally good, with limitations mentioned by no more than one service; however, limited voluntary and community resources such as social groups were reported by a number of services, two services reported a lack of services to address employment and two services reported a lack of services to address sexual functioning problems. In intervention services, mood was identified as one of the most prevalent problem areas at the first SCC contact and the most prevalent problem area at later contacts.

The challenge in multicentre rehabilitation trials is to provide some guidance on the intervention to capture the main features, enhance external validity and improve generalisability while making it sufficiently flexible for it to be acceptable to staff and deliverable in a range of service models. Our approach was to manualise the intervention, supported by training days, with an opportunity to practise delivery before the start of patient recruitment. The care plan was well completed but we were perhaps less successful in changing the behaviours and mindset of the SCCs, as illustrated by the observation discussed earlier, that some SCCs focused the assessment on certain areas for all patients. Further work should explore how to embed behaviour change techniques in both intervention training and delivery and the intervention itself.

Context

Although the role of the SCC had been recommended in the *National Service Framework for Older People*,¹⁶ our pre-trial survey revealed that relatively few services had adopted this model and even fewer used a dedicated SCC role. It might be suggested therefore that the services that were recruited to the trial were particularly forward thinking and slightly atypical compared with other services across the UK.

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. Similar approaches have been developed (e.g. GM-SAT for 6-month reviews³⁴). This indicates that our thinking is feasible, practical and appropriate for ongoing service development. However, because of the increased awareness of the longer-term needs of stroke patients and carers, as promoted through the work of the Stroke Improvement Programme, the SCCs in the control arm may have adapted their practice accordingly. However, none of the control SCCs reported using structured review tools in the survey and interview that they completed after the end of the trial.

It would seem that longer-term outcomes for patients after stroke do remain quite poor. A Stroke Association unmet needs survey⁴ demonstrated the range and depth of unmet needs. Our own work reported similar outcomes (see *Chapter 4*).

The trial was not designed to evaluate whether the SCC service was effective but whether the structured patient-centred system of care improved patient outcomes. Our hypothesis was that the system of care configured around patient needs would be more holistic and more responsive in addressing the well-recognised unmet needs of patients after stroke.

Further analysis is ongoing to determine whether some subsets of patients, possibly over selected time periods, did have an enhanced outcome from the intervention approach, or whether service/process factors contributed to differences in outcomes. A realist evaluation of the trial has also been undertaken,⁸⁸ which may shed further light on how the SCCs have implemented the system of care.

The trial results apply to a heterogeneous population. It might be that the SCC service should be targeted more towards patients (and carers) with specific needs, leading to a more specialised bespoke service.

Chapter 4 Project 3: Longer-term Unmet Needs after Stroke study

Abstract

Aim

The study aim was to finalise the development of the LUNS questionnaire and evaluate the acceptability, test–retest reliability and validity of the resulting 22-item questionnaire for measuring longer-term unmet needs of patients living at home post stroke.

Methods

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 questionnaire, GHQ-12, FAI and Short Form questionnaire-12 item (SF-12) was posted to participants 3 or 6 months after stroke to assess acceptability and validity. The LUNS questionnaire was re-sent 1 week after receiving back the first pack to assess test–retest reliability. Semistructured interviews were conducted with participants who reported low unmet need on the LUNS questionnaire to explore whether they genuinely considered this to be the case.

Results

In total, 850 patients, including 199 (23%) with impaired communication and/or cognition, were recruited. A total of 529 pack 1s were returned (69% of those sent), with 3.5% missing LUNS items, comparable with the concurrent measures. The median number of unmet needs was four (range 0–19) and participants reporting low unmet need verified this to be the case and that they did not have other unmet needs not captured by the LUNS questionnaire. Identification of an unmet need was consistently associated with poorer outcomes on concurrent measures. The test–retest reliability of the LUNS questionnaire ($n=326$) was moderate to good (77.9–98.8% item agreement, $\kappa=0.45–0.67$).

Conclusions

The LUNS questionnaire shows suitable acceptability, test–retest reliability and validity for identifying longer-term unmet needs after stroke.

Introduction

Background

Stroke is the leading cause of complex disability in adults.⁸⁹ Research into the longer-term experiences of stroke survivors has found that they experience a range of difficulties, including, for example, incontinence, depression, lack of information, pain, and restrictions in social and household activities.^{5,90–93} Many of these problems are highly prevalent and exist even a decade after stroke,⁹⁴ suggesting that they are not appropriately identified or addressed by service providers. To address the diverse and complex difficulties that stroke survivors face, effective methods are required to identify their unmet needs. Regular patient reviews, as part of an integrated longer-term stroke pathway, are recommended^{2,15} and could incorporate needs assessment. Measuring unmet need is also a way of identifying stroke service deficiencies⁹⁵ and this may enable effective commissioning and provision of services. Assessment of needs can be defined as the ability to benefit from health (or social care)⁹⁶ and unmet needs may be defined as 'expressed needs that are not satisfied by current service provision' (p. 1052).⁹⁷

Existing instruments to measure problems after stroke, such as the FAI,⁹⁸ tend to deal with limited aspects of the stroke experience and therefore do not capture the range of domains pertinent to longer-term life after stroke. A recent survey in the UK identified the unmet needs of stroke survivors but the survey instrument was not evaluated for reliability.⁴ Tools designed for measuring unmet needs in people recovering from stroke have been developed for research purposes but are long and have poor response rates.^{99–101} There is a need for a short, easy-to-complete tool for identifying unmet needs after stroke.

Development of the Longer-term Unmet Needs after Stroke questionnaire

We developed a 22-item questionnaire (termed 'LUNS') to provide a method for identifying the longer-term unmet needs of stroke survivors. A multistage iterative process was used to develop, refine and carry out preliminary testing of the LUNS questionnaire, summarised in *Figure 13* and described in detail below.

Items for the LUNS tool were identified through systematic reviewing of qualitative and quantitative literature reporting the longer-term stroke experience^{24,25} and, subsequently, semistructured interviews with stroke patients and carers.²⁶ The data were represented in a framework comprising 92 longer-term stroke problem types organised into six domains (transfer of care, information, services, social and emotional consequences, caring role, and health problems and related areas).

This framework was used as a basis for constructing an initial series of 48 statements representing patient unmet needs (items relating to the domain of caring role were excluded). Through internal peer review, similar items were consolidated (such as bathing and dental into personal care) and statements were removed, leaving 28 items. The 28-item LUNS tool underwent small-scale reliability testing with 29 stroke

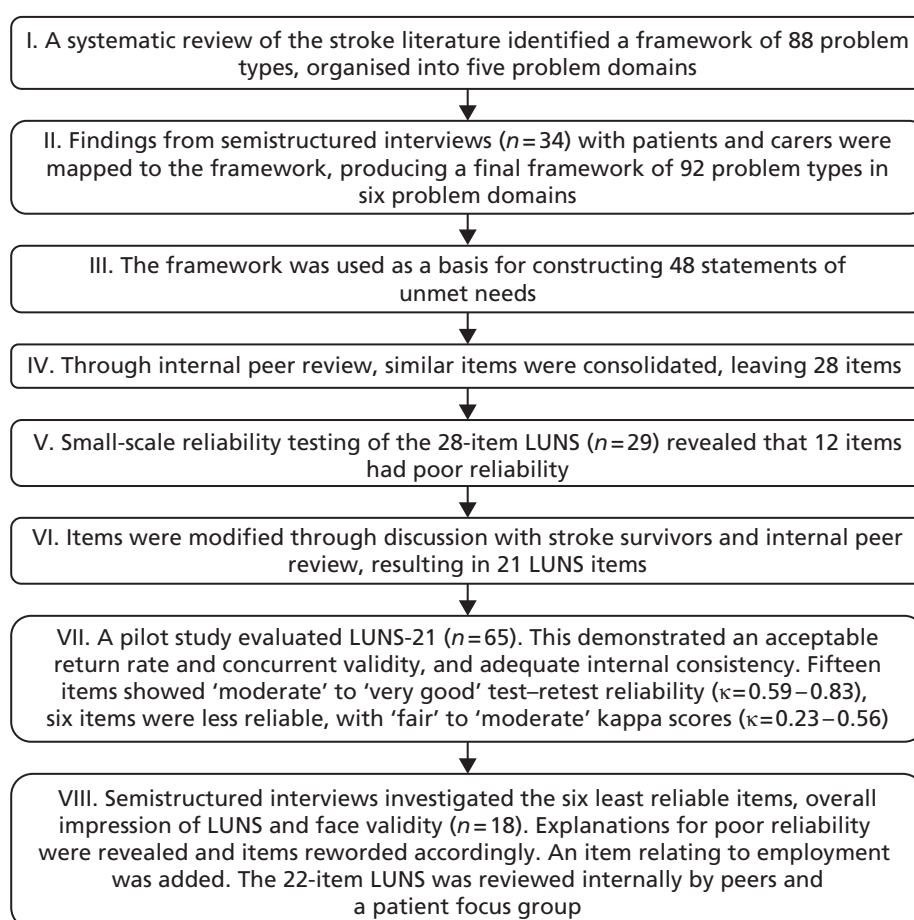


FIGURE 13 Tool development summary.

patients, revealing that 12 items had poor test–retest reliability. Further modification to each item within the tool was facilitated by discussion with members of two stroke clubs, a patient research advisory group and internal peer review. This resulted in a 21-item LUNS tool.

Pilot study

To further evaluate the 21-item LUNS tool it was combined in a self-completion A4 booklet, along with the Hospital Anxiety and Depression Scale (HADS)¹⁰² and the Nottingham Extended Activities of Daily Living (NEADL) Index.¹⁰³ The style of the questionnaire booklet used here was informed by previous work¹⁰⁴ and the booklet was reviewed by members of the CRAG. The acceptability, reliability and validity of the 21-item LUNS tool were evaluated in a three-centre pilot study. A total of 65 patients living at home at 2–21 months post stroke were sent the booklet at two time points. Of these, 48 patients (74%) completed both booklets at a median interval of 10 days, with only 0.1% of the LUNS items not completed (after chasing missing data). The 21-item LUNS tool showed good discriminant validity with HADS, with cases of anxiety or depression reporting more unmet needs, and acceptable concurrent validity with respect to HADS and NEADL (correlation coefficients were -0.424 for NEADL, 0.588 for HADS anxiety and 0.547 for HADS depression). Internal consistency was adequate with a Cronbach's alpha of 0.814 . Of the 21 LUNS items, 15 showed moderate to very good test–retest reliability (88–98% agreement between the two time points, $\kappa=0.59$ – 0.83). The remaining six items were less reliable [77–90% agreement, kappa fair for two items ($\kappa=0.23$ – 0.24) and moderate for four items ($\kappa=0.50$ – 0.56)].

These items were investigated in semistructured interviews with 18 patients, following their completion of the LUNS questionnaire. The six items were included in the interview topic guide, along with four general questions (scoping all other LUNS items) relating to ease of completion, face validity, sensitivity and general impression of the LUNS tool. The recorded completion time for the 21-item LUNS tool was a median of 6 minutes (range 2–12 minutes). All interviewees reported that the LUNS tool was acceptable and unobtrusive and reflected their experiences of stroke. Possible explanations for poor reliability were revealed during the interviews and the six items were reworded accordingly. An item relating to employment after stroke was added.

The resulting 22-item LUNS tool was internally peer reviewed and then circulated to members of a patient group for feedback in a subsequent focus group. The focus group agreed that employment was an important issue and should be included. In the final 22-item LUNS tool, each item has a 'yes/no' response, with the 'no' option applying to either no need or the need is met. Problem domains are information, services, social and emotional consequences, and health problems and related areas. The LUNS questionnaire is provided in *Appendix 11*.

Objectives

The primary objective of the LUNS study was to evaluate the acceptability, test–retest reliability and validity of the LUNS questionnaire for identifying longer-term unmet needs of patients living at home post stroke.

Secondary objectives were to:

- evaluate whether the LUNS questionnaire has suitable properties to be used to give a score for measuring the level of unmet need (internal consistency, dimensionality)
- explore perceptions of unmet need using qualitative methods.

Methods

This study was approved by the Bradford Research Ethics Committee.

Study design

The LUNS questionnaire was evaluated in a large multicentre study. It was administered by post at 3–6 months post stroke in a self-completion questionnaire pack of the same style as that used in the pilot study. The pack contained the LUNS questionnaire and four validated questionnaires on health status, which were used as concurrent measures to assess the validity of the LUNS questionnaire (see *Data collection*). There are no measures of unmet need capable of capturing broad life areas in this population with which we could evaluate the concurrent validity of the LUNS tool; therefore, the LUNS tool was compared with health measures that could reflect the level of need. The LUNS questionnaire was also administered at a second time point to assess test–retest reliability.

The study was conducted in two phases. Factors such as cognitive impairment and unfamiliarity with the language may affect ability to accurately complete a questionnaire. To assess properties of the LUNS tool without interference from these factors, in phase 1 a selected population of English-speaking patients without communication or cognitive impairment was selected. Interim analysis of phase 1 data was conducted to ensure adequate acceptability, test–retest reliability and validity of the tool in this optimised group before proceeding to phase 2. To ensure inclusion of a sample with a broad range of stroke impairments in phase 2, we recruited patients who had spent longer in hospital (likely to be more disabled) and set a target of 50% of patients with cognitive or communication impairment; patients who did not speak English were also included in this group because it was expected that they would have difficulty completing an English-language questionnaire. This target was reduced to 40% during recruitment to meet target timelines.

Participants

Patients were recruited by SRN staff from stroke units across England. Eligibility criteria were purposefully broad: a diagnosed new stroke, age ≥ 16 years and patient being discharged to his or her own home or that of his or her carer. Patients were not eligible if concurrent illness required palliative care or if permanent discharge to a nursing or residential home was planned.

In addition to the above, patients were eligible for phase 1 only if they were English speaking, had no cognitive or communication impairment and had undergone a minimum hospital stay of 72 hours. In the second phase, patients who were unable to read and understand English were recruited if they had an English-speaking carer, patients with a communication or cognitive impairment were included and the minimum hospital stay was increased to 14 days.

With verbal consent, cognition and communication were assessed in both phases using 6CIT⁶⁵ or the Frenchay Aphasia Screening Test (FAST)¹⁰⁵ respectively. Patients who scored ≥ 8 on 6CIT were considered to have cognitive impairment and patients who scored ≤ 6 for FAST comprehension or ≤ 3 for FAST reading were considered to have communication impairment. The group assessed as having no communication or cognitive impairment and who are English speaking are described as the ‘no impairment group’ whereas those assessed as having a cognitive or communication impairment or who are not English speaking are described as the ‘impairment group’ (not speaking English could be considered an impairment in relation to completing an English-language questionnaire).

Written informed consent was obtained from patients before collection of baseline data or, when applicable in the second phase, a relative or friend of a patient lacking capacity was asked to consider the patient’s wishes and provide a consultee declaration.

Recruited patients who became ineligible (e.g. moved to a nursing home) were withdrawn from follow-up and analysis.

Data collection

Baseline data were collected on the ward by SRN staff. Demographic information, stroke details, pre- and post-stroke Barthel Index scores³⁸ and comorbidities¹⁰⁶ were recorded.

After confirming patients' contact details and survival status through GP or NHS database records, the LUNS tool was posted to the participants' home address in a self-completion questionnaire pack. The first pack (pack 1) contained the LUNS tool and the following validated and reliable measures:

- Impairment Manikin¹⁰⁷ – This asks whether the respondent has completely recovered from stroke and includes a diagram of a body on which patients indicate ongoing problems, for example difficulties with their leg or vision.
- GHQ-12⁶² – A measure of emotional health and well-being. A higher score indicates a poorer level of emotional well-being.
- FAI⁹⁸ – A measure of extended activities of daily living. The FAI is scored from 0 to 45 with a higher score indicating a higher activity level.
- SF-12¹⁰⁸ – A measure of health-related quality of life. The two component scores of the SF-12 [mental component score (MCS) and physical component score (PCS)] were used. Scores are standardised to a 0–100 scale, with 50 representing the norm value in the general population, <50 indicating health worse than the norm and >50 indicating health better than the norm.

The second pack (pack 2) included the LUNS and SF-12 tools. Both packs included a question asking whether any help was needed with completion of the questionnaires and pack 2 included a question asking whether the patient had experienced any health changes since completing pack 1. Proxy responses were allowed.

In phase 1, pack 1 was posted to study participants at 3 or 6 months post stroke (dependent on their date of recruitment into the study). This was to enable timely completion of data collection and the interim analysis. In phase 2 all pack 1s were posted at 6 months post stroke when patients were more likely to be home from hospital (considering the increased length of stay and the possibility of cognitive or communication impairment). Using these time points allowed patients a period of time living at home so that they could understand their longer-term needs. Patients were asked to complete the pack and return it to the research team using a prepaid addressed envelope. Patients who had not returned their pack to the study team within 2 weeks were telephoned to check receipt and if necessary the pack was re-sent. If questionnaires were missing <50% of the data, patients were telephoned to complete the missing data. Questionnaires missing $\geq 50\%$ of the data were re-sent. To assess test–retest reliability, pack 2 was sent approximately 1 week after the fully completed pack 1 was received, or if missing data in pack 1 had not been returned within 2 weeks.

Sample size

A sample size of 350 was required in phase 1 for the interim analysis evaluating whether the LUNS tool was suitable for this optimised group. The sample size in phase 2 was 500 to give a total sample size of 850 to assess the full psychometric properties of the LUNS tool. For the psychometric Rasch analysis,¹⁰⁹ a sample size of 243 is required to generate 99% confidence that item calibrations are stable within half a logit, even with poor scale targeting.¹⁰⁶ In phase 1, with an estimated response rate of 70%, a sample size of 350 would generate 245 cases, which is adequate. Phase 2 targeted a more impaired sample and so a lower response rate was anticipated. A response rate of 50% was estimated within this target population, meaning that a sample size of 500 would generate 250 cases. Phase 1 and phase 2 data can also be pooled to create a more powerful analysis.

Statistical methods

Baseline data were summarised using descriptive statistics and compared using Mann–Whitney *U*-test, chi-squared and independent *t*-tests for responders and non-responders to pack 1. The number and types of unmet needs reported in pack 1 were summarised and individual unmet needs were compared between the impairment group and the no-impairment group using Pearson’s chi-squared test.

The acceptability of the LUNS tool was determined by the percentage of pack 1s returned and the amount of non-completed items on initial receipt.

The test–retest reliability of the LUNS tool was assessed by comparing the percentage agreement for pack 1 and pack 2 and kappa statistics for individual items.¹¹¹ SF-12 test–retest results were calculated to provide context to the LUNS results. Patients who identified a change in their health status between packs 1 and 2 were excluded from the test–retest reliability assessment. The strength of agreement for kappa was defined as ranging from poor ($\kappa=0-0.20$) to fair ($\kappa=0.21-0.40$), moderate ($\kappa=0.41-0.60$), good ($\kappa=0.61-0.80$) and to very good ($\kappa=0.81-1$).¹¹²

The Mann–Whitney *U*-test was used to test differences in health status (GHQ-12, FAI, SF-12) between the group who identified unmet need and the group who identified no unmet need on each LUNS item. FAI total scores were calculated only for patients who were sent pack 1 at 6 months post stroke because of the inclusion of questions regarding the preceding 3 and 6 months.

Whether the LUNS questionnaire measures a single underlying dimension or multiple separate dimensions was investigated. Factor analysis allows us to produce an internally reliable scale by identifying the items that most correlate with each other.¹¹³ It was first hypothesised that the LUNS tool would fit one dimension and would be tested using confirmatory factor analysis; should this fail, exploratory factor analysis would be used to explore potential dimensions. Factor analysis was carried out using MPlus computer software (version 6; Muthén & Muthén, Los Angeles, CA, USA).

A Cronbach’s coefficient alpha value¹¹⁴ was also calculated for the item set. Cronbach’s coefficient alpha is referred to as a measure of internal consistency reliability and is the proportion of variance in a set of scores that can be attributed to a common influence on the scores of the individual items.¹¹⁵ However, it has also been argued that alpha is unrelated to the internal structure of the test and should therefore be viewed with caution.¹¹⁶

Additionally, Rasch methods¹⁰⁹ were used to formally test the LUNS tool against a unidimensional measurement model. Rasch analysis provides a unified framework to assess a number of measurement characteristics of individual items, as well as the total scale. Rasch analysis was carried out using RUMM2030 computer software (RUMM Laboratory, Perth, WA, Australia). Full details of Rasch analysis and the various tests of fit available can be found elsewhere.^{117,118} Briefly, we examined individual person and item fit, with fit residuals between ± 2.5 displaying adequate fit. Chi-squared and analysis of variance (ANOVA) item fit statistics were also used to identify measurement anomalies. Differential item functioning (DIF) was examined to identify any bias by sample subgroup, considering age, gender, living arrangements (alone/with someone) and cognitive status (impairment or no impairment). Response dependency occurs when the response to one item has a direct influence on the response to another item, indicated by a positive residual correlation >0.2 . Targeting was considered to assess the relative distributions of the item and person locations. The person separation index (PSI) and Cronbach’s alpha statistics were used to assess the internal consistency (reliability) of the LUNS questionnaire.

Qualitative evaluation of unmet needs

During phase 2, a substudy was designed to further understand whether stroke patients who self-reported having no unmet needs on the LUNS questionnaire genuinely feel that they have no unmet needs or whether their unmet needs were missed by the questionnaire. Purposive sampling selected people who self-reported no (0) or low-level (1) unmet needs within a single region (Yorkshire) and semistructured

interviews were conducted. A topic guide was written to ask about current problems people may have, how these are managed and how they may be identified as unmet needs. Data analysis used a thematic approach, working through the data until a small number of themes were identified that sufficiently describe the data.

Results

Key results have also been published elsewhere.¹¹⁹

Participant flow

A total of 350 participants were recruited from 29 sites in phase 1. In total, 237 pack 1s and 200 pack 2s were returned and included in the interim analysis. Interim analysis of phase 1 data found that the LUNS tool demonstrated adequate acceptability, test-retest reliability and validity to progress to phase 2 of the study. In phase 2, 500 participants were recruited from 40 sites. All results are reported for the combined study population of 850. Recruitment, questionnaire returns, losses and withdrawals for the combined phase 1 and phase 2 study population are summarised in *Figure 14*.

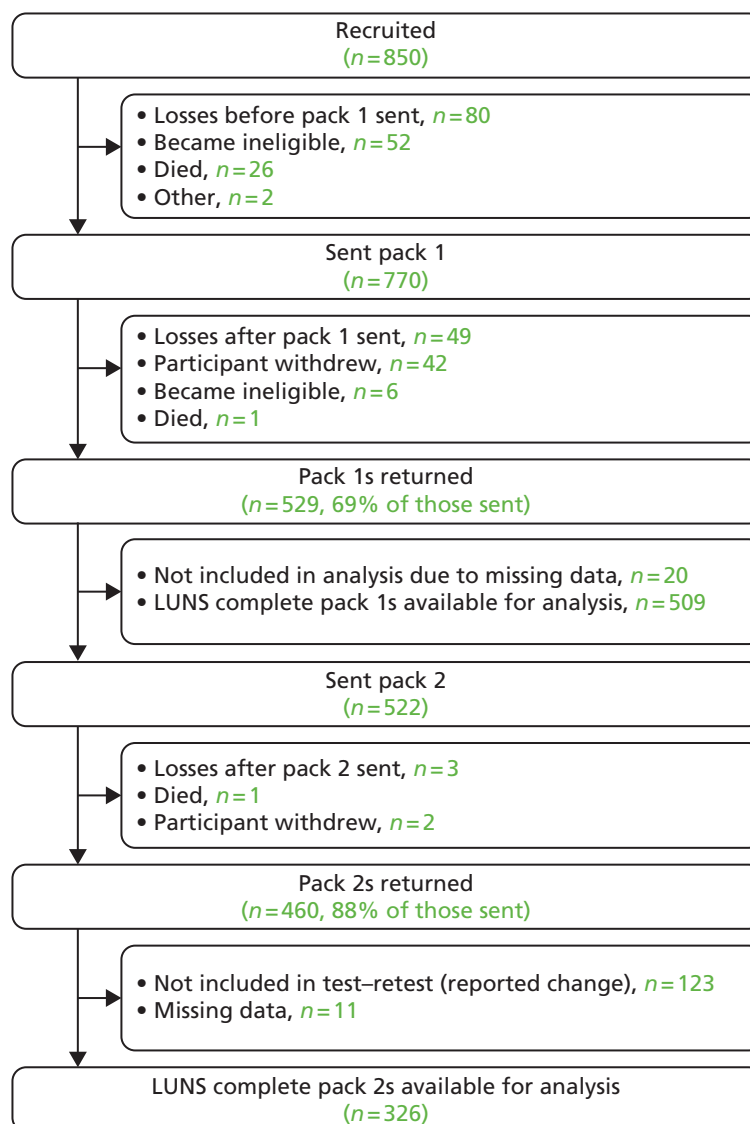


FIGURE 14 Study flow chart. Reproduced with permission from LoTS care LUNS study team.¹¹⁹

Recruitment

Recruitment to phase 1 was conducted between 11 December 2008 and 1 May 2009. Phase 1 follow-up was completed on 26 September 2012. Recruitment to phase 2 was conducted between 1 February 2010 and 10 January 2011. Follow-up was completed on 29 June 2011.

Baseline data

Of the 850 patients recruited, 199 (23%) had a communication or cognitive impairment or did not speak English. The 6CIT identified cognitive impairments in 138 patients, the FAST identified communication difficulties in 56 patients, three people did not speak English and two people could not provide a 6CIT or FAST score but were assessed as having a cognitive impairment. The median age of the population was 73 years and the median time in hospital was 12 days in phase 1 and 42 days in phase 2. Comorbidities are shown in *Table 49* and additional baseline characteristics are shown in *Table 50*.

Table 50 also shows the baseline demographic and clinical characteristics of patients returning or not returning questionnaire pack 1 (responders and non-responders respectively). Overall, responders had a lower level of cognitive and physical impairment than non-responders. Significant differences ($p < 0.01$) were observed for number of previous strokes, ethnicity, communication or cognitive impairment, and post-stroke Barthel Index score. No other significant differences were found when comparing responders with non-responders.

The baseline characteristics of the no-impairment and impairment groups were broadly similar, except that the impairment group was slightly older, had a longer hospital stay and was more disabled according

TABLE 49 Self-reported comorbidities at baseline for those recruited

Comorbidity	Problem identified, <i>n</i> (%)
Heart problem	249 (29)
High blood pressure	496 (58)
Lung disease	108 (13)
Diabetes	158 (19)
Ulcer or stomach disease	91 (11)
Kidney disease	41 (5)
Liver disease	6 (1)
Anaemia/blood disease	66 (8)
Cancer	70 (8)
Depression	126 (15)
Arthritis	337 (40)
Back pain	242 (29)

TABLE 50 Baseline characteristics for all recruited patients

Characteristic	Responders (N=529), n (%)	Non-responders (N=231), n (%)	All recruited (N=850), n (%)
Age (years), median (range)	73 (28–96)	69 (29–98)	73 (28–98)
Gender: male	288 (54)	129 (56)	458 (54)
Living alone pre stroke	201 (38)	102 (44)	343 (40)
Days in hospital, median	25	28	27
First-ever stroke ^a	439 (83)	169 (73)	687 (81)
Ethnicity: white ^a	521 (99)	220 (95)	827 (97)
Have communication or cognitive impairment ^a	91 (17)	63 (27)	199 (23)
Post-stroke Barthel Index score ^a			
Median score (range)	18 (0–20)	17 (0–20)	17 (0–20)
20 (independent)	148 (28)	43 (19)	201 (24)
15–19 (mild disability)	204 (39)	104 (45)	333 (39)
<15 (moderate to very severe disability)	176 (33)	84 (36)	311 (37)
Stroke: pathological classification			
Cerebral infarction	472 (89)	207 (90)	761 (90)
Primary intracerebral haemorrhage	49 (9)	20 (9)	74 (9)
Other	8 (2)	4 (2)	14 (2)
Stroke: clinical classification			
Left hemiparesis	262 (50)	94 (41)	397 (47)
Right hemiparesis	195 (37)	106 (46)	341 (40)
Brain stem	14 (3)	5 (2)	22 (3)
Other	58 (11)	26 (11)	89 (11)

^a Significant differences between responders and non-responders ($p < 0.01$).
Adapted from LoTS care LUNS study team.¹¹⁹

to the Barthel Index score; in addition, a greater proportion of the impairment group had suffered a haemorrhage or had right hemiparesis (*Table 51*).

Numbers analysed

In total, 529 pack 1s were returned. Of these, 20 were excluded because of missing LUNS items and 509 were included to assess acceptability, for comparison with concurrent measures, for calculation of Cronbach's alpha and for factor analysis (423 in the no-impairment group and 86 in the impairment group). Of the pack 2s, 460 were returned and, of these, 124 were excluded because of a reported change in health status and 336 were included in the test-retest analysis (275 in the no-impairment group and 61 in the impairment group).

Rasch analysis was based on the responses of 449 participants (phases 1 and 2 are included but only the pack 1 data from each phase). All 529 response sets were read into the analysis but one person had no LUNS data (all missing) and 79 persons were removed from the analysis as they were judged to be 'extreme'. An extreme person is someone who is either at the floor or the ceiling of the scale, meaning that they have scored either maximally or minimally on the scale. Extreme patients are removed from the analysis as they do not offer any information; they are beyond the measurement parameters of the scale.

TABLE 51 Baseline characteristics of the no-impairment and impairment groups

Characteristic	No-impairment responders (<i>N</i> =438), <i>n</i> (%)	Impairment responders (<i>N</i> =91), <i>n</i> (%)
Age (years), median (range)	72 (30–96)	79 (28–96)
Gender: male	243 (56)	45 (50)
Living alone pre stroke	168 (38)	33 (36)
Days in hospital, median (range)	22 (4–214)	46 (15–267)
First-ever stroke	366 (84)	73 (80)
Ethnicity: white	431 (98)	90 (99)
Post-stroke Barthel Index score		
Median score (range)	18 (0–20)	15 (0–20)
20 (independent)	137 (31)	11 (12)
15–19 (mild disability)	168 (38)	36 (40)
< 15 (moderate to very severe disability)	132 (30)	44 (49)
Stroke: pathological classification		
Cerebral infarction	394 (90)	78 (86)
Primary intracerebral haemorrhage	36 (8)	13 (14)
Other	8 (2)	0 (0)
Stroke: clinical classification		
Left hemiparesis	228 (52)	24 (37)
Right hemiparesis	151 (35)	44 (48)
Brain stem	13 (3)	1 (1)
Other	46 (11)	12 (13)

In this case, all of the extreme patients were at the floor of the scale, meaning that they had no unmet needs.

Response to questionnaire packs

Packs were sent out for completion at 3 or 6 months post stroke, with the median time between stroke and completion 3 months (range 3–6 months) (*n*=115) and 6 months (range 5–10 months) (*n*=414) respectively.

Of all patients who returned pack 1, 213 (40%) reported that they had received some kind of help to complete the pack. The majority (68–76%) of those receiving help reported help with ticking boxes or reading or discussing the questions; in addition, 14 (6%) reported that someone had completed the pack on their behalf without consulting them (proxy completion) and two (1%) reported help with translating the questions. Proxy completion represented 2.6% of all patients who returned pack 1.

Of the responders with no impairment, 32% reported receiving help to complete pack 1, compared with 78% in the impairment group of responders. In the no-impairment group, 1.3% of the packs were completed on the patients' behalf by proxy, compared with 10.1% in the impairment group.

The median number of unmet needs as measured by the LUNS questionnaire was four (range 0–19), with the prevalence of individual unmet needs ranging from 3% to 58%. The most commonly reported unmet

need was for more information; this was followed by unmet needs in the areas of falls and memory/concentration.

In total, 16% ($n=69$) of the no-impairment group and 12% ($n=10$) of the impairment group reported no unmet needs (first pack only). The total number of unmet needs reported was higher on average for the impairment group than for those with no impairment (Figure 15). The median number of unmet needs for the no-impairment group was four and the mode was zero (range 0–19). For the impairment group, the median number of unmet needs was five and the mode was five (range 0–17).

A significantly higher proportion of patients in the group with impairment than in the group with no impairment had unmet needs in the areas of memory/concentration, incontinence and accessible holidays (Figure 16). The proportion of responders who identified memory/concentration as an unmet need was 26% ($n=114$) in the no-impairment group and 45% ($n=41$) in the impairment group.

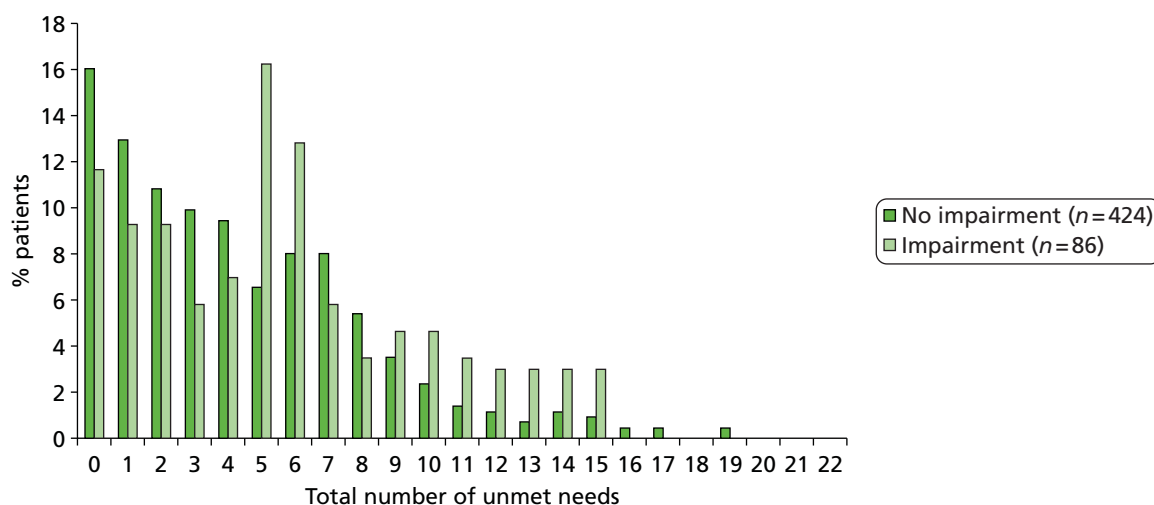


FIGURE 15 Total number of unmet needs reported by individuals.

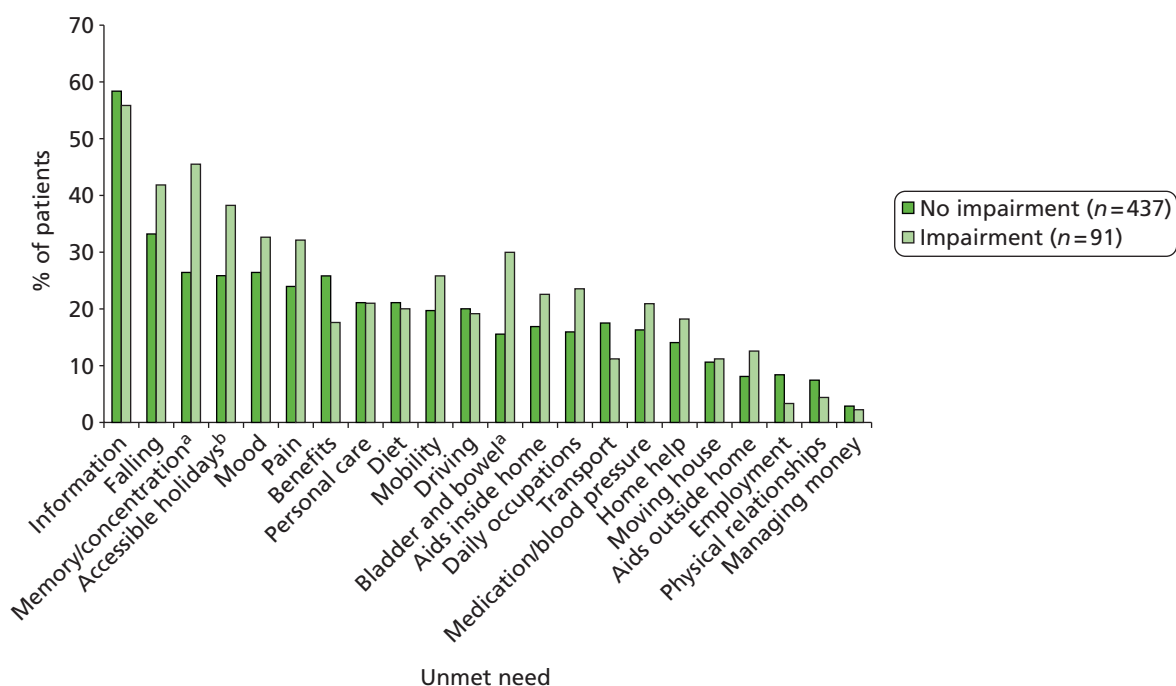


FIGURE 16 Types of unmet need in the impairment and no-impairment groups. a, $p < 0.005$; b, $p < 0.05$.

On the Impairment Manikin, responders reported impairments as listed in *Table 52*. A lower proportion of the no-impairment group than of the impairment group reported difficulties with speech and thinking.

Primary analysis: evaluation of acceptability, validity and test–retest reliability

Acceptability

Responses to pack 1 were received from 529 patients (69% of those sent) (see *Figure 14*). On initial receipt, 85% of the returned questionnaires were fully completed and, overall, 3.5% of the LUNS items were not completed. *Table 53* shows that acceptability of the LUNS questionnaire was comparable to that of the concurrent measures.

Test–retest reliability

Of the pack 2 responders, 336 (73%) reported no health changes between completing pack 1 and completing pack 2. Test–retest reliability was assessed in this group only. The median time between completion of packs 1 and 2 was 14 days (range 3–96 days). The percentage agreement for individual items was between 77.9% and 98.8%, with 19 items having >85% agreement (*Table 54*). Kappa values were between 0.445 and 0.673, with 14 items showing moderate agreement of between 0.445 and 0.593 and eight items showing good agreement of between 0.611 and 0.673. As a comparison, assessment of test–retest reliability of individual items of the SF-12 resulted in kappa scores between 0.34 and 0.57 and a percentage agreement between 44% and 73%.

TABLE 52 Manikin responses

Impairment of	No impairment, <i>n</i> (%)	Impairment, <i>n</i> (%)
Completely recovered from stroke	81 (19)	5 (6)
Thinking	136 (31)	46 (51)
Speech	106 (24)	40 (44)
Vision	97 (22)	28 (31)
Swallowing	58 (13)	11 (12)
Right arm	101 (23)	44 (48)
Left arm	156 (36)	26 (29)
Right leg	115 (26)	34 (37)
Left leg	166 (38)	27 (30)

TABLE 53 Acceptability: missing data

Questionnaire	Questionnaires returned completed (before prompting for missing data) (% of responders)	Items missing (before prompting for missing data) (% of all items received)	Prompts sent (% of all items received)	Items completed after prompting for missing data (% of total prompts sent)
LUNS	451 (85)	412 (3.5)	385 (3.3)	299 (78)
GHQ-12	474 (90)	168 (2.7)	141 (2.2)	108 (77)
FAI	466 (88)	162 (2.2)	119 (1.2)	103 (87)
SF-12	442 (84)	254 (4.0)	204 (3.2)	161 (79)

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TABLE 54 Test–retest reliability

Item	Kappa	Agreement (%)
Physical relationships	0.673 ^a	95.8
Managing money	0.661 ^a	98.8
Accessible holidays	0.660 ^a	88.1
Pain	0.653 ^a	88.0
Driving	0.630 ^a	89.8
Memory/concentration	0.620 ^a	86.6
Information	0.616 ^a	80.9
Employment	0.611 ^a	95.2
Benefits	0.593 ^a	86.6
Daily occupations	0.583 ^a	90.7
Bladder/bowel	0.562 ^a	89.3
Mood	0.554 ^a	84.5
Aids/adaptations outside	0.554 ^a	93.7
Diet	0.549 ^a	86.0
Personal care	0.548 ^a	87.1
Home help	0.546 ^a	90.3
Moving house	0.545 ^a	93.1
Transport	0.514 ^a	86.5
Aids/adaptations inside	0.493 ^a	85.8
Falling	0.492 ^a	77.9
Mobility	0.452 ^a	85.5
Medication/blood pressure	0.445 ^a	85.7

^a $p < 0.01$.

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Comparison of unmet need with health status

For each individual LUNS item, the group of responders who identified unmet need had significantly poorer health scores on the GHQ-12 than those who identified no unmet need ($p < 0.05$). This significant difference in health status between those who did and those who did not identify unmet need was also observed for 21 LUNS items using the SF-12 MCS, 15 LUNS items using the SF-12 PCS and 14 LUNS items using the FAI. Table 55 shows the LUNS items for which the group with unmet need had significantly poorer health than the group with no unmet need ($p < 0.05$) on the concurrent measures.

Subgroup analyses

Of the no-impairment group, 71% ($n = 438$) of those sent the first questionnaire pack returned it, compared with 8% ($n = 91$) in the impairment group. Missing data on first receipt of the LUNS questionnaire for the respective groups was 3.4% (no impairment) and 4.1% (impairment) of all items, compared with 2.0–3.9% and 2.5–6.0% missing data on the concurrent questionnaires in the no-impairment and impairment groups respectively. In total, 86% of the no-impairment group LUNS questionnaires and 84% of the impairment group LUNS questionnaires were returned fully completed; ranges for the concurrent questionnaires were 84–93% for the no impairment group and 81–88% of the impairment group.

TABLE 55 Comparison of unmet need with concurrent measures: concurrent measures for which the group identifying an unmet need had significantly poorer health ($p < 0.05$) than the group with no unmet need

LUNS items	Concurrent measure
Pain	GHQ-12
Mobility	FAI
Falls	SF-12 PCS
Aids/adaptations inside	SF-12 MCS
Transport	
Home help	
Moving home	
Personal care	
Bladder/bowel	
Memory	
Mood/concentration	
Daily occupations	
Accessible holidays	
Driving	GHQ-12
Benefits	SF-12 MCS
	SF-12 PCS
Aids/adaptations outside	GHQ-12
	FAI
	SF-12 MCS
Information	GHQ-12
Medication	SF-12 MCS
Diet	
Money	
Physical relationships	
Employment	GHQ-12

Reproduced with permission from LoTS care LUNS study team.¹¹⁹

Test-retest was assessed in 275 responders with no impairment and in 61 responders with impairment who reported no health changes between pack 1 and pack 2. The percentage agreement for individual items was > 85% for 20 items for the no-impairment group and for 10 items for the impairment group. Kappa values ranged between 0.423 and 0.855 in the no-impairment group (Table 56) and between 0.253 and 0.673 in the impairment group (Table 57).

The results of testing for significant differences ($p < 0.05$) in the concurrent measure scores between the group who identified unmet need and the group who did not identify unmet need (item by item) are summarised in Table 58. More items have a significant difference for those with no impairment compared with those with impairment.

When looking at health scores, there are fewer LUNS items for which there is a significant difference between the group who identified unmet need and the group who had no unmet need (according to LUNS) on the physical health measures (SF-12 PCS and FAI), and more LUNS items for which there is a significant difference between the groups on the mental health measures (SF-12 MCS and GHQ-12).

TABLE 56 Test–retest analysis in the no-impairment group

Agreement	No. of items	Agreement (%)	Kappa
Moderate	10	78–95	0.42–0.60
Good	11	82–96	0.61–0.69
Very good	1	100	0.86

TABLE 57 Test–retest analysis in the impairment group

Agreement	No. of items	Agreement (%)	Kappa
Fair	7	78–95	0.25–0.38
Moderate	12	75–92	0.41–0.56
Good	3	87–97	0.65–0.67

TABLE 58 Comparison with concurrent measures

Measure	No. of LUNS items (out of a possible 22) on which the group of responders who identified unmet need had a significantly poorer health score ($p < 0.05$)	
	No impairment	Impairment
SF-12 PCS	15	2
SF-12 MCS	21	4
GHQ-12	22	8
FAI	18	1

Ancillary analyses: evaluation of internal consistency and dimensionality

Cronbach's alpha

The Cronbach's alpha value for the 22 LUNS items was 0.815.

Factor analysis

A confirmatory factor analysis on one dimension failed. Exploratory analysis was conducted to reveal that a three- or four-dimension solution could be taken (root-mean-square error of approximation of a three-factor solution = 0.034; root-mean-square error of approximation of a four-factor solution = 0.027); however, both are affected by response dependency within the items. LUNS-17 (identified by Rasch analysis; see following section) also failed a single-dimension confirmatory factor analysis, and exploratory factor analysis suggested that four dimensions were present.

Rasch analysis

The LUNS-22 PSI was 0.66 and overall chi-squared probability was < 0.0001 . Three items (information, driving and daily occupations) were found to be poor fitting because of under- or overdiscrimination (all displayed significant chi-squared and ANOVA item misfit). There were response dependencies between items relating to aids/adaptations inside and aids/adaptations outside (0.224) and between mood and memory/concentration (0.223). DIF analysis showed a bias by age for the item relating to employment and a bias by age and gender for the item relating to physical relationships. Removing the five problematic items (with regard to fit indices and DIF) and accounting for the apparent response dependency within the scale results in a 17-item solution (LUNS-17), which displayed reasonable model fit as none of the items were individually misfitting. However, this 17-item tool remains unsuitable for use as a scale because of

poor targeting and reliability/internal consistency issues ($PSI=0.52$), The low PSI also reduces the power of the tests of fit, meaning that the observed adequate fit may be misleading. The Cronbach's alpha value at this point is 0.77, but this does not take into account the targeting, or the response dependency that is present. The targeting plot can be seen in *Figure 17*, in which it is apparent that there is a skew between the locations of the items and the locations of the sample that is being measured.

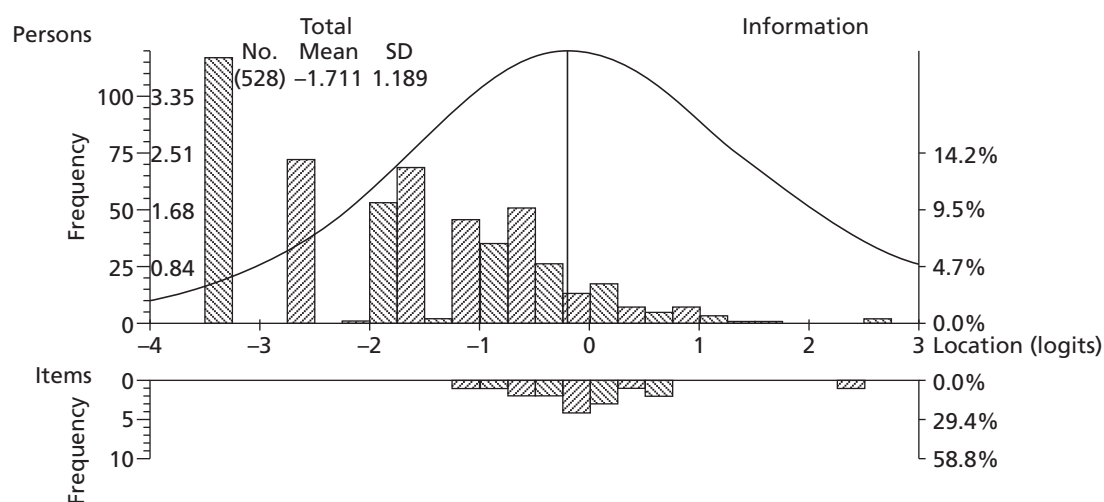


FIGURE 17 The LUNS Rasch targeting plot, displaying the relative distributions of person and item logit locations on the underlying 'unmet need' continuum. Grouping set to Interval length of 0.25 making 28 groups. $n=528$, mean=-1.711, SD=1.189.

Qualitative evaluation of unmet needs

In total, 10 semistructured interviews were conducted. Eight interviewees were male and the median age was 78 years. Nine interviewees lived with their husband/wife and one lived alone. During the LUNS study, six participants had identified no unmet needs, three participants identified one unmet need in either the first or the second pack and one participant identified one unmet need in both the first and the second packs. The qualitative study found that most people felt that they genuinely had no unmet needs. Despite this, all interviewees were able to identify current problems. However, interviewees often rejected the word 'problem' and therefore these are termed 'identified issues'. Identified issues may relate to stroke, comorbidities and/or ageing. The type, impact and importance of these issues varied. People can be living with significant limitations yet still identify no unmet needs. People may be in the process of seeking help for their issues or may feel that they are managing them. Issues were grouped according to their effect on life (number of people who reported each in brackets):

- leg, arm or hand pain, weakness, spasticity or other limitation (nine)
- walking, getting out, mobility (nine)
- other (nine) (e.g. feeling slow, frustrated, experiencing a changed or strained relationship with partner, weight gain, breathlessness)
- balance or falls (eight)
- hobbies, leisure (seven)
- feeling tired (six)
- mood, anxiety (five)
- domestic activities (four)
- social life (four)
- memory and/or concentration (three)
- vision (two)
- throat and voice (two)
- communication (two)

- bladder and bowel (two)
- personal care (two)
- holiday (one)
- crying (one)
- sleeping (one).

The following themes emerged:

- Level of acceptance – relates to adjusted expectations; high levels of acceptance were common and this links with experience of ageing and may explain how issues can become redefined in the context of current life.
- Support received – people are often receiving support from their partner; family, friends or services also provide support.
- Relative situation – people compare themselves to other people and report feeling fortunate and valuing information from peers.
- Presentation of character – some people identify themselves as proud, being independent and/or determined.
- Experience of frustration – frustration was common and includes limitations in relation to carrying out tasks or things taking longer to do, for example.
- Experience of services – people have experiences and expectations about services, including what treatment is available and acceptable to ask for.

Discussion

Interpretation

The LUNS questionnaire was developed to identify the longer-term unmet needs of stroke survivors. It consists of 22 items, covering information, services, social and emotional consequences and health problems and related areas. The study aim was to evaluate the acceptability, test–retest reliability and validity of the LUNS questionnaire in a broad sample of patients living at home post stroke. The response rate (69%) and minimal missing data, comparable to those for concurrent measures, suggest that the LUNS questionnaire is acceptable to the target group. Individual-item test–retest reliability was good and compares favourably to that for SF-12. It was found that identification of an individual unmet need was consistently associated with poorer outcomes on the concurrent health measures, demonstrating validity. Interestingly, unmet need was more strongly associated with lower mental health than with lower physical health or activity.

The acceptability of the LUNS questionnaire was lower in stroke survivors with cognitive or communication impairment than in those with no impairment. However, the acceptability in stroke survivors with cognitive or communication impairment was comparable to the acceptability of concurrent measures in this group. The test–retest reliability of LUNS items was slightly lower for the impairment group and comparison with concurrent measures suggests a reduced association between LUNS items and health status. Cognitive and communication impairments were assessed at baseline; however, Impairment Manikin results suggest that cognitive and communication impairment caused by stroke may persist up to 3 or 6 months post stroke for some people.

A secondary aim was to evaluate the internal consistency and dimensionality of the LUNS questionnaire. An initial Cronbach's alpha value of 0.815 suggests a reasonable level of internal consistency among the 22 LUNS items. However, additional factor and Rasch analysis revealed that the LUNS questionnaire does not function as a scale because of multidimensionality and poor targeting; therefore, items cannot be added up to give a total score for level of unmet need.

A substudy interviewed a sample of patients who identified a low level of unmet need (no or one unmet need) to further understand self-reported unmet need following stroke. People in this study felt that they genuinely had no unmet needs, yet all participants identified current issues or problems, which may relate to stroke, comorbidities or ageing. Six themes demonstrate the importance of adjusting: help received from others; comparisons to other people; characteristics such as pride, independence and determination; frustration when engaging in activities; and experiences and expectations of services. This adds to the understanding of how problems are managed and what shapes the identification and perceptions of unmet needs.

To put the LUNS questionnaire in context, few suitable tools exist to assess an individual's unmet needs following stroke. The Stroke Association needs survey consists of 44 items and has not been psychometrically evaluated.⁴ The Southampton Needs Assessment Questionnaire has not been evaluated for test-retest reliability⁹⁹ and the postal response rate was low at 49%.¹⁰⁰ This questionnaire was evaluated only in people aged ≤ 65 years, yet older adults make up the majority of the stroke population.¹²⁰ The Stroke Impact Scale is long (59 multiple choice items) and low postal response rates of 41%¹⁰⁴ and 63%¹⁰¹ have been reported.

Generalisability and limitations

Comparison with data from the UK NSA population¹²⁰ indicates that the LUNS study sample is reasonably representative of the wider UK stroke population (age, gender, time in hospital, post-stroke Barthel Index score). The ethnicity of the sample is representative of the ethnicity of the population aged 65+ years in England in 2001.⁸⁵ By setting a target for the proportion of patients with communication and cognitive impairments, and allowing proxy responses, the LUNS questionnaire has been evaluated on a sample with varying stroke severity. The target recruitment of the impairment group was reduced to meet study deadlines. Inherent barriers exist to the recruitment and inclusion in research of stroke survivors with cognitive and communication impairments. Therefore, stroke survivors with communication or cognitive impairment should be actively included, especially with regard to health or needs assessment and questionnaire evaluation. Lower test-retest reliability and problems relating to validity may be properties of all questionnaires when including stroke survivors with cognitive or communication impairment.

The LUNS questionnaire demonstrated a response rate and median number of unmet needs that are similar to those found for a UK stroke needs survey (response rate 60–78%, median unmet needs four).⁴ A median of two unmet needs has been reported during post-stroke reviews using GM-SAT.³⁴ The LUNS questionnaire is a pragmatic tool which can identify the unmet needs of stroke survivors that relate to either stroke or comorbidities. These include unmet needs that may require inputs from health providers and other providers such as local authorities and third-sector organisations. Results from the LoTS care trial (see *Chapter 3, Overview of stroke care co-ordinator practice*) indicate that SCCs currently refer/signpost stroke patients to such whole system services. It is possible that the LUNS questionnaire may also have wider relevance beyond stroke care, to capture general issues that affect older people with long-term conditions.

Use of dichotomous responses is considered a strength as it is simple and results in an unambiguous response.¹²¹ The potential complexity of double-barrelled questions was managed by providing instructions to tick 'no' if there is no need or if the need has been met. As a result, the LUNS questionnaire is quick for stroke survivors to complete and easy to interpret; items ticked 'yes' indicate the type and number of unmet needs that an individual has. The results show that, for the majority of individual items, responders commonly tick 'no'; as such, this may result in vulnerability to a floor effect.

When assessing validity we were unable to compare the LUNS questionnaire with validated benchmark measures of unmet need as no such tools exist. Therefore, health status questionnaires were chosen that could reflect health-related needs.

It is acknowledged that some topics do not specifically map onto the LUNS questionnaire, for example fatigue, vision and communication. However, tool development incorporated stroke patient- and carer-identified problems and, furthermore, the qualitative exploration of the unmet needs study did not find that the LUNS questionnaire was missing these or any other needs. Iterative development and robust methods were used to capture evidence from the literature and the views of experts and > 150 patients. The subjectivity of unmet needs meant that patient involvement was an important part of the development of the LUNS questionnaire, and patient understanding of items demonstrates provenance.

Recommendations for research and implications for health care

We have demonstrated that the LUNS questionnaire has adequate acceptability, test–retest reliability and validity to provide a simple method for identifying longer-term unmet needs after stroke. Policy recommends that stroke patients are reviewed in the longer term^{15,55} and that this includes measurement of unmet needs. The LUNS questionnaire is suitable to be used during individual patient consultations to guide service responses. It is also suitable to be used to promote service development, compare different services or inform commissioning, for example evaluating whether services are meeting patients' needs by measuring the percentage of the local stroke population whose mobility needs are unmet. Further research is needed to evaluate the sensitivity to change of the LUNS questionnaire, to determine whether it can be used to monitor change at a patient or service level over time. Results from factor and Rasch analysis suggest that the LUNS questionnaire should be used at the individual-item level rather than to give a score representing the burden of unmet need.

The observed lower test–retest reliability and validity of the LUNS questionnaire in patients with cognitive or communication impairment suggests that it may be important to research the accuracy of proxy responses and potentially to develop a version of the questionnaire that is suitable for people with communication impairment.

The subtlety and complexity of measuring unmet needs described in the substudy interviews should be considered when planning stroke reviews and using questionnaire tools, for example to ensure that individual circumstances are considered when assessing unmet need.

Chapter 5 Project 4: adjustment after stroke study

Abstract

Aim

The study aimed to investigate longer-term recovery and adjustment post stroke with a particular focus on the processes and mechanisms that contribute to social inactivity and/or social activity.

Study design

A qualitative substudy of the system of care trial was undertaken, drawing on grounded theory techniques.

Methods

A purposive sampling strategy was adopted to identify trial participants who were less or more socially active than anticipated based on social activity and physical disability outcome measures and to ensure variation in key characteristics known to shape adjustment post stroke (age, socioeconomic status, living alone). A combination of qualitative methods was used, including multiple semistructured interviews, limited observations, solicited diaries, and informal and formal support mapping techniques.

Results

In total, 22 stroke survivors and 12 carers/significant others participated in the study. From participants' accounts, four different post-stroke recovery trajectories have been identified: (1) disruption followed by adjustment and acceptance; (2) cycles of disruption followed by adjustment and acceptance; (3) disruption without adjustment and acceptance; (4) stroke as a continuation of ongoing decline. The different trajectories illustrate how multiple interacting factors shape the process and meaning of recovery and adjustment over time and therefore social participation. The factors that shape the different trajectories were identified.

Conclusions

Knowledge of different recovery trajectories and the factors that shape adjustment and social participation post stroke may enable stroke survivors, caregivers and professionals to identify factors that act as barriers to adjustment and social participation. This may help stroke survivors shape their own recovery trajectory and facilitate professionals in better tailoring services provided.

Introduction

There has been great interest in the experience of and meaning attributed to recovery and adjustment following stroke. Much existing research, however, has focused on particular aspects of recovery and adjustment rather than examining the process in its complexity over time. Furthermore, studies have tended to focus on the first 12 months after stroke. This qualitative study aimed to explore the interacting factors that shaped the meaning and process of recovery and adjustment of stroke survivors who had had a stroke at least 12 months previously. In particular, the study aimed to understand the social dimensions of recovery and adjustment, focusing on social activity and participation post stroke.

Background

Many factors are known to affect the process of adjustment following stroke and these factors may impact on social participation. They include:

- physical and functional improvement
- emotional factors
- the understanding given to the stroke, rehabilitation and disability
- stigma
- formal and informal support
- various contextual factors.

Physical and functional recovery shapes longer-term outcomes after stroke.^{25,122,123} Stroke-related impairments and the resulting changed relationship that people have with their body can result in people experiencing their body as being unreliable.¹²³ In addition to the physical and functional implications of stroke, various emotional and psychological consequences have been highlighted in the literature, including depression, low mood, apathy, aggression, irritability and anxiety.^{10,124,125}

People's perceptions of stroke, rehabilitation and disability also shape longer-term outcomes following stroke and the process of adjustment. Chronic conditions can disrupt previous roles, relationships and structures of everyday life as well as expectations for the future.¹²⁶ The disruption can be meaningful both in terms of its significance to a person's sense of self and biography and in terms of its effect on a person's ability to carry out everyday activities.^{126,127}

Although little has been written specifically about experiences of stigma post stroke, the existing literature details how some people are concerned about how others (including strangers) perceive them, that relationships and friendships change and that people may become anxious about engaging in social situations and may experience agoraphobia.¹²⁵ People may also try to cover up the effects of their stroke.^{122,128}

Social support from families, friends, neighbours and support groups has been shown to be extremely important in terms of instrumental, informational and emotional support post stroke.^{129–131} Formal services, including access to and withdrawal from these, also shape longer-term outcomes.^{122,132,133} In addition, socioeconomic factors, health inequalities, patterns of health service use and local resource allocation have implications for life after stroke.¹³³

Social inactivity and social isolation are experienced by many people who have had stroke.²⁵ The wider literature indicates that those who perceive themselves to be socially isolated are more likely to experience anxiety and stress,^{134–136} which may increase their vulnerability to physical and mental health problems.¹³⁴ Living alone and low social participation are risk factors for disability among older men, and dissatisfaction with social relationships is significantly associated with disability for both older men and older women.¹³⁶ Social isolation and loneliness may therefore have implications for rehabilitation following stroke. Furthermore, stroke-related impairments may restrict a person's ability to engage in social activities and may contribute to him or her becoming socially isolated.²⁵ Thus, stroke-related impairments may themselves compound isolation and loneliness. Existing data,^{18,37} however, suggest that even those who recover physically and functionally well following stroke may still become socially inactive. There is a need, therefore, to further explore the relationship between the process of recovery, including physical and functional improvement, and social participation post stroke.

Although the existing literature provides an understanding of multiple factors that influence life after stroke, the complex process of recovery and adjustment is not fully understood. Furthermore, there is a lack of clarity as to the processes and mechanisms that influence social activity and social participation, as well as the relationship between recovery and social participation. This study addresses these gaps by exploring the process of recovery and the role of social participation in that process from the perspective of

stroke survivors. By understanding the process of recovery and adjustment over time, steps can be taken to further support the adjustment of stroke survivors and their carers and help to improve services and longer-term outcomes.

Aims and objectives

The study aimed to investigate longer-term recovery and adjustment post stroke with a particular focus on social activity and participation. The primary and secondary objectives are:

- primary objective: to understand the processes and mechanisms that contribute to stroke survivors' social inactivity and/or social activity post stroke
- secondary objectives:
 - to comprehend what stroke survivors (and carers) understand to be a good recovery post stroke
 - to understand stroke survivors' (and carers') experiences of the stroke and the process of adjustment (within the context of their ongoing lives/biography)
 - to comprehend stroke survivors' (and carers') experiences of the social and cultural context in which adaptation occurs post stroke
 - to develop a better definition of poor adjustment post stroke and determine the prevalence of poor adjustment among the stroke population.

Methods

Study design

The adjustment after stroke study is a substudy of the stroke system of care trial (see *Chapter 3*). The study adopted a grounded theory approach^{138–140} and a combination of qualitative methods was used to understand the process of adjustment following stroke, including semistructured interviews, limited observations and solicited diaries.

This study used data collected by the trial to purposively sample stroke survivors and study their recovery and adjustment over time. As the study aimed to explore adjustment after stroke and in particular to understand the processes and mechanisms that contributed to social participation following stroke, the study recruited stroke survivors who were less or more socially active than anticipated. Analysis was conducted on an existing data set with a similar population to that of the stroke system of care trial³⁶ to identify categories based on pre-stroke and 12-month post-stroke Barthel Index scores and FAI scores. Three categories were identified: better than expected, failure to thrive and doing as expected (doing well). *Table 59* provides definitions of the categories and *Appendix 12* provides further information regarding the development of these categories.

TABLE 59 Definitions of the categories

Category	Reduction in Barthel Index score (between pre stroke and 12 months post stroke)	Reduction in FAI score (between pre stroke and 12 months post stroke)	Excluding
A: better than expected	>4	≤16	Those who have a 12-month FAI score of 0
B: failure to thrive	≤4	>16	Not applicable
C: doing as expected (doing well)	≤4	≤7	Those who have a 12-month FAI score of 0

This study was approved by Bradford and Scotland A Research Ethics Committees. A SMG was established to oversee the running of the project. If researchers had any concerns with regard to emerging ethical issues (including the safety of participants) they were able to discuss this with the chief investigator and, if deemed appropriate, the wider SMG to reach a consensus on how to proceed. Pseudonyms are used throughout the document.

Eligibility criteria

All participating stroke survivors had taken part in and completed the stroke system of care trial by returning the 12-month questionnaire pack and therefore were subject to the trial inclusion and exclusion criteria at the point of recruitment into the trial (see *Chapter 3* for the trial eligibility criteria).

Stroke survivors who were less or more socially active than anticipated, as defined by the categories discussed earlier, were identified by screening the trial database (see *Appendix 12* for further details).

Stroke survivors were excluded from this substudy if they had moved into 24-hour care following recruitment to the trial, as this is already known to shape adjustment after stroke and is associated with a decrease in social activity as well as an increase in social isolation and loneliness.

Although the primary focus of the study was on the process of adjustment from the perspective of the stroke survivor, it is acknowledged that carers (and the dynamic between the stroke survivor and the carer) are important to the process. Therefore, carers who consented to take part in the trial and whose relative/friend was identified as a potential participant for this substudy were also approached to take part. Those stroke survivors who were identified as potential participants and whose carer did not take part in the trial were asked if they had a carer or significant other (who may not be a carer) who would be interested in taking part. Stroke survivors receiving palliative care and their carers/significant others were also excluded.

Sampling strategy

A purposive sampling strategy was adopted to identify stroke survivors who were less or more socially active than anticipated. Because of the exploratory nature of this study, 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. These included age, socioeconomic status and whether the stroke survivor lived alone or with others. In addition, both male and female stroke survivors were sampled.

Following the identification of potential participants, a researcher telephoned them to assess eligibility and interest in the study. Suitable participants were sent an information sheet and this was followed by a telephone call several days later, at which the first interview was arranged if appropriate. Written consent and/or consultee declaration for those lacking the capacity to consent was obtained face to face during this first visit.

Data collection methods

A combination of qualitative methods was used, including semistructured interviews, solicited diaries, observations and mapping of formal and informal support networks. *Figure 18* illustrates the data collection procedure.



FIGURE 18 Data collection procedure for adjustment after stroke study.

Initial 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). Participants discussed their understanding and perception of the stroke, recovery and adjustment; the physical, functional, emotional and social consequences of the stroke; and changes that they had experienced in their lives since the stroke. Limited observations were also carried out by the researchers. These comprised environmental observations, which included neighbourhood observations (description of the location of the residence and nearby environment, rural/urban/suburban setting, local amenities, availability of public transport, evidence of social problems, accessibility issues, etc.) and household observations (type of home, description of aids and adaptations made to home, use of space including if participant is still sleeping downstairs, etc.). These observations provided contextual information regarding the immediate environment and adaptations made to the home, which informed the topic guide for the follow-up interview (specifically with regard to discussions concerning managing stroke-related impairments and engaging in everyday, leisure and social activities). In addition, observations were also conducted alongside the interview to record contextual information, for instance interactions with and between participants, gestures and mannerisms, physical demonstrations of impairments and use of objects by participants during the interview. Notes of non-verbal actions were added to the verbatim interview transcripts to aid understanding and interpretation.

Diary

At the end of the first interview stroke survivors and their carers/significant others were asked if they would be willing to keep either a written or audio diary for a period of 4 weeks (this was optional). The diary-interview method¹⁴¹⁻¹⁴⁶ has been used previously in health research with people with chronic illnesses. Diaries can capture the 'contemporaneous flow of public and private events' (p. 170),¹⁴⁷ 'transient phenomena' (p. 265)¹⁴¹ and hidden accounts that do not often emerge in one-off face-to-face interviews.

Participants were asked to record meaningful events and experiences as well as their thoughts and feelings. They were free to decide what information they chose to include, how frequently they recorded an entry and how much time they spent on the diary. The researchers telephoned participants weekly during the 4 weeks that they kept the diary as this has been shown to remind participants about the diary and provide an additional source of data.¹⁴¹

In the diaries participants chose to record information relating to their day-to-day experiences and difficulties; factors that facilitated and/or hindered social participation; their social support networks; their physical and functional impairments; their feelings; and other contextual information.

Follow-up interview

Participants' first interviews and diaries were transcribed and analysed before the follow-up interviews. In accordance with a grounded theory approach,¹³⁸⁻¹⁴⁰ the topic guides for the second interviews were developed and refined based on the ongoing analysis of the first interviews, observations and diaries. The majority of follow-up interviews took place 3-4 months after the first interview.

To explore participants' informal and formal support networks in greater detail the researchers undertook mapping exercises during the follow-up interviews. The exercises enabled the participants to illustrate and discuss informal and formal support that had been important to them since the stroke. The approach used in this study drew on the hierarchical mapping technique.¹⁴⁸ Participants were given a diagram in which they were depicted at the centre of three concentric circles, which represented different levels of support. Participants were then asked to place onto the concentric circles people/services who they felt had offered support, with the most supportive being placed in the circle closest to the centre. The researchers engaged participants in conversation throughout the exercise to explore the maps produced in depth. Mapping informal support allowed the researchers to gain an understanding of participants' experiences of their (changing) social relationships and the support that these different relationships provided. Formal support mapping involved participants recording services used (including health and social care services, volunteer

services and peer support groups), how helpful participants found such support and how formal support changed over time.

Data analysis

A grounded theory approach to data analysis was taken, which entailed simultaneous data collection and analysis.^{138–140,149} Analysis of the data involved careful rereading of the transcripts of interviews and diaries. This was followed by three phases of coding to facilitate the development of themes and theories: open coding involved descriptively coding the data line by line (open codes were numerous and included 'daily routine', 'getting out of the house', 'pain', 'frustration', 'family encourages to do things and go out', 'does not go out' and 'sees some improvement'); focused coding involved grouping the descriptive codes and forming categories (focused codes included 'activities – pre stroke', 'activities – post stroke', 'loss and uncertainty', 'everyday life work', 'meaning as consequence', 'meaning as significance', 'relationships over time', 'sense of recovery' and 'role of informal support'); theoretical coding involved examining the relationships between the categories and developing an explanation of the process of adjustment (the theoretical codes were a typology of recovery trajectories).^{138,140} The software program NVivo 8 (QSR International, Southport, UK) was used to store, organise and code the data. Memos concerning coding and emerging themes and theories were also recorded.

The interpretations made were tested by the use of 'constant comparison',¹³⁹ whereby data segments and the developing codes and categories are compared. In this study, data segments from different data collection methods were also compared (interview, diary and observation data) to add depth and complexity to the analysis. This constant comparison was carried out, first, within case (so data segments from the same participant were compared) to produce an understanding of each individual's process of recovery and adjustment over time and, second, across cases (so data segments were compared across participants) to provide an understanding of similarities and differences in the process of recovery and adjustment over time for different participants.

As the research aimed to explore the meaning and process of recovery post stroke, and thus the interacting factors that shaped activity and social participation over time, time became an important analytical device. As analysis progressed and the researchers began to explore individual and across-case recovery and adjustment, concepts of the illness trajectory and recovery trajectory became particularly important.^{150–153} The concept of the illness trajectory comprises several interacting elements: the course of the chronic illness; work related to managing and living with that chronic illness (including illness work, everyday life work, biographical work); and the impact that the chronic illness and such work have on the person with the chronic illness and their relationships with others. Of importance, therefore, is the dynamic between subjective experience, the course of the chronic illness and the management of that illness. In this instance, recovery trajectories post stroke can be understood as the interplay between the course of the stroke and rehabilitation; the work required to manage and live with stroke-related impairments; and the subjective experience and meanings given to the stroke, stroke-related impairments, the process of rehabilitation and the work to manage and live with the stroke-related impairments and the impact that these have on the stroke survivor and their relationships with others. Analysis, therefore, led to the identification of different types of recovery trajectory (a typology of recovery trajectories) as well as the exploration of the different processes and mechanisms that shaped these different recovery trajectories.

Standard approaches to demonstrating trustworthiness and quality in qualitative research were used.^{154–157} Throughout the data collection and analysis process, data, codes and emerging categories and theories were presented to and discussed with the study steering group at regular intervals. The emerging findings were also presented to academic audiences and therapy staff who currently work with stroke survivors as well as stroke survivors and their carers. Comments received were considered alongside ongoing analysis.

Results

Recruitment

In total, 22 stroke survivors and 12 carers/significant others were recruited to the study from November 2010 to December 2011. The period of time between stroke and the first interview ranged from 14 to 24 months, with most participants being interviewed for the first time at either 14 months (five stroke survivors) or 15 months (eight stroke survivors) post stroke. For most participants the second interview took place 3–4 months after the first interview. Those stroke survivors whose carers/significant others also participated in the study were given the option of being interviewed together or separately; all decided to be interviewed together. *Table 60* details the numbers of stroke survivors and carers/significant others who participated in each phase of data collection. Two stroke survivors and one carer/significant other were lost to follow-up.

Table 61 summarises some of the characteristics of the participating stroke survivors (age at time of stroke, living circumstances, life and health before stroke and stroke-related impairments). *Table 62* summarises the forms of support that participating stroke survivors reported receiving, including formal support following discharge home from the hospital, formal support provision at the time of the interviews and informal support.

Recovery trajectories

We examined the process of recovery and adjustment over time (which we have termed recovery trajectories) of 22 stroke survivors. From the accounts of participating stroke survivors and their carers/significant others, different recovery trajectories have been identified, as well as the inter-related factors that participants perceived as having shaped these trajectories, and what was meaningful in terms of recovery and adjustment.

This section will explore the different recovery trajectories from the perspective of those adjusting to and living with the effects of stroke. From participants' accounts, four different recovery trajectories have been identified: (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.

Stroke experienced as a disruptive event

For participants in three of the four trajectory categories (the 20 stroke survivors in trajectories 1, 2 and 3), the stroke was experienced as being a disruptive event. Participants spoke of this disruption in similar terms and tended to experience this sense of disruption most acutely in the period post discharge home. This disruption was meaningful for participating stroke survivors both in terms of its significance (the effects that the stroke had on their identity and biography) and in terms of its consequences (the difficulties and challenges that the stroke impairments presented in terms of their day-to-day activities).

TABLE 60 Numbers of stroke survivors and carers participating in each phase of data collection

Participants	First interview and observations	Diary	Second interview and mapping
Stroke survivors	22 ^a	12	20
Carers	12	3	11

^a 12 from the more socially active than anticipated group, eight from the less socially active than anticipated group and two from the doing as expected (doing well) group (based on pre-stroke and 12-month post-stroke Barthel Index and FAI scores).

TABLE 61 Summary of the characteristics of participating stroke survivors

Name (pseudonym)	Age at time of stroke (years)	Category (from Barthel Index/FAI scores)	Living circumstances	Summary of life pre stroke (as reported during interviews)	Stroke impairments (as reported at the time of the first interview, unless indicated otherwise)
Matt	57	Better than expected	Lives with wife and son in their own house	Independent, restricted mobility and fatigue because of pre-existing chronic condition	Impaired mobility, problems with balance, walks with frame/two sticks, some memory loss
Olive	88	Better than expected	Lives alone in supported bungalow	Independent, pre-existing chronic conditions but did not present these as having a big impact on her life	Impaired mobility, short-term memory problems, sight and speech temporarily impaired following stroke but now almost fully returned
Eric	65	Better than expected	Lives alone in his own house	Independent, registered blind	Weakened right side, mild expressive aphasia, impaired mobility, limited function in right hand
Alf	64	Better than expected	Lives alone in a rented ground floor flat	Independent, generally healthy, arthritis	Weakened left side, impaired mobility, reduced function in left hand, impaired memory, speech temporarily impaired following stroke
Bernard	62	Better than expected	Lives alone in sheltered accommodation	Lived in sheltered accommodation and had paid carers before stroke; had a range of pre-existing chronic health conditions	Weakened side, impaired mobility, fatigue, uses mobility scooter and/or walks with stick, speech temporarily impaired following stroke
Barry	63	Better than expected	Lives with wife in their own house	Independent, working full time, generally healthy	Weakened right side, limited function in right arm and hand, impaired mobility (walks with stick), depression
Sal	65	Better than expected	Lives alone in a council-owned flat	Independent, working full time (volunteer role), arthritis and another chronic condition that had resulted in some mobility impairment, but walked unaided	Weakened right side, limited use of right hand, impaired mobility, problems with balance, pins and needles/ burning sensation in right side, impaired vision (improved over time), short-term memory problems
Rita	67	Better than expected	Lives alone in a flat	Independent, generally healthy, transient ischaemic attacks before stroke	Weakened left side, memory problems, minor sight problems, problems with balance
Peter	81	Better than expected	Lives with wife in their own bungalow	Independent, restrictions because of pre-existing chronic condition requiring regular hospital visits	Impaired vision (lost virtually all sight in his right eye), short-term memory problems
Dave	57	Better than expected	Lives with wife in their own house	Other health problems and disabilities, profoundly deaf	Weakened left side, limited function in left arm, mobility impairments, fatigue
Greg	71	Better than expected	Lives with wife in their own house	Life restricted because of pre-existing chronic condition, rarely left house, impaired mobility	Weakened left side, impaired function in left arm/hand, impaired function in left leg, incontinent, decreased concentration

TABLE 61 Summary of the characteristics of participating stroke survivors (*continued*)

Name (pseudonym)	Age at time of stroke (years)	Category (from Barthel Index/FAI scores)	Living circumstances	Summary of life pre stroke (as reported during interviews)	Stroke impairments (as reported at the time of the first interview, unless indicated otherwise)
John	61	Better than expected	Lives with wife in their own house	Independent, diabetes, other chronic health condition	Some numbness and mild weakness on right side, impaired mobility
June	66	Doing as expected (doing well)	Lives with her husband in their own bungalow	Independent, working part time, cares for dependent adult son	Some problems with short-term memory, initially had problems tolerating some of the medication, loss of stamina, fatigue
Emily	77	Doing as expected (doing well)	Lives with husband in their own house	Generally healthy, transient ischaemic attack before stroke	Weakened right side, impaired mobility, fatigue
Lyn	55	Failure to thrive	Lives with brother	Independent, mobility slightly impaired because of pre-existing condition	Weakened right side, weak right leg, impaired mobility (walks with four-pronged stick/wheelchair user), paralysed right arm, speech slightly impaired
Joseph	77	Failure to thrive	Lives with wife in their own bungalow	Independent, still working part time/odd jobs	Weakened right side, aphasia, limited function in right arm/hand, weakened right leg, impaired mobility (walks short distances inside with stick/wheelchair user), needs support with most activities of daily living
Phil	52	Failure to thrive	Lives with wife	Independent, working full time, generally healthy, on medication for high blood pressure	Weakened left side, impaired mobility (walks with stick/wheelchair user), limited function in hand, impaired vision (left eye)
May	65	Failure to thrive	Lives with her husband in their own house	Independent, restrictions because of impairments from previous stroke (12 years previously) including some visual impairment	Weakened left side, limited function in left arm, weakened left leg, impaired mobility (three-pronged walking stick/wheelchair user)
Harry	85	Failure to thrive	Lives alone in bungalow	Independent, tremor in hand, impaired mobility (minor)	Weakened left side, impaired mobility, problems with balance, weakened facial muscles
Jack	69	Failure to thrive	Lives with wife in their own house	Independent, generally healthy	Weakened right side, aphasia, paralysed right arm/hand, impaired mobility
Margaret	72	Failure to thrive	Lives alone in her own house	Independent, previous acute health problems including a heart attack	Impaired mobility (uses walking frame in the house/ stair lift to get upstairs)
Jim	73	Failure to thrive	Lives with wife in their own house	Independent, diabetes, arthritis	Weakened left side, mobility impairments (needs walking frame when outside)

TABLE 62 Summary of the formal and informal support received by participating stroke survivors (self-reported at second interview)

Name (pseudonym)	Formal support post discharge	Formal support at time of interview	Informal support
Matt	Physiotherapist (6 months), occupational therapist (6 months), paid carers (6 weeks), Stroke Association worker	No formal support	Wife, son, members of extended family, neighbours
Olive	'Hospital team' helped to prepare house for discharge, paid carers (every day for 4 weeks)	Paid carer (one visit per week), day centre, exercise class, transport provided to/from centre and class	Hairdresser, friends, neighbours, granddaughter
Eric	Physiotherapist, sensory team, housing authority (help with gardening)	Sensory team	Sister (lives nearby), friends
Alf	Physiotherapist, outpatient stroke clinic, Age Concern	No formal support	Daughter, son, sister, friends
Bernard	Physiotherapist, paid carers	Paid carers, painting class, sheltered housing social events	Friend, sister, other residents
Barry	Physiotherapist (6 weeks), occupational therapist (6 weeks), rehabilitation centre, paid carers (6 weeks)	Re-referred to rehabilitation centre and physiotherapist, pharmacist, chiropodist	Wife, daughter, son and daughter-in-law, grandchildren, mother-in-law, siblings, friends, neighbours
Sal	Stroke nurse (visit once every 6–8 weeks)	No formal support, GP had referred her to community physiotherapist	Brother, neighbours, friend's daughter
Rita	Physiotherapist, paid carer, Stroke Association worker, social services	Paid carer	Friends, son (mostly over telephone), daughter (mostly over telephone)
Peter	Outpatient stroke consultant appointment once every 3 months	Outpatient stroke consultant appointment once every 3 months	Wife, son, friends
Dave	Physiotherapist, occupational therapist, paid carers	Physiotherapist	Wife, sons, sister and brother-in-law, son's girlfriend
Greg	Physiotherapist, occupational therapist, paid carers (four visits per day)	Paid carers (three/four visits per day)	Wife, sister, neighbour
John	Physiotherapist, outpatient visits to stroke clinic	No formal support	Wife, son, daughter, daughter-in-law, son-in-law
June	No formal support	No formal support	Husband, best friend, son, siblings, friends
Emily	Outpatient physiotherapy clinic	No formal support	Husband, sons, friends and neighbours, church community, guides
Lyn	Physiotherapist (12 months), paid carers	Paid carers, day centre	Brother, ex sister-in-law, friends, extended family
Joseph	Physiotherapist (re-referred following bad fall)	Volunteer physiotherapist, day centre, bowling group, transport (to and from activities), sitting service, volunteer to support him using mobility scooter, carer support group	Wife, son, neighbours, friends

TABLE 62 Summary of the formal and informal support received by participating stroke survivors (self-reported at second interview) (*continued*)

Name (pseudonym)	Formal support post discharge	Formal support at time of interview	Informal support
Phil	Occupational therapist visits (regular), Different Strokes, charitable organisation that helps people get back to work	Occupational therapist visits (less frequent), gym for stroke survivors held at open prison	Wife (works), daughter
May	Unclear	No formal support	Husband, daughter, son, some members of extended family, neighbour
Harry	Physiotherapist, occupational therapist, paid carers (6 weeks), Stroke Association worker, person from a local charity visited (6 weeks), support from social services to fill in financial forms	No formal support	Daughter and her partner, son and daughter-in-law
Jack	Physiotherapist, speech and language therapist, paid carers, home assistance	Paid carer (reduced), referred to speech and language therapist	Wife, daughter and son-in-law, son and daughter-in-law, brother, friends
Margaret	Physiotherapist, emergency alarm	No formal support	Stepson, neighbour (and neighbour's daughter), church community (visit very occasionally)
Jim	Physiotherapist, emergency alarm, health checks with nurse	No formal support	Wife, daughter, son, friend

Following discharge home, participating stroke survivors presented their lives as having changed dramatically and they experienced a period of loss, a reduction in their ability to carry out everyday activities, an unreliable body, changed roles and relationships and feelings of not belonging in their home and surrounding environment. Even those who had previously experienced an acute and/or a chronic illness viewed the stroke as being a big event in their life:

It [the stroke] is very hard, I've had serious illnesses in my life when it has been touch and go and I've got over it, but even that, it's not like a stroke, I never thought it, it's not like a stroke.

Olive

Many spoke about being unable to carry out everyday tasks and activities, which they had taken for granted before the stroke:

I couldn't do two things at a time. I used to get in a terrible muddle. I mean, I've always been used to, because my son's got a special diet, serving up two or three different meals at the same time. But, I'd get to Sunday dinner and I couldn't handle plating up, you know, for six people. I'd forget the sprouts on one, I'd go, 'oh'. That really threw me.

June

Such mundane activities were imbued with meaning and, because of their inability to carry them out, became markers of the disruptive nature of the stroke and their changed body, relationships and self.

With regard to their bodies, participants spoke of their stroke-related physical and cognitive impairments, of feeling strange in their body (bodily strangeness) and of instances when their body was unreliable and embarrassing. Many spoke of losing confidence as a result of their unpredictable and impaired body:

'But I mean it [mobility problems] knocked my confidence something terrible at first'

Matt

Many also spoke of feeling unfamiliar or of not belonging in their immediate physical environment post discharge. Of particular importance was feeling 'lost' or awkward in their own home:

'You don't get the same feeling at the end of it [acute illness] that you get with a stroke when you come home, that, that terrible lost feeling ... you feel utterly lost in your own place'

Olive

Some lived downstairs following discharge home, which marked a significant change in the way that they lived in their home.

Recovery trajectory 1: disruption followed by adjustment and acceptance

This trajectory was characterised by participants experiencing the stroke as a disruptive event and then over time experiencing a process of recovery, adjustment and acceptance. Nine of the 22 stroke survivors presented this trajectory: Matt, Olive, Eric, Alf, Bernard, June, Lyn, Joseph and Phil.

Process of meaningful recovery over time

Initially, following discharge home, participants focused on their physical and functional rehabilitation and felt that they experienced some improvements in the months after their return home. For many, this sense of physical/functional improvement occurred in the first 6 months post stroke. Some experienced a more rapid improvement than others, with one participant stating that she had almost completely rehabilitated by 16 months post stroke, whereas another experienced significant improvement between 24 and 31 months post stroke. The 'speed' of this initial phase of physical/functional improvement was dependent on the severity of the impairment as well as the support received.

This initial period of physical/functional improvement was meaningful to participating stroke survivors as they understood this as enabling them to return to carrying out some activities of daily living (e.g. washing and dressing themselves). The process of recovery, therefore, was shaped not only by physical/functional improvements but also by the subjective meanings and importance given to the improvements experienced – these stroke survivors, therefore, perceived this to be a meaningful recovery that enabled them to return to carrying out some tasks:

RH: *So just talking about from when you first came out of hospital till now, have you seen any changes?*

Matt: *Oh yeah, majorly, yeah. I mean I was in bed when I first came home.*

Suzie (Matt's wife): *Couldn't really do any, you couldn't dress yourself or anything could you really?*

For many, there was a sense of relief and achievement that they had managed to regain some function and were able to return to carrying out such tasks.

Stroke survivors described being housebound when first leaving hospital and in some cases being restricted to one room of the house. For those who initially moved into a room downstairs on their return from hospital, being able to get upstairs to their bedroom was often a major achievement. This was often a result of some physical/functional improvement, but also sometimes required certain adaptations to be made, for instance the installation of hand rails, grab bars or a banister on both sides of the stairs. Phil could not use the stairs when he first came home and had a bed moved to the dining room. He spoke of how this room became a space in which he ate, slept and went to the toilet. For Phil, being able to climb the stairs, return to his bed and use the upstairs bathroom was described as a milestone in his recovery.

Leaving the home was also described as an important milestone in this initial phase of recovery. Leaving the house was almost always facilitated by formal support – family or friends at first – before the stroke survivor gained the confidence to venture out alone:

I didn't go out of the house for about what, three month, you know, and then I just, Fred me mate, I said, 'Fred come on, walk me to the shops', and it was a job to walk to the shops, but I stuck with it, you know, I stuck with it so I got better and better, now I can go out on me own.

Eric

For some, leaving the house continued to require the assistance of others, which was facilitated by having family live nearby or having friends and neighbours to help. For instance, Phil described his sister as his 'chauffeuress' during the day whereas Alf's daughter took him out several times a week.

For these stroke survivors, therefore, the process of recovery in the period post discharge was shaped not only by physical/functional improvements but also by the meaning given to such improvements and by working to achieve meaningful milestones through one's own action, as well as through the initiative and support of others.

Adjusting to and managing impairments

Most stroke survivors had residual impairments and their bodies could be problematic and sometimes unreliable; however, over time, they gained knowledge about how to manage their bodies and became more familiar with their impairments. Through experiencing some improvement, gaining knowledge about how to manage their altered body and by 'having a go', stroke survivors began, over time, to regain a degree of confidence in their body and ability to undertake everyday activities:

Yeah, I don't feel too bad [going out on his own], if I take my time like, I have a little walking frame with wheels on that's in the car. [...] And so I'll get my sticks and I've got some clips on, I can stick clips in and push that round, yeah, a bit more confident than I was. I was glad they were there before [his wife and son], you know, but now I'm sort of I have to have a go myself, got to try and do it myself.

Matt

Stroke survivors spoke at length about taking charge of their situation, of adjustments they had made and about how they managed their impairments. Stroke survivors would pace their activities and schedule in time for rest. Many would meticulously plan their activities to enable them to carry out everyday tasks (i.e. activities of daily living, domestic and household tasks) and engage in social events.

Stroke survivors within this trajectory attempted to return to a range of previously valued activities with mixed success; however, most were able to engage in some meaningful activities by adapting activities, substituting activities or taking up new activities. Some were able to return to previously valued activities that had importance for their identity and role within their family and/or community (e.g. being able to prepare a family meal, carrying out DIY) as well as leisure and social activities (e.g. going to the pub, going out for a meal, visiting friends and family). The ability to return to such activities was determined in part by the degree and nature of their impairments, the level of support that they received and the types of activities that they engaged in prior to the stroke. For instance, Phil was unable to return to physically demanding activities following his stroke; however, with support from his family and accessible facilities he was able to go to the pub and attend football matches, both of which had also been of importance to him before his stroke.

Some stroke survivors had also taken the opportunity to experience new activities. For instance, Olive had started going to an exercise class once a week, Phil attended a gym for stroke survivors at an open prison, Matt took up gardening and Lyn took up card making:

I made loads [greetings cards], yeah, I made one for Julie for her niece's birthday and I made one for my, for Mary for her friend's birthday and it's got 'Best Friend' on it, I made one for her, and I made some Easter cards for Julie and Sammi, because Sammi going to treasure it, and oh I've made lots, yeah, it'll be surprising how many cards I've made, yes. I did a Mother's Day card for Julie, yeah, well the carer had to help me for Mother's Day card, yeah, but I done all sorts, yes I did.

Lyn

For some, taking up new activities provided an opportunity for social interaction. In addition to the benefits for his physical health and recovery, Phil spoke of attending the gym as an activity that he enjoyed and of the 'banter' he would have with the men who helped him (paralleling how he described his relationships with his work colleagues prior to the stroke). For many, the importance of relationships, interactions and social contact was emphasised:

Even though I find that very, you know [laughs] it's very hard, I'm in a lot of pain when I come home [from the exercise class]. But that, there again, I enjoy that because there's men go there as well and they are so funny. They have you in stitches laughing [laughs] and it's the best, laughter is the best tonic in the world

Olive

Olive lived alone and, although her stroke-related impairments made it more difficult for her to go out and visit her friends, because of reduced mobility and not being able to drive, she found new ways of engaging with friends and took up opportunities offered to her to interact with others.

Many of these new activities had been initiated and/or were facilitated by formal support, for instance Olive was transported to and from her class by a local charity, Matt was encouraged and supported to take up gardening by his occupational therapist and Lyn started making cards at a day centre. Many also drew on support from family or friends to facilitate them in undertaking activities.

Returning to and taking up new activities gave meaning and purpose to stroke survivors' daily lives. Such activities enabled them to maintain (albeit perhaps in a slightly altered form) existing roles and relationships. Matt spoke of how he had grown closer to his wife since his stroke, as they now did more everyday things together.

A changed but meaningful life

Important to the process of recovery and adjustment over time was the ability to come to terms with the changed self. All but one stroke survivor who presented this trajectory spoke of their lives since the stroke as being different from their pre-stroke lives and they still spoke of loss. In particular, they spoke of the loss of freedom, independence and spontaneity in their lives. Stroke survivors missed activities that they were no longer able to do. For instance, Lyn wished to be able to go into town and window shop with her friends, as opposed to her friends visiting her at home:

Now my friends, because they come to see me, you know, but I don't go nowhere now

Lyn

Matt missed being able to go out and visit family and friends by himself without his wife and/or son. Olive missed being able to do things spontaneously and being able to drive to visit her friends who lived some distance away. Phil said:

I used to be very independent, I just used to fly off here, there and everywhere else, go whenever or wherever I wanted to which I can't achieve any more.

Eric spoke of how he would stay locally since the stroke and would limit him to places that were served by local bus routes:

I used to do a lot of walking, a hell of a lot of walking, every day, sometimes I'd walk ten or 12 miles a day, but three times a week, you know, but I can't do that anymore, you know, can't do that anymore.

Eric

Eric described life after stroke as 'more difficult', 'slower' and 'quieter', but to a certain extent accepted a quieter and slower pace of life as an inevitable part of getting older:

I mean I'm 66 now so I'd have to slow down anyway, you know, so just slowing down a bit more that's all, you know, but like I say, I don't sit feeling sorry for myself or getting depressed

Eric

These stroke survivors continued to face challenges and difficulties from living with their stroke-related impairments and many were aware of their fragile independence and/or their dependence on others. Despite these losses and challenges, however, the overall picture presented was one of disruption followed by a process of recovery, adjustment and acceptance over time. Stroke survivors felt that they were managing to live a life that was acceptable and meaningful to them and their families.

Recovery trajectory 2: cycles of disruption followed by adjustment and acceptance

This trajectory follows a similar pattern to the previous trajectory in that stroke survivors presented a similar account of experiencing the stroke as a disruptive event followed by a process of recovery, adjustment and acceptance. Their lives were interrupted again, however, by a further disruptive event that impacted on the adjustment process. Five of the 22 participating stroke survivors fell into this recovery trajectory: Barry, Sal, Rita, Emily and Jim.

For all stroke survivors in this trajectory the second disruptive event was connected to their stroke or to comorbid conditions interacting with their stroke-related impairments. Emily had a bad fall and dislocated her shoulder. Barry had an acute illness, which meant that he was unable to manage the depression he had experienced following his stroke. Both Sal's and Jim's stroke-related impairments interacted with their worsening arthritis and Rita experienced a small second stroke.

For Barry and Sal the second disruptive event was associated not only with their stroke-related impairments interacting with a new or worsening pre-existing health condition, but also with shifts in their social world. Barry had managed his post-stroke depression by keeping active and talking about his feelings with his daughter. His acute illness and reduced contact with his daughter meant that he was unable to manage his depression.

Sal began to feel embarrassed by her stroke-related impairments and, combined with her worsening mobility, this contributed to her resigning from her full-time volunteer post:

I went to read the minutes at one of the meetings down in the office, 'cos I was the chairperson, and I couldn't get the minutes out, I couldn't read them fast enough to get them out. I was tripping over myself and that was embarrassing and it was two weeks after that that I resigned. [...] I thought, 'well, I'm not doing my job if I'm not, you know, reading the minutes out' so, well, that's part of my job, so um I just resigned.

Sal

This second period of disruption meant that stroke survivors felt that they had gone 'backwards' in terms of their recovery post stroke and it also exacerbated their feelings of vulnerability and knocked their confidence. It therefore impacted on the process of adjustment and acceptance. Emily experienced a

disruption to the process of adjustment when she tripped and fell in her home, dislocating her shoulder. Emily described how it had put her 'back to how it was when I had the stroke':

Well you knew I dislocated my shoulder so that's put me back quite a bit but I am now going forward again because I lost my confidence, obviously, didn't dare walk without my husband and I was just starting to do that and then snow came so I didn't do it then obviously [laughs] and but since then I'm now going down the town by myself and going out to the shops by myself ... so it really, it put me back to how it was when I had the stroke in other words. My mind said 'oh no, I've gone back a whole year' but now it's back to normal, to how I was I think almost.

Emily

Emily's husband Ken explained that it was as if she'd 'gone back to square one'. Ken described the aftermath of the fall as similar to that of the stroke, stating that he had to take over all household roles and responsibilities again.

Emily, Rita and Barry all felt that following this second period of disruption they began to improve physically and functionally once more; however, most claimed that it had put back their recovery and prevented further progress over the following few months. Barry, in particular, explained how it was taking a long time to recover following his acute illness and 3 months later he was still not back to where he was before the acute event:

Up to Christmas I were doing fine, then Christmas ... it just, I just wanted to die, top and bottom I didn't want to be here. And then when, I got over it [acute illness], didn't I? It's too a long time to get back to how I were ... but, it's hard to explain. Even now, I'm still not 100% like I was [before acute illness]

Barry

Rita attributed her smaller second stroke to her stressful journey home from Spain, which involved long flight delays that deprived her of rest. Rita experienced this as a major knock to her confidence, which represented a step backwards in her recovery and adjustment. Her subsequent fear of flying also isolated her from her family who lived in Ireland. Rita described how a family crisis and self-determination, however, led her to overcome her fear:

When my daughter said what had happened [she had been diagnosed with breast cancer] and nobody could do it for me, so I just had to dig the heels in and go over there on my own. It was frightening but, did it.

Rita

Rita's positive experience of receiving assistance at the airport and her successful engagement in a range of social activities while with her family helped her to grow in confidence again.

However, two participants, Jim and Sal, did not speak about improvements following their second period of disruption. It was during the second interview that Jim spoke of his worsening mobility. In between the two interviews he had experienced a bad fall (he had fallen out of bed) and was struggling to get upstairs. At this time he felt that he was still 'going backwards' and did not speak of any improvement.

Sal differed slightly in the way that she experienced the second disruptive event in that, unlike the others, she did not feel that it caused her to go 'backwards' in her recovery but that it led to a much bigger change in her life. Sal felt that she had recovered and adjusted quickly following her stroke and she returned to her full-time volunteer role only 3 months after discharge home. However, 11 months later she claimed that her work had become too much for her and she went from having a full-time job to only leaving her flat once a week to drive to the supermarket. Not only had Sal's stroke-related impairments caused her embarrassment at work, her mobility declined because of her worsening arthritis, compounding the effects of her stroke, and she

became very wary of falling. Giving up her full-time volunteer role was very disruptive to her life and sense of self and Sal felt that this was the biggest impact that the stroke had had on her life. Sal's life, therefore, changed quite dramatically over a period of a few weeks, which she was struggling to comprehend during the first interview. However, 3 months later Sal had begun to make sense of these changes. Unlike the other stroke survivors in this trajectory, though, she did not talk about improving following this second disruptive event, but was adjusting to and starting to accept her less active lifestyle. She was more accepting of help offered by friends and neighbours and talked of how she needed to slow down as she aged:

I suppose I've realised that when I was told to slow down before, I should have slowed down, you can't always do what you want to do, there comes a stage where you have to cut something out and not add things onto your list, do you know what I mean, which I was always doing, adding different things onto my list.

Sal

For stroke survivors in this trajectory changes in their health and social support networks, as well as incidents such as a fall, created new instances of disruption that impacted on their process of recovery and adjustment.

Recovery trajectory 3: disruption without adjustment and acceptance

Unlike those in trajectories 1 and 2, for participants in this trajectory the disruption caused by the stroke was not followed by a process of recovery, adjustment and acceptance. Instead, stroke survivors presented their lives as continuing to be disrupted and unmanageable. Six of the 22 participating stroke survivors presented this trajectory: Peter, Dave, May, Harry, Jack and Margaret.

Whereas other stroke survivors talked of a period of some physical/functional improvement following discharge home, stroke survivors who narrated this trajectory focused on their residual impairments. The severity of the stroke and residual impairments varied amongst this group and did not necessarily differ from those in the other trajectories. The importance and consequences attributed to their stroke-related impairments, however, meant that they were understood as having a great impact on their lives (including those that could be considered quite mild impairments).

Some seemed unable to envision a recovery or meaningful life without regaining function in their affected limbs, which prevented them from resuming their previous life. For instance, Dave had a paralysed left arm following his stroke. Despite being told by physiotherapists that, although he may see some further improvement, it is unlikely that he will regain function in his arm, Dave was unable to accept this:

I keep asking the same question, is everything going to come back to normal? And the question [sic] they keep giving me, "no", and I can't take no for an answer [bangs right hand on the table]

Dave

Several stroke survivors had other health conditions and impairments that had constrained their lives in some way before their stroke; however, the stroke was still viewed as causing significant and dramatic restrictions in their lives. For instance, Peter's only impairment was the loss of sight in his right eye, which meant that he was unable to drive. He was unable to visit family members and engage in activities that he used to enjoy. Interestingly, although his wife spoke about how their lives had become restricted before his stroke because of his other health conditions, Peter felt that his stroke was the cause of his restrictions as the stroke took away his only remaining option for getting out and about (driving).

A focus on returning to their pre-stroke bodies and lives shaped this recovery trajectory. Many of the stroke survivors continued to compare their bodies and their lives with how they were before the stroke and focused on the losses that they had experienced and their desire to return to their 'old' self and life:

I know I have so far to go till I get back anywhere near my old self

May

This lack of meaningful functional improvement and preoccupation with returning to their 'normal' pre-stroke bodies contributed to the ongoing sense of disruption caused by the stroke.

Although they had made some changes and adaptations, overall their focus remained on what they were unable to do and what they had lost rather than what they were now able to do. The small improvements some experienced in their lives and their ability to manage their impairments were not marked with the same sense of achievement as for those in the other trajectories. Overall, there was a sense of ongoing restriction and lack of recovery. These stroke survivors were struggling to come to terms with the impact of the stroke and create a meaningful life for themselves:

So that was like cutting my legs off because I'd been driving for sixty odd years and then suddenly to lose it, you know, you lose your means of transport and we can't get anywhere now, this is the problem.

Peter

Many needed support to get out of the house, which, although not uncommon among the stroke survivors interviewed, was a particular source of frustration for these participants. Peter felt that he was stuck in the house a lot more now:

you can't do the things you'd like to do obviously and get around as much as you used to, you know, I'm housebound a lot more

Peter

In contrast to those in the other trajectories, those who experienced ongoing disruption were often unable to return to, or had not succeeded in returning to, activities and occupations that they felt were meaningful and important. Neither did they manage to adapt activities that they had previously enjoyed to enable them to continue to participate in them in some, albeit altered, form.

Stroke survivors in this trajectory were also unlikely to take up new activities following their stroke. May was one of the few participants in this trajectory who tried something new following her stroke by joining a stroke group; however, she did not enjoy the activities that they engaged in and soon stopped going.

These stroke survivors therefore tended to feel that their days were extremely repetitive and lacked meaningful activities. Following her stroke, Margaret was unable to knit and was not able to leave the house independently. She described her day as consisting of coming downstairs, making a coffee, watching television in her chair, having her dinner and going to bed. She highlighted the monotony and boredom of this routine through repetitive entries in an audio diary, such as the following:

Up, coffee, telly, [next-door neighbour's daughter] came in and did a bit of cleaning, telly all afternoon, tea, bed by six. Another lovely day [said in a sarcastic tone] and I am totally, totally bored to death.

(Margaret, 1 December)

Had another exciting day [said in a sarcastic tone]. Up, coffee, telly, tea, bed.

(Margaret, 4 December)

Stroke survivors felt that the stroke had ruined their life. Margaret claimed that she was no longer living but rather 'existing from day to day':

It's just ruined me really, totally ... I was so active before, y'know, because as I say, y'know, I can't turn me own fire on, I can't put a plug in the bath, I can't pick up me kettle, y'know. They might seem damn silly things but they're so frustrating, y'know, that you can't do them. No, it hasn't been

very nice [Margaret begins to cry]. I say me prayers every night, I say 'Don't let me wake up when it's morning', but he ain't listening to me. I'd just like to go to bed and, y'know, not wake up, because y'know it isn't living, y'know, you're just existing, that's all it is. I don't know. I keep saying I'm going to save up £10,000 and go to Sweden [laughs] and have a cocktail over there ... it's just ruined my life really. It isn't living, it's just, you're just existing from day to day.

Margaret

Being unable to undertake everyday and meaningful activities impacted on their relationships with family and friends and their ability to engage socially with others. Some felt unable to establish a role within their family or were unable to visit and spend time with their family. May, in particular, felt that her inability to fulfil her 'role' in her marriage with regard to the housework, managing the finances, cooking for her husband and being physically intimate had had a negative impact on her marriage:

I gave Bob [her husband] a bad time, I think he so good to put up with me, but it is not doing our marriage much good

May

She spoke quite openly about the difficulties and tensions that had developed in their relationship since her stroke and the daily arguments that they now had.

Some stroke survivors felt that they had withdrawn from their social life by stopping going out and/or inviting people to their house to visit. This self-withdrawal was often connected to feelings of embarrassment and/or shame about either their stroke-related impairments or the effect that the impairments had had on their ability to carry out everyday tasks (e.g. cleaning the house and/or using a knife or fork). This impacted on their ability and willingness to leave the house and/or engage in social activities. Several stroke survivors had stopped going out for meals as they had difficulty eating and found this embarrassing. For instance, the stigma associated with his paralysed arm prevented Dave from engaging in a number of social and relational activities, including going out for a meal and holding his grandchild. May was unable to tidy and clean her home and she described her husband as being unable to do these kinds of tasks to an acceptable standard. She was ashamed of the 'state' of her house and so she did not like to invite her extended family and friends over to visit. As she was also restricted in terms of getting out and about and was unable to visit others, this meant that she had less contact with some family members and friends:

Bob (May's husband): because the house is in such a state, and we know what state it is, there's not getting away from it, [May] doesn't like having people in the house because, obviously ...

May: I'm ashamed of it.

May also described the negative emotions that she experienced and the reactions from other people when she used her wheelchair, which meant that she was reluctant to go outside.

Some stroke survivors also felt that others had withdrawn from them and some felt very let down by friends who they expected to have been more supportive. During the mapping exercise, May specifically asked where she could place those friends whom she felt had let her down. Margaret also described her isolation following her stroke as being due to the abandonment or withdrawal of others, stating that:

when you're actually disabled nobody really wants to know you, y'know, where you thought you had friends you don't have 'em anymore

Several stroke survivors spoke about the emotional impact of the stroke and the restrictions that it had caused. May described feeling very angry about the stroke and the impact that it had had on her life. She also spoke about disliking the reactions that she gets from other people. She feels that they are either overly sympathetic or that they do not acknowledge her impairments and limitations:

So I don't like to gain sympathy, I don't want sympathy, like I said before, if people aren't helpful and it's obvious I need that if, I get cross, and if they're too helpful, I get cross, I told you that in the diary, so I mean it is a stupid mindset, I know that, but I'm sure I'm not the only one, I'm sure I'm not the only one who reacts like that, you know. You want to be normal, you don't want to be treated different, but you do need help sometimes.

May

Dave described the stroke as having affected him 'mentally', that he gets very down but doesn't like others to know this. He described his life as deteriorating and spoke of death several times during the two interviews:

My life to me it's started to deteriorate. I have always said, I've got this, this and this, the next thing what's going to happen that'll be it [makes a cut throat gesture], end of story

Dave

Although other participating stroke survivors mentioned the limitations of the formal support that they had received following their stroke, this was particularly apparent in the accounts of those in this trajectory. Many felt disappointed and let down by the formal support that they had received, which may be because of the quality and type of support received and/or because of their high expectations of recovery and services. Both Peter and May describe receiving very little formal support following discharge home. Margaret expressed disappointment with the rehabilitation services that she had received, although she also suggested that she may have refused rehabilitation both in hospital (as she wanted to return home) and while at home (because of the pain that she experienced):

the physios were coming but when they'd been me leg just felt like jelly and twice, well three times I nearly fell in there and at night-time the pain in me leg was horrible. So one of em came one day, I said, 'No, don't do it', and so I've never seen em since.

Margaret

Harry felt abandoned after formal services had withdrawn:

It's all the same 'cause you don't get them [services], that's what I'm saying, times when you need them they stop them. You're going on alright when you come out of hospital, yeah felt great, but gradually I got worse, but they don't bother with you when you're getting worse, they say, 'No, dig hole in the garden and chuck him in'.

Harry

Margaret suggested that she also had a lack of knowledge about navigating health and social care services:

Somebody once said, 'who's your social worker?' I said, 'I haven't got one', y'know. I don't know who to ring or anything ... So you don't know what's out there, y'know, or anything.

Margaret

Most felt uneasy with their level of dependence on their partners and/or adult children and, as they did not feel that they had recovered this degree of dependency continued over time. May was very dependent on her husband and felt extremely uncomfortable that her husband emptied her commode and did various personal care tasks for her. Dave had very limited function in his left arm, had some difficulty walking

without the aid of a stick, was unable to fully wash or dress himself and said that he felt physically tired a lot more, despite engaging in little physical activity. This meant that he depended on others to do the jobs around the house that he used to be able to do, which he described as ‘lowering’ himself:

I did all the rooms and tiling and painting and, I mean all these jobs I could be doing meself. I don't like asking other people to do it but at end of the day you've got to lower yourself and say, 'Will you do me that?'

Dave

Other stroke survivors spoke of their dependence on others and their desire to retain some independence. Both May and Dave spoke about the support that they received from family and friends in very emotive terms.

Although many of the factors discussed above were familiar to those who presented an alternative trajectory, for these stroke survivors these issues were emphasised, remained unresolved and shaped an ongoing sense of disruption. The meaning given to their stroke-related impairments and their focus on regaining their previous lives and bodies meant that they did not experience a meaningful recovery. They were unable, therefore, to go through a process of meaningful recovery, adjustment and acceptance over time. Lives were presented as being disrupted.

Recovery trajectory 4: stroke as a continuation of ongoing decline

The fourth trajectory, of continuing ongoing decline, is characterised by a long and gradual decline in health, everyday activities and social participation. There were only two participating stroke survivors who presented this trajectory: Greg and John.

For stroke survivors in this trajectory, the stroke was not understood as being a disruptive event. For Greg, the stroke was one of a series of factors that contributed to an ongoing decline. On reflection, Greg and his wife Ann identified numerous events (both health related and social events) that had contributed to this decline, starting in the mid-1980s. These included the onset of his degenerative condition and his subsequent early retirement from work on medical grounds; Ann's retirement, which led to Greg giving up the domestic tasks and walking the dog; Greg giving up driving because he did not feel that his legs were strong enough to drive, which is when he stopped going out of the house; and finally his stroke, which contributed to his worsening mobility and restricted his movement within the house:

It all seemed to start when, as I say, when we finished with the motor and getting out and about with it, driving a bit, and ever since then it seemed to quietly go down, you know, sort of go downhill if you will [...] I don't know, it's a weird sort of thing if you will, but as I say, the telly's here, telly's on.

Greg

John had diabetes and suffered from kidney problems and minor visual impairments. He spent most of the interview talking of his other health conditions. For John, the stroke appeared to be understood as just another complication of his diabetes:

I mean from a medical point of view, yeah well diabetic you know which will lead to this, which will lead to this, which will lead to this so it's obvious that as a diabetic you're going to have trouble with your eyes, you're going to have trouble with your feelings and things like that and you're going to have all this, that and the other and you're going to, you know, be more liable to have a stroke or a heart attack or whatever.

John

Neither Greg nor John felt that the impairments caused by the stroke had a big impact on their lives. Greg identified several consequences of the stroke, including his weakened left arm and subsequent lack of confidence in using his Zimmer frame™ (Zimmer Holdings Inc., Warsaw, IN, USA), the further reduction

in his mobility, a lack of concentration and incontinence. Despite these impairments, however, both Greg and his wife Ann felt that there had been little change in his life following the stroke. Greg felt that the biggest difference was that he was no longer able to go up and down the stairs, so he had his bedroom in the front room. Although he talked of sometimes feeling trapped in the front room at night, he also said that he had got used to living downstairs. The stroke had not impacted greatly on his life nor changed how he felt his future would pan out. When asked about the impact that the stroke has had on his life, Greg replied:

I mean it weren't as though we were dashing about a hundred miles an hour [before the stroke] was it?

Greg

John also identified stroke-related impairments but he described himself as having 'got away very lightly' with the stroke. He felt that he had only minimal long-term physical impairments. John was left with a limp and some numbness in his left hand side but presented himself as able to accept any limitations from the stroke. One of the major problems affecting his social participation, however, is fatigue, which he attributes to his diabetes rather than the stroke.

Although the stroke did mark the end of paid employment for John, which could have been viewed as having a big impact on his life, his other medical problems had already resulted in a decline in the duties that he was able to perform:

I thoroughly enjoyed [my job] you know until this, I started to get the medical problems due to the diabetic thing which were getting to the stage where, you know, when I couldn't operate as efficiently shall we say that, was still doing the job but I'm getting more and more on light duties you know. And then of course when this happened that was the end of it all.

John

In fact, John felt that he was already too ill to work prior to the stroke and he had been medically assessed for incapacity benefits but was judged to be 'not ill enough' to give up work.

For Greg, his physical decline coincided with a gradual disengagement with everyday activities and the social and physical worlds beyond the house. Greg presented himself as being content and accepting of his life and did not desire to go outside or participate in any particular activity. He did not talk of loss or of missing being able to do things or go to different places. He acknowledged that this frustrated Ann and spoke of trying to get out of the house and going out in the future, but reiterated that he was happy with life as it was. When he talked of going outside he identified the potential problems, difficulties and barriers associated with this. Ann felt that he had got in a 'rut' and that he was 'laid back' and 'happy in his own environment'.

This trajectory is therefore marked by a gradual decline in health. The stroke was not viewed as being disruptive and the impact on the stroke survivors' lives was considered to be minimal. They were accepting of the consequences of the stroke and viewed these as being part of other health conditions and/or the process of declining health. Life post stroke was therefore understood as being much the same as life before the stroke.

Processes and mechanisms shaping recovery trajectories

The different trajectories illustrate how multiple interacting factors shape the process and meaning of recovery and adjustment over time and therefore social participation. The key processes and mechanisms that shaped the different recovery trajectories are summarised in the following sections.

Recovery, adjustment and acceptance over time

When discussing their lives post stroke and their recovery trajectory, stroke survivors identified multiple and interacting factors that shaped this process. This suggests that the process of recovery, adjustment and acceptance is complex and multifaceted.

Interacting factors that supported a process of recovery, adjustment and acceptance over time included:

- A process of recovery that included physical/functional improvements that were understood as being meaningful, and the achievement of important milestones through actively taking charge of their situation and the initiative and support of formal services, family and friends.
- This process of meaningful recovery contributed to an increase in confidence and a knowledge about managing their impairments. This enabled them to plan and undertake different tasks and activities.
- Stroke survivors engaging in meaningful activities by returning to previously valued activities, substituting activities or taking up new activities. Engaging in everyday tasks and activities enabled stroke survivors to maintain a role in their family/community and 'do' relationships (i.e. enabled them to maintain and establish relationships through the doing of everyday activities/tasks). Such activities also gave pleasure and structure to stroke survivors' lives.
- Stroke survivors successfully managing loss and creating a different but meaningful life.

Lack of recovery, adjustment and acceptance over time (ongoing disruption)

Interacting processes and mechanisms that affected the process of recovery, adjustment and acceptance and contributed to a sense of ongoing disruption included:

- Stroke survivors focusing on their lives before the stroke and the significance and consequences of the stroke and related impairments. These stroke survivors did not feel as if they had experienced a meaningful recovery.
- This lack of meaningful recovery, which included the sense that they had not reached important milestones, contributed to an ongoing sense of uncertainty and a lack of confidence in their abilities.
- Stroke survivors being unable to undertake previously valued activities, to substitute other activities or to take up new activities. This often impacted on social contact, relationships with others and the person's role in the household.
- Stroke survivors experiencing tensions in their relationships and/or struggling to establish/maintain supportive relationships.
- Withdrawing from social situations because of feelings of embarrassment associated with their stroke-related impairments. Although feelings of embarrassment were experienced by stroke survivors across the different recovery trajectories, those who reported adjustment and acceptance either felt that this had lessened over time or still engaged in social activities despite such feelings.

What is a good (social) recovery post stroke?

For those who experienced disruption following stroke (stroke survivors in trajectories 1, 2 and 3), there seem to be two understandings of a good (or acceptable) recovery post stroke. For those in trajectory 3, who experienced ongoing disruption, their understanding of an acceptable recovery was one that would enable them to return to their pre-stroke lives and bodies. This focus on recovery as returning to how they were before the stroke (both physically and socially) contributed to their inability to adjust, accept and create a meaningful life post stroke.

For those in trajectories 1 and 2, however, recovery was not necessarily about their ability to return to how they (and their lives) were before their stroke. What constituted a good (acceptable) recovery was a process of adjustment and acceptance that enabled them to manage and come to terms with the losses that they had experienced and to create a different but meaningful new life. This involved a complex process comprising some physical/functional improvement that was understood as being meaningful;

the achievement of milestones that were important to them; actively taking charge of their situation; the initiative and support of formal support, family and friends; and engagement in everyday tasks and activities that enabled them to maintain and enact (and sometimes establish) relationships.

Critical reflection on the eligibility criteria and sampling strategy (developing a better definition of poor adjustment post stroke)

It was anticipated that the criteria used for sampling stroke survivors (based on the change between pre-stroke and 12-month post-stroke Barthel Index and FAI scores) would be associated with the recovery trajectories identified; however, this was not the case. For example, those who were categorised as 'doing better than expected' (more socially active than anticipated) did not necessarily have a different recovery trajectory from those who were categorised as less socially active than anticipated ('failing to thrive'). Nor did the category predict the recovery trajectory identified through the analysis of the qualitative data (see *Appendix 12, Figure 25*).

It is important to note that a purposive sampling strategy was used and therefore the stroke survivors interviewed were not randomly selected to represent their associated category (i.e. those interviewed who were categorised as 'doing better than expected' were not necessarily representative of the population of those 'doing better than expected'). This means that caution needs to be taken in interpreting the observation that the outcome measures were not clearly linked to the recovery trajectory identified. This lack of apparent connection perhaps emphasises the complexity of assessing recovery and adjustment after stroke, because of the multiple and interacting subjective and objective factors that stroke survivors identify as influencing their recovery and adjustment. It was anticipated by the study team that the Barthel Index and FAI could be used to define poor adjustment post stroke; however, based on the findings of this study these outcome measures alone probably cannot tell us enough about the experiences of stroke survivors post stroke to allow us to conclude whether they are recovering and adjusting well or not.

Discussion

Summary and discussion of key findings

This qualitative substudy examined the process of recovery and adjustment over time of 22 stroke survivors and 12 carers. From participants' accounts four different recovery trajectories have been identified: (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.

Participants' accounts of their lives post stroke comprised complex and interacting factors that shaped recovery and adjustment. The existing literature has previously discussed important aspects of recovery and adjustment following stroke,^{10,23,25,121–125,128–133} including pre-existing factors (age, other health conditions and previous knowledge of stroke) that may mitigate the disrupting impact of the stroke.^{158,159} Although insightful, such research has often treated post-stroke adjustment as a static event (i.e. stroke survivors either experience disruption following stroke or do not experience disruption) rather than as a complex multifaceted ongoing process. This study contributes to this wider body of literature by identifying different types of recovery trajectories through examination of the process and meaning of recovery and adjustment over time. Furthermore, this study has explored how certain factors interact and shape the meaning and process of recovery and adjustment over time, and thus stroke survivors' social participation.

Interestingly, for those stroke survivors who experienced meaningful recovery, adjustment and acceptance (those in trajectories 1 and 2), recovery was not about returning to their pre-stroke lives but was a process that enabled them to manage loss and create a different but meaningful life. For those stroke survivors who experienced ongoing disruption, however, the focus was on returning to their pre-stroke bodies and lives. This has implications for existing literature in which recovery post stroke is understood as being linked to the extent to which stroke survivors are able to re-establish continuity with their previous self and life.¹⁶⁰

This study found that stroke survivors develop different understandings of what constitutes recovery and therefore a more nuanced notion of recovery needs to be acknowledged and explored in the stroke literature. Furthermore, the findings suggest that those who experienced meaningful recovery, adjustment and acceptance over time did so not only by establishing some markers of continuity with their previous self but also by managing loss and creatively establishing new elements of their self and life. For some, therefore, the process of meaningful recovery and adjustment following stroke involves more than establishing markers of continuity with their pre-stroke body, identity and life.

A further point of interest is the importance of everydayness in stroke survivors' discussions of their life post stroke and the significance that being able to participate in meaningful but everyday tasks has for enacting and maintaining relationships. Interviews were often dominated by talk about everyday activities and how stroke survivors managed (or not) their stroke-related impairments to enable them to engage in everyday tasks and activities. Although everyday activities and the importance of meaningful activities have been discussed in the stroke literature,^{25,122} the meaning and role of everyday tasks and activities in enacting relationships and social participation have been overlooked. Although mundane, everyday tasks and activities, and one's ability to carry them out, are important components of 'doing' relationships (i.e. actively maintaining relationships) and fulfilling roles within the household/social sphere (i.e. being a father, mother and/or friend). The ability of stroke survivors to manage their impairments to engage in everyday tasks and meaningful activities shaped the meaning and process of recovery post stroke and thus their social participation.

Strengths and weaknesses

This substudy drew on a grounded theory approach to qualitative research¹³⁸⁻¹⁴⁰ and made use of multiple qualitative methods, including semistructured interviews, limited observations, solicited diaries and support network mapping techniques, to understand the process of adjustment following stroke. In total, 22 stroke survivors and 12 carers/significant others participated in the study. A total of 42 interviews were conducted and 15 diaries were completed. A further strength of the study was that participating stroke survivors were purposively sampled to include those who were less or more socially active than anticipated (based on their pre-stroke and 12-month post-stroke Barthel Index and FAI scores). The sample was also purposively selected to ensure variation in key characteristics that are known to shape adjustment and social participation post stroke. These included age, socioeconomic status and whether the stroke survivor lived alone or with others. This enabled the exploration of recovery and adjustment in a varied, data-rich sample.

Although the purposive sampling strategy enabled the recruitment of a diverse group of participants, we were unable to conduct secondary theoretical sampling often undertaken in grounded theory studies. This was because of time constraints and data limitations of the quantitative trial (i.e. the information collected for the trial did not contain information required for the theoretical sampling of potential participants). Themes and theories developed in the ongoing analysis were therefore tested through the refinement of interview topic guides, ongoing data collection and the follow-up interviews.¹³⁸

The categories based on the Barthel Index and FAI scores did not appear to be associated with the recovery trajectories identified from the qualitative data and therefore we were unable to develop a definition of poor adjustment post stroke based on these measures to be used to evaluate the prevalence of poor adjustment.

Implications for health and social care

This study suggests that, ideally, health and/or social care professionals should routinely monitor stroke survivors' progress during the 6- and 12-month reviews by incorporating into the reviews a discussion around the factors identified that shape adjustment post stroke (and in particular barriers to adjustment). They would then be able to refer stroke survivors for further specialist support if required. Such support services would work with stroke survivors and their carers to find creative ways of managing impairments and coping with loss to enable meaningful activity, and thereby sustain relationships and enable social

interaction, to facilitate stroke survivors through a process of meaningful recovery, adjustment and acceptance, as well as helping to prevent and/or address ongoing and/or further instances of disruption. Changes in stroke survivors' social support and health, as well as incidents such as a fall, can create new challenges that need to be overcome and/or can result in stroke survivors going 'backwards' in their process of recovery and adjustment post stroke. This suggests the need for services to be able to respond to such potentially disrupting events and changing needs. As GPs are often the first point of call for many, it would be appropriate to devise a tool that prompts GPs to discuss the adjustment process, possible barriers and changes in health and support during their consultations with stroke survivors.

Case studies illustrating the different recovery trajectories may be informative for stroke survivors and carers and may also be useful as a resource for training health and social care professionals who work with stroke survivors in the longer term.

The findings have been discussed with therapy staff as well as with stroke survivors and their carers. Through these workshops several further implications of this exploratory study were identified. These included how health-care professionals could support stroke survivors to adjust and adapt to life post stroke by moving from an initial focus on functional improvement to working with patients to create a meaningful life post stroke and mobilising stroke survivors' informal support networks (thus supporting the recovery trajectory of disruption followed by adjustment and acceptance); supporting stroke survivors to come to terms with the likelihood that their lives will be different post stroke; and signposting stroke survivors and their families to alternative emotional and relational support, such as Relate. Stroke survivors and their carers felt that it was important that there should be a single health/social care professional who they could contact and/or who would contact them from time to time to provide ongoing advice and support into the longer term.

Recommendations for future research

A number of participating stroke survivors felt their lives continued to be disrupted, even over a year after the stroke. They felt unable to manage the stroke-related impairments and engage in activities to create a meaningful life. It is worth noting that half of these stroke survivors were still receiving some form of formal support for their stroke-related impairments at the time of data collection, but that most felt dissatisfied with the support that they received, some were unaware of other support available and some may have initially rejected support that had been offered. Stroke survivors who experience ongoing disruption may therefore be hard to engage but perhaps have the most to gain from longer-term tailored support. We plan to further explore resource use of participating stroke survivors using the trial data from the economic analysis. It may also be informative to compare stroke survivors' recovery trajectories with unmet needs, identified using the LUNS questionnaire and GHQ-12 scores, collected as part of the trial data.

Future research is needed to further explore the different recovery trajectories and how, in routine practice, the process of adjustment can be monitored and supported and how potential barriers to adjustment can be identified and overcome.

Further research is also needed to examine how health and social care professionals can accurately identify stroke survivors' recovery trajectories, in particular those who experience ongoing disruption or a period of further disruption following their stroke. There is the potential to identify stroke survivors who may be vulnerable to experiencing ongoing and/or further disruption while they are inpatients, while they are receiving support at home following discharge and/or during their 6- and 12-month reviews.

Chapter 6 Conclusions/recommendations

This programme grant has been completed as specified in the original application, on time and with all objectives met. In projects 3 and 4 we have delivered considerably more than originally intended. Through a programme of interlinked studies we have developed and evaluated interventions and tools that aim to improve the longer-term outcomes for stroke patients and their carers and have explored adjustment post stroke. This was achieved through the production of evidence-based treatment algorithms focused on problems identified by patients and carers; the robust evaluation of a new system of care; the development and evaluation of a monitoring tool for longer-term unmet needs after stroke; and qualitative exploration of barriers that impede stroke recovery.

In project 1 we updated previously developed evidence-based treatment algorithms addressing identified and reported patient and carer post-stroke problems. Evidence relating to 16 patient- and/or carer-centred problem areas was comprehensively searched through the development and implementation of a structured search protocol. The methodology that we adopted supported the practical implementation of evidence and is transferable to other clinical areas. This review of the evidence also served the dual purpose of allowing us to identify patient-centred evidence gaps. We plan to review the evidence gaps in the context of the 2013 NICE stroke rehabilitation guidelines.¹⁶¹

These updated treatment algorithms replaced the existing algorithms that underpinned our manualised system of care. Working with community-based SCCs across England, Scotland, Wales and Northern Ireland, we undertook a cluster RCT evaluation of this new system of care to determine the effects on patient and carer outcomes and its cost-effectiveness. The system of care included a care plan containing a structured assessment and goal and action planner, a manual containing the treatment algorithms linked to the assessment questions and a checklist of the assessment areas for patients, underpinned by a problem-solving approach.

In the trial evaluation of the new system of care it was clearly important to facilitate implementation by the SCCs randomised to the intervention. This was supported by working with the SCCs on the intervention documentation. By gaining their input into the design, content and layout, the intervention care plan replaced their previously used systems, thus embedding the structured assessment system within routine practice. We preset a high bar for compliance – that 75% of the structured assessment was delivered. Of patients seen by the intervention SCCs, 89% received at least one structured assessment and 96% of the initial assessments achieved compliance.

The trial design was a pragmatic one in that we sought to implement the new system of care as it would have been implemented in usual practice. Implementation was carefully thought through and planned. It was based on a survey of services undertaken, both before and after services were recruited into the trial, and detailed discussion, including site visits, during set-up. Implementation of a multicentre cluster trial was extremely challenging against the backdrop of changing bureaucracy related to the NHS approval system. The case study we submitted to the Academy of Medical Sciences review¹⁶² (included in *Appendix 6*) demonstrates the difficulties that we faced. We required 69 research and development (R&D) approvals from 62 trusts to cover the 32 SCC services involved in the trial. The time taken to receive all R&D approvals for a service ranged from 1 to 10 months. Despite this, the trial (with the support of the UK SRNs) was completed to time and target and we achieved our sample size of 800. This makes it one of the world's largest completed stroke rehabilitation trials. The data generated, including the health economic data, provide insight into the problems faced and resources utilised by a large cohort of stroke patients and their carers from across the UK.

The trial was rigorously implemented and had a robust design. The inclusion of sites in England, Scotland, Wales and Northern Ireland supports the generalisability of the results. The return rate of outcome measures and loss to follow-up were in line with our sample size predictions, with >75% of patients completing outcome measures at 6 months.

In project 3 we tested and demonstrated the validity, test–retest reliability and acceptability of a novel monitoring tool (LUNS) to identify individual- and service-level unmet needs relevant to longer-term stroke care. This component of the programme grant was enlarged significantly from our submitted grant application. The sample size was increased to provide a more robust evaluation of the questionnaire.

In project 4 we undertook a study to explore quantitatively and qualitatively the adjustment of patients and carers to stroke. However, the methodology was enhanced in that, instead of the proposed one-off interview, two interviews were conducted either side of a period of diary keeping. This enabled a much richer picture of life after stroke to emerge and the identification of recovery trajectories and facilitators of, and barriers to, adjustment.

The limitations of the individual projects are discussed in the specific chapters. Overall, we believe that we have delivered a complex programme successfully.

In conducting a large multicentre cluster RCT across the UK we have demonstrated that this methodology (appropriately conducted) is feasible in stroke rehabilitation research. By the engagement of 29 clinical stroke services, including community stroke services, many of which had not been involved in research previously, we have increased the clinical capacity for and understanding of research. We hope that the conduct of large trials such as this marks a step change in stroke rehabilitation research and will facilitate future large trials to address important clinical questions. Our research illuminated some ongoing challenges, which include the identification of appropriate outcome measures. With the support of our trial steering committee we have undertaken a 1-day workshop with colleagues from stroke care and statistics (the First Leeds Colloquium on Stroke Rehabilitation Research) to share our ‘lessons learnt’ and debate methodological issues in stroke research, specifically in relation to the evaluation of complex interventions. A summary of the discussions is being prepared for publication.

Foreseen challenges in delivering the programme included the protracted approvals process for studies, the complexities of running a huge multicentre study across the UK and undertaking research with a generally older, vulnerable patient group. Unforeseen challenges included a national postal strike (inconvenient when awaiting the return of postal outcomes), organising training on a day that had ‘the worst weather this decade’ and working with sites that included isolated rural communities (one SCC used a ferry, plane and bus to reach the national training day and the trial manager was unable to undertake a planned site visit as a result of ferry cancellations because of bad weather). The programme was implemented with the assistance of the hugely supportive NIHR SRN in England and the research networks in Scotland, Wales and Northern Ireland, which enable the recruitment of large numbers of participants to studies.

Stroke is a family illness that can have devastating consequences for the patient, their family and society. Despite tremendous advances in the treatment of acute (and hyperacute) stroke, rehabilitation remains the cornerstone of treatment for many and the longer-term outcome remains poor. Our research programme was in part predicated on the recommendation for continuing post-stroke care in the *National Service Framework for Older People* and the recommendation for implementing a SCC role.¹⁶ This has been supported by subsequent reports, most specifically the NSS published in December 2007.¹⁵ Our thinking and the contents of this programme of work, which was commissioned in summer 2007, were innovative and novel at that time and are absolutely in keeping with the recommendations of the NSS. The strategy, supported by the Stroke Improvement Programme, highlighted the need for a review 6 months after stroke, and other review tools (e.g. the GM-SAT³⁴) have been developed that are similar to our own structured assessment. Despite these advances, however, the survey of McKeivitt and colleagues⁴ (which utilised some of the LUNS questions) of 1257 stroke survivors demonstrated that many stroke survivors still have unmet needs. The range and number of unmet needs are similar to those reported in our own work (projects 2 and 3). The unmet needs identified are similar to the problems addressed in the system of care structured assessment, confirming that the assessment had internal validity.

We undertook a cluster RCT of this complex intervention in the hope that positive evaluation would lead to widespread commissioning of this system of care. It is disappointing that the purposely developed patient- and carer-centred approach did not result in improved outcomes for this group of patients or their carers, with total health and social care costs similar between the control group and the intervention group. This highlights the complexity and heterogeneity of post-stroke problems and the difficulty in addressing these.

We have outlined the detailed work that we undertook to develop the treatment manual and structured assessment. These were focused on patient- and carer-centred problems and we conducted a rigorous review of the evidence supported by peer review to update the treatment algorithms. The manual was well received by the SCCs and acknowledged as a useful resource, particularly for staff new to the role. There was good compliance with the structured assessment, with on average >90% of the assessment areas discussed, and this involved no additional SCC time compared with usual practice. In total, 96% of SCCs reported that the assessment was both easy to use and useful. The assessment questions and treatment manual are therefore a useful resource that underpins the implementation of evidence-based treatment for post-stroke patients and their carers. This wider more holistic model with an emphasis on patient-identified problems is in keeping with the current drive for integration of care, considering and addressing both health and social well-being. The manual promotes interdisciplinary planning and supports staff to move from multidisciplinary to more interdisciplinary work.

Our planned further analyses and the in-depth qualitative exploration undertaken in project 4 go some way to not only explaining the trial results but also providing indicators for future research. It is interesting that our suggestion that outcomes assessment of functional and social activity would be a reasonable indicator of 'poorer' or 'better than expected' adjustment proved to be unfounded. This indicates (perhaps not surprisingly) that such outcome measures are not necessarily an accurate marker of someone's recovery from and adjustment after stroke. But our interpretation, as we suspected, was narrow in focus; the measure of someone's recovery after stroke is not necessarily about their ability to live busy, active and hectic (social) lives, or even to return to how they were (and their lives were) before their stroke. To stroke survivors in project 4, what constituted a 'good'/'acceptable' recovery was the ability to find ways to carry out everyday tasks and activities that enabled them to maintain and enact (and sometimes establish) relationships that were important and meaningful to them, that is, the ability to find ways to 'be' a person and to 'do' relationships.

That information provision is the most commonly reported unmet need is in keeping with previous work.⁴ As discussed earlier, words used do not necessarily fully capture meaning. Although 'information' is commonly required, this can reflect a range of thought processes including that stroke survivors may feel unsure whether they are fully informed and, despite being in receipt of considerable information, feel that they should remain open to further information if it is available. 'Information' may act as a surrogate marker for 'wanted something but not sure what'. The provision of appropriate and timely information remains a challenge. It is likely that information needs will change over time and 'generic' leaflets become less applicable. Our Cochrane review⁴⁵ suggested slight benefits for structured information provision (e.g. information booklets with an opportunity for feedback) in terms of improving outcomes for patients and carers after stroke. It is interesting, however, that stroke survivors have gained benefits from the provision of information even 3 years after stroke.¹⁶³ Our research⁴³ and that of others¹⁶⁴ indicates that the provision of information must be an integral part of all services provided to people with a long-term condition such as stroke and it has recently been suggested that a more intensive individually tailored approach may provide some benefit.¹⁶⁵ The improved provision of information to stroke survivors about their condition and the services available to them will support self-management, which can be developed as they adjust to their new health state.¹⁶⁶

We hoped that the system of care would be delivered by the SCCs through a more problem-solving approach to post-stroke care. Although some SCCs did adopt this new mode of delivery, it appeared that not all did so. The emphasis on supporting stroke patients and carers to help themselves was occasionally

lost in a more predominant 'doing for' service model. A more iterative training and education programme for staff would help to address this issue. This would also contribute to the formalisation of a more targeted treatment plan.

We acknowledge that the lack of improvement in patient and carer outcomes may be attributable to insufficient provision in the area of need. This is particularly the case with respect to the management of psychological issues. Mood was one of the most prevalent and persistent problem areas identified yet most SCCs reported that difficulties exist for addressing this problem, with 12 services reporting an extreme lack of appropriate psychological services. Both mood and cognition were common unmet needs. Co-applicant Allan House has been instrumental in the recent development of the stepped care model for psychological interventions after stroke.¹⁶⁷ SCCs would be well placed to provide level 1 and 2 support (addressing mild/moderate symptoms of mood and cognition). A number of services also reported that there were limited voluntary and community resources such as social groups.

The heterogeneity of stroke survivors, who have a wide range of problems and unmet needs, as revealed in our projects, indicates that targeted more bespoke interventions may be the way forward. We believe that the structured assessment is a useful tool but greater consideration should be given to delivery and formulation of a subsequent treatment plan. Stratification of the patient group may be required. 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, enabling identification of specific problems that require addressing, such as pain management; other patients (and carers) might require minimum further involvement but could benefit from a programme of supported self-management. Such programmes are effective in other long-term conditions¹⁶⁸ and there is a suggestion of benefit in stroke.^{169,170} Building on our assessment tools and qualitative research exploring adjustment after stroke, there is the potential to identify stroke survivors who may be vulnerable to experiencing ongoing and/or further disruption. In addition, it would be beneficial to use theory-based predictors of behaviours that impact on longer-term stroke outcomes. Further work is required to refine these models and scope content (e.g. the self-management materials) appropriate for this heterogeneous client group.

Family members are key supporters for stroke survivors; further synthesis of this programme's outputs and other work¹⁷¹ is required to determine how best to prepare them for this role to facilitate longer-term adjustment. It is interesting in this work that stroke survivors emphasised the importance of being able to undertake activities of daily living, not only for the practical benefits but also for the emotional and social benefits of being able to interact in the 'normal' world.

There have been considerable research and clinical gains in stroke care during the implementation of this programme. The emphasis on the delivery of acute, hyperacute and early rehabilitation treatment has been addressed recently with the publication of the NICE guidelines on rehabilitation after stroke.¹⁵⁹ However, this programme of work is a timely reminder that stroke is a challenging condition for many and that further work is required to refine the longer-term care pathway to support stroke survivors and their families in achieving optimal outcomes.

Recommendations for research

In project 1, updating of the treatment algorithms enabled us to produce a comprehensive review of evidence gaps. Our detailed programme of research has explored the difficulties facing patients and their carers in the first year after stroke. Through this work a number of research recommendations have emerged.

When evaluated using a robust cluster RCT design, the system of care was not more effective than usual care at improving patient and carer outcomes. The research team will continue to explore the large data set available [informed by the outputs of the adjustment after stroke study (project 4)] to investigate whether subgroups of patients may have shown evidence of benefit.

In addition, we recommend that:

- Further research should be undertaken to explore the approach of stratifying patients after initial assessment, with subsequent input being tailored to level of need.
- The role of supported self-management should be further investigated.
- The LUNS tool is appropriate to identify unmet need and that a similar tool for carers should be developed. Consideration should also be given to the evaluation of proxy responses and development of an aphasia-friendly version of the LUNS tool.
- Future research is needed to further explore the different recovery trajectories and how, in routine practice, the process of adjustment can be monitored and supported and how potential barriers to adjustment can be identified and overcome.

Research methodology

We have demonstrated that cluster trials are feasible in rehabilitation research. However, they require rigorous implementation and are preferably (as with this trial) delivered through a CTRU. We believe that this research has highlighted the exciting new opportunities available with the establishment of the NIHR SRN in England and the research networks in Scotland, Wales and Northern Ireland. For the first time large cohorts of patients can be recruited, facilitating higher-quality and more timely research.¹⁷² Overcoming the barriers of small sample sizes is a major step forward. It is now timely to reflect on and refine methods:

- The value of tandem process and realist evaluations is acknowledged and approaches to synthesising the evidence should be further refined.
- The spectrum of pragmatic to explanatory trials needs to be carefully considered in trial design.¹⁷³
- It is essential that there is discussion and debate about methods, procedures for trial implementation and factors such as therapy effects, to inform planning of the next generation of rehabilitation research.
- The UK SRNs provided tremendous support to our research team and enabled us to deliver two large studies. It is important that researchers engage with the networks as soon as possible when planning a study to gain realistic insights into what is feasible and what additional resources may be required.
- The mechanics of how the clinical research network might influence the study sample must be considered. For example, we purposefully amended the entry criteria for participants in project 3 to ensure that sufficient patients with cognitive or communication impairments were recruited. The difficulties of recruiting carers when they are not included in the network performance management statistics have been acknowledged.
- Screening data are particularly important in cluster trials to enable monitoring of bias. This is likely to be an additional burden for clinical research network staff and the resources required should be considered at the planning stage.
- Our studies have again highlighted the challenges of outcome assessment in this population group and we have indicated the dissonance between objective outcome assessment and patients' subjective views. Further work is required to successfully address this.

Implications for health care

Policy recommends that stroke patients are reviewed in the longer term^{15,55} and that this includes measurement of unmet needs. The LUNS questionnaire has been shown to be suitable for identifying longer-term unmet needs post stroke and therefore could be used for this purpose. It is possible that the LUNS tool may have wider relevance beyond stroke care, to capture general issues that affect older people with long-term conditions.

A structured assessment based on stroke patient- and carer-identified problems and linked to evidence-based treatment algorithms has been developed and implemented in a range of UK stroke services. The assessment and the associated manual can be used in clinical practice to enhance evidence-based care,

for example the assessment provides a structured way of ensuring that an evidence-based post-stroke review is carried out and the manual serves as a repository of evidence-based practice, which could be useful for training inexperienced staff. They may be of particular use for developing services in sites currently without organised long-term care for stroke. The manual would support staff to form a broader professional base to facilitate moving from multidisciplinary to interdisciplinary 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; other patients (and carers) might require minimum further involvement but could benefit from a programme of supported self-management.

We anticipate that case studies illustrating the different recovery trajectories identified in the adjustment after stroke study (project 4) may be useful as a resource both for stroke survivors/carers and for health and social care professionals who work with stroke survivors.

Implications for commissioners

Service provision

The work reported here will inform commissioning strategies. We have identified evidence gaps and unmet needs and have provided case studies of the challenges that patients and their families face after stroke.

Continuous audit of the community-based care of stroke patients, in particular covering the transfer of care, would ensure that patients referred to community services received those services. This was highlighted as an area of concern in the system of care trial in which (despite extensive discussions and planning meetings) a number of patients either were incorrectly referred or did not receive the expected referral to the SCC.

Commissioners need to be aware of gaps in service provision in the stroke care pathway. The LUNS questionnaire could be used as a survey tool to assess the extent to which community services are meeting the needs of their stroke patients, for example measuring the percentage of the local stroke population whose mobility needs are not met. Such data could be used to compare different services, promote service development or guide commissioning of services to enhance outcomes. It is fundamental to any assessment of needs that there are mechanisms in place to address those needs.

There should be a greater emphasis on integrated working at the level of the individual and the level of the service. For the health professional an emphasis on a problem/handicap rather than an impairment-focused approach to assessment of patient and carer needs is required. Services should be interlinked appropriately rather than operating independently.

Training and education

Unidisciplinary staff should be supported through appropriate training and education to broaden their skills and understanding to enable them to more successfully address patient and carer needs. We consider that interdisciplinary working is important for the success of the system of care methodology, and the system of care trial highlighted that, although some participating SCCs worked in this way, others focused their assessment on a limited number of areas for all patients. Such training might include case studies of the different recovery trajectories (project 4) and guidance on how to provide psychological support as outlined in the stepped care model for psychological interventions after stroke. This may mitigate against the observed lack of access to psychological services for stroke patients.

Acknowledgements

This programme grant was implemented with the help, support and good humour of over a thousand people. Our thanks go to them all.

A huge thank you to all of the stroke patients and their carers who participated in the studies. We also appreciate that 136 stroke survivors have expressed a wish to be informed of any future research projects in which they may participate.

Thanks to the NIHR SRN, particularly the managers and researchers, who worked so hard to enable us to achieve the sample size for two of our projects (projects 2 and 3) – a massive effort from all.

Thanks to Terry Brady and friends and colleagues in the CRAG who provided endless advice and guidance on the implementation of the research.

Many thanks to colleagues at the University of Leeds CTRU and Bradford Teaching Hospitals NHS Foundation Trust [including the Academic Unit of Elderly Care and Rehabilitation, the Finance Office (Alec Cowell) and human resources staff] who provided support and advice throughout the lifetime of this programme.

Project 1

With thanks to Ruth Lambley who initially co-ordinated this project.

Thanks also to Deirdre Andre and colleagues, University of Leeds Health Sciences Library, for undertaking literature searching throughout the programme grant, for the reference guides in project 1, two updates of the Cochrane review on information provision and repeated reviews of the literature related to longer-term outcomes after stroke.

We thank the external peer reviewers of the references guides and Kate Hill, Jane Smith and John Green for reviewing literature from the searches.

Project 2

Thanks to Dr Peter Wanklyn and Dr Tony Rudd who assisted with the intervention training.

The trial involved hundreds of people across the 32 sites. This included staff from R&D, clinical teams and administrative staff at the different sites.

Thanks go to a hugely supportive and helpful trial steering committee: Professor Helen Rodgers (chair), Professor Jonathan Mant, Professor Kerry Hood, Professor Avril Drummond, Professor Peter Langhorne and Mrs Joan Firth (lay representative).

Thanks to Renee Romeo for assistance during the design of the economic evaluation and Margaret Heslin for assistance with unit cost collation.

Thanks go to Andrew Carter and Alison Ferguson for data management support, Maria Efthymiou for statistical input, Joanne Copeland for supervision of trial co-ordination, Nick Hearfield and Muna Matouk for administration of patient questionnaires and Danielle Beaumont for assistance with trial co-ordination.

Project 3

We thank Sue Bogle (Aysgarth Statistics) for statistical support in the pilot study, Chung Fu for data management support, Nick Preston for assistance with statistical analyses and Jane Smith for assistance with study co-ordination.

Project 4

We thank the stroke survivors who provided advice and feedback at the YSRN stroke survivor and carer annual events and members of the YSRN Therapy Group.

Thanks to Ivana Holloway for providing reports of potential participants from the trial database.

Intellectual property

All intellectual property arising from the research is owned by Bradford Teaching Hospitals NHS Foundation Trust.

The intellectual property arising from the research includes:

- the LUNS questionnaire (UK Copyright Service Registration No: 284656482)
- the LoTS care manual and treatment algorithms
- the LoTS care structured assessment
- the case studies of recovery trajectories.

Reuse is permitted free of charge for academic and non-commercial research purposes; for teaching and training purposes relating to the provision of health and social care; and for the evaluation and provision of health and social care. Any and all reuse requires prior written permission from Bradford Teaching Hospitals NHS Foundation Trust (contact corresponding author).

Contributions of authors

Major contributors to the programme

Anne Forster (Professor of Stroke Rehabilitation) was the programme lead, the chief investigator for project 2, the lead for project 1 and the chief investigator for project 3 (from January 2009).

Kirste Mellish was the programme manager from September 2009 to December 2012.

Amanda Farrin (Professor of Clinical Trials and Evaluation of Complex Interventions) was the programme statistician and the supervising statistician for project 2.

Bipin Bhakta (Professor of Rehabilitation Medicine) had input across the programme and was the outcome measure evaluation lead for project 3.

Allan House (Professor of Liaison Psychiatry) had input across the programme and contributed to the intervention training in project 2.

Jenny Hewison (Professor of the Psychology of Healthcare) had input across the programme.

Jenni Murray (Senior Research Fellow) was the lead for project 1 and the chief investigator for project 3 (to December 2008) and made substantial contributions to the development of the intervention.

Anita Patel (Reader) was the health economist for project 2.

Martin Knapp (Professor of Health Economics) was the supervising health economist for project 2.

Rachel Breen was the programme manager from September 2007 to June 2009.

John Young (Professor of Elderly Care Medicine) had input across the programme and shared clinical expertise.

Major contributors to individual projects

Project 2

Katie Chapman was the trial manager; **Ivana Holloway** was the trial statistician; **Jane Nixon** was the lead for the CTRU; and **Rosemary Shannon** and **Natasha Alvarado** were responsible for the qualitative process data; **Shamaila Anwar** was the trial co-ordinator.

Project 3

Rosemary Shannon was the study co-ordinator and the research fellow for the qualitative study; **Mike Horton** was the project statistician; **Natasha Alvarado** was the research assistant (pilot study); and **Alan Tennant** was the supervising statistician.

Project 4

Rebecca Hawkins was the senior research fellow and chief investigator; **Adam Jowett** was the research fellow; and **Mary Godfrey** was the supervising qualitative researcher.

Publications

Forster A, Young J, Nixon J, Chapman K, Murray J, Patel A, *et al.* Protocol of a cluster randomized trial evaluation of a patient and carer-centered system of longer-term stroke care (LoTS care) [published online ahead of print 19 February 2013]. *Int J Stroke* 2013. doi:10.1111/ij.s.12038

LoTS care LUNS study team. Validation of the longer-term unmet needs after stroke (LUNS) monitoring tool: a multicentre study. *Clin Rehabil* 2013;**27**:1020–8.

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Appendix 1 Development of the system of care

Development of a primary care-based service for stroke aftercare

Submitted November 1999; funded by the Stroke Association.

Purpose

Recent research has clarified aspects of acute hospital care for stroke patients but important longer-term issues remain and can be addressed adequately only in the primary care setting.^{1,2} These include continuing rehabilitation to minimise handicap; provision of home adaptations, equipment and access to services; psychological support; and responding to intercurrent events. At present, involvement of the primary care health team in stroke is inconsistent. No systematic approach has been developed for routine monitoring, problem identification and co-ordination of services to assist stroke patients and their families as they continue to recover from their stroke and make life adjustments to its consequences. The lack of engagement of primary care in stroke is in particular contrast to the situation with other chronic diseases such as asthma and diabetes, for which a strategic shift from secondary to primary care has occurred. In this initial developmental project the elements of a primary care-based service for stroke will be systematically defined and tested by pilot implementation with process change measurement.

Background

Stroke as a community care issue

Community-based observational studies over three decades have left little doubt about the daily life struggle for victims and their families as they grapple with the longer-term consequences of their stroke illness.³⁻⁷ The practical difficulties include lack of information about their condition,⁸ poor knowledge of the services and benefits available^{4,9} and fragmented community services¹⁰ that are poorly focused.¹¹ Social activities may be restricted despite apparently good physical recovery.^{5,12} Falls and consequent morbidity are also common.¹³ Three inter-related themes can be proposed as important stroke challenges: longer-term perspective; greater emphasis on handicap rather than disability; and addressing psychosocial and adjustment needs.¹ Ideally, all require a primary care perspective.

Primary care approach to longer-term stroke management

The role of the primary care health team in the longer-term support of stroke patients and their families has received scant attention amongst the vastness of contemporary stroke literature. Currently, primary care health teams behave reactively, responding to 'crises' rather than putting into place a proactive preventative strategy. The challenge is to engage the primary care health team in post-stroke care to assess, support and co-ordinate relevant services to minimise longer-term stroke morbidity. This is a difficult task as primary care is hard pressed. Yet opportunities exist, particularly in respect of practice nurses, nurse practitioners and the extended role of community nurses, within the new structure of the primary care group.

Questions to be answered

1. To define the types of longer-term problems most frequently encountered, methods for systematic assessment, and optimal management based on best available evidence.
2. To develop a generalisable primary care-based structure capable of supporting a process of routine and systematic management for post-acute stroke care for both patients and their carers.
3. To develop a post-acute assessment system with supporting training for use by primary health-care teams to promote continuing rehabilitation, access and co-ordination of supporting services, and psychosocial support.

Plan of investigation

Simple and single interventions are rarely effective in rehabilitation.¹⁴ We are therefore seeking to develop a complex intervention embedded in a clearly described organisational structure for delivery. The work has been broken down into stages progressed and co-ordinated by a project group comprising the grant applicants, a patient representative from a local stroke club, Dr Robert Ashworth (GP with academic links), and the project research assistant.

Stage 1: preparatory work (9 months)

This will entail producing a report identifying the most frequently encountered post-acute stroke problems and their optimal management based on best available evidence. This will be achieved by (a) literature searching; (b) existing collaboration with the Glasgow-based systematic review of community rehabilitation stroke studies; (c) current work reviewing models of community care (Nuffield Institute for Health); (d) examples of good practice: the Stroke Association has identified six community care stroke projects that demonstrate successful innovative practice and these are under descriptive evaluation by Professor Chamberlain, who has kindly made the interim reports available to us; and (e) interviews with regional Stroke Association staff who have daily contact with stroke patients.

Stage 2: user involvement (4 months)

We will form focus groups of 10–12 patients and carers in at least three localities: Bradford, Sheffield and Leeds. The groups will receive a presentation of the stage 1 findings and suggestions from the project group to date and be invited to make a critical appraisal of these ideas. We wish to examine for areas of agreement and disagreement: to determine the extent to which the conclusions from stage 1 'fit' with their experiences. Facilitation of the groups will be by Nuffield Institute for Health staff, who have considerable experience with this type of sensitive exploratory research. The discussions and dynamics of the focus groups will be recorded by contemporaneous note taking by a research assistant. Some individual interviews with assistance from carers will also be necessary to ensure that people with dysphasia are included. Other individual interviews will be arranged if particular areas of ambiguity emerge that require greater clarification.

Stage 3: consolidation (3 months)

The distillations from the focus groups will be synthesised around three key areas:

1. the main patient and carer stroke problems to be encompassed
2. guidance on the optimum responses to those problems
3. an outline format and content for the proces of co-ordinating the inputs from the primary care team.

Stage 4: involvement of the primary care team (4 months)

This would begin with a series of half-day workshops in four areas [Leeds, Bradford, Sheffield and Skipton, North Yorkshire (rural)] for invited primary care professionals – mixed groups of GPs, nurses, therapists and social service staff. Within each workshop there would be a facilitated debate about what primary care teams currently do for stroke patients and what they would like to do in the light of the 'good practice' literature formulated in stage 3. More specifically, we will address two key questions:

1. Who can take lead responsibility? (e.g., GP, practice nurse, nurse practitioner, community nurse, therapist)
2. How will this be organised?
 - i. Patient perspective: visiting frequency, telephone checks
 - ii. Primary care perspective: co-ordination of community agencies, a reliable system for case finding, assessing and reviewing needs, nature and range of inputs required.

The workshop conclusions will be summarised and returned to the participants for consultation and refinements.

Stage 5: development of materials and training (4 months)

Implementation of a primary care-based stroke service requires well-presented documentation describing content, process and organisation, and supporting knowledge and skills training. At present, we anticipate a 2-day residential course: 1 day to discuss the nature and consequences of stroke and 1 day to work through the new primary care-based stroke service. Follow-up work will include the participating primary care teams collating lists of local agencies and disability services and developing an initial case load of (say) four patients. These practical experiences will be used for discussion at a second training school session 6 weeks after the first. The training will be organised at the Nuffield Institute for Health, which is well equipped for residential courses and near to the proposed pilot site.

Stage 6: pilot implementation (12 months)

The primary care-based stroke service will be established as a pilot project in north Bradford where provisional access has been obtained. Ethics committee approval for this phase of the study will be requested. The purpose of the pilot is:

1. to test the feasibility of the primary care stroke service
2. to determine if the new intervention influences the process of care (not clinical outcomes at this stage)
3. to prepare for a future evaluation of the primary care-based stroke service by a multisite RCT.

Feasibility study

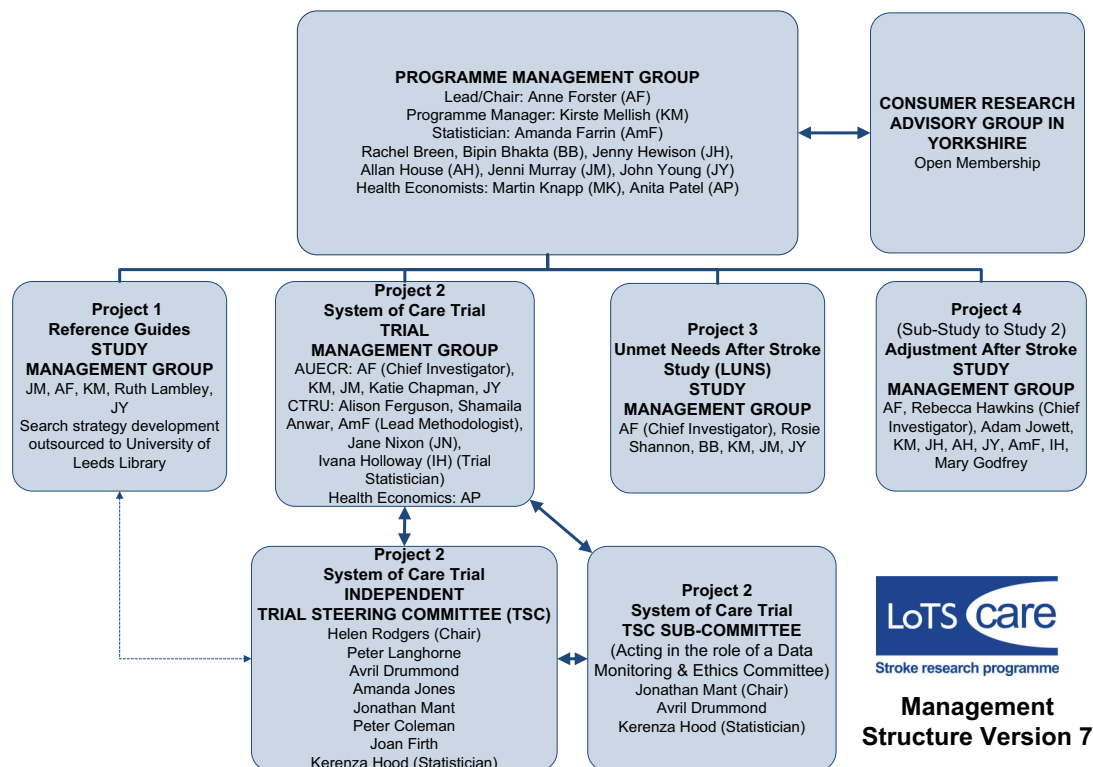
This will begin with the training of the participating primary health-care teams using the system designed in stage 5. Over 4 months 50 patients will be recruited at various stages of the 'stroke career': post discharge to 1-year post stroke onset. Acceptability of the assessment process for patients and families will be determined by regular discussion between research and primary care staff, by non-responses to assessment questions and by interviews with patients. At the end of the feasibility study a workshop will be held for the participating staff to discuss their experiences, identify key issues and problems and suggest refinements. Similarly, we will organise a focus group with participating patients selected on the basis of positive and negative experiences.

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Appendix 2 Programme management structure



Appendix 3 Project 1: sample (contact 1) of the care plan

Contact 1 (Community-based)

Not including telephone calls to make appointments

Date: Day Month Year Carer involved? Yes No N/A Telephone
 Type of contact: Face-to-face Clinic Home Other, specify:
 Your name Location:
 Profession e.g. nurse NHS Band

Carer information

Client checklist provided in advance of the assessment

Does the patient have a carer?
 Defined as: main informal carer who provides the patient with practical support a minimum of once per week
 Yes No

Was a carer assessment completed?
 Yes No Carer assessments routinely provided by other services
 Yes No Carer not present
 Reason assessment not completed:
 Not offered (reason):
 Other (reason):

Patient does not have a carer (as per definition) but has care package provided Number of times a day/week

Patient assessment questions

Remember to ask all of the questions	Response	IF NOT asked: indicate why
<i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	No problem. No further action. <input type="checkbox"/>	Problem. Please go to ACTION PLAN <input type="checkbox"/>
Transfer of Care: Reference guide 1		
Has a discharge plan been prepared by the hospital? Have you had a home visit? What was the outcome? <i>Discuss issues around knowledge and understanding of their care plan, their involvement, falls management and sources of information.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Communication & Information: Reference guide 2		
Have you been given clear information about your condition, treatment and services available?	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name Patients D.O.B. NHS number

6

Contact 1

Remember to ask all of the questions	Response	IF NOT asked: indicate why
<i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	No problem. No further action. <input type="checkbox"/>	Problem. Please go to ACTION PLAN <input type="checkbox"/>
Medicines & General Health: Reference guide 3		
Do you have any problems with your medication? <i>For example, side-effects, drug cocktail, non-prescription drugs</i> Is medication being regularly reviewed by a doctor/nurse? <i>Medication can be recorded on page 4.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have any problems taking your medication? <i>For example, opening packets, remembering, swallowing (check for swallowing assessment).</i>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have any other health problems? <i>Tick about smoking cessation, alcohol consumption, diet and weight loss.</i> Check if other health problems are being regularly reviewed.	<input type="checkbox"/>	<input type="checkbox"/>
Pain: Reference guide 4 (assessment scale available)		
Do you have any pain? Is the pain being treated? Is the treatment helping?	<input type="checkbox"/>	<input type="checkbox"/>
Mobility / Falls: Reference guide 5 (assessment scale available)		
Can you get around indoors?	<input type="checkbox"/>	<input type="checkbox"/>
Can you get out of your house?	<input type="checkbox"/>	<input type="checkbox"/>
How confident are you about carrying out various daily activities without falling?	<input type="checkbox"/>	<input type="checkbox"/>
How do you feel about your recovery so far? <i>Discuss patterns of physical and emotional recovery.</i>	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name Patients D.O.B. NHS number

7

Contact 1 patient assessment questions (continued)

Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	Response		If NOT asked: <i>indicate why</i>	
	No problem: No further action.	Problem: Please go to ACTION PLAN	Already addressed	Other: Please explain in notes section
Personal Hygiene & Dressing: Reference guide 6				
Are you having any difficulty with personal care like washing, cutting your nails, oral hygiene or dressing? Do you ever need help? <i>If applicable, discuss satisfaction with homecare services (e.g. dressing, bathing).</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shopping & Meal Preparation: Reference guide 7				
Can you prepare your own meals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Can you go shopping?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are you getting the right food?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
House & Home: Reference guide 8 (assessment scale available)				
Can you do your housework? Does anyone help you with your housework? Do you have any problems with your accommodation? <i>If applicable, discuss satisfaction with homecare services (e.g. cleaning, shopping and laundry).</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cognition: Reference guide 9 (assessment scale available)				
Do you often have a problem remembering things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you often forget where you have put things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you find it difficult to concentrate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name: _____ Patients D.O.B: _____ Day: _____ Month: _____ Year: _____ NHS number: _____ 8

Contact 1

Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	Response		If NOT asked: <i>indicate why</i>	
	No problem: No further action.	Problem: Please go to ACTION PLAN	Already addressed	Other: Please explain in notes section
Driving & General Transport: Reference guide 10 (assessment scale available)				
Do you have trouble with transport?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Finances & Benefits: Reference guide 11				
Do you have any difficulty managing your money?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are you able to pay your bills?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are you receiving all the benefits you are entitled to? Use a benefits checklist.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Continence: Reference guide 12 (assessment scale available)				
Do you ever have accidents with your bladder/bowel? How is this being managed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sexual Functioning: Reference guide 13 (assessment scale available)				
Some people after a stroke experience sexual problems such as lack of interest or practical difficulties. Have you experienced any changes sexually since your stroke?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name: _____ Patients D.O.B: _____ Day: _____ Month: _____ Year: _____ NHS number: _____ 9

Contact 1 patient assessment questions (continued)

	Response		If NOT asked: indicate why
	No problem. No further action.	Problem. Please go to ACTION PLAN	
Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	<input type="checkbox"/>	<input type="checkbox"/>	Other. Please explain in notes section.
Patient Mood: Reference guide 14 (assessment scale available)			
Have you recently felt very sad or fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you felt anxious, frightened or worried?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Do you find it difficult to control your emotions? Discuss as appropriate frustration and irritability.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you been offered or are you having any treatment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a partner, relative or friend you feel close to? Do you get on well? Can you talk about your worries or problems with them? <i>Discuss feelings of burden.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient Social Needs: Reference guide 15			
How do you spend your day? Do you have enough to do? Are you happy with your social life? Do you wish you had more social contact with others? <i>Discuss work as appropriate, changes in role, relationships, personality, attitude and interests. Discuss any social changes and lack of energy. Discuss patient's social life since the stroke as compared with pre-stroke, and any thoughts about the future.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other			
Are you having any other problems relating to your stroke? <i>For reading, swallowing, speech & language difficulties, sleeping, vision, numbness, or weakness? For other problems, please explain in notes section. Ask about their expectations and general patterns of physical and emotional recovery. Discuss motivation and how much control they feel they have in their recovery.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name Patient's D.O.B. / / NHS number:

Notes

Contact 1

Patient's Name Patient's D.O.B. / / NHS number:

Contact 1

Contact 1 goal and action planner

Client information: During your assessment you will plan and agree some goals to work towards or actions to take with your stroke care co-ordinator (SCC). The actions and goals may be set for you or for your SCC. After you have attempted your goals and actions, record the outcome below.

Duration of assessment contact (time spent with patient) : : (hours:minutes)
 Time spent discussing patient in MDT – please complete table on back page.
 Time for additional note writing : : (hours:minutes)

Problem (Please number problems)	Assessment question(s)/ Related reference guide(s) number	Goal or action	Patient/ SCC	Date set	Date review	Review of outcome Please write a: Goal achieved, b: Nearly there but extra guidance required, c: Struggling with goal – To be reviewed in next contact (exclude assessment contact time, include phone calls etc.)	Duration spent on each SCC action between date set and date review. (HH:MM) (exclude assessment contact time, include phone calls etc.)
1. Difficulty going shopping because of parking and walking problems	5, 7 & 10	Obtain Blue badge	Patient	01.02.2009	01.03.2009	a. Blue Badge obtained	20 mins

LOTS care trial team use only: Reference guides used: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other

Total number of goals/actions:

Total number of patient goals/actions:

Total number achieved:

Total duration: : :

Patient's Name:

Patient's D.O.B: / /

Patient's NHS number:

Contact 1 CARER assessment questions (optional)

Date: Day Month Year

Type of contact: Face-to-face Telephone

Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	Response		If NOT asked: indicate why	
	No problem. No further action.	Problem. Please go to ACTION PLAN	Already addressed	Other. Please explain in notes section
Transfer of Care: Reference guide 1 Check issues around involvement in care plan and understanding of situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Communication & Information: Reference guide 2 Have you been given clear information about [the patient's] condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medicines & General Health: Reference guide 3 Do you have any health concerns? Are you receiving treatment? Is the treatment helping?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mobility / Falls: Reference guide 5 Have you been shown how to handle [the patient]? Do you have any concerns about moving and handling [the patient]? Do you know what to do in the event of [the patient] falling?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patients Name Patients D.O.B. Day Month Year NHS number:

Contact 1 (carer)

Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	Response		If NOT asked: indicate why	
	No problem. No further action.	Problem. Please go to ACTION PLAN	Already addressed	Other. Please explain in notes section
Personal Hygiene & Dressing: Reference guide 6 Do you have any problems providing personal care for [the patient] like washing, cutting their nails, dressing or toileting? Do you ever need help?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shopping & Meal Preparation: Reference guide 7 Do you have trouble getting to the shops? Do you have any problems preparing meals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
House & Home: Reference guide 8 (assessment scale available) Do you have any trouble with household chores (e.g. cleaning, laundry)? Do you need help maintaining the garden or with general household jobs (e.g. changing fuses, checking smoke alarm battery etc.)? If applicable, discuss satisfaction with homecare services (e.g. cleaning, shopping, laundry).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patients Name Patients D.O.B. Day Month Year NHS number:

Contact 1 CARER assessment questions (optional)

Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	Response		IF NOT asked: indicate why	
	No problem. No further action.	Problem. Tick to ACTION PLAN	Already addressed	Other. Please explain in notes section.
Driving & General Transport: Reference guide 10 (assessment scale available)				
Do you have any trouble with transport?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>If the patient is eligible: Has a blue badge been applied for?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you require refresher lessons for driving?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Finances & Benefits: Reference guide 11				
Do you have any difficulty managing your money? Are you able to pay your bills? Are you sure you are receiving all the benefits you are entitled to? Check against benefits checklist.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sexual Functioning: Reference guide 13 (assessment scale available)				
Some couples experience sexual problems after stroke. These may include practical problems or psychological difficulties such as fear or lack of interest. Have you or your partner experienced any changes sexually since the stroke?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name

Patient's D.O.B Day Month Year

NHS number:

16

Contact 1 (carer)

Remember to ask all of the questions <i>If there is a problem but it is not going to be addressed now, please tick the problem box and record in the action plan that it will be revisited next time.</i>	Response		IF NOT asked: indicate why	
	No problem. No further action.	Problem. Tick to ACTION PLAN	Already addressed	Other. Please explain in notes section.
Patient Mood: Reference guide 14 (assessment scale available)				
Do you find it difficult or stressful caring for [the patient]?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carer Social and Emotional Needs: Reference guide 16:				
Do you feel you need a break or much more support for yourself? Discuss barriers to taking a break and what is available to them (e.g. local support groups, respite homes, other relatives).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other				
Do they have any other concerns or problems which have not been covered? If not already covered, discuss carers support groups and the benefits of a carer's assessment with social services.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Patient's Name

Patient's D.O.B Day Month Year

NHS number:

17

Contact 1 CARER goal and action planner (optional)

Client information: During your assessment you will plan and agree some goals to work towards or actions to take with your stroke care co-ordinator (SCC). The actions and goals may be set for you or for your SCC. After you have attempted your goals and actions, record the outcome below.

Contact 1 (carer)

Duration of assessment contact (time spent with carer) : : (hours/minutes)
 Time for additional note writing : (hours/minutes)

Problem (Please number problems)	Assessment question(s)/ Related reference guide(s) number	Goal or action	Carer/ SCC	Date set review	Review of outcome Please write a: Goal achieved, b: Nearly there but extra guidance required, c: Struggling with goal – To be reviewed in next contact	Duration spent on each SCC action between date set and date review. (HH:MM) (exclude assessment contact time, include phone calls etc.)

LOTS care trial team use only:
 Total number of problems identified
 Reference guides used:
 1 2 3 4 5 6 7 8
 9 10 11 12 13 14 15 16 Other

Total number of goals/actions:
 Total number of carer goals/actions:
 Total number achieved:

Total duration: : :

Patients' Name D.O.B. Day Month Year
 NHS number

Patients' Name D.O.B. Day Month Year
 NHS number

Patients' Name D.O.B. Day Month Year
 NHS number

Appendix 4 Project 1: example search strategies (pain)

Database(s): Ovid MEDLINE(R)

Date range searched: 1995 to February week 3 2008.

Date of search: 4 March 2008.

Search strategy

#	Searches
1	cerebrovascular disorders/
2	exp basal ganglia cerebrovascular disease/
3	exp brain ischemia/
4	exp carotid artery diseases/
5	cerebrovascular accident/
6	exp brain infarction/
7	exp cerebrovascular trauma/
8	exp hypoxia-ischemia, brain/
9	exp intracranial arterial diseases/
10	intracranial arteriovenous malformations/
11	exp "intracranial embolism and thrombosis"/
12	exp intracranial hemorrhages/
13	vasospasm, intracranial/
14	vertebral artery dissection/
15	aneurysm, ruptured/
16	brain injuries/
17	brain injury, chronic/
18	exp carotid arteries/
19	endarterectomy, carotid/
20	endarterectomy/
21	*heart septal defects, atrial/
22	*atrial fibrillation/
23	(stroke or poststroke or post-stroke or cerebrovasc\$ or brain vas\$ or cerebral vas\$ or cva or apoplex\$ or isch? emi\$ attack\$ or tia or tias or neurologic\$ deficit or SAH or AVM).tw.
24	((brain\$ or cerebr\$ or cerebell\$ or cortical or vertebrobasilar or hemispher\$ or intracran\$ or intracerebral\$ or infratentorial or supratentorial or MCA or anterior circulation or posterior circulation or basal ganglia) adj10 (isch? emi\$ or infarct\$ or thrombo\$ or emboli\$ or occlus\$ or hypox\$ or vasospasm or obstruction or vasculopathy)).tw.
25	((lacunal or cortical) adj5 infarct\$).tw.
26	((brain\$ or cerebr\$ or cerebell\$ or intracerebral or intracran\$ or parenchymal or intraventricular or infratentorial or supratentorial or basal gangli\$ or subarachnoid or putaminal or putamen or posterior fossa) adj10 (haemorrhage\$ or hemorrhage\$ or haematoma\$ or hematoma\$ or bleed\$)).tw.

#	Searches
27	((brain or cerebral or intracranial or communicating or giant or basilar or vertebral artery or berry or saccular or ruptured) adj10 aneurysm\$).tw.
28	(vertebral artery dissection or cerebral art\$ disease\$).tw.
29	((brain or intracranial or basal ganglia or lenticulostriate) adj10 (vascular adj5 (disease\$ or disorder or accident or injur\$ or trauma\$ or insult or event))).tw.
30	((isch?emic or apoplectic) adj5 (event or events or insult or attack\$)).tw.
31	((cerebral vein or cerebral venous or sinus or sagittal) adj5 thrombo\$).tw.
32	(CVDST or CVT).tw.
33	((intracranial or cerebral art\$ or basilar art\$ or vertebral art\$ or vertebrobasilar or vertebral basilar) adj5 (stenosis or isch?emia or insufficiency or arteriosclero\$ or atherosclero\$ or occlus\$)).tw.
34	((venous or arteriovenous or brain vasc\$) adj5 malformation\$).tw.
35	((brain or cerebral) adj5 (angioma\$ or hemangioma\$ or haemangioma\$)).tw.
36	carotid\$.tw.
37	(patent foramen ovale or PFO).tw.
38	((atrial or atrium or auricular) adj fibrillation).tw.
39	asymptomatic cervical bruit.tw.
40	exp aphasia/ or anomia/ or hemiplegia/ or hemianopsia/ or exp paresis/ or deglutition disorders/ or dysarthria/ or pseudobulbar palsy/ or muscle spasticity/
41	(aphasi\$ or apraxi\$ or dysphasi\$ or dysphagi\$ or deglutition disorder\$ or swallow\$ disorder\$ or dysarthri\$ or hemipleg\$ or hemipar\$ or paresis or paretic or hemiaop\$ or hemineglect or spasticity or anomia\$ or dynomi\$ or acquired brain injur\$ or hemiball\$).tw.
42	((unilateral or visual or hemispatial or attentional or spatial) adj10 neglect).tw.
43	or/1-42
44	limit 43 to english language
45	exp Pain/
46	pain\$.tw.
47	arm/
48	shoulder/
49	Shoulder Joint/
50	Shoulder Dislocation/
51	Shoulder Pain/
52	(arm\$ or shoulder\$).tw.
53	(upper limb\$ or upper extremity\$).tw.
54	allodynia.tw.
55	Complex regional pain syndromes/
56	crps\$2.tw.
57	((post-traumatic or posttraumatic) adj2 dystrophy).tw.
58	(reflex adj2 sympathetic adj2 dystrophy).tw.
59	(sympathetic adj2 dystrophy adj2 syndrome).tw.
60	(sympathetic adj2 reflex adj2 dystrophy).tw.
61	or/45-60
62	44 and 61

#	Searches
63	(exp child/ or exp infant/) not exp adult/
64	62 not 63
65	guideline.pt.
66	practice guideline.pt.
67	Practice Guidelines as Topic/
68	guideline\$.tw.
69	Guidelines as topic/
70	consensus development conference, NIH.pt.
71	nih consensus statement.jn.
72	consensus development conference.pt.
73	consensus.tw.
74	Consensus/
75	Consensus Development Conferences as topic/
76	Consensus Development Conferences, NIH/
77	or/65-76
78	(review or review, tutorial or review, academic).pt.
79	(medline or medlars or embase).tw,sh.
80	(scisearch or psycinfo or psychinfo).tw,sh.
81	(psychlit or psyclit).tw,sh.
82	cinahl.tw,sh.
83	((hand adj2 search\$) or (manual\$ adj2 search\$)).tw,sh.
84	(electronic database\$ or bibliographic database\$ or computeri?ed database\$ or online database\$).tw,sh.
85	(pooling or pooled or mantel haenszel).tw,sh.
86	(peto or dersimonian or der simonian or fixed effect).tw,sh.
87	or/78-86
88	meta-analysis.pt.
89	meta-analysis as topic/
90	(meta-analys\$ or meta analys\$ or metanalys\$).tw,sh.
91	(systematic\$ adj5 review\$).tw,sh.
92	(systematic\$ adj5 overview\$).tw,sh.
93	(quantitativ\$ adj5 review\$).tw,sh.
94	(quantitativ\$ adj5 overview\$).tw,sh.
95	(quantitativ\$ adj5 synthesis\$).tw,sh.
96	(methodologic\$ adj5 review\$).tw,sh.
97	(methodologic\$ adj5 overview\$).tw,sh.
98	(integrative research review\$ or research integration).tw.
99	or/88-98
100	randomized controlled trial.pt.
101	controlled clinical trial.pt.

#	Searches
102	randomized.ab.
103	placebo.ab.
104	drug therapy.fs.
105	randomly.ab.
106	trial.ab.
107	groups.ab.
108	or/100-107
109	humans.sh.
110	108 and 109
111	64 and 77
112	limit 111 to yr="1995 - 2008"
113	64 and (87 or 99)
114	113 not 112
115	limit 114 to yr="1995 - 2008"
116	64 and 110
117	116 not (112 or 115)
118	limit 117 to yr="1995 - 2008"

Databases: EMBASE Classic + EMBASE

Date range searched: 1995 to 2008 week 09.

Date of search: 4 March 2008.

Search strategy

#	Searches
1	exp cerebrovascular disease/
2	stroke\$.tw.
3	cerebrovascular\$.tw.
4	(cerebral or cerebellar or brainstem or vertebrobasilar).tw.
5	(infarct\$ or isch?emi\$ or thrombo\$ or emboli\$).tw.
6	4 and 5
7	carotid\$.tw.
8	(cerebral or intracerebral or intracranial or parenchymal).tw.
9	(brain or intraventricular or brainstem or cerebellar).tw.
10	(infratentorial or supratentorial or subarachnoid).tw.
11	8 or 9 or 10
12	(haemorrhage or hemorrhage or haematoma or hematoma).tw.
13	(bleeding or aneurysm).tw.
14	12 or 13

#	Searches
15	11 and 14
16	thrombo\$.tw.
17	(intracranial or (venous adj5 sinus) or (sagittal adj5 venous) or sagittal vein).tw.
18	16 and 17
19	transient isch?emic attack\$.tw.
20	reversible isch\$ neurologic\$.tw.
21	venous malformation\$.tw.
22	arteriovenous malformation\$.tw.
23	21 or 22
24	11 and 23
25	exp aphasia/
26	exp dysphasia/
27	hemianopia/
28	hemiplegia/
29	hemiparesis/
30	(aphas\$ or dysphas\$ or hemianop).tw.
31	(hemipleg\$ or hemipar\$).tw.
32	exp carotid artery surgery/
33	or/1-3,6-7,15,18-20,24-32
34	human/
35	nonhuman/
36	34 and 35
37	35 not 36
38	33 not 37
39	exp Pain/
40	pain\$.tw.
41	ARM MOVEMENT/ or ARM/ or arm muscle/ or ARM WEAKNESS/
42	SHOULDER DISLOCATION/ or SHOULDER PAIN/ or SHOULDER/ or shoulder injury/ or shoulder girdle/ or shoulder hand syndrome/ or frozen shoulder/
43	(arm\$ or shoulder\$).tw.
44	upper limb\$.tw.
45	upper extremity\$.tw.
46	Allodynia/
47	allodynia.tw.
48	exp Complex regional pain syndrome/
49	crps\$2.tw.
50	((post-traumatic or posttraumatic) adj2 dystrophy).tw.
51	(reflex adj2 sympathetic adj2 dystrophy).tw.
52	(sympathetic adj2 dystrophy adj2 syndrome).tw.
53	(sympathetic adj2 reflex adj2 dystrophy).tw.

#	Searches
54	or/39-53
55	38 and 54
56	(exp child/ or exp infant/) not (exp adult/ or exp adolescent/)
57	55 not 56
58	limit 57 to english language
59	((clinical or practice) adj2 guideline\$.tw.
60	(consensus adj3 statement\$.tw.
61	CONSENSUS/
62	exp practice guideline/
63	guideline\$.ti.
64	guidelines/
65	(consensus adj2 development).mp.
66	(evidence adj2 based adj2 (protocol\$ or guideline\$)).tw.
67	(clinical adj2 protocol\$).tw.
68	nursing protocol/
69	consensus conference.tw.
70	or/59-69
71	exp review/
72	(medline or medlars or embase or pubmed).ti,ab,sh.
73	(scisearch or psychlit or psyclit).ti,ab,sh.
74	(psycinfo or psychinfo).ti,ab,sh.
75	cinahl.ti,ab,sh.
76	((hand adj2 search\$) or (manual\$ adj search\$)).tw.
77	((electronic adj database\$) or (bibliographic adj database\$)).tw.
78	((pooled adj analys\$) or pooling).tw.
79	(peto or dersimonian or (fixed adj effect) or mantel haenszel).tw.
80	RETRACTED ARTICLE/
81	or/72-80
82	71 and 81
83	exp meta analysis/
84	meta?analys\$.tw,sh.
85	(systematic\$ adj5 review\$).tw,sh.
86	(systematic\$ adj5 overview\$).tw,sh.
87	(quantitativ\$ adj5 review\$).tw,sh.
88	(quantitativ\$ adj5 overview\$).tw,sh.
89	(methodologic\$ adj5 review\$).tw,sh.
90	(methodologic\$ adj5 overview\$).tw,sh.
91	((integrative adj5 research adj5 review\$) or (research adj5 integration)).tw.
92	(quantitativ\$ adj5 synthesi\$).tw,sh.

#	Searches
93	or/83-92
94	82 or 93
95	clinical trial/
96	randomized controlled trial/
97	randomization/
98	single blind procedure/
99	double blind procedure/
100	crossover procedure/
101	placebo/
102	randomi?ed controlled trial\$.tw.
103	rct.tw.
104	random allocation.tw.
105	randomly allocated.tw.
106	allocated randomly.tw.
107	(allocated adj2 random).tw.
108	single blind\$.tw.
109	double blind\$.tw.
110	((treble or triple) adj blind\$).tw.
111	placebo\$.tw.
112	prospective study/
113	or/95-112
114	case study/
115	case report.tw.
116	abstract report/
117	letter/
118	or/114-117
119	113 not 118
120	58 and 70
121	limit 120 to yr="1995 - 2008"
122	58 and 94
123	limit 122 to yr="1995 - 2008"
124	123 not 121
125	58 and 119
126	limit 125 to yr="1995 - 2008"
127	126 not (121 or 124)

Appendix 5 Project 1: example reference guide (pain)

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4

PAIN - REFERENCE GUIDE 4

The problem

Pain and discomfort are more common than often appreciated after a stroke. There are a variety of pain syndromes that can affect stroke patients. Many patients will have a pre-existing cause for pain such as arthritis that can be exaggerated by reduced movement and/or poor posture after a stroke. Two types of pain specific to stroke are hemiplegic shoulder pain (affecting approximately a third of patients at 6 months after hospital discharge), and post-stroke central pain (affecting around 2% of patients). Pain may be underdiagnosed in patients with cognitive impairment and communication difficulties. However, even in the presence of severe cognitive and communication impairment, many individuals may have their pain assessed using appropriate observational scales (**Note 1** below). Headache type pain is also common although this may be more closely related to anxiety than the stroke *per se*.

Hemiplegic Shoulder Pain is a complex, incompletely understood pain syndrome and usually requires multi-disciplinary management to optimise outcome. Patients at higher risk for developing hemiplegic shoulder pain appear to be those with more severe upper limb paralysis. Inappropriate handling techniques by formal and informal carers may increase the likelihood of traction injury, especially when there is a flaccid shoulder. Every patient with arm weakness should be asked about shoulder pain.

The flaccid shoulder This is characterised by a "floppy" arm (low tone) in which the shoulder joint becomes subluxed (downward displacement of the top of the humerus relative to the scapular joint), and the subluxation causes traction damage to surrounding shoulder soft tissues and nerves.

The spastic shoulder This is characterised by increased tone around the shoulder with associated reduction in range of movement.

Central Post-Stroke Pain (CPSP) - This is characterised by an unpleasant, burning or stabbing type of pain affecting the shoulder, usually in conjunction with the arm and sometimes the whole stroke affected side. It may be associated with allodynia (pain from stimuli which are not normally painful) and / or sensory disturbance. Evidence suggests that cold temperatures often aggravate CPSP. Static magnet for

the relief of neuropathic pain have been tested in other conditions and *may* have a place in stroke (Eccles, 2005), although as yet no trials have been reported.

The evidence and addressing the problem

The flaccid shoulder requires particular care and handling, even in the absence of pain. The arm should be appropriately supported at all times for example with a wheelchair arm support and pillows at night. The preferred position of the arm to minimise shoulder damage is where the shoulder blade is protracted (drawn forward) and the shoulder joint in slight abduction (in front of the body) and neutral rotation (approximately level with the breast area). Further, the arm should be positioned forward, the wrist neutral or slight supination (palm up) and the fingers extended. A physiotherapist will advise on appropriate positioning of the limb and passive range of motion exercises.

Spastic shoulder The use of analgesics (paracetamol, dihydrocodeine, non-steroidal anti-inflammatory drugs) is of uncertain value but a carefully monitored therapeutic trial is worthwhile providing there are no contra-indications (for NSAIDs: peptic ulceration, anticoagulation therapy: renal impairment). Physiotherapy input should aim to teach accurate arm positioning and provide carer training in gentle passive elevation of the shoulder. For patients with persisting shoulder pain, techniques such as high intensity transcutaneous nerve stimulation (TENS) may be useful. There is conflicting evidence for effectiveness of functional electrical stimulation (Teasell, 2008). Injection of Botulinum toxin into spastic muscles may also be considered.

CPSP Analgesics are not effective. Anticonvulsants (Gabapentin or carbamazepine) or low dose tricyclic antidepressants are the preferred agents.

Local Services Find out contact details and referral process for local pain clinic (if available).

Evidence: Comprehensively reviewed in Teasell R, *et. al.*, Evidenced based review of the management of post stroke pain, July 2008

www.ebrsr.com/uploads/Appendix_-_Pain.pdf.

4

Note 1: Observational changes associated with pain (taken from the RCP, BGS and BPS guidelines on assessment of pain (2007))

Type	Description
Autonomic	Pallor, sweating, tachypnoea, altered breathing patterns, tachycardia, hypertension
Facial expressions	Grimacing, wincing, frowning, rapid blinking, brow raising, brow lowering, cheek raising, eyelid tightening, nose wrinkling, lip corner pulling, chin raising, lip puckering.
Body movement	Alter gait, pacing, rocking, hand wringing, repetitive movements, increased tone, guarding, bracing
Verbalisations/vocalisations	Sighing, grunting, groaning, moaning, screaming, calling out, aggressive/offensive speech
Interpersonal interactions	Aggression, withdrawal, resisting
Changes in activity patterns	Wandering, altered sleep, altered rest patterns
Mental status changes	Confusion, crying, distress, irritability

* Individual behaviours differ so check behaviour pattern with main carer

Note 2: some patients may have altered sensation, which impairs normal pain sensation. They therefore may not be able to tell if, for example, a fire is too hot or their fingers are catching in the spokes of the wheelchair.

Assessments

Checklist of non-verbal pain indicators: http://prc.coh.org/PainNOA/CNPI_Tool.pdf

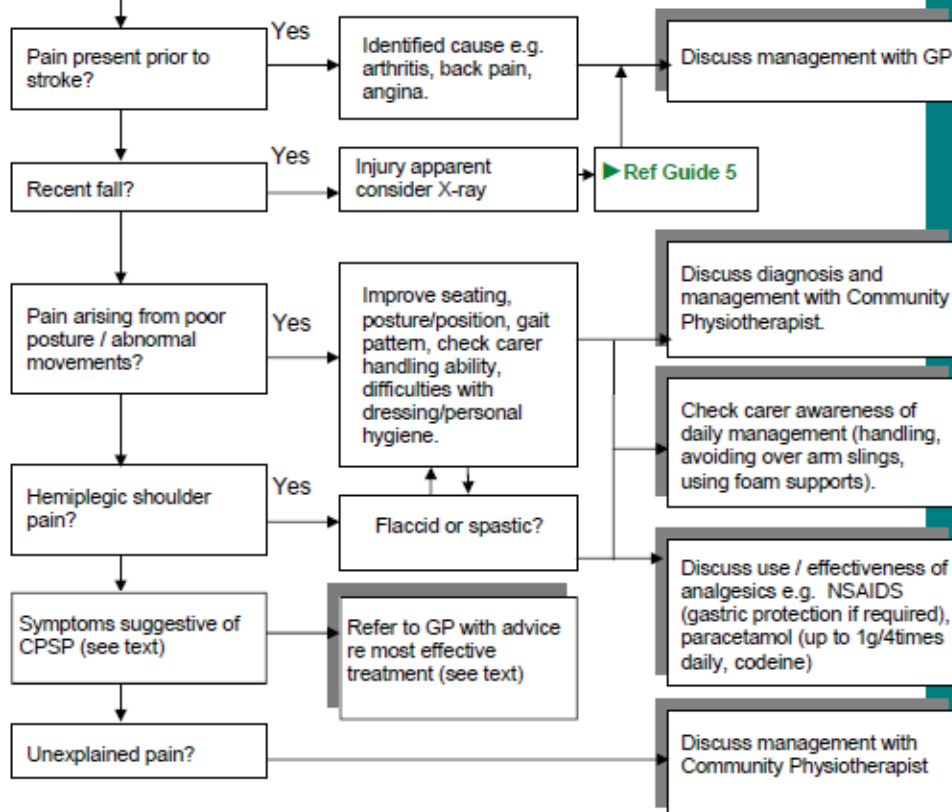
McGill pain questionnaire: www.cebp.nl/vault_public/filesystem/?ID=1400

PAIN - REFERENCE GUIDE 4

Carry out pain assessment covering description, measurement, cause (see below) and significance of the pain. If cognitive / communication impairment use specialist assessment tools (Assessment Scales in References) or use checklist of behavioural signs ^(Note 1).

If unsure about pain type, discuss with Physiotherapist with stroke expertise or Stroke Consultant.

Consider depression as an aggravating factor that modulates pain perception (the reverse is also true) (► Ref Guide 14)



At review:

- Ask about presence of pain as a consequence of stroke (even if pain was not present at first assessment - repeat at each contact);
- Ensure consistency when monitoring pain by using the same scale at each assessment (advise other health professionals of scale used and provide as necessary);
- If interventions prove ineffective, refer to GP for appropriate analgesics;
- Consider referral (within one month of treatment onset) to specialist pain service for unmanageable pain syndromes.

Appendix 6 Project 2: evidence submitted to the Academy of Medical Sciences for the review on research governance

The following case study was submitted as evidence to the Academy of Medical sciences for the review on research governance.¹⁶²

Case study: cluster randomised trial evaluation of a patient- and carer-centred system of longer-term stroke care (Longer-Term Stroke care trial)

Introduction

The LoTS care trial is part of a NIHR-funded programme of research that aims to improve outcomes after stroke by addressing the longer-term needs of patients and carers living at home in the community. It is a cluster RCT evaluating the clinical effectiveness and cost-effectiveness of a new system of care (LoTS care intervention) in comparison to usual practice, as delivered by SCCs, for 800 stroke patients (with and without carers) living at home in the community. The system of care involves the use of a structured assessment linked to a manual containing reference guides and evidence-based treatment algorithms to identify individual patient and carer needs and create action plans for those patients and carers.

Trial organisation

The trial is managed by the Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds and is sponsored by the Bradford Teaching Hospitals NHS Foundation Trust. It is adopted by the SRN (prior to the NIHR co-ordinated system for gaining NHS permission). The trial involves 32 services across the UK, each of which is composed of a SCC-led community service and the hospitals that refer patients to them, such that 62 separate trusts are involved. After all approvals are in place, SCC services are randomised to either the LoTS care intervention or the control (usual practice) (cluster randomisation); after a training period for intervention services to embed this practice into their service, services then use the practice to which they have been randomised with all patients referred to them throughout the duration of the trial. Patients are recruited to the trial in hospital (for the majority of patients) or in the community by a stroke researcher who is separate from the clinical team, before their first appointment with the SCC service. Patients (and carers) who consent to the trial have a baseline assessment undertaken by the researcher and are asked to complete questionnaires assessing psychological and functional outcomes at baseline and 6 and 12 months after recruitment.

Trial timelines

The NIHR-funded research programme runs for 5 years from October 2007 until September 2012. The initial application for ethics approval for the trial was made in January 2008 and the first patient was recruited in July 2009 (phase 1 services) and February 2010 (phase 2 services). The steps leading up to the first patient being recruited are summarised in *Table 63* and are discussed in more detail below. Recruitment of 800 patients is required to be completed by the end of 2010, with 12 months' follow-up completed in January 2012, allowing time for analysis and writing up of results by the end of the programme. The original programme timescale was 55 months; however, this was extended to 60 months to accommodate the protracted set-up and approval times at the start of the trial.

TABLE 63 Longer-Term Stroke care trial: summary of timelines to first patient recruited

		2008			2009												2010		
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	J	F		
Ethics (England, Wales, Northern Ireland)	Submission																		
	Resubmission																		
	Approval																		
Ethics (Scotland)	Submission																		
	Resubmission																		
	Approval																		
Phase 1 ^a	Local set-up																		
	R&D approvals																		
	Randomisation																		
	Training (intervention)																		
	First patient recruited																		
Phase 2 ^a	Local set-up																		
	R&D approvals																		
	Randomisation																		
	Training (intervention)																		
	First patient recruited																		

^a Phase 1 and phase 2 differ only in the timelines. Shading represents the duration of the task. Crosses represent the dates the tasks were completed.

Ethics approval

The review process was efficient (1–2 months). However, approval was delayed because of initial rejections, which appeared to be based on a lack of understanding of the cluster randomised design of the trial. In addition, separate ethics approvals were required for Scotland and the rest of the UK because of the inclusion of adults lacking capacity.

Local set-up

This involved establishing interest and the suitability of SCC services and the hospitals from which they received referrals, determining which acute trusts and primary care trusts are involved, identifying principal and co-investigators and preparing R&D applications. In the majority of services the principal investigator was required to take responsibility for the trial over the whole service, with co-investigators at each of the sites involved. In some services, the principal investigator was able to take responsibility for the trial only at an individual trust, resulting in more than one principal investigator for the service. The intervention is delivered in the primary care trust whereas the majority of patients are recruited from acute trusts, so agreement was required as to who would take responsibility. Delays were caused by differing trust policies regarding who could be principal investigator; many acute trusts would accept principal investigators employed by their own trust only and others required that the principal investigator must be a consultant, despite this being a non-CTIMP (Clinical Trial of an Investigational Medicinal Product) study delivered by stroke research nurses and SCCs. There were also delays in the issuing of honorary contracts for those principal investigators not employed by the acute trusts. Set-up times ranged from 0.5 to 12.2 months, with a median time of 4.1 months. Set-up times for individual services are given in *Tables 64a* and *b*.

TABLE 64a Longer-Term Stroke care trial: timelines for set-up and R&D approval (phase 1)

SRN (at time of trial set-up)	Service	Number of trusts	Set-up (months)	Trust	R&D approval trust (months)	R&D approval service (months)	Set-up and approval (months)
None	Aylesbury	2	3.7	Buckinghamshire Hospitals NHS Trust	2.6	2.6	6.3
				Buckinghamshire PCT	0.6		
North-east	Hartlepool	2	6.2	North Tees and Hartlepool NHS Foundation Trust	2.6	2.6	8.8
				Hartlepool PCT	1.8		
	Peterlee	4	6.1	North Tees and Hartlepool NHS Foundation Trust	2.6	2.6	8.7
				City Hospitals Sunderland NHS Foundation Trust	2.5		
				County Durham and Darlington NHS Foundation Trust	0.5		
				County Durham PCT and Darlington PCT	2.4		
Stockton-on-Tees	2	5.5	North Tees and Hartlepool NHS Foundation Trust	2.6	2.6	8.1	
			North Tees PCT	1.8			

continued

TABLE 64a Longer-Term Stroke care trial: timelines for set-up and R&D approval (phase 1) (continued)

SRN (at time of trial set-up)	Service	Number of trusts	Set-up (months)	Trust	R&D approval trust (months)	R&D approval service (months)	Set-up and approval (months)
Northern Ireland	Dungannon	2	2.8	Southern Health and Social Care Trust	2.8	3.0	5.8
				Western Health and Social Care Trust	3.0		
	Newry	1	4.1	Southern Health and Social Care Trust	2.8	2.8	6.9
	Omagh	1	4.7	Western Health and Social Care Trust	3.0	3.0	7.7
North-west	Manchester	3	2.2	Central Manchester and Manchester Children's University Hospitals NHS Trust	2.6	2.6	4.8
				Pennine Acute Hospitals NHS Trust	2.6		
				Manchester PCT	2.0		
South-east	Surrey	2	4.6	Ashford and St Peter's Hospitals NHS Trust	1.1	1.7	6.3
				Surrey PCT	1.7		
Wales	Cardiff	1	3.2	Cardiff and Vale NHS Trust	3.5	3.5	6.7
	Swansea	1	4.2	Abertawe Bro Morgannwg University Health Board	3.1	3.1	7.3
West Midlands	Coventry	2	4.2	University Hospitals Coventry and Warwickshire NHS Trust	4.2	4.4	8.6
				Coventry Teaching PCT	4.4		
	Walsall	2	3.2	Walsall Hospitals NHS Trust	3.5	3.5	6.7
				Walsall PCT	2.6		
	Wolverhampton	2	0.9	The Royal Wolverhampton Hospitals NHS Trust	2.1	2.1	3.0
			Wolverhampton City PCT	0.6			

PCT, primary care trust.

TABLE 64b Longer-Term Stroke care trial: timelines for set-up and R&D approval (phase 2)

SRN (at time of trial set-up)	Service	Number of trusts	Set-up (months)	Trust	R&D approval trust (months)	R&D approval service (months)	Set-up and approval (months)
None	Cheltenham	2	4.0	Gloucestershire Hospitals NHS Foundation Trust	9.3	9.3	13.3
				NHS Gloucestershire	9.3		
	Gloucester	2		Gloucestershire Hospitals NHS Foundation Trust	9.3	9.3	13.3
				NHS Gloucestershire	9.3		
	Ipswich	2	3.3	Ipswich Hospital NHS Trust	9.1	9.1	12.4
				Suffolk PCT	8.0		
	Lyndhurst	3	4.0	Southampton University Hospitals NHS Trust	9.1	9.1	13.1
				Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust	2.5		
				Hampshire Community Health Care	8.5		
	Peninsula	Cornwall	4	7.3	Royal Cornwall Hospitals NHS Trust	2.6	2.6
Cornwall and Isles of Scilly PCT					1.5		
Plymouth Teaching PCT					1.2		
Plymouth Hospitals NHS Trust					1.8		
Exeter		2	3.0	Royal Devon and Exeter NHS Foundation Trust	3.0	3.0	6.0
				Devon PCT	3.0		
Williton		1	0.5	Somerset PCT	1.8	1.8	2.3
Scotland	Dunoon	2	10.6	NHS Greater Glasgow and Clyde	2.5	2.5	13.1
				NHS Highland	1.7		
	Oban	1	11.7	NHS Highland	1.7	1.7	13.4
Trent	Chesterfield	2	9.4	Chesterfield Royal Hospital NHS Foundation Trust	2.7	4.4	13.8
				Derbyshire County PCT	4.4		
	Norwich	2	3.6	Norfolk and Norwich University Hospitals NHS Foundation Trust	1.8	2.5	6.1
				NHS Norfolk	2.5		

continued

TABLE 64b Longer-Term Stroke care trial: timelines for set-up and R&D approval (phase 2) (continued)

SRN (at time of trial set-up)	Service	Number of trusts	Set-up (months)	Trust	R&D approval trust (months)	R&D approval service (months)	Set-up and approval (months)	
North-west	Blackpool	2	0.6	Blackpool PCT	2.9	2.9	3.5	
				Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	1.9			
	Ellesmere Port	1	11.3	NHS Western Cheshire	2.8	2.8	14.1	
	East Lancashire	4	0.6	East Lancashire Hospitals NHS Trust	0.5	1.3	1.9	
				Airedale NHS Trust	1.3			
				Pennine Acute Hospitals NHS Trust	1.2			
	Preston	3	9.3	NHS East Lancashire	0.7	6.9	6.9	16.2
				Southport and Ormskirk Hospital NHS Trust	6.9			
				Lancashire Teaching Hospitals NHS Foundation Trust	1.7			
	St Helens	3	12.2	NHS Central Lancashire	1.2	2.7	2.7	14.9
				St Helens and Knowsley Teaching Hospitals NHS Trust	2.7			
				Warrington and Halton Hospitals NHS Foundation Trust	1.9			
South-east	Gravesend	4	10.2	NHS Halton and St Helens	2.2	2.7	12.9	
				Maidstone and Tunbridge Wells NHS Trust	2.7			
				Dartford and Gravesham NHS Trust	1.7			
				NHS West Kent	0.8			
	Worthing	2	2.7	Guy's and St Thomas' NHS Foundation Trust	0.8	10.4	10.4	13.1
				Western Sussex Hospitals NHS Trust	10.4			
				West Sussex PCT	1.4			

PCT, primary care trust.

Research and development approval (NHS permission)

Sixty-nine R&D approvals from 62 trusts were required to cover the 32 SCC services involved in the trial. The number of trusts involved in a service ranged from one to four. Because of the unpredictability of R&D approval timelines, it was required that all approvals at a service had to be in place before that service could be randomised. The randomisation had to be staggered into two phases according to the time taken to obtain R&D approvals, with 14 services in phase 1 and 18 services in phase 2.

All R&D applications were submitted after ethics approval (Scotland or the rest of the UK as appropriate) was in place. The time taken to receive all R&D approvals for a service ranged from 1.3 to 10.4 months (median 2.8 months), with R&D approvals from individual trusts taking between 0.5 and 10.4 months (median 2.5 months). In total, 42% of trusts gave approval in <2 months, 35% in 2–3 months, 10% in 3–4 months and the remaining 13% in 7–10 months. R&D approval times for individual services and trusts are given in *Table 64a* and *b*.

Common problems that were encountered included:

- lack of understanding of the cluster randomised trial design
- changes requested to the model non-commercial agreement (Schedule 2: division of responsibilities) and delays in sign-off
- local requirements for documentation in addition to the standard forms and documents
- reluctance to provide approval without a named stroke researcher; in some cases this was necessary as the SRN/trial funds could not provide a researcher until approval was in place
- insistence that consent could be taken only by a physician rather than by a stroke researcher
- requirement to provide documentary evidence of indemnity despite the trial having a NHS sponsor
- pressure from R&D departments (and the NHS sponsor) to prevent researchers from implementing ethics-approved amendments until R&D departments have also approved the amendments, and delays in approving amendments by R&D departments.

Conclusions

The LoTS care trial is a publicly funded trial with the potential to improve the longer-term care of stroke patients and carers. Substantial delays were caused in the time to first patient recruited by the time taken to obtain R&D approvals from the large number of trusts involved and local policies disproportionate to the risk of the study. It is suggested that a target of R&D approval within 2 months be implemented. Of the 62 trusts involved in the LoTS care trial, 77% gave R&D approval within 3 months and 42% within 2 months, suggesting that 2 months is an achievable target, in addition to bringing R&D approval in line with ethics and Medicines and Healthcare products Regulatory Agency approval timelines.

Appendix 7 Project 2: unit costs

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Residential and nursing home				
Residential care home	Night	75	1	
Nursing home	Night	76	1	
Inpatient services				
A – Nervous system	Bed-day	356	2	Tab TNEI_L: weighted mean of codes A
B – Eyes and periorbita	Bed-day	587	2	Tab TNEI_L: weighted mean of codes B
C – Mouth, head, neck and ears	Bed-day	503	2	Tab TNEI_L: weighted mean of codes C
D – Respiratory system	Bed-day	316	2	Tab TNEI_L: weighted mean of codes D
E – Cardiac surgery and primary cardiac conditions	Bed-day	438	2	Tab TNEI_L: weighted mean of codes E
F – Digestive system	Bed-day	415	2	Tab TNEI_L: weighted mean of codes F
G – Hepatobiliary and pancreatic systems	Bed-day	385	2	Tab TNEI_L: weighted mean of codes G
H – Musculoskeletal system	Bed-day	471	2	Tab TNEI_L: weighted mean of codes H
J – Skin, breast and burns	Bed-day	391	2	Tab TNEI_L: weighted mean of codes J
K – Endocrine and metabolic system	Bed-day	317	2	Tab TNEI_L: weighted mean of codes K
L – Urinary tract and male reproductive systems	Bed-day	339	2	Tab TNEI_L: weighted mean of codes L
M – Female reproductive system and assisted reproduction	Bed-day	580	2	Tab TNEI_L: weighted mean of codes M
N – Obstetrics	Bed-day	792	2	Tab TNEI_L: weighted mean of codes N
P – Diseases of childhood and neonates	Bed-day	559	2	Tab TNEI_L: weighted mean of codes P
Q – Vascular system	Bed-day	457	2	Tab TNEI_L: weighted mean of codes Q
R – Radiology and nuclear medicine	Bed-day	497	2	Tab TNEI_L: weighted mean of codes R
S – Haematology, chemotherapy, radiotherapy and specialist palliative care	Bed-day	434	2	Tab TNEI_L: weighted mean of codes S
W – Immunology, infectious diseases and other contacts	Bed-day	444	2	Tab TNEI_L: weighted mean of codes W
Geriatric	Bed-day	336	2	Costed as 'stroke rehabilitation'
Oncology/cancer	Bed-day	425	2	Costed as 'general medical'
Surgery	Bed-day	425	2	Costed as 'general medical'

continued

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Intensive care	Bed day	1213	2	Index tab TCCSALCCU: Critical Care Services – Adult: Critical Care Unit
Acute stroke/stroke unit	Bed-day	315	2	Tab TNEI_L: weighted average of ischaemic and haemorrhagic stroke
Stroke rehabilitation/stroke/stroke ward	Bed-day	336	2	Tab TREHAB_CSRS_LEVEL_1_BEDDAY_APC: VC04Z (rehabilitation for stroke) cost. Assumption this is per bed-day
General medical	Bed-day	425	2	Tab TNEI_L: weighted average of all costs
Inpatient services				
A – Nervous system	Stay	2500	2	Tab TNEI_L: weighted mean of codes A
B – Eyes and periorbita	Stay	2249	2	Tab TNEI_L: weighted mean of codes B
C – Mouth, head, neck and ears	Stay	1966	2	Tab TNEI_L: weighted mean of codes C
D – Respiratory system	Stay	1999	2	Tab TNEI_L: weighted mean of codes D
E – Cardiac surgery and primary cardiac conditions	Stay	1996	2	Tab TNEI_L: weighted mean of codes E
F – Digestive system	Stay	2341	2	Tab TNEI_L: weighted mean of codes F
G – Hepatobiliary and pancreatic systems	Stay	2523	2	Tab TNEI_L: weighted mean of codes G
H – Musculoskeletal system	Stay	3720	2	Tab TNEI_L: weighted mean of codes H
J – Skin, breast and burns	Stay	2617	2	Tab TNEI_L: weighted mean of codes J
K – Endocrine and metabolic system	Stay	1789	2	Tab TNEI_L: weighted mean of codes K
L – Urinary tract and male reproductive systems	Stay	2370	2	Tab TNEI_L: weighted mean of codes L
M – Female reproductive system and assisted Reproduction	Stay	2050	2	Tab TNEI_L: weighted mean of codes M
N – Obstetrics	Stay	2330	2	Tab TNEI_L: weighted mean of codes N
P – Diseases of childhood and neonates	Stay	1721	2	Tab TNEI_L: weighted mean of codes P
Q – Vascular system	Stay	4057	2	Tab TNEI_L: weighted mean of codes Q
R – Radiology and nuclear medicine	Bed-day	5328	2	Tab TNEI_L: weighted mean of codes R
S – Haematology, chemotherapy, radiotherapy and specialist palliative care	Stay	2686	2	Tab TNEI_L: weighted mean of codes S
W – Immunology, infectious diseases and other contacts	Stay	4717	2	Tab TNEI_L: weighted mean of codes W
Oncology/cancer	Stay	2378	2	Costed as 'general medical'
Surgery	Stay	2378	2	Costed as 'general medical'
Acute stroke/stroke unit	Stay	2884	2	Tab TNEI_L: weighted average of ischaemic and haemorrhagic stroke
General medical	Stay	2378	2	Tab TNEI_L: weighted average of all costs

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Day hospital/day cases				
A – Nervous system	Activity	633	2	Tab TDC: weighted mean of codes A
B – Eyes and periorbita	Activity	762	2	Tab TDC: weighted mean of codes B
C – Mouth, head, neck and ears	Activity	761	2	Tab TDC: weighted mean of codes C
D – Respiratory system	Activity	578	2	Tab TDC: weighted mean of codes D
E – Cardiac surgery and primary cardiac conditions	Activity	1190	2	Tab TDC: weighted mean of codes E
F – Digestive system	Activity	560	2	Tab TDC: weighted mean of codes F
G – Hepatobiliary and pancreatic systems	Activity	949	2	Tab TDC: weighted mean of codes G
H – Musculoskeletal system	Activity	980	2	Tab TDC: weighted mean of codes H
J – Skin, breast and burns	Activity	685	2	Tab TDC: weighted mean of codes J
K – Endocrine and metabolic system	Activity	379	2	Tab TDC: weighted mean of codes K
L – Urinary tract and male reproductive systems	Activity	494	2	Tab TDC: weighted mean of codes L
M – Female reproductive system and assisted reproduction	Activity	719	2	Tab TDC: weighted mean of codes M
N – Obstetrics	Activity	230	2	Tab TDC: weighted mean of codes N
P – Diseases of childhood and neonates	Activity	692	2	Tab TDC: weighted mean of codes P
Q – Vascular system	Activity	750	2	Tab TDC: weighted mean of codes Q
R – Radiology and nuclear medicine	Activity	956	2	Tab TDC: weighted mean of codes R
S – Haematology, chemotherapy, radiotherapy and specialist palliative care	Activity	451	2	Tab TDC: weighted mean of codes S
V – Multiple trauma, emergency medicine and rehabilitation	Activity	991	2	Tab TDC: weighted mean of codes V
W – Immunology, infectious diseases and other contacts	Activity	407	2	Tab TDC: weighted mean of codes W
Overall day hospital	Activity	664	2	Index tab: Day Cases HRG Data – TDC
Surgery	Activity	664	2	Costed as 'overall day hospital'
Stroke	Activity	664	2	Costed as 'overall day hospital'

continued

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Outpatient services				
A&E	Activity	113	2	Total – OPATT Tab: Service code 180
General surgery	Activity	119	2	Total – OPATT Tab: Service code 100
Urology	Activity	102	2	Total – OPATT Tab: Service code 101
Breast surgery	Activity	127	2	Total – OPATT Tab: Service code 103
Colorectal surgery	Activity	106	2	Total – OPATT Tab: Service code 104
Hepatobiliary and pancreatic surgery	Activity	156	2	Total – OPATT Tab: Service code 105
Upper gastrointestinal surgery	Activity	111	2	Total – OPATT Tab: Service code 106
Vascular surgery	Activity	133	2	Total – OPATT Tab: Service code 107
Ear, nose and throat	Activity	92	2	Total – OPATT Tab: Service code 120
Ophthalmology	Activity	83	2	Total – OPATT Tab: Service code 130
Oral surgery	Activity	110	2	Total – OPATT Tab: Service code 140
Restorative dentistry	Activity	114	2	Total – OPATT Tab: Service code 141
Orthodontics	Activity	112	2	Total – OPATT Tab: Service code 143
Maxillofacial surgery	Activity	109	2	Total – OPATT Tab: Service code 144
Neurosurgery	Activity	157	2	Total – OPATT Tab: Service code 150
Plastic surgery	Activity	89	2	Total – OPATT Tab: Service code 160
Burns care	Activity	160	2	Total – OPATT Tab: Service code 161
Cardiothoracic surgery	Activity	211	2	Total – OPATT Tab: Service code 170
Cardiac surgery	Activity	230	2	Total – OPATT Tab: Service code 172
Thoracic surgery	Activity	204	2	Total – OPATT Tab: Service code 173
Anaesthetics	Activity	84	2	Total – OPATT Tab: Service code 190
Pain management	Activity	128	2	Total – OPATT Tab: Service code 191
Critical care medicine	Activity	139	2	Total – OPATT Tab: Service code 192
General medicine	Activity	153	2	Total – OPATT Tab: Service code 300
Endocrinology	Activity	140	2	Total – OPATT Tab: Service code 302
Clinical haematology	Activity	152	2	Total – OPATT Tab: Service code 303
Clinical physiology	Activity	53	2	Total – OPATT Tab: Service code 304
Clinical pharmacology	Activity	139	2	Total – OPATT Tab: Service code 305
Hepatology	Activity	202	2	Total – OPATT Tab: Service code 306
Diabetic medicine	Activity	130	2	Total – OPATT Tab: Service code 307
Haemophilia	Activity	772	2	Total – OPATT Tab: Service code 309
Audiological medicine	Activity	92	2	Total – OPATT Tab: Service code 310
Clinical genetics	Activity	672	2	Total – OPATT Tab: Service code 311

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Clinical cytogenetics and molecular genetics	Activity	185	2	Total – OPATT Tab: Service code 312
Clinical immunology and allergy	Activity	161	2	Total – OPATT Tab: Service code 313
Rehabilitation	Activity	122	2	Total – OPATT Tab: Service code 314
Palliative medicine	Activity	191	2	Total – OPATT Tab: Service code 315
Clinical immunology	Activity	215	2	Total – OPATT Tab: Service code 316
Allergy	Activity	124	2	Total – OPATT Tab: Service code 317
Respite care	Activity	17	2	Total – OPATT Tab: Service code 319
Cardiology	Activity	134	2	Total – OPATT Tab: Service code 320
Clinical microbiology	Activity	206	2	Total – OPATT Tab: Service code 322
Spinal injuries	Activity	253	2	Total – OPATT Tab: Service code 323
Anticoagulant service	Activity	21	2	Total – OPATT Tab: Service code 324
Dermatology	Activity	95	2	Total – OPATT Tab: Service code 330
Respiratory medicine	Activity	148	2	Total – OPATT Tab: Service code 340
Respiratory physiology	Activity	161	2	Total – OPATT Tab: Service code 341
Infectious diseases	Activity	241	2	Total – OPATT Tab: Service code 350
Tropical medicine	Activity	228	2	Total – OPATT Tab: Service code 352
Genitourinary medicine	Activity	153	2	Total – OPATT Tab: Service code 360
Nephrology	Activity	164	2	Total – OPATT Tab: Service code 361
Medical oncology	Activity	123	2	Total – OPATT Tab: Service code 370
Nuclear medicine	Activity	99	2	Total – OPATT Tab: Service code 371
Neurology	Activity	168	2	Total – OPATT Tab: Service code 400
Clinical neurophysiology	Activity	170	2	Total – OPATT Tab: Service code 401
Rheumatology	Activity	138	2	Total – OPATT Tab: Service code 410
Geriatric medicine	Activity	205	2	Total – OPATT Tab: Service code 430
Dental medicine specialties	Activity	101	2	Total – OPATT Tab: Service code 450
Medical ophthalmology	Activity	89	2	Total – OPATT Tab: Service code 460
Obstetrics	Activity	112	2	Total – OPATT Tab: Service code 501
Gynaecology	Activity	118	2	Total – OPATT Tab: Service code 502
Gynaecological oncology	Activity	134	2	Total – OPATT Tab: Service code 503
Midwife episode	Activity	63	2	Total – OPATT Tab: Service code 560
Podiatry	Activity	43	2	Total – OPATT Tab: Service code 653
Orthoptics	Activity	54	2	Total – OPATT Tab: Service code 655
Clinical oncology	Activity	126	2	Total – OPATT Tab: Service code 800
Diagnostic imaging	Activity	30	2	Total – OPATT Tab: Service code 812
Chemical pathology	Activity	67	2	Total – OPATT Tab: Service code 822

continued

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Audiology	Activity	113	2	Total – OPATT Tab: Service code 840
Trauma and orthopaedics: non-trauma	Activity	99	2	Total – OPATT Tab: Service code 110N
Trauma and orthopaedics: trauma	Activity	101	2	Total – OPATT Tab: Service code 110T
Medical gastroenterology	Activity	128	2	Total – OPATT Tab: Service code 301M
Surgical gastroenterology	Activity	116	2	Total – OPATT Tab: Service code 301S
Endocrine surgery	Activity	123	2	Total – OPATT Tab: Service code 302S
Physiotherapy	Activity	38	2	Total – OPATT Tab: Service code 650A
Occupational therapy	Activity	56	2	Total – OPATT Tab: Service code 651A
Speech and language therapy	Activity	98	2	Total – OPATT Tab: Service code 652A
Dietetics	Activity	55	2	Total – OPATT Tab: Service code 654A
Breast MDT meetings	Activity	89	2	Total – OPATT Tab: Service code CMDT_B
Colorectal MDT meetings	Activity	137	2	Total – OPATT Tab: Service code CMDT_C
Local gynaecology MDT meetings	Activity	111	2	Total – OPATT Tab: Service code CMDT_LG
Specialist gynaecology MDT meetings	Activity	120	2	Total – OPATT Tab: Service code CMDT_SpG
Specialist UGI meetings	Activity	125	2	Total – OPATT Tab: Service code CMDT_SpU
Radiography	Activity	29	2	Total – OPATT Tab: Service code DAFP
Sexual and reproductive health clinic (previously referred to as family planning clinic)	Activity	65	2	Total – OPATT Tab: Service code FPC
HIV/AIDS	Activity	515	2	Total – OPATT Tab: Service code H/A
Stroke	Activity	168	2	Costed as 'neurology'
Mental health	Activity	179	2	A weighted average of all hospital outpatient services was calculated. Index tab: variables: TMHCSOPFAF, TMHCSOPFANF, TMHCSOPFUAF, TMHCSOPFUANF, TMHCSOPSSFAF, TMHCSOPSSFANF, TMHCSOPSSFUAF, TMHCSOPSSFUANF
Blood tests	Activity	3	2	TDAPS Tab: DAP839 code
Radiology	Activity	109	2	Index tab: TRADTHPY_TREAT_OP: Radiotherapy treatment: outpatient
Community-based services				
GP, surgery	Visit	30	3	Average surgery consultation lasting 11.7 minutes. Includes direct care staff costs; excludes qualification costs (p. 149)
GP, home	Visit	99	3	Average home visit lasting 23.4 minutes. Includes travel time and direct care staff costs; excludes qualification costs (p. 149)

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
GP, telephone consultation	Call	18	3	Average telephone consultation lasting 7.1 minutes. Includes direct care staff costs; excludes qualification costs (p. 149)
Practice nurse, surgery	Visit	11	3	Cost per consultation based on per-hour face-to-face × duration of contact. Excludes qualification costs (p. 146)
Practice nurse, telephone call	Call	9	3	Assume ratio of time spent on telephone consultation compared with face-to-face consultation is same as for GP (83.07%). On this basis, a face-to-face nurse consultation of 15.5 minutes at £11.10 translates to a 12.88-minute telephone consultation at £9.22 – (pp. 146 and 149)
Repeat prescription request (without nurse/doctor contact)	Request	13	3	Assume 5 minutes of GP time, i.e. 5 × £2.56 per surgery/clinic minute. Includes direct care staff costs; excludes qualification costs (p. 149)
Physiotherapist home	Visit	56	3, 4	Excludes qualification costs (p. 133). Based on the length of contact (60 minutes) and travel time and cost from PSSRU 2010 (p. 151) as none available in 2011 (£31 per hour for 60 minutes)
Physiotherapist surgery	Visit	26	3, 4	Excludes qualification costs (p. 133). Based on the length of contact (30 minutes) from PSSRU 2010 (p. 151) as none available in 2011 (£31 per hour for 30 minutes)
Physiotherapist visit elsewhere (not private)	Visit	38	2	Costed as 'hospital outpatient visit'
Occupational therapist, home	Visit	56	3, 4	Excludes qualification costs (p. 132). Based on the length of contact (60 minutes) and travel time and cost from PSSRU 2010 (p. 152) as none available in 2011 (£31 per hour for 60 minutes)
Occupational therapist, surgery	Visit	26	3	Excludes qualification costs (p. 132). Based on the length of contact (30 minutes) from PSSRU 2010 (p. 152) as none available in 2011 (£31 per hour for 30 minutes)
Occupational therapist visit elsewhere (not private)	Visit	56	2	Costed as 'hospital outpatient visit'
Speech and language therapist, home	Visit	56	3, 4	Excludes qualification costs (p. 135). Based on the length of contact (60 minutes) and travel time and cost from PSSRU 2010 (p. 153) as none available in 2011 (£31 per hour for 60 minutes)
Speech and language therapist, surgery	Visit	26	3, 4	Excludes qualification costs (p. 135). Based on the length of contact (30 minutes) from PSSRU 2010 (p. 153) as none available in 2011 (£31 per hour for 30 minutes)
Speech and language therapist visit elsewhere (not private)	Visit	98	2	Costed as 'hospital outpatient visit'

continued

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Community or district nurse	Visit	34	3, 4	Excludes qualification costs (p. 141). Based on the length of contact (20 minutes) and travel time and cost from PSSRU 2010 (p. 159) as none available in 2011 (£44 per hour for 20 minutes)
Health visitor	Visit	23	3, 4	Excludes qualification costs (p. 143). Based on the length of contact (20 minutes) and travel cost from PSSRU 2010 (p. 161) as none available in 2011 (£64 per hour of home visiting for 20 minutes)
Geriatrician	Contact	46	3	Assume 20-minute contact with medical consultant (£137 per contract-hour). Excludes qualification costs (p. 203)
Psychiatrist	Contact	131	2	Index tab: Mental Health Consultant Services (Community Setting) – Follow Up Contact Face to Face – TMHCSCFUAF
Psychologist	Contact	135	3	Assume 1-hour contact (£135 per hour of client contact) (p. 137)
Chiropodist	Visit	11	3, 4	£22 per hour (p. 136). Based on half-hour clinic visit stated in PSSRU 2010 as no information in 2011 version
Chiropractor	Contact	28	9	Assume mid-point cost per session from range of £20–35 per 30-minute appointment
Osteopath	Contact	43	8	Assume mid-point cost per session from range of £35–50 per 30- to 40-minute contact
Dentist	Activity	78	2	Tab TOCS: Community Dental Services – CN20
Optician	Eye test	20	7	Eye test rate (£20) at Boots Opticians (as at 15 November 2011)
Day hospital	Half-day	75	2	Tab TDCFRAD: half the cost of day-care facilities for elderly patients (DCF20)
Social club	Session	36	3	Local authority day care for older people (p. 28)
Lunch club	Visit	12	4	Voluntary day care for older people. Meals cost £1.90 per client-day and other running costs amount to £38.90 per client-day. Assumes £1.90 per meal and one-quarter of other running costs (p. 55). 2009/10 costs uprated using PSS pay and prices inflation rate
Drop-in centre	Session	36	4	Local authority day care for older people (p. 28)
Meals on wheels	Meal	6	3	Weekly cost of £43, assume one meal per day (p. 103)
Frozen meals	Meal	3	3	Assume half the cost of meals on wheels

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Home care worker	Hour	24	3	Local authority home-care worker per hour of face-to-face contact, weighted average accounting for different rates for day/evening/weekday/weekends (p. 160)
Social worker	Hour	152	3	Per hour of face-to-face contact. Excludes qualification costs (p. 156)
Social worker, telephone call	Call	13	3	Assume 15 minutes of social worker time based on £53 per hour of client-related work. Excludes qualification costs (p. 156)
Social services day-care centre	Visit	12	3	Local authority day care for older people (p. 28). Session cost £36. Assumed session lasts 3 hours to derive hourly cost of £12
Intermediate care team	Contact	15	3	Based on a scheme for people having difficulty managing at home or who have been recently discharged from hospital or who are considering entry to a residential care home (p. 31). Weekly cost £427. Assumed quarter day contact
Value of time				
National average wage (opportunity cost)	Hour	15	5	Table 1.5a: hourly gross pay for all employees, UK, 2010. Mean, not affected by absence=£14.60
Leisure time cost (opportunity cost)	Hour	5	6	Table 2: £4.80 per hour of non-working time per person (resource cost, non-commuting reasons); 2010 rate inflated to 2011 rate using PSS pay and prices inflation rate
Other services				
NHS Direct	Call	16	10	
SCC				
NHS Agenda for Change band 1	Hourly cost/ travel cost	19/9	11	Assuming:
NHS Agenda for Change band 2	Hourly cost/ travel cost	20/10	11	(a) 25.44% employer contribution to National Insurance and superannuation for NHS band 7 staff as per the unit cost for a nurse team manager (4). Includes travel/transport cost
NHS Agenda for Change band 3	Hourly cost/ travel cost	23/11	11	(b) 65.46% indirect and capital overheads for NHS band 7 staff as per the unit cost for a nurse team manager (2). Includes travel/transport cost
NHS Agenda for Change band 4	Hourly cost/ travel cost	27/13	11	(c) 41.3 weeks per annum (taking off 27 days annual leave, eight bank holidays, five study/training days and 12 sickness days) and a 37.5-hour working week as per the unit cost for a nurse team manager (4)
NHS Agenda for Change band 5	Hourly cost/ travel cost	32/16	11	(d) 30 minutes' travel time for non-clinic contacts. Travel costs are included in staff overheads
NHS Agenda for Change band 6	Hourly cost/ travel cost	39/20	11	
NHS Agenda for Change band 7	Hourly cost/ travel cost	47/24	11	
NHS Agenda for Change BAND 8	Hourly cost/ travel cost	78/39	11	

continued

Item	Unit	Unit cost (£, 2010/11 prices)	Source ^a	Notes
Stroke MDT meetings	Hour	284	4	Assuming that the team consists of one each of a medical consultant, band 7 nurse, physiotherapist, occupational therapist and speech and language therapist. Based on unit costs for hospital-based staff, excluding qualification costs

AIDS, acquired immunodeficiency syndrome; CMDT-B, breast cancer multidisciplinary team meetings; CMDT-C, colorectal cancer multidisciplinary team meetings; CMDT-LG, Local gynaecological cancer multidisciplinary team meetings; CMDT-SpG, specialist gynaecological cancer multidisciplinary team meetings; CMDT-SpU, specialist upper gastrointestinal cancer multidisciplinary team meetings; DAPF, direct access plain film; FPC, sexual and reproductive health clinic attendances; H/A, HIV/AIDS; HIV, human immunodeficiency virus; OPATT, Outpatient Attendances; PSS, Personal Social Services; PSSRU, Personal Social Services Research Unit; TDADS, Direct Access: Diagnostic Services; TDAPS, Direct Access: Pathology Services; TDC, Day Cases HRG Data; TDCFRAD, Day Care Facilities: Regular Attendances; TDIAGIM_OP, Diagnostic Imaging: Outpatient; TMHCSCFUAF, Mental Health Consultant Services (Community Setting) – Follow Up Contact Face to Face; TMHC SOPFAF, Mental Health Consultant Services (Outpatient Setting) – First Attendance Face to Face; TMHC SOPFANF, Mental Health Consultant Services (Outpatient Setting) – First Attendance Non-Face to Face; TMHC SOPFUAF, Mental Health Consultant Services (Outpatient Setting) – Follow-up Attendance Face to Face; TMHC SOPFUANF, Mental Health Consultant Services (Outpatient Setting) – Follow-up Attendance Non-Face to Face; TMHC SOPSSFAF, Mental Health Consultant Services (Outpatient Setting) – Specialist Services First Attendance Face to Face; TMHC SOPSSFANF, Mental Health Consultant Services (Outpatient Setting) – Specialist Services First Attendance Non-Face to Face; TMHC SOPSSFUAF, Mental Health Consultant Services (Outpatient Setting) – Specialist Services Follow-up Attendance Face to Face; TMHC SOPSSFUANF, Mental Health Consultant Services (Outpatient Setting) – Specialist Services Follow-up Attendance Non-Face to Face; TNEI_L, Non-Elective Inpatient (Long Stay); TOCS, Other Community Services; TOPROC, Outpatient Procedures; TPARB, Paramedic Services: Category B/Amber; TPTS_OP, Patient Transport Services: Outpatient; TREHAB_CSRS_LEVEL_1_BEDDAY_APC, 'Complex Specialised' Rehabilitation Services; UGI, upper gastrointestinal.

- a (1) Health and Social Care Information Centre. *Personal Social Services: Expenditure and Unit Costs, England, 2010–11*. URL: www.ic.nhs.uk/webfiles/publications/009_Social_Care/pssexpcosts1011/Final_Report_PSSEX1_201011.pdf (accessed 29 August 2012). (2) Department of Health. *NHS Trust Reference Cost Schedules* (Appendix NSRC1). URL: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131140 (accessed 28 August 2012). (3) Curtis L. *Unit Costs of Health and Social Care 2011*. Canterbury: PSSRU, University of Kent; 2011. URL: www.pssru.ac.uk/archive/pdf/uc/uc2011/uc2011.pdf (accessed 30 August 2012). (4) Curtis L. *Unit Costs of Health and Social Care 2010*. Canterbury: PSSRU, University of Kent; 2010. URL: www.pssru.ac.uk/project-pages/unit-costs/2010/index.php (accessed 30 August 2012). (5) Office for National Statistics. *Annual Survey of Hours and Earnings, 2010 Revised*. URL: www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-238620 (accessed 23 November 2011). (6) Department for Transport. *TAG Unit 3.5.6: Values of Time and Operating Costs*. URL: www.dft.gov.uk/webtag/documents/expert/unit3.5.6.php#01 (accessed 22 November 2012). (7) Boots website. URL: www.boots.com/en/GBP10-eye-test_1240962/ (accessed 15 November 2011). (8) NHS Choices. *Osteopathy*. URL: www.nhs.uk/conditions/Osteopathy/Pages/Introduction.aspx (accessed 15 November 2011). (9) NHS Choices. *Chiropractor*. URL: www.nhs.uk/Conditions/chiropractic/Pages/Introduction.aspx (accessed 15 November 2011). (10) NHS Direct, 2010. 2009–10 prices inflated to 2010–11 prices. URL: www.nhsdirect.nhs.uk/about/~media/files/boardpapers/november2010/board%20scorecard%20-%20header%20sheet.ashx (accessed 10 June 2011). (11) NHS Employers. *Pay Circular (AforC) 2/2010. Changes to NHS Terms and Conditions of Service Handbook (Amendment 17): Pay and Conditions for NHS Staff Covered by the Agenda for Change Agreement*. 22 February 2010. URL: www.nhsemployers.org/Aboutus/Publications/PayCirculars/Pages/PayCircularAforC22010.aspx (accessed 11 December 2012).

Appendix 8 Project 2: additional results

Pre-recruitment screening data

Data are from 26 (out of 32) randomised services and were collected before the recruitment of participants in these services.

TABLE 65 Pre-recruitment screening data summaries by treatment arm (age, gender and ethnicity)

Demographic characteristics	Control (N=730)	Intervention (N=427)	Total (N=1157)
Age (years)			
Mean (SD)	73.6 (12.58)	72.9 (12.72)	73.4 (12.64)
Median (range)	76.0 (29.0–101.0)	75.0 (32.0–100.0)	75.0 (29.0–101.0)
Missing	13	3	16
Gender, n (%)			
Male	372 (51.0)	220 (51.5)	592 (51.2)
Ethnicity, n (%)			
White	681 (93.3)	411 (96.3)	1092 (94.4)

TABLE 66 Pre-recruitment screening data summaries by treatment arm (modified Rankin Scale)

Modified Rankin Scale score	Control (N=730), n (%)	Intervention (N=427), n (%)	Total (N=1157), n (%)
0	59 (8.1)	15 (3.5)	74 (6.4)
1	114 (15.6)	70 (16.4)	184 (15.9)
2	138 (18.9)	91 (21.3)	229 (19.8)
3	169 (23.2)	132 (30.9)	301 (26.0)
4	114 (15.6)	73 (17.1)	187 (16.2)
5	38 (5.2)	42 (9.8)	80 (6.9)
Missing	98 (13.4)	4 (0.9)	102 (8.8)

Screening data: non-registered patients by service and treatment arm

TABLE 67 Screening data: reasons not assessed

Site	Out of screened, n (%)		Reasons not assessed – out of not assessed, n (%)					
	Assessed	Not Assessed	Missed by clinical research team	Patient died	SCC referral withdrawn because of sudden acute illness	Transferred to another health-care setting	LoTS care trial closed to recruitment	Missing
Control sites								
1	78 (91.8)	7 (8.2)	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
3	176 (90.7)	18 (9.3)	1 (5.6)	17 (94.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
4	85 (96.6)	3 (3.4)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
8	49 (98.0)	1 (2.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
10	62 (82.7)	13 (17.3)	12 (92.3)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
11	59 (100.0)	0 (0.0)						
14	127 (80.4)	31 (19.6)	23 (74.2)	5 (16.1)	1 (3.2)	2 (6.5)	0 (0.0)	0 (0.0)
15	149 (89.8)	17 (10.2)	16 (94.1)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)
18	39 (100.0)	0 (0.0)						
19	86 (97.7)	2 (2.3)	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
22	57 (76.0)	18 (24.0)	13 (72.2)	2 (11.1)	3 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)
25	22 (100.0)	0 (0.0)						
29	99 (79.2)	26 (20.8)	24 (92.3)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)
32	93 (75.6)	30 (24.4)	28 (93.3)	2 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	1181 (87.7)	166 (12.3)	129 (77.7)	28 (16.9)	6 (3.6)	2 (1.2)	0 (0.0)	1 (0.6)
Intervention sites								
2	67 (89.3)	8 (10.7)	8 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
5	76 (82.6)	16 (17.4)	16 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
6	47 (85.5)	8 (14.5)	6 (75.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
7	96 (99.0)	1 (1.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
9	53 (82.8)	11 (17.2)	11 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
12	88 (94.6)	5 (5.4)	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
13	88 (95.7)	4 (4.3)	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
16	59 (88.1)	8 (11.9)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (50.0)	0 (0.0)
20	3 (100.0)	0 (0.0)						
23	24 (80.0)	6 (20.0)	0 (0.0)	0 (0.0)	1 (16.7)	4 (66.7)	1 (16.7)	0 (0.0)
24	46 (62.2)	28 (37.8)	27 (96.4)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	171 (93.4)	12 (6.6)	8 (66.7)	4 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
27	35 (94.6)	2 (5.4)	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)
30	61 (100.0)	0 (0.0)						
31	97 (82.2)	21 (17.8)	16 (76.2)	0 (0.0)	0 (0.0)	4 (19.0)	0 (0.0)	1 (4.8)
Total	1011 (88.6)	130 (11.4)	105 (80.8)	9 (6.9)	2 (1.5)	8 (6.2)	5 (3.8)	1 (0.8)

TABLE 68 Screening data: reasons not eligible

Site	Eligible	Not eligible	Reasons not eligible – out of not eligible, n (%)										Reason not known	Other	Missing	
			No primary diagnosis of stroke	Not referred to a SCC on discharge or within 6 weeks of stroke	Had first home or outpatient SCC assessment	Unlikely to survive > 3 months	Nursing or residential care	Previously registered into the LoTS care trial	In another study overlapping with the LoTS care trial	Discharged out of SCC area						
Control sites																
1	40 (51.3)	38 (48.7)	2 (5.3)	3 (7.9)	0 (0.0)	7 (18.4)	13 (34.2)	0 (0.0)	0 (0.0)	0 (0.0)	13 (34.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
3	98 (55.7)	78 (44.3)	2 (2.6)	1 (1.3)	0 (0.0)	19 (24.4)	30 (38.5)	0 (0.0)	0 (0.0)	25 (32.1)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
4	54 (63.5)	31 (36.5)	16 (51.6)	0 (0.0)	3 (9.7)	2 (6.5)	6 (19.4)	0 (0.0)	0 (0.0)	0 (0.0)	3 (9.7)	1 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	
8	45 (91.8)	4 (8.2)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
10	30 (48.4)	32 (51.6)	3 (9.4)	0 (0.0)	0 (0.0)	2 (6.3)	25 (78.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
11	57 (96.6)	2 (3.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
14	96 (75.6)	31 (24.4)	12 (38.7)	0 (0.0)	0 (0.0)	7 (22.6)	1 (3.2)	1 (3.2)	0 (0.0)	0 (0.0)	8 (25.8)	3 (9.7)	0 (0.0)	0 (0.0)	0 (0.0)	
15	86 (57.7)	63 (42.3)	20 (31.7)	1 (1.6)	0 (0.0)	10 (15.9)	19 (30.2)	0 (0.0)	0 (0.0)	2 (3.2)	11 (17.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
18	39 (100.0)	0 (0.0)														
19	61 (70.9)	25 (29.1)	5 (20.0)	1 (4.0)	1 (4.0)	2 (8.0)	15 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	
22	42 (73.7)	15 (26.3)	2 (13.3)	0 (0.0)	1 (6.7)	1 (6.7)	7 (46.7)	0 (0.0)	0 (0.0)	2 (13.3)	1 (6.7)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	
25	22 (100.0)	0 (0.0)														
29	54 (54.5)	45 (45.5)	3 (6.7)	4 (8.9)	0 (0.0)	3 (6.7)	24 (53.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (22.2)	0 (0.0)	0 (0.0)	1 (2.2)	
32	35 (37.6)	58 (62.4)	3 (5.2)	2 (3.4)	0 (0.0)	0 (0.0)	27 (46.6)	0 (0.0)	0 (0.0)	0 (0.0)	26 (44.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Total	759 (64.3)	422 (35.7)	69 (16.4)	12 (2.8)	5 (1.2)	54 (12.8)	171 (40.5)	0 (0.0)	0 (0.0)	29 (6.9)	65 (15.4)	16 (3.8)	0 (0.0)	0 (0.0)	1 (0.2)	

continued

TABLE 68 Screening data: reasons not eligible (*continued*)

Site	Out of assessed, n (%)		Reasons not eligible – out of not eligible, n (%)										
	Eligible	Not eligible	No primary diagnosis of stroke	Not referred to a SCC on discharge or within 6 weeks of stroke	Had first home or outpatient SCC assessment	Unlikely to survive >3 months	Nursing or residential care	Previously registered into the LoTS care trial	In another study overlapping with the LoTS care trial	Discharged out of SCC area	Reason not known	Other	Missing
Intervention sites													
2	38 (56.7)	29 (43.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (10.3)	21 (72.4)	0 (0.0)	0 (0.0)	2 (6.9)	3 (10.3)	0 (0.0)	0 (0.0)
5	43 (56.6)	33 (43.4)	5 (15.2)	0 (0.0)	0 (0.0)	6 (18.2)	22 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
6	37 (78.7)	10 (21.3)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (40.0)	0 (0.0)	1 (10.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)
7	55 (57.3)	41 (42.7)	23 (56.1)	1 (2.4)	5 (12.2)	4 (9.8)	8 (19.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
9	33 (62.3)	20 (37.7)	8 (40.0)	0 (0.0)	0 (0.0)	2 (10.0)	10 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
12	72 (81.8)	16 (18.2)	2 (12.5)	0 (0.0)	0 (0.0)	2 (12.5)	11 (68.8)	0 (0.0)	0 (0.0)	1 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)
13	57 (64.8)	31 (35.2)	5 (16.1)	0 (0.0)	0 (0.0)	3 (9.7)	9 (29.0)	0 (0.0)	0 (0.0)	1 (3.2)	13 (41.9)	0 (0.0)	0 (0.0)
16	47 (79.7)	12 (20.3)	1 (8.3)	0 (0.0)	0 (0.0)	2 (16.7)	5 (41.7)	0 (0.0)	0 (0.0)	3 (25.0)	1 (8.3)	0 (0.0)	0 (0.0)
20	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
23	23 (95.8)	1 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
24	44 (95.7)	2 (4.3)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	71 (41.5)	100 (58.5)	37 (37.0)	1 (1.0)	0 (0.0)	20 (20.0)	37 (37.0)	1 (1.0)	0 (0.0)	3 (3.0)	0 (0.0)	1 (1.0)	0 (0.0)
27	33 (94.3)	2 (5.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)
30	46 (75.4)	15 (24.6)	2 (13.3)	0 (0.0)	0 (0.0)	2 (13.3)	8 (53.3)	0 (0.0)	0 (0.0)	3 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)
31	60 (61.9)	37 (38.1)	3 (8.1)	0 (0.0)	0 (0.0)	2 (5.4)	21 (56.8)	0 (0.0)	2 (5.4)	9 (24.3)	0 (0.0)	0 (0.0)	0 (0.0)
Total	661 (65.4)	350 (34.6)	88 (25.1)	2 (0.6)	5 (1.4)	46 (13.1)	159 (45.4)	1 (0.3)	3 (0.9)	27 (7.7)	18 (5.1)	1 (0.3)	0 (0.0)

TABLE 69 Screening data: reasons not consented

Site	Out of eligible, n (%)		Reasons not consented – out of not consented, n (%)									
	Consented	Not consented	Patient refused	Patient declaration refused	Patient died	Patient does not have the capacity to provide consent and no consultee	Patient not approached/ deemed unsuitable for this study	Does not speak English	Missed by clinical research team	Unable to complete follow-up questionnaires	Other	Missing
Control sites												
1	17 (42.5)	23 (57.5)	10 (43.5)	5 (21.7)	0 (0.0)	6 (26.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (8.7)
3	19 (19.4)	79 (80.6)	50 (63.3)	5 (6.3)	0 (0.0)	11 (13.9)	6 (7.6)	3 (3.8)	0 (0.0)	4 (5.1)	0 (0.0)	0 (0.0)
4	32 (59.3)	22 (40.7)	16 (72.7)	1 (4.5)	0 (0.0)	4 (18.2)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
8	28 (62.2)	17 (37.8)	10 (58.8)	1 (5.9)	0 (0.0)	6 (35.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
10	18 (60.0)	12 (40.0)	6 (50.0)	0 (0.0)	3 (25.0)	3 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
11	46 (80.7)	11 (19.3)	6 (54.5)	1 (9.1)	0 (0.0)	4 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
14	32 (33.3)	64 (66.7)	42 (65.6)	2 (3.1)	0 (0.0)	8 (12.5)	2 (3.1)	1 (1.6)	6 (9.4)	1 (1.6)	2 (3.1)	0 (0.0)
15	50 (58.1)	36 (41.9)	30 (83.3)	1 (2.8)	0 (0.0)	2 (5.6)	0 (0.0)	1 (2.8)	0 (0.0)	2 (5.6)	0 (0.0)	0 (0.0)
18	36 (92.3)	3 (7.7)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
19	46 (75.4)	15 (24.6)	12 (80.0)	0 (0.0)	0 (0.0)	3 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
22	23 (54.8)	19 (45.2)	7 (36.8)	4 (21.1)	0 (0.0)	6 (31.6)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
25	20 (90.9)	2 (9.1)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
29	42 (77.8)	12 (22.2)	7 (58.3)	3 (25.0)	0 (0.0)	2 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
32	17 (48.6)	18 (51.4)	15 (83.3)	0 (0.0)	0 (0.0)	3 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	426 (56.1)	333 (43.9)	216 (64.9)	23 (6.9)	3 (0.9)	58 (17.4)	10 (3.0)	6 (1.8)	6 (1.8)	7 (2.1)	2 (0.6)	2 (0.6)

continued

TABLE 69 Screening data: reasons not consented (continued)

Site	Out of eligible, n (%)		Reasons not consented – out of not consented, n (%)									
	Consented	Not consented	Patient refused	Consulantee declaration refused	Patient died	Patient does not have the capacity to provide consent and no consultee	Patient not approached/ deemed unsuitable for this study	Does not speak English	Missed by clinical research team	Unable to complete follow-up questionnaires	Other	Missing
Intervention sites												
2	28 (73.7)	10 (26.3)	9 (90.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
5	19 (44.2)	24 (55.8)	12 (50.0)	0 (0.0)	4 (16.7)	8 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
6	31 (83.8)	6 (16.2)	2 (33.3)	2 (33.3)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
7	34 (61.8)	21 (38.2)	12 (57.1)	1 (4.8)	0 (0.0)	7 (33.3)	0 (0.0)	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
9	17 (51.5)	16 (48.5)	11 (68.8)	0 (0.0)	0 (0.0)	5 (31.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
12	45 (62.5)	27 (37.5)	23 (85.2)	2 (7.4)	0 (0.0)	2 (7.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
13	46 (80.7)	11 (19.3)	10 (90.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
16	27 (57.4)	20 (42.6)	12 (60.0)	4 (20.0)	2 (10.0)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)
20	2 (100.0)	0 (0.0)										
23	14 (60.9)	9 (39.1)	5 (55.6)	0 (0.0)	0 (0.0)	2 (22.2)	0 (0.0)	0 (0.0)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)
24	27 (61.4)	17 (38.6)	14 (82.4)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	2 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	45 (63.4)	26 (36.6)	11 (42.3)	0 (0.0)	0 (0.0)	3 (11.5)	6 (23.1)	0 (0.0)	3 (11.5)	2 (7.7)	0 (0.0)	1 (3.8)
27	27 (81.8)	6 (18.2)	5 (83.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)
30	33 (71.7)	13 (28.3)	8 (61.5)	0 (0.0)	4 (30.8)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
31	18 (30.0)	42 (70.0)	9 (21.4)	2 (4.8)	0 (0.0)	13 (31.0)	8 (19.0)	0 (0.0)	9 (21.4)	1 (2.4)	0 (0.0)	0 (0.0)
Total	413 (62.5)	248 (37.5)	143 (57.7)	12 (4.8)	10 (4.0)	45 (18.1)	14 (5.6)	3 (1.2)	14 (5.6)	4 (1.6)	2 (0.8)	1 (0.4)

TABLE 70 Screening data: reasons not registered

Site	Out of consented, <i>n</i> (%)		Reasons not registered – out of not registered, <i>n</i> (%)			
	Registered	Not registered	Baseline forms not completed/retrieved	Patient died	No longer eligible	Missing
Control sites						
1	15 (88.2)	2 (11.8)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)
3	18 (94.7)	1 (5.3)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
4	32 (100.0)	0 (0.0)				
8	25 (89.3)	3 (10.7)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
10	17 (94.4)	1 (5.6)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
11	45 (97.8)	1 (2.2)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
14	29 (90.6)	3 (9.4)	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)
15	4 (92.0)	4 (8.0)	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
18	35 (97.2)	1 (2.8)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)
19	45 (97.8)	1 (2.2)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
22	19 (82.6)	4 (17.4)	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
25	18 (90.0)	2 (10.0)	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)
29	41 (97.6)	1 (2.4)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)
32	14 (82.4)	3 (17.6)	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)
Total	399 (93.7)	27 (6.3)	19 (70.4)	1 (3.7)	6 (22.2)	1 (3.7)
Intervention sites						
2	27 (96.4)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
5	19 (100.0)	0 (0.0)				
6	30 (96.8)	1 (3.2)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
7	31 (91.2)	3 (8.8)	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)
9	17 (100.0)	0 (0.0)				
12	45 (100.0)	0 (0.0)				
13	45 (97.8)	1 (2.2)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
16	27 (100.0)	0 (0.0)				
20	2 (100.0)	0 (0.0)				
23	13 (92.9)	1 (7.1)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
24	27 (100.0)	0 (0.0)				
26	45 (100.0)	0 (0.0)				
27	26 (96.3)	1 (3.7)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
30	29 (87.9)	4 (12.1)	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)
31	18 (100.0)	0 (0.0)				
Total	401 (97.1)	12 (2.9)	7 (58.3)	0 (0.0)	4 (33.3)	1 (8.3)

Patients with carers: baseline characteristics

TABLE 71 Patients with carers: baseline demographics

Demographic characteristics	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Patient age (years)			
Mean (SD)	72.8 (11.51)	72.5 (12.06)	72.6 (11.77)
Median (range)	73.1 (38.3–98.8)	75.1 (28.3–95.7)	74.5 (28.3–98.8)
Missing	0	0	0
Ethnicity			
White	97 (97.0)	103 (95.4)	200 (96.2)
Mixed – white and black Caribbean	0 (0.0)	1 (0.9)	1 (0.5)
Asian – Indian	0 (0.0)	1 (0.9)	1 (0.5)
Asian – Pakistani	1 (1.0)	0 (0.0)	1 (0.5)
Asian – Bangladeshi	0 (0.0)	1 (0.9)	1 (0.5)
Other Asian background	1 (1.0)	0 (0.0)	1 (0.5)
Black – Caribbean	0 (0.0)	1 (0.9)	1 (0.5)
Other black background	1 (1.0)	0 (0.0)	1 (0.5)
Other ethnic group	0 (0.0)	1 (0.9)	1 (0.5)
Gender			
Male	58 (58.0)	58 (53.7)	116 (55.8)
Female	42 (42.0)	50 (46.3)	92 (44.2)

TABLE 72 Patients with carers: baseline education and employment

Education/employment	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Has the patient had any formal education?			
Yes	97 (97.0)	99 (91.7)	196 (94.2)
No	2 (2.0)	9 (8.3)	11 (5.3)
Missing	1 (1.0)	0 (0.0)	1 (0.5)
If yes, at what age did the patient leave education?			
≤16 years	75 (77.3)	83 (83.8)	158 (80.6)
17–20 years	20 (20.6)	11 (11.1)	31 (15.8)
≥21 years	1 (1.0)	4 (4.0)	5 (2.6)
Unknown	1 (1.0)	1 (1.0)	2 (1.0)
If yes, has the patient received more education since leaving school?			
Yes	26 (26.8)	38 (38.4)	64 (32.7)
No	64 (66.0)	60 (60.6)	124 (63.3)
Missing	7 (7.2)	1 (1.0)	8 (4.1)
Main employment before stroke			
Working full time (≥30 hours per week)	14 (14.0)	12 (11.1)	26 (12.5)
Working part time (<30 hours per week)	3 (3.0)	3 (2.8)	6 (2.9)
At home and not looking for work (e.g. looking after home/family)	6 (6.0)	3 (2.8)	9 (4.3)
Unemployed and looking for work	2 (2.0)	1 (0.9)	3 (1.4)
Retired	72 (72.0)	84 (77.8)	156 (75.0)
Made redundant/took early retirement	1 (1.0)	0 (0.0)	1 (0.5)
Unable to work (for medical and/or other reasons)	2 (2.0)	5 (4.6)	7 (3.4)

TABLE 73 Patients with carers: baseline characteristics of current stroke

Stroke characteristics	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Source of referral to the SCC			
Before hospital discharge (including community hospital)	94 (94.0)	100 (92.6)	194 (93.3)
After discharge from hospital (including community hospital)	6 (6.0)	7 (6.5)	13 (6.3)
Missing	0 (0.0)	1 (0.9)	1 (0.5)
Pathological classification of current stroke			
Cerebral infarction	81 (81.0)	95 (88.0)	176 (84.6)
Primary intracerebral haemorrhage	12 (12.0)	12 (11.1)	24 (11.5)
Other	7 (7.0)	1 (0.9)	8 (3.8)
Clinical classification of stroke symptoms			
Left hemiparesis	47 (47.0)	41 (38.0)	88 (42.3)
Right hemiparesis	42 (42.0)	51 (47.2)	93 (44.7)
Brain stem	4 (4.0)	4 (3.7)	8 (3.8)
Other	7 (7.0)	12 (11.1)	19 (9.1)
Has the patient had a previous stroke?			
Yes	17 (17.0)	28 (25.9)	45 (21.6)
No	81 (81.0)	80 (74.1)	161 (77.4)
Missing	2 (2.0)	0 (0.0)	2 (1.0)

TABLE 74 Patients with carers: baseline patient current ability

Ability after stroke	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Can the patient talk and are they orientated?			
Yes	92 (92.0)	93 (86.1)	185 (88.9)
No	8 (8.0)	14 (13.0)	22 (10.6)
Missing	0 (0.0)	1 (0.9)	1 (0.5)
Can the patient lift both arms of the bed?			
Yes	74 (74.0)	80 (74.1)	154 (74.0)
No	26 (26.0)	28 (25.9)	54 (26.0)
Can the patient walk without help from others?			
Yes	56 (56.0)	50 (46.3)	106 (51.0)
No	44 (44.0)	58 (53.7)	102 (49.0)
Is patient's language ability normal?			
Yes	76 (76.0)	72 (66.7)	148 (71.2)
No	24 (24.0)	36 (33.3)	60 (28.8)
If not, does the patient have dysphasia?			
Yes	18 (75.0)	31 (86.1)	49 (81.7)
No	6 (25.0)	5 (13.9)	11 (18.3)
If the patient has dysphasia, what type of dysphasia?			
Receptive	2 (11.1)	0 (0.0)	2 (4.1)
Expressive	11 (61.1)	23 (74.2)	34 (69.4)
Global	3 (16.7)	1 (3.2)	4 (8.2)
Missing	2 (11.1)	7 (22.6)	9 (18.4)
If not, does the patient have dysarthria?			
Yes	8 (33.3)	7 (19.4)	15 (25.0)
No	16 (66.7)	29 (80.6)	45 (75.0)
Was the patient able to answer the 6CIT?			
Yes	85 (85.0)	81 (75.0)	166 (79.8)
No	15 (15.0)	27 (25.0)	42 (20.2)
If not, why not?			
Stroke-related communication problems	12 (80.0)	22 (81.5)	34 (81.0)
Other	3 (20.0)	5 (18.5)	8 (19.0)

TABLE 75 Patients with carers: baseline length of inpatient stay

Inpatient stay	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Overall time from admission to discharge for patients with a hospital stay related to this stroke incident (days)			
Mean (SD)	42.2 (42.0)	51.6 (49.8)	47.1 (46.3)
Median (range)	29 (2–181)	37 (1–220)	33 (1–220)
Missing	0	0	0

Follow-up

Categories in these tables are mutually exclusive and their content contains information that explains the CONSORT diagram in more detail.

TABLE 76 Patient follow-up at 6 months

Questionnaire completion	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Primary end point questionnaires			
Questionnaire completed	294 (73.7)	308 (76.8)	602 (75.3)
Completed primary outcome call	6 (1.5)	2 (0.5)	8 (1.0)
Patient died	23 (5.8)	30 (7.5)	53 (6.6)
Patient withdrew	18 (4.5)	4 (1.0)	22 (2.8)
Questionnaire returned after cut-off point	5 (1.3)	8 (2.0)	13 (1.6)
Questionnaire returned but too many missing items	11 (2.8)	8 (2.0)	19 (2.4)
Questionnaire not returned	42 (10.5)	41 (10.2)	83 (10.4)
Reason questionnaire not returned			
Too poorly	4 (1.0)	2 (0.5)	6 (0.8)
Could not get hold of participant	22 (5.5)	22 (5.5)	44 (5.5)
Confirmed received questionnaire and would return	6 (1.5)	6 (1.5)	12 (1.5)
No recollection of participation	0 (0.0)	2 (0.5)	2 (0.3)
Other	10 (2.5)	9 (2.2)	19 (2.4)

TABLE 77 Patient follow-up at 12 months

Questionnaire completion	Control (N=399), n (%)	Intervention (N=401), n (%)	Total (N=800), n (%)
Patient GHQ-12 questionnaire			
Questionnaire completed	265 (66.4)	280 (69.8)	545 (68.1)
Completed primary outcome call	3 (0.8)	1 (0.2)	4 (0.5)
Patient died	32 (8.0)	35 (8.7)	67 (8.4)
Patient withdrew	34 (8.5)	12 (3.0)	46 (5.8)
Questionnaire returned but too many missing items	3 (0.8)	6 (1.5)	9 (1.1)
Questionnaire not returned	62 (15.5)	67 (16.7)	129 (16.1)
Reason questionnaire not returned			
Too poorly	3 (0.8)	3 (0.7)	6 (0.8)
Could not get hold of participant	29 (7.3)	35 (8.7)	64 (8.0)
Confirmed received questionnaire and would return	9 (2.3)	10 (2.5)	19 (2.4)
No time to complete the questionnaire	0 (0.0)	1 (0.2)	1 (0.1)
No recollection of participation	0 (0.0)	1 (0.2)	1 (0.1)
Other	21 (5.3)	17 (4.2)	38 (4.8)

TABLE 78 Carer follow-up at 6 months

Questionnaire completion	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Carer GHQ-12 questionnaire			
Questionnaire completed	82 (82.0)	80 (74.1)	162 (77.9)
Patient or caregiver died	6 (6.0)	9 (8.3)	15 (7.2)
Patient or caregiver withdrew	3 (3.0)	0 (0.0)	3 (1.4)
Questionnaire not returned	9 (9.0)	19 (17.6)	28 (13.5)
Reason questionnaire not returned			
Could not get hold of participant	3 (3.0)	6 (5.6)	9 (4.3)
Confirmed received questionnaire and would return	2 (2.0)	6 (5.6)	8 (3.8)
Other	4 (4.0)	7 (6.5)	11 (5.3)

TABLE 79 Carer follow-up at 12 months

Questionnaire completion	Control (N=100), n (%)	Intervention (N=108), n (%)	Total (N=208), n (%)
Carer GHQ-12 questionnaire			
Questionnaire completed	71 (71.0)	73 (67.6)	144 (69.2)
Patient or caregiver died	11 (11.0)	11 (10.2)	22 (10.6)
Patient or caregiver withdrew	8 (8.0)	3 (2.8)	11 (5.3)
Questionnaire not returned	10 (10.0)	21 (19.4)	31 (14.9)
Reason questionnaire not returned			
Could not get hold of participant	4 (4.0)	8 (7.4)	12 (5.8)
Confirmed received questionnaire and would return	2 (2.0)	8 (7.4)	10 (4.8)
Other	4 (4.0)	5 (4.6)	9 (4.3)

Patient-reported outcomes

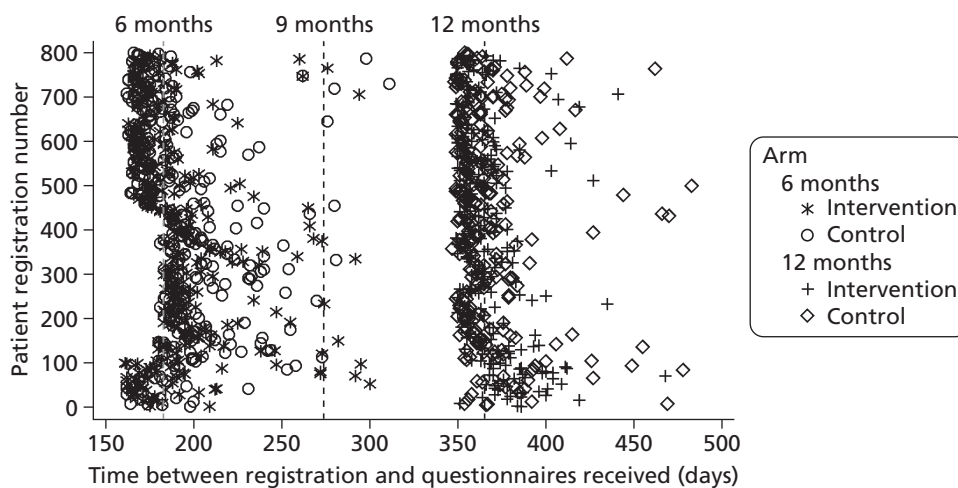


FIGURE 19 Time between registration and receiving questionnaires: patients.

Carer-reported outcomes

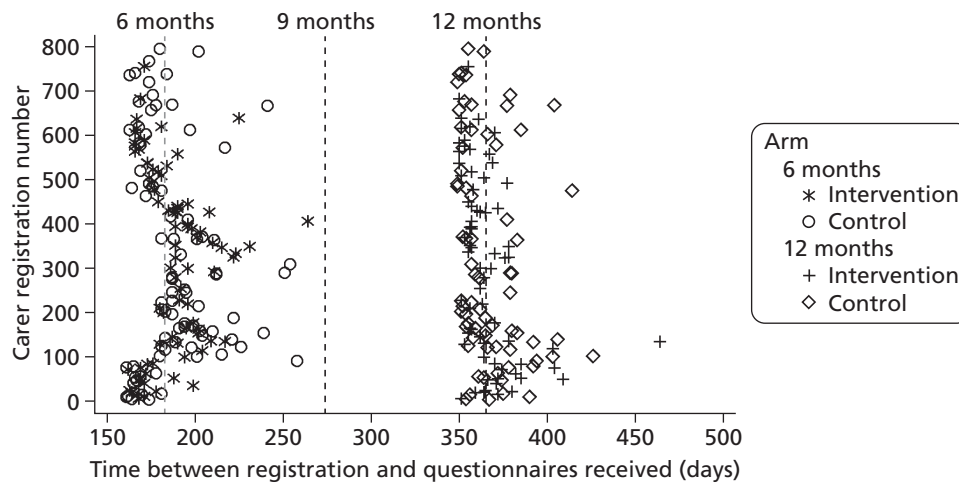


FIGURE 20 Time between registration and receiving questionnaires: carers. Carer registration number is the same as the registration number of their patient.

Withdrawals

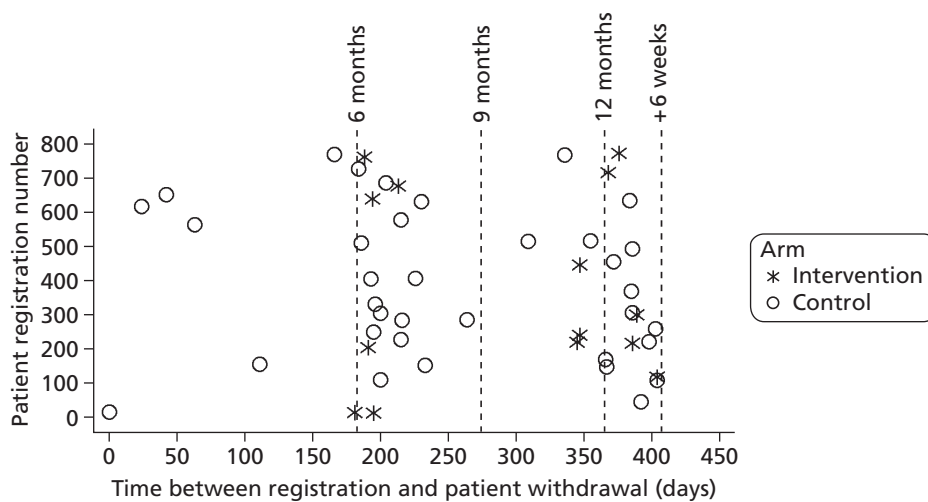


FIGURE 21 Time between registration and patient withdrawal.

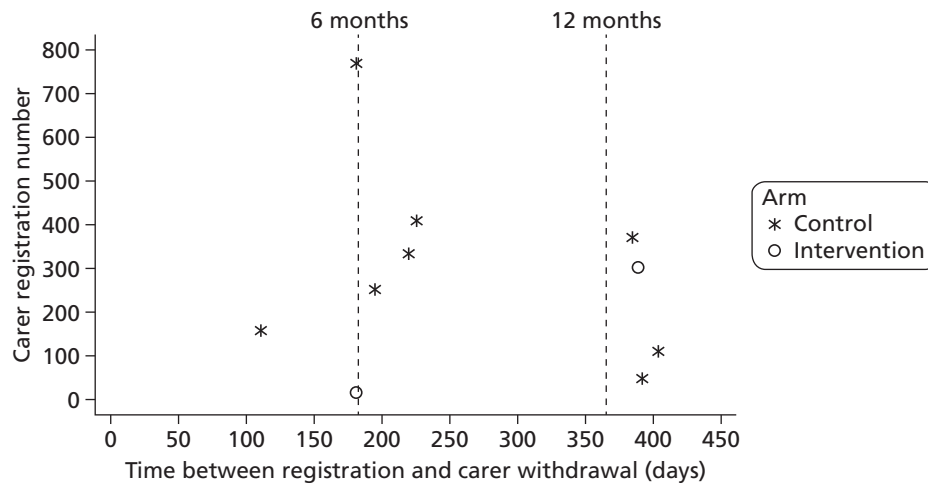


FIGURE 22 Time between registration and carer withdrawal. Carer registration number is the same as the registration number of their patient.

Appendix 9 Project 2: implementation of control and intervention services

Differences in delivery of the intervention between services

Quantitative data to describe delivery of the intervention (see *Chapter 3, Process data: implementation of control and intervention services*) were transcribed from the care plans by two researchers. During this process, informal observations were made on the way that the care plans were completed. It was observed that, in some services, care plans were clearly different from patient to patient and gave an impression of the patients' personalities, overall situations and priorities. Each patient had a unique combination of problems identified in the assessment and addressed in the goal and action planner and individualised goals and actions. This can be illustrated by the wide range of problem areas addressed in the goal and action planner (*Figure 23a*). In other services, care plans were more uniform, being difficult to distinguish from one patient to another, and it appeared that the SCC was focusing the assessment on certain areas for all patients, despite asking questions in all of the assessment areas. Patients tended to have a similar range of problems identified in the assessment and addressed in the goal and action planner and goals

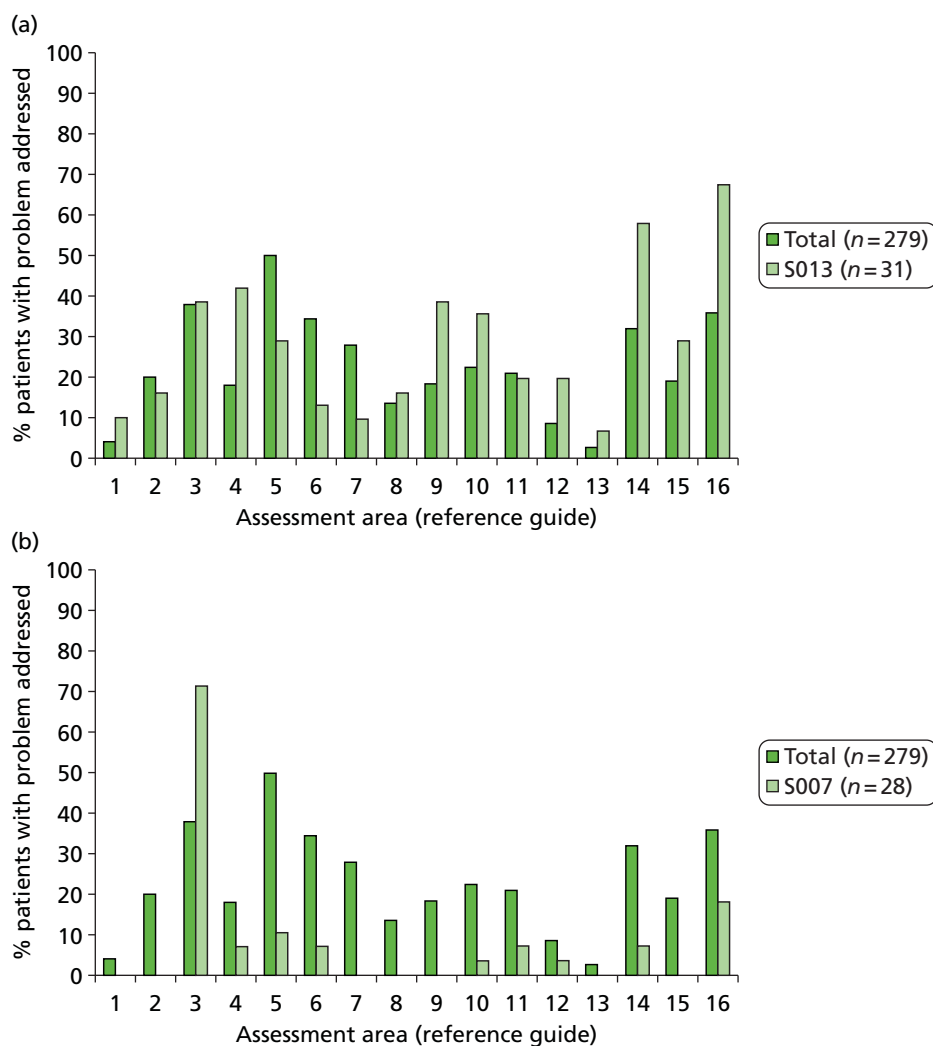


FIGURE 23 Problem areas addressed in the goal and action planner at contact one in two example services compared with all patients. (a) Example of a service (S013) addressing a wide range of problem areas; and (b) example of a service (S007) addressing a limited range of problem areas.

and actions were more standardised. This is illustrated by the problems addressed in the goal and action planner being clustered in a limited number of areas (*Figure 23b*). In this example, the majority of problems addressed relate to medicines and general health (assessment area 3), including medications, blood pressure, smoking cessation and reduction of alcohol consumption. When services focused on certain areas, these areas were general health/secondary prevention, mobility and/or personal and domestic activities of daily living. Such variations in the apparent needs of patients between services appeared to be greater than would be likely from any variations in case mix.

These observations have several possible interpretations relating to how the intervention has been delivered:

- Differences in the extent to which the assessment was patient led and holistic and based on a collaborative discussion with the patient.
- Differences in the approach to documentation. The implications of this are dependent on how and by whom the document is subsequently used in the service.
- The assessment and follow-up may be limited by boundaries of the SCC role, for example SCC responsibility may end with an onward referral to a therapist, who is then the one to set patient-centred goals.
- It is possible that problems are identified and addressed only in areas in which a service is available to meet the need, depending on existing processes and the availability of onward referrals and resources. For example, mood may be addressed only if a psychology service is available.
- Specific areas of the assessment may be focused on as a result of local priorities and commissioner requirements. Such requirements may also dictate the number of contacts that a SCC has with a patient, with some services having only one contact with the majority of patients (*Table 80*).
- The assessment is implemented by the SCC using existing knowledge, skills and experience; therefore, the areas focused on may be influenced by familiarity with and expertise in those areas.

TABLE 80 Intervention: number of patient contacts with the SCC per service within 12 months of registration

Service	Mean (SD)	Median (range)
S002 (<i>n</i> =19)	1.6 (0.60)	2.0 (1.0–3.0)
S005 (<i>n</i> =15)	1.3 (0.49)	1.0 (1.0–2.0)
S006 (<i>n</i> =26)	1.0 (0.20)	1.0 (1.0–2.0)
S007 (<i>n</i> =28)	2.2 (0.79)	2.0 (1.0–4.0)
S009 (<i>n</i> =16)	1.6 (1.09)	1.0 (1.0–5.0)
S012 (<i>n</i> =24)	1.8 (0.72)	2.0 (1.0–4.0)
S013 (<i>n</i> =31)	3.0 (1.02)	3.0 (1.0–5.0)
S016 (<i>n</i> =19)	3.2 (1.62)	3.0 (1.0–6.0)
S020 (<i>n</i> =1)	2.0	2.0 (2.0–2.0)
S023 (<i>n</i> =11)	3.2 (1.08)	4.0 (1.0–4.0)
S024 (<i>n</i> =10)	1.9 (0.57)	2.0 (1.0–3.0)
S026 (<i>n</i> =29)	2.5 (0.91)	3.0 (1.0–4.0)
S027 (<i>n</i> =26)	1.8 (0.75)	2.0 (1.0–4.0)
S030 (<i>n</i> =10)	3.9 (1.79)	4.5 (1.0–6.0)
S031 (<i>n</i> =14)	1.4 (0.50)	1.0 (1.0–2.0)
Total (<i>n</i> =279)	2.1 (1.16)	2.0 (1.0–6.0)

Description of control and intervention services based on stroke care co-ordinator interviews and surveys

For all services randomised, SCCs completed a survey and semistructured interview before randomisation. A second semistructured interview was conducted with SCCs in all services that recruited participants (29 services, 31 SCCs), midway through recruitment. A second survey and third semistructured interview were completed by 25 services (12 control, 13 intervention; 27 SCCs: 14 control, 13 intervention) after the end of the 12-month follow-up (some SCCs were no longer in post by this time). The interviews were informed by SCC responses to the surveys. These data have been reviewed, focusing on the final interview, to describe practice in control services and summarise how intervention services used the system of care and whether it changed their practice.

Control services

Patients were generally seen at home but outpatient clinics and telephone calls were also used. Family would be included in the patient assessment when present and carer reviews were conducted ad hoc (e.g. if the carer appeared to be struggling).

All services aimed to provide a holistic initial assessment, covering broad areas of physical, social and psychological health, activities of daily living, and so on. Methods for capturing this usually involved documentation that had been developed locally by the SCC or team and which had evolved over time. Some services mentioned using a conversational manner, for example asking about daily routines and how a patient was managing after stroke, responding to the patient rather than following the documentation in order. Documentation was based on an integrated pathway tool (two services), a form based on the local neurology rehabilitation outpatients documentation (one service) or a copy of documentation used by other community staff in the area (one service). Two services described focusing their initial visit on high-priority areas such as medical stability and risks at home. Eight services reported using additional standardised tools where relevant (e.g. HADS, Carer Strain Index, Barthel Index, modified Rankin Scale).

Three services identified that some issues were not routinely covered (e.g. finances, sexual functioning and employment) but would be discussed if raised by a patient, or the SCC would raise it if he or she felt that it was relevant (e.g. asking younger people about employment – one service). Some issues would be raised at later meetings either because it might not be appropriate at the first visit (sexual functioning and mood) or because there was not enough time during the first visit (four services). Some SCCs viewed assessment as ongoing and needing time to build a rapport.

Stroke care co-ordinators often write an action list rather than specific patient goals. Six services identified that patients agree goals or actions for them to work on. Actions and goals are reviewed at each visit (two services) and may be chased by ringing either the patient or the place where the referral was made to (nine services). Most services report focusing on how patients perceive their problems and what they want to achieve. Three services reported encouraging patients to carry out actions themselves, including self-referral. One service would sometimes offer the Bridges stroke self-management booklet (see www.bridges-stroke.org.uk/) to help motivate patients and encourage them to set their own goals, and another service routinely gave patients 'hand-held' records in which health-care information was recorded and they could note their own goals.

At reviews, the majority of services (10 SCCs) do not provide a full holistic review but instead focus on changes, reviewing goals or asking about the main areas using a shortened version of the initial assessment. Two services may be providing full holistic assessments (no data for the remaining four services).

The SCC role is seen as providing education and secondary prevention advice, gathering information about patient problems and co-ordinating onward referrals. Services report that their practice is informed by experience, which has built up over years, by local knowledge and from speaking to others either within or

without the team. Five services also reported being influenced by national or profession-specific guidelines (such as those from RCP and NICE). Seven services use an organised local resource list or manual to facilitate referrals they make or to provide to patients for self-referral.

Several services reported that major difficulties exist for addressing problems relating to mood, with extremely limited psychological services available in seven services. Services to address employment, benefits, younger stroke, and speech and language therapy were also lacking (each reported by one service). Several services noted that local social groups and day centre services are either lacking or more limited than previously, possibly because places are full. Three services reported largely good links for making patient referrals. Most services report that patients are aware that they can call to ask for help or to re-refer.

Intervention services

For seven services the LoTS care checklist was usually/sometimes sent to patients and usually/sometimes used by patients; this includes a minority who gave the checklist out at (rather than before) the first visit. Five services did not give the checklist out, largely because of the practicalities of getting the checklist to patients before the first visit. Services who used the checklist commented that it was positive for one or more of the following reasons: giving the patient ownership or time to prepare; helping the patient know what to expect; helping to manage awkward questions; contributing to a more successful assessment; helping to get to the crux of the matter quicker (but with no reduction in overall assessment time).

Five services reported that patients are normally seen in outpatient clinics and four services reported that patients are normally seen at home.

When it was mentioned, family would normally be included in the patient assessment when present. Carer reviews may be conducted ad hoc; two services provided carer assessments more consistently and three services did not provide carer assessments (because this was covered by another service, e.g. the Stroke Association).

Three services focus their initial visit on high-priority areas such as risk and immediate patient-identified problems. Three services guided assessment primarily using conversation and then using the care plan to ensure that all areas are covered. The care plan was used at both the initial assessment and the reviews for at least five services. At least eight other services were using the care plan but it is not clear whether this was at the initial assessment or at both the initial assessment and the reviews. It is often not clear whether all questions were asked; however, one service commented that it carried out holistic reviews because patients can deteriorate or their situation can change.

Eight services reported that they might not cover everything at the initial visit (although they felt that all areas would be addressed at some point) because of one or more of the following reasons: there is a lot to ask and they do not want to overwhelm the patient; patients may be fatigued; the initial visit is shortly after hospital discharge and so it may not be appropriate to perform a full assessment; the assessment is seen as ongoing. In total, 10 services highlighted that the sexual function question was often not appropriate (e.g. with family present, without having time to build a relationship with the patient) and some SCCs felt uncomfortable asking this question. These SCCs felt that patients need time to get to know the SCC and so this area might be addressed later on. However, this area may not be addressed for all patients and some SCCs would rely on patients having seen this question on the checklist and raising it themselves.

Most services used the goal and action planner, mainly to record actions (rather than patient-specific goals). Actions and goals are reviewed at each visit (minimum nine services) and may be chased by ringing either the patient or the place where the referral was made to (minimum eight services). One service reported using the client goal planner from the manual.

The benefits of using the care plan include it being an organised formalised system, being able to ask specific questions and potentially capturing problems sooner. A disadvantage of the care plan is that it does not cover all areas (e.g. speech and language therapy, limb function, vision, allergies). SCCs found their own ways of managing this by taking paper prompts.

For some services the care plan data do not reflect the full care given to patients, for example formal reviews being carried out by a nursing outpatient clinic not using the system of care.

The SCC role is seen as providing information and secondary prevention advice to patients (minimum five services) and co-ordinating overall care and referrals (minimum 11 services). Services report that their practice is informed by experience, which has built up over years, by local knowledge and from speaking to others either within or without the team (12 services). One service reported that it also tries to keep up to date with research and evidence-based practice. Two services use an organised local resource list to facilitate referrals.

When asked whether the manual was used, three services reported regularly using the manual, two services used the manual at first but felt that they got to know its contents, another five services may have used the manual a little and four services reported not using the manual. Regarding the manual algorithms, two services initially used these on visits but found them too cumbersome and so they stopped taking the manual to visits but might look at it on return to the office. Two services found the frequency table about fatigue helpful to reassure their patients and some found the reference guide on sexual function useful.

Nine services reported that the manual might be useful for providing ideas and confidence when considering how to respond to a problem, particularly for a SCC who is not used to dealing with the problem or who wants to consider other ideas or check his or her thinking. Six services said that the manual would be valuable for junior staff.

Difficulties exist for addressing problems relating to mood for most services, with extremely limited psychological services for five services. Seven services reported that other services were difficult to access or were limited, including voluntary/community resources, services to address employment, services to address transport, therapy, addiction treatment, podiatry, social work, optometry (each reported by one service) and service responses for sexual functioning (two services).

Most SCCs report focusing on what is important for patients, letting them raise issues through conversation and trying to incorporate their perspective. Most services involve patients in action planning, either through collaborative problem-solving, writing actions together or encouraging them to decide on their priorities. One service reported that the system of care helped them implement patient-centred practice. Four services reported encouraging patients to carry out actions themselves, including self-referral. Three services routinely gave patients a copy of their care plan or goals, whereas another three did not routinely give patients any such documentation.

Stroke care co-ordinators may share the dual role of working in the co-ordinator and profession-specific role (at least six services). One of these commented that patients can get confused about who they have seen and SCCs feel that their roles can become merged or the co-ordinator role takes over the profession-specific role. A minority of services did not identify as having a coordinator role, with co-ordination limited to the first visit (formal reviews are not provided by their service).

Most services will approach discharge through collaborative discussion with the patient. Patients are usually able to call SCCs to ask for help or re-refer themselves. Three services can either use inactive caseloads or offer patients a break and visit them in the future.

Appendix 10 Project 2: resource use

TABLE 81 Resource use at baseline (in the previous 3 months)

Resource	Unit	Intervention (n=401)			Control (n=398)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Index stroke admission ^b	Bed-days	99	39	44	99	30	35
Residential care home	Night	0	–	–	0	–	–
Nursing home	Night	0	–	–	0	–	–
Inpatient services	Bed-day	7	11	24	10	7	6
Day hospital/day cases	Activity	9	1	1	6	1	<1
A&E	Visit	7	11	24	10	7	6
Outpatient services	Visit	8	2	4	10	1	1
Physiotherapist, hospital ^c	Visit	3	3	4	4	2	2
Occupational therapist, hospital ^c	Visit	<1	2	1	1	3	2
Speech and language therapist, hospital ^c	Visit	1	3	2	1	2	1
Community-based services							
GP							
Surgery visit	Visit	49	2	1	44	2	2
Home visit	Visit	9	2	1	11	2	2
Telephone call	Call	10	2	1	12	2	1
Repeat prescription	Occurrence	47	2	1	49	2	1
Practice nurse							
Surgery visit	Visit	26	2	1	23	2	2
Telephone call	Call	3	2	1	3	1	1
Physiotherapist							
Home visit	Visit	1	4	5	1	7	4
Surgery visit	Visit	1	2	2	2	3	2
Elsewhere	Visit	<1	1	0	0	–	–
Occupational therapist							
Home visit	Visit	1	1	1	1	1	1
Surgery visit	Visit	<1	3	11	<1	3	–
Elsewhere	Visit	0	–	–	0	–	–
Speech and language therapist							
Home visit	Visit	<1	1	–	0	–	–
Surgery visit	Visit	0	–	–	<1	3	–
Elsewhere	Visit	0	–	–	0	–	–

continued

TABLE 81 Resource use at baseline (in the previous 3 months) (continued)

Resource	Unit	Intervention (n=401)			Control (n=398)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Social worker							
Home visit	Visit	1	2	1	2	2	1
Telephone call	Call	1	2	2	1	2	1
Community/district nurse	Contact	5	3	3	6	5	10
Health visitor	Contact	<1	3	2	1	2	1
Geriatrician	Contact	0	–	–	1	1	0
Psychiatrist	Contact	<1	2	–	0	–	–
Psychologist	Contact	<1	1	–	0	–	–
Chiropodist	Contact	10	2	1	12	1	1
Chiropractor	Contact	<1	1	–	<1	1	–
Osteopath	Contact	<1	2	–	0	–	–
Dentist	Contact	12	1	1	12	1	1
Optician	Contact	12	1	<1	12	1	<1
Day hospital	Half-day	1	2	1	1	1	<1
Social club	Half-day	3	9	7	3	12	12
Lunch club	Visit	1	7	9	1	4	2
Drop-in centre	Visit	1	2	1	1	4	5
Meals on wheels	Meal	0	–	–	<1	5	–
Frozen meals	Meal	<1	4	4	1	4	4
Home help, personal care	Visit	1	42	46	2	53	55
Home help, household care	Visit	1	30	43	2	20	28
Home help, shopping care	Visit	<1	2	1	1	8	5
Social services day-care centre	Hour	0	–	–	<1	90	–
Intermediate care team	Contact	<1	3	1	0	–	–
Other services	Occurrence	2	5	11	2	1	<1
Informal care from co-residents							
Personal care	Hour	3	47	43	3	219	320
Providing transport	Hour	3	78	205	6	37	56
Preparing meals	Hour	4	138	175	6	134	141
Housework/laundry	Hour	4	147	186	6	95	93
DIY	Hour	2	97	247	3	40	65
Gardening	Hour	3	94	207	4	31	44
Shopping	Hour	4	81	184	5	41	47
Outings	Hour	2	106	231	3	44	63
Socialising	Hour	3	415	604	3	202	428
Help managing finances	Hour	3	77	214	4	31	40

TABLE 81 Resource use at baseline (in the previous 3 months) (*continued*)

Resource	Unit	Intervention (n=401)			Control (n=398)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Informal care from non-residents							
Personal care	Hour	1	39	29	1	171	281
Providing transport	Hour	6	25	23	4	39	48
Preparing meals	Hour	3	66	72	2	48	65
Housework/laundry	Hour	4	43	39	4	24	20
DIY	Hour	3	19	19	2	10	7
Gardening	Hour	4	18	14	3	18	14
Shopping	Hour	5	24	15	4	28	21
Outings	Hour	5	28	56	3	23	16
Socialising	Hour	5	95	115	5	78	100
Help managing finances	Hour	2	19	14	2	12	7

a Mean for valid user values only.

b Not included in the evaluation.

c Separate from other outpatient visits. Further visits to these services are also included in the broader outpatient visit numbers.

TABLE 82 Resource use at 6 months (in the previous 6 months)

Resource	Unit	Intervention (n=307)			Control (n=295)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Residential care home	Night	3	58	62	4	39	48
Nursing home	Night	2	59	49	2	63	58
Inpatient services	Bed-day	19	15	18	19	14	27
Day hospital/day cases	Activity	12	1	1	8	1	1
A&E	Visit	17	2	2	14	2	1
Outpatient services	Visit	44	3	3	40	3	5
Physiotherapist, hospital ^b	Visit	12	8	8	17	7	8
Occupational therapist, hospital ^b	Visit	5	3	3	9	8	13
Speech and language therapist, hospital ^b	Visit	6	4	3	8	3	3
Community-based services							
GP							
Surgery visit	Visit	57	3	2	60	3	2
Home visit	Visit	24	2	2	22	2	1
Telephone call	Call	20	2	2	21	2	3
Repeat prescription	Occurrence	52	3	4	51	5	3
Practice nurse							
Surgery visit	Visit	33	3	3	40	3	3
Telephone call	Call	7	2	2	8	2	2

continued

TABLE 82 Resource use at 6 months (in the previous 6 months) (continued)

Resource	Unit	Intervention (n=307)			Control (n=295)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Physiotherapist							
Home visit	Visit	28	8	9	22	8	10
Surgery visit	Visit	3	4	3	4	3	3
Elsewhere	Visit	1	15	22	6	8	11
Occupational therapist							
Home visit	Visit	26	5	8	24	6	7
Surgery visit	Visit	1	2	2	1	2	1
Elsewhere	Visit	1	14	23	3	9	14
Speech and language therapist							
Home visit	Visit	11	4	3	13	4	4
Surgery visit	Visit	2	3	2	1	3	3
Elsewhere	Visit	1	10	8	2	3	2
Social worker							
Home visit	Visit	12	2	1	11	2	1
Telephone call	Call	8	3	2	5	3	2
Community/district nurse	Contact	23	7	21	23	4	9
Health visitor	Contact	5	2	1	8	10	27
Geriatrician	Contact	1	3	1	1	1	1
Psychiatrist	Contact	2	2	1	1	2	1
Psychologist	Contact	3	3	1	3	2	1
Chiropodist	Contact	18	2	2	16	2	1
Chiropractor	Contact	<1	3	–	1	1	1
Osteopath	Contact	<1	4	–	<1	1	–
Dentist	Contact	21	2	1	14	1	1
Optician	Contact	20	1	1	22	1	1
Day hospital	Half-day	6	8	18	4	6	6
Social club	Half-day	5	12	16	3	8	8
Lunch club	Visit	2	6	4	2	11	8
Drop-in centre	Visit	2	7	5	<1	6	–
Meals on wheels	Meal	0	–	–	<1	5	–
Frozen meals	Meal	2	21	24	1	30	14
Home help, personal care	Visit	5	49	67	5	78	138
Home help, household care	Visit	3	61	127	2	42	63
Home help, shopping care	Visit	2	12	13	1	13	12
Social services day-care centre	Hour	<1	6	–	<1	4	3
Intermediate care team	Contact	5	57	167	3	7	11
Other services	Occurrence	8	6	15	8	9	16

TABLE 82 Resource use at 6 months (in the previous 6 months) (*continued*)

Resource	Unit	Intervention (n=307)			Control (n=295)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Informal care from co-residents							
Personal care	Hour	15	385	834	14	242	324
Providing transport	Hour	15	108	140	14	120	126
Preparing meals	Hour	19	249	234	14	249	200
Housework/laundry	Hour	18	244	305	14	204	163
DIY	Hour	9	87	224	4	49	51
Gardening	Hour	11	80	94	8	60	52
Shopping	Hour	16	115	122	15	95	113
Outings	Hour	14	116	142	9	93	87
Socialising	Hour	14	728	1125	9	489	488
Help managing finances	Hour	13	89	123	11	124	225
Informal care from non-residents							
Personal care	Hour	8	110	96	6	110	102
Providing transport	Hour	14	63	82	14	58	58
Preparing meals	Hour	8	104	135	6	85	98
Housework/laundry	Hour	9	80	82	7	45	43
DIY	Hour	6	20	20	4	24	35
Gardening	Hour	9	26	36	7	32	37
Shopping	Hour	11	48	48	11	44	35
Outings	Hour	13	57	98	11	54	62
Socialising	Hour	13	156	163	9	146	218
Help managing finances	Hour	7	60	69	5	33	36

a Mean for valid user values only.

b Separate from other outpatient visits. Further visits to these services are also included in the broader outpatient visit numbers.

TABLE 83 Resource use at 12 months (in the previous 6 months)

Resource	Unit	Intervention (n=283)			Control (n=268)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Residential care home	Night	2	81	84	2	46	76
Nursing home	Night	1	92	91	1	103	112
Inpatient services	Bed-day	16	9	15	15	8	9
Day hospital/day cases	Activity	8	2	1	10	1	<1
A&E	Visit	12	2	1	10	2	1
Outpatient services	Visit	36	3	3	37	3	5
Physiotherapist, hospital ^b	Visit	14	6	6	12	6	8

continued

TABLE 83 Resource use at 12 months (in the previous 6 months) (continued)

Resource	Unit	Intervention (n=283)			Control (n=268)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Occupational therapist, hospital ^b	Visit	4	1	1	7	3	2
Speech and language therapist, hospital ^b	Visit	6	8	7	2	2	1
Community-based services							
GP							
Surgery visit	Visit	53	3	3	60	3	2
Home visit	Visit	15	3	4	13	3	6
Telephone call	Call	18	2	1	13	3	3
Repeat prescription	Occurrence	49	5	3	54	5	2
Practice nurse							
Surgery visit	Visit	35	3	4	44	3	4
Telephone call	Call	6	2	2	8	3	3
Physiotherapist							
Home visit	Visit	7	9	14	7	5	7
Surgery visit	Visit	4	2	1	4	2	2
Elsewhere	Visit	2	12	12	1	16	26
Occupational therapist							
Home visit	Visit	6	2	2	7	5	6
Surgery visit	Visit	1	3	2	1	2	0
Elsewhere	Visit	<1	5	–	1	4	3
Speech and language therapist							
Home visit	Visit	3	3	4	3	2	1
Surgery visit	Visit	1	1	0	0	–	–
Elsewhere	Visit	0	–	–	<1	6	–
Social worker							
Home visit	Visit	8	2	1	4	2	1
Telephone call	Call	5	3	1	2	1	1
Community/district nurse	Contact	15	8	27	14	4	5
Health visitor	Contact	5	2	1	3	2	1
Geriatrician	Contact	1	1	0	1	1	0
Psychiatrist	Contact	2	6	8	1	2	1
Psychologist	Contact	2	2	1	2	2	1
Chiropodist	Contact	18	2	1	18	2	2
Chiropractor	Contact	<1	1	–	1	2	1
Osteopath	Contact	1	2	–	<1	3	–
Dentist	Contact	27	2	1	22	2	1
Optician	Contact	21	1	<1	24	1	1

TABLE 83 Resource use at 12 months (in the previous 6 months) (*continued*)

Resource	Unit	Intervention (n=283)			Control (n=268)		
		Users (%)	Mean ^a	SD	Users (%)	Mean ^a	SD
Day hospital	Half-day	5	5	6	6	4	4
Social club	Half-day	4	13	12	3	13	15
Lunch club	Visit	2	9	8	2	14	11
Drop-in centre	Visit	1	2	1	2	10	10
Meals on wheels	Meal	0	–	–	<1	150	–
Frozen meals	Meal	1	5	5	1	24	23
Home help, personal care	Visit	2	194	306	2	163	169
Home help, household care	Visit	1	5	6	1	9	3
Home help, shopping care	Visit	<1	1	–	<1	5	–
Social services day-care centre	Hour	2	56	64	1	20	10
Intermediate care team	Contact	0	–	–	1	5	5
Other services	Occurrence	6	4	6	3	2	1
Informal care from co-residents							
Personal care	Hour	11	564	1695	6	460	1035
Providing transport	Hour	12	202	357	10	134	278
Preparing meals	Hour	14	317	336	9	213	203
Housework/laundry	Hour	14	339	769	11	210	235
DIY	Hour	7	157	455	4	67	83
Gardening	Hour	9	137	390	8	81	160
Shopping	Hour	11	175	349	10	80	141
Outings	Hour	11	173	378	7	123	176
Socialising	Hour	11	550	776	7	343	488
Help managing finances	Hour	9	169	403	8	63	117
Informal care from non-residents							
Personal care	Hour	5	209	356	3	186	349
Providing transport	Hour	12	53	66	11	42	40
Preparing meals	Hour	7	106	170	4	87	84
Housework/laundry	Hour	9	107	154	7	60	67
DIY	Hour	5	46	43	7	34	44
Gardening	Hour	6	38	37	6	31	36
Shopping	Hour	8	62	72	8	44	39
Outings	Hour	11	63	135	9	47	46
Socialising	Hour	12	222	356	8	116	140
Help managing finances	Hour	5	49	64	4	44	37

^a Mean for valid user values only.

^b Separate from other outpatient visits. Further visits to these services are also included in the broader outpatient visit numbers.

Appendix 11 Project 3: The Longer-term Unmet Needs after Stroke questionnaire

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Page 1 of 2

Longer-term Unmet Needs after Stroke



Please read each statement and answer it as follows

Tick 'YES' if you agree with the statement

Tick 'NO' if you do not agree with the statement or it doesn't apply to you

	YES	NO
1. I would like more information about my stroke (e.g. what is a stroke, why it has happened to me and how to avoid having another one)	<input type="checkbox"/>	<input type="checkbox"/>
2. I haven't had my medication/blood pressure checked for some time and would like a check up	<input type="checkbox"/>	<input type="checkbox"/>
3. I regularly get pain and nothing seems to ease it	<input type="checkbox"/>	<input type="checkbox"/>
4. My walking and general moving seems to be getting worse and I'm not getting any help with this	<input type="checkbox"/>	<input type="checkbox"/>
5. I am worried that I might fall (again) and this is stopping me from doing my usual things	<input type="checkbox"/>	<input type="checkbox"/>
6. I need additional aids (e.g. kitchen equipment) or adaptations (e.g. stair lift, grab rails) inside the home	<input type="checkbox"/>	<input type="checkbox"/>
7. I need adaptations outside the home (e.g. ramp, rail) but they haven't been ordered yet or I've been waiting too long	<input type="checkbox"/>	<input type="checkbox"/>
8. I need some help / advice about getting back to driving and / or getting a blue badge	<input type="checkbox"/>	<input type="checkbox"/>
9. I would like to find out about travelling on buses, taxis and / or trains	<input type="checkbox"/>	<input type="checkbox"/>
10. I would like outside help to get jobs done in my home (e.g. cleaning, cooking, ironing, fixing things)	<input type="checkbox"/>	<input type="checkbox"/>

Please Turn Over

	YES	NO
11. I would like to look into the options for moving to another home	<input type="checkbox"/>	<input type="checkbox"/>
12. I would like some advice about how to improve my diet (e.g. alcohol, sugar, fat and salt intakes)	<input type="checkbox"/>	<input type="checkbox"/>
13. I need some advice to help me manage my money better (e.g. paying bills, getting my pension)	<input type="checkbox"/>	<input type="checkbox"/>
14. I would like help to find out about, or to apply for benefits	<input type="checkbox"/>	<input type="checkbox"/>
15. I would like advice on employment after stroke	<input type="checkbox"/>	<input type="checkbox"/>
16. I need more help with things like cutting my toenails, washing myself or dental care (including dentures)	<input type="checkbox"/>	<input type="checkbox"/>
17. I have problems with my bladder / bowel (accidents, constipation, diarrhoea) and would like some help with this	<input type="checkbox"/>	<input type="checkbox"/>
18. I am concerned about my physical relationship with my partner and would like some advice or information	<input type="checkbox"/>	<input type="checkbox"/>
19. I forget things quite a lot or find it hard to concentrate and would like some help with this	<input type="checkbox"/>	<input type="checkbox"/>
20. I often feel quite low, angry or worried and would like to find out what help is available	<input type="checkbox"/>	<input type="checkbox"/>
21. I would like to occupy my day better (e.g. social outings, home library, hobbies) but don't know how to go about it	<input type="checkbox"/>	<input type="checkbox"/>
22. I would like to find out about holidays / breaks (including transport) that cater for people with disabilities	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 12 Project 4: categories of social activity

Description of the categories used in the purposive sampling strategy for the adjustment after stroke study

The adjustment after stroke study aimed to explore adjustment and recovery post stroke, including the processes and mechanisms that contributed to social participation following stroke. To achieve this, the study was designed to enable a purposeful sample of stroke survivors to be recruited, comprising those who were less or more socially active than anticipated for their level of functional ability.

Before being recruited to the adjustment after stroke study, participating stroke survivors had to complete the LoTS care stroke system of care trial. The trial database contained information about each trial participant, including their Barthel Index and FAI scores pre stroke and 12 months post stroke. The Barthel Index measures current ability to carry out basic activities of daily living (e.g. continence, ability to get dressed, mobility, feeding). The FAI measures the frequency of extended activities of daily living (e.g. leisure activities, social occasions, housework, travelling). These could be used to help identify potential participants for the substudy.

The trial was ongoing at the time that the sampling strategy for the adjustment after stroke study was designed. Analysis was therefore conducted on an existing data set,³⁶ with a similar population to that of the stroke system of care trial, to identify criteria to enable us to distinguish between stroke survivors in terms of their social activity level (based on Barthel Index and FAI scores). In this population the median (interquartile range) reduction in Barthel Index score and FAI score from pre stroke to 12 months post stroke was 4 (1–8) and 16 (7–26) respectively. Three main categories of stroke survivors were defined: 'doing better than expected', 'failing to thrive' and 'doing as expected (doing well)'. *Figure 24* plots the reduction in Barthel Index and FAI scores from pre stroke to 12 months post stroke for the existing data set and highlights the three different categories identified. *Table 84* provides the definitions for the three

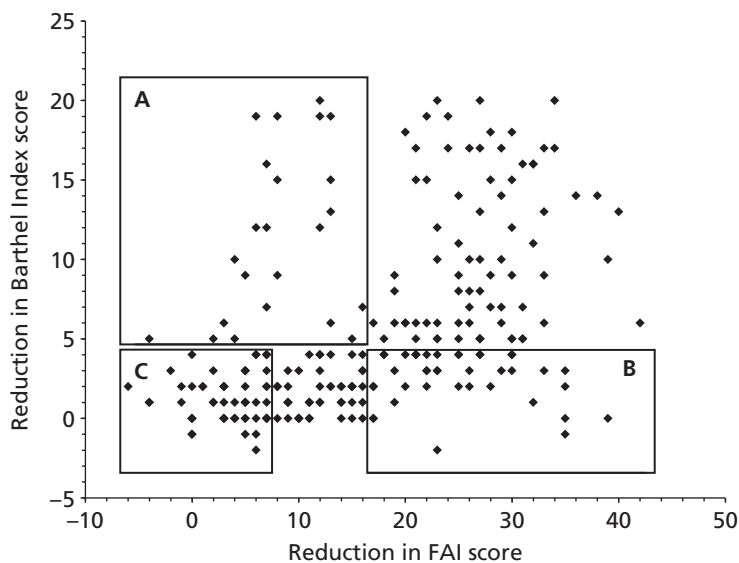


FIGURE 24 Reduction in Barthel Index and FAI scores from pre stroke to 12 months post stroke. A, better than expected; B, failure to thrive; C, doing as expected (doing well).

TABLE 84 Definitions of the categories

Category	Reduction in Barthel Index score (between pre stroke and 12 months post stroke)	Reduction in FAI score (between pre stroke and 12 months post stroke)	Excluding
A: better than expected	>4	≤16	Those who have a 12-month FAI score of 0
B: failure to thrive	≤4	>16	Not applicable
C: doing as expected (doing well)	≤4	≤7	Those who have a 12-month FAI score of 0

different categories as well as any exclusions made to take account of the potential floor effect in FAI score. The trial database was screened on a monthly basis to identify potential participants who fell into each of the three categories for recruitment to the substudy. Initially, the recruitment of those in the 'doing better than expected' and 'failure to thrive' categories was prioritised, with an attempt made to recruit those in the extremes of these categories to enable maximum variation within the sample.

The relationship between the categories and identified recovery trajectories

It was anticipated that the categories, based on changes in Barthel Index and FAI scores from pre stroke to 12 months post stroke, would be indicative of stroke survivors' adjustment after stroke. These objective measures, however, did not predict the recovery trajectory that each participating stroke survivor identified. *Table 85* summarises the numbers of participating stroke survivors who fell into each of the four recovery trajectories, arranged according to the different categories: doing better than expected, failure to thrive and doing as expected (doing well). *Figure 25* shows the reductions in FAI and Barthel Index scores from pre stroke to 12 months post stroke for participating stroke survivors in the different recovery trajectories.

TABLE 85 Numbers of stroke survivors by category and recovery trajectory

Category	No. of stroke survivors recruited	Recovery trajectory (identified from analysis of qualitative data)	No. of stroke survivors in each trajectory by category
A: doing better than expected	12	Disruption followed by adjustment and acceptance	5
		Cycles of disruption followed by adjustment and acceptance	3
		Disruption without adjustment and acceptance	2
		Stroke as continuation of ongoing decline	2
B: failure to thrive	8	Disruption followed by adjustment and acceptance	3
		Cycles of disruption followed by adjustment and acceptance	1
		Disruption without adjustment and acceptance	4
		Stroke as continuation of ongoing decline	0
C: doing as expected (doing well)	2	Disruption followed by adjustment and acceptance	1
		Cycles of disruption followed by adjustment and acceptance	1
		Disruption without adjustment and acceptance	0
		Stroke as continuation of ongoing decline	0

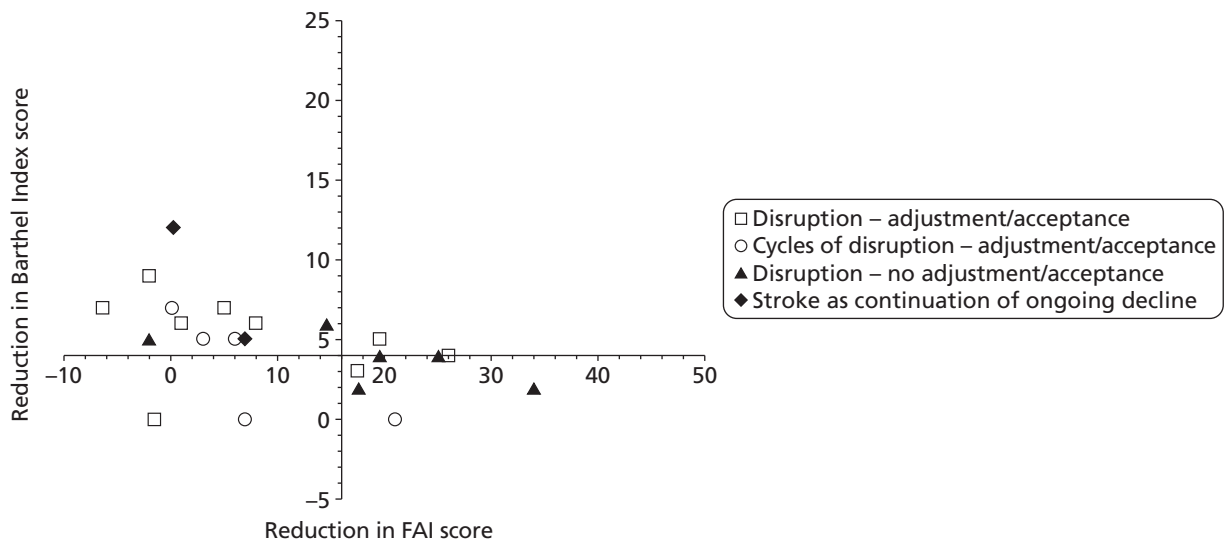


FIGURE 25 Reduction in FAI and Barthel Index scores from pre stroke to 12 months post stroke for participating stroke survivors in the different recovery trajectories.

It is important to note that a purposive sampling strategy was used and therefore the stroke survivors interviewed were not randomly selected to represent their associated category (i.e. those interviewed who were categorised as 'doing better than expected' were not necessarily representative of the population of those 'doing better than expected'). There is, however, no clear relationship between the participating stroke survivors' category and the recovery trajectory identified from the qualitative data. This is perhaps unsurprising given that participants' narratives indicate that multiple, interacting factors shape the process of recovery, adjustment and acceptance over time. This demonstrates that we cannot reduce our understanding of recovery and adjustment to outcome measures such as the Barthel Index and the FAI.

Appendix 13 Dissemination activities

Publications directly attributable to the programme

Published

Forster A, Young J, Nixon J, Chapman K, Murray J, Patel A, *et al.* Protocol of a cluster randomized trial evaluation of a patient and carer-centered system of longer-term stroke care (LoTS care) [published online ahead of print 19 February 2013]. *Int J Stroke* 2013. doi:10.1111/ijss.12038

LoTS care LUNS study team. Validation of the longer-term unmet needs after stroke (LUNS) monitoring tool: a multicentre study. *Clin Rehabil* 2013;**27**:1020–8.

Planned

- Update of the LoTS care stroke system of care reference guides.
- Clinical effectiveness and cost-effectiveness of the LoTS care stroke system of care: results of the cluster RCT.
- Implementation of the LoTS care stroke system of care in the trial.
- Exploratory analyses of patient and service factors and trial outcomes.
- Evaluation of the LUNS tool as a scale (internal consistency, dimensionality).
- Comparison of the LUNS tool results in patients with and without cognitive/language impairments.
- Qualitative evaluation of longer-term unmet needs after stroke.
- Correlation of longer-term unmet needs after stroke with other variables.
- Adjustment after stroke study: methodology.
- Adjustment after stroke study: results.
- Adjustment after stroke study: literature review on factors influencing adjustment post stroke.

Cofunded publications

Published

Smith J, Forster A, Young J. On behalf of the Cochrane Group for information provision after stroke. Cochrane review: information provision for stroke patients and their caregivers. *Clin Rehabil* 2009;**23**:195–206.

Murray J, Young J, Forster A. Measuring outcomes in the longer term after a stroke. *Clin Rehabil* 2009;**23**:918–21.

McKevitt C, Fudge N, Redfern J, Sheldenkar A, Crichton S, Rudd AR, *et al.* Self-reported long-term needs after stroke. *Stroke* 2011;**42**:1398–403.

Forster A, Brown L, Smith J, House A, Knapp P, Wright J, *et al.* Information provision for stroke patients and their caregivers. *Cochrane Database Syst Rev* 2012;**11**:CD001919.

Planned

- Overcoming the obstacles for multicentre trials in rehabilitation [LoTS care/Training Caregivers After Stroke (TRACS) trials].
- Design challenges in cluster RCTs (LoTS care/TRACS trials).
- Appropriate safety monitoring in stroke rehabilitation trials (LoTS care/TRACS trials).
- Recruitment of carers to stroke trials (LoTS care/TRACS trials).
- Follow-up response rates in postal questionnaires sent to stroke patients and their carers (LoTS care/TRACS trials).
- Statistical methodology (LoTS care/TRACS trials).
- Realist evaluation of the LoTS care system of care trial.

Other dissemination activities

- A summary of all results and links to publications will be published on the LoTS care trial website (www.lotscare.co.uk).
- A summary of the results of the LoTS care system of care trial and the LUNS study have been sent to those participants who requested this (307 and 229 participants in the two studies respectively).
- Results will be disseminated at appropriate national and international conferences, including those in the fields of stroke, health services research and medical sociology.
- Results of the LoTS care system of care trial and the LUNS study will be disseminated to participating SRNs and clinical staff through regional meetings.
- The LUNS questionnaire for identifying longer-term unmet needs after stroke is available free of charge for non-commercial use on request from the corresponding author.
- We anticipate that case studies illustrating the different recovery trajectories identified in the adjustment after stroke study may be useful as a resource both for stroke survivors/carers and for health and social care professionals who work with stroke survivors.
- Although the LoTS care system of care was not demonstrated to improve clinical outcomes, components of it may have utility, for example the assessment provides a structured way of ensuring that an evidence-based post-stroke review is carried out and the manual serves as a repository of evidence-based practice that could be useful for training inexperienced staff; these may be of particular use for developing services in sites currently without organised long-term care for stroke.

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HTA
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