Development of Complex Interventions in Stroke Care
A Systematic Review

Judith Redfern, MSc; Christopher McKeivitt, PhD; Charles D.A. Wolfe, MD, FFPHM, FRCOG

Background and Purpose—Stroke care is complex, requiring input from professionals, patients and carers. Identifying and developing appropriate intervention components to meet these complex needs is difficult. The Medical Research Council (MRC) Framework for developing and evaluating ‘complex’ (nonpharmacological) interventions aims to improve intervention development. This study uses the Framework to review complex interventions in stroke care.

Methods—Systematic review with multiple search strategies (electronic databases, recent journals, gray literature) was used. The MRC Framework was used to guide the search strategy and assess study quality. ‘Complex interventions’ were defined as educational/psychosocial interventions to change knowledge, beliefs or behaviors.

Results—Sixty-seven studies were included: 39 randomized controlled trials (RCT) and 28 other designs. Complex interventions targeted healthcare professionals (17), and patients, carers and the general population (21 targeting primary or secondary prevention; 30 targeting adjustment and recovery after stroke). Compared with recovery studies, primary and secondary prevention studies were significantly less likely to have been evaluated in RCTs. Interventions evaluated in RCTs were significantly less likely to influence primary outcomes (26%) compared with other designs (44%). Theoretical grounding to support intervention choice was reported in 40 studies but only 14 were theoretically ‘well developed’; 21 RCTs listed multiple primary outcome measures, with 10 listing 5 or more. Of these only 3 reported considering statistical power before recruitment and none was sufficiently powered.

Conclusion—Few complex interventions in stroke care have been adequately developed or evaluated. This may explain failures to demonstrate efficacy. In future, greater attention is needed to theoretical development and methodological quality. (Stroke. 2006;37:0000-0000.)

Key Words: methodology ■ prevention ■ randomized controlled trials ■ stroke

Stroke prevention and management are complex processes requiring intervention at multiple levels (physiological, psychological, social, environmental). Although there is considerable evidence to support the use of pharmacological interventions in aspects of stroke care, the best way to intervene to improve health outcomes using nonpharmacological ‘complex interventions’ is often unclear. Complex interventions often have particular characteristics making them less likely to succeed when evaluated using randomized controlled trial (RCT) methods, such as having multiple components, aiming to target multiple outcomes, being difficult to implement or evaluate, or aiming to achieve outcomes which are notoriously difficult to influence. Even when RCTs of complex interventions are successful it is difficult to fully understand how and why the interventions work. For example, it is now widely accepted that stroke units save lives and that these units should feature particular characteristics (assessment and monitoring, early management, multidisciplinary team rehabilitation) but we still have relatively little understanding of how these components interact to improve outcomes. A number of models exist to assist in developing and evaluating of complex interventions with the aim of improving intervention quality. The UK Medical Research Council (MRC) Framework outlines 5 key phases for intervention development, paralleling those used in pharmaceutical trials (Figure). The Framework does not prescribe specific research methods to be used in intervention development but does recommend specific questions to be addressed in each phase in order to ensure that studies are well designed. The Framework also states that efficacy must be tested in a RCT. Recent studies have started to use this Framework to guide the development of complex interventions including those in stroke care.

Methods
The review included published research articles of evaluations of complex interventions in stroke prevention and management. Be-
Iterative phases of the MRC Framework for developing complex interventions

cause there is little clarity over the definition of a ‘complex intervention’, we defined complex interventions as educational or psychosocial interventions aimed at changing knowledge, beliefs or behaviors. Specific rehabilitation or therapy interventions and those targeted at service organization were excluded. These included: diagnostic tools; nonpharmacological therapies (including complementary medicine, physiotherapy, occupational therapy, speech and language therapy, cognitive-behavioral therapy); stroke units; early discharge interventions; integrated stroke care-pathways.

The review was not restricted by language or study design but interventions evaluated only in preliminary analyses or pilot studies were excluded.

Search Strategy

Multiple search strategies were used: electronic online database searches; hand searching of individual journals; and a ‘gray literature’ search. Five online databases were searched: MEDLINE 1966 to 2005; EMBASE 1980 to 2005; PsycINFO 1967 to 2005; Science Citation Index (SCI) and Social Science Citation Index (SSCI) 1900 to 2005. Recent journals (2000–2005) were hand searched to crosscheck for articles not identified by the electronic search (Stroke, Cerebrovascular Diseases, Lancet, New England Journal of Medicine, JAMA, BMJ, Health Education Research, Health Psychology, British Journal of Health Psychology, Social Science and Medicine, Patient Education and Counseling, Journal of Advanced Nursing, Health Promotion International). Existing reviews, UK health education and health policy documents were searched, as were the reference lists of included articles. Both a MeSH subject heading search and a key word search were conducted (last searched November 2005). The choice of search terms was guided by the MRC Framework and included multiple key words and phrases.

Articles describing the theoretical or methodological development of included studies were retrieved in addition to those documenting the evaluation itself.

One investigator (J.R.) conducted the search and rated studies for inclusion. Where it was unclear whether or not a study should be included, relevant articles were retrieved and discussed with a second investigator (C.M.) until consensus was achieved. In one case where the article could not be retrieved, the authors were contacted to request the full article. Decisions on 4 studies published in languages other than English were made based on translations of the abstract. The key article of 1 study judged to be relevant was retrieved in Chinese and translated in full.

Interventions were categorized by study aim and target group, and data extracted into predetermined tables to ensure standardization across studies.

Analysis

Because the review focused on the influence of theoretical and methodological development rather than on intervention efficacy, a meta-analysis was not conducted.

A number of criteria exist for evaluating study quality but most are not relevant in the context of this review (for example ‘blinding’ is a less relevant criterion to assess most complex interventions where it is impossible to conceal from intervention recipients or providers whether or not they have received the intervention). Instead, we used the MRC Framework recommendations for study development to define quality criteria. Studies were first classified according to the reported development process and whether the intervention was theoretically grounded (Table 1). Secondly, they were classified according to the chosen evaluation methods: RCT versus other designs; outcome measures (primary and secondary outcomes and use of standardized assessment measures) and consideration of statistical power. We considered it unlikely that studies would report explicit ‘phases’ of intervention development because the MRC Framework is not routinely used for this purpose. Studies might also predate the Framework.

The impact of interventions on outcomes (study ‘success’) was defined using three categories: interventions demonstrating a significant beneficial impact on all primary outcomes were defined as ‘successful’; those having a beneficial impact on at least one but not all primary outcomes were defined as ‘partially successful’; those which either failed to demonstrate an impact on any primary outcomes, or demonstrated a detrimental impact were defined as ‘failed’. Simple frequencies were used to describe study characteristics and chi-square tests used to explore associations between aspects of study design and outcomes.

Results

Over 12 000 references were identified and 733 retrieved yielding 95 articles covering 67 complex intervention studies. Six hundred and thirty-eight articles were excluded: 293 were not evaluation studies; 217 referred to specific interventions excluded from the review; 98 were not stroke specific; 21 reported pilot or preliminary findings only; 9 were not

The results of searches (1), (2) and (3) were combined with the Boolean operator ‘AND’.


The results of the searches (1), (2) and (3) were combined with the Boolean operator ‘AND’. The results of the MeSH subject heading and key word searches were then combined with the Boolean operator ‘OR’.
of the included studies, 40 were evaluated using RCTs and 27 using quasi-experimental, observational or qualitative designs. Interventions covered 4 broad themes: those aimed at changing professional behaviors in preventing and managing stroke (supplemental Table I, available online at http://stroke.ahajournals.org); those targeted at people from the general population and patients to improve primary and secondary prevention (supplemental Table II, available online at http://stroke.ahajournals.org); and those targeted at stroke patients and carers to improve recovery and adjustment after stroke (supplemental Table III, available online at http://stroke.ahajournals.org). Professional interventions included locally disseminated guidelines,11–14 stroke orders or protocols,15–20 a tool to aid clinical decision making21; and training or academic detailing.22–31 Primary prevention interventions included information and feedback,32,33 media campaigns,34,35 peer support and education,36 patient decision-aids,37–39 and multifactorial educational, screening and monitoring programs.40–47 Secondary prevention interventions included a shared medical record,48 an intervention incorporating a shared record plus monitoring,49 and multifaceted interventions incorporating educational and psychosocial components.50–52 Interventions to improve adjustment and recovery included information booklets/records,53–58 education, training and counseling,59–74 and social or emotional support.9,75–90

There were significant differences in the success of studies in different areas (χ²=12.64, df=4, P=0.013). Interventions to improve recovery, in particular social support or information interventions, were less likely to succeed, 12 (41.3%) failed compared with 3 (15.0%) primary/secondary prevention interventions and 3 (17.7%) professional interventions. However, prevention interventions and professional interventions were also less likely to have been evaluated using RCT methods (9, 45% and 6, 35% respectively compared with 24, 80% of interventions to improve recovery).

**TABLE 1. Criteria to Assess Theoretical Quality**

<table>
<thead>
<tr>
<th>Quality Assessment</th>
<th>Theoretical Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) Well grounded</td>
<td>The intervention itself was informed by some form of literature review and in addition by</td>
</tr>
<tr>
<td></td>
<td>either an established theoretical framework or empirical investigation conducted by the</td>
</tr>
<tr>
<td></td>
<td>authors.</td>
</tr>
<tr>
<td>B) Moderately grounded</td>
<td>A detailed analysis of at least one of the following was reported: an established</td>
</tr>
<tr>
<td></td>
<td>theoretical framework; evidence from a published systematic review supporting the</td>
</tr>
<tr>
<td></td>
<td>intervention; empirical investigation conducted by the authors; or review of empirical</td>
</tr>
<tr>
<td></td>
<td>studies conducted by the authors supporting the intervention.</td>
</tr>
<tr>
<td>C) Minimally grounded</td>
<td>A brief overview of literature was reported in support of the intervention or a detailed</td>
</tr>
<tr>
<td></td>
<td>review of the study area but not specifically in support of the intervention.</td>
</tr>
<tr>
<td>D) No theoretical grounding</td>
<td>Interventions did not report any research/cite any literature to support the use of the</td>
</tr>
<tr>
<td></td>
<td>intervention.</td>
</tr>
</tbody>
</table>

**THEORETICAL GROUNDING**

Theoretical grounding was difficult to establish from published reports because most studies presented only a brief introduction to the study area and an overview of the methods. Forty-two of the 67 studies reported some form of theoretical grounding for their intervention (supplemental Tables I to III) but only 14 were judged to be theoretically well developed (an ‘A’ rating).

Table 2 presents a list of theoretical research in support of the interventions. Although most studies included some form of literature review, this was not necessarily in support of the chosen intervention. Only 8 studies reported attempts to systematically review the literature or cited an existing systematic review. Nineteen studies referenced published theoretical frameworks to support their intervention choice (mostly from the psychological literature) and 13 conducted empirical research to inform intervention development.

**Outcome Assessment**

Study outcome measures are presented in Table 3. A range of single item questions, standardized/published scales (53 in total), or author-developed scales (15) were used. Author designed outcome measures (with or without validation) were mostly used to assess knowledge or satisfaction with care but also to assess self-rated quality of life, health expectations, ‘recovery-efficacy’, illness perceptions, assertiveness, decision-making and confidence. There was no association between type of measure (single item or scale), measure development (published or author developed) and study outcomes. Most studies used multiple measures to evaluate impact. Twenty-one RCTs and 16 quasi-experimental/obser-
vational studies listed 3 or more primary outcomes of interest with 10 RCTs and 12 non-RCTs listing 5 or more primary outcomes (supplemental Tables I to III). Studies with large numbers of primary outcomes (5 or more) were statistically less likely to be completely successful than those with fewer outcomes (5, 22.7% compared with 17, 38.6%) but were also less likely to fail (2, 9.1% compared with 16, 36.4% respectively, $\chi^2 = 12.1$, df = 2, $P = 0.002$).

Table 3. Summary of Primary Outcome Measures

<table>
<thead>
<tr>
<th>Measure: Professional Interventions</th>
<th>Primary/Secondary Prevention</th>
<th>Recovery &amp; Adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td>N=7</td>
<td>N=7</td>
</tr>
<tr>
<td>Refs. 13, 18, 23, 25, 26, 28, 30</td>
<td>Refs. 33, 34, 36, 37, 45–47</td>
<td>Refs. 55–60, 69, 72, 86</td>
</tr>
<tr>
<td>Psychological and social adjustment, perceived health-status, self-rated quality of life, social resources, confidence and self-esteem</td>
<td>N=1</td>
<td>N=1</td>
</tr>
<tr>
<td>Ref. 17</td>
<td>Refs. 54, 57, 59, 61, 64, 67–71, 73, 77, 79, 82, 84, 85, 87</td>
<td></td>
</tr>
<tr>
<td>Satisfaction</td>
<td>N=1</td>
<td>N=2</td>
</tr>
<tr>
<td>Ref. 11</td>
<td>Refs. 36, 37</td>
<td>Refs. 9, 53, 56, 58, 59, 64, 69, 75, 77, 84, 86, 87</td>
</tr>
<tr>
<td>Physical functioning, independence, disability in activities of daily living</td>
<td>N=1</td>
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</tr>
<tr>
<td>Ref. 17</td>
<td>Refs. 54, 58, 62, 68, 77, 84, 86, 87</td>
<td></td>
</tr>
<tr>
<td>Mood: anxiety and depression</td>
<td>N=1</td>
<td>N=8</td>
</tr>
<tr>
<td>Ref. 17</td>
<td>Refs. 58, 61, 64, 67, 68, 77, 84, 86, 87</td>
<td></td>
</tr>
<tr>
<td>Mortality, morbidity and institutionalization</td>
<td>N=2</td>
<td>N=6</td>
</tr>
<tr>
<td>Refs. 12, 24</td>
<td>Refs. 40, 42–45, 51</td>
<td>Ref. 68</td>
</tr>
<tr>
<td>Changes in clinical practice</td>
<td>N=9</td>
<td>N=1</td>
</tr>
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Methodological Quality

There were significant differences in the success of interventions using different evaluation methods ($\chi^2 = 17.2$, df = 2, $P < 0.001$). Only 4 non-RCT studies distinguished between primary and secondary outcomes, but all achieved at least partial success and 12 (44.4%) achieved all of their aims. One study conducted a qualitative evaluation of a family nursing intervention concluding that all aspects of the intervention were useful, but did not specifically test a hypothesis. Ten (25.6%) trials were successful, 11 (28.2%) were partially successful but nearly half (18, 46%) were unsuccessful. Sixteen (41.0%) RCT studies included a power calculation; 6/21 RCT studies with multiple (>2) primary outcomes reported considering statistical power (Table 4). One study considered power for 4/7 primary outcomes and although it was still slightly underpowered (it did not reach the target recruitment figure) it was successful in influencing all of the outcomes for which power was estimated. In the only study to consider power for all measures, the authors anticipated that the intervention would lead to a 25% difference between groups in all risk factor control outcomes. The intervention did not have the anticipated impact, the authors concluding that risk factor control rates in the control group were better than expected, and consequently that the study was underpowered. Only one RCT study reported conducting any form of exploratory trial of the intervention before the main study. It was used to test the feasibility of implementing a telephone intervention to provide nursing follow-up to improve adjustment and

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recovery and to test the validity of outcome measures. In one of the social support intervention studies, the authors had already conducted an RCT of 1 of the intervention components (the information pack) which could be described as a pilot evaluation. The authors also conducted research to inform their power calculation before the main trial and this work could be defined as the “modeling phase” of development. However, because this was the only study that did so, the relationship between study quality and success is difficult to assess. Studies reporting a power calculation to inform trial methods were no more likely to have been successful than those which did not report considering statistical power.

<table>
<thead>
<tr>
<th>Study &amp; Date</th>
<th>Outcome Measures</th>
<th>Time Point</th>
<th>Power Calculation</th>
<th>No. Recruited</th>
<th>Impact on Primary Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allen 2004, USA</td>
<td>Global “well-being” (5 domain score developed by authors)</td>
<td>3 months postintervention</td>
<td>96 patients gives 90% power to detect small to moderate effect sizes across the five domains (\alpha=0.05).</td>
<td>96</td>
<td>There was a significant effect size of 0.53 on the global test score. Effect sizes were significant on all domains</td>
</tr>
<tr>
<td>Boter 2004, Netherlands</td>
<td>Dissatisfaction with stroke care (Satisfaction with Stroke Care questionnaire - SASC-19)</td>
<td>6 months postdischarge</td>
<td>524 participants gives 80% power to detect a 50% reduction in dissatisfaction ((\alpha) not reported)</td>
<td>536</td>
<td>No statistical differences in dissatisfaction scores between groups except intervention patients had higher scores on role limitation.</td>
</tr>
<tr>
<td>Clark 2003, Australia</td>
<td>1) Family functioning (McMaster Family Assessment Device–FAD) 2) Functional status (Barthel Index - BI) 3) Social recovery (Adelaide Activities Profile - AAP)</td>
<td>6 months postdischarge</td>
<td>30 families give 80% power to detect a 0.14 decline in FAD from premorbid state to 6 months ((\alpha) not reported).</td>
<td>62</td>
<td>FAD scores remained stable in the intervention arm but declined in the control arm. The BI was slightly higher for the intervention group than controls. The AAP was better in the intervention group than control group for domestic chores, household maintenance and social activities.</td>
</tr>
<tr>
<td>Ellis 2005, UK</td>
<td>1) All relevant risk factors controlled 2) Blood pressure &lt; 140/85 3) Smoking cessation 4) Blood glucose &lt; 8.0 mmol/L 5) HbA1c &lt; 7.5% 6) Cholesterol &lt; 5.0 mmol/L</td>
<td>5 months postintervention</td>
<td>89 patients per group gives power to detect a change from 25% risk factor ‘on target’ to 50% ((\alpha) not reported)</td>
<td>205</td>
<td>After adjusting for baseline differences the intervention had no significant impact for any risk factors.</td>
</tr>
<tr>
<td>Forster 1996, UK</td>
<td>Improvement in social activities (Frenchay Activities Index–FAI)</td>
<td>12 months postrecruitment</td>
<td>160–220 patients gives 90% power to detect a 4-point improvement in the FAI ((\alpha) not reported)</td>
<td>240</td>
<td>No significant differences in FAI between groups. Qualitative analysis revealed that aspects of the nursing role (concern, attention, empathy and interest) were valued by the patients and careers.</td>
</tr>
<tr>
<td>Harari 2004, UK</td>
<td>Self-reported bowel movements (BM) per week</td>
<td>1, 3, 6 and 12 months postintervention</td>
<td>120 patients would give 90% power to detect a 54% increment in BMs/week ((\alpha) not reported)</td>
<td>146</td>
<td>Mean No. of BMs per week was higher in the intervention group compared to the controls and persisted at 12 months. Self-rated normal BMs were also higher in the intervention group.</td>
</tr>
<tr>
<td>Kaira 2004, UK</td>
<td>1) Death and institutionalization</td>
<td>3 &amp; 12 months poststroke</td>
<td>300 patients would give the study 80% power to detect:</td>
<td>268</td>
<td>No significant differences were found in mortality/institutionalization. Patients in the intervention arm had lower median HAD scores and higher median Euroqol scores. A higher proportion were less disabled and had low Rankin scores at 3-months.</td>
</tr>
</tbody>
</table>
Impact of Study Quality on Outcomes

After adjusting for aspects of methodological quality (study design and statistical power) there was no evidence that theoretical development was associated with success in primary outcomes. Six RCT studies were judged to be theoretically well developed and included a power calculation; 2 of these were successful,50,54 2 were partially successful84,86,88 and 2 unsuccessful.9,71 Of the 2 successful interventions, the first had a significant impact on family functioning, which remained stable in the intervention group but declined over...
time in the control group; the second had a significant effect on an author-defined (and validated) global well-being score (0.53 effect size), but the implications of this for clinical practice are difficult to interpret. Five non-RCT studies were also considered well developed; 1 of these was successful, 3 were partially successful, and 1 did not test a specific hypothesis. If the theoretically moderately well developed studies (‘B’ rated) and well developed studies (‘A’ rated) are combined, the findings remain the same with no clear evidence that theoretical or methodological quality was associated with improved outcome.

### Discussion

This review aimed to investigate theoretical and methodological quality in the development and evaluation of complex interventions in stroke care and the impact of this on study outcomes. The 67 intervention studies included in the review were targeted at a range of health outcomes. The majority of interventions identified were targeted at an individual level (general public, stroke patients, carer-givers and health professionals) rather than at a social or environmental level. This may reflect the chosen search criteria because environmental and social interventions are more likely to be targeted at the general population and aim to prevent a range of diseases. Such studies might not have been found unless they included stroke specific outcomes.

Observational or quasi-experimental studies tended to yield better outcome success than RCT designs. Differences may reflect difficulties in demonstrating success using RCT methods, but may also be influenced by publication bias, because journals are more likely to publish studies if there is a significant treatment effect. If journals are less likely to publish nonsignificant results for observational or quasi-experimental studies than for RCTs, then interventions evaluated in RCTs would appear to be less successful than those evaluated using other methods.

Study design may also explain the apparent lack of success of interventions focusing on patient and carer adjustment and recovery because these studies were more likely to be evaluated in RCTs. There were few RCT studies evaluating interventions in primary or secondary prevention, possibly reflecting problems of recruitment, randomisation and follow-up, for relevant community interventions. Such interventions may also present ethical difficulties attributable to the requirement that researchers withhold the intervention from some groups/patients. For the studies included in this review, a number of novel quasi-experimental methods were used in an attempt to overcome such difficulties, including matched controls, time-lag controls, or ‘before and after’ studies, with or without qualitative evaluation. However, the MRC framework suggests that these methods are inadequate for evaluating efficacy because nonrandom allocation of participants may lead to bias. Using the MRC Framework (with its focus on RCTs) as a marker of quality in complex intervention evaluation may lead to exclusion of those interventions which best serve the needs of disadvantaged groups (because these groups are more difficult to identify, recruit and retain in research studies). It may also lead to exclusion of interventions that have the most impact on longer-term population health goals (such as mortality rates or behavior change). Although theoretically longer-term follow up is not a problem of RCTs, in practice RCTs are more difficult and expensive to conduct over long periods of time.

One of the potential strengths of the MRC Framework is that it sets standards for theoretical and methodological development within an RCT design such as highlighting the importance of considering statistical power. However, a substantial proportion of the RCTs in this review did not include a power calculation to justify sample size. No relationship was found between reporting a power calculation and study success, possibly because many of the studies that did not conduct a power calculation were still adequately powered; conversely, not all of the studies that reported a power calculation did achieve statistical power. Consideration of statistical power should be more than an

### TABLE 4. Continued

<table>
<thead>
<tr>
<th>Study &amp; Date</th>
<th>Outcome Measures</th>
<th>Time Point</th>
<th>Power Calculation</th>
<th>No. Recruited</th>
<th>Impact on Primary Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilling 2005, UK</td>
<td>Satisfaction with services (Pound Scale)</td>
<td>3 &amp; 12 months postrandomisation</td>
<td>336 patients give 80% power to detect a 15% difference in satisfaction between groups (α not reported).</td>
<td>340</td>
<td>No difference in overall satisfaction score between groups for either patients or carers. Satisfaction with some aspects of care was higher in the intervention group than the control group for patients and carers at particular time points but no consistent patterns.</td>
</tr>
<tr>
<td>Van Den Hueil 2000, Netherlands</td>
<td>1) Confidence in knowledge about relevant themes related to being a caregiver (a new instrument developed by the authors) 2) Use of active coping strategies (Utrecht Coping List)</td>
<td>14 weeks from baseline</td>
<td>76 respondents per group gives 80% power to detect a medium effect in outcomes; 547 respondents per group would give 80% power to detect small effects (α not reported).</td>
<td>130 group 1 78 group 2 49 group 3</td>
<td>Both interventions achieved small increases in confidence in knowledge of patient care and use of active coping strategies The group program achieved a small increase in social support seeking. No differences between home and group support.</td>
</tr>
</tbody>
</table>
administrative task and needs to be theoretically justified. Exploratory evaluations before the main study could have been used to make more realistic estimates of intervention impact. Authors could then have adjusted sampling or outcome measures at the outset.

For most of the studies there was little evidence that authors considered the theoretical development, or the mechanisms by which the intervention was expected to influence outcomes. However, this was not necessarily the fault of the investigators. For example, in 2 social-support intervention studies the interventions were existing services rather than services designed specifically for the study.\textsuperscript{77,84}

Lack of clarity about the mechanisms by which interventions work makes it difficult to pool the results of similar studies in systematic reviews or meta-analyses, because although intervention components appear similar, we do not know whether interventions are delivering similar ‘packages’ of care. In one systematic review of problem solving interventions for carers after stroke, the authors concluded that poor theoretical and methodological quality coupled with a diverse range of intervention components made it impossible to draw conclusions about efficacy.\textsuperscript{98} Similar problems have been reported in systematic reviews of other complex stroke interventions such as information and education.\textsuperscript{99}

Requirements for study design and presentation of results inevitably change over time and our review is limited in that inferences about study development are based on published or reported information only. It is possible that some studies did actually conduct empirical work or pilot their interventions but did not report it. However, it is of concern that so few studies reported an appropriate literature review or considered established theory. It would not be acceptable within a standard clinical trial to test out a pharmaceutical intervention in a phase III study without sufficient understanding of the mechanisms by which the drug influences bodily processes. Yet, complex health service interventions seem to be developed based on ad-hoc assumptions, and evaluated using methods where at the end of the study it is impossible to understand the reasons for success or failure.

Complex interventions often aim to influence a number of outcomes, or outcomes that are difficult to encapsulate in a single measure. In just over half of the studies multiple outcome measures were used. In some cases, authors may have incorporated multiple measures in the hope that by ‘hedging their bets’ it would enhance the chance of at least one of the measures showing a significant result. Non-RCT studies were particularly poor at specifying the main outcomes of interest and this may explain why they were less likely to have failed. However, this was not necessarily the fault of the investigators. An evaluation of intervention implementation (process evaluation\textsuperscript{2}) could have enlightened our understanding.

Conclusion

This literature review has highlighted inadequacies in the development and evaluation of complex interventions in stroke care. Using the MRC Framework as a measure of quality, we found studies to be lacking in terms of theoretical and methodological rigour. This may explain the negative results commonly reported in RCTs. In the future, researchers should pay greater attention to theoretical and methodological rigour. However, new methods also need to be developed to help unpack intervention complexity. Qualitative methods and process evaluation could be used to help interpret trial findings\textsuperscript{100} but more research to investigate their role alongside RCTs and their potential impact on study outcomes is required.

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Disclosures

None.

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2. Booth J, Hillier VF, Waters KR, Davidson I. Effects of a stroke reha-

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27. Booth J, Hillier VF, Waters KR, Davidson I. Effects of a stroke reha-
10 Stroke September 2006


<table>
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<th>Participants</th>
<th>Components, 'Dose' &amp; Duration</th>
<th>Theoretical Rating</th>
<th>Study Design*</th>
<th>No. Primary Outcome Measures</th>
<th>Success in Primary Outcomes**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Booth 2005, UK</td>
<td>37 patients; 6 nursing staff</td>
<td>7 hours of education delivered by a senior therapist, covering positioning, therapeutic handling of patients and facilitation of morning activities. Teaching methods included: 1) formal lectures 2) simulated patient demonstrations 3) video demonstrations, 4) experiential learning.</td>
<td>A</td>
<td>QE</td>
<td>2</td>
<td>P</td>
</tr>
<tr>
<td>Bray 2005, Australia</td>
<td>61 paramedics in emergency services units: 18 intervention; 43 control</td>
<td>1) One hour education session covering: stroke aetiology, symptoms, risk factors, assessment, documentation of onset, diagnosis and management 2) Instruction in the use of Melbourne Ambulance Stroke Screen assessment tool (MASS)</td>
<td>B</td>
<td>QE</td>
<td>2</td>
<td>P</td>
</tr>
<tr>
<td>CASPR 2005, USA</td>
<td>423 patients with a diagnosis of ischaemic stroke at 6 hospitals</td>
<td>Stroke 'orders' provided on hospital discharge containing templates and checklists of best practice recommendations for nurses to complete.</td>
<td>A</td>
<td>BA</td>
<td>6</td>
<td>P</td>
</tr>
<tr>
<td>Eo 2002, South Korea</td>
<td>164 paramedics</td>
<td>Training in stroke knowledge from 3 emergency specialists covering stroke definition, signs and symptoms, prehospital neurological examination, and emergency care. 'Dose' not specified.</td>
<td>D</td>
<td>BA</td>
<td>7</td>
<td>P</td>
</tr>
<tr>
<td>Forster 1999, UK</td>
<td>32/40 nurses</td>
<td>1) Two theory-based lectures from a physiotherapist 2) A 2-hour interactive practical session. Program delivery designed to fit around shifts, to improve access to training.</td>
<td>B</td>
<td>BA+Qual</td>
<td>2</td>
<td>S</td>
</tr>
<tr>
<td>Heineman 2003, USA</td>
<td>131/352 doctors; 134/244 other health professionals</td>
<td>1) One 1-hour lecture covering the clinical practice guidelines. 2) A packet of information on post stroke rehabilitation.</td>
<td>B</td>
<td>BA</td>
<td>1</td>
<td>P</td>
</tr>
<tr>
<td>Jackson 2004, Australia</td>
<td>162/272 general practitioners</td>
<td>1) All practitioners receive copies of guidelines on prescribing highlighting under-use of antithrombotics 2) One educational visit from a pharmacist 3) Distribution of computer mouse pads embossed with AF guidelines in a flowchart form and RHH anticoagulation guidelines.</td>
<td>C</td>
<td>QE</td>
<td>3</td>
<td>P</td>
</tr>
<tr>
<td>Monaghan 2005, UK</td>
<td>75 patients admitted to a stroke rehabilitation ward.</td>
<td>Intervention 1 1) A form for recording problems in achieving patients' rehabilitation goals to encourage patient participation in goal setting. Intervention 2 2) Discussion of patients' treatment plans at the foot of the patient's bed so patients could become involved in planning.</td>
<td>C</td>
<td>QE-TS</td>
<td>5</td>
<td>P</td>
</tr>
<tr>
<td>Nir 2004, Israel</td>
<td>155 stroke survivors aged 57–93: 82 intervention; 73 control</td>
<td>A 19-day structured written nursing rehabilitation program consisting of a guidebook and feedback form with topics addressing common stroke problems, tailored to the individual patient and caregiver (focusing on affective, cognitive and instrumental domains).</td>
<td>D</td>
<td>RCT</td>
<td>7</td>
<td>P</td>
</tr>
<tr>
<td>Pennington 2005, UK</td>
<td>717 stroke patients; 36 speech and language therapists and their teams</td>
<td>Two teaching strategies to improve adherence to clinical guidelines on speech and language therapy: 1) 2.5 days training over 7 weeks in clinical governance, evidence based healthcare, critical appraisal, research methods, and evidence-based guidelines (short talks, group discussion, problem-based learning and self directed study).</td>
<td>B</td>
<td>RCT</td>
<td>1</td>
<td>F</td>
</tr>
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<td>Study, Date &amp; Country</td>
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<td><strong>PRISM 2003,21 UK</strong></td>
<td>1952 acute ischaemic stroke patients attending 16 hospital centres. Clinicians (N) unknown.</td>
<td>2) 5 fortnightly training days (as above), plus 2.5 additional training days on how to implement practice change</td>
<td></td>
<td>RCT</td>
<td>1</td>
<td>F</td>
</tr>
<tr>
<td><strong>PROTECT, 2004,18–20 USA</strong></td>
<td>130/144 consecutive patients acute stroke/TIA patients admitted to a university hospital stroke service.</td>
<td>A toolkit to improve initiation and maintenance of 8 secondary prevention program goals in hospital. The toolkit includes: 1) pocket cards with program goals 2) patient information sheets 3) preprinted admission orders 4) educational sheet to document implementation. 5) telephone call at 2–4 weeks post discharge</td>
<td></td>
<td>C</td>
<td>BA</td>
<td>8</td>
</tr>
<tr>
<td><strong>SAFRE, 2004,24 Australia</strong></td>
<td>715 patients, 121 physicians, 452 residential care staff</td>
<td>1) Two 30-minute outreach detailing visits by a pharmacist in the physician’s surgery focusing on evidence-based guidelines on falls prevention. 2) Audit data on fall rates, prescribing patterns and risk reduction practices.</td>
<td></td>
<td>B</td>
<td>RCT</td>
<td>1</td>
</tr>
<tr>
<td><strong>Sheik 2004,12 USA</strong></td>
<td>Medicare beneficiaries aged 65+ years in 14 states.</td>
<td>1) Development of indicators, outcome measures, conferences, meetings, newsletters 2) State-wide data feedback on indications, contraindications for treatment 3) Local data analysis to evaluate quality</td>
<td></td>
<td>D</td>
<td>QE-MC</td>
<td>2</td>
</tr>
<tr>
<td><strong>Silagy 2002,13 Australia</strong></td>
<td>243 General practitioners</td>
<td>Single dissemination of locally adapted guidelines developed using: 1) formal assessment of national scientific evidence by a multidisciplinary team 2) panel meetings 3) open forum sessions</td>
<td></td>
<td>D</td>
<td>RCT</td>
<td>2</td>
</tr>
<tr>
<td><strong>Williams 2003,14 UK</strong></td>
<td>Professionals admitting a single teaching hospital</td>
<td>A multidisciplinary online clinical information service (MOCS) providing best practice evidence including stroke care.</td>
<td></td>
<td>C</td>
<td>QE-TS</td>
<td>1</td>
</tr>
<tr>
<td><strong>Zhang 2003,30,31 China</strong></td>
<td>8 Community nurses and 60 stroke patients discharged to the community</td>
<td>A self-care training program for nurses with standardized, individualized and family focused components tailored to the patient’s rehabilitation needs</td>
<td></td>
<td>B</td>
<td>RCT</td>
<td>4</td>
</tr>
</tbody>
</table>

*Design abbreviations: Randomised Controlled Trial (RCT); Quasi-experimental study (QE); time series controlled design (QE-TS); before and after study (BA); qualitative evaluation (Qual).**Outcome success: successful in all primary outcomes (S); partially successful, ie, success in at least one but not all primary outcomes (P); failure in all primary outcomes (F).
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</tr>
</thead>
<tbody>
<tr>
<td>Agewall 1994, Sweden</td>
<td>508 male treated hypertensives aged 50–72 with high cholesterol, diabetes or smoking</td>
<td>1) Group information on risk factors 2) Ongoing monitoring and prescription of pharmacological therapy 3) Smoking cessation program: physician visits and five 1 hour weekly meetings, prescription of nicotine gum.</td>
<td>C</td>
<td>RCT</td>
<td>8</td>
<td>P</td>
</tr>
<tr>
<td>Allen 2004, USA</td>
<td>96 stroke/TIA patients</td>
<td>1) In-home bio-psychosocial assessment (1-month postdischarge) 2) Review by an interdisciplinary stroke team within 7 days. 3) Delivery of personalized self-management plans on risk factor and depression management to patients and primary care professionals.</td>
<td>A</td>
<td>RCT</td>
<td>1</td>
<td>S</td>
</tr>
<tr>
<td>Banet 1997, USA</td>
<td>52 patients discharged after first stroke</td>
<td>1) Shared medical record 2) Inpatient teaching 3) American Stroke Association leaflets One-off intervention delivered in hospital</td>
<td>C</td>
<td>RCT</td>
<td>3</td>
<td>F</td>
</tr>
<tr>
<td>Becker 2001, USA</td>
<td>547/6087 English speaking respondents to a telephone survey</td>
<td>A 4-month social marketing intervention educating people about stroke, the need to call 911, and the need to attend risk factor screenings. Delivered through: 1) public service announcements 2) television, 3) advertising in newspapers 4) public stroke screenings. 5) distribution of ‘Brain attack’ fliers advertising the screenings</td>
<td>C</td>
<td>BA</td>
<td>4</td>
<td>P</td>
</tr>
<tr>
<td>DAAFI 2005, Canada</td>
<td>Adult community NVAF patients, with no indications/ contraindications for Warfarin.</td>
<td>A decision aid booklet for patients outlining the risks and benefits of anticoagulant therapy</td>
<td>B</td>
<td>RCT</td>
<td>1</td>
<td>S</td>
</tr>
<tr>
<td>Ellis 2005, UK</td>
<td>205 patients diagnosed with stroke, TIA or amaurosis fugax 3 months previously, one or more risk factors &amp; no cognitive impairments.</td>
<td>1) Monthly risk factor monitoring reviews (over a 3 month period) from a specialist stroke nurse delivered in outpatients departments. 2) Individualized secondary prevention advice tailored to the patient’s functional ability. 3) Patient-held record detailing risk factor control targets, updated at each visit.</td>
<td>B</td>
<td>RCT</td>
<td>6</td>
<td>F</td>
</tr>
<tr>
<td>Eriksson 1997, Sweden</td>
<td>295 patients with hypertension diabetes or post-MI attending county health institutions</td>
<td>38 hours of stroke prevention training plus a 4-day refresher course one year later: 1) Patient education and discussion on exercise, relaxation, physiology, food preparation, addiction and healthy living. 2) Formal lectures on hypertension, diabetes, MI, and nutrition. 3) Individual guidance from a dietician, a physiotherapist, a fitness assistant, a nurse and a physician.</td>
<td>B</td>
<td>BA</td>
<td>5</td>
<td>P</td>
</tr>
<tr>
<td>Fang 1999, China</td>
<td>General population: 18786 intervention, 18876 control.</td>
<td>1) Fortnightly risk factor monitoring visits 1987–1990 for patients with hypertension or diabetes. 2) Weekly visits from intervention doctors providing individualized treatment. 3) Health education program to all the residents.</td>
<td>C</td>
<td>QE</td>
<td>1</td>
<td>S</td>
</tr>
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<tr>
<td>Glanz 1986, USA</td>
<td>67 (intervention) and 43 (control) participants at 2 senior citizen centers</td>
<td>1) A single education session plus 2 booster sessions to train peer facilitators (PF) in stroke, TIA, risk factor control stress management, medication, communication skills and health service use. 2) Peer support and education delivered by PFs to elderly care residents (<em>dose</em> not reported)</td>
<td>B</td>
<td>QE</td>
<td>9</td>
<td>S</td>
</tr>
<tr>
<td>HDFP 1984, USA</td>
<td>10,940 participants with a diastolic blood pressure ≤90 mm Hg</td>
<td>Stepped care therapy at clinics involving: 1) blood pressure assessment and follow-up. 2) goal setting and prescription of pharmacological therapy to reduce diastolic blood pressure &lt;90 mm Hg</td>
<td>D</td>
<td>RCT</td>
<td>2</td>
<td>S</td>
</tr>
<tr>
<td>Iso 1998, Japan</td>
<td>General population: 3219 (full), 1468 (minimal)</td>
<td>Minimal intervention (control) 1) Blood pressure screening 2) Follow-up every 2 years. Full intervention (cases) 3) Blood pressure screening 4) Referral to clinics for high risk individuals 5) Health education at screening sites 6) Adult classes and nurse home visits 7) Training about healthy diet 8) Community-wide media disseminated education to encourage participation in screening</td>
<td>D</td>
<td>QE</td>
<td>5</td>
<td>S</td>
</tr>
<tr>
<td>Jiang 2004, China</td>
<td>1558 people with first stroke: 736 intervention; 820 control</td>
<td>1) Hypertension screening over a 3-year period 2) Monitoring and counselling</td>
<td>B</td>
<td>OE</td>
<td>2</td>
<td>S</td>
</tr>
<tr>
<td>Lin 2004, Taiwan</td>
<td>4977/5965 people in the general population aged 40+ years</td>
<td>1) Hypertension screening plus follow-up delivered by 143 volunteer villagers at 1 year and 3.5 years 2) Health education 3) Village based hypertension campaigns 4) Yearly weight control and smoking cessation classes 5) Yearly television broadcasts</td>
<td>A</td>
<td>BA</td>
<td>4</td>
<td>S</td>
</tr>
<tr>
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<tr>
<td>Lindsey 2000, USA</td>
<td>3116 people living in a northwestern community</td>
<td>A multifactorial campaign 1) 1-hour TV broadcast advertising a stroke screening schedule (2 months before screening. 2) Local newspaper articles on stroke plus the screening schedule.</td>
<td>D</td>
<td>BA+ control</td>
<td>1</td>
<td>S</td>
</tr>
<tr>
<td>Man-Son-Hing 1999, USA/Canada</td>
<td>287 patients with atrial fibrillation from an aspirin cohort study</td>
<td>1) Single delivery of a patient decision booklet, plus a personal worksheet on consequences of stroke and Warfarin monitoring. Estimates of stroke risk for different therapies provided 2) Physicians receive a manual on the decision aid.</td>
<td>B</td>
<td>RCT</td>
<td>5</td>
<td>S</td>
</tr>
<tr>
<td>Mazor 2002, USA</td>
<td>A convenience sample of 177 volunteers, aged 18 yrs, able to read and write English and without specialist stroke knowledge.</td>
<td>Single ‘dose’ information packet interventions: 1) short factual information on stroke 2) facts + pathophysiology 3) facts + explanations of causal links 4) pathophysiology and explanation 5) fictitious account of a person having a stroke</td>
<td>B</td>
<td>RCT</td>
<td>1</td>
<td>P</td>
</tr>
<tr>
<td>Rimmer 2000, USA</td>
<td>35 stroke survivors&gt;6 months poststroke</td>
<td>3 educational sessions over 12 weeks: 1) fitness class 2) hands-on meal preparation 3) psychosocial intervention incorporating ‘Stages of Change’ model</td>
<td>B</td>
<td>QE</td>
<td>8</td>
<td>P</td>
</tr>
<tr>
<td>Stern 1998, USA</td>
<td>657 adults living in the community or senior independent living settings</td>
<td>Intervention one 1) A professionally produced slide/audio educational program on stroke types and the warning signs. Intervention two 1) Slide/audio program</td>
<td>B</td>
<td>BA</td>
<td>1</td>
<td>S</td>
</tr>
<tr>
<td>Willoughby 2001, USA</td>
<td>85/107 volunteers attending a stroke screening program</td>
<td>1) Single screening for stroke risk factors 2) Nurse counselling on ways to reduce stroke risk; 3) Dietician and pharmacist advice; 4) National Stroke Association stroke reduction plan.</td>
<td>C</td>
<td>BA</td>
<td>3</td>
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</tr>
</thead>
<tbody>
<tr>
<td>Ayana 2001,53 UK</td>
<td>252 stroke inpatients</td>
<td>A patient-held record used over a 6-month period for therapists to record details of each of the main needs/problems they dealt with. Patients could also record their own comments.</td>
<td>B</td>
<td>QE-TS</td>
<td>3</td>
<td>P</td>
</tr>
<tr>
<td>Boter 2004,75,76 Netherlands</td>
<td>536/691 hospitalized first stroke patients. Strict eligibility criteria</td>
<td>1) Three telephone contacts by a specialist stroke nurse 2) One home visit-duration tailored to the individual family. Nurses provided information, reassurance and problem solving advice using a standardized checklist of topics</td>
<td>C</td>
<td>RCT</td>
<td>1</td>
<td>F</td>
</tr>
<tr>
<td>Clark 2003,54 Australia</td>
<td>62 community stroke patients and spouses; 32 intervention, 30 control.</td>
<td>1) Stroke information package covering stroke consequences, secondary prevention, coping and social support services 2) Three 1-hour visits from a social worker at three time points: 3-weeks, 2-months and 5-months post discharge</td>
<td>A</td>
<td>RCT</td>
<td>3</td>
<td>S</td>
</tr>
<tr>
<td>Dennis 1997,77 UK</td>
<td>417 stroke patients</td>
<td>Individualised stroke Family Support Officer visits (ranging between 0 and 17 contacts) aiming to: 1) coordinate between health care services, social services and voluntary agencies. 2) provide counselling.</td>
<td>D</td>
<td>RCT</td>
<td>12</td>
<td>F</td>
</tr>
<tr>
<td>Duhamel 2004,78 Canada</td>
<td>2 MI patients and their families (spouse or caregiver); 2 stroke patients and their families.</td>
<td>Family systems nursing intervention delivered at 2 week intervals: 1) five 30-minute preclinical sessions with nursing staff only 2) five 60-minute clinical sessions in which family members participated in finding solutions to facilitate rehabilitation.</td>
<td>A</td>
<td>Qual</td>
<td>The authors used a constructivist approach and did test specific hypotheses.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evans 1984,59 USA</td>
<td>43 stroke patients and carers/family members</td>
<td>1) Single stroke class including formal teaching and group discussion on: stroke physiology, cognitive and perceptual changes, home visits, home modifications and architectural barriers. 2) Folder with resource materials.</td>
<td>B</td>
<td>BA</td>
<td>2</td>
<td>S</td>
</tr>
<tr>
<td>Evans 1998,60 USA</td>
<td>188 stroke carers</td>
<td>Intervention 1: 2 weekly education sessions 1) OT-led classes during 3rd week of hospitalization, lecture+video on consequences of stroke. 2) Social worker-led class within 3 days of first OT-led class, on treatments. Intervention 2: counselling delivered over 12+weeks 3) Education as above 4) Seven 1-hour sessions with social workers trained in cognitive behavioural therapy to develop coping strategies.</td>
<td>B</td>
<td>RCT</td>
<td>4</td>
<td>S</td>
</tr>
</tbody>
</table>
### TABLE III. Continued

<table>
<thead>
<tr>
<th>Study, Date, Country</th>
<th>Participants</th>
<th>Components, ‘Dose’ &amp; Duration</th>
<th>Theoretical Rating</th>
<th>Study Design</th>
<th>No. Primary Outcome Measures</th>
<th>Success in Primary Outcomes**</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIRST 2004,62,63 USA</td>
<td>291/1683 stroke patients aged 45+ admitted to 4 acute-care hospitals and 4 rehabilitation hospitals.</td>
<td>15 weekly/fortnightly family meetings lasting ~90 minutes during the first 6 months post-stroke provided by a clinical psychologist or social worker and including: 1) education 2) social support network cohesion 3) training in problem solving</td>
<td>A</td>
<td>RCT</td>
<td>1</td>
<td>F</td>
</tr>
<tr>
<td>Forster 1996,79,80,81 UK</td>
<td>240 patients with stroke</td>
<td>1) ~8 visits from a nurse support worker over 6 months providing advice on goal setting, problem-solving and specific issues. 2) Information packs containing detailed information on benefits.</td>
<td>A</td>
<td>RCT + Qual</td>
<td>1</td>
<td>F</td>
</tr>
<tr>
<td>Frank 2000,65 UK</td>
<td>39 community patients less than 2 years post stroke</td>
<td>1) Workbook intervention designed to increase perceptions of control. 2) Two weekly telephone follow-ups to give patients the opportunity to ask questions.</td>
<td>C</td>
<td>RCT</td>
<td>3</td>
<td>F</td>
</tr>
<tr>
<td>Friedland 1992,62,63 Canada</td>
<td>88 community stroke patients recently discharged from an OT agency</td>
<td>8–12 weekly social support sessions from occupational therapists focusing on mapping individual social support systems, identifying deficiencies and goal setting.</td>
<td>C</td>
<td>RCT</td>
<td>2</td>
<td>F</td>
</tr>
<tr>
<td>Geddes 1989,84 UK</td>
<td>19 patients lacking social support admitted to a stroke rehabilitation unit; 61 controls.</td>
<td>Social support intervention involving the use of ‘substitute families’ for patients discharged from hospital after stroke. It is unclear how long the intervention lasted</td>
<td>D</td>
<td>QE</td>
<td>3</td>
<td>S</td>
</tr>
<tr>
<td>Grant 2001,64,65 USA</td>
<td>74 hospitalized ischemic stroke survivors and their primary carers.</td>
<td>1) Four weekly sessions from a nurse at 1–4 weeks post-discharge to provide training in problem solving for family carers. 2) Fortnightly telephone follow up by nurses at 6–12 weeks post-discharge</td>
<td>A</td>
<td>RCT</td>
<td>6</td>
<td>P</td>
</tr>
<tr>
<td>Harari 2004,66 UK</td>
<td>148/1715 hospital stroke patients. Patients included if they had &gt;1 criteria used to diagnose bowel problems, no severe deficits. Patients without social networks or unlikely to finish the trial excluded.</td>
<td>1) One-off assessment using an evidence-based protocol by a trained nurse 2) Targeted patient and carer education; provision of a booklet 3) Diagnostic summary and treatment recommendations sent to the patient’s GP and ward physician.</td>
<td>B</td>
<td>RCT</td>
<td>1</td>
<td>S</td>
</tr>
<tr>
<td>Hartke 2003,67 USA</td>
<td>88/500 spouses of stroke survivors acting as primary carers for ≥1 month</td>
<td>Eight 1-hour telephone support sessions for stroke carers facilitated by a psychologist, social worker or nurse covering stroke facts, communication, problem solving, stress, and goal-setting</td>
<td>A</td>
<td>RCT</td>
<td>5</td>
<td>F</td>
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<td>Johnson &amp; Pearson 2000, USA</td>
<td>41/430 community stroke survivors responding to a mailing</td>
<td>Eight 2-hour structured classes delivered over a 4-week period covering stroke facts, disability, emotional aspects of stroke, self-esteem, and ways of encouraging a positive active lifestyle.</td>
<td>A QE-MC</td>
<td>3</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Kalra 2004, UK</td>
<td>268/300 patients randomized, 134 intervention, 134 control</td>
<td>1) Three to 5 (30–45 minutes) tailored hands-on caregiver training sessions on common stroke related problems before discharge from hospital 2) One follow-up home training session post discharge. Training focused on instruction about common stroke related problems</td>
<td>B RCT</td>
<td>7</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>Lai 2004, China</td>
<td>21 stroke patients living at home</td>
<td>Weekly 1.5 hours video conferencing rehabilitation sessions delivered over 8 weeks and provided by a physiotherapist: 1) educational talks on stroke physiology, symptoms, clinical and social services, risk factor control, psychosocial impact, and safety in the home. 2) 30 minute exercise sessions focusing on strength and balance 3) social support</td>
<td>B BA+Qual</td>
<td>5</td>
<td>P</td>
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<tr>
<td>Larson 2005, Sweden</td>
<td>91/253 eligible spouses of stroke patients completing one-year follow-up.</td>
<td>Six 20–30 minute education and support sessions (lectures plus group discussions) focusing on stroke facts and delivered over a 6-month period in hospital by specialist stroke nurses.</td>
<td>C RCT</td>
<td>4</td>
<td>F</td>
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<tr>
<td>Lincoln 2003, UK</td>
<td>250 stroke patients admitted to hospital and their informal carers: 126 intervention, 124 control.</td>
<td>1) Contact from a Family Support Officer 2 weeks after recruitment, to provide liaison with the rehabilitation team whilst in hospital. 2) Postdischarge follow-up at home for up to 9 months to discuss problems, offer information and support and direct families to appropriate services.</td>
<td>B RCT</td>
<td>6</td>
<td>P</td>
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</tr>
<tr>
<td>Lomer 1987, UK</td>
<td>91 stroke patients admitted to medical and elderly care wards at 2 teaching hospitals.</td>
<td>Single distribution of an information leaflet delivered 2 weeks after admission to hospital with simple hand drawn illustrations focusing on stroke facts, available services, financial benefits, and staff contact details.</td>
<td>B RCT</td>
<td>4</td>
<td>P</td>
<td></td>
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<tr>
<td>Lorenc 1992, UK</td>
<td>30 patients hospitalized as a result of stroke</td>
<td>Intervention one 1) Information pack. Intervention two 2) Information pack plus instruction on how to read and understand the information.</td>
<td>C RCT</td>
<td>2</td>
<td>P</td>
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</table>
| Mant 2000,57,58 UK     | 323 patients with stroke and 267 carers          | 1) Visits from a family support officer. No. of visits individualised at their discretion (average of 1 hospital visit, 1 home visit and 3 phone calls over a 6-month period)  
2) Information leaflets.  
One-off mailing of an information pack containing Stroke Association publications delivered one month after stroke. | A                  | RCT          | 4                           | P                        |
| Mant 1998,57 UK        | 71 acute stroke patients                         | Single mailing of a booklet containing information covering: persisting symptoms, aims of rehabilitation, instructions on daily living activities, exercises prescribed, local and national addresses/contacts for people with stroke.                                                                                                                                  | D                  | RCT          | 3                           | F                        |
| Pain 1990,58 UK        | 36 patients admitted to hospital with a CVA for at least 10 days and discharged home with a relative or carer | 1) Six 1-hour small group sessions for patients and carers delivered by a range of healthcare professionals covering stroke and consequences, the role of staff and caring for stroke patients  
2) Leaflets and telephone hotline No. for more information. | B                  | RCT          | 3                           | P                        |
2) 20-minute review meetings with the multidisciplinary team to provide information about patients’ progress, answer questions and develop shared rehabilitation goals. Frequency of meetings not reported.  
3) Twice-weekly visits from a social worker for 16 weeks (action depended on the individual). | A                  | Cluster RCT  | 1                           | F                        |
2) 20-minute review meetings with the multidisciplinary team to provide information about patients’ progress, answer questions and develop shared rehabilitation goals. Frequency of meetings not reported.  
3) Twice-weekly visits from a social worker for 16 weeks (action depended on the individual). | B                  | RCT          | 1                           | F                        |
| Tilling 2005,9,89 UK   | 340/513 hospital and community stroke patients. | Home visits from a family support officer to provide information, emotional support and prevention advice to families and patients. Frequency and duration of support was tailored to the individual family.                                                                                                                                                                                                 | A                  | RCT          | 1                           | F                        |
| Towle 1989,90 UK       | 44 patients with depression ≥1-year poststroke   | Intervention 1  
1) Information booklet including addresses of stroke clubs, social services and OT departments; descriptions of financial benefits.  
2) Information booklet (as above)  
3) Twice-weekly visits from a social worker for 16 weeks (action depended on the individual). | D                  | RCT          | 3                           | F                        |
| van den Huevel 2000,73,74 Netherlands | 257 carers (130 group program, 78 home visit, 49 controls) | Intervention 1  
1) Eight 2-hour group education sessions. | B                  | RCT          | 2                           | S                        |
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<tr>
<td>Intervention 2</td>
<td></td>
<td>2) Four 2-hour home visit education sessions. Both interventions started 4 weeks after recruitment and lasted 10 weeks. Both were led by experienced nurses and included educational sessions, discussion on stroke causes and consequences and occupational therapy.</td>
<td></td>
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</tbody>
</table>

*Design abbreviations: Randomized Controlled Trial (RCT); Quasi-experimental study (QE); time series controlled design (QE-TS); before and after study (BA); qualitative evaluation (Qual).

**Outcome success: successful in all primary outcomes (S); partially successful, ie, success in at least one but not all primary outcomes (P); failure in all primary outcomes (F).
Development of Complex Interventions in Stroke Care. A Systematic Review
Judith Redfern, Christopher McKevitt and Charles D.A. Wolfe

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