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**Stroke
Rehabilitation
Services:
Systematic Reviews
of the Clinical and
Economic Evidence**

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**Stroke Rehabilitation Services:
Systematic Reviews of the Clinical and Economic Evidence**

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March 2003

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All authors participated in planning the project.

Hussein Z. Noorani: reviewed clinical literature; composed drafts of the executive summary, introduction, clinical review and overall conclusions and revised manuscript drafts.

Bruce Brady: reviewed economic literature, composed the economic review, and revised manuscript drafts.

Lynda McGahan: reviewed clinical and economic literature, assisted in drafting the clinical review and revised manuscript drafts.

Robert Teasell: reviewed clinical literature, assisted in drafting the introduction and clinical review and revised manuscript drafts.

Becky Skidmore: designed and executed the literature search strategies, wrote the methods section and associated appendix on literature searching, and verified and formatted the bibliographic references.

Timothy J. Doherty: reviewed clinical literature, assisted in drafting the clinical review and revised manuscript drafts.

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Conflicts of Interest

Hussein Z. Noorani, Bruce Brady, Lynda McGahan, Robert Teasell, Becky Skidmore and Timothy J. Doherty disclosed no conflicts of interest.



Stroke Rehabilitation Services: Systematic Reviews of the Clinical and Economic Evidence

Technology Name

Stroke rehabilitation services and programs

Disease/Condition

There are over 40,000 strokes each year and stroke is the fourth leading cause of mortality in Canada. Death and disability from stroke costs the Canadian economy approximately \$2.7 billion per year.

Technology Description

Stroke rehabilitation offers the opportunity to reduce the burden of disability after a stroke. Stroke rehabilitation services vary widely in terms of intensity of therapy and place of care. Four different models are assessed in the CCOHTA report.

The Issue

The wide variety of organizational models for the delivery of stroke rehabilitation services raises the issue of which organizational models are most clinically effective and cost-effective.

Assessment Objectives

To examine the clinical and cost effectiveness of four stroke rehabilitation interventions:

- stroke unit care (specialized interdisciplinary teams of physicians and other professional staff caring exclusively for stroke patients) versus care on general medical/geriatric wards (stroke patients are cared for along with patients with other medical conditions);
- impact of different intensities of therapies (varying duration of therapies);

- early support discharge (releasing patients from hospital earlier than usual, using organized interdisciplinary teams to essentially support patients at home) versus usual care; and
- rehabilitation in the community (hospital-based outpatient therapy clinics or home-based therapy) versus usual care.

Methodology

A systematic review of the literature found 22 randomized controlled clinical trials and 14 primary economic studies. The study population included men and women of all ages, in hospital-based and community-based settings, who fulfilled a clinical definition of stroke. Only trials with a follow-up period of six months or longer were selected for the clinical review. The trials used various outcome measures.

Conclusions

Stroke patients who receive organized care in a stroke unit are more likely to be alive, independent and living at home after a stroke than those who receive care in a general ward, with some evidence of comparable costs. For patients with mild or moderate disability, early supported discharge services produces greater independence at modestly lower costs compared to usual care. However, no firm conclusions could be drawn regarding the impact of different intensities of rehabilitation, and no significant differences were observed in primary outcomes between home-based rehabilitation and usual care.

This summary is based on a comprehensive health technology assessment report available from CCOHTA's web site (www.ccohta.ca): Noorani HZ, Brady B, McGahan L, Teasell R, Skidmore B, Doherty TJ. **Stroke rehabilitation services: systematic reviews of the clinical and economic evidence.**

EXECUTIVE SUMMARY

The Issue

Stroke is the fourth leading cause of mortality in Canada; there are over 40,000 patients who experience a stroke each year. Stroke costs the Canadian economy approximately \$2.7 billion annually and 3 million hospital days. Rehabilitation offers the opportunity to reduce the burden of disability after stroke; however, given the resource intensive nature of rehabilitation, it is imperative that it be used in an evidence-based and cost-effective manner.

Objectives

The general objectives of this report were to evaluate the clinical effectiveness and cost-effectiveness of rehabilitation interventions after stroke through systematic reviews of clinical and economic studies. Specifically, four comparisons were used to assess outcomes: (1) stroke unit (SU) care versus care on a general medical ward (GMW) or geriatric ward; (2) the impact of different intensities of rehabilitation therapies; (3) early supported discharge (ESD) services versus usual care; and (4) rehabilitation in the community as compared to usual care.

Clinical Effectiveness Review

Methods: Published literature between January 1995 and July 2002 was identified by searching various databases using DIALOG[®] and other bibliographic systems. Randomized controlled trials (RCTs) with a follow-up period of six months or longer post-randomization were sought. Outcome measures included death, physical dependency as primarily assessed by the Barthel Index (BI), the number of patients in institutions or at home at the end of scheduled follow-up, health related quality of life (HRQoL) and length of hospital stay following randomization. Trial quality was assessed in terms of the method of randomization, concealment of treatment allocation, blinding of outcome assessment and handling of patient attrition in the analysis. Binary data for each trial were expressed as odds ratios (OR) and 95% confidence interval (CI) and continuous data as weighted mean difference (WMD). Sensitivity analysis was done to assess the impact of follow-up and trial quality on mortality rates between the intervention and control groups.

Results: Of 1,629 citation titles and abstracts examined, 68 articles were retrieved for full-text review. Twenty-two RCTs, reported in 37 articles, met the inclusion criteria. These consisted of six trials for the first comparison (1,709 patients), three trials for the second comparison (642 patients), five trials for the third comparison (940 patients) and eight trials for the fourth comparison (1,182 patients). These RCTs were undertaken in 9 countries, with 12 (55%) conducted in the United Kingdom. No US or Canadian trials met the inclusion criteria. The methodological quality of trials varied, but was on average, moderate to good. Elderly patients were recruited within these trials with an average age of 72 years (range of 63 to 80 years) and no overall differences were observed in patient gender. Compared with GMW care, SU care reduced the odds of death (OR 0.60, 95% CI 0.42; 0.86) and increased the odds of living at home (OR 1.42, 95% CI 1.05; 1.92) at final follow-up (median 15 months). The estimated number needed to treat to prevent 1 death was 11 (range, 7 to 25). The observed mortality benefits remained up to 10 years after a stroke and there was little difference in the outcome of death when stratified by trial quality. No reductions in the odds of death were observed for the other comparisons. The pooled

OR (0.94) across six trials demonstrated a trend to reduced institutionalized care in SU patients at follow-up; however, this did not reach statistical significance (95% CI 0.69; 1.27). Patients who received either SU care or ESD services were more able to live at home independently, compared to patients receiving usual care. ESD patients showed significant reductions in the length of hospital stay equivalent to approximately 10 days. There was no indication that interventions in any of the four comparisons improved HRQoL.

Economic Review

Methods: An economic filter replaced the clinical trial filter in the literature search strategy. The study design was either an economic evaluation or a comparative cost analysis. The main study characteristics and results for each comparison were summarized in tables, including information on mean costs per patient, the percentage change in costs (relative to the comparator) and statistical significance.

Results: Of 634 citation titles and abstracts examined, 76 articles were retrieved for full-text review. Fourteen primary studies met the inclusion criteria: three studies of SU care, eight studies of ESD services and three studies of community rehabilitation. No primary studies of different therapy intensities were identified. All studies were classified as cost-consequences analysis or comparative cost analysis. Ten studies were set in Europe [six (43%) in the United Kingdom], two in Australia, one in Hong Kong and one in Canada (Montreal). The type of comparators and the scope of included costs varied widely between studies. There was also uncertainty about the similarity of the rehabilitation "packages" included under each intervention category. The time horizon in these studies was generally short (one year or less). Most studies were considered to be of moderate quality. There was some evidence that the cost of rehabilitation in a SU is comparable to that in other hospital wards. There is fair economic evidence that ESD services are modestly less costly than usual care, although this is qualified by caveats concerning the heterogeneity of the interventions and comparators, the limited applicability of the results to more disabled patients, and the uncertain impact of ESD services on informal caregivers. At this time, there is insufficient evidence concerning the relative cost of community rehabilitation.

Conclusions

Stroke patients who receive organized inpatient care in a SU are more likely to be alive, independent and living at home after a stroke. There was a trend to reduced institutionalization. There is some evidence that the total cost of SU rehabilitation is comparable to care provided in another type of hospital ward. Insufficient evidence makes it impossible to draw conclusions about the effect of different intensities of rehabilitation on outcomes post-stroke. There is moderate evidence that ESD services can provide care at modestly lower total costs (versus usual care) for stroke patients with mild or moderate disability. No significant differences were observed in primary outcomes between home-based rehabilitation and usual care and no firm conclusions can be drawn regarding its relative total cost. Several notable methodological problems were encountered when analysing the clinical and economic evidence. To allow stronger conclusions about the clinical effectiveness, quality of life and cost-effectiveness of rehabilitation interventions after stroke, further research would be required, particularly in a Canadian setting.

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ABBREVIATIONS

ADL:	Activities of Daily Living
BI:	Barthel Index
CCA:	cost-consequence analysis
CE:	cost-effective
CHC:	conventional hospital care
CI:	confidence interval
DH:	day hospital
ESD:	early supported discharge
GMW:	general medical ward
GP:	general practitioner
HP:	home physiotherapy
HR:	home rehabilitation
HRQoL:	health related quality of life
HTA:	health technology assessment
LOHS:	length of hospital stay
LOS:	length of stay (including stay in hospital and/or institutions)
NS:	no significant difference
NHP:	Nottingham Health Profile
NNT:	number needed to treat
OR:	odds ratio
RCT:	randomized controlled trials
RM:	Reference Manager [®]
RS:	Rankin Scale
SD:	statistically significant difference
SF-36:	Medical Outcomes Study 36-item Short-Form Health Survey
SIP:	Sickness Impact Profile
SU:	stroke unit
UK:	United Kingdom
WMD:	weighted mean difference

GLOSSARY OF TERMS USED IN THE ANALYSIS^a

Confidence interval (CI): The range within which the ‘true’ value of the effect of an intervention is expected to lie with a given degree of certainty. Confidence intervals represent the distribution probability of random errors, but not systematic errors (bias).

Fixed effects model: A mathematical model for combining the results of studies that assumes that the effect is truly constant in all populations studied. Thus, only within-study variation is taken to influence the uncertainty of results and it produces narrower confidence intervals than the random effects model.

Forest plot: This presents the individual study effects with their confidence intervals as horizontal lines, the box in the middle of the horizontal line representing the mean effect. When using odds ratios (or relative risk) as the effect measure, the effects are usually plotted on a log-scale to introduce symmetry to the plot. The vertical line drawn at an odds ratio (or relative risk) of one (unity) represents ‘no effect’ and a confidence interval overlapping this vertical line represents the lack of a statistically significant effect. Different sized boxes may be plotted for each of the individual studies, the size of the box increasing with the weight that the study takes in the analysis.

Funnel plot: This is a statistical method that displays publication bias. Funnel plots show the distribution of effect sizes according to sample sizes (or inverse of variance). It is to be expected that points (each representing an effect size) will fill a funnel shape, there being more variability in reported effect sizes for smaller studies. Large gaps in the funnel indicate a group of publications that may be “missing”.

Heterogeneity: This is the variability or difference between studies in terms of key characteristics (clinical heterogeneity), quality (methodological heterogeneity) and effects (heterogeneity of results). Statistical tests of heterogeneity may be used to assess whether the observed variability in study results (effect sizes) is greater than that expected to occur by chance.

Odds Ratio (OR): This measure is the ratio of the odds of an event in the intervention group to the odds of an event in the control group. An OR of one indicates no difference between comparison groups. For undesirable outcomes an OR less than one indicates that the intervention was effective in reducing the risk of that outcome.

Publication bias: This term refers to a bias in the research literature where the likelihood of publication of a study is influenced by the significance of its results. For example, studies in which an intervention is not found to be effective may be less likely to be published. Systematic reviews that fail to identify such studies may overestimate the true effect of an intervention by disproportionately reporting on effective studies.

^a Adapted from Khan et al. (2001)²⁴

Random effects model: This is a mathematical model for combining the results of studies that allows for variation in the effect amongst the population studied. Thus, both within-study variation and between-studies variation are included in the assessment of the uncertainty of results.

Sensitivity analysis: Sensitivity analysis is an analysis used to determine how the results of a systematic review change due to variations arising from uncertain decisions or assumptions about the data and the methods that were used.

Weighted mean difference (WMD): Where studies have measured an outcome on the same scale, the weight given to the mean difference in each study is usually equal to the inverse of the variance.

1 INTRODUCTION

1.1 Background

Stroke is the fourth leading cause of mortality in Canada, accounting for 16,000 deaths annually.¹ The Heart and Stroke Foundation of Canada estimates that there are between 40,000 to 50,000 strokes in Canada each year.^{1,2} Stroke costs the Canadian economy approximately \$2.7 billion a year, and Canadians spend a total of 3 million days in hospital due to physical disability from stroke.¹

Stroke rehabilitation is regarded as one of the key components in the spectrum of stroke care. When a person survives a stroke, rehabilitation is thought to be a critical component of therapy that helps survivors maximize their quality of life physically, cognitively, emotionally and socially.³ Although it is reasonable to conclude that many people who suffer a stroke will require some rehabilitation, it is currently unclear how much and what type are actually needed. The level of neurological impairment, disability and handicap of stroke survivors varies considerably, as does the length, type and intensity of rehabilitation that they require.³

The economic and human costs of stroke are considerable, including the costs of disability and suffering. Despite this, stroke survivors, their families and health professionals often do not have access to well-organized, high-quality stroke rehabilitation services.³ Such services of stroke rehabilitation are critically important to ensure that:

- the right intensity of stroke rehabilitation is given at the right time such that the functional outcome following stroke is maximized;
- the changing needs of stroke survivors are monitored and services are adapted to meet these changing needs;
- health care providers, including those working in acute care settings and community agencies, work as partners to provide stroke rehabilitation in an integrated fashion; and
- rehabilitation is based on the most up-to-date evidence and research and uses the most effective techniques and approaches.³

1.2 Technology Overview

1.2.1 Stroke unit care versus care on a general medical ward or geriatric ward

Stroke units (SUs) specialize in the care of stroke patients; there is access to appropriate therapies and therapists exclusively treat stroke patients. There is greater attention paid to prevention and treatment of the complications of a stroke. SUs tend to be interdisciplinary where physicians, therapists, nursing and social work staff work together as a team, holding regular team meetings and maintaining close inter-working relationships.⁴ Careful discharge planning

with early involvement of the family are also general characteristics of SUs. In Canada, many stroke patients do not have access to SU care.⁴

General medical wards (GMWs) are not intended to specialize in the care of stroke patients. Therapy is provided but therapists may not regularly meet to discuss patient progress or work together on discharge planning.³ Therapists may work independently and do not necessarily coordinate their efforts. They also treat stroke patients along with patients with other medical conditions, which tends to limit their expertise in stroke patients in particular.³ While geriatric wards generally function similar to GMWs, greater focus is provided to frail elderly patients. Geriatric wards may provide more of a team approach to stroke rehabilitation but they do not specialize in the rehabilitation of stroke patients; rather they specialize in the management of elderly patients with medical problems.³

Early comparative trials have demonstrated that patients who had undergone stroke rehabilitation had fewer deficits in activities of daily living (ADL) at discharge, had lower one-year mortality and were less likely to be in institutional care at follow-up.³ However, pre-selection of patients and concerns about observer measurement bias were obvious limitations of these studies, making it difficult to draw meaningful conclusions.

Two secondary reviews have looked at the benefits of interdisciplinary stroke rehabilitation when compared to treatment on general wards.^{5,6} The first review, published by Evans et al. (1995), compared the clinical effectiveness of inpatient rehabilitation programs with medical care.⁶ By meta-analysis of eight randomized controlled trials (RCTs), no significant inter-group differences were observed with respect to rates of survival (odds ratio (OR) 1.20, 99% confidence interval (CI) 0.84 to 1.55). However, patients undergoing some form of interdisciplinary rehabilitation were reported to return home more frequently than those undergoing usual care (n=6 trials, OR 0.63, 99% CI 0.37; 0.88).⁶ The significance of these findings to our current comparison (SU care vs. care on a GMW or a geriatric ward) is limited given the rehabilitation-mix review between SU care and GMW within the intervention groups in Evans et al.⁶

The Stroke Unit Trialists' Collaboration within the Cochrane Review Group has reported reductions for SU care in comparison to usual services in the odds of death (OR 0.86, 95% CI 0.71; 0.94), the odds of death or institutionalized care (0.80, 0.71 to 0.90) and death or dependency (0.78, 0.68-0.89) at one year follow-up.⁵ The most recent amendment to the Cochrane review was April 2001 and overall included 23 trials. Limitations of this analysis were inclusion of a diverse group of RCTs and the relatively old publication date (from the mid-1980s) of some of these trials with prolonged length of hospital stay (LOHS > 100 days) compared to current practice.⁵

1.2.2 Impact of different intensities of rehabilitation therapies

Stroke rehabilitation involves the use of therapy, delivered by rehabilitation therapists. Studies of intensity primarily focus on the delivery of physiotherapy and occupational therapy.³ Since therapy is generally provided on a one-to-one basis, intensity of therapy is measured by the amount of time spent by the therapist in treating the individual patient, and can be measured in

actual time or number of therapy sessions provided over a specific period of time. The underlying assumption being explored in these studies is that if rehabilitation therapies are helpful to patients then more therapy should result in better outcomes. This assumption has been the subject of two meta-analyses,^{7,8} a health technology assessment (HTA) report from the Centre for Clinical Effectiveness at Monash University in Australia (1998)⁹ and one descriptive review.¹⁰

Langhorne et al. (1996) in a meta-analysis of seven RCTs (n=597 patients) looking at the effects of differing intensities of physiotherapy showed a non-significant reduction in death (OR 0.60, 95% CI 0.33; 1.09) and a significant reduction in the combined outcome of death or dependency (OR 0.54, 95% CI 0.34; 0.85), with higher intensities of treatment provided within four months post-stroke.⁸ In general, the relevant trials in the Langhorne et al. review were relatively heterogeneous, examining different interventions (mixture of physiotherapy and occupational therapy) in a variety of patient groups at various intervals after stroke. Different outcome measures were used within these trials and data were incomplete in two of these trials.⁸ (These factors call into question the utility of undertaking a meta-analysis of the included studies.)

Kwakkel et al. (1997) undertook a meta-analysis of eight RCTs (n=623) and one non-randomized study looking at the effects of the intensity of stroke rehabilitation.⁷ These investigators also found a small, but statistically significant, intensity-effect on activities of daily living (ADL) and functional outcome parameters.⁷ The study limitations of Langhorne et al. (1996) discussed above also apply to Kwakkel et al. The HTA report from the Centre for Clinical Effectiveness at Monash University in Australia (1998) was a review of the evidence-base evaluating the impact of physiotherapy intensity on functional outcome in stroke patients.⁹ The results of the literature search strategy undertaken for this latter review identified eight RCTs,⁹ all of which were included in the above meta-analysis by Kwakkel et al. While the Kwakkel et al. meta-analysis was ranked as providing Level 1 evidence (evidence obtained from a systematic review or a meta-analysis of at least two relevant RCTs) concerns about validity were raised:

- The question of whether they were comparing ‘like with like’ arises because different studies looked at different intensity measures: strength, frequency, length, amount, duration etc.
- Some consideration of occupational therapy as well as physiotherapy was included in the study and not clearly differentiated.
- Patients were sent home at some time during their rehabilitation, cutting short a clear understanding of how much therapy they would have received otherwise.
- By their own account, Kwakkel et al. stated that results were included from three ‘confounded’ trials. The authors also warn “generalization of the results of the present research synthesis is difficult because of the low methodological quality of the included studies”.⁹

A descriptive review was undertaken by van der Lee et al. (2001) to evaluate the impact, in general, of exercise therapy for arm function in stroke patients.¹⁰ These investigators reported that more therapy might be beneficial in this study population when followed up to one year. These benefits were reported in five (of eight) trials with a difference in the intensity or duration

of exercise therapy between the intervention and control groups.¹⁰ None of these secondary reviews evaluated the impact of increases in intensity or duration of therapy on the health related quality of life (HRQoL) of the study population.

1.2.3 Early supported discharge (ESD) services versus usual care

ESD involves an organized interdisciplinary stroke rehabilitation team managing patients in their own communities, essentially recreating in-hospital rehabilitation unit care at home. The concept of ESD has arisen out of concerns that patients may prefer not to be in hospital and that in-patient interdisciplinary stroke rehabilitation may not provide for optimal outcomes, given that the goal is to establish skills that are applicable to the home environment itself. In addition, rehabilitating patients in their own homes or communities avoids the accommodation costs of an in-hospital stay.

When examining the results of studies reporting the outcomes of patients who received ESD, it is important to consider the process by which patients were selected for inclusion. If the eligibility criteria are very restrictive and many potential patients excluded, this results in bias in sample selection which in turn influences the generalizability of the results. In previous studies that have looked at ESD, patients with more moderate or severe strokes have generally been excluded.³

Two secondary studies have been undertaken to compare ESD services to usual hospital care.^{11,12} The first was a systematic review undertaken by the New Zealand HTA agency and published in January 1999.¹² Five studies that evaluated the effectiveness of ESD were identified; no significant differences were observed in outcome (death, dependency or institutionalization) between those discharged early compared to those in the control groups after one year of follow-up. In all cases, those randomized to the ESD group had significantly shorter LOHS (mean value of 13 days for the ESD group compared to 23 days for the control group, $p < 0.05$).¹²

The second review was a meta-analysis conducted by the Cochrane Stroke Group, dated March 2001.¹¹ Overall, for four trials, the ORs (95% CI) reported for death, death or institutionalization, and death or dependency at six months of follow-up were 0.87 (0.39 to 1.93), 0.69 (0.36 to 1.31) and 0.88 (0.49 to 1.57), respectively. Apparent benefits were more evident in the three trials evaluating a coordinated ESD team. Patients in the ESD group showed significant reductions ($p < 0.001$) in LOHS equivalent to approximately nine days.¹¹ The meta-analysis was based on very limited information; four single-centre trials recruited a minority (13% to 45%) of stroke patients admitted to urban hospitals.¹¹ There also was considerable heterogeneity in the results of these trials, calling into question the feasibility of pooling the data for these trials. Despite these limitations, the findings from the Cochrane Stroke Group are consistent with those of the New Zealand HTA report discussed above.

1.2.4 Rehabilitation in the community versus usual care

Rehabilitation in the community can be provided in basically two settings: 1) hospital based outpatient therapy clinics and 2) home-based therapies. In the case of hospital based outpatient therapy, rehabilitation expertise is generally already available in the hospital. Therapists can see

more patients in a shorter period of time since they do not have to travel to a stroke patient's home. It also allows them to take advantage of the equipment resources of the hospital. Home-based therapy has the advantage of providing therapy to a stroke patient in a "real-world" setting and removes the need for transportation to hospital, which can be a barrier for some patients.

At least five reviews have been published since 1995 that have considered home-based rehabilitation versus hospital-based rehabilitation.¹²⁻¹⁶ Three of these reviews are secondary analyses of two trials published in the United Kingdom (UK) in 1992 and 1993.^{12,15,16} No significant differences in outcomes between home-based rehabilitation and usual care regarding dependency or HRQoL were observed in patients (and care providers) when the data were combined for the two trials (n=451 patients). A meta-analysis undertaken by the Cochrane Stroke Group on "services for helping acute stroke patients avoid hospital admission" was also identified.¹⁴ An update of this Cochrane review was undertaken in May 1999 and included analysis of four trials, three of which were RCTs. In the pooled analyses, there were no statistically significant differences between patient outcomes (death, death or institutionalization, death or dependency, HRQoL) of the intervention and control groups. In terms of LOHS, there was a trend toward increased bed use (about extra four days) in the home-based group for both trials for which data were available.¹⁴ A systematic review of the scientific evidence on effects and costs of home rehabilitation after stroke was undertaken by Britton & Andersson (2000).¹³ Six RCTs were identified (literature search up to December 1999). Two of these were the UK trials reviewed above. Overall, no statistically significant differences were observed regarding outcomes of home rehabilitation versus hospital-based alternatives.¹³

2 OBJECTIVES

The general objectives of this review are to evaluate:

- (1) the clinical effectiveness of rehabilitation interventions after stroke through a systematic review of RCT evidence; and
- (2) the cost-effectiveness of rehabilitation interventions after stroke through a systematic review of economic evaluations.

The study comparisons include:

- (1) SU care versus care on a GMW or geriatric ward;
- (2) the impact of different intensities of rehabilitation therapies;
- (3) ESD services versus usual care; and
- (4) rehabilitation in the community versus usual care.

3 CLINICAL EFFECTIVENESS REVIEW

3.1 Methods

3.1.1 Literature search strategy

Published literature addressing the clinical questions was obtained by searching a number of databases (Appendix 1). On the DIALOG[®] system, Allied and Complementary Medicine[™], EMBASE[®], HealthSTAR[®], Manual, Alternative and Natural Therapy[®] (MANTIS[™]), MEDLINE[®], PASCAL, SciSearch[®] and SPORTDiscus were searched, resulting in 1,267 unique records.

Retrieval was limited to the publication years 1995 onward and there were no language restrictions. The year 1995 was chosen as the beginning date for the literature search to provide an update of the evidence-base on this topic from previously published reviews. Database alerts/updates were established and incorporated in the analysis up until July 31, 2002 on all the originally searched databases except SPORTDiscus. Clinical updates were also run on Current Contents Search[®] and SciSearch[®] updates but were discontinued August 2001.

Parallel searches were run on AgeLine, CINAHL and PubMed; many records were duplicates of the original DIALOG[®] search. Searches were performed and updated on the CD ROM version of The Cochrane Library.

Grey literature was obtained through searching a number of specialized rehabilitation databases such as those of the National Rehabilitation Information Center and PEDro, as well as the Web sites of HTA and related agencies and their associated databases. Clinical trial registries were also searched for information on completed and ongoing trials. The Google[™] search engine was used to search for a variety of Internet materials. Further information was sought by hand searching the bibliographies of selected papers and through contacts with appropriate experts and agencies.

Reference Manager[®] (RM), citation management software, was used to manage the references obtained from all DIALOG[®] databases, AgeLine, CINAHL and PubMed. Relevant references identified in The Cochrane Library and from the various grey literature sources were also incorporated in the RM database. The database was customized to include study objectives and reviewer comments and new report formats were added to allow this information to be exchanged and consolidated electronically.

3.1.2 Inclusion and exclusion criteria

Studies were included or excluded on the basis of the following criteria:

Study design: RCTs of stroke rehabilitation under one of the four study comparisons with a follow-up period of six months or more post-randomization were sought. Six months of follow-up was chosen as a cut-off point for the primary analysis based on input from team members with clinical expertise in stroke care and review of literature in the rehabilitation field.^{3,17}

Population: The included population was men and women of all ages, in both hospital-based and community-based settings, who fulfilled a clinical definition of stroke (focal neurological deficit caused by cerebrovascular disease).

Types of intervention: Stroke rehabilitation was defined as an inpatient, outpatient, community or home-based intervention that is applied to a stroke patient. Specifically the intervention groups under each of the four study comparisons had the following general features:

- a) SU care: coordinated interdisciplinary team care; nursing integration with team care; specialization of physicians, nurses and therapists; education for staff and patients; and caregiver involvement;
- b) increased intensity of rehabilitation therapies: patients who receive therapy for longer periods of time or at a higher level of intensity;
- c) ESD services: interventions which aim to accelerate discharge from hospital with the provision of support in a community setting (home, day hospital, outpatient clinic); and
- d) community rehabilitation: interventions provided in a community setting with an aim of preventing admission to hospital.

The respective control groups had the following features:

- a) care on a GMW or geriatric ward;
- b) routine or standard intensity level of therapy;
- c) usual in-hospital care and discharge services; and
- d) usual care, as defined within the individual trials.

3.1.3 Outcome measures

Primary outcomes included:

- a) death;
- b) physical dependence as assessed by the BI and the Rankin Scale (RS);^b

^b Both scales have been used to assess ADL in stroke survivors;¹⁸ the BI is the more widely-used scale and is reported to be a reliable measure post-stroke.^{18,20} The BI used for this review was the 20-point scale (0-20) and is shown in Appendix 2. The original BI used a 100-point scale (0-100). The 20-point scale was adopted to clarify rating instructions and reorder some of the items; the 10 items and their associated weight on both scales are the same.^{18,20} Where the BI was scored on a 100-point scale within individual trials, the total score was divided by a component of 5 for purposes of comparability and pooling of the results between studies. Stroke severity, defined as

- c) the number of patients in institutions (nursing homes or chronic-care hospitals) at the end of scheduled follow-up; or
- d) the number of patients at home at the end of scheduled follow-up.

Secondary outcomes included:

- a) LOHS following randomization;^c and
- b) HRQoL^d

3.1.4 Data extraction strategy

Two reviewers (HN & RT) independently selected trials for each of the four study comparisons included in this review. A third reviewer (LM) was also involved in independently selecting trials for the first study comparison on SU care. Disagreements about any study inclusions were resolved by consensus among the three reviewers. A fourth reviewer (TD), not involved in the initial selection, independently reviewed a list of selected trials compiled for each comparison. Two reviewers (HN and LM for comparisons #1 and #2, HN and RT for comparisons #3 and #4) independently extracted the data once the trials were formally included in the review. If multiple articles conducted by a single group of investigators were identified, the article with the latest follow-up on outcomes was used as the primary citation for the trial. Multiple publications by the same investigative group are identified under each comparison in the results section. The inclusion/exclusion forms and data extraction forms are shown in Appendices 4A and 5A.

3.1.5 Quality assessment

Quality of trials was assessed in terms of (1) the use of adequate random allocation methods (by computer-generation or table of random numbers, drawing lots of envelopes, coin tossing, shuffling cards or by throwing dice), (2) the adequate concealment of treatment allocation at recruitment (through a central randomization site or by sequentially numbered, sealed envelopes), (3) blinding of outcome assessors and (4) completeness of follow-up or adherence to the intention-to-treat principle during analysis. Empirical evidence exists for the importance of assessing these factors for the quality of RCTs.²³ These factors were assessed on a 5-point scoring system; the higher the score, the higher the quality (possible range 0 to 5).¹⁷ Quality assessment was included as part of the data extraction process (Appendix 5A).

dependency at the time of randomization (usually within 1 week of the index stroke), was categorized as mild stroke being equivalent to a BI of 10-20, moderate stroke to a BI of 3-9, and severe stroke to a BI of 0-2.⁵

^c For the study comparison on rehabilitation in the community versus usual care, given the nature of the intervention, this was assessed as inter-group differences with respect to hospital readmission rates.

^d Our review focused on validated generic measures of HRQoL (Nottingham Health Profile (NHP), Sickness Impact Profile (SIP), Medical Outcomes Study 36-item Short-Form Health Survey (SF-36)). These measures are the most frequently used HRQoL instruments in research with stroke survivors.^{18,21,22} A summary (description and psychometric properties) of these instruments is provided in Appendix 3.

3.1.6 Data analysis methods

Where data pooling was considered appropriate, binary outcomes for each trial have been expressed as OR and 95% CI. Continuous variables have been expressed as weighted mean differences (WMD) and 95% CI. Data from each trial were pooled as appropriate using a fixed effects model, except where heterogeneity existed according to the χ^2 statistic, when a random effects model was used.²⁴ In the presence of heterogeneity and depending on the number of trials identified, sensitivity analyses was undertaken to assess the impact of follow-up and trial quality on mortality rates between the intervention and control groups; death was the clinical outcome reported in most trials under each of the study comparisons. Sensitivity analysis was performed to test the impact of follow-up on survival rates between the intervention and control groups.

Statistical analyses were performed using Review Manager v.4.1 software. Where data pooling was considered inappropriate (single trial reporting on a specific outcome, continuous variables reported as median values), mean values and their range were used for simple computation within trials for each of the study outcomes (see Glossary for explanation of the key concepts used in this analysis).

3.2 Results

3.2.1 Quantity and quality of research available

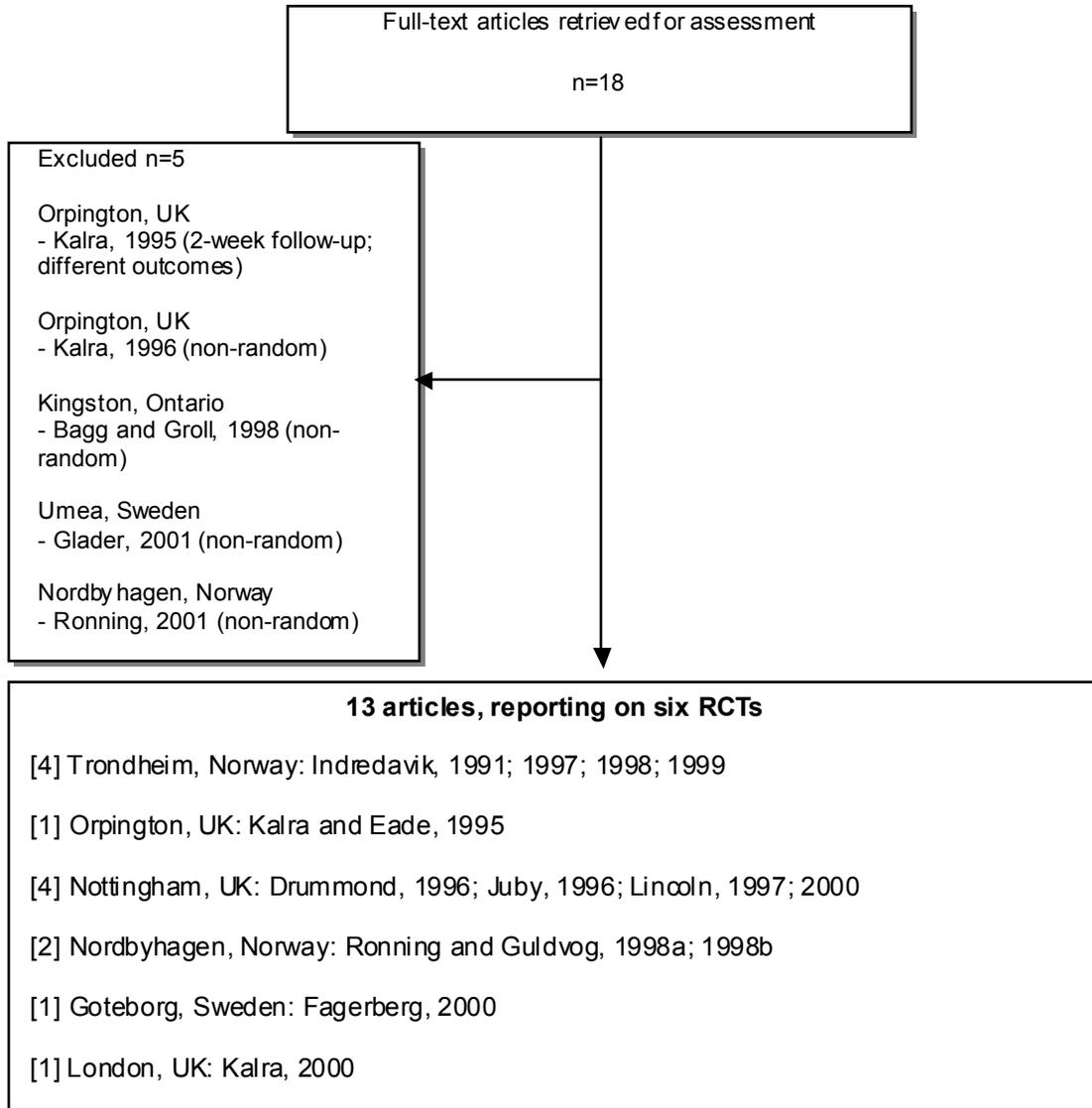
Of 1,629 citation titles and abstracts examined, 68 articles were retrieved for full-text review. Twenty-two RCTs, reported in 37 articles (2%) of the original 1,629 citations, met the inclusion criteria. These consisted of six trials for the first comparison, three trials for the second comparison, five trials for the third comparison and eight trials for the fourth comparison. The study and patient characteristics for each of the comparisons are tabulated under the respective sections and appendices of the report.

3.2.2 Assessment of clinical effectiveness

(1) SU care versus care on a GMW or geriatric ward

Eighteen articles were retrieved reporting on SU care versus care on a GMW or geriatric ward. Thirteen articles, reporting on six RCTs, met the selection criteria²⁵⁻³⁷ and five did not.³⁸⁻⁴² The flow document for selection is displayed in Figure 1 below:

Figure 1: Summary of the selection of articles for inclusion



a) Trial characteristics and quality

The six RCTs were undertaken in three countries: three trials in the UK, two in Norway and one in Sweden (Figure 1). Three RCTs were reported in multiple publications:

- The Trondheim trial from Norway was reported in four articles.³²⁻³⁵ Three articles reported on primary outcomes at different follow-up periods; Indredavik et al. (1991) at 12 months,³² Indredavik et al. (1997) at 5 years,³³ and Indredavik et al. (1999) at 10 years.³⁵ Indredavik et al. (1998) reported on HRQoL on the same patient groups at five years post-stroke.³⁴
- The Nottingham trial from the UK was reported in four articles.²⁶⁻²⁹ Juby et al. (1996) reported on death, median BI score, and proportion of patients discharged at home at 6 months and at 12 months.²⁷ Lincoln et al. (2000) reported follow-up data on death, the BI (reported as percentage of patients considered independent or partly independent) and proportion of patients discharged at home at 5 years.²⁹ Drummond et al. (1996) was a sub-group analysis on ADL at 12 months,²⁶ and Lincoln et al. (1997) reported on perceptual impairment.²⁸
- The Nordbyhagen trial from Norway was reported in two articles.^{30,31} Rønning and Guldvog (1998a) reported on death at 18 months of follow-up (n=802 patients).³⁰ Rønning and Guldvog (1998b) reported on death, BI, proportion of patients requiring institutional care and LOHS at 7 months (n=570 patients).³¹ There was some degree of overlap in recruitment periods between the two articles: January 1, 1993 to January 31, 1995 for Rønning and Guldvog (1998a)³⁰ and March 1, 1994 to December 31, 1995 for Rønning and Guldvog (1998b).³¹ Rønning and Guldvog (1998a) was used for the outcome of death and Rønning and Guldvog (1998b) was used for baseline characteristics and other study outcomes. No significant differences were observed in baseline patient characteristics between these two articles.

The primary intervention group in all studies was rehabilitation on a SU. Comprising an interdisciplinary team of neurologists, specialized nurses, physiotherapists, occupational therapists and speech therapists, the care-team planned treatment and support after discharge. In all trials, patients in the control group received GMW care. GMW care consisted of traditional medical treatment without specialized attention within the framework of a team approach: patients were evaluated by a neurologist and were offered physiotherapy and/or occupational therapy.

Of the six trials, two (33%) used adequate methods of randomization,^{36,37} four (67%) used adequate sequences for allocation concealment^{25,32,36,37} and four (67%) reported blinding of outcome assessors.^{27,32,36,37} No patients were lost to follow-up in five trials,^{25,29,31,35,36} in the remaining trial by Kalra et al. (2000),³⁷ three patients (2%) were lost to follow-up at 6 months and at 12 months in the control group (n=152) with no drop-outs reported in the intervention group. Four trials (67%) contained an intention-to-treat analysis.^{25,32,36,37} The mean quality score was 4 (range, 2 to 5). Details of the trial characteristics and quality assessment scores for the six trials are shown in Appendix 6.

b) Patient characteristics

The six trials included 1,709 patients in total. The average age of the patients recruited was 76 years (Table 1). Female patients comprised at least 50% of the cases in both groups. Five (83%) trials reported the baseline BI score between groups; on average, stroke severity for patients in both groups was moderate (Table 1).^{25,31,32,36,37}

Table 1: Summary of patient characteristics

Patient characteristics	Intervention	Control
Mean sample size (range)	152 (34-271)	133 (37-279)
Mean age (range of means)	75 (69-80) yrs	76 (68-80) yrs
Mean % females (range)	55 (47-75)%	51 (35-71)%
Mean time between stroke onset and randomization (range)	6 (0-14) days	6 (0-14) days
Mean BI score (range)	7.6 (3-9.4)	7.8 (3-10)

c) Primary outcomes

Death

Outcome measures were reported at various follow-up periods within the six trials (range, 6 months to 10 years). Death was an outcome measure in all six trials. SU care showed a reduction in the odds of death (OR 0.60, 95% CI 0.42; 0.86) recorded at final follow-up (median, 15 months) (Figure 2). A random effects model was used for the pooled estimate for death as there was heterogeneity between the trials according to the χ^2 statistic using the fixed effects model (p=0.03). The presence of funnel plot asymmetry for death across the six trials suggests some evidence of publication bias (Figure 3). The estimated number needed to treat (NNT) to prevent 1 death is 11 (range, 7 to 25).

Figure 2: Forest plot of pooled estimates for death

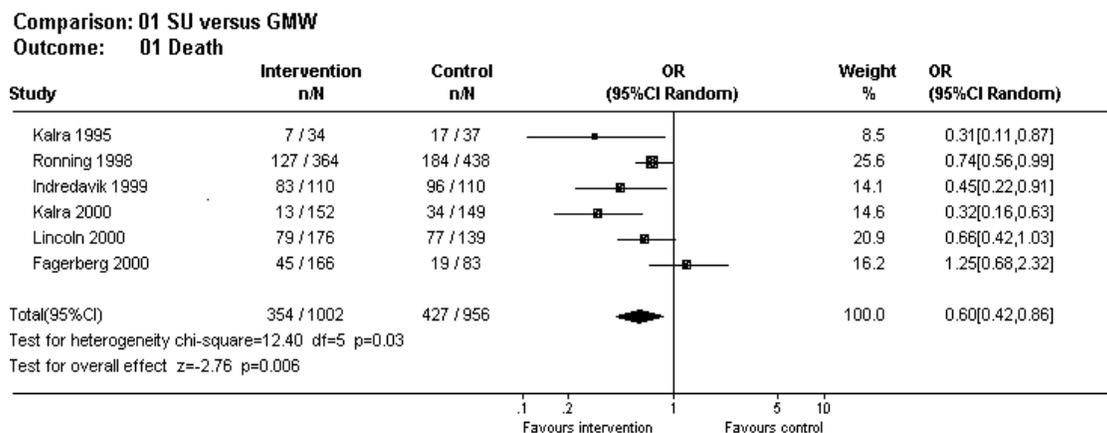
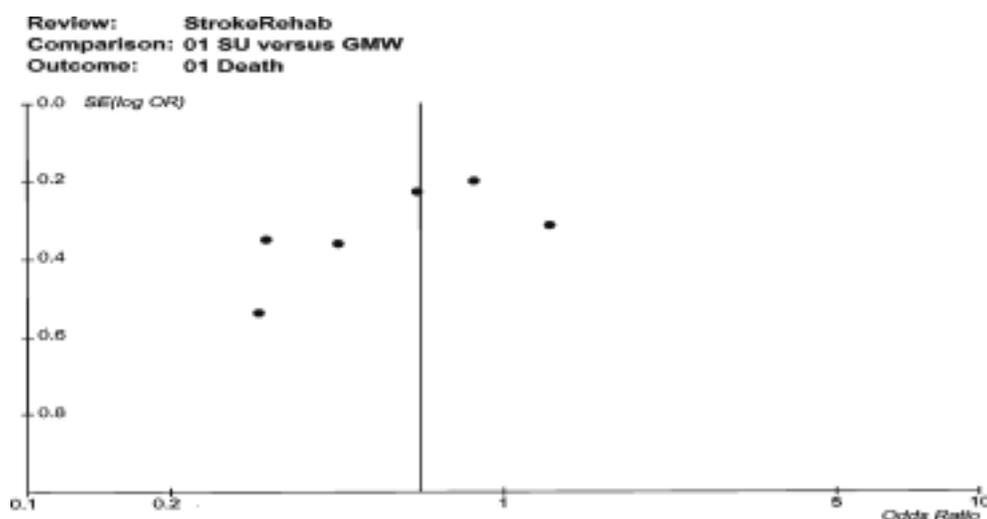


Figure 3: Funnel plot for all six trials reporting on death



Physical dependence

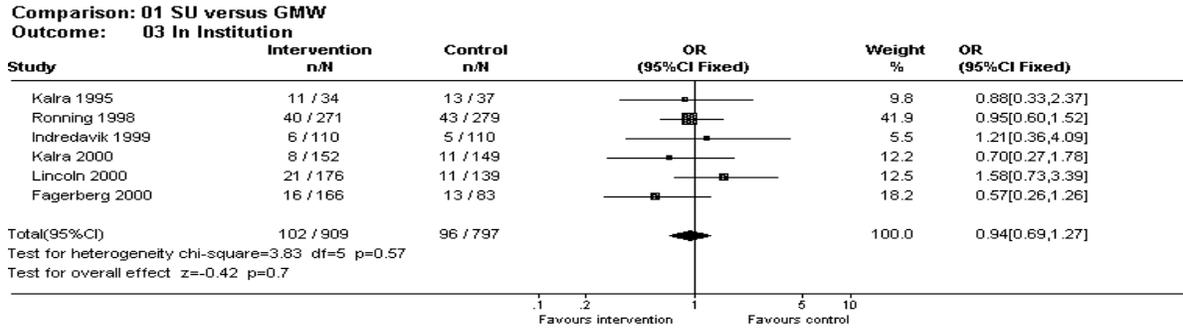
Three trials reported the median BI score between the intervention and control groups,^{25,27,31} and one trial by Fagerberg et al. (2000) reported the mean BI score.³⁶ When the scores were combined for the three studies reporting on the median BI score, a one-point rise in the BI score was observed at 12 months in SU patients (13.9, range 8 to 17) compared to GMW patients (12.9; range, 6 to 16.8). Fagerberg et al. also reported a one-point rise in the BI at 12 months in SU patients (16.4 vs. 15.2).³⁶

Three trials reported on the percentage of patients considered independent or partly independent on the BI.^{29,35,37} In one long-term follow-up RCT by Indredavik et al., over twice the number of intervention patients, compared to controls, were considered independent (BI score ≥ 19 , on a scale of 0-20) or partly independent (BI score ≥ 12) with respect to ADL at both 5 years³³ and 10 years after stroke.³⁵ Kalra et al. (2000) also reported a higher frequency of independence in SU patients at 12 months (87% vs. 69% with BI score of 15-20, $p=0.001$).³⁷ The trial by Kalra et al., in addition, reported functional status using the RS at 12 months: the proportion of patients judged independent (RS score of 0 to 3) was higher in the intervention group compared to controls (85% vs. 66%, OR 1.27, 95% CI 1.13; 1.47).³⁷

Institutional care

All six trials reported on the proportion of patients requiring institutional care within 10 years of follow-up. The pooled OR across trials demonstrated a trend to reduced institutional care in patients in the SU group (OR 0.94) compared to GMW controls with up to 10 years of follow-up; this did not reach statistical significance (95% CI 0.69; 1.27) using the fixed effects model (Figure 4). Similar findings were observed in institutional care between groups using the random effects model (OR 0.93, 95% CI 0.69; 1.26).

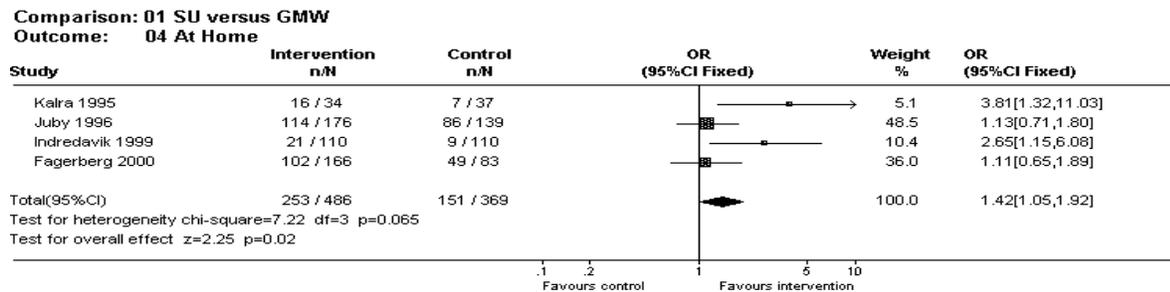
Figure 4: Forest plot of pooled estimates for institutional care



Discharge to home

Four trials reported on the proportion of patients discharged to home with 10 years of follow-up.^{25,27,35,36} A higher percentage of intervention patients were discharged to home compared to controls (OR 1.42, 95% CI 1.05; 1.92) (Figure 5).

Figure 5: Forest plot of pooled estimates for discharge to home*



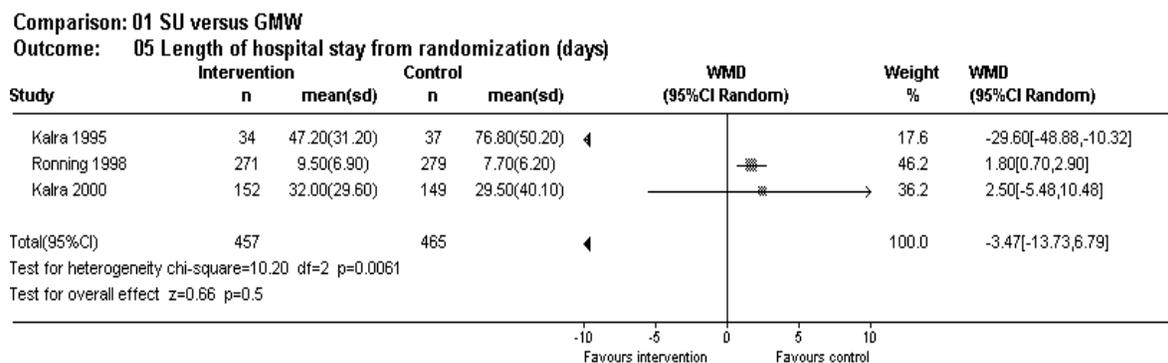
* OR>1 favours SU care

d) Secondary outcomes

LOHS

Four trials assessed inter-group differences with respect to LOHS: one at 7 months³⁰ and three at 12 months.^{25,36,37} No significant inter-group differences were observed in LOHS (OR -3.47, 95% CI -13.73; 6.79) when data were pooled from three RCTs (Figure 6).^{25,30,37} The trial by Fagerberg et al. (2000) reported a reduction in LOHS with SU care compared to GMW care (mean values: 28.3 days vs. 35.8 days); however, these data were excluded from the pooled analysis for LOHS as no standard deviation around these values was reported by Fagerberg et al.³⁶

Figure 6: Forest plot of pooled estimates for LOHS



HRQoL

Two trials assessed the impact on HRQoL of intervention patients compared to controls (Appendix 10).^{34,36} Both trials used the NHP as their HRQoL measure. Fagerberg et al. (2000),³⁶ reported no significant inter-group differences in the NHP score at 12 months, but Indredavik et al. (1998),³⁴ reported higher NHP scores in patients treated in the SU when measured at five years of follow-up.

e) Sensitivity analysis

As death was an outcome measure in all six trials, sensitivity analysis was undertaken to test the impact of follow-up on survival rates between the intervention and control groups. The results of the analysis are summarized below in Table 2. SU care showed a reduction in the odds of death at all periods of follow-up in comparison to GMW care (Table 2).

Table 2: Sensitivity analysis of impact of follow-up on death rates

Follow-up	OR (95% CI)
0-6 months	0.50 (0.30 to 0.85); n=2 ^{27,37}
7-18 months	0.63 (0.41 to 0.98); n=5 ^{*25,27,30,36,37}
at 5 years	0.63 (0.44 to 0.89); n=2 ^{29,33}
at 10 years	0.45 (0.22 to 0.91); n=1 ³⁵

n = number of trials contributing to pooling

*Test of heterogeneity significant (p<0.05) and random-effects meta-analysis model used

Of six trials, the methodological quality for two trials was 5,^{36,37} for one trial was 4,³³ for two trials was 3^{25,27} and for one trial was 2.³¹ There was little difference in the outcome of death when stratified by trial quality; the pooled OR at various levels of quality demonstrated a reduction in death with SU care in comparison to GMW care (OR 0.54 to 0.74). The results, however, did not reach statistical significance (95% CI 0.16; 2.45) for the two trials with a quality score of 5, given the conflicting results on this outcome between these two trials (Table 3).^{36,37}

Table 3: Sensitivity analysis of impact of trial quality on death rates

Trial Quality	OR (95% CI)
0-2	0.74 (0.56 to 0.99); n=1 ³¹
3-4	0.54 (0.38 to 0.77); n=3 ^{25,27,33}
5	0.63 (0.16 to 2.45); n=2 ^{36,37}

n = number of trials contributing to pooling

*Test of heterogeneity significant (p<0.05) and random-effects meta analysis model used

f) Summary

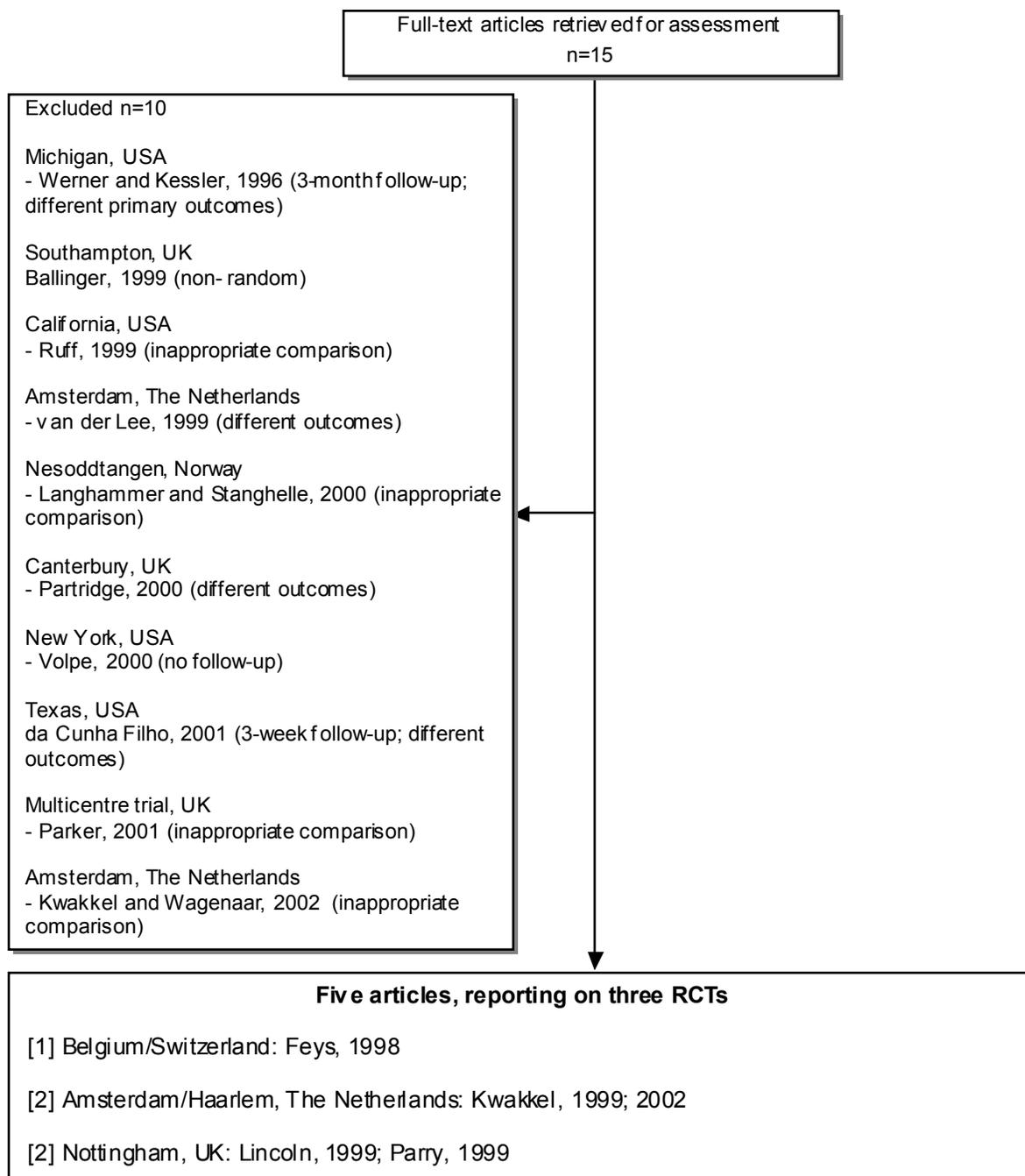
Six RCTs, reported in 13 articles, were reviewed: 1,709 patients in total. On average, the RCTs were assessed to be of good quality. Stroke severity for patients in both groups was moderate. Compared with GMW care, SU care showed reductions in the odds of death recorded at final follow-up (median 15 months) across six trials (OR 0.60, 95% CI 0.42; 0.86), and an increase in the odds of living at home across four trials (OR 1.42, 95% CI 1.05; 1.92). The estimated NNT to prevent 1 death is 11 (range, 7 to 25). Sensitivity analyses indicated that the observed mortality benefits remained up to 10 years after stroke. There was little difference in the outcome of death when stratified by trial quality.

There was some evidence that SU patients are more likely to undergo recovery as assessed by the BI compared to GMW patients. The pooled OR across six trials demonstrated a reduction in institutionalized care in SU patients compared to GMW patients at final follow-up (OR 0.94); however, this did not reach statistical significance (95% CI 0.69; 1.27). It was not possible to determine whether SU care resulted in decreased hospital stay. No systematic differences in HRQoL were observed between groups within five years post-stroke.

(2) Impact of different intensities of rehabilitation therapies

Fifteen articles were retrieved which examined whether patients who receive therapy for longer periods of time or at higher levels of intensity realize greater benefits when compared to patients who receive usual care. Five articles, reporting on three RCTs, met the inclusion criteria⁴³⁻⁴⁷ and ten articles did not.⁴⁸⁻⁵⁷ The flow document for selection is displayed in Figure 7 below:

Figure 7: Summary of the selection of articles for inclusion



a) Trial characteristics and quality

The three RCTs were undertaken in four countries: one in both Belgium and Switzerland, one in the Netherlands and one in the UK (Figure 7). Two RCTs were reported in multiple publications.

- The Amsterdam trial from the Netherlands was reported in two articles.^{44,45} Kwakkel et al. (1999) reported on BI and HRQoL at 6 months,⁴⁴ and Kwakkel et al. (2002) reported on these outcomes on the same patient groups at 12 months.⁴⁵
- The Nottingham trial from the UK was reported in two articles.^{46,47} Lincoln et al. (1999) reported on death and the BI score at 6 months⁴⁶ and Parry et al. (1999) reported a subgroup analysis on the effects of severity of arm impairment also at 6 months post-stroke.⁴⁷

Patients in the intervention group, on average, received 25 hours (range, 10-50 hours) of additional therapy during a period of 10 weeks (range, 5 to 20 weeks) across the three trials. Therapy primarily consisted of a combination of physiotherapy and occupational therapy. Two trials (67%) used adequate methods of randomization and adequate sequences for allocation concealment^{44,46} and all three trials reported blinding of outcome assessors. No patients were lost to follow-up across the three trials, with one trial⁴⁴ using an intention-to-treat analysis. The mean quality score was 4 (range, 2 to 5). Details of the trial characteristics and quality assessment scores for the three trials are shown in Appendix 7.

b) Patient characteristics

The three RCTs included 642 patients in total. The mean overall sample size across trials was larger in the intervention group compared to the control group (Table 4). The intervention and control groups were similar with respect to patient age and gender. The average age of the patients recruited was 68 years. Two (67%) trials reported the baseline BI score between groups; stroke severity for patients in both groups was moderate (Table 4).^{44,46}

Table 4: Summary of patient characteristics

Patient Characteristics	Intervention	Control
Mean sample size (range)	100 (50-187)	61 (37-95)
Mean age (range of means)	69 (66-73) yrs	67 (63-73) yrs
Mean % females (range)	47 (38-55)%	53 (44-62)%
Mean time between stroke onset and randomization (range)	13 (7-24) days	14 (7-24) days
Mean BI score (range)	5.75 (5.5-6)	6.25 (5.5-7)

c) Primary outcomes

Data pooling was considered inappropriate for this comparison given the following reporting characteristics. Death was an outcome measure in only one trial.⁴⁶ The BI was used in all three trials; however, two trials provided quantitative changes in the BI score between groups, expressed as median values.^{45,46} No differences were observed between groups with respect to death, or dependency as measured by the BI. None of these trials used the RS to assess functional status. These trials did not report outcomes with respect to discharge to home or institutional care.

d) Secondary outcomes

These trials did not report on LOHS. Only one trial (n=101 patients) assessed the impact on HRQoL of increased intensity of therapy (Appendix 10).⁴⁵ Compared to the control group, patients in the intervention group received 50 hours of additional therapy over a 20-week period. No overall significant differences were observed between groups at 12 months on each of two indices: NHP and the SIP.⁴⁵

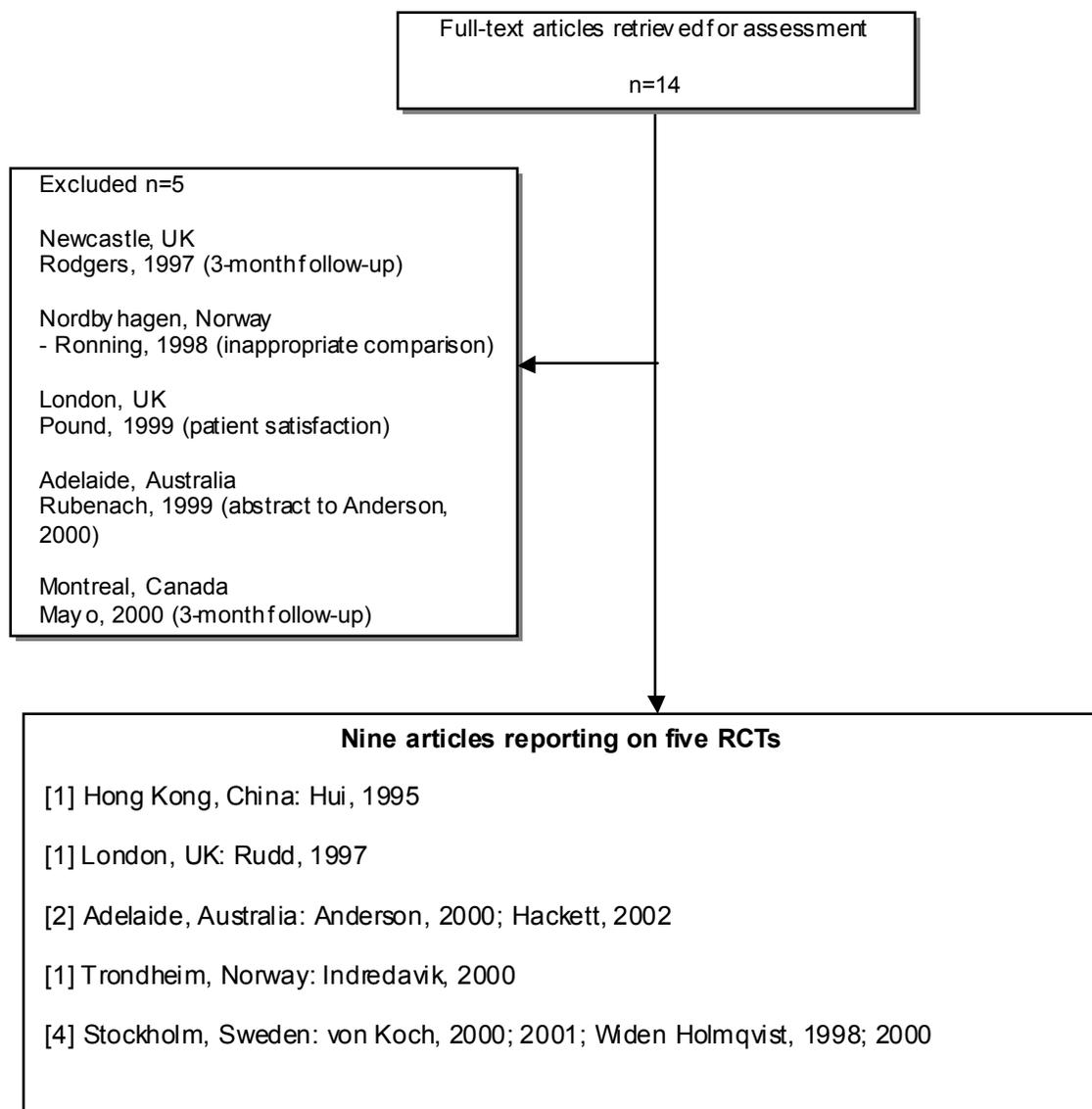
e) Summary

Three RCTs, reported in five articles, were reviewed: 642 patients in total. On average, as with the first comparison on SU care, the RCTs were assessed to be of good quality. Stroke severity for patients in both groups was moderate. Data pooling was considered inappropriate for this comparison for all the study outcomes given the reporting characteristics of these trials. No differences were observed, based on intensity level of rehabilitation, for either death or dependency. No data were reported with respect to discharge to home, institutional care, or in LOHS.

(3) ESD services versus usual care

Fourteen articles were retrieved reporting on ESD services versus usual care. Nine articles, reporting on five RCTs, met the inclusion criteria⁵⁸⁻⁶⁶ and five did not.⁶⁷⁻⁷¹ The flow document for selection is displayed in Figure 8 below:

Figure 8: Summary of the selection of articles for inclusion



a) Trial characteristics and quality

The five RCTs were undertaken in five countries: one each in Australia, China, Norway, Sweden and the UK (Figure 8). Two RCTs were reported in multiple publications:

- The Adelaide trial from Australia was reported in two articles.^{60,61} Anderson et al. (2000) reported on death, the BI, rates of admission to institutional care, LOHS and HRQoL at six months;⁶⁰ Hackett et al. (2002) was a follow-up report on HRQoL in the same patient population at 12-months.⁶¹
- The Stockholm trial from Sweden was reported in four articles.⁶³⁻⁶⁶ Widén Holmqvist et al. (1998) reported on trial methodology (and outcomes of BI, LOHS and HRQoL at three months),⁶⁵ and von Koch et al. reported on the same outcomes at both six months⁶³ and at 12 months.⁶⁴ The fourth article by Widén Holmqvist et al. (2000) reported on the impact on family caregivers and patient satisfaction at six months post-stroke.⁶⁶

The intervention group(s) consisted of ESD services provided by an interdisciplinary team of professionals: the care team consisted of both physiotherapists and occupational therapists in all trials with the inclusion of speech therapists in three trials^{59,60,65} and physician and nursing support in two trials.^{60,62} Based on reported characteristics in four RCTs, ESD services were provided for up to five months (range, 1 week to 19 weeks) for patients randomized to the intervention group.^{59,60,62,65} In three trials, ESD services provided for the intervention groups were an extension of SU care.^{59,60,62} The control group consisted of patients undergoing conventional rehabilitation; in one trial, this care was provided on a SU,⁶² in two trials on geriatric wards^{58,65} and in the remaining two trials, a combination of SU, GMW and/or geriatric ward care.^{59,60}

Three RCTs (60%) used adequate methods of randomization and adequate sequences for allocation concealment^{59,60,65} and three (60%) reported blinding of outcome assessors.^{60,62,65} Follow-up of 80% or greater at final assessment was achieved in three trials,^{60,62,65} with two of these trials using an intention-to-treat analysis.^{60,62} Of the remaining two trials, 16 (of 59) intervention patients and 17 (of 61) controls were lost to follow-up at six months in the RCT by Hui et al. (1995),⁵⁸ and the trial by Rudd et al. (1997) reported drop-out rates of 32 (of 167) intervention patients and 38 controls (of 164) at 12 months for the outcomes of death and institutional care.⁵⁹ The mean score was 3 (range of 1 to 5) Details of the trial characteristics and quality assessment scores for the six trials are shown in Appendix 8.

b) Patient characteristics

The five RCTs included 940 patients in total. No overall differences were observed in either of the patient characteristics at baseline between the intervention and control groups (Table 5). Four (80%) trials reported the baseline BI score between groups;^{58-60,62} stroke severity for patients in both groups was mild (Table 5).

Table 5: Summary of patient characteristics

Patient Characteristics	Intervention	Control
Mean sample size (range)	94 (42-167)	94 (41-164)
Mean age (range of means)	72 (70-74) yrs	73 (71-74) yrs
Mean % females (range)	47 (38-58)%	50 (43-56)%
Mean time between stroke onset and randomization (range)	11 (6-23) days	11 (6-23) days
Mean BI score (range)	13.5 (9.9-17)	13.6 (10.4-17.2)

c) Primary outcomes

Death

Outcome measures were reported at six months in three trials,^{58,60,62} and up to 12 months in two trials.^{59,64} Death was an outcome measure in three trials.^{58,60,62} No reduction in the odds of death for ESD patients compared to controls (OR 1.01, 95% CI 0.54; 1.89) was recorded at six months (Figure 9). The presence of funnel plot asymmetry for death across the three trials suggests a possibility of publication bias (Figure 10). These three trials reported conflicting results. There was variation in sample size between trials, with one RCT by Indredavik et al. (2000) contributing to over two-thirds of the total sample size.⁶²

Figure 9: Forest plot of pooled estimates for death

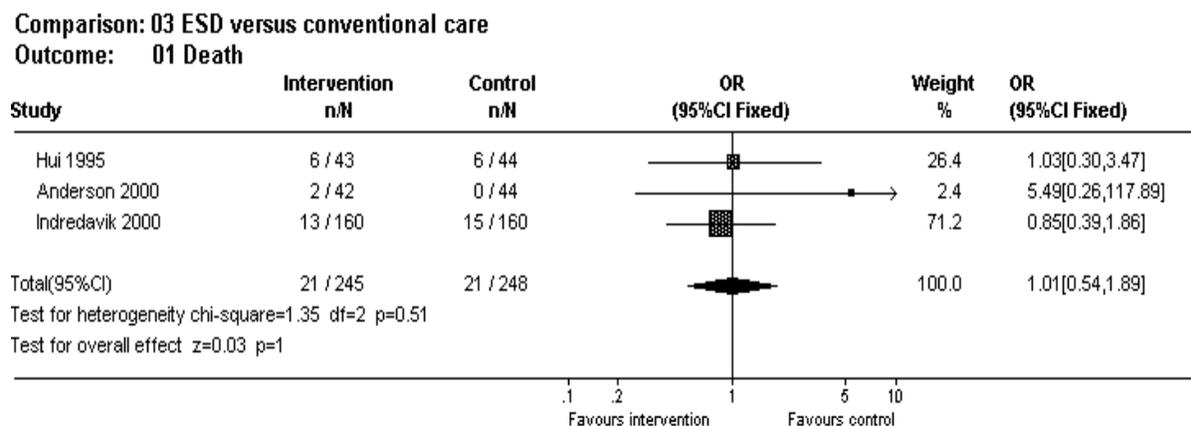
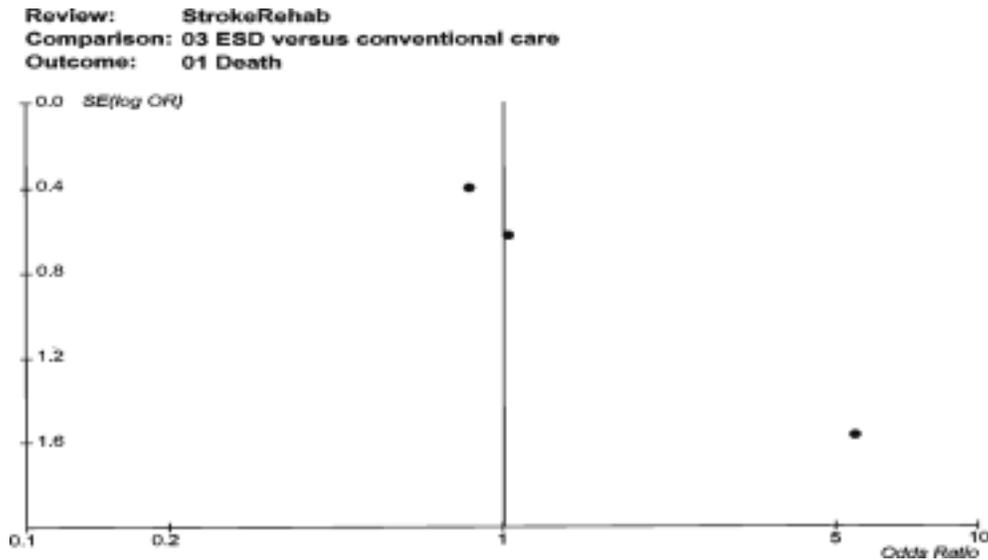


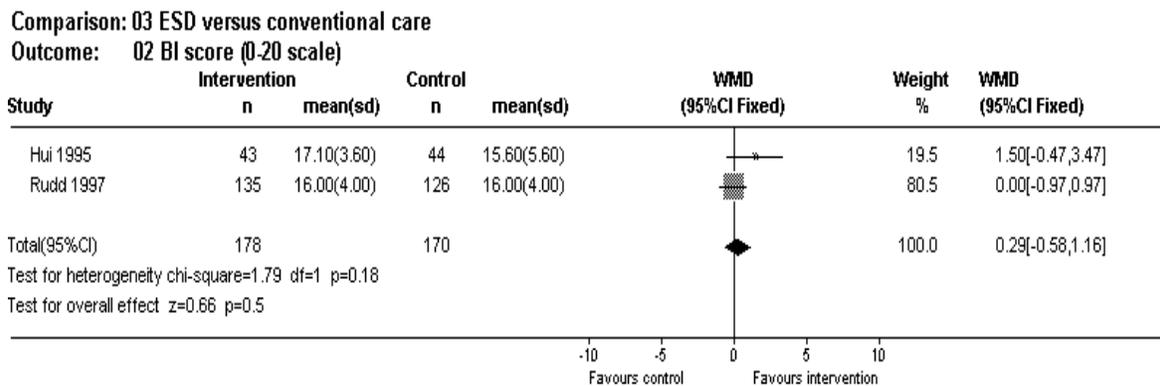
Figure 10: Funnel plot for three trials reporting on death



Physical dependence

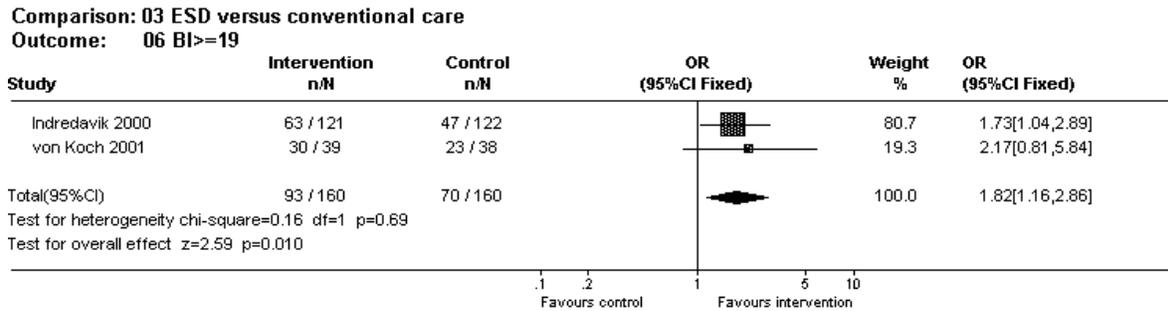
Two trials reported the mean BI score,^{58,59} and one trial the median BI score.⁶⁰ Two additional trials reported the proportion of patients considered independent on the BI.^{62,64} Although no significant differences were observed between groups in the mean BI score (WMD 0.29, 95% CI -0.58; 1.16) (Figure 11), a higher percentage of intervention patients were considered independent with respect to ADL (BI score ≥ 19) compared to patients randomized to the control group (OR 1.82, 95% CI 1.16; 2.86) (Figure 12). One trial conducted by Indredavik et al. (2000) reported functional status using the RS: the proportion of patients judged independent (RS ≤ 2 score) was higher in the ESD group (58% versus 40%, $p=0.006$).⁶²

Figure 11: Forest plot of pooled estimates for BI (0-20 scale)*



*WMD>1 favours ESD services

Figure 12: Forest plot of pooled estimates for BI ≥ 19 *

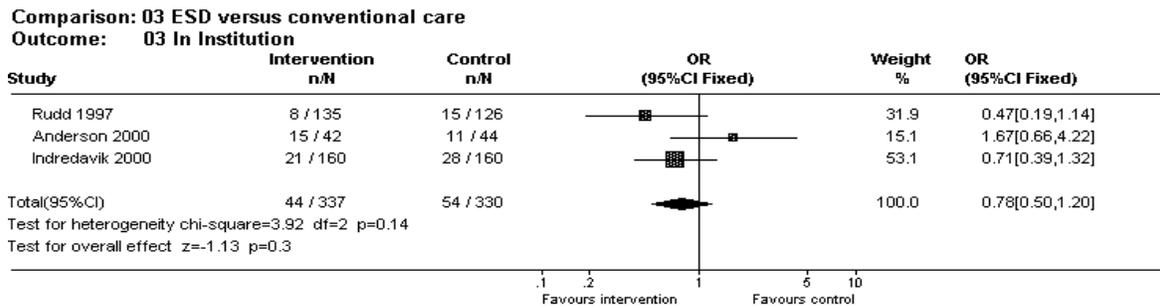


*OR>1 favours ESD services

Institutional care

Three trials reported on the proportion of patients requiring institutional care.^{59,60,62} No significant differences were observed in rates of admission to institutional care (OR 0.78, 95% CI 0.50; 1.20) between the ESD group and controls within one year of follow-up (Figure 13).

Figure 13: Forest plot of pooled estimates for institutional care



Discharge to home

Only one trial, by Indredavik et al. (2000), reported on the proportion of patients at home after six months; no significant differences were observed between groups (79% of intervention patients vs. 73% of controls, p=0.24).⁶²

d) Secondary outcomes

LOHS

Three trials assessed inter-group differences with respect to LOHS from randomization to follow-up.^{59,60,64} These differences were expressed as mean values in two trials, with one of these trials also reporting on the standard deviation; a third trial expressed this difference as a median value. In all cases, those randomized to the ESD group had significantly shorter LOHS post-randomization (from a range of 12-33 days in the control group to 2-18 days in the intervention group, p<0.05).

HRQoL

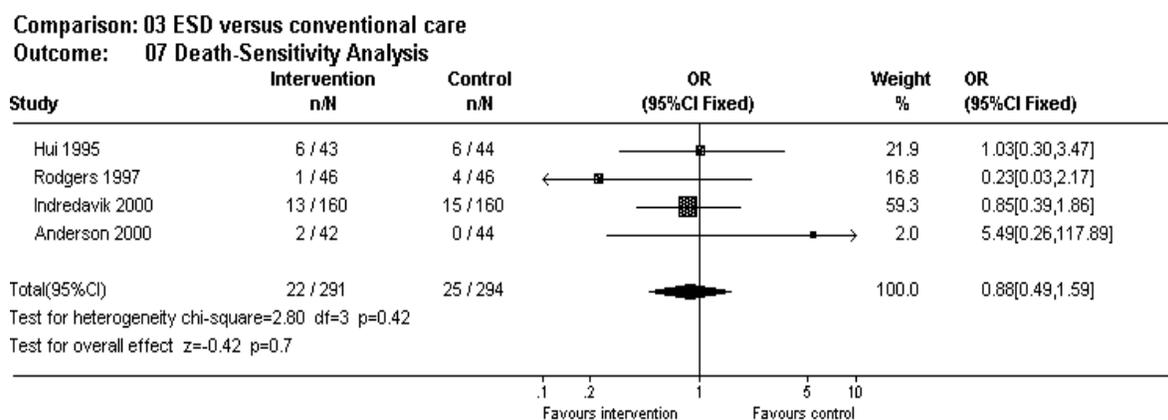
Three trials, reported in five articles, assessed the impact on HRQoL of ESD services compared to in-patient rehabilitation (Appendix 10).^{59-61,63,64} Three HRQoL measures were used within these trials: NHP expressed as mean or median values in two trials, SF-36 in one trial and SIP in one trial. No significant differences were observed between groups at 12 months of follow-up.

e) Sensitivity analysis

Two RCTs assessing outcomes up to three months post-stroke were excluded from the primary analysis based on the inclusion criterion requiring six months or longer of follow-up (Figure 8); these two trials met the other study inclusion criteria.^{67,71} Of these, the trial by Rodgers et al. (1997) reported on survival rates between ESD services and usual care.⁶⁷ The second trial by Mayo et al. (2000) reported on the BI score, LOHS and HRQoL between the two groups.⁷¹ No differences were reported in the BI, although patients in the intervention group had shorter LOHS (by six days) and significantly higher scores on the SF-36 physical health component than the control group.⁷¹

Compared to the baseline analysis (Figure 9; OR 1.01, 95% CI 0.54; 1.89), including the mortality data from Rodgers et al. (1997) resulted in no significant difference in the odds of death in the ESD group compared to usual care controls (OR 0.88, 95% CI 0.49; 1.59) (Figure 14).

Figure 14: Forest plot of sensitivity analysis of pooled estimates for death



For the three trials reporting on death (all at six months) assessment of quality showed variation: for one trial the score was 5,⁶⁰ for one trial it was 3,⁶² and for the remaining trial it was 1.⁵⁸ The trial by Anderson et al. (2000) (quality = 5) reported no mortality in controls at six months; a 5% mortality rate was reported in ESD patients.⁶⁰ The trial by Indredavik et al. (2000), contributing over 70% of the overall patient numbers (quality = 3) demonstrated a trend towards reduction in death in ESD patients (OR 0.85).⁶² Despite not reaching statistical significance (95% CI 0.39; 1.86), the Anderson et al. trial⁶² was more favourable to ESD services with respect to survival in comparison to the trial by Hui et al. (1995)⁵⁸ (quality = 1) (Figures 9 and 14).

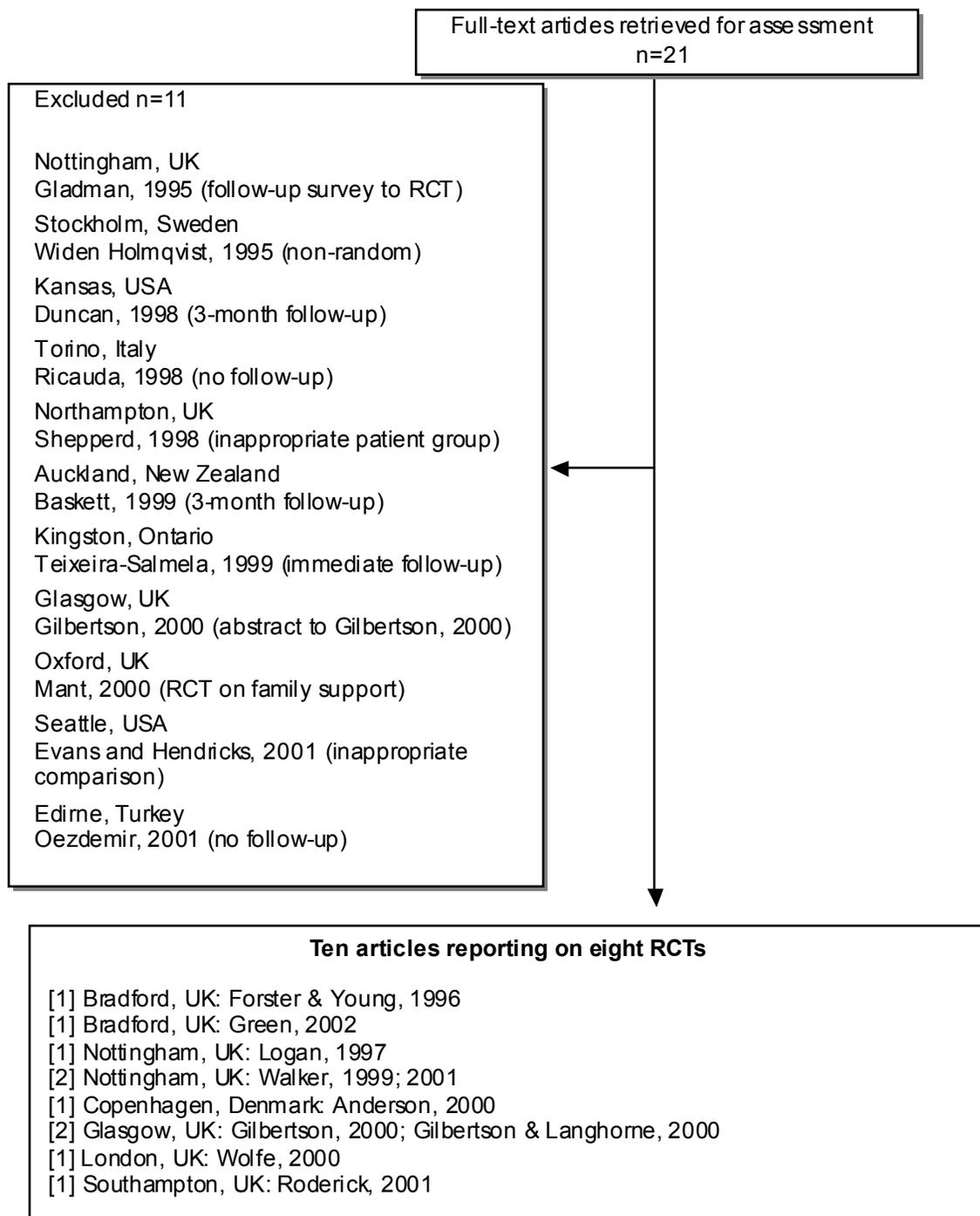
f) Summary

Five RCTs, reported in nine articles, were reviewed: 940 patients in total. Trial quality varied and was on average moderate. Stroke severity for patients in both groups was mild. No reduction in the odds of death or institutionalized care for ESD patients compared to controls was recorded at six months of follow-up. Variation in follow-up periods did not impact on these findings with respect to the odds of death between groups. No significant differences were observed between groups in the mean BI score; however, a higher percentage of intervention patients were considered independent (BI score ≥ 19) compared to controls (OR 1.82, 95% CI 1.16; 2.86) in two trials. ESD patients showed significant reductions in LOHS (approximately 10 days), compared to controls. No differences between groups were observed in the proportion of patients at home at follow-up or in HRQoL.

(4) Rehabilitation in the community versus usual care

Twenty-one articles were retrieved reporting on rehabilitation within the community versus usual care. Ten articles, reporting on eight RCTs, met the inclusion criteria⁷²⁻⁸¹ and eleven did not.⁸²⁻⁹² The flow document for selection is displayed in Figure 15.

Figure 15: Summary of the selection of trials for inclusion



a) Trial characteristics and quality

The eight RCTs were undertaken in two countries: one in Denmark and seven in the UK (Figure 15). Two of the RCTs were reported in multiple publications:

- The Nottingham trial from the UK was reported in two articles.^{75,76} Walker et al. (1999) reported on the median BI score between groups at six months,⁷⁵ and Walker et al. (2001) reported on this outcome at 12 months after stroke.⁷⁶
- The Glasgow trial from the UK was reported in two articles.^{78,79} Gilbertson et al. (2000) reported on death and the BI score between groups at six months,⁷⁹ and Gilbertson and Langhorne (2000) reported on occupational performance and service satisfaction on the same patient groups during the same follow-up period.⁷⁸

The intervention group(s) in each of the eight trials had home-based rehabilitation services provided by an interdisciplinary team of professionals including physicians, nurses, occupational therapists and physiotherapists. The home-based rehabilitation team was primarily comprised of occupational therapists in four trials (50%). Based on reported characteristics in four trials, home-based services were provided for an average of six visits over five months (range, 3 to 10 visits over 16 weeks to 12 months) for patients randomized to the intervention group. The control group consisted of patients undergoing routine rehabilitation services either in a hospital or community setting.

Of the eight trials, all used adequate methods of randomization and adequate sequences for allocation concealment. Six trials (75%) reported blinding of outcome assessors.^{73-75,77,79,81} Follow-up of 80% or greater (range, 80% to 100%) at final assessment was achieved in six trials.^{72,73,75,77,79,81} An intention-to-treat analysis was performed in seven trials,^{72-74,77,79-81} including trials by Logan et al. (1997) and Wolfe et al. (2000) that reported overall drop-out rates at follow-up of 25%⁷⁴ and 26%,⁸⁰ respectively. The mean quality score was 5 (range, 4 to 5). Details of the trial characteristics and quality assessment scores for the six trials are shown in Appendix 9.

b) Patient characteristics

The eight RCTs included 1,182 patients in total. No overall differences were observed in either of the patient characteristics at baseline between the intervention and control groups within these trials (Table 6). All trials recruited elderly patients (>70 years of age). Seven (88%) trials reported the baseline BI score between groups. Stroke severity for patients in both groups was mild (Table 6).^{72,73,75,77,79-81}

Table 6: Summary of patient characteristics

Patient characteristics	Intervention	Control
Mean sample size (range)	77 (23-120)	71 (20-120)
Mean age (range of means)	73 (71-78) yrs	74 (71-80) yrs
Mean % females (range)	53 (45-59)%	52 (43-60)%
Mean time between stroke onset and randomization (range)	30 (27-365) days	30 (27-365) days
Mean BI score (range)	16.5 (12.6-18)	16.5 (12.8-18)

c) Primary outcomes

Death

Outcome measures were reported at six months in four trials,^{74,77,79,81} at six months and nine months in one trial⁷³ and up to 12 months in three trials.^{72,76,80} Death was an outcome measure in three (38%) trials:^{74,77,79} no significant inter-group differences were observed for death at six months (OR 1.12, 95% CI 0.50; 2.52) (Figure 16), although there was some heterogeneity between these trials (Figure 17).

Figure 16: Forest plot of pooled estimates for death

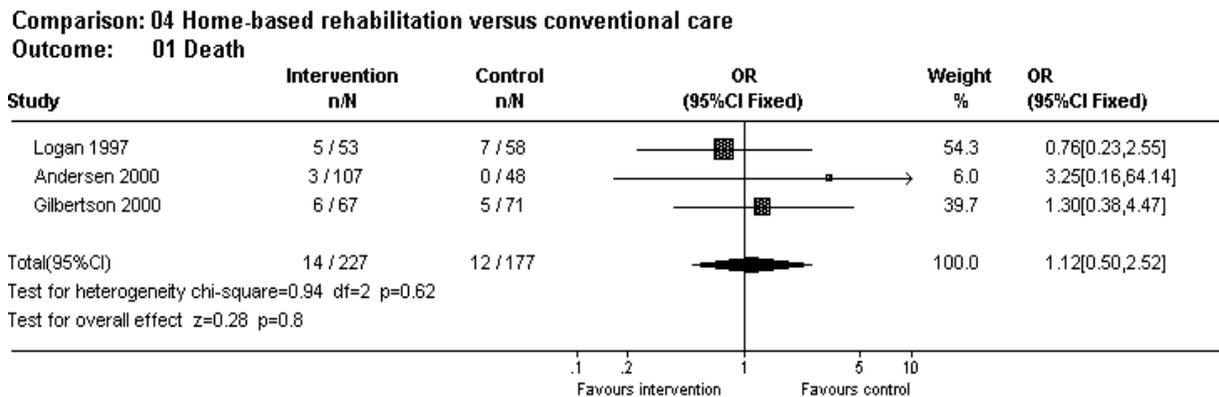
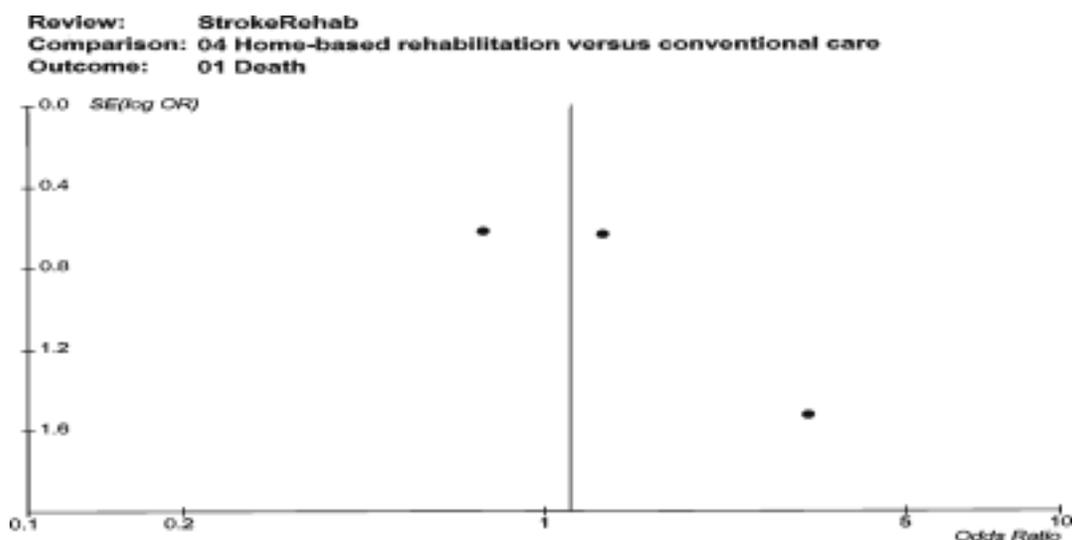


Figure 17: Funnel plot for three trials reporting on death



Physical dependence

BI was used in seven (88%) trials and expressed in all trials as median values.^{72-74,76,79-81} No significant inter-group differences were observed in the BI score in the intervention (17.6 (range, 1 to 20) and control 17.4 (range, 2 to 20) groups at 12 months of follow-up. One trial, by Wolfe et al. (2000), reported functional status using the RS; in this trial, no statistically significant differences were observed between groups in the proportion of patients with an RS>3 score at 12 months (53% versus 41%, p=0.49).⁸⁰

Institutional care

One trial, by Andersen et al. (2000), reported on the proportion of patients requiring institutional care. No significant differences between the intervention and control groups were observed six months after discharge from inpatient rehabilitation, but patient numbers were small (n=155).⁷⁷

d) Secondary outcomes

Hospital readmission rates

Two trials assessed inter-group differences with respect to hospital readmission rates: one trial expressed this outcome as a median value⁸¹ and the other trial as a mean value.⁷⁷ Both trials reported >50% reduction in rate of readmission in the intervention group compared to controls (12 days versus 19 days across the two trials).

HRQoL

Three RCTs (38%) assessed the impact on HRQoL of home-based services compared to usual care (Appendix 10).^{72,80,81} Two HRQoL measures were used within these trials: two trials used NHP (expressed as median values)^{72,80} and one used SF-36.⁸¹ No significant differences were observed between groups at 12 months of follow-up.

Sensitivity analysis

Two RCTs assessing outcomes up to three months post-stroke were excluded from the primary analysis based on the inclusion criterion which required six months or longer of follow-up (Figure 8); these two trials met the other study inclusion criteria.^{84,86} Neither of these trials reported on death as an outcome.

e) Summary

Eight RCTs, reported in ten articles, were reviewed: 1,182 patients in total. The eight trials were of high methodological quality. Stroke severity for patients in both groups was mild. No significant inter-group differences were observed for death or dependency across trials. There was no indication that home-based services resulted in decreased institutional care, although this outcome was reported in only one trial (n=155). Patients in the home-based intervention group showed reductions in hospital readmission rates (approximately seven days) compared to controls. No differences in HRQoL were observed between groups one year post-stroke.

4 REVIEW OF ECONOMIC EVALUATIONS

4.1 Methods

4.1.1 Literature search strategy

Appendix 1 contains the detailed search strategy for both the clinical and economic literature. The search strategy for the economic literature was modelled on that used for the clinical literature, but with an economics filter replacing the clinical trial filter. The latter filter was excluded, as this would have eliminated economic evaluations based on decision-analytic models. Therefore, both trial-based and (non-trial-based) modelling studies were retrieved in the search.

The search of the economic literature was performed using the same databases as for the clinical literature, with the exception of SciSearch[®]. This resulted in 375 unique records for the DIALOG[®] search (not including overlap with the clinical search results). The searches in DIALOG[®] and CINAHL were limited to literature published from January 1995 onwards, consistent with the search for the clinical literature, although PubMed was searched from January 1990. Searches were also performed and updated regularly on the CD ROM versions of The Cochrane Library and the Health Economic Evaluations Database (HEED). As with the clinical search, database alerts/updates were established and incorporated in the analysis up until July 31, 2002 on all the originally searched databases except SPORTDiscus.

Grey literature was obtained through using the same methods listed for the clinical search. Specialized databases included the AAPM&R cost-effectiveness bibliography database.⁹³ RM was also used to manage the economic literature identified, in a way similar to its use to manage the results of the clinical search.

4.1.2 Inclusion and exclusion criteria

An economic study was eligible for inclusion if it met each of the following three criteria:

Study design: Included studies could be primary studies that were either an economic evaluation or a comparative cost analysis. Reviews were used when discussing results.

An economic evaluation is defined as the comparative analysis of two or more alternative interventions, in terms of both their costs and consequences. Economic evaluations can be of various types, including:

- a) cost-consequences analysis (no attempt is made to aggregate across different kinds of consequences);
- b) cost-minimization analysis (requires evidence that the intervention and comparator are equally effective);
- c) cost-effectiveness analysis (defined here in the more specific sense where consequences are measured in natural units);

- d) cost-utility analysis (consequences are measured in units such as quality-adjusted life-years); and
- e) cost-benefit analysis (consequences are measured in dollars).

A cost analysis had to be a comparative analysis of relevant alternatives, examining costs at the micro level and expressing them in monetary terms (such as dollar amounts). Studies that only assessed resource use, such as LOHS were excluded from the economic review, unless there was an indication of costs per bed-day. (Note that these studies were included in the clinical review.)

Population: To be eligible for inclusion, the population of the study had to meet the population criteria and clinical definition of stroke referred to in Section 3.1.2 of this report.

Types of intervention: To be eligible for inclusion, the intervention and control / comparator in the study had to fall within one of the four study comparisons defined in Section 3.1.2 of this report.

4.1.3 Data extraction strategy

Two reviewers (BB and LM) conducted an independent screening of all citation titles and abstracts retrieved for the economic component (Appendix 4B). The reviewers read the citation abstracts (or titles only, if the abstract was not available) to make inclusion decisions for subsequent full-text review. An economic study was included for comprehensive review if it met each of the three eligibility criteria. Where disagreement or uncertainty occurred, the paper was retained for the next step in the process. Disagreement between the reviewers was resolved through consensus.

One reviewer (BB) extracted and documented the relevant information from each included study using a data extraction form (Appendix 5B). The form was developed by one reviewer (BB) based on the design of forms and checklists from several sources.^{24,94-98} The form includes study description, selection criteria, methods, results and conclusions, as well as reviewer comments (Appendix 5B). Primary economic studies were classified as trial-based or model-based.

4.1.4 Quality assessment strategy

No attempt was made to formally score the quality of the included studies since there are no validated instruments for scoring the overall quality of economic evaluations. However, significant study limitations or weaknesses were noted during the data extraction process.

4.1.5 Data analysis methods

Data synthesis involves collating and summarizing the information that is extracted from studies included in a review.²⁴ For our report, the main characteristics and results (i.e. the relative costs and benefits of alternatives) of these studies have been summarized in tables.

The results of the studies were not pooled quantitatively, given the considerable variation in study characteristics (i.e. intervention definitions, patient populations, study design, methods of analysis, and sources of data), as shown in Appendices 11 to 13. However, for each of the interventions, the “trend” in health outcomes, the mean costs per patient and the percentage change in costs (relative to the comparator) are presented in Table 8, as well as information on statistically significant differences, where such information was reported. It is noted that reference to cost “savings” indicates the value of resources freed, for instance the release of hospital beds, and may not translate into actual financial “savings” as such.

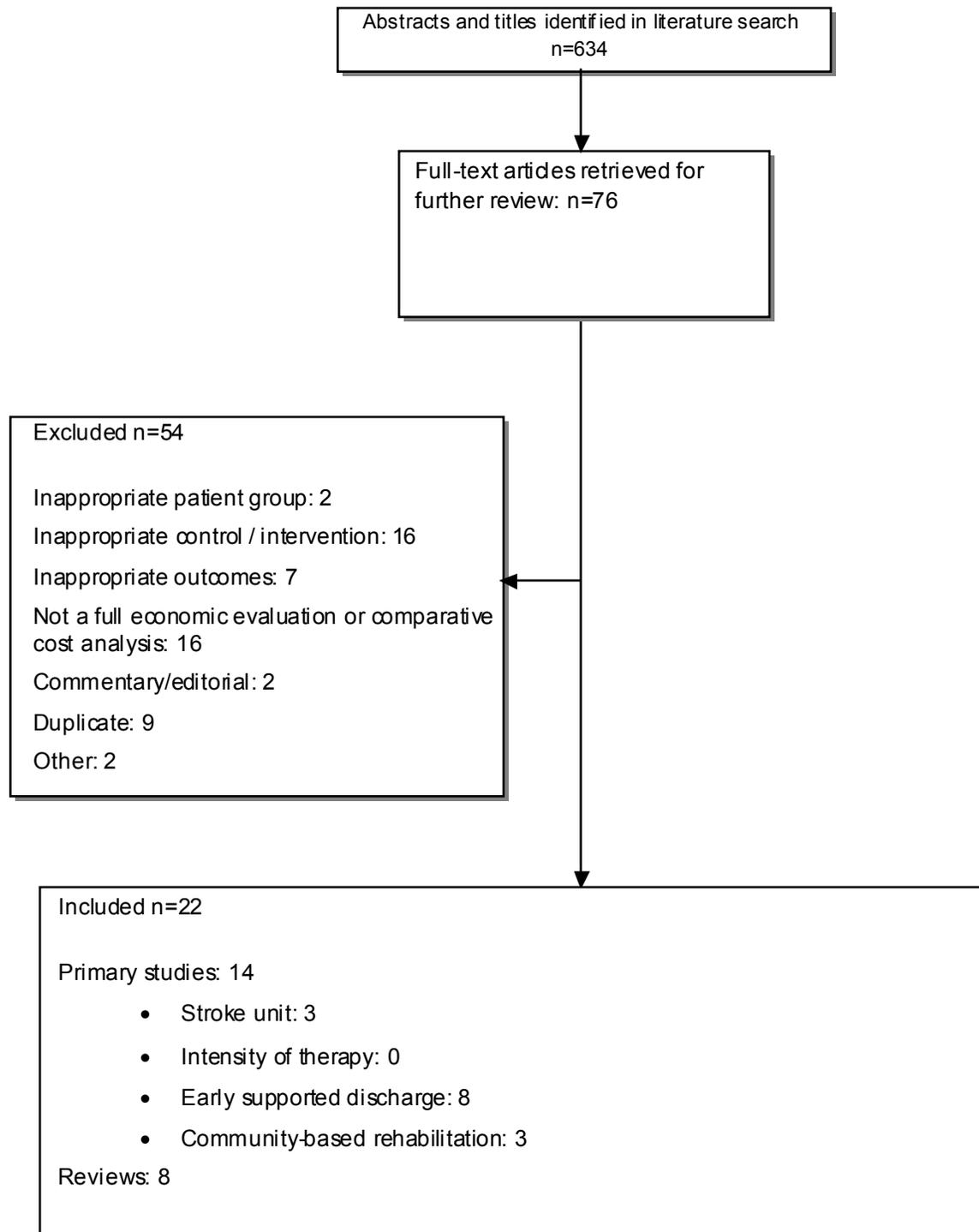
Formulating conclusions about the trend in total cost of each of the four interventions relative to alternatives was based on judgement about the quality of the economic evidence, taking into account: the number of studies, the consistency of cost trends across studies (including statistical significance and sensitivity analysis), the relevance of the studies to the Canadian health care system and the methodological quality and limitations of the studies (studies judged to be of higher quality were given more weight). The economic evidence for each intervention was classified as ‘good’, ‘moderate’, ‘some’ and ‘insufficient’ (i.e. the question can not be answered).

4.2 Results

4.2.1 Quantity and quality of research available

Table 7 below summarizes the flow of selection of economic studies. A total of 634 citation titles and abstracts were retrieved for the economic component. This number represents the sum total of unique records identified from all databases and other sources searched, including database updates and alerts. From this quantity, 76 full-text articles were identified for retrieval and further review. Of these, 14 primary studies met all three eligibility criteria for inclusion. In addition, eight reviews were identified which met the inclusion criteria.^{12,13,15,99-103} Table 7 also identifies the reasons for exclusion of the 54 full-text articles.

Table 7: Selection of articles for inclusion in economic review



4.2.2 Assessment of economic evaluations

a) *Study characteristics*

The characteristics of the 14 primary economic studies are summarized below, based on information which was extracted from the studies (Appendices 11 to 13):

1. Types of rehabilitation intervention: three studies¹⁰⁴⁻¹⁰⁶ evaluated SU care, eight studies^{58,64,107-112} evaluated ESD services, and three studies^{81,113,114} evaluated community-based rehabilitation (specifically at a day hospital or the patient's own home). One of the studies on community-based rehabilitation evaluated physiotherapy.¹¹³
2. Comparator: in five studies¹⁰⁴⁻¹⁰⁸ the comparator was in-patient hospital rehabilitation (on neurology, internal medicine or general medicine wards), including all three of the studies that evaluated SUs. Rehabilitation in a day hospital (or as an 'outpatient') was the comparator in three studies.^{81,113,114} There was a mixture of comparators in six studies^{58,64,109-112} (i.e. usual care defined as rehabilitation in a hospital as an inpatient, at a geriatric day hospital, at home, or as an outpatient). In at least two studies^{58,112} a sizeable number of the 'usual care' patients received no further rehabilitation after randomization.
3. Population: in at least four studies^{64,107,111,112} the population appeared to consist mostly of patients with mild to moderate stroke severity/disability. At least three studies^{105,108,114} appeared to have a full range of stroke severity/disability levels in the trial population, based on the stratified results. Of the studies based on specific trial data (excluding the Major¹⁰⁴ and Anderson (2002)¹¹¹ studies), four^{105,106,109,114} had 250 to 350 participants, and seven^{58,64,81,108,110,112,113} had sample sizes near 100. One study¹⁰⁷ had a very small number of participants in the intervention arm (n=15). The data on clinical outcomes in two studies were based on a meta-analysis of published trials: the Anderson (2002) study¹¹¹ (n=1277) and the Major study¹⁰⁴ (n=2770).
4. Type of economic studies: all of the studies were classified (by BB) as cost-consequences analyses or comparative cost analyses. Some of the studies,^{104,106} although labelled by their authors as another type of economic evaluation (e.g. cost-effectiveness analysis), were classified (by BB) as cost-consequences analysis because the results for costs and health outcomes were not combined into a ratio using a single measure of health outcome.⁹⁷ In addition, a number of studies^{105,110,112,113} were labelled by their authors as cost-minimization analysis on the basis of non-significant differences in health outcomes; this label was considered inappropriate because equivalence (vs. non-significant difference) of health outcomes in the alternatives was not demonstrated. This topic is discussed more generally in Briggs et al.¹¹⁵
5. Study design: 11 studies can be classified as trial-based (i.e. a specific trial, or trials, are the source of data on health outcomes and resource use), whereas three studies^{104,106,111} are model-based (i.e. using data from a number of sources in a model). All trial-based studies were randomized except for the Holmqvist study.¹⁰⁷

6. Location: 10 studies are set in Europe (six^{81,104,108,109,113,114} in the UK, three^{64,105,107} in Sweden and one¹⁰⁶ in Germany), two studies^{110,111} in Australia, one study⁵⁸ in Hong Kong and one study¹¹² in Canada (Montreal).
7. Perspective: a health service payer perspective was taken in all studies, with some studies^{81,112,114} also including the costs of social services and/or institutional care, to varying degrees. Five studies^{64,105,107,110,113} also included broader elements of a societal perspective, with some consideration of the indirect costs to informal caregivers and/or direct costs to patient.
8. Time horizon: generally short, with a period of one year or less in all but one study (six studies were one year, five studies^{58,81,108,110,114} were six months, one study¹¹² was three months and one study¹¹³ was only eight weeks in duration). The one mixed trial/model-based study¹⁰⁶ had a lifetime time horizon (beginning from age 45). As a group, the studies of SU care had the longest time horizon.
9. Types of health outcomes: presented mostly in terms of mortality and degree of disability (mostly using BI or another generic ADL index). Other health outcomes in the studies include discharge to long-term care or own home, patient's subjective health status, stress on the informal caregiver, and process measures (e.g. patient satisfaction with care).
10. Types of costs: some studies were more comprehensive than others through inclusion of certain types of direct costs, although this seems to be due in part to the nature of the interventions evaluated. Studies of home rehabilitation tended to include the costs of social/community services. Some studies valued the time that therapists spent traveling^{107,109,114} and the cost of program overhead.^{107-109,114} Some studies were more explicit about reporting the costs of hospital readmissions^{58,108,110,112,114} or ambulance transport.^{81,114} In at least one study there appears to be some uncertainty by the authors about the extent that stay in institutions is accounted for.¹⁰⁴ Some studies^{64,105,107,110,113} included the indirect costs of time spent by informal caregivers, for instance, in helping a spouse and in related travel. No studies included the indirect cost of lost earnings / productivity, by either patients or their informal caregivers, with some studies indicating that the work-related earnings of these groups were relatively modest as most were retired.
11. Year of data for costs and resources use: in six studies^{58,105,107,108,113,114} the data predates 1997 (two of these studies^{113,114} use data for years prior to 1991), with the remaining eight studies based on data from years 1997 or later. Seven of the studies^{64,81,105,106,110-112} were published in year 2000 or later, with the remaining seven studies published between 1993 and 1999.
12. Sensitivity analysis: nine studies^{81,104,108-114} conducted sensitivity analyses. Some studies^{105,108,113,114} stratified results according the degree of disability (descriptive level, ADL or BI score, or ward of discharge).

In general, the economic evidence was considered to be of moderate (versus high) quality, as indicated by a number of limitations in the economic evidence:

- the interventions and their comparators were heterogeneous entities (e.g. the mixture of various comparators, likely differences in the components of interventions classified under the same category and the lack a clear definition of the alternatives in the papers);
- no primary studies relate to comparison #2 (i.e. impact of different intensities of rehabilitation therapies);
- the scope of cost data included in studies varied, and less than half of the studies included the indirect costs of patients and their caregivers;
- all but one of the studies¹⁰⁶ have short time horizons (one year or less);
- small sample size (i.e. lacking the power to detect statistically significant differences in costs) was a problem with many of the studies;
- many of the studies included patients with predominantly mild to moderate stroke severity / disability, with more severe cases underrepresented; and
- the data in six studies were old, predating 1997.

Also, it is important to note that only one study was set in Canada, which should be taken into account when considering the relevance of these studies to the Canadian health system.

b) Economic results

The results of the primary economic studies are shown in Appendices 11 to 13, and summarized in Table 8 which appears at the end of this section.

c) SU care versus care on a GMW or geriatric ward

Three studies evaluated the costs of SU care.¹⁰⁴⁻¹⁰⁶ In all three studies the comparator was conventional rehabilitation on another type of hospital ward.

The results of the three studies indicated that SU care had slightly lower costs than rehabilitation on other hospital wards, with small savings reported in the studies by Claesson et al. (2000) [11%, not significant (NS)] and Hagenmeyer et al. (2002) (6%, statistical significance not reported). The studies indicated that:

- a) patients with a first stroke between ages 65 to 75 were likely to benefit most from SU rehabilitation (Hagenmeyer);
- b) the lower SU costs for nursing care were partly offset by higher outpatient costs (Claesson and Hagenmeyer); and
- c) informal care costs were lower for those in SU care (US\$2424 versus US\$3708, NS), amounting to 10% of the total costs of SU care (Claesson).^e

^e Informal care costs relate to SU care in terms of when patients leave hospital they are cared for at home- those with worse outcomes may have more informal care

There is therefore some evidence that the cost of SU rehabilitation is comparable to that in other hospital wards. There were some strengths in these studies:

- The lifetime analysis of the Hagenmeyer study considered important long-term consequences (e.g. the higher incidence, and costs, of recurrent stroke due to increased survival of patients cared in SUs).
- Outcomes were based on data from relatively larger trials: the Claesson (n=249) and the Hagenmeyer (n=316) studies were based on individual trials, and the Major study (n=2770) was based on data from a meta-analysis of published trials.
- All studies considered the costs of community/outpatient care in the analysis.
- There is a consistent trend toward marginally lower costs across different countries (Sweden, Germany and the UK) and for different comparators (regular, general, medical, internal medicine or neurological wards).

On the other hand, it is noted that only limited sensitivity analyses were undertaken and statistical significance was not tested in the studies. The Claesson study (n=249) was underpowered, given the large variability in costs (the author stated that 400 participants were needed to detect 25% difference in costs after one year).

d) ESD services versus usual care

Eight studies evaluated ESD services.^{58,64,107-112} The studies were set in a wide range of countries: Canada (1), Australia (2), Hong Kong (1), Sweden (2) and the UK (2).

The comparator in two studies^{107,108} was hospital rehabilitation; the other six studies compared ESD services to “conventional” rehabilitation, which was generally a mixture of interventions variously defined in each of the trials. The Hui et al. (1995) study⁵⁸ compared rehabilitation in a day hospital with standard outpatient follow-up after discharge (the latter was described as “no comprehensive elderly care” in one paper¹¹⁶).

All studies were based on data from single trials except for the Anderson et al. (2002) study, which used data from a meta-analysis of published trials.¹¹¹ All studies had a health service perspective and some studies also collected data on informal carer burden or costs.^{64,107,110,112} The duration of home rehabilitation varied from four weeks in some studies^{111,112} to up to four months after discharge.⁶⁴

In terms of methodological quality, three studies were considered high quality: the Beech (1999) and Anderson (2002) studies had a large number of participants who were followed for one year and used a good costing methodology.^{109,111} The Teng et al. (2003) study was set in Canada and used a good costing methodology, though it had smaller numbers (n=114), was of shorter duration (three months) and included mostly patients with mild disability.¹¹² Three studies were of medium quality, as they were smaller trials (n=83 to 92) with duration of six months to one year.^{64,108,110}

These six higher-quality studies, using a variety of perspectives, showed a trend toward modest cost savings, ranging from 4% to 30%. The difference in costs was reported to be statistically significant only in the Canadian study, which also showed the greatest cost savings in relative

terms (30%), equating to savings of C\$3281 over the three-month period of the trial. This study also reported that total costs for ESD service group did not vary (NS) by functional level.¹¹²

The two remaining studies, Holmqvist¹⁰⁷ and Hui,⁵⁸ showed higher costs for ESD services. However, these studies were considered by BB to be low quality and were given little weight because: (i) the data in both studies were old (1990/92 and 1992/93, respectively), (ii) the Holmqvist study was a non-randomized pilot study with only 15 patients in the ESD service arm, and (iii) the Hui study was set in Hong Kong, where clinical practice and cost structures could differ substantially from Canada.

Four of the higher-quality studies found that lower ESD costs were robust in sensitivity analysis.¹⁰⁸⁻¹¹¹ Two studies reported conflicting evidence on cost differences for different levels of patient functioning: the Anderson (2000) study showed greater cost savings [significant difference (SD)] for less disabled patients in the ESD arm,¹¹⁰ whereas McNamee et al. (1998) showed costs were greater (SD) in the ESD group (vs. the comparator) for better functioning patients (BI range, 13 to 20).¹⁰⁸ In terms of health outcomes, no significant differences were reported in the studies, except for improved ADL (SD) for the ESD group in the von Koch et al. (2001) study.⁶⁴

Overall, the six higher-quality studies (including the Canadian study) provide moderate evidence that the costs of ESD services are modestly lower than for 'usual care'. However, there are several qualifications:

1. Service variation: it is difficult to generalize the findings compared to any one alternative, given the mixture of comparators in the studies. For example, in the Teng study the comparator was a mixture of interventions (inpatient and outpatient rehabilitation, private care and home care), with some patients not receiving any rehabilitation services.¹¹² In addition, the duration of home rehabilitation varied in the studies (from four weeks up to four months), so the intensity of rehabilitation may be a confounding factor.¹⁰³
2. Patient characteristics: a number of the trials on which the studies were based included patients with mostly mild to moderate disability levels.^{64,111,112} Therefore, the results may be relevant only to this patient group and the impact of ESD services on more disabled patients needs further study.
3. Informal care: the impact of ESD services on shifting costs (and burden) from the health service to informal caregivers is not clear. Informal caregiving was explicitly costed in only two studies and the findings of these studies conflict: the Anderson (2000) study¹¹⁰ found these costs to be higher for ESD services (Australian\$1135 vs Australian\$695, statistical significance not reported), whereas the von Koch study⁶⁴ found the costs to be lower (NS) for patients receiving ESD services. The Teng study reported that informal caregivers of patients receiving ESD services were less burdened (NS), though this was not costed and the patients generally had mild disabilities. A study by Holmqvist (2000)⁶⁶ reported no significant difference in time spent by family caregivers.

e) *Rehabilitation in the community versus usual care*

Two studies, by Gladman et al. (1994)¹¹⁴ and Roderick et al. (2001),⁸¹ compared the costs of community rehabilitation with rehabilitation in a day hospital (outpatient rehabilitation as well in Gladman). Both studies were set in the UK and included health and community/social services. Roderick reported that the study patients were older and more disabled than those in the Gladman study. Neither study reported a statically significant difference in health outcomes.

Both the Gladman (27%, statistical significance not reported) and Roderick (26%, NS), studies reported the cost of community rehabilitation to be higher than that of the comparator. Roderick reported that the shorter LOHS and lower costs to the health service for community rehabilitation were offset by higher costs to social service.

However, these findings should be viewed cautiously due to limitations of these studies:

- the data from the studies was relatively old (1988-90 in Gladman and 1996/97 in Roderick) and the time horizon was short (six months);
- the comparator was restricted (i.e. to day hospital);
- the cost to informal caregivers was not included;
- one review¹² has indicated that the Gladman study may have been biased against community rehabilitation and those patients in the comparator arm had a better functional status at baseline;
- in neither study were the results statistically significant (Roderick et al. themselves reported the trial was underpowered, especially after considering loss to follow-up); and
- although the findings of the Roderick study were robust in the sensitivity analysis, those of the Gladman study were very dependent on patient characteristics (ward of discharge) and assumptions about the cost of the ambulance service.

A third study by Young and Forster (1993)¹¹³ focused exclusively on physiotherapy in the UK, comparing physiotherapy at home with that in a day hospital. The Young study indicated that home physiotherapy led to modest improvements in some outcomes, as well as lower direct costs (38% lower, median, SD). There was no significant differences in lost carer leisure time, carer stress and community support. Sensitivity analysis showed the cost results were robust. Young concluded that home-based physiotherapy is more cost-effective than physiotherapy at a day hospital. However, the results of this study were discounted, given that the focus of the study was physiotherapy, and the trial was dated (years 1988/89), small (n=95) and of short duration (eight weeks).

In conclusion, there is insufficient evidence regarding the relative cost of community rehabilitation (versus usual care), given the limitations of these two studies. Both Gladman and Roderick suggest that a range of service options be provided for stroke patients discharged from hospital.^{81,114}

Table 8: Primary economic studies

Author; Year (country)	Comparator	Study Design		Cost Per Patient (intervention vs comparator)	Health Outcomes	Comments
		Study type • no. of patient • follow-up period	Perspective (range of costs)	Mean values per patient • % change • statistical test		
Stroke unit (SU) care						
Major, 1998 (UK) ¹⁰⁴	Hospital rehab (GMW)	Model with data from meta-analysis of RCTs • n = 2770 • 1 year	Hospital & some care in institutions	£256 saved (stat not reported)	Better survival (NS), return home & independence (SD)	Costs modestly higher in worst-case scenario; LOS data is heterogeneous; main cost are for nursing
Claesson, 2000 (Sweden) ¹⁰⁵	Conventional rehab (GMW)	RCT • n = 249 • 1 year	Health service & informal care	US\$25,400 vs US\$ 28,500 • 11% less (NS) Informal caregiver costs: US\$2424 vs US\$3708 (NS)	NS in outcomes	Outpt & informal caregiver are 30% of total costs (important to include of all costs)
Hagenmayer, 2002 (Germany) ¹⁰⁶	Hospital rehab (various wards)	Model & trial • n = 316 • Lifetime	Health service	Euros 29,000 vs Euros 30,800 • 6% less (stat not reported)	Better survival but increased risk of recurrent stroke	Based on lifetime model
Community rehabilitation / home rehabilitation (HR)						
Young, 1993 (UK) ¹¹³	Day hospital physiotherapy	RCT • n = 95 • 8 weeks	Health & community services (also informal caregiver time)	£385 vs £620 (median) • 38% less (SD) • NS in carer leisure time	Home rehab showed modest advantage (NS)	Physiotherapy only evaluated; short follow-up; home rehab outcomes underestimated
Gladman, 1994 (UK) ¹¹⁴	Day hospital or outpatient rehab	RCT • n = 327 • 6 months	Health & social services	£408 vs £320 • 27% higher (stat not reported)	NS in outcomes	*Results differ by ward of discharge; cost difference is very sensitive to cost of ambulance
Roderick, 2001 (UK) ⁸¹	Geriatric day hospital rehab	RCT • n = 140 • 6 months	Health & social services	£3070 vs £2428 • 26% higher (NS)	NS in outcomes	Home rehab had lower health service costs, offset by higher social service costs

Abbreviations: NS = no significant difference; SD = significant difference; NT = not tested; LOS = length of stay (including stay in hospital and/or institutions)

Author; Year (country)	Comparator	Study Design		Cost Per Patient (intervention vs comparator)	Health Outcomes	Comments
		Study type <ul style="list-style-type: none"> no. of patient follow-up period 	Perspective (range of costs)	Mean values per patient <ul style="list-style-type: none"> % change statistical test 		
Early supported discharge (ESD) services						
Hui; 1995 (Hong Kong) ⁵⁸	Conventional management (not comprehensive)	RCT <ul style="list-style-type: none"> n = 120 6 months 	Health service	HK\$58,000 vs HK\$52,000 <ul style="list-style-type: none"> 12% higher (NS) 	Same number of deaths; NS in BI change	Intervention is rehab in day hospital; doubtful relevance to Canada
Holmqvist; 1996 (Sweden) ¹⁰⁷	Hospital rehab	Non-RCT <ul style="list-style-type: none"> n = 78 (15 in ESD) 1 year 	Health service (informal caregiver costs separately)	SEK 88,500 vs SEK 86,800 <ul style="list-style-type: none"> 2% higher (stat not reported) 	Not reported	High ESD readmission costs due to one patient; informal caregiver spent modest amount of time (18% of total cost)
McNamee; 1998 (UK) ¹⁰⁸	Conventional hospital rehab	RCT <ul style="list-style-type: none"> n = 92 6 months 	Health & social service	£7155 vs £7480 <ul style="list-style-type: none"> 4% less (NS) £3600 vs £1200 (SD) for pts with BI 13-20 	NS in outcomes	Findings robust in sensitivity analysis; results differ by BI score; NS lower costs for BI < 13
Beech; 1999 (UK) ¹⁰⁹	Conventional rehab (mix)	RCT <ul style="list-style-type: none"> n = 331 1 year 	Health & social service	£6800 vs £7400 <ul style="list-style-type: none"> 8% less (stat not reported) 	NS in outcomes	Findings robust in sensitivity analysis; LOHS 12 vs 18 days (SD)
Anderson; 2000 (Australia) ¹¹⁰	Conventional care	RCT <ul style="list-style-type: none"> n = 86 6 months 	Societal (health service, pt & informal caregiver)	A\$8040 vs A\$10,054 <ul style="list-style-type: none"> 20% less (NS) Informal caregiver time: A\$1135 vs A\$695 	No adverse impact but may worsen mental health of informal caregiver	Findings robust in sensitivity analysis; may worsen informal caregiver mental health; cost savings greater (SD) for higher BI
von Koch; 2001 (Sweden) ⁶⁴	Conventional rehab (mix)	RCT <ul style="list-style-type: none"> n = 83 1 year 	Health service (resource use for community services, pts & informal caregiver)	SEK 71,959 vs SEK 91,453 <ul style="list-style-type: none"> 21% less (stat not reported) Inpt hospital days 18 vs 33 (SD); NS for other resources 	Better ADL (SD); lower death or dependence (NS)	Including community & informal care costs may show ESD even cheaper, as fewer home-help visits
Anderson; 2002 (Australia) ¹¹¹	Conventional rehab (mix)	Model with data from meta-analysis of RCTs <ul style="list-style-type: none"> n = 1277 1 year 	Health care system	US\$9941 vs US\$11,390 <ul style="list-style-type: none"> 13% less (stat not reported) 	NS in outcomes	Costs findings robust in sensitivities; LOHS lower (SD) for ESD in all 6 studies
Teng; 2003 (Canada) ¹¹²	Usual care (mix)	RCT <ul style="list-style-type: none"> n = 114 3 months 	Health service (also informal caregiver burden)	C\$7784 vs C\$11,065 <ul style="list-style-type: none"> 30% less (SD) 	Less burden for informal caregiver (NS)	Pts have milder functional limitations; ESD costs did not vary by functional level; readmissions an important factor in cost difference

5 DISCUSSION

5.1 Study Limitations

Limitations of the available data can be categorized under two specific areas: study methodology and those inherent to the available literature.

Study methodology:

- the study design was restricted to RCTs of stroke rehabilitation under one of the four study comparisons. The RCT requirement may have overlooked data applicable for this assessment but including observational studies could move the trend of intervention towards more positive outcomes. Based on previous systematic reviews which include observational studies, this may be particularly true with the comparison on the impact of intensities [e.g. the review by Kwakkel et al. (1997)⁷]; and
- a follow-up period of six months or longer post-randomization was used as an inclusion criterion for trials. Sensitivity analysis was performed to test the impact of follow-up on mortality rates between the intervention and control groups. Sensitivity analysis included trials reporting on death which were excluded from the primary analysis solely based on this criterion of six months or longer of follow-up. Variations in follow-up had no significant impact on mortality rates between the intervention and control groups.

Literature:

Determining the efficacy of stroke rehabilitation presents many challenges:

- there are problems inherent to the condition itself such as spontaneous neurological recovery and daily fluctuation in individual function;
- the interventions studied were often not well defined, with variation in the interventions delivered;
- the BI score can be subject to biases in reporting (the BI, the most commonly used outcome measure for functional status, is limited by its lack of cognitive and language assessments although, it is well-validated, reliable and simple to perform);
- because stroke patients, if they are not involved in a formal stroke rehabilitation program, still require access to rehabilitation therapies, it is impractical (for ethical and practical reasons) to have a no-treatment control group;
- some of the stroke rehabilitation trials included in this review did not consider stroke severity;
- many studies were small; and
- the scarcity of Canadian data, especially for the economic evaluation, limits the relevance of these findings to the Canadian health system.

These limitations point in general to the need for longer-term studies which include and measure all consequences and costs, including the costs associated with informal caregiving and hospital readmissions. Furthermore, there is a need for better reporting in published studies including a fuller and clearer description of the elements of stroke rehabilitation services.

5.2 Assessment of Clinical Effectiveness

5.2.1 SU care versus care on a GMW or geriatric ward

This comparison addressed the question of whether patients receiving organized SU care are more likely to survive, regain independence and return home, than those receiving conventional care in GMWs. SU care comprised of an interdisciplinary team of neurologists, specialized nurses, physiotherapists, occupational therapists and speech therapists with the care team involved in planning treatment and support after discharge. GMW care consisted of traditional medical treatment without specialized attention within the framework of a team approach: patients were evaluated by a neurologist and were offered physiotherapy and/or occupational therapy.

Meta-analysis of six RCTs (1,709 patients in total with an average age of 76 years) demonstrated that patients who had suffered a stroke of moderate severity who receive care in a SU (in comparison to a GMW) are more likely to be alive and living at home after ten years of follow-up after the stroke (median follow-up of 15 months). There is evidence that patients who receive SU care are more likely to undergo recovery, as assessed by the BI across three trials, compared to patients in the control group. There was no decrease in LOHS with SU care.

It has been speculated that a SU provides superior care compared to a GMW due to specialization of the interdisciplinary team, allowing for more rapid acquisition of knowledge and experience in the treatment of stroke patients when highly motivated care providers treat stroke patients primarily.^{4,117} According to one group, SUs also tend to provide greater intensity of stroke care, are more aware of the complications associated with stroke (including secondary stroke prevention) and provide improved discharge planning.⁴

Our review confirms the principle finding of the Stroke Unit Trialists' Collaboration within the Cochrane review that SU care significantly reduces the odds of death compared to GMW care.⁵ Our review provides a number of additional findings: (1) the observed odds reduction in death is more statistically robust (40% vs. 14%); and (2) the scheduled length of follow-up of trials included in our review is longer (median follow-up of 15 months, range 6 months-10 years; versus median follow-up of 12 months, range 6 weeks-12 months). Sensitivity analyses indicate that the observed mortality benefits were preserved with up to ten years of follow-up.

Unlike our review, the Cochrane review did not use a formal scoring system to record methodological quality of included studies but did take into account the method of allocation concealment, completeness of follow-up, presence of an intention-to-treat analysis, and the presence of a "blinded" assessment of outcome.⁵ Based on these measures, the trials included in both reviews could be judged to be of moderate to good quality. Sensitivity analyses for our review revealed little difference in the outcome of death when trials were stratified by quality.

Our review also supports the previous findings of the Cochrane review that patients receiving SU care are more likely to regain independence and return home than those receiving GMW care. A one-point rise in the BI score was observed in SU patients compared to GMW patients; this could be clinically significant if it signifies a change from being dependent to partially

independent or from partially independent to independent with respect to one of 10 very important items. SU care was not associated with a decrease in LOHS both in our review and the Cochrane review. The analysis of LOHS in the current review is complicated by the small number of trials (n=3) reporting on this outcome and the significant heterogeneity between trials.

We observed a trend towards reduction in the odds of institutional care in SU patients at follow-up. The analysis within the Cochrane review reported a statistical reduction in the combined outcome of death or institutionalization (institutional care was not assessed as an independent outcome).⁵ There also was some observed heterogeneity between the trials in the Cochrane review that was largely attributable to a short and variable period of follow-up. There is currently little evidence that SU care improves HRQoL, although only two trials have assessed this outcome using validated measures. No assessment of HRQoL has been undertaken on this comparison in the two reviews previously done in this area.^{5,6}

5.2.2 Impact of different intensities of rehabilitation therapies

This comparison addressed the question of whether patients who receive therapy for longer periods of time or at a higher level of intensity realize greater benefits when compared to patients who receive conventional care. Patients in the intervention group, on average, received 25 hours of additional therapy provided over 10 weeks. Three RCTs, judged to be of good methodological quality, reported in five articles, were included: 642 patients in total (average age 68 years). Data pooling was considered inappropriate for this comparison for all outcomes given the reporting characteristics of these trials. Death was an outcome measure in only one trial and the BI in all three trials. No significant differences were observed based on intensity level of rehabilitation provided for either death or dependency. None of these trials used the RS to assess functional status and no data were reported for outcomes related to patients discharged to home, institutional care, or in LOHS. No systematic improvement was observed in HRQoL with increased intensity of therapy in the one trial reporting this outcome.

The three previous reviews that we identified reported that more therapy might be beneficial at up to one-year of follow-up.^{7,8,10} As noted earlier, however, the findings of these reviews suffered from limitations arising from the trials including the heterogeneity of the interventions (e.g. mixture of physiotherapy and occupational therapy), use of various outcome measures and the low statistical power of trials.⁹ Unlike trials from the previous reviews (which were of poor methodological quality), the three trials included in our review were assessed to be of moderate to good quality, thus making it possible that the results for this comparison may be dependent on trial quality.

5.2.3 ESD services versus usual care

This comparison addressed the question of whether patients receiving ESD services realize greater benefits in relation to patients receiving conventional care. ESD services in all trials included both physiotherapists and occupational therapists; these services were provided for up to five months. Five RCTs, reported in nine articles, were included: 940 patients in total. The five trials varied in terms of methodological quality and recruited patients with an average age of 73 years.

No reduction in the odds of death or institutionalized care for ESD patients compared to controls was recorded at six months of follow-up, although there was heterogeneity among the trials. This heterogeneity, at least in part, may relate to the degree of organization of ESD services within the individual trials and raises the possibility that subtle aspects of service quality, regardless of whether that service is delivered in a hospital or community setting, may have a measurable impact on patient outcomes.

No significant differences were observed in the mean BI score between groups within three trials; however, a higher percentage of intervention patients were considered independent with respect to ADL (BI score ≥ 19) compared to patients randomized to the control group across two trials. One trial reported functional status using the RS: the proportion of patients judged independent (RS ≤ 2 score) was higher in the ESD group compared to controls.

Only one trial reported on the proportion of patients at home at follow-up; no significant differences were observed between the groups at six months.

Our review supports the previous findings of the review undertaken by the New Zealand HTA agency¹² and the Cochrane review.¹¹ All three reviews found no significant difference in outcomes for death, institutionalization and dependency between those discharged early compared with those in the “conventional care” groups. Variations in follow-up did not significantly impact these results.

ESD trials suggest that stroke patients discharged early from an acute hospital unit can be successfully rehabilitated in the community by an interdisciplinary stroke rehabilitation team. These patients are able to attain similar functional outcomes when compared to patients received in-patient rehabilitation. The RCTs included for ESD services had tight inclusion criteria, admitting only those patients who had strokes of milder severity;^{59,65} in other words, these were stroke patients where the nursing care could reasonably be provided by the family at home. There are difficulties with these inclusion criteria. The ability to generalize the results to more severely affected patients who make up the bulk of stroke patients admitted to rehabilitation units is not known.

In all three reviews, those randomized to the ESD group have significantly shorter LOHS. The range of LOHS from randomization in this review was 2 to 18 days in the ESD group and 12 to 33 days in the control group. Overall, this represents over a 50% reduction in LOHS in the ESD group. Our review observed no significant differences in HRQoL in ESD patients compared to patients in the control group at 12 months of follow-up. Neither of the previous reviews^{11,12} formally evaluated the impact of ESD services on the HRQoL of the study population.

5.2.4 Rehabilitation in the community versus usual care

This comparison addressed the question of whether community rehabilitation after stroke is better than the more conventional alternatives. Eight RCTs, reported in ten articles, were included: 1,182 patients in total. Overall, the eight trials were judged to be of high methodological quality. They recruited patients with an average age of 74 years. No significant inter-group differences were observed for death or dependency as assessed by the BI at up to one year of follow-up. There was no indication that home-based services resulted in decreased institutional care, although there was heterogeneity among the trials. No systematic improvement was observed in HRQoL in intervention patients compared to controls across three trials reporting this outcome one year post-stroke.

The results of our review are in keeping with those of previous reviews¹²⁻¹⁶ which found no significant differences in both the primary and secondary outcomes of home rehabilitation versus hospital-based alternatives. All eight trials identified in our review were not identified in the previous reviews: findings from six trials (75%) were published in the year 2000 or later. As evidenced by the pooled analysis for death, the trials identified for this review are characterized by considerable heterogeneity, which makes it difficult to draw specific conclusions. Another methodological concern, which must be acknowledged, is that seven trials (88%) identified for this review, are from the UK, albeit from different centres.

5.3 Assessment of Economic Evaluations

Economic studies were found for three of the four interventions under review; no economic studies were found concerning the impact of different intensities of rehabilitation therapies. Taking into account the characteristics of the studies and the methodologies they used, most studies were considered to be of moderate quality.

The three studies on SU rehabilitation provide some evidence that the cost of SU rehabilitation is comparable to rehabilitation in a ‘conventional’ hospital ward. However, Warlow makes two points in this regard: (i) smaller hospitals may have too few acute stroke patients to make stroke-specific services viable; and (ii) the most successful SU model may be a comprehensive one which provides acute care and at least a few weeks of rehabilitation (versus having separate units for acute care and rehabilitation).¹⁰²

Eight studies evaluated ESD services. The six higher-quality studies (excluding the Holmqvist and Hui studies) reported a trend toward modestly lower costs for ESD services compared to usual care. This finding was statistically significant in only the Canadian study, which also demonstrated the greatest cost savings (30%) of all the ESD studies, amounting to about C\$3300 over the three months of the study. As a whole, there is fair economic evidence that the cost of ESD services is modestly lower than for usual care. However, this conclusion is qualified by caveats concerning: (a) the heterogeneous nature of the “packages” of care, (b) the limited applicability of the study results to more disabled patients and (c) the uncertain impact of ESD services on informal caregivers.

The two main studies of rehabilitation in the community showed the costs were higher (NS) than at a day hospital, but when the limitations of these studies are considered, no firm conclusion can be drawn at this point. A third study (Young) was given little weight when assessing the economic evidence on community rehabilitation as it evaluated physiotherapy only and was small, dated and of short duration.¹¹³

Some general problems make comparisons of costs difficult:

- Design of studies: including the difficulty in adequately blinding trials, the short duration of studies (all but one study were one year or less) and inadequate study population numbers to detect significant differences between alternatives with regard to costs. Longer-term studies (> one year) of ESD services and community rehabilitation that include the cost to informal caregivers are needed; these costs may increase relative to hospital costs after one year and excluding them may bias the results from a societal perspective.
- Study heterogeneity: including differences in terms of the scope of costs included in the studies (most did not include the costs of informal care), the variety of comparator interventions evaluated (in many studies the comparator was a mixture of different models of care), as well as uncertainty about the similarity of the elements of rehabilitation ‘packages’ that were classified under the same intervention category.
- External validity (relevance) of studies: the data in some of the studies was old (in six studies the data pre-dates 1997), applies to only a limited portion of the stroke population (study populations had mostly moderate to mild levels of stroke severity or disability) or is from a country where clinical practice, the organization of care and relative costs have questionable relevance to Canada¹¹⁸ (only one study was set in Canada). Even in the case of the Canadian (Montreal) study, it is questionable how relevant certain aspects of the trial (e.g. comparator) would be for other parts of Canada.

Addendum:

Following external review of this report, one of the regularly scheduled literature updates identified a prospective, non-randomized cohort study by Andersson et al. (2002),¹¹⁹ which was set in Sweden during the period 1996 to 1998. This study (n=123) compared the costs of home-based (i.e. community) and hospital-based rehabilitation after stroke. The study found that mean total costs (including acute hospital care, rehabilitation, home-help services and nursing home care) did not differ significantly between the two groups at 12 months of follow-up (SEK 194,700 for hospital-based patients versus SEK 190,500 for home-based patients, a difference of 2%; based on current exchange rates, this is equivalent to C\$34,000 versus C\$33,300, respectively). However, the home-based group incurred much higher costs for home-help services, offset by much lower costs for rehabilitation. It is noted that the patients in the home-based group were significantly more dependent at baseline. The results of this study do not alter our overall findings regarding community-based rehabilitation: no firm conclusion can be drawn at this point regarding the cost of community rehabilitation versus usual care.

6 CONCLUSIONS

Stroke patients who receive organized inpatient care in a SU are more likely to be alive, independent and living at home after a stroke. There was a trend to reduced institutionalization. There is some evidence that the total cost of SU rehabilitation is comparable to care provided in another type of hospital ward. Insufficient evidence makes it impossible to draw conclusions about the effect of different intensities of rehabilitation on outcomes post-stroke. There is moderate evidence that ESD services can provide care at modestly total lower costs (versus usual care) for stroke patients with mild or moderate disability. No significant differences were observed in primary outcomes between home-based rehabilitation and usual care and no firm conclusions can be drawn regarding its relative total cost. Several notable methodological problems were encountered when analysing the clinical and economic evidence. To allow stronger conclusions about the clinical effectiveness, quality of life and cost-effectiveness of rehabilitation interventions after stroke, further research would be required, particularly in a Canadian setting.

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Appendix 1: Literature Search Strategy

Search Legend

!	Explode (i.e., concept plus all sub-hierarchies)
*	Truncation symbol, any number of characters
?	Truncation symbol, single character
n	Near/next (i.e., terms are near/next to one another, any order)
“ ”	Phrase
l	Link (i.e., to subheading)
ti	Title
ab	Abstract
de	Descriptor
dt	Publication type
tn	Trade name
mn	Manufacturer name
nd	Device name
md	Device manufacturer
rn	Registry number (i.e., CAS)
tw	Text word

DATABASES	LIMITS	KEYWORDS/DESCRIPTORS
<p>DIALOG[®]</p> <p>Allied and Complementary Medicine[™]</p> <p>EMBASE[®]</p> <p>HealthSTAR[®]</p> <p>Manual, Alternative and Natural Therapy[®] (MANTIS[™])</p> <p>MEDLINE[®]</p> <p>PASCAL</p> <p>SciSearch</p> <p>SPORTDiscus</p>	<p>1995-</p>	<p>Clinical search:</p> <p>EMBASE: stroke/de OR cerebrovascular accident/de OR cerebrovascular disease/de OR brain infarction!/de OR brain hemorrhage!/de OR brain ischemia!/de</p> <p>MEDLINE/HealthSTAR: cerebrovascular accident!/de OR cerebrovascular disorders/de OR brain ischemia!/de OR cerebral hemorrhage!/de OR cerebral infarction!/de OR brain infarction!/de OR intracranial embolism and thrombosis!/de</p> <p>All databases: stroke/ti,ab OR “cerebrovascular accident*” OR “cerebrovascular disorder*” OR “cerebral ischemia” OR “cerebral ischaemia” OR “brain ischemia” OR “brain ischaemia” OR “cerebral hemorrhag*” OR “cerebral haemorrhag*” OR “brain hemorrhag*” OR “brain haemorrhag*” OR “cerebral infarction*” OR “brain infarction*”</p> <p style="text-align: center;">AND</p> <p>EMBASE: rehabilitation!/de OR physiotherapy!/de</p> <p>MEDLINE/HealthSTAR: rehabilitation!/de</p> <p>All databases: rehabilit* OR “exercis* therap*” OR physiotherap* OR “speech therap*” OR “language therap*” OR “occupation* therap*” OR</p>

		<p>“recreation* therap*”</p> <p style="text-align: center;">AND</p> <p>EMBASE: controlled study!/de OR meta-analysis/de OR randomized controlled trial/de</p> <p>MEDLINE/HealthSTAR: double-blind method/de OR meta-analysis/de OR random allocation/de OR dt=meta-analysis OR dt=randomized controlled trial OR dt=controlled clinical trial</p> <p>All databases: random* OR “double blind*” OR “double dumm*” OR “double mask*” OR “triple blind*” OR “triple dumm*” OR “triple mask*” OR “treble blind*” OR “treble dumm*” OR “treble mask*” OR placebo* OR “meta analy*” OR metaanaly* OR “quantitative* review*” OR “quantitative* overview*” OR “systematic* review*” OR “systematic* overview*” OR “methodologic* review*” OR “methodologic* overview*” OR “control* stud*” OR “control* trial*” OR RCT? OR “control* clinical stud*” OR “control* clinical trial*”</p> <p style="text-align: center;">AND</p> <p>All databases: human OR people OR person? OR wom?n OR man OR men OR adult? OR elderly OR aged OR “middle age*” OR middle-age*</p> <p><i>Performed 22 May 2001</i> 1267 unique records Allied and Complementary Medicine- 5 hits EMBASE - 745 hits HealthSTAR - 15 hits MANTIS™ – 2 hits MEDLINE - 418 records PASCAL - 25 hits SciSearch - 57 hits SPORTDiscus - 0 hits</p>
National Library of Medicine PubMed	1999:2001 Human	<p><i>Same descriptors and keywords as per DIALOG MEDLINE search.</i> <i>All keywords limited to title and abstract fields.</i></p> <p><i>Performed 2 Aug 2001</i> 164 records</p>
AART Webplace AgeLine		<p>Clinical search: strokes/de OR <i>same keywords as per DIALOG search</i></p> <p style="text-align: center;">AND</p>

		<p>rehabilitation/de OR occupational therapy/de OR physical therapy/de OR recreational therapy/de OR <i>same keywords as per DIALOG search</i></p> <p><i>Performed 13 June 2001</i> 2 records</p>
<p><i>OVID Technologies</i></p> <p>CINAHL</p>	1995-	<p>Clinical search:</p> <p>cerebral vascular accident/de OR cerebral hemorrhage!/de OR cerebral ischemia/de OR cerebral aneurysm/de OR <i>same keywords as per DIALOG search</i></p> <p style="text-align: center;">AND</p> <p>Rehabilitation!/de OR recreational therapy/de OR <i>same keywords as per DIALOG search</i></p> <p style="text-align: center;">AND</p> <p>meta analysis/de OR single-blind studies/de OR double-blind studies/de OR triple-blind studies/de OR random assignment/de OR clinical trials/de OR systematic random sample/de OR systematic review/de OR quantitative studies/de OR <i>same keywords as per DIALOG search</i></p> <p><i>Performed 19 Aug 2001</i> 240 records</p>
<p><i>The Cochrane Collaboration & Update Software Ltd.</i></p> <p>The Cochrane Library, 2002, Issue 3</p>	1995-	<p>Clinical search:</p> <p>cerebrovascular disorders!/de OR cerebral hemorrhage!/de OR cerebral infarction!/de OR stroke OR “cerebrovascular accident*” OR “cerebrovascular disorder*” OR “cerebral ischemia” OR “cerebral ischaemia” OR “brain ischemia” OR “brain ischaemia” OR “cerebral hemorrhag*” OR “cerebral haemorrhag*” OR “brain hemorrhag*” OR “brain haemorrhag*” OR “cerebral infarction*” OR “brain infarction*”</p> <p style="text-align: center;">AND</p> <p>rehabilitation!/de OR rehabilit* OR “exercise therap*” OR physiotherap* OR “speech therap*” OR “language therap*” OR “occupation* therap*” OR “recreation* therap*”</p> <p>The Cochrane Database of Systematic Reviews = 62 complete reviews, 24 protocols; The Database of Abstracts of Reviews of Effectiveness = 31 records; The Cochrane Controlled Trials Register = 1045 references; The Cochrane Database of Methodology Reviews = 2 records; The Cochrane Methodology Register = 9 records; Abstracts by INAHTA and other healthcare technology agencies = 11 records; The NHS Economic Evaluation Database = 69 records</p>

<p><i>DIALOG</i>[®]</p> <p>Alerts: Allied and Complementary Medicine[™] Current Contents Search[®] EMBASE[®] Alert Manual, Alternative and Natural Therapy[®] (MANTIS[™]) MEDLINE[®] PASCAL SciSearch</p>	<p>Human (MEDLINE only)</p>	<p>Clinical search:</p> <p><i>Same descriptors and keywords as per DIALOG MEDLINE search. Current Contents Search and SciSearch discontinued 17 Aug 2001</i></p>
<p><i>DIALOG</i>[®]</p> <p>Allied and Complementary Medicine[™] EMBASE[®] HealthSTAR[®] Manual, Alternative and Natural Therapy[®] (MANTIS[™]) MEDLINE[®] PASCAL SPORTDiscus</p>	<p>1995:2001</p>	<p>Economic search:</p> <p><i>Same descriptors and keywords as per DIALOG clinical search, excluding clinical trial filter and adding economic filter, below</i></p> <p>EMBASE: pharmacoeconomics/de OR economic aspect/de OR economic evaluation/de OR cost effectiveness analysis/de OR cost benefit analysis/de OR cost utility analysis/de OR health care cost/de OR quality adjusted life year/de OR</p> <p>MEDLINE/HealthSTAR: economics!/de OR Quality-adjusted life years/de</p> <p>All databases: economic*/ti,ab OR cost*/ti,ab OR price*/ti,ab OR expenditure*/ti,ab OR budget*/ti,ab OR QALY*/ti,ab OR “willingness to pay” OR value(2n)li fe</p> <p style="text-align: center;">AND</p> <p>All databases: human OR people OR person? OR wom?n OR man OR men OR adult? OR elderly OR aged OR “middle age*” OR middle-age*</p> <p><i>Performed 27 Aug 2001 375 unique records (excludes overlap with clinical search)</i></p> <p>Allied and Complementary Medicine - 2 hits EMBASE - 83 hits HealthSTAR - 23 hits MANTIS – 5 hits MEDLINE - 256 records PASCAL - 6 hits SPORTDiscus - 0 hits</p>

<p><i>National Library of Medicine</i></p> <p>PubMed</p>	<p>1990:2001 Human</p>	<p>Economic search:</p> <p><i>Same keywords as per PubMed clinical search, excluding clinical trial filter and adding economic filter, below</i></p> <p>economics!/de OR quality-adjusted life years/de OR economic*/ti,ab OR cost/ti,ab OR costs/ti,ab OR costed/ti,ab OR costing/ti,ab OR price*/ti,ab OR expenditure*/ti,ab OR budget*/ti,ab OR QALY*/ti,ab OR “value to life”/ti,ab OR “value of live”/ti,ab OR “willingness to pay”/ti,ab</p> <p><i>Performed 5 Sept 2001</i> <i>247 records</i></p>
<p><i>AARP Webplace</i></p> <p>AgeLine</p>		<p>Economic search:</p> <p><i>Same keywords as per MEDLINE, excluding clinical trial filter and adding economic filter, below</i></p> <p>economic patterns/de OR cost effectiveness/de OR health service costs/de</p> <p><i>Performed 13 June 2001</i> <i>1 unique record</i></p>
<p><i>Ovid Technologies</i></p> <p>CINAHL</p>	<p>1995-</p>	<p>Economic search:</p> <p><i>Same descriptors and keywords as per CINAHL clinical search, excluding clinical trial filter and adding economic filter, below</i></p> <p>economics!/de OR cost benefit analysis!/de OR health care costs!/de OR economic*/ti,ab OR cost*/ti,ab OR price*/ti,ab OR expenditure*/ti,ab OR budget*/ti,ab OR qaly*/ti,ab OR willingness to pay/ti,ab OR quality adjusted life years/tw</p> <p style="text-align: center;">NOT</p> <p>funding source/de</p> <p><i>Performed 20 Aug 2001</i> <i>86 records</i></p>
<p><i>The Cochrane Collaboration & Update Software Ltd.</i></p> <p>The Cochrane Library, 2002, Issue 3</p>		<p>Economic search:</p> <p>economics!/de OR quality adjusted life years!/de OR economic* OR cost* OR price* OR expenditure* OR budget* OR qaly* OR “willingness to pay”</p> <p>The Cochrane Database of Systematic Reviews = 4 complete reviews, 17 protocols; The Database of Abstracts of Reviews of Effectiveness</p>

		= 28 records; The Cochrane Controlled Trials Register = 59 references; The Cochrane Database of Methodology Reviews = 2 record; Abstracts by INAHTA and other healthcare technology agencies = 8 records; The NHS Economic Evaluation Database = 69 records
National Rehabilitation Information Center (NARIC) Various databases		Same keywords as per MEDLINE, etc. Regular updates received.
PEDro: The physiotherapy evidence database	1995-	cerebrovascular OR stroke Updated 10 May 2002 86 records
OHE-IFPMA Database Ltd. HEED: health economic evaluations database July 2002 issue		Economic search: cerebrovascular OR cerebral OR stroke AND rehabilitat* OR physiother* OR exercis* 37 records
DIALOG® Alerts: Allied and Complementary Medicine™ EMBASE® Alert Manual, Alternative and Natural Therapy® (MANTIS™) MEDLINE® PASCAL	Human (MEDLINE only)	Economic search: Same descriptors and keywords as per MEDLINE, etc.
Websites of HTA and related agencies; clinical trial registries; other databases		NZHTA; AHRQ; National Research Register; University of York NHS Centre for Reviews and Dissemination – CRD databases; LILACS; etc.

Appendix 2: The Barthel Index^f

Bowels

0= incontinent (or needs to be given enemata); 1= occasional accident (once a week);
2= continent

Bladder

0= incontinent, or catheterized and unable to manage alone; 1= occasional accident (maximum once per 24 hours); 2= continent

Grooming

0= needs help with personal care; 1= independent face/hair/teeth/shaving (implements provided)

Toilet use

0= dependent; 1= needs some help, but can do something alone; 2= independent (on and off, dressing, wiping)

Feeding

0= unable; 1= needs help cutting, spreading butter, etc.; 2= independent

Transfer (bed to chair and back)

0= unable, no sitting balance; 1= major help (one or two people, physical), can sit;
2= minor help (verbal or physical); 3= independent

Mobility

0= immobile; 1= wheelchair independent, including corners; 2= walks with help of one person (verbal or physical); 3= independent (but may use any aid; for example, stick)

Dressing

0= dependent; 1= needs help but can do about half unaided; 2= independent (including buttons, zips, laces, etc.)

Stairs

0= unable; 1= needs help (verbal, physical, carrying aid); 2= independent

Bathing

0= dependent; 1= independent (or in shower)

Total score: 0-20

^f Adapted from Wade (1992)¹⁸

The Barthel Index: guidelines

- The index should be used as a record of what a patient does, *not* as a record of what a patient could do.
- The main aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason.
- The need for supervision renders the patient *not* independent.
- A patient's performance should be established using the best available evidence. Asking the patient, friends/relatives and nurses are the usual sources, but direct observation and common sense are also important. However direct testing is not needed.
- Usually the patient's performance over the preceding 24-48 hours is important, but occasionally longer periods will be relevant.
- Middle categories imply that the patient supplies over 50 per cent of the effort.
- Use of aids to be independent is allowed.

Bowels (preceding week)

- If needs enema from nurse, then 'incontinent'; Occasional= once a week

Bladder (preceding week)

A catheterized patient who can completely manage the catheter alone is regarded as 'continent'.

Grooming (preceding 24-48 hours)

Refers to personal hygiene: doing teeth, fitting false teeth, doing hair, shaving, washing face. Implements can be provided by helper.

Toilet use

- Should be able to reach toilet/commode, undress sufficiently, clean self, dress and leave; With help= can wipe self and do some of above

Feeding

- Able to eat any normal food (not only soft food). Food cooked and served by others but not cut up; Help= food cut up, patient feeds self

Transfer

- From bed to chair and back; Dependent= no sitting balance (unable to sit); two people to lift; Major help= one strong/skilled, or two normal people-can sit up; Minor help= one person easily, *or* needs any supervision

Mobility

- Refers to mobility about house or ward, indoors• May use aid• If in wheelchair, must negotiate corners/doors unaided; Help= by one untrained person, including supervision and moral support

Dressing

- Should be able to select and put on all clothes, which may be adapted; Half= help with buttons, zips, etc., but can put on some garments alone

Stairs

- Must carry any walking aid used to be independent

Bathing

- Usually the most difficult activity; Must get in and out unsupervised and wash self Independent in shower= 'independent' if unsupervised and unaided

Appendix 3: Summary of HRQOL Instruments Used in this Review^g

Instrument	Description	Psychometrics
Nottingham Health Profile (NHP)	A generic, 38-item instrument that measures subjective health in six areas: energy, pain, emotional reactions, sleep, social isolation, and physical mobility, using dichotomous <i>yes/no</i> responses.	Test-retest reliability: subscales-energy (0.77), pain (0.79), emotional reactions (0.80), sleep (0.85), social isolation (0.78), and physical mobility (0.85).
Medical Outcomes Study 36-item Short-Form Health Survey (SF-36)	A generic, 36-item instrument that measures general health concepts in eight areas: physical functioning, role-physical, role-emotional, bodily pain, general health, vitality, social functioning, and mental health using either dichotomous <i>yes/no</i> responses or three to six point Likert-type responses.	Validity: construct, convergent, discriminant; internal consistency reliability: sub-scales-physical functioning (0.93), role-physical (0.84), role-emotional (0.83), bodily pain (0.82), general health (0.78), vitality (0.87), social functioning (0.85) and mental health (0.90).
Sickness Impact Profile (SIP)	A generic, 136-item instrument that is a behaviourally based measure of perceived health status in 12 areas: sleep/rest, eating, work, home management, ambulation, recreation/pastimes, mobility, body care/movement, social interaction, alertness behavior, emotional behavior, and communication using dichotomous <i>yes/no</i> responses.	Validity: convergent, discriminant, clinical; test-retest reliability: 0.92; internal consistency reliability: 0.94.

^g Adapted from Bays (2001)²¹

Appendix 4: Study Inclusion/Exclusion Forms

(A) Clinical Review

Study ID:

Citation:

Year:

Reviewer:

HN:

RT:

LM:

TD:

	HN:	RT:	LM:	TD:
1. Random allocation?		Yes ___ No ___		Can't Tell ___
2. Parallel group RCT? or cross over study (must be randomized initial allocation)		Yes ___ No ___		Can't Tell ___
3. Participants post Stroke/CVA/ Brain Ischemia/Cerebral Hemorrhage		Yes ___ No ___		Can't Tell ___
4. Type of intervention (answer part a, part b, part c, <u>or</u> part d.)				
a. Stroke unit care vs. care on a general medical or geriatric ward		Yes ___ No ___		Can't Tell ___
b. Impact of different intensities of rehabilitation therapies		Yes ___ No ___		Can't Tell ___
c. Early supported discharge services versus usual care ^h		Yes ___ No ___		Can't Tell ___
d. Community rehabilitation versus usual care ⁱ		Yes ___ No ___		Can't Tell ___
5. Duration of follow up equal to or greater than 6 months from randomization?		Yes ___ No ___		Can't Tell ___
6. Assesses stroke impairment, functional outcome or health-related quality of life (HRQoL) assessment?		Yes ___ No ___		Can't Tell ___

SCORING

Highlight one of the following: If 1-6 all "Yes", include study; If any of 1-6 "Can't tell" and the rest "Yes" or if all 1-6 are "Can't tell", order full paper; If any of 1-6 "No", exclude study

^h 'Usual care' as defined in the study

ⁱ 'Usual care' as defined in the study

(B) Economic Review

Study ID:

Citation:

Year:

Reviewer:

BB:

LM:

1. Type of study (answer part a or part b.)

a. Full economic evaluation?^j Yes ___ No ___ Can't Tell ___

b. Cost study? Yes ___ No ___ Can't Tell ___

2. Participants post Stroke/CVA/
Brain Ischemia/Cerebral Hemorrhage Yes ___ No ___ Can't Tell ___

3. Study objectives (answer part a, part b, part c, or part d.)

a. Stroke unit care versus care on a general medical/geriatric ward
Yes ___ No ___ Can't Tell ___

b. Impact of different intensities of rehabilitation therapies
Yes ___ No ___ Can't Tell ___

c. Early supported discharge services versus usual care^k
Yes ___ No ___ Can't Tell ___

d. Community rehabilitation versus usual care^l
Yes ___ No ___ Can't Tell ___

SCORING

Highlight one of the following: If 1-3 all "Yes", include study; If any of 1-3 "Can't tell" and the rest "Yes" or if all 1-3 are "Can't tell", order full paper; If any of 1-3 "No", exclude study

^j Defined as the comparative analysis of two or more treatment alternatives in terms of both their costs and consequences. Includes cost-minimization (needs evidence consequences of treatment alternatives are identical); cost-effectiveness, cost-utility, and cost-benefit analysis.

^k 'Usual care' as defined in the study

^l 'Usual care' as defined in the study

Appendix 5: Data Extraction and Quality Assessment Forms

(A) Clinical Review

Reviewer: **HN:** **LM:** **RT:** **TD:**

Date:

Study ID:

Full Citation^m

Country (or countries) where study undertaken

Language of publication

Conflict of interest

Other reports of this trialⁿ: (Give full citation)

^m If multiple studies by single group of investigators, cite the trial with the latest follow-up

ⁿ As cited in the reference list of the paper

1. Data Source

Published only _____

Unpublished only _____

Mixed _____

2. Trial dates

Start of recruitment: _____

End of recruitment: _____

3. Study inclusion/exclusion criteria

a. Inclusion criteria

b. Exclusion criteria

c. Numbers of patients excluded^o

^o If reported give breakdown of overall number of exclusions by category

4. Description of study population

a. Intervention (I)

Number Randomized: _____ Time after stroke onset [median & IQR]: _____

Sex [N & (%)]: _____ Age [mean years & SD]: _____

Other Baseline Characteristics (e.g. stroke severity):

b. Intervention (II)

c. Control

Number Randomized: _____ Time after stroke onset [median & IQR]: _____

Sex [N & (%)]: _____ Age [mean & SD]: _____

Other Baseline Characteristics (e.g. stroke severity):

5. Description of intervention & control (comparison) provided

a. Intervention (I)

b. Intervention (II)

c. Control

d. Setting

Multi centre: _____ Single centre: _____

6. Outcomes collected. Tick all available

a. Primary outcomes

Death: _____ **Dependency:** _____ **Home/Institutional care at follow-up:** _____

b. Secondary outcomes

HRQoL (Should include psychological/physical & social function)

Specify: _____

Length of stay in hospital: _____

c. Other outcomes [list below]

7. Duration of follow-up

_____ months [mean (SD) or median & (range)]

8. Results

Outcomes	Intervention (I)	Intervention (II)	Control
Death (n/%) At Home (n/%) In Institution (n/%) Length of hospital stay (days)			
Barthel Index Baseline (mean ± SD) 6-month FU Final FU Change Rankin score Baseline (mean ± SD) 6-month FU Final FU Change <i>Health related quality of life/psychological assessment.</i> Measure used: Baseline (mean ± SD) 6-month FU Final FU Change			

Changes in other outcomes: _____

9. Any Other Notes/Observations (including, if applicable, results of subgroup analyses)

10. Quality Assessment

	Yes/No/Can't tell	Score
A) <u>Randomization procedure</u>		
A1. Was the trial described as "randomized"?		If yes, score 1
Was allocation truly random?		If yes, score 1
Was allocation quasi-random or		
Was allocation systematic or		
Was method of randomization not stated or unclear?		
B) <u>Allocation concealment</u>		
Was concealment adequate?		If yes, score 1
Was concealment inadequate?		
Was concealment unclear?		
C) <u>Method of blinding</u>		
Was the trial described as double blind?		
Was the treatment allocation masked from the participants?		
Was the treatment allocation masked from the investigators?		
Was the treatment allocation masked at the outcome assessments?		If yes, score 1
D) <u>Completeness of trial</u>		
Were the numbers of withdrawals in each group stated?		If withdrawals $\leq 20\%$ or yes to intention to treat analysis score 1
Was an intention-to-treat analysis performed?		
What were the drop-out (and crossover) rates in each group of the trial for each of the main outcomes?		
Are there substantial differences in completeness between the groups?		
Quality Score (0-5)		

B) Economic Review

Stroke rehabilitation interventions	
Study identification	
Reference ID	
Author; title; journal name; publication date	
Study selection criteria	
Type of study	
Population	
Type of intervention	
Other reason for exclusion	
Study description & methods	
Study question – narrative	
Study population & size	
Intervention description	
Comparator	
Geographic location; currency; year of data	
Analytic methods	
Analytical perspective	
Time horizon	
Technique of evaluation	
Discounting	
Type of sensitivity analysis Sub-group analysis	
Data / Input Parameters	
Health outcomes	
Clinical outcomes:	
Primary & secondary	
Duration of follow-up	
Productivity changes & lost time by patient or carer	
Adverse events	
Data sources (gathered, derived or assumed)	
Health-related quality-of-life:	
Outcomes	
Instrument / method	
Subjects' values elicited	

Costs		
Types of costs		
Data sources (for resource use & unit prices)		
Other parameters / assumptions		
Data source & justification		
Study Results		
Results		
Key or Base Case results for:	Intervention:	Comparator:
Health outcomes Final		
Baseline		
Difference		
Incremental		
Resource use Final		
Baseline		
Difference		
Incremental		
Costs Final		
Baseline		
Difference		
Incremental		
Incremental cost-effectiveness ratio		
Standardized costs		
Sensitivity analyses results Sub-group results		
Summary		
Conclusions of Author		
Conflict of interest:		
Global impression of study quality (score 1–5)		
Comments		

Appendix 6: Primary Clinical Studies of SU Care

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (Years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay in days (SD)	
Kalra and Eade, 1995 ²⁵ (United Kingdom)	I: 34 C: 37	9 days BI score I: 3 C: 3	I: 75 C: 71	I: 77 C: 80	I: The 13-bed stroke rehabilitation unit is situated in a modern block and has dedicated physiotherapy and occupational therapy areas on the ward. C: General medical ward: Medical and nursing care, physiotherapy, speech and occupational therapy input, dietary and pharmacy advice, and social worker support are freely available to stroke patients on general medical wards. However, significant differences of the wards from the stroke rehabilitation unit include (1) emphasis on acute rather than rehabilitation care, (2) deficiencies in multidisciplinary planning and goal setting, (3) lack of patient/caregiver involvement, (4) inadequate support or counseling facilities, and (5) undue nihilism about stroke outcome.	12 months I: 34 C: 37	I: 7 C: 17	I: 8; C: 6 (median)	I: 11 C: 13	I: 16 C: 7	I: 47.2 (31.2) C: 76.8 (50.2)	3

I: intervention; C: control; BI score: Barthel Index; N/R: not reported

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay in days (SD)	
Ronning and Guldvog, 1998a, ³⁰ 1998b ³¹ (Norway)	I: 271 C: 279	Within 24 hours BI score I: 9 C: 10	I: 47 C: 47	I: 77 C: 76	I: The 10-bed acute SU could expand or contract with demand. The medical treatment in the SU followed current practice guidelines for the management of patients with acute stroke. The staff was multidisciplinary with neurologists, trained nurses, physiotherapists, occupational therapists, and speech therapists. The physiotherapists followed the Bobath technique and instructed the staff to follow this approach during 24 hours. The team met with the relatives weekly to plan treatment and support after discharge. C: The hospital has one department of medicine with five wards. Stroke patients were admitted to all these wards, dependent on capacity. Patients treated within the general medical wards (GMW) were given traditional, good medical treatment without special efforts or standardized effort toward this patient group. Patients were offered physiotherapy, occupational therapy, and evaluation of a neurologist when it was requested by the staff.	7 months I: 271 C: 279	I: 127 (n= 364) ^p C: 184 (n= 438) ¹	I: 16.6 C: 16.8 (median)	I: 40 C: 43	N/R	I: 9.5 (6.9) C: 7.7 (6.2)	2

^p From Ronning and Guldvog (1998b);³¹ refer to section 3.2.2 of text

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay in days (SD)	
Juby, 1996; ²⁷ Lincoln, 2000 ²⁹ (United Kingdom)	I: 176 C: 139	Within 14 days	I: 47 C: 35	I: 69 C: 68	I: 15-bed SU located in one of two teaching hospitals. Detailed multidisciplinary assessment and ward-based rehabilitation is combined with careful and co-ordinated discharge procedures. C: Conventional wards	6 months	I: 16 C: 17	I: 17 C: 15 (median)	N/R	I: 121 C: 89	N/R	3
		No BI score				12 months	I: 25 C: 26	I: 17 C: 16 (median)	N/R	I: 114 C: 86	N/R	
						5 years	I: 79 C: 77	(BI \leq 18) I: 60 C: 37	I: 21 C: 11	N/R	N/R	
Indredavik, 1997; ³³ 1999 ³⁵ (Norway)	I: 110 C: 110	At admit	I: 49 C: 50	I: 72 C: 74	I: The SU, located in the Department of Medicine, in our hospital is a combined acute and rehabilitation SU. We have a team approach to nursing and rehabilitation, emphasizing patient and family participation. Functional training and a modified motor relearning program are the basic rehabilitation approaches. C: The patients in the general ward received acute medical care, physiotherapy, and occupational therapy, but not within the framework of a team approach.	5 years	I: 65 C: 78	(BI \geq 19) I: 26 C: 10 (BI \geq 12) I: 38 C: 20	I: 7 C: 12	I: 38 C: 20	N/R	4
		BI score I: 9.4 C: 8.7				10 years	I: 83 C: 96	(BI \geq 19) I: 14 C: 6 (BI \geq 12) I: 22 C: 9	I: 6 C: 5	I: 21 C: 9	N/R	

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay in days (SD)	
Kalra, 2000 ³⁷ (United Kingdom)	I: 152 C: 152	Within 3 days BI score I: 8 C: 9	I: 47 C: 51	I: 75 C: 77	I: Care on the stroke unit (acute and rehabilitation) was provided by a stroke physician supported by a multidisciplinary team with specialist experience in stroke management. C: GW- Patients allocated to stroke-team care were managed on general wards and remained under the care of admitting physicians.	6 months I: 152 C: 149 12 months I: 152 C: 149	I: 10 C: 25 I: 13 C: 34	N/R (BI \geq 15) I: 131 C: 102 RS (O-6 scale) I: 129 C: 99	I: 9 C: 12 I: 8 C: 11	N/R N/R	N/R I: 32 (29.6) C: 29.5 (40.1)	5
Fagerberg, 2000 ³⁶ (Sweden)	I: 166 C: 83	Within 7 days BI score I: 8.8 C: 8.4	I: 66 C: 54	I: 80 C: 80	I: SU care was organized in a care continuum with 2 acute stroke units and 2 stroke units at geriatric wards working according to identical principles that had been agreed on. The members of each stroke unit team were a physician, a stroke nurse (who followed a modified primary nursing approach, including contacts with family members and social institutions), a physiotherapist, and an occupational therapist. C: The other patients were treated in 6 general medical wards. There was no standardized program for this treatment, and there were no extra resources for the management of stroke patients.	12 months I: 166 C: 83	I: 45 C: 19	I: 16.4 C: 15.2 (no SD)	I: 16 C: 13	I: 102 C: 49	I: 28.3 C: 35.8 (no SD)	5

Appendix 7: Primary Clinical Studies of Impact of Different Intensities

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay in days (SD)	
Fey's, 1998 ⁴⁶ (Belgium/ Switzerland)	I: 50 C: 50	I: 21 days C: 24 days (p<0.05) No BI score	I: 38 C: 44	I: 66 C: 63	15 hours of additional therapy in both groups applied on a daily basis during a period of 6 weeks. I: Patient positioned in a rocking chair with an inflatable splint used to support the affected arm and involving motor and sensory stimulation; C: Patient positioned in a rocking chair with arm rested on a cushion on the patient's lap and no additional stimulation	6 months I: 50 C: 50	N/R	p=NS between groups	N/R	N/R	N/R	2
Kwakkel, 1999; ⁴⁴ 2002 ⁴⁵ (The Netherlands)	I: 64 C: 37	7 days BI score I: 5.5 C: 5.5	I: 55 C: 62	I: 67 C: 64	All groups received 15 minutes per day of leg rehabilitation, 15 minutes per day arm rehabilitation, and 1.5 hours per week ADL training by an occupational therapist I: Arm and leg rehabilitation for 30 minutes on 5 days per week for 20 weeks (50 hours) C: Immobilization of the paretic arm and leg by an inflatable pressure splint	6 months I: 64 C: 37 12 months I: 64 C: 37	N/R	I: 18 C: 17 (median) I: 17 C: 17 (median)	N/R	N/R	N/R	5
Lincoln, 1999; ⁴⁶ (United Kingdom)	I: 187 C: 95	12 days BI score I: 6 C: 7	I: 47 C: 53	I: 73 C: 73	I: 10 hours of additional physiotherapy by a senior therapist or a physiotherapy assistant, applied during a period of 5 weeks C: Routine physiotherapy (3-4 hrs/week) following the Bobath method	6 months I: 187 C: 95	I: 27 C: 11	I: 16 C: 16 (median)	N/R	N/R	N/R	5

Appendix 8: Primary Clinical Studies of ESD Services

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay in days (SD)	
Hui, 1995 ^{5b} (China)	I: 59 C: 61	6 days BI score I: 9.9 C: 10.4	I: 58 C: 54	I: 73 C: 74	I: Patients under care of geriatric team discharged home as soon as the team felt they were able to cope and given follow-up rehabilitation at the day hospital. (incl. Physio/Occup. therapy) C: Inpatient rehabilitation on the same stroke rehabilitation ward until patients considered by the neurologist to have reached full potential before discharge to homes or geriatric centres.	6 months I: 43 C: 44	I: 6 C: 6	I: 17.1 (3.6) C: 15.6 (5.6)	N/R	N/R	N/R	1
Rudd 1997 ^{5b} (United Kingdom)	I: 167 C: 164	23 days BI score I: 15 C: 15	I: 45 C: 43	I: 70 C: 72	I: Patients remained in hospital until the required package of social services care could be organized and any home adaptations undertaken. After discharge, patients were given a planned course of domiciliary physiotherapy, occupational therapy, and speech therapy, with visits as frequently as considered appropriate (maximum one daily visit from each therapist). Patients received care from the team for a maximum of three months. C: Patients allocated to conventional care continued with their treatment, discharge planning, and outpatient care in the normal way. About half of the admitted patients receive treatment in a SU, with the remainder being treated in GMW or geriatric wards.	12 months Death and Instit -ion I: 135 C: 126 Length of Stay I: 165 C: 163	N/R	I: 16 C: 16	I: 8 C: 15	N/R	I: 12 (19) C: 18 (24)	3

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay (days)	
Widen Holmgvist, 1998 ⁶⁵ Von Koch, 2000, ⁶³ 2001 ⁶⁴ (Sweden)	I: 42 C: 41	5-7 days No BI score	I: 46 C: 45	I: 71 C: 73	I: Two physical therapists, two occupational therapists, and one speech therapist associated with the stroke unit formed the team of the home rehabilitation outreach service. A program approximately 3 to 4 months in duration was tailored for each patient. If continued rehabilitation was required after such a period, the patient was referred to routine outpatient rehabilitation. C: Routine rehabilitation service. In this context, routine rehabilitation denotes a heterogeneous set of interventions ranging from the best established in the hospital, day care, and/or outpatient care, to others introduced during the study period, such as daily afferent sensory stimulation by low-frequency transcutaneous electrical nerve stimulation and home-based rehabilitation initiated by the Department of Geriatrics.	6 months I: 40 C: 38	N/R	(BI \geq 19) I: 31 C: 23	N/R	N/R	N/R	5
						12 months I: 39 C: 38	N/R	I: 30 C: 23	N/R	N/R	I: 18 C: 33 p=0.002	

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay (days)	
Anderson, 2000 ⁶⁰ (Australia)	I: 42 C: 44	14 days BI score I: 17 C: 17.2	I: 38 C: 50	I: 72 C: 71	I: A community rehabilitation team was formed that comprised a full-time program coordinator (an occupational therapist); a consultant in rehabilitation; and physiotherapists, occupational therapists, social workers, speech therapists, and rehabilitation nurses most of whom had experience in community therapy. Efforts were made for any adaptations to the home, therapy, and other care to be organized so that discharge from hospital could occur within 48 hours of randomization. The median duration of rehabilitation was 5 weeks (range, 1 to 19 weeks). C: Patients randomized to the control group received conventional care and rehabilitation in hospital, either on an acute-care medical/geriatric ward or in a multidisciplinary stroke rehabilitation unit run by specialists in rehabilitation or geriatric medicine. For these patients, care pathways were used, and discharge planning and follow-up care as an outpatient or in the community was organized according to usual policy.	6 months I: 42 C: 44	I: 2 C: 0	I: 19.2 C: 19.6 (median)	I: 15 C: 11	N/R	I: 2 C: 11.5 N/R median	5

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay (days)	
Indregavik, 2000 ⁶² (Norway)	I: 160 C: 160	≤7 days BI score I: 12.1 C: 11.7	I: 46 C: 56	I: 74 C: 74	I: Extended stroke unit service: Ordinary stroke unit service (OSUS) combined with service from a mobile team offering ESD and coordinating further rehabilitation and follow-up in close cooperation with the primary healthcare system (nurse, physiotherapist, occupational therapist, and part- time services of a physician). Close follow-up by the mobile team was present for the first month after discharge to home. C: OSUS: combined acute and rehabilitation stroke unit and further follow-up organized by rehabilitation clinics and/or the primary health care system.	6 months Death, Instit -ion and Home I: 160 C: 160 BI score I: 121 C: 122	I: 13 C: 15	(BI≥19) I: 63 C: 47	I: 21 C: 28	I: 126 C: 117	N/R	3

Appendix 9: Primary Clinical Studies of Community Rehabilitation

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay (days)	
Forster and Young, 1996 ⁷² (United Kingdom)	I: 120 C: 120	Within 6 weeks BI score I: 17 C: 16	I: 45 C: 49	I: 73 C: 73	I: Visits by specialist outreach nurses over 12 months to provide information, advice and support; (average of seven visits) C: Usual care with no nurse visits	6 months I: 110 C: 115 12 months I: 102 C: 105	N/R N/R	I: 18 C: 17 I: 18 I: 17	N/R	N/R	N/R	4
Logan, 1997 ⁷⁴ (United Kingdom)	I: 53 C: 58	- No BI score	I: 57 C: 43	I: 71 C: 74	I: Enhanced home-based service seen and treated by a single research occupational therapist. The patients received on average six visits within a 4- month time period. C: Usual home-based service The patients received on average 2.5 visits within a 2- month time period.	6 months I: 45 C: 38	I: 5 C: 7	I: 16 C: 16 (median)	N/R	N/R	N/R	5
Walker, 1999, ⁷⁵ 2001 ⁷⁶ (United Kingdom)	I: 94 C: 91	Within 30 days I: 18 C: 18	I: 45 C: 54	I: 74 C: 75	I: Received visits from a research occupational therapist for up to 5 months; 1-15 visits with a mean of 6 visits. The frequency of visits were agreed upon by the therapist, patients, and if relevant, the carer(s). C: No visits/additional input from the therapist, but may have received input from existing services as with routine service.	6 months I: 84 C: 79 12 months I: 73 C: 74	N/R	I: 20 C: 18 I: 19 C: 18	N/R	N/R	N/R	5

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay (days)	
Andersen, 2000 ⁷⁷ (Denmark)	I: 107 C: 48	- BI score I: 16.2 C: 15.4	I: 59 C: 44	I: 72 C: 68	I: Physician (trained in geriatric rehabilitation at home, including stroke rehabilitation) intervention consisting of three 1-hour home visits (at 2, 6, and 12 weeks after discharge) or physiotherapist intervention at home during a 6-week period immediately after discharge. The average number of visits per patient was 2.9 (range 1-8). C: Standard aftercare, including outpatient rehabilitation, and home care to compensate for disability. Standard aftercare did not include follow-up home visits.	6 months Death & Institution I: 107 C: 48 Length of Stay I: 38 C: 28	I: 3 C: 0	N/R	I: 2 C: 3	N/R	I: 16.5 (22.5) C: 26 (38)	5
Gilbertson, 2000 ⁷⁹ (United Kingdom)	I: 67 C: 71	27 days BI score I: 17 C: 18	I: 57 C: 56	I: 71 C: 71	I: Six-week home programme delivered by a occupational therapist, comprising around 10 visits each lasting 30-45 minutes tailored to recovery goals identified by the patient. C: Routine services including inpatient multidisciplinary rehabilitation, a pre-discharge home visit for selected patients, the provision of support services and equipment, regular review at a stroke unit, and selected patients referred for a medical day hospital.	6 months I: 67 C: 71	I: 6 C: 5	I: 17 C: 17 (median)	N/R	N/R	N/R	5

Author, Year (Country)	Baseline Characteristics				Intervention & Control Characteristics	F/U Period & No.	Outcomes at Follow-up					Quality Score
	No.	Time after onset & BI score	Female (%)	Age (years)			Death	BI score (0-20 scale)	Institution	Home	Length of stay (days)	
Wolfe, 2000 ⁸⁰ (United Kingdom)	I: 23 C: 20	N/R BI score I: 17 C: 17	I: 57 C: 60	I: 72 C: 76	I: Home rehabilitation from a multidisciplinary team. Patients received care from the team for a maximum of three months (average of three sessions). C: Usual community care	12 months I: 15 C: 17	N/R	I: 18 C: 20 (median) <hr/> (RS>3) I: 8 C: 7 (median)	N/R	N/R	N/R	4
Roderick, 2001 ⁸¹ (United Kingdom)	I: 66 C: 74	N/R BI score I: 12.6 C: 12.8	I: 50 C: 57	I: 78 C: 80	I: Home rehabilitation comprising of one full-time senior physiotherapist and one half-time senior occupational therapist (and a consultant geriatrician to review cases) using a goal- setting approach. Outpatient speech and language therapy was provided for this group. Session on average in three 15- min blocks for six two-week periods. C: Rehabilitation in geriatric day-hospitals. Session on two 15-min blocks for same duration.	6 months I: 54 C: 58	N/R	I: 17 C: 15.5 (median)	N/R	N/R	I: 7 C: 11 (medi- an)	5
Green, 2002 ⁷³ (United Kingdom)	I: 85 C: 85	1 year BI score I: 18 C: 18	I: 42 C: 46	I: 72 C: 74	I: Community physiotherapy service C: Usual care	6 months I: 73 C: 77 <hr/> 9 months I: 72 C: 74	N/R	I: 18 C: 18 (median) <hr/> I: 18 C: 18 (median)	N/R	N/R	N/R	5

Appendix 10: Summary of Results of HRQoL Studies

Author, Year (Country)	No.	HRQoL Measure	Intervention and Control Characteristics	Domains	Results
<i>Comparison (1): Stroke unit care versus care on a general medical or geriatric ward</i>					
Indredavik, 1998 ³⁴ (Norway)	I: 37 C: 25	NHP	I: The SU, located in the Department of Medicine, in our hospital is a combined acute and rehabilitation SU. We have a team approach to nursing and rehabilitation, emphasizing patient and family participation. Functional training and a modified motor relearning program are the basic rehabilitation approaches. C: The patients in the general ward received acute medical care, physiotherapy, and occupational therapy, but not within the framework of a team approach.	Global scores	At 5 years: NHP scores- I: 78; C: 63 [p=0.009] (no SD) For BI ≥19: NHP score- I: 82; C: 77.5 For BI <19: NHP score-I: 69; C: 55
Fagerberg, 2000 ³⁶ (Sweden)	I: 116 C: 57	NHP	I: Stroke unit care was organized in a care continuum with 2 acute stroke units and 2 stroke units at geriatric wards working according to identical principles that had been agreed on. The members of each stroke unit team were a physician, a stroke nurse (who followed a modified primary nursing approach, including contacts with family members and social institutions), a physiotherapist, and an occupational therapist. C: The other patients were treated in 6 general medical wards. There was no standardized program for this treatment, and there were no extra resources for the management of stroke patients.	Global score	At 12 months NHP score: I: 23; C: 26 [p=NS] (no SD)

Author, Year (Country)	No.	HRQoI Measure	Intervention and Control Characteristics	Domains	Results
<i>Comparison (2): Impact of different intensities of rehabilitation therapies</i>					
Kwakkel, 2002 ⁴⁵ (The Netherlands)	I: 64 C: 37	NHP; SIP	<p>All groups received 15 minutes per day of leg rehabilitation, 15 minutes per day arm rehabilitation, and 1.5 hours per week ADL training by an occupational therapist</p> <p>I: Arm and leg rehabilitation for 30 minutes on 5 days per week for 20 weeks (50 hours)</p> <p>C: Immobilization of the paretic arm and leg by an inflatable pressure splint</p>	<p>NHP: Part 1 consists of 38 yes/no questions describing health-related behaviour in six domains of daily life (energy, physical mobility, sleep, pain, emotional reactions, and social isolation).</p> <p>FAI: The first part of this index assesses the frequency of performance of ten activities (meal preparation, washing up, clothes washing, light and heavy housework, social outings, local shopping, walking outside >15 min, actively pursuing a hobby, driving a car, travelling by bus) during the previous 12 weeks; the second part assesses five activities (outings and car rides, gardening, household maintenance, reading, and paid work) during the previous 26 weeks.</p> <p>SIP: 68-item version that assesses six domains of health-related functional status (somatic autonomy, mobility control, psychological autonomy and communication, social behaviour, emotional stability, and mobility range), explaining 94% of the total variance of the original 136-item version.</p>	<p>At 12 months:</p> <p>NHP I: 10.3 (7.8) C: 11.7 (8.4)</p> <p>SIP I: 26.5 (13.6) C: 31.2 (11.6)</p> <p>[p=NS for all measures]</p>

Author, Year (Country)	No.	HRQoI Measure	Intervention and Control Characteristics	Domains	Results
<i>Comparison (3): Early supported discharge services versus usual care</i>					
Rudd, 1997 ⁶⁰ (United Kingdom)	I: 102 C: 113	NHP	I: Patients remained in hospital until the required package of social services care could be organized and any home adaptations undertaken. After discharge, patients were given a planned course of domiciliary physiotherapy, occupational therapy, and speech therapy, with visits as frequently as considered appropriate (maximum one daily visit from each therapist). Patients received care from the team for a maximum of three months. C: Patients allocated to conventional care continued with their treatment, discharge planning, and outpatient care in the normal way. About half of the patients who are admitted receive treatment in a stroke unit, with the remainder being treated in general medical or elderly care wards.	Energy; Pain; Emotion; Sleep; Social and Physical mobility	NHP score (0-45; higher score indicating poor status) At 12 months: I: 15 (23); C: 17 (35) [p=0.11]
Anderson, 2000; ⁶⁰ Hackett, 2002 ⁶¹ (Australia)	I: 42 C: 44	SF-36; NHP	I: A community rehabilitation team was formed that comprised a full-time program coordinator (an occupational therapist); a consultant in rehabilitation; and physiotherapists, occupational therapists, social workers, speech therapists, and rehabilitation nurses most of whom had experience in community therapy. Efforts were made for any adaptations to the home, therapy, and other care to be organized so that discharge from hospital could occur within 48 hours of randomization. C: Patients randomized to the control group received conventional care and rehabilitation in hospital, either on an acute-care medical/geriatric ward or in a multidisciplinary stroke rehabilitation unit run by specialists in rehabilitation or geriatric medicine. For these patients, care pathways were used, and discharge planning and follow-up care as an outpatient or in the community was organized according to usual policy.	Physical, Social, Mental by SF-36; Energy, Pain, Emotion, Sleep, Social and Physical by NHP	At 6 months & 12 months: SF-36: [p=NS between groups] At 6 months: NHP: I: 10.7; C: 7.5 (median) [p=NS between groups]

Author, Year (Country)	No.	HRQoI Measure	Intervention and Control Characteristics	Domains	Results
<i>Comparison (3): Early supported discharge services versus usual care</i>					
Von Koch, 2000, ⁶³ 2001 ⁶⁴ (Sweden)	I: 40 C: 38	SIP	<p>I: Two physical therapists, two occupational therapists, and one speech therapist associated with the stroke unit formed the team of the home rehabilitation outreach service. A program approximately 3 to 4 months in duration was tailored for each patient. If continued rehabilitation was required after such a period, the patient was referred to routine outpatient rehabilitation.</p> <p>C: Routine rehabilitation service. In this context, routine rehabilitation denotes a heterogeneous set of interventions ranging from the best established in the hospital, day care, and/or outpatient care, to others introduced during the study period, such as daily afferent sensory stimulation by low-frequency transcutaneous electrical nerve stimulation and home-based rehabilitation initiated by the Department of Geriatrics.</p>	Perceived dysfunction by SIP	<p>At 6 months: SIP score (0-100) I: 16 (8-24); C: 12 (7-26) [p=0.89]</p> <p>At 12 months: I: 15 (8-31); C: 13 (6-22) [p=0.36]</p>

Author, Year (Country)	No.	HRQoI Measure	Intervention and Control Characteristics	Domains	Results
<i>Comparison (4): Community rehabilitation versus usual care</i>					
Forster and Young, 1996 ⁷² (United Kingdom)	I: 88 C: 89	NHP	I: Visits by specialist outreach nurses over 12 months to provide information, advice and support; (average of seven visits) C: Usual care with no nurse visits	Excluding the physical mobility section	At 6 months: I: 96 (25-169) C: 84 (29-175) At 12 months I: 97 (24-184) C: 80 (26-172)
Wolfe, 2000 ⁸⁰ (United Kingdom)	I: 15 C: 17	NHP	I: Home rehabilitation from a multidisciplinary team. Patients received care from the team for a maximum of three months (average of three sessions). C: Usual community care	Overall score	At 12 months: I: 5 (0-28) C: 12 (0-26) [p=0.16]
Roderick, 2001 ⁸¹ (United Kingdom)	I: 49 C: 50	SF-36	I: Home rehabilitation comprising of one full-time senior physiotherapist and one half-time senior occupational therapist (and a consultant geriatrician to review cases) using a goal-setting approach. Outpatient speech and language therapy was provided for this group. Session on average in three 15-min blocks for six two-week periods. C: Rehabilitation in geriatric day-hospitals. Session on two 15-min blocks for same duration.	Physical; Mental	At 6 months: Physical health: I: 35 (26.5-44) C: 33 (27-39) [p=0.22] Mental health: I: 57 (50-63) C: 57 (51-63) [p=0.99]

Appendix 11: Primary Economic Studies of SU Care

Study	Major; 1998¹⁰⁴	Claesson; 2000¹⁰⁵	Hagenmeyer; 2000¹⁰⁶
Intervention & comparator	<ol style="list-style-type: none"> Stroke unit Conventional rehab (CR) on general medical ward 	<ol style="list-style-type: none"> SU care (non-intensive with continuum of care) CR (in GMW) 	<ol style="list-style-type: none"> Stroke units (SU), early mobilization & interdisciplinary rehab Conventional tx & rehab (CR), on hospital ward (regular, internal medicine or neurology)
Study population	<ul style="list-style-type: none"> Based on meta-analysis of published RCT (n = 1277) 	<ul style="list-style-type: none"> Pts age > 69 admitted within 7 days, living at their home & without recognized need for care n = 249 	<ul style="list-style-type: none"> UK trial for stroke incidence German trial for outcomes & utilization data n = 316
Study design	CCA based on simple model using multiple sources of data	CCA based on RCT	CCA using mix of modelling & trial data
Perspective	Health service & institutional care	Health service & informal care	Health service
Time horizon	1 year	1 year	Life-time (long-term events modeled; cohort followed from age 45 to 95)
Health outcomes	Outcome on discharge from hospital: <ul style="list-style-type: none"> Death Discharged to institutional care Discharged to own home & physically dependent / independent 	<ul style="list-style-type: none"> Mortality, functioning & r pts living at home after 1 year 	<ul style="list-style-type: none"> Mortality (1, 6 & 12 months); survival; recurrent stroke; need for LT care; LOS for acute care (German trial, 1995)
Costs	<ul style="list-style-type: none"> Direct costs to health service Includes: hospital costs Some institutional care included (Many sources; LOS data from 18 trials) 	<ul style="list-style-type: none"> Inpt care, outpt care, institutional care, community services & informal care 	<ul style="list-style-type: none"> Direct health care costs Includes: acute hospital; inpt rehab; community rehab; nursing care; outpt care, drugs, aids
Country Currency & year of data	<ul style="list-style-type: none"> UK UK£; 1997 	<ul style="list-style-type: none"> Sweden SEK & US dollars 1996 	<ul style="list-style-type: none"> Germany Euros; 2000
Base Case results for health outcomes	For SU pts (vs CR): <ul style="list-style-type: none"> More survive ($\Delta = 4\%$, 0-7%) More independent ($\Delta = 5\%$, 1-8%) More return home In cohort of 100 pts, SU rehab results in: <ul style="list-style-type: none"> 26 fewer bed-days 1 fewer pt discharged to institution 5 more pts discharged home 	<ul style="list-style-type: none"> After 1 year, NS Δ in mortality, functioning or living at home In ST, some outcomes better for SU pts 	<ul style="list-style-type: none"> 45 year old in SU adds 1.6 years to 15.4 years survival of CR pts Pts with 1st stroke between age 65-75 benefit most from SU Risk of 1st & 2nd recurrent stroke \uparrow by 6% & 20% for SU pts

Study	Major; 1998 ¹⁰⁴	Claesson; 2000 ¹⁰⁵	Hagenmeyer; 2000 ¹⁰⁶
Base Case results for resources use & costs	<ul style="list-style-type: none"> In cohort of 100 pts, SU rehab results in saving resources valued at £25,600 (£250 per pt) in 1st year In worst case scenario, SU achieves ↑ outcomes for modest cost ↑ In best case scenario, SU achieves ↑ outcomes & releases resources Nursing staff costs are a main driver of inpt cost (81% of total costs) 	<ul style="list-style-type: none"> Total costs: SU = US\$25,373 vs CR = US\$28,507 (11%↓, NS) Total SU costs: inpt & institutional care = 70%; outpt care = 21%; informal care = 10% Informal care costs: SU = US\$2424 vs CR = US\$3708 (NS) Stroke severity: mild = US\$15,970, moderate = US\$39,254, severe = US\$32,836 (p < 0.001) [age or non-stroke diagnosis NS different] 	<p>Total lifetime costs for average stroke pt:</p> <ul style="list-style-type: none"> For SU = Euros 29,000 For CR = Euros 30,800 <p>SU pt cost components (%Δ vs CR):</p> <ul style="list-style-type: none"> Acute hospital = 28% (Δ = 0%) Inpt rehab = 3% (Δ = ↓ 12%) <ol style="list-style-type: none"> Community rehab = 4% (Δ = ↑ 12%) Nursing care = 29% (Δ = ↓ 20%) Outpt care, drugs = 36% (Δ = ↑ 13%)
Sensitivity analysis	Yes	<ul style="list-style-type: none"> None 	
Author conclusions	<ul style="list-style-type: none"> SU may ↓ costs & ↑ survivors & disability-free survival Within limitations of analysis, SU are likely to be more CE than CR on general wards 	<ul style="list-style-type: none"> Total costs did not differ (NS) Total costs showed large variation related to stroke severity at onset Costs outside hospital are considerable % of total costs 	<ul style="list-style-type: none"> Modelling needed for stroke given important long-term consequences (e.g. stroke recurrences & nursing) Longer survival for SU pts leads to increased recurrence of stroke vs CR Nursing care large share of total cost SU most effective in added survival for pts with 1st stroke age 65-75 For SU pts, ↓ time in dependency & ↓ nursing care costs vs CR
Comments	<ul style="list-style-type: none"> Numerous assumptions about LOS Difficult to generalize about LOS as: (a) trials define LOS differently; (b) much heterogeneity in results Extent to which LOS data includes institutional care is uncertain Costs to pt, family & community after discharge are not included Long-term costs & consequences of SU not established & adverse outcome may only be delayed (Trondheim data shows sustained benefit for SU at 5 years) Need better quality data to improve economic analysis Uneven resource implications among groups from switching to care in SU 	<ul style="list-style-type: none"> Important to include of all costs; Likely that outpt & informal care costs would increase further after 1 year (hospital costs high in year 1) Informal care conservatively estimate (costed using leisure time) <p>Limitations:</p> <ul style="list-style-type: none"> Study had limited statistical power (400 pts needed to detect 25% difference in costs after 1 year); with large variability in costs, larger LT study is required to assess CE Pts in SU received significantly more OT & PT 	<ul style="list-style-type: none"> Abstract only (German report) Unclear why 45 year old chosen No discounting in Base Case

Appendix 12: Primary Economic Studies of ESD Services

Study	Holmqvist; 1996 ¹⁰⁷	McNamee; 1998 ¹⁰⁸	Beech; 1999 ¹⁰⁹
Intervention & comparator	<ol style="list-style-type: none"> ESD to home rehab Hospital rehab (dept neurology or other) 	<ol style="list-style-type: none"> ESD to home rehab Conventional hospital care (CHC) rehab 	<ol style="list-style-type: none"> ESD to home rehab Conventional rehab (CR): SU; geriatric DH; outpt rehab; generic HR
Study population	<ul style="list-style-type: none"> Pts independently feeding & continent after 1 week n = 15 (comparator n = 63) 	<ul style="list-style-type: none"> Stroke pts admitted within 72 hours of onset; no co-morbidities n = 92 	<ul style="list-style-type: none"> Similar pt characteristics at baseline (NS) n = 331
Study design	Cost analysis based on non-randomized trial (retrospectively selected control)	Cost analysis based on RCT	Cost analysis based on RCT
Perspective	Health service	Health service & social services	Health service & social services
Time horizon	1 year	Costs - 6 months; outcomes – 3 months	1 year
Health outcomes	For ESD only: pt satisfaction; pt & spouse subjective health	Readmission rate, mortality rate, global health status, functional abilities using BI; level of carer stress	Not reported
Costs	<ul style="list-style-type: none"> Direct cost to health service (trial) Includes: hospital; outpt & GP visits; rehab at home (including therapist travel time & admin) For ESD only: informal carer time; social services; transport; equipment 	<ul style="list-style-type: none"> Direct costs to health / social services Includes: hospital (incl readmission); day hospital; GP & outpt visits For ESD only: rehab home visits (also, district nursing; social work; home care visits; visit travel time) 	<ul style="list-style-type: none"> Direct costs to health/social services Includes contacts with: <ol style="list-style-type: none"> Therapists (direct & indirect costs of travelling; overheads; admin) Health providers (hospital; GP; DH) Social services (e.g. home help)
Country Currency & year of data	<ul style="list-style-type: none"> Sweden SEK; 1990/92 	<ul style="list-style-type: none"> UK UK£; 1995/96 	<ul style="list-style-type: none"> UK UK£; 1997
Base Case results for health outcomes	ESD pt satisfaction with care = 92%	No SD in outcomes (details reported in Ref 5965)	No SD in outcomes (details reported in Ref 5984)
Base Case results for resources use & costs	<ul style="list-style-type: none"> Mean days LOS: ESD = 14 vs hospital = 27 Direct costs: ESD = SEK 88,500 vs hospital = SEK 86,800 (SEK 55,400 vs SEK 69,900 if readmissions excluded) Total costs for ESD only: SEK 127,700 (18% family carers & 13% other direct costs) Informal care ↓ over 3 months 	<ul style="list-style-type: none"> Mean LOHS days: ESD = 27 vs CHC = 54 (SD) Mean total cost: ESD = £7155 vs CHC = £7480 (NS) ESD has ↑ community rehab & GP costs; CHC has ↑ DH costs 	<ul style="list-style-type: none"> Mean LOHS days: ESD = 12 vs CR = 18 (SD) Mean total cost: ESD = £6800 vs CR = £7400 Mean inpt cost: ESD = £4900 vs CR = £6300 Mean other cost: ESD = £1900 vs CR = £1100 Readmissions same for ESD & CR

Study	Holmqvist; 1996 ¹⁰⁷	McNamee; 1998 ¹⁰⁸	Beech; 1999 ¹⁰⁹
Sensitivity analysis	None	Mean total cost for ESD vs CHC: 1. BI 0-8: £14,600 vs £16,000 (NS) 2. BI 9-12: £5700 vs £6400 (NS) 3. BI 13-20: £3600 vs £1200 (SD) • Results robust to hospital per diem • ESD implementation costs = £800	<ul style="list-style-type: none"> • ↓ hospital overheads & ↓ LOHS for CR does not change conclusions
Author conclusions	<ul style="list-style-type: none"> • Informal carers spent modest amount of time caring for ESD pts & overall appears acceptable. • ESD had ↓ initial LOHS but ↑ readmission costs. • ESD is a feasible, possibly cheaper, intx to complement current practice 	<ul style="list-style-type: none"> • No SD in costs of ESD vs CHC • Inverse relationship between BI score & total costs • Outcomes similar for ESD & CHC • ESD is a CE alternative, if shown not to lead to inferior outcomes 	<ul style="list-style-type: none"> • Overall results indicate ESD is feasible & CE (same outcomes achieved at lower average cost) <p>Finding is robust to:</p> <ol style="list-style-type: none"> 1. Large changes in assumed allowance for hospital overheads 2. Impact of intx on average hospital LOS
Comments	<ul style="list-style-type: none"> • Exploratory study to get rough estimate of ESD costs • Appears that total ESD cost (including informal carer & HR costs) exceeds total hospital rehab cost • Small sample size • Non-random trial; retrospect control • Severely disabled pts overrepresented in ESD; high readmission cost for 1 pt 	<ul style="list-style-type: none"> • Costs lower for independent pts in CHC; costs lower for dependent pts in ESD but may not be appropriate • Costs for CHC likely underestimated • Only ¼ of stroke pts eligible for study • Study not powered to detect clinically important differences • No investigator blinding 	ESD should not be considered as financially saving but as freeing up hospital beds to ↑ stroke caseload

Study	Teng; 2003¹¹²	Anderson; 2000¹¹⁰	v on Koch; 2001⁶⁴
Intervention & comparator	<ol style="list-style-type: none"> ESD to home rehab (for 4 weeks) Usual care - varied (inpt, outpt, private care, home care); some pts received no rehab 	<ol style="list-style-type: none"> ESD with home-based rehab CR (inpt rehab & community care) 	<ol style="list-style-type: none"> ESD to home rehab (lasting up to 4 months after discharge) CR (SU rehab & if required, rehab in geriatric or rehab dept as inpt or in day care)
Study population	<ul style="list-style-type: none"> Pts requiring rehab with caregiver at home; tended to have mild disability n = 114 (two groups comparable) 	<ul style="list-style-type: none"> Pts requiring rehab n = 86 	<ul style="list-style-type: none"> Moderately impaired pts 5-7 days after stroke from a SU n = 83
Study design	Cost analysis based on RCT	Cost analysis based on RCT	CCA using regression analysis, based on RCT
Perspective	Health service	Societal (health service, pt & caregiver)	Health service (resource use reported for community services, pts & caregivers)
Time horizon	3 months follow-up from randomization	6 months follow-up from randomization	1 year follow-up
Health outcomes	<ul style="list-style-type: none"> BI & SF-36 (physical & mental) 	<ul style="list-style-type: none"> None specifically reported 	<ul style="list-style-type: none"> Mortality, motor capacity, dysphasia, BI ADL, social activities, perceived dysfunction & self-reported falls
Costs	<ul style="list-style-type: none"> Direct costs to health service: acute care hospital, readmissions, ER visits, inpt rehab, home visits, outpt visits, community services Included overheads & allowance for land & buildings 	<ul style="list-style-type: none"> Direct (hospital, home rehab, community services; readmissions, included overhead costs) Assumed direct pt costs & indirect costs (caregiver costs) 	<ul style="list-style-type: none"> Inpt hospital care, outpt health care, health-related services Resource use for community service & informal care
Country Currency & year of data	<ul style="list-style-type: none"> Canada (Montreal) Canadian dollars 1997/98 	<ul style="list-style-type: none"> Australia Australian dollars 1997/98 	<ul style="list-style-type: none"> Sweden SEK 1997/98 (?)
Base Case results for health outcomes	<ul style="list-style-type: none"> Lower burden for ESD caregivers (NS), even for pts with less function ESD had higher functioning on SF-36 (not BI) 	<ul style="list-style-type: none"> Does not have adverse impact on pt outcomes, but may worsen mental health of caregivers 	<ul style="list-style-type: none"> ESD had improved ADL (SD) Deaths or dependencies: ESD = 25% vs CR = 44% (NS, p = 0.074)

Study	Teng; 2003 ¹¹²	Anderson; 2000 ¹¹⁰	von Koch; 2001 ⁶⁴
Base Case results for resources use & costs	<ul style="list-style-type: none"> Total cost from randomization: ESD = C\$7784 vs usual care = C\$11,065 (↓ 30%, p < .001) ESD 4 week home care = C\$934 Readmission: ESD = C\$364 vs usual care = C\$1793 Initial acute care: ESD = C\$1383 vs usual care = C\$2220 	<ul style="list-style-type: none"> Total costs from randomization: ESD = A\$8040 vs CR = A\$10,054 (↓ 20%, p = 0.14) ESD home program = A\$3068 Hospital: ESD = A\$3142 vs CR = A\$7820 Caregiver time: ESD = A\$1135 vs CR = A\$695 	<ul style="list-style-type: none"> Health services: ESD = SEK71,959 vs CR = SEK91,453 (Δ = 21%) Inpt days (initial & recurrent): ESD = 18 vs CR = 33 (p = 0.002) NS differences for most community services, informal care & home adaptations; ESD had 61% fewer home-help visits (NS) Family carer hours per week: 141 vs 212 (NS) ~50% of all pts received informal care 1 year after stroke onset
Sensitivity analysis	<ul style="list-style-type: none"> Reduced overheads showed ESD had lower costs 	<ul style="list-style-type: none"> ESD lower except when hospital costs 50% ↓ ESD shows greater cost savings for less disabled pts (SD) 	<ul style="list-style-type: none"> None performed
Author conclusions	<ul style="list-style-type: none"> ESD was more effective with lower costs & lower caregiver burden ESD costs did not vary by functional level 	<ul style="list-style-type: none"> ESD less costly than conventional hospital rehab Mild disability likely to be most CE 	<ul style="list-style-type: none"> ESD was no less beneficial & was 21% cheaper vs CR Lower inpt resources for ESD It is likely that including a full range of costs would show ESD is even cheaper, as it used less home-help
Comments	<ul style="list-style-type: none"> Readmissions account for much of cost difference <p>Limitations:</p> <ul style="list-style-type: none"> Short follow-up (3 months) Pts of mild disability (mean BI = 84) (generalizability suspect) Usual care varied & some pts received no rehab [NB: selection criteria = inpt rehab] No private costs (caregivers) included (may be less for ESD) 	<ul style="list-style-type: none"> Result due to lower ESD hospital costs Higher ESD caregiver costs may reflect early discharge Cost expected to be lower for established ESD program 	<p>Limitations:</p> <ul style="list-style-type: none"> No ITT analysis - pts lost to follow-up (n = 6) were not included in analysis unless stated, although their status was reported No sensitivity analysis performed

Study	Anderson; 2002 ¹¹¹	Hui; 1995 ⁵⁸
Intervention & comparator	<ol style="list-style-type: none"> ESD (duration of about 4 weeks) Conventional rehab (mixture) 	<ol style="list-style-type: none"> Day hospital (DH) Conventional medical management (CMM): outpt care by neurologist; not comprehensive care
Study population	<ul style="list-style-type: none"> Medically stable with mild to moderate disability level Based on meta-analysis of 7 published RCT (n = 1277) 	<ul style="list-style-type: none"> Inpt rehab then discharged to tx Groups A: BI < 16; BI: 16-19 Excluded: age < 65; BI = 20; previous stroke n = 120 (comparable)
Study design	Cost consequences using model <ul style="list-style-type: none"> CMA assuming no difference in effects Data based on meta-analysis of RCTs using Australian unit costs 	CCA based on RCT
Perspective	Health care system	Health service
Time horizon	1 year	6 months after hospital discharge
Health outcomes	<ul style="list-style-type: none"> Mortality, admissions to institutional care, risk of disability, hospital readmission, LOHS (using 7 RCT) 	Death; function score using BI (RCT)
Costs	<ul style="list-style-type: none"> Direct costs: hospital care, community services & institutional care Meta-analysis of 4 ESD cost studies: Beech (#3722), McNamee (#3720), Holmqvist (#3717), Anderson (#3747) Australian unit costs applied 	<ul style="list-style-type: none"> Direct costs to health service (RCT) Includes: inpt stay (acute, rehab & readmission); outpt & GP visits
Country Currency & year of data	<ul style="list-style-type: none"> Australia Australia & USA dollars 1998/99 	<ul style="list-style-type: none"> Hong Kong HK\$; 1992/93
Base Case results for health outcomes	<ul style="list-style-type: none"> No SD on mortality or other clinical outcomes 	<ul style="list-style-type: none"> At 6 months: no SD in BI for Groups A & B; same # deaths; similar # dropouts At 3 months: geriatric DH Group A stat ↑ in BI; same #deaths

Study	Anderson; 2002 ¹¹¹	Hui; 1995 ⁵⁸
Base Case results for resources use & costs	<ul style="list-style-type: none"> • Overall mean costs: ESD = US\$9941 vs CR = US\$11,390 (ESD 13% lower) • Initial hospitalization costs: ESD = US\$5245 vs CR US\$8435 • ESD reduced LOHS by 13 days (95% 7 to 19 days) • Outpt therapy costs: ESD = US\$2259 vs CR = US\$617 • Community care costs: ESD = US\$1572 vs CR = US\$1140 • Institutional care: ESD = US\$ 809 vs CR = US\$1196 	<ul style="list-style-type: none"> • At 6 months: total mean costs in geriatric DH = HK\$58,000 vs CMM = HK\$52,000 (NS) • At 6 months, geriatric DH has stat ↓ outpt v isits & readmissions • At 3 months: total mean costs = HK\$54,000 vs CMM = HK\$45,000 (NS)
Sensitivity analysis	<p>Findings are robust:</p> <ol style="list-style-type: none"> 1. ESD costs lower (3%) even if therapy & community resource use of both groups increased by 50% 2. ESD slightly more expensive than CR if cost of hospital & institutional day cost reduced by 50%, but not if reduced to 75% base cost 	None
Author conclusions	<ul style="list-style-type: none"> • ESD may reduce LOHS without compromising clinical outcomes • ESD is cost saving vs CR for an important subgroup of stroke pts (perhaps 20% - 40%) 	Compared with CMM, geriatric DH hastened functional recovery & ↓ outpt visits in elderly pts without additional cost
Comments	<ul style="list-style-type: none"> • Reduced LOHS consistent across studies but use of community services & therapy was incomplete & variable across studies <p>Limitations:</p> <ol style="list-style-type: none"> 1. Studies differ in terms of regions, policies, pt case mix, intx package, duration of tx, length of follow-up. However, broadly similar urban pops & delivery 2. Lack of stat power due to small heterogeneous trials 3. LT effects of Intx uncertain 4. Costs ignored: drugs, carer costs, start-up costs 5. Variability in study reporting, e.g. medians (vs means) & timing of resource use (consist & complete reporting) 6. Rehab duration or intensity may differ in ESD vs CR 7. ESD savings are only indicative (e.g. freed up beds) 8. The results are most likely to be generalizable to schemes of similar organization, size & scope 	<ul style="list-style-type: none"> • No SD in costs/outcomes at 6 months • CMM not clearly defined • Generalizing results to Canada questionable (costs/practice differ) • Short follow-up • Author says geriatric DH may be more CE in long-term as ↓ outpt/ readmission • Use of community services similar

Appendix 13: Primary Economic Studies of Community Rehabilitation

Study	Gladman; 1994¹¹⁴	Young; 1993¹¹³	Roderick; 2001⁸¹
Intervention & comparator	<ol style="list-style-type: none"> Home rehab (HR) Hospital-based rehab: <ul style="list-style-type: none"> Day hospital (DH) Outpatient rehab 	<ol style="list-style-type: none"> Home physiotherapy (HP) Day hospital (DH) physiotherapy 	<ol style="list-style-type: none"> Home rehab (HR) Rehab at geriatric day hospital (DH)
Study population	<ul style="list-style-type: none"> Stroke pts after hospital discharge Stratified by ward at discharge (SU, GMW, geriatric ward) n = 327 	<ul style="list-style-type: none"> Stroke pts leaving hospital n = 95 	<ul style="list-style-type: none"> Pts 55+ requiring rehab n = 140 (two groups comparable)
Study design	CCA based on RCT	CCA based on RCT	Cost analysis based on RCT
Perspective	<ul style="list-style-type: none"> Health service Also, some societal costs separately 	<ul style="list-style-type: none"> Health service (national & local) Also, carer lost leisure time 	Health service & social services
Time horizon	6 months after hospital discharge	8 weeks	6 months follow-up from randomization
Health outcomes	<ul style="list-style-type: none"> Death or institutionalization at 6 months; functional ability using BI; perceived health; carer satisfaction & social engagement 	<ul style="list-style-type: none"> Functioning using BI & physical abilities (e.g. walking); also pt & carer stress 	<ul style="list-style-type: none"> BI, SF-36, Rivermead Mobility Index, Frenchay Activities Index, mental state
Costs	<ul style="list-style-type: none"> Direct costs to health service Includes: DH & outpt rehab; home care; hospital readmissions; med outpt visits; program overheads; therapist travel; ambulance travel Separately, social services 	<ul style="list-style-type: none"> Direct costs to health & community services Includes: rehab costs & community support costs (district nursing, home care & other local services) Separately, loss of carer leisure time 	Costs include: <ul style="list-style-type: none"> Health service (day hospital, HR, hospital, ambulance, GP) Social service Overheads included
Country Currency & year of data	<ul style="list-style-type: none"> UK UK£; 1989/90 	<ul style="list-style-type: none"> UK UK£; 1988/89 	<ul style="list-style-type: none"> UK UK£ 1996/97
Base Case results for health outcomes	At 6 months: <ul style="list-style-type: none"> Overall, no SD in outcomes When pts stratified, SD in by ward of discharge 	<ul style="list-style-type: none"> Both tx showed sig improvement in physical abilities HP showed modest advantage in some areas (e.g. BI & walking) No SD in pt & carer stress 	<ul style="list-style-type: none"> No significant differences in pt outcomes, but HR pts had NS improvement in physical function (BI & mobility) & social activity

Study	Gladman; 1994 ¹¹⁴	Young; 1993 ¹¹³	Roderick; 2001 ⁸¹
Base Case results for resources use & costs	<p>At 6 months:</p> <ul style="list-style-type: none"> Overall, ↓ direct costs for DH & OR ($\Delta = £88$ or 27%; mean DH/OR = £320 vs HR = £408) No SD in social services <p>Results vary when pts stratified:</p> <ul style="list-style-type: none"> SU – HR ↑ outcomes, ↑ cost GMW – OR same outcomes & ↓ cost (vs HR) Geriatric ward – DH ↑ outcomes, ↑ cost 	<ul style="list-style-type: none"> HP stat ↓ direct costs ($\Delta = \downarrow £285$ SD, median DH = £620 vs HP = £385) No SD in community support No SD in loss in carer leisure time 	<ul style="list-style-type: none"> Total costs: HR = £3070 vs DH = £2428 (NS) Health services only: HR = £1965 vs DH = £2057 Rehab costs: HR = £1170 vs DH = £1146 (NS) HR: more nurse visits & more social services DH: more inpt days & more outpt visits
Sensitivity analysis	<ul style="list-style-type: none"> A more expensive (more realistic) ambulance service makes DH & outpt rehab more costly than HR 	<ul style="list-style-type: none"> Cost differences maintained when most & least disabled excluded Reducing attendance at DH (15 visits) to HP level (11 visits) would still make HP less expensive 	<ul style="list-style-type: none"> Rehab cost results sensitive to HR caseload; health service cost results robust
Author conclusions	<ul style="list-style-type: none"> Different CE patterns observed when pts stratified. Results very sensitive to cost of ambulance transport. A range of services required for pts leaving hospital. 	<ul style="list-style-type: none"> HP more CE than DH, given that direct costs for HP < DH (& indirect costs are similar). HP has greater clinical efficiency (11 vs 15 visits). 	<ul style="list-style-type: none"> No SD in total costs, with lower health service costs in HR group offset by higher social service costs A mixed model of rehab may be appropriate
Comments	<ul style="list-style-type: none"> Overall results mask some important patterns in the stratified data Good (full) costing method Older pts tended to be on geriatric ward & DH; younger pts tended to be with SU & outpt rehab Ref 5965 says results bias against HR since hospital pts ↑ baseline BI 	<ul style="list-style-type: none"> Author considers it cost-minimization analysis, but RCT indicated better outcomes for HP <p>Limitations:</p> <ul style="list-style-type: none"> Very short follow-up (8 weeks) Absolute costs should not be considered appropriate for Canada Results of RCT suggest HP shows better outcomes (motor function & BI), so HP efficacy underestimated 	<ul style="list-style-type: none"> For both groups, therapy provided until maximum potential for recovery was reached Higher HR costs due to small number of more disabled pts Study was underpowered, especially after loss to follow-up Study pts were older & more disabled than in Young & Gladman studies

Legend:

ADL = Activities of Daily Living; BI = Barthel Index; CCA = cost-consequences analysis; CE = cost-effective; CHC = conventional hospital care; CMM = Conventional medical mgmt; CR = conventional rehabilitation; DH = day hospital; ESD = early supported discharge; GMW = general medical ward; HP = home physiotherapy; HR = home rehabilitation; Inpt = inpatient; Intx = intervention; LOHS = length of hospital stay; LOS = length of stay (including stay in hospital and/or institutions); LT = long-term; NS = no significant difference; OR = odds ratio; Outpt = hospital patient; Pt = patients; SD = (statistically) significant difference; SU = stroke unit ; Tx = treatment

Numerical differences between alternatives: ↑ = higher vs alternative; ↓ = lower vs alternative; Δ = change (vs alternative)