

Cochrane Database of Systematic Reviews

Therapy-based rehabilitation services for patients living at home more than one year after stroke (Review)
Aziz NA, Leonardi-Bee J, Phillips MF, Gladman J, Legg LA, Walker M
Aziz NA, Leonardi-Bee J, Phillips MF, Gladman J, Legg LA, Walker M.
Therapy-based rehabilitation services for patients living at home more than one year after stroke. Cochrane Database of Systematic Reviews 2008, Issue 2. Art. No.: CD005952. DOI: 10.1002/14651858.CD005952.pub2.

www.cochranelibrary.com

i



TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	3
OBJECTIVES	3
METHODS	3
RESULTS	5
DISCUSSION	8
AUTHORS' CONCLUSIONS	9
ACKNOWLEDGEMENTS	9
REFERENCES	10
CHARACTERISTICS OF STUDIES	12
DATA AND ANALYSES	17
Analysis 1.1. Comparison 1 Performance in personal activities of daily living, Outcome 1 Barthel Index	17
Analysis 2.1. Comparison 2 Case fatality at the end of follow up, Outcome 1 Case fatality at the end of follow up	17
Analysis 3.1. Comparison 3 Patient's performance in extended activities of daily living by the end of scheduled follow up, Outcome 1 Patient's performance in activities of daily living (Frenchay Activities Index).	18
Analysis 3.2. Comparison 3 Patient's performance in extended activities of daily living by the end of scheduled follow up, Outcome 2 Patient's performance in activities of daily living (Nottingham EADL).	18
Analysis 4.1. Comparison 4 Patient's subjective health status at the end of scheduled follow up, Outcome 1 Sickness Index Profile.	19
Analysis 5.1. Comparison 5 Patient's mood at the end of scheduled follow up, Outcome 1 Patient's mood at the end of scheduled follow up.	19
Analysis 6.1. Comparison 6 Carer's mood at the end of scheduled follow up, Outcome 1 Carer's mood at the end of scheduled follow up.	19
APPENDICES	20
WHAT'S NEW	21
CONTRIBUTIONS OF AUTHORS	21
DECLARATIONS OF INTEREST	21
NDEX TERMS	21



[Intervention Review]

Therapy-based rehabilitation services for patients living at home more than one year after stroke

Noor Azah Aziz¹, Jo Leonardi-Bee², Margaret F Phillips³, John Gladman⁴, Lynn A Legg⁵, Marion Walker⁶

¹Department of Family Medicine, Medical Faculty, Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia. ²Division of Epidemiology and Public Health, The University of Nottingham, Nottingham, UK. ³Division of Rehabilitation Medicine, University of Nottingham, Derby, UK. ⁴Rehabilitation and Ageing, Community Health Sciences, Queen Medical Centre, University of Nottingham, Nottingham, UK. ⁵Academic Section of Geriatric Medicine, University of Glasgow, Glasgow, UK. ⁶Stroke Medicine, Division of Rehabilitation and Ageing, School of Community and Health Sciences, University of Nottingham, Nottingham, UK

Contact address: Noor Azah Aziz, Department of Family Medicine, Medical Faculty, Universiti Kebangsaan Malaysia, Cheras, Kuala Lumpur, 53000, Malaysia. azah@mail.hukm.ukm.my, a.azah@yahoo.co.uk.

Editorial group: Cochrane Stroke Group.

Publication status and date: Edited (no change to conclusions), published in Issue 1, 2010.

Citation: Aziz NA, Leonardi-Bee J, Phillips MF, Gladman J, Legg LA, Walker M. Therapy-based rehabilitation services for patients living at home more than one year after stroke. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD005952. DOI: 10.1002/14651858.CD005952.pub2.

Copyright © 2010 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Current practice of rehabilitation intervention mainly concentrates on the first six months of stroke. At present, there is no agreed consensus about the benefits of such a service more than one year after stroke.

Objectives

To ascertain whether therapy-based rehabilitation services can influence outcome one year or more after stroke.

Search methods

We searched the trials registers of the following Cochrane Review Groups: Stroke Group (last searched September 2007), Effective Practice and Organisation of Care Group (last searched October 2006) and Dementia and Cognitive Improvement Group (last searched October 2006). We also searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 4, 2006), MEDLINE (1966 to October 2006), EMBASE (1980 to October 2006), CINAHL (1982 to October 2006), AMED (1985 to October 2006), PEDro (1952 to October 2006), British Nursing Index (1993 to October 2006), DARE (1994 to October 2006), HMIC (1979 to October 2006) and NHS EED (1991 to October 2006). We also searched dissertation databases and ongoing trials and research registers, scanned reference lists and contacted researchers and experts in the field.

Selection criteria

All randomised controlled trials of community-based stroke patients, in which at least 75% were recruited one year after stroke and received a therapy-based rehabilitation intervention that was compared with conventional care.

Data collection and analysis

Two review authors independently selected trials and extracted data on a number of pre-specified outcomes. The primary outcomes were the proportion of participants who had deteriorated or were dependent in personal activities of daily living at the end of scheduled follow up.



Main results

We identified five trials of 487 participants that were eligible for the review. Overall, there was inconclusive evidence as to whether therapy-based rehabilitation intervention one year after stroke was able to influence any relevant patient or carer outcome. Trials varied in design, type of interventions provided, quality, and outcomes assessed.

Authors' conclusions

This review highlights the dearth of evidence investigating long-term therapy-based rehabilitation interventions for patients with stroke.

PLAIN LANGUAGE SUMMARY

Therapy-based rehabilitation services for patients living at home more than one year after stroke

It is unclear if rehabilitation provided more than one year after a stroke can improve recovery. People who are recovering from a stroke for one year or more often have persistent disabilities. Although therapy-based rehabilitation for such patients is an accepted part of stroke management, the evidence base for such practice is unclear. We identified only five clinical trials, including 487 participants, which showed a tendency towards improved recovery but the results were inconclusive.



BACKGROUND

Stroke remains the leading cause of death and disability both in developed and developing countries (MacKay 2004). In 2004 the World Health Organization (WHO) predicted that the number of stroke cases will increase, despite stable incidence rates, due to the increasing trend in ageing populations worldwide. In the United Kingdom alone, stroke remains the third leading cause of death with an estimated 110,000 first stroke cases reported yearly (Mitchell 2004). It has also been reported that approximately 450,000 disabled stroke survivors are now residing in the United Kingdom, with 33% functionally dependent at one year post stroke (Stroke Assoc 1998).

Systematic literature searches have demonstrated that there have been numerous developments in the field of stroke management, especially in managing acute stroke patients in a hospital setting. Multi-disciplinary team organisation has been recognised as an important and significant factor in post-acute stroke care (Langhorne 2001). More recently, a systematic review examining the effectiveness of early supported discharge services for acute stroke patients found that these services can reduce the length of hospital stay but remains unclear about further costs and benefits to patient outcome (ESDT 2005).

Current practice of rehabilitation interventions mainly concentrate on the first six months of stroke (RCP 2004). This period of intervention has possibly been based on published data on the pattern of stroke recovery, suggesting that most recovery occurs within the first six months after stroke (Tilling 2001). However, several studies have documented that many stroke patients have persistent disability at one year after stroke (Lincoln 2000; Wade 1992). The Outpatient Service Trialists systematic review found that people living at home within a year of having a stroke and receiving therapy-based rehabilitation services at home were more independent in their activities of daily living (ADL) and less likely to deteriorate in their ability to perform such activities (OST 2004). The European Stroke Initiative in 2003 suggested that active rehabilitation should be administered as long as an objective improvement in neurological dysfunction is observed in patients (Hacke 2000).

Despite continuing disability, the provision of therapy-based rehabilitation services a year or more post stroke is low. At present, there is no agreed consensus about the benefits of such a service more than one year after stroke. We planned to systematically review the available literature including all randomised trials in view of the null hypothesis that therapy-based rehabilitation services did not affect the recovery of patients living at home more than one year after stroke.

OBJECTIVES

In this systematic review, we addressed the following questions.
(1) Can therapy-based rehabilitation services influence the outcome of stroke patients (and carers) one year or more after the index stroke?

(2) Which outcomes are influenced by therapy-based rehabilitation services, for example, dependency, social activities, mood or functional deterioration?

METHODS

Criteria for considering studies for this review

Types of studies

We included all unconfounded, truly randomised controlled trials of stroke patients or trials which included a defined subgroup of stroke patients, resident in the community more than one year after stroke onset, receiving a therapy-based rehabilitation service intervention which is compared with conventional care (that is, normal or usual care or no intervention). Conventional care is defined as the routine or usual care patients have received after one year post stroke. This included any therapy provided in outpatient department or day hospital.

Types of participants

We included studies which recruited participants with a clinical diagnosis of stroke regardless of their age or sex or ethnic group, as long as they were resident in a community setting and were randomised to treatment more than one year after stroke onset. We included studies where at least 75% of participants were more than one year after stroke at randomisation. We followed the WHO criteria for stroke, that is 'a clinical syndrome of presumed vascular origin characterised by rapidly developing sign of focal or global disturbance of cerebral functions lasting more than 24 hours or leading to death' (WHO 1978). We excluded trials with subarachnoid haemorrhage, unless a subgroup of stroke patients could be identified for which there were separate results.

Types of interventions

We reviewed trials that investigated therapy-based rehabilitation services with the following features.

- (1) Outpatient: the intervention must be targeted towards stroke patients living at home (nursing home, residential, or any other type of residential address). The exact type (e.g. domiciliary, day hospital, home-based care, outpatient clinic) was recorded but not used as an exclusion criterion.
- (2) Therapy-based rehabilitation: interventions provided by a qualified physiotherapist, occupational therapist or multidisciplinary staff, or under the supervision of qualified therapy staff working with patients to improve task-orientated behaviour (e.g. walking, dressing) and to reduce disability (OST 2004).
- (3) Services: any intervention that required an organisational and staffing structure (that is one that requires rehabilitation therapy staff). Inclusion criteria for services were: (a) where an intervention was tested at the service level, not at the level of a specific therapeutic technique; (b) where the service intervention was routinely directed to a wide group of stroke patients. We included trials which received no routine intervention or normal practice. The exact type of control was recorded but not used as an exclusion criterion.

Types of outcome measures

We used the following outcomes to assess the objectives of this systematic review. The outcomes reflected the full burden of disabling illness and probable target of therapy-based rehabilitation services (OST 2004). We recorded the following outcomes to represent the full burden of disabling illness.



Primary outcome measures

- (1) Death or poor outcome (deterioration, dependency, institutionalisation) defined as the combined poor outcome of being dead or (a) experiencing a deterioration in ability to perform activities of daily living (that is, experiencing a drop in a given ADL score from baseline); or (b) dependent (as determined by a given ADL scale); or (c) requiring new institutional care placement at the end of scheduled follow up.
- (2) Performance in activities of daily living (feeding, dressing, bathing, toileting, mobility and transfers) at the end of scheduled follow up.

Secondary outcome measures

- (1) Case fatality (death) at the end of follow up.
- (2) Patient's performance in extended activities of daily living (EADL) by the end of scheduled follow up.
- (3) Patient's subjective health status or quality of life at the end of scheduled follow up.
- (4) Patient's mood at the end of scheduled follow up.
- (5) Carer's mood at the end of scheduled follow up.
- (6) Re-admission to hospital and days spent in hospital at the end of scheduled follow up.
- (7) Patient and carer satisfaction with services at the end of scheduled follow up.

Secondary outcome measures (2), (3), (4), and (5) were measured using available measures as reported within the studies. We recorded outcomes which reflected resource use (that is, readmission to hospital and days spent in hospital, patient and carer satisfaction with services) by the end of scheduled follow up.

Search methods for identification of studies

See: 'Specialized register' section in Cochrane Stroke Group

We searched the trials register of the following Cochrane Review Groups: Stroke Group (last searched September 2007), Effective Practice and Organisation of Care Group (last searched October 2006), and Dementia and Cognitive Improvement Group (last searched October 2006). We searched the following electronic databases: the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2006, Issue 4), MEDLINE (1966 to October 2006) (Appendix 1), EMBASE (1980 to October 2006), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1982 to October 2006), Allied and Complementary Medicine Database (AMED) (1985 to October 2006), Physiotherapy Evidence Database (PEDro) (1952 to October 2006), British Nursing Index (1993 to October 2006), Database of Abstracts of Reviews of Effects (DARE) (1994 to October 2006), Health Management Information Consortium database (HMIC) (1979 to October 2006), NHS Economic Evaluation Database (NHS EED) (1991 to October 2006), Dissertation Abstracts (1961 to October 2006), Aslib Index to UK theses (1970 to October 2006), National Research Register (http:// www.nrr.nhs.uk/, Issue 4, 2006), Medical Research Council Register (http://www.ctu.mrc.ac.uk/, October 2006), Current Research in Britain (CRIB) (http://www.rcuk.ac.uk/, October 2006), HSRPRoj (http://www.nlm.nih.gov/hsproj/, October 2006). In order to avoid duplication, the Cochrane Stroke Group Trials Search Co-ordinator was regularly consulted. Due to the nature of the intervention under investigation in this review, we anticipated that relatively few references would be retrieved; therefore to increase the sensitivity

we did not use the Cochrane trials filter for locating randomised controlled trials.

References from published studies

We scanned through reference lists of relevant articles and original papers for evidence of possible additional studies.

Unpublished literature and personal communication

We approached the authors of relevant trials, members of the Cochrane Stroke Group, and stroke physicians interested in rehabilitation services and asked whether they were aware of any other relevant studies.

Language

No language restrictions were imposed on the searches or the identified studies.

Data collection and analysis

Study selection

Two review authors (NA, MW) checked the titles and abstracts identified from the searches. If it was clear that the study did not refer to a randomised controlled trial of therapy-based rehabilitation, it was excluded. Two review authors (NA, MW) independently assessed each study to determine whether it met the pre-defined selection criteria; any disagreements were resolved through discussion and overall consensus with the review team. We reported excluded studies and reasons for exclusion in the 'Characteristics of excluded studies' table.

Assessment of methodological quality

Two review authors (NA, MW) independently assessed the quality of the included studies. This quality assessment included an evaluation of the following components:

- (1) the method of generation of the randomisation sequence;
- (2) the method of allocation concealment (considered adequate if the assignment cannot be foreseen);
- (3) who was blinded or not blinded (participants, clinicians, outcome assessors);
- (4) how many participants were lost to follow up in each arm (split into post-randomisation exclusions and later losses if possible);
- (5) whether the participants were analysed in the groups to which they were originally randomised (intention to treat).

We assessed additional components for each trial since these may produce biased estimates of treatment effect. The additional components were:

- (6) sample size calculation declared;
- (7) inclusion and exclusion criteria defined;
- (8) time to follow up;
- (9) baseline comparability of severity, age, and gender;
- (10) conflict of interest;
- (11) appropriateness of statistical analyses (this criterion was considered if the original data could not be extracted from the publication).

We recorded this information in the 'Characteristics of included studies' table and a description of the quality of each study was given based on these components.



Data extraction

Three review authors (NA, MW and JL-B) performed data extraction independently and any disagreements were resolved through discussion with the review team. If possible, we obtained any missing data from the authors of the relevant studies. We used a standardised data collection form in order to summarise the information from the trials. One author (JL-B) entered and checked the data. If available, we sought individual patient data from the original trialists, which were standardised and re-analysed and the resulting group data used in preference to the published data.

Data synthesis

For studies with a similar type of therapy-based rehabilitation we performed a meta-analysis to calculate a weighted treatment effect across trials using a random-effects model (DerSimonian and Laird model). We expressed the results as odds ratios (OR) with 95% confidence intervals (CI) for dichotomous outcomes, and standardised mean differences (SMD) with 95% CI for continuous outcomes. The results were also expressed as the number needed to treat, if appropriate, for a range of plausible control event rates. Where it was not possible to perform a meta-analysis, either due to too much heterogeneity or where there is a lack of evidence, we summarised the data for each study. Results from cluster randomised controlled trials were extracted directly from the published article, and were not pooled with the results from the parallel group trials.

We assessed heterogeneity between the studies using I squared (I²) (Higgins 2002). If substantial heterogeneity (I² greater than 50%) existed between studies for the primary outcome measures, we explored reasons for the heterogeneity, such as types of service. Owing to a lack of eligible studies we did not conduct a sensitivity analysis to explore methodological quality.

Data relating to dependency were dichotomised irrespective of the scale used, (e.g. Barthel Index 0 to 55; modified Rankin score 3 to 5). Where non-consistent cut offs were used across trials, we used the raw individual patient data to create consistent categories. Where more than one disability or dependency measurement scale has been used within a trial, the most frequently used measurement scale across trials was used for the primary analysis. We conducted sensitivity analyses to examine the effects of the individual measurement scales. We defined deterioration as any worsening in activities of daily living as measured by a recognised and validated assessment, for example Barthel Index scale and Nottingham Extended Daily Living Scale.

RESULTS

Description of studies

We performed an analysis of the titles of articles and type of studies identified from the searches, and 250 potentially eligible abstracts were identified. After excluding clinical reviews, trials that looked at hospital-based rehabilitation, and non-randomised controlled trials, we sought the full text articles for a total of 35 trials. We excluded a total of 30 trials for three major reasons: (1) not being a randomised controlled trial (Collen 1991; Eng 2003; van de Gaag 2005; Weiss 2000; Woodhead 1997); (2) not having a targeted service level intervention (Chu 2004; Page 2004; Sun 2001); or (3) not recruiting participants one year post stroke (Allen 2002; Andersen 2002; Corr 1995; Drummond 1995; Duncan 1998;

Frayne 2000; Gilbertson 2000; Jongbloed 1991; Lincoln 2004; Logan 2003; Logan 2004; Logan 1997; Meikle 1979; Salbach 2004; Salbach 2005; Sandhu 1993; Smith 1981; von Koch 2001; Walker 1999; Wall 1987; Wolfe 2000; Young 1992). We did not identify any ongoing trials from the searches. Therefore, this systematic review is based on evidence from the remaining five trials (Green 2002; Mulder 1989; Sackley 2006; Wade 1992; Werner 1996) which cumulatively recruited, and had outcome data relating to, 487 participants. Three of the included trials used parallel group designs (Green 2002; Mulder 1989; Werner 1996), one used a cross-over design (Wade 1992), and one used a cluster randomisation design (Sackley 2006).

Participant characteristics

(1) Demographic characteristics

The mean age of participants in the included studies ranged from 55 to 89 years. The trial which had the highest mean age recruited participants from care homes (Sackley 2006); unlike the other trials included in this review, this study demonstrated significant imbalances in sex ratio, with the number of male participants in the intervention group as 11 out of 63 (17%), which was the lowest of all the included trials. The percentages of males in the remaining four studies (Green 2002; Mulder 1989; Wade 1992; Werner 1996) ranged from 50% to 59% (Mulder 1989; Werner 1996). One trial used a 3:1 random stratification method for randomising participants into the trial (Mulder 1989), and another trial recruited five additional controls later in the study due to high drop-out rates of the initial participants randomised to the control group (Werner 1996). Full details of the demographic characteristics are included in the 'Characteristics of included studies' table.

(2) Stroke severity (Barthel Index scores) at baseline

Baseline Barthel Index scores were available from three studies (Green 2002; Sackley 2006; Wade 1992). All trials reported Barthel Index scores using the 20 point scale. Baseline Barthel scores were similar between the intervention and control groups within each of these trials. Data were not provided on stroke severity at baseline in the remaining two trials (Mulder 1989; Werner 1996).

Exclusion criteria

Four trials excluded patients with serious or severe co-morbidities that would interfere with outcome assessment or interventional programmes (Green 2002; Mulder 1989; Wade 1992; Werner 1996). Other exclusion criteria used by the included trials were: causes other than stroke for mobility problem (Green 2002; Wade 1992); had received a rehabilitation intervention programme at least four months prior to the start of the trial (Green 2002; Werner 1996); an age limit for recruitment of more than 50 years old (Green 2002) and more than 70 years old (Mulder 1989); a history of dementia (Green 2002); patients were bedfast (Green 2002); functional comprehension was less than 60% (Werner 1996); had a clinical sensory deficit (Werner 1996); had recurrent stroke (Werner 1996); acute illness (Sackley 2006); admitted for end-of-life care (Sackley 2006); had diminished tolerance for exertion (Mulder 1989); or resumed work before the trial (Mulder 1989).

Definition of stroke

One trial documented either clinical presentation or computerised tomography (CT) scan as criteria for stroke (Mulder 1989), whereas the other four trials (Green 2002; Sackley 2006; Wade 1992; Werner 1996) did not specify the definition of stroke in their studies.



Recruitment

Four trials (Green 2002; Mulder 1989; Wade 1992; Werner 1996) recruited participants from community rehabilitation facilities. One study (Sackley 2006) recruited participants from 12 nursing or residential homes in Oxfordshire. One study employed additional measures for recruiting participants which included advertisements, radio broadcast, and help from general practitioners (GPs) and community workers (Wade 1992). Four trials recruited participants one year or more after stroke (Green 2002; Sackley 2006; Wade 1992; Werner 1996), whereas the remaining study (Mulder 1989) recruited participants within a set time frame of six months to five years after stroke. Nevertheless, the final results showed that all participants recruited for this study were a year or more after stroke onset.

Characteristics of participants' stroke status and care prior to recruitment

(1) Stroke status

Information on the type of stroke was available for three trials (Green 2002; Mulder 1989; Wade 1992). With respect to the type of stroke, one study (Green 2002) reported 31% (26/85) of participants in the intervention group had a left hemiparesis compared to 47% (40/85) in the control group; 66% (56/85) with a right hemiparesis in the intervention group compared to 52% (44/85) in the control group; and 4% in the intervention group have had other types of stroke compared to 1% in the control group. Mulder and colleagues (Mulder 1989) documented that 47% (18/38) of participants in the intervention group had a left hemiplegia compared to 27% (5/18) in the control group; 24% (9/38) with a right hemiplegia in the intervention group compared to 39% (7/18) in the control group. Only one study reported the percentage of participants with a previous stroke (Green 2002), where 24% of participants were known to have had at least one episode of previous stroke prior to randomisation. In the Werner 1996 study, the mean number of years post-acute stroke was three years (standard deviation 1.8 years), whereas Mulder 1989 reported the mean number of years post stroke as 2.5 years (range eight months to seven years). There was no information on years post stroke reported from the three remaining trials (Green 2002; Sackley 2006; Wade 1992).

With regards to the sequale of stroke, impairment in communication was reported in three studies (Green 2002; Mulder 1989; Wade 1992). In the Green 2002 study, aphasia was reported as 39% (33/85) in the intervention group compared with 26% (22/85) in the control group. Mulder and colleagues (Mulder 1989) documented that 7.9% (3/38) in the intervention group had limited communication compared to 11% (2/18) in the control group. In the Wade 1992 study, clinically-judged abnormal communication was reported in 12% (6/49) of participants in the early intervention group compared to 11% (5/45) of participants in the late intervention group. Two other complications were also reported in this study: clinically-judged abnormal cognition, which was reported in 10% (5/49) of participants in the early intervention group compared with 11% (5/45) of participants in the late intervention group; and sensory loss was reported in 45% (22/49) of participants in the early intervention group compared with 58% (26/45) of participants in the late intervention group. Impairment of short orientation and memory concentration was reported in the Sackley 2006 trial, with 62% (39/63) of participants reported with this sequale in the intervention group compared with 58% (32/55) of participants in the standard care (control) group.

(2) Stroke care

One trial (Green 2002) reported that 75% of participants in the intervention group were admitted to hospital at the time of stroke compared with 76% (65/85) of participants in the control group. Another trial (Wade 1992) documented the mean delay in treatment for participants in the early intervention group was 53 months (standard deviation 29.5 months) compared with 59.6 months (standard deviation 35.3 months) in the late intervention group. No similar data were available for the other three trials (Mulder 1989; Sackley 2006; Werner 1996). Only two trials provided information regarding type of care received by participants prior to recruitment. In the Wade 1992 trial, 27% (13/49) of participants in the early intervention group lived alone compared with 20% (9/45) in the late intervention group; 67% (33/49) of participants in the early intervention group were with carers compared with 71% (32/45) of participants in the late intervention group; and 6% (3/49) of participants in the early intervention group compared with 9% (4/45) of participants in the late intervention group were institutionalised prior to recruitment. In the Green 2002 trial, 24% (20/85) of participants in the intervention group compared with 31% (26/85) of participants in the control group lived alone prior to recruitment, and no other type of care was further described. In the Wade 1992 trial, 10% (5/49) of participants in the early intervention group compared with 9.0% (4/45) of participants in the late intervention group had received physiotherapy before randomisation. There were no data available on type of health services or any other services received by the participants prior to randomisation.

Study intervention and comparison

For details of the comparisons made within the five trials, please refer to 'Characteristics of included studies' table. Two of the trials focused on a problem-solving approach with a single discipline rehabilitation intervention (physiotherapy), although the exact interventional approach applied in each study was different (Green 2002; Wade 1992). One further study focused on a single discipline intervention (occupational therapy) (Sackley 2006). Two trials used a multi-disciplinary rehabilitation intervention where a combination of physiotherapy and occupational therapy in a outpatient setting was used (Mulder 1989; Werner 1996). For the Green 2002 trial, a problem solving approach by a registered physiotherapist using an assessment was used. Participants were seen in their own home or at the outpatient rehabilitation centres. In the Wade 1992 trial, although a similar problem solving approach was used as the method of intervention, the trial compared early intervention and late intervention groups, using same-treatment modalities but in different time periods. The intervention was based on goal-orientated therapy, offering advice to solve problems identified during the initial assessments. The Mulder 1989 study compared one intervention group and three control groups in a structured rehabilitation programme that encompassed meetings and activities, supervised by a physiotherapist and an occupational therapist. The trial did not explain the nature of the activities received by the control groups. In the Werner 1996 trial, the intervention was based on functional task modalities administered by a registered physiotherapist and an occupational therapist in an outpatient rehabilitation setting. In the Sackley 2006 trial, the trial compared treatment intervention against routine care using a client-centred approach, where the intervention was provided by a qualified occupational therapist targeted towards improving independence in personal activities of daily living.



Intensity of intervention

All five trials provided information regarding the intensity of intervention given to participants. Two trials (Mulder 1989; Werner 1996) provided fixed structured sessions to participants in the intervention groups, whereas in the other three trials (Green 2002; Sackley 2006; Wade 1992) the intervention sessions were tailored according to the participant's baseline assessments. In the Werner 1996 trial, an intensive 12-week programme was provided that encompassed an hour of physiotherapy and occupational therapy for four days each week. In the Mulder 1989 trial a longer intervention period consisting of 22 fortnightly meetings for a total duration of a year was provided, where each meeting lasted 2.5 hours with activities encompassing exercises or games, discussions and recreational activities. The Green 2002 trial described their intervention programme as a standard maximum contact of 13 weeks with a minimum of three contacts per person during the intervention period. The trial by Wade 1992 used a mean of four visits (standard deviation 2.5 visits) per participant, with most participants being seen one to six times during the intervention period. Participants in this study spent on average two hours and four minutes (standard deviation 28 minutes) during each session. The Sackley 2006 trial provided a flexible three-month intervention period dependent on the agreed goals between the participant and therapist. The intervention sessions were designed to address the multi-faceted needs of the care-home participants that encompassed task specific practices, provision of aids and adaptations and specific therapeutic interventions (Sackley 2006).

Risk of bias in included studies

Five trials fulfilled the inclusion criteria for the review (Green 2002; Mulder 1989; Sackley 2006; Wade 1992; Werner 1996). Two of the five trials were deemed to be of a high methodological quality, with evidence of blinded randomisation procedures, concealment of allocation and masked outcome assessment (Green 2002; Sackley 2006). Two trials (Green 2002; Sackley 2006) used a clearly concealed randomisation procedure. The Green 2002 trial used random number tables as a randomisation method with numbered, sealed opaque envelopes for allocation concealment, whereas the Sackley 2006 trial used a computer-generated, numbered sequence to allocate participating homes into predetermined strata. The Wade 1992 and Werner 1996 trials used block randomisation methods but did not provide any description regarding randomisation or the method of concealment. The Mulder 1989 trial did not describe the method of randomisation in the trial. Four trials (Green 2002; Sackley 2006; Wade 1992; Werner 1996) used an equivocal blinded final outcome assessment for all participants in the trials, whereas the remaining trial (Mulder 1989) did not report a clear blinding procedure of the final outcome assessor. Full details of the methodological quality are provided in the 'Characteristics of included studies' table.

(1) Intention-to-treat analysis

Out of a total of 487 participants enrolled in the five studies, 65 participants (13.4%) were reported to be lost to follow up. Two trials (Green 2002; Wade 1992) performed an intention-to-treat analysis. One trial (Sackley 2006) stated they were going to perform an intention-to-treat analysis, but modified their analysis strategy during the course of the trial as there were many deaths occurring before the follow up. The remaining two trials (Mulder 1989; Werner

1996) did not mention the use of intention-to-treat analysis in their trials

(2) Declaration of sample size calculation

Two trials (Green 2002; Wade 1992) reported a sample size calculation using data from published literature and allowing for the possibility of potential drop outs. Although the Sackley 2006 trial did not perform a formal sample size calculation, they estimated the number of homes included in the trial from local available resources. The remaining two trials (Mulder 1989; Werner 1996) did not declare a sample size calculation for their studies.

(3) Inclusion and exclusion criteria defined

All five included trials clearly defined exclusion and inclusion criteria in the trials. Full details are provided in the 'Characteristics of included studies' table.

(4) Time to follow up

All five included trials had adequate time periods for follow up after the intervention. Sackley 2006 trial had the shortest follow-up period of three months post intervention, whereas the Mulder 1989 trial had the longest follow-up period of 12 months post intervention. The Wade 1992 trial chose six months as the follow-up period after the interventional period. The remaining two trials (Green 2002; Werner 1996) chose nine months as the follow-up period after the intervention.

(5) Baseline comparability of severity, age and gender

Four of the five trials (Green 2002; Sackley 2006; Wade 1992; Werner 1996) reported no differences in baseline characteristics in term of stroke severity, gender and age differences between participants allocated to the intervention or control groups. The remaining trial (Mulder 1989) reported no differences in baseline characteristics for age and stroke characteristics (hand function, communication and hemineglect), but reported more women and more participants with right-sided hemiplegia. In addition, this trial reported a high drop-out rate from the study, however final analysis showed no differences in the percentage of drop outs between the intervention and the control group . Another trial (Werner 1996) also reported high rates of drop out from the study, and thus recruited five additional controls towards the end of the study; however no difference in baseline comparability of the groups were reported.

(6) Conflict of interest

No conflicts of interest were reported in any of the five included trials.

(7) Appropriateness of statistical analyses

Data were extracted from four of the five trials (Green 2002; Mulder 1989; Wade 1992; Werner 1996) and included in the meta-analyses if appropriate. The remaining trial by Sackley and colleagues (Sackley 2006) was designed as a cluster randomised controlled trial and results from this trial were directly extracted from the publication and therefore re-analysis was not performed. The analyses used within the Sackley 2006 trial were deemed as appropriate. The cross-over trial (Wade 1992) was analysed using data from the first phase of the study and combined with the results from other parallel groups studies as appropriate.



Effects of interventions

Primary outcome measures

Four trials (Green 2002; Sackley 2006; Wade 1992; Werner 1996) reported data relating to the primary outcome measures of the review.

Death or poor outcome

Death or poor outcome was defined as the number of participants that were dead at the end of the trial or deteriorated in performing activities of daily living. Only one trial (Sackley 2006) reported global poor outcome at the end of six-month follow up. A significant difference in global poor outcome was seen between the intervention and control groups relating to a 26% difference in favour of the intervention group (51% versus 76%) (95% CI, 3% to 48%; P = 0.03, using x^2 test and adjusted for cluster design). There were no data available for the remaining four trials (Green 2002; Mulder 1989; Wade 1992; Werner 1996) regarding death or poor outcome.

Comparison 1.1: Performance in personal activities of daily living

The Barthel Index was used in three trials (Green 2002; Sackley 2006; Wade 1992). Data from the parallel group RCTs were available for 235 participants (Green 2002; Wade 1992). The pooled result from the two trials found no significant difference in the outcome between the two intervention groups (SMD -0.06, 95% CI -0.32 to 0.20; P = 0.65). No heterogeneity was detected between the trials (I² = 0%). One cluster RCT (Sackley 2006) also reported no significant difference in the Barthel Index scores between intervention and control groups (difference 1.9, 95% CI -0.7 to 4.4; P = 0.12, using x² test and adjusted for cluster design).

Secondary outcome measures

Comparison 2.1: Case fatality at the end of follow up

Data on case fatality were available from three trials consisting of 320 participants (Green 2002; Mulder 1989; Wade 1992). The pooled analysis found no significant difference in the risk of death at the end of scheduled follow up (OR 0.85, 95% CI 0.22 to 3.26; P = 0.81). Low levels of heterogeneity were detected between the trials ($I^2 = 14.8\%$).

Comparisons 3.1 and 3.2: Patient's performance in extended activities of daily living by the end of scheduled follow up

The Frenchay Activities Index was used in two trials (Green 2002; Wade 1992) and the Nottingham Extended ADL was used in one trial (Wade 1992). Data were available from 235 participants for the Frenchay Activities Index, and a pooled analysis of the two trials found no significant difference in the scores between the intervention and control groups at the end of scheduled follow up (SMD -0.17, 95% CI -0.43 to 0.08; P = 0.19). No heterogeneity was detected between the trials (I² = 0%). Data were available from 89 participants for the Nottingham EADL score, and an individual analysis of one trial (Wade 1992) trial found no significant difference in the Nottingham EADL scores between the intervention and control groups at the end of scheduled follow up (SMD -0.31, 95% CI -0.55 to 0.29; P = 0.54).

Comparison 4.1: Patient's subjective health status at the end of scheduled follow up

The Sickness Index Profile was used in only one trial (Werner 1996). An individual analysis of 40 participants from this trial found no difference in the scores between the intervention and control groups (SMD 0.24, 95% CI -0.44 to 0.92; P = 0.49).

Comparison 5.1 Patient's mood at the end of scheduled follow up

The Hospital Anxiety and Depression Scale was used in two trials (Green 2002; Sackley 2006). A pooled analysis of data from 212 participants found no difference in the scores between the intervention and control groups at the end of scheduled follow up (SMD 0.02, 95% CI -0.34 to 0.38; P = 0.90). Moderate levels of heterogeneity were detected between the trials (I² = 43%). One trial (Werner 1996) used the Beck's Depression Scale, but reported the results as a change in patients' mood between baseline and end of follow up, and therefore could not be included in the meta-analysis. No significant difference was found in the change in patient's mood between the intervention and control group (P = 0.37, unpaired t-test).

Comparison 6.1: Carer's mood at the end of scheduled follow up

Only one trial reported carer's mood at the end of scheduled follow up using General Health Questionnaire-28 as an outcome assessment (Green 2002). An individual analysis of 70 participants from this study found no difference in scores between the intervention and control groups (SMD -0.33, 95% CI -0.80 to 0.15; P = 0.18).

Re-admission to hospital and days spent in hospital at the end of scheduled follow up

None reported

Patient and carer satisfaction with services at the end of scheduled follow up

None reported

DISCUSSION

In recent years the importance of therapy-based rehabilitation services a year or more after stroke has received little attention. The provision of further rehabilitation at this time point may be particularly relevant as this aspect of care aims to promote patients' independence and reintegration into the community. To date, the benefits of such services have not been fully evaluated. Hence, this systematic review assessed the effectiveness of therapy-based rehabilitation for stroke patients living at home a year or more after stroke. It also sought to address which outcome may have been influenced by the rehabilitation intervention provided.

Findings

The review has been constrained by the studies available to us. Overall, there was inconclusive evidence whether therapy-based rehabilitation interventions one year or more after stroke was able to influence any relevant patient or carer outcome. This review found a paucity of trials evaluating rehabilitation interventions at a year or more after stroke and those that were available varied in methodological design, type of interventions provided and the quality and outcomes assessed.



The primary outcome of this review, death or deterioration in ability to perform activities of daily living, was not reported in all included trials. These findings are consistent with those of the Outpatient Service Trialist review (OST 2004) which found that none of the trials reported a similar outcome. In this review, the trial intervention was either a single discipline intervention (physiotherapist, occupational therapist) or a combined intervention. However, all trials showed a similar approach that was based on a problem-solving method as a focus of intervention. This may suggest that, although each trial was different in design and methodology, the nature of the rehabilitation intervention itself shared a common aim, that is to reduce the level of disability by altering task-orientated behaviour and goal-orientated activities.

Finally, although this review failed to demonstrate potential benefits of rehabilitation intervention a year or more after stroke, it must be emphasized that the lack of evidence of benefit is not the same as evidence of a lack of benefit.

Limitations of review

A considerable amount of literature has been identified during the review process, but of the 35 trials, only five were randomised controlled trials looking at one year or more after stroke. We believe our search strategy was comprehensive as we were able to identify a number of unpublished studies and were able to contact some of the original trialists for additional information, hence minimizing the risk of publication bias.

In our review there are a number of methodological concerns which must be acknowledged. Firstly, of the five trials meeting the inclusion criteria, only four were eligible for meta-analysis. The trial by Sackley et al (Sackley 2006) was a cluster RCT, hence it was different in design and therefore did not qualify to be pooled with the other RCTs. Trials were of variable quality with concealed randomisation in two trials, blinding of outcome assessors in four trials and intention-to-treat analysis in two trials. Therefore, the results of the individual trials need to be interpreted with caution. Secondly, the findings from this review are restricted by the limited number of comparable outcome measures used. Included trials demonstrated clinical heterogeneity in the intervention tested, duration of follow up and the selection criteria for participants included. However, in order to maintain the robustness of the findings from the review, we have stated in advance the criteria for trial inclusion and acceptable outcomes to reflect the range of limited activity and participation that we feel are related with longer-term stroke. Finally, two of the included trials were

subjected to considerable rates of attrition which may raise the possibility of bias.

In view of the heterogeneous nature of the trials reviewed, interpretation was a major difficulty in this review. Therefore the overall results of the analysis should not be viewed as conclusive evidence of the benefit of rehabilitation intervention one year or more after stroke. To provide a more detailed understanding of the variation between the trials we have described the individual characteristics of the trials included in the review.

This review highlights the dearth of evidence investigating long-term therapy-based rehabilitation interventions for patients with stroke. Evaluations of stroke rehabilitation interventions have previously focussed on the acute phase of care, most likely due to a perception that rehabilitation potential has plateaued by six months after stroke. The fact that there are currently only a few services that offer routine follow up after six months of stroke may have further contributed to the lack of evidence for this area.

AUTHORS' CONCLUSIONS

Implications for practice

The National Stroke Strategy emphasises the need for long-term rehabilitation for stroke patients, but yet this review shows that there is insufficient evidence to support the development of such services. Whilst we are in support of such long-term services, it is mandatory that these services are evaluated as they are being implemented.

Implications for research

The analysis was based on a review of trials with different methodological qualities that restricts the overall findings of this review. Future trials in rehabilitation interventions should incorporate standardised methodological qualities such as clearly defined randomisation and allocation concealment methods, intention-to-treat analysis, clearly defined rehabilitation interventions and standardised outcomes to be used in each trial. This proposal is needed to provide more robust analysis in future meta-analysis in this topic.

ACKNOWLEDGEMENTS

We thank Prof John Green (Bradford), Prof Catherine Sackley (Birmingham), Prof Derick Wade (Oxford), Prof Robert Werner (Michigan) and Prof AHM Mulder (Netherlands) for their contribution to this review.



REFERENCES

References to studies included in this review

Green 2002 (published data only)

Green J, Forster A, Boyle S. Physiotherapy for patients with mobility problems, more than one year after stroke. A randomised controlled trial. *Lancet* 2002;**359**:199-203.

Mulder 1989 (published data only)

Mulder AHM, De Witte LP, Diederick JPM. Evaluation of a rehabilitation after-care programme for stroke patients. *Journal of Rehabilitation Sciences* 1989;**2**(4):97-103.

Sackley 2006 (published data only)

Sackley C, Wade DT, Mant D, Atkinson JC, Yudkin P, Cardoso K, et al. Cluster randomized pilot controlled trial of an occupational therapy intervention for residents with stroke in UK care homes. *Stroke* 2006;**37**:2336-41.

Wade 1992 {published data only}

Wade DT, Collen FM, Robb GF, Warlow CP. Physiotherapy intervention late after stroke and mobility. *BMJ* 1992;**304**:609-13.

Werner 1996 (published data only)

Werner RA, Kessler S. Effectiveness of an intensive outpatient rehabilitation program for postacute stroke patient. American Journal of Physical Medicine and Rehabilitation 1996;**75**(2):114-20.

References to studies excluded from this review

Allen 2002 (published data only)

Allen KR, Hazelett S, Jarjoura D, Wickstrom GC, Hua K, Weinhardt J, et al. Effectiveness of a post-discharge care management model for stroke and transient ischaemic attack. A randomized trial. *Journal of Stroke and Cerebrovascular Diseases* 2002;**11**(2):88-98.

Andersen 2002 {published data only}

Andersen HE, Eriksen K, Schultz Larsen K, Forchhammer BH. Follow-up services for stroke survivors after hospital discharge - a randomized control study. *Clinical Rehabilitation* 2002;**16**:593-603.

Chu 2004 (published data only)

Chu KS, Eng JJ, Dawson AS. Water-based exercise for cardiovascular fitness in people with chronic stroke. A randomised controlled trial. *Archives of Physical Medicine & Rehabilitation* 2004;**85**(6):870-4.

Collen 1991 {published data only}

Collen FM, Wade DT. Residual mobility problems after stroke. *International Disability Studies* 1991;**13**:12-5.

Corr 1995 {published data only}

Corr S, Bayer A. Occupational therapy for stroke patients after hospital discharge - a randomized controlled trial. *Clinical Rehabilitation* 1995;**9**:291-6.

Drummond 1995 {published data only}

Drummond AER, Walker MF. A randomized controlled trial of leisure rehabilitation after stroke. *Clinical Rehabilitation* 1995;**9**:283-90.

Duncan 1998 {published data only}

Duncan P, Richards L, Wallace D, Stroker Yates J, Pohl P, Luchies C, et al. A randomized controlled pilot study of a home based exercise program for individuals with mild and moderate stroke. *Stroke* 1998;**29**:2055-60.

Eng 2003 (published data only)

Eng JJ, Sisto S, Lavine P. A community based group exercise program for person with chronic stroke. *Medicine & Science in Sports and Exercise* 2003;**35**(8):1271-8.

Frayne 2000 {published data only}

* Frayne J, Brodtman A, Voselis H, Haartsen J, Fiddes K. Study of home intervention post stroke SHIPS Stroke Trials Directory. *Stroke* 2000;**31**(11):3 (Abst 387).

Gilbertson 2000 {published data only}

Gilbertson L, Langhorne P, Walker A, Allen A, Murray GD. Domiciliary occupational therapy for patients with stroke discharged from hospital: randomised controlled trial. *BMJ* 2000;**320**:603-6.

Jongbloed 1991 {published data only}

Jongbloed L, Morgan D. An investigation of involvement in leisure activities after a stroke. *American Journal of Occupational Therapy* 1991;**45**:420-7.

Lincoln 2004 {published data only}

Lincoln NB, Walker MF, Dixon A, Knights P. Evaluation of a multi-professional community stroke team: a randomized controlled trial. *Clinical Rehabilitation* 2004;**18**:40-7.

Logan 1997 {published data only}

Logan PA, Ahern J, Gladman JRF, Lincoln NB. A randomized controlled trial of enhanced social service occupational therapy for stroke patients. *Clinical Rehabilitation* 1997;**11**:107-13.

Logan 2003 (published data only)

Logan PA, Gladman JRF, Drummond AER, Radford KA. A study of intervention and related outcomes in a randomized controlled trial of occupational therapy and leisure therapy for community stroke patients. *Clinical Rehabilitation* 2003;**17**(3):249-55.

Logan 2004 (published data only)

Logan P, Gladman JR. Occupational therapy to increase outdoor activity. *BMJ* 2004;**329**:1372-5.

Meikle 1979 {published data only}

Meikle M, Weschler E, Tupper A, Benenson M, Butler J, Mulhall D, et al. Comparative trial of volunteer and professional treatments of dysphasia after stroke. *BMJ* 1979;**2**:87-9.



Page 2004 (published data only)

Page SJ, Sisto S, Lavine P. Efficacy of modified constraint induced movement therapy in chronic stroke. A single blinded randomised controlled therapy. *Archives of Physical Medicine & Rehabilitation* 2004;**85**(1):14-8.

Salbach 2004 (published data only)

Salbach NM, Mayo NE, Wood-Dauphinee S. A task orientation intervention enhances walking distance and speed in the first year post stroke: A randomised controlled trial. *Clinical Rehabilitation* 2004;**18**(5):509-19.

Salbach 2005 (published data only)

Salbach NM, Mayo NE, Robinchaud-Ekstrand S, Hanley JA, Richards CL, Wood-Dauphinee S. The effect of a task orientated walking intervention on improving balance, self efficacy post stroke. A randomized controlled trial. *Journal of the American Geriatrics Society* 2005;**53**(4):576-82.

Sandhu 1993 {published data only}

Sandhu H, Jannisen J, Bresa M. Functional retraining at home of extended care patients. *Australian and New Zealand Journal of Medicine* 1993;**23**:226.

Smith 1981 {published data only}

* Smith DS, Goldenberg E, Ashburn A, Kinsella G, Sheikh K, Brennan PJ, et al. Remedial therapy after stroke: A randomized controlled trial. *BMJ* 1981;**282**:517-20.

Sun 2001 (published data only)

* Sun YH, Wang L, Wang ZS. Effects of the home-based occupational therapy on motor function of limbs in patients with hemiplegia. *Hong Kong Medical Journal* 2001;**7**(4):25 (Abstract P9).

van de Gaag 2005 {published data only}

van der Gaag A, Smith L, Davis L, Moss B, Cornelius V, Laing S, et al. Therapy and support services for people with long term stroke and aphasia and their relatives. A six months follow-up study. *Clinical Rehabilitation* 2005;**19**(4):372-80.

von Koch 2001 (published data only)

von Koch L, Widen Holmqvist L, Kostulas V, Almazan J, Pedro-Cuesta J. A randomized controlled trial of rehabilitation at home after stroke; a one year follow-up of patient outcome, resource use and cost. *Cerebrovascular Disease* 2001;**12**:131-8.

Walker 1999 {published data only}

Walker MF, Gladman JRF, Lincoln NB. Occupational therapy for stroke patients not admitted to hospital: a randomised controlled trial. *Lancet* 1999;**354**:278-80.

Wall 1987 {published data only}

Wall JC, Turnbull GI. Evaluation of outpatient physiotherapy and home exercise program in the management of gait asymmetry in residual stroke. *Journal of Neurologic Rehabilitation* 1987;**3**:115-23.

Weiss 2000 (published data only)

Weiss A, Suzuki T, Bean J. High intensity strength training improves strength and functional performance after stroke. *Clinical Rehabilitation* 2000;**79**(4):369-76.

Wolfe 2000 {published data only}

Wolfe CDA, Tilling K, Rudd AG. The effectiveness of community based rehabilitation for stroke patients who remained at home; a pilot randomized trial. *Clinical Rehabilitation* 2000;**14**:563-9.

Woodhead 1997 {published data only}

Woodhead H, Fortey Y. The rehabilitation of Mabel. An interdisciplinary project. *British Journal Community Health Nursing* 1997;**2**(7):327-31.

Young 1992 {published data only}

Young JB, Forster A. The Bradford community stroke trial: results at six months. *BMJ* 1992;**304**:1085-9.

Additional references

ESDT 2005

Early Supported Discharge Trialists. Services for reducing duration of hospital care for acute stroke patients. *Cochrane Database of Systematic Reviews* 2005, Issue 4. [Art. No.: CD000443. DOI: 10.1002/14651858.CD000443]

Hacke 2000

Hacke W, Kaste M, Olsen TS, Orgogozo JM, Bogousslavsky J. European Stroke Initiative (EUSI) recommendations for stroke management. The European Stroke Initiative writing committee. *European Journal of Neurology* 2000;**7**:607-23.

Higgins 2002

Higgins JPT, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Statistics in Medicine* 2002;**21**:1539-58.

Langhorne 2001

Langhorne P, Duncan P. Does the organization of post acute stroke care really matter?. *Stroke* 2001;**32**:268-74.

Lincoln 2000

Lincoln NB, Gladman J, Berman P, Noad R, Challen K. Functional recovery of community stroke patients. *Disability and Rehabilitation* 2000;**22**(3):135-9.

MacKay 2004

MacKay J, Mensah GA, Mendis S, Greenlund K. The atlas of heart disease and stroke. World Health Organization. Geneva: WHO, 2004:25.

Mitchell 2004

Mitchell E, Moore K. Stroke: holistic care and management. *Nursing Standard* 2004;**33**(18):43-52.

OST 2004

Outpatient Service Trialists. Therapy based rehabilitation services for stroke patients at home. *Cochrane Database of Systematic Reviews* 2004, Issue 4. [Art. No.: CD002925. DOI: 10.1002/14651858.CD002925]



RCP 2004

Intercollegiate Stroke Working Party. National Clinical Guidelines for Stroke (2nd Edition). Royal College of Physicians 2004:79.

Stroke Assoc 1998

The Stroke Association. Stroke care: reducing the burden of disease. The Stroke Association. London, 1998.

Tilling 2001

Tilling K, Jonathan AC, Rudd AG, Glass TA. A new method for predicting recovery after stroke. *Stroke* 2001;**32**:2867-73.

WHO 1978

World Health Organization. Cerebrovascular disorders: a clinical and research classification. World Health Organization. Vol. **43**, Geneva: Offset Publication, 1978.

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Green 2002

Methods	Parallel group RCT with randomisation at individual level Randomisation used random number tables and four length random permuted blocks Allocation concealment: opaque sealed envelopes Blinding: blinded outcome assessor				
Participants	UK (Bradford) 170 participants (85 intervention and 85 control) Mean age 71.5 years, 58% male Barthel score at baseline: intervention group mean 18 (IQR 16 to 19); control group mean 18 (IQR 16) Clinical definition of stroke Participants recruited from hospital and community stroke register Inclusion criteria: older than 50 years, had a stroke a year or more and had associated mobility prol lems. Mobility problem was defined as: use of a mobility aid, fall in the previous three months, unal to manage stairs/slopes/uneven surfaces independently and slow gait speed				
Interventions	Community physiotherapy intervention versus no treatment at participant's home or outpatient rehabilitation centres Assessments at 3, 6 and 9 months at participants' homes Intervention based on problem-solving approach. Intervention done by established community physiotherapy service (13 staff) as part of usual work Standard maximum contact of 13 weeks with a minimum of 3 contacts per participant				
Outcomes	Outcome at 9 months Primary outcome: Barthel ADL, Rivermead Mobility Index Secondary outcome: death, Frenchay Activities Index, Hospital Anxiety & Depression Scale Carer: General Health Questionnaire - 28				
Notes					
Risk of bias					
Bias	Authors' judgement	Support for judgement			
Allocation concealment?	Low risk	A - Adequate			

Mulder 1989

Methods Parallel group RCT with randomisation at individual level

^{*} Indicates the major publication for the study



Maddan 1000 iii	
Mulder 1989 (Continued)	Randomisation used stratification method (3:1 ratio) based on age, sex, marital status and presence or absence of hemineglect Allocation concealment: not provided Blinding: not provided
Participants	Netherlands (Maastrict) 56 participants (38 intervention and 18 control). Analyses were based only at the first follow-up assessment points (at 13 to 28 weeks) Mean age 55.1 years, 53% male Participants recruited from a rehabilitation centre in the Netherlands Inclusion criteria: two-tier selection. First tier: participant < 70 years old, living within 30 km, not having serious progressive disease and not having resumed work. Second tier: expected ability to function in a group as assessed by the rehabilitation team
Interventions	Aftercare programme in the rehabilitation centre versus control Assessments at baseline, during the programme and 6 months after the programs ended Participants were divided into 3 experimental groups and one control group The intervention groups received occupational and physiotherapy (exercises, games, recreational activities and education sessions) to improve physical fitness and stimulate social contacts Intervention provided by physiotherapist and occupational therapist from the rehabilitation centre Participants attended a programme of 22 fortnightly meetings during a year, each meeting lasted 2.5 hours
Outcomes	Primary outcome: none Secondary outcome: death, Sickness Index Profile
Notes	
Risk of bias	
Bias	Authors' judgement Support for judgement
Allocation concealment?	Unclear risk B - Unclear
Sackley 2006	
Methods	Cluster RCT with 12 care homes were group into 4 strata and within each stratum, pair of homes were allocated randomly into interventional or control group Randomisation used computer-generated random numbers Allocation concealment: adequate Blinding: blinded outcome assessor
Participants	UK (Oxfordshire) 118 participants (63 residents from 6 homes in intervention group and 55 residents from 6 homes in control group) Mean age 88.6 years Participants recruited from 12 nursing and residential homes Barthel Score at baseline: intervention mean 10.1 (SD 5.7); control mean 9.5 (SD 5.2) Inclusion criteria: resident in nursing and residential homes, had moderate to severe stroke-related disability (Barthel Index score 4 to 15 inclusive)
Interventions	Occupational therapy intervention versus usual care (control) Assessments at baseline, 3 and 6 months Intervention delivered at level of the individual, targeted towards improving independence in personal ADL



Sackle	y 2006	(Continued)
--------	--------	-------------

Intervention provided by experienced, qualified occupational therapist attached to the home. Intervention followed a routine process using a client-centred approach and included a continuous process of assessment, treatment and reassessment

Intervention period was 3 months

Outcomes Primary outcome: Barthel Index

Secondary outcome: poor global outcome, Rivermead Mobility Index

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Wade 1992

Methods	Cross-over RCT with randomisation at individual level Restricted randomisation using permutated number tables Allocation concealment: not clear Blinding: blinded outcome assessment			
Participants	UK (Oxfordshire) 94 participants (49 intervention and 45 control) Mean age 72.3 years; 50% male Barthel Index score at baseline: control mean 16.2 (SD 3.1), intervention mean 17.0 (SD 2.8) Clinician definition of stroke Patients recruited from Oxfordshire Stroke Project, Rivermead Rehabilitation Centre, local practitioners and radio broadcasting Inclusion criteria: mobility problems more than 1 year after stroke, used walking or mobility aid, fall in previous 3 months, unable to manage stairs/slopes/uneven surfaces independently and had slow gait speed			
Interventions	Early rehabilitation intervention (immediate) at home versus delayed (after 3 months) by physiothera- py Intervention based on problem-solving method Interventions included: identifying individual mobility problems, setting pre-determined set goals and offering advice to solve the problems Mean numbers of visits: 4 (range 1 to 11) with mean length of visits 2 hours and 4 minutes Services provided by qualified physiotherapists			
Outcomes	Assessment at baseline, 3 and 6 months Primary outcome: Barthel ADL, Rivermead Motor Assessment Secondary outcome: death, Frenchay Activities Index, Nottingham EADL, Hospital Anxiety & Depression Scale			
Notes				

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment? Unclear risk		B - Unclear



Verner 1996					
Methods	Parallel group RCT with randomisation at individual level Randomisation using 3-digit number tables 5 additional controls were added later due to high drop out Allocation concealment: unclear Blinding: blinded outcome assessor				
Participants	US (Ann Arbor) 49 participants (28 intervention and 16 controls, with later addition of 5 controls) Mean age 59 +/- 9 years with 50% male Clinical (or radiological) definition of stroke Participants recruited from 3 local outpatient rehabilitation programs in Michigan Inclusion criteria: between 6 months and 5 years post stroke, functional communication profile score > 60%, no clinical sign of medical co-morbidities, no generalised sensory deficit, no history of recurrent stroke, no therapeutic intervention in the last 4 months and evidence of functional limitation <7 Functional Independence Measure				
Interventions	Assessments at 0, 3 an Intervention directed t ing, stretching, mobilis Intervention done by r	on programme versus usual care d 9 months owards functional tasks and treatment modalities which included strengthen- sation and muscle re-training programs egistered occupational therapist and physiotherapist. Intervention consisted of rehabilitation programme (1 hour of physical and 1 hour of occupational thera-			
Outcomes	Primary outcome: Functional Independence Measure Secondary outcome: Becks Depression Scale, Sickness Index Profile				
Notes					
Risk of bias					
Bias	Authors' judgement	Support for judgement			
Allocation concealment?	Unclear risk	B - Unclear			

ADL: activities of daily living IQR: interquartile range

Nottingham EADL: Nottingham extended activities of daily living

RCT: randomised controlled trial

SD: standard deviation

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion		
Allen 2002	Randomisation less than one year		
Andersen 2002	Randomisation less than one year		
Chu 2004	Intervention not targeted at service level		
Collen 1991	Non-randomised controlled trial		
Corr 1995	Randomisation less than one year		



Study	Reason for exclusion
Drummond 1995	Randomisation less than one year
Duncan 1998	Randomisation less than one year
Eng 2003	Non-randomised controlled trial
Frayne 2000	Patients not living at home at the time of randomisation
Gilbertson 2000	Randomisation less than one year
Jongbloed 1991	Randomisation less than one year
Lincoln 2004	Randomisation less than one year
Logan 1997	Randomisation less than one year
Logan 2003	Randomisation less than one year
Logan 2004	Randomisation less than one year
Meikle 1979	Randomisation less than one year
Page 2004	Intervention not targeted at the service level
Salbach 2004	Randomisation less than one year
Salbach 2005	Randomisation less than one year
Sandhu 1993	Patients not living at home at the time of randomisation
Smith 1981	Randomisation less than one year
Sun 2001	Intervention not targeted at the service level
van de Gaag 2005	Non-randomised controlled trials
von Koch 2001	Randomisation less than one year
Walker 1999	Randomisation less than one year
Wall 1987	Randomisation less than one year
Weiss 2000	Non-randomised controlled trial
Wolfe 2000	Randomisation less than one year
Woodhead 1997	Non-randomised controlled trial
Young 1992	Randomisation less than one year



DATA AND ANALYSES

Comparison 1. Performance in personal activities of daily living

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Barthel Index	2	235	Std. Mean Difference (IV, Random, 95% CI)	-0.06 [-0.32, 0.20]

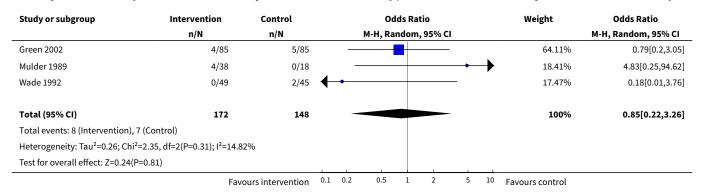
Analysis 1.1. Comparison 1 Performance in personal activities of daily living, Outcome 1 Barthel Index.

Study or subgroup	Inte	rvention	С	Control		Std. N	Mean Difference		Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)		Rai	ndom, 95% CI			Random, 95% CI
Green 2002	72	18 (2.2)	74	18 (3)		_			62.34%	0[-0.32,0.32]
Wade 1992	48	16.2 (3.1)	41	16.7 (3.2)					37.66%	-0.16[-0.58,0.26]
Total ***	120		115			-			100%	-0.06[-0.32,0.2]
Heterogeneity: Tau ² =0; Chi ² =	0.34, df=1(P=0.5	5); I ² =0%								
Test for overall effect: Z=0.45	(P=0.65)									
			Fa	vours control	-1	-0.5	0 0.5	1	Favours in	tervention

Comparison 2. Case fatality at the end of follow up

Outcome or subgroup title	No. of studies	No. of par- ticipants	Statistical method	Effect size
1 Case fatality at the end of follow up	3	320	Odds Ratio (M-H, Random, 95% CI)	0.85 [0.22, 3.26]

Analysis 2.1. Comparison 2 Case fatality at the end of follow up, Outcome 1 Case fatality at the end of follow up.





Comparison 3. Patient's performance in extended activities of daily living by the end of scheduled follow up

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient's performance in activities of daily liv- ing (Frenchay Activities Index)	2	235	Std. Mean Difference (IV, Random, 95% CI)	-0.17 [-0.43, 0.08]
2 Patient's performance in activities of daily liv- ing (Nottingham EADL)	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not se- lected

Analysis 3.1. Comparison 3 Patient's performance in extended activities of daily living by the end of scheduled follow up, Outcome 1 Patient's performance in activities of daily living (Frenchay Activities Index).

Study or subgroup	Inte	rvention	c	Control		Std. N	lean Difference	Weight	Std. Mean Difference	
	N	Mean(SD)	N	Mean(SD)		Rar	ndom, 95% CI		Random, 95% CI	
Green 2002	72	12 (10.7)	74	14 (11.1)				62.24%	-0.18[-0.51,0.14]	
Wade 1992	48	11.5 (8.4)	41	12.9 (9.5)				37.76%	-0.16[-0.57,0.26]	
Total ***	120		115			-		100%	-0.17[-0.43,0.08]	
Heterogeneity: Tau ² =0; Chi ² =	0.01, df=1(P=0.9	2); I ² =0%								
Test for overall effect: Z=1.31	(P=0.19)									
			Fa	vours control	-1	-0.5	0 0.5	1 Favours in	tervention	

Analysis 3.2. Comparison 3 Patient's performance in extended activities of daily living by the end of scheduled follow up, Outcome 2 Patient's performance in activities of daily living (Nottingham EADL).

Study or subgroup	Int	tervention	vention Control		Std. Mean Difference			Std. Mean Difference		
	N	Mean(SD)	N	Mean(SD)	Ra	ndom, 95%	6 CI		Random, 95% CI	
Wade 1992	48	25.5 (13.7)	41	27.4 (15.2)		-	-		-0.13[-0.55,0.29]	
				Favours control -1	-0.5	0	0.5	1	Favours intervention	

Comparison 4. Patient's subjective health status at the end of scheduled follow up

Outcome or subgroup title	No. of studies	No. of par- ticipants	Statistical method	Effect size
1 Sickness Index Profile	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected



Analysis 4.1. Comparison 4 Patient's subjective health status at the end of scheduled follow up, Outcome 1 Sickness Index Profile.

Study or subgroup	Int	ervention	rvention Cor			Std. M	lean Diffe		Std. Mean Difference	
	N	Mean(SD)	N	Mean(SD)		Rar	idom, 95%	6 CI		Random, 95% CI
Werner 1996	28	5.2 (10.6)	12	2.6 (10.6)						0.24[-0.44,0.92]
				Favours control	-1	-0.5	0	0.5	1	Favours intervention

Comparison 5. Patient's mood at the end of scheduled follow up

Outcome or subgroup title	No. of studies	No. of par- ticipants	Statistical method	Effect size
1 Patient's mood at the end of scheduled follow up	2	212	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.34, 0.38]

Analysis 5.1. Comparison 5 Patient's mood at the end of scheduled follow up, Outcome 1 Patient's mood at the end of scheduled follow up.

Study or subgroup	Inte	ervention	C	Control		Std. I	Mean Difference		Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)		Ra	ndom, 95% CI			Random, 95% CI
Green 2002	62	8 (5.2)	61	7 (5.2)			-		54.65%	0.19[-0.16,0.55]
Wade 1992	48	6.5 (3.7)	41	7.2 (4.1)			-		45.35%	-0.18[-0.6,0.24]
Total ***	110		102			-			100%	0.02[-0.34,0.38]
Heterogeneity: Tau ² =0.03; Ch	i ² =1.75, df=1(P=	0.19); I ² =42.94%								
Test for overall effect: Z=0.13((P=0.9)									
			Fa	vours control	-1	-0.5	0 0.5	1	Favours in	tervention

Comparison 6. Carer's mood at the end of scheduled follow up

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Carer's mood at the end of scheduled follow up	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not select- ed

Analysis 6.1. Comparison 6 Carer's mood at the end of scheduled follow up, Outcome 1 Carer's mood at the end of scheduled follow up.

Study or subgroup	Int	ervention		Control		Std. N	lean Diffe	rence		Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)		Rar	idom, 95%	CI		Random, 95% CI
Green 2002	36	3 (4.4)	34	5 (7.4)	-	+				-0.33[-0.8,0.15]
				Favours control	1	-0.5	0	0.5	1	Favours intervention



APPENDICES

Appendix 1. MEDLINE search strategy

Search strategy for MEDLINE (Ovid)

- 1. exp cerebrovascular disorders/
- 2. stroke\$.tw.
- 3. cva\$.tw.
- 4. cerebrovascular\$.tw.
- 5. cerebral vascular\$.tw.
- 6. (cerebral or cerebellar or brain\$ or vertebrobasilar).tw.
- 7. (infarct\$ or isch?emi\$ or thrombo\$ or emboli\$ or apoplexy).tw.
- 8. 6 and 7
- 9. (cerebral or brain\$ or subarachnoid).tw.
- 10. (haemorrhage or hemorrhage or haematoma or hematoma or bleeding).tw.
- 11.9 and 10
- 12. hemiplegia/
- 13. exp aphasia/
- 14. hemianopsia/
- 15. (aphasia\$ or dysphasia\$ or hemianop\$ or hemipleg\$ or hemipar\$ or poststroke).tw.
- 16. 1 or 2 or 3 or 4 or 5 or 8 or 11 or 12 or 13 or 14 or 15
- 17. exp cerebrovascular disorder/rh
- 18. hemiplegia/rh
- 19. exp aphasia/rh
- 20. hemianopsia/rh
- 21. 17 or 18 or 19 or 20
- 22. exp rehabilitation/
- 23. patient education/
- 24. Health Education/
- 25. exp diet therapy/
- 26. exp nutrition/
- 27. exp nutritional support/
- 28. therapy, computer assisted/
- 29. rehabilitat\$.tw.
- 30. ((occupational or speech or language or exercise) and therap\$).tw.
- 31. physiotherap\$.tw.
- 32. tertiary prevention.tw.
- 33. ((treatment or therap\$ or training or education\$ or healthcare) adj10 (program\$ or intervention\$ or approach\$)).tw.
- 34. ((diet or nutrition) and (therap\$ or modif\$ or program\$)).tw.
- 35. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
- 36. 16 and 35
- 37. 21 or 36
- 38. community health services/
- 39. social work/
- 40. community hospital/
- 41. ambulatory care/
- 42. outpatient clinics, hospital/
- 43. ambulatory care facilities/
- 44. day care/
- 45. patient care/
- 46. continuity of patient care/
- 47. patient care team/
- 48. patient transfer/
- 49. primary health care/
- 50. comprehensive health care/
- 51. rehabilitation centers/
- 52. sheltered workshops/
- 53. fitness centers/
- 54. community health centers/



- 55. rehabilitation, vocational/
- 56. outpatients/
- 57. exp home care services/
- 58. community health services/
- 59. social support/
- 60. health services for the aged/
- 61. community.tw.
- 62. domiciliary.tw.
- 63. (home or home-care or home-based).tw.
- 64. early supported discharge.tw.
- 65. outpatient\$.tw.
- 66. day?patient\$.tw.
- 67. outreach.tw.
- 68. multidisciplinary team.tw.
- 69. patient care team.tw.
- 70. stroke unit\$.tw.
- 71. day hospital\$.tw.
- 72. 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71

73. 37 and 72

WHAT'S NEW

Date	Event	Description
6 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

NA, MW and LL planned and wrote the first draft of the protocol and revised the subsequent drafts. NA and MW performed the searches, checked eligibility, extracted data and independently assessed the quality of the included studies. NA and JL-B planned the analyses, extracted data from the studies, conducted analyses of the selected studies, commented on and subsequently revised the protocol. MW, MP, JG, JL-B and LL provided data, advice, comments and helped revise the protocol and the systematic review.

DECLARATIONS OF INTEREST

None known

INDEX TERMS

Medical Subject Headings (MeSH)

*Long-Term Care; *Outpatients; Randomized Controlled Trials as Topic; Recovery of Function; Stroke [*therapy]; Stroke Rehabilitation; Time Factors; Treatment Outcome

MeSH check words

Humans