Home-based therapy programmes for upper limb functional recovery following stroke (Protocol)

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[Intervention Protocol]

Home-based therapy programmes for upper limb functional recovery following stroke

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the effects of home-based therapy programmes for upper limb recovery in patients with upper limb impairment following stroke, compared with:

(1) placebo or no intervention;

(2) usual care.

Question to be answered

Are home-based therapy programmes effective at improving upper limb recovery in patients with upper limb impairment after stroke?

BACKGROUND

Stroke is a major cause of death and disability throughout the world, consuming significant resources (Isard 1992). It is therefore imperative that stroke services are effective and efficient. Problems affecting the upper limb following stroke are often persistent and disabling, with only 20% (Parker 1986) to 56% (Nakayama 1994) of patients regaining useful upper limb function after three months. In addition, motor impairment has been shown to be the most influential factor in determining well-being one year after stroke (Wyller 1998). Improving upper limb function is therefore often a core element of rehabilitation after stroke in order to maximise patient outcomes and reduce disability (Langhorne 2003).

Increasingly the trend within health service delivery (including stroke care) is toward decreasing lengths of stay for inpatient care and moving care into the community, which has lead to the development of home-based stroke services (ESDT 2005). A Cochrane review of therapy-based rehabilitation services for stroke patients at home (OPT 2006) found such services reduce the odds of a poor outcome in ability to perform activities of daily living (ADL) and have a beneficial effect on a patient's ability to perform personal ADL and extended ADL compared to conventional or no care. This review specifically investigated therapy service interventions primarily aiming to improve task-orientated behaviour (not upper limb interventions or outcomes) and was based on a review of heterogeneous interventions. This planned review intends to exclusively investigate the effects of home-based therapy programmes targeted at upper limb recovery.

The effectiveness of specific upper limb interventions has been, or is in the process of being reviewed within other Cochrane systematic reviews: EMG biofeedback (Woodford 2004), electrostimulation (Pomeroy 2006), mental practice (Stevenson 2006), constraint-induced movement therapy (Sirtori 2003), repetitive task training (French 2006) and simultaneous bilateral training (Coupar 2007). This planned review does not intend to replicate or overlap with these other reviews, as the focus will be on programmes of interventions completed at home rather than on a specific intervention.

With an increased focus on home-based stroke services and the undertaking of programmes of interventions, targeted at upper limb recovery within clinical practice, a systematic review of home-based therapy programmes for individuals with upper limb impairment following stroke is deemed appropriate.

OBJECTIVES

To determine the effects of home-based therapy programmes for upper limb recovery in patients with upper limb impairment following stroke, compared with:

(1) placebo or no intervention;

(2) usual care.

Question to be answered

Are home-based therapy programmes effective at improving upper limb recovery in patients with upper limb impairment after stroke?

METHODS

Criteria for considering studies for this review

Types of studies

We will include controlled trials if participants have been randomly assigned (that is, each participant has an equal chance of being in either group). Random allocation could be completed by having computer-generated random numbers or using sequentially-numbered opaque sealed envelopes. We will include only the first phase of cross-over studies to exclude any carry-over or learning effects.

We will include trials with or without blinding of participants, treating therapist(s) and assessor(s). We will document and present information on these variables within the review. Studies must include an intervention group of a home-based therapy programme and a comparison group of placebo or usual care ('conventional' or 'traditional'). We will also include studies that include a home-based therapy programme in addition to usual care compared with usual care alone. Usual care will be determined by the original trial authors when it is considered to be a normal or usual component of stroke rehabilitation. We will document the description of the usual care and we will seek additional information from study authors if necessary.

We will only include studies if the therapist has visited the patient in their own home (at least once) to prescribe treatment.

Types of participants

We will include participants with a clinical diagnosis of stroke - 'a syndrome of rapidly developing symptoms and signs of focal, and at times, global, loss of cerebral function lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin' (WHO 1989) - regardless of time since onset, initial upper limb impairment, ability to follow instructions, co-morbidities, previous strokes or location of stroke. We will collect and document data on these variables, and will then use this data to carry out appropriate subgroup analysis. We will include studies that also recruited participants with other neurological disorders if more than 50% of participants are stroke patients; we will contact study authors for relevant data if required. We will include only participants living in their own homes (that is, at their permanent address). This may include care homes and other forms of supported or sheltered accommodation.

Types of interventions

Studies must investigate a home-based therapy programme, targeted at upper limb recovery following stroke. For the purposes of this review home-based therapy programmes will be defined as those including the following elements:
(1) carried out in the patient's home (that is, at their permanent address; this may include care homes and other forms of supported or sheltered accommodation);
(2) prescribed by healthcare professionals or individuals under the supervision of healthcare professionals;
(3) including more than one specific intervention targeted at upper limb recovery.
The rationale for including only these trials with more than one specific intervention is to avoid studies of single upper limb interventions. The focus of this review is a 'programme' of therapy. A programme of therapy will always include several different treatment interventions. The effectiveness of single interventions for the upper limb are assessed in other reviews. Excluding trials that assess only one specific intervention will effectively limit this review to trials of 'programmes', reduce or avoid overlap with other reviews, and reflect clinical reality. We will, however, record trials that investigate one specific intervention administered within patients' own homes.
We will include studies of complex packages of rehabilitation if the administered package includes interventions targeted at upper limb recovery and includes the three elements outlined above. If this information is not clear from the study then we will attempt to contact the trial authors for clarification.
Any duration or intensity of programme will be included and subgroup analysis completed as appropriate. We will document the professional background, training and experience of the person(s) delivering the intervention and we will seek additional information from the study author(s) if necessary.

Types of outcome measures

The primary or initial aim of many upper limb interventions is often to improve functional movement and reduce impairment. However, it is debatable how meaningful these aspects are to individual patients. The most important goal for patients is arguably to improve their ability to participate in and independently achieve activities of daily living. Additionally, this is the over-arching aim of all rehabilitation interventions. Since the key motivation of this review is to improve patient care and ensure meaningful outcomes, performance in activities of daily living was chosen as a primary outcome of interest.

Primary *o*utcomes

(1) Performance in activities of daily living (including feeding, toileting, dressing, bathing, simple mobility and transfers). Measures will be global measures of activities of daily living such as the Barthel Index. It must be acknowledged that many of the existing measures of performance in activities of daily living have limitations relating to sensitivity and specificity for measuring a change in upper limb function, and therefore a second primary outcome specific to upper limb function is proposed.
(2) Functional movement (such as measures of active movement, co-ordination, dexterity, manipulation, grasp/grip/pinch). Measures are likely to include the Action Research Arm Test, the Rivermead Motor Assessment (RMA), Motricity Index and the 10 hole peg test.

Secondary *o*utcomes

(1) Performance in extended activities of daily living (including shopping, household tasks). Measures are likely to include the Nottingham Extended Activities of Daily Living.
(2) Motor impairment (measures of general upper limb impairment, muscle strength, muscle tone). Measures are likely to include muscle testing, the Ashworth scale, the Fugl-Meyer scale and upper limb kinematics.

Additional outcomes

(1) Adverse events (such as death, pain).
Outcomes will be completed at the end of intervention period and at the end of scheduled follow up.

Search methods for identification of studies

See: 'Specialized register' section in Cochrane Stroke Group
We will search the Cochrane Stroke Group Trials Register. In addition, we will search the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, latest issue), MEDLINE (1950 to present), EMBASE (1980 to present) CINAHL (1982 to present) and AMED (1985 to present) (Appendix 1).
We will also search the following occupational therapy and physiotherapy databases:

- OTseeker (http://www.otseeker.com/);
- OT Search (http://www.aota.org/otsearch/index.asp);
- Physiotherapy Evidence database (PEDro, http://www.pedro.fhs.usyd.edu.au/index.html), Chartered Society of Physiotherapy Research Database;
- REHABDATA (http://www.naric.com/research/rehab/default.cfm).

We will develop search strategies in consultation with the Cochrane Stroke Group's Trials Search Co-ordinator to avoid duplication of effort.
We will identify and handsearch relevant journals and conference proceedings that have not been searched on behalf of The Cochrane Collaboration. In an effort to identify further published, unpublished and ongoing trials we will:
(1) check reference lists of all relevant articles;

(2) search ongoing trials and research registers including ClinicalTrials.gov (http://www.clinicaltrials.gov/) and the National Research Register (http://www.nrr.nhs.uk/search.htm);
(3) contact investigators known to be involved in research in this area;
(4) search Science Citation Index using the cited reference search;
(5) search dissertation abstracts (http://wwwlib.umi.com/dissertations/search).

Data collection and analysis

Identification of relevant trials

One review author (FC) will read the titles of the identified references and eliminate any obviously irrelevant studies. We will then obtain the abstracts for the remaining studies and, based on the inclusion criteria (types of studies, types of participants, aims of interventions, outcome measures), two review authors (FC and PvV or CS) will independently rank these as 'possibly relevant' or 'definitely irrelevant'. If both review authors identify a trial as 'definitely irrelevant' we will exclude this trial at this point. We will retrieve the full text of trials categorised as 'possibly relevant', review them and classify them as 'include', 'exclude' or 'unsure'. We will exclude trials classified as 'exclude' by both review authors. If there is disagreement between review authors, or a decision cannot be reached, we will seek consensus through discussion, including a third review author if necessary.

Documentation of methodological quality

Two review authors will independently assess the methodological quality of the studies using a standard critical appraisal assessment form. Assessment of the quality of studies will focus on potential areas of bias within the studies as this has been shown to affect the estimation of effectiveness of interventions. We will consider and document the following:
(1) generation of randomisation sequence;
(2) allocation concealment;
(3) baseline comparison between groups;
(4) blinding of outcome assessor;
(5) blinding of participants;
(6) blinding of therapists;
(7) intention-to-treat analysis possibility;
(8) number of patients lost to follow up;
(9) possibility to contamination or co-intervention by therapists providing intervention;
(10) other potential confounders.
Any disagreements between the two review authors will be resolved through discussion, including a third review author if necessary. We will contact trial authors for clarification and to obtain missing data if required.

Data extraction

Two review authors will independently extract data from the studies using a standard data extraction form. We will attempt to obtain any missing data by contacting trial authors. If possible we will document:
(1) participant details (including age, gender, place of residence, type of stroke, time since stroke, initial upper limb impairment, co-morbid conditions, premorbid disability);
(2) the inclusion and exclusion criteria;
(3) the duration/intensity/frequency of intervention;
(4) a brief description of the home-based therapy programme (including details of administered therapy programme (including if part of early supported discharge or standard discharge protocol), involvement of treating therapist and qualifications and experience of treating therapist(s));
(5) the comparison intervention;
(6) the outcomes.

Comparisons to be made

(1) Home-based therapy programme versus placebo or no intervention
(2) Home-based therapy programme versus usual care
(3) Home-based therapy programme plus usual care versus usual care
We will document and report information relating to 'usual care' including any treatment provided to participants in this group and the amount/intensity of any such treatment. We will contact authors for more information if required.

Data analysis

For each comparison the study results for performance in activities of daily living, measures of upper limb functional movement, measures of motor impairment, and adverse effects will be used if documented. We will use The Cochrane Collaboration's Review Manager software, RevMan 4.2, for all analyses. If possible, we will use intention-to treat analyses.
We will analyse dichotomous data using the odds ratio and 95% confidence interval employing a fixed-effect model with exploration of sources of heterogeneity. Activities of daily living data, such as the Barthel Index, will be treated as continuous outcomes and mean and standard deviation data will be recorded. We will analyse continuous outcomes as the standardised mean difference and 95% confidence intervals. Results will be subjected to a random-effects meta-analysis to take account of statistical heterogeneity. Heterogeneity will be determined using the I-squared (I^2)statistic (I^2 greater than 50% is considered substantial heterogeneity). If heterogeneity is found to be present, we will explore and present possible causes.
We will undertake the following subgroup analyses if there is sufficient data on the primary outcomes:
(1) initial upper limb severity;

(2) place of residence (own home, residential or nursing care);
(3) self practice versus no self practice;
(4) duration, intensity and frequency of intervention (intervention less than four weeks and intervention more than four weeks, intervention less than three times a week and intervention more than three times a week).
Subgroup analysis will be completed using the Deeks method (Deeks 2001).
Sensitivity analysis based on methodological quality of studies will also be completed (clarity of randomisation procedure and allocation concealment, blinding of outcome assessor, intention-to-treat analysis, type of study).

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

We will use the following search strategy, using a combination of controlled vocabulary (MeSH) and free text terms, for MEDLINE and will modify it to suit other databases.

1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or cerebrovascular accident/ or exp brain infarction/ or exp cerebrovascular trauma/ or exp hypoxia-ischemia, brain/ or exp intracranial arterial diseases/ or intracranial arteriovenous malformations/ or exp "Intracranial Embolism and Thrombosis"/ or exp intracranial hemorrhages/ or vasospasm, intracranial/ or vertebral artery dissection/
2. (stroke or poststroke or post-stroke or cerebrovasc$ or brain vasc$ or cerebral vasc$ or cva$ or apoplex$ or SAH).tw.
3. ((brain$ or cerebr$ or cerebell$ or intracran$ or intracerebral) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$)).tw.
4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage$ or hemorrhage$ or haematoma$ or hematoma$ or bleed$)).tw.
5. hemiplegia/ or exp paresis/
6. (hemipleg$ or hemipar$ or paresis or paretic).tw.
7. 1 or 2 or 3 or 4 or 5 or 6
8. exp Upper Extremity/
9. (upper adj3 (limb$ or extremity)).tw.
10. (arm or shoulder or elbow or forearm or hand or wrist or finger or fingers).tw.
11. 8 or 9 or 10
12. 7 and 11
13. community health services/ or community health nursing/ or community networks/ or home care services/ or home care services, hospital-based/ or home nursing/
14. homebound persons/ or home health aides/ or home care agencies/ or house calls/ or primary health care/ or aftercare/
15. residential facilities/ or assisted living facilities/ or group homes/ or halfway houses/ or homes for the aged/ or exp nursing homes/
16. housing for the elderly/ or long-term care/ or institutionalization/
17. (home$ or house$ or domicile or domiciliary or community or institution$ or outreach or sheltered accomm$).tw.
18. ((resident$ or long-term) adj5 (care or facilit$)).tw.
19. or/13-18
20. 12 and 19

WHAT'S NEW

Last assessed as up-to-date: 7 May 2007.

Date	Event	Description
9 July 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2007

CONTRIBUTIONS OF AUTHORS

Fiona Coupar (FC): principal author of the protocol, protocol development, searching for trials, study selection, quality assessment, data extraction and data entry, completion of analysis, interpretation of results and writing and updating the review.

Paulette van Vliet (PvV): assistance with drafting the protocol, searching for trials, study selection, quality assessment, data extraction, interpretation of results and assistance with writing and updating the review.

Catherine Sackley (CS): assistance with drafting the protocol and study selection, extracting data and analysis and interpreting results. Catherine will proof read all drafts and provide suggestions.

Alex Pollock (AP): assistance with drafting the protocol and completion of the analysis and interpretation of the results. Alex will proof read all drafts and provide suggestions, act as a third party should disagreements arise, and provide advice and assistance at all stages of development.

Lynn Legg (LL): assistance with drafting the protocol and analysis and interpretation of results. Lynn will also provide advice and assistance at all stages of development.

DECLARATIONS OF INTEREST

None known

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Internal sources

- Greater Glasgow Health Board Managed Clinical Network for Stroke, UK.

External sources

- Chest, Heart and Stroke Scotland, UK.