Occupational therapy for cognitive impairment in stroke patients (Protocol)

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[Intervention Protocol]

Occupational therapy for cognitive impairment in stroke patients

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ABSTRACT

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

This review aims to determine whether occupational therapy for cognitive impairment in stroke patients improves function.

BACKGROUND

Stroke is a leading cause of chronic disability in many developed countries in the world (CDCP 2003; Thrift 2000). A frequent consequence of stroke is cognitive impairment (Patel 2003; Tatemichi 1994). Patel et al found that, in the three-year period after the onset of their first stroke, up to 39% of patients had cognitive impairment (Patel 2003). The impact of stroke on cognitive function may occur in different domains such as attention, memory, orientation, and problem solving (Tatemichi 1994). A significant relationship has been found between cognitive abilities and functional performance (Abreu 1987; Hanson 1997; Poole 1991). Thus, cognitive impairment can reduce the independence of people who have had a stroke when performing basic activities of daily living (such as eating, dressing, and toileting) and instrumental activities of daily living (such as housework and social interactions) (Hochstenbach 2000; Patel 2003; Zinn 2004). As a result, people with cognitive impairment following stroke often require ongoing care and support, which can place a strain on caregivers and society (Blake 2002; Doyle 2002). Therefore, it is important for researchers and clinicians to identify effective interventions to treat cognitive impairment following stroke.

Occupational therapy plays a unique and important role in a multidisciplinary approach to the treatment of cognitive impairment. Occupational therapists assess and treat cognitive deficits to assist patients to reach their maximum level of functional independence and fulfil desired and required life roles after stroke (Poole 1991). The two general techniques used by occupational therapists to treat cognitive impairment are remedial and compensatory approaches (Blundon 2000; Poole 1991; Radomski 1994). Based on the concept of the plasticity of the human brain and its ability to reorganise after being damaged, the remedial approach aims to promote patients' function by retraining deficits in specific cognitive domains (e.g. attention, memory, and organisation). This approach assumes that retrained skills will transfer to functional performance more broadly than the immediate task including such activities of daily living as managing finances or planning household tasks. The compensatory approach utilises patients' residual strengths to compensate for deficits and aims to restore their function by teaching and assisting them and their families to develop strategies to overcome performance deficits. Debate exists around the validity of the assumptions and the effectiveness of these approaches. It has been argued that the skills acquired through repetitive drill-like exercises using a remedial approach may not be readily transferred to daily living activities (Cobble 1991). Furthermore, direct training in specific functional activities as part of the compensatory approach may not necessarily generalise to improved performance in everyday activities in home, work or school, and in leisure contexts (Hanson 1997). A comprehensive systematic review may help to clarify these debates and examine the effectiveness of occupational therapy in treating cognitive impairment.

To our knowledge, there is no systematic review that has specifically examined the effectiveness of occupational therapy in treating cognitive impairment in people with stroke. A review by Cicerone et al has addressed the issue of the effectiveness of cognitive rehabilitation in stroke patients; however it is not specific to occupational therapy (Cicerone 2000; Cicerone 2005). Two reviews have examined the effectiveness of occupational therapy with stroke patients in general, but did not focus on the treatment of cognitive impairment (Ma 2002; Steultjens 2003). As occupational therapy is considered to be an important part of the multidisciplinary management of stroke, and treatment of cognitive impairment is a common focus of this intervention, it is important to review the effectiveness of occupational therapy in assisting people with cognitive impairment after stroke to improve their functional independence.

OBJECTIVES

This review aims to determine whether occupational therapy for cognitive impairment in stroke patients improves function.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) in the review. We will also include clinical trials where participants are quasi-randomly assigned to one of two or more treatment groups. Cross-over trials will be considered as RCTs according to The Cochrane Collaboration's guidelines (Higgins 2005).

Types of participants

Participants will be adults (aged 18 years or over) with clinically defined stroke and confirmed cognitive impairment as specified in the trial. We will exclude trials where the focus of the intervention was on improving language skills or perceptual skills, or both. We will exclude trials with mixed aetiology groups unless participants who have had (and only had) a stroke comprise more than 50% of the participants. We will include these trials only when data are either provided separately for participants with stroke in the published article or are available from the trial authors.

Types of interventions

We will include all occupational therapy interventions for cognitive impairment in people with stroke. Occupational therapy interventions in this review are defined as interventions indexed in major international occupational therapy texts (Katz 2005; Pedretti

2001; Trombly 2002). Furthermore, if papers reporting an intervention were authored by an occupational therapist or the intervention in the study was administered by occupational therapists, or both, we will also include these. These interventions may take either a remedial or a compensatory approach, or both. The remedial approach focuses on training specific cognitive deficits using media such as pencil and paper, computer tasks, and board games. In a compensatory approach, interventions may include (1) training skills for daily activities (e.g. dressing, ambulation, driving, managing a meal) and vocation using compensatory strategies; (2) advising and educating about the use of assistive devices that aid cognitive function, such as an alarm watch, a hand-held computer, or a medication container; and (3) educating patients, families, and caregivers about strategies to overcome patients' cognitive impairment. The dynamic interactional approach (previously referred to as multicontextual) is an integrated approach, encompassing both remedial and compensatory elements to encourage generalisation of the treatment effect achieved in a clinical setting to patients' real life performance situation (Toglia 2005). We will consider the dynamic interactional approach as a third type of intervention in this review, separate from remedial and compensatory approaches. We will not include trials examining drug effects on cognitive function following stroke.

Types of outcome measures

The primary outcome measure will be assessments of basic activities of daily living. We will consider assessments of instrumental activities of daily living, community integration, resumption of life roles, and specific cognitive functions, such as attention and memory or general cognitive function, as secondary outcome measures. We will describe differences in adverse outcomes (such as death) between the treatment groups.

Search methods for identification of studies

See: 'Specialized register' section in Cochrane Stroke Group
We will search the Cochrane Stroke Group Trials Register and the Cochrane Dementia and Cognitive Improvement Group Trials Register. In addition, we will search the following electronic bibliographic databases: the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, latest issue), MEDLINE (1966 to present), EMBASE (1980 to present), CINAHL (1982 to present), PsycINFO (1840 to present), PsycBITE (Psychological Database for Brain Impairment Treatment Efficacy), OTseeker, and Dissertation Abstracts. We will consult an experienced medical librarian about the search strategies for each database. These will include four major areas: stroke, cognitive impairment, occupational therapy interventions, and trial methodology (Appendix 1).
In an effort to identify further published, unpublished, and ongoing trials, we will:

(1) use the cited reference search in Science Citation Index (SCI) and Social Science Citation Index (SSCI) to track relevant references;
(2) scan reference lists of identified studies and reviews;
(3) handsearch relevant occupational therapy journals, including supplements and conference abstracts that are not indexed in the above databases and which have not already been searched on behalf of The Cochrane Collaboration. The journals that we will handsearch are:

- *American Journal of Occupational Therapy* (1947 to 1949);
- *Australian Occupational Therapy Journal* (1963 to 1990);
- *Asian Journal of Occupational Therapy* (2001 to 2006);
- *Canadian Journal of Occupational Therapy* (1955 to 1965);
- *Hong Kong Journal of Occupational Therapy* (2001 to latest issue);
- *Indian Journal of Occupational Therapy* (2001 to 2005);
- *Journal of Occupational Science Australia* (1993 to 1994);
- *New Zealand Journal of Occupational Therapy* (1957 to 1978, 1990 to 1995);
- *Occupational Therapy in Health Care* (1984 to 1986);
- *Occupational Therapy and Rehabilitation* (1938 to 1951);
- *South African Journal of Occupational Therapy* (1959 to 1991).

(4) identify unpublished research by searching Dissertation Abstracts and contacting key researchers in the area; and
(5) scan the abstracts of non-English language studies if they are available in English.

Data collection and analysis

Study selection

One review author (CK) will review the titles identified in references and searches and eliminate obviously irrelevant studies. We will obtain the abstracts of the remaining studies. Using the titles and abstracts obtained from the searches, two review authors (CK and TH or SB) will independently complete the first study selection according to the four inclusion criteria (types of studies, participants, interventions, and outcome measures). The first study selection will result in the categories of included, excluded, or unsure. The full texts of the studies that are marked as included or unsure will be obtained and two review authors (CK and TH or SB) will independently complete the second study selection to finally decide on each trial's inclusion or exclusion. We will resolve disagreement by discussion based on the inclusion criteria. If no consensus is reached, a third review author will arbitrate.

Assessment of methodological quality

We will present the included trials in tabular form to summarise their methodological quality. There are four sources of potential

bias in trials of intervention effectiveness: selection bias, performance bias, detection bias, and attrition bias. According to the definition by Juni et al, selection bias refers to biased allocation of participants to comparison groups (i.e. absence of, or inadequate, allocation concealment) (Juni 2001). We will assess the method of allocation concealment of the selected studies according to three categories using the criteria suggested in the Cochrane Handbook: A - adequate; B - unclear; and C - inadequate (Higgins 2005). Performance bias refers to unequal provision of care apart from the treatment under evaluation (i.e. lack of blinding of therapists or participants, or both). Detection bias refers to biased assessment of outcome (i.e. lack of blinding of outcome assessors). Attrition bias refers to biased occurrence and handling of deviations from the treatment protocol (i.e. lack of analysis according to intention to treat) and loss to follow up. To evaluate the four types of bias in each eligible trial, the eight internal validity items adapted from the PEDro scale will be applied in this review (Table 1) (Moseley 2002). After reviewing a trial, each of the eight items will be assigned 'Yes' (present) or 'No' (absent or not reported) to indicate the methodological quality of the selected studies according to the criteria used in the OTseeker database (http://www.otseeker.com/scale.htm).

Table 1. Criteria for assessing the methodological quality of trials

Criteria	Rating*
Selection bias	
(1) Participants were randomly allocated to groups (in a crossover study, participants were randomly allocated an order in which treatments were received)	Yes/No
(2) Allocation was concealed	Yes/No
(3) The groups were similar at baseline regarding the most important prognostic indicators	Yes/No
Performance bias	
(4) There was blinding of all participants	Yes/No
(5) There was blinding of all therapists who administered the therapy	Yes/No
Detection bias	
(6) There was blinding of all assessors who measured at least one key outcome	Yes/No
Attrition bias	

Table 1. Criteria for assessing the methodological quality of trials (*Continued*)

(7) Measures of at least one key outcome were obtained from more than 85% of the participants initially allocated to groups	Yes/No
(8) All participants for whom outcome measures were available received the treatment or control condition as allocated or, if this was not the case, data for at least one key outcome were analysed by 'intention to treat'	Yes/No
*Yes/No according to criteria used in the OTseeker database (http://www.otseeker.com/scale.htm#1)	

Data extraction

Two review authors (TH and SB) will independently record the following information using a self-developed data extraction form.
(1) Sample characteristics such as: age, level of education, sex, first or recurrent stroke, type and severity of stroke, time since onset of stroke, type of cognitive impairment, sample size, number of drop outs.
(2) Methodological quality: according to the eight internal validity items as described in Table 01 (Table 1).
(3) Details of the interventions: type of interventions (remedial, compensatory, or dynamic interactional approach), materials used in interventions (e.g. cards, boards, paper and pencil exercises, computer games), duration and frequency of interventions and follow up, individual or group therapy.
(4) Outcome measures: the outcome measures used in the trial and when they were administered.
We will extract data from published reports or request data from the first author when necessary. For each trial, we will require the following summary statistics for each outcome that is measured as continuous data: the mean change in the outcome from baseline, the standard error of the mean change, and the number of participants in each treatment group at each assessment. Where changes from baseline are not reported, we will extract, if available, the mean, the standard deviation, and the number of participants in each treatment group at each time point. For dichotomous data, we will extract the number of participants and the number assessed on the outcome of interest in each treatment group.
The baseline assessment is defined as the latest available assessment prior to randomisation, but no longer than two months prior. In cross-over trials, we will not analyse further any data collected after the cross over.
We will resolve differences in data extraction by discussion. If no consensus can be achieved, the third review author will be consulted. We will attempt to contact study authors to obtain missing information.

Data analysis

The outcomes measured in clinical trials of cognitive impairment often arise from an ordinal rating scale. Where the rating scales used in the trials have a reasonably large number of categories (more than 10) we will treat the data as continuous outcomes arising from a normal distribution.
If the results of trials are found to be similar, we will synthesise these using meta-analysis. For continuous data, since trials may not use the same rating scale to assess an outcome, we will calculate two types of estimate. The measure of the treatment difference for any outcome will be the weighted mean difference when the pooled trials use the same rating scale or test, and the standardised mean difference (the absolute mean difference divided by the standard deviation) when they use different rating scales or tests. We will calculate each one, together with the corresponding 95% confidence interval (CI). For dichotomous data, we will compute the relative risk or odds ratio with 95% CI.
The results of all trials will be pooled to present the overall estimate of the treatment effect using a fixed-effect model and viewed to assess heterogeneity. We will test heterogeneity between trial results by using I-squared (I^2) estimates (Higgins 2003). An I^2 value above 75% will be considered substantial, indicating heterogeneity between trial results. In this case, subgroup analysis (e.g. separating participants with different severity or separating different treatment duration) will be applied to see if homogeneous results can be generated. Otherwise, a random-effects model will be used (in which case the confidence intervals will be broader than those of a fixed-effect model).

Sensitivity analysis

We will carry out sensitivity analysis to evaluate the effect of trial quality by analysing separately the following categories of studies:
(1) trials with and without adequate randomisation and concealment of treatment allocation;
(2) trials with and without intention-to-treat analysis;
(3) trials with follow-up periods of less than 6 months' duration, 6 to 12 months' duration, and more than 12 months' duration.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

The following search strategy will be used for MEDLINE and adapted for the other databases.
MEDLINE (Ovid)
1. exp cerebrovascular disorders/ or brain injuries/ or brain injury, chronic/
2. (stroke$ or cva or poststroke or post-stroke).tw.
3. (cerebrovasc$ or cerebral vascular).tw.
4. (cerebral or cerebellar or brain$ or vertebrobasilar).tw.
5. (infarct$ or isch?emi$ or thrombo$ or emboli$ or apoplexy).tw.
6. 4 and 5
7. (cerebral or brain or subarachnoid).tw.
8. (haemorrhage or hemorrhage or haematoma or hematoma or bleed$).tw.
9. 7 and 8
10. exp hemiplegia/ or exp paresis/
11. (hemipar$ or hemipleg$ or brain injur$).tw.
12. 1 or 2 or 3 or 6 or 9 or 10 or 11
13. cognition disorders/ or confusion/ or neurobehavioral manifestations/ or memory disorders/
14. (agnosia or amnesia or confusion or inattention).tw.
15. cognition/ or Arousal/ or Orientation/ or Attention/ or memory/ or perception/ or mental processes/ or thinking/ or Concept Formation/ or Algorithms/ or "Recognition (Psychology)"/ or Judgment/ or Awareness/ or Problem Solving/ or "Generalization (Psychology)"/ or "Transfer (Psychology)"/ or comprehension/ or Impulsive Behavior/ or Learning/
16. ((cogniti$ or arous$ or orientat$ or attention$ or concentrat$ or memor$ or recall or percept$ or think$ or sequenc$ or algorithm$ or judg?ment$ or awareness or problem solving or generali?ation or transfer or comprehension or learning) adj10 (disorder$ or declin$ or dysfunct$ or impair$ or deficit$ or abilit$ or problem$)).tw.

17. (dysexecutive syndrome$ or mental process$ or (concept adj5 formation) or impulsive behavio?r$ or executive function$).tw.
18. 13 or 14 or 15 or 16 or 17
19. Randomized Controlled Trials/ or random allocation/ or Controlled Clinical Trials/ or control groups/ or clinical trials/ or clinical trials, phase i/ or clinical trials, phase ii/ or clinical trials, phase iii/ or clinical trials, phase iv/
20. double-blind method/ or single-blind method/ or cross-over studies/ or Program Evaluation/ or meta-analysis/
21. randomized controlled trial.pt. or controlled clinical trial.pt. or clinical trial.pt. or meta analysis.pt.
22. random$.tw.
23. (controlled adj5 (trial$ or stud$)).tw.
24. (clinical$ adj5 trial$).tw.
25. ((control or treatment or experiment$ or intervention) adj5 (group$ or subject$ or patient$)).tw.
26. (quasi-random$ or quasi random$ or pseudo-random$ or pseudo random$).tw.
27. ((control or experiment$ or conservative) adj5 (treatment or therapy or procedure or manage$)).tw.
28. ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.
29. (coin adj5 (flip or flipped or toss$)).tw.
30. versus.tw.
31. (cross-over or cross over or crossover).tw.
32. (assign$ or alternate or allocat$ or counterbalance$ or multiple baseline).tw.
33. controls.tw.
34. (treatment$ adj6 order).tw.
35. (meta-analy$ or metaanaly$ or meta analy$ or systematic review or systematic overview).tw.
36. or/19-35
37. occupational therapy/
38. Rehabilitation/ or Rehabilitation, Vocational/
39. activities of daily living/ or self care/
40. automobile driving/ or exp transportation/
41. "Task performance and analysis"/ or Work simplification/
42. exp leisure activities/
43. Home care services/ or Home care services, hospital-based/
44. Recovery of function/
45. exp work/ or Human activities/
46. occupational therap$.tw.
47. ("activities of daily living" or ADL or EADL or IADL).tw.
48. rehabilitation.tw.
49. ((self or personal) adj5 (care or manage$)).tw.
50. (dressing or feeding or eating or toilet$ or bathing or mobil$ or driving or public transport or public transportation).tw.
51. exp self-help devices/
52. (assistive adj5 (device$ or technology)).tw.
53. or/37-52
54. 12 and 18 and 36 and 53
55. limit 54 to (humans and "all adult (19 plus years)")
56. apraxias/ or apraxia, ideomotor/ or neglect/ or exp dementia/ or exp Arm/ or exp Hand/ or exp Depressive Disorder/ or depression/ or exp Pharmaceutical Preparations/ or exp Drug Therapy/
57. (apraxi$ or dysprax$ or aphasi$ or dysphasi$ or dementia or alzheimer$).ti.
58. atrial.tw.
59. 56 or 57 or 58
60. 55 not 59
61. (dose$ or drug$).tw.
62. 60 not 61
63. Magnetic Resonance Imaging/ or Diffusion Magnetic Resonance Imaging/ or Imaging, Three-Dimensional/ or Diagnostic Imaging/ or Radionuclide Imaging/ or Magnetic Resonance Imaging, Cine/
64. 62 not 63
65. (MRI or fMRI).tw.
66. 64 not 65

WHAT'S NEW

Last assessed as up-to-date: 18 September 2006.

10 July 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 2, 2007

CONTRIBUTIONS OF AUTHORS

Tammy Hoffmann: conceiving, designing, and co-ordinating the review; advising on search strategies; screening search results; screening retrieved papers against inclusion criteria; appraising the quality of papers; extracting data from papers; managing and analysing the data for review; interpreting the data (providing methodological, clinical, and policy perspectives); and writing the review.

Sally Bennett: screening retrieved papers against inclusion criteria; appraising the quality of papers; extracting data from papers; managing and analysing the data for the review; interpreting the data (providing methodological, clinical, and policy perspectives); and writing the review.

Chia-Lin Koh: designing the review; designing search strategies; undertaking searches; screening search results; organising the retrieval of papers; screening retrieved papers against inclusion criteria; writing to authors of papers for additional information; providing additional data about papers; obtaining and screening data on unpublished studies; managing and analysing the data for review; interpreting the data (providing methodological, clinical, and policy perspectives); and writing the review.

Kryss McKenna: conceiving, designing, and co-ordinating the review; advising on search strategies; and screening search results.

DECLARATIONS OF INTEREST

None known