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## OCCUPATIONAL THERAPY FOR COGNITIVE IMPAIRMENT IN STROKE PATIENTS

### (Protocol)

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### BACKGROUND

A stroke is a clinically defined syndrome of rapidly developing symptoms or signs of focal loss of cerebral function with no apparent cause other than that of vascular origin. The syndrome varies in severity from recovery in a day to incomplete recovery, severe disability and death (Warlow 1996). Neurological symptoms can vary widely and can result in sensory-motor, cognitive (such as apraxia and agnosia) and psycho-social impairments. Especially the cognitive symptoms are important determinants for functional recovery (Hochstenbach 2000). In the Netherlands, approximately 170 of each 100,000 persons suffer from a stroke each year. Thirty-five percent of the patients are not able to perform self-care activities after one year (Limburg 2000).

The treatment of stroke often has a multi-disciplinary character. In the acute phase, the therapy is focused on prevention of medical complications. In the rehabilitation phase the aim is at decreasing the consequences of the illness for daily functioning and social participation. In addition, the aim is also to allow the individual and the family to come to terms with the loss of role within the family and within society (Moser 2000).

Occupational therapists are involved in providing cognitive rehabilitation to individuals with a stroke by retraining them in fulfilling self-care, work and leisure roles. In particular, they aim at facilitating task performance by improving relevant performing skills, by developing and teaching compensatory strategies to overcome lost performance skills or a combination of both strategies (Gillen 1998). Because cognitive functions play a major role in this process and because 63% of the stroke in- and outpatients treated in occupational therapy suffer from cognitive impairments (Driessen 1997) treatment of cognitive impairment is a main topic in occupational therapy. Neuropsychological assessment focuses on clarifying the nature and severity of cognitive impairments. Occupational therapy, on the other hand, aims assessment and treatment at the influence of impairments on the performance of daily living tasks. Training focuses on (re-) learning self care activities, leisure activities, and on the use of assistive devices (Driessen 1997). In addition, the occupational therapist educates and shares information with the family and primary care giver about the patient's ability to perform and about how to provide proper assistance (Tomlinson 1998). Although occupational therapy is considered to be an important part of the multi-disciplinary management of stroke, the efficacy of occupational therapy for cognitive impairment in stroke patients on functional performance and social participation has not been systematically reviewed before.

### OBJECTIVES

To examine whether occupational therapy interventions improve outcomes for stroke patients with cognitive impairments. The cognitive impairments are classified according to Lezak (Lezak 1995).

### CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

#### Types of studies

Studies with one of the following designs will be entered in the review:

- 1) Randomised controlled clinical trial (RCT): An experiment in which investigators randomly allocate eligible people into treatment and control groups. Cross-over trials will be considered as RCTs according to the Cochrane Collaboration Guidelines (Clarke 2000).
- 2) Controlled clinical trial (CCT): an experiment in which eligible people are in a non-randomised way allocated to the treatment and the control groups
- 3) Other than controlled designs (OD): patient series and pre-post studies. These designs are included because of the aim to state all available evidence and the experience that RCTs/CCTs are not widely evolved in OT research. ODs can only in a limited way contribute to the best evidence synthesis

#### Types of participants

Studies with adult patients with explicitly confirmed cognitive impairments and who fulfil a clinical definition of stroke will be included. The classification of cognitive impairments (Lezak 1995) anticipates three dimensions: cognitive functions, personality/emotional processes and executive functions. This review will focus on the impairments in the cognitive functions e.g. in sensory reception (such as hemianopia), in agnosia (visual

object and visual spatial agnosia, stereo agnosia), in thinking (such as abstracting, organizing and planning), in expressive functions (ideomotor apraxia, ideational apraxia) and in mental activities (such as attention and neglect). Studies with mixed group patients (i.e. some described as having a stroke with cognitive impairments and others not) will be excluded.

### Types of intervention

In stroke patients, occupational therapy can include a variety of interventions. In this review occupational therapy in cognitively impaired stroke patients will be operationalized into the following four interventions:

- 1) training of cognitive functions;
- 2) training of skills;
- 3) advice and instruction in the use of assistive devices; and
- 4) education of family and primary care givers.

All studies with interventions as specified above, that meet the description according to a group of four experienced occupational therapists and reviewer CHME (see: Methods of the review), are eligible for inclusion in this review.

### Types of outcome measures

Primary outcomes measured: studies that use one or more of the following outcome measures: primary ADL (such as Barthel Index (Mahoney 1965)) and Extended ADL (such as the Nottingham Extended ADL scale (Nouri 1987)) and social participation (such as the London Handicap Scale (Harwood 1994)).

Secondary outcomes: studies that measure the treated cognitive functions with reliable and valid neuropsychological tests. Lezak (Lezak 1995) gives a broad description of assessment instruments for each type of impairment and will be used as reference. These secondary measures are regarded as process measures, i.e. measures considered to be indicators of a successful treatment. Such process measures can only contribute in a limited way to the best evidence synthesis.

### SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

This review will draw on the search strategy for the Stroke Groups as a whole. Relevant trials will be identified in the specialised Trials Register (see review group details for more information). The search strategy is divided into three sections:

- 1) Stroke: a shortened form of the master strategy of the Stroke Group suitable for rehabilitation trials recommended by the Trials Search Coordinator of the Cochrane Stroke Group.
- 2) Occupational therapy
- 3) Cognitive impairment

The strategy for MEDLINE (Ovid) 1966 to date

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. (hemipleg\$ or hemipar\$ or post-stroke or poststroke).tw.
14. 1 or 2 or 3 or 4 or 5 or 8 or 11 or 12 or 13
15. Occupational therapy/
16. activities of daily living/
17. exp rehabilitation, vocational/ or Rehabilitation/ or Self care/
18. automobile driving/ or exp transportation/
19. "Task performance and analysis"/ or "Time and motion studies"/ or Work simplification/
20. exp leisure activities/
21. Home care services/ or Home care services, hospital-based/
22. Recovery of function/
23. exp work/ or Human activities/
24. Social adjustment/ or Social behavior/ or Social facilitation/
25. Social environment/ or Social support/
26. exp Counseling/
27. Goals/
28. occupational therap\$.tw.
29. (activities of daily living or adl\$ or eadl\$).tw.
30. rehabilitation.tw.
31. ((self or personal) adj5 (care or manage\$)).tw.
32. (dressing or feeding or eating or toilet\$ or bathing or mobil\$ or driving or public transport\$).tw.

33. ((daily or domestic or house or home) adj5 (activit\$ or task\$ or skill\$ or chore\$)).tw.
34. leisure.tw.
35. (recover\$ adj5 function\$).tw.
36. (social adj5 (activit\$ or function\$ or support\$ or skill\$ or adjust\$ or behavior\$ or facilitat\$)).tw.
37. (counsel?ing or goal\$ or work or employment).tw.
38. exp self-help devices/
39. (assistive adj5 (device\$ or technology)).tw.
40. exp splints/ or (splint\$ or sling\$).tw.
41. or/15-40
42. exp cognition disorders/ or exp cognition/
43. exp perceptual disorders/ or exp perception/
44. exp memory disorders/ or exp memory/
45. sensation disorders/ or sensation/
46. exp confusion/ or attention/ or exp apraxias/
47. ((cognit\$ or percept\$ or memory or sensation or visuo?spatial or visuo?perceptual or attention\$) adj5 (disorder\$ or decline or dysfunction or impair\$ or deficit\$ or ability)).tw.
48. Neurobehavioral Manifestations/
49. (agnosia or amnesia or apraxia or dyspraxia or confusion or inattention or hemi-inattention or hemi-inattention or visual recognition or concentration or spatial awareness).tw.
50. (hemineglect or hemi-neglect).tw.
51. ((unilateral or spatial) adj5 neglect).tw.
52. or/42-51
53. 14 and 41 and 52
54. limit 53 to human

Additionally the following databases will be searched:

- a) CINAHL (1982 to- )
- b) EMBASE (1988 to- )
- c) SCISEARCH (1974 to -)
- d) AMED (1985 to- )
- e) Cochrane Controlled Trials Register
- f) The databases of the libraries of medical and rehabilitation literature of the Dutch National Institute Allied Health Professions (NPI) and of the Netherlands Institute for Health Services Research (Nivel)
- g) The database of the Rehabilitation and Related Therapies (RRT) Field of the Cochrane Collaboration

The search strategy will be adapted by an experienced medical librarian to make it applicable for the other databases.

- 1) The same databases will be searched to identify reviews about the effectiveness of occupational therapy
- 2) The reference lists of the identified studies and reviews will be scanned for relevant studies.
- 3) Authors of papers reporting trials about the effectiveness of occupational therapy in cognitive impaired stroke patients will be contacted by mail and asked for any (un)published studies relevant for this systematic review. A list of trials identified so far will be enclosed.
- 4) Authors of abstracts will be asked for a full written report.

## METHODS OF THE REVIEW

Selection for inclusion in the review, assessment of the methodological quality, and data extraction will be performed in three separate steps. Three reviewers (EMJS, EHCC, CHME) will independently take part in these procedures. Prior to all steps, assessment procedures are tested in a sample of three articles by two reviewers. A standard form for each step will be made.

### Selection for inclusion

Because of the broad search strategy we expect to find a large number of non relevant articles. The procedure for inclusion of the studies will be based on the recommendations by Van Tulder et al (Van Tulder 1997): The first selection, based on titles and abstracts, will be independently performed by two reviewers (EMJS and CHME). This first selection can result in probable inclusion of the study, exclusion of the study, or can be indecisive. The second step for inclusion (definite include or exclude) will be independently done by two reviewers (EMJS and CHME), using full reports and considering the criteria stated above. Disagreements regarding inclusion status will be resolved by discussion. If no consensus is met, a third reviewer (EHCC) decides. Finally, a group of four occupational therapists and reviewer CHME will assess the criteria for 'type of intervention' and, if appropriate, classify the type of intervention into one of the four different interventions or combinations of interventions. Consensus will be reached by discussion.

### Assessment of methodological quality

The variety in study designs to be included in this systematic review necessitates the use of different quality assessment tools. The methodological quality of RCTs and CCTs will be rated by a list recommended by Van Tulder (Van Tulder 1997). The list, containing specified criteria proposed by Jadad (Jadad 1996) and Verhagen et al (Verhagen 1998), consists of 11 criteria for internal validity, 6 descriptive criteria and 2 statistical criteria (Appendix 2). One modification was made in the specification of the criterion 'eligibility': the 'condition of interest' (the impairment or disability that indicated referral to occupational therapy) is added as an eligibility criterion, as proposed by Wells (Wells 2000). All criteria are scored as yes, no, or unclear. Equal weight will be

applied to all items. Studies are considered to be of 'high quality' if at least 6 criteria for internal validity, 3 descriptive criteria and one statistical criterion are scored positively.

The methodological quality of ODs will be rated using an adapted version of the Van Tulder list. Some items (concerning randomisation, similarity of patient groups, blinding of care-provider, blinding of patient) are considered inapplicable to ODs and are removed from the list. Some items are reformulated to make the item applicable to one patient group (for instance: "were co-interventions avoided or comparable?" is reformulated into "were co-interventions avoided?") or to make the item applicable for the design of the study (for instance: "was the outcome assessor blinded to the intervention" is reformulated into: "was the care-provider not involved in the outcome assessment?") The final list of criteria used in OD consists of 7 criteria for internal validity, 4 descriptive criteria and 2 statistical criteria (Appendix 1). All criteria are scored as yes, no, or unclear. Equal weight will be applied to all items. Studies are considered to be of 'sufficient quality' if at least 4 out of 7 criteria for internal validity, 2 descriptive criteria and one statistical criteria are scored positively. Of course, the distinction between ODs with a sufficient or non-sufficient quality is a relative one: the internal validity of ODs is weaker than RCTs/CCTs internal validity.

The methodological quality of the included trials will be independently assessed by two reviewers (EMJS, EHCC). Disagreements will be resolved by discussion. If no consensus is met, a third reviewer (CHME) will decide.

#### APPENDIX 1: CRITERIA OF METHODOLOGICAL QUALITY

##### RCTs, CCTs

###### Patient selection

- a) were the eligibility criteria specified?
- b) treatment allocation:
  - 1) was a method of randomisation performed?
  - 2) was the treatment allocation concealed?
- c) were the groups similar at baseline regarding the most important prognostic indicators?

###### Interventions

- d) were the index and control interventions explicitly described?
- e) was the care provider blinded for the intervention?
- f) were co-interventions avoided or comparable?
- g) was the compliance acceptable in all groups?
- h) was the patient blinded to the intervention?

###### Outcome measurement

- i) Was the outcome assessor blinded to the interventions?
- j) were the outcome measures relevant?
- k) were adverse effects described?
- l) was the withdrawal/drop out rate described and acceptable?
- m) timing follow-up measurements:
  - 1) was a short-term follow-up measurement performed?
  - 2) was a long-term follow-up measurement performed?
- n) was the timing of the outcome assessment in both groups comparable?

###### Statistics

- o) was the sample size for each group described?
- p) did the analysis include an intention-to-treat analysis?
- q) were point estimates and measures of variability presented for the primary outcome measures?

##### OD

###### Patient selection

- a) were the eligibility criteria specified?

###### Interventions

- d) was the intervention explicitly described?
- f) were cointerventions avoided?
- g) was the compliance acceptable?

###### Outcome measurement

- i) Was the outcome assessor not involved in the treatment?
- j) were the outcome measures relevant?
- k) were adverse effects described?
- l) was the withdrawal/drop out rate described and acceptable?
- m) timing follow-up measurements:
  - a) was a short-term follow-up measurement performed?
  - b) was a long-term follow-up measurement performed?
- n) was the timing of the outcome assessment in all patients comparable?

###### Statistics

- o) was the sample size of the patient group described?

p) did the analysis include an intention-to-treat analysis?

q) were point estimates and measures of variability presented for the primary outcome measures?

Internal validity: b, e, f, g, h, i, j, l, n, p; descriptive criteria: a, c, d, k, m; statistical criteria: o, q.

Data extraction.

The following information will be systematically extracted by EMJS and EHCC independently:

1. Study characteristics: number of participating patients, specified criteria for diagnosis of stroke, in and exclusion criteria, type of experimental and control interventions, co-interventions, features of interventions (duration, frequency, trial setting), number of drop-outs.
2. Patient characteristics: sex, age, time since onset of stroke, disease severity, type of cognitive impairment
3. Outcome and process measures assessed at base line, immediately after finishing the intervention, within six months follow up and after six or more months follow up

Data synthesis.

For continuous variables standardized mean difference with corresponding 95% confidence interval will be computed if possible. In cases of missing data standard deviations will be computed if possible from available data. For dichotomous variables: (Peto) odds ratios with corresponding 95% confidence interval will be computed.

Analysis of the results.

In this review four different intervention categories are anticipated:

- 1) training of cognitive functions;
- 2) training of skills;
- 3) advice and instruction in the use of assistive devices; and
- 4) education of family and primary care giver.

Other categories can occur when combination of interventions are evaluated. Analyses will be performed separately for each intervention category. In cross-over trials without a wash-out period between interventions, data after the 'cross-over' would not be further analysed. The primary analysis will focus on comparisons of an occupational therapy intervention with a 'no treatment' control group. However, if studies compare the effect of more than the two intervention groups, two reviewers (EMJS, CHME) will decide by consensus, how these comparisons will be classified. In particular, if two interventions are compared, the predominant contrast needs to be the occupational therapy treatment provided.

For each intervention category a decision will be made whether to apply a quantitative (e.g. meta-analysis) or a qualitative, e.g. a best evidence synthesis approach for the analysis of the data. The qualitative approach will be considered appropriate if included studies within one intervention category are clinically diverse and/or statistically heterogeneous. Clinical diversity among studies will be assessed by two reviewers (EMJS, CHME) taking into account the classification of patients (severity of the disease), interventions (duration, frequency and setting) and outcome measures (dimensions of outcome measures). Disagreement will be resolved by discussion. Statistical heterogeneity will be determined by the sign test. If a meta-analysis is appropriate the pooled standardized mean difference will be computed using a random effects model. In cases of too much diversity and/or heterogeneity a best evidence synthesis will be applied. The best-evidence synthesis is based upon the one proposed by Van Tulder (Van Tulder 2001) and adapted for the purpose of this review. If the amount of studies that show evidence is less than 50% of the total number of found studies within the same category of methodological quality and study design (RCT, CCT or OD) we will state no evidence.

Strong evidence:

provided by consistent, statistically significant findings in outcome measures in at least two high quality RCTs

Moderate evidence:

provided by consistent, statistically significant findings in outcome measures in at least one high quality RCT and at least one low quality RCT or high quality CCT.

Limited evidence:

provided by statistically significant findings in outcome measures in at least one high quality RCT, or provided by consistent, statistically significant findings in outcome measures in at least two high quality CCTs (in the absence of high quality RCTs).

Indicative findings:

provided by statistically significant findings in outcome and/or process measures in at least one high quality CCTs or low quality RCTs (in the absence of high quality RCTs), or provided by consistent, statistically significant findings in outcome and/or process measures in at least two high quality ODs.

No evidence:

in case results of eligible studies do not meet the criteria for one of the above stated levels of evidence, or in case of conflicting results among RCTs and CCTs, or in case of no eligible studies.

Sensitivity analyses will be performed on the separate methodological quality items: randomisation, allocation concealment, loss to follow up and blinding of outcome assessor. Another sensitivity analysis will be performed by re-analysing the results excluding all ODs.

#### **POTENTIAL CONFLICT OF INTEREST**

None known

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## COVER SHEET

Title	<b>Occupational therapy for cognitive impairment in stroke patients</b>
Reviewer(s)	<b>Steultjens EMJ, Dekker J, Bouter LM, van de Nes JCM, Cup EHC, van den Ende CHM</b>
Contribution of reviewer(s)	<b>EMJ Steultjens, researcher on this project, is the author of the protocol. J Dekker, LM Bouter and Mrs CHM van den Ende are her supervisors and discussed all choices made on methodological issues. EMJS and CHME took part in the inclusion procedure. Mrs EHC Cup, occupational therapist, discussed all the choices made on occupational therapy issues and took part with EMJS and CHME in the rating of the methodological quality. J van de Nes is a neurologist who checked the protocol on relevant issues from a medical perspective. All authors made comments on several versions of the protocol and approved the final version.</b>
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## SOURCES OF SUPPORT

### Extramural sources of support

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- No sources of support supplied

## ADDITIONAL TABLES

Additional tables are not available for this protocol