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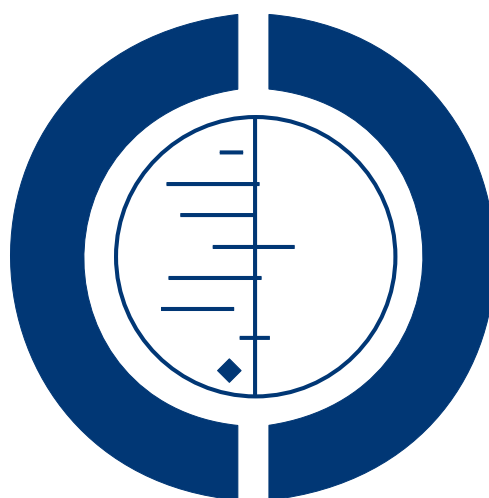
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Rehabilitation for improving automobile driving after stroke (Protocol)

George S, Crotty M, Gelinas I, Devos H



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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
BACKGROUND	1
OBJECTIVES	2
METHODS	2
REFERENCES	4
APPENDICES	6
HISTORY	8
CONTRIBUTIONS OF AUTHORS	8
DECLARATIONS OF INTEREST	8

[Intervention Protocol]

Rehabilitation for improving automobile driving after stroke

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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 any intervention, with the specific aim of maximising driving skills or with an outcome of assessed driving skills, improves the driving performance for patients following stroke.

BACKGROUND

Description of the condition

Stroke is a major cause of disability around the world (CDCP 2000; Mathers 2001). One impact of stroke is on the ability to drive an automobile. Stroke can prevent driving completely or increase the risk of crashing whilst driving (Sagberg 2006). Research indicates that cessation of driving is associated with depression (Legh-Smith 1986) and social isolation (Lister 1999). Driving is believed to make an important contribution to quality of life, and transport plays a critical role in supporting healthy ageing (OECD 2001).

In recent decades there has been an increased survival rate and longevity following stroke, which has resulted in an increase in the number of people with perceptual and cognitive impairments who wish to resume driving (Korner-Bitensky 2006). People with stroke have a range of deficits that may influence their driving ability, including reduced visual fields (Gilhotra 2002), visual scan-

ning, attention, information processing speed, and visuospatial skills (Fisk 2002a; Fisk 2002b; Galski 1997; Lings 1991; Simms 1985; Sundet 1995; Szyk 1993). These deficits translate into a reduction in on-road driving abilities, including difficulty with observation, and delayed planning of vehicle manoeuvres (Lundqvist 2000).

In the post-acute rehabilitation phase, 30% to 50% of stroke survivors return to driving after stroke (Fisk 1997; Legh-Smith 1986; Sagberg 2006). Factors which positively influence the likelihood of returning to driving include being younger (Legh-Smith 1986), having a lower level of disability (Fisk 1997; Legh-Smith 1986), having fewer attention deficits (Fisk 2002b), and being provided with advice and assessment related to driving (Fisk 1997).

Description of the intervention

Two approaches to rehabilitation for driving following stroke used by clinicians (Mazer 2004) include: retraining the underlying skill deficits through training of perceptual, cognitive, physical or visual

skills; and a contextual approach using driving simulators, on-road driving in the form of lessons, and cognitive tasks with a context-specific driving focus. The retraining of underlying skill deficits takes a number of forms, including the use of paper and pencil tasks; off-the-shelf activities and cognitive games; and devices such as specialised computer programs and other apparatus designed for the retraining of a specific skill set. The approach of the retraining of underlying skill deficits assumes that retrained cognitive and perceptual skills will transfer to functional performance in on-road driving skills. Despite there being a weak relationship between cognitive deficits and actual driving performance (Bouillon 2006), this is a common approach in driving rehabilitation. The contextual approach takes the form of driving lessons, or driving simulators that range from replica cars to driving-specific computerised programs, or cognitive skills with a context-specific driving focus, such as route finding, give-way scenarios, and matching signs with driving situations. The contextual approach of retraining aims to improve the skill set of the drivers themselves.

Why it is important to do this review

To our knowledge, there is no systematic review that has specifically examined the effectiveness of rehabilitation approaches to retrain driving skills following stroke. There is limited information to guide policy and practice on interventions related to driving for people with stroke (Mazer 2004). Other systematic reviews relevant to this review have been performed in relation to cognitive rehabilitation for attention deficits following stroke (Lincoln 2008), occupational therapy for patients with problems in activities of daily living after stroke (Legg 2008), and occupational therapy for cognitive impairment in stroke patients (Hoffmann 2008). These reviews cover relevant areas, such as the effectiveness of the remedial and functional approach in therapy for stroke. They differ from our proposed review in that the interventions themselves are not specifically aimed at improving driving skills. Additionally, the primary outcomes are measures of impairment or functional outcomes that relate to the ability to perform a range of daily tasks, not driving.

OBJECTIVES

This review aims to determine whether any intervention, with the specific aim of maximising driving skills or with an outcome of assessed driving skills, improves the driving performance for patients following stroke.

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 trials that used a quasi-randomised technique (for example, allocated by date of birth), and studies that compare rehabilitation interventions with either no intervention or an alternative intervention. We will consider cross-over trials as RCTs according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008).

Types of participants

All participants will be confirmed to have a stroke, by neurological examination or computerised tomography (CT) scan, or both, and be aged 16 years or over. We will exclude trials if data cannot be provided separately for participants with stroke in the published article, or cannot be obtained from the authors of the trial.

Types of interventions

We will include all rehabilitation interventions. These will include: training with driving lessons; driving simulators; training on devices aimed at improving skills related to driving such as attention, speed of processing, co-ordination; and driving-related cognitive tasks such as route finding.

Types of outcome measures

Primary outcomes

The primary outcome measure will be performance in an on-road assessment. Examples of on-road assessment include a standardised assessment, which includes both a closed course and in-traffic section that grades in complexity from low to moderate traffic and progresses to areas with higher traffic (Akinwuntan 2003; Devos 2009). Thirteen items are evaluated on the road-test, which are scored using predefined criteria on a four-point scale. Performance will be rated as categorical.

Secondary outcomes

We will consider assessments of visual attention, reaction time, visual scanning, self-efficacy, executive reasoning ability, and tests of visual perception, functional measures, and death as secondary outcome measures. Examples of secondary outcome assessments include: the Useful Field of View assessment (Visual Awareness Inc. 2002), Adelaide Driving Self-Efficacy Scale (George 2007), Trail making test Parts A and B (Reitan 1986), and component tests from the Stroke Drivers Screening Assessment (Lincoln 2004).

Search methods for identification of studies

See the 'Specialised register' section in the [Cochrane Stroke Group](#) module.

Electronic searches

We will search the Cochrane Stroke 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 (1950 to present) ([Appendix 1](#)), EMBASE (1980 to present), CINAHL (1982 to present) AMED (1985 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 regarding the search strategies for each database which will include the following areas: stroke, automobile driving, and a trials filter. There will be no language restriction and we will obtain translations for potentially relevant trials published in languages other than English.

Searching other resources

To identify further published, unpublished, and ongoing trials, we will:

1. search the following ongoing trials registers: Current Controlled Trials (www.controlled-trials.com), National Institute of Health Clinical Trials Database (<http://www.clinicaltrials.gov/>), Stroke Trials Registry (www.strokecenter.org/trials/);
2. use the Cited Reference Search within Science Citation Index (SCI) and Social Science Citation Index (SSCI) to track relevant references;
3. scan the reference lists of all identified studies and reviews;
4. contact key researchers and authors in the area, including governmental licensing authorities and engineering departments;
5. handsearch all occupational therapy, traffic and stroke journals, including supplements and conference abstracts that are not indexed in the databases listed above, and have not been searched on behalf of The Cochrane Collaboration to date. 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);

- *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).

Data collection and analysis

Selection of studies

Two review authors (SG and IG or HD) will review the titles identified from the database searches. These same two review authors will assess the trials based on 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. We will obtain the full text of those studies in the categories of included and unsure, and two review authors (SG and IG or HD) will independently complete the second study selection to make a final decision on each trial's inclusion or exclusion. A third review author (MC) will moderate any disagreements.

Data extraction and management

Two review authors (IG and SG or HD) will independently record information using a pre-designed data extraction form. We will use the same criteria as those outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2008](#)) to evaluate each trial. We will pilot the form on five papers and will make relevant changes to it in response to the findings of the pilot. We will then review the remaining studies using the adjusted extraction form. We will include the following information in the data extraction form:

1. citation details of the study;
 2. the trial setting (e.g. hospital, community, outpatients);
 3. inclusion and exclusion criteria;
 4. participant details: descriptive characteristics including age, sex, location of stroke, type of stroke, time since onset of stroke, functional abilities of sample, years of driving experience, driving exposure prior to stroke, sample size and number of drop outs;
 5. methodological quality: according to The Cochrane Collaboration's tool for assessing risk ([Appendix 2](#));
 6. interventions: description of the intervention, duration and dosage, comparison intervention;
 7. outcome measures: primary and secondary outcome measures and when they were administered (i.e. pre-training, post-training and follow up), adverse events.
- We will contact study authors for clarification when necessary. A third review author (MC) will resolve disagreements.

Assessment of risk of bias in included studies

Two review authors will independently use The Cochrane Collaboration's tool for assessing risk of bias to assess the methodological quality of studies included in the review (Appendix 2). The tool includes assessment of randomisation (sequence generation and allocation concealment), blinding, completeness of outcome data, selection of outcomes reported, and other sources of bias including intention-to-treat analysis.

Measures of treatment effect

We will classify outcome measures in terms of the area they assess, for example on-road ability, visual attention, reaction time, visual scanning, executive reasoning ability and tests of visual perception. Two independent reviewing authors will be involved in classifying outcome measures.

Unit of analysis issues

The unit of randomisation in these trials is the individual patient.

Dealing with missing data

We will perform intention-to-treat analysis if possible to include all patients randomised. Where drop-outs have been clearly identified for an outcome assessment, we will use the actual denominator of the patients contributing data. We will contact study authors to obtain any missing data.

Assessment of heterogeneity

We will pool all results of the trials to present an overall estimate of the treatment effect using a fixed-effect model. We will assess heterogeneity by the visual inspection of the forest plot (analysis) combined with the I^2 statistic (Higgins 2003). We will perform

subgroup analyses (for example, different stroke severity, varying treatment dosage, time since stroke that intervention is commenced), and the impact on heterogeneity described to see if homogenous results can be generated. Alternatively, we will use a random-effects model.

Assessment of reporting biases

We will assess publication bias by preparing a funnel plot if sufficient data are available. We will investigate selective outcome reporting through the comparison of the methods sections of papers with the results reported.

Data synthesis

For continuous data, since trials often use different rating scales to assess the same outcome, we will calculate two types of estimates for measure of treatment difference. We will use the mean difference (MD) when the same test is used in the pooled trials, and the standardised mean difference (SMD) when different tests are used. In both cases, we will calculate the corresponding 95% confidence interval (CI). We will calculate relative risks with 95% CI for dichotomous outcomes.

Subgroup analysis and investigation of heterogeneity

We will perform subgroup analyses to determine whether outcomes vary according to the type and severity of stroke, time since onset of stroke, and dosage of intervention.

Sensitivity analysis

We will perform sensitivity analyses to examine the impact of risk of bias in included studies using the Risk of bias assessment tool (Appendix 2).

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* Indicates the major publication for the study

APPENDICES

Appendix I. Medline search strategy

We will use the following search strategy for MEDLINE and modify it for the other databases.

MEDLINE (Ovid)

1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or brain injuries/ or brain injuries, chronic/
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 parietic or brain injur\$).tw.
7. or/1-6
8. automobile driving/ or automobiles/ or motor vehicles/
9. automobile driver examination/ or accidents, traffic/
10. (driver or drivers or driving or motor vehicle\$ or automobile\$ or motorist\$ or traffic accident\$ or car accident\$ or on-road assessment\$).tw.
11. ((car or cars or vehicle\$) adj5 drive).tw.
12. or/8-11
13. 7 and 12
14. Randomized Controlled Trials as Topic/
15. random allocation/
16. Controlled Clinical Trials as Topic/
17. control groups/
18. clinical trials as topic/
19. double-blind method/
20. single-blind method/
21. cross-over studies/
22. Multicenter Studies as Topic/
23. Therapies, Investigational/
24. Research Design/
25. Program Evaluation/
26. evaluation studies as topic/
27. randomized controlled trial.pt.
28. controlled clinical trial.pt.
29. (clinical trial).pt.
30. multicenter study.pt.
31. (evaluation studies or comparative study).pt.
32. random\$.tw.
33. (controlled adj5 (trial\$ or stud\$)).tw.
34. (clinical\$ adj5 trial\$).tw.
35. ((control or treatment or experiment\$ or intervention) adj5 (group\$ or subject\$ or patient\$)).tw.
36. (quasi-random\$ or quasi random\$ or pseudo-random\$ or pseudo random\$).tw.
37. ((multicenter or multicentre or therapeutic) adj5 (trial\$ or stud\$)).tw.
38. ((control or experiment\$ or conservative) adj5 (treatment or therapy or procedure or manage\$)).tw.
39. ((singl\$ or doubl\$ or tripl\$ or trebl\$) adj5 (blind\$ or mask\$)).tw.
40. (coin adj5 (flip or flipped or toss\$)).tw.

41. latin square.tw.
 42. versus.tw.
 43. (cross-over or cross over or crossover).tw.
 44. sham.tw.
 45. (assign\$ or alternate or allocat\$ or counterbalance\$ or multiple baseline).tw.
 46. controls.tw.
 47. (treatment\$ adj6 order).tw.
 48. or/14-47
 49. 13 and 48

Appendix 2. Risk of Bias Assessment Tool

Table 8.5.a: The Cochrane Collaboration's tool for assessing risk of bias

Domain	Description	Review authors' judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Was the allocation sequence adequately generated?
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors <i>Assessments should be made for each main outcome (or class of outcomes)</i>	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data <i>Assessments should be made for each main outcome (or class of outcomes)</i>	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors	Were incomplete outcome data adequately addressed?
Selective outcome reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found	Are reports of the study free of suggestion of selective outcome reporting?

(Continued)

Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry	Was the study apparently free of other problems that could put it at a high risk of bias?
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HISTORY

Protocol first published: Issue 2, 2010

CONTRIBUTIONS OF AUTHORS

Stacey George (guarantor of the review): conceiving, designing, and co-ordinating the review; advising on search strategies; screening search results; screening retrieved papers against inclusion criteria; appraising the quality of the 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.

Maria Crotty: conceiving, designing, and co-ordinating the review; advising on search strategies; searching for trials; interpreting the data (providing methodological, clinical, and policy perspectives); and writing the review.

Isabelle Gelinas: selecting the trials; extracting data; managing and analysing the data for review; interpreting the data (providing methodological, clinical and policy perspectives); and writing the review.

Hanos Devos: selecting the trials; extracting data; managing and analysing the data for review; interpreting the data (providing methodological, clinical, and policy perspectives); and writing the review.

DECLARATIONS OF INTEREST

The authors have been involved in studies that will be included in the review. Such studies will be appraised by other independent review authors.