

Systematic Review Protocol

Title/Topic

A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke.

Centre conducting review

The Scottish Centre for Evidence Based Care of Older People, Glasgow, Scotland: a Collaborating Centre of the Joanna Briggs Institute

Primary reviewer/contact

Ms Maggie Lawrence
Research Fellow/Training and Reviews Co-ordinator
K413, Buchanan House
School of Nursing, Midwifery and Community Health
Glasgow Caledonian University
Glasgow, G4 0BA, Scotland, UK
E.mail: Margaret.Lawrence@gcal.ac.uk
Tel. +44 (0) 141 331 8863

Secondary reviewer

Dr Susan Kerr
Reader
K403, Buchanan House
School of Nursing, Midwifery and Community Health
Glasgow Caledonian University
Glasgow, G4 0BA, Scotland, UK

Associate reviewer

Ms Caroline McVey
K417, Buchanan House
School of Nursing, Midwifery and Community Health
Glasgow Caledonian University
Glasgow, G4 0BA, Scotland, UK

Commencement date

20.03.09

Expected Completion date

31.12.09

Background

Each year, approximately 15 million people worldwide have a stroke; of these, 5 million die and another 5 million are chronically disabled, resulting in considerable burden for individuals, families, wider communities and government exchequers^{1, 2}. In 2002, ischaemic heart disease and stroke together accounted for 36% of mortality in the developed world, with stroke being the second highest cause of death and fourth leading cause of disability among adults^{3, 4}. In the United Kingdom, the incidence is high and stroke is the most common cause of disability in the community-dwelling adult population¹; in Scotland, there are approximately 13,000 cases per year⁵. Major modifiable risk factors for stroke include; hypertension, abnormal blood lipids, tobacco use, obesity, unhealthy diet and physical inactivity. Other significant modifiable risk factors include alcohol use, and psychosocial stress¹.

Stroke recurs in approximately 25% of patients during the first 5 years post-stroke; recurrence may result in death, increased disability or institutionalisation^{6, 7}. Risk factors for recurrence are the same as those for first-ever stroke^{8, 9}. Improvements in the control of high blood pressure, the increase in the use of statins and a reduction in the use of tobacco have resulted in a decline in the incidence of stroke in many developed countries, including Scotland. However, the incidence of stroke is still high and the prevalence is rising due to the ageing demographic of the global population^{1, 10}. Projections of mortality and burden of disease indicate that in 2030 stroke is likely to remain the second highest cause of death worldwide¹¹. It is important therefore, that effective health promotion strategies and interventions are implemented, including those designed to address the modifiable lifestyle risk factors for stroke and recurrent stroke i.e. tobacco use, alcohol consumption, diet and physical activity¹².

To date, the focus of primary prevention research and reviews has been on pharmacological and lifestyle interventions and health promotion campaigns, which have targeted the general population or high-risk groups¹³. However, despite the fact that international and national evidence-based guidelines support the need for early instigation of secondary prevention measures, including surgery, pharmacotherapy and lifestyle interventions^{14, 15}, a scoping exercise suggests that, to date, no systematic review of the literature has been undertaken to assess the effectiveness of lifestyle interventions following stroke. This systematic review will therefore seek to identify what evidence is available and to determine what is known about the effectiveness of lifestyle interventions designed to prevent stroke recurrence. The information gathered will be used to inform the development and testing of future family-centred, secondary prevention, lifestyle interventions.

Objectives

This systematic review seeks to establish the effectiveness of secondary prevention behavioural interventions, which address one or more modifiable lifestyle risk factors for recurrent stroke.

More specifically, the objectives are:

1. to identify secondary prevention behavioural interventions which address one or more modifiable lifestyle risk factors for recurrent stroke i.e. tobacco, alcohol, diet, physical activity
2. to determine the effectiveness of identified interventions in improving behavioural, physiological, psychological and learning outcomes.

Criteria for considering studies for this review

Types of studies

The review will consider any randomised controlled trials (RCTs); in the absence of RCTs other research designs, such as non-randomised controlled trials, before and after studies, case control studies and cohort studies will be considered for inclusion to enable the identification of current best evidence regarding the effectiveness of secondary prevention behavioural interventions which address modifiable lifestyle risk factors for recurrent stroke.

Types of participants

The review will consider studies that include adults (aged ≥ 18 years) who have had a stroke and/or minor stroke/transient ischaemic attack (TIA) and studies of mixed populations where the stroke data can be extracted. A broad definition of stroke has been adopted which includes ischaemic stroke, haemorrhagic stroke, subarachnoid haemorrhage and TIA (WHO, 2007). The review will also consider studies that include adults with vascular and other co-morbidities. However, studies that include participants with impaired cognition will be excluded as this patient group have distinct needs in terms of behavioural interventions.

Types of interventions/Phenomena of Interest

The review will consider studies that evaluate educational/health promotion interventions, brief interventions and other behavioural interventions, designed to address the prevention of recurrent stroke.

Types of outcome measures/anticipated outcomes

The review will consider studies that include the following primary and secondary outcome measures in relation to secondary prevention lifestyle interventions following stroke.

Primary outcome measures

Lifestyle: behaviour change in terms of tobacco use, alcohol consumption, diet or physical activity

Physiological outcomes: blood pressure, cotinine levels, carbon monoxide (CO) monitoring blood sugar, blood lipids, weight, Body Mass Index (BMI), waist circumference, exercise tolerance, respiratory functioning, mean corpuscular volume (MCV), gamma-glutamyl transferase (GGT)

Secondary outcome measures

Psychological outcomes: wellbeing; life satisfaction; Quality of Life; self-rated health

Learning outcomes: knowledge of signs and symptoms and appropriate response; knowledge of risk factors for stroke; health-related attitudes; beliefs

Stroke recurrence: the incidence of recurrent stroke and other vascular events amongst the study population.

Search strategy for identification of studies

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be used in this review. An initial scoping search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies.

Databases to be searched

MEDLINE

All EMB Reviews

PsycINFO 1967 - 2009

British Nursing Index and Archive 1985 - 2009

CINAHL

Cochrane Stroke Group Trials Register

Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue)

EMBASE (1980 to present)

AMED (1985 to present)

ASSIA

Grey literature:

Dissertation abstracts

Conference Proceedings

Mednar

Initial keywords

Stroke/Cerebrovascular accident
Transient ischaemic attack/ Minor stroke
Health promotion/ Secondary prevention
Alcohol/ethanol
Tobacco
Smoking/cessation
Diet
Healthy eating
Exercise
Physical activity

Delimiters

Dates (currency): no date limit will be set.

Language: no language limit will be set, as members of the Collaborating Centre are able to translate papers written in a range of languages.

Bibliographic management

We will use RefWorks to store and manage the results of the electronic database searches.

Methods of the review

All identified material will be screened for relevance using broad inclusion criteria i.e. 'stroke' and one or more of the four lifestyle behaviours that form the focus of our review i.e. tobacco use, alcohol consumption, diet and physical activity. Where there is insufficient evidence in the title and abstract to make a decision, full-text papers will be retrieved.

All relevant papers will then be screened according to four narrow inclusion criteria relating to study design, population, intervention and outcomes, as described above.

Critical Appraisal

Quantitative papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I), and any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data extraction

Quantitative data will be extracted from papers included in the review using the standardised data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives (Appendix III).

Data synthesis

Quantitative papers will, where possible be pooled in statistical meta-analysis using the JBI-MAStARI. All results will be subject to double data entry. Odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed using the standard Chi-square. Where statistical pooling is not possible the findings will be presented in narrative form.

Acknowledgements

Queen's Nursing Institute, Scotland, for funding the Lisbeth Hockey Research Training Fellowship 2008 - 2010 (Associate Reviewer funded through this source).

Potential conflicts of interest

None

References

1. World Health Organisation (WHO). World Health Report. 2002 Available <http://www.who.int/whr/2002/en/> [accessed 15th May 2009]
2. Mackay J, Mansah, G. The atlas of heart disease and stroke. Geneva: World Health Organization, 2004.
3. Mathers CD, Lopez AD, Murray CJL. The Burden of Disease and Mortality by Condition: Data, Methods, and Results for 2001. In: Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJL, (Eds.). Global Burden of Disease and Risk Factors: pp. 45-93. New York: Oxford University Press, 2006.
4. Lopez AD, Mathers CD, Ezatti M, Jamieson DT, Murray DJL. Global Burden of Disease and Risk Factors. New York/Washington: New York: Oxford University Press, 2006
5. Scottish Health Statistics. Table IS1:1996-2005. 2006. Available: <http://www.isdscotland.org/> [accessed 11.12.06]
6. Redfern J, McKeivitt C, Wolfe C.. Risk management after stroke: the limits of a patient-centred approach. *Health, Risk & Society*. 2006; 8(2):123-141.
7. Hankey G, Spiesser J, Hakimi Z, Carita P, Gabriel, S. Time frame and predictors of recovery from disability following recurrent ischemic stroke. *Neurology* 2007; 68(3): 202-205.
8. Hankey G. Stroke: Your questions answered. Edinburgh: Churchill-Livingstone, 2002.
9. Chest Heart and Stroke Scotland (CHSS). Reducing the risk of stroke. [Patient Information Booklet, Stroke Series SS3]. Edinburgh: CHSS, 2004.
10. Scottish Government. Health in Scotland. Annual report of the Chief Medical Officer. 2008. Edinburgh: Scottish Government, 2007.
11. Mathers CD, Loncar D. Projections of Global Mortality and Burden of Disease from 2002 to 2030. *PLoS Medicine* 3(11). doi:10.1371/journal.pmed.0030442, 2006.
12. Sit J, Yip V, Ko S, Gun A, Lee J. A quasi-experimental study on a community-based stroke prevention programme for clients with minor stroke. *Journal of Clinical Nursing* 2007; 16(2):272-281.

13. Goldstein LB, Adams R, Alberts MJ, Appel LJ, Brass LM, Bushnell CD. Primary Prevention of Ischaemic Stroke. A Guideline from the American Heart Association/American Stroke Association Council. *Stroke* 2006; 37:1583-1633.
14. Graham I, Atar D, Borch-Johnsen K, Boysen G, Burell G, Cifkova R, Dallongeville J, De Backer G, Ebrahim S, Gjelsvik B, Herrman-Lingen C, Hoes A, Humphries S, Lipton M, Perk J, Priori S, Pyörälä K, Reiner Z, Ruilope L, Sans-Menéndez S, Scholte op Reimer W, Weissberg P, Wood D, Yarnell J, Zamorano J. European guidelines on cardiovascular disease prevention in clinical practice. *European Heart Journal* 2007; 28(19):2375-2414.
15. Scottish Intercollegiate Guidelines Network (SIGN). SIGN 108: Management of Patients with Stroke or TIA: Assessment, Investigation, Immediate Management and Secondary Prevention. Edinburgh: SIGN, 2008.

Appendix I

JBI MASTARI: Critical Appraisal of Evidence of Effectiveness

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

- 1) Was the assignment to treatment groups truly random?
yes no not clear NA
- 2) Were participants blinded to treatment allocation?
yes no not clear NA
- 3) Was allocation to treatment groups concealed from the allocator?
yes no not clear NA
- 4) Were the outcomes of people who withdrew described and included in the analysis?
yes no not clear NA
- 5) Were those assessing the outcomes blind to the treatment allocation
yes no not clear NA
- 6) Were control and treatment groups comparable at entry?
yes no not clear NA
- 7) Were groups treated identically other than for the named interventions?
yes no not clear NA
- 8) Were outcomes measured in the same way for all groups?
yes no not clear NA
- 9) Were outcomes measured in a reliable way?
yes no not clear NA
- 10) Was appropriate statistical analysis used?
yes no not clear NA

Overall appraisal: Include Exclude Seek further info

Comments (including reasons for exclusion):

Appendix II
Data Extraction Form (Quantitative Data)

Author Record Number

Journal

Year

Reviewer

Method _____

Setting _____

Participants _____

Number of Participants

Group A Group B

Interventions

Intervention A _____

Intervention B _____

Outcome Measures

Outcome Description	Scale/Measure

Results

Dichotomous Data

Outcome	Treatment Group Number/total number	Control Group Number/total number

Continuous Data

Outcome	Treatment Group Mean & SD (number)	Control Group Mean & SD (number)

Authors Conclusion

Reviewers Conclusion

Appendix III
Review-specific data extraction tool

Bibliographic details	
ID	
Author	
Year/country	
Title	
Citation	
Contact details	

Study design		
Study Aim		
Sample		
Inclusion Criteria		
Exclusion Criteria		
	Intervention group	Control /comparison group
Sample size		
Recruitment Location		
Gender		
Age		
Ethnicity		
Socioeconomic		
Employment status		
Marital status		
Educational status		
Living Arrangements		
Stroke		
Definition		
Type		
Lesion location		
Severity		
Aphasia		
Cognitive impairment		
Affective disorders		
Co-morbidities		
Family history		

Intervention		
Theory		
Type		
Content		
Duration & frequency		
Who delivered the intervention?		
Did they have specific training?		
Intervention materials		
Structure		
Intervention Location		
Cost to participants		
Cost effectiveness		
Funder/provider		
Transport issues		
Family involvement		
Intervention for control group		
Outcomes		
	Intervention group	Control /comparison group
Measurement time points		
Who collected the data?		
Data collection tools		
Data collection methods		
Physiological variables measured		
Physiological results at baseline		
Physiological results at Time 1		
Psychological outcome measures		
Psychological results at baseline		
Psychological results at Time 1		
Knowledge: stroke warning signs		
Knowledge: risk factors		
Medication compliance		
Salt consumption		
Attitudes at Baseline		
Attitudes at Time 1		
Beliefs at baseline		
Beliefs at Time 1		