Reducing Recurrent Stroke: Methodology of the Motivational Interviewing in Stroke (MIST) randomised clinical trial

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Abstract

Rationale Recurrent stroke is prevalent in both developed and developing countries, contributing significantly to disability and death. Recurrent stroke rates can be reduced by adequate risk factor management. However, adherence to prescribed medications and lifestyle changes recommended by physicians at discharge after stroke is poor. Motivational Interviewing early after stroke occurrence has the potential to prevent recurrent stroke.

Aims The overall aim of the study is to determine the effectiveness of motivational interviewing in improving adherence to medication and lifestyle changes recommended by treating physicians at and after hospital discharge in stroke patients 12 months post-stroke, to reduce risk factors for recurrent stroke.

Design Recruitment of 430 first-ever stroke participants will occur in the Auckland and Waikato regions. Randomisation will be to intervention or usual care groups. Participants randomised to intervention will receive four Motivational Interviews and five follow-up assessments over 12 months. Non-intervention participants will be assessed at the same time points.

Study outcomes Primary outcome measures are changes in systolic blood pressure and low-density lipoprotein levels 12 months post stroke. Secondary outcomes include self-reported adherence and barriers to prescribed medications.

Discussion The results of the MIST trial will add to our understanding of whether Motivational Interviewing may be potentially beneficial in the management of stroke and other diseases where similar lifestyle factors or medication adherence are relevant.

Introduction

Strokes recur in 6-25% of people (1, 2), usually in the first year (1). By 5-years post-stroke, the cumulative risk of recurrent stroke is 30%-40%. Recurrent stroke may lead to greater disability, institutionalisation, increased risk of dementia and a high risk of death (3), and therefore poorer health and economic outcomes (4).

Management strategies for secondary stroke prevention are well established. The landmark INTERSTROKE studies suggest that 10 risk factors are associated with 90% of the risk of first-ever stroke (5). Recurrent strokes are largely preventable using similar strategies to that of primary stroke prevention (6). In a systematic review, lifestyle modifications were shown to be effective for secondary stroke prevention with improvements seen in both lifestyle behaviour changes and physiological outcomes (7). While adherence to prescribed medications and/or recommendations to lifestyle changes after first stroke are effective strategies to reduce recurrent stroke, in practice the implementation of these recommendations is poor (8, 9). Targeting adherence may be key to reducing the incidence of recurrent stroke, therefore it is both appropriate and timely to conduct trials to assess whether new approaches may improve patient adherence to evidence-based guidelines for secondary stroke prevention (10) after hospital discharge.

Motivational Interviewing (MI) is a structured, patient-focused (11, 12) and cost-effective (13) intervention that was originally developed for the treatment of people with problem drinking, addictions (14, 15), stroke (16, 17), traumatic brain injury (18), and cardiovascular disease (19). The objective of MI is to help the client to explore their ambivalence towards behaviour change, and by resolving this ambivalence, facilitating positive behaviour change in the individual (20).

A significant benefit of MI on mood early after stroke over usual stroke care was recently demonstrated in a randomised controlled trial (16). While this intervention has been identified as a high research priority (21), no studies have been carried out specifically to test the effectiveness of

MI in reducing risk factors related to recurrent stroke. Given its potential to encourage patients to adhere to medication and life-style changes recommended by clinicians, this trial is designed to assess the effectiveness of MI in reducing outcomes related to recurrent stroke.

Objectives

The overall aim of the study is to determine the effectiveness of MI in improving adherence to medication and lifestyle changes recommended by treating physicians at and after hospital discharge in stroke patients 12 months post-randomisation.

Methods

Trial Design

This is a phase III single-blind randomised controlled trial of participants with first ever stroke (excluding subarachnoid haemorrhage) followed for 12-months after randomisation. Participants are randomised to either the MI intervention group, (henceforth referred to as MI) or usual care (UC). Recruitment for the trial commenced on 1st March 2011 with the population based ARCOS IV Incidence and Outcomes Study (22). Figure 1 (Appendix 1) is a flowchart of the overall trial design of the MIST study.

Patient Population- inclusion and exclusion criteria

Inclusion Criteria: All consecutive adult (16 years or older) stroke survivors who had a first ever stroke and are residents of Auckland or Waikato Region. Stroke is defined according to the World Health Organisation definition as "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin" (23). A diagnostic review committee comprising four stroke neurologists meet fortnightly to confirm the diagnosis of stroke and classification of all ischaemic cases (22).

Exclusion criteria: (1) recurrent stroke (excluding clinically silent previous strokes); (2) a diagnosis of subarachnoid haemorrhage; (3) significant impairments precluding participation (e.g., aphasia); (4) inability to give informed consent; (6) another condition likely to impact their participation in the trial (e.g., life-threatening condition other than cardiovascular disease); (5) expected discharge to hospital/nursing home setting where adherence to lifestyle recommendations and medications is beyond participant control.

Ethical Approval and trial registration

The study was given ethical approval by the Northern X Regional Ethics Committee for experiments in human subjects and the Auckland University of Technology Ethics Committee. The trial is registered with the Australian New Zealand Clinical Trial Registry (Trial Registration Number: ACTRN 12610000715077).

Recruitment

Between 1st March 2011 and 29th February 2012, potential participants were recruited for the trial from the main ARCOS IV Incidence and Outcomes study (22). Additional participants were recruited from the Waikato region for the same period. From 1st March 2012, participants will be recruited

from all four Auckland public hospitals and the recruitment period is expected to continue up to December 2013. Daily searches of admissions data are carried out in all four Auckland region public hospitals for records suggestive of a diagnosis of first-ever stroke.

Informed consent

Potentially eligible participants are identified by a hospital-based research assistant (RA) via regular checks of each hospital database for new admissions and participation at weekly medical and diagnostic team meetings for relevant hospital wards/units. Potential participants are approached by an RA to give informed consent to participate.

Screening

All participants who meet the main inclusion criteria and provide informed consent undergo a face-to-face detailed screening process with a study RA to ensure that they meet the eligibility criteria for randomisation into the trial. Table 1 (Appendix 1) shows the eligibility screening criteria used to identify participants eligible for randomisation.

Randomisation

Eligible study participants are randomised to either the MI or UC groups using web-based computerised randomisation software. A stratified minimisation algorithm is used to randomize participants in order to balance possible prognostic factors (i.e., age [<70, 70+], stroke severity [Barthel Index <18 and ≥18], gender and ethnicity [European, non-European]) across the two groups.

Additional information regarding randomisation procedures are in Appendix 2.

Blinding

To reduce measurement bias, follow-up assessments are carried out by individual community-based RAs who are blind to the treatment allocation of the participant and not involved in the delivery of the intervention. See Appendix 2 for additional information.

Motivational Interviewing Intervention

The trial intervention is based on the principles of MI as described by Miller and Rollnick (24). To assist the interviewers in adhering to a standardised approach and format when conducting the intervention, an intervention manual has been developed providing guidance for each of the intervention time points and appropriate tools to assist in the interviewing process.

MI interviews are conducted at 28 days, 3, 6 and 9 months post stroke (see flowchart Figure 1 Appendix 1). Further details of the trial intervention are in Appendix 2.

Primary Outcomes

Primary outcome measures are (1) change in systolic blood pressure (SBP) and (2) low-density lipoprotein (LDL)-cholesterol levels at 12 months post stroke.

Secondary Outcomes

Secondary outcome measures are: (a) self-reported adherence to prescribed medications, including self-reported use of anti-platelet/anticoagulant medications, statin and blood pressure lowering therapy medications as prescribed (and cross-checked with electronic medication dispense records, where available); (b) self-reported barriers to adherence to medications; (c) cardiovascular events (new stroke or coronary heart disease, both fatal and non-fatal); (d) quality of life as measured by the SF-36 (25); (e) mood as measured by the Hospital Anxiety and Depression Scale (HADS) (26); (f) change in other blood lipid levels (HDL-cholesterol, total cholesterol, and triglycerides); (g) physical disability as measured by the Barthel Index (27) at 12 month and; (h) healthcare resource consumption and cost-effectiveness of the intervention.

Outcome assessments (Table 2, Appendix 1) are carried out at 28 days, 3, 6, 9 and 12 months following stroke.

Withdrawals and Loss to follow-up

Participants are able to withdraw their involvement in the study at any time. The "intention-to-treat" principle will apply for participants who withdraw from the study or are lost to follow-up, so that data from up to and including their last completed assessment will be included in the analyses.

Data Management

Data management services including statistical analyses are contracted to the National Institute for Health Innovation (NIHI), The University of Auckland. For further details see Appendix 2.

Data Safety Monitoring

See Appendix 2

Sample size

Four hundred and thirty participants are required to provide 85% power at α=0.05 (two-sided) to detect a 0.25 mmol/l difference in LDL-cholesterol (SD 0.8 mmol/L), and 80% power to detect a 4 mmHg difference in SBP (SD 14 mmHg), respectively, between UC and MI groups, assuming 10% loss to follow-up.

Statistical analyses

All statistical analyses will be performed using SAS version 9.3 (SAS Institute Inc. Cary NC). All tests of significance will be two-tailed and at 5% significance level throughout the analyses. Further details are available in Appendix 2.

Cost effectiveness

The cost effectiveness of the study will be determined by comparing the costs and outcomes associated with the control group with the group provided with MI. For additional information see Appendix 2.

Study organisation and funding

The study is hosted at the National Institute for Stroke and Applied Neurosciences at AUT University, Auckland New Zealand. The research is funded by the Health Research Council of New Zealand.

Summary

The MIST study is a randomised clinical trial designed to test the effectiveness of MI for the secondary prevention of stroke. To the best of our knowledge, this is one of the largest clinical trials of MI to be carried out at a population level. This intervention has the potential benefits of being adapted in the community as a cost-effective means of reducing stroke burden. In addressing the values and goals of individuals after stroke, MI may present a multifactorial approach to concomitant reduction of risk factors.

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MIST Data Safety Monitoring Committee and ARCOS IV Steering Committee, see Appendix 2.

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