Improving Adherence to Secondary Stroke Prevention Strategies Through Motivational Interviewing
Randomized Controlled Trial

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Background and Purpose—Stroke recurrence rates are high (20%–25%) and have not declined over past 3 decades. This study tested effectiveness of motivational interviewing (MI) for reducing stroke recurrence, measured by improving adherence to recommended medication and lifestyle changes compared with usual care.

Methods—Single-blind, prospective phase III randomized controlled trial of 386 people with stroke assigned to either MI treatment (4 sessions at 28 days, 3, 6, and 9 months post stroke) or usual care; with outcomes assessed at 28 days, 3, 6, 9, and 12 months post stroke. Primary outcomes were change in systolic blood pressure and low-density lipoprotein cholesterol levels as indicators of adherence at 12 months. Secondary outcomes included self-reported adherence, new stroke, or coronary heart disease events (both fatal and nonfatal); quality of life (Short Form-36); and mood (Hospital Anxiety and Depression Scale).

Results—MI did not significantly change measures of blood pressure (mean difference in change, −0.2.35 [95% confidence interval, −6.16 to 1.47]) or cholesterol (mean difference in change, −0.0.12 [95% confidence interval, −0.30 to 0.06]). However, it had positive effects on self-reported medication adherence at 6 months (1.979; 95% confidence interval, 1.56–11.84; P=0.0049) and 9 months (4.295; 95% confidence interval, 1.56–11.84; P=0.0049) post stroke. Improvement across other measures was also observed, but the differences between MI and usual care groups were not statistically significant.

Conclusions—MI improved self-reported medication adherence. All other effects were nonsignificant, though in the direction of a treatment effect. Further study is required to determine whether MI leads to improvement in other important areas of functioning (eg, caregiver burden).

Clinical Trial Registration—URL: http://www.anzctr.org.au. Unique identifier: ACTRN-12610000715077.

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Key Words: blood pressure ■ motivational interviewing ■ randomized controlled trial ■ secondary prevention ■ stroke

S

stroke recurr in ≈25% of patients in the first year,14 with a 5-year cumulative recurrent risk of 30% to 40%.5 Recurrent stroke leads to greater disability and case fatality.6,7 The stroke recurrence rate has not changed over the past 20 years.4 Evidence-based secondary stroke prevention guidelines improve stroke outcomes and reduce costs,8 but remain underutilized.9,10 Poor preventive care training,11 discharge planning,12,13 risk factor management, and communication with stroke patients/family9 are likely contributors.11,14

Motivational interviewing (MI) aims to improve adherence to medication and lifestyle changes. MI facilitates intrinsic motivation to change behavior15 and attempts to increase awareness of potential problems, consequences, and risks as a result of a behavior16 and seeks to help people think differently about their behavior and consider potential gains through change.17 MI is structured, patient-focused,18–23 and more cost-effective24 than many other behavior change methods.25,26 MI was developed for substance abuse management21,22,27,28 but
is increasingly used in other populations, showing positive results in improving mood post stroke,29–33 traumatic brain injury,34 cardiovascular disease,26,35,36 and diabetes mellitus.37

This trial aimed to determine the effectiveness of MI in improving adherence to medications (particularly blood pressure [BP] and cholesterol lowering medications) in stroke patients enrolled into a larger population-based stroke study. Changes in systolic BP and low-density lipoprotein (LDL) cholesterol levels were assessed as primary outcomes. Other lipid fractions (high-density lipoprotein cholesterol, total cholesterol, triglycerides, and glycohemoglobin), self-reported adherence, occurrence of new stroke/coronary heart disease (fatal/nonfatal), changes in quality of life, and mood were also assessed.

Methods
Three hundred eighty-six people aged ≥16 years with stroke (excluding subarachnoid hemorrhage) were enrolled. The methodology is described in detail elsewhere,38 but briefly, potential participants were identified by a hospital-based research assistant through checking hospital databases and attendance at weekly team meetings for relevant wards/units. Eligible candidates were approached in inpatient wards within 28 days of stroke. Medical notes of consenting individuals were reviewed and face-to-face screening conducted to explain the study and determine eligibility. Participants provided

Figure. Study design and recruitment. LDL indicates low-density lipoprotein.
Table 1. Demographics and Primary Outcomes at Baseline for Participants in Motivational Interviewing and Usual Care Groups

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Motivational Interviewing (n=193, %)</th>
<th>Usual Care (n=193, %)</th>
<th>Significance of Group Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity</td>
<td>χ², P Value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maori</td>
<td>5.70, 0.127</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pacific Islander</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand European/other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td>0.53, 0.765</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/civil union/de facto</td>
<td>135 (69.9) 140 (72.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>9 (4.7) 10 (5.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separated/divorced/widowed</td>
<td>49 (25.4) 43 (22.3)</td>
<td></td>
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</tr>
<tr>
<td>Prior living situation</td>
<td>1.43, 0.489</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with family</td>
<td>141 (73.1) 148 (76.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with others</td>
<td>6 (3.1) 8 (4.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>46 (23.8) 37 (19.2)</td>
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<tr>
<td>Prior dwelling place</td>
<td>4.81, 0.439</td>
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<tr>
<td>Own home</td>
<td>124 (64.2) 141 (73.1)</td>
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<td></td>
</tr>
<tr>
<td>Rented</td>
<td>40 (20.7) 31 (16.1)</td>
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<tr>
<td>Living with friends/family</td>
<td>10 (5.2) 6 (3.1)</td>
<td></td>
<td></td>
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<tr>
<td>Retirement village/similar</td>
<td>16 (8.3) 10 (5.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest home/private hospital</td>
<td>1 (0.5) 1 (0.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.0) 3 (1.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>0 1 (0.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used prestroke</td>
<td>0.01, 0.919</td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>94 (48.7) 95 (49.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>99 (51.3) 98 (50.8)</td>
<td></td>
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<tr>
<td>Completed high school</td>
<td>0.28, 0.597</td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>155 (80.3) 159 (82.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>37 (19.2) 33 (17.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.5) 1 (0.5)</td>
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<tr>
<td>Highest further qualification</td>
<td>2.62, 0.453</td>
<td></td>
<td></td>
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<tr>
<td>Degree</td>
<td>34 (17.6) 42 (21.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diploma/certificate</td>
<td>33 (17.1) 42 (21.8)</td>
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<td></td>
</tr>
<tr>
<td>Trade/technical</td>
<td>31 (16.1) 27 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>6 (3.1) 12 (6.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>89 (46.1) 70 (36.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment type</td>
<td>6.59, 0.582</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>15 (7.8) 18 (9.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managerial/technical</td>
<td>35 (18.1) 38 (19.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skilled nonmanual</td>
<td>20 (10.4) 9 (4.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skilled manual</td>
<td>17 (8.8) 16 (8.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partly skilled</td>
<td>7 (3.6) 6 (3.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unskilled</td>
<td>10 (5.2) 8 (4.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Armed forces</td>
<td>1 (0.5) 1 (0.5)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Continued

<table>
<thead>
<tr>
<th>Significance of Group Differences</th>
<th>Motivational Interviewing (n=193, %)</th>
<th>Usual Care (n=193, %)</th>
<th>t Score, P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unemployed/retired</td>
<td>85 (44.0) 89 (46.1)</td>
<td></td>
<td>7.49, 0.723</td>
</tr>
<tr>
<td>Other</td>
<td>3 (1.6) 7 (3.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications in the month prestroke</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>77 (39.9) 72 (37.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dipyridamole</td>
<td>8 (4.1) 4 (2.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>7 (3.6) 6 (3.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td>8 (4.1) 8 (4.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure–lowering drugs</td>
<td>108 (56) 106 (54.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid-lowering therapy</td>
<td>61 (31.6) 69 (35.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes medication</td>
<td>25 (13.0) 26 (13.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mood modification therapy</td>
<td>14 (7.3) 17 (8.8)</td>
<td></td>
<td></td>
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<tr>
<td>Recreational drugs</td>
<td>1 (0.5) 0 (0.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplements</td>
<td>16 (8.3) 24 (12.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral contraceptive</td>
<td>1 (0.5) 2 (1.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Primary outcomes at baseline, mean (SD)

<table>
<thead>
<tr>
<th>HDL indicates high-density lipoprotein; and LDL, low-density lipoprotein.</th>
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</thead>
<tbody>
<tr>
<td>Systolic blood pressure, mmHg</td>
</tr>
<tr>
<td>Diastolic blood pressure, mmHg</td>
</tr>
<tr>
<td>Blood lipids LDL, mmol/L</td>
</tr>
<tr>
<td>Blood lipids HDL, mmol/L</td>
</tr>
<tr>
<td>Total cholesterol, mmol/L</td>
</tr>
</tbody>
</table>

Written informed consent. The study was approved by the regional ethics committee (NTX/10/09/091) and registered with Australian Clinical Trials Register (ACTRN-12610000715077).

Stroke was defined using World Health Organization diagnostic criteria.19 Individuals were excluded if (1) they had impairment precluding participation (eg, aphasia, psychiatric conditions, cognitive impairment); (2) they were unable to converse in English; (3) they were unable to give informed consent; (4) they had another condition likely to affect participation (eg, significant aphasia); (5) they were receiving psychiatric/psychological treatment that could contaminate the findings; (6) they were discharged to hospital/nursing home setting where medications are given by staff; or (7) participation was likely to overburden the individual. Figure summarizes recruitment.

Participants were randomized to MI or usual care (UC). In accordance with New Zealand Clinical Guidelines for Stroke management,24 individuals are admitted to specialized stroke care units in a designated area under the care of an interdisciplinary team. After discharge, individuals are followed by their general practitioner or at a designated Stroke Clinic on a regular basis (eg, every 3 to 6 months). If further rehabilitation is required stroke-specific community–based rehabilitation teams are available. Regular reviews are recommended if residual impairment is present.

Treatment allocation was concealed from staff using an online randomization service. Stratified minimization randomization balanced for possible prognostic factors (ie, age [<70, 70+], sex, ethnicity [European, non-European], and Barthel Index [≤18, >18]) across the groups.42 Randomization information was not accessible to staff
conducting outcome assessments. After randomization, a letter was sent to participants’ general practitioners to inform them of their patients’ participation and remind them of recommendations to monitor BP and lipid levels post stroke. A letter was also sent to participants with a reminder to obtain BP and blood lipid levels from their general practitioner 12 months post stroke. A second reminder was sent with a blood lipid test form, 1 month before the 12-month assessment date.

Intervention
The MI group received 4 MI sessions at 28 days, 3, 6, and 9 months post stroke. Sessions were audio-recorded. The initial interview was conducted face-to-face either in hospital or in the participants’ primary place of residence if he/she had been discharged. Subsequent interviews were conducted by telephone. If a telephone interview was not possible (eg, participant request, difficulty hearing), interviews were conducted face-to-face in the participants’ primary place of residence. This occurred for 30%, 40%, and 21% of the 3-, 6-, and 9-month interviews, respectively. Initial interviews took 30 minutes, whereas follow-up sessions took ≈60 to 90 minutes, whereas follow-up sessions took 30 minutes. A manual describing the intervention in detail is provided (online-only Data Supplement).

All MI sessions were administered by trained researchers under the supervision of an MI trainer, who also provided ongoing training and feedback throughout the study to ensure the fidelity of the intervention. Participants were assigned 1 MI interviewer, who remained consistent across the study whenever possible.

Measures
Assessments were conducted 28 days, 3, 6, 9, and 12 months post stroke over the telephone by trained researchers, who were blind to randomization status and were not involved in providing the MI intervention.

Primary outcomes were change in systolic BP and LDL cholesterol levels from baseline to 12 months post randomization. Secondary outcomes were new cardiovascular events (eg, presence/absence of further stroke, myocardial infarction), quality of life (Short Form-3642), change in other lipid fractions (high-density lipoprotein cholesterol and total cholesterol), and change in mood (Hospital Anxiety and Depression Scale43), and medication adherence. Medication adherence was determined by asking whether (in the past 7 days) they had taken all of their medication as prescribed; for each medication, they were asked to indicate number of doses/pills missed; if they just forgot (yes/no), the reason for the missed dose(s); and to provide detail if side effects were noted. The validity of self-reports of adherence was cross-checked with electronic medication dispense records, where available. To not unduly bias reporting of adherence, every attempt was made to ensure that measures of adherence conducted at 28 days, 3, 6, and 9 months preceded MI sessions. Measures were completed before MI sessions for 66% to 84% of participants across the 4 assessments.

The Short Form-3642 assesses health-related quality of life. It has been validated in New Zealand44 and contains 8 scales, which produce a Physical Component Score and Mental Component Score. Higher scores (range, 0–100) indicate better quality of life.

The Hospital Anxiety and Depression Scale43 contains 14 statements (‘I have lost interest in things’), 7 relating to anxiety and 7 to

Table 3. **Self-Reported Adherence and Presence of Further Cardiovascular Events Across 12-Month Follow-Up**

<table>
<thead>
<tr>
<th></th>
<th>Motivational Interviewing</th>
<th>Usual Care</th>
<th>Unadjusted Relative Risk</th>
<th>Adjusted Odds Ratio*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>Estimate (95% CI)</td>
<td>P Value</td>
</tr>
<tr>
<td>Self-reported adherence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>172 (91.9)</td>
<td>176 (90.9)</td>
<td>1.011 (0.95–1.08)</td>
<td>0.7519</td>
</tr>
<tr>
<td>6 mo</td>
<td>175 (92.0)</td>
<td>171 (85.4)</td>
<td>1.078 (1.00–1.16)</td>
<td>0.0516</td>
</tr>
<tr>
<td>9 mo</td>
<td>159 (96.9)</td>
<td>161 (88.2)</td>
<td>1.098 (1.03–1.17)</td>
<td>0.0033†</td>
</tr>
<tr>
<td>12 mo</td>
<td>161 (93.2)</td>
<td>165 (92.7)</td>
<td>1.005 (0.95–1.07)</td>
<td>0.8766</td>
</tr>
<tr>
<td>Cardiovascular events (12 mo)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>193 (2.1)</td>
<td>193 (3.1)</td>
<td>1.333 (0.30–5.88)</td>
<td>1.0000</td>
</tr>
<tr>
<td>Stroke</td>
<td>193 (2.1)</td>
<td>193 (6.3)</td>
<td>0.667 (0.19–2.33)</td>
<td>0.5216</td>
</tr>
<tr>
<td>TIA</td>
<td>193 (2.1)</td>
<td>193 (4.2)</td>
<td>1.000 (0.25–3.94)</td>
<td>1.0000</td>
</tr>
<tr>
<td>MI</td>
<td>193 (2.1)</td>
<td>193 (2.1)</td>
<td>1.000 (0.14–7.03)</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Repeated measures taken into account using random effect; interaction between treatment group and visit included. MI indicates myocardial infarction; and TIA, transient ischemic attack.

*Logistic regression adjusting for age, Barthel Index, ethnicity, and sex.
†No imputation, only observed data.
Table 4. Analyses for Change in Systolic Blood Pressure and LDL From Baseline to 12 Months

<table>
<thead>
<tr>
<th></th>
<th>Descriptive Summary</th>
<th>Adjusted Regression Analysis</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Motivational Interviewing</td>
<td>Usual Care</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Intention to treat analysis (ITT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change to 12 mo</td>
<td>163</td>
<td>−22.04 (28.42)</td>
</tr>
<tr>
<td>LDL cholesterol, mmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change to 12 mo</td>
<td>119</td>
<td>−0.33 (0.89)</td>
</tr>
<tr>
<td>Sensitivity analysis (SA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 12 mo</td>
<td>163</td>
<td>137.75 (21.58)</td>
</tr>
<tr>
<td>LDL cholesterol, mmol/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 12 mo</td>
<td>140</td>
<td>2.14 (0.80)</td>
</tr>
</tbody>
</table>

ITT: missing values imputed (last observation carried forward); LDL: baseline used if 12-month data had different fasting status. SBP model adjusted for baseline outcome, age, Barthel Index, ethnicity, and sex; LDL model also adjusted for fasting vs other status. SA: 12-month data not imputed. LDL 12-month data used regardless of baseline fasting status; Model adjusted for age, Barthel Index, ethnicity, and sex for SBP; for LDL, adjustment also for fasting status. LDL indicates low-density lipoprotein.

Analyses

Analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC). All tests were 2-sided with a 5% level of significance. With a sample of 364 stroke patients (including 20% drop-outs), this trial had 90% power to detect 20% improvement in adherence to lipid-lowering or antithrombotic medications. Only 302 stroke patients (20% drop-outs; 90% power) were required to detect 20% improvement in adherence to BP-lowering medications.

Baseline demographic/clinical characteristics of all randomized participants were summarized using descriptive statistics, and baseline imbalance was tested between UC and MI groups. Unadjusted relative risks were first calculated on self-reported adherence and cardiovascular events. Generalized linear regression models were then used to estimate treatment differences on primary and secondary outcomes, adjusting for baseline outcome and stratification factors. Treatment evaluations were performed on the principle of intention-to-treat. Sensitivity analysis was conducted on observed data to evaluate the robustness of main trial results. No imputation was considered on secondary outcomes, and there was no adjustment on multiple testing. Tabulated data are consistent with CONSORT 2010 guidelines.

Results

Table 1 provides descriptive information for MI and UC groups. Randomization achieved good balance between the groups. Both groups were prescribed medications at similar rates over time (Table 2), and self-reported adherence was high (>85%) in both groups at each time point (Table 3).

The groups did not differ significantly in reporting of side effects at any of the assessments (P>0.05), although more of those in the UC group (n=12, 6.2%) reported forgetting to take medications than in the MI group (n=4, 2.1%) at 9 months (P=0.042). Of the 26 individuals, who reported other reasons for not adhering, 11 (44%) did not wish to take medication, 8 (32%) indicated their prescription ran out, 2 (8%) said they were unaware of the prescription, 2 (8%) said taking medication was inconvenient, and 3 (12%) stated a preference for naturopathic alternatives, changed their dose to see how they would do, or that it was expensive. The groups did not differ significantly in reporting these barriers (P>0.05).

There was a significant treatment effect for self-reported adherence at 9 months and this approached significance at 6 months.

There was no difference in the number of cardiovascular events in the MI and UC groups over 12 months (<7%; Table 3). The reduction in systolic BP in both groups was large (>15 mmHg) and clinically and statistically significant but there were no statistically significant differences between the groups (Table 4), and the direction of change is in the direction expected for a treatment effect. LDL cholesterol levels did not differ between or within the groups from baseline to 12 months. BP, lipid profile, mood, and quality of life measures did not change across the intervention period (Table 5), with no effect of treatment.

Discussion

Although MI did not significantly improve performance on the primary outcomes (ie, systolic BP; LDL cholesterol), it did have a favorable effect on self-reported medication adherence after incident stroke. MI also resulted in a trend for improvement across other measures related to adherence (eg, systolic BP), although these effects were not statistically significant.
The effect of MI on medication adherence neared significance at 6 months and reached significance at 9 months, which likely reflects the timing of the final MI session.

MI aims to improve adherence through increasing participant motivation, and it was hoped that improved adherence would be associated with improved broader outcomes. There was a trend toward better overall recovery in the MI group, but the study was not adequately powered to detect a clinically relevant difference in cardiovascular outcomes and the 12-month follow-up period may have been too short for changes in adherence to affect more distant outcomes.

Previous MI studies have shown significant reductions in depressed mood and mortality 12 months post stroke. In this study, depression and anxiety were both reduced over time, but this did not differ between the groups. This may be because of the timing and intensity of the intervention, as we provided 3 MI sessions spaced over 9 months. An earlier study provided weekly sessions for ≤4 weeks beginning within 4 weeks post stroke. Other studies post stroke have not examined talk-based therapies delivered so early poststroke nor found such benefits. Together, the findings suggest that MI enhances adaptive behavioral changes post stroke (such as medication adherence) and suggests further research is warranted regarding

<table>
<thead>
<tr>
<th>Table 5. Analysis of Additional Biological Markers, Mood, and Quality of Life</th>
</tr>
</thead>
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Missing values not imputed. HADS indicates Hospital Anxiety and Depression Scale; HDL, high-density lipoprotein; and SF-36, Short Form-36. *Model adjusted for baseline outcome, age, Barthel Index, ethnicity, and sex.
frequency and timing of MI sessions. Detailed comparison of the current trial with others is difficult as previous trials predominantly focus on different population groups.28–37

The strengths of the study are that it was the first full-scale randomized controlled trial to evaluate the impact of MI on adherence and cardiovascular consequences of adherence in stroke survivors; it had a large sample statistically powered to identify change in the primary outcome; it had a low attrition rate, and missing data were low. The main limitations were (1) the strict inclusion criteria may limit generalizability; (2) use of imputation using last-value-carried-forward, while a sound approach, may have reduced ability to detect statistically significant changes in primary outcomes as values were carried forward in 16% of cases for systolic BP and as much as 38% for LDL, and (3) because of the nature of MI, it was not possible to blind participants which may have influenced self-report outcomes. Although medication adherence measured by self-report is simple and inexpensive and is validated for use in clinical settings, it may have led to overestimation of adherence.49,50 Provision of a specified timeframe (the past 7 days) and including questions about specific behavior (eg, number of pills missed) are known to have improved self-report accuracy in this context.51,52 As noted in the Methods section, validity of self-reports was cross-checked with electronic medication dispense records where available, which suggests accurate reporting. Long-term sustainability of the treatment effect beyond 12 months post randomization requires evaluation.

Notwithstanding these limitations, MI had a positive effect on self-reported adherence suggesting it may be beneficial. Whether this intervention is cost-effective and leads to improvement in other important areas of functioning (eg, caregiver burden) and whether its positive effects are maintained long-term should be a subject of further research in an adequately powered study with sufficient follow-up in order to accrue enough clinical events.

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Disclosures
None.

References


Improving Adherence to Secondary Stroke Prevention Strategies Through Motivational Interviewing: Randomized Controlled Trial

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## Motivational Interviewing Intervention Manual

### MIST Study

**SUPPLEMENTAL MATERIAL**

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Motivational Interviewing Training

Topics covered during Motivational Interviewing training
Copies of training materials
1. The “Intervention” refers to performing Motivational Interviewing with the participants randomly allocated into the intervention (MI) group, rather than the control or Usual Care (UC) group. Please refer to the MIST Study Protocol and MIST Manual of Procedures for more information on procedures relating to other aspects of the research trial.

2. Engagement into study. All study participants (whether allocated to MI or UC groups) are recruited into the study following the same procedures. See study document MIST Study: Contacting and Recruiting Participants v1 for further details.
   a. Recruitment by hospital-based research assistants:
      Stroke patients are screened for initial inclusion and exclusion criteria during hospital admission immediately following stroke. Potentially eligible participants are approached by hospital-based research assistants with information about the study during their hospital admission. The potential participant may consent or decline to take part in the study. Details of potentially eligible study participants who are discharged before being approached are passed on to community-based research assistants to contact about the study.
   b. Recruitment by community-based research assistants:
      Potentially eligible participants are contacted with information about the study by community-based research assistants.
   c. All recruiters
      i. Explain motivational interviewing to get more eligible people enrolled and answer initial questions about the study.
      ii. Highlight that motivational interviewing is a collaborative conversation about a patient’s health behaviors, goals, and barriers to help them become healthier and happier. Our goal is to help patients prevent a second stroke by using motivational interviewing.
      iii. Explain the time commitment required (maximum of approximately 1.5 hrs every 3 months over 1 year)
      iv. Explain the process for MI group (4x MI and 4x follow-up phone calls) and UC group (4x follow-up phone calls)
      v. Gain informed consent
      vi. Complete eligibility screening (Form E)
      vii. Complete demographic information (Form B)
      viii. Ask for caregiver/significant other consent to complete Form CG at 28 Days, 6 months and 12 months post-stroke.
      ix. Complete initial follow-up questionnaire (Form T)
      x. Inform Study Manager of new study participant.

3. Follow ARCOS Mental Health Guidelines if a consented study participant shows symptoms of depression or anxiety on the HADs questionnaire in Form T or if you have concerns about the participant’s safety or the safety of others.
Intervention Protocol

1. Ensure that interviewer has completed basic motivational training including shadowing at least two interviews.

2. One day prior to interviews
   a. Contact the client to confirm the interview day and time. If any observers will be part of the interview ask for the client’s permission at this time.
   b. Ensure the interview date, time and location is in the interviewer’s Outlook calendar so that study managers know where you are. Include study participant ID, initials and address in location field so manager can see these details. NOTE: Ensure your outlook calendar is viewable to everyone.
   c. Find a work colleague to be your “buddy” to text before you go into the interview and when you leave the interview. If you cannot find a “buddy” then Emma and/or Amy can be back-up contacts.

3. On the day of the interview
   a. Review the client case notes to refresh pertinent information
   b. Check recording equipment and ensure that there are spare batteries
   c. Plan on arriving 15 minutes early
   d. Text message or let your buddy or a manager know in person that you are going to an appointment. Make an arrangement for how you will notify them when you have finished the appointment, e.g. send a text or see in office.
   e. Remove any distractions. Put mobile phone on silent if a face-to-face interview. If a phone interview move away from the computer and/or any clutter. For telephone interviews book a private meeting room with a speaker phone (e.g. room AA123, AA256 or AA203) when the appointment time is made. To book a room contact George Palmer on gpalmer@aut.ac.nz or extension 9005.
   f. Ground yourself 5-10 minutes prior to the start of the interview. Practice your mindfulness ritual

4. Start the interview
   a. Re-introduce yourself by name and job title and show your AUT ID, if a face-to-face meeting
   b. Observe any cultural practices, such as removing shoes in the house, when doing interviews
   c. Remind the client that the interview will be recorded and that colleagues working on the study may listen in for training purposes. If there are any observers at this point confirm permission from the client for the observer to listen in.
   d. Remind the client that motivational interviewing is most effective when they are not distracted by other things such as people, computers, or phones.
   e. Take notes as needed.
   f. If, at any time, you feel unsafe or that the interview is unsafe for the client, you can end the interview. Depending on the extent of the concern, you can wrap-up and follow-up later or leave urgently.
      i. Examples of red flags for clients include moderate to severe depressive symptoms, suicide and/or self-harming. Report these signs to a program manager after an interview so appropriate actions may be taken.
ii. Please refer to the ARCOS Mental Health Guidelines, Mental Health Record Form and Advice for Depression for additional information. Please complete the Form T if you have concerns.

  g. Call 111 if you have an emergency

5. Wrap-up the interview
   a. End with a summary that makes connections and highlights the client’s values and strengths.
   b. Restate any goals or other commitments to change.
   c. Ask the client if your summary, and the stated goals, sound accurate.
   d. Ask the client how the interview went for them including what worked well and what could be improved, e.g. “At our next interview, is there anything I can do different?”, or “How can I best support you?”.
   e. Remind participant of the timing of the next interview and let them know you will call to confirm closer to the date.
   f. Thank them for participating and for the willingness to share.
   g. Stop the recording.

6. After the interview
   a. Let your buddy know you have left the interview and when you will be due back in the office if you have another scheduled appointment.
   b. Complete and load “Form MI”. Be sure to include relevant client notes and your interview self-assessment
   c. Report any red flags to the program manager. Red flags include, but are not limited to, any concerns the client may pose to your safety or their own health/safety.
   d. Follow-up on any requests made by the participant, such as names and referrals to providers or health information.
   e. Practice self-care. If you need to discuss an interview or client you may start by contacting the Motivational Interviewing trainer and/or program managers. If you need additional support with self-care please contact the program manager.

7. What to do if you don’t hear from your buddy
   a. If you have not heard from your colleague who had a scheduled appointment within 30 minutes of the arranged time for making contact, phone the MI interviewer on their mobile phone.
   b. If there is no answer, let the Programme Manager or Study Manager know immediately. If the Programme Manager and Study Manager cannot be located, contact the ARCOS Research Fellow (Rita) or the Study Principle Investigator.
   c. The Programme Manager will contact the study participant to determine if the interviewer attended the appointment or has left the appointment.
   d. If there are any concerns about the safety of the interviewer the Programme Manager will contact the police.

Refer to **Actions Flow Chart** in appendix (to be added)
Intervention Protocol: Initial Contact

1. Make initial contact with the study participant to ensure they have all of the information about the study goals, process, understand motivational interviewing and to set-up a first appointment. If not, offer to send participant information about the study and arrange a time to phone the participant back (e.g. 2-3 days).
2. Introduce yourself by name and job title.
3. When you first call, ask if the client has a few minutes to discuss the stroke study the enrolled in with Auckland University of Technology with you.
4. Avoid using acronyms with the clients, such as AUT, MIST and MI. You may use these acronyms daily but the client does not. Use the full word.
5. If you were passed on the participant details from another researcher/manager, explain that you were given their name by a colleague and that you believe they have consented to take part in the motivational interviewing stroke study.
6. Explain the goal of the study is to prevent second stroke using the intervention of motivational interviewing.
7. Explain what motivational interviewing is (see sample dialogue, page 7)
8. Ask if there are any questions about the below information
   a. Intervention verses control group
   b. Keep the other assessor blind by not disclosing part of intervention group
   c. Give name of Form T assessor if known
   d. Interviews done over course of 12 months, with 4 interviews in total
   e. Each interview between 30-60 minutes
   f. Interviews can be stopped at any time
   g. Interviews are recorded
   h. Typically first interview is face-to-face and future interviews over-the-phone
   i. Support people are allowed but it’s preferred client is undistracted and comfortable with giving honest answers
   j. Explain that confidentiality is ensured unless you are concerned they will harm themselves in some way
9. Set up a first interview appointment time
   a. First interview should be arranged for 2 weeks on either side of the due date (28 days post-stroke). Interviews falling outside this time and any interviews that cannot be conducted for any reason should be notified to the Study Manager as protocol violations.
   b. Arrange interview times outside of other commitments and distractions
   c. Confirm their address and how to find their house
   d. Confirm their contact details
   e. Give them your work office and mobile number
   f. Confirm meeting date, time, and location
   g. Enter appointment details in Outlook calendar, cc Program Manager and MIST Study Manager
Intervention Protocol: Initial Contact

Sample Dialogue

“Hello. My name is _____________ and I am a clinical research assistant with Auckland University of Technology. Do you have a few minutes to discuss the stroke study that you enrolled in with our university?

I was given your name by my colleague at Auckland University of Technology and I believe you have consented to participate in our study to try to prevent a second stroke by using a technique called Motivational Interviewing. Does this sound familiar to you?

I would like to explain the study now so I can be sure you fully understand what it’s about and what we’ll be doing. You’ve agreed to take part in the Motivational Interviewing Stoke Trial and the purpose of this study is to help patients in their recovery from stroke and reduce the risk of them having another one.

Of all the people who agree to participate in the study, half will receive motivational interviewing and the other half will not. You have been selected for the group that receives motivational interviewing. It’s really important that the other people from our team do not know which patients are receiving the motivational interviews. Is that ok? (NOTE: Give the name of the Form T assessor if possible.)

Motivational Interviewing is a style of intervention that is designed to help build a person’s motivation to change. It will probably just feel like a conversation where we will explore things together. I am not a health expert and I will not be telling you what to do but I am training in how to help you explore your own health and wellbeing and what areas you may want to improve to prevent stroke.

It is most effective when you are undistracted by other people, television, computers, etc. Please plan to find a quiet place where you can be alone and focus on yourself.

There will be four motivational interviews over the course of 12 months. I will be doing your first motivational interview soon and I will contact you again in 3 months, 6 months and 9 months time to arrange further interviews. The first interview will be face-to-face and the following interviews can be done over the telephone if this is suitable for you.
Intervention Protocol: Initial Contact Sample Dialogue Continued

The first interview typically takes around one hour and the rest take about 30 minutes. We can stop the interview at any time if you need too.

I will record the interviews as part of the research project and I may take notes during the interview to help me recall key facts so that I can offer you the best intervention possible.

If you don’t understand what I’m saying at any point, please just tell me so I can word it differently, and I’ll also do the same if that’s ok.

I would like to arrange a date and time that is convenient for you to meet in the near future.

(NOTE: Try to arrange it two weeks, on either side, of intervention date.)

You are welcome to have a support person with you for the interview but it’s preferable for you to be alone so you can both focus on the interview and also get privacy to explore what matters most to you.

(NOTE: Try to facilitate this by offering an interview date and time outside of any family visits or childcare commitments. If they do plan to have someone there take note of it.)

Can I confirm your address? Are there any tricks to finding your place?

Can I confirm your mobile number? My number, in case you need to contact me for anything before the interview is _____________.

(NOTE: Give work mobile number.)

Thank you for your time today. I look forward to meeting with you on the _________________.

(NOTE: Confirm meeting day, time and location.)”
Intervention Protocol: First Interview

1. Follow all "Interview Protocol" listed previously
   a. Remember to reintroduce yourself by name and job title. Show your photo id if at a face-to-face meeting.
   b. Try to avoid acronyms such as AUT or MIST. Use the full word.
   c. Wrap-up with a summary and get client input on how the interview went.

2. Explain that you are here for the first motivational interview and that the appointment will take about one hour.

3. Encourage them to minimize any distractions now, if they need too.

4. Remind the study participant that the interviews are recorded and begin recording. If the participant does not wish the interview to be recorded, explain that the main purpose of the recording is to make sure that you are following intervention guidelines, the recording is anonymous and stored securely. The recording may be listened to by your trainer and immediate research colleagues for training and assessment purposes only.

5. Review the purpose of the study ('Setting the stage')
   a. For example you might say, "Today we will use a technique called motivational interviewing to discuss how the different areas of your wellbeing, such as physical and mental health, impact your life and your ability to prevent a second stroke."

6. Start the interview with a broad question that frames the purpose of the study ('Where are they now?')
   a. For example, “Can you share with me what has been recommended that you do to prevent a second stroke?”
   b. Follow-up with a question such as how they feel about those recommendations and/or how the implementation of those recommendations is going.
   c. Time: approximately 5 to 10 minutes

7. The first interview is an opportunity to get to know the client and to build rapport and trust. Discover what motivates them and what they value.

8. Help them dream big ('Looking forward to the future')
   a. Facilitate clients expressing longer-term possibilities and creating a vision of their best self. Avoid goal setting in this first interview. For example, ask “Can we talk a bit about the future? Where would you like to be in a year’s time?”
   "If you had a realistic magic wand what would your life look like in one year’s time?"
Intervention Protocol: Follow-Up Interviews

1. Follow all “Interview Protocol” listed previously
   a. Remember to reintroduce yourself by name and job title. Show your photo id if at a face-to-face meeting.
   b. Try to avoid acronyms such as AUT or MIST. Use the full word.
   c. Wrap-up with a summary and get client input on how the interview went.

2. Explain that you are here for the follow-up motivational interview and that the appointment will take about half an hour.

3. Encourage them to minimize any distractions now, if they need to.

4. Remind them that the interviews are recorded and begin recording.

5. Thank them for their time and honor their commitment to improving their own health by participating in the motivational interviewing intervention.

6. The second and third interviews are an opportunity to use the values, dreams and vision of the client that you gained in the first interview to apply to motivating change and commitment to goals.

7. Begin with a broad, positive question such as “Can you share with me something positive that has happened since we last spoke?”
   a. Note: You do not start by reviewing the last conversation. Begin broad and on a positive focusing for example on values, dreaming or goals
   b. If the client moves toward negative topics, try to draw back to a positive, e.g. “It sounds like you’ve had a hard time, has any good come from that?”

8. Explore with clients what areas in their life they would like to improve and facilitate their commitment to make healthy change. Ideas on how to motivate change include:
   a. Use positive reinforcement for any changes made or any change talk expressed. Also acknowledge any progress towards recovery and ask how the participant feels about these.
   b. Ask what the broader benefits of change have been and any negatives they have identified. Reinforce any coping skills used in dealing with these and also acknowledge determination.
   c. Ask what has gone well with their plans and what has gone less well. Express empathy and ask questions that allow for problem-solving and future planning.
   d. Ask how important they feel the changes are now and again how confident they are that they can make these changes – use scales if needed.
   e. Acknowledge any reduction in motivation or confidence since the last interview and explore why this is. Also encourage the participant to identify what would need to change in the future for motivation and confidence to increase.
f. Recognize ambivalence as a normal part of change and ask questions that highlight discrepancies or strengthen commitment to change. Do this in a motivational way.

**Intervention Protocol: Follow-Up Interviews Continued**

g. Ask the participant whether they have any new changes they want to make. Ask what these changes would look like and how it would feel. Allow space for the participant to consider any potential barriers and how they might manage these.

h. Ask the participant to look back and identify any strengths or skills they have used in the past which may transferable to current issues.

i. If a client is ready to commit to change, set one to five SMART goals with the client. Ensure that the goals are:
   i. Specific
   ii. Measurable
   iii. Attainable
   iv. Realistic
   v. Timely

j. Only give advice or information if the participant is open to this and you have asked for permission. One opportunity to share ideas with clients would be in a brainstorming session.
Intervention Protocol: Final Interview

1. Follow all “Interview Protocol” listed previously
   a. Remember to reintroduce yourself by name and job title. Show your photo id if at a face-to-face meeting.
   b. Try to avoid acronyms such as AUT or MIST. Use the full word.
   c. Wrap-up with a summary and get client input on how the interview went.

2. Explain that you are here for the follow-up motivational interview and that the appointment will take about half an hour.

3. Encourage them to minimize any distractions now, if they need to.

4. Remind them that the interviews are recorded and begin recording.

5. Thank them for their time and honor their commitment to improving their own health by participating in the motivational interviewing intervention.

6. The final interview is an opportunity to help the client recognize and honor their personal growth and strengths while helping them plan for continued improvement in the future. You can blend the visioning focus of the first interview with the goal setting focus of the second and third interview.

7. **Begin with a broad, positive question** such as “Can you share with me something positive that has happened since we last spoke?”

8. You can ask which changes they plan to maintain and whether there are any new changes they plan to implement in the future. Allow space for them to identify any potential barriers to these changes and how they might manage these.

9. End on a positive summarizing the changes they feel they have made and the changes they intend to continue with.

10. Express confidence in their ability to continue with the changes and/or achieve future goals.

11. Ask the participant about their experience of engaging in the study and in motivational interviewing such as what have they enjoyed and what have they have found difficult?

12. Express gratitude for their participation and wish them well on their upcoming adventures.

13. Remind the participant that there will be one more contact with [name of Form T assessor] in 3 months’ time to complete the telephone questionnaire. It is still important not to let [the Form T assessor] know that you have taken part in these interviews.
Motivational Interviewing Techniques

1. Follow the clients lead
2. Build trust and rapport
3. Ask open-ended questions (additional information on following pages)
4. Active listening: listen for facts and feelings
5. Reflect: simple and complex reflections that show you are listening and facilitate the client to clarify, expand and/or rephrase (rethink) what they feel and say
6. Summarize: simply summarize what they have said and/or make connections between themes in the conversation
7. Avoid making judgments and having an agenda
8. Express empathy
9. Roll with resistance- give the client autonomy and a sense of power over both the process and the outcomes
10. Consider their readiness to change- Transtheoretical model
   a. Pre-contemplation
   b. Contemplation
   c. Preparation
   d. Action
   e. Maintenance
11. Identify ambivalence
12. Discuss their decisional balance- internal and external motivators, and the pros and cons of staying the same and of making changes
13. Discuss barriers to change
14. Focus on personal strengths, values and motivators
15. Set SMART goals using confidence and importance rulers
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Motivational Interviewing Techniques: Open-Ended Questions

1. Remember: “how” and “what” questions lead to open-ended answers.

2. Try to avoid questions that can be simply answered “yes” or “no”.

3. Listen and pause.

4. Reflect twice as much as you ask questions.

5. Ask one question at a time. If they don’t answer straight away then you can ask if you need to clarify.

6. The client should work harder than you. Don’t think too much about your questions. Reflect and listen if you’re not sure what to ask.

7. You do not have to explore any specific area of wellbeing, but you can make connections to various areas of wellbeing, such as:
   a. Social
      i. Friends
      ii. Family
      iii. Colleagues
      iv. Mentors
   b. Occupational
      i. Paid work
      ii. Unpaid work
      iii. Ergonomics
   c. Financial
      i. Relationship with money
      ii. Not necessarily debt management, savings or wealth accumulation
      iii. Living within means
   d. Spiritual
      i. Spirituality: connections with something higher than themselves
      ii. Faith: values and beliefs
      iii. Religion: organized spirituality and faith
   e. Mental and Emotional
      i. Stress
      ii. Self Esteem
      iii. Self Efficacy
   f. Environmental
      i. Where they live
      ii. Where they work
      iii. Where they play or recreate
   g. Physical
      i. Nutrition
      ii. Mobility
      iii. Physical Activity
      iv. Sleep
Motivational Interviewing Techniques: Open-Ended Questions Continued

8. **Sample open-ended questions below.** NOTE: These are not in any particular order and it would not likely be appropriate to ask them all in one interview.
   a. What was the highlight from the last week?
   b. What you enjoy doing?
   c. Tell me about what makes you happy?
   d. How has stroke impacted on your life?
   e. What was life like before the stroke?
   f. What did your GP tell you about your stroke?
   g. Can you compare what life was like before the stroke and now?
   h. What are your goals?
   i. In an ideal world, what would your life be like in 1-3 years?
   j. If you had a ‘realistic magic wand’ what would life be like in 5 years?
   k. What would you like to achieve in the next 3 months?
   l. Tell me about a time when you felt great in your life.
   m. I would love to hear more about how your ____________ wellness connects to your overall wellbeing. What do you do well with your ____________ wellness?
   n. What happens when you feel ________________?
   o. How can I best support you right now?
   p. Tell me about a success you have had since we last met.
   q. Others:
Appendix

(to be completed)

Actions Flowchart

Toolkit: Templates for use during interviews, e.g. areas of wellbeing, weighing up change, etc