The 12-Month Effects of Early Motivational Interviewing After Acute Stroke

A Randomized Controlled Trial

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Background and Purpose—The purpose of this study was to determine whether motivational interviewing (MI), a patient-centered counseling technique, can benefit patients' mood and mortality poststroke.

Methods—This was a single-center, open, randomized, controlled trial. The setting was a hospital with a stroke unit. Four hundred eleven consecutive patients on the stroke register were >18 years old, not known to be moving out-of-area postdischarge, not receiving psychiatric or clinical psychology intervention, and were without severe cognitive or communication problems preventing participation in interviews. All patients received usual stroke care. Patients in the intervention group also received 4 individual, weekly sessions of MI. The primary outcome was the proportion of patients with normal mood measured by the 28-item General Health Questionnaire (normal <5; low ≥5) using a mailed questionnaire at 12 months poststroke.

Results—At 12-month follow-up (including imputed data), 37.7% patients in the control group and 48.0% patients in the intervention group had normal mood. Twenty-five (12.8%) of 195 patients in the control group and 13 (6.5%) of 199 patients in the intervention group had died. A significant benefit of motivational interviewing over usual stroke care was found for mood ($P=0.020$; OR, 1.66; 95% CI, 1.08 to 2.55) and mortality ($P=0.035$; OR, 2.14; 95% CI, 1.06 to 4.38).

Conclusions—Results suggest that motivational interviewing improves patients' mood and reduces mortality 12 months poststroke.

Clinical Trial Registration—URL: www.controlled-trials.com. Unique identifier: ISRCTN54465472.

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Key Words: depression ■ mortality ■ motivational interviewing ■ psyc & behavior

Psychological problems are common poststroke.[1] There is a strong relationship between early psychological problems and recovery with depressed stroke patients lacking motivation to participate in rehabilitation, making less progress[2] and failing to engage in leisure and social activities.[3] Depression is associated with increased healthcare use,[4] mortality,[5–8] suicidal ideation,[9,10] and suicide[11] poststroke.

Studies addressing psychological problems directly using pharmacological methods,[12–14] and indirectly, for example, by improving social support,[15,16] have been inconclusive. Community-based psychological interventions have mostly proved ineffective at treating depression poststroke.[14] However, community-based studies begin late poststroke (from 1 month[17] to 39 months[18]) and target depressed patients when depression may have already interfered with rehabilitation and recovery. Psychological interventions initiated early poststroke might prevent and/or treat depression.[13,19–21]

Motivational interviewing (MI) is a talk-based therapy that has been applied to many health problems requiring behavior change but could also support adjustment.[22] Negative psychological outcomes such as depression could result from failure to adjust poststroke.[23] We applied MI in a randomized controlled trial early poststroke.[19] Further details of this intervention are given in our article reporting results to 3-month follow-up,[19] which suggested MI improved mood 3 months poststroke. Here we report our results at 12-month follow-up.

Methods

Design

This was a single-center, open, randomized controlled trial (International Standard Randomized Controlled Trial, ISRCTN54465472). Ethical approval was obtained from the Research Ethics Committee, and the procedures were in accordance with university and National Health Service guidance. Full details of methods were given previ-

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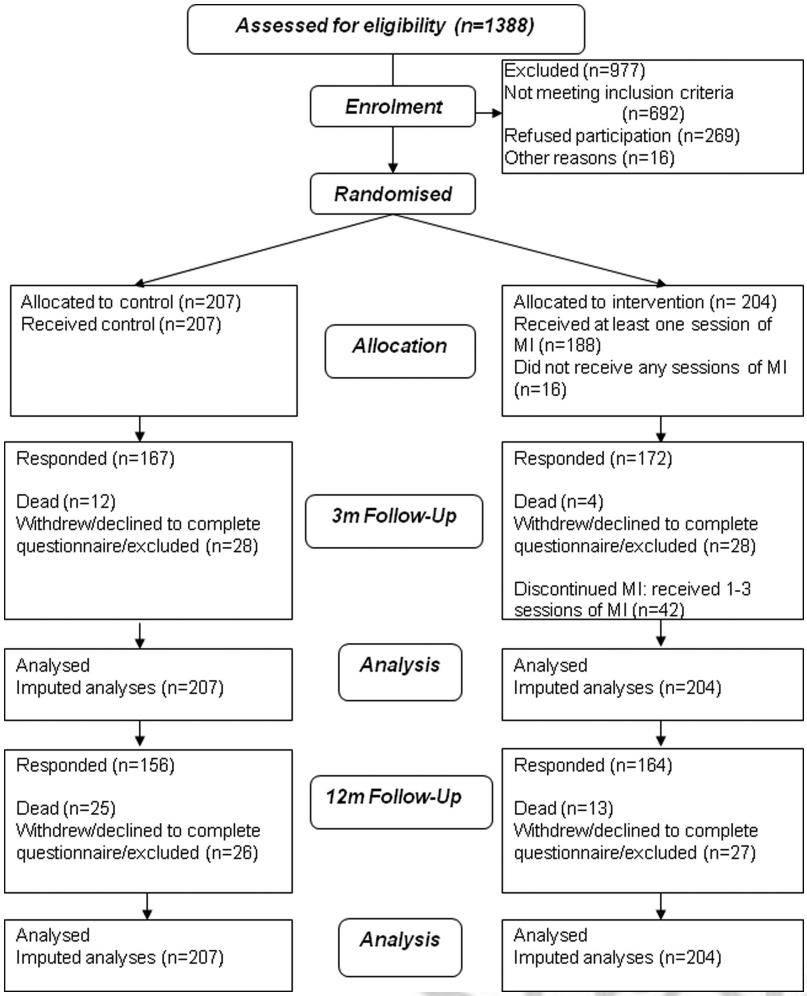

Figure 1. Trial profile.

ously.[17] Brief methods and details of 12-month analysis are detailed subsequently.

Setting

This study was conducted at a hospital serving an urban population of approximately 250 000 people.

Patients

All patients with suspected acute stroke admitted to the hospital are identified on a stroke register. Patients admitted between July 2002 and January 2005, meeting the inclusion criteria, were invited to participate. Inclusion criterion was >18 years old. Exclusion criteria were severe cognitive or communication problems preventing participation in interviews, known to be moving out-of-area postdischarge, and already receiving psychiatric or clinical psychology intervention. Patients who agreed to participate and provided written informed consent were randomized between Days 5 and 28 poststroke.

Randomization

A research nurse randomized patients (1:1 ratio) to either usual care (control) or MI (intervention) using minimization over sex, age (<65 and 65+ years), baseline function in activities of daily living (ADL; Barthel: 18 to 20; 11 to 17; 0 to 10),[24] and location (acute stroke unit or not).[19] The same nurse then assigned intervention group patients to 1 of 4 therapists using an opaque sealed envelope in a pseudo-randomized blocked design. The therapists were not involved in the initial assessment of patients, randomization, or assignment of patients to therapists.

Procedure

Between Days 5 and 7 poststroke, routine clinical data were recorded on age, sex, history of stroke or transient ischemic attack, type (ischemic stroke/intracerebral hemorrhage), and ADL (Barthel).[24] Patients who consented to participate completed a baseline assessment with a research nurse before randomization, which included: mood (28-item General Health Questionnaire [GHQ-28])[25]; beliefs and expectations of recovery (Stroke Expectations Questionnaire [SEQ])[26]; and ADL (Barthel).[24]

Usual Care

All patients received usual medical, nursing, and therapy input, including inpatient care and discharge planning through multidisciplinary team meetings and a Stroke Review Clinic appointment at 1, 3, and 6 months poststroke. Clinical psychology was not available for patients with stroke; patients identified with psychological problems were reported to their clinician who reassessed the patient and referred them to a psychiatrist if appropriate.

Motivational Interviewing

Patients in the intervention group received up to four 30- to 60-minute sessions of MI. In the initial session, the therapist set the agenda so the patient talked about their adjustment to stroke and current concerns. Therapists elicited patients' personal, realistic goals for recovery and perceived barriers to attaining these. By working with patients' dilemmas and ambivalence, and through supporting and reinforcing optimism and self-efficacy, therapists enabled patients to identify their own solutions. Details of therapist

training, supervision, and quality assessment of application of MI techniques are in the original report.[19]

Outcome Assessments

Before contacting the patient, hospital records and the patient's general practitioner were consulted to ensure they were alive. For those who had died, date of death was recorded. Surviving patients were sent a questionnaire. Patients not returning questionnaires within 2 weeks were telephoned by a second research nurse, blind to group allocation, and given the option of declining, having a further questionnaire posted, completing the questionnaire over the telephone, or receiving a home visit to assist.

Responses on returned questionnaires were checked for completeness and signs of emotional distress (GHQ-28 >14 and/or responding positively to items indicating suicidal thoughts). For missing items, patients were contacted and asked for their response. Data entry was by someone blind to group allocation. For patients showing signs of emotional distress, the hospital clinical team or general practitioner was contacted.

Primary Outcome: Mood (GHQ-28)

The GHQ-28[25] is a well-validated and widely used questionnaire for the assessment of mood problems.[27] The robustness and validity of this measure has been proven for standard use and administration over the telephone in stroke.[28]

Secondary Outcomes

Secondary outcomes were status (alive/dead), depression screen (Yale),[29] ADL (Barthel[24]; Nottingham Extended Activities of Daily Living),[30] and beliefs and expectations of recovery (SEQ).[26]

Statistical Analysis

Mood (GHQ-28) was dichotomized (normal [<5] or low [≥5]). The Yale was treated as dichotomous (yes/no), the Barthel as categorical (18 to 20 [good—mostly independent]; 11 to 17 [moderate—somewhat dependent]; 0 to 10 [poor—mostly dependent]; dead), and SEQ as scale data. For the SEQ, we examined beliefs (SEQ help subscale), expectations (SEQ happen subscale), and the difference between beliefs and expectations.

Details of the sample size calculation were provided previously.[17] Inferential analysis was by intention to treat according to an analysis plan drawn up by the statistician and the steering group, peer-reviewed by stroke experts (P.L. and N.L.), and posted on the Clinical Practice Research Unit Web site.

The effects of the intervention on mood and depression screen were analyzed using logistic regression, and its effect on Barthel was analyzed using generalized ordinal regression.[31] The effects on the Nottingham Extended Activities of Daily Living and SEQ were analyzed using general linear modeling. Analysis was adjusted using the baseline value of the outcome variable, when measured, and the factors used for minimization. Where data were missing, imputations were performed as described previously.[17]

Analysis was performed using SPSS (Version 17) and Stata (Version 9). Inferential analyses used a 5% significance level and standard (large sample) 95% CIs using bootstrapping (bias-corrected approach) to assess the sensitivity to the validity of large-sample (asymptotic) results.

Results

Details of sampling, recruitment, randomization, and attrition at 3-month follow-up were reported previously.[19] Figure 1 shows patient flow through the trial. By the 12-month follow-up, 38 patients had died. Of the remainder, 320 completed the questionnaire (response rate 85.8%), of which 3 were partially completed. Twenty-three declined, and 30 were lost to follow-up (16 withdrew/no response, 14 other). Table 1 displays baseline information by group. Patients receiving MI started the intervention 2 to 4 weeks poststroke (median time to first session 18.5 days; interquartile range, 12 to 29 days).

Table 1. Patients' Characteristics*

Variable	Control (n=207)	Intervention (n=204)
Median (IQR) age, y	70 (61–77)	70 (61–78)
Male sex	122 (58.9%)	118 (57.8%)
Stroke type (n=197; 192)		
Ischemic	187 (95.4%)	178 (92.7%)
Primary intracerebral hemorrhage	10 (4.6%)	14 (7.3%)
Median (IQR) Barthel at day 7 (n=180; 183)	16 (9–20)	16 (9–20)
History of stroke or TIA (n=204; 199)	61 (29.9%)	43 (21.6%)
Normal mood (GHQ-28 <5; n=197; 195)	74 (37.6%)	72 (36.9%)
Not often feeling sad or depressed (Yale; n=200; 197)	108 (54.0%)	114 (57.9%)
SEQ (n=200; 197)		
Mean (SD) beliefs	55.8 (6.1)	56.4 (6.3)
Mean (SD) expectations	53.7 (7.7)	55.0 (7.1)
Mean (SD) difference between expectations and beliefs	−2.1 (4.6)	−1.4 (4.0)
Function/dependence in ADL (Barthel pretrial screen)		
Mild (18–20)	99 (47.8%)	100 (49.0%)
Moderate (11–17)	62 (30.0%)	61 (29.9%)
Severe (0–10)	46 (22.2%)	43 (21.1%)

IQR indicates interquartile range; TIA, transient ischemic attack; GHQ-28, 28-item General Health Questionnaire; SEQ, Stroke Expectations Questionnaire; ADL, activities of daily living; SD, standard deviation.

*For variable column, numbers in parentheses indicate no. of patients with data available (control; intervention). Results are frequency (percentage) unless stated.

Outcome statistics for 3-month follow-up were reported previously.[19] Outcome at 12 months poststroke is detailed in Table 2. The significant benefit of MI seen at 3 months remained at 12 months (P=0.02; OR [normal mood], 1.66; 95% CI, 1.08 to 2.55). However, there was no longer a protective effect against depression screen (P=0.80). Figures 2 and 3 illustrate the progression of mood scores from baseline to 12-month follow-up for the patients with normal and low baseline mood, respectively.

There were no significant differences between groups on mean SEQ beliefs score (P=0.61) or mean SEQ expectations score (P=0.37). However, the mean difference between beliefs and expectations was of borderline significance (P=0.05; 95% CI, −2.6 to 0.0). On average, the intervention group had a lower expectations score relative to the beliefs score than the control group (Table 2). Although there was no significant effect of MI over usual care on ADL measured by the Nottingham Extended Activities of Daily Living (P=0.79) or Barthel (OR [mild/no dependence relative to worse outcome], 1.28; 95% CI, 0.85 to 1.93; P=0.24; OR [mild or moderate dependence relative to worse outcome], 1.18; 95% CI, 0.70 to 2.00; P=0.54), there was a protective effect of MI on death (OR [alive relative to dead], 2.15; 95% CI, 1.06 to 4.38; P=0.03). Bootstrapping demonstrated little sensitivity of the confidence limits to large sample assumptions, except for Barthel. However, the protective effect of MI

Table 2. Effect of MI on 12-Month Outcomes Poststroke: Results Are Frequency (Percentage) Unless Otherwise Stated

Variable	Control	Intervention	OR (95% CI) (intervention/control)*
Normal mood (GHQ-28 <5; n=155; 162)	66 (42.6%)	88 (54.3%)	1.66 (1.08 to 2.55)
Not often feeling sad or depressed (Yale; n=156; 164)	69 (44.2%)	74 (45.1%)	1.10 (0.74 to 1.64)
Function/dependence in ADL (Barthel; n=181; 177)			
Mild /no dependence (18–20)	88 (48.6%)	96 (54.2%)	1.0
Moderate dependence (11–17)	56 (30.9%)	50 (28.2%)	1.28 (0.85 to 1.93)
High dependence (0–10)	12 (6.6%)	18 (10.2%)	1.18 (0.70 to 2.00)
Dead	25 (13.8%)	13 (7.3%)	2.15 (1.06 to 4.38)
Variable Mean (SD)	Control	Intervention	Adjusted Difference in Means: Intervention–Control (95% CI)*
SEQ beliefs (n=151; 162)	51.2 (9.7)	53.0 (9.9)	0.5 (−1.4 to 2.4)
SEQ expectations (n=152; 162)	48.6 (10.8)	48.9 (11.6)	−1.0 (−3.2 to 1.2)
Difference between SEQ expectations and beliefs (n=151; 162)	−2.7 (6.1)	−4.0 (6.2)	−1.3 (−2.6 to 0.0)
NEADL (n=156; 164)	12.7 (6.9)	12.9 (7.0)	0.2 (−1.2 to 1.5)

MI indicates motivational interviewing; GHQ-28, 28-item General Health Questionnaire; ADL, activities of daily living; SEQ, Stroke Expectations Questionnaire; NEADL, Nottingham Extended Activities of Daily Living; OR, odds ratio; CI, confidence interval; SD, standard deviation.

*After imputation.

on death and bounds for its likely magnitude was confirmed by logistic regression analysis of alive or dead, for which the bias-corrected bootstrap CI of the OR was 1.06 to 4.73.

Discussion

This study has shown that, in a representative sample of patients able to participate in talk-based therapy, MI had a beneficial effect on patient mood 3 and 12 months poststroke. Furthermore, MI potentially had a long-term protective effect on survival. There was no demonstrable impact of MI on ADL or beliefs and expectations of recovery. However, MI might have influenced the difference between beliefs and expectations.

No other study of a talk-based intervention poststroke has shown a beneficial effect on mood, although a care-management intervention[20] and a psychosocial intervention targeting behavior change (with antidepressants)[21] found positive results. Our results could be attributed to having a usual care arm rather than an attention control, that is, those assigned control doing worse due to awareness they were denied intervention or those assigned intervention doing

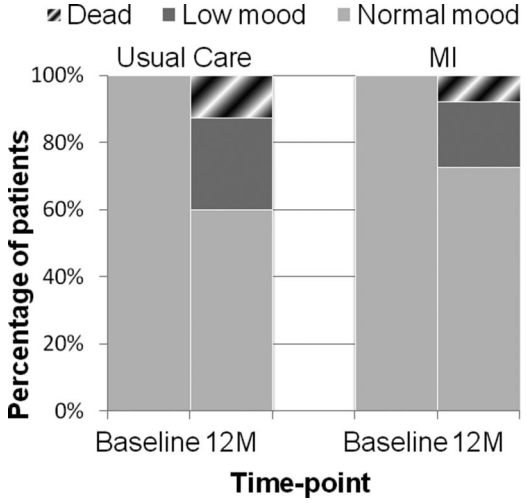

Figure 2. Mood scores from baseline to 12 months (patients with normal mood at baseline).

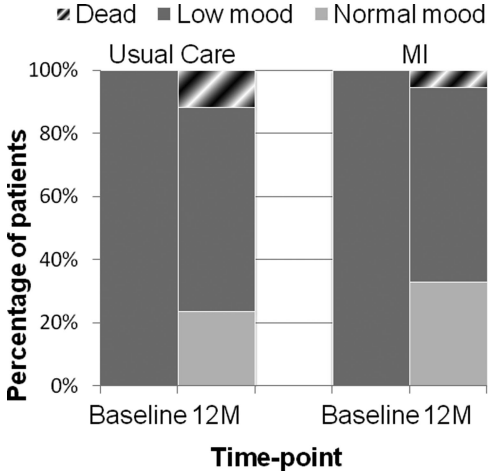

Figure 3. Mood scores from baseline to 12 months (patients with low mood at baseline).

better due to receiving extra attention. However, factors, discussed previously, militate against this.[19] Other methodological issues may explain the differences between our results and other negative studies, including timing and intensity of intervention and training of therapists.

Our intervention began within 4 weeks poststroke; no other studies have examined talk-based interventions this early. The care management[20] and Living Well with Stroke (LWwS)[21] trials began soon poststroke (between 1 and 2 months and within 4 months, respectively). Early intervention is common to studies that positively influenced mood and may reflect prevention of mood problems; however, it cannot be the only explanation for success of these interventions. Other studies of psychosocial interventions poststroke initiated interventions early (eg, discharge,[32] 30 days[33]) without positive results. Additionally, our study included patients with normal and low baseline mood (Figures 2 and 3).

The MI intervention was relatively brief, as were the care-management[20] and LWwS[21] trials (1 interview plus 6 telephone sessions over 12 weeks and 9 sessions over 8 weeks, respectively). In other studies of counseling poststroke, without beneficial effects, patients received between 3[33] and 12 sessions[34] at monthly intervals. Thus, frequency of sessions may influence success more than timeframe.

Our therapists received 4 days training by an MI trainer followed by 10 practice sessions and close supervision from a senior clinical psychologist. The care-management[20] and LWwS[21] trials used very structured interventions but no personal supervision of therapists. Where other studies have given training, the level of intervention-specific, psychology-based training may not have been as high.[14] A Cochrane review for treatment of depression poststroke suggested therapists should use a manualized and prespecified framework for therapy and be trained and supervised in therapy delivery.[14] Developing a training and supervision manual should be integral to the application of MI poststroke.

The beneficial effects of MI on mood and potentially survival poststroke suggest that applying MI in this context was appropriate. Results of follow-up at both time points were fairly consistent, and fewer deaths were seen in the intervention than control group, consistent with previous research demonstrating the negative association between mood and survival.[5–8,11] No other intervention has been shown to improve mood and survival poststroke, yet the protective effect of MI on survival suggests that improving mood could increase survival poststroke.

Interestingly, there was no effect of MI on mood measured by the Yale at the 12-month follow-up, although there was at the 3-month follow-up.[19] Potentially, the Yale assesses different aspects of mood than the GHQ-28. Beliefs and expectations of recovery was measured in this trial by the SEQ, because this reflects the theoretical underpinnings of MI and is known to be related to outcome poststroke.[26] The lack of effect of MI on beliefs and expectations of recovery may be due to the SEQ's inability to detect change. However, the difference between SEQ beliefs and expectations reduced over time in the MI group, suggesting that those who received MI might be, on average, more realistic about recovery than those receiving usual care. Those receiving MI were also less likely to be depressed, perhaps reflecting better adjustment. However, this must be interpreted cautiously, because the association was weak and no validated norms for the SEQ exist.

The lack of effect of MI on ADL was surprising given that the intervention influenced mood and mood is related to function in ADL poststroke.[35] The LWwS[19] trial also saw no improvement in ADL (Barthel).[24] However, the trial[19] did show beneficial effects on mood and other functional outcomes measured by the World Health Organization classification[36] and the Stroke Impact Scale (mobility subscales).[37] The Barthel[24] can lack sensitivity to detect change, and so we also used the Nottingham Extended Activities of Daily Living.[30] Both scales are commonly used in stroke research in the United Kingdom; however, because neither scale demonstrated an effect, they may have insufficient sensitivity to be used in trials of psychological interventions. Future use of more sensitive measures may allow better detection of functional improvements.

MI was effective with just 4 sessions, which would facilitate introduction within stroke care. MI techniques are relatively straightforward to learn. None of our therapists were clinical psychologists, suggesting that MI could be learned by other healthcare professionals. However, it should be emphasized that the therapists in this study did receive regular clinical psychologist supervision.

We allocated 4 therapists to treat 204 patients; 1 therapist left prematurely, having delivered sessions to 11 patients, and was not replaced. If MI only needed a few MI therapists per center, this would facilitate introduction in practice, but practicalities need further exploration. Potential therapist effects need consideration in future trials of talk-based therapy,[38] because there were some differences between the therapists even in this trial.[39] Furthermore, clarification of therapist characteristics affecting outcome of talk-based therapies will be crucial for successful widespread implementation of MI.

The majority of patients in this trial (52.2%) had moderate to severe baseline Barthel scores. Because talk-based therapies require participation in conversation, it is unsurprising that the most severe cases are excluded from trials. This is a limitation of all talk-based therapies poststroke and future work exploring the inclusion of patients with more severe communication problems, and by implication more severe strokes, will be beneficial. An additional limitation of this trial is that data on cause of death were not obtained; therefore, the protective effect of MI on death may be an incidental, chance finding.

Psychological issues must be addressed early in stroke rehabilitation; however, there is a lack of robust evidence guiding prevention or treatment of problems.[40] Although the MI applied here targeted explicit psychological mechanisms,[19,22] the mechanisms by which MI was effective, and how it influenced mood and survival require further exploration. For psychological interventions, examining how they affect patient outcomes alone is insufficient; consideration of issues for implementation into clinical practice must be examined. We need to understand what patient characteristics such as cognitive and/or communication abilities and external

factors such as therapist effects may influence success of interventions. This knowledge will increase the likelihood of success and appropriate targeting for future interventions.

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