Evaluation of brief interventions for managing depression and anxiety symptoms during early discharge period after stroke: a pilot randomized controlled trial

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Background: Prevalence estimates for depression and anxiety in individuals post-stroke are approximately 33 and 29%, yet there are few effective preventive interventions. Interventions which commence pre-discharge and continue during the early post-discharge period may support individuals during the critical transition to home adjustment period. This study aimed to evaluate the efficacy of a self-management intervention and a coping skills intervention, compared to usual care, on anxiety and depression post-stroke.
Methods: A pilot, three-arm randomized trial involving 33 stroke patients (coping skills: *n*=11, self-management: *n*=12, usual care: *n*=10) recruited from an Australian stroke unit. Both interventions were eight 1-hour weekly sessions, with the first two pre-discharge and the remainder at home; targeted both anxiety and depression; and tailored content to individuals. Primary outcome was severity of depressive and anxiety symptoms (measured using Montgomery andÅsberg Depression Rating Scale and Hospital Anxiety and Depression Scale). Secondary measures were: self-efficacy, stroke knowledge, basic and extended activities of daily living, and quality of life. Outcome measures were administered at baseline, one week post-intervention, and at a three month follow-up by a blinded assessor.
Results: Thirty (91%) participants completed the trial. Immediately post-intervention there was a small improvement in stroke knowledge and a small increase in depression symptoms (on one of the two measures of depression symptoms) in the coping skills group compared to usual care. These differences did not remain significant at the 3-month follow-up, nor were there any other significant differences.
Conclusion: Neither a coping skills nor self-management intervention reduced anxiety nor depression symptoms early post-stroke more than usual care. Lack of statistical power may have contributed to the non-significant findings in this pilot study.

Keywords: Stroke, Depression, Anxiety, Randomized controlled trial, Patient education, Cognitive therapy

Introduction

Stroke is one of the main causes of disease burden in Australia and the world[36] and emotional disturbance following stroke is common. Prevalence estimates for depression and anxiety in patients post-stroke are approximately 33 and 29%, respectively[16]. Chronic psychological disorders are associated with poor stroke recovery and functional limitations in self-care, quality of life and social functioning.[10,12,43,46,48] Early mood symptoms after stroke are associated with continued depression at 1 year[29] and depression (33% of individuals) and anxiety (29% of individuals) at 5 years[30] post-stroke, highlighting the need for effective early interventions for individuals with stroke.

The Cochrane review of interventions for treating post-stroke anxiety could not recommend any effective interventions and concluded that further randomized trials were needed.[7] Pharmacological interventions for the prevention of post-stroke depression are not effective and a few trials of non-pharmacological interventions have shown a small effect.[15] A home-based therapy intervention,

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consisting of weekly phone calls and monthly home visits for 12 months, resulted in better social functioning at 6 months, but had no effect on mood.[14] Better mood in intervention group participants has been found for a problem-solving focused intervention[21] and a motivational interviewing intervention.[49] Most previous studies have explored the effect of interventions on daily functioning (either as primary or secondary outcomes), with only two studies using a psychological outcome as the primary endpoint.[21,50] No existing studies addressed post-stroke anxiety and in all but one study,[50] the intervention commenced post-discharge. In Watkins *et al.*'s study, the intervention commenced pre-discharge and participants were followed up for 12 months, with intervention group participants demonstrating significantly better mood and lower mortality.[50]

Gaps in existing research include evaluation of interventions which commence pre-discharge and studies which evaluate intervention effects on both functional and psychological outcomes. Additionally, as depression and anxiety often occur concurrently,[10,12] interventions which target both conditions may be beneficial. However, there are no studies of interventions which focus on both anxiety and depression.

A self-management approach can potentially enhance mood and thus alleviate symptoms of both depression and anxiety. While there have been a few small trials demonstrating effectiveness of self-management interventions in stroke patients,[6,24,25] the effect of such interventions on patient mood is unclear. None of these trials measured mood as a primary outcome and patients were recruited from several months to several years post-stroke. There is therefore a need to explore the impact of a self-management intervention on early post-stroke emotional adjustment. The self-management intervention developed for this trial was based on the chronic disease self-management framework of Lorig and Holman[32] and also built on previous work[19] about meeting individuals' informational needs. Additionally it targeted problem-solving skills, addressed practical needs that individuals may have during the transition period, and aimed to improve participants' performance of relevant functional activities (if identified by them as an area of concern) as dependence in basic and instrumental activities of daily living is a predictor of emotional distress post-stroke.[47]

An alternative approach which can be structured to address both anxiety and depression is one that focuses on teaching patients coping skills. The coping skills intervention evaluated in this study incorporated a broader range of psychotherapy approaches than motivational interviewing and employed both *core* and *individualised* components. It was based on a cognitive-behavioural approach adapted for individuals with brain injury[26] and targeted the development of self-awareness and coping and emotion self-regulation skills prior to discharge and supported their application as individuals adjusted to life at home. Preliminary research[40] supported the efficacy of using a self-awareness approach for individuals with stroke and traumatic brain injury. Further details of these interventions are provided in the methods section and results tables.

Both interventions were designed to commence prior to hospital discharge and continue during the early post-discharge period, thus supporting individuals during the critical transition to home adjustment period. Both self-management and coping skills interventions are integral components in the management of brain injury and other chronic diseases.[25,40] However, there have been no direct comparisons of the impact of these interventions on the emotional adjustment and functional performance of patients post-stroke. The present study aimed to evaluate the effectiveness of two brief early interventions, compared to standard care, for managing depression and anxiety symptoms following stroke. It was hypothesised that at post-intervention and 3-month follow-up: (1) both interventions would be associated with lower levels of depression and anxiety symptoms, and greater stroke knowledge, self-efficacy, functional performance, and quality of life outcomes than standard care; (2) the self-management intervention would be associated with higher levels of stroke knowledge and functional performance than the coping skills intervention; and (3) the coping skills intervention would be associated with lower levels of depression and anxiety symptoms than the self-management intervention.

Methods

Participants

The study was a three-arm randomized trial which ran from October 2009 until April 2011. Participants ($N=33$) with stroke were recruited on a consecutive admission basis from the stroke unit of a large tertiary hospital in Brisbane, Australia. Treating therapists and/or neurologists screened participants to ensure that they met the following eligibility criteria: diagnosis of stroke, adequate English and expressive and receptive communication skills, adequate cognitive capacity to provide informed consent, absence of a neurodegenerative condition (e.g. dementia), discharge destination within 50 km of the hospital, and discharge location other than residential care.

Procedure

After providing informed consent, participants were randomly allocated using a predetermined computer generated randomization sequence, prepared by a person independent of the study, to one of three groups: (1) coping skills intervention; (2) self-management intervention; or (3) usual care (control group). Outcomes were assessed in a face-to-face interview conducted by a research assistant (a registered psychologist) who was blind to group allocation. This was done at: Time 1 (baseline, within a week of randomization), Time 2 (post-intervention — 1 week post-intervention for intervention group participants or approximately two months post-discharge for usual care group participants), and at Time 3 (follow-up — 3 months following intervention conclusion and at approximately 5 months post-discharge for usual care patients). Data were not formally collected on any additional health services used by participants beyond the interventions provided in this study. This study obtained ethical approval from relevant university and hospital human ethics committees and was registered with the Australia and New Zealand Clinical Trials Registry (registration number: ACTRN12609000741280).

Demographic details (age, gender, marital status, years of education, stroke type and hemisphere, previous stroke, presence of stroke related impairment, and pre-morbid psychological history) were collected at the baseline interview and confirmed by medical chart review. Previous diagnoses of depression and anxiety and relevant medications were identified by the treating team and from a review of medical charts.

Interventions

Both interventions were designed to consist of eight face-to-face 1-hour sessions, with the aim of the first two sessions being delivered in hospital before discharge and the remaining sessions provided at the patient's home. Neither of the health professionals who provided the interventions was a member of the stroke unit team. Both were employed specifically to provide the intervention for this trial.

Coping skills intervention

The coping skills intervention consisted of eight sessions delivered by one clinical psychologist and included cognitive and behavioral exercises designed to improve self-awareness and coping skills.[40] It included activities to prepare individuals for discharge and to adjust post-discharge (e.g. psycho-education, self-monitoring, graduated activity participation, and cognitive restructuring). Intervention components (Table 1) included debriefing about the experience of having a stroke, and goal setting using the principles of motivational interviewing in the first two sessions. The following five sessions were individually tailored, and incorporated components of psychoeducation, graded activity participation and behavioral activation, cognitive techniques, cognitive rehabilitation and skills training, family support and involvement, and grief work. The final session covered a review of program, goal setting and planning for the future.

Self-management intervention

The self-management intervention consisted of eight sessions delivered by one occupational therapist who was experienced in working with stroke patients. It included the provision and reinforcement of individualized written information, and activities that were aimed at assisting individuals to learn problem-solving skills, communicate with health professionals, and adjust to life post-stroke. The first session included an assessment of information needs using the 'What you need to know about stroke' education package checklist and subsequent provision of a tailored written education package.[20] An additional checklist titled "Identifying areas of concern" was developed for this study and also completed in the first session. It was developed from a review of the literature about patient-identified concerns following stroke.[23,35,38] The therapist worked with participants to identify their highest priority concern and develop a structured plan using a goal setting aid called "My Action Plan."[4] The second session involved going through the education package and the participant's area of concern of highest priority, with subsequent sessions tailored to the need of the individual participant. Typical topics that were covered are described in Table 2.

Usual care

All participants received the usual multidisciplinary assessment and treatment (core team consists of medicine, nursing, physiotherapy, occupational therapy, and speech pathology) including education and advice, as provided to patients at this stroke unit before and throughout the discharge process. Formal educational opportunities were minimal, with no structured stroke education or support groups offered at the recruitment site. Written materials were also not routinely provided and none of the available materials addressed post-stroke depression or anxiety.

Outcome measures

The primary outcome was the severity of depressive and anxiety symptoms, measured using the

Table 1 Elements of the coping skills intervention and the number of participants in this group that received each component

Element of coping skills intervention	Brief description	Participants receiving this component, *n* (%)
Debriefing	Debriefing of the experience of having a stroke	10 (100)
Goal setting	First session: goal setting for the program using principles of motivational interviewing to facilitate readiness to change. Final session: review of program, goal setting and planning for the future	10 (100)
Psychoeducation	Psychoeducation regarding the mechanisms and effects of stroke	9 (90)
Coping skills training	Identification of coping resources, personal strengths and values and personal metaphors to support adjustment and role transition	8 (80)
Graded activity participation; behavioral activation	Graded activity participation and behavioral activation focusing on positive psychology principles of meaning, engagement and pleasure	7 (70)
Cognitive techniques	Cognitive techniques including mindfulness and behavioral experiments to increase self-awareness of strengths and difficulties (i.e. predicting performance on tasks, completing tasks, evaluating outcomes and guided self-reflection)	6 (60)
Cognitive rehabilitation	Cognitive rehabilitation and skills training — e.g. memory aids, problem-solving	4 (40)
Family support and involvement	Family education and enlisting natural supports	6 (60)
Grief work	For example, reading other people's stories about stroke and writing their own	3 (30)

Montgomery andÅsberg Depression Rating Scale (MADRS) and Hospital Anxiety and Depression Scale (HADS). The MADRS is a clinician-rated scale which assesses the presence and severity of 10 depression symptoms on a scale from 0 to 6. Total scores range from 0–60, with higher scores indicating a greater severity of depression. The diagnostic threshold for depression is a score of 6,[42] while the use of 12 as a cutoff for depression requiring treatment is recommended in clinical practice.[37] When used in a sample of people with acquired brain injury, including those with stroke, its internal consistency has been calculated as 0.77.[2] The Structured Interview Guide for the MADRS was used — when administered face to face, the total score has demonstrated excellent inter-rater reliability (r=0.93) and high internal consistency (0.90).[52] The HADS is a well-established screening tool for anxiety and depression, measures symptom severity and is suitable for repeated administration.[1,53] It has two subscales (anxiety and depression) each with a score ranging from 0 to 21, with internal consistency of 0.83 for the anxiety subscale and 0.82 for the depression subscale.[3] Norms that have been established for HAD scores are: non-cases (0–7), possible cases (8–10), and definite cases (11–21).[53] Secondary outcome measures included the Stroke Self-Efficacy Questionnaire, Nottingham Extended Activities of Daily Living (Nottingham EADL) Scale, Stroke Knowledge Questionnaire, Stroke and Aphasia Quality of Life Scale — general (SAQOL-g), and the Modified Barthel Index (MBI).

The Stroke Self-Efficacy Questionnaire has been previously used in the stroke population.[11,20] The 10 items (each scored on a 10-point Likert scale) draw on both general health and stroke education literature and some components of existing self-efficacy tools.[33,51] The Nottingham EADL Scale is a widely used tool to measure performance in extended activities of daily living.[39] It is comprised of 22 items grouped into four categories: mobility (including public transport); kitchen tasks; domestic tasks; leisure activities. Each item is scored on a four-point scale. It was designed for use with people with stroke and its validity and reliability have been established.[13]

The Stroke Knowledge Questionnaire is a previously validated tool[11,19] which has demonstrated good

Table 2 Elements of the self-management intervention and the number of participants in this group that received each component

Element of self- management intervention	Brief description	Participants receiving this component, *n* (%)
Relaxation/stress management training	Stress management education, relaxation training, practice of this and provision of resources (handouts describing step-by-step guide; audio CD of guided relaxation exercises)	11 (100)
Cognitive and emotional educational	Discussion of impact of thoughts on feelings/actions and realistic appraisal of situations; goal setting; advice on recognizing and managing emotional dysfunction; education on impact of stroke on cognition; advice on and practice of using memory strategies	11 (100)
Fatigue management	Education about fatigue management strategies including recognizing and 'budgeting', scheduling in relation to values and goals, benefits of managing fatigue proactively and relationship to feelings of personal efficacy	11 (100)
Goal setting	Motivational interviewing techniques; active goal setting (using a goal setting sheet and providing ratings of intention for change) — progress reviewed in subsequent sessions	11 (100)
Referral to community providers	Evaluation of support needs post-discharge (personal and instrumental activities of daily living, community support); referral to tertiary/community support agencies; education about community supports for future use	7 (64)
Education about stroke impact and lifestyle modification advice	Education and supported learning (using "What I need to know about stroke" package) about impact of stroke on life, strategies for minimizing impact, and lifestyle modification as requested (using motivational interviewing)	11 (100)
Return to driving advice and support	Discussion about legal obligations, need for medical clearance, driving assessment, and impact of stroke on driving; support options when ceasing driving and information about alternate modes of transport	6 (55)
Return to work advice	Advice and guidance about return to work process; education about graded return to work and impact of post-stroke fatigue on return to work	6 (55)
Communicating with health professionals	Discussion about forming collaborative relationships with health professionals, recording questions, and preparing for appointments	5 (45)
Education about communication concerns	Education and supported learning (using "What I need to know about stroke" package) about communication after stroke; problem solving regarding communication concerns; referral to community supports, services and/or speech pathologist	5 (45)
Support for basic activities of daily living of concern	Review of basic activities of daily living identified by participants as causing concern and strategies and advice provided	4 (36)

test–retest reliability.[18] Response options for each of the 25 items are: true, false and do not know (the latter is scored as incorrect, but is designed to minimize guess responses). The SAQOL-g was developed for use in the stroke population, has demonstrated strong psychometric properties[17] and has been used in stroke populations.[11,19] The MBI is a widely used instrument which measures a person's performance in 10 self-care activities.[42] The MBI has excellent validity, reliability,[31] and internal consistency ($\alpha 0.90$)[42] and is widely used in stroke populations (see for example, Refs. 34 and 41).

Data analysis

Analysis was completed using SPSS (version 20)[22] and on an intention to treat basis and missing data were addressed using the last observation carried forward procedure.[45] ANCOVAs were used to examine between-group differences on each outcome score at Time 2 (post-intervention) and Time 3 (follow-up) with baseline scores used as covariate. A formal power calculation to determine target sample size was not able to be performed due to the lack of previous intervention research in this area and hence a lack of effect size and variance data for the primary

outcome measures for this population. However, a target sample size of 64 participants (on average eight eligible and consenting individuals per month), based on previous research by two of the authors (TH, SE) at the recruiting hospital, was calculated as feasible during the 8 months that were available for the recruitment phase of this study.

Results

Figure 1 shows the flow of participants through the study. One self-management group participant did not receive the full intervention, discontinuing after three sessions due to a move interstate. One coping skills group participant did not receive the intervention, discontinuing after the baseline assessment due to being diagnosed with cancer. Recruitment was more difficult than anticipated, with both the number of eligible patients and the number of consenting individuals much lower during the recruitment period than previously experienced during trials at the same hospital. Demographic and clinical details of participants are shown in Table 3. The baseline scores and ANCOVA results at both follow-up time points are shown in Tables 4 and 5. Group allocation did not significantly influence any outcome at Time 2 (post-intervention), except for small gains in stroke knowledge and an increase in depression symptoms (on the HADs subscale) in the coping skills group, when compared to the usual care group. At Time 3 (follow-up), there were no significant differences for any outcome between either the coping skills group and the usual care group or between the self-management group and the usual care group.

Details of the interventions provided

Not all participants received the intervention sessions as intended with the first two sessions in hospital and the remaining six at the participant's home. Of the nine coping skills group participants who received all eight

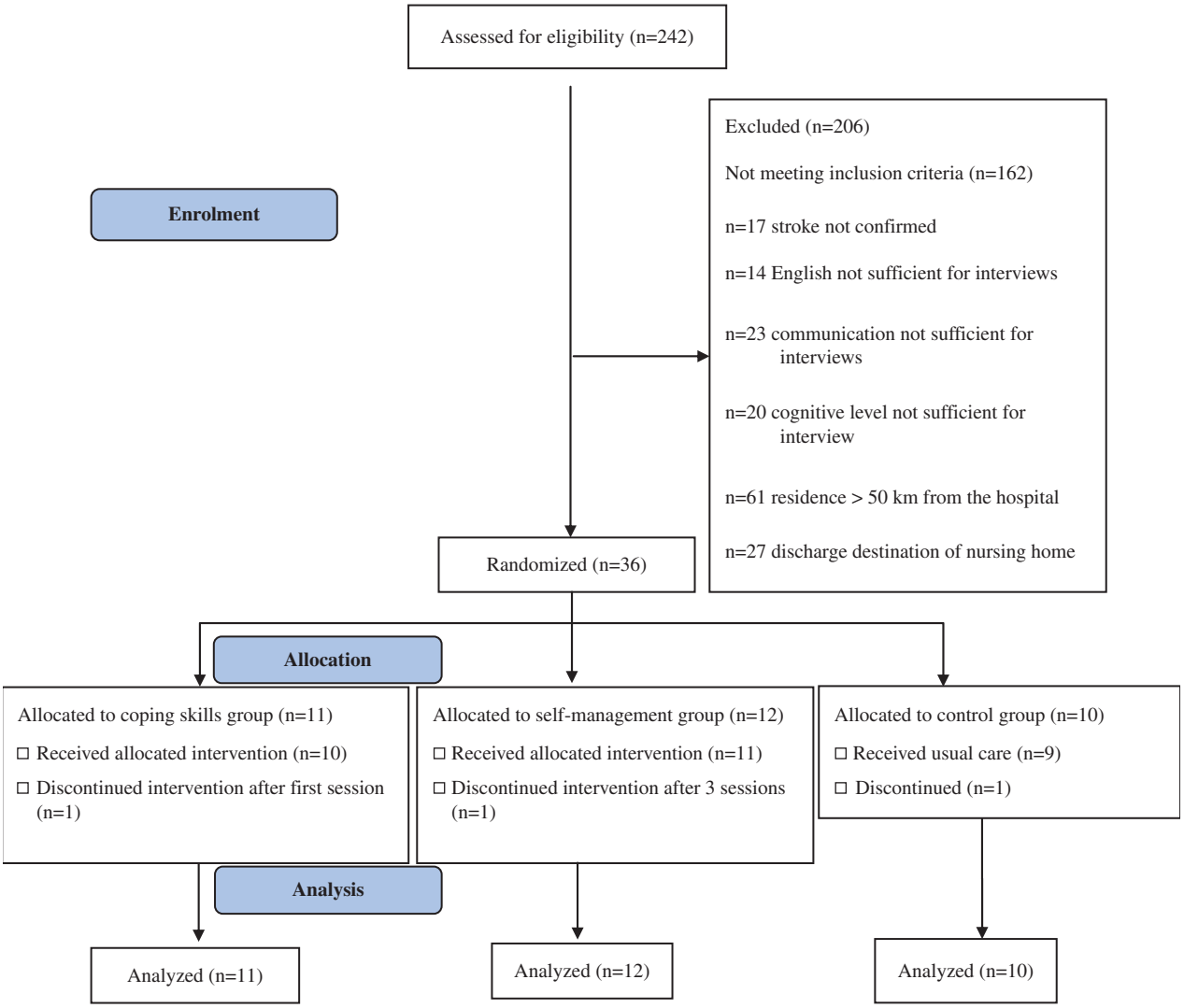

Figure 1 Flow of participants through the study

Table 3 Demographic and clinical details of participants

	Coping skills group (n=11) n (%) unless specified otherwise	Self-management group (n=12) n (%) unless specified otherwise	Control group (n=10) n (%) unless specified otherwise
Age in years, mean (SD)	63.6 (13.0)	60.8 (11.7)	57.0 (14.2)
Female	4 (36.4)	3 (25.0)	4 (40.0)
Marital status:			
Single	2 (18.2)	2 (16.7)	0
Married	8 (72.7)	9 (75.0)	8 (80.0)
Widowed or divorced	1 (9.1)	1 (8.3)	2 (20.0)
Years of education, mean (SD)	10.5 (1.8)	11.8 (2.3)	13.6 (2.4)
Stroke type*:			
LACI	3 (27.3)	3 (25.0)	0
PACI	4 (36.4)	2 (16.7)	2 (20.0)
POCI	2 (18.2)	1 (8.3)	2 (20.0)
TACI	1 (9.1)	0	1 (10.0)
ICH	0	1 (8.3)	1 (10.0)
Other	1 (9.1)	5 (41.7)	4 (40.0)
Hemisphere affected:			
Left	3 (27.3)	6 (50.0)	1 (10.0)
Right	7 (63.6)	5 (41.7)	8 (80.0)
Bilateral	1 (9.1)	1 (8.3)	1 (10.0)
Previous stroke:			
None	7 (63.6)	9 (75.0)	6 (60.0)
One	2 (18.2)	3 (25.0)	2 (20.0)
Two or more	2 (18.2)	0	2 (20.0)
Presence of stroke-related impairments:			
Aphasia	1 (9.1)	2 (16.7)	1 (10.0)
Dysarthria	5 (45.5)	4 (33.3)	4 (40.0)
Perceptual	1 (9.1)	1 (8.3)	0
Visual	3 (27.3)	3 (25.0)	3 (30.0)
Hemiplegia	10 (90.1)	8 (66.7)	7 (70.0)
Previous diagnosis of anxiety or depression	2 (18.2)	4 (33.3)	1 (10.0)
Anxiolytic or antidepressant use:			
Currently	3 (27.3)	2 (16.7)	0
Previous	2 (18.2)	3 (25.0)	1 (10.0)
MMSE, mean (SD)^	27.7 (2.0)	26.8 (2.8)	28.2 (2.3)

Note: *TACI=total anterior circulation infarct; PACI=partial anterior circulation infarct; LACI=lacunar infarct; POCI=posterior circulation infarct; and ICH=intracerebral hemorrhage
^MMSE=Mini Mental State Examination score (score 0–30, with lower scores indicating possible cognitive difficulties).

sessions, one participant received all sessions while still in hospital due to an unanticipated protracted hospital stay, and one participant received all sessions at home due to being discharged earlier than anticipated. Of the 11 self-management group participants who received all the sessions, one participant received all sessions at home, one had all sessions while in hospital, and three had half of their sessions in hospital and half at home. As both of the interventions were tailored to participants' needs, the number of participants in each of the intervention groups that received the various elements of the interventions is provided in Table 1 (coping skills) and Table 2 (self-management). Where written materials are mentioned, copies of these can be obtained by contacting the lead author.

Discussion

This study explored the effects of interventions for managing anxiety and depression during the period of hospital discharge and the community reintegration period following discharge after stroke. It is the first study to focus on preventing symptoms of both anxiety and depression and one of very few studies in which the intervention was designed to commence prior to hospital discharge and continue beyond discharge, with the aim of supporting individuals during the vulnerable period of transitioning home. However, in this small pilot trial, the effect of either intervention is unclear. Immediately post-intervention, there was a small improvement in stroke knowledge and also a small increase in depression symptoms (on one of the two measures of depression symptoms) in the coping skills group compared to the usual care group. These differences did not remain significant at the 3-month follow-up, nor were there any other significant differences between the participants who received usual care and participants in either of the intervention groups.

Table 4 Outcome measure scores at Time 1 and Time 2 and between-group differences (ANCOVA results) at Time 2

	Baseline (Time 1) (mean, SD)			Post-intervention (Time 2) ANCOVA with baseline score as covariate Adjusted mean, standard error			Post-intervention (Time 2) Pairwise comparisons Mean difference (95% CI)			
Outcome (score range)	Coping skills $n=11$	Self Mx $n=12$	Usual care $n=10$	Coping skills $n=11$	Self Mx $n=12$	Usual care $n=10$	Coping skills versus usual care	*P* value	Self Mx versus usual care	*P* value
MADRS (0–60)	13.6, 5.7	14.5, 5.6	15.9, 5.8	14.5, 0.7	14.5, 0.6	14.9, 0.7	0.4 (−1.6 to 2.4)	0.709	0.3 (−1.6 to 2.3)	0.716
HADS — Anxiety (0–21)	5.3, 2.9	7.5, 3.0	8.4, 3.1	7.3, 0.5	7.4, 0.5	6.8, 0.5	−0.5 (−2.0 to 1.0)	0.507	−0.6 (−2.0 to 0.8)	0.376
HADS — Depression (0–21)	6.2, 2.2	6.1, 2.5	7.3, 2.9	7.9, 0.5	6.6, 0.4	6.4, 0.5	−1.5 (−2.8 to (0.1)	0.034	−0.1 (−1.5 to 1.2)	0.842
Modified Barthel Index (0–100)	50.2, 31.2	78.2, 19.2	63.8, 26.1	74.4, 2.6	75.4, 2.5	69.2, 2.6	−5.3 (−12.8 to 2.3)	0.164	−6.2 (−13.6 to 1.2)	0.099
Self-efficacy questionnaire — Total (9–90)	73.0, 11.2	67.8, 10.5	67.0, 14.8	70.3, 1.3	71.7, 1.2	70.3, 1.3	−0.1 (−3.9 to 3.7)	0.965	−1.5 (−5.1 to 2.2)	0.419
Nottingham EADL Scale (0–66)	19.0, 16.2	23.3, 17.5	26.2, 18.1	40.4, 3.0	41.1, 2.9	40.1, 3.2	−0.3 (−9.3 to 8.8)	0.950	−1.0 (−9.8 to 7.8)	0.817
Stroke knowledge questionnaire (0–25)	16.5, 5.8	19.8, 3.0	19.2, 4.2	21.2, 0.4	20.1, 0.4	19.9, 0.4	−1.3 (−2.5 to (0.1)	0.036	−0.2 (−1.3 to 1.0)	0.760
SAQOL-g0-5	3.6, 0.5	3.7, 0.5	3.6, 0.7	3.8, 0.1	3.9, 0.1	3.7, 0.1	−0.1 (−0.3 to 0.9)	0.233	−0.2 (−0.4 to 0.03)	0.083
SAQOL Psychosocial 0–5	3.1, 0.7	3.4, 0.6	3.0, 0.3	3.2, 0.1	3.4, 0.1	3.2, 0.1	−0.01 (−0.3 to 0.3)	0.929	−0.2 (−0.5 to 0.1)	0.205
SAQOL Physical 0–5	3.2, 0.9	3.6, 0.6	3.4, 0.9	3.8, 0.1	3.8, 0.1	3.6, 0.1	−0.1 (−0.4 to 0.10)	0.247	−0.2 (−0.4 to 0.05)	0.131
SAQOL Communication 0–5	4.3, 0.8	4.2, 0.9	4.0, 0.6	4.3, 0.1	4.4, 0.1	4.4, 0.1	0.1 (−0.1 to 0.27)	0.380	0.1 (−0.1 to 0.24)	0.530
STAI — Trait anxiety (20–80)	41.0, 8.4	38.5, 7.9	47.4, 10.7	42.4, 0.5	42.2, 0.5	41.6, 0.6	−0.8 (−2.3 to 0.8)	0.311	−0.6 (−2.1 to 1.0)	0.481
STAI — State anxiety (20–80)	43.7, 11.5	41.4, 8.4	46.3, 6.5	43.9, 0.9	43.3, 0.9	43.6, 1.0	−0.2 (−3.0 to 2.6)	0.878	0.3 (−2.5 to 3.1)	0.829

Table 5 Outcome measure scores at Time 3 and between-group differences (ANCOVA results) at Time 3

Outcome (score range)	Follow-up (Time 3) ANCOVA with baseline score as covariate Adjusted mean, standard error			Follow=up (Time 3) Pairwise comparisons Mean difference (95% CI)			
	Coping skills *n*=11	Self Mx *n*=12	Usual care *n*=10	Coping skills versus usual care	*P* value	Self Mx versus usual care	*P* value
MADRS (0–60)	12.8, 0.8	13.0, 0.8	14.1, 0.8	1.3 (−1.1 to 3.7)	0.260	1.1 (−1.2 to 3.5)	0.323
HADS — Anxiety (0–21)	5.7, 0.5	6.7, 0.5	6.7, 0.5	1.0 (−0.5 to 2.5)	0.193	−0.03 (−1.4 to 1.4)	0.965
HADS — Depression (0–21)	5.7, 0.7	6.4, 0.6	7.0, 0.7	1.3 (−0.6 to 3.3)	0.177	0.5 (−1.4 to 2.5)	0.565
Modified Barthel Index (0–100)	80.7, 2.7	81.7, 2.6	80.9, 2.7	0.2 (−7.7 to 8.0)	0.965	−0.9 (−8.6 to 6.9)	0.823
Self-efficacy questionnaire — Total (9–90)	70.9, 1.2	71.7, 1.1	69.7, 1.2	−1.2 (−4.6 to 2.2)	0.474	−2.0 (−5.3 to 1.3)	0.229
Nottingham EADL scale (0–66)	48.2, 3.0	45.3, 2.8	49.1, 3.1	1.0 (−7.9 to 9.8)	0.827	3.8 (−4.8 to 12.4)	0.371
Stroke knowledge questionnaire (0–25)	20.9, 0.6	20.3, 0.5	20.5, 0.6	−0.4 (−2.1 to 1.3)	0.607	0.1 (−1.5 to 1.7)	0.855
SAQOL-g 0–5	4.0, 0.1	4.0, 0.1	3.9, 0.1	−0.1 (−0.4 to 0.1)	0.330	−0.1 (−0.4 to 0.2)	0.429
SAQOL Psychosocial 0–5	3.5, 0.1	3.5, 0.1	3.5, 0.1	−0.02 (−0.4 to 0.4)	0.938	−0.02 (−0.4 to 0.4)	0.936
SAQOL Physical 0–5	4.0, 0.1	4.0, 0.1	3.8, 0.1	−0.2 (−0.4 to 0.04)	0.111	0.1 (−0.3 to 0.1)	0.246
SAQOL Communication 0–5	4.5, 0.1	4.5, 0.1	4.6, 0.1	0.1 (−0.1 to .0.4)	0.334	0.1 (−0.1 to 0.4)	0.286
STAI — Trait anxiety (20–80)	42.2, 0.5	41.8, 0.5	41.5, 0.5	−0.7 (−2.2 to 0.8)	0.361	−0.3 (−1.9 to 1.2)	0.660
STAI — State anxiety (20–80)	43.0, 1.0	41.4, 1.0	42.4, 1.1	−0.6 (−3.5 to 2.4)	0.696	1.0 (−2.0 to 3.9)	0.504

The non-significant findings are in contrast to the Cochrane review of interventions for preventing post-stroke depression which found some evidence for psychotherapy to produce small treatment effects[15] and a large trial (n=411) of four sessions of motivational interviewing which found significantly better mood at 3-month follow-up[49] and better mood and lower mortality at 12-month follow-up in intervention group participants.[50] There are no existing randomized trials of interventions to prevent post-stroke anxiety to which the results of the current study can be compared.

There are several potential reasons for a lack of clear effect of either intervention. Recruitment was more difficult than anticipated and consequently, with approximately half of the target sample size was recruited, it is likely that the study was underpowered. While the timing of our intervention post-stroke was in line with recommendations of the Cochrane review about future research needs,[15] the spread of the sessions (weekly) and the amount of time that the sessions continued for (approximately 8 weeks after discharge, sometimes less) may not have been sufficient during a period of transition that is often dynamic and fluctuating. No intervention has previously tried to address symptoms of both depression and anxiety in post-stroke individuals and it is possible that the broader focus of the interventions evaluated in this study, compared to previous studies, is not effective for individuals early after stroke. Additionally, participants in our study were, on average, not very symptomatic with fairly low baseline scores, leaving less potential for improvement in symptoms as a result of an intervention. It is possible that a minimal improvement in symptoms may have been meaningful to some individual participants, but this was not explored in study analyses.

The reason for the small differences in stroke knowledge and depression post-intervention for participants in the coping skills group, relative to usual care, is unclear. The focus of the coping skills intervention on enhancing self-awareness of post-stroke changes and identifying thought patterns (e.g. worry about future strokes) may have enhanced participants' receptivity to receiving stroke-related information. Further, the more specific focus on emotions (i.e. expression and regulation) in the coping skills intervention, which did not occur in the self-management group, may have heightened participants' awareness of the implications of their stroke, thus resulting in an increase in self-reported symptoms of depression immediately after the intervention (but not at the 3-month follow-up).

Limitations

An underpowered study as a result of the small sample size may have resulted in a Type II error, which limits the ability of the study to accurately evaluate the effectiveness of these interventions. The therapists who provided the interventions anecdotally reported many positive comments from participants about the usefulness of the interventions; however the lack of a pre-planned qualitative component limits interpretation of the results and participants' perceptions about the interventions. Despite their previous use with stroke patients, several outcome measures may have lacked the sensitivity to detect changes resulting from interventions of a psychosocial nature. Finally, as with many post-stroke psychological intervention trials, the inclusion criteria used may limit the representativeness of the study, as does the use of a single recruitment site.

Future research

Future studies should use a mixed-methods design that allows collection of both quantitative and qualitative data. Additionally, assessing the impact of the interventions on carers or family members would enhance the data, and there is evidence that caregivers' psychosocial wellbeing benefits from psychoeducation programs.[8] Given ongoing limited resources, methods to identify and/or predict those patients most at risk of depression or anxiety (see, for example, Ref. 9) and those able to benefit from intervention are warranted. Owing to the high prevalence of anxiety in community stroke survivors[5] and the lack of randomized trials of interventions for treating or preventing post-stroke anxiety, further research into such interventions, either as standalone interventions or as part of a multi-component intervention, are needed. For example, lower level studies (e.g. single group pre-test and post-test study, case studies) have shown that relaxation training[28] and modified cognitive-behavioral therapy[28,43] may have potential to manage post-stroke anxiety.

Conclusion

The provision of a coping skills or self-management intervention designed to manage anxiety and depressive symptoms during the hospital to home discharge period did not clearly influence stroke participants' outcomes post-intervention or at a 3-month follow-up. Further research employing a mixed-methods design with a larger sample size is recommended to evaluate interventions which focus on managing post-stroke anxiety and depressive symptoms.

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Disclaimer Statements

Contributors

All authors contributed equally.

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Conflicts of interest

No conflicts of interest to declare.

Ethics approval

This study obtained ethical approval from relevant university and hospital human ethics committees and was registered with the Australia and New Zealand Clinical Trials Registry (registration number: ACTRN12609000741280).

References

1 Aben I, Verhey F, Lousberg R, Lodder J, Honig A. Validity of the Beck Depression Inventory, Hospital Anxiety and Depression Scale, SCL-90, and Hamilton Depression Rating Scale as screening instruments for depression in stroke patients. *Psychosomatics*. 2002;43:386–393.

2 Andersson S, Krogstad JM, Finset A. Apathy and depressed mood in acquired brain damage: relationship to lesion localization and psychophysiological reactivity. *Psychol Med.* 1999; 29:447–456.

3 Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res.* 2002;52:69–77.

4 Bodenheimer T, Davis C, Holman H. Helping patients adopt healthier behaviors. *Clin Diabetes*. 2007;25:66–70.

5 Broomfield N, Scoular A, Welsh P, Walters M, Evans J. Post-stroke anxiety is prevalent at the population level, especially among socially deprived and younger age community stroke survivors. *Int J Stroke*. 2013;, doi: 10.1111/ijs.12109.

6 Cadilhac D, Hoffmann S, Kilkenny M, *et al.* A Phase II multicentered, single-blind, randomized, controlled trial of the stroke self-management program. *Stroke*. 2011;42:1673–1679.
7 Campbell Burton C, Holmes J, Murray J, *et al.* Interventions for treating anxiety after stroke. *Cochrane Database Syst Rev.* 2011; (12):CD008860.
8 Cheng H, Chau CS. The effectiveness of psychosocial interventions for stroke family caregivers and stroke survivors: a systematic review and meta-analysis. *Patient Educ Couns.* 2014;95(1):30–44.
9 de Man-van Ginkel J, Hafsteinsdottir T, Lindeman E, Ettema R, Grobbee D, Schuurmans M. In-hospital risk prediction for post-stroke depression: development and validation of the Post-stroke Depression Prediction Scale. *Stroke.* 2013;44: 2441–2445.
10 Donnellan C, Hickey A, Hevey D, O'Neill D. Effect of mood symptoms on recovery one year after stroke. *Int J Geriatr Psychiatry.* 2010;25:1288–1295.
11 Eames S, Hoffmann T, Worrall L, Read S, Wong A. Randomised controlled trial of an education and support package for stroke patients and their carers. *BMJ Open.* 2013;:3(5).
12 Fure B, Wyller T, Engedal K, Thommessen B. Emotional symptoms in acute ischemic stroke. *Internat J Geriatr Psychiatry.* 2006;21:382–387.
13 Gladman J. Validity of the Extended ADL scale in stroke patients. *Age Ageing*. 1993;22(Suppl 3):P3–d-P4.
14 Goldberg G, Segal M, Berk S, Schall R, Gershkoff AT. Stroke transition after inpatient rehabilitation. *Top Stroke Rehabil.* 1997;4:64–79.
15 Hackett M, Anderson C, House A, Halteh C. Interventions for preventing depression after stroke. *Cochrane Database Syst Rev.* 2008; (3):CD003689.
16 Hackett M, Yapa C, Parag V, Anderson C. Frequency of depression after stroke: a systematic review of observational studies. *Stroke.* 2005;36:1330–1340.
17 Hilari K. The impact of stroke: are people with aphasia different to those without? *Disabil Rehabil.* 2011;33:211–218.
18 Hoffmann T. *Development and evaluation of a computer-generated individualised written education package for patients following stroke and their carers*. unpublished doctoral thesis. Brisbane: The University of Queensland; 2005.
19 Hoffmann T, McKenna K, Worrall L, Read S. Randomised trial of a computer-generated tailored written education package for patients following stroke. *Age Ageing*. 2007;36: 280–286.
20 Hoffmann T, Worrall L, Eames S, Ryan A. Measuring outcomes in people who have had a stroke and their carers: Can the telephone be used? *Top Stroke Rehabil.* 2010;17:119–127.
21 House A. The treatment of depression after stroke. *J Psychosom Res.* 2000;48:235.
22 IBM Corp.. *IBM SPSS Statistics for Windows*. Version 20.0. Armonk, NY: IBM Corp. 2011.
23 Jerome D, Dehail P, Daviet JC, *et al.* Stroke in under-75-year-olds: expectations, concerns and need. *Ann Phys Rehabil Med.* 2009;52:525–537.
24 Jones F, Mandy A, Partridge C. Changing self-efficacy in individuals following a first time stroke: preliminary study of a novel self-management intervention. *Clin Rehabil.* 2009;23: 522–533.
25 Kendall E, Catalano T, Kuipers P, Posner N, Buys N, Charker J. Recovery following stroke: the role of self-management education. *Soc Sci Med.* 2007;64:735–746.
26 Khan-Bourne N, Brown R. Cognitive behaviour therapy for the treatment of depression in individuals with brain injury. *Neuropsychol Rehabil.* 2003;13:89–107.
27 Kneebone I, Jeffries F. Treating anxiety after stroke using cognitive-behaviour therapy: two cases. *Neuropsychol Rehabil.* 2013;23:798–810.
28 Kneebone I, Walker-Samuel N, Swanston J, Otto E. Relaxation training after stroke: potential to reduce anxiety. *Dis Rehabil.* 2014;36(9):771–774.
29 Kouwenhoven S, Kirkevold M, Engedal K, Kim H. Depression in acute stroke: prevalence, dominant symptoms and associated factors. A systematic literature review. *Dis Rehabil.* 2011;33: 539–556.
30 Lincoln N, Brinkmann N, Cunningham S, *et al.* Anxiety and depression after stroke: a 5 year follow-up. *Dis Rehabil.* 2013; 35:140–145.
31 Loewen S, Anderson B. Reliability of the Modified Motor Assessment Scale and the Barthel Index. *Phys Ther.* 1988;68: 1077–1081.
32 Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. *Ann Behav Med.* 2003;26: 1–7.
33 Lorig K, Stewart A, Ritter P, Gonzales V, Laurent D, Lynch J. *Outcome Measures for Health Education and Other Health Care Interventions*. . Thousand Oaks, CA: Sage Publications Inc. 1996.
34 Mak A, Mackenzie A, Lui M. Changing needs of Chinese family caregivers of stroke survivors. *J Clin Nurs.* 2007;16: 971–979.
35 Martin BJ, Yip B, Hearty M, Marletta S, Hill R. Outcome, functional recovery and unmet needs following acute stroke. Experience of patient follow up at 6 to 9 months in a newly established stroke service. *Scott Med J.* 2002;7:136–137.
36 Mathers C, Vos E, Stevenson C, Begg S. The burden of disease and injury in Australia. *Bull World Health Org.* 2001;79:1076.
37 Montgomery S, Asberg M. A new depression scale designed to be sensitive to change. *Br J Psychiatry.* 1979;134:382–389.
38 Moreland JD, Depaul VG, Dehueck AL, *et al.* Needs assessment of individuals with stroke after discharge from hospital stratified by acute Functional Independence Measure score. *Disabil Rehabil.* 2009;31:2185–2195.
39 Nouri F, Lincoln N. An extended activities of daily living scale for stroke patients. *Clin Rehabil.* 1987;1:301–305.
40 Ownsworth T, Fleming J, Shum D, Kuipers P, Strong JA. Randomised controlled trial (RCT) for facilitating goal attainment and improving psychosocial function following acquired brain injury: comparison of three intervention formats. *J Rehabil Med.* 2008;40:81–88.
41 Redzuan N, Engkasan J, Mazlan M, Abdullah S. Effectiveness of a video-based therapy program at home after acute stroke: a randomized controlled trial. *Arch Phys Med Rehabil.* 2012; 93:2177–2183.
42 Shah S, Vanclay F, Cooper B. Improving the sensitivity of the Barthel Index for stroke rehabilitation. *J Clin Epidemol.* 1989; 42:703–709.
43 Shields C, Ownsworth T. An integration of third wave cognitive behavioural interventions following stroke: a case study. *Neurodisabil Psychother.* 2013;1:39–69.
44 Shimoda K, Robinson R. Effect of Anxiety Disorder on Impairment and Recovery From Stroke. *J Neuropsychiatry Clin Neurosci.* 1998;10:34–40.
45 Streiner D, Geddes J. Intention to treat analysis in clinical trials when there are missing data. *Evid Based Mental Health*. 2001;4: 70–71.
46 Tang W, Lau C, Mok V, Ungvari G, Wong K. Impact of anxiety on health-related quality of life after stroke: a cross-sectional study. *Arch Phys Med Rehabil.* 2013;94:2535–2541.
47 Thomas S, Lincoln N. Predictors of emotional distress after stroke. *Stroke.* 2008;39:1240–1245.
48 van de Weg F, Kuik D, Lankhorst G. Post-stroke depression and functional outcome: a cohort study investigating the influence of depression on functional recovery from stroke. *Clin Rehabil.* 1999;13:268–272.
49 Watkins C, Auton M, Deans C, *et al.* Motivational interviewing early after acute stroke. *Stroke.* 2007;38:1004–1009.
50 Watkins C, Wathan J, Leathley M, *et al.* The 12-month effects of early motivational interviewing after acute stroke. *Stroke.* 2011;42:1956–1961.
51 Wensing M, Wetzels R, Hermsen J, Baker R. Do elderly patients feel more enabled if they had been actively involved in primary care consultations? *Patient Edu Couns.* 2007;68: 265–269.
52 Williams JBW, Kobak KA. Development and reliability of a structured interview guide for the Montgomery–Asberg Depression Rating Scale (SIGMA). *Br J Psychiatry.* 2008; 192:52–58.
53 Zigmond A, Snaith R. The Hospital Anxiety and Depression Scale. *Acta Psychiatry Scand.* 1983;67:361–370.