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A psychosocial intervention for stroke survivors and carers: 12 month outcomes of a randomized controlled trial

Cover title: Psychosocial intervention for stroke survivors and carers

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ABSTRACT

Background and Purpose: Stroke can have a devastating impact on the mental and physical health of stroke survivors and their carers. We aimed to evaluate the effectiveness of a novel psychosocial intervention designed to improve health outcomes in both groups.

Methods: We conducted a randomized controlled trial of a personalized psychosocial intervention (8 one hour weekly sessions plus 1 booster) compared to usual care for adult stroke survivors and carers. Participants recruited from hospital services and community referrals completed questionnaires at baseline, 3, 6 and 12 months. Primary outcomes were quality of life and self-efficacy; secondary outcomes were depressive and anxiety symptoms, coping, illness perception, work and social adjustment, carer strain and carer satisfaction. Mixed-effect model repeated measures analysis between groups and across time was conducted.

Results: Of the 173 participants recruited (89 stroke survivors; 84 carers), a total of 137 participants - 73 stroke survivors (intervention n=42; usual care n=31) and 64 carers (intervention n=35; usual care n=29) - underwent analysis up to 12 months. No statistically significant differences were found in the primary outcomes between groups over time, though a significant improvement in carer satisfaction was found at 6 months in the intervention group compared to the usual care group.

Conclusion: A personalized psychosocial intervention resulted in a significant improvement in carer satisfaction at 6 months but in no other outcomes. A lack of available services and barriers to social engagement may have impeded the effectiveness of this intervention.

Introduction

Stroke can have a profound impact on the psychosocial health of stroke survivors and their carers.¹⁻⁴ For example, one-third of stroke survivors experience post-stroke depression,⁵ two-thirds of carers experience depressive or anxiety symptoms,³ and both groups report diminished quality of life (QoL).^{3,6} Interventions for stroke survivors and carers which have sought to improve psychosocial outcomes, such as QoL or depressive symptoms, have often emphasized rehabilitation and psychological approaches.^{1-3,7} However, such approaches may neglect important social factors such as family functioning,⁸ social support^{9,10} and relational changes that occur as a result of the stroke and caring role.¹¹⁻¹³ Diminished social functioning is associated with depression¹² and diminished QoL¹⁴ in stroke survivors and is thought to increase burden¹⁵ and decrease social participation¹³ in carers.

There is some evidence that psychosocial interventions can improve outcomes such as QoL,¹⁶⁻¹⁹ depressive symptoms^{4,17,19-22} and use of health care resources³ in stroke survivors and QoL,¹⁻⁴ depressive symptoms²³⁻²⁶ and coping in carers,²⁷⁻³⁰ but limited evidence pertaining to other important outcomes such as self-efficacy, anxiety, carer strain and carer satisfaction.¹⁻⁴ However, a recent systematic review of 31 randomized controlled trials (RCTs) and a meta-analysis of 11 RCTs of psychosocial interventions for stroke survivors, carers and survivor-carer dyads reported improvements in depression, coping and anxiety.⁴ Meta-analysis (11 trials; n=1280) of depressive symptoms found that in seven trials psychosocial interventions reduced depressive symptoms in stroke survivors (SMD: -0.36, 95% CI -0.73 to 0.00; p=0.05) and in six trials reduced depressive symptoms in carers (SMD: -0.20, 95% CI -.40 to 0.00; p = 0.05). These psychosocial interventions for stroke survivors,^{22,28-30} carers^{33,40} and survivor-carer dyads^{46,47,49}

utilized motivational interviewing,²⁹ transitional care,³⁰ problem solving and psychoeducation²² and anti-depressant medication with behavioural support.²⁸ Psychosocial interventions using social support, psychoeducation and problem-solving improved coping in carers^{35,37,38,50} and survivor-carer dyads^{46,47} to varying levels. One study reported statistically significant improvements in stroke survivor anxiety.²⁰ Lessons learned from this systematic review include the challenging nature of defining, designing, implementing and evaluating psychosocial interventions for people who have a variety of support needs

Demonstrating clear evidence of the effectiveness of psychosocial interventions when such interventions by their very nature are complex poses a significant challenge. This is illustrated by the difficulty in describing and interpreting the wide variety of studies purporting to deliver and evaluate psychosocial interventions. Study designs, populations, interventions, comparators and outcomes often vary considerably. We used the lessons learned from our systematic review,⁴ including the difficulty in engaging stroke survivors and carers in complex interventions and authoritative policy statements¹ to inform the design of a new study.

In this study we aimed to describe and evaluate the effectiveness of a novel psychosocial intervention compared to usual care for stroke survivors and carers. Primary outcomes were QoL and self-efficacy; secondary outcomes were depressive and anxiety symptoms, coping, work and social adjustment, illness perception, carer strain and carer satisfaction.

Methods

This RCT evaluated a workbook-based psychosocial intervention (8 one-hour weekly sessions plus 1 booster) for stroke survivors and carers compared to usual care at baseline, 3, 6 and 12 months. This intervention was based on a collaborative therapy framework,³¹ which emphasizes the uniqueness of each individual's recovery, and the need for services to work collaboratively with them.³¹ Study recruitment was from March 2016 to September 2017 with data collection concluded in September 2018 at completion of the trial. The trial was conducted and reported according to CONSORT statement.³² This trial was approved by St. Vincent's Hospital Human Research Ethics Committee (HREC-A 031/12) and overseen by a steering committee. Written informed consent from each participant was obtained. The study protocol is reported elsewhere;³³ there were no significant deviations from this.

Participants

Participants were recruited from three metropolitan hospitals and community referrals in Melbourne, Australia. Eligible participants met the following criteria: diagnosis of stroke as identified from medical records or self-nominated carer of a stroke patient; 18 years or older; ability to converse in English without an interpreter or professional assistance; absence of developmental disability or amnesic disorders impairing their ability to learn from the intervention; and absence of serious comorbid illness, including severe forms of aphasia and cognitive impairment, as identified by the senior nurse.

Randomization, allocation and blinding

De-identified cases were randomly allocated to either the intervention or usual care group. Allocation was determined by a computerized block randomization sequence, conducted by a

researcher external to the trial. Participants were randomized immediately after consent and before baseline assessments: alone if they were not consenting as a dyad; dyads were randomized together to circumvent contamination. Due to the participatory nature of the intervention and the use of self-report measures, participants and investigators could not be effectively blinded.

Intervention

In addition to usual stroke care,³³ the intervention group received a program of personalized psychosocial support - Stroke Care Optimal Health Program (SCOHP) - delivered over 8 one-hour weekly sessions, followed by a 'booster' session at three months (Table 1). Participants received a structured workbook and professional facilitator (psychologist) who worked with them on an individualized basis and offered flexible delivery times (weekend, afterhours) and modes (face-to-face, telephone, Skype). Participants receiving face-to-face support could choose between attending the hospital or receiving home visits. The workbook was comprised of educational information and self-management and reflective exercises which culminated in a health plan. Modules addressed: what is optimal health; I-can-do model; medication; collaborative partners and strategies; timeline activities; visioning and goal setting; building health plans; my health journal (see Table One). Survivor-carer dyads could choose to participate individually or jointly.

Enhancing self-efficacy is at the centre of SCOHP which, in turn, aims to improve self-management skills and optimize mental health and the capacity to access key supports. It combines skill-building (e.g. problem solving, stress management, goal setting) with

146 psychoeducational strategies, based on an individual assessment of need, tailored to each
147 patient and carer.

148 ***Usual care***

149 The usual care group received standard stroke care according to national stroke guidelines,³⁴
150 which included secondary prevention (lifestyle modification, adherence to pharmacotherapy,
151 diabetes management), rehabilitation (goal setting, physical activity, cognition and perception),
152 managing complications (nutrition, oral hygiene, mood disturbance) and community
153 participation and long-term care (self-management, return to work, support).

154 ***Data collection***

155 As shown in Table 2, participants completed self-reported questionnaires at baseline, 3, 6, and
156 12 months. Only the stroke intervention group was assessed at baseline by OHP facilitators
157 using the modified Rankin Scale as it is a clinician-measured instrument. The measurement
158 instruments are described below (see Primary and Secondary Outcomes).

159 ***Primary outcomes***

160 Primary outcomes were QoL and self-efficacy.

161 **Quality of life** was measured by the Australian Assessment of Quality of Life-6 Dimensions
162 (AQoL-6D)³⁵ and the 3-level EuroQoL-5-dimensions (EQ-5D-3L).³⁶ These two instruments were
163 also chosen to perform a health economic cost analysis (to be reported separately). The AQoL-
164 6D assesses six domains of QoL (relationships, 3 items; independent living, 4 items; coping, 3
165 items; mental health, 4 items; senses, 3 items; pain, 3 items) with items summed to an overall

score; higher scores suggest better QoL. The AQoL-6D has good internal consistency.³⁵ The EQ-5D-3L³⁶ assesses five domains of QoL: self-care, mobility, pain, usual activities, discomfort, depression and anxiety. Respondents self-rate their level of severity for each dimension using a 3-level scale. The EQ-5D-3L has an acceptable level of reliability and has been validated for with stroke survivors scoring 1.24 on the Shannon Index.³⁷ For the study data, across all time points, the minimum Cronbach α score for QoL was 0.90, indicating strong internal consistency.

Self-efficacy was measured by the General Self-Efficacy Scale (GSES),³⁸ a 10-item measure comprised of a 4-point scale. Items are summed giving a score range of 10 to 40; higher scores signify greater levels of self-efficacy. Internal consistency of the GSES is deemed acceptable.³⁹ For the study data, across all time points, the minimum Cronbach α score for self-efficacy was 0.89, indicating strong internal consistency.

Secondary outcomes

Secondary outcomes were anxiety and depression, coping, illness perceptions, work and social adjustment, carer strain and carer satisfaction. Each outcome measure used has reported good reliability and validity and been used widely in stroke populations.

Depression and anxiety were measured by the Hospital Anxiety and Depression Scale (HADS),⁴⁰ a 14-item questionnaire that assesses depressive (7-items) and anxiety symptoms (7-items) on a 4-point Likert scale with scores between 16-21 indicating the presence of a mood disorder.⁴⁰ The HADS is widely used and validated with stroke populations.⁴¹ For the study data, across all time points, the minimum Cronbach α score for depression and anxiety were 0.83 and 0.82 respectively, both indicating strong internal consistency.

Coping was measured by the Brief COPE Inventory (B-COPE),⁴² a 28-item questionnaire comprising 14 subscales of two items each and can be divided into adaptive (16 items) or maladaptive (12 items) coping with a 4-point rating scale. The B-COPE has good internal consistency, test-retest reliability and concurrent and convergent validity.⁴³ For the study data, across all time points, the minimum Cronbach α score for adaptive and maladaptive coping were 0.82 and 0.70, indicating strong and acceptable internal consistency respectively.

Illness perception was measured by the Brief Illness Perception Questionnaire (BIPQ),⁴⁴ a 10-item instrument evaluating cognitive perceptions of illness in eight dimensions: timeline, emotional response, consequences, personal control, treatment control, identity, understanding and concern. Items are assessed using an 11-point rating scale. The BIPQ had good test-retest reliability and predictive ability.⁴⁴ For the study data, across all time points, the minimum Cronbach α score for illness perception was 0.70, indicating acceptable internal consistency.

Work and social adjustment was measured by the Work and Social Adjustment Scale (WSAS),⁴⁵ a 5-item questionnaire that assesses social functioning on a 6-point scale. The WSAS has good internal consistency.⁴⁵ For the study data, across all time points, the minimum Cronbach α score for work and social adjustment was 0.91, indicating strong internal consistency.

Carer strain was measured by the Modified Caregiver Strain Index (MCSI),⁴⁶ a 13-item questionnaire that assesses carer strain on a 3-point scale. The MCSI has good internal reliability.⁴⁶ For the study data, across all time points, the minimum Cronbach α score for carer strain was 0.85, indicating strong internal consistency.

Carer satisfaction was measured by the Carer Assessment of Satisfaction Index (CASI),⁴⁷ a 30-item questionnaire that assesses carer satisfaction on a 4-point scale associated with the person being cared for (10 items), the carer (12 items) or interpersonal dynamics (8 items). The CASI has satisfactory internal consistency and construct validity.⁴⁷ For the study data, across all time points, the minimum Cronbach α score for carer satisfaction was 0.94, indicating strong internal consistency.

Table 2 shows the time points for administration of the primary and secondary outcome measures.

Statistical analysis

We planned to use intention-to-treat (ITT) analyses to prevent overestimation of efficacy,³³ but considering the probability of missing data in this trial ITT may have underestimated the intervention effect⁴⁸ decided against this. Demographic data were analyzed for group differences. A mixed effects model repeated measures (MMRM) was used to determine changes in outcomes over time and between groups (intervention/usual care).

Sample size

Power was calculated to detect a medium effect size of Cohen's $d = 0.50$. This was chosen as a clinically meaningful effect size that may be compared with previous RCTs in the area of stroke management programs.⁴⁹ Calculations assumed two primary outcomes (QoL and self-efficacy), four assessment points (baseline, 3, 6, 12 months), a study-wide type I error rate (α) of .05, a correlation of post-treatment scores with baseline measurements (ρ) of 0.81, and a two-tailed

statistical test.⁵⁰ Including 20% attrition, a total of 168 participants (42 carers and stroke survivors in the SCOHP and usual care groups) was the target.

Results

Of the 173 participants recruited, complete data from 137 (73 stroke survivors; 64 carers) were obtained and analyzed (Figure 1) according to the group assigned during randomization.

Participant characteristics

Participant characteristics (Tables 3 and 4) reflect the stroke population.⁵¹ Survivors in the intervention (SCOHP) and usual care groups had a mean age of 69 and 67 years respectively, with those aged 80 years or older comprising 11% and 23% of the SCOHP and usual care groups respectively, and females comprising 52% and 35% of both group respectively. One-fifth were born outside Australia. The Cronbach α for each outcome measure at each time point (baseline, 3, 6 and 12 months) is shown in Table 5.

No group differences were detected, with the exception of ‘months since stroke’: an analysis of frequencies identified this as a serendipitous effect of randomization. As per the modified Rankin Scale (mRS),⁵² of the stroke survivors in the SCOHP group, 1 (2%) reported ‘No symptoms’, 8 (19%) ‘No significant disability’, 9 (21%) ‘Slight disability’, 15 (36%) ‘Moderate disability’, 7 (17%) ‘Moderately severe disability’, and 2 (5%) unknown level of disability. It was not possible to use the mRS in the usual care group.

Carers were aged between 31 to 89 (mean 65) and 26 to 87 (mean 61) years in the SCOHP and usual care groups respectively. Carers were usually female (74% SCOHP; 79% usual

care) and the partner of a stroke survivor (79% SCOHP; 73% usual care). In comparison, stroke survivors and carers were most often married, living in their own home and had completed further education after high school.

Effects of the intervention

The results (Table 6) between groups and over time did not show a significant improvement in the primary outcomes, QoL or self-efficacy. However, there was a significant improvement in carer satisfaction (in relation to the person being cared for) in favour of the SCOHP group at 6 months. There were no other statistically significant findings.

Discussion

In a randomized controlled trial of a psychosocial intervention (SCOHP) for stroke survivors and carers, we found no evidence that it improved between groups and over time the primary outcomes of QoL and self-efficacy. Nor, with the exception of carer satisfaction, did SCOHP improve secondary outcomes of depressive and anxiety symptoms, coping, illness perceptions, work and social adjustment and carer strain in stroke survivors and carers. This accords with previous trials evaluating interventions to improve both of these outcomes in this population,^{19,30,53-55} with only a few studies showing significant improvements in QoL.¹⁶⁻¹⁸ Strengths of this trial include basing the intervention on prior trials in our systematic review and our own pilot data, conducting an RCT, having a control group comprising survivors and carers, and obtaining some new Australian specific data.

Though QoL is deemed an important outcome in this population, its improvement has often proven elusive and this may help explain these neutral findings.¹⁻⁴ Notable exceptions are

psychosocial and educational interventions that have been used in conjunction with physical rehabilitation in hospital and community settings.^{16,17} For example, an RCT of 243 stroke survivors in the UK evaluating a community-based exercise and education scheme held twice weekly for eight weeks for stroke survivors and carers, facilitated by volunteers and exercise instructor and using group work and peer support, reported improvements in QoL.¹⁶ Another RCT of 101 community-living stroke survivors in Canada evaluating a 12-month specialized rehabilitation strategy involving an interprofessional team reported improvements in QoL.¹⁷ While the focus, content, duration, intensity and mode of delivery of interventions varied in these two trials, consideration may need to be given to incorporating such approaches into our intervention to examine whether it impacts on QoL and other outcomes in survivors and carers. SCOHP did not use rehabilitation techniques and thus may have not fully met the support needs of the participants, resulting in largely neutral results. Carers' QoL is likely impacted by their partner's stroke⁵⁶⁻⁵⁹ and may be compounded by carers' lack of routine access to health services which, in turn, likely increases burden,⁶⁰ including psychological,⁶¹ and exacerbates their QoL.⁶²

Regarding the other primary outcome, we incorporated self-efficacy principles in the intervention in order to strengthen the participants' belief that they can accomplish chosen tasks in order to help them better self-manage their stroke/carer role. Significant improvements in self-efficacy have been reported in self-management and education interventions in other chronic diseases, including cardiovascular disease and diabetes,⁶³⁻⁶⁵ but not stroke.^{19,30,53,54} The lack of effectiveness of SCOHP on this outcome may be due to an impoverished service environment. For example, completion of the SCOHP modules culminates

in a health plan. However, a number of barriers to participants accessing services during the trial became apparent, including: limited availability of stroke/carer-specific services (e.g. Stroke Foundation, Stroke Association, Carers Australia);^{34,66,67} most stroke survivors no longer qualifying for important adult services such as the National Disability Insurance Scheme (NDIS)⁶⁸ and adult mental health services⁶⁹ due to their age; and those requiring additional support services (e.g. neurology clinic, department of housing) often encountering complex referral pathways and extensive wait times. Thus participants may not benefit from these services within the trial period. Future interventions should train facilitators in stroke-specific services/referral pathways to improve access and advocate for greater resources.

We found no evidence that SCOHP had a significant effect on depression and anxiety, coping, illness perceptions, work and social adjustment, carer strain or carer satisfaction, findings consistent with other trials of such interventions in this population.¹⁻³ Possible explanations for a lack of effectiveness may relate to study population, contextual factors or intervention content, mode of delivery or dose. This warrants further exploration.

Our finding of a statistically significant difference in carer satisfaction (regarding the person being cared for) in favour of SCOHP is not wholly unsurprising. Considering the scant resources available to carers in countries like Australia^{62,63} and the additional responsibilities carers take on (e.g., medication administration, showering, household duties), SCOHP may have helped alleviate this burden and increased carer satisfaction by enhancing their self-efficacy. However, it is no surprise that carers feel burdened and overwhelmed,^{54,57,60,64,65,70} which may explain why carers were far more difficult to identify, recruit and retain than stroke survivors, with carer attrition higher than that of stroke survivors and 'failure to return the questionnaire'

being offered as the principal reason. The level of participation expected of them in SCOHP may have exceeded their capacity. This is an important consideration for participation in future trials.

Depression and anxiety contribute substantially to the disease burden of stroke survivors and carers.^{4,60,71} There is some evidence that psychosocial interventions can reduce depressive symptoms in stroke survivors^{4,17,21,22} and carers^{4,23,25} but little evidence pertaining to its impact on anxiety.^{4,20} However, our trial included a high percentage of stroke survivors aged 80 years and older (usual care 22%, intervention 12%), a population with increased disability which is a risk factor for post-stroke depression.⁷¹ Indeed, older cohorts such as ours may experience declining mobility and diminished functioning which can inhibit social participation and compound depression. Thus, we were surprised that our intervention had no effect in reducing depressive symptoms, which contrasts with the findings from a recent systematic review and meta-analysis which showed that psychosocial interventions reduced depressive symptoms in stroke survivors and their carers.⁴

In terms of the intervention, participants were offered a variety of modes of delivery, but we found that in most instances they availed themselves of face-to-face sessions, invariably during weekdays. An earlier review of psychosocial interventions for stroke survivors suggested that between five to nine sessions is optimal, though informal feedback from our participants indicated that on-going support was required.¹ Though it is unlikely that mode of delivery made a difference to any outcome, this is an avenue worth further exploration. Future trials should include stroke survivors and carers in their project advisory teams to inform the design,

production and conduct of the study, with special regard to the selection of outcome measures taking into consideration any burden that they may impose.

It should be acknowledged that the trial was underpowered. We aimed to recruit 168 participants (42 survivors and carers in each group) and, although we exceeded this number, complete data were obtained from only 137 of them. Thus, with the exception of stroke survivors in the SCOHP group, there were insufficient numbers of participants (survivors and carers) in the other groups to meet our target sample size. This was despite repeated attempts employing various strategies to enhance recruitment, including reminders. Feedback from participants indicated that lengthy questionnaires, difficulty in posting them and the intensity of physical rehabilitation schedules contributed to drop outs and failure to return questionnaires.

Despite the lack of effectiveness of our intervention, the trial had a number of strengths. First, it was conducted and reported in accordance with CONSORT guidelines.³² Second, this comprehensive psychosocial intervention is among the first to be offered to stroke survivors and carers in Australia and, as such, has contributed new knowledge pertaining to a 'real world' practice environment, including identifying deficiencies in service organization and delivery, which is of great import to local clinicians and researchers. Third, the trial was analyzed using a robust strategy, which featured MMRM analysis and contributed new knowledge regarding the characteristics of stroke service users.

The findings from this trial should be interpreted in light of the following limitations. First, this preliminary RCT was small in size and experienced significant attrition rates which is

likely influenced by the disability associated with stroke survivors and the heavy burden among carers; larger trials are required to confirm or refute these findings. Also, some imbalance in randomization was noted. Blinding of outcomes assessors (i.e. participants) or staff was impossible and they could discern who was or was not receiving usual care; although this is a limitation it is a consequence of conducting trials in a real life setting. It is probable that too many outcome measures were included, which imposed an unrealistic burden on participants and resulted in a reduced sample. Difficulties were also acknowledged in using clinician-based measures, for example the mRS could not be collected in the usual care group. Future trials should consider the impact of dyadic relationships amongst participants and analyze accordingly. Finally, it was noted that there was a significant difference in the time elapsed since stroke between the intervention and usual care group; this could have impacted the findings.

Conclusion

Stroke survivors and their carers have many complex and unresolved needs. Interventions aimed at improving their psychosocial health should focus on preferred choice of intervention, including its mode, content and duration of delivery, and the most appropriate outcomes. Measures of patient and carer experience, which would bolster evidence of effectiveness, should also be incorporated.

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Disclosures

376 None.

377 **Clinical Trial Registration:** ACTRN12615001046594. Registered on 7 October 2015

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Table 1. Content and structure of the intervention

Session	Theme	Focus	Purpose
1	What is health?	Optimal health wheel	Increase ability to understand health as comprised of social, physical, emotional, intellectual, vocational and spiritual dimensions
2	I-can-do model A	Health plan A	Explore strengths and vulnerabilities
3	I-can-do model B	Health plan B	Explore strengths and vulnerabilities
4	Medication	Medication monitoring	Improve knowledge and efficacy regarding medication
5	Collaborative partners/strategies	Identifying partners and support	Consider supports which could be included in the health plan
6	Change enhancement	Understanding the past; planning for the future	Contextualize past and allow for new possibilities to be conceived and planned
7	Goal setting	Planning for the future	Emphasize role of autonomy and choice in adapting post-stroke
8	Health plans	Advanced care planning	Consolidate past 8-weeks into a health care plan designed by participant
9	Booster	Reflect and revise	Reflect on health plan and its efficacy. Opportunity to talk through additional changes/adjustments to plan and process

Table 2. Primary and secondary outcome measures and time points

	Stroke survivor				Carer			
	T1	T2	T3	T4	T1	T2	T3	T4
Outcome measure								
AQoL-6D	X	X	X	X	X	X	X	X
EQ-5D-3L	X	X	X	X	X	X	X	X
GSES	X	X	X	X	X	X	X	X
HADS	X	X	X	X	X	X	X	X
Brief COPE	X	X	X	X	X	X	X	X
BIPQ	X	X	X	X				
WSAS	X	X	X	X	X	X	X	X
MCSI					X	X	X	X
CASI					X	X	X	X

Key: T1 Baseline; T2 3 months; T3 6 months; T4 12 months; AQoL-6D Assessment of Quality of Life-6 Dimensions; EQ-5D-3L European Quality of Life-5-Dimensions; GSES General Self-Efficacy Scale; HADS Hospital Anxiety and Depression Scale; Brief COPE Brief version of the COPE Inventory; BIPQ Brief Illness Perception Questionnaire; WSAS Work and Social Adjustment Scale; MCSI Modified Caregiver Strain Index; CASI Carer Assessment of Satisfaction Index

Table 3. Baseline characteristics of stroke survivors in the SCOHP and usual care groups

Stroke survivors (n=73)	SCOHP (n=42)	Usual care (n=31)	p-value
Age (mean, SD, range) years	67 (13.7, 27-88)	69 (11.9, 48-88)	0.55
Gender (n, %)			0.15
Female	22 (52)	11 (35)	
Male	20 (48)	20 (65)	
Country of birth (n, %)			0.38
Australia	31 (75)	21 (69)	
New Zealand/Asia Pacific	0	1 (3)	
Asia	4 (9)	2 (6)	
UK	4 (9)	2 (6)	
Europe	1 (2)	2 (6)	
Not stated	2 (5)	3 (9)	
Education (n, %)			0.12
Postgraduate	18 (43)	6 (19)	
Undergraduate	3 (7)	3 (10)	
Further	5 (12)	3 (9)	
Secondary	12 (29)	17 (56)	
Other	4 (9)	2 (6)	
Marital status (n, %)			0.61
Married	26 (62)	19 (63)	
De facto	2 (5)	3 (9)	
Divorced/separated	4 (9)	3 (9)	
Single	7 (17)	6 (19)	
Widowed	2 (5)	0	
Other	1 (2)	0	
Accommodation (n, %)			0.62
Own house	27 (64)	17 (55)	
Rental	11 (26)	6 (19)	
Public housing	2 (5)	1 (3)	
Lives with family	3 (7)	1 (3)	
Supported	1 (2)	3 (9)	
Other	2 (5)	4 (12)	
Lives with (n, %)			0.90
Partner	20 (49)	15 (49)	
Family	11 (26)	6 (19)	
Alone	8 (19)	8 (26)	
Friends	1 (2)	1 (3)	
Boarders	1 (2)	0	
Other	1 (2)	1 (3)	
Months since stroke (SD)	70 (117)	28 (28)	0.05
Independent t-test (continuous variables) and Pearson Chi-squared (categorical variables)			

Table 4. Baseline characteristics of carers in the SCOHP and usual care groups

Carers (n=64)	SCOHP (n=35)	Usual care (n=29)	p-value
Age (mean, SD, range) years	65 (13.4, 31-89)	61 (14, 26-87)	0.32
Gender (n, %)			0.63
Female	23 (74)	23 (79)	
Male	9 (26)	6 (21)	
Country of birth (n, %)			0.39
Australia	24 (69)	22 (76)	
New Zealand/Asia Pacific	4 (12)	0	
Asia	1 (3)	1 (3)	
UK	3 (8)	2 (7)	
Europe	3 (8)	2 (7)	
Not stated	0	2 (7)	
Education (n, %)			0.89
Postgraduate	10 (30)	8 (28)	
Undergraduate	8 (23)	6 (21)	
Further	2 (6)	2 (7)	
Secondary	10 (30)	11 (37)	
Other	5 (11)	2 (7)	
Marital status (n, %)			0.25
Married	28 (79)	17 (59)	
De facto	2 (6)	6 (20)	
Divorced/separated	3 (9)	4 (14)	
Single	1 (3)	2 (7)	
Other	1 (3)	0	
Accommodation (n, %)			0.21
Own house	26 (74)	15 (52)	
Rental	4 (11)	7 (25)	
Public housing	0	2 (7)	
Lives with family	3 (9)	1 (3)	
Supported	1 (3)	1 (3)	
Other	1 (3)	3 (10)	
Lives with (n, %)			0.13
Partner	20 (56)	14 (49)	
Family	10 (29)	9 (31)	
Alone	2 (6)	6 (20)	
Other	3 (9)	1 (3)	
Relationship to stroke survivor (n, %)			0.58
Partner	28 (79)	21 (73)	
Parent	3 (9)	6 (21)	
Sibling	1 (3)	1 (3)	
Other	1 (3)	1 (3)	

Independent t-test (continuous variables) and Pearson Chi-squared (categorical variables)

Table 5. The Cronbach α for each outcome (measure) at the four time points

Outcome	Baseline	3 months	6 months	12 months
QoL (AQoL)	0.91	0.91	0.92	0.90
Self-efficacy (GSES)	0.89	0.93	0.92	0.95
Depressive symptoms (HADS)	0.83	0.86	0.90	0.86
Anxiety symptoms (HADS)	0.84	0.82	0.85	0.90
Adaptive coping (Brief COPE)	0.86	0.83	0.87	0.82
Maladaptive coping (Brief COPE)	0.70	0.70	0.72	0.73
Illness perception (BIPQ)	0.70	0.69	0.68	0.71
Work and social adjustment (WSAS)	0.91	0.93	0.93	0.94
Caregiver strain (MCSI)	0.85	0.89	0.89	0.89
Carer satisfaction (CASI)	0.96	0.94	0.95	0.96

Key: AQoL-6D Assessment of Quality of Life-6 Dimensions; GSES General Self-Efficacy Scale; HADS Hospital Anxiety and Depression Scale; Brief COPE Brief version of the COPE Inventory; BIPQ Brief Illness Perception Questionnaire; WSAS Work and Social Adjustment Scale; MCSI Modified Caregiver Strain Index; CASI Carer Assessment of Satisfaction Index

Table 6. The effect of the intervention (SCOHP) between groups and over time

Outcome (measure)	Stroke survivor			<i>p</i> - value	Carer		
	SCOHP Mean (SD)	UC Mean (SD)	SCHOP Mean (SD)		UC Mean (SD)	<i>p</i> - value	
<i>Primary:</i>							
Quality of life (AQOL)							
Baseline	0.61 (0.20)	0.63 (0.24)	0.71	0.71 (0.19)	0.72 (0.21)	0.96	
3 months	0.59 (0.18)	0.62 (0.27)	0.63	0.77 (0.13)	0.71 (0.19)	0.25	
6 months	0.58 (0.18)	0.63 (0.27)	0.40	0.70 (0.16)	0.72 (0.22)	0.74	
12 months	0.58 (0.19)	0.64 (0.27)	0.32	0.72 (0.18)	0.69 (0.24)	0.69	
Quality of life (EQ-5D)							
Baseline	65.05 (18.01)	58.72 (23.19)	0.21	73.88 (17.49)	74.93 (17.00)	0.81	
3 months	68.67 (20.34)	65.45 (23.01)	0.60	79.22 (13.19)	71.29 (15.89)	0.11	
6 months	64.03 (21.73)	67.08 (18.24)	0.58	70.13 (19.13)	74.60 (19.02)	0.45	
12 months	62.55 (20.50)	67.00 (22.62)	0.46	72.94 (19.94)	69.83 (19.78)	0.64	
Self-efficacy (GSES)							
Baseline	30.55 (5.29)	27.93 (6.14)	0.06	30.52 (3.13)	30.89 (4.52)	0.73	
3 months	29.51 (5.97)	29.64 (7.21)	0.94	31.15 (3.16)	31.25 (5.78)	0.95	
6 months	30.30 (4.28)	29.75 (7.02)	0.72	31.31 (4.39)	30.14 (6.64)	0.49	
12 months	29.81 (4.87)	30.40 (8.04)	0.75	30.61 (7.02)	31.38 (5.24)	0.69	
<i>Secondary:</i>							
Depressive symptoms (HADS)							
Baseline	6.31 (4.20)	6.40 (4.52)	0.93	5.14 (3.47)	5.31 (4.27)	0.86	
3 months	6.19 (4.44)	6.88 (5.09)	0.59	4.20 (2.64)	6.10 (5.35)	0.16	
6 months	6.71 (3.85)	6.40 (5.38)	0.80	5.27 (3.80)	5.52 (5.25)	0.85	
12 months	6.57 (5.07)	6.72 (5.51)	0.91	5.33 (3.92)	5.77 (5.01)	0.76	
Anxiety symptoms (HADS)							
Baseline	7.33 (3.78)	6.83 (4.55)	0.62	6.97 (4.14)	6.86 (4.32)	0.91	
3 months	6.64 (3.58)	7.00 (4.34)	0.73	6.10 (3.38)	6.90 (4.05)	0.52	
6 months	7.35 (3.28)	6.44 (5.05)	0.41	6.22 (3.82)	6.47 (5.20)	0.85	
12 months	6.53 (3.72)	6.96 (5.15)	0.73	6.27 (3.35)	7.54 (5.90)	0.42	
Adaptive coping (Brief COPE)							
Baseline	2.71 (0.64)	2.56 (0.71)	0.24	2.30 (0.77)	2.25 (0.68)	0.80	
3 months	2.71 (0.64)	2.47 (0.66)	0.19	2.10 (0.69)	1.98 (0.77)	0.62	
6 months	2.58 (0.79)	2.39 (0.70)	0.39	2.18 (0.66)	1.98 (0.75)	0.35	
12 months	2.39 (0.71)	2.38 (0.68)	0.95	2.28 (0.78)	2.24 (0.80)	0.87	
Maladaptive coping (Brief COPE)							
Baseline	1.86 (0.47)	1.89 (0.54)	0.85	1.69 (0.46)	1.57 (0.50)	0.35	
3 months	1.89 (0.47)	2.04 (0.69)	0.37	1.51 (0.38)	1.55 (0.45)	0.73	
6 months	1.89 (0.41)	1.92 (0.68)	0.85	1.60 (0.43)	1.68 (0.58)	0.59	
12 months	1.94 (0.51)	1.85 (0.66)	0.59	1.60 (0.42)	1.72 (0.62)	0.55	
Social functioning (WSAS)							
Baseline	18.80 (11.46)	19.69 (12.83)	0.76	14.73 (10.44)	15.65 (12.32)	0.76	

905	3 months	20.00 (11.14)	17.16 (13.41)	0.40	15.05 (10.97)	17.44 (11.96)	0.53
906	6 months	20.41 (11.89)	15.25 (12.82)	0.12	17.47 (10.60)	15.45 (11.72)	0.65
907	12 months	18.85 (12.72)	16.12 (13.85)	0.46	18.31 (11.35)	16.38 (14.04)	0.63
908	Illness perceptions (BIPQ)						
909	Baseline	44.55 (12.73)	42.39 (15.67)	0.52			
910	3 months	44.84 (13.07)	39.04 (15.54)	0.13			
911	6 months	45.76 (12.82)	39.54 (15.21)	0.10			
912	12 months	42.30 (15.40)	39.96 (16.97)	0.60			
913	Carer satisfaction (CASI): person cared for						
914	Baseline				2.21 (0.78)	2.16 (0.66)	0.78
915	3 months				2.08 (0.61)	2.06 (0.73)	0.92
916	6 months				2.30 (0.47)	1.74 (0.86)	0.01**
917	12 months				2.30 (0.75)	1.92 (0.89)	0.16
918	Carer satisfaction (CASI): family carer						
919	Baseline				1.54 (0.73)	1.50 (0.81)	0.85
920	3 months				1.47 (0.51)	1.40 (0.67)	0.68
921	6 months				1.66 (0.60)	1.32 (0.76)	0.10
922	12 months				1.62 (0.67)	1.46 (0.77)	0.48
923	Carer satisfaction (CASI): interpersonal dynamic						
924	Baseline				2.06 (0.93)	2.03 (0.89)	0.88
925	3 months				1.90 (0.86)	1.82 (0.84)	0.76
926	6 months				2.04 (0.77)	1.70 (0.90)	0.19
927	12 months				1.98 (0.81)	1.72 (0.99)	0.38
928	Carer strain (MCSI)						
929	Baseline				10.81 (5.55)	11.19 (6.45)	0.80
930	3 months				9.78 (5.43)	11.52 (7.18)	0.41
931	6 months				11.13 (5.67)	9.75 (6.46)	0.46
932	12 months				11.52 (5.20)	9.00 (6.79)	0.20

** p -value <0.01

Independent t -test (continuous variables) and Pearson Chi-squared (categorical variables)

Figure 1. Participant flow chart