The Stroke and Carer Optimal Health Program (SCOHP) for psychosocial health:

A randomised controlled trial

Submitted by

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Declaration

This thesis contains no material that has been extracted in whole or in part from a thesis that I have submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person's work has been used without due acknowledgment in the main text of the thesis.

All research procedures reported in the thesis received the approval of the relevant Ethics/Safety Committees at ACU (HREC 2015-256R) and St Vincent's Hospital/Eastern Health (HREC-A 031/12).

Collaborative arrangements and assistance are detailed in Appendix Two.

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List of publications

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List of awards and work related to this research

SCHOLARSHIPS AND AWARDS

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ACADEMIC COMMITTEES

TRIPOD Steering Committee, St Vincent’s Hospital (2015-2019)

INTERNATIONAL CONFERENCE PRESENTATIONS

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HIGHER DEGREE & RESEARCH SEMINAR PRESENTATIONS

Stroke Week – Research Forum (St Vincent's Hospital) "SCOHP – Research update" (2017)

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TRIPOD Research Planning Day (St Vincent's Hospital) "SCOHP research update" (2017)

Mary MacKillop Institute for Health Research Staff Retreat (ACU) (2016) "Stroke and Carer Optimal Health Program - Research update."

Collaborative Research Network Symposium (CRN) "ICT and recruitment" (2015)

GEM Team Meeting (St Vincent's Hospital) "SCOHP" (2015)

Eric Seal Mental Health (St Vincent's Hospital) "Evaluation of the effectiveness of the Stroke and Carer Optimal Health Program: A randomised controlled trial" (2015)

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Abstract

Background: Stroke is a leading cause of death and disability in Australia and internationally. Stroke affects not just the physical health of the survivor; it can also have a devastating impact on their psychosocial health. Likewise, the psychosocial health of carers can often be adversely affected. It is unclear if psychosocial interventions could improve the psychosocial health of stroke survivors and their carers. This thesis presents a program of research which is comprised of a systematic review and meta-analysis, a randomised controlled trial and analysis of psychosocial mediators. The primary aim of this study was to examine and contribute to the evidence regarding the efficacy of psychosocial interventions that seek to improve the psychosocial outcomes of stroke survivors and their carers, compared to usual care. The secondary aim was to identify potential psychosocial mediators that affect stroke survivors and explore these in relation to the post-stroke experience.

Firstly, a systematic review (*n* = 31) and meta-analysis (*n* = 11) evaluated the effectiveness of psychosocial interventions on depressive symptoms, anxiety symptoms, QoL, self-efficacy, coping, carer strain and carer satisfaction among stroke survivors, carers and survivor-carer dyads. Thirty-one randomised controlled trials (*n* = 5715) were included in the systematic review. Improvements in depressive symptoms, anxiety symptoms, QOL and coping were identified. A meta-analysis (11 trials; *n* = 1280) addressing depressive symptoms identified seven trials of psychosocial interventions that reduced depressive symptoms in stroke survivors (SMD: -0.36, 95% CI -0.73 to 0.00; p = 0.05) with six of these reducing depressive symptoms in carers (SMD: -0.20, 95% CI -.40 to 0.00; p = 0.05).

A prospective RCT ($n = 173$) of a psychosocial intervention for stroke survivors ($n = 89$) and carers ($n = 84$) was conducted. Stroke survivors and carers evaluated a 9-week personalised psychosocial intervention, compared to usual care. Participants completed questionnaires at baseline, and 3, 6, 12 months. Primary measures included health-related quality of life (AQoL-6D and EQ-5D) and self-efficacy (GSE), while secondary measures included depression and anxiety (HADS); coping (Brief COPE); work and social adjustment (WSAS); carer strain (MCSI); carer satisfaction (CASI); and treatment evaluation (TEI-SF and CEQ). A mixed-effect model– repeated measures analysis between groups and across time was conducted with data from 137 participants.

Finally, an analysis of psychosocial mediators was completed from the baseline data of 72 of the stroke survivors that participated in the RCT. Using Structural Equation Modeling, it was determined the 67% of the variation in quality of life was explained by this model. Illness perceptions had a significant direct influence on maladaptive coping, depression and anxiety ($\beta = 0.37$, p < 0.001, $\beta = 0.43$, $p < 0.001$, $\beta = 0.43$, $p < 0.001$, respectively). Maladaptive coping had a significant direct influence on quality of life ($\beta = -.22$, $p < 0.001$). The relationship between illness perceptions and QOL were found to be fully mediated by depression and anxiety, with the relationship between illness perceptions and depression and anxiety being partially mediated by maladaptive coping. A significant positive correlation between depression and anxiety ($p < 0.05$) was noted.

Overall, this program of research contributed significant and original findings regarding the effectiveness of existing psychosocial interventions, the effectiveness of a previously untested psychosocial intervention and shed light on the role of psychosocial mediators for stroke survivors and carers.

Glossary of key terms

Carer: In this thesis, the term 'carer' denotes a carer of a stroke survivor, unless otherwise specified. 'Carers' are distinguished from professional caregivers (e.g. nurses, disability workers, domestic support workers) because they are not paid for performing this role and often do not have formal training (e.g. completing lifting and mobility activities) (Kalra et al., 2004).

Common Sense Model (CSM): This model purports that symptoms of an illness affect individual outcomes while mediated by illness perceptions and coping patterns (Leventhal & Meyer, 1980).

Dyad: The term 'dyad' is used to describe the stroke survivor and their carer as a pair and posits that patient and carer outcomes are inter-related and inter-dependent (Lyons & Lee, 2018).

Optimal Health Program (OHP): A psychosocial support program originally developed for individuals who experience mental illness (Gilbert et al., 2012) that has been adapted in this program of research for trial with a stroke and carer population.

Psychological component: Psychological components address an individual's thought processes and behaviours (e.g. motivational interviewing, counselling), measured using tools that contain psychological sub-scales or questions (Gerrig & Zimbardo, 2002).

Psychosocial interventions: Consist of at least one psychological and at least one social component (Thompson & Ski, 2013).

Social component: Social components relate to an individual's relationship with others, including spouses, family, friends and the broader community (e.g. family counseling, service links), often measured by sub-scales or questions within validated quality of life scales (Northcott, Moss, Harrison & Hilari, 2015).

Stroke: is the sudden onset acute non-epileptic neurologic dysfunction affecting the brain, retina or spinal cord, resulting from either vascular occlusion or vessel rupture with haemorrhage (Coupland, Qureshi, Jenkins, & Davis, 2017)

Stroke and Carer Optimal Health Program: The adaptation of the Optimal Health Program for a stroke and carer population.

Stroke survivor: An individual who has survived a stroke/s (Stroke Foundation, 2017a).

List of common abbreviations

AQoL-6D	Assessment of quality of life-6 dimensions
BIPQ	Brief illness perceptions questionnaire
BFI-10	Big five inventory
Brief COPE	abbreviated version of the COPE Inventory
CASI	Carers assessment of satisfaction index
CEQ	Credibility/expectancy questionnaire
EM	Expectation-maximization
EQ-5D-3L	European quality of life-3 levels
GSE	General self-efficacy scale
HADS	Hospital anxiety and depression scale
HCUQ	Health care utilisation questionnaire
MCSI	Modified caregiver strain index
MMRM	Mixed-effects model, repeated measures
OHP	Optimal Health Program
QALY	Quality adjusted life year
RCT	Randomised controlled trial
SCOHP	Stroke and carer optimal health program
TEI-SF	Treatment evaluation inventory-short form
TRIPOD	Translating Research, Integrated Public health Outcomes and Delivery
WSAS	Work and social adjustment scale

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1.1 Chapter introduction

Stroke is the second highest cause of mortality and the third leading cause of disability worldwide (Feigin, Norrving & Mensah, 2017). The sudden and often catastrophic changes caused by stroke can affect the mental, emotional and social health of both stroke survivors and their carers (Andrew et al., 2014; Bakas et al., 2014; Bakas, McCarthy & Miller, 2017; Cheng, Chair & Chau, 2014). Around 30% of stroke survivors experience depression, triple the prevalence of depression in the general population (Australian Bureau of Statistics, 2015; Towfighi et al., 2017). None-the-less, most stroke survivors return to live in the community with the help of their carers despite ongoing disability and psychological challenges (Ski, Castle, Lautenschlager, Moore & Thompson, 2015). Carers of stroke survivors also face increased psychological morbidity and burden as a result of their caring role (Loh, Tan, Zhang & Ho, 2017). Two-thirds of stroke carers are estimated to experience depression or anxiety (Cheng et al., 2014). Health service pathways to address psychological issues for stroke survivors and their carers are limited as healthcare systems are already oversubscribed and under-resourced (Lindsay, Furie, Davis, Donnan & Norrving, 2014). Thus, innovative solutions are required to support the psychological and social health of stroke survivors and their carers. Psychosocial interventions, which combine psychological and social components, have the potential to improve the psychosocial outcomes of stroke survivors and their carer outcomes.

This thesis presents a program of research that evaluated the effectiveness of one psychosocial intervention that aimed to improve the psychosocial health of stroke survivors and/or carers, and also analysed psychosocial mediators in stroke survivors.

1.2 Stroke

A stroke is the sudden onset of acute non-epileptic neurologic dysfunction affecting the brain, retina or spinal cord, resulting from either vascular occlusion or vessel rupture with haemorrhage (Coupland, Qureshi, Jenkins & Davis, 2017). This blockage, or bleed, prevents a sufficient supply of blood and oxygen from reaching brain cells. As a result, cells that were starved of oxygen and nutrients die and the affected areas of the brain cause individuals to experience neurological impairments (Stroke Foundation, 2017a). It is important to note that the term 'stroke' actually refers to a family of cerebrovascular diseases, not just a single condition (Benjamin et al., 2017; Sacco et al., 2013). There are two primary types of stroke - ischaemic stroke in which the blood vessel becomes blocked and haemorrhagic stroke where there is bleeding in the brain from a ruptured blood vessel (Sacco et al., 2013). Transient ischaemic attack (TIA) is a subset of stroke and is characterised by signs and symptoms of brain ischemia that resolve in less than one hour and does not cause brain cells to die or produce permanent damage (Mozaffarian et al., 2016). Thus, TIA differs fundamentally from both ischaemic and haemorrhagic stroke. For this reason TIA was not included in the scope of this research.

Haemorrhagic and ischaemic stroke can produce serious and disabling symptoms corresponding with the parts of the brain or central nervous system injured by the stroke. For example, injury to the cerebrum may affect voluntary motor functions such as speech, emotions, intellectual or cognitive functioning, vision, tactile and spatial neglect, whereas injury to the cerebellum may cause problems with muscle movements, balance and posture (Winstein et al., 2016). Additionally, a stroke within the brain stem may cause respiratory dysfunction, loss of consciousness including coma, motor/sensory pathway disruption, and dysfunction of cranial nerves (Chen et al., 2000). Common stroke symptoms include mobility and balance deficits, motor control issues, bladder and bowel control and difficulty with speech (Miller et al., 2010). In addition to the physical disabilities caused by a stroke, individuals often experience psychological and social sequelae, such as depression, anxiety and social isolation (Kruithof, van Mierlo, Visser-Meily, van Heugten & Post, 2013). As a result, the personal burden experienced by stroke survivors can include loss of employment (Hackett, Glozier, Jan & Lindley, 2012), reduced exercise participation (Billinger et al., 2014) and potential loss of independent living (Nguyen et al., 2015).

The stroke literature has a predominantly medical focus, likely shaped by the urgent and sudden circumstances in which a stroke occurs. The disabling impact of a stroke may be immediately evident in individuals who have pronounced physical disability or speech difficulties. In contrast, the sometimes subtle presentations that indicate psychological distress in stoke survivors can be missed by clinicians (Vuletić, Sapina, Lozert, Lezaić & Morović, 2012) so this distress is notably under-treated (Winstein et al., 2016). While much progress has been made regarding clinical treatment for stroke, interventions do not usually address the psychological distress commonly experienced by stroke survivors and their carers.

1.3 The burden of stroke in Australia

In 2017, 475,000 Australians (2% of the population) were estimated to have had a stroke at some point in their lives (Stroke Foundation, 2017b), with a further 8,400 mortalities reported in 2015 (Australian Institute of Health and Welfare [AIHW], 2018). In 2014, approximately 35,200 stroke events were reported in Australia, with a higher population prevalence in men (2%) than in women (1%) (AIHW, 2018). Of all strokes in Australia, 70% are first-time strokes (AIHW, 2013). Further, half of all strokes in Australia occur in individuals aged 75 years and older (National Stroke Foundation, 2010). Indeed, stroke is an increasingly common and expensive challenge for healthcare providers (Meschia et al., 2014).

Around one third of Australian stroke survivors acquired a new disability (i.e. a limitation or impairment that restricts everyday activities for a minimum of 6 months) (AIHW, 2013), though this is not well reported in the scholarly literature. An Australian study from 2014 was developed with input from of stroke survivors and carers from the Australian National Stroke Registry and the National Stroke Foundation. This survey of community-dwelling stroke survivors reported that their stroke affected their ability to work (54%), use their feet or legs (40%), use their arms or fingers (53%), or affected their speech (25%), emotional health (16%) or sight (12%). Additionally, an Australian cross-sectional study of community-dwelling stroke survivors (*n* = 765), 12 months post-stroke, found that 84% of the participants reported unmet health needs, including emotional problems (73%) and leisure participation (64%) (Andrew et al., 2014). Of note, this study excluded stroke survivors who were no longer living in the community. Thus, further studies are required to map the disability of these individuals and confirm the findings concur with primary data.

Information about carers of stroke survivors in Australia is limited. The available information indicates that Australian carers carry a heavy burden responding to the physical, psychological and financial needs of a stroke survivor (AIHW, 2013; Hussain, Wark, Dillon & Ryan, 2016). In 2009 it was estimated that there were 74,965 carers living with stroke survivors; 70% were female and almost two-thirds were over 60 years of age (AIHW, 2013). Carers themselves also face great burden, psychosocial and physical, and often struggle to navigate the few service pathways available to them in the Australian healthcare system (Ski & O'Connell, 2007). For example, 13% of Australian carers of stroke survivors reported not receiving respite services despite needing it (AIHW, 2013). In qualitative interviews, carers report how they often struggle to cope with their new circumstances (El Masry, Mullan & Hackett, 2013). For example, an Australian cross-sectional study of rurally located stroke carers (*n* = 222) found that almost half reported high levels of psychological distress, with more than 70% reporting depressive symptoms (Hussain et al., 2016).

Economically it was estimated that in 2012 stroke cost Australia was more than (AUD) $5 billion; with (AUD) $3 billion due to lost productivity, (AUD) $881 million in health costs and (AUD) $222 million in carer costs (National Stroke Foundation, 2013). Indeed, the economic costs associated with stroke also greatly impact on the community.

1.4 International burden of stroke

Stroke not only poses a major challenge in Australia but worldwide. In 2014, the World Health Organisation estimated that there were 6.7 million fatal strokes globally (World Health Organisation, 2014). Also, many stroke survivors will experience more than one stroke. For example, in the USA approximately 795,000 people have a stroke each year, of which 185,000 are a recurrent stroke (Benjamin et al., 2017). Stroke is a common and destructive disease affecting both first world and emerging economies (Global Burden of Disease 2013 Mortality and Causes of Death Collaborators, 2015; World Health

Organisation, 2014). Globally, stroke is the third greatest cause of disability (Feigin et al., 2017). The American Heart Association and American Stroke Association have reported that the improved management of modifiable risk factors (e.g. hypertension, smoking, diabetes) and advances in stroke-care have led to a decline in stroke-related fatalities; although these figures may understate the impact of mental health stressors that are described in scholarly literature and therefore downplay their importance (Lackland et al., 2014). At the same time, advancements in stroke care appear to have increased the number of stroke survivors living with a disability (Nguyen et al., 2015). A US retrospective cohort study of stroke survivors (*n* = 2,085) reported that 85% of participants preferred discharge to the home-environment, with 25% reporting minor impairment and a further 25% reporting severe impairment (Nguyen et al., 2015). A further 10% of the stroke survivors were discharged into institutional care (Nguyen et al., 2015), placing additional strain on resources.

Stroke and its disabling consequences create substantial global economic burden. For example, the first five years post-stroke in England, Wales and Northern Ireland was estimated to cost £3.6 billion (Xu et al., 2017). Authors of a review of international epidemiological literature addressing the global burden of stroke from the past 20 years forecast the cost of stroke to rise dramatically over the next decade (Mukherjee & Patil, 2011; Ovbiagele et al., 2013). For example, it has been estimated that the annual total cost of stroke care in the US will increase by 129% to a total of (USD) $240.67 billion, between 2012 and 2030 (Ovbiagele et al., 2013).

1.5 Psychosocial health

The abrupt nature of stroke and its devastating impact on the body can overshadow serious psychosocial health issues, which are also a fundamental part of the stroke etiology. It may be some time before current stroke healthcare systems can fulfil the World Health Organisation definition of health, as “a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity” (1946, p. 100). Although there is growing evidence that psychosocial health is essential to a stroke recovery and carer wellbeing, little progress has been made in addressing these issues, as reflected in studies that do not report on the acceptability of interventions or the impact on family and carers, as has been recommended by stroke and carer organisations (Carers Australia, 2018; Stroke Association of Victoria, 2018).

In the simplest terms, ‘psychosocial health’ combines both psychological and social aspects of one’s health (Thompson & Ski, 2013). For example, ‘psychological’ components describe the behaviours and mental processes that constitute psychological health (Gerrig & Zimbardo, 2002, p. 2). Within a stroke context, psychological components include coping skills (Lo Buono, Corallo, Bramanti & Marino, 2017) and behavioural adaption (Bakas et al., 2009). Meanwhile, ‘social components’ take into account how individuals, families, groups and the community interact (Northcott et al., 2015). Within the context of stroke, social components include survivor-carer dyad functioning, family functioning and the interaction with health services (Ostwald et al., 2014; Savini et al., 2015).

1.6 Psychosocial impact of stroke

Damage to a stroke survivor’s psychological and social health is often inconspicuous, frequently undiagnosed and subsequently under-treated (Hollender, 2014). In fact, over a decade ago, the Australian National Stroke Foundation (2007) reported that many stroke survivors feel as though the impact of stroke turns their world upside-down. Around 1 in 4 stroke survivors describe the impact as equal to or worse than death

(Sturm et al., 2004). Many also describe it as falling into a black hole (Cadilhac et al., 2017). It is widely established that the QoL of stroke survivors is diminished post-stroke (Bakas et al., 2014; Bakas et al., 2017; Cadilhac et al., 2017; Lo Buono et al., 2017; van Mierlo, van Heugten, Post, Hoekstra & Visser-Meily, 2018). The QoL of stroke survivors is reportedly lower than that of the general population and is affected by the physical, psychological and social ramifications of the stroke (Ski & O'Connell, 2007). A wide range of physical factors have been associated with poor QoL in stroke survivors, including risk of falls and incontinence (Katona, Schmidt, Schupp & Graessel, 2015; Visser et al., 2015). A systematic review of longitudinal studies (*n* = 9) exploring the psychological factors affecting the QoL of stroke survivors reports that internal locus of control, self-worth, hope, optimism and effective coping styles were each associated with better QoL (van Mierlo et al., 2014). However, these findings should be considered within the limitations of the study including that there were only nine studies, of which each study only required 50% of more stroke survivor participants to be included. Future reviews should explore and compare these results with those of ‘stroke only’ studies. Importantly, social participation has been identified as a determinant of QoL, negatively affected by the physical (Huang et al., 2013) and psychological impact of the stroke (Lo Buono et al., 2017).

Depression and depressive symptoms are common amongst stroke survivors. Depression is a serious medical condition that is defined in the Diagnostic and Statistical Manual of Mental Disorders (Version 5) as a disruption to an individual’s ability to regulate their own mood resulting in a sad, irritable or empty mood, which presents alongside somatic and cognitive changes and lasts more than two weeks (American Psychiatric Association, 2013). Depression and depressive symptoms constitute a spectrum of depressive presentations in which ‘depression’ meets the criteria required for a clinical diagnosis. In contrast, the term ‘depressive symptoms’ denotes subthreshold depressive characteristics but not a clinically diagnosed disorder (Rodríguez, Nuevo, Chatterji & Ayuso-Mateos, 2012). Depression can negatively affect the stroke survivor’s physical outcomes (e.g. increased risk of mortality, reduced participation in rehabilitation) (De Ryck et al., 2014; Hollender, 2014; Pan, Sun, Okereke, Rexrode & Hu, 2011) and constitutes a serious medical condition that requires treatment in its own right. A cohort study (n = 220) from the UK, Switzerland, Belgium, and Germany reported that the prevalence of depression and anxiety, using the Hospital Anxiety and Depression Scale (HADS), was 29% in survivors up to 5 years post-stroke and with symptoms higher at five years than six months for 33% of survivors (Lincoln et al., 2013). However, this study excluded stroke survivors older than 85 years old, who are more likely to not be discharged to the community and, therefore, are likely to experience greater levels of anxiety and depression (Saposnik, Cote, Phillips, Gubitz, Bayer, Minuk, & Black, 2008). Furthermore, depression often goes unrecognised by clinicians as well as by stroke survivors and their carers (Klinedinst, Dunbar & Clark, 2012)

Anxiety is also common amongst stroke survivors (Cumming, Blomstrand, Skoog & Linden, 2016; Wright, Wu, Chun & Mead, 2017). Anxiety disorders are characterised by general features such as irritability, somatic changes, increased worry and nervous tension (American Psychiatric Association, 2013). Subtypes of anxiety include generalised anxiety disorder (GAD), obsessive compulsive disorder (OCD) and phobic disorder (American Psychiatric Association, 2013). Anxiety and anxiety symptoms are a part of a spectrum of anxious presentations in which ‘anxiety’ fulfills the criteria required for a clinical diagnosis, while the term ‘anxiety symptoms’ denotes subthreshold anxious characteristics but not a clinically diagnosed disorder (American Psychiatric Association, 2013; Karsten, Nolen, Penninx & Hartman, 2011).

A systematic review and meta-analysis of observational studies (*n* = 44 publication; 5,760 stroke survivors) found that the prevalence of anxiety in stroke survivors increased over time, with 20% of stroke survivors having experienced anxiety at one-month post-stroke, rising to 24% by six months post-stroke (Campbell Burton et al., 2012). With regards to the subtypes of anxiety, a case-controlled study (*n* = 149) from Sweden reported the prevalence of GAD as 27%, OCD as 9% and phobic disorder as 24%; of note, the mean age of the participants was 81 years old (Cumming et al., 2016).

Self-efficacy determines an individual's belief about their ability to accomplish a chosen task (Bandura, 1995, p. 2) and is, therefore, essential to recovery after a stroke (Glass et al., 2004; Hoffmann, Ownsworth, Eames & Shum, 2015; Kendall et al., 2007). A systematic review that evaluated stroke survivor self-efficacy reported that survivors with high self-efficacy completed their daily activities more easily than stroke survivors with low self-efficacy; adding that self-efficacy was positively associated with QoL and negatively associated with depression (Korpershoek, van der Bijl & Hafsteinsdóttir, 2011). However, this systematic review included observational studies, thus it may have been difficult to critically assess for these outcomes using only external observation rather than self-report. The relationship between self-efficacy, psychological illness, such as depressive symptoms, and social participation is complex. Of concern, a longitudinal study from Germany (*n* =88) found that decreased self-efficacy was associated with depressive symptoms at 6 months post-stroke (Volz, Möbus, Letsch & Werheid, 2016) and hypothesised that the decrease in self-efficacy and depressive symptoms was a reflection of the stroke survivor's high expectations after commencing rehabilitation and subsequent dissatisfaction with their long-term recovery.

An individual’s attempt to mediate stress via behaviour and cognitive processes is commonly referred to as ‘coping’ (Lazarus & Folkman, 1984, p. 141). Stroke survivors are often besieged with a range of physical, psychological and social stressors as a result of the stroke (Lo Buono et al., 2017). The very nature of the stroke (i.e. a traumatic brain injury) can impede the ability of some stroke survivors to engage with the level of executive functioning that is required for adaptive coping strategies (Kegel, Dux & Macko, 2014). Illness perceptions (e.g. an individual’s cognitive and emotional representations of their illness experience) (Broadbent, Petrie, Main & Weinman, 2006) and coping are thought to mediate important physical and psychosocial outcomes (Aujla et al., 2016; Hagger & Orbell, 2003).Social participation is an essential part of health, yet many stroke survivors experience varying degrees of social inactivity (Padberg et al., 2016) and isolation (Lou, Carstensen, Jørgensen & Nielsen, 2017). A meta-analysis of the prevalence of psychosocial outcomes revealed that post-stroke depression and anxiety are not only associated with each other, but they also impact an individual’s social health, exacerbating social difficulties that can result from the loss of mobility and independence post-stroke (Ayerbe, Ayis, Wolfe & Rudd, 2013). A 1993 US longitudinal study of ischaemic stroke survivors (*n* = 46) showed that participants (even if very disabled) who engaged in social activities with the assistance of family and friends reported faster and more extensive functional recovery (Glass, Matchar, Belyea & Feussner, 1993); although these findings are yet to be confirmed by similar but more highly powered studies. Although this point has not been investigated more recently, it highlights the potential importance of social participation and how it is a part of a holistic health system. A systematic review of observational studies found that depression in particular negatively impacts upon social factors (e.g. social isolation, living alone, place of residence, social support) (Hackett & Anderson, 2005); however, more rigorous studies using validated measures are required to quantify this impact. Conversely, depression can lead to a loss of motivation and increased social isolation (Towfighi et al., 2017). Likewise, feelings of anxiety can lead to avoidant behaviour, including the avoidance of social situations (Chun, Whiteley, Dennis, Mead & Carson, 2018). Regarding community support, stroke survivor services are limited and may be difficult to access. For example, an Australian cross-sectional study (*n* = 222) of carers found that 33% of the participants' stroke survivors did not receive a referral for continued rehabilitation post-discharge (Hussain et al., 2016. It is important that stroke studies more fully explore the social participation of stroke survivors.

1.7 Carers of stroke survivors

The stroke literature refers to a carer as an individual who provides care and support for another person who is chronically ill or disabled (Bakas et al., 2014). In this thesis, the term 'carer' will be used to denote a carer of a stroke survivor unless otherwise specified. 'Carers' are distinguished from professional caregivers (e.g. nurses, disability workers, domestic support workers) because they are not paid for performing this role and often do not have formal training (e.g. completing lifting and mobility activities) (Kalra et al., 2004). Carers may provide physical (Grant, Hunt & Steadman, 2014), emotional (Jin, Lobchuk, Chernomas & Pooyania, 2017) and financial support (Ski et al., 2015). In fact, carers often play an important role in assisting stroke survivors to complete their activities of daily living (ADL) (Legg, Lewis, Schofield-Robinson, Drummond & Langhorne, 2017).

Stroke affects the psychological and social health of the carer as well as the stroke survivor (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). In 2009 it was estimated that there were 74,965 carers living with stroke survivors; 70% were female and almost two-thirds were over 60 years of age (Australian Institute of Health and Welfare, 2013). Since more than 90% of Australian stroke survivors will return to live with their family, with varying degrees of disability, supporting the psychosocial health of the carer is imperative (Australian Institute of Health and Welfare, 2013; Ski & O'Connell, 2007). The intense and all- encompassing nature of the carer role places a huge burden on carers (Oliva-Moreno et al., 2018). Previous research has documented the high level of burden that carers experience, estimating the prevalence of severe burden at 44%, declining to 36% within five years of stroke (Jaracz et al., 2015). In reality, carers themselves are often not in good health and can display increased levels of depression (Towfighi et al., 2017), anxiety (Karahan et al., 2014), strain (Pandian, Gandhi, Lindley & Bettger, 2016) and carer burden (Eldred & Sykes, 2008), as well as decreased QoL (Greenwood, Mackenzie, Cloud & Wilson, 2008) and lack of satisfaction with health services (Rodgers et al., 1999).

Quality of life is an important gauge of the overall impact of caring, as it typically measures a combination of psychological, social and physical indicators (Rombough, Howse, Bagg & Bartfay, 2007). The ongoing physical and emotional support that carers provide, in addition to the emotional and behavioural state of the stroke survivor, impacts upon the carer’s QoL (Cramm, Strating & Nieboer, 2012). Recent systematic reviews have identified how few interventions improve the QoL of carers (Bakas et al., 2014; Cheng et al., 2014). Never-the-less, one systematic review of 18 RCT’s of carer interventions (Cheng et al., 2014) identified one RCT of a cognitive behavioural therapy (CBT) intervention which demonstrated improvements in the psychological and social subscales of the World Health Organisation Quality of Life Questionnaire (WHOQOL BREF) (Wilz & Barskova, 2007). Furthermore, important psychosocial interventions such as self- efficacy are rarely addressed in the literature.

Self-efficacy is central to the caring role as it supports the successful completion of caring and self-care duties. Currently, there is a dearth of research directly addressing the self-efficacy of carers (Robinson-Smith, Harmer, Sheeran & Bellino Vallo, 2016; van den Heuvel, de Witte, Nooyen-Haazen, Sanderman & Meyboom-de Jong, 2000). A small number of interventions have attempted to improve the self-efficacy of carers, although these studies did not report significant improvements (Glass et al., 2004; Hoffmann et al., 2015; Kendall et al., 2007). Future research into self-efficacy could inform interventions to assist carers to complete their caring role with greater ease and also help them to improve their health outcomes, such as depressive symptoms, anxiety symptoms and physical health.

Carers have a lot to cope with. Despite this, there is insufficient literature or research addressing how carers cope or how their coping can be improved. Carer coping can include problem solving and threat appraisal (King, Hartke & Houle, 2010). A US study which assessed 253 survivor-carer dyads before discharge from acute rehabilitation (King et al., 2010) reported that carers who had high threat appraisal also experienced greater negative outcomes, such as anxiety and lack of preparedness. Identifying effective interventions that support carers to cope with their experience is essential not only for their welfare but also for the welfare of the stroke survivor.

A small body of literature describes positive aspects of the caring experience – as identified by carers of stroke survivors. The intense and all-encompassing nature of the carer role is reportedly places a huge burden on carers is still noted in contemporary literature (Oliva- Moreno et al., 2018).

More often than not stroke has a detrimental impact on carers' social health (Greenwood, Pelone & Hassenkamp, 2016), impacting upon their relationship with the stroke survivor and limiting interaction with their broader social network (O'Brien et al., 2014). In 2009 in Australia, almost three-quarters of carers of stroke survivors were spousal partners (Australian Institute of Health and Welfare, 2013). Consequently, these spousal relationships often undergo significant change, affecting marital satisfaction and family dynamics (Gillespie & Campbell, 2011). Furthermore, relationships that were once reciprocal may become more one-sided post-stroke as the carer adapts to meet the functional and emotional needs of the stroke survivor (Grant et al., 2014). A survey (*n* =2,700) by the National Stroke Foundation in the UK conducted in 2012 showed that 10% of carer respondents had considered ending their relationship or had terminated it (Stroke Association, 2013).

Carers often receive little formal support from health services despite often experiencing distress (Jaracz et al., 2015; Ski & O'Connell, 2005; Ski & O'Connell, 2007). Due to this lack of support, carers often feel as though they have been left to manage the burden of caring on their own, in turn contributing to devastating levels of psychosocial stress in this population (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). As a result, many carers are unprepared for their role post-discharge (Luker et al, 2017). The American Heart Association (Winstein et al., 2016) states that carers should receive psychosocial support throughout their recovery journeys; though this has not been routinely implemented to date (Stroke Association, 2013).

1.8 The survivor-carer dyad

As indicated, stroke has a considerable impact on the stroke survivor-carer dyad (Savini et al., 2015). Although stroke literature often describes stroke survivors and their carers separately, the term ‘dyad’ is used to describe the stroke survivor and their carer as a pair (Bergström, Eriksson, von Koch & Tham, 2011). Dyad interventions target the stroke survivor and the carer, involving both of them as active participants (Bakas et al., 2014). This dyadic approach emphasises the relationship between the stoke survivor and the carer, as an essential in determining individual and joint outcomes (Lyons & Lee, 2018; McCarthy, Lyons & Powers, 2011). Individual members within the dyad influence each other’s emotions, cognitions and behaviours, in turn, outcomes such as carer and stroke survivor QoL are connected and often interdependent (Campbell & Kashy, 2002).

Most recently, survivor-carer dyad literature has explored a ‘partner effect’ (Chung, Bakas, Plue & Williams, 2016; Cramm et al., 2012; Godwin, Swank, Vaeth & Ostwald, 2013; Wan-Fei et al., 2017). However, further research is required to confirm these findings due to the small sample sizes in these studies. For example, in 2016 a US secondary analysis of data from 112 dyads reported that a ‘partner effect’ was evident amongst the dyads; carers reported higher depressive symptoms if the survivor reported low-self-esteem, while survivors reported higher depressive symptoms if their carer reported low-self-esteem or low optimism (Chung et al., 2016). In a similar vein, a 2017 cross-sectional study of 30 dyads in Malaysia showed that carer depression was linked to poor QoL in stroke survivors, although the sample was small (*n* = 112) and young compared to the average age of a stroke survivor and carer (Wan-Fei et al., 2017). The interrelated nature of the survivor-carer dyad creates a complex and multifaceted dynamic that is only now beginning to be explored.

1.9 Psychosocial interventions

‘Psychosocial interventions’ are those that consist of at least one psychological and at least one social component (Thompson & Ski, 2013). A psychological component addresses an individual's behaviour and mind, including emotion and cognition and may include psycho-education, CBT, counselling, motivational interviewing and problem solving (Bakas et al., 2014; Bakas et al., 2017; Brereton, Carroll & Barnston, 2007; Lui, Ross & Thompson, 2005). A social component addresses how individuals participate in: social activities, peer support groups, family functioning; and skills training to improve communication (Cheng et al., 2014; Eldred & Sykes, 2008). Thus, interventions that provide only psychological support or only social support are not considered psychosocial.

Psychosocial interventions are adaptable and should be investigated for use with stroke survivors and carers. Psychosocial interventions can be conducted face-to-face (Markle-Reid et al., 2011), via telephone (Bishop et al., 2014; Shyu, Kuo, Chen & Chen, 2010) or via the internet (Barbabella et al., 2016; Heron & Smyth, 2010). Moreover, psychosocial interventions can be delivered in a variety of settings including hospitals (Alexopoulos et al., 2012), rehabilitation facilities (Draper et al., 2007) and the home environment (Bishop et al., 2014; Shyu et al., 2010); making them suitable for evaluation within real-world clinical settings. Further, psychosocial interventions can be adapted to a wide range of health conditions and outcomes. For example, psychosocial interventions can be incorporated into rehabilitation (Harrington et al., 2010) and educational interventions (Larson et al., 2005). In particular, psychosocial collaborative care interventions that utilise self-management have been deemed appropriate to be applied in the current Australian stroke-care system (O'Brien et al., 2014).

Psychosocial interventions have been overlooked in stroke literature and are yet to be evaluated exclusively - despite the ability of these interventions to directly address the psychological and social components underpinning stroke survivor and carer psychosocial health outcomes. A small number of reviews have evaluated psychosocial interventions, however these reviews have been integrated with interventions that are social-only, psychological-only or educational interventions; therefore the true impact of psychosocial interventions has not yet been ascertained (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014; Lui et al., 2005).

The adaptation of psychosocial interventions for use by stroke survivors and carers is an important subject of investigation. Past psychosocial interventions for stroke survivors have incorporated psychosocial elements into physical rehabilitation programs (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014); although this has often been done without the support of an overarching framework (Medical Research Council, 2010). However, it is also possible to adapt interventions for stroke survivors and carers from existing mental health interventions (Castle & Gilbert, 2006) in order to target mental health outcomes more specifically. It is important that mental health and psychosocial health intervention are explored and adapted within stroke literature as there is good evidence that individuals may experience poor mental health many years after physical symptoms have diminished (Crichton, Bray, McKevitt, Rudd & Wolfe, 2016).

This program of research evaluates the adaptation of the Optimal Health Program which was originally developed for a mental health population into Stroke and Carer Optimal Health Program which targets the psychosocial health of stroke survivors and carers. Both interventions are underpinned by the collaborative care framework and mental health case management. The collaborative care framework allows the intervention to be person-centered and flexible in its mode of delivery which makes it suitable for use in mental health and stroke populations. Notably, the original OHP was not developed or evaluated for carers. The development of the SCOHP to support carers is a unique innovation which may, in turn, inform the development of future applications for mental health carers. Another unique innovation was the development of the 8-week OHP book and program which has been utilised by SCOHP.

1.10 Psychosocial mediators in stroke

How psychosocial and clinical outcomes (e.g. degree of disability) interact in stroke survivors is not well understood. It is critical that the relationship between psychosocial outcomes and clinical outcomes are documented to inform the findings from psychosocial interventions that target psychosocial outcomes in stroke survivors, and the development of future interventions for stroke survivors. One such method is through the analysis of mediators through methods such as the Common Sense Model (CSM) by Leventhal and Myer (1980) which considers the impact of illness perceptions and coping.

Chapter Four details the origins and mechanics of this approach but in short the CSM arose from social cognitive theory and has been used to explore psychological mediators in numerous chronic illnesses including autoimmune disorders (Knowles, Wilson, Connell & Kamm, 2011), diabetes (Breland, McAndrew, Burns, Leventhal & Leventhal, 2013) and arthritis (Knowles et al., 2016). Featuring an adaptive hierarchical model it is theorised that: i) an individual forms representations of their illness experience; ii) the individual responds with coping responses and/or behaviours; iii) an individual appraises these coping response (Hale, Treharne & Kitas, 2007). Hence, illness perceptions and coping are considered essential components of the CSM model (Hagger & Orbell, 2003; Leventhal & Meyer, 1980) and are further detailed in Chapter Four.

The CSM purports that the symptoms of an illness (e.g. severity of disability post-stroke) affect individual outcomes (e.g. QoL) while being mediated by illness perceptions and coping patterns. Therefore, the use of CSM could establish: i) how illness perceptions mediate self-efficacy and coping in stroke survivors; ii) how self- efficacy, carer mental health and coping patterns mediate illness perceptions, anxiety/depressive symptoms and QoL.

Illness perceptions refer to the individual’s emotional and cognitive perceptions relating to their illness, as conceptualised by five dimensions:

Identity: How is identity impacted by having an illness?

Consequence: How much does the illness impact on my physical and psychosocial health?

Causes: What factors cause or influence the illness?

Timeline: Is the illness chronic, acute or cyclical?

Cure/control: Can the illness be cured or controlled? (Broadbent et al., 2006).

Research into illness perceptions of stroke survivors is limited although there is substantial evidence regarding how illness perceptions affect the QoL and mental health of individuals with other chronic diseases (Hagger & Orbell, 2003).

The concept of ‘coping’ is also central to the CSM. The theories of Lazarus and Folkman (1984) detail how individuals attempt to mediate stress behaviourally and cognitively. Three kinds of coping are often discussed in the literature (Donnellan, Hevey, Hickey & O'Neill, 2006):

1. Adaptive (or problem-focused) coping – seeks to alter the situation
2. Maladaptive coping – seeks to regulate emotional responses
3. Avoidant coping – regulates through avoidance

Although the CSM has been used to investigate psychological mediators in a number chronic diseases (Knowles et al., 2011; Knowles et al., 2016), investigations into stroke using CSM are preliminary (Phillips, Diefenbach, Abrams & Horowitz, 2015). Accordingly, this CSM analysis of stroke survivors will make a significant contribution to existing stoke literature. Using the CSM analysis, this PhD research will seek to establish the mediators of illness perceptions and coping patterns, their impact on illness symptoms (e.g. level of disability post-stroke) and individual outcomes in stroke survivors. Although the CSM is unable to detail the precise coping procedures utilised by participants it will, none-the-less, identify the mediating effect of different coping styles which can be used to inform the development.

1.11 Evidence gap

Stroke is a serious and costly disease in Australia and internationally (Australian Institute of Health and Welfare, 2016; Benjamin et al., 2017). Despite efforts to understand and treat individuals affected by stroke, including carers, there remain a number of gaps in the evidence that are yet to be addressed. Firstly, the psychosocial sequelae experienced by stroke survivors and carers is a source of substantial burden which remains largely unaddressed. Currently, psychosocial interventions are not routinely offered to stroke survivors and/or their carers, despite the need for urgent intervention. As a result, many stroke survivors and carers do not receive adequate support to match their psychosocial deficits (Lou et al., 2017).

Secondly, in the body of stroke literature addressing the psychosocial health of stroke survivors and carers, the term ‘psychosocial’ lacks a clear and concrete definition. In particular, past reviews of psychosocial interventions have often failed to implement a clear and consistent definition of ‘psychosocial’ (i.e. including both psychological and social components) (Cheng et al., 2014; Eldred & Sykes, 2008), while others have not exclusively reviewed psychosocial interventions (Bakas et al., 2014; Bakas et al., 2017). Consequently, the effectiveness of specific psychosocial interventions that aim to improve psychosocial outcomes is yet to be established.

A number of methodological issues have been noted in studies addressing psychosocial interventions for stroke. Overall, there is a lack of high quality, well-detailed studies of interventions targeting the psychosocial outcomes of stroke survivors and carers (Bakas et al., 2014; Cheng et al., 2014). Further, the longitudinal impact of psychosocial interventions on the psychosocial outcomes of stroke survivors has not been comprehensively established. In particular, infrequently reported outcomes such as carer satisfaction (Grant, Elliott, Weaver, Bartolucci & Giger, 2002; Johnson, Onuma, Owolabi & Sachdev, 2016; Rodgers et al., 1999) lack comprehensive longitudinal research. Currently, research into mediating factors that affect clinical indicators (e.g. degree of disability) is also not well established. The addition of qualitative evaluation can help answer questions which cannot be answered using quantitative methods alone, including the participant’s experience of the intervention and practical considerations that are not captured in surveys (El Masry et al., 2013).

In summary, the rationale for this program of research is to address the identified gaps in the evidence-base, namely:

- Establish the effectiveness of existing interventions for improving the psychosocial health of stroke survivors and carers
- Conduct an RCT of a psychosocial intervention for stroke survivors and carers

- Complete secondary analysis of stroke survivor data in order to establish the relationship between psychosocial mediators i.e. QoL, coping, self-efficacy, anxiety, depression, illness perceptions

This will be achieved using robust and systematic research methods designed to address the methodological issues identified in the literature.

1.12 Aims, objectives and hypotheses for the research

1.12.1 Aims of the program of research

This program of research aimed to examine and contribute to the evidence regarding the efficacy of psychosocial interventions that seek to improve the psychosocial outcomes of stroke survivors and their carers; and identify and explore psychosocial mediators that affect stroke survivors

1.12.2 Objectives of the research

Objective 1. To examine the evidence to date regarding the effectiveness of psychosocial interventions for stroke survivors and carers.

Objective 2. To develop and evaluate the impact of a psychosocial intervention on the psychosocial health of stroke survivors and carers.

Objective 3. To identify and explore the mediating relationship between psychosocial variables in stroke survivors.

To meet the research aims and objectives, a program of research was planned to conduct a systematic review and meta-analysis, a randomised controlled trial of an intervention and a secondary analysis of psychosocial mediators. Further chapters will detail these studies.

1.12.3 Researcher involvement

The research candidate was selected for a competitive Translating Research, Integrated Public Health Outcomes and Delivery (TRIPOD) PhD scholarship ($30,000 pa) commencing the 1st of July, 2015. TRIPOD aims to improve the mental health of individuals with chronic diseases and is currently evaluating the effectiveness of the Optimal Health Program (OHP) in individuals with stroke, chronic kidney disease and diabetes. The research candidate was assigned to be responsible for the adaptation, implementation, management and reporting of a randomised controlled trial (RCT) of a specific psychosocial intervention for stroke survivors and carers, the Stroke and Carer Optimal Health Program (SCHOP).

Developed by St Vincent's Hospital (Melbourne), the SCOHP was adapted from the OHP. The OHP originally aimed to support individuals who experience mental illness self-manage their condition (Gilbert et al., 2012). A quasi-experimental trial of the OHP for adults with a mental illness (*n* = 240) was conducted in a community mental health setting; OHP was compared to usual care (Gilbert et al., 2012). This trial found significant improvements in health and social functioning (Gilbert et al., 2012). Based on these findings a broader project to adapt the OHP to respond to mental health issues in individuals with chronic physical illnesses was undertaken – including this trial of the SCOHP.

The research candidate contributed to the development and direction of both the SCOHP and TRIPOD. The research candidate is a member of the TRIPOD Steering Committee which meets bi-monthly and includes researchers and clinicians from St Vincent's Hospital, the Australian Catholic University, the University of Melbourne and Swinburne

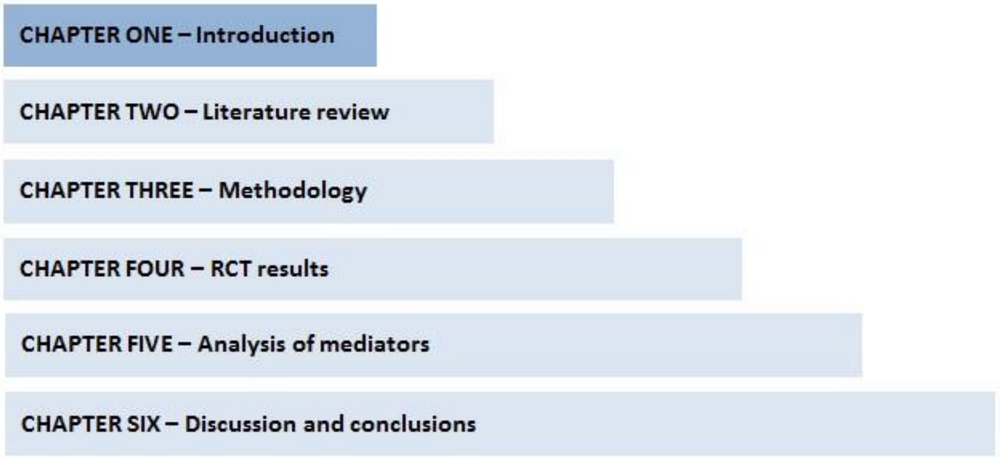
University of Technology. The research candidate’s position within the TRIPOD project has provided her an opportunity to work within the broader research community, increasing her professional network and developing strong collaborative project management skills.

The Principal Investigator for this project, Professor David Castle Chair of Psychiatry at St Vincent’s Hospital, is also a member of the research candidate’s supervisory panel. This program of research is funded through the Collaborative Research Network (CRN).

The conduct of this program of research constituted a largely independent role for the research candidate, which will be detailed further in the thesis (Chapter Seven). To be noted, the TRIPOD Steering Committee contributed some technical advice regarding the design of the RCT and the selection of measures to ensure consistency across all three arms (stroke, chronic kidney disease and diabetes) of the TRIPOD research program. A reflection of the researcher’s experience, including development of the role, challenges and lessons learned is described in Chapter Seven.

1.13 Organisation of thesis

The thesis is structured as detailed below. This diagram will be shown at the top of each chapter and the current chapter will be highlighted as shown below.



1.14. Chapter synthesis

This chapter has introduced some important literature, both scholarly and from primary data, that addresses the complexities that stroke survivors and their carers experience. In particular this chapter introduced important data attesting to the high prevalence and incidence of stroke in Australia (AIHW, 2018;); and globally (World Health Organisation, 2014; Benjamin et al., 2017) and then contrasted this against the lack of psychosocial support (Andrew et al., 2014; Bakas et al., 2014; Bakas, McCarthy & Miller, 2017; Cheng, Chair & Chau, 2014). The following chapter further investigates gaps in the literature relating to the systematic review of psychosocial interventions for stroke survivors and their carers and explores their effectiveness with regard to the outcomes of interest included in this program of research.

1.15 Chapter summary

This chapter has presented an overview of stroke and its ongoing complications for stroke survivors and carers. The research problem of poor psychosocial health among stroke survivors and carers was introduced in this chapter, highlighting a gap in the literature and research evidence regarding psychosocial care, particularly for carers. Of note, in this thesis the published articles are presented within the thesis format. The following chapter presents a published systematic review of research evidence for the effect of psychosocial interventions for stroke survivors and carers, which highlights the need for more research on this topic. In Chapter Three the methodology of a novel psychosocial intervention (SCHOP) is presented. The results and findings of the SCHOP RCT are presented in Chapter Four. The study findings, including the mediators to the psychosocial intervention are discussed in Chapter Five. A discussion of the findings and conclusions drawn are presented in Chapter Six, including recommendations are made for future research and practice for stroke survivors and their carers.

Chapter Two - Literature Review

2.1 Chapter introduction

Chapter One detailed the lasting impact of a stroke on the psychosocial health of survivors and their carers (Benjamin et al., 2017; Hussain et al., 2016). To date, few interventions that have been shown to be effective at improving the psychosocial outcomes of stroke survivors and their carers.

Although, strong associations between stroke survivor and carer health and wellbeing have been demonstrated in previous studies (McCarthy et al., 2011; Savini et al., 2015) , the evidence for interventions to improve the psychosocial outcomes of stroke survivors, and/or their carers, has not been examined in a systematic review. As a result, it is not possible to get a sense of how interventions delivered to carers only, or to stroke survivors only, compare to those interventions delivered to dyads. Furthermore, since definitions vary across the published reviews addressing this topic, drawing conclusions across reviews is problematic. Presently, it is not possible to compare the effectiveness of interventions across the entirety of the stroke population (stroke survivors, carers and survivor-carer dyads); this constitutes a gap that needs to be addressed. To address this gap, a systematic review of psychosocial interventions, which contain one or more psychological and social components, applied to either stroke survivors, or carers and to survivor-carer dyads, was deemed an important addition to the literature.

A systematic review and meta-analysis was undertaken and published in 2019. This is presented in the following section 2.2 in journal publication format. This review addressed Objective 1 (1.12.2) of the overall program of research presented in this thesis.

2.2 Publication - Minshall et al (2019)

Minshall, C., Pascoe, M., Thompson, T. R., Castle, D. J., McCabe, M., Chau, J, P-C., Jenkins, Z., Cameron, J. (2019). Psychosocial interventions for stroke survivors, carers and survivor-carer dyads: A systematic review and meta-analysis. *Topics in Stroke Rehabilitation, 26(7): 554-564*.

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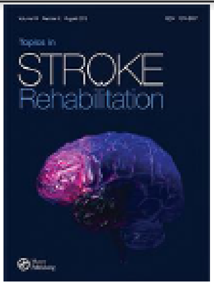

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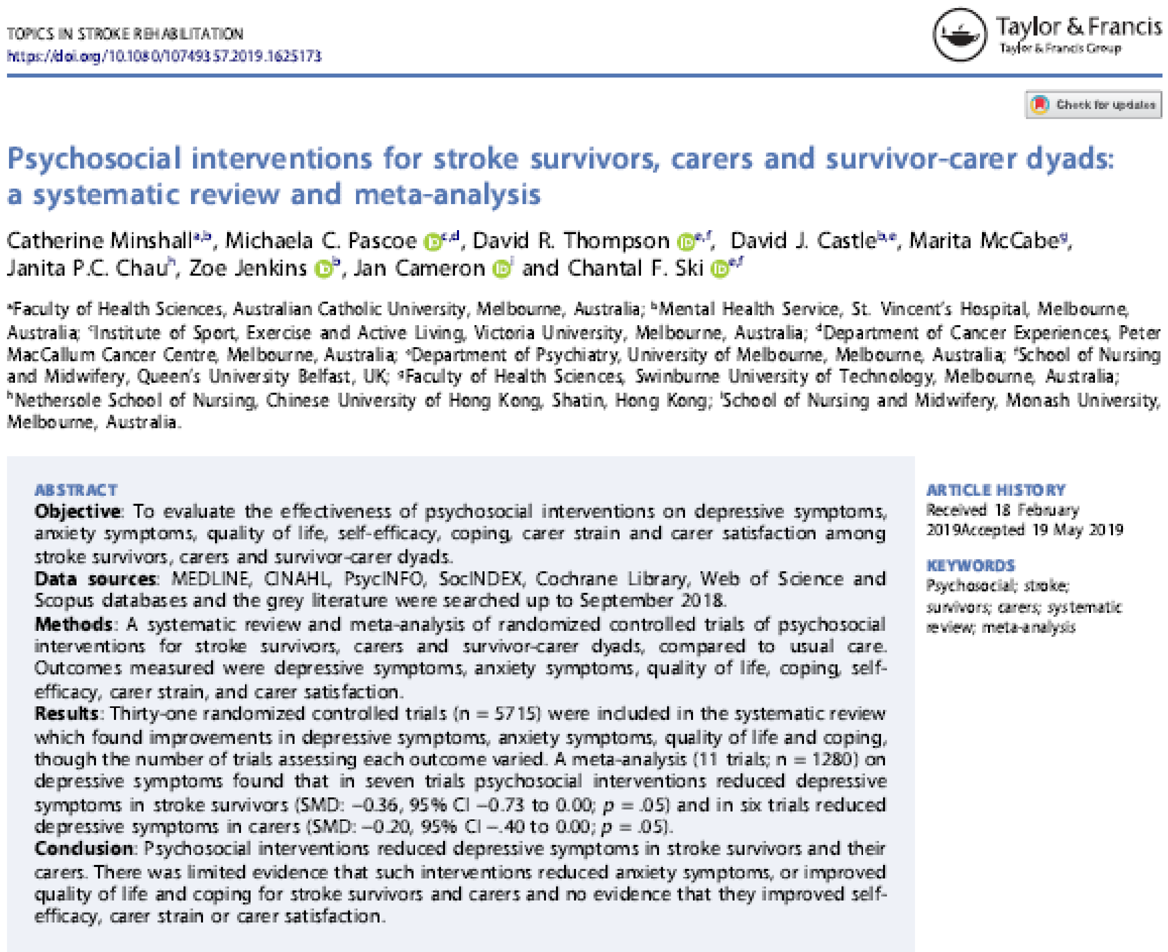

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Psychosocial interventions for stroke survivors, carers and survivor-carer dyads: a systematic review and meta-analysis

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ABSTRACT

Objective: To evaluate the effectiveness of psychosocial interventions on depressive symptoms, anxiety symptoms, quality of life, self-efficacy, coping, carer strain and carer satisfaction among stroke survivors, carers and survivor-carer dyads.

Data sources: MEDLINE, CINAHL, PsycINFO, SocINDEX, Cochrane Library, Web of Science and Scopus databases and the grey literature were searched up to September 2018.

Methods: A systematic review and meta-analysis of randomized controlled trials of psychosocial interventions for stroke survivors, carers and survivor-carer dyads, compared to usual care. Outcomes measured were depressive symptoms, anxiety symptoms, quality of life, coping, self-efficacy, carer strain, and carer satisfaction.

Results: Thirty-one randomized controlled trials (n = 5715) were included in the systematic review which found improvements in depressive symptoms, anxiety symptoms, quality of life and coping, though the number of trials assessing each outcome varied. A meta-analysis (11 trials; n = 1280) on 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* = .05) and in six trials reduced depressive symptoms in carers (SMD: −0.20, 95% CI −.40 to 0.00; *p* = .05).

Conclusion: Psychosocial interventions reduced depressive symptoms in stroke survivors and their carers. There was limited evidence that such interventions reduced anxiety symptoms, or improved quality of life and coping for stroke survivors and carers and no evidence that they improved self-efficacy, carer strain or carer satisfaction.

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2.3 Further considerations

The participant, intervention, control and outcome (PICO) criteria used for this review was:

P – stroke survivors and their carers

I - psychosocial intervention

C – usual care

O – depressive symptoms, anxiety symptoms, QoL, self-efficacy, coping, carer strain and carer satisfaction

The PICO criteria are reported in the 'Criteria' section (p. 36) and were used to focus the broad reach of the search terms. In this search strategy the 'Criteria' were used to screen the interventions individually, since it was noted that psychosocial interventions are so inconsistently defined that relying on author labelling was unreliable.

It is a limitation of this publication that the control is not more specifically defined.

The funnel plots included less than 10 studies and should be interpreted accordingly. In particular, the Cochrane Guidelines for 'Recommendations on testing for funnel plot asymmetry' states that it is ideal to include 10 or more studies to increase to specificity of the test (The Cochrane Collaboration, 2011); therefore, this is a limitation of these funnel plots.

This review identified the following gaps:

- Existing systematic reviews did not explicitly define "psychosocial interventions" (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014).

- Existing reviews included studies that were behavioural-only to psychological-only (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014, Eldred & Sykes, 2008).

- Depression and QOL were the most frequently measured outcomes, yet this review found that most of these were ineffective.

- Important outcomes such as self-efficacy, anxiety and carer strain were infrequently measured

- Effective interventions were not found for self-efficacy, carer strain and carer satisfaction

Overall, it is important that innovative psychosocial interventions are developed and trialed to meet these gaps.

This review identifies that psychosocial health is often not specifically targeted in research interventions. Interventions which addressed components such as problem solving (Bakas et al., 2015; Cheng et al., 2018; Fang et al., 2017; Inci et al, 2016) or coping (Cheng et al., 2018; van den Heuval et al., 2000; van den Heuval et al., 2002) were linked to significant results and should be incorporated into future interventions.

2.4 Chapter synthesis

This systematic review and meta-analysis has highlighted gaps in the literature related to how ‘psychosocial interventions’ have been defined by previous systematic review authors, who have included behavioural and psychological studies in their reviews (e.g. Andrew et al., 2014; Bakas et al., 2014; Bakas, McCarthy & Miller, 2017; Cheng, Chair & Chau, 2014). This has made it difficult to accurately ascertain the impact of psychosocial interventions on stroke survivors and carers. The systematic review and meta-analysis provide rigorous information regarding the effectiveness of these key outcomes of interest amongst stroke survivors and carers. Many of the studies were determined to be of low quality. Overall, the findings listed in “Table 2. Systematic review - Summary of significant findings” demonstrate that problem solving is an important component featured in interventions with significant outcomes reported for depression, coping and QOL; this is important as the SCOHP intervention is designed to improve problem solving also. The development of SCOHP was thus further informed by the systematic review and meta-analysis presented in this chapter. The following chapter details how the outcomes of interest presented in this chapter will be addressed in the trial’s methodology.

2.5 Chapter Two summary

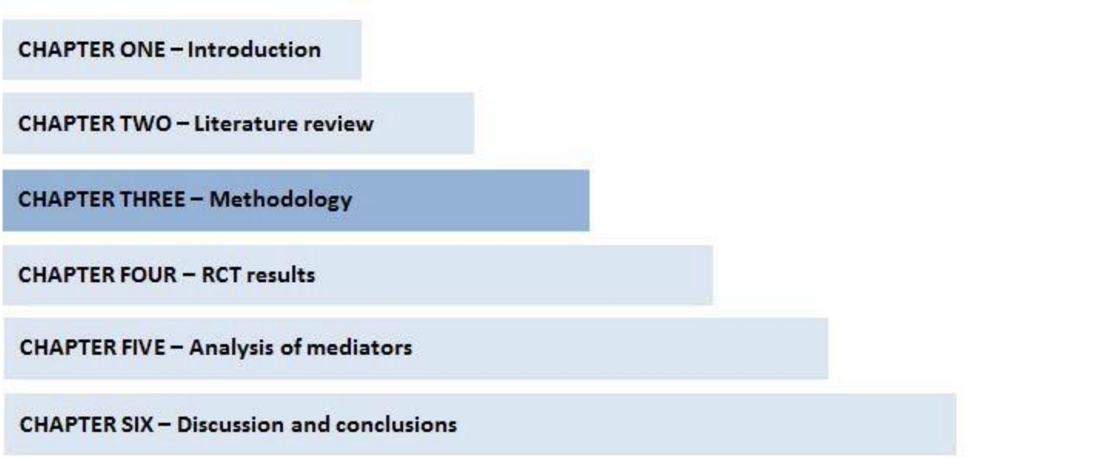
This chapter presented a systematic review and meta-analysis that addressed Objective 1 of this program of research. The synthesised results establish the impact of psychosocial interventions on depressive and anxiety symptoms, QoL, coping, self-efficacy, carer strain, and carer satisfaction stroke for survivors, carers and/or survivor-carer dyads. The meta-analysis showed that these psychosocial interventions i) improved depressive symptoms in carers and stroke survivors; ii) improvedthe depressive symptoms,anxietysymptoms, and QoL in stroke survivors; and iii) improves carer and survivor-carer dyad QoL, depressive symptoms and coping. These findings are important as they establish a substantial gap in knowledge, showing that there are relatively few trials that have improved psychosocial outcomes in this population.

This systematic review and meta-analysis informed the development of SCOHP as it demonstrated that important psychosocial outcomes remained inadequately addressed (e.g. anxiety, carer strain and satisfaction). SCOHP was considered appropriate to target this range of outcomes as it had been based on the Optimal Health Program (OHP) (Gilbert et al., 2012; O'Brien et al., 2014) which is a multifaceted collaborative care intervention conducted one-on-one over nine weeks. The OHP was adapted specifically for stroke survivors and carers to reflect their particular needs including flexible delivery modes (e.g. face-to- face, Skype, telephone), settings (e.g. in patient, home visit, Skype/telephone), stroke specific information and support for intervention facilitators.

Further methodology is detailed in Chapter Three.

Chapter Three - Research Design and Methodology

3.1 Chapter introduction



In Chapter One the background and context of the program of research which forms the subject of this thesis was established. In Chapter Two a systematic review and meta-analysis addressing the psychosocial health of stroke survivors and carers was presented and highlighted important gaps in the literature. In particular, it was identified that psychosocial interventions for stroke survivors, carers and survivor-carers have not been comprehensively evaluated to date. Importantly, the review also identified a lack of data regarding effective interventions targeting key outcomes of interest, including anxiety and carer strain. Additionally, the importance of delineating and understanding potential mediators of psychosocial outcomes in the stroke population was also outlined. In response to the evidence gaps identified in Chapter Two, this Chapter will present the research design and methodology adopted to address the aim and objectives of this research project, and detail the methods used for the two studies conducted for this PhD research program, including:

Study 1) A randomised controlled trial (RCT) of a psychosocial intervention for stroke survivors and carers; and Study 2) Secondary analysis of psychosocial mediators in stroke survivors.

Study 1: RCT of a psychosocial intervention for stroke survivors and carers. Section 3.2 below presents the design of this RCT and justifies the methods used, as well as presenting the hypotheses for this trial. The specific methods used in this RCT are presented in the form of a published research protocol paper with further details presented in this chapter. Please note: the protocol article was published under the PhD candidate's maiden name 'Brasier'.

Study 2: An analysis of psychosocial mediators in stroke survivors, underpinned by the CSM. Section 3.2 below presents the methodology and design for this secondary analysis. The specific methods used in this study are presented in the form of a published paper with further details included in this chapter.

3.2 Research methodology

3.2.1 Research design for the RCT

Quantitative research is used to evaluate interventions since it uses a structured way to objectively measure and analyse data (McCusker & Gunaydin, 2015). The RCT is a particular study design that uses quantitative research methods to evaluate whether a new intervention or treatment is more effective than standard or usual care (Bhide, Shah & Acharya, 2018). Participants in RCTs are randomly allocated to one of two, or more clinical interventions/treatments groups, with one of the interventions being the standard of comparison, or control. The random allocation of participants to either the intervention or comparison groups ensures that assignment is done by chance and therefore reduces between-group differences (Vogt, Gardner & Haeffele, 2012). When designed and conducted effectively, RCTs are considered the ‘gold standard’ for the evaluation of health interventions (Schulz, Altman, Moher & CONSORT Group, 2010). Therefore, a RCT design was chosen to evaluate the effectiveness of the SCOHP.

The fundamental steps in designing and conducting a RCT are (Kirk, 2013):

- Formulating hypotheses
- Determining the independent variables (e.g. SCOHP) and dependent variables (e.g. QoL, self-efficacy, depression, anxiety, coping, carer strain and satisfaction)
- Determining the number of participants
- Specifying procedures for assigning participants to intervention/control groups
- Designing the statistical analysis.

The hypothesis for this RCT alongside the independent and dependent variables is detailed in section 3.3.1. The number of participants, statistical analysis and randomisation schedule is detailed in the published protocol paper, see Chapter Three (section 3.7).

When designing this study it was noted that ‘experimental design – RCT’ is categorised as Level 1c (The Joanna Briggs Institute, 2014), the highest level of design for studying effectiveness of an intervention. Having determined that an RCT would provide a sufficiently high level of evidence, the CONSORT 2010 Statement (Schulz et al., 2010) was consulted and used to guide the implementation and reporting of this RCT.

3.3 Methods for the RCT

3.3.1 Hypotheses

Hypothesis 1. Stroke survivors and carers in the SCOHP will show improved QoL and self-efficacy at 3, 6 and 12 months, post-baseline, compared to usual care.

Hypothesis 2. Stroke survivors and carers in the SCOHP will show reduced depressive and anxiety symptoms and improved social and workplace functioning, illness perceptions, plus (for carers only) reduced carer strain and enhanced service satisfaction at 3, 6 and 12 months, post-baseline, compared to usual care.

These hypotheses are presented in the published protocol paper, Chapter Three.

3.4 RCT

The methods implemented in this RCT are detailed in the following published study protocol, see Chapter Three (section 3.7).

This paper details the intervention (including length, frequency, content and delivery modes), setting, participants, recruitment, consent process, randomisation and blinding, outcome measures and statistical analysis. A detailed description of the data analysis methods, including intention to treat analysis, missing data strategies, data analysis and power calculations is also summarised.

3.5 Ethics

This research was conducted in line with the 'National Statement on Ethical Conduct in Human Research' (Anderson, 2011). Ethics approval was granted by St Vincent's Hospital (HREC-A 031/12), ACU (HREC 2015-256R) and the Peter James Centre. Of note, St Vincent's ethics application (HREC-A 031/12) was amended to include the Peter James Centre as a 'recruitment only site'; no site specific reference was required for this addition. The candidate also received ethics approval to use the TRIPOD Database at St Vincent's Hospital (HREC A 149/14); this HREC is administered outside of SCOHP by TRIPOD.

3.6 Consent

This study required the informed consent of both stroke survivors and carers prior to participation; consent via proxy was not used. The processes and procedures for acquiring consent are described on page 5 of the protocol paper, Chapter Three (section 3.7).

In line with the National Statement of Ethical Conduct in Human Research (Anderson, 2011) potential participants were informed of the consent procedure, possible risks and benefits, right to withdraw, privacy and the trial contacts for complaints and queries verbally during recruitment and in writing as outlined in the Participant Information and Consent Form.

In the context of stroke research, informed consent requires the survivors have sufficient cognitive capacity post-stroke to understand the potential risks and benefits of the intervention (National Health and Medical Research Council, 2007 [2015 update]; Rose & Kasner, 2011). Screening for cognitive capacity was assessed using the clinical judgement of the referring senior clinician i.e. Nurse Unit Manager. Only individuals assessed as being able to provide informed consent were referred to the trial. Individuals who could not provide informed consent were excluded by a senior clinician during referral/screening.

3.7 Publication – Brasier (Minshall) et al. (2016)

Brasier (Minshall), C., Ski, C. F., Thompson, D. R., Cameron, J., O'Brien, C., Lutenschlager, N. T., Gonzales, G., Hsueh, Y. A., Moore, G., Knoweles, S. R., Rossell, S. L., Haseldon, Castel, D. J. (2016). The Stroke and Carer Optimal Health Program (SCOHP) to enhance psychosocial health: Study protocol for a randomised controlled trial. *Trials*, *17*, 466.

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Brasier *et al. Trials* (2016) 17:446
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Trials

STUDY PROTOCOL

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The Stroke and Carer Optimal Health Program (SCOHP) to enhance psychosocial health: study protocol for a randomized controlled trial

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Abstract

Background: Stroke is a leading cause of disability and distress, and often profoundly affects the quality of life of stroke survivors and their carers. With the support of carers, many stroke survivors are returning to live in the community despite the presence of disability and ongoing challenges. The sudden and catastrophic changes caused by stroke affects the mental, emotional and social health of both stroke survivors and carers. The aim of this study is to evaluate a Stroke and Carer Optimal Health Program (SCOHP) that adopts a person-centred approach and engages collaborative therapy to educate, support and improve the psychosocial health of stroke survivors and their carers.

Methods: This study is a prospective randomised controlled trial. It will include a total of 168 stroke survivors and carers randomly allocated into an intervention group (SCOHP) or a control group (usual care). Participants randomised to the intervention group will receive nine (8 + 1 booster) sessions guided by a structured workbook. The primary outcome measures for stroke survivors and carers will be health-related quality of life (AQoL-6D and EQ-5D) and self-efficacy (GSE). Secondary outcome measures will include: anxiety and depression (HADS); coping (Brief COPE); work and social adjustment (WSAS); carer strain (MCSI); carer satisfaction (CASI); and treatment evaluation (TEI-SF and CEQ). Process evaluation and a health economic cost analysis will also be conducted.

Discussion: We believe that this is an innovative intervention that engages the stroke survivor and carer and will be significant in improving the psychosocial health, increasing independence and reducing treatment-related costs in this vulnerable patient-carer dyad. In addition, we expect that the intervention will assist carers and stroke survivors to negotiate the complexity of health services across the trajectory of care and provide practical skills to improve self-management.

Trial registration: ACTRN12615001046594. Registered on 7 October 2015.

Keywords: Carer, Collaborative therapy, Cost-effectiveness, Dyad, Psychosocial, Randomised controlled trial, Stroke

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Abbreviations: AQoL-6D, Assessment of Quality of Life-6 dimensions; BFI-10, Big Five Inventory-10 item; BIPQ, Brief Illness Perceptions Questionnaire; Brief COPE, abbreviated version of the COPE Inventory; CASI, Carers Assessment of Satisfaction Index; CEQ, Credibility/Expectancy Questionnaire; EM, expectation-maximization; EQ-5D-3L, European Quality of Life-5 dimensions-3 levels; GSE, General Self-Efficacy Scale; HADS, Hospital Anxiety and Depression Scale; HCUQ, Health Care Utilisation Questionnaire; MCSI, Modified Caregiver Strain Index; MMRM, Mixed-effects Model, Repeated Measures; MMSE, Mini-Mental State Examination; MRS, Modified Rankin Scale; OHP, Optimal Health Program; QALY, quality-adjusted life year; RCT, randomised controlled trial; SCOHP, Stroke and Carer Optimal Health Program; TEI-SF, Treatment Evaluation Inventory-Short Form; TRIPOD, Translating Research, Integrated Public Health Outcomes and Delivery; WSAS, Work and Social Adjustment Scale

Background

Stroke is the second leading cause worldwide of death (11 %) and serious long-term disability [1, 2]. The significant burden of stroke extends across individuals, families and health systems globally [2, 3]. For the carer, a sudden shift from an acute hospital stay to informal care is experienced, as a family member or significant other contends with a new role and a dependent loved one [4, 5]. Equally important are the healthcare professionals who administer appropriate medical treatment and fulfil ongoing management and education roles for the stroke survivor across the illness trajectory [6]. However, in an oversubscribed and under-resourced health environment other innovative support methods are warranted. The Stroke and Carer Optimal Health Program (SCOHP) will adopt a person-centred approach combining collaborative therapy and care co-ordination to support and improve the mental and physical health of stroke survivors and their carers.

Importance of the stroke-survivor-carer dyadic relationship

The strength of the dyadic relationship is crucial for achieving optimal mental and physical health for both the stroke survivor and carer. Alongside the stroke survivor, the carer must adjust to the immediate and long-term effects that require varying degrees of assistance and a consequent reduction in occupational and social activities [4, 7]. The nonprofessional carer role is complex and under-recognised encompassing information provision, managing emotions, social support, health maintenance and problem solving [8, 9]. The new-found role of carer is accompanied by intricacies and interdependencies including potential role reversals and unexpected physical, cognitive and emotional demands [8–11]. In addition, studies continue to report that early hospital discharge combined with a lack of appropriate planning can adversely impact rehabilitation and contribute to carer burden [12, 13]. Subsequently, carers also experience adverse health effects with high rates of depression, anxiety, increased morbidity and mortality [13–15]. This is of great concern given that informal carer involvement in rehabilitation is imperative to recovery.

Stroke psychosocial interventions

In recent years research into the field of stroke has shifted from a physical emphasis to include psychological elements with a focus on carers; however, the stroke survivor/carer dyad has received minimal attention. Further, the evidence base regarding the effectiveness of support interventions for carers and/or stroke survivors is insufficient and inconsistent, primarily owing to methodological issues such as the diversity of intervention outcome measurements [6, 16, 17].

One of the most robust published studies was a randomised controlled trial of tailored psychoeducational modules and skill-building strategies (e.g. hands-on caregiver training and goal setting) delivered to 300 informal carers of stroke patients over three to five inpatient sessions and one home visit, which improved survivor and caregiver outcomes and reduced costs [18]. However, home visits are not always feasible and the individually tailored topics and goal setting focused more on the care of the stroke survivor than on the carer's own self-care.

A recent critical analysis of 17 caregiver and 15 caregiver/stroke survivor dyad intervention studies produced evidence-based recommendations for the implementation and future design of stroke informal caregiver and dyad interventions [6]. Based on American Heart Association guidelines for classes and levels of evidence, interventions identified at the highest level of evidence were those that:

- combine skill-building (e.g. problem solving, stress management, goal setting) with psychoeducational strategies
- tailor interventions to the needs of stroke caregivers based on needs assessments along the continuum of care
- deliver the program face to face and/or by telephone (when in-person contact is not possible)
- offer an optimal number of sessions, which is between five and nine [6].

Unfortunately, few validated psychosocial interventions specific to carers are available, and for those that are, the mechanisms of effectiveness are rarely described [19]. A recent review evaluating the effectiveness of psychosocial interventions for informal carers found limited evidence regarding the effectiveness of psychosocial interventions, although psychoeducation, consisting of training in problem solving and stress coping, reduced depression and improved carer sense of competency at the trend level [16]. Overall, current limited evidence points towards more rigorous design of multidisciplinary psychosocial interventions, sustainability of outcomes and inclusion of the stroke survivor-carer dyad.

Translating Research, Integrated Public Health Outcomes and Delivery (TRIPOD)

This randomised controlled trial (RCT) is part of a larger research program – TRIPOD – which will evaluate our Optimal Health Program (OHP) across three chronic conditions; namely stroke, diabetes mellitus and chronic kidney disease, including cost-effectiveness analyses. Based on a collaborative therapy framework [20], the OHP was originally developed to support people with mental illness [21, 22]. The initial trial, in an adult mental health service, demonstrated significant improvements in health and social functioning, reduced hospital admissions and net cost savings per patient [22]. A key aspect of collaborative therapy is recognising that 'recovery' and chronic models of health care are not dichotomous [20]. With the intention of enhancing self-efficacy, self-management, care coordination and quality of life, the OHP has been adapted within the broader context of chronic disease. Thus, in the current series of trials our OHP is used to implement this therapeutic framework to enable clinicians and consumers to work systematically towards the achievement of optimal psychosocial health outcomes within mainstream health services [23]. The self-management foundations of the OHP are particularly relevant for adults affected by stroke and their carers who face the daily challenge of managing various and often simultaneous aspects of their disease such as managing multiple medications, cognitive training, ongoing appointments, and physiotherapy as well as coping with the emotional impact of stroke and their care regimen. This protocol describes an RCT (SCOHP) that has been designed to evaluate the OHP for those affected by stroke – survivors and carers.

Qualitative study: informing development of an optimal health program

Healthcare provider experiences of carers have been researched, but little is written about how these can inform development of support programs. In collaboration with the National Stroke Foundation, Carers Victoria and three consumers (one carer and two stroke survivors) a qualitative study was undertaken to inform development of an Optimal Health Program (OHP) to support carers of those who have experienced a stroke [24]. The aims of the qualitative study were to inform SCOHP by: (1) exploring healthcare provider perceptions of stroke carer roles and support needs and (2) examining carer needs across the stroke care trajectory. To achieve this, we conducted four semi-structured focus groups (*n* = 23) of stroke healthcare providers across acute, subacute, and community rehabilitation services. Focus group facilitators used a semi-structured focus group schedule to guide discussions. Sessions were then recorded, transcribed, and analysed using thematic and content analysis. Table 1 shows the three key themes and sub-themes that emerged from the data, which highlight the distinct roles of healthcare providers and carers.

The findings of this study were used to inform the development of the OHP, specifically in terms of having: staged information across the illness trajectory; flexible support during transition periods; and a balance of practical tools and empathic communications around the impact of stroke. In summary, the discussions held with health providers supported the integration of an OHP for carers within existing stroke care services across acute and community settings.

Research aims

The aim of the study is to determine whether a stroke-specific OHP (SCOHP) improves the psychosocial health of stroke survivors and their carers, compared to usual care. The primary objective is to identify the impact of the OHP on levels of self-efficacy and quality of life for those affected by stroke. Secondary objectives are to evaluate the impact of the SCOHP on depression, anxiety, social and workplace functioning, self-management, and illness perceptions of and coping with stroke, and carer strain and satisfaction.

In addition, a health economic cost analysis will be performed, assuming an Australia-wide implementation, to identify any cost savings of SCOHP over current practice. Quality-adjusted life years (QALYs) will be measured using the Assessment of Quality of Life-6D (AQoL-6D) [25] and European Quality of Life-5 dimensions-3 levels

Table 1 Themes and sub-themes from thematic analysis

Themes	Sub-themes
Transition	Healthcare provider roles across stages of the stroke trajectory
	Carer transition to a caring role and how this changes over time
Information	Delivery of information by healthcare provider
	The carers' response to information and difficulties comprehending implications
Impact of stroke	Healthcare provider role in supporting the carer and person with stroke and maintaining hope
	Carers' experiences of the impact of stroke

Table 2 Primary and secondary outcome assessments and time points for SCOHP

	Carer				Stroke survivor			
Assessment tools	BL	3	6	12	BL	3	6	12
Primary outcomes								
AQoL-6D (20 items)	X	X	X	X	X	X	X	X
GSE (10 items)	X	X	X	X	X	X	X	X
Secondary outcomes								
BIPQ (8 items)					X	X	X	X
Brief COPE (28 items)	X	X	X	X	X	X	X	X
CASI (30 items)	X	X	X	X				
CEQ (6 items)	X				X			
EQ-5D -3 L (6 items)	X	X	X	X	X	X	X	X
HADS (14 items)	X	X	X	X	X	X	X	X
HCUQ (10 items)	X	X	X	X	X	X	X	X
MCSI (13 items)	X	X	X	X				
TEI-SF (9 items)				X				X
BFI-10 (10 items)		X				X		
WSAS (5 items)	X	X	X	X	X	X	X	X

AQoL-6D Assessment of Quality of Life-6 dimensions, *GSE* General Self-Efficacy Scale, *BIPQ* Brief Illness Perceptions Questionnaire, *Brief COPE* abbreviated version of the COPE Inventory, *CASI* Carers' Assessment of Satisfaction Index, *CEQ* Credibility/Expectancy Questionnaire, *EQ-5D-3L* European Quality of Life-5-dimensions-3 levels, *HADS* Hospital Anxiety and Depression Scale, *HCUQ* Health Care Utilisation Questionnaire, *MCSI* Modified Caregiver Strain Index, *TEI-SF* Treatment Evaluation Inventory-Short Form, *BFI-10* Big Five Inventory-10 item, *WSAS* Work and Social Adjustment Scale

(EQ-5D-3L) [26]. Process evaluation using focus groups will also be conducted with patients and clinicians to assess the effectiveness of the SCOHP, implementation, uptake and service delivery.

Methods

General design

This is a prospective randomised controlled trial to evaluate the effectiveness of the SCOHP for improving the psychosocial health of those who have experienced stroke and their carers. The SCOHP will be delivered as an 8-week individualised support program, with an additional booster session, and will be compared to usual care. Assessments will take place at baseline, 3, 6, and 12 months. The study protocol was approved by the St Vincent's Hospital Human Research Ethics Committee (HREC-A 019/14). An executive steering committee (all authors) oversees project planning, conduct and ongoing data collation.

Setting

The study will be conducted at the neurology unit of St Vincent's Hospital, a large metropolitan teaching hospital in Melbourne, Australia. Between 2011 and 2012, 737 patients were admitted to St Vincent's Hospital, with a principal diagnosis of stroke. The stroke unit at St Vincent's Hospital, Melbourne will enable planned recruitment of 168 participants for the SCOHP program over a 2-year period.

Participants

A total of 84 patients diagnosed with stroke, and 84 carers of these patients, will be recruited into the RCT. For the purposes of this study, stroke is defined as cerebral infarction or parenchymal haemorrhage confirmed by medical records. The following criteria are to be met for inclusion into the RCT: (1) diagnosis of stroke for patient or self-nominated carer of a stroke patient; (2) 18 years or older; (3) ability to converse in English without an interpreter or professional assistance; (4) absence of developmental disability or amnestic syndrome impairing their ability to learn from the intervention; and (5) absence of serious comorbid illness, including severe forms of aphasia, as identified by the nurse unit manager, and cognitive impairment, as identified from medical notes scoring lower than 24 on the Mini-Mental State Examination (MMSE) [27]. As the OHP adopts a holistic approach to managing chronic disease, patients may enter the program at any stage along the continuum of care.

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 RCT research in the area of chronic disease management programs [28]. Calculations assumed two primary outcomes (health-related quality of life and General Self-Efficacy Scale (GSE) scores), four assessment points (baseline, 3-month, 6-month, and 12-month), a study-wide type I error rate (α) of .05, and hence a type II error rate (β) of 0.20 (power of 0.80), a correlation of post-treatment scores with baseline measurements (ρ) of 0.81, and a two-tailed statistical test [29]. To detect an effect size of Cohen's $d = 0.50$, 53 participants in each of the control and intervention groups will be required. Allowing for up to 20 % attrition, a total of 168 participants, or 42 carers and stroke survivors in control and intervention groups will be recruited.

Study procedures

Recruitment

Potential patients who have been diagnosed with stroke and/or their carer will be identified by clinical staff (e.g. neurologist, nurse) and provided with a study flyer. Patients and/or carers will be asked permission for a researcher to approach them to discuss the program in more detail. If agreeable, they will be approached, informed and formally consented by the research assistant. Study fliers will also be posted online through community organisations and will include contact details for the research team. Participants from the community may contact researchers directly to request further information. Planned recruitment will occur over an 18-month period (see Fig. 1).

Consent

The process of consent will be in accordance with the Declaration of Helsinki. Nurse unit managers were consulted to determine a patient's eligibility for the study. Senior clinicians and the research team were consulted in instances when it was unclear if an individual met the inclusion criteria. All eligible patients and carers will be fully informed that they are being asked to participate in an RCT. The procedures involved in the study, and the chances of being assigned randomly to one of two groups will be explained verbally and via an information sheet approved by the hospital's Human Research Ethics Committee. A signed consent form will be obtained from each participant. Participants will be made aware of their right to withdraw from the study at any time without any effects on their clinical management.

Randomisation and blinding

Using a computer-generated block randomisation sequence created by a researcher independent of the study, participants will be allocated to treatment or control group. The allocation sequence will be generated using random numbers and participants will be randomised progressively as they consent. Patients and carers will be randomized as dyads. Patients or carer will be randomized alone if they are not participating as a dyad. Due to the nature and length of the intervention, it is not possible to blind either participant or investigator to the treatment allocation.

Intervention: SCOHP

The SCOHP is delivered at a nominated place of convenience by the participant i.e. home, hospital, community health centre. Dyads have the option of either receiving the intervention independently or together. The SCOHP comprises a modular format of eight sequential sessions plus a booster, based on a structured workbook. Participants are encouraged throughout the program to identify

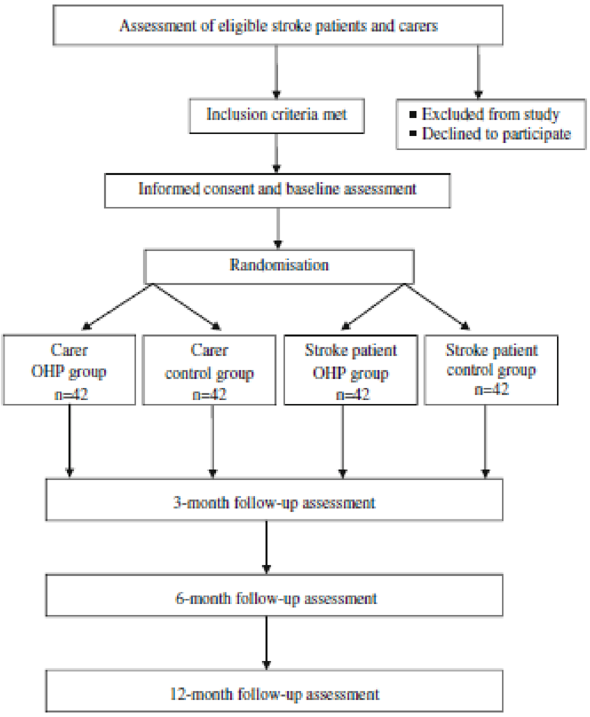

Fig. 1 Flowchart of the Stroke and Carer Optimal Health Program (SCOHP) randomised controlled trial (RCT)

areas of stroke- or carer-related health concerns on which they would like to focus. Sessions are approximately 1 hour in duration and held weekly, apart from the 'booster' session, which is held 3 months after session 8. Learning is cumulative with each session designed to build on the previous session including tasks to complete between sessions, i.e. journaling and coping strategies (e.g. breathing exercises).

In summary, session 1 introduces SCOHP within the six domains of the 'Optimal Health Wheel': social, physical, emotional, intellectual, employment and spiritual as documented in the workbook. This session provides participants with the opportunity to explore and understand stroke self-management behaviour from a holistic perspective. Sessions 2 and 3 initiate development of a health plan exploring the implications and potential complications of stroke in terms of strengths and vulnerabilities, and understanding and monitoring disease impact (e.g. emotional burden and physical weakness). Session 4 focuses on medication management and metabolic monitoring. Session 5 expands the health plan to include key stroke partnerships and supports in the community and online (e.g. www.strokefoundation.com.au). Change enhancement is the focus in session 6, in terms of understanding past events and establishing new proactive avenues for change. The aim of session 7 is goal setting via creative problem solving and planning around the complexities of stroke. To cement a shift in focus of the person's illness from being 'dependent on' services to being 'supported by' services, session 8 strategises stroke advanced care planning that incorporates wellbeing maintenance and sustainability. The goal of the 'booster session' (session 9) is to review health plans, consolidate progress, and reflect on achievements towards health-related goals.

A health professional (e.g. nurse, psychologist) trained in the approach (2-day workshop plus regular supervision and fidelity checks) will facilitate each session. The facilitator will draw on carer and stroke-specific information in concordance with individual circumstances. Examples include the relationship between depression and caregiving or physical impairments of stroke, availability of stroke and carer supports in the community, and coping strategies for addressing anxiety and stress related to new roles and circumstances. The emphasis is on collaboration between facilitator and participant to arrive at goals for the program that stem from the participant's main concerns and needs. The facilitator will encourage participants to identify their early warning signs of stress and illness and integrate healthy coping strategies to prevent the build-up of stress. Facilitators may also discuss and arrange referrals for other services in conjunction with the multidisciplinary team depending on participant needs. Additionally, facilitators will work with the multidisciplinary team to coordinate visits. Participants in rural and regional areas will have the option of participating in sessions via phone or Skype.

Control

The comparison group will receive usual care and no SCOHP intervention. As participants will be recruited from a variety of settings (hospital outpatients, community organisations) we anticipate variation in standard care received. To capture this variation, all participants will complete the Health Care Utilisation Questionnaire (HCUQ) [30] at each time point. Participants in the control group will have the option of completing the SCOHP at the end of the trial once evaluation is complete.

Outcome measurements

Table 2 details the primary and secondary outcome measures and time points for carers and stroke survivors. Participants complete the measures independently unless a specific request is made for assistance e.g. due to vision or motor skill impairment. Primary outcome measures for both stroke survivors and carers are quality of life and self-efficacy. Health-related quality of life will be assessed using the (AQoL-6D) [25], which consists of six dimensions of health and a global 'utility' score and the EuroQol-5D (EQ-5D) [26]. Self-efficacy is to be assessed using the General Self-Efficacy Scale (GSE) [31] a measure of perceived self-efficacy in response to daily challenges and stressful life events. Secondary measures for both stroke survivors and carers are: coping strategies as measured using an abbreviated version of the COPE inventory, the Brief COPE [32]; symptom severity and caseness of depression and anxiety disorders as assessed using the Hospital Anxiety and Depression Scale (HADS) [33]; a 10-item measure of the Big Five personality dimensions (BFI-10) [34]; effect of an individual's mental health on their ability to function via the Work and Social Adjustment Scale (WSAS) [35]; treatment expectancy and rationale credibility of the clinical study as assessed with the Credibility/Expectancy Questionnaire (CEQ) [36]; perceived satisfactoriness of treatment as assessed using the Treatment Evaluation Inventory-Short Form (TEI-SF) [37]; and health care utilisation and its economic impact assessed by the Health Care Utilisation Questionnaire (HCUQ) [30]. Stroke survivors will also be assessed for cognitive and emotional responses to stroke using the Brief Illness Perceptions Questionnaire (BIPQ) [38]. In addition, carers will be assessed for carer strain using the Modified Caregiver Strain Index (MCSI) [39] and carer satisfaction as assessed by the Carer Assessment of Satisfaction Index (CASI) [40].

Due to the potential for variability of 'usual care' in the control group, key aspects of usual care will be assessed with the HCUQ. Furthermore, medical records will be reviewed to determine stroke diagnostic information and clinical indices including the Modified Rankin Scale (MRS), which measures the degree of disability/dependence after a stroke.

Program assessment and treatment fidelity

The SCOHP facilitators will be trained in program delivery, receive a structured manual/protocol and monthly group supervision with the clinical investigators (with individual supervision provided as needed in between group sessions). The purpose of supervision will be to discuss problems in study procedures and ensure standardised activity. The SCOHP sessions will be audio recorded with a random selection rated by independent assessors in compliance with the SCOHP protocol. Variations from the protocol will be identified and relayed to the facilitator. Facilitators will complete a summary of each session using a standard template and send these notes to the research team. Session notes will include OHP topics covered, participant concerns raised, and needs for supervision. Additionally, content of sessions regarding participant requirement and concerns will be discussed at supervision meetings.

Post-intervention focus groups will be held for clinicians and participants. Participants will be informed during consent (both written and verbal) of the option to participate in focus groups, and that the purpose is to ascertain an in-depth understanding of their experiences of the study, advantages and disadvantages of conducting the study/program in their services (for clinicians), and recommendations for components to include or exclude from the SCOHP. It will be made clear to participants when consenting that the number of focus groups will be limited; such that they will only be run until data saturation is achieved. It is envisioned that data saturation will be reached after 2 to 3 focus groups, each containing 8 to 12 individuals. To increase objectivity, focus group facilitators will be independent researchers who were not OHP facilitators. The pragmatic data analysis approach of Halcomb and Davidson [42] will be used for the purpose of focus group data analysis. In summary, identifying key passages and words will be independently analyzed, coded, and categorized (classifying key passages and words within themes) drawing on pragmatic thematic analysis to form emergent themes.

Statistical analyses

Intention-to-treat analyses will be employed to prevent overestimation of efficacy. Categorical variables will be analysed using chi-squared tests (or Fisher's exact test for small samples). A mixed-effects model, repeated measures (MMRM) approach will be used to examine the longitudinal profile of continuous variables at 3, 6 and 12 months post-baseline. For all MMRM analyses, baseline scores will be used as covariates and the models will include prespecified fixed effects of treatment, clinician, and time, and treatment-by-time and treatment-by-clinician interactions.

Secondary analyses using analysis of covariance will be conducted to compare change scores during treatment and follow-up phases for primary, secondary, and process outcomes using the fixed, continuous covariate of baseline score as well as the categorical fixed effects of treatment group, clinician, and treatment-by-clinician interactions.

Although the attrition rate is not expected to vary by treatment condition, we will attempt to identify key predictors of attrition status (i.e. demographic and baseline clinical characteristics) and test for differences between conditions. Assuming the data are missing at random, several procedures offer effective approaches that may attenuate attrition. Maximum likelihood models (i.e. MMRM), with time as a random variable, allow the use of all available data from all assessments, reducing bias and increasing power [43]. In addition, multiple imputation procedures that utilise the expectation-maximization (EM) algorithm with bootstrap estimates of standard errors will be used to address attrition. The application of these procedures can provide unbiased estimates, even in the face of substantial missing data [44].

A full economic evaluation will occur alongside the proposed RCT. Healthcare outcomes and costs will be compared between participants in the control and interventional conditions. Healthcare system (medical record) and self-reported information via the HCUQ [30] will be used to generate analyses. The utility measurements of participant quality of life will be assessed using AQoL-6D [25] developed in Australia and the EQ-5D-3L [26] developed in Europe. The potential long-term (lifetime) impact on cost and effectiveness of intervention beyond the trial period will be extrapolated using the Markov process modelling method.

Discussion

Stroke can carry severe consequences for the patient and their informal carers or family members who often feel inadequately prepared to deal with the physical, cognitive and emotional demands [1–3]. Carers experience adverse health effects with high rates of depression [13], anxiety [14] and mortality [15]. The informal caring role is pivotal in maintaining stroke survivors in the community but this comes at a significant cost to the carer [4, 9–12]. It is therefore important to develop programs that will support the carer's coping and minimise the level of burden and ill-health they experience.

The crucial evidence gap lies in the integration and co-ordination of patient and carer support programs within health service delivery. Integral to SCOHP is its integration of carer and patient support within health services from acute to community care. Engaging with multiple clinicians can be a daunting task, both for patients and informal carers. The SCOHP assists in negotiating this complexity by adopting a person-centred approach across the patient trajectory. In addition, stroke survivor and stroke carer psychosocial health is rarely studied as a dyad, thus this RCT is expected to make a significant contribution to improve the mental health and wellbeing of patients who have experienced stroke and their carers.

There are several strengths to this study protocol. Primarily, in the inclusion of the 'patient-carer dyad' tailored to each individual, for both intervention and assessment purposes. Integration and rollout of the RCT in a clinical setting was purposefully incorporated to identify the adaptability of the intervention to a 'real-world setting' i.e. co-ordination and communication between departments. If successful, the simultaneous evaluation of RCTs across three of the most burdensome chronic conditions will provide evidence for the potential applicability of the intervention to extend to other chronic diseases. To our knowledge this is the first trial to include a comprehensive health economic cost analysis in the assessment of an educational, psychosocial intervention aimed at improving the mental and physical health of stroke survivors and their carers.

This series of trials follows common ethical principles applied in RCTs. Participants receive verbal and written information before consenting and before study procedures, they are not exposed to any risks, participation is voluntary and they may withdraw at any time without reason and without their usual care being affected in any way. Participants in the control group are also offered the intervention at the end of the follow-up period.

Trial status

Patient recruitment was ongoing at the time of manuscript submission. Data collection will continue until at least December 2017.

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Authors' contributions

DJC, CFS, NTL and DRT conceived the study. DJC developed the original OHP. GG, SLR, JC and SK contributed to study design. DJC, GM, RH and CLO designed the staff training protocol. YH designed the health economic analysis of the data. CB drafted the study protocol. All authors reviewed and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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3.8 Methodology for the analysis of psychosocial mediators

In order to understand the relationship between psychosocial outcomes in stroke survivors better, a secondary analysis of mediators was completed using baseline data from the RCT.

3.9 Hypotheses

Hypothesis 1. Illness perceptions mediate the relationship between self-efficacy and individual coping patterns.

Hypothesis 2. Self-efficacy, coping patterns mediate the relationship between Illness perceptions and depressive symptoms and anxiety symptoms, and QoL.

These hypotheses are presented in a published paper (see Chapter Five, section 5.2).

3.11 Chapter synthesis

This chapter presents the methodology designed to explore the outcomes of interest detailed in Chapter Two, while further details of methods are included in published papers in Chapter Two and Three of this thesis. Importantly the methodology was designed to include outcomes that are infrequently measured in other trials of psychosocial interventions for stroke survivors (e.g. self-efficacy and anxiety). Adherence to the CONSORT Guideline (Schulz et al., 2010) ensures the quality of the SCOHP trial, which is important as many of the trials identified in the systematic review were of low quality.

3.10 Further considerations

Future research should include the completion of the focus group for stroke and carer participants. The feedback from these participants may shed light on why the intervention was not successful. Feedback from the participants regarding the components of the intervention that they found most helpful would be invaluable. Inquiry should include whether this general OHP intervention contained enough stroke specific information to be effective.

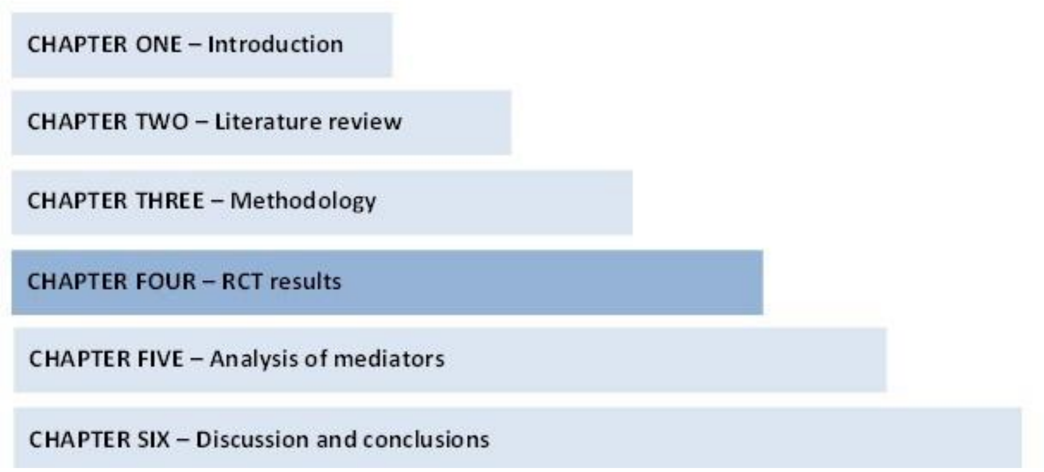
An analysis of cost effectiveness was included in the protocol. Data collection has been completed and is awaiting on specialty analysis; this analysis is beyond the scope of this PhD.

3.12 Chapter Three summary

The study protocol presented in this chapter detailed the methodology of an RCT of an intervention to improve the psychosocial health (QoL, self-efficacy, depression, anxiety, coping, carer strain and satisfaction) of stroke survivors and carers. Previous chapters have detailed the research problem regarding the detrimental impact of a stroke on the psychosocial health of stroke survivors and carers and, therefore, the need to restore their ‘optimal health’ by utilising a psychosocial intervention is paramount. Chapter Three has detailed the rationale and methods used to answer this research question, along with the study hypotheses. It has also detailed why an RCT methodology was selected to evaluate the effectiveness of a psychosocial interventions. The results of the RCT are presented in Chapter Four, while the results of analysis of baseline mediator variables is presented in Chapter Six.

Chapter Four Results: Randomised Controlled Trial of a Psychosocial Intervention for Stroke Survivors and their Carers

4.1 Chapter introduction



Chapter One provided the background of this research and established the need for improved psychosocial interventions for stroke survivors and carers. Chapter Two identified insufficiencies in existing stroke literature that supported the evaluation of new psychosocial interventions. Chapter Three detailed the methodology of the RCT of a new psychosocial intervention for stroke survivors.

Chapter Four is the first of two results chapters presenting the findings of two studies from this program of research.

<u>Study 1: The results of the RCT of a psychosocial intervention for stroke survivors and carers.</u>

This chapter is in the form of a published manuscript. The publication provides further detail regarding the methodology and methods. It also presents the findings, including the participants, participant flow chart, characteristics of the participants, group equivalences and effect of the intervention across time and between groups.

4.2 Publication - Minshall et al (2019)

Minshall, C., Castle, D. J., Thompson, D. R., Pascoe, M., Cameron, J., Apputhurai, P.,Knowles, S. R., Ski, C. F. (2019). A psychosocial intervention for stroke survivors and carers: 12–month outcomes of a randomized controlled trial, *Topics in Stroke Rehabilitation, 26,* 1-14. [Submitted to Topics in Stroke Rehabilitation, July 2019]

Presented verbatim as per submitted article.

Abstract

Background and purpose: Stroke can have a devastating impact on the psychosocial health of stroke survivors and their carers. This trial evaluates the effectiveness of the Stroke and Carer Optimal Health Program which sought to improve the psychosocial health of stroke survivors and carers.

Methods: This prospective randomised controlled trial for adult stroke survivors and carers evaluated a 9-week personalised psychosocial intervention, compared to usual care. Participants from hospital services and community referrals completed questionnaires at baseline, 3, 6, 12 months. Primary measures: health-related quality of life (AQoL-6D and EQ-5D) and self-efficacy (GSE). Secondary measures: depression and anxiety (HADS); coping (Brief COPE); work and social adjustment (WSAS); illness perceptions (BIPQ); carer strain (MCSI); carer satisfaction (CASI); and treatment evaluation (TEI-SF and CEQ). Mixed-effect model–repeated measures analysis between groups and across time was conducted.

Results: In total 173 participants were recruited; 89 stroke survivors (intervention *n* = 50; usual care n=39) and 84 carers (intervention *n* = 44; usual care *n* = 40). Analysis included 137 participants; 73 stroke survivors (intervention *n* = 42; usual care *n* = 31) and 64 carers (intervention *n* = 35; usual care *n* = 29). A statistically significant improvement at the 6 month time point in carer satisfaction in the intervention group, compared to usual care.

Conclusions: This trial showed statistically a significant improvement in carer satisfaction at 6 months, compared to usual care. A lack of available services and barriers to social engagement may have impeded the impact of this psychosocial interventions for stroke survivors and carers.

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

Introduction

Stroke can profoundly impact the psychosocial health of stroke survivors and their carers (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). Post-stroke depressive disorder affects around one-third of stroke survivors (Towfighi et al., 2017) and further, two-thirds of carers experience depressive or anxiety symptoms (Cheng et al., 2014). Both, stroke survivors and carers report diminished quality of life (QoL) (Cheng et al., 2014; van Mierlo et al., 2018). Stroke and carer interventions which have sought to improve psychosocial outcomes, such as QoL or depressive symptoms, have often emphasised rehabilitation and psychological approaches (Bakas et al., 2014;

Bakas et al., 2017; Cheng et al., 2014; Eldred & Sykes, 2008). However, these approaches can sometimes neglect important social factors such as family functioning (Gillespie & Campbell, 2011), social support (Volz et al., 2016) and relational changes that occur as a result of the caring/survivor role (Greenwood et al., 2008; Greenwood, Mackenzie, Cloud & Wilson, 2009; Lou et al., 2017). Diminished social functioning has been associated with depression (Northcott et al., 2015) and diminished QoL (Northcott et al., 2015) in stroke survivors and is thought to contribute to burden (Rigby, Gubitz & Phillips, 2009) and decreased social participation in carers (Lou et al., 2017).

Psychosocial interventions are comprised of both social and psychological components, generally measured using tools that contain both psychological and social sub-scales, or questions related to both social and psychological outcomes (Thompson & Ski, 2013). There is some evidence that these interventions can improve QoL (Harrington et al., 2010; Markle-Reid et al., 2011; Robinson-Smith et al., 2016; Wong & Yeung, 2015) and reduce depressive symptoms (Fang et al., 2017; Mitchell et al., 2009; Robinson-Smith et al., 2016; Watkins et al., 2007; Wong & Yeung, 2015) in stroke survivors. Likewise, a smaller number of psychosocial interventions have been shown to improve QoL, ameliorate depressive symptoms (Bakas et al., 2015; Grant et al., 2002; Ostwald et al., 2014; Smith et al., 2012) and enhance coping in carers (Cheng et al., 2018; İnci & Temel, 2016; van den Heuvel et al., 2000; van den Heuvel et al., 2002). However, many trials have struggled to improve the psychosocial health of the survivor-carer dyad (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). Further still, important outcomes such as self-efficacy, anxiety symptoms,carer strain and carer satisfaction are yet to be effectively addressed following psychosocial intervention (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014).

The primary objective was to evaluate the impact of the SCOHP on the QoL and self-efficacy of stroke survivors and carers at 3, 6 and 12 months, post-baseline, compared to usual care. The secondary objective was to evaluate the impact of the SCOHP on depressive and anxiety symptoms, social and workplace functioning, illness perceptions of stroke survivors and carers, plus carer strain and satisfaction, compared to usual care.

Methods

This 9-week prospective randomised controlled trial evaluated a psychosocial intervention (SCOHP) for stroke survivors and carers, measured at baseline, 3, 6, and 12 months compared to usual care (ACTRN12615001046594). Recruitment was conducted from March 2016 to September 2017. Data collection concluded in September 2018 at the completion of the trial. This RCT was conducted and reported according to the 'CONSORT Statement' (Schulz et al., 2010). Minor revision of the data analysis method was conducted as detailed under 'Statistical methods'. No further changes to the protocol occurred. Overseen by a multi-disciplinary steering committee this trial was approved by a Melbourne Metropolitan Human Research Ethics Committee (HREC-A 031/12). Written informed consent was obtained from all participants. The study protocol is described elsewhere (see Chapter Three) and is summarised below.

Participants

Criteria

Participants were recruited from three metropolitan hospitals in Melbourne, Australia. Community referrals were also assessed for inclusion. 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 amnestic syndrome 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 nurse unit manager.

Randomisation, allocation and blinding

De-identified cases were randomly allocated to either the intervention or usual care group. Allocation was determined by a computerised block randomisation sequence, conducted by a researcher external to the trial. Participants were randomised immediately after consent and before baseline assessments. Participants were randomised alone if not they were not consenting as a dyad; while dyads were randomised together to circumvent contamination. Due to the participatory nature of the intervention and the use of self-reported measures, participants and investigators could not be blinded; this is discussed in the limitations.

Intervention: The Stroke and Carer Optimal Health Program (SCOHP)

The intervention group received standard stroke medical care (Stroke Foundation, 2017a) plus a 9-week personalised psychosocial program. Participants receiving SCOHP were guided by a structured workbook and professional program facilitator to work with one-on-one for the duration of the SCOHP. Sessions were approximately 1-hour in duration and held once weekly; the final ‘booster’ was conducted three-months after Session 8. Program facilitators offered flexible delivery arrangements (e.g. weekend and afterhours) and mode of delivery (face-to-face, by telephone or Skype).

Table 5. Program structure of the SCOHP

Session	Theme	Focus	Purpose
Session 1	What is health?	Optimal health wheel	Increase one’s ability to understand health as comprised of social, physical, emotional, intellectual, vocational and spiritual
Session 2	I-can-do model A	Health plan A	Explores one’s strengths and vulnerabilities
Session 3	I-can-do model B	Health plan B	Explores one’s strengths and vulnerabilities (continued)
Session 4	Medication	Medication monitoring	Improves knowledge and efficacy regarding medication
Session 5	Collaborative partners/strategies	Identifies partners and support	Considers the availability of supports which could be included in the health plan
Session 6	Change enhancement	Understanding the past; planning for a future	Contextualises the past and allows for new possibilities to be conceived and planed for
Session 7	Goal setting	Planning for the future	Emphasises the role of autonomy and choice in adapting post-stroke
Session 8	Health plans	Advanced care planning	Consolidates the past 8-weeks into a health care plan designed by the participant
Session 9	Booster	Reflect and revise	Reflection on the health plan and its efficacy. A chance to talk through additional changes/adjustments to the plan and the process of revision

Comparison arm

The usual care received standard stroke care as informed by Australian national stroke guidelines (Stroke Foundation, 2017a).

Primary outcomes

Primary outcomes included health-related quality of life (Assessment of Quality of Life-6 Dimensions [AQoL-6D] and European Quality of Life-5-dimensions [EQ-5D-3L]) and self-efficacy (General Self-Efficacy Scale [GSE]).

The AQoL-6D (Allen, Inder, Lewin, Attia & Kelly, 2013) is a 20 item questionnaire that assesses QoL. The items are summed to an overall score 20-99 in which higher scores suggest better QoL. The AQoL-6D scale has demonstrated internal consistency (Cronbach's α range 0.73-0.86).

The EQ-5D-3L (Rabin & de Charro, 2001) is a 6 item questionnaire and a three point scale that assesses QoL. The items are summed to an overall score of best (5) and the worst (25). The EQ-5D-3L has demonstrated an acceptable level of reliability and has been validated for use with stroke survivors scoring 1.24 on the Shannon Index (Janssen et al., 2013).

Items are summed giving a score range of 10 to 40; higher scores signify greater levels of self-efficacy. Analyses of test-retest reliability for the GES in a neurological cohort reported intraclass correlation coefficient values from 0.69 to 0.80 and internal consistency (coefficient alpha) at 0.95 (Nilsson, Hagell & Iwarsson, 2015).

Secondary outcomes

Secondary outcomes included depression and anxiety (Hospital Anxiety and Depression Scale [HADS] (Snaith, 2003), coping (Brief COPE Inventory [B-COPE]) (Carver, 1997), illness perceptions (Brief Illness Perception Questionnaire [BIPQ] (Broadbent et al., 2006), work and social adjustment (WSAS) (Mundt et al., 2001), carer strain (Modified Caregiver Strain Index [MCSI]) (Thornton & Travis, 2003), carer satisfaction (Carer's Assessment of Satisfaction Index [CASI]) (McKee et al., 2009).

The HADS (Snaith, 2003) is a 14-item questionnaire that assesses depressive (7-items) and anxiety symptoms (7-items). Each items is on a 4-point Likert scale. Subscales are summed and interpreted as 0-7 (normal), 8-10 (mild), 11-15 (moderate), and 16-21 (severe). Scores between 16-21 indicate the presence of a mood disorder (Snaith, 2003). The HADS is validated for use with the stroke population and has been reported to have over 60% specificity and 80% sensitivity (Burton & Tyson, 2015).

The Brief-COPE (Carver, 1997) is a 14-subscale questionnaire; with two items per subscale. Acceptable test-retest reliability when measured over 12 months has been established, as well as concurrent and convergent validity (Cooper, Katona & Livingston, 2008).

The BIPQ (Broadbent et al., 2006) is a 8-item questionnaire that evaluates cognitive perceptions of illness in eight dimensions. Items are assessed using an 11-point rating scale. This scale has been validated for use in mental health conditions and chronic diseases (e.g. arthritis, diabetes, chronic pain) (Weinman, Petrie, Moss-morris & Horne, 1996).

The WSAS (Mundt et al., 2001) is a 5-item questionnaire that assesses social functioning. A 6- point scale in which 0 = "not impaired at all" and 5 = "very severely impaired". The maximum score is 40, with lower scores indicating better functioning. A comprehensive evaluation reported the internal scale consistency as 0.70 to 0.94, test-retest was 0.73 (Mundt et al., 2001).

The MCSI is a 13-item questionnaire that assesses carer strain (Thornton & Travis, 2003). A 3-point scale in which 0 = "no", 1 = "yes, sometimes" and 2 = "yes, on a regular basis is utilised internal consistency of Cronbach's α of 0.70 to 0.94 and a test-retest score of 0.73 (Thornton & Travis, 2003).

The CASI (McKee et al., 2009) is a 30-item questionnaire that assesses carer satisfaction. A 4-point scale is used. When compared across three countries (n = 295, 35.9% UK, 29.8% Italy and 34.3% Poland) the items recorded a Cronbach α score of between 0.72 and 0.90 (McKee et al., 2009).

Primary and secondary assessments and time points are detailed in Table 4.

The utilisation of ITT analysis, as described in the protocol (see Chapter Three,) was revised. Considering the probability of missing data in this trial the ITT may have underestimated intervention effect according to recent literature (Shrier, Verhagen & Stovitz, 2017). Demographic data was analysed for group differences. A mixed effect model, repeated measures (MMRM) was conducted on primary and secondary outcomes to determine changes over time and between groups (interventions/usual care).

Statistical analysis

The utilisation of ITT analysis, as described in the protocol (see Chapter Three) was revised. Considering the probability of missing data in this trial the ITT may have underestimated intervention effect according to recent literature (Shrier et al., 2017). Demographic data was analysed for group differences. A mixed effect model, repeated measures (MMRM) was conducted on primary and secondary outcomes to determine changes over time and between groups (interventions/usual care).

Sample size

Power was calculated according to a medium effect size of Cohen's d = 0.50. Calculations were based on 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, and hence a type II error rate (β) of 0.20 (power of 0.80), a correlation of post-treatment scores with baseline measurements (ρ) of 0.81, and a two-tailed statistical test (Diggle, Heagerty, Liang & Zeger, 2002). To encompass an estimated 20% attrition, a total of 168 participants (42 stroke survivors and 42 carers in intervention and usual care groups) was the target.

Results

In total 173 participants were randomised, and the 137 (73 stroke survivors; 64 carers) who completed the baseline questionnaire (see figure 7) were included in analysis. Analyses were conducted according to the groups assigned during randomisation.

Participant characteristics

Participant characteristics are presented in table 6 and 7. The flow of participants from randomisation to intervention completion is presented in figure 7. Group differences at baseline were detected for ‘months since stroke’, an analysis of frequencies identified this as a serendipitous effect of the randomisation. No other group differences were identified.

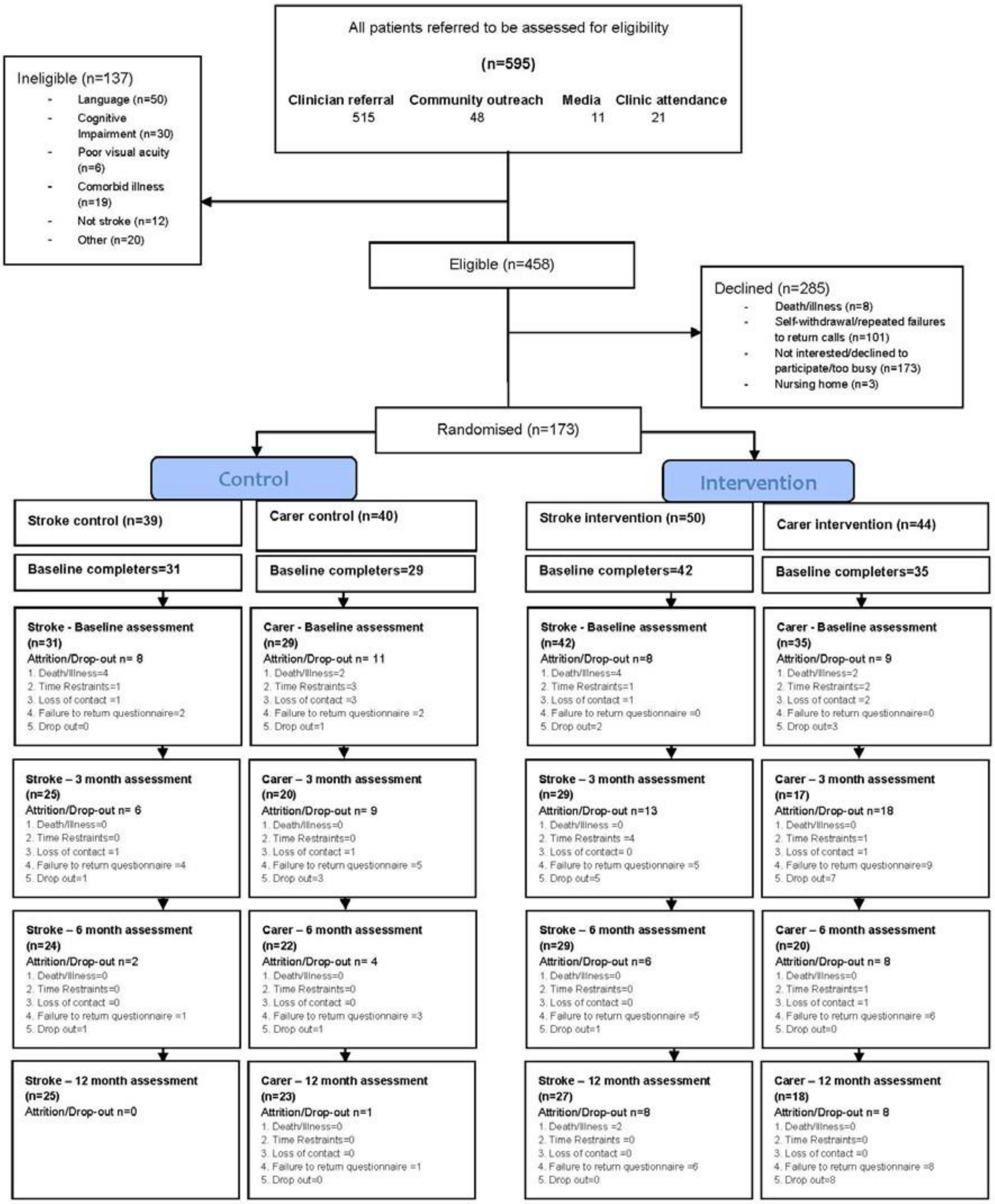


Figure 7. Participant flow chart

Characteristics of the participants

Table 6. Stroke survivor baseline completers characteristics with group equivalence

Survivor characteristics (*n* = 73)	**Usual care (*n* = 31)**	**SCOHP (*n* = 42)**	***P* value**
Age, mean years, (SD, range)	69 (11.9, 48-88)	67 (13.72, 27-88)	0.55
Gender n (%)			
Female	11 (35)	22 (52)	0.152
Male	20 (65)	20 (48)	
Country of birth n (%)			0.387
Australia	21 (69)	31 (75)	
New Zealand/Asia Pacific	1 (3)	0	
Asia	2 (6)	4 (9)	
United Kingdom	2 (6)	4 (9)	
Europe	2 (6)	1 (2)	
Not stated	3 (9)	2 (5)	
Education n (%)			
Post-graduate	6 (19)	18 (43)	0.122
Under-graduate	3 (10)	3 (7)	
TAFE	3 (9)	5 (12)	
Secondary	17 (56)	12 (29)	
Other	2 (6)	4 (9)	
Marital status n (%)			0.612
Married	19 (63)	26 (62)	
Defacto	3 (9)	2 (5)	
Divorced/separated	3 (9)	4 (9)	
Single	6 (19)	7 (17)	
Widowed	0	2 (5)	
Other	0	1 (2)	
Accommodation n (%)			0.625
Own house	17 (55)	27 (64)	
Rental	5 (15)	7 (17)	
Public housing	1 (3)	2 (5)	
Lives with family	1 (3)	3 (7)	
Supported accommodation	3 (9)	1 (2)	
Other	4 (12)	2 (5)	
Lives with n (%)			0.906
Partner	15 (49)	20 (49)	
Family	6 (19)	11 (26)	
Alone	8 (26)	8 (19)	
Friends	1 (3)	1 (2)	
Boarders	0	1 (2)	
Other	1 (3)	1 (2)	
Months since stroke mean (SD)	28 (28.2)	69.95 (117.1)	0.054

Difference between baseline completers. Independent *t* test (continuous variables) and Pearson Chi-Squared (categorical variables). *p*<0.05. SCOHP, Stroke and Carers Optimal Health Program.

Table 7. Carer baseline completers characteristics with group equivalence

Carer characteristics (*n* = 64)	**Usual care (*n* = 29)**	**SCOHP (*n* = 35)**	***P* value**
Age, mean years, (SD, range)	61 (14, 26-87)	65 (13.4, 31-89)	0.324
Gender n (%)			0.637
Female	23 (79)	23 (74)	
Male	6 (21)	9 (26)	
Country of birth n (%)			0.392
Australia	22 (76)	24 (69)	
New Zealand/Asia Pacific	0	4 (12)	
Asia	1 (3)	1 (3)	
United Kingdom	2 (7)	3 (8)	
Europe	2 (7)	3 (8)	
Not stated	2 (7)	0	
Education n (%)			0.892
Post-graduate	8 (28)	10 (30)	
Under-graduate	6 (21)	8 (23)	
TAFE	2 (7)	2 (6)	
Secondary	11 (37)	10 (30)	
Other	2 (7)	5 (11)	
Marital status n (%)			0.259
Married	17 (59)	28 (79)	
Defacto	6 (20)	2 (6)	
Divorced/separated	4 (14)	3 (9)	
Single	2 (7)	1 (3)	
Other	0	1 (3)	
Accommodation n (%)			0.218
Own house	15 (52)	26 (74)	
Rental	7 (25)	4 (11)	
Public housing	2 (7)	0	
Lives with family	1 (3)	3 (9)	
Supported accommodation	1 (3)	1 (3)	
Other	3 (10)	1 (3)	
Lives with n (%)			0.133
Partner	14 (49)	20 (56)	
Family	9 (31)	10 (29)	
Alone	6 (20)	2 (6)	
Other	0	3 (9)	
Relationship to stroke survivor n (%)			0.583
Partner	21 (73)	28 (79)	
Parent	6 (21)	3 (9)	
Sibling	1 (3)	1 (3)	
Other	1 (3)	3 (9)	

Difference between baseline completers. Independent *t*-test (continuous variables) and Pearson Chi-Squared (categorical variables). $p<0.05$. SCOHP, Stroke and Carers Optimal Health Program.

Effects of the intervention

The results between groups and over time are detailed in Table 8. There were no differences observed between the intervention and usual care group on any of the outcomes, or at any time point in both carers and stroke survivors. No adverse effects of the intervention were reported.

Table 8. The effect of the intervention between groups and over time

	STROKE			**CARER**		
Outcome measure	**SCOHP, Mean (SD)**	**Usual care, Mean (SD)**	***P* value**	**SCOHP, Mean (SD)**	**Usual care, Mean (SD)**	***P* value**
PRIMARY OUTCOMES						
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 (GSE)						
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
SECONDARY OUTCOMES						
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 (B-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 (B-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 (038)	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
3 months	20.00 (11.14)	17.16 (13.41)	0.40	15.05 (10.97)	17.44 (11.96)	0.53
6 months	20.41 (11.89)	15.25 (12.82)	0.12	17.47 (10.60)	15.45 (11.72)	0.65
12 months	18.85 (12.72)	16.12 (13.85)	0.46	18.31 (11.35)	16.38 (14.04)	0.63
Illness perceptions (BIPQ)				x	x	x
Baseline	44.55 (12.73)	42.39 (15.67)	0.52	x	x	x
3 months	44.84 (13.07)	39.04 (15.54)	0.13	x	x	x
6 months	45.76 (12.82)	39.54 (15.21)	0.10	x	x	x
12 months	42.30 (15.40)	39.96 (16.97)	0.60	x	x	x
Cared for person (CASI)	x	x	x			
Baseline	x	x	x	2.21 (0.78)	2.16 (0.66)	0.78

3 months	x	x	x	2.08 (0.61)	2.06 (0.73)	0.92
6 months	x	x	x	2.30 (0.47)	1.74 (0.86)	0.01**
12 months	x	x	x	2.30 (0.75)	1.92 (0.89)	0.16
Family caregiver (CASI)	x	x	x			
Baseline	x	x	x	1.54 (0.73)	1.50 (0.81)	0.85
3 months	x	x	x	1.47 (0.51)	1.40 (0.67)	0.68
6 months	x	x	x	1.66 (0.60)	1.32 (0.76)	0.10
12 months	x	x	x	1.62 (0.67)	1.46 (0.77)	0.48
Interpersonal dynamic (CASI)	x	x	x			
Baseline	x	x	x	2.06 (0.93)	2.03 (0.89)	0.88
3 months	x	x	x	1.90 (0.86)	1.82 (0.84)	0.76
6 months	x	x	x	2.04 (0.77)	1.70 (0.90)	0.19
12 months	x	x	x	1.98 (0.81)	1.72 (0.99)	0.38
Carer strain (MCSI)	x	x	x			
Baseline	x	x	x	10.81 (5.55)	11.19 (6.45)	0.8
3 months	x	x	x	9.78 (5.43)	11.52 (7.18)	0.41
6 months	x	x	x	11.13 (5.67)	9.75 (6.46)	0.46
12 months	X	x	x	11.52 (5.20)	9.00 (6.79)	0.2

** p-value of >0.01

Discussion

This RCT evaluated the effectiveness of SCOHP, a psychosocial intervention which aimed to improve QoL, self-efficacy, depressive and anxiety symptoms, coping, work and social adjustment, carer strain and carer satisfaction in stroke survivors and carers. This RCT identified a statistically significant improvement in the intervention group for carer satisfaction according to the cared for person subscale of the CASI at 6 months. No further statistically significant changes in the outcomes were found.

The improvement of carers satisfaction with series at 6 months according to the 'cared for person' subscale of the CASI is an important result as improvements in satisfaction have not been noted by other similar RCT's (Grant et al., 2002; Johnson et al., 2016; Rodgers et al., 1999). It is likely that this improvement in satisfaction may have built over the first 6 months as participants became more knowledgeable and practiced in their ability to work with services. Knowing that there are substantial limitations in the services available to stroke survivors and their carers one could suggest that over a 12 month period carers satisfaction could decrease if their needs, and the needs of the stroke survivor were not being met by services; this concurs with the literature (Andrew et al., 2014; National Stroke Foundation, 2007).

This trial did not provide evidence that the SCOHP improved QoL or self-efficacy, however this is consistent with past trials which have shown limited success in improving outcomes. Past trials that aim to increase self-efficacy have also reported a lack of significant benefit (Glass et al., 2004; Hoffmann et al., 2015; Kendall et al., 2007; Robinson-Smith et al., 2016; van den Heuvel et al., 2000). Generally speaking, QoL has also proven difficult to improve in this population; with only a small number of interventions having proved effective (Harrington et al., 2010; Markle-Reid et al., 2011; Wong & Yeung, 2015). Our findings are consistent with past reviews that have reported a mixture of significant and non-significant findings for the same outcomes in this population (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014).

The current study may have failed to improve QoL as it did not incorporate rehabilitation services (Harrington et al., 2010; Markle-Reid et al., 2011). For example, an RCT evaluating a self-management intervention of 43 stroke survivors in Canada that utilised a multi-disciplinary team, including rehabilitation clinicians reported improvements in QoL and recommended an integrated approach to stroke care (Markle-Reid et al., 2011). Another RCT of 243 stroke survivors from the United Kingdom that employed rehabilitation clinicians to deliver group work along with peer support did improve QoL and was a cost-effective approach (Harrington et al., 2010). Both of the aforementioned trials employ a multidisciplinary team (Harrington et al., 2010; Markle-Reid et al., 2011); in contrast the SCOHP is delivered by a single facilitator which may reduce the range of expertise required to improve the QoL of stroke survivors and carers. Revision of the SCOHP to incorporate multidisciplinary and rehabilitation services may improve its impact on QoL.

After stroke, it is not only the survivor whose QoL is impacted by this cardiovascular event requiring measured interventions to address this health outcome. The QoL of their carer are often detrimentally impacted with little evidence from research to inform clinicians how to address this (Ogunlana et al., 2014; Opara & Jaracz, 2010). Unlike stroke survivors, carers are neither admitted nor discharged from health services. As a result carers are greatly under-served and often experience increased burden (Akosile, Banjo, Okoye, Ibikunle & Odole, 2018); this being in turn associated with poor QoL (Pucciarelli et al., 2017; Ski et al., 2015).

Considering the scant resources available to carers in countries like Australia (National Stroke Foundation, 2007, 2010) and the additional responsibilities that carers take on (e.g. medication administration, showering, household duties) it is no surprise that carers feel burdened and overwhelmed (Camak, 2015; Ski et al., 2015). Participant feedback from SCOHP attested to the severity and frequency of this perceived burden.

Reflecting this burden, carers were far more difficult to identify, recruit and retain than stroke survivors in our trial. Not only did carers drop out more frequently than survivors, ‘failure to return the questionnaire’ was noted as the principal reason for carer attrition. For carers who are already stressed the level of participation required by SCOHP may have exceeded their capacity; this is an important issue to consider when designing interventions that aim to engage carers. For example, interventions/services that reduce carer burden could be implemented prior to psychosocial interventions with that aim to engage carers.

This trial incorporated self-efficacy principles in order to strengthen the participant's belief that they can accomplish chosen task/s (Bandura, 1995, p. 2) in order to help them better manage the consequences of the stroke/carer role. Significant improvements in self-efficacy had been noted in studies of other chronic diseases including diabetes (Siti Khuzaimah Ahmad, Hejar Abdul, Halimatus Sakdiah, Sazlina & Mohd Hanafi Azman, 2018; Wichit, 2018) and cardiovascular health (Hannah & Holly, 2010; Sol, van Der Graaf, van Petersen & Visseren, 2011) but not stroke (Glass et al., 2004; Hoffmann et al., 2015; Kendall et al., 2007; Robinson-Smith et al., 2016; van den Heuvel et al., 2000). It is possible that stroke-based self-efficacy studies may be failing to achieve significant improvements due to impoverishments in the service environment. For example, the modules in the SCOHP culminate in a health plan, a number of barriers to accessing services became apparent during the trial. Participants typically had access to a small number stroke/carer specific services (e.g. Stroke Foundation, Stroke Association, Carers Australia) (Carers Australia, 2018; Stroke Association of Victoria, 2018; Stroke Foundation, 2017a).

Importantly, most of the stroke survivors in this trial no longer qualified for important adult services including National Disability Insurance Scheme (NDIS) (Commonwealth of Australia, 2011) and adult mental health services (Department of Health and Human Services, 2015) due to their age, which further limited support options. Participants who required additional support services (e.g. neurology, department of housing) often encountered complex referral pathways and extensive wait times; as a result participants may not see the benefits of these services within the trail timeline. Future interventions should train facilitators in stroke specific services/referral pathways to improve participant access to key services and should advocate for greater availability of resources.

Depression and anxiety contribute substantially to the disease burden of stroke survivors and carers (Loh et al., 2017; Towfighi et al., 2017). Despite this, anxiety remains under-researched and there are few effective interventions to inform the development of programs such as SCOHP (Fang et al., 2017). In comparison, there is some evidence that psychosocial interventions can reduce depression in stroke survivors (Mitchell et al., 2009; Watkins et al., 2007; Wong & Yeung, 2015) and carers (Bakas et al., 2015; Grant et al., 2002). However, our trial included a high proportion of stroke survivors aged 80 years and older (usual care 22%, SCOHP 12%); this population has increased disability which is a risk factor for post-stroke depression (Robinson & Ricardo, 2016). Indeed, older cohorts such as ours may experience declining mobility and diminished functioning which can interfere with social participation, compounding depression.

Speaking more broadly, the lack of significant results in this trial reflects difficulties that other trials have had addressing outcomes such as depression and anxiety, as well as lesser reported outcomes such as coping, illness perceptions, work and social adjustment and carer strain (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014).

This trial had a number of strengths. Firstly, it was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) checklist for RCT's (Schulz et al., 2010). The SCHOP is among the first to offer a comprehensive psychosocial intervention to stroke survivors and carers in Victoria, Australia. As such, it contributes new knowledge regarding the practice environment, including deficiencies in the service environment which is of great importance to local clinicians and researchers. The trial was analysed using a robust strategy which featured MMRM analysis and contributes new knowledge regarding the characteristics of individuals using local stroke services.

The results of this trial should be interpreted in light of the following limitations. This preliminary RCT was small in size; larger trials are required to confirm or refute these findings. The size of the trial is likely limited by the severity of disability among the stroke survivors and the overwhelming role of caring for a survivor. Future studies would benefit from the collection of disease measures in both the intervention and usual care group. Additionally, this RCT was unable to blind outcomes assessors (i.e. the participants) or investigators as it was easily discernible who was or was not receiving usual care; this was unavoidable due to the nature of the intervention. Self-reported questionnaires are subject to bias. However, this trial sought to capture the perceived experiences of the participants; therefore this method was appropriate and pragmatic.

Conclusion

To-date, stroke research has found limited benefit for psychosocial interventions. We adapted a well-established and evidence based psychosocial intervention and evaluated in both stroke survivors and carers. Findings show that this study did not significantly improve the psychosocial health of stroke survivors or carers. It is likely that the complex needs of this group outweighed the benefit of the intervention, indicating that further research is needed.

4.3 Chapter synthesis

This trial was developed in light of the findings of the systematic review which informed the development of the methodology. Past interventions seeking to improve the psychosocial outcomes of stroke survivors and carers had reported significant findings (Bakas et al., 2015, Cheng et al., 2018, Fang et al., 2017, Grant et al., 2002, Harrington et al., 2010, Inci et al., 2016, Larson et al., 2005, Markle-Reid et al., 2011, Ostwald et al., 2014, Robinson-Smith et al., 2016, Smith et al., 2012, van den Heuvel et al., 2000, van den Heuvel et al., 2002, Watkins et al., 2007, Wong et al., 2015). However, SCOHP reported minimal improvements. It is likely that self-management, which is popular within mental health interventions (Castle et al., 2010; Gilbert et al., 2012), is not effective in a stroke survivor and carer populations.

4.4 Further considerations

Important implications arose from this trial. For example a large number of participants declined the study, according to the recruitment team, due to overwhelming rehabilitation and caring duties, a lack of interest or discomfort discussing mental health. Further, this RCT addressed potential barriers such as lack of services and barriers to social engagement experienced by this population. This needs further exploration in future research. It is a limitation of this trial that it did not include an analysis of differences between participants who completed the intervention and those who dropped-out (attrition). Also, it is a limitation of this research that specific dyad-based analysis was not conducted on the dyads that participated. Standard care was not specifically measured in this trial; future trials should measure this using validated instruments. Participants were given an extended period to return questionnaires; if the time points lapsed they were sent the next questionnaire and the previous became missing data.

4.5 Chapter Four summary

This Chapter has provided details of a RCT conducted to provide important insight in to the effectiveness of psychosocial interventions in stroke survivors and carers. This RCT contributes to a better understanding of the research problem outlined in Chapter One and corroborates the evidence found in a systematic review and meta-analysis (Chapter Two) regarding the difficulty of improving the psychosocial outcomes of stroke survivors and carers; especially important outcomes such as anxiety (Fang et al., 2017), self-efficacy (Glass et al., 2004; Hoffmann et al., 2015; Kendall et al., 2007; Robinson-Smith et al., 2016; van den Heuvel et al., 2000) and satisfaction (Grant et al., 2002; Johnson et al., 2016; Rodgers et al., 1999) which have have not been improved by previous interventions. The methods outlined in Chapter Three supported the rigorous and trustworthy evaluation of the trial data including the utilisation of the CONSORT checklist interventions (Schulz, Altman, Moher & CONSORT Group, 2010). This RCT identified minimal significant improvement across any of the 14 outcomes of interest. This perhaps could be impacted by confounders impacting recruitment and retention such as the burden of the study. None- the-less, the trial contributes new knowledge to this field of research and suggests that the use of self-management interventions may not be suitable for these populations. In particular, the development of this innovative trial methodology could inform future stroke/carer evaluations whereby the intervention may be able to be simplified to improve recruitment techniques and participant retention. This RCT address potential barriers such as lack of services and barriers to social engagement experienced by this population.

Leading on from this Chapter Five will present an exploration of a number of key outcomes also discussed in Chapter Four (QoL, self-efficacy, depression, anxiety and coping). The analysis of mediation and moderators conducted in the second study may be useful in understanding the results of the systematic review and meta-analysis, as well as informing the development of new interventions.

Chapter Five - Results: The Results of Baseline Analysis of Psychosocial Mediators in Stroke Survivors

5.1 Chapter introduction

CHAPTER ONE – Introduction
CHAPTER TWO – Literature review
CHAPTER THREE – Methodology
CHAPTER FOUR – RCT results
CHAPTER FIVE – Analysis of mediators
CHAPTER SIX – Discussion and conclusions

Chapter One and Two outlined the importance in developing effective psychosocial interventions for stroke survivor and carers, demonstrating how few effective interventions are currently available. Accordingly, Chapter Three detailed the proposed method for the RCT presented in Chapter Four, in which a trial was undertaken to respond to these gaps by adapting a proven psychosocial intervention from mental health (Castle et al., 2010; Gilbert et al., 2012). In this chapter, baseline data from this RCT forms the basis of an analysis of mediators for stroke survivors. Chapter Five is the second of two results chapters that detail the findings of this program of research, as outlined in Chapter Three.

Chapter Five presents a published manuscript of Study 2: An analysis of psychosocial mediators in stroke

survivors, underpinned by the CSM.

5.2 Publication - Minshall et al (2019)

Minshall, C., Ski, C. F., Apputhurai, P., Thompson, D. R., Castle, D. J. (2019) Exploring the Common Sense Model (CSM) and interrelationships between illness perceptions, coping strategies, psychological distress and quality of life in post-stroke, *0, e1.* [Submitted to Clinical Psychology in Clinical Settings, July 2019]

Presented verbatim as per submitted manuscript.

Abstract

Background: Stroke survivors' mental health and QoL are detrimentally affected post- stroke. This study evaluated the potential mediating role of self-efficacy, coping style, depression and anxiety on the relationship between illness perceptions and quality of life in patients diagnosed with stroke.

Methods: Participants comprised of 72 stroke survivors (32 females; mean [SD] age 65.09 [14.14] years; male mean [SD] age 69.83[11.81]). Measures in this study included illness perceptions (Brief Illness Perceptions Questionnaire; BIPQ), coping styles (Carver Brief COPE scale; B-COPE), depression and anxiety (Hospital Anxiety and Depression Scale; HADS), self-efficacy (General Self-Efficacy Scale; GSE) and QoL (Assessment of QoL; AQOL-6D).

Results: Using SEM, a final model had a good fit ($\chi^2 (1) = 3.17$, $p = 0.075$, $\chi2/N = 0.23$, RMSEA < 0.07, CFI > 0.97, GFI > 0.97, SMSR<0.05). Sixty seven percent of the variation in quality of life is explained by this model. Illness perceptions had a significant direct influence on maladaptive coping, depression and anxiety ($\beta = 0.37$, $p < 0.001$, $\beta = 0.43$, $p < 0.001$, $\beta = 0.43$, $p < 0.001$, respectively). Maladaptive coping had a significant direct influence on quality of life ($\beta = -.22$, $p < 0.001$). The relationship between illness perceptions and quality of life is fully mediated by depression and anxiety. Also the relationship between illness perceptions and

depression and anxiety are partially mediated by maladaptive coping. A significant positive correlation between depression and anxiety (*p*< 0.05) was noted.

Discussion: Although, these calculations were based on a small sample size this provides initial validation of the CSM in a post-stroke cohort. Based on these results, we argue that psychosocial interventions could improve quality of life by targeting key mediators such as depression, anxiety and maladaptive coping.

Background

Stroke is the second highest cause of mortality and the third leading cause of disability worldwide (Feigin et al., 2017). Stroke is a neurological condition that occurs when a blockage or bleed in the brain results in oxygen deprivation and associated cell death (Sacco et al., 2013). Stroke can produce a myriad of symptoms including cognitive, motor/sensory, and language impairments (Sacco et al., 2013). In addition, the detrimental impact of stroke on survivors psychosocial health is widely noted (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). With stroke healthcare costs exceeding $606 million in Australia in 2008-2009 (Australian Institute of Health and Welfare, 2013) the physical, emotional and fiduciary cost of stroke are deeply concerning.

Stroke survivors commonly experience diminished psychosocial health including increased depression and anxiety, as well as reduced QoL (Bakas et al., 2014; Bakas et al., 2017). Stroke survivor’s QoL can be adversely affected by the physical, psychological and social impact of a stroke (Bakas et al., 2014; Bakas et al., 2017). For example, depression and anxiety are also a serious threat to the psychosocial health of stroke survivors, potentially impacting on QoL (Tang, Lau, Mok, Ungvari & Wong, 2013; Towfighi et al., 2017). Recent systematic reviews (Mitchell et al., 2017;

Schöttke & Giabbiconi, 2015) concur that around one-third of stroke survivors experience depression. Of concern, depression has been linked to poor rehabilitation outcomes (Hollender, 2014) as well as decreased QoL amongst stroke survivors (Zhang et al., 2017). Self-efficacy has been found to be strongly correlated with QoL and depression up to 6 months post-stroke and recommended as a focal point when facing re- integration in to the community (Robinson-Smith, Johnston & Allen, 2000; Volz et al., 2016). Although anxiety remains under-reported, it is estimated to effect around 25% of stroke survivors and has also been linked to diminished health outcomes (Chun et al., 2018).

The Common Sense Model (CSM) developed by Leventhal and colleagues (1980; 2016) can be used to understand the psychosocial health of stroke survivors by establishing the relationship between illness symptoms and individual outcomes (e.g. QoL) which are mediated by illness perceptions and coping style. The CSM has been applied to numerous chronic illnesses including gastrointestinal disorders (Knowles, Wilson, Connell, & Kamm, 2011), diabetes (Breland, McAndrew, Burns, Leventhal, & Leventhal, 2013) and arthritis (Knowles et al., 2016). However, little research has been conducted to address the CSM amongst stroke survivors (Hagger & Orbell, 2003; Klinedinst et al., 2012; Phillips et al., 2015). Of the CSM models that do address stroke populations a cross-sectional study of 44 stroke survivor and carer dyads found that overall stroke survivors and carers often did not identify symptoms of depression (Klinedinst et al., 2012). A retrospective study of 600 stroke survivors that utilised the CSM found that cognitive illness beliefs and affective response predicted future stroke and medication adherence.

In the CSM it is proposed that disease activity shares an integral link with illness perception (Leventhal et al., 2016). Indeed, illness perceptions are a fundamental component of the CSM model and refer to the cognitive and emotional perceptions that individuals develop in response to becoming aware of a threat to their health (Leventhal et al., 2016). Concisely described by Broadbent et al. (2006) illness perceptions are comprised by five dimensions: chronicity, is the illness chronic, acute or cyclical?; consequence, how much does the illness impact on my physical and psychosocial well-being?; causes, what factors caused or influenced the illness?; identity, how is one impacted by having an illness?; and cure/control, can the illness be cured or controlled? If the CSM is upheld, then the relationship between stroke survivor illness perceptions and QoL will be mediated by self-efficacy, coping style, depression and anxiety.

Similar to illness perceptions, 'coping' strategies are central to the CSM. According to Lazarus and Folkman (1984), individuals mediate stress through behaviour and cognition. In CSM 'adaptive coping' strategies seek to change the situation (e.g. planning, problem solving), while 'maladaptive coping' strategies seek to regulate emotional distress (e.g. praying, avoiding) (Lazarus & Folkman, 1984).

Given the effectiveness of implementing the CSM in other chronic conditions and the importance of psychosocial mediators in health, this study sought to explore the CSM in stroke survivors, using Structural Equation Modelling (SEM). It was hypothesised that: (1) poorer illness perceptions, lower self-efficacy, and maladaptive coping would be associated with increased depression, anxiety and poorer QoL, and (2) aligned with CSM, self-efficacy, coping style, depression and anxiety would mediate the relationship between illness perceptions and QoL.

Methods

Participants comprised of 72 stroke survivors (32 females; mean [SD] age 65.09 [14.14] years; male mean [SD] age 69.83[11.81]), 61 percent were married, 7 percent were defacto, 8 percent were divorced, 2 percent were separated, 17 percent were single, 3 percent were widowed and 2 percent identified their relationship as 'other'. Mean time since stroke was 33 months. Participants were recruited as part of the Stroke and Carer Optimal Health Program (SCOHP) trial, the details of which have been reported elsewhere (Chapter Three).

Materials

Brief Illness Perceptions Questionnaire (Broadbent, Petrie, Main & Weinman, 2006).

The BIPQ is a 10-item questionnaire evaluating emotional/ cognitive representations of illness throughout eight dimensions: emotional response, consequences, timeline, personal control, treatment control, identity, concern and understanding (Broadbent, 2006, p. 631). Items were assessed according to a 11-point rating scale. For example, "How much does your illness affect your life: 0 [not at all] – 10 [severely affects my life]" (Broadbent et al., 2006, p. 637).

Our analysis of inter items correlation in which items 3, 4 and 7 were reversed to be uniform with the other items in the scale. Confirmatory factor analyses was completed, using the Amos statistical package (version 24), in order to check the construct. We found that illness perception had a good model fit using fit indexes by

Hu and Bentler (1999): χ^2 p>.05; χ^2/N =1-3, CFI >.95, TLI>.95, SRMR <.05] and strong internal consistency (0.80) using 5 items: “how much does your illness affect your life?; how long do you think your illness will continue?; how much do you experience symptoms from your illness?; how concerned are you about your illness; how much does your illness affect you emotionally?” (Broadbent et al., 2006, p. 637). We calculated illness perceptions by calculating their subscale ranges 1 – 10, in which high scores reflected poor emotional and cognitive representations of illness.

Carver Brief coping questionnaire (Carver, 1997).

The Brief-COPE is comprised of 14-subscale questionnaire, with two items per subscale. A 4-point rating scale is used, for example: “1 [I haven’t been doing this at all] to 3 [I’ve been doing this a lot]” (Carver et al., 1997, p. 95).

Consistent with Carver (Carver, Scheier & Kumari Weintraub, 1989), we completed a Principal Component Analysis (PCA) with an Oblimin rotation on the COPE items. The first two components were chosen, for parsimony, as they were strongly weighted and had the most variance. CFA and Cronbach alpha were used to evaluate each component, with item-if-deleted analyses to improve internal consistency and model fit. Both scales maladaptive coping and adaptive coping scales were identified and had a good fit.

Our analysis also found that the five items for maladaptive coping “I’ve been giving up trying to deal with it; I’ve been refusing to believe that it has happened; I’ve been criticising myself; I’ve been giving up the attempt to cope; I’ve been blaming myself for things that happened” (Carver et al., 1997, p. 95)) had an internal consistency of .0.72. Further, adaptive coping had 7 items: “I’ve been concentrating my efforts on doing something about the situation I'm in; I’ve been getting emotional support from others;

I’ve been getting help and advice from other people; I’ve been trying to come up with a strategy about what to do; I’ve been getting comfort and understanding from someone; I’ve been trying to get advice or help from other people about what to do;. I’ve been thinking hard about what steps to take” (Carver et al., 1997, p. 95) had an internal consistency of 0.83.

Self-efficacy measured by the General Self-efficacy Scale (Schwarzer & Jerusalem, 1995a)

The General Self-Efficacy Scale is a 10-item measure which assesses an individual’s belief that they can overcome challenges and situations in their own life, utilising a 4-point scale: “1 [Not at all true]” to “4 [Exactly true]” *(Schwarzer & Jerusalem, 1995, p.38).* Items are summed giving a score range of 10 to 40; higher scores signify greater levels of self-efficacy (Schwarzer & Jerusalem, 1995a).

Hospital Anxiety and Depression Scale (Snaith, 2003)

The HADS is a 14-item self-report questionnaire that assesses depression (7 items) and anxiety (7 items) and within the past seven days. Questions are assessed via a 4-point Likert scale. For example, “I feel tense or ‘wound up’” 0 = [not at all] to 3 = [most of the time] (Snaith, 2003, p. 2). Scores between 16-21 indicate the presence of a mood disorder (Snaith, 2003).

Assessment of Quality of Life-6 Dimensions (Allen et al., 2013).

The AQoL-6D is a multi-attribute self-reported questionnaire that provides a multidimensional of health related quality (Allen et al., 2013). Comprised of 20 items which assess 6 domains of QoL (relationships – 3 items, independent living – 4 items, coping – 3 items, mental health – 4 items, senses – 3 items and pain – 3 items). Items have between 4 to 6 response options which can be combined to provide an overall score of QoL; higher scores suggest impairment to QoL.

Statistical analysis

Exploratory analysis of the data, plus visual inspection, found that the study variables met SEM's assumptions (e.g. normality, linearity). In order to compare the relationships between study variables correlational analyses was completed. In accordance with the CSM, a SEM was completed using the Amos statistical package. Hu and Bentler (1999) recommend criteria to guide which paths or variables should be removed according to the examination of modification indices, standardised residuals, and a significant improvement in fit (i.e. significant change in χ^2/N as well as an increase in standard goodness of fit measures [$\chi^2 P > 0.05$; $\chi^2/N = 1–3$, RMSEA < 0.07, CFI > 0.95, GFI > 0.95]).

Results

Table 9 reports the descriptive and correlational analyses of the hypothesised CSM variables. Illness perceptions and maladaptive coping had a significant positive correlation, as well as both having significant positive correlations with anxiety and depression and significant negative correlations with QoL and self-efficacy. Adaptive coping did not have a significant correlation with any of the study variables. In addition, quality of life had a significant negative correlation with depression and anxiety, and a significant positive correlation with self-efficacy.

Table 9. Pearson’s correlation and descriptive statistics of the scales

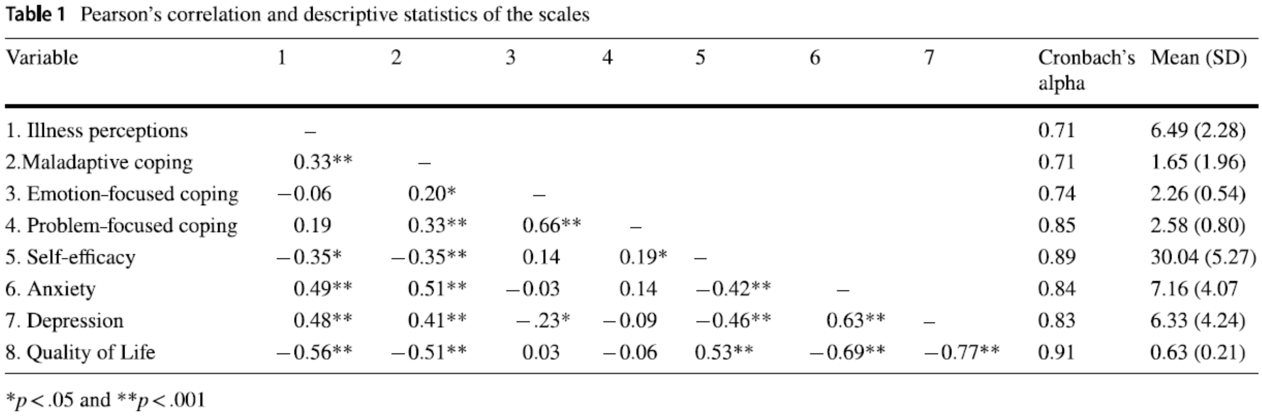


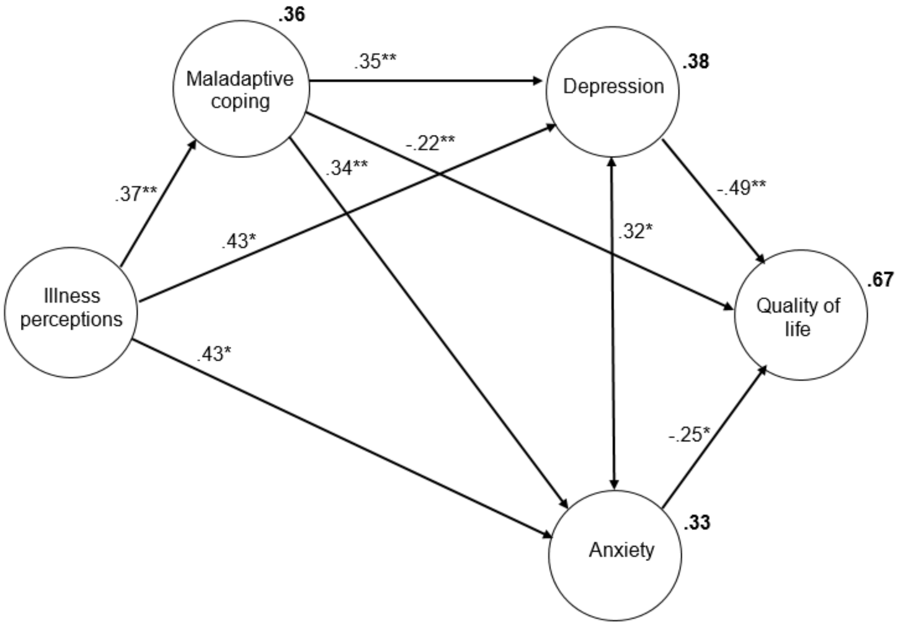
Table 1 Pearson’s correlation and descriptive statistics of the scales

Variable	1	2	3	4	5	6	7	Cronbach’s alpha	Mean (SD)
1. Illness perceptions	–							0.71	6.49 (2.28)
2.Maladaptive coping	0.33**	–						0.71	1.65 (1.96)
3. Emotion-focused coping	−0.06	0.20*	–					0.74	2.26 (0.54)
4. Problem-focused coping	0.19	0.33**	0.66**	–				0.85	2.58 (0.80)
5. Self-efficacy	−0.35*	−0.35**	0.14	0.19*	–			0.89	30.04 (5.27)
6. Anxiety	0.49**	0.51**	−0.03	0.14	−0.42**	–		0.84	7.16 (4.07
7. Depression	0.48**	0.41**	−.23*	−0.09	−0.46**	0.63**	–	0.83	6.33 (4.24)
8. Quality of Life	−0.56**	−0.51**	0.03	−0.06	0.53**	−0.69**	−0.77**	0.91	0.63 (0.21)

*$p < .05$ and **$p < .001$

Consistent with the CSM, illness perceptions, maladaptive and adaptive coping, self-efficacy, depression, anxiety and QoL were specified in this SEM. The principal model, based on CFA, was populated with the validated measurement models for all variables which were signified as latent variables. In order to decrease the models measurement error, single indicator latent variables were stipulated with variance and subscale internal consistency.

The final model was developed by eliminating non-significant pathways and variables which did not contribute significantly to the fit of the model. This removal process continued until a parsimonious and theoretically valid model that established the ‘best fit’ was derived. This iterative method identified a number of paths and variables as non-significant contributors, as a result, the pathways between illness perceptions and adaptive coping; illness perceptions and self-efficacy; adaptive coping and depression; and adaptive coping and anxiety were removed from the model. In spite of the small sample size, the final model (Figure 8) had a good fit (χ^2 (1) = 3.17, p = 0.075, χ^2/N = 0.23, RMSEA < 0.07, CFI > 0.97, GFI > 0.97, SMSR<0.05) with 67% of the variation in quality of life explained. Illness perceptions directly influenced maladaptive coping, depression and anxiety (β = 0.37, p < 0.001, β = 0.43, p < 0.001, β = 0.43, p < 0.001, respectively). Maladaptive coping directly influenced QoL (β = -.22, p < 0.001). The relationship between illness perceptions and QoL is fully mediated by maladaptive coping, depression and anxiety. Also the relationship between illness perceptions and both depressions and anxiety are partially mediated by maladaptive coping. A significant positive correlation between both depression and anxiety (p< 0.05) was noted.



(p = ** <.001, * <.01)

Figure 8. Final SEM model

Discussion

It is well established that the psychosocial health of stroke survivors is adversely impacted post-stroke (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). However the influential factors that impact on survivor outcomes are not well understood (Galligan, Hevey, Coen & Harbison, 2015). Therefore, this study sought to identify the key mediating factors determining the relationship between illness perceptions and QoL in stroke survivors using a theoretically based model; the CSM. Overall, this model had a good fit, explaining 67% of the variation in QoL. Depression, anxiety and maladaptive coping style were shown as important mediators of the QoL in stroke survivors.

Support for the first hypothesis was found as poor illness perceptions and maladaptive coping were associated with higher levels of depression and anxiety, plus lower levels of QoL. These findings are consistent with other CSM models in which poor illness perceptions are associated with higher levels of depression and anxiety (McAndrew et al., 2018; Skinner et al., 2014). These findings also concur with stroke research which has established an association between depression and anxiety (Ayerbe et al., 2013). Further, the model corresponds with previous CSM models that have associated poor illness perceptions with poor QoL (Cartwright, Endean & Porter, 2009; McAndrew et al., 2018; Willemse, van der Doef & van Middendorp, 2018) and maladaptive coping associated with depression, anxiety and QoL (Snell, Siegert, Hay-Smith & Surgenor, 2011; Woodhouse, Hebbard & Knowles, 2018).

Support for the second hypothesis was evidenced in part as only maladaptive coping style, depression and anxiety were identified as mediators in the relationship between illness perceptions and QoL. In CSM coping mediates the impact of the illness on dependent variables such as depression and anxiety (Leventhal et al., 2016). However, in the model we were only able to account for the impact of maladaptive coping while adaptive coping was removed from the model because it was not associated with the other study outcomes. It is possible that stroke survivors are primed for maladaptive coping responses due to negative cultural beliefs about illness and age which may outweigh the impact of any adaptive coping mechanisms (Lincoln, Kneebone & Macniven, 2011; National Stroke Foundation, 2007). Similar CSM models of other chronic diseases (Knowles et al., 2017; Woodhouse et al., 2018) have also had difficulty accounting for the impact of both adaptive and maladaptive coping in their models. Self-efficacy was also removed due to the lack of significant relationships. It is possible that self-efficacy may not relate to these variables prior to intervention. Consistent with the CSM, illness perceptions directly influenced depression, anxiety and maladaptive coping which in turn influenced QoL. Until now the psychosocial factors mediating QoL in stroke survivors had not been determined. Importantly, these findings suggest that interventions which improve coping could be of particular value to stroke survivors as they may also reduce depression and anxiety, plus improve QoL according to the model. In practice, few interventions target the coping strategies of stroke survivors (Maryam et al., 2015; Ostwald et al., 2014; Robinson-Smith et al., 2016). However, Robinson-Smith et al. 2016 completed a randomised controlled trial (n = 20) of a coping-based intervention which improved coping and depression (Robinson-Smith et al., 2016) consistent with the model; larger trials will be required to confirm or refute these findings.

The study highlights new findings regarding the physical, psychological and social attributes that constitute QoL in stroke survivors (Lo Buono et al., 2017; van Mierlo et al., 2014). In the past stroke literature has often emphasised the relationship between physical impairment and QoL (Chen et al., 2015; Cumming, Brodtmann, Darby & Bernhardt, 2014; Lin et al., 2018; Pulman & Buckley, 2013). However these findings suggests that a number of key relationships between psychosocial outcomes influence QoL (e.g. the relationship between QoL and illness perceptions, maladaptive coping, depression and anxiety in stroke survivors). Also these findings suggest that stroke survivors' illness perceptions influenced maladaptive coping, which in turn directly influenced QoL; this concurs with the CSM model and past literature (Knowles et al., 2016; Vaske, Kenn, Keil, Rief & Stenzel, 2016).It is interesting that illness perceptions did not influence the QoL of stroke survivors directly but instead exerted influence via maladaptive coping, depression and anxiety; these new findings suggest that QoL may be most effectively improved by targeting these inter-relationships.

This model draws attention to insufficiencies in the way stroke treatment approaches depression and anxiety. Currently, interventions for stroke survivors' usually only target depression (Alexopoulos et al., 2012; Ertel et al., 2007; Glass et al., 2004; Mitchell et al., 2009; Watkins et al., 2007). Yet, anxiety remain under-diagnosed and under-treated amongst stroke survivors despite being linked to poor functional outcomes (Winstein et al., 2016). The findings draw attention to treating both depression and anxiety as they are associated and influence QoL. Therefore, interventions should target both depression and anxiety for optimal results, including improved QoL.

The model is among the first to explore the illness perceptions of stroke survivors (Phillips et al., 2015). Interestingly, in the model illness perceptions and maladaptive coping were associated with higher levels of depression and anxiety and lower levels of

QoL. Like previous CSM study's the model identified a relationship between illness perceptions and depression anxiety (Paschalides et al., 2004; Skinner et al., 2014); this relationship in turn impacts on QoL and is an important juncture in which an intervention could be conducted. The findings also concur with previous reviews of stroke interventions that have found that effective coping strategies are linked to low QoL (van Mierlo et al., 2014).

Findings pertinent to understanding the role of maladaptive coping in the psychosocial health of stroke survivors were identified in this study. Although adaptive coping was not featured in this model, previous studies have not addressed the role of maladaptive coping in the stroke survivor cohort. There is some evidence to suggest that interventions targeting stroke survivors and carers can improve coping (İnci & Temel, 2016; Ostwald et al., 2014; Robinson-Smith et al., 2016; van den Heuvel et al., 2000; van den Heuvel et al., 2002). The provision of effective coping-based interventions should be made available to stroke survivors throughout the continuum of care. Additionally, this model should be assessed in stroke survivors that have completed coping-based psychosocial interventions to explore post-intervention changes to the model.

The following limitations should guide the interpretation of these results. Self-report questionnaire were the basis of data collection; therefore, the answers may reflect the bias and perceptions of the respondent's. The replication of this study using a larger sample size is required to enable generalisation of the study's findings. As the data is being cross-sectional, causal (true mediation) relationship could not be tested. Future trials should incorporate a measure of illness or symptoms to more completely test the full CSM in this population.

Conclusion

This is the first study to explore the interrelationships between illness perceptions, self-efficacy, coping strategies, and anxiety and depression on QoL in a post-stroke cohort using SEM. The findings identified important psychosocial mediators (maladaptive coping, depression, anxiety) which impact on stroke survivors. Importantly this model draws attention to the relationship between depression and anxiety; and their mediating impact QoL. Both depression and anxiety are impacted illness perceptions. Stroke survivors often fail to receive support for their psychosocial health, targeting depression, anxiety and maladaptive coping may improve stroke survivors QoL.

5.3 Chapter synthesis

This chapter presented a study that addressed the underlying relationship between many of the key outcomes of interest in this program of research. Importantly it established a relationship between depression and anxiety. This is important because, of the 25 studies in the systematic review that measured depression, only nine reported significant reductions (Bakas et al., 2015; Fang et al., 2017; Grant et al., 2002; Mitchell et al., 2009; Ostwald et al., 2014; Robinson-Smith et al., 2016; Smith et al., 2012; Watkins et al., 2007; Wong & Yeung, 2015) and, of these only two also measured anxiety (Fang et al., 2017; 2014; Robinson-Smith et al., 2016); while a further two measured anxiety only. It is likely that anxiety is an important confounder affecting our results, according to our analysis of mediators.

5.4 Further considerations

The limited efficacy of the stroke and carer interventions in improving psychosocial interventions suggests that modeling may play a pivotal role in understanding the relationship between these outcomes. The modeling described in this chapter highlight the importance of addressing depression and anxiety at the same time. Future research into SCOHP should revise it to specifically target these relationships more effectively. For example, SCOHP could be modified to include a specific module on depression and anxiety which could include psychoeducation and self-help strategies. Of note, this analysis focuses on data collected from the stroke survivor participants (n = 73) in line with the CSM model which is a model of symptomology. Future research should utilise carer data to explore the relationship between key carer outcomes. Dyadic analysis was outside the scope of this thesis; this is a limitation of this research which should be explored in future research.

5.5 Chapter summary

This Chapter and the included publication provide important insight in to the psychosocial mediators that shape the psychosocial health of stroke survivors. Chapter Five builds on the literature described in Chapter One and Chapter Two which addresses the psychosocial health of stroke survivors. Chapter Five extends the method outlined in Chapter Three in order to gain information about the relationships between psychosocial outcomes in this cohort, thereby enriching this program of research. Therefore, the understanding gained from the analysis of mediators provided in Chapter Five could be of value to the development of future interventions. Chapter Six will discuss the findings of this program of research, including implications.

Chapter Six - Discussion and Conclusions

6.1 Chapter introduction

CHAPTER ONE – Introduction
CHAPTER TWO – Literature review
CHAPTER THREE – Methodology
CHAPTER FOUR – RCT results
CHAPTER FIVE – Analysis of mediators
CHAPTER SIX – Discussion and conclusions

This program of research was undertaken in order to examine and improve the psychosocial health of stroke survivors and their carers. In particular, this research evaluated the efficacy of a psychosocial intervention (SCHOP) for stroke survivors and their carers. Further, a secondary analysis of psychosocial mediators in stroke survivors was conducted. This chapter integrates the results from Study Two within the broader literature and highlights the significant and original contribution derived from this research. The strengths and limitations of this research are outlined and discussed in comparison with similar studies and the overall field of practice. Lastly, recommendations for future research and implications for practice are detailed.

6.2 Research purpose

This program of research aimed to examine and contribute to the evidence regarding the efficacy of psychosocial interventions that seek to improve the psychosocial outcomes of stroke survivors and their carers; and identify and explore psychosocial mediators that affect stroke survivors. This aim was addressed by answering three objectives i) examine the evidence to date regarding the effectiveness of psychosocial interventions for stroke survivors and carers; ii) identify the impact of one psychosocial intervention, the SCOHP, on the psychosocial health of stroke survivors and carers; and iii) identify and explore the relationship between psychosocial variables in stroke survivors.

6.3.1 Objective One: Examine the evidence to date regarding the effectiveness of psychosocial interventions for stroke survivors and carers.

A systematic review and meta-analysis of psychosocial interventions for stroke survivors and carers was undertaken as detailed in Chapter Two. These findings suggest that psychosocial interventions may be helpful in improving some psychosocial variables (i.e. depressive/anxiety symptoms, QoL, coping) in stroke survivors, carers and/or dyads. Overall, many interventions did not improve psychosocial outcomes in this population, justifying investigation of new interventions.

This body of research established important new findings regarding the effectiveness of psychosocial interventions. To begin with, this systematic review and meta-analysis of psychosocial interventions for stroke survivors and carers is the first review to exclusively review psychosocial interventions for stroke survivors and carers, as opposed to previous reviews where psychosocial interventions were reviewed alongside general intervention trials (Bakas et al., 2014; Bakas et al., 2017; Greenwood et al., 2008), psychological interventions (Cheng et al., 2014; Eldred & Sykes, 2008) and social interventions (Cheng et al., 2014).

The meta-analysis is the first to demonstrate that psychosocial interventions are effective when directed at stroke survivors and carers, but not dyads. This should be interpreted in light of the limited evidence available and the small number of included publications which may limit it's generalisability as may the large number of potential participants that were excluded due to needing an interpreter because of cognitive deficits. Unfortunately, the data reported for other outcomes were not sufficient to complete meta-analysis; this is a limitation of the literature that could be resolved through better reporting of means and standard deviations. Overall, this research highlighted that there is insufficient meta-analysis of the impact of psychosocial interventions on key psychosocial outcomes for stroke survivors and their carers.

The systematic review identified a number of psychosocial interventions that significantly improved outcomes of interest (depressive symptoms, anxiety symptoms, QoL, coping) in the study population. This review did not find evidence that psychosocial interventions improved self-efficacy or carer strain. A significant improvement in carer satisfaction was noted in the intervention group, compared to usual care, at 6 months but not at the other timepoints. This concurs with past reviews which have looked at a mixture of psychosocial and intervention trials and found little evidence that these interventions improve self-efficacy, carer strain and carer satisfaction (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). Overall, the systematic review highlighted the difficulty of improving the psychosocial health of stroke survivors and carers. Thereby, this review suggests that interventions to improve the psychosocial health of stroke survivors and carers require further development, thereby justifying the trial of new interventions. It is a limitation of the systematic review that psychosocial interventions with a physical rehabilitation component were not explored separately, which may have led to heterogeneity. Future reviews should determine how physical rehabilitation components impact the findings. Likewise, the included publications did not use analysis methods to calculate the impact of the dyadic relationship on the outcomes; this would be an important topic of future studies.

6.3.2 Objective Two: Identify the impact of one psychosocial intervention, the SCOHP, on the psychosocial health of stroke survivors and carers.

> A RCT of SCOHP was conducted, as detailed in Chapter Three and Four. No significant effect was identified between groups or across time for stroke survivors. A significant improvement was noted in the intervention group, compared to usual care, in carer satisfaction was noted at 6 months but not at the other timepoints. Limitations in the service environment may have impacted on the effectiveness of the intervention. Adaptation of the intervention in light of these findings may improve SCOHP's effectiveness.

This was the first trial to evaluate the effectiveness of the OHP when adapted for a stroke population (SCOHP). Stroke survivors in the intervention group had a mean age of 67 years and the usual carer group had a mean age of 69 years. This is younger than the average Australian stroke survivor, which is estimated to be around 75 years of age (National Stroke Foundation, 2010); thus this may limit generalisability. Similarly to previous research, most stroke survivors lived with their spouse/partner (Australian Institute of Health and Welfare, 2013). No major significant results were identified between groups or across time. Therefore, it was not possible to uphold hypothesis one: *'stroke survivors and carers in the SCOHP will show improved QoL and self-efficacy* *at 3, 6 and 12 months, post-baseline, compared to usual care'*. Likewise, it was not possible to uphold hypothesis two: *'stroke survivors and carers in the SCOHP will show reduced depressive and anxiety symptoms and improved social and workplace functioning, illness perceptions, plus improved carer strain and satisfaction at 3, 6 and 12 months, post- baseline, compared to usual care'*.

A significant difference in 'time since stroke' was noted between the stroke survivor's usual care and intervention group. Although there were no significant group differences for carers, their results should also be interpreted in light of the group differences in 'time since stroke' amongst the survivor participants as this may have a bearing on the carer burden.
However, these differences may be partially mitigated by the period of expedited functional recovery in first 6 months of stroke recovery; both groups are therefore expected to be comparable in terms of their functional recovery trajectory (Dhamoon, Moon, Paik, Sacco & Elkind, 2012; Langhorne, Bernhardt & Kwakkel, 2011). On the other hand, the impact of on-going frustration and unmet expectations regarding recovery targets may also lead to frustration and loss of hope (Stroke Association, 2013). Lessons from this trial could lead to the adaption of the SCHOP or inform the development of effective psychosocial interventions for stroke survivors and carers.

Unexpected patient characteristics may have contributed to the lack of significant results. For example, although the mean age of stroke participants was around 70 years of age, this trial included individuals aged >85 years and older in the intervention. This subset of the stroke population is known to be difficult to study, have increased disability, and less evidence-base to guide treatment (Benjamin et al., 2017). This RCT suggests that interventions such as SCOHP, that rely on social or services connections, may not be effective in this age-group.

Further, demographic data from this RCT contributes new information regarding the multi-cultural service environment in which the trial occurred; this may have also contributed to the lack of significant results. Considering that non-English speakers were excluded, first generation immigrants constituted around 30% of the overall sample for both stroke survivors and carers. Considering the culturally and linguistically diverse (CALD) characteristics of this service population, the effectiveness of the SCOHP may be improved by completing further CALD capacity building (Victorian Transcultural Psychiatry Unit, 2011). Furthermore, little is known about how immigration affects stroke outcomes (Jacobs, 2010; Saposnik et al., 2010). Future interventions should consider the impact of migration and CALD factors on research and service population.

The SCOHP utilises components such as problem solving and coping skills which have been shown to be effective at improving the psychosocial outcomes of stroke survivors and carers when used in other interventions (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). None-the-less, minimal significant results were reported in the trial of SCHOP. One possible explanation may hark back to the adaption of the SCOHP from the OHP. The OHP was originally designed to be broad in scope in order to be applicable across different disease populations (Gilbert et al., 2012; Ski, Thompson & Castle, 2016). In contrast, interventions included in the systematic review and meta-analysis were designed specifically for stroke survivors and/or carers. As such, effective interventions often targeted unmet needs specific to this population including physical rehabilitation (Markle-Reid et al., 2011; Wong & Yeung, 2015), discharge planning

(Wong & Yeung, 2015), communication (Robinson-Smith et al., 2016), stroke education (İnci & Temel, 2016) and caregiver training (Bakas et al., 2015). Further tailoring of the OHP to reflect the specific unmet needs of this population may improve its effectiveness.

6.3.3 Objective Three: Identify and explore the relationship between psychosocial variables in stroke survivors

An analysis of psychosocial mediators was conducted, as detailed in Chapter Five. This research was among the first to uphold the CSM in a stroke population and detail the relationship between psychosocial variables in this population. This analysis addressed two hypotheses. Hypothesis one: *'illness perceptions mediate the relationship between self-efficacy and individual coping patterns'*. This model did not support hypothesis one. Hypothesis two*: 'self-efficacy, coping patterns mediate the relationship between illness perceptions and depression, anxiety and QoL'*, was partially supported as maladaptive coping mediated the relationship between illness perceptions and depression, anxiety and QoL, as described in Chapter 5. The role of illness perceptions, adaptive and maladaptive coping had not previously been explored in stroke literature although these factors can inform the development of effective stoke interventions.

The analysis of mediators study did not inform the feasibility of the trial as it used data collected from the RCT. However, it was conducted in order to help inform future trials and understand why SCOHP and previous psychosocial intervention may have been successful or unsuccessful, as described in the systematic review. For example, this modeling showed that anxiety and depression were associated; it is likely that SCOHP did not support these outcomes sufficiently. Also, previous stroke literature does not address the important impact of 'illness perceptions' although this modeling showed that it had a direct and significant impact upon coping, depression and anxiety. Future interventions should consider these results and consider the impact of illness perceptions and the relationship between depression and anxiety when designing psychosocial interventions for stroke survivors.

6.4 Strengths of the research

1. To ensure the highest possible quality this RCT was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) checklist for RCTs (Schulz et al., 2010) which is reported in Appendix 4. As such, this RCT was conducted according to the highest standards of design which are expected to contribute rigorous and trustworthy findings while minimising bias (Lilienfeld, McKay & Hollon, 2018). The analysis of psychosocial mediators in stroke survivors was of the baseline data collected during the RCT. MMRM analysis provided a robust analysis method that was appropriate from comparing between groups and across time, as well as dealing with missing of the research data (Schafer & Graham, 2002). This analysis was completed using SEM which is considered a robust analysis establishing the relationship between multiple latent variables (Perrin, Heesacker, Stidham, Rittman & Gonzalez-Rothi, 2008). This research provides insight in to local stroke survivors, this is important because much of the literature is international and little is known about the Victorian stroke cohort. Therefore, overall the research has been conducted and reported with rigor.

2. This RCT targeted stroke survivors, carers and dyads. Previously, the majority of interventions for those affected by stroke targeted survivors only (Alexopoulos et al., 2012; Ertel et al., 2007; Fang et al., 2017; Forster et al., 2015; Glass et al., 2004; Harrington et al., 2010; Hoffmann et al., 2015; Kendall et al., 2007; Markle-Reid et al., 2011; Mitchell et al., 2009; Watkins et al., 2007; Wong & Yeung, 2015) or carers only (Bakas et al., 2015; Bakas et al., 2009; Draper et al., 2007; Grant et al., 2002; Hartke & King, 2003; İnci & Temel, 2016; Johnston et al., 2007; Larson et al., 2005; van den Heuvel et al., 2000; van den Heuvel et al., 2002) . However, recent literature has suggested that dyad experiences are interrelated with interconnected outcomes (Lyons & Lee, 2018) and this has been observed among survivor and carer dyads (McCarthy et al., 2011); therefore it is important to explore interventions which could be delivered to survivors and carers at the same time. Future studies should analyse studies using methods using dyadic analysis; ii) the impact of the intervention. In terms of developing complex interventions, future interventions should follow the appropriate guidelines which stipulate that the development of the intervention must consider the variability in the population, causal links between the outcomes, and use of large sample sizes (Medical Research Council, 2010). A strength of this research is that it explored an intervention that has been adapted to improve the psychosocial health of stroke survivor and carers.
3. This research produced a substantial dataset regarding the demographic details of 137 participants (stroke survivors *n* = 89; carers *n* = 84) that have utilised the local stroke service system. These demographics capture information regarding the age and CALD characteristics of the service population. Outcomes such as self-efficacy, carer strain and carer satisfaction are rarely reported; this

database contributes important new data regarding these outcomes. These findings contribute new findings regarding the local service population that has not been captured in national stroke datasets such as AuSCR (Cadilhac et al., 2010) which contain limited psychosocial variables (i.e. QoL). Further exploration of this data may yield more new findings and inform future research.

6.5 Limitations of the research

The results of this study should be viewed within the following limitations. Firstly, the trial excluded individuals that were not fluent English communicators, including those with significant aphasia or dysphasia. English language skills were the crux of the intervention so it was imperative that participants were capable and confident in reading, writing and conversing in English so that the effect of the intervention was not underestimated. Future trials of SCOHP should be adapted for aphasic participants through the inclusion of simplified manuals and the use of pictorial language aids (Palmer & Paterson, 2013). Future trials of the SCOHP should increase access to CALD participants by providing the intervention in other languages. However, considering the resources required for translating a large workbook-based intervention and provided translators this was not feasible in a trial of this size. The study should also have utilised stroke survivors and carers in a steering or advisory committee to enrich the project and identify possible confounders and comment on the complexity of the intervention.

Secondly, this RCT was unable to include individuals with learning difficulties/cognitive deficits as these conditions can interfere with evaluation. However, the OHP should be adapted and re-evaluated for individuals with these conditions as cognitive deficits are a common consequence of stroke (Benjamin et al., 2017). Due to the participatory nature of the study neither participants nor investigator staff were able to be blinded to allocation. This is a limitation that has been noted by similar stroke interventions (Alexopoulos et al., 2012; Draper et al., 2007) and a consideration when conducting an evaluation in a real life practice setting. Although the study reached the power indicated in the protocol there was a large attrition rate which impacted on the overall amount of usable data; a steering committee which included stroke survivors and carers may have advised the research team if any of these 14 measures were unimportant.

Thirdly, there were a number of difficulties in recruiting carers. To-begin-with, identifying carers was often a difficult process as i) many carers, including siblings and children who provide care may not identify themselves as carers. It was noted by recruitment staff that medical files often did not contain carer information. This reflects cultural ideas about who is the carer and may reflect how carers are not considered central partners in the care of stroke survivors.

Finally, considering the broad scope of the search strategy, a wide range of psychosocial interventions were included, which may have been a limitation of the systematic review.

This trial utilised self-reported questionnaires as clinical indicators of psychosocial outcomes were not possible. Although this is traditionally considered a limitation (Rosenman, Tennekoon & Hill, 2011), considering that the trial was seeking to evaluate the perceived changes in psychosocial health of the participants it remains in line with the overall aims of the trial.

It was not possible to complete a cost-effectiveness analysis as intended due to changes in staffing.

6.6 Feedback from participants and clinicians

Although the trial design did not include formal pathways for collecting participant feedback, research staff worked closely with participants and potential participants and received feedback about the trial. Overall, feedback from participants reflected that, for the most part, support was desperately needed. As a matter of fact, this trial was often a primary source of support. Feedback from stroke survivors most often emphasised the importance of supporting the carer. Carers reported that they often lacked support and were unable to identify other sources of support. A number of the participants had contacted the Stroke Association of Australia or the National Stroke Association but reported that they had exhausted resources available through these organisations.

Feedback regarding improvements to the SCOHP were received. The length and difficulty of the questionnaires was noted. Difficulty returning the questionnaires is also an area for improvement; carers reported struggling to find time to return them and stroke survivors reported challenges to mobility that interfered with returning the questionnaires. In the future, feedback obtained by the research team should be rigorously collected and used to inform future research.

6.7 Observations from the research candidate

In hindsight, it appears that this trial may have underestimated the impact of a number of practical factors including the immensity of the work undertaken by carers, the lack of social /service resources and the impact of aging on the functioning of the potential participants. As a result, practical aspects of the trial were affected including the time allocated for recruitment, data collection and missing data. Additionally, the research candidate became aware through the conduct of the trial how little support this population receives, especially carers. Although there initially appeared to be many services available to survivors they were often quickly exhausted and many times required complicated referral pathways.

Furthermore, current stroke literature often seeks to reduce the burden stroke places on the health system by shifting the burden of care to carers; this is a difficult process to witness. Carers typically experience profound stress, often at a time in their life when physical and financial resources are strained; this approach lacks compassion at times.

The research candidate notes that there appeared to be a number of barriers to social participation from survivors and carers. Stroke survivors usually have their licence suspended on medical grounds after their stroke and can find mobility difficult. It was noted during the intervention that many carers were only able to participate if their survivor attended with them because they could not leave them unattended. Overall, many participants expressed to the research team that they faced substantial barriers to participation in the trial which may have impacted on recruitment and attrition. Considering the impact of aging, co-morbid conditions, reduced mobility and intense rehabilitation schedules this trial may not have been sufficiently tailored to these cohorts. Of note, carer attrition was higher than that of stroke survivors, with ‘failure to return the questionnaire’ being offered as the principal reason. Indeed, the research team reported that carers often struggled to fit the trial into their daily lives; future trials should streamline data collection and prioritise key outcome measures. Overall, the level of participation expected for SCOHP may have exceeded the capacity of many stroke survivors and carers. This is an important consideration for participation in future trials.

6.8 Implications

Overall, the completion of this program of research has contributed new information that can enrich stroke research service and inform how services are developed. The implications of these findings are discussed below.

6.8.1 The effectiveness of psychosocial interventions for stroke survivors and carers

Similar to past trials of psychological and social interventions, psychosocial interventions also struggle to improve the psychosocial health of stroke survivors and/or carers is difficult to achieve (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). The helpfulness of self-management interventions which rely on service pathways and social participation are not effective in this population and this should be critically investigated in future research; while methodological and practical factors should also be explored.

6.8.2 Stroke research

The lessons learned from this research have value for local researchers and can be used to design and implement better studies. For example, this trial highlighted challenges in recruiting and retaining stroke survivors and carers; this concurs with findings of international trials (Boden-Albala et al., 2015; Hadidi, Buckwalter, Lindquist & Rangen, 2012; Johnson et al., 2018). At the beginning, this trial underestimated factors experienced by the participants (e.g. overwhelm, limited resources, level of impairment) which affected recruitment, retention and data collection. Lessons learned regarding the length of time and personal support required by this participant group is important for other researchers.

It is well noted that the recruitment, retention and data collection of stroke survivors and carers is challenging (Boden-Albala et al., 2015; Diver et al., 2017; Hadidi et al., 2012; Thayabaranathan et al., 2016); these factors may have impacted on the results. The recruitment period of this trial was extended to meet the target outlined in the protocol. Overall, 18% of stoke survivors and 22% for carers withdrew after baseline. This is lower than some psychosocial trials for stroke survivors and carers which have reported up 50% of recruited participants as withdrawn (Fang et al., 2017; Rodgers et al., 1999; van den Heuvel et al., 2002). Overall, participants who completed the 3 month questionnaire were strongly retained through to the completion of the trial. These lessons highlight the importance of preparing for the challenges that are associated with stroke research.

6.8.3 Service provision

Observations and informal feedback from the participants highlight that although significant improvements in the outcomes of interest were not found, the provision of the SCOHP provided the participants with support to which they would not otherwise have had access. Feedback from the participants suggest that the individuals who completed the intervention were glad to receive support and that they found the delivery mode and contents of the intervention acceptable; as discussed in the implications.

It is possible that the SCOHP would have been more effective if the service environment had been better resourced and more accessible to the participants. None-the-less, the SCOHP highlighted that more support services for stroke survivors is urgently required; as discussed in the implications below. The SCOHP centres on an individual’s ability to improve their health outcomes by incorporating services and social relationships. However, if the individual was limited in their ability to connect to services and relationships due to environmental factors (e.g. lack of services, long waitlists, brief service interactions) or limitations in their capacity (e.g. mobility, revocation of drivers licence, frailty) the effectiveness of the intervention may diminish. It is well established that stroke survivors experience reduced social and activity interaction (Andrew et al., 2014). Further, stroke support in Victoria is limited and consists mainly of primary care services, the Stroke Association of Victoria, the National Stroke Association and, to an extent, Carers Australia. Supports such as housing, home help, psychological support and outpatient support often carry long waitlists and pose challenges in terms of accessibility. This highlights the lack of support available to stroke survivors and carers.

Lack of services, carer burden and restricted social capacity could have reduced the effectiveness of the intervention and should be considered by researchers and clinicians moving forward.

Furthermore, future studies should include i) updated meta-analysis which include the results from SCOHP; ii) measurements of satisfaction; iii) qualitative components; iv) cost effectiveness which are in line with the 2010 Medical Research Council recommendations (Medical Research Council, 2010).

6.8.4 Implications for the OHP

Although this trial did not provide evidence that the adaption of the OHP was effective when delivered to stroke survivors and carers, this is important information as this intervention has not been tested on this population previously. It is noted that the stroke and carer participants faced substantial hurdles that may have impeded better outcomes. Considering the favorable feedback received from participants regarding the acceptability of the intervention and the facilitators, as well as past trials that demonstrate attest to the effectiveness of the OHP (Gilbert et al., 2012; O’Brien et al., 2014), further evaluation of the OHP should continue.

6.9 Recommendations

A number of important implications were derived from the results of this trial which in turn informs these recommendations regarding stroke research and service development. This program of research highlighted important gaps in the stroke literature. Although the systematic review was able to identify a number of successful interventions for QoL, depression, anxiety and coping, when viewed by a population group the evidence was often scant. Also, the systematic review highlighted the lack of effective psychosocial interventions for self-efficacy, carer strain and carer satisfaction, which concurred with earlier systematic reviews that noted either absence or thinness of research addressing these outcomes and advances the knowledge regarding these underserved outcomes (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014).

Therefore, it is recommended that further research be conducted to establish the effectiveness of psychosocial interventions for stroke survivors and carers.

The meta-analysis contributed unique findings and was the first to analyse the effectiveness of psychosocial interventions when i) delivered to and measured in stroke survivors; ii) delivered to and measured in carers; and iii) delivered to carers and measured in stroke survivors. Therefore, it is recommended that further meta-analysis is conducted in order to establish a richer discourse from which to interpret and develop stroke research.

Importantly, findings from the RCT suggest that the development of psychosocial interventions that emphasize self-management may improve carer satisfaction. Carer satisfaction is under-represented in existing stroke literature and previous reviews have not identified any interventions that significantly improved these outcomes (Bakas et al., 2014; Bakas et al., 2017; Cheng et al., 2014). Therefore, it is recommended that carer satisfaction be explored in greater detail and the mechanisms that contribute to the significant improvement in this outcome at the 6 month time point should be identified through qualitative feedback (Creswell, 1994; Creswell, Hanson, Clark Plano & Morales, 2007).

The CSM analysis of psychosocial mediators is an important original contribution. This analysis of mediators was among the first to apply the CSM model to a stroke population (Hagger & Orbell, 2003; Klinedinst et al., 2012; Phillips et al., 2015) and contributes important knowledge regarding the relationship between the mediating relationship between QoL, and maladaptive coping, anxiety, depression. In reality, there is limited literature addressing the relationship between key psychosocial outcomes in stroke survivors. Therefore, it is recommended that i) future CSM analysis should explore the relationship between carer outcomes, in addition to stroke outcomes; ii) additional outcomes are tested (e.g. carer strain, carer satisfaction), including those pertaining to the measurement of disease severity.

It is recommended that the findings of this research inform the care of stroke survivors and carers. In particular, addressing the findings regarding the barriers and challenges of this population in accessing support is paramount. Carer literature has long described the hardships endured by stroke carers (Denham et al., 2018; Eldred & Sykes, 2008; Greenwood et al., 2008; Thomas, Dalton, Harden, Eastwood & Parker, 2017). This research concurs with existing literature, which indicates that carers are insufficiently supported (Ellis, Mant, Langhorne, Dennis & Winner, 2010; Gillespie & Campbell, 2011; Greenwood et al., 2009). It was noted during the RCT that the lack of formal involvement in hospital systems meant that carers were very difficult to recruit and staff often did not know if a patient had a carer. Additionally, health services should consider their duty of care to the carer and play a more active role in supporting the carer pre and post-discharge.

Findings from this program of research highlight substantial gaps in research which may in turn affect stroke care. For example, this research established that despite significant prevalence, anxiety was repeatedly overlooked as an outcome of interest when designing intervention trials (Bakas et al., 2014; Bakas et al., 2017). Further, the trial of the OHP did not appear to improve anxiety in stroke survivors. Therefore, it is recommended that anxiety, and other important psychosocial outcomes, are explored further and that this literature is used to inform stroke care.

This trial of the SCOHP suggests that there were many factors (e.g. lack of carer support, limited services) that could have reduced the effectiveness of this intervention in this population. However, feedback from the participants indicated that they valued the intervention and wanted to engage in support. It is recommended that the SCOHP be adapted for those with languages other than English, cognitive impairment, aphasia and potentially other chronic diseases.

6.10 Chapter synthesis

This program of research established that stroke survivors (Cadilhac et al., 2017; Lo Buono et al., 2017; van Mierlo, van Heugten, Post, Hoekstra & Visser-Meily, 2018) and carers (Ski & O'Connell, 2007) were subject to poor psychosocial health. Further, our systematic review found that existing psychosocial interventions were largely ineffective (see Chapter Two); with key outcomes remaining unimproved. Based on this an innovative method to trial the SCOHP was developed and implemented. Overall, the RCT resulted in minimal improvement. This lack of improvement may have been the result of too little support (Ellis, Mant, Langhorne, Dennis & Winner, 2010; Gillespie & Campbell, 2011; Greenwood et al., 2009) and insufficient understanding of the underlying relationships between psychosocial mediators.

6.11 Conclusion

The overarching aim of this program of research was to explore and contribute new findings regarding the psychosocial health of stroke survivors and carers. This included conducting an RCT to establish the effectiveness of a psychosocial intervention that sought to improve QoL, self-efficacy, depression, anxiety, coping, carer strain and carer satisfaction for stroke survivors and their carers, compared to usual care. This trial enabled an analysis of psychosocial mediators in stroke survivors to be undertaken. There was mixed evidence for the effectiveness of the psychosocial interventions. Although the systematic review provided examples of interventions that significantly improved some psychosocial outcomes, many outcomes of interest had nil or limited evidence of effectiveness. Furthermore, the RCT produced minimal evidence that the intervention was effective. Importantly, the analysis of mediators contributed new understandings about the importance of psychosocial outcomes in stroke survivors and how they contribute to QoL. For example, the relationship maladaptive coping, depression, anxiety and QoL had not been established previously.

Arising from the findings of this program of research, further research is required to establish effective strategies to support stroke survivors and their carers to experience improved psychosocial health.

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Appendix 1. Summary of publications

CHAPTER TWO: Paper One

Minshall, C., Pascoe, M., Thompson, T. R., Castle, D. J., McCabe, M., Chau, J, P-C., Jenkins, Z., Cameron, J., Ski, C. (2019). Psychosocial interventions for stroke survivors, carers and survivor-carer dyads: A systematic review and meta-analysis. *Topics in Stroke Rehabilitation*. [PUBLISHED JULY 2019]

CHAPTER THREE: Paper Two

This chapter presents the published study protocol paper - Brasier (Minshall), C., Ski, C. F., Thompson, D. R., Cameron, J., O'Brien, C., Lutenschlager, N. T., Gonzales, G., Hsueh, Y. A., Moore, G., Knoweles, S. R., Rossell, S. L., Haseldon, Castel, D. J. (2016) The Stroke and Carer Optimal Health Program (SCOHP) to enhance psychosocial health: Study protocol for a randomised controlled trial. *Trials*. 17:466 [PUBLISHED SEPTEMBER 2016]

CHAPTER FOUR: Paper Three

Minshall, C., Castle, D. J., Thompson, D. R., Pascoe, M., Cameron, J., Apputhurai, P., Knowles, S. R., Jenkins, Z., Ski, C. F. (2019). Stroke and Carer Optimal Health Program (SCOHP) a psychosocial intervention: 12 month outcomes of a randomised controlled trial. [SUBMITTED JULY 2019]

CHAPTER FIVE: Paper Four

Minhsall, C., Ski, C. F., Apputhurai, P., Thompson, D. R., Castle, D. J., Jenkins, Z., Knowles, R. (2019) Exploring the Common Sense Model (CSM) and interrelationships between illness perceptions, coping strategies, psychological distress and quality of life in post-stroke. [SUBMITTED JULY 2019]

Appendix 2. Signed statement of authorship and sources

CHAPTER ONE – Introduction	
Catherine Minshall	Overall Contribution 100%
I acknowledge that my contribution to the above chapter is 100% Signed [redacted] Catherine Minshall	
CHAPTER TWO – Literature Review	
Minshall, C., Pascoe, M., Thompson, T. R., Castle, D. J., McCabe, M., Chau, J, P-C., Jenkins, Z., Cameron, J., Ski, C. (2019). Psychosocial interventions for stroke survivors, carers and survivor-carer dyads: A systematic review and meta-analysis. *Topics in Stroke Rehabilitation*. [ACCEPTED May 2019]	
Catherine Minshall	Overall Contribution 75% Overall chapter structure, introduction, conclusion Conducted systematic review Manuscript preparations and revisions

<table>
<tr><td colspan="2">I acknowledge that my contribution to the above publication is 75% per cent
Signed [redacted]
Catherine Minshall</td></tr>
<tr><td>Michaela Pascoe</td><td>Overall Contribution 10%
Conducted meta-analysis
Preparation of meta-analysis results
Manuscript revisions</td></tr>
<tr><td colspan="2">I acknowledge that my contribution to the above chapter is 10% per cent
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Michaela Pascoe</td></tr>
<tr><td>Zoe Jenkins</td><td>Overall contribution 3%
Second reviewer for systematic review</td></tr>
<tr><td colspan="2">I acknowledge that my contribution to the above chapter is 3% per cent</td></tr>
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Signed [redacted] Zoe Jenkins	
Janita Chau	Overall contribution 2% Concept and design of systematic review Manuscript revisions
I acknowledge that my contribution to the above chapter is 2% per cent [redacted] Janita Chau	
Supervisory Panel (A/Prof Chantal Ski; Prof David Thompson; Prof David Castel; Prof Marita McCabe; Dr Jan Cameron)	Overall Contribution 10% Concept and design of systematic review Manuscript revisions

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Signed by A/Prof Chantal Ski on behalf of the Supervisory Panel</td></tr>
<tr><td colspan="2">CHAPTER THREE - Methodology</td></tr>
<tr><td colspan="2">This chapter presents the published study protocol paper - Brasier (Minshall), C., Ski, C. F., Thompson, D. R., Cameron, J., O'Brien, C., Lutenschlager, N. T., Gonzales, G., Hsueh, Y. A., Moore, G., Knoweles, S. R., Rossell, S. L., Haseldon, Castel, D. J. (2016) The Stroke and Carer Optimal Health Program (SCOHP) to enhance psychosocial health: Study protocol for a randomised controlled trial. *Trials*. 17:466 [PUBLISHED SEPTEMBER 2016]
Please note: Catherine Minshall has published this article under her maiden name "Brasier"</td></tr>
<tr><td>Catherine Minshall</td><td>Overall Contribution 70%
Concept and design of study
Manuscript preparation and revisions</td></tr>
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(A/Prof Chantal Ski; Prof David Thompson; Prof David Castle; Dr Jan Cameron; Casey O’Brien; Prof Nicola Lautenschlager; Dr Graeme Gonzales; Dr Arthur Hsueh; Dr Gaye Moore; Prof Simon Knowles, Prof Susan Rossell)</td></tr>
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Concept and design of study
Manuscript previsions</td></tr>
<tr><td colspan="2">CHAPTER FOUR – Results from the RCT</td></tr>
<tr><td colspan="2">Minshall, C., Castle, D. J., Thompson, D. R., Pascoe, M., Cameron, J., Apputhurai, P., Knowles, S. R., Jenkins, Z., Ski, C. F. (2019). Stroke and Carer Optimal Health Program (SCOHP) a psychosocial intervention: 12 month outcomes of a randomised controlled trial. [SUBMITTED JULY 2019]</td></tr>
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Catherine Minshall	Overall Contribution 70% Concept and design of study Conduct of trial including recruitment and data collection Data preparation, management and analysis Manuscript preparation and revisions
I acknowledge that my contribution to the above chapter is 70% per cent Signed [redacted] Catherine Minshall	
Pragalathan Apputhurai	Overall Contribution 10% Data analysis Manuscript preparation and revision
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Pragalathan Apputhurai</td></tr>
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Concept and design of the study
Manuscript preparations and revision</td></tr>
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Supervisory Panel (Prof Paul Fulbrook; Dr Sandra Miles; A/Prof Chantal Ski; Prof David Thompson; Prof David Castel; Prof Marita McCabe; Dr Jan Cameron)	Overall Contribution 10% Concept and design of study Oversight of study Manuscript revisions
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CHAPTER FIVE - Results from the analysis of psychosocial mediators in stroke survivors	
Minhsall, C., Ski, C. F., Apputhurai, P., Thompson, D. R., Castle, D. J., Jenkins, Z., Knowles, R. (2019) Exploring the Common Sense Model (CSM) and interrelationships between illness perceptions, coping strategies, psychological distress and quality of life in post-stroke. [SUBMITTED JULY 2019]	
Catherine Minshall	Overall Contribution 70% Concept and design of study Conduct of trial including recruitment and data collection Data preparation, management and analysis

	Manuscript preparation and revisions
I acknowledge that my contribution to the above chapter is 70% per cent Signed Catherine Minshall [redacted]	
Prof Simon Knowles	Overall contribution 10% Concept and design of study Critical revision of drafts
I acknowledge that my contribution to the above chapter is 10% per cent Signe[redacted]………………………………….. Prof Simon Knowles	
Pragalathan Apputhurai	Overall contribution 10% Major contribution to statistical analysis
I acknowledge that my contribution to the above chapter is 10% per cent	

Signed [redacted] Pragalathan Apputhurai	
Zoe Jenkins	Overall contribution 2% Manuscript revision
I acknowledge that my contribution to the above chapter is 2% per cent [redacted] Signed Zoe Jenkins	
Supervisory Panel (Prof Paul Fullbrook; Dr Sandra Miles; A/Prof Chantal Ski; Prof David Thompson; Prof David Castel; Prof Marita McCabe; Dr Jan Cameron)	Overall Contribution 10% Concept and design of study Oversight of study Manuscript revisions
I acknowledge that my contribution to the above chapter is [redacted] 10% per cent Signed Signed by Prof Fulbrook on behalf of the Supervisory Panel	

Catherine Minshall	Overall Contribution 80% Concept and design of study Conduct of trial and data collection Data preparation, management and analysis Manuscript preparation and revisions
I acknowledge that my contribution to the above chapter is 80% per cent [redacted] Signed Catherine Minshall	
Pragalathan Apputhurai	Overall Contribution 10% Major contribution to statistical analysis Critical revision on manuscript drafts
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[redacted] Signed Pragalathan Apputhurai [redacted]	
Supervisory Panel (Prof Paul Fulbrook, Dr Sandra Miles; A/Prof Chantal Ski; Prof David Thompson; Prof David Castel; Dr Jan Cameron)	Overall Contribution 10% Concept and design of study Oversight of study Manuscript revisions
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CHAPTER SIX – Discussion and Conclusion	
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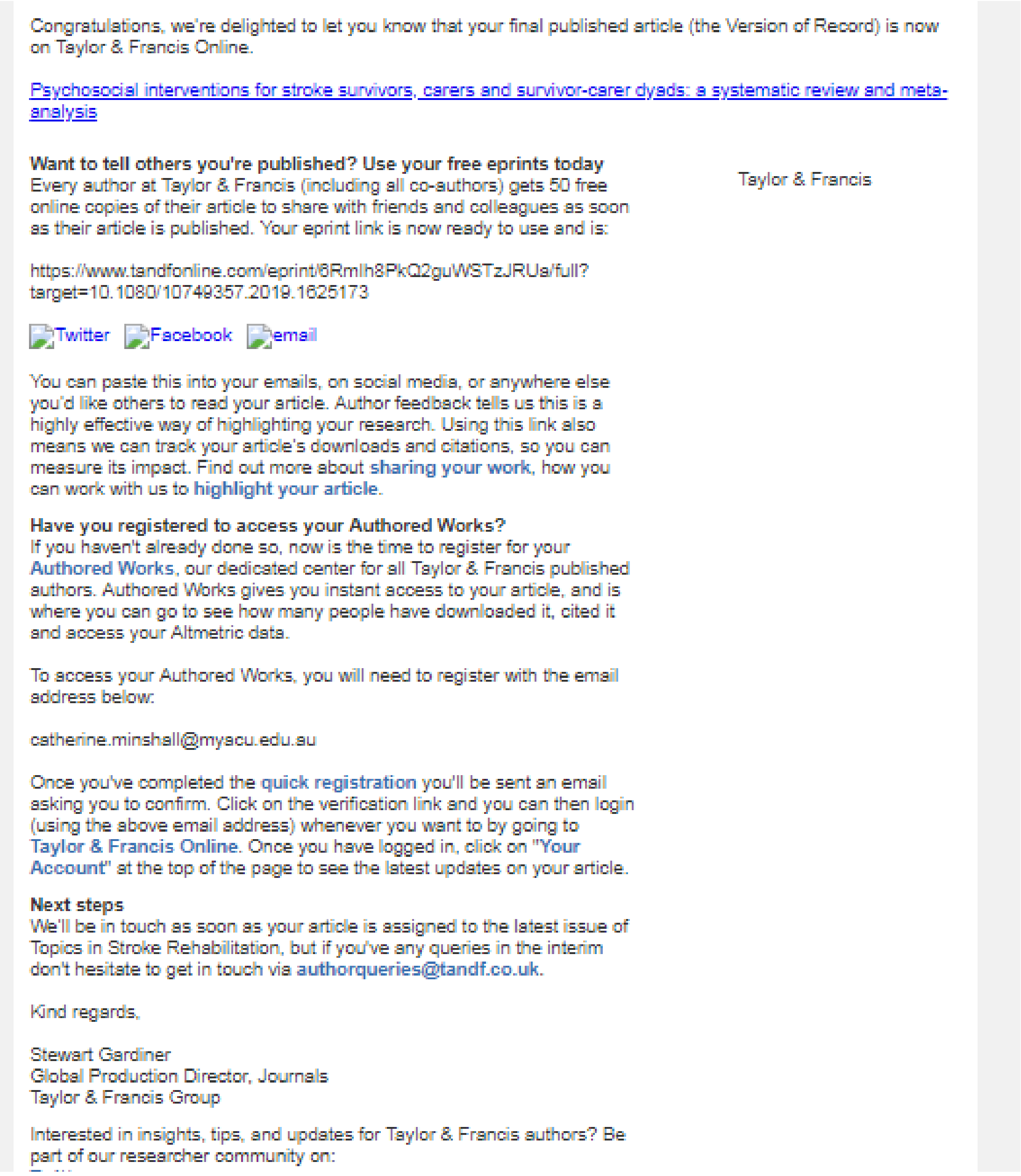
Appendix 3. Paper One – Proof of publication



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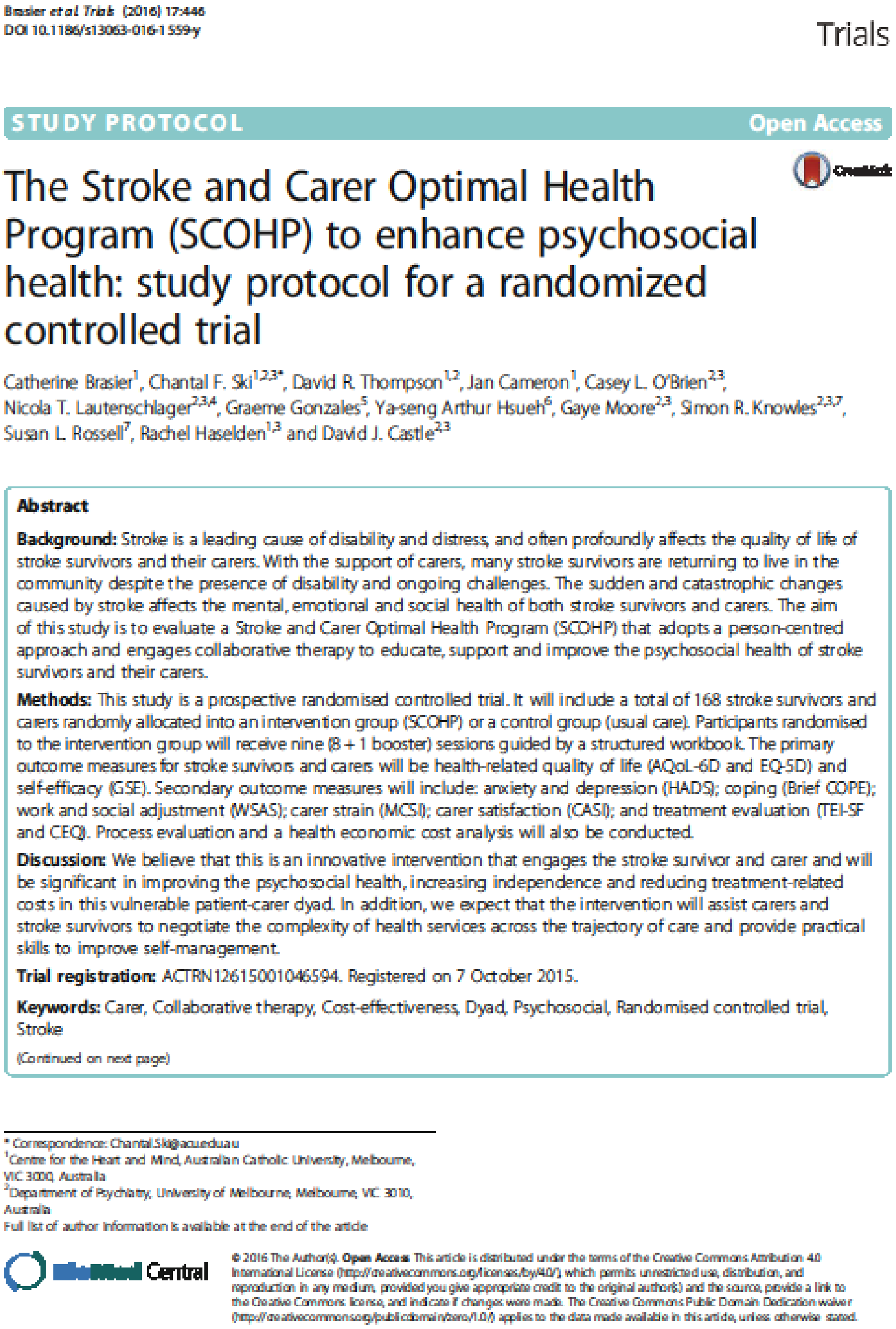

Brasier *et al. Trials* (2016) 17:446
DOI 10.1186/s13063-016-1559-y

Trials

STUDY PROTOCOL

Open Access

The Stroke and Carer Optimal Health Program (SCOHP) to enhance psychosocial health: study protocol for a randomized controlled trial

Catherine Brasier[1], Chantal F. Ski[1,2,3*], David R. Thompson[1,2], Jan Cameron[1], Casey L. O'Brien[2,3], Nicola T. Lautenschlager[2,3,4], Graeme Gonzales[5], Ya-seng Arthur Hsueh[6], Gaye Moore[2,3], Simon R. Knowles[2,3,7], Susan L. Rossell[7], Rachel Haselden[1,3] and David J. Castle[2,3]

Abstract

Background: Stroke is a leading cause of disability and distress, and often profoundly affects the quality of life of stroke survivors and their carers. With the support of carers, many stroke survivors are returning to live in the community despite the presence of disability and ongoing challenges. The sudden and catastrophic changes caused by stroke affects the mental, emotional and social health of both stroke survivors and carers. The aim of this study is to evaluate a Stroke and Carer Optimal Health Program (SCOHP) that adopts a person-centred approach and engages collaborative therapy to educate, support and improve the psychosocial health of stroke survivors and their carers.

Methods: This study is a prospective randomised controlled trial. It will include a total of 168 stroke survivors and carers randomly allocated into an intervention group (SCOHP) or a control group (usual care). Participants randomised to the intervention group will receive nine (8 + 1 booster) sessions guided by a structured workbook. The primary outcome measures for stroke survivors and carers will be health-related quality of life (AQoL-6D and EQ-5D) and self-efficacy (GSE). Secondary outcome measures will include: anxiety and depression (HADS); coping (Brief COPE); work and social adjustment (WSAS); carer strain (MCSI); carer satisfaction (CASI); and treatment evaluation (TEI-SF and CEQ). Process evaluation and a health economic cost analysis will also be conducted.

Discussion: We believe that this is an innovative intervention that engages the stroke survivor and carer and will be significant in improving the psychosocial health, increasing independence and reducing treatment-related costs in this vulnerable patient-carer dyad. In addition, we expect that the intervention will assist carers and stroke survivors to negotiate the complexity of health services across the trajectory of care and provide practical skills to improve self-management.

Trial registration: ACTRN12615001046594. Registered on 7 October 2015.

Keywords: Carer, Collaborative therapy, Cost-effectiveness, Dyad, Psychosocial, Randomised controlled trial, Stroke

(Continued on next page)

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are, the mechanisms of effectiveness are rarely described [19]. A recent review evaluating the effectiveness of psychosocial interventions for informal carers found limited evidence regarding the effectiveness of psychosocial interventions, although psychoeducation, consisting of training in problem solving and stress coping, reduced depression and improved carer sense of competency at the trend level [16]. Overall, current limited evidence points towards more rigorous design of multidisciplinary psychosocial interventions, sustainability of outcomes and inclusion of the stroke survivor-carer dyad.

Translating Research, Integrated Public Health Outcomes and Delivery (TRIPOD)

This randomised controlled trial (RCT) is part of a larger research program – TRIPOD – which will evaluate our Optimal Health Program (OHP) across three chronic conditions; namely stroke, diabetes mellitus and chronic kidney disease, including cost-effectiveness analyses. Based on a collaborative therapy framework [20], the OHP was originally developed to support people with mental illness [21, 22]. The initial trial, in an adult mental health service, demonstrated significant improvements in health and social functioning, reduced hospital admissions and net cost savings per patient [22]. A key aspect of collaborative therapy is recognising that 'recovery' and chronic models of health care are not dichotomous [20]. With the intention of enhancing self-efficacy, self-management, care coordination and quality of life, the OHP has been adapted within the broader context of chronic disease. Thus, in the current series of trials our OHP is used to implement this therapeutic framework to enable clinicians and consumers to work systematically towards the achievement of optimal psychosocial health outcomes within mainstream health services [23]. The self-management foundations of the OHP are particularly relevant for adults affected by stroke and their carers who face the daily challenge of managing various and often simultaneous aspects of their disease such as managing multiple medications, cognitive training, ongoing appointments, and physiotherapy as well as coping with the emotional impact of stroke and their care regimen. This protocol describes an RCT (SCOHP) that has been designed to evaluate the OHP for those affected by stroke – survivors and carers.

Qualitative study: informing development of an optimal health program

Healthcare provider experiences of carers have been researched, but little is written about how these can inform development of support programs. In collaboration with the National Stroke Foundation, Carers Victoria and three consumers (one carer and two stroke survivors) a qualitative study was undertaken to inform development of an Optimal Health Program (OHP) to support carers of those who have experienced a stroke [24]. The aims of the qualitative study were to inform SCOHP by: (1) exploring healthcare provider perceptions of stroke carer roles and support needs and (2) examining carer needs across the stroke care trajectory. To achieve this, we conducted four semi-structured focus groups (*n* = 23) of stroke healthcare providers across acute, subacute, and community rehabilitation services. Focus group facilitators used a semi-structured focus group schedule to guide discussions. Sessions were then recorded, transcribed, and analysed using thematic and content analysis. Table 1 shows the three key themes and sub-themes that emerged from the data, which highlight the distinct roles of healthcare providers and carers.

The findings of this study were used to inform the development of the OHP, specifically in terms of having: staged information across the illness trajectory; flexible support during transition periods; and a balance of practical tools and empathic communications around the impact of stroke. In summary, the discussions held with health providers supported the integration of an OHP for carers within existing stroke care services across acute and community settings.

Research aims

The aim of the study is to determine whether a stroke-specific OHP (SCOHP) improves the psychosocial health of stroke survivors and their carers, compared to usual care. The primary objective is to identify the impact of the OHP on levels of self-efficacy and quality of life for those affected by stroke. Secondary objectives are to evaluate the impact of the SCOHP on depression, anxiety, social and workplace functioning, self-management, and illness perceptions of and coping with stroke, and carer strain and satisfaction.

In addition, a health economic cost analysis will be performed, assuming an Australia-wide implementation, to identify any cost savings of SCOHP over current practice. Quality-adjusted life years (QALYs) will be measured using the Assessment of Quality of Life-6D (AQoL-6D) [25] and European Quality of Life-5 dimensions-3 levels

Table 1 Themes and sub-themes from thematic analysis

Themes	Sub-themes
Transition	Healthcare provider roles across stages of the stroke trajectory
	Carer transition to a caring role and how this changes over time
Information	Delivery of information by healthcare provider
	The carers' response to information and difficulties comprehending implications
Impact of stroke	Healthcare provider role in supporting the carer and person with stroke and maintaining hope
	Carers' experiences of the impact of stroke

Table 2 Primary and secondary outcome assessments and time points for SCOHP

	Carer				Stroke survivor			
Assessment tools	BL	3	6	12	BL	3	6	12
Primary outcomes								
AQoL-6D (20 items)	X	X	X	X	X	X	X	X
GSE (10 items)	X	X	X	X	X	X	X	X
Secondary outcomes								
BIPQ (8 items)					X	X	X	X
Brief COPE (28 items)	X	X	X	X	X	X	X	X
CASI (30 items)	X	X	X	X				
CEQ (6 items)	X				X			
EQ-5D -3 L (6 items)	X	X	X	X	X	X	X	X
HADS (14 items)	X	X	X	X	X	X	X	X
HCUQ (10 items)	X	X	X	X	X	X	X	X
MCSI (13 items)	X	X	X	X				
TEI-SF (9 items)				X				X
BFI-10 (10 items)		X				X		
WSAS (5 items)	X	X	X	X	X	X	X	X

AQoL-6D Assessment of Quality of Life-6 dimensions, *GSE* General Self-Efficacy Scale, *BIPQ* Brief Illness Perceptions Questionnaire, *Brief COPE* abbreviated version of the COPE Inventory, *CASI* Carers' Assessment of Satisfaction Index, *CEQ* Credibility/Expectancy Questionnaire, *EQ-5D-3L* European Quality of Life-5-dimensions-3 levels, *HADS* Hospital Anxiety and Depression Scale, *HCUQ* Health Care Utilisation Questionnaire, *MCSI* Modified Caregiver Strain Index, *TEI-SF* Treatment Evaluation Inventory-Short Form, *BFI-10* Big Five Inventory-10 item, *WSAS* Work and Social Adjustment Scale

(EQ-5D-3L) [26]. Process evaluation using focus groups will also be conducted with patients and clinicians to assess the effectiveness of the SCOHP, implementation, uptake and service delivery.

Methods

General design

This is a prospective randomised controlled trial to evaluate the effectiveness of the SCOHP for improving the psychosocial health of those who have experienced stroke and their carers. The SCOHP will be delivered as an 8-week individualised support program, with an additional booster session, and will be compared to usual care. Assessments will take place at baseline, 3, 6, and 12 months. The study protocol was approved by the St Vincent's Hospital Human Research Ethics Committee (HREC-A 019/14). An executive steering committee (all authors) oversees project planning, conduct and ongoing data collation.

Setting

The study will be conducted at the neurology unit of St Vincent's Hospital, a large metropolitan teaching hospital in Melbourne, Australia. Between 2011 and 2012, 737 patients were admitted to St Vincent's Hospital, with a principal diagnosis of stroke. The stroke unit at St Vincent's Hospital, Melbourne will enable planned recruitment of 168 participants for the SCOHP program over a 2-year period.

Participants

A total of 84 patients diagnosed with stroke, and 84 carers of these patients, will be recruited into the RCT. For the purposes of this study, stroke is defined as cerebral infarction or parenchymal haemorrhage confirmed by medical records. The following criteria are to be met for inclusion into the RCT: (1) diagnosis of stroke for patient or self-nominated carer of a stroke patient; (2) 18 years or older; (3) ability to converse in English without an interpreter or professional assistance; (4) absence of developmental disability or amnestic syndrome impairing their ability to learn from the intervention; and (5) absence of serious comorbid illness, including severe forms of aphasia, as identified by the nurse unit manager, and cognitive impairment, as identified from medical notes scoring lower than 24 on the Mini-Mental State Examination (MMSE) [27]. As the OHP adopts a holistic approach to managing chronic disease, patients may enter the program at any stage along the continuum of care.

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 RCT research in the area of chronic disease management programs [28]. Calculations assumed two primary outcomes (health-related quality of life and General Self-Efficacy Scale (GSE) scores), four assessment points (baseline, 3-month, 6-month, and 12-month), a study-wide type I error rate (α) of .05, and hence a type II error rate (β) of 0.20 (power of 0.80), a correlation of post-treatment scores with baseline measurements (ρ) of 0.81, and a two-tailed statistical test [29]. To detect an effect size of Cohen's $d = 0.50$, 53 participants in each of the control and intervention groups will be required. Allowing for up to 20 % attrition, a total of 168 participants, or 42 carers and stroke survivors in control and intervention groups will be recruited.

Study procedures

Recruitment

Potential patients who have been diagnosed with stroke and/or their carer will be identified by clinical staff (e.g. neurologist, nurse) and provided with a study flyer. Patients and/or carers will be asked permission for a researcher to approach them to discuss the program in more detail. If agreeable, they will be approached, informed and formally consented by the research assistant. Study fliers will also be posted online through community organisations and will include contact details for the research team. Participants from the community may contact researchers directly to request further information. Planned recruitment will occur over an 18-month period (see Fig. 1).

Consent

The process of consent will be in accordance with the Declaration of Helsinki. Nurse unit managers were consulted to determine a patient's eligibility for the study. Senior clinicians and the research team were consulted in instances when it was unclear if an individual met the inclusion criteria. All eligible patients and carers will be fully informed that they are being asked to participate in an RCT. The procedures involved in the study, and the chances of being assigned randomly to one of two groups will be explained verbally and via an information sheet approved by the hospital's Human Research Ethics Committee. A signed consent form will be obtained from each participant. Participants will be made aware of their right to withdraw from the study at any time without any effects on their clinical management.

Randomisation and blinding

Using a computer-generated block randomisation sequence created by a researcher independent of the study, participants will be allocated to treatment or control group. The allocation sequence will be generated using random numbers and participants will be randomised progressively as they consent. Patients and carers will be randomized as dyads. Patients or carer will be randomized alone if they are not participating as a dyad. Due to the nature and length of the intervention, it is not possible to blind either participant or investigator to the treatment allocation.

Intervention: SCOHP

The SCOHP is delivered at a nominated place of convenience by the participant i.e. home, hospital, community health centre. Dyads have the option of either receiving the intervention independently or together. The SCOHP comprises a modular format of eight sequential sessions plus a booster, based on a structured workbook. Participants are encouraged throughout the program to identify

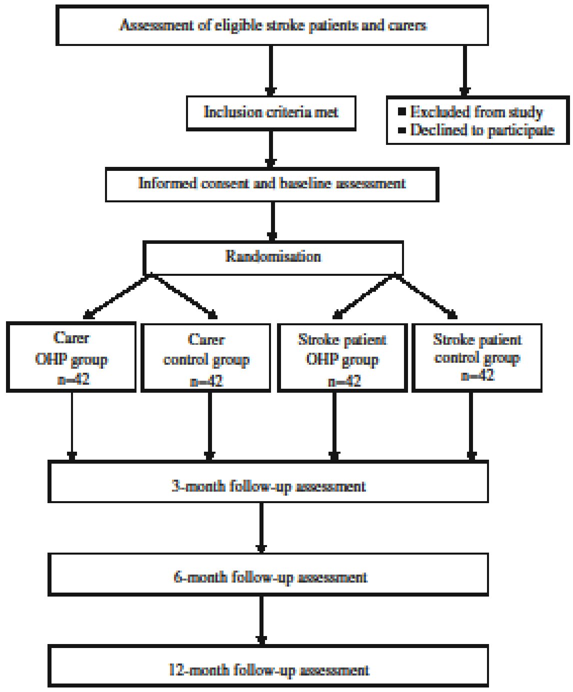

Fig. 1 Flowchart of the Stroke and Carer Optimal Health Program (SCOHP) randomised controlled trial (RCT)

areas of stroke- or carer-related health concerns on which they would like to focus. Sessions are approximately 1 hour in duration and held weekly, apart from the 'booster' session, which is held 3 months after session 8. Learning is cumulative with each session designed to build on the previous session including tasks to complete between sessions, i.e. journaling and coping strategies (e.g. breathing exercises).

In summary, session 1 introduces SCOHP within the six domains of the 'Optimal Health Wheel': social, physical, emotional, intellectual, employment and spiritual as documented in the workbook. This session provides participants with the opportunity to explore and understand stroke self-management behaviour from a holistic perspective. Sessions 2 and 3 initiate development of a health plan exploring the implications and potential complications of stroke in terms of strengths and vulnerabilities, and understanding and monitoring disease impact (e.g. emotional burden and physical weakness). Session 4 focuses on medication management and metabolic monitoring. Session 5 expands the health plan to include key stroke partnerships and supports in the community and online (e.g. www.strokefoundation.com.au). Change enhancement is the focus in session 6, in terms of understanding past events and establishing new proactive avenues for change. The aim of session 7 is goal setting via creative problem solving and planning around the complexities of stroke. To cement a shift in focus of the person's illness from being 'dependent on' services to being 'supported by' services, session 8 strategises stroke advanced care planning that incorporates wellbeing maintenance and sustainability. The goal of the 'booster session' (session 9) is to review health plans, consolidate progress, and reflect on achievements towards health-related goals.

A health professional (e.g. nurse, psychologist) trained in the approach (2-day workshop plus regular supervision and fidelity checks) will facilitate each session. The facilitator will draw on carer and stroke-specific information in concordance with individual circumstances. Examples include the relationship between depression and caregiving or physical impairments of stroke, availability of stroke and carer supports in the community, and coping strategies for addressing anxiety and stress related to new roles and circumstances. The emphasis is on collaboration between facilitator and participant to arrive at goals for the program that stem from the participant's main concerns and needs. The facilitator will encourage participants to identify their early warning signs of stress and illness and integrate healthy coping strategies to prevent the build-up of stress. Facilitators may also discuss and arrange referrals for other services in conjunction with the multidisciplinary team depending on participant needs. Additionally, facilitators will work with the multidisciplinary team to coordinate visits. Participants in rural and regional areas will have the option of participating in sessions via phone or Skype.

Control

The comparison group will receive usual care and no SCOHP intervention. As participants will be recruited from a variety of settings (hospital outpatients, community organisations) we anticipate variation in standard care received. To capture this variation, all participants will complete the Health Care Utilisation Questionnaire (HCUQ) [30] at each time point. Participants in the control group will have the option of completing the SCOHP at the end of the trial once evaluation is complete.

Outcome measurements

Table 2 details the primary and secondary outcome measures and time points for carers and stroke survivors. Participants complete the measures independently unless a specific request is made for assistance e.g. due to vision or motor skill impairment. Primary outcome measures for both stroke survivors and carers are quality of life and self-efficacy. Health-related quality of life will be assessed using the (AQoL-6D) [25], which consists of six dimensions of health and a global 'utility' score and the EuroQol-5D (EQ-5D) [26]. Self-efficacy is to be assessed using the General Self-Efficacy Scale (GSE) [31] a measure of perceived self-efficacy in response to daily challenges and stressful life events. Secondary measures for both stroke survivors and carers are: coping strategies as measured using an abbreviated version of the COPE inventory, the Brief COPE [32]; symptom severity and caseness of depression and anxiety disorders as assessed using the Hospital Anxiety and Depression Scale (HADS) [33]; a 10-item measure of the Big Five personality dimensions (BFI-10) [34]; effect of an individual's mental health on their ability to function via the Work and Social Adjustment Scale (WSAS) [35]; treatment expectancy and rationale credibility of the clinical study as assessed with the Credibility/Expectancy Questionnaire (CEQ) [36]; perceived satisfactoriness of treatment as assessed using the Treatment Evaluation Inventory-Short Form (TEI-SF) [37]; and health care utilisation and its economic impact assessed by the Health Care Utilisation Questionnaire (HCUQ) [30]. Stroke survivors will also be assessed for cognitive and emotional responses to stroke using the Brief Illness Perceptions Questionnaire (BIPQ) [38]. In addition, carers will be assessed for carer strain using the Modified Caregiver Strain Index (MCSI) [39] and carer satisfaction as assessed by the Carer Assessment of Satisfaction Index (CASI) [40].

Due to the potential for variability of 'usual care' in the control group, key aspects of usual care will be assessed with the HCUQ. Furthermore, medical records will be reviewed to determine stroke diagnostic information and clinical indices including the Modified Rankin Scale (MRS), which measures the degree of disability/dependence after a stroke.

Program assessment and treatment fidelity

The SCOHP facilitators will be trained in program delivery, receive a structured manual/protocol and monthly group supervision with the clinical investigators (with individual supervision provided as needed in between group sessions). The purpose of supervision will be to discuss problems in study procedures and ensure standardised activity. The SCOHP sessions will be audio recorded with a random selection rated by independent assessors in compliance with the SCOHP protocol. Variations from the protocol will be identified and relayed to the facilitator. Facilitators will complete a summary of each session using a standard template and send these notes to the research team. Session notes will include OHP topics covered, participant concerns raised, and needs for supervision. Additionally, content of sessions regarding participant requirement and concerns will be discussed at supervision meetings.

Post-intervention focus groups will be held for clinicians and participants. Participants will be informed during consent (both written and verbal) of the option to participate in focus groups, and that the purpose is to ascertain an in-depth understanding of their experiences of the study, advantages and disadvantages of conducting the study/program in their services (for clinicians), and recommendations for components to include or exclude from the SCOHP. It will be made clear to participants when consenting that the number of focus groups will be limited; such that they will only be run until data saturation is achieved. It is envisioned that data saturation will be reached after 2 to 3 focus groups, each containing 8 to 12 individuals. To increase objectivity, focus group facilitators will be independent researchers who were not OHP facilitators. The pragmatic data analysis approach of Halcomb and Davidson [42] will be used for the purpose of focus group data analysis. In summary, identifying key passages and words will be independently analyzed, coded, and categorized (classifying key passages and words within themes) drawing on pragmatic thematic analysis to form emergent themes.

Statistical analyses

Intention-to-treat analyses will be employed to prevent overestimation of efficacy. Categorical variables will be analysed using chi-squared tests (or Fisher's exact test for small samples). A mixed-effects model, repeated measures (MMRM) approach will be used to examine the longitudinal profile of continuous variables at 3, 6 and 12 months post-baseline. For all MMRM analyses, baseline scores will be used as covariates and the models will include prespecified fixed effects of treatment, clinician, and time, and treatment-by-time and treatment-by-clinician interactions.

Secondary analyses using analysis of covariance will be conducted to compare change scores during treatment and follow-up phases for primary, secondary, and process outcomes using the fixed, continuous covariate of baseline score as well as the categorical fixed effects of treatment group, clinician, and treatment-by-clinician interactions.

Although the attrition rate is not expected to vary by treatment condition, we will attempt to identify key predictors of attrition status (i.e. demographic and baseline clinical characteristics) and test for differences between conditions. Assuming the data are missing at random, several procedures offer effective approaches that may attenuate attrition. Maximum likelihood models (i.e. MMRM), with time as a random variable, allow the use of all available data from all assessments, reducing bias and increasing power [43]. In addition, multiple imputation procedures that utilise the expectation-maximization (EM) algorithm with bootstrap estimates of standard errors will be used to address attrition. The application of these procedures can provide unbiased estimates, even in the face of substantial missing data [44].

A full economic evaluation will occur alongside the proposed RCT. Healthcare outcomes and costs will be compared between participants in the control and interventional conditions. Healthcare system (medical record) and self-reported information via the HCUQ [30] will be used to generate analyses. The utility measurements of participant quality of life will be assessed using AQoL-6D [25] developed in Australia and the EQ-5D-3L [26] developed in Europe. The potential long-term (lifetime) impact on cost and effectiveness of intervention beyond the trial period will be extrapolated using the Markov process modelling method.

Discussion

Stroke can carry severe consequences for the patient and their informal carers or family members who often feel inadequately prepared to deal with the physical, cognitive and emotional demands [1–3]. Carers experience adverse health effects with high rates of depression [13], anxiety [14] and mortality [15]. The informal caring role is pivotal in maintaining stroke survivors in the community but this comes at a significant cost to the carer [4, 9–12]. It is therefore important to develop programs that will support the carer's coping and minimise the level of burden and ill-health they experience.

The crucial evidence gap lies in the integration and co-ordination of patient and carer support programs within health service delivery. Integral to SCOHP is its integration of carer and patient support within health services from acute to community care. Engaging with multiple clinicians can be a daunting task, both for patients and informal carers. The SCOHP assists in negotiating this complexity by adopting a person-centred approach across the patient trajectory. In addition, stroke survivor and stroke carer psychosocial health is rarely studied as a dyad, thus this RCT is expected to make a significant contribution to improve the mental health and wellbeing of patients who have experienced stroke and their carers.

There are several strengths to this study protocol. Primarily, in the inclusion of the 'patient-carer dyad' tailored to each individual, for both intervention and assessment purposes. Integration and rollout of the RCT in a clinical setting was purposefully incorporated to identify the adaptability of the intervention to a 'real-world setting', i.e. co-ordination and communication between departments. If successful, the simultaneous evaluation of RCTs across three of the most burdensome chronic conditions will provide evidence for the potential applicability of the intervention to extend to other chronic diseases. To our knowledge this is the first trial to include a comprehensive health economic cost analysis in the assessment of an educational, psychosocial intervention aimed at improving the mental and physical health of stroke survivors and their carers.

This series of trials follows common ethical principles applied in RCTs. Participants receive verbal and written information before consenting and before study procedures, they are not exposed to any risks, participation is voluntary and they may withdraw at any time without reason and without their usual care being affected in any way. Participants in the control group are also offered the intervention at the end of the follow-up period.

Trial status

Patient recruitment was ongoing at the time of manuscript submission. Data collection will continue until at least December 2017.

Acknowledgements

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Authors' contributions

DJC, CFS, NTL and DRT conceived the study. DJC developed the original OHP. GG, SLR, JC and SK contributed to study design. DJC, GM, RH and CLO designed the staff training protocol. YH designed the health economic analysis of the data. CB drafted the study protocol. All authors reviewed and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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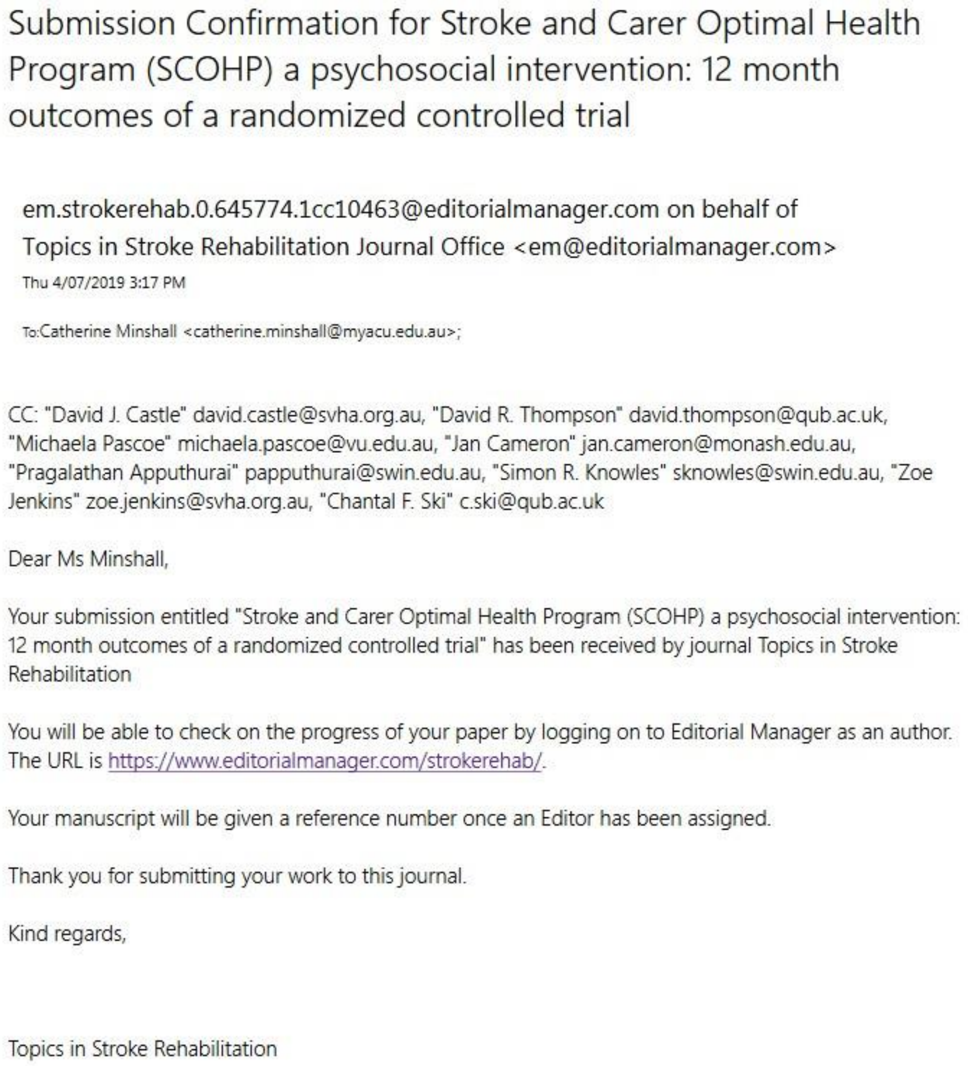
Appendix 5. Confirmation of submission – RCT 12 month outcomes



Submission Confirmation for Stroke and Carer Optimal Health Program (SCOHP) a psychosocial intervention: 12 month outcomes of a randomized controlled trial

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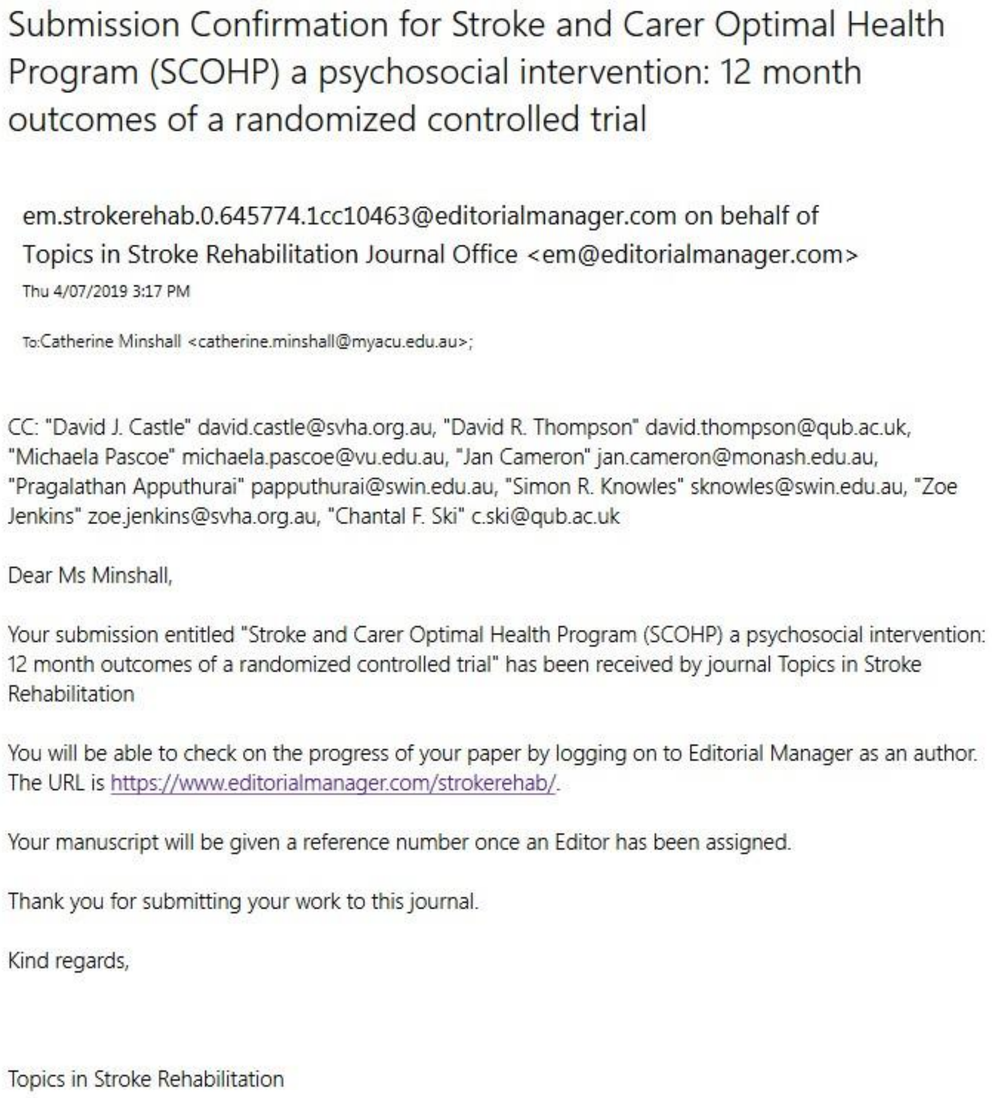
Topics in Stroke Rehabilitation

Appendix 6. Paper Three - Confirmation of submission



Submission Confirmation for Stroke and Carer Optimal Health Program (SCOHP) a psychosocial intervention: 12 month outcomes of a randomized controlled trial

em.strokerehab.0.645774.1cc10463@editorialmanager.com on behalf of Topics in Stroke Rehabilitation Journal Office <em@editorialmanager.com>

Thu 4/07/2019 3:17 PM

To:Catherine Minshall <catherine.minshall@myacu.edu.au>;

CC: "David J. Castle" david.castle@svha.org.au, "David R. Thompson" david.thompson@qub.ac.uk, "Michaela Pascoe" michaela.pascoe@vu.edu.au, "Jan Cameron" jan.cameron@monash.edu.au, "Pragalathan Apputhurai" papputhurai@swin.edu.au, "Simon R. Knowles" sknowles@swin.edu.au, "Zoe Jenkins" zoe.jenkins@svha.org.au, "Chantal F. Ski" c.ski@qub.ac.uk

Dear Ms Minshall,

Your submission entitled "Stroke and Carer Optimal Health Program (SCOHP) a psychosocial intervention: 12 month outcomes of a randomized controlled trial" has been received by journal Topics in Stroke Rehabilitation

You will be able to check on the progress of your paper by logging on to Editorial Manager as an author. The URL is https://www.editorialmanager.com/strokerehab/.

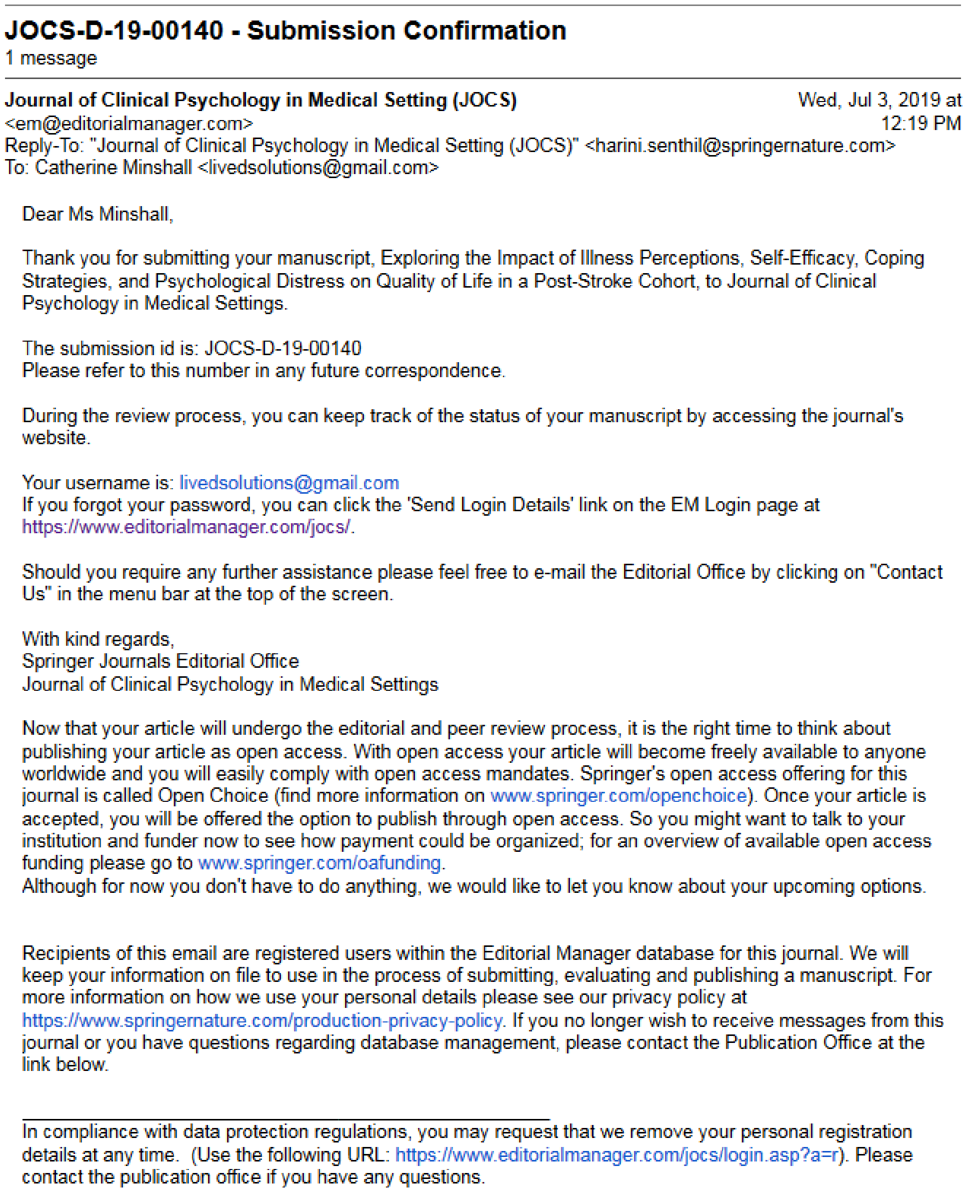
Your manuscript will be given a reference number once an Editor has been assigned.

Thank you for submitting your work to this journal.

Kind regards,

Topics in Stroke Rehabilitation

Appendix 7. Paper Four - Confirmation of submission



JOCS-D-19-00140 - Submission Confirmation

1 message

Journal of Clinical Psychology in Medical Setting (JOCS) <em@editorialmanager.com>
Wed, Jul 3, 2019 at 12:19 PM
Reply-To: "Journal of Clinical Psychology in Medical Setting (JOCS)" <harini.senthil@springernature.com>
To: Catherine Minshall <livedsolutions@gmail.com>

Dear Ms Minshall,

Thank you for submitting your manuscript, Exploring the Impact of Illness Perceptions, Self-Efficacy, Coping Strategies, and Psychological Distress on Quality of Life in a Post-Stroke Cohort, to Journal of Clinical Psychology in Medical Settings.

The submission id is: JOCS-D-19-00140
Please refer to this number in any future correspondence.

During the review process, you can keep track of the status of your manuscript by accessing the journal's website.

Your username is: livedsolutions@gmail.com
If you forgot your password, you can click the 'Send Login Details' link on the EM Login page at https://www.editorialmanager.com/jocs/.

Should you require any further assistance please feel free to e-mail the Editorial Office by clicking on "Contact Us" in the menu bar at the top of the screen.

With kind regards,
Springer Journals Editorial Office
Journal of Clinical Psychology in Medical Settings

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Although for now you don't have to do anything, we would like to let you know about your upcoming options.

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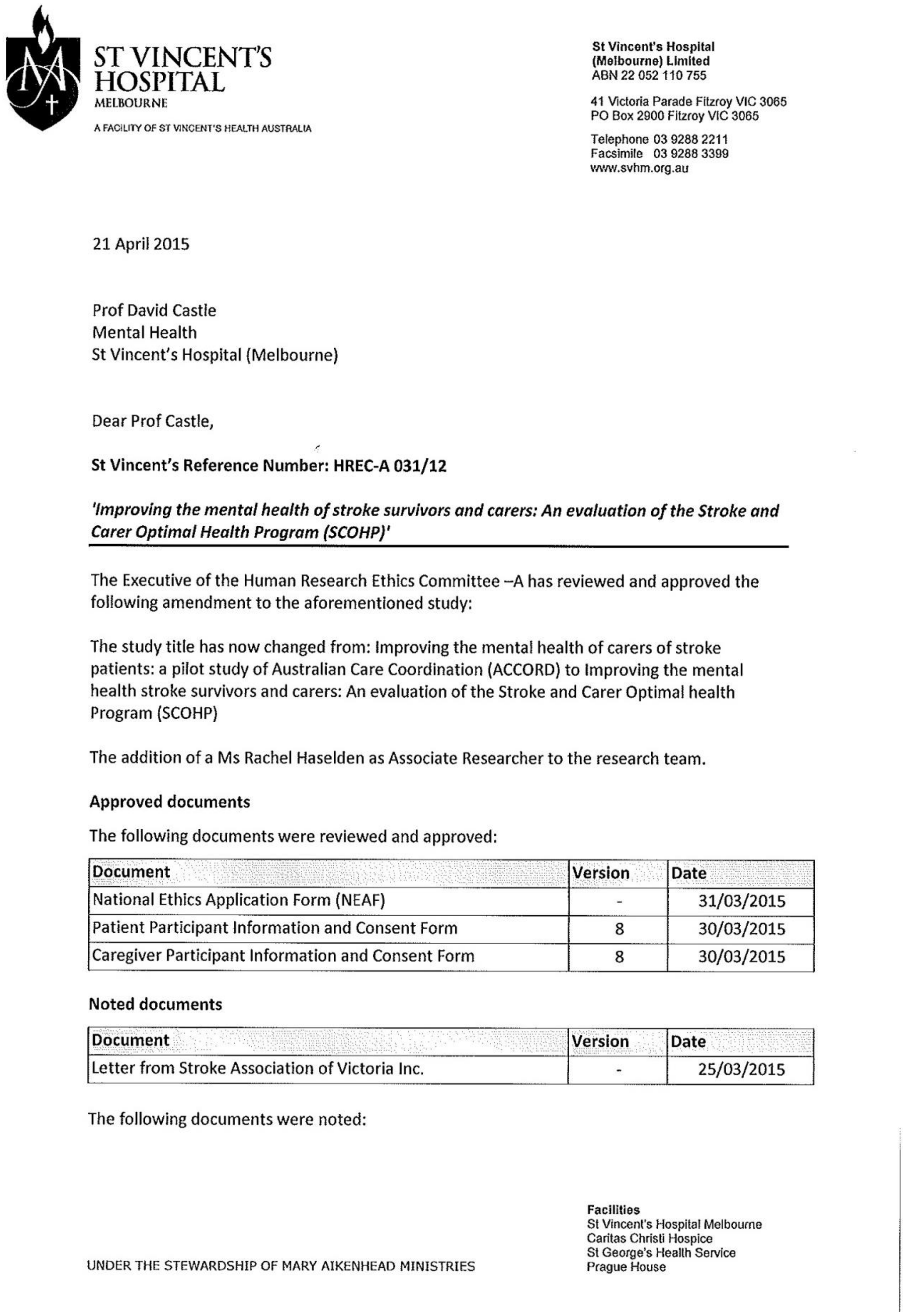
Appendix 8. Approvals from Human Ethics and Research Committees



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21 April 2015

Prof David Castle
Mental Health
St Vincent's Hospital (Melbourne)

Dear Prof Castle,

St Vincent's Reference Number: HREC-A 031/12

'Improving the mental health of stroke survivors and carers: An evaluation of the Stroke and Carer Optimal Health Program (SCOHP)'

The Executive of the Human Research Ethics Committee –A has reviewed and approved the following amendment to the aforementioned study:

The study title has now changed from: Improving the mental health of carers of stroke patients: a pilot study of Australian Care Coordination (ACCORD) to Improving the mental health stroke survivors and carers: An evaluation of the Stroke and Carer Optimal health Program (SCOHP)

The addition of a Ms Rachel Haselden as Associate Researcher to the research team.

Approved documents

The following documents were reviewed and approved:

Document	Version	Date
National Ethics Application Form (NEAF)	-	31/03/2015
Patient Participant Information and Consent Form	8	30/03/2015
Caregiver Participant Information and Consent Form	8	30/03/2015

Noted documents

Document	Version	Date
Letter from Stroke Association of Victoria Inc.	-	25/03/2015

The following documents were noted:

UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

Facilities
St Vincent's Hospital Melbourne
Caritas Christi Hospice
St George's Health Service
Prague House

Approval Status: FINAL

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007).*

Approval is subject to:

- The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research (2007).
- Immediate notification to the Research Governance Unit of any serious adverse events on participants.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- Notification of approved amendments to the study.
- Submission of an annual report, due on the anniversary date of approval, for the duration of the study.
- Submission of reviewing HREC approval for any proposed modifications to the project;
- Submission of a final report and papers published on completion of project;
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

St Vincent's Hospital Reference:	**HREC-A 031/12**
Please quote this reference on all Correspondence	

This approval will be noted by the full HREC at the next available meeting.

The HREC wishes you and your colleagues every success in your research.

Y [redacted]

Ms Leanne Clinch
Senior Administrative Officer and HREC-A Secretary
Research Governance Unit
St Vincent's Hospital (Melbourne)

2015-256R Registration of External Ethics Approval

Kylie Pashley <Kylie.Pashley@acu.edu.au> on behalf of Res Ethics <Res.Ethics@acu.edu.au>
Mon 30/11/2015, 3:52 PM
Chantal Ski <Chantal.Ski@acu.edu.au>; Catherine Brasier; +1 more

ethics

Dear Chantal,

Principal Investigator: A/Prof Chantal Ski
Co-Investigato: Prof David Thompson, Dr Jan Cameron,
Student Researcher: Catherine Brasier
Ethics Register Number: 2015-256R
Project Title: Improving the mental health of stroke survivors and carers: An evaluation of the Stroke and Carer Optimal Health Program (SCOHP)
Risk Level: Multi Site
Date Approved: 30/11/2015
Ethics Clearance End Date: 30/11/2018

The Australian Catholic University Human Research Ethics Committee has considered your application for registration of an externally approved ethics protocol and notes that this application has received ethics approval from St Vincent's Hospital, Melbourne [Reference: HREC-A 031/12].

The ACU HREC accepts the ethics approval with no additional requirements, save that ACU HREC is informed of any modifications of the research proposal and that copies of all progress reports and any other documents be forwarded to it. Any complaints involving ACU staff must also be notified to ACU HREC (National Statement 5.3.3).

We wish you well in this research project.

Regards,

Kylie Pashley
on behalf of ACU HREC Chair, Dr Nadia Crittenden
Ethics Officer | Research Services
Office of the Deputy Vice Chancellor (Research)
res.ethics@acu.edu.au

easternhealth
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Fax (03) 9895 4896
info@easternhealth.org.au
ABN 68 223 819 017

www.easternhealth.org.au

Approval to Recruit at Eastern Health

Eastern Health HREC
Ph: 03 9895 3398
Fax: 03 9094 9610
Email: ethics@easternhealth.org.au
www.easternhealth.org.au/research

19 February 2016

Ms Catherine Brasier
Mary MacKillop Institute for Health Research
Centre for the Heart and Mind
St Vincent's Hospital and ACU
Melbourne 3000

Dear Catherine

Stroke and Carer Optimal Health Program (SCOHP)

Principal Investigator: Professor David Castle
Eastern Health Contact Person: Mr John Ferraro
Eastern Health Site: Peter James Centre
HREC Approval: St Vincent's Hospital Melbourne HREC-A 031/12

Thank you for your email with respect to recruitment of participants at Peter James Centre.

It is understood that potential participants will be identified by clinical staff and provided with information about the study. Patients and/or carers will be asked permission for a researcher to approach them to discuss the program in more detail.

The Program Director Continuing Care has approved the recruitment of participants at Peter James Centre.

Kind Regards

[redacted]

Chris Rose'Meyer
Manager
Eastern Health Office of Research and Ethics

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Telephone 03 9231 2211
Facsimile 03 9231 3399
www.svhm.org.au

19 May 2016

Prof David Castle
Mental Health
St Vincent's Hospital (Melbourne)

Dear Prof Castle,

St Vincent's Reference Number: HREC-A 031/12

'Improving the mental health of stroke survivors and carers: An evaluation of the Stroke and Carer Optimal Health Program (SCOHP)'

The Executive of the St Vincent's Hospital (Melbourne) Human Research Ethics Committee (HREC) A has reviewed and approved the following amendments:

- **Addition of The Peter James Centre (Eastern Health) as a recruitment site.**

Approved Documents

Document	Version	Date
National Ethics Application Form (AU/1/52D524)	2.2 (2014)	03 May 2016
Letter of Support from Eastern Health signed by John Ferraro	N/A	17 Feb 2016

The amendment has received governance approval at the following site:

- **St Vincent's Hospital Melbourne**

Noted Documents:

Document	Version	Date
HREC Amendment Form	Aug 2014	12 May 2016

Approval Status: FINAL

Approval is given in accordance with the research conforming to the National Health and Medical Research Council Act 1992 and the National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)

UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

Facilities
St Vincent's Hospital Melbourne
Caritas Christi Hospice
St George's Health Service
Prague House

Approval is subject to:

- The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)
- Immediate notification to the Research Governance Unit of any serious adverse events on participants.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion.
- Submission of reviewing HREC approval for any proposed modifications to the project.
- Submission of a final report and papers published on completion of project.
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

St Vincent's Hospital Reference: HREC-A 031/12
Please quote these numbers on all Correspondence

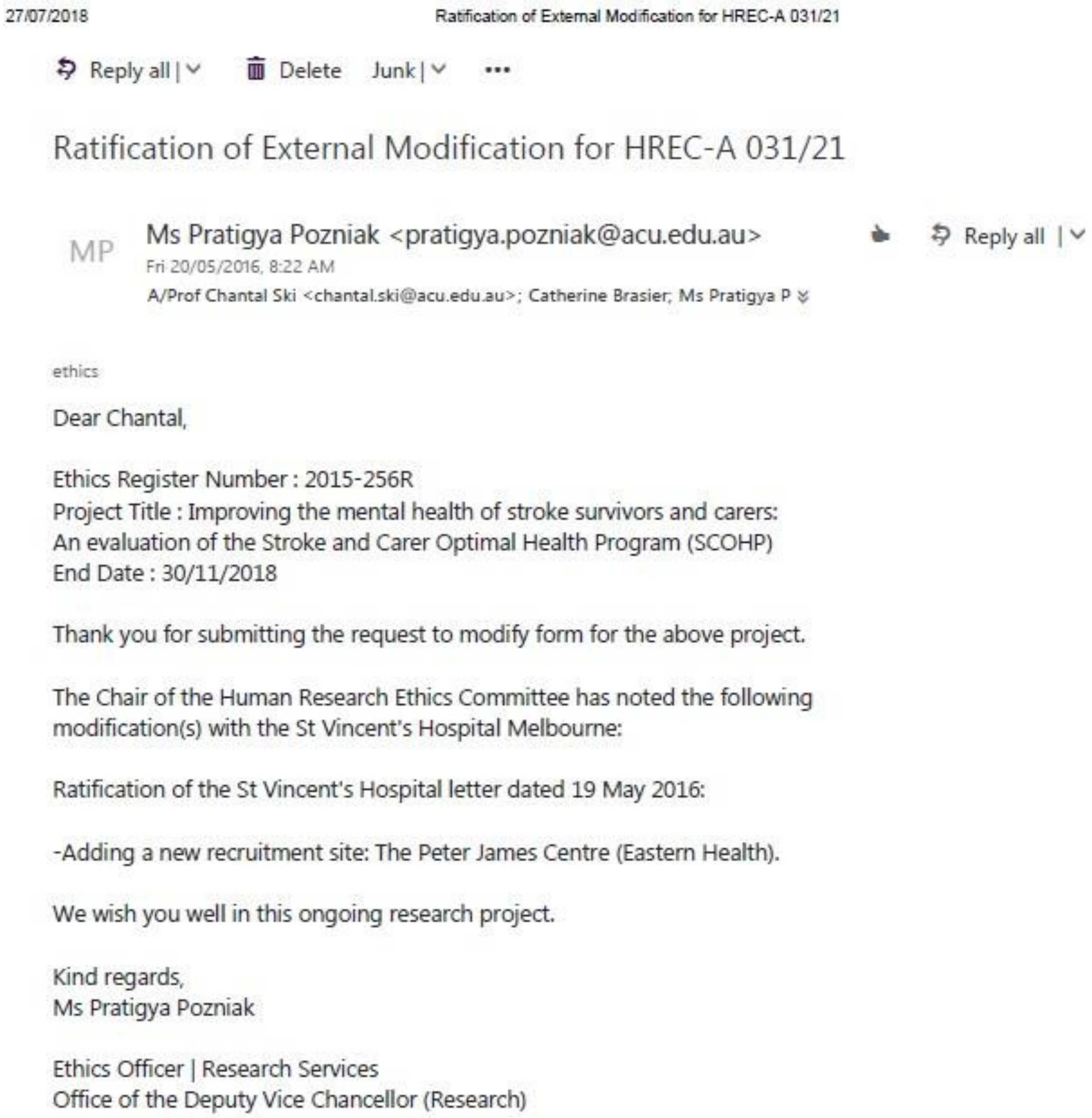
This approval will be noted by the full HREC at the next available meeting.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

[redacted]

Azeezat Olusola Onipe
Senior Administrative Officer & HREC Secretary
Research Governance Unit
St Vincent's Hospital (Melbourne)



Ratification of External Modification for HREC-A 031/21

Ms Pratigya Pozniak <pratigya.pozniak@acu.edu.au>
Fri 20/05/2016, 8:22 AM
A/Prof Chantal Ski <chantal.ski@acu.edu.au>; Catherine Brasier; Ms Pratigya P

ethics

Dear Chantal,

Ethics Register Number : 2015-256R
Project Title : Improving the mental health of stroke survivors and carers: An evaluation of the Stroke and Carer Optimal Health Program (SCOHP)
End Date : 30/11/2018

Thank you for submitting the request to modify form for the above project.

The Chair of the Human Research Ethics Committee has noted the following modification(s) with the St Vincent's Hospital Melbourne:

Ratification of the St Vincent's Hospital letter dated 19 May 2016:

-Adding a new recruitment site: The Peter James Centre (Eastern Health).

We wish you well in this ongoing research project.

Kind regards,
Ms Pratigya Pozniak

Ethics Officer | Research Services
Office of the Deputy Vice Chancellor (Research)

Appendix 9. Master Participant Information and Consent Form (Master)

St Vincent's Hospital (Melbourne)

Participant Information and Consent Form

Stroke Survivor [or Carers]: 8-session program plus booster

Version 8 Dated: 30 March 2015

Protocol No, (STV): HREC-A 031/21

Full Project Title:	Improving the mental health of stroke survivors and carers: An evaluation of the Stroke and Carer Optimal Health Program (SCOHP)
Principal Researcher:	Professor David Castle

This Participant Information and Consent Form are **5** pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this research project because you are being treated for a stroke, or have previously received treatment for a stroke.

This Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose and Background

This is a research study about the needs of people who have been diagnosed with stroke and needs of people who care for survivors of stroke. The research focusses on supporting people with stroke and their carers by providing an 8-session individualised or group program called the Optimal Health Program. There is a booster session approximately a month after the program finishes.

In Australia, there are approximately 60,000 new strokes per year and half occur in people over the age of 75. The incidence of strokes is estimated to rise with each year with an enormous cost to the community. Stroke is a disease with severe consequences for the patient and their carers or family members, who often feel inadequately prepared to deal with the demands.

You are invited to participate in this research project because you have experienced a stroke. The research has been initiated by St Vincent's Hospital (Melbourne) and will involve 166 participants who have received treatment for stroke and 166 carers of people with living with the effects of stroke. The research will be conducted on site at St Vincent's Hospital (Fitzroy) and St George's Hospital (Kew).

3. Procedures

If you agree to take part in this project you will be randomly assigned to either the Optimal Health Program group or a control (care as usual) group. Both groups will involve completing brief questionnaires which will take approximately 40 minutes, once at the start of the program, and then at 3, 6 and 12 month's time.

If you agree to take part in this project you will be allowing the study coordinator to access your medical records at St Vincent's Hospital, Melbourne collecting information on your medical history, diagnosis, length of stay in hospital and care needs. Your information will be used in conjunction with an 8 week support program that will be offered to you and a person involved in your care.

You will be asked to attend a series of support sessions. The sessions will be led by health professionals with training in the Optimal Health Program. The sessions are approximately one hour long and will be conducted at an agreed time.

The sessions are designed to help you adjust to any difficulties you might be experiencing after a stroke. You may choose to receive either eight one-on-one sessions with a health professional, who will guide you through the program. Alternatively, you may wish to participate in eight group sessions. You can attend these sessions by yourself or with the person involved in your care.

For participants in the control group the Optimal Health Program is available after their 12 month questionnaire is completed.

The research we are conducting focusses on your experience of the Optimal Health program, including how helpful you find the program to be.

At a later date you may also wish to be involved in a 1-hour focus group which will evaluate the program. Your feedback is highly valued and will be crucial to our research.

4. Possible Benefits

We cannot guarantee or promise that you will receive any benefits from this project. It is hoped that the Optimal Health Program will be of help to you. Participating in the program is likely to increase your access to information regarding your health, and may help you to develop additional skills for living a healthier lifestyle. The results of your participation may also enhance the quality of services offered to survivors of stroke in the future.

5. Possible Risks

As some of the content of the program will address sensitive issues there is a chance that you will feel some distress. The study coordinator and healthcare professionals administering the Optimal Health Program will support you in their capacity and can provide a referral for counselling if required. We encourage you to utilise external counselling services or make an appointment with your General Practitioner if you feel particularly distressed. All professional counselling is provided by staff outside the research team.

6. Privacy, Confidentiality and Disclosure of Information

This study is one of three arms that sits within the study is called the TRIPOD study (Translating Research, Integrated Public health Outcomes and Delivery). The TRIPOD research investigates the use of the Optimal Health Program for chronic illness including dialysis and diabetes. The storage of information in a single database will improve our ability to analyse data and produce high quality research. The database is likely to help healthcare professionals better understand the effects of chronic illness and the needs of patients. The database may also show how helpful current healthcare services are, and may help us to improve these services.

All data will be stored separately from the register of participants. All information will be placed in a locked filing cabinet in the locked office in Mental Health in accordance with National Health and Medical Research Council requirements; where personal information about research participants is collected, stored, accessed, used, or disposed of, a researcher must strive to ensure that the privacy, confidentiality and cultural sensitivities of the participants are respected. All computerised data will be stored on a secure drive within the St Vincent's Hospital (Melbourne) database in a de-identified manner, with password access for project staff only. Only the study coordinator will have access to this data, or the master list that links participants to the de-identified data. The data will be kept for a period of 7 years following publication and then disposed of as confidential waste.

Any information obtained in connection with this study and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to submit a report of the results for publication in peer-reviewed journals. In any publication, information will be provided in such a way that you cannot be identified.

7. Results of Project

If you would like to receive information about the project outcomes please contact the researchers responsible for this project (see Section 8 below) and an excutive summary of the key findings will be posted to you on completion of the project.

8. Further Information or Any Problems

If you require further information or if you have any problems concerning this project, you can contact the principal investigator or associate researchers. The researchers responsible for this project are:

- Professor David Castle, Psychiatric Chair, Mental Health: (03) 9321 4571, Chief Investigator,
- Dr Gaye Moore, Study Coordinator: (03) 9321 2293

9. Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Liaison Officer at St Vincent's Hospital (Melbourne) on Telephone (03) 9321 3108. You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator.

10. Research Participant Rights

If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at St Vincent's Hospital (Melbourne) on Telephone: (03) 9321 3930.

11. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, and your relationship with those treating you.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

You may withdraw from the research at any time. If you decide to withdraw from this project, please notify a member of the research team.

12. Reimbursement for your costs

You will be reimbursed for any travel expenses incurred as a result of your participation. Please retain any receipts for costs incurred while attending sessions for the study and the study coordinator will organise payment at the end of each month.

13. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Research Involving Humans* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. The ethical aspects of this research project have been approved by the Human Research Ethics Committee of St Vincent’s Hospital (Melbourne).

Participant Consent Form – Stroke Survivors

St Vincent's Hospital (Melbourne)

Version 8: Dated 30 March 2015

Protocol No, (STV): HREC-A 031/21

Site: St Vincent's Hospital, Melbourne

Full Project Title: Improving the mental health of stroke survivors and carers: An evaluation of the Stroke and Carer Optimal Health Program (SCOHP)

I have read and I understand the Participant Information.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this project according to the conditions in the Participant Information.

I will be given a copy of the Participant Information to keep.

I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Consent to participate (please circle) **Yes** **No**

Participant's Name (printed) ………………………………………………….

Signature ……………………………………… **Date**……………..

Researcher's Name (printed) ………………………………………………….

Signature ………………………………………………… **Date**……………..

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the Consent Form must date their own signature.

Appendix 10. CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Ch. 4, p. 129
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Ch. 4, p. 129
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Ch 4, p. 129-132
	2b	Specific objectives or hypotheses	Ch 4, p. 132
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Ch 4, p. 132
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Ch 4, 132
Participants	4a	Eligibility criteria for participants	Ch 4, p. 133
	4b	Settings and locations where the data were collected	Ch 4, 132
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Ch 4, 133-134
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Ch 4, p. 134-135

	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not required
Sample size	7a	How sample size was determined	Ch 4, p. 138
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not required
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Ch 44, p. 132
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Ch 4 – p. 133
Allocation Concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Ch 4, p. 133
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Ch 4, p. 133
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Ch 4, p. 133
	11b	If relevant, description of the similarity of interventions	Not required
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Ch 4, p. 137-138
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not required
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Ch 4, p. 138
	13b	For each group, losses and exclusions after randomisation, together with reasons	Ch 4, p. 139

Recruitment	14a	Dates defining the periods of recruitment and follow-up	Ch 4, p.
	14b	Why the trial ended or was stopped	Not required
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Ch 4, p. 140-141
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Ch 4 , p. 140-141
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Ch 4 – p.142-144
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not required
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not required
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	No harms reported
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Ch 4, p. 149-150
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Ch 4, 144-150
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Ch 4, 144-150
Other information			
Registration	23	Registration number and name of trial registry	Appendix 16, p. 277
Protocol	24	Where the full trial protocol can be accessed, if available	Ch 3 –Protocol paper, p.106-127

Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Ch 1, p. 44

Appendix 11. Demographics questionnaire

DEMOGRAPHICS

Date of completion: ____/____/_______		
1	What is your date of birth	____/____/_______
2	What is your postcode?	
3	Gender *(Please tick the appropriate box)*	Male 1 ☐ Female 2 ☐
4	Country of Birth	
5	If not born in Australia, how old were you when you arrived in Australia?	__________________________ 1 ☐ N/A
6	Which ethnic group do you identify with? *(Please tick the appropriate box)*	1 ☐ Aboriginal & Torres Strait Islander 2 ☐ Anglo-Celtic (Caucasian) 3 ☐ Central Asian (Sri-Lankan, Indian, Bangladeshi, Pakistan) 4 ☐ East Asian (Chinese, Japanese, Korean, Mongolian, Taiwanese) 5 ☐ Middle Eastern 6 ☐ African 7 ☐ Other European 8 ☐ Other (please specify) _______________________________
7	Do you speak a language other than English at home? *(Please tick the appropriate box)*	1 ☐ Yes. Which language? ________________________ 2 ☐ No
8	What is the highest education level you have completed? *(Please tick the appropriate box)*	1 ☐ Primary School 2 ☐ Secondary School 3 ☐ Tertiary – undergraduate 4 ☐ Tertiary – post graduate 5 ☐ TAFE 6 ☐ Other (please specify) _________________________
9	Employment status *(Please tick the appropriate box)*	1 ☐ Student 2 ☐ Full-time employed 3 ☐ Part-time employed 4 ☐ Home duties 5 ☐ Unemployed 6 ☐ Unable to work because of illness 7 ☐ Other (please specify) _______________________________
10	Approximately how many hours did you work last week?	__________________________ 1 ☐ N/A
11	Most recent hourly wage rate?	__________________________ 1 ☐ N/A
12	Marital status *(Please tick the appropriate box)*	1 ☐ Single 2 ☐ Defacto 3 ☐ Separated 4 ☐ Married 5 ☐ Divorced 6 ☐ Widowed 7 ☐ Other (please specify) _______________________________
13	Do you have any dependents? people who rely on you for support and live with you? *(Please tick the appropriate box)*	1 ☐ Yes. How many? ___________________________________ 2 ☐ No

DEMOGRAPHICS - CONTINUED

14	What type of accommodation do you live in? *(Please tick the appropriate box)*	1 ☐ Own house 2 ☐ Board with friends/family 3 ☐ Private rental 4 ☐ Public housing 5 ☐ Live with friends 6 ☐ Boarding House 7 ☐ Live with family 8 ☐ Homeless 9 ☐ Supported accommodation 10 ☐ Other (please specify) ______________________________
15	Who do you live with? *(Please tick the appropriate box)*	1 ☐ Alone 2 ☐ Partner or Spouse 3 ☐ Family 4 ☐ Friends 5 ☐ Housemates 6 ☐ Other boarders/residents 7 ☐ Other (please specify) ______________________________
16	Do you take any medication? *(Please tick the appropriate box)*	1 ☐ No. Please go to question 20. 2 ☐ Yes
17	Do you know what each of your medicines is for? *(Please tick the appropriate box)*	1 ☐ Yes, all of them 2 ☐ Some of them 3 ☐ No, none of them
18	Do you ever have trouble remembering when to take your medicine? *(Please tick the appropriate box)*	1 ☐ Yes, most of the time 2 ☐ Sometimes 3 ☐ No, never
19	Are there other reasons you sometimes don't take your medicine? *(Please tick the appropriate box)*	1 ☐ I do not feel I need it 2 ☐ The pills are hard to swallow 3 ☐ I have too many medications 4 ☐ I run out of medication 5 ☐ I don't like the way my medication makes me feel 6 ☐ Taking medication reminds me I have a disease 7 ☐ I don't know when to take my medication 8 ☐ I only take my medication when I feel a flare-up is coming 9 ☐ Other__________________________
20	Smoking: How many cigarettes do you smoke a day on average? *(Please tick the appropriate box)*	1 ☐ Never smoked 2 ☐ Former smoker 3 ☐ 1-10 4 ☐ 11-20 5 ☐ 20+
21	Alcohol consumption: How often do you drink alcohol and how much do you consume? *(Please tick the appropriate box)*	1 ☐ Don't drink at all 2 ☐ Drink occasionally (once a week or less) 3 ☐ Drink only on weekends (moderate use) 4 ☐ Drink only on weekends to intoxication 5 ☐ Drink every day in moderate amounts 6 ☐ Drink every day to intoxication
22	Have you had any major medical illnesses or surgeries? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes. Please specify ________________________________

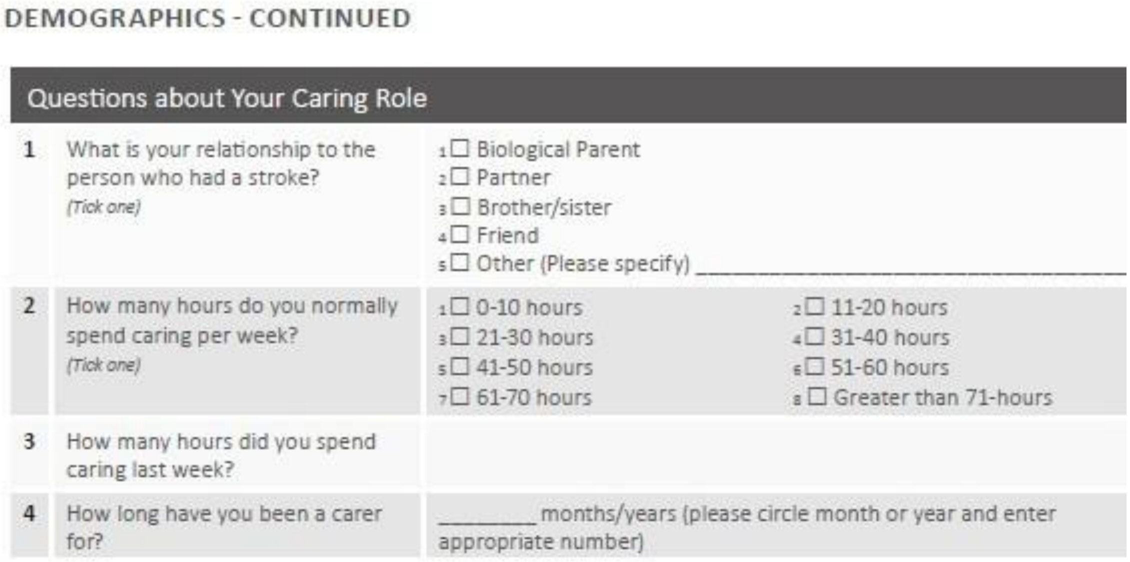
DEMOGRAPHICS - CONTINUED

23	Is there any history of illness in your family? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes. Please specify ______________________________
24	Have you been diagnosed with any psychiatric disorder? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes. Please specify _________________________
25	Have you ever seen a professional for mental health support? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes. Please specify (e.g. psychiatrist, psychologist) __________________________ Current? 3 ☐ Yes 4 ☐ No
26	Did you find the experience with the mental health support professional helpful? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes 3 ☐ Both helpful and unhelpful Please specify why ______________________________ ____
27	Have you ever spent time in hospital for mental health related issues? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes
28	Have you presented to the emergency department (ED) in the last 12 months? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes If yes please list reason(s) below: _______________________ ____
29	Have you been admitted to hospital over the past 12 months? *(Please tick the appropriate box)*	1 ☐ No 2 ☐ Yes If yes please list reason(s) below: _______________________ ____
30	Have you ever been diagnosed with the following neurological conditions? *(Please tick all that apply)*	1 ☐ Acquired brain injury 2 ☐ Alcoholism 3 ☐ Dementia 4 ☐ Huntington's disease 5 ☐ Migraines 6 ☐ Parkinson's disease 7 ☐ Stroke 8 ☐ Substance abuse 9 ☐ Autism 10 ☐ Epilepsy (seizures) 11 ☐ Multiple sclerosis admission 12 ☐ Drug overdose requiring hospital admission 13 ☐ Head Injury requiring hospital admission 14 ☐ None of the above 15 ☐ Other (please specify) __________________________
31	What service supports do you currently use? *(Please tick all that apply)*	1 ☐ General practitioner (GP) 2 ☐ Royal District Nursing Service (RDNS) 3 ☐ Council Services (e.g. Meals on Wheels, Home Help) 4 ☐ Respite Services 5 ☐ Mental Health Professional (e.g. counsellor, psychologist) 6 ☐ Carer organisations (e.g., Carers Victoria) 7 ☐ CentreLink 8 ☐ Other (please specify) __________________________

DEMOGRAPHICS - CONTINUED

32	What topics/issues would you like to see addressed in health support services? *(Please tick all that apply)*	1 ☐ Expressing emotions about my illness 2 ☐ How to communicate with family and/or friends about my illness 3 ☐ Strategies for managing emotions 4 ☐ How to improve self-esteem 5 ☐ Space to talk about concerns other than my illness (e.g. work, relationships, life events) 6 ☐ Information on managing my illness 7 ☐ None of the above
33	What types of support do you think you need in relation to coping with your situation? *(Please tick all that apply)*	1 ☐ Individual professional counselling 2 ☐ Information on managing my illness 3 ☐ Understanding & support from friends 4 ☐ Support with work/uni/school tasks 5 ☐ Group professional counselling 6 ☐ Understanding & support from family 7 ☐ Having fun activities to do 8 ☐ Medicine to help cope with stress 9 ☐ Relaxation/visualisation strategies 10 ☐ Online/telephone counselling 11 ☐ Other (specify) ____________________________________
34	What do you think are the barriers to accessing care for your situation? *(Please tick all that apply)*	1 ☐ Time commitment required 2 ☐ Cost 3 ☐ Lack of services in local area 4 ☐ Lack of motivation 5 ☐ Cultural 6 ☐ Other (specify) ____________________
35	Are you involved with any type of social, sporting, religious or other community group or association?	1 ☐ No 2 ☐ Yes. Please specify ___________________________
36	Considering a 7 –day period how many times on average do you do the following kinds of exercise for more than 15 minutes during your free time?	1 ☐ a)Strenuous exercise (heart beats rapidly) _____ times per week 2 ☐ b)Moderate exercise (not exhausting) _____ times per week 3 ☐ c)Mild exercise (minimal effort) _____ times per week
37	Considering a 7 –day period during your leisure time how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?	1 ☐ Often 2 ☐ Sometimes 1 ☐ Never or rarely
38	Are you on any particular diet?	1 ☐ No 2 ☐ Yes. Please specify ___________________________

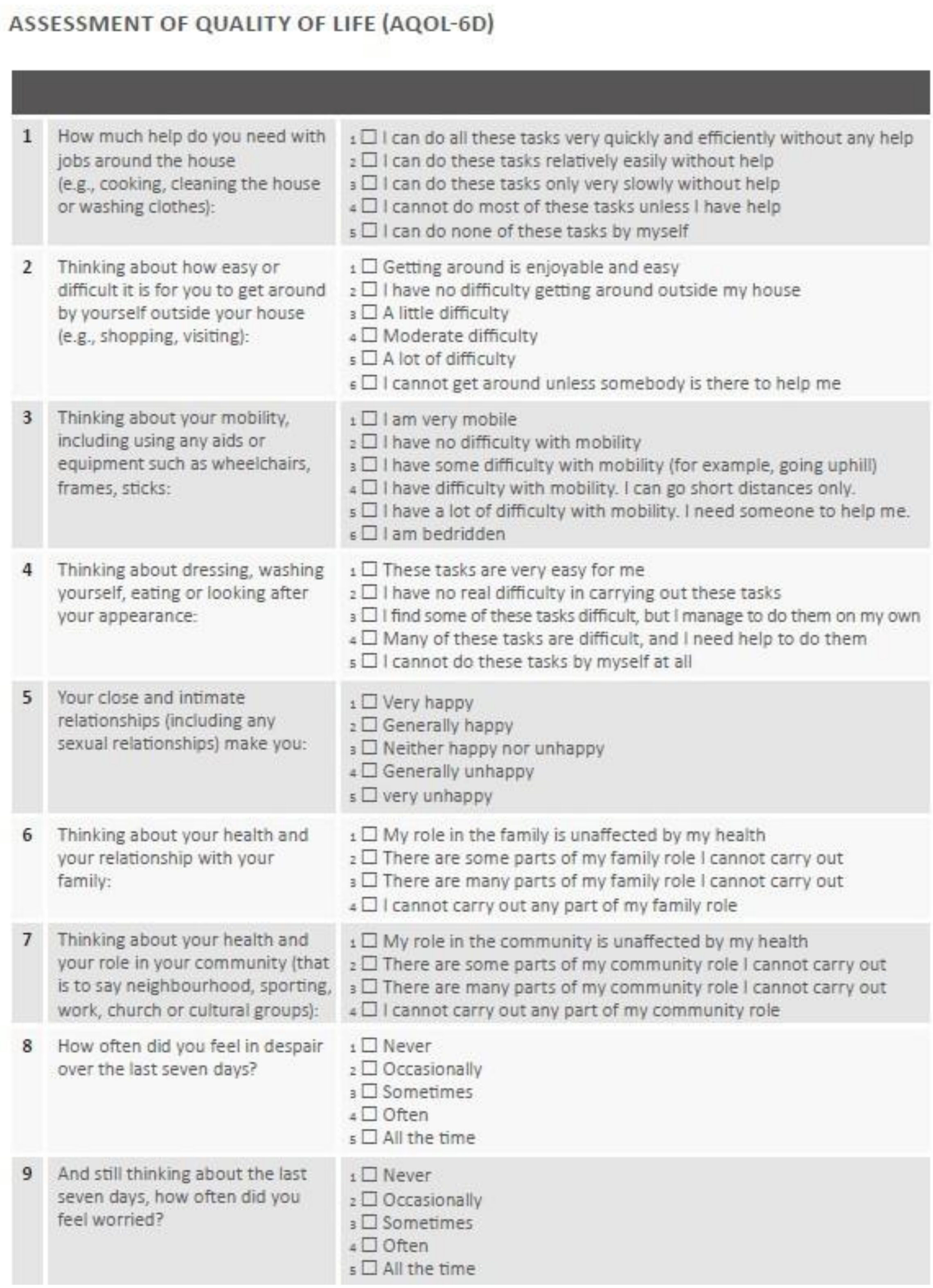
Appendix 12. Demographics - Carer only questions



DEMOGRAPHICS - CONTINUED

	Questions about Your Caring Role		
1	What is your relationship to the person who had a stroke? *(Tick one)*	1☐ Biological Parent 2☐ Partner 3☐ Brother/sister 4☐ Friend 5☐ Other (Please specify) ____________________________________	
2	How many hours do you normally spend caring per week? *(Tick one)*	1☐ 0-10 hours 3☐ 21-30 hours 5☐ 41-50 hours 7☐ 61-70 hours	2☐ 11-20 hours 4☐ 31-40 hours 6☐ 51-60 hours 8☐ Greater than 71-hours
3	How many hours did you spend caring last week?		
4	How long have you been a carer for?	_________ months/years (please circle month or year and enter appropriate number)	

Appendix 13. Stroke survivor and carer measurement tools



ASSESSMENT OF QUALITY OF LIFE (AQOL-6D)

1	How much help do you need with jobs around the house (e.g., cooking, cleaning the house or washing clothes):	1 ☐ I can do all these tasks very quickly and efficiently without any help 2 ☐ I can do these tasks relatively easily without help 3 ☐ I can do these tasks only very slowly without help 4 ☐ I cannot do most of these tasks unless I have help 5 ☐ I can do none of these tasks by myself
2	Thinking about how easy or difficult it is for you to get around by yourself outside your house (e.g., shopping, visiting):	1 ☐ Getting around is enjoyable and easy 2 ☐ I have no difficulty getting around outside my house 3 ☐ A little difficulty 4 ☐ Moderate difficulty 5 ☐ A lot of difficulty 6 ☐ I cannot get around unless somebody is there to help me
3	Thinking about your mobility, including using any aids or equipment such as wheelchairs, frames, sticks:	1 ☐ I am very mobile 2 ☐ I have no difficulty with mobility 3 ☐ I have some difficulty with mobility (for example, going uphill) 4 ☐ I have difficulty with mobility. I can go short distances only. 5 ☐ I have a lot of difficulty with mobility. I need someone to help me. 6 ☐ I am bedridden
4	Thinking about dressing, washing yourself, eating or looking after your appearance:	1 ☐ These tasks are very easy for me 2 ☐ I have no real difficulty in carrying out these tasks 3 ☐ I find some of these tasks difficult, but I manage to do them on my own 4 ☐ Many of these tasks are difficult, and I need help to do them 5 ☐ I cannot do these tasks by myself at all
5	Your close and intimate relationships (including any sexual relationships) make you:	1 ☐ Very happy 2 ☐ Generally happy 3 ☐ Neither happy nor unhappy 4 ☐ Generally unhappy 5 ☐ very unhappy
6	Thinking about your health and your relationship with your family:	1 ☐ My role in the family is unaffected by my health 2 ☐ There are some parts of my family role I cannot carry out 3 ☐ There are many parts of my family role I cannot carry out 4 ☐ I cannot carry out any part of my family role
7	Thinking about your health and your role in your community (that is to say neighbourhood, sporting, work, church or cultural groups):	1 ☐ My role in the community is unaffected by my health 2 ☐ There are some parts of my community role I cannot carry out 3 ☐ There are many parts of my community role I cannot carry out 4 ☐ I cannot carry out any part of my community role
8	How often did you feel in despair over the last seven days?	1 ☐ Never 2 ☐ Occasionally 3 ☐ Sometimes 4 ☐ Often 5 ☐ All the time
9	And still thinking about the last seven days, how often did you feel worried?	1 ☐ Never 2 ☐ Occasionally 3 ☐ Sometimes 4 ☐ Often 5 ☐ All the time

ASSESSMENT OF QUALITY OF LIFE (AQOL-6D) - CONTINUED

10	How often do you feel sad?	1 ☐ Never 2 ☐ Rarely 3 ☐ Some of the time 4 ☐ Usually 5 ☐ Nearly all the time
11	When you think about whether you are calm and tranquil or agitated:	I am 1 ☐ Always calm and tranquil 2 ☐ Usually calm and tranquil 3 ☐ Sometimes calm and tranquil, sometimes agitated 4 ☐ Usually agitated 5 ☐ Always agitated
12	Thinking about how much energy you have to do the things you want to do:	I am 1 ☐ Always full of energy 2 ☐ Usually full of energy 3 ☐ Occasionally energetic 4 ☐ Usually tired and lacking energy 5 ☐ Always tired and lacking energy
13	How often do you feel in control of your life?	1 ☐ Always 2 ☐ Mostly 3 ☐ Sometimes 4 ☐ Only occasionally 5 ☐ Never
14	How much do you feel you can cope with life's problems?	1 ☐ Completely 2 ☐ Mostly 3 ☐ Partly 4 ☐ Very little 5 ☐ Not at all
15	Thinking about how often you experience serious pain:	I experience it 1 ☐ Very rarely 2 ☐ Less than once a week 3 ☐ Three to four times a week 4 ☐ Most of the time
16	How much pain or discomfort do you experience:	1 ☐ None at all 2 ☐ I have moderate pain 3 ☐ I suffer from severe pain 4 ☐ I suffer unbearable pain
17	How often does pain interfere with your usual activities?	1 ☐ Never 2 ☐ Rarely 3 ☐ Sometimes 4 ☐ Often 5 ☐ Always

QUALITY OF LIFE (EQ-5D-3L)

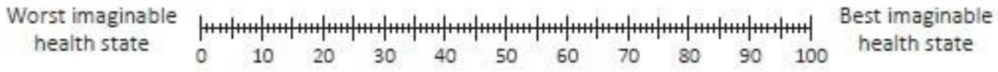
By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Health Questionnaire		
1	Mobility	1 ☐ I have no problems in walking about 2 ☐ I have some problems in walking about 3 ☐ I am confined to bed
2	Self-Care	1 ☐ I have no problems with self-care 2 ☐ I have some problems washing or dressing myself 3 ☐ I am unable to wash or dress myself
3	Usual Activities *(e.g. work, study, housework, family or leisure activities)*	1 ☐ I have no problems with performing my usual activities 2 ☐ I have some problems with performing my usual activities 3 ☐ I am unable to perform my usual activities
4	Pain/Discomfort	1 ☐ I have no pain or discomfort 2 ☐ I have moderate pain or discomfort 3 ☐ I have extreme pain or discomfort
5	Anxiety/Depression	1 ☐ I am not anxious or depressed 2 ☐ I am moderately anxious or depressed 3 ☐ I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

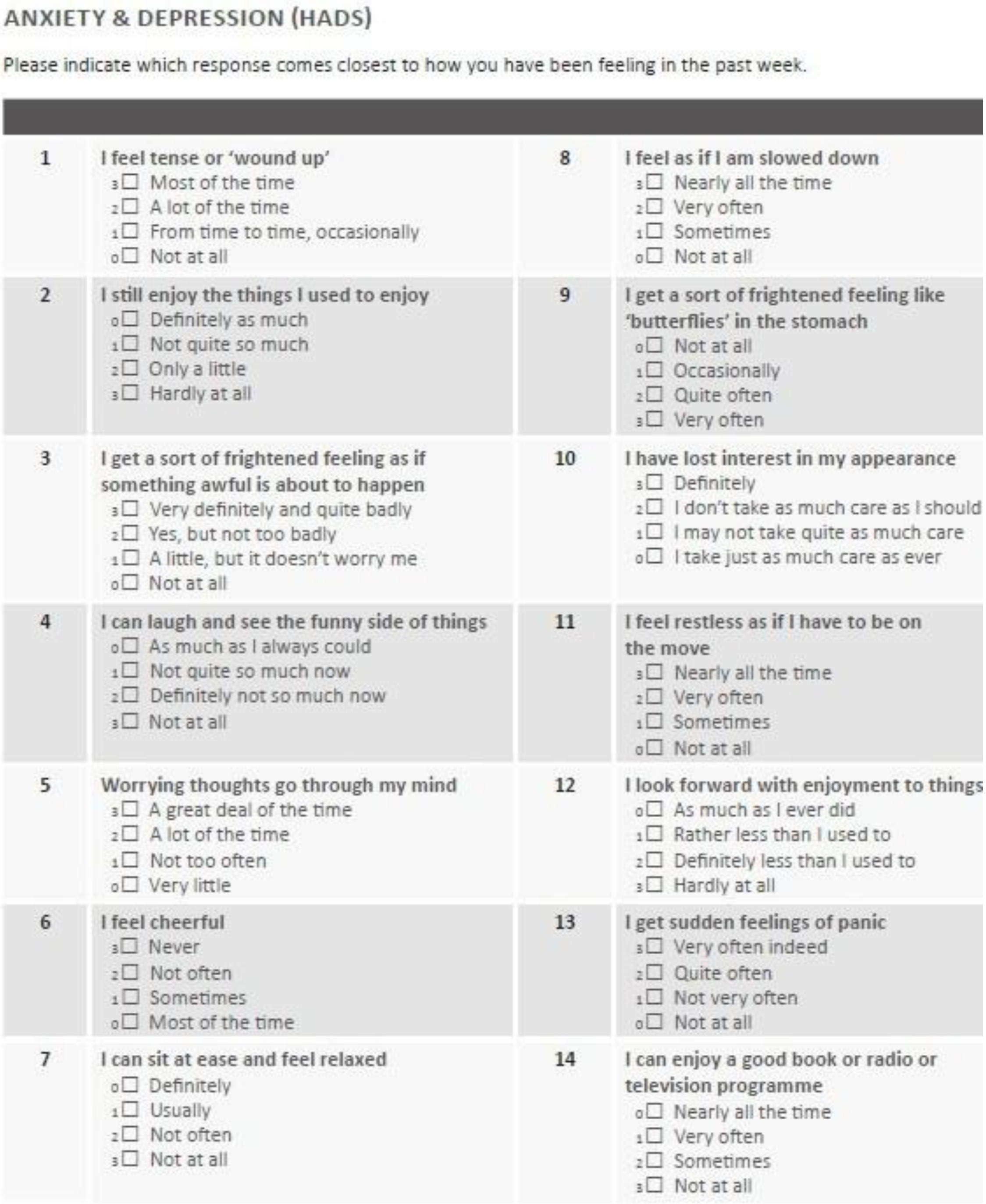
Your own health state today



SELF-EFFICACY (GSE)

Using the scale below, circle the number that best describes how true the statement has been for you DURING THE PAST WEEK.

		Not at all true	Hardly true	Moderately true	Exactly true
1	I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2	If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
3	It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
4	I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5	Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6	I can solve most problems if I invest the necessary effort.	1	2	3	4
7	I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8	When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9	If I am in trouble, I can usually think of a solution.	1	2	3	4
10	I can usually handle whatever comes my way.	1	2	3	4



ANXIETY & DEPRESSION (HADS)

Please indicate which response comes closest to how you have been feeling in the past week.

1	**I feel tense or 'wound up'** 3☐ Most of the time 2☐ A lot of the time 1☐ From time to time, occasionally 0☐ Not at all	8	**I feel as if I am slowed down** 3☐ Nearly all the time 2☐ Very often 1☐ Sometimes 0☐ Not at all
2	**I still enjoy the things I used to enjoy** 0☐ Definitely as much 1☐ Not quite so much 2☐ Only a little 3☐ Hardly at all	9	**I get a sort of frightened feeling like 'butterflies' in the stomach** 0☐ Not at all 1☐ Occasionally 2☐ Quite often 3☐ Very often
3	**I get a sort of frightened feeling as if something awful is about to happen** 3☐ Very definitely and quite badly 2☐ Yes, but not too badly 1☐ A little, but it doesn't worry me 0☐ Not at all	10	**I have lost interest in my appearance** 3☐ Definitely 2☐ I don't take as much care as I should 1☐ I may not take quite as much care 0☐ I take just as much care as ever
4	**I can laugh and see the funny side of things** 0☐ As much as I always could 1☐ Not quite so much now 2☐ Definitely not so much now 3☐ Not at all	11	**I feel restless as if I have to be on the move** 3☐ Nearly all the time 2☐ Very often 1☐ Sometimes 0☐ Not at all
5	**Worrying thoughts go through my mind** 3☐ A great deal of the time 2☐ A lot of the time 1☐ Not too often 0☐ Very little	12	**I look forward with enjoyment to things** 0☐ As much as I ever did 1☐ Rather less than I used to 2☐ Definitely less than I used to 3☐ Hardly at all
6	**I feel cheerful** 3☐ Never 2☐ Not often 1☐ Sometimes 0☐ Most of the time	13	**I get sudden feelings of panic** 3☐ Very often indeed 2☐ Quite often 1☐ Not very often 0☐ Not at all
7	**I can sit at ease and feel relaxed** 0☐ Definitely 1☐ Usually 2☐ Not often 3☐ Not at all	14	**I can enjoy a good book or radio or television programme** 0☐ Nearly all the time 1☐ Very often 2☐ Sometimes 3☐ Not at all

COPING STRATEGIES (B-COPE)

Please indicate to what extent you've been doing what each statement below says. Not whether it's working - just whether or not you're doing it.

		I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
1	I've been turning to work or other activities to take my mind off things.	1	2	3	4
2	I've been concentrating my efforts on doing something about the situation I'm in.	1	2	3	4
3	I've been saying to myself "this isn't real".	1	2	3	4
4	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4
5	I've been getting emotional support from others.	1	2	3	4
6	I've been giving up trying to deal with it.	1	2	3	4
7	I've been taking action to try to make the situation better.	1	2	3	4
8	I've been refusing to believe that it has happened.	1	2	3	4
9	I've been saying things to let my unpleasant feelings escape.	1	2	3	4
10	I've been getting help and advice from other people.	1	2	3	4
11	I've been using alcohol or other drugs to help me get through it.	1	2	3	4
12	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4
13	I've been criticizing myself.	1	2	3	4
14	I've been trying to come up with a strategy about what to do.	1	2	3	4
15	I've been getting comfort and understanding from someone.	1	2	3	4
16	I've been giving up the attempt to cope.	1	2	3	4
17	I've been looking for something good in what is happening.	1	2	3	4

COPING STRATEGIES (B-COPE)

Please indicate to what extent you've been doing what each statement below says. Not whether it's working - just whether or not you're doing it.

		I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
1	I've been turning to work or other activities to take my mind off things.	1	2	3	4
2	I've been concentrating my efforts on doing something about the situation I'm in.	1	2	3	4
3	I've been saying to myself "this isn't real".	1	2	3	4
4	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4
5	I've been getting emotional support from others.	1	2	3	4
6	I've been giving up trying to deal with it.	1	2	3	4
7	I've been taking action to try to make the situation better.	1	2	3	4
8	I've been refusing to believe that it has happened.	1	2	3	4
9	I've been saying things to let my unpleasant feelings escape.	1	2	3	4
10	I've been getting help and advice from other people.	1	2	3	4
11	I've been using alcohol or other drugs to help me get through it.	1	2	3	4
12	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4
13	I've been criticizing myself.	1	2	3	4
14	I've been trying to come up with a strategy about what to do.	1	2	3	4
15	I've been getting comfort and understanding from someone.	1	2	3	4
16	I've been giving up the attempt to cope.	1	2	3	4
17	I've been looking for something good in what is happening.	1	2	3	4

PERSONALITY (BFI-10)

How well do the following statements describe your personality?

	I see myself as someone who ...	Disagree Strongly	Disagree a little	Neither agree nor disagree	Agree a little	Agree Strongly
1	... is reserved	1	2	3	4	5
2	... is generally trusting	1	2	3	4	5
3	... tends to be lazy	1	2	3	4	5
4	... is relaxed, handles stress well	1	2	3	4	5
5	... has few artistic interests	1	2	3	4	5
6	... is outgoing, sociable	1	2	3	4	5
7	... tends to find fault with others	1	2	3	4	5
8	... does a thorough job	1	2	3	4	5
9	... gets nervous easily	1	2	3	4	5
10	... has an active imagination	1	2	3	4	5

WORK & SOCIAL ADJUSTMENT (WSAS)

Rate each of the following questions on a 0 to 8 scale: 0 indicates no impairment at all and 8 indicates very severe impairment.

		Not at all impaired								Very severely impaired
1	Because of my caring role, my ability to work is impaired.	0	1	2	3	4	5	6	7	8
2	Because of my caring role, my home management (cleaning, tidying, shopping, cooking, looking after home or children, paying bills) is impaired.	0	1	2	3	4	5	6	7	8
3	Because of my caring role, my social leisure activities (with other people, such as parties, bars, clubs, outings, visits, dating, home entertainment) are impaired.	0	1	2	3	4	5	6	7	8
4	Because of my caring role, my private leisure activities (done alone, such as reading, gardening, collecting, sewing, walking alone) are impaired.	0	1	2	3	4	5	6	7	8
5	Because of my caring role, my ability to form and maintain close relationships with others, including those I live with, is impaired.	0	1	2	3	4	5	6	7	8

TREATMENT EVALUATION (TEI-SF)

Please indicate how you feel about the treatment.

	Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I find this program to be an acceptable way of improving my wellbeing.	1	2	3	4	5
2	I would be willing to use this program if I had to improve my wellbeing.	1	2	3	4	5
3	I believe that it would be acceptable to use this program without a person's consent.	1	2	3	4	5
4	I like the program used in this way.	1	2	3	4	5
5	I believe this program is likely to be effective.	1	2	3	4	5
6	I believe a person will experience discomfort during the program	1	2	3	4	5
7	I believe this program is likely to result in permanent improvement.	1	2	3	4	5
8	I believe it would be acceptable to use this program with individuals who cannot choose treatments for themselves.	1	2	3	4	5
9	Overall, I have a positive reaction to this program.	1	2	3	4	5

COURSE EXPERIENCE (CEQ)

Please indicate how much you believe, right now, that the program you are receiving will help to improve your wellbeing.

Set I

Please answer in terms of what you **think** about the program.

		not at all logical				somewhat logical				very logical
1	At this point, how logical does the program offered to you seem?	1	2	3	4	5	6	7	8	9
		not at all useful				somewhat useful				very useful
2	At this point, how successful do you think this program will be in improving your wellbeing?	1	2	3	4	5	6	7	8	9
		not at all confident				somewhat confident				very confident
3	How confident would you be in recommending this program to a friend who experiences similar problems?	1	2	3	4	5	6	7	8	9

4	By the end of the program period, how much improvement in your wellbeing do you think will occur?	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

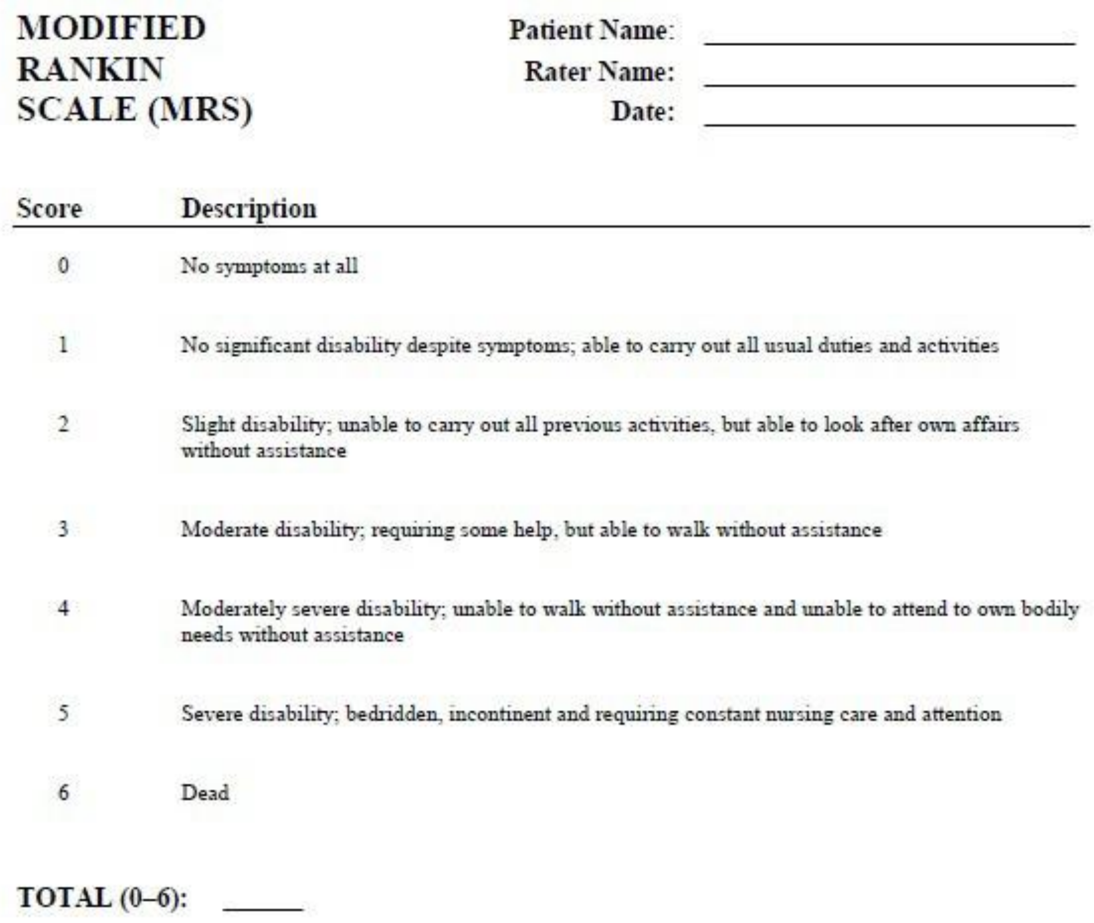
Set II

Please answer in terms of what you **feel** about the program.

		not at all				somewhat				very much
1	At this point, how much do you really feel that the program will help you to improve your wellbeing?	1	2	3	4	5	6	7	8	9

2	By the end of the program period, how much improvement in your wellbeing do you really feel will occur?	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

Appendix 14. Stroke survivor only measurement tools



MODIFIED RANKIN SCALE (MRS)

Patient Name: ____________________

Rater Name: ____________________

Date: ____________________

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

ILLNESS PERCEPTIONS (BIPQ)

For the following questions, please circle the number that best corresponds to your views:

		no affect at all										severely affects my life
1	How much does your illness affect your life?	0	1	2	3	4	5	6	7	8	9	10
		a very short time										forever
2	How long do you think your illness will continue?	0	1	2	3	4	5	6	7	8	9	10
		absolutely no control										extreme amount of control
3	How much control do you feel you have over your illness?	0	1	2	3	4	5	6	7	8	9	10
		not at all										extremely helpful
4	How much do you think your treatment can help your illness?	0	1	2	3	4	5	6	7	8	9	10
		no symptoms at all										many severe symptoms
5	How much do you experience symptoms from your illness?	0	1	2	3	4	5	6	7	8	9	10
		not at all concerned										extremely concerned
6	How concerned are you about your illness?	0	1	2	3	4	5	6	7	8	9	10
		don't understand at all										understand very clearly
7	How well do you feel you understand your illness?	0	1	2	3	4	5	6	7	8	9	10
		not at all affected emotionally										extremely affected emotionally
8	How much does your illness affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)	0	1	2	3	4	5	6	7	8	9	10

Appendix 15. Carer only measurement tools

CAREGIVER STRAIN (MCSI)

Please indicate which response best applies to you.

		Yes, On a Regular Basis	Yes, Sometimes	No
1	**My sleep is disturbed** (For example: the person I care for is in and out of bed or wanders around at night)	2 ☐	1 ☐	0 ☐
2	**Caregiving is inconvenient** (For example: helping takes so much time or it's a long drive over to help)	2 ☐	1 ☐	0 ☐
3	**Caregiving is a physical strain** (For example: lifting in or out of a chair; effort or concentration is required)	2 ☐	1 ☐	0 ☐
4	**Caregiving is confining** (For example: helping restricts free time or I cannot go visiting)	2 ☐	1 ☐	0 ☐
5	**There have been family adjustments** (For example: helping has disrupted my routine; there is no privacy)	2 ☐	1 ☐	0 ☐
6	**There have been changes in personal plans** (For example: I had to turn down a job; I could not go on vacation)	2 ☐	1 ☐	0 ☐
7	**There have been other demands on my time** (For example: other family members need me)	2 ☐	1 ☐	0 ☐
8	**There have been emotional adjustments** (For example: severe arguments about caregiving)	2 ☐	1 ☐	0 ☐
9	**Some behavior is upsetting** (For example: incontinence; the person cared for has trouble remembering things; or the person I care for accuses people of taking things)	2 ☐	1 ☐	0 ☐
10	**It is upsetting to find the person I care for has changed so much from his/her former self** (For example: he/she is a different person than he/she used to be)	2 ☐	1 ☐	0 ☐
11	**There have been work adjustments** (For example: I have to take time off for caregiving duties)	2 ☐	1 ☐	0 ☐
12	**Caregiving is a financial strain**	2 ☐	1 ☐	0 ☐
13	**I feel completely overwhelmed** (For example: I worry about the person I care for; I have concerns about how I will manage)	2 ☐	1 ☐	0 ☐

CARERS' SATISFACTION (CASI)

Although caring can be difficult, it can also be satisfying. For each statement, please indicate how it applies to you.

		This doesn't tend to apply to my situation	This applies to me. I find it provides:		
Caring can be satisfying because:			no real satisfaction	quite a lot of satisfaction	a great deal of satisfaction
1	Caring has allowed me to develop new skills and abilities	0	1	2	3
2	The person I care for is appreciative of what I do	0	1	2	3
3	Caring has brought me closer to the person I care for	0	1	2	3
4	It's good to see small improvements in their condition	0	1	2	3
5	I am able to help the person I care for reach their full potential	0	1	2	3
6	I am able to repay their past acts of kindness	0	1	2	3
7	Caring provides a challenge	0	1	2	3
8	Despite all their problems the person I care for does not grumble or moan	0	1	2	3
9	It is nice to see the person I care for clean, comfortable and well turned out	0	1	2	3
10	Caring enables me to fulfil my sense of duty	0	1	2	3
11	I am the sort of person who enjoys helping people	0	1	2	3
12	I get pleasure from seeing the person I care for happy	0	1	2	3
13	It's good to help the person I care for overcome difficulties and problems	0	1	2	3
14	It's nice when something I do gives the person I care for pleasure	0	1	2	3
15	Knowing the person I care for the way I do, means I can give better care than anyone else	0	1	2	3

CARERS' SATISFACTION (CASI) - CONTINUED

		This doesn't tend to apply to my situation	This applies to me. I find it provides:		
Caring can be satisfying because:			no real satisfaction	quite a lot of satisfaction	a great deal of satisfaction
16	Caring has helped me to grow and develop as a person	0	1	2	3
17	It's nice to feel appreciated by those family and friends I value	0	1	2	3
18	Caring has strengthened close family ties and relationships	0	1	2	3
19	It helps to stop me from feeling guilty	0	1	2	3
20	I am able to keep the person I care for out of an institution	0	1	2	3
21	I feel that if the situation were reversed, the person I care for would do the same for me	0	1	2	3
22	I am able to ensure that the person I care for has their needs tended to	0	1	2	3
23	Caring has given me the chance to widen my interests and contacts	0	1	2	3
24	Maintaining the dignity of the person I care for is important to me	0	1	2	3
25	I am able to test myself and overcome difficulties	0	1	2	3
26	Caring is one way of showing my faith	0	1	2	3
27	Caring has provided a purpose in my life that I did not have before	0	1	2	3
28	At the end of the day I know I will have done the best I could	0	1	2	3
29	Caring is one way of expressing my love for the person I care for	0	1	2	3
30	Caring makes me feel needed and wanted	0	1	2	3

Appendix 16. Complete list of abbreviated terms

AQoL-6D, Assessment of quality of life-6 dimensions; BFI-10, Big five inventory; BIPQ, Brief illness perceptions questionnaire; Brief COPE, abbreviated version of the COPE Inventory; CASI, Carers assessment of satisfaction index; CBT, cognitive behavioural therapy; CEQ, Credibility/expectancy questionnaire; CES-D = Center for Epidemiologic Studies Depression Scale; CG = carer; CMA, Comprehensive Meta-Analysis; CRN, Collaborative Research Network; CSQ = Client Satisfaction Questionnaire; DCI = Dyadic Coping Instrument; EM, Expectation-maximization; EQ-5D = EuroQol Group-5 Dimensions; EQ-5D-3L, European quality of life-3 levels; F-COPES = Family Crisis Oriented Personal Evaluation Scales; FCCI = Family Caregiving Consequence Inventory; GAD, generalised anxiety disorder; GDS = Geriatric Depression Scale; GHQ = General Health Questionnaire; GSE, General self-efficacy scale; HADS = Hospital Anxiety and Depression Scale; HADS, Hospital anxiety and depression scale; HAM-D = Hamilton Depression Rating Scale; HCUQ, Health care utilisation questionnaire; HRSD = Hamilton Rating Scale for Depression; ITT, intention to treat; K-10 = Kessler 10-item; MADRS = Montgomery and Asberg Depression Rating Scale; MMSE, mini-mental state examination; MCSI, Modified caregiver strain index; MMRM, Mixed-effects model, repeated measures; mRS, modified Rankin Scale; OCD, obsessive compulsive disorder; OHP, Optimal health program; PHQ-9 = Patient Health Questionnaire Depression Scale; PICO, population, interventions, comparison and outcomes; QALY, Quality adjusted life year; QLI-stroke = Quality of Life Index - Stroke Version; QLQ = Quality of Life Questionnaire; QALYs, Quality Adjusted Life Years; RCT, Randomised controlled trial; REFFI = Recovery Efficacy - Adapted Questionnaire; SAQOL-g = Stroke Knowledge Questionnaire; SCOHP, Stroke and carer optimal health program; SE Scale, Self-Efficacy Scale; SF-36 = Short Form 36-item; SIS = Stroke Impact Scale; SMD, standard mean differences; SS = stroke survivor; SS, stroke survivor; SSEQ = Stroke Self-Efficacy Questionnaire; SSQOL = Stroke Specific Quality of Life Scale; SSQOL-Pr = Stroke Specific Quality of Life Scale-Proxy; SUPPH = Strategies Used to Promote Peoples' Health; TEI-SF, Treatment evaluation inventory-short form; TRIPOD, Translating research, integrated public health outcomes and delivery; UC = usual care; WHO, World Health Organisation; WHOQOL BREF, World Health Organisation Quality of Life Questionnaire – Brief; WHOQOL-SRPB = World Health Organization - Quality of Life - Spirituality, Religion and Personal Beliefs; WSAS, Work and social adjustment scale; CONSORT, Consolidated Standards of Reporting Trials; SEM, structural equation modelling.

Appendix 17. Study registrations

Trial registration: ACTRN12615001046594 / 07.10.2015

Review registration: PROSPERO CRD42017071129

Appendix 18. Examples of database search strategy

	MEDLINE/PUBMED
	STROKE – Population
S1	Stroke OR cerebral haemorrhage OR cerebrovascular disorders OR brain ischemia OR intracranial hemorrhages OR intracranial embolism and thrombosis OR ischemia
	Word in title OR abstract:
S2	Stroke OR “cerebrovascular accident*” OR CVA OR “cerebral vascular accident*” OR apoplex*
S3	(brain OR cerebr* OR intracran*) N2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
	OR S1 + S2 + S3 = S4
	CARER – Population
	MeSH Headings (MH):
S5	Caregivers OR spouses OR family OR family health
	Word in title OR abstract:
S6	carer* OR caregiver* OR “care giver*” OR caring OR spouse OR famil* OR partner* OR sibling*
	OR S5 + S6 = S7
	DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome
	MeSH Headings (MH):
S8	Depression OR depressive disorder OR anxiety OR anxiety disorder OR mood disorders OR quality of life OR stress psychological OR dysthymic disorder OR mental health OR mental disorders
	Word in title OR abstract:
S9	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR stress* OR strain* OR burden
	OR S10 + S11 = S12
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
	MeSH Headings (MH):
S10	Psychology OR motivation OR motivational interviewing OR counselling OR family therapy OR family relations OR family nursing OR problem solving OR social support OR cognitive therapy OR cognition
	Word in title OR abstract:
S11	Psychosocial OR social OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
S12	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) N2 (therap* OR chang* OR interview* OR counsel*)
	OR S12 + S13 + S14 = S15

	PSYCINFO
	STROKE – Population
	Descriptor Headings (DE):
S1	Cerebrovascular disorder OR cerebral haemorrhage OR cerebrovascular accidents, cerebral ischemia
	Word in title OR abstract:
S2	Stroke OR “cerebrovascular accident*” OR CVA OR “cerebral vascular accident*” OR apoplex*
S3	(brain OR cerebr* OR intracran*) N2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
	OR S1 + S2 + S3 = S4
	CARER – Population
	Descriptor Headings (DE):
S5	"Caregivers" OR "Caring Behaviors" OR "Caregiver Burden" OR "Family" OR "Family" OR "Family Relations" OR "Spouses" OR “marriage”
	Word in title OR abstract:
S6	carer* OR caregiver* OR “care giver” OR caring OR spouse OR famil* OR partner* OR sibling*
	OR S5 + S6 = S7
	DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome
	Descriptor Headings (DE):
S8	Depression (Emotion) OR Affective Disorders OR Anxiety Disorders OR Emotional States OR Anxiety OR Quality of Life OR Stress OR Dysthymic Disorder OR Mental Health OR Mental Disorders OR Chronic mental illness
	Word in title OR abstract:
S9	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR stress* OR strain* OR burden
	OR S10 + S11 = S12
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
	Descriptor Headings (DE):
S10	Psychology OR motivation OR motivational interviewing OR counselling OR family therapy OR problem solving OR social support OR cognitive therapy OR cognitive behavioural therapy
	Word in title OR abstract:
S11	Psychosocial OR social OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
S12	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) N2 (therap* OR chang* OR interview* OR counsel*)
	OR S12 + S13 + S14 = S15

	CINAHL/EBSCO
	STROKE – Population
	MeSH Headings:
S1	(DE "STROKE") OR (DE "CEREBROVASCULAR disease")
	Word in title OR abstract:
	Stroke OR “cerebrovascular accident*” OR CVA OR “cerebral vascular accident*” OR apoplex*
S2	(brain OR cerebr* OR intracran*) N2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
S3	**OR S1 + S2 + S3 = S4**
	CARER – Population
	MeSH Headings:
	((DE "CARE of people" OR DE "CARE of the sick") AND (DE "CARING" OR DE "SPOUSES")) OR (DE "FAMILIES")
	Word in title OR abstract:
	carer* OR caregiver* OR “care giver” OR caring OR spouse OR famil* OR partner* OR sibling*
	OR S5 + S6 = S7
	DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome
S5	**MeSH Headings:**
	((((((DE "MENTAL depression" OR DE "MENTAL health") OR (DE "ANXIETY" OR DE "ANXIETY disorders")) OR (DE "MOOD (Psychology)" OR DE "AFFECT (Psychology)" OR DE "AFFECTIVE disorders")) OR (DE "QUALITY of life")) OR (DE "WELL-being")) OR (DE "STRESS (Psychology)")) OR (DE "MENTAL illness")
	Word in title OR abstract:
S6	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR stress* OR strain* OR burden
	OR S10 + S11 = S12
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
	MeSH Headings:
S8	PSYCHOLOGY") AND (DE "MOTIVATION (Psychology)" OR DE "MOTIVATIONAL interviewing")) OR (DE "COUNSELING")) OR (DE "FAMILIES")) OR (DE "PROBLEM solving")) OR (DE "COGNITIVE therapy")) OR (DE "COGNITION")) AND (DE "SUPPORT groups" OR DE "PSYCHOSOCIAL factors" OR DE "REHABILITATION"
	Word in title OR abstract:
S9	Psychosocial OR social OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
S10	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) N2 (therap* OR chang* OR interview* OR counsel*)
	OR S12 + S13 + S14 = S15

	SOCINDEX
	STROKE – Population
	MeSH Headings:
S1	Stroke OR cerebrovascular disease
	Word in title OR abstract:
S2	Stroke OR “cerebrovascular accident*” OR CVA OR “cerebral vascular accident*” OR apoplex*
S3	(brain OR cerebr* OR intracran*) N2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
	OR S1 + S2 + S3 = S4
	CARER – Population
	MeSH Headings:
	Caring OR spouses OR families OR care of people OR care of the sick
	Word in title OR abstract:
	carer* OR caregiver* OR “care giver” OR caring OR spouse OR famil* OR partner* OR sibling*
	OR S5 + S6 = S7
S5	**DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome**
	MeSH Headings:
	Mental depression OR anxiety OR anxiety disorder OR mood (psychology) OR quality of life OR stress (psychology) OR stress and diseaseOR mental health OR affect (psychology) OR affective disorders OR mental illness OR well-being
S6	**Word in title OR abstract:**
	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR stress* OR strain* OR burden
	OR S10 + S11 = S12
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
S8	**MeSH Headings:**
	Psychology OR motivation (psychology) OR motivational interviewing OR counseling OR family therapy OR family relations OR family nursing OR problem solving OR social support OR cognitive therapy OR cognition OR family psychotherapy OR psychosocial factors
S9	**Word in title OR abstract:**
S10	Psychosocial OR social OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) N2 (therap* OR chang* OR interview* OR counsel*)
	OR S12 + S13 + S14 = S15

	COCHRANE CENTRAL REGISTER OF CONTROLLED TRIALS (CENTRAL)
	STROKE – Population
	MeSH Headings:
S1	Stroke OR cerebral haemorrhage OR cerebrovascular disorders OR brain ischemia OR intracranial hemorrhages OR intracranial embolism and thrombosis OR ischemia
	Word in title OR abstract OR keywords:
S2	Stroke OR “cerebrovascular accident*” OR CVA OR “cerebral vascular accident*” OR apoplex*
S3	(brain OR cerebr* OR intracran*) N2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
	OR S1 + S2 + S3 = S4
	CARER – Population
	MeSH Headings:
	Caregivers OR spouses OR family OR family health OR marriage
	Word in title OR abstract OR keywords:
	carer* OR caregiver* OR “care giver” OR caring OR spouse OR famil* OR partner* OR sibling*
	OR S5 + S6 = S7
S5	**DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome**
	MeSH Headings:
	Depression OR stress, psychological OR depressive disorder OR anxiety OR anxiety disorder OR affect OR mood disorders OR quality of life OR stress psychological OR dysthymic disorder OR mental health OR mental disorders
S6	**Word in title OR abstract OR keywords:**
	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR stress* OR strain* OR burden
	OR S10 + S11 = S12
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
S8	**MeSH Headings:**
	Psychology OR motivation OR motivational interviewing OR counselling OR family therapy OR family nursing OR problem solving OR social participation OR cognitive therapy OR cognition
S9	**Word in title OR abstract OR keywords:**
S10	Psychosocial OR social OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
S11	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) N2 (therap* OR chang* OR interview* OR counsel*)

	SCOPUS (title & abstract search only – no MeSH) #20 AND #21 AND #30 AND #31
	STROKE – Population
	Word in title OR abstract:
S1	Stroke OR “cerebrovascular accident*” OR CVA OR “cerebral vascular accident*” OR apoplex*
	(brain OR cerebr* OR intracran*) NEXT/2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
	OR S1 + S2 = S3
	CARER – Population
	Word in title OR abstract:
	carer* OR caregiver* OR “care giver” OR caring OR spouse OR famil* OR partner* OR sibling*
	DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome
	Word in title OR abstract:
S4	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR stress* OR strain* OR burden
	OR = S4
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
	Word in title OR abstract:
S5	Psychosocial OR social OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
S6	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) NEXT/2 (therap* OR chang* OR interview* OR counsel*)

	Web-of-Science (title only – no MeSH)
	STROKE – Population
	topic:
S1	Stroke OR “cerebrovascular accident” OR CVA OR “cerebral vascular accident” OR apoplex*
S2	(brain OR cerebr* OR intracran*) NEXT/2 (vascular OR ischemi* OR infarct* OR thrombo* OR emboli* OR hemorrhag*)
	OR S1 + S2 = S3
	CARER – Population
	topic
	carer* OR caregiver* OR “care giver” OR caring OR spouse OR famil* OR partner* OR sibling*
	DEPRESSION, ANXIETY & QUALITY OF LIFE - Outcome
	topic
S4	Depress* OR melencholi* OR dysthemi* OR mood OR affective disorders OR anxiety OR anxious OR “quality of life” OR coping OR stress OR strain OR satisfaction OR “mental health” OR wellbeing* OR health* OR stress* OR strain* OR burden
	OR = S4
	PSYCHOSOCIAL, MOTIVATION & BEHAVIOUR - Intervention
	topic
S5	Psychosocial OR social OR psychology OR “problem solving*” OR problemsolving* OR problem-solving* OR support OR network OR “family relations” OR peer
S6	(Motivation* OR cognitive OR behaviour* OR behavior* OR non-invasive) NEXT/2 (therap* OR chang* OR interview* OR counsel*)

Appendix 19. Curriculum vitae

Curriculum Vitae Catherine Brasier Minshall

Catherine.Brasier@myacu.edu.au

EDUCATION & QUALIFICATIONS

2015-2019 **PhD Candidate** – Stroke and Carer Optimal Health Program (SCOHP) for psychosocial health: a randomised controlled trial
ACU in partnership with St Vincent's Hospital, University of Melbourne,
Swinburne University of Technology
(Submission date 28.5.2019)
2014 Bachelor of Social Work (Hons)
La Trobe University
2015 Certificate IV Training and Assessment
HIA
2008 Certificate IV Alcohol and Other Drugs Counselling
Holmesglen Tafe
2003 Bachelor of Arts
Monash University

DIRECT PRACTICE ROLES

2007-16 **Mind Australia** - Community mental health support worker
(Complex Care, intensive outreach, adult and youth residential rehabilitation)
2010 **Youth Support and Advocacy Service** - Youth support worker **2009** **NEAMI** - Community mental health support worker **INDUSTRY ROLES**
2019 **The University of Melbourne** – Consumer Academic - Recovery and Social Justice Unit, The Centre for Mental Health, MSPGH
2019 **Swinburne University of Technology** – Trainer – Cert IV Mental Health Peer Support Work
2017-19 **Victorian Mental Health Interprofessional Network /Department of Health and Human Services** – Academic/research consultant – *scoping review/publication*
2017-19 **Victorian Mental Health Interprofessional Network** – Professional supervision for lived experience workforce
2017-18 **Office of the Chief Psychiatrist/Victorian Mental Health Interprofessional Network** – Led review of clinical guidelines of inpatient leave (by invitation)
2015-18 **St Vincent's Hospital** - Honorary research fellow – mental health and chronic illness
2015-18 NorthWestern Mental Health - Consumer, Carer Advisory Group (CCAG)
Specialist consumer consultant (data analysis, research design, policy)
2015-16 **The University of Melbourne -** Research consultant/guest lecturer
2013-16 **World Social Work Day Conference** - Presenter, venue co-ordinator and organising committee member

AREAS OF PROFESSIONAL EXPERTISE

Recovery-orientated practice
Workforce development
Development and implementation of recovery-plans
Person-centred, strengths-based practice
Risk assessment and crisis intervention
Carer and family support
Inclusive practice (LGBITQ+, CALD, disability)

Substance and dual diagnosis support

Mental health service provision, integration, policy/clinical guidelines PUBLICATIONS

2018 "Psychosocial interventions for stroke survivors, carers and survivor-carer dyads: a systematic review and meta-analysis" Minshall et al., *Topics in Stroke Rehabilitation*, (2019), Impact factor 2.930 [ACCEPTED] , Impact factor: 1.4

2018 "Models to guide cross-sector collaboration between mental health and alcohol and other drug services – a scoping review" Minshall et al., *Advances in Mental Health,* [UNDER SUBMISSION]

2018 Stroke survivors and their carers often have poor mental health. Here's how we can help them" Minshall and Ski, The Conversation (2018).

2016 "Stroke and Carer Optimal Health Program (SCOHP) for psychosocial health: a randomised controlled trial" Brasier (Minshall) et al., *Trials* (2016), 17:466, Impact factor: 2.067

Collaborators: University of Melbourne, Swinburne University Technology, St Vincent's Hospital, Queens University (UK)

CONFRENCE PRESENTATIONS

2019 **Euro Heart Care Conference**, brief presentation , *"Examination of the impact of illness Perceptions, self-efficacy, coping strategies, psychological distress on quality of life post-stroke",* Paris (2nd May, 2019). *(Presented by A/Prof C. Ski)*

2018 Smart Strokes Conference, poster presentation, *"Effectiveness of psychosocial interventions on stroke survivors, their carers and stroke-carer dyads"*, Gold Coast (10th-11th August 2017)

2016 The Australian Society for Medical Research: Victorian Student Research Symposium, poster presentation, *"Evaluation of the Effectiveness of the Stroke and Carer Optimal Health Program: A Randomised Controlled Trial*", Melbourne (3rd June 2016)

2016 **World Social Work Day Conference**, *"Mental Health and Stroke: Beyond Recovery"*, Melbourne (15th March 2016)

2014 World Social Work Day Conference, *"Research in the Age of Facebook"*, Melbourne (23rd March 2014)

PROFESSIONAL PRESENTATIONS

2019 Expert Forum – Peer support for personality type/Complex trauma Barwon Health

2017 Stroke Week – Research Forum (St Vincent's) "SCOHP – Research Update"

2017 Victorian Mental Health Interprofessional Network – "Cross Sector Collaboration – a Literature Review"

2017 Melbourne Health "The 2014 Mental Health Act"

2017 Australian Association of Social Workers (AASW) "Once a Consumer, Always a Consumer??"

2017 Institute for Health and Aging (ACU) "A Critical Review of Stroke Literature" **2017 TRIPOD Research Planning Day** (St Vincent's) "SCOHP Research Update" **2016 The University of Melbourne – Guest Lecture** (School of Social Work)
"Mental Health and *Psychosocial Recovery"*

2016 Mary MacKillop Institute for Health Research Staff Retreat (ACU) "Stroke and Carer Optimal Health Program - Research Update"

2015 Collaborative Research Network Symposium (CRN) "ICT and Recruitment"

2015 - 16 **Melbourne Health** "Applying Risk Concepts in Clinical Practice"

2015 GEM Team Meeting (STV Hospital) **"**SCOHP"

2015 **Eric Seal Mental Health** (STV Hospital) "Evaluation of the Effectiveness of the Stroke and Carer Optimal Health Program: a Randomised Controlled Trial*"*

2015 St Vincent's Stroke Research Symposium (St Vincent's Hospital) "SCOHP"

2015 St Vincent's Hospital National Stroke Week (St Vincent's Hospital) "Referral Pathways to SCOHP"

2015 **The University of Melbourne – Guest Lecture** (School of Social Work) "What is Recovery?"

2015 **The University of Melbourne - Social Work Research Colloquium "**Ethical Considerations in Participatory Research"

2015 **Mercy Health - Recovery Launch** (special guest) "Rethinking Recovery"

2015 **Melbourne Health** "Mental State Examination: an Introduction"

2013 Australian Association of Social Work (AASW) - Victorian Mental Health Network "Is this Recovery?"

SCHOLARSHIPS AND AWARDS

2015-18 Australian Catholic University, competitive PhD scholarship (TRIPOD) $90,000

ACADEMIC AND HEALTH COMMITTEES AND GROUPS

2018 Victorian Mental Health Interprofessional Leadership Network's Cross-sector Reference Group

2015-18 St Vincent's Hospital Translating Research Integrated Public Outcomes and Delivery recruitment (TRIPOD) Steering Committee

2015-17 NorthWestern Mental Health - Consumer, Carer Advisory Group (CCAG)

PEER REVIEWER

2018 International Journal of Stroke (Impact factor 3.314)

2018-19 PLOS ONE (Impact factor 3.5)

PROFESSIONAL AFFILIATIONS

2018 Australian Association of Social Workers

2018 North Western Melbourne Cross Sector Managers Network

PROFESSIONAL TRAINING

2018 Grant writing with Professor Jim Salis

2018 NVIVO – basic applications

2017 Presenting at formal scientific conferences – How to maximise your impact

2017 SPSS fundamentals for researchers – The University of Melbourne **2016** Structural equation modeling – Australian Catholic University **2016** Systematic reviews - Australian Catholic University

2016 Writing up applied research for publication - Australian Catholic University

2016 Building and managing your online research identity - Australian Catholic University

2016 Introduction to SPSS - Australian Catholic University

2016 Understanding research methods - University of London (online)

2016 Scholarly communication - Moscow Institute of Physics & Technology (online)

2015 Advanced SPSS data analysis - Australian Catholic University

2015 Introduction to systematic reviews & meta-analysis – John Hopkins University (online)

2015 Endnote for researchers - Australian Catholic University

2015 Effective writing - Australian Catholic University

2015 How to undertake small clinical studies – The University of Melbourne/ Melbourne Health

2014 Writing qualitative research - Masterclass Kathy Charmaz – Bouverie Centre

2014 Scientific writing - Writing clear science

2014 Digital Writers Masterclass - Emerging writers festival

PROFESSIONAL DEVELOPMENT – MEETINGS AND EVENTS

2018 Organisation for Psychological Research in Stroke: Annual research meeting - Monash University

2018 Intersectionality: what is it and why it matters – Victorian Alcohol and Drug Association's