THE EFFECTS OF A MULTI-DIMENSION REHABILITATION PROGRAMME FOR REDUCING FEAR OF FALLING IN PATIENTS WITH CHRONIC STROKE: A RANDOMIZED, CONTROLLED TRIAL

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CERTIFICATE OF ORIGINALITY

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ABSTRACT

Stroke is a chronic and disabling age-related disease worldwide. Current projections estimate that the global number of people with stroke will reach 77 million by 2030 as a consequence of increased life expectancy and decreased mortality rates. Falling is a major complication after stroke, and the fear of falling is a major psychological contributor to an increased risk of falling. Studies have suggested that physical training, including functional and task-oriented balance training (TOBT) and gait rehabilitation, can effectively reduce the fear of falling in people with stroke.

Cognitive behavioral therapy (CBT) is a psychotherapeutic approach that aims to redirect an individual's maladaptive thoughts and behaviors. CBT has shown promising results with various health issues, such as depression and chronic back pain, and clinical trials have demonstrated its ability to reduce the fear of falling in healthy older adults.

TOBT is a form of physical training that has been clinically proven to improve the recovery of motor function after stroke. A meta-analysis revealed that a 2- to 6-week course of TOBT could improve upper and lower limb motor function and balance performance in people with stroke, which could reduce fear of falling.

Given the evidence available, one could reasonably hypothesize that the addition of CBT would augment the benefits of TOBT in reducing fear of falling in people with stroke. Therefore, this study aimed to compare the combination of CBT

or general health education (GHE) with TOBT (CBT + TOBT or GHE + TOBT, respectively) to determine whether the former would more rapidly and effectively improve the fear of falling in people with stroke. We further anticipated that the combination of CBT and TOBT would induce earlier and greater improvements in fear avoidance behaviors exhibited by people with stroke and in related health variables such as balance performance, fall risk, independent daily living, community integration, and health-related quality of life.

This thesis begins with a systematic review and meta-analysis (study 1) of the effects of CBT with respect to reducing the fear of falling and improving balance performance in older adults. The positive findings of our systematic review and meta-analysis suggest that CBT may effectively reduce the fear of falling in older adults.

In study 2, we investigated the abilities of subjective balance confidence, walking endurance, and fear avoidance behavior to predict the level of community reintegration in community-dwelling people with stroke. Notably, we identified fear avoidance behavior as the most potent predictor of the level of community reintegration in this population. This finding was consistent with our hypothesis that an improved fear of falling could enhance the level of community reintegration in people with stroke.

In addition to determining an intervention to effectively reduce the fear of falling, it is also important to identify outcome measures that reflect its effectiveness. After reviewing the evidence in support of CBT's ability to reduce the fear of falling and investigating the predictive role of fear avoidance behavior in community reintegration of people with stroke, we conducted three cross-sectional studies to identify reliable and valid outcome measures for the main study which investigated the effectiveness of combined CBT with TOBT in improving fear of falling in people with stroke. We then examined the psychometric properties of three potential assessment tools in cross-sectional studies 3 through 5. In studies 3 and 4, we examined the psychometric properties of the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) and the Short-form Physiological Profile Assessment (S-PPA), respectively. Both measures proved valid and reliable for assessment of fear avoidance behavior and fall risk, respectively, in people with stroke. In study 5, we translated and validated the Community Integration Measure (CIM) and demonstrated that the Chinese version of CIM is a valid and reliable tool for assessment of the level of community reintegration in Hong Kong Chinese people with stroke.

To facilitate replication and create an impactful clinical application, we developed a detailed protocol for the main study in study 6. In study 7, our main study, we examined whether the combination of CBT + TOBT would be more effective than the combination of GHE + TOBT for reducing the fear of falling and fear avoidance behavior and improving balance performance, fall risk, independent living, health-related quality of life, and community reintegration in community-dwelling people with stroke.

In our main study, we compared the effectiveness of CBT + TOBT (experimental group) and GHE + TOBT (control group) in reducing the fear of falling and thus reducing fear avoidance behavior and improving balance performance, fall

risk, independent living, health-related quality of life, and community reintegration after a stroke. Eighty-nine subjects were randomized into either the experimental group or the control group and participated in 90-minute interventions 2 days per week for 8 weeks. The outcomes were assessed at baseline, after 4 and 8 weeks of intervention, and 3 and 12 months after the intervention ended. In summary, our findings reveal that the participants in the CBT + TOBT group reported greater improvements than those in the control group regarding fear of falling, fear avoidance behavior, balance performance, independent daily living, and community reintegration over time from the end of the intervention to the 12-month follow-up visit and greater improvement in physical function at the 12-month follow-up visit. The CBT + TOBT and GHE + TOBT groups both demonstrated significant reductions from baseline in the fear of falling and significant improvements in balance performance and physical function from mid-intervention (4 weeks) to the 12-month follow-up visit and significant reductions in fear avoidance behavior over time from the end of the intervention to the 12-month follow-up visit. However, only the CBT + TOBT group exhibited significant improvements in independent daily living and community reintegration from the end of the intervention to the 12-month follow-up visit.

RESEARCH OUTPUT ARISING FROM THIS THESIS

PUBLICATIONS

Liu TW, Ng GY, Chung RC, Ng SS. Cognitive behavioural therapy for fear of falling and balance among older people: a systematic review and meta-analysis. *Age Ageing* 2018, 47: 520-527.

Liu TW, Ng, SS, Kwong, PW, Ng GY. Fear avoidance behavior, not walking endurance, predicts the community reintegration of community-dwelling stroke survivors. *Archives of Physical Medicine and Rehabilitation* 2015, 96: 1684-90.

Liu TW, Ng SS. The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly for assessing fear and activity avoidance among stroke survivors. *PLoS ONE* 2019, 14(4): 0214796.

Liu TW, Ng SS. Assessing fall risks in community-dwelling stroke survivors with Short-form Physiological Profile Assessment (S-PPA). Manuscript has been submitted to peer-review journal *PLoS ONE* (accepted).

Liu TW, Ng SS, Ng GY. Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure for use in patients with chronic Stroke. *BioMed Research International* 2014, ID623836, doi: 10.1155/2014/623836.

Liu TW, Ng GY, Ng SM. Effectiveness of a combination of cognitive behavioral therapy and task-oriented balance training in reducing the fear of falling in patients with chronic stroke: study protocol for a randomized controlled trial. *Trial* 2018, 19: 168. /doi.org/10.1186/s13063-018-2549-z.

Liu TW, Ng GY, Chung RC, Ng SS. Decreasing fear of falling in chronic stroke survivors through cognitive behavior therapy and task-oriented training. *Stroke* 2019, 50:148-154.

CONFERENCE PRESENTATIONS

Liu TW, Ng SS, Ng GY. Effects of the cognitive behavioural therapy (CBT) on fear of falling with stroke patients: a pilot randomized controlled trial. The 7th World Congress of the International Society of Physical and Rehabilitation Medicine, Beijing, 17-20 June 2013.

Liu TW, Ng SS, Ng GY. Translation of Chinese version of Community Integration Measure (CIM) for use in patients with chronic stroke. The 7th World Congress of the International Society of Physical and Rehabilitation Medicine, Beijing, 17-20 June 2013.

Liu TW, Ng SS, Ng GY. Structural validity of the Chinese (Cantonese) version of the Community Integration Measure (CIM): Evidence from stroke survivors in Hong Kong. The 9th Pan-Pacific Conference on Rehabilitation cum 21st Annual Congress of Gerontology, Hong Kong, November 29-30, 2014.

Liu TW, Ng SS, Kwong PW, Ng GY. Performance of muscle functions, functional mobility and postural stability in stroke survivors with impaired subjective balance confidence. The 9th Pan-Pacific Conference on Rehabilitation cum 21st Annual Congress of Gerontology, Hong Kong, November 29-30, 2014.

Liu TW, Ng SS, Kwong PW, Ng GY. Fear-avoidance behavior is a good predictor of community integration in patients with stroke. The U.S. – Hong Kong 2015 Conference: Putting Aging Research and Clinical Practice in Cultural Context, Hong Kong, Jan 5-6, 2015.

Liu TW, Ng SS, Ng GY. Correlates of fear avoidance behaviours among community-dwelling seniors with chronic stroke. The 12th International Symposium on Healthy Aging “Wellness and Longevity: From Science to Service”, Hong Kong, 11-12 March 2017

Liu TW, Ng SS. The Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) for stroke survivors: Its Internal Consistency and Convergent Validity. The 11th Pan-Pacific Conference on Rehabilitation cum 21st Annual Congress of Gerontology, Hong Kong, November 17-18, 2018.

Liu TW, Ng SS. Structural validity of the Chinese (Cantonese) version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C): Evidence from Chinese community-dwelling stroke survivors in Hong Kong. Rehabilitation International Asia & Pacific Regional Conference, Macau, June 26-28, 2019.

Liu TW, Ng SS. Test-retest reliability of the Short-form Physiological Profile Assessment (S-PPA) for community-dwelling stroke patients. The 6th Annual Public Health Conference, Thailand, July 11-13, 2019 (Pending for acceptance).

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LIST OF ABBREVIATIONS

10MWT	10-Metre walk test
6MWT	6-Minute Walk Test
ABC	Activities-Specific Balance Confidence scale
AMT	Abbreviated Mental Test
ADL	Activities of daily living
BBS	Berg Balance Scale
CBT	Cognitive behavioral therapy
CG	Control Group
CHART	Craig Handicap Assessment and Reporting Tool
CIM	Community Integration Measure
CIQ	Community Integration Questionnaire
CI	Confidence Interval
DALYs	disability-adjusted life-years
EG	Experimental Group
FES	Falls Efficacy Scale
FES-I	FES International
FRT	Functional Reach Test
GDS	Geriatric Depression Scale
GHE	General Health Education
HA	Hospital Authority
HKSAR	Hong Kong Special Administrative Region
ICC	Intraclass correlation coefficient
IADL	Instrumental activities of daily living
ICF	International Classification of Functioning, Disability and Health
MCS	Mental Health Summary
PAF	Principal axis factoring
PCA	Principal Component Analysis
PCS	Physical Health Summary
PEDro	Physical Therapy Evidence Database scale

PPA	Physiological Profile Approach
RCT	Randomized Controlled Trial
RNLI	Return to Normal Life Living Index
SAFE	Survey of Activities and Fear of Falling in the Elderly
SF36	Short Form (36) Health Survey
SF12	Short Form (12) Health Survey
TOBT	Task-oriented balance training
TUG	Timed Up and Go
WHO	World Health Organization

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Chapter 1

General introduction

1.1 Epidemiology of stroke

Stroke is defined as an acute clinical syndrome involving a focal (or global) cerebral deficit that persists for more than 24 hours (World Health Organization [WHO], 1976). Etiologically, stroke can be classified as either ischemic or hemorrhagic. Ischemic strokes, which account for 80% of all stroke cases, are caused by arterial obstruction, and the remaining 20% are caused by intracerebral and subarachnoid hemorrhage (Rodgers, 2013).

Stroke is the second leading cause of death worldwide (Donnan, Fisher, Madeod & Davis, 2008). According to global statistics, stroke is responsible for approximately 5.5 million deaths each year (Mukherjee & Patil, 2011), which corresponds to 9% of all deaths (Donnan et al., 2008). Worldwide, the annual numbers of first-ever strokes and the total number of stroke deaths are expected to reach 23 million and 7.8 million, respectively, by 2030 (Strong, Mathers & Bonita, 2007). In Hong Kong, stroke is the fourth leading cause of death (Hospital Authority [HA], 2010), accounting for approximately 3000 lives, or 7.5% of all deaths between 1981 and 2013 (Hong Kong Special Administrative Region [HKSAR], 2016). The annual incidence of stroke in Hong Kong, which has approximately 7 million residents, is approximately 200 per 100,000 (Chau et al., 2011). From 1999–2007, the Hong Kong Hospital Authority treated 166,355 cases of stroke, of which 71% were primary incidents (Chau et al., 2011).

Stroke is associated with a huge socioeconomic burden. The direct economic costs of stroke include both health expenditures and social expenditures, such as the costs required to ensure care (Martinex-Vila & Irimia, 2004). The indirect economic costs of stroke refer to the potential loss of resources, such as productivity. The estimated total economic costs of stroke account for 2% to 4% of the total health care expenditures worldwide (Donnan et al., 2008), with total costs of £9 billion in the UK during 2009 (Saka, McGuire & Wolfe, 2009) and $33.6 billion in the United States during 2011 (Mozaffarian et al., 2015). Moreover, stroke is the seventh leading cause of a loss of disability-adjusted life-years (DALYs). Annually, a total of 43.7 million losses of DALYs are associated with stroke; these account for 3.2% of all lost DALYs worldwide (Mukherjee & Patil, 2011).

Currently, the global population is aging. Worldwide, the number of people 65 years of age or older is projected to reach 800 million by 2025 (WHO, 2004). The incidence of stroke is associated with age and doubles during each decade after 55 years (Marinigh, Lip, Fiotti, Giansante & Lane, 2009). The combination of population aging and decreases in mortality rates has led researchers to project that the population of people with stroke will expand to 77 million worldwide by 2030 (Strong et al., 2007) and to 160,000 in Hong Kong by 2036 (Yu et al., 2012). The projected increase in the population of people with stroke has strong implications with regard to the abilities of stroke rehabilitation services to cope with stroke-related disabilities.

1.2 Impairments after stroke

Sensorimotor deficits are the main cause of disability after stroke (Langhome, Coupar & Pollock, 2009). As many as 50% to 74% (Carey, 1995) and up to 80% (Warlow et al., 2008) of people with stroke are reported to develop sensory and motor impairments, respectively. In addition, stroke may lead to cognitive disorders and mood disturbances (Bowen, Knapp, Hoffman & Lowe, 2005).

1.2.1 Sensorimotor impairment

1.2.1.1 Sensory impairment

Tyson, Crow, Connell, Winward, and Hiller (2013) pooled the data of 439 people with stroke from five studies and reported the preservation of gross lower limb sensory functions in most people with stroke (244 of 439, 55% with intact overall sensation). Notably, demographic factors and variables of stroke pathology, including stroke type, hemiplegic side, and time since stroke, did not affect the loss of lower-limb sensory functions in people with stroke with respect to the presence or absence of impairment. However, stroke-related impairments, including weakness and neglect, were shown to have significant influences on lower limb sensory impairment in people with stroke. Lower limb sensory loss was also found to correlate with mobility, balance, and activities of daily living (ADLs) in people with stroke (r=0.17 to 0.32) (Tyson et al., 2013). Tactile sensation and proprioceptive discrimination were most frequently reported lower limb sensory losses (i.e., absent or impaired). A severe upper limb sensory loss can cause a patient to avoid the use of the affected hand during manual activities and affect motor skills and functional restoration (Bohls & Mcintyre, 2005).

1.2.1.2 Motor impairment

Muscle weakness, spasticity, and loss of dexterity are the major forms of motor impairment after stroke (Meythaler, Guin-Renfroe, Brunner & Hadley, 2001). Muscle weakness refers to a decrease in strength or an inability to generate voluntary muscle contractions of a normal magnitude in any muscle group (Olney & Richards, 1996). Muscle weakness is commonly observed in the lower and upper extremities of people with stroke (Ng & Shepherd, 2013). In these patients, gait may be affected (Flansbjer, Miller, Downham & Lexell, 2008) by the reduced capacity of the paretic lower limb to maintain normal functions like balance, posture, and the initiation or control of movement. Muscle weakness in the lower extremities can compromise patients' walking performance (Carvalho, Sunnerhagen & Willen, 2013), limit their ability to participate in activities (Ng & Shepherd, 2013), and may eventually restrict their social participation (Flansbjer et al., 2008). Muscle weakness in the upper limb affects the performance of ADLs. For example, Bohannon (1991) reported that deficits in both the elbow-flexion strength and active elbow-flexion range-of-motion correlated significantly with the hand-to-mouth maneuver (r=-0.85 to 0.83).

Spasticity refers to a velocity-dependent increase in muscle resistance caused by impaired supraspinal inhibitory signals (Bethoux, 2015). Up to one third of people with stroke experience spasticity-induced tonic stretch flexes, disrupted agonist-antagonist sequencing, passive tissue stiffness, and co-contraction (Singer, Mansfield, Danells, Mcllroy & Mochizuki, 2013). These complications could impair the walking abilities and ADLs of people with stroke (Meythaler et al., 2001) and were identified as significant predictors of the risk of falling in community-dwelling people with stroke (Soyuer & Ozturk, 2007). Moreover, upper limb spasticity could restrict movements such as wrist and finger extension (Pundik, Falcohook, McCabe, Litinas & Daly, 2014) and control of finger extension movement and force (Carey, 1995).

1.2.1.3 Loss of dexterity

Dexterity refers to the ability to coordinate muscular activity to perform motor tasks (Canning, Ada, Adams & O'Dwyer, 2004). Dexterity plays a vital role in the organization of hand-and-finger movement and is therefore fundamental to ADLs, such as writing or using a computer (O'Brien, Acosta, Huerta & Thibaut, 2017). A loss of dexterity implies that an individual has lost the ability to coordinate voluntary muscle activities and thus could not effectively meet environmental demands. Both muscle weakness and loss of dexterity can contribute to reduced movement speed (Bohannon, 1991). Ada, O'Dwyer, Green, William & Neilson (1996) further demonstrated that these factors are distinct entities that contribute to poor muscle control in a study of 17 people with stroke. Lang and Beebe (2007) revealed that movement control in the proximal, middle, and distal segments of the upper extremities correlated significantly with hand function in people with stroke, as measured by the active range of motion (r=0.47 to 0.80), individuation indices (r=0.43 to 0.78), and stationary indices (r=0.36 to 0.72).

1.2.2 Cognitive disorders and mood disturbances

Cognition involves the domains of attention and concentration, memory, visual-spatial perception, apraxia, and executive functioning (Gillespie et al., 2015).

People with stroke often experience difficulties across cognitive domains. For example, in a study by Middleton et al. (2014), up to 76% of people with subacute stroke and 67% of people with stroke reported at least mild cognitive impairment in one or more cognitive domains. The evidence suggests that impaired cognitive impairment, including the domains of memory, orientation, verbal skills, visuospatial ability, abstract reasoning and attentional skills, is associated with impairments of functional movement (Tatemichi et al., 1994) and impaired quality of life in people with stroke (Cumming, Salkeld, Thomas & Szonyi, 2014).

Depression is most common type of mood disturbance after stroke, affecting up to 40% of people with stroke (Haghgoo, Pazuki, Hosseini & Rassafiani, 2013). Previous studies showed that 5% to 54% of people with stroke exhibited depression 1 month after stroke (Kouwenhoven, Kirkevold, Engedal & Kim, 2011), and depression was found in 30% to 62% of people with stroke at the time of hospital discharge (Paolucci, 2008). Moreover, significant negative correlations of depression after stroke with quality of life ($r=-0.74$; $p<0.001$) and performance of ADLs ($r=-0.82$; $p<0.001$) were identified in community-dwelling people with stroke (Haghgoo et al., 2013).

Anxiety is another major type of mood disturbance that may emerge after stroke. In a prospective study by Ayerbe, Ayis, Crichton, Wolfe and Rudd (2014), 1257 of 2179 people with stroke (cumulative incidence 57.5%) had developed at least temporary anxiety during a 10-year follow-up period. Another 57% to 73% of study participants reported concomitant depression and anxiety. Moreover, anxiety showed a negative correlation with the mental domain of quality of life, as measured using the Short Form (36) Health Survey (SF36) (Ware, Kosinski & Keller, 1993) or Short Form (12) Health Survey (SF12) (Ware, Kosinski & Kelleral, 2002). Other pseudo-depressive manifestations, including apathy and catastrophic reactions, were similarly found to correlate significantly with impairments in ADLs (Starkstein et al., 1993; Starkstein, 1996). Of these latter manifestations, catastrophic reaction was thought to be the origin of fear of falling after stroke (Delbaere, Crombez, van Haastregt & Vlaeyen, 2009). This secondary psychological consequence is a more pervasive and serious problem than an actual fall (Cumming et al., 2000; McAuley, Mihalko & Rosengren, 1997).

1.3 Falls and fall-related injuries in people with stroke

A falls is an event wherein a person comes to rest unintentionally on the ground, floor, or a lower surface (WHO, 2007). Falls and fall-related injuries are among the most common and serious complications of stroke (Sze, Wong, Leung & Woo, 2001). Approximately 12% to 39% of people with stroke in stroke rehabilitation units (Froster & Young, 1995; Nyberg & Gustafson, 1995) and up to

73% to 80% of people with stroke in the community experience a fall (Sze et al., 2001; Hyndman, Ashburn & Stack, 2002). In a study of 2032 community-dwelling Chinese elderly aged at least 70 years of age in Hong Kong, Ho, Woo, Chan, Yuen, and Sham (1996) reported an approximate prevalence of falling of 18%. Moreover, people with a history of cerebrovascular disease had a 1.9-fold higher risk of falling.

Studies have reported that 25% to 55% of falls after stroke result in injury (Tutuarima, van der Meulen, de Hann & Limburg, 1997; Mackintosh, Hill, Dodd, Goldie & Culham, 2005). Falls place large financial burdens on health care systems, and the related costs increase with the fall frequency and severity of injury. One study by Rizzo et al. (1998) reported high estimated health care costs associated with one or more injurious falls, with annual rates as high as USD $19,440. Although fall-related injuries are usually mild (e.g., bruises or grazes) (Mackintosh et al., 2005), people with stroke were reported to have a 2- to 4-fold higher rate of hip fracture than the general elderly population (Ramnermark, Nyberg, Borssen, Olsson & Gustafson, 1998).

The increased risk of falling after a stroke has been attributed to many factors (Stapleton, Ashburn & Stack, 2001), including disease-specific mechanisms such as balance and gait deficits (Weerdesteyn, de Niet, van Duijnhoven & Geurts, 2008), which are mainly attributable to underlying physiological impairments such as muscle weakness, spasticity, loss of selective motor control, due to altered spatiotemporal parameters, and kinematic changes during functional movement (Sheffler & Chase, 2015). Weakness in various muscles over the paretic side, particularly the hip, knee, and ankle extensors, may compromise the standing capacities of hemiplegic patients (Bohannon, 1987) and various parameters associated with gait performance, including gait speed (Bohannon, 1989; 1991), cadence (Bohannon, 1987), endurance (Kondo & Kobayshi, 1993), balance, and independence (Gruendel, 1992). A loss of selective motor control may reduce the patient's ability to coordinate lower limb muscle contractions, resulting in a tendency to vault over the non-paretic limb. The affected spatiotemporal parameters may include step length, stride length, and cadence, whereas the kinematic changes after stroke may include decreased paretic hip and knee flexion (Sheffler & Chase, 2015), which may eventually lead to reduced walking speed and abnormal gait pattern (Sheffler & Chase, 2015).

The circumstances associated with falling comprise another important contributor to the risk of falling after stroke. Community-dwelling people with stroke usually fall while walking on level ground (Froster & Young, 1995; Hyndman et al., 2002) and while turning and rising from sitting to standing (Hyndman et al., 2002). One study found that people with stroke had a higher failure rate than able-bodied subjects (14% vs 0.5%), particularly during obstacle avoidance tasks (Den Otter, Geurts, de Haart, Mulder & Duysens, 2005).

Psychological factors also contribute to an increased risk of falling. The evidence suggests that people with stroke with a greater fear of falling are more likely to fall than those with a lower level of fear (Pang & Eng, 2008; Simpson, Miller & Eng, 2011). For example, a study by Simpson et al. (2011) revealed that people with stroke with a fear of falling had a 1.77-fold higher likelihood of falling, compared to matched controls.

1.4 Fear of falling in people with stroke

1.4.1 Definition of fear of falling

The term "fear of falling" was first coined to describe a phobic reaction to standing or walking after an accidental fall (Bhala, O'Donnell & Thoppil, 1982). This reaction was considered a type of post-fall behavioral syndrome that reflected the fearful anticipation of falling (Tideiksaar, 1989). Tinetti, Richman, and Powell (1990) postulated that fear of falling originated from low self-efficacy, in accordance with the theory of efficacy.

According to Bandura (1997), self-efficacy differs from self-confidence because the former refers to one's self-perceived capability to perform a specific activity, whereas self-confidence refers to one's self-perceived capabilities to perform general activities. Self-efficacy may determine both an individual's task performance and task outcomes. Powell et al. (1995) further delineated self-efficacy with regard to balance performance as falls self-efficacy and balance self-efficacy. Falls self-efficacy refers to a person's confidence in his or her ability to perform general daily activities without losing balance, and balance self-efficacy refers to a person's confidence in his or her ability to perform specific tasks without a loss of balance. Although the term falls self-efficacy is not situation-specific and theoretically should be described as "balance self-confidence," recent studies have applied these two constructs interchangeably (Tang et al., 2015).

1.4.2 Prevalence of fear of falling in people with stroke

The fear of falling is prevalent in people with stroke (Watanabe, 2005; Ng, 2011). The reported prevalence of a fear of falling ranges from 21% to 85% in general populations of community-dwelling older people (Liu, Ng, Kwong & Ng, 2015; Schmid et al., 2009). The prevalence of a fear of falling among community-dwelling people with stroke is comparable. For example, Liu et al. (2015) reported an approximate prevalence of the fear of falling of 65% in a sample of 45 community-dwelling Hong Kong Chinese older adults (≥65 years of age). Among people with stroke, the prevalence of fear of falling varies across stages after stroke. For example, one report described a prevalence of fear of falling of 54% (Schmid et al., 2009) before discharge from an acute stroke unit, whereas this prevalence had decreased to 44% at 6 months after stroke (Schmid et al., 2011). In a local study, 25 of 45 community-dwelling people with stroke at least 50 years of age (Liu et al., 2015) reported a fear of falling, as measured by the Chinese version of the Activity-Based Balance Confidence scale (ABC-C) (Mak, Lau, Law, Cheung & Wong, 2007).

1.4.3 Correlates of the fear of falling in people with stroke

The fear of falling is significantly associated with a history of falls (Andersson, Kamwendo & Appelros, 2008). People with stroke with a history of falls reported a greater fear of falling than non-fallers ($p=0.04$) (Belgen, Beninato, Sullivan & Karielwalla, 2006). Although a fear of falling may develop in the absence of previous falls, the fear of falling has been mainly attributed to fall experiences after stroke (Friedman, Munoz, West, Rubin & Fried, 2002) In a community-based study, Andersson et al. (2008) interviewed 140 people with stroke at 6 or 12 months after hospital discharge and reported that nearly 60% of those ($n=42$) who had experienced falls expressed a fear of falling, as assessed by the Falls Efficacy Scale (FES). In another survey (Watanabe, 2005), up to 88% of people with stroke who experienced falls after discharge from an inpatient rehabilitation facility reported a fear of falling as assessed using a dichotomous question (Are you afraid of falling?).

In other studies of people with stroke, in which fear of falling was operationally defined as impaired balance self-confidence, showed significant associations with balance performance (Belgen et al., 2006; Rosen, Sunnerhagen, & Kreuter, 2005; Schmid et al., 2012) and gait control (Obembe, Olaogu & Adedoyin, 2014). For example, Rosen et al. (2005) identified a significant positive correlation (r=0.49) between balance performance, as measured by the Berg Balance Scale (BBS) (Berg, Wood-Dauphinee & William, 1995), and the balance self-confidence, as measured by the Swedish version of the FES (FES-S) (Hellstrom & Lindmark, 1999) in people with stroke. Obembe et al. (2014) reported a significant positive correlation (r=0.46) between the normal gait speed and balance self-confidence among people with stroke, as measured by the Activities-Specific Balance Confidence (ABC) scale (Powell & Meyers, 1995). During the inpatient rehabilitation phase, the balance self-confidence showed a positive correlation with walking velocity (partial R^2=0.29, p<0.001) and a negative correlation with a state of quiet standing with eyes open (partial R^2=0.11, p=0.002). In that study, these parameters were measured using the shift amplitude of the anteroposterior center of pressure and gait performance in people with stroke, as measured using the double support time and variations in step length, step width, and step time during the gait cycle (Schinkel-Ivy, Inness & Mansfield, 2016).

In addition to balance performance and gait control, the fear of falling is associated with other health-related outcomes, including poor physical function, as assessed by the Birgitta Lindmark motor assessment scale (Andersson et al., 2008), and a reduced performance during ADLs, as assessed using the Modified Barthel Index (Kim & Park, 2014). Mood disturbances, including anxiety ($r=0.40$, $p<0.05$) (Kim et al., 2012a) and depression ($r=-0.37$, $p=0.006$) (Obembe, Mapayi, Johnson, Agunbiade & Emechete, 2013), were also reported to be positively associated with the fear of falling or negatively associated with balance self-confidence, respectively. The impairments in balance and ADL performance, diminished physical condition, and mood disturbances positively associated with the fear of falling may compromise the patient's activity level, social participation (Schmid et al., 2012; Pang, Eng & Miller (2007), and quality of life (Schmid et al., 2009; 2011). Other sociodemographic variables, including greater age (odds ratio, 2.4; 95% confidence interval [CI], 1.2 to 4.7) and female sex (odds ratio, 1.5; 95% CI, 0.5 to 4.4), showed positive association with a fear of falling (Andersson et al., 2008).

Recent studies (Kim & Park, 2014; Schmid et al., 2012; Pang et al., 2007) have suggested that the fear of falling may limit a patient's activity, restrict their social participation and reintegration into the community, and eventually lead to actual falls (Friedman et al., 2002). In turn, these actual falls would further increase the fear of falling. This spiral of loss is widely recognized as the vicious circle of “fear of falling and actuals,” which hinders stroke recovery in a population that already faces a greater risk of falling due to motor function impairment.

1.5 Fear of falling management model

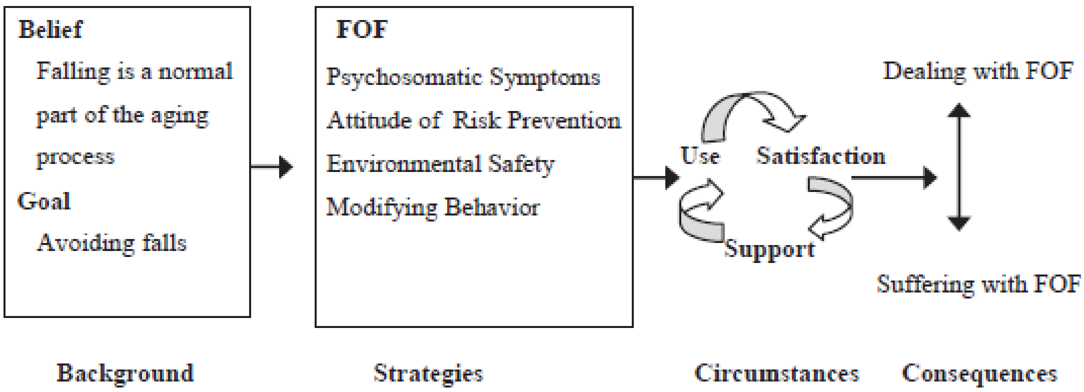
Although no causal theory or framework can fully explain the development of a fear of falling, Huang (2005) explored the “process of fear of falling management.” In a qualitative study, Huang (2005) interviewed 25 community-dwelling older adults to analyze their perceptions and experiences of fear of falling and developed a fear of falling management model to postulate how strategies to cope with fear are driven by beliefs about falls.

In Huang’s model (2005), falling is considered a normal process of aging. A person develops four main coping themes to meet the goal of fall avoidance, including the development of psychosomatic symptoms, adoption of an attitude of risk prevention, attention to environmental safety, and behavior modification. The person then develops coping strategies associated with these main coping themes.

These strategies and the satisfaction achieved by the person and support from family and significant others then influences the effects of the fear of falling.

The model describes the consequences of a fear of falling as a continuum ranging from “dealing with fear of falling” to “suffering with fear of falling.” The former is characterized by familial support of the adopted strategies and satisfaction of the older person, which minimize the effects of a fear of falling. Conversely, the adoption of negative coping strategies would lead to adverse physical and psychological effects. The adoption of either negative or positive coping strategies was influenced by three interrelating circumstances, including: (1) the levels to which management strategies were used; (2) how satisfied the elder was with the outcome of the strategies, and (3) whether strategies were supported by family or/and significant others. However, although Huang (2005) categorized the coping strategies of older adults with a fear of falling, the model does not provide a theoretical framework to direct therapeutic interventions in subsequent clinical trials.

Figure 1.1 Fear of falling management model (Huang, 2005)



1.6 Interventions to improve the fear of falling in people with stroke

Various types of interventions have been developed to reduce the fear of falling in people with stroke. Table 1.1 summarizes the findings of six previous randomized clinical trials (RCTs) including a total of 268 subjects (36% female; sample sizes, 20–83). At baseline, one study included subjects who had experienced at least one fall episode during the 3 months before the study (Lau, Yip & Pang, 2012). Another study reported that all subjects had a history of falling before the study but did not include details (Jung, Yu & Kang, 2012), and the remaining four studies did not report the participants' histories of falls before the study (Holmgren, Gosman-Hedstrom, Lindstrom & Wester, 2010; Hung et al., 2014; Salbach et al., 2005; Yang, Tsai, Chuang, Sung & Wang, 2008).

Of the six RCTs, two applied exercise therapy (Holmegren et al., 2010) and one applied exergaming (Hung et al., 2014), in which the participants engage in physical exertion while playing video games. Two studies examined the combined effects of virtual reality and treadmill training (Jung et al., 2012; Yang et al., 2008). Finally, one study evaluated whole-body vibration with treadmill training (Lau et al., 2012). The interventions ranged from 3 to 12 weeks, and the number of intervention sessions ranged from 9 to 30, with durations of 9–45 minutes.

Table 1.1 Summary of randomized controlled trials

Study, year	Participants	Intervention /Control	Measure of fear of falling	Assessment timing (months)	No. of session	Frequency	Session length	Results of fear of falling
Holmgren, 2010	IG: n = 15, mean age 77.7 – 7.6, 40% women CG: n=19, mean age 79.2 – 7.5, 37% women Post stroke duration: 3 – 6 months Unknown fall history	IG: tailor-made exercise on physical activity and functional performance CG: group discussions	FES-I	Post intervention, 3 month follow-up, 6 month follow-up	30	Once every 3 days for 5 weeks	45 min	IG FES-I post intervention and 3 months follow-up showed significant improvement than CG
Hung, 2014	IG: n = 13, mean age 55.38 + 9.95, 38% women CG: n = 15, mean age 53.40 – 10.03 , 33% women Post stroke duration (month): IG: 21 + 11.26 CG: 15.93 +8.02 Unknown fall history	IG: exergaming CG: weight-shift training	FES-I	Post intervention, 3 month follow-up	24	Twice per week for 12 weeks	30 min	No significant improvement in FES-I between IG and CG
Jung, 2012	IG: n = 11, mean age 60.5 – 8.6, 36% women CG: n = 10, mean age 63.6 – 5.1, 40% women Post stroke duration (month): IG: 12.6 +3.3 CG: 15.4 + 4.7	IG: VR with treadmill training CG: treadmill training	ABC	Post intervention	15	5 times a week for 3 weeks	30 min	IG had significant improvement in fear of falling compared with CG post-intervention

	Unknown fall history							
Lau, 2012	IG: n = 41, mean age 57.3 – 11.3; 37% women CG: n = 41, mean age 57.4 – 11.1, 22% women Post stroke duration (month): IG: 4.6 + 3.5 CG: 5.3 + 4.2 Both IG and CG: 4 subject with at least one fall in the past 3 months	IG: WBV with dynamic leg exercises; CG: dynamic leg exercise	ABC	Post intervention, 1 month follow-up	24	3 times a week for 8 weeks	9 – 15 min	No significant improvement in IG compared with CG
Salbach, 2005	IG: n = 41, mean age not reported, 39% women CG: n = 42, 36% women Post stroke period: less than 1 year post stroke Unknown fall history	IG: walking training CG: upper extremity training	ABC	Post intervention	18	3 times a week for 6 weeks	Not mentioned	IG had better improvement than the CG.
Yang, 2008	IG: n = 11, mean age 55.45 + 12.15, 55% women CG: n = 9, mean age 60.89 + 9.25, 44% women Post stroke duration (year): CG: 6.10 + 10.32 IG: 5.93 + 4.17 Unknown fall history	IG: VR with treadmill training CG: treadmill training	ABC	Post intervention, 1 month	9	3 times a week for 3 weeks	20	No significant improvement between the IG and CG.

Note: IG, intervention group; CG, control group; n, number; FES-I, Falls Efficacy Scale-International; VR, virtual reality; WBV, whole body vibration.

To evaluate the effects of the interventions, four of the six RCTs (Jung et al., 2012; Lau et al., 2012; Salbach et al., 2005; Yang et al., 2008) used the ABC to assess the fear of falling, and two studies (Holmgren et al., 2010; Hung et al., 2014) used the FES-International (FES-I).

Each of the six previously described RCTs included two intervention arms. Two studies compared groups who participated in physical training, such as gait training (Salbach et al., 2005) or functional exercise (Holmgren et al., 2010), with attention control groups. Three studies compared the combined applications of physical training with other components, including virtual reality (Jung et al., 2012; Yang et al., 2008) and whole-body vibration (Lau et al., 2012). One study (Hung et al., 2014) compared exergaming and weight-shift training. In summary, physical training alone led to a greater reduction in the fear of falling than the control conditions (Holmgren et al., 2010; Salbach et al., 2005), although no significant differences in efficacy were observed between exergaming and weight-shift training (Hung et al., 2014). The combined use of treadmill training with virtual reality yielded greater improvements than the treadmill alone (Jung et al., 2012; Yang et al., 2018). However, Lau et al. (2012) found that the combination of whole-body vibration and dynamic leg exercise was not superior to dynamic leg exercise alone for reducing the fear of falling.

1.7 Cognitive behavioral therapy

Cognitive behavioral therapy (CBT) is a psychotherapeutic approach that works with a patient's thoughts and actions to achieve therapeutic goals (Zusman, 2005). CBT uses educational and psychological techniques to redirect negative cognitive, emotional, or behavioral affects and help patients to develop and apply coping mechanisms in their daily lives (Zusman, 2005).

Few studies have investigated the effects of CBT on the incidence of falls and fear of falling in older adults (Zijlstra et al., 2009; Clemson et al., 2004). A recent study of 540 community-dwelling healthy older adults with and without a history of falling (Zijlstra et al., 2009) found that an 8-week course of CBT could improve balance self-efficacy and fear-avoidance behavior. Notably, those effects persisted for at least 6 months after the intervention had ended. Another study of 310 healthy older adults who had a history of falling within 12 months before the study or who had expressed concerns about falling (Clemson et al., 2004) found that a 7-week CBT program could reduce the incidence of falling by 31%. Although previous clinical trials investigated the effects of CBT in reducing fear of falling among the older people, it has not yet been applied in reducing the fear of falling among other disease specific populations, such as stroke.

Clinically, CBT has been proven effective for various health issues such as depression (Dobkin et al., 2011; Pearce & Koenig, 2013), anxiety (Brokovec, Newman, Pinus & Lytlel, 2002; DiMauro, Domingues, Fernandex & Tolin, 2013), insomnia (Wagley, Rybarczyk, Nay, Danish & Lund, 2013; Vitello et al., 2013), and chronic back pain (Boersma et al., 2003). Other studies have demonstrated the applicability of CBT for psychological problems in people with stroke. For example, Kneebone and Jeffries (2013) administered CBT to two older (>60 years) people with stroke with anxiety. Notably, both subjects exhibited improvement; one exhibited a 21.4% reduction in anxiety after eight CBT sessions within 4 months, and the other exhibited a 100% reduction in anxiety after seven CBT sessions within 3 to 4 months. However, that case study did not include a control.

Self-efficacy, defined as self-confidence in one's capability for task performance (Bandura, 1997), is a crucial component of chronic illness management (Ray, Allegrante & Lorig, 2005). Perceived self-efficacy influences our motivations, mediates behavior, and ultimately determines our performance of tasks. In people with stroke, self-efficacy is associated with various health issues, including balance performance (Rosen et al., 2005; Hellstrom, Lindmark, Wahlberg & Fugl-Meyer, 2003; Pang et al., 2007; Salbach, Mayo, Hanley, Richards & Wood-Dauphinee, 2006); fatigue severity (Micheal, Allen & Macko, 2006), depression (Salbach et al., 2006), and community reintegration (Pang et al., 2007).

Among people with stroke, falls are affected by environmental, physical (including stroke-specific impairments), and psychological factors, including thoughts and concerns about falling. Existing interventions intended to improve the fear of falling have focused predominantly on physical factors, with the aim of enhancing balance self-efficacy by achieving a sense of mastery. These interventions suggest that the appropriate application of other sources of self-efficacy could feasibly lead to further or greater improvements.

According to Bandura's theory of self-efficacy, various CBT techniques could enhance the balance self-efficacy of people with stroke. For example, the educational element could enhance self-perceived efficacy via verbal persuasion. CBT could be used to identify and dispute the false beliefs held by people with stroke about falls and capabilities of activities and thus reduced their psychological responses, and group interventions could provide a platform for vicarious learning. Therefore, CBT could be used as an adjunct to physical training to improve the fear of falling in people with stroke by encompassing various sources of self-efficacy.

Although previous studies used CBT as a means to reduce the fear of falling in healthy older adults (Zijlstra et al., 2009; Clemson et al., 2004), the actual effects of CBT in this regard have not been reviewed systematically. A strategy to improve balance performance and reduce the fear of falling in people with stroke is needed to prevent the development of this fear before an actual fall or prevent the exacerbation of an existing fear. The favorable results reported by Zijlstra et al. (2009) from a study of community-dwelling older adults warrant an enhanced version of CBT group intervention to address the physical, environmental, and psychological factors associated with falling in community-dwelling people with stroke.

1.8 Community reintegration and stroke rehabilitation

Community reintegration is an important area of stroke rehabilitation research. This term refers to the process by which an individual with a disabling condition re-enters society (Dijkers, 1998). Community reintegration is the ultimate goal of rehabilitation (Wood-Dauphinee, Opzoomer, Williams, Marhand & Spitzer, 1988) and is closely related to quality of life in those with disabling conditions (Huebner, Johnson, Bennet & Schneck, 2003).

Studies have reported that people with stroke experience a low level of community reintegration (Carter, Buckley, Ferraro, Rordorf & Ogilvy, 2000; Pang et al., 2007; Clarke, Black, Badley, Lawrence & Williams, 2009). For example, in a study by Carter et al. (2000), 45% of 246 study participants reported an impaired level of community integration, as measured by the Return to Normal Life Living Index (RNLI). In another local study, Pang et al. (2007) reported that only 11% of 63 older community-dwelling people with stroke were fully satisfied with their level of community reintegration, as measured by the RNLI. Several correlates were found to associate with the extent of community reintegration by people with stroke, including age ($r=-0.22$, $p=0.036$) (Obembe et al., 2013), walking endurance ($r=0.65$, $p<0.0001$) (Murtezani, Hundozi, Osmani, Krasniqi & Rama, 2009), functional balance ($r=0.55$, $p<0.001$) (Murtezani et al., 2009), improvement in functional disability ($r=0.63$, $p<0.0001$) (Murtezani et al., 2009), balance confidence ($r=0.53$, $p<0.01$) (Pang et al., 2007), and depression ($r=-0.37$, $p=0.006$) (Obembe et al., 2013).

The identification of predictors of community reintegration is an important target in stroke rehabilitation. Some studies suggest that walking endurance (Mayo et al., 1999), depression (Obembe et al., 2013), and balance confidence (Pang et al., 2007) are important predictors of community reintegration among people with stroke. For example, in a study by Pang et al. (2007), balance confidence, as measured by the ABC, was identified as an independent predictor of community reintegration in 63 community-dwelling people with stroke. This finding accounted for 6.5% of the variance in the reported RNLI scores. In 90 people with stroke, Obembe et al. (2013) identified depression, as measured by the Geriatric Depression Scale (GDS), as another important independent variable in a model that included age, motor function, and depression were included as the predictive variables. This model explained 41% of the variance in RNLI scores. However, Obembe et al. (2013) did not report the individual contributions of the predictive variables in their study.

Although subjective balance confidence is associated with various health outcomes and plays an important role in predicting community reintegration, fear avoidance behavior has not been well-elucidated among people with stroke. Fear avoidance behavior is the behavioral translation and reflection of impaired subjective balance confidence. People with stroke may or may not exhibit fear avoidance behavior. To our knowledge, no previous study has investigated fear avoidance behavior among people with stroke, and no validated measure has been developed to evaluate this parameter in people with stroke. In addition, the role of fear avoidance behavior as a predictor of community reintegration has not been well studied. No existing clinical trial has sought to address fear avoidance behavior and community reintegration among people with stroke.

1.9 Assessment tools for community reintegration, fear avoidance behavior, and fall risks

1.9.1 Community Integration Measure (CIM)

McColl, Davies, Carlson, Johnston, and Minnes (2001) developed the CIM to measure the level of community reintegration in people with chronic illness. This 10-item self-reporting instrument is scored on a 5-point Likert scale ("strongly disagree" to "strongly agree") with a maximum composite score of 50. A higher score indicates a higher level of community reintegration. The original CIM measured the unidimensional construct of community reintegration using a one-factor structure and has been proven valid and reliable in people with brain injury (Griffen, Hanks & Meachen, 2010; Reistetter, Spencer, Trujillo & Abreu, 2005) and spinal cord injury (de Wolf, Lane-Brown, Tate, Middleton & Cameron, 2010).

In addition to the CIM, several measures have been developed to evaluate the level of community reintegration in people with chronic illness. These include the 11-item RNLI, the 27-item Craig Handicap Assessment and Reporting Tool (CHART), and the Community Integration Questionnaire (CIQ). These measures were all developed according to the developers' definitions of community reintegration, whereas the CIM was developed based on the International

Classification of Functioning, Disability, and Health (ICF). Although the CIM is now widely applied to people with brain injury and spinal cord injury, it has not yet been translated from English into any other language nor validated in people with stroke.

1.9.2 Survey of Activities and Fear of Falling in the Elderly (SAFE)

Lachman et al. (1998) developed the Survey of Activities and Fear of Falling in the Elderly (SAFE), which was intended to evaluate fear avoidance behavior due to a fear of falling. The original SAFE comprised 11 items regarding the self-perceived and observable ADLs and instrumental ADLs (IADLs) and was scored using a 4-point Likert scale (0=not all worried, 1=a little worried, 2=somewhat worried, 3=very worried). A higher score represented a higher level of fear avoidance behavior. The development study reported that the SAFE exhibited excellent internal consistency (Cronbach alpha=0.91) and convergent validity with the FES (r=-0.76) in community-dwelling healthy older adults. This measure featured a one-factor structure and demonstrated criterion validity with quality of life, as measured using the Medical Outcome Study Short Form 36 (SF-36) (r=-0.37 to 0.55, p<0.001), and discriminant validity for distinguishing subjects with and without a fear of falling. The Chinese (Cantonese) version of the SAFE (SAFE-C) revealed excellent internal consistency (Cronbach's alpha=0.95) in a study of older adults with depressive symptoms. However, this measure has not been validated after stroke.

1.9.3 Short-form Physiological Profile Approach (S-PPA)

Lord, Menz, and Tideman (2003) developed the Physiological Profile Approach (PPA) to assess the risk of falling, based on five physiological factors that contribute to the maintenance of physical stability, including vestibular function, peripheral sensation, muscle force, vision, and reaction time. Although the original PPA comprised 16 items, a simplified version, the Short-form Physiological Profile Approach (S-PPA), includes only five items: (1) the Melbourne Edge Test to assess visual contrast sensitivity, (2) a lower limb matching test to assess proprioception, (3) the response time (in ms) to a light stimulus as measured with a handheld electronic timer to assess the hand reaction time, (4) a knee extension test to assess the muscle force, and (5) a postural sway test to assess balance. These five item scores are then weighted and used to calculate a composite score, which is expressed in standard units (z-score) of -2 to 4 (-2 to 1, very low fall risk; 3 to 4, very marked fall risk). The original PPA was validated in residents of an intermediate care hostel (Lord, Clark & Webster, 1991) and community-dwelling older women (Lord, Ward, Williams & Anstey, 1994), and the items on the S-PPA were found to exhibit poor to excellent test-retest reliability (r=0.50 to 0.97) (Lord et al., 2003).

Although the S-PPA has been applied to older adults (Lord et al., 1991; Lord et al., 1994) and people with chronic illnesses such as diabetes mellitus (Lord et al., 1993) and stroke (Dean, Richards & Malouin, 2010), it has not yet been validated in people with stroke.

1.10 Summary

Population of stroke increases globally. Sensorimotor impairments, cognitive impairments and mood disturbances are the common impairments after stroke. Given these stroke-specific impairments, falls and fall-related injury are prevalent and serious complications after stroke.

Fear of falling is a psychological factor contributing to an increased fall risks and common among the stroke population. Fear of falling is negatively associated with balance performance and various health-related outcomes, such as physical function, performance of ADLs, social participation, community reintegration and quality of life of the people with stroke. Our literature review found that physical training, such as gait training and exergaming, can effectively reduce the fear of falling among people with stroke, according to previous clinical trials. Notably, recent clinical trials have demonstrated the effectiveness of CBT in healthy older adults. These and other recent findings suggest that CBT may be an effective adjunct intervention with physical training for reducing the fear of falling in people with stroke.

Chapter 2

Thesis outline

2.1 Research gaps

Task-oriented balance training (TOBT) is a goal-directed rehabilitative intervention that involves the practice of functional movement in a natural environment (Ng & Hui-Chan, 2007). TOBT requires patients to undertake task-specific activities that would normally require use of the weakened muscle. Cognitive behavioral therapy (CBT), an alternative form of psychological treatment, has been identified as an effective adjunct therapy to improve balance self-efficacy and reduce fear-avoidance behavior in older adults (Zijlstra et al., 2009). Therefore, CBT is expected to augment the effects of TOBT in people with stroke. Based on the review of previous literature related to the fear of falling in chapter 1, we have identified the following research gaps.

First, previous studies demonstrated the effectiveness of physical interventions in reducing the fear of falling and improving the associated health outcomes of people with stroke. However, no study has summarized the results of previous studies whether of psychological interventions i.e. CBT could improve the fear of falling and related health outcomes. Second, although previous studies investigated the role of subjective balance confidence in stroke recovery and community reintegration, the role of fear avoidance behavior and its relationship with community reintegration have not been explored in community-dwelling people with stroke. Third, although the CIM (McColl et al., 2001), Survey of Activities and Fear of Falling in the Elderly (SAFE) (Lachman et al., 1998), and Short-form Physiological Profile Approach (S-PPA) (Lord et al., 2003) have been validated in older adults, these assessment tools have not been validated in a population of people with stroke. Fourth, TOBT is known to effectively improve balance performance in people with stroke, and CBT is known to effectively improve the fear of falling in healthy older adults. However, no study has investigated whether the combination of CBT + TOBT would yield greater benefits than general health education (GHE) + TOBT in improving the fear of falling in people with stroke. Moreover, it is not known whether the greater benefits of CBT + TOBT would consequently improve fear avoidance behaviors, balance performance, fall risk, independent daily living, health-related quality of life, and community reintegration in this population.

2.2 Null hypothesis

The null hypothesis is that the efficacy of CBT + TOBT will not differ significantly from that of GHE + TOBT in terms of promoting balance self-efficacy and consequently reducing the fear avoidance behavior and fall risk, enhancing balance performance, and improving community reintegration and health-related quality of life in people with stroke.

2.3 Aim and objectives

The aim of this thesis was to determine whether CBT + TOBT would augment the positive treatment effects of the latter approach in terms of the fear of falling and the consequent improvements in fear avoidance behavior, balance performance, fall risk, independent daily living, community reintegration, and health-related quality of life in community-dwelling people with stroke. This research project was divided into 4 phases. Phase 1 aimed at filling up the knowledge that whether CBT is effective in reducing fear of falling and improving balance performance in population other than stroke, such as the healthy older people. Phase 2 aimed at filling up the knowledge gap that whether an intervention targeting on fear avoidance behavior could improve the community reintegration in people with stroke. Phase 3 aimed at developing the methodological design of the main study. Phase 4 aimed at answering the research question that whether the combined use of CBT and TOBT is more effective than the combined use of general health education (GHE) and TOBT for reducing the fear of falling and improving the related health outcomes, and in turn leading to the improvement of community reintegration of people with stroke. Additionally, the objectives of this thesis were as follows:

1. To systematically review and meta-analyze the effects of CBT on the fear of falling and balance in older adults;

2. To determine whether fear avoidance behavior contributes independently to community reintegration and to quantify the relative contribution of this factor to community reintegration together with walking endurance and subjective balance confidence in people with stroke;

3. To validate the Chinese version of the SAFE, including internal consistency, test-retest reliability, concurrent validity, and factor structure, and investigate the magnitude of the fear of falling among people with stroke in Hong Kong;

4. To validate the S-PPA, including the inter-rater reliability, test-retest reliability, concurrent validity, convergent validity, and known-group validity, as well as the ability of this measure to identify the fall status when applied to people with stroke in Hong Kong;

5. To translate and adapt culturally the contents of the English version of the CIM into the Chinese (Cantonese) language (CIM-C); report the results of an initial validation of the CIM-C, including the content validity, internal consistency, test-retest reliability, and factor structure in a Chinese setting; and investigate the level of community integration among people with stroke in Hong Kong;

6. To develop a study protocol to evaluate the effects of CBT + TOBT in terms of reducing the fear of falling; and

7. To evaluate whether CBT + TOBT is more effective than GHE + TOBT for reducing the fear of falling and consequently improving fear avoidance behavior, balance performance, fall risk, independent daily living, enhancing community reintegration, and health-related quality of life in community-dwelling people with stroke.

2.4 Outline of the dissertation

This dissertation mainly aims to present the findings from a comparison of the effects of CBT + TOBT vs. GHE + TOBT. The former is expected to yield superior results in terms of reducing the fear of falling and consequently improving fear avoidance behavior, balance performance, fall risk, independent daily living, health-related quality of life, and community reintegration. The studies arising from this dissertation have been outlined in this chapter, and the details and findings are presented in chapters 3–7 of this thesis.

2.4.1 Chapter 3: Cognitive behavioral therapy for the fear of falling and balance in older adults: A systematic review and meta-analysis

A systematic search was used to identify six clinical trials that investigated the effects of CBT in terms of reducing the fear of falling and improving balance performance among older adults. These studies were included in a systematic review and meta-analysis.

2.4.2 Chapter 4: The predictive roles of fear of falling, fear avoidance behavior and balance in community reintegration of community-dwelling people with stroke

This chapter investigates the roles of fear avoidance behavior, subjective balance confidence, and walking endurance as predictors of the level of community reintegration in community-dwelling people with stroke.

2.4.3 Chapter 5: General methodology

This chapter presents the general methodology of our main study, including the research design, participant inclusion and exclusion criteria and the outcome measures. Results of 3 cross-sectional studies, including: (i) validation of the

Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C), (ii) validation of the Short-form Physiological Profile Assessment (S-PPA), and (iii) translation and validation of the CIM-C, were also reported.

2.4.4 Chapter 6: Reducing the fear of falling with cognitive behavioral therapy and task-oriented balance training

This chapter describes a newly designed study protocol to evaluate the effects of CBT + TOBT in terms of reducing the fear of falling. In addition, it compares the results of interventions based on CBT + TOBT and GHE + TOBT in 89 study participants from a randomized controlled clinical trial and discusses the findings.

2.4.5 Chapter 7: Summary and conclusion of the thesis

This chapter summarizes the findings from all chapters and suggests directions for future studies, as well as clinical implications.

Chapter 3

Cognitive behavioral therapy for fear of falling and balance in older adults: A systematic review and meta-analysis

This chapter has been published a peer-reviewed journal.

- Liu TW, Ng GY, Chung RC, Ng SS. Cognitive behavioural therapy for fear of falling and balance among older people: a systematic review and meta-analysis. *Age Ageing* 2018, 47: 520-527. (Appendix 3.1)

3.1 Abstract

Although there has no previous clinical trial using cognitive behavioral therapy (CBT) in reducing the fear of falling among people with stroke, it was reported to yield promising results when applied in reducing the fear of falling in community-dwelling older adults (Clemson et al., 2004; Zijlstra et al., 2009). However, no study has evaluated and synthesized the effects of CBT reported in these clinical trials. In this chapter, we aim to report the results of our study (study 1), which involved a systematic review and meta-analysis of the results of recent clinical trials regarding the use of CBT to reduce the fear of falling and enhance balance performance in community-dwelling older adults.

A systematic search for randomized controlled trials (RCTs) that addressed the fear of falling and balance were identified in searches of six electronic databases, concurrent registered clinical trials, forward citations, and the reference lists of three previous systematic reviews. Six trials involving 1626 participants were identified. Four trials used group-based interventions, whereas two adopted individual interventions. The intervention periods ranged from 4 to 20 weeks, and the numbers and durations of face-to-face contact events varied. The core components of the CBT interventions included cognitive restructuring, personal

goal setting, and the promotion of physical activities. The risk of bias was low across the included studies.

Our study results suggest that relative to the control groups, CBT interventions yielded significant immediate (Hedges' g=0.33; 95% CI, 0.21 to 0.46) and retained reductions in the fear of falling for up to 12 months (Hedges' g=0.30; 95% CI, 0.17 to 0.43) and a significant improvement in balance performance for up to 6 months after the intervention (Hedges' g=0.23; 95% CI, 0.07 to 0.39). From these findings, we conclude that CBT effectively reduces the fear of falling and improves balance performance in older adults.

3.2 Introduction

The fear of falling refers to the fearful anticipation of falls. This fear can develop in people with or without a history of falls (Friedman et al., 2002) and occurs commonly among community-dwelling older adults (estimated prevalence: 29% to 76%) (Arfken, Lach, Birge & Miller, 1994; Zijlstra et al., 2007a; Vellas, Wayne, Romero, Baumgartner & Garry, 1997; Gaxatte et al., 2011; Kim & So, 2013). At an optimal level, a fear of falling is self-protective and can lead to the adoption of fall prevention strategies and the avoidance of activities and situations associated with a high risk of falling. However, excessive fear can lead to reductions in balance performance (Vellas et al., 1997; Li, Fisher, Harmer, McAuley & Wilson, 2003) and activity levels (Tinetti, Mendes de Leon, Doucette & Baker, 1994; Li et al., 2003), restricted social participation (Suzuki, Ohyama, Yamada & Kanamori, 2002; Lachman et al., 1998), and a compromised quality of life (Suzuki et al., 2002; Cumming, Salkeld, Thomas & Szonyi, 2000). In extreme situations, this fear may lead to an inability to stand or walk, regardless of the actual physical capacity. Clinically, Bhala et al. (1982) used the term "ptophobia" to describe these extreme phobic reactions after falls.

Three recent systematic reviews have provided a comprehensive overview of the current research-based evidence regarding interventions aimed at reducing the fear of falling (Sjosten, Vappio & Kivela, 2008; Zijlstra, van Haastregt, van Eijk, Yardley & Kempen, 2007b; Bula, Monod, Hoskovec & Rochat, 2011) in older adults. The reviewed clinical trials adopted two principal forms of intervention (physiological interventions, such as Tai Chi and balance exercise, and psychological interventions, such as relaxation exercises and CBT) as either single factorial or multifactorial interventions. The evidence from these three systematic reviews suggests that the interventions could potentially reduce the fear of falling and improve balance performance in older adults. Eleven of the 19 (58%) studies reviewed by Zijlstra et al. (2007b) found that CBT could effectively reduce the fear of falling, whereas 25 of the 46 (54%) studies reviewed by Bula et al.

(2011) and 13 of the 21 (62%) reviewed by Sjosten et al. (2008) reported positive findings with the use of CBT as an intervention. However, those reviews did not report the effect sizes of the interventions.

To more precisely understand these results, Kumar et al. (2016) conducted a review and meta-analysis of the effects of interventions aimed at reducing the fear of falling among older adults. Regarding the merits of physical training as a means of preventing falls and improving balance, Kumar et al. (2016) synthesized 25 RCTs and quasi-RCTs involving exercise interventions such as training for (1) gait, balance, and function; (2) strength or resistance; (3) flexibility; (4) three-dimensional exercise (e.g., Tai Chi); and (5) endurance. The reported effect sizes of the exercise interventions on the fear of falling among older adults were small to moderate (standardized mean difference [SMD], 0.37; 95% CI, 0.18 to 0.56), and these effects did not vary with the type, frequency, or duration of intervention. However, no previous review or meta-analysis has addressed the psychological interventions (e.g., CBT) aimed at reducing the fear of falling in older adults.

CBT is an umbrella term that refers to psychotherapeutic interventions intended to modify an individual's thoughts and behavior. Theoretically, CBT focuses directly on impaired balance confidence and an unrealistic anticipation of falling, and its clinical efficacy has been established in literature related to various health and psychosocial topics. The feasibility of CBT as an intervention for older adults with a fear of falling has also been demonstrated in several recent clinical trials. However, our current state of knowledge regarding the ability of CBT to reduce the fear of falling among older adults is limited to the narrative evidence presented in reviews by Bula et al. (2011), Sjosten et al. (2008), and Zijlstra et al. (2007b). However, these reviews only included two RCTs with CBT interventions (Tennstedt et al., 1998; Zijlstra et al., 2009).

Given the emerging research evidence, we conducted a review of published clinical trials concerning psychological interventions intended to reduce the fear of falling and/or improve balance and balance self-efficacy in older adults. This study aimed to enhance our understanding of the use of CBT to reduce the fear of falling. The specific objectives were to (i) assess the quality of the reviewed studies, (ii) evaluate the overall effects of CBT on the fear of falling or balance self-efficacy and balance, and (iii) examine the relative efficacy of CBT when compared with control conditions.

3.3 Methods

The reporting of this study adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Moher, Liberati, Tetzlaff, Altman &

PRISMA Group, 2010). The protocol for the study was developed in accordance with the Cochrane Handbook for systematic reviews (Higgins & Green, 2011) and registered in the PROSPERO database of systematic reviews (registration number CRD42017069111).

3.3.1 Eligibility criteria

3.3.1.1 Types of participants

We included studies in which the participants were community-dwelling older adults aged 60 or above. The cut-off point of 60 years was determined according to the United Nations definition (WHO, 2017).

3.3.1.2 Types of interventions

As there is no agreed definition of CBT, we defined it as a psychotherapeutic technique with a cognitive restructuring component with or without behavioral modification procedures. We included any type of CBT that aimed to reduce fear of falling or enhance balance self-efficacy, including face-to-face clinician-delivered, clinician-guided telephone contact, and internet- or computer-delivered therapy.

3.3.1.3 Types of comparators

Trials with the following comparison arms were included: (1) trials that compared CBT with an inactive control such as a wait-list control, care-as-usual, or treatment-as-usual; and (2) trials that compared exercise therapy with and without CBT. We defined exercise therapy, with reference to the Medline Subject Heading, as physical activities designed to achieve specific therapeutic goals with the purpose of restoring, maintaining, or improving normal musculoskeletal functions.

3.3.1.4 Types of outcome measures

Trials with at least one validated measure of either fear of falling or balance at both baseline and post-intervention were included. If more than one validated measure was used, priority was given according to the following rules:

a. For fear of falling, the primary measures were the Falls Efficacy Scale (FES) (Tinetti et al., 1990) and the Activities-specific Balance Confidence scale (ABC) (Powell & Meyers, 1995), then any other validated measure.

b. For balance performance, the primary measure was the Berg Balance Scale

(Berg et al., 1989), and then any other validated measure.

3.3.1.5 Types of studies

We included all clinical trials that involved a pre-post study design or RCT published in a peer-reviewed journal in English.

3.3.2 Excluded studies

Studies were excluded if they examined the effects of CBT using a population under the age of 60 or with a specific disease or condition such as cerebral vascular disease or spinal cord injury. Psychological treatments such as guided imagery and relaxation exercises that did not include a cognitive restructuring component were excluded, as were case studies.

3.3.3 Data source and searches

In June 2017, a computerized literature search was performed on the following six electronic bibliographic databases: MEDLINE (1965-present), Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, Web of Science, Excerpta Medica database (EMBASE), and Cochrane Library.

Our search strategy included combinations of keywords organized in three search blocks: (i) elderly or older people or older person or aging; (ii) fear of falling or balance confidence or balance self-efficacy or fall self-efficacy or falls; and (iii) cognitive behavioral therapy or CBT. The specific search strategies are summarized in Appendix 3.2. We also searched concurrent clinical trials on the "ClinicalTrial.com" website. The reference lists of the selected studies and those of the Sjosten et al. (2008), Zijlstra et al. (2007b), and Bula et al. (2011) systematic reviews were checked for additional eligible studies.

3.3.4 Study selection

Titles and abstracts were independently screened by two independent assessors, NS and LT, to identify potentially relevant articles. After screening, the full texts of the selected articles were reviewed to assess their eligibility for inclusion. Both NS and LT independently reviewed the remaining articles, and any discrepancies in the eligibility for inclusion were resolved by discussion with the third assessor (NG).

3.3.5 Data extraction

For the coding of studies, LT independently extracted data on the methodology and outcome measures using a standardized data extraction sheet, then the extracted information was independently double-checked by a research assistant. The extracted information included (i) methods (year of study, design, and assessment); (ii) participants (living status, number of participants, and age); (3) interventions (frequency, duration, and number of sessions, background of therapists, and delivery format); and (4) primary and secondary outcome measures.

3.3.6 Methodological quality

To assess the methodological quality, the included studies were independently rated by two raters (LT and NS) using the Physical Therapy Evidence Database (PEDro) scale (Maher, Sherrington, Herbert, Moseley & Elsins, 2003). PEDro was initially developed to rate the quality of RCTs on the Physiotherapy Evidence database (Maher et al., 2003). It has been widely used to rate the quality of over 3,000 RCTs in the PEDro database with overall "fair" to "good" interrater reliability (intraclass correrlation coefficient, ICC=0.56) and demonstrated to have discriminative validity on 3 items which were essential to assess the quality of RCTs, including randomisation, concealed allocation and blinding. Thus, PEDro was adopted to evaluate the methodological quality in this study in view of its psychometric property and merits on assessing RCTs.

The PEDro scale includes 11 items. One item was used to assess the external validity and the remaining 10 items assessed the following criteria with "Yes/No" response options: items 1 and 2 assessed the method used to generate and conceal the allocation sequence; item 3 assessed similarity at baseline; items 4-6 assessed the blinding of subjects, therapists, and assessors; item 7 assessed whether > 85% of outcome data were reported; item 8 assessed whether an intention-to-treat approach was used; item 9 assessed whether a between-groups comparison was made; and item 10 assessed whether both point estimates and measures of variability were reported. Two raters independently assessed the methodological quality of the reviewed studies, and any discrepancies were resolved by discussion among the two raters. The methodological quality was categorized as "high" (6-10 points), "fair" (4-5 points), or "poor" (< 3) (Maher et al., 2003).

3.3.7 Statistical analyses

3.3.7.1 Within-group effect size

To evaluate the overall effects, the mean change was calculated as the difference between baseline and post-intervention or baseline and last follow-up assessment (for studies with follow-up assessment), and divided by the pooled standard deviation (Hedges' g) of each outcome measure with a confidence interval of 95%. A conservative correlation value of 0.5 was adopted to assess the dependence among measures between time points.

3.3.7.2 Between-groups effect size

To evaluate the relative efficacy, we calculated the effect sizes for each comparison between CBT and control conditions by subtracting the mean score of the post-intervention CBT group from the mean score of the control group, and then dividing the result by the pooled standard deviation of the two groups with a confidence interval of 95%.

We used the Comprehensive Meta-Analysis software (version 2.0, Biostat Inc.) to calculate the pooled mean effect sizes. The effect sizes were defined as small (0.2), medium (0.5), or large (> 0.8), as recommended by Cohen (1998). Fixed effects models were adopted unless there was significant heterogeneity.

3.3.7.3 Testing homogeneity

Heterogeneity was estimated using I-squared (I^2) and Q-statistics. The I^2 value is the percentage of variance in a pooled effect that can be attributed to heterogeneity, and scores of 25%, 50%, and 75% represent low, moderate, and high heterogeneity, respectively. The Q-statistic indicates the p-value for heterogeneity. A random effects model was adopted for the meta-analysis if the Q-statistic indicated significant heterogeneity (p-value < 0.05).

3.3.7.4 Subgroup analysis

If two or more trials were available, a predefined subgroup analysis was conducted to determine the differences in outcomes between individual CBT and group-based CBT with baseline and post-intervention (and last follow-up assessment if available) using mixed effects models; random effects models were used to pool within subgroups and significant differences between subgroups were tested using fixed effects models.

3.3.7.5 Sensitivity analysis

Sensitivity analyses were conducted to analyze between-groups effect sizes by (i) removing trials with a pre-post study design and low quality studies with PEDro scores below 6, and (ii) removing trials that compared exercise with and without CBT.

3.3.7.6 Risk of bias across studies

To inspect the publication bias, funnel plots were generated and Egger's regression test was conducted on the outcome. Dual and Tweedie's trim and fill procedure (Duval, 2000) was conducted to adjust the effect size if publication bias was noted.

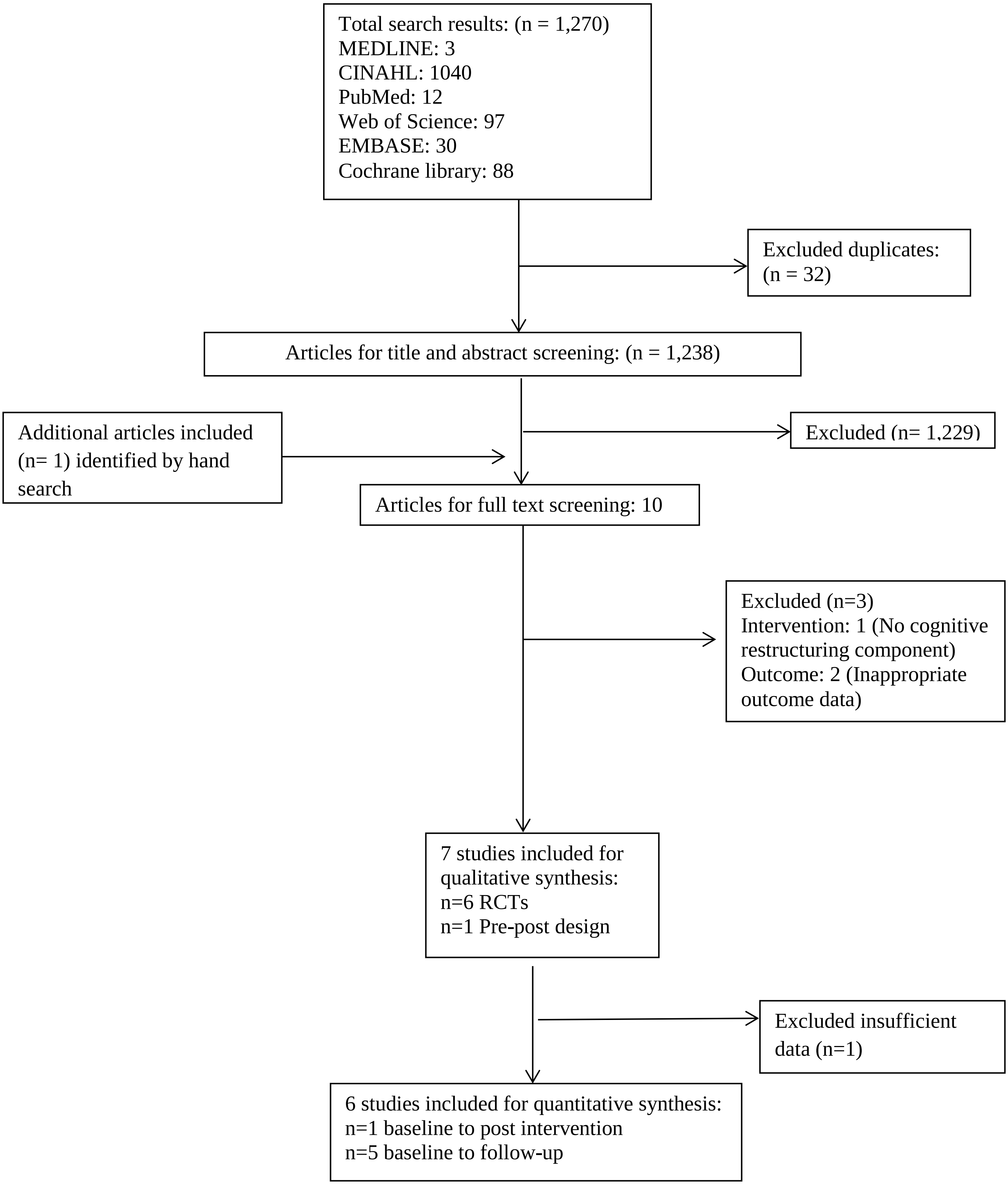
3.4 Results

3.4.1 Study selection

The search of the electronic databases yielded a total of 1,270 publications. No discrepancy was noted between the title and abstract screening. After screening the titles and abstracts, 1,229 studies did not meet our eligibility criteria. An additional study (Tennstedt et al., 1998) was identified in Bula et al. (2011)

reference list. The full texts of the remaining 10 studies were retrieved and assessed, of which 7 were included in our systematic review and 6 in our meta-analysis. Figure 3.1 illustrates the study flow.

Figure 3.1 The study flow diagram



3.4.2 Study characteristics

The characteristics of the seven included studies are summarized in Table 3.1. The publication dates ranged from 1998 to 2016.

3.4.2.1 Participants

The 7 reviewed studies included a total of 1,659 participants, of whom 74% were female (n = 1231), and the study sample sizes ranged from 33 to 434. The majority (n = 1,579, 95%) of the participants were recruited from the general community and the other 80 (5%) were nursing home residents. At baseline, one study (n = 122) included subjects with at least one episode of fall in the year before the study (Liu & Tsui, 2014). Three studies (n = 299) (Huang, Yang, & Liu, 2011; Huang, Chung, Chen, Chin, & Wang, 2016; Alexander, Sartor-Glittenberg, Bordenave, & Bordenave, 2015) reported that 82% (Huang et al., 2011), 56% (Huang et al., 2016), and 48% (Alexander, Sartor-Glittenberg, Bordenave & Bordenave, 2015) of participants had at least one fall episode in the year before the studies began. Tennstedt et al. (1998) reported that 23% of participants and Dorresteijn et al. (2016) that 61% of participants had at least one fall episode 3 months and 6 months before the studies began, respectively.

Table 3.1 Characteristics of included studies (n=7)

Study, year	Design	Participants	Intervention /Control	CBT Treatment components	Measures	Assessment timing (months)	No. of session	Frequency	Session length	Background of CBT therapist
Alexander, 2015	Pre-post	Community-living, n=33 Mean age = 74.3, 72% female (n=23)	I: Group CBT C: N.A	CR, GS, PA	ABC PAR-Q	2	8	weekly	120 min	Health professions graduates)
Dorrestejin, 2016	RCT	Community-living, I: n=194 Mean age = 78.38, 68% female (n=132) C: n=195 Mean age = 78.25, 72% female (n=141)	I: Individual home-based CBT C: CAU	CR, PE, GS, PS	FES-I FEI-AB GARS Fall calendar	5, 12	3 home visits 4 telephone contacts	7 sessions across 4 months	Home-visit: 60 – 75 min Telephone: 35 min	Nurse
Liu, 2014	RCT	Community-living, I: n=58 Mean age = 74.5, 87% female (n=56) C: n=64 Mean age = 74.52, 86% female (n=50)	I: Group Tai Chi + CBT C: Group Tai Chi	CR, GS, PA, PS	CFES-I PWI-CV TMS	2, 4	8	weekly	Tai Chi: 60 min per session CBI: 60 – 90 min per session	Not reported
Huang, 2011	RCT	Community-living, I1: n=62, 54% female (n = 34) I2: n=62, 64% female (n=40) C: n=62, 56% female (n = 35) Age≥60	I1: Group CBT I2: Group CBT with Tai Chi C1: CAU	CR, PA	GFFM FES TMS ISSB-C WHOQOL-BREF-TW Falls Record Checklist	2, 5	8	weekly	60 – 90 min per session	Nurse
Huang,	RCT	Nursing homes,	I1: Group	CR, PA	GFFM		8	weekly	20 – 25 min	Nurse

2016		I1: n=27 Mean age = 77.9, 59% female (n=16) I2: n=27 Mean age = 79.1, 48% female (n=13) C: n = 26 Mean age = 81.3, 42% female (n=11)	CBT I2: Group CBT with Tai Chi C: CAU		FES Falls Record Checklist TDQ TMS MFET					
Parry, 2016	RCT	Community-living, I: n=210 Mean age = 75.8, 69% female (n=146) C: n =205 Mean age = 75.3, 70% female (n = 145)	I: Individual CBT C: TAU	CR, PA, GS	FES-I Pain rating scale Fall record HADS WHOQOL-OLD EQ-5D (5L) SF-6D SF-36 SDPI LSNS-6 DJGLS SPPB FRT HGS	2, 6, 12	8 plus 1 booster session 6 months after	weekly	45 min (with 15 min preparation time)	Health-care assistants
Tennstedt, 1998	RCT	Community-living, I: n=216 C: n=218 Mean age of participants of both group: 77.8, 89% female (n=389)	I: Group CBT C: 1 social contact control session for 120 min	CR, PE, GS, PA	MFES Author defined questions/scales SIP IAS	1.5, 6, 12	8	Twice a week	120 min	Not mentioned

Note: I, intervention; C, control; n, number; CBT, cognitive behavioural therapy; CR, cognitive restructuring; GS, goal setting; PA, promotion of activities; ABC, Activities-specific Balance Confidence (ABC) Scale; PAR-Q, Physical-Activity Readiness Questionnaire; RCT, randomised controlled trial; CAU, care-as-usual; PE, physical exercises; PS, promotion of safety; FES-I, Falls Efficacy Scale-International; FEI-AB, Falls Efficacy Scale-International Avoidance Behavior; GARS, Groningen Activity Restriction

Scale; CFES-I, the Chinese version of the Falls Efficacy Scale-International; PWI-CV, the Chinese version of the Personal Wellbeing Index; TMS, Tinetti Mobility Scale; ; GFFM, Geriatric Fear of Falling Measure; FES, Falls Efficacy Scale; ISSB-C, the Chinese version of the Inventory of Social Supportive Behaviors; WHOQOL-brief-TW, the Taiwanese version of the World Health Organisation Quality of Life-BREF; TDQ, the Taiwanese Depression Questionnaire; MFET, Micro Force Evaluation and Testing Device; TAU, treatment-as-usual; MFES; HADS, Hospital Anxiety and Depression Scale; WHOQOL-OLD, World Health Orgainization Quality of Life questionnaire-older adults module; LEQ-5D (5L), European Quality of Life-5 Dimensions, the five-level version; SF-6D, Short Form questionnaire-36 items; SDPI, Social Disconnectedness and Perceived Isolation scale; LSNS-6, Lubben Social Network; DJGLS, De Jong Gierveld Loneliness Scale; SPPB, Short Physical Performance Battery; FRT, functional reach test; HGS, handgrip strength; PE, physical exercise; MFES, Modified Falls Efficacy Scale; SIP, the abbreviated Sickness Impact Profile; IAS, the Intended Activity scale.

3.4.2.2 Intervention

The studies delivered CBT in different formats: five were group-based interventions (Tennstedt et al., 1998; Huang et al., 2011; Huang et al., 2016; Liu, 2014; Alexander et al., 2015) and two were individual interventions (Dorresteijn et al., 2016; Parry et al., 2016). Six studies adopted face-to-face contact (Tennstedt et al., 1998; Huang et al., 2011; Huang et al., 2016; Liu & Tsui, 2014; Parry et al., 2016; Alexander et al., 2015) and one study (Dorresteijn et al., 2016) used both face-to-face and telephone contact. The length of intervention ranged from 4 to 20 weeks, and the number of face-to-face sessions ranged from 3 to 9 (8 therapy sessions and 1 booster) with durations of 20 to 120 minutes.

One study (Parry et al., 2016) developed the study protocol through interviews with people aged > 60 with a significant fear of falling (Fall Efficacy Scale – International, (FES-I) score > 23) (Yardley et al., 2005). Six studies (Tennstedt et al., 1998; Huang et al., 2011; Huang et al., 2016; Liu & Tsui, 2014; Alexander et al., 2015; Dorresteijn et al., 2016) referred to the protocol of a program titled "A Matter of Balance" that was originally developed to reduce the fear of falling among older adults (Tennstedt et al., 1998). The main themes of the CBT interventions were to improve self-perceived balance efficacy and to change attitudes and maladaptive beliefs about the consequences of falls. Core components of the CBT interventions for reducing fear of falling included cognitive restructuring, personal goal setting, and promotion of activities. The CBT interventions were delivered by nurses in three studies (Dorresteijn et al., 2016; Huang et al., 2011; Huang et al., 2016), by health care assistants in one study (Parry et al., 2016), by therapists with an unknown background in two studies (Liu & Tsui, 2014; Tennstedt et al., 1998), and by graduates of health professions (occupational therapist, physical therapist, and athletic training) in one study (Alexander et al., 2015).

3.4.2.3 Comparisons

Four studies (Dorresteijn et al., 2016; Liu & Tsui, 2014; Parry et al., 2016; Tennstedt et al., 1998) comprised two intervention arms. Dorresteiijn et al. (2016) compared CBT with care-as-usual, Parry et al. (2016) compared CBT with treatment-as-usual, Tennstedt et al. (1998) compared CBT with an attention-placebo control (social control group), and Liu and Tsui (2014) compared the combined use of CBT and Tai Chi with Tai Chi alone. Two studies (Huang et al., 2011; Huang et al., 2016) were three-arm trials in which CBT was compared with care-as-usual and CBT with Tai Chi. Alexander et al. (2015) used a pre- and post-treatment design. Among the six studies that included a follow-up assessment, the mean follow-up period from immediate post-intervention to final measurement was 9.00±4.12 months, ranging from 4 to 12 months.

3.4.2.4 Outcomes

The treatment effects of fear of falling were assessed by the Activities-specific Balance Confidence scale (Powell & Meyers, 1995) in one study (Alexander et al., 2015), and the remaining six studies adopted the FES (Tinetti et al., 1990) (including the FES-I) (Yardley et al., 2005), the Chinese version of the Falls Efficacy Scale-International (CFES-I) (Zhang, Ishikawa-Takata, Yamazaki, Morita & Ohta, 2006) , and a modified version of the Falls Efficacy Scale (MFES) (Tennstedt et al., 1998). Balance was assessed in four studies, three of which (Liu & Tsui, 2014; Huang et al., 2011; Huang et al., 2016) used the Tinetti Mobility Scale (TMS) (Tinetti, Williams, & Mayewski, 1986) and one (Parry et al., 2016) used the functional reach test.

3.4.2.5 Adverse events

None of the studies reported any adverse events.

3.4.3 Methodological quality

Table 3.2 summarizes the methodological quality of the RCTs. The mean PEDro (Maher et al., 2003) score was 6.67±1.51, representing high methodological quality overall. The most common shortcomings of the included studies were >15% follow-up measurement and blinding of subjects and therapists. Assessor blinding was achieved in all of the studies except those by Parry et al. (2016) and Tennstedt et al. (1998). The shortcomings highlight that the study designs were limited by the feasibility of blinding of subjects and therapists and high attrition rates among the clinical trials with follow-up assessments. All of the studies adhered to random allocation, baseline comparability, intention-to-treat analysis, and between-groups comparison.

Table 3.2 Methodological quality (Physical Therapy Evidence Database (PEDro) scores)

	Dorrestejin, 2016	Liu, 2014	Huang, 2011	Huang, 2016	Parry, 2016	Tennstedt, 1998
Eligibility*	Y	Y	Y	Y	Y	Y
Random allocation	Y	Y	Y	Y	Y	Y
Allocation concealment	Y	Y	Y	Y	Y	X
Similar baseline	Y	Y	Y	Y	Y	Y
Subject blinding	X	X	X	X	X	X
Therapist blinding	X	X	X	X	X	X
Assessor blinding	Y	Y	Y	Y	X	X
≥85% follow-up measurement	X	X	Y	Y	X	X
Intention-to-treat analysis	Y	Y	Y	Y	Y	Y
Between-group comparison of outcome measures	Y	Y	Y	Y	Y	Y
Point estimates and variability of outcome measures	Y	Y	Y	Y	Y	X
Total score	7	7	8	8	6	4

*Item not included in quality assessment

3.4.4 Quantitative data analyses

3.4.4.1 Within-group effect size

3.4.4.1.1 Fear of falling

Our analysis (Figure 3.2) revealed a significant ($p<0.001$) but small effect size (Hedges' g) point estimate of 0.38 for the immediate effect of CBT on fear of falling (n=5) (Alexander et al., 2015; Dorresteijn et al., 2016; Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) (95% CI 0.29–0.48) in the random effects model, as there was significant heterogeneity (I^2=62%, p=0.03). We found a significant (p=0.001) small effect size point estimate of 0.42 for the retention effect on fear of falling (n=4) (Dorresteijn et al., 2016; Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) (95% confidence interval (CI) 0.31–0.52) in the random effects model, as there was significant heterogeneity (I^2=75%, p=0.006).

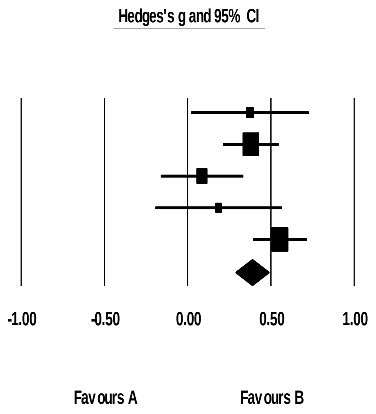
3.4.4.1.2 Balance performance

Our analysis of three studies (Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) revealed an insignificant (p=0.58) small effect size point estimate of -0.10 for the immediate effect of CBT intervention on balance (95% CI -0.44–0.25) in the random effects model, as there was significant heterogeneity (I^2=81%, p=0.004). Our analysis also showed an insignificant (p=0.99) small effect size point estimate of -0.004 for the retention effect on balance fear of falling (n=3) (Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) (95% CI -0.56–0.55) in the random effects model, as there was significant heterogeneity (I^2=92%, p<0.001).

Figure 3.2 Meta-analysis and forest plots of (A) 5 studies using CBT for overall effects on fear of falling immediately after the interventions ended, (B) 4 studies using CBT for overall effects on fear of falling at the last follow-up; (C) 3 studies using CBT for overall effects on balance immediately after the interventions ended; and (D) 3 stuides using CBT for overall effects on balance at the last follow-up.

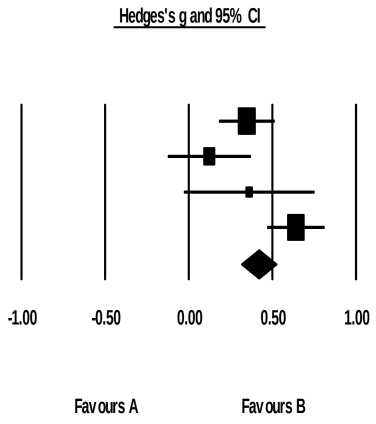
A. Fear of falling, overall immediate effects

Study name	Outcome	Statistics for each study						
		Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Alexander et al., 2015	Fear of falling	0.374	0.181	0.033	0.019	0.730	2.063	0.039
Dorresteijn et al., 2016	Fear of falling	0.380	0.087	0.008	0.210	0.550	4.376	0.000
Huang et al., 2011	Fear of falling	0.086	0.128	0.016	-0.164	0.337	0.677	0.498
Huang et al., 2016	Fear of falling	0.186	0.195	0.038	-0.197	0.569	0.950	0.342
Parry et al, 2016	Fear of falling	0.554	0.084	0.007	0.390	0.717	6.630	0.000
		0.384	0.050	0.003	0.285	0.483	7.624	0.000



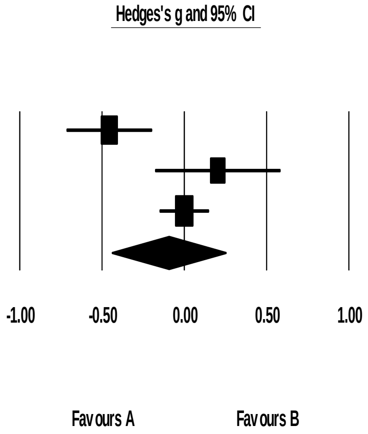
B. Fear of falling, overall retention effects

Study name	Outcome	Statistics for each study						
		Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Dorresteijn et al., 2016	Fear of falling	0.347	0.086	0.007	0.178	0.516	4.024	0.000
Huang et al., 2011	Fear of falling	0.123	0.128	0.016	-0.128	0.374	0.961	0.337
Huang et al., 2016	Fear of falling	0.362	0.200	0.040	-0.031	0.754	1.806	0.071
Parry et al, 2016	Fear of falling	0.641	0.089	0.008	0.466	0.815	7.201	0.000
		0.416	0.054	0.003	0.310	0.521	7.739	0.000



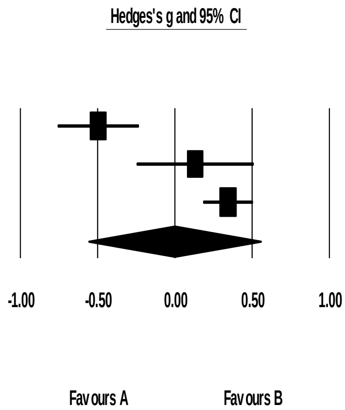
C. Balance, overall immediate effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
			Statistics for each study						
Huang et al, 2011	CBT	balance	-0.456	0.134	0.018	-0.718	-0.193	-3.398	0.001
Huang et al, 2016	CBT	balance	0.204	0.196	0.038	-0.180	0.587	1.039	0.299
Parry et al, 2016	CBT	balance	0.000	0.078	0.006	-0.152	0.152	0.000	1.000
			-0.097	0.176	0.031	-0.443	0.248	-0.552	0.581



D. Balance, overall retention effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
			Statistics for each study						
Huang et al, 2011	CBT	balance	-0.496	0.135	0.018	-0.761	-0.231	-3.666	0.000
Huang et al, 2016	CBT	balance	0.131	0.195	0.038	-0.250	0.513	0.675	0.500
Parry et al, 2016	CBT	balance	0.344	0.083	0.007	0.181	0.508	4.131	0.000
			-0.004	0.285	0.081	-0.562	0.554	-0.015	0.988



Note: CI, confidence interval

3.4.4.2 Between-groups effects of CBT versus control groups

3.4.4.2.1 Fear of falling

Figure 3.3 summarizes the between-groups effects of CBT compared with control conditions. For the immediate effect following CBT intervention, our analysis of five studies (Dorresteijn et al., 2016; Liu & Tsui, 2014; Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) revealed a significant ($p<0.001$) small effect size point estimate of 0.33 in favor of CBT compared with control for fear of falling (95% CI 0.21–0.46), based on a fixed effects model as no significant heterogeneity was found ($I^2=0\%$, $p=0.793$). Our analysis (n=5) showed a significant ($p<0.001$) small effect size point estimate of 0.30 (95% CI 0.17–0.43) for the retention effect in favor of CBT compared with control on fear of falling (n=5) in the fixed effects model, as there was no significant heterogeneity ($I^2=0\%$, $p=0.625$).

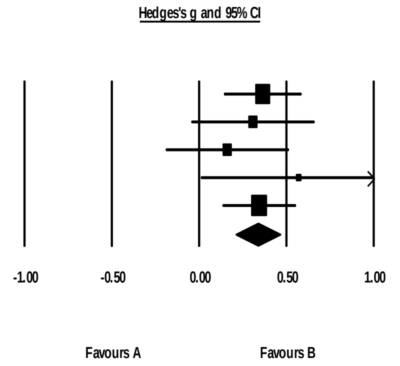
3.4.4.2.2 Balance performance

For the immediate effect of CBT intervention on balance, our analysis of four studies (Liu & Tsui, 2014; Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) indicated an insignificant ($p=0.058$) small effect size point estimate of 0.15 (95% CI -0.01–0.31) in favor of CBT compared with control, based on a fixed effects model as there was no significant heterogeneity ($I^2=21\%$, $p=0.283$). For the retention effect, our analysis of four studies (Liu & Tsui, 2014; Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) showed a significant ($p=0.005$) small effect size point estimate of 0.23 (95% CI 0.07–0.39) for CBT compared with control, based on a fixed effects model as there was no significant heterogeneity ($I^2=0\%$, $p=0.59$).

Figure 3.3 Meta-analysis and forest plots of (A) 5 studies using CBT for relative efficacy on fear of falling immediately after the interventions ended, (B) 5 studies using CBT for relative efficacy on fear of falling at the last follow-up; (C) 3 studies using CBT for relative efficacy on balance immediately after the interventions ended; and (D) 3 stuides using CBT for relative efficacy on balance at the last follow-up.

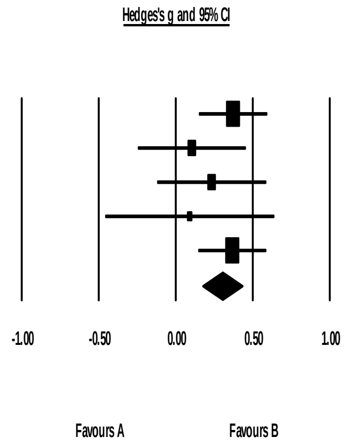
A. Fear of falling, relative efficacy, immediate effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Dorresteijn et al., 2016	CBT vs. Care as usual	Fear of falling	0.364	0.114	0.013	0.140	0.589	3.186	0.001
Liu et al., 2014	CBT + Tai Chi vs. Tai Chi	Fear of falling	0.309	0.181	0.033	-0.047	0.664	1.702	0.089
Huang et al., 2011	CBT vs. Care as usual	Fear of falling	0.162	0.181	0.033	-0.193	0.516	0.893	0.372
Huang et al., 2016	CBT vs. Care as usual	Fear of falling	0.571	0.287	0.082	0.008	1.133	1.988	0.047
Parry et al, 2016	CBT vs Care as usual	Fear of falling	0.344	0.109	0.012	0.131	0.557	3.170	0.002
			0.334	0.065	0.004	0.206	0.462	5.114	0.000



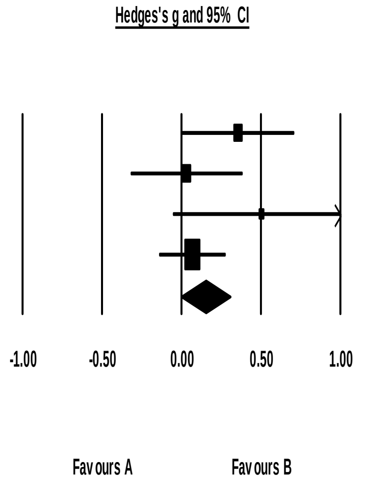
B. Fear of falling, relative efficacy, retention effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Dorresteijn et al., 2016	CBT vs. Care as usual	Fear of falling	0.372	0.114	0.013	0.148	0.597	3.254	0.001
Liu et al., 2014	CBT + Tai Chi vs. Tai Chi	Fear of falling	0.105	0.180	0.033	-0.249	0.458	0.581	0.561
Huang et al., 2011	CBT vs. Care as usual	Fear of falling	0.233	0.182	0.033	-0.123	0.590	1.282	0.200
Huang et al., 2016	CBT vs. Care as usual	Fear of falling	0.091	0.281	0.079	-0.461	0.642	0.323	0.747
Parry et al, 2016	CBT vs. Care as usual	Fear of falling	0.367	0.114	0.013	0.144	0.590	3.229	0.001
			0.300	0.066	0.004	0.170	0.430	4.526	0.000



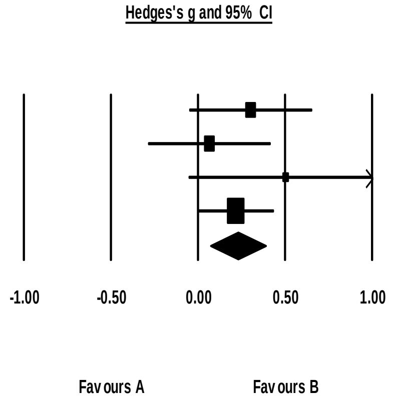
C. Balance, relative efficacy, immediate effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Liu et al., 2014	CBT + Tai Chi vs. Tai Chi	balance	0.356	0.182	0.033	0.000	0.712	1.960	0.050
Huang et al., 2011	CBT vs. Care as usua	balance	0.033	0.181	0.033	-0.322	0.387	0.180	0.857
Huang et al., 2016	CBT vs. Care as usua	balance	0.504	0.286	0.082	-0.056	1.064	1.763	0.078
Parry et al, 2016	CBT vs. Care as usua	balance	0.069	0.108	0.012	-0.143	0.280	0.638	0.523
			0.150	0.079	0.006	-0.005	0.305	1.893	0.058



D. Balance, relative efficacy, retention effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Liu et al., 2014	CBT + Tai Chi vs. Tai Chi	balance	0.303	0.181	0.033	-0.053	0.658	1.670	0.095
Huang et al., 2011	CBT vs. Care as usua	balance	0.066	0.181	0.033	-0.289	0.420	0.363	0.716
Huang et al., 2016	CBT vs. Care as usua	balance	0.504	0.286	0.082	-0.056	1.064	1.763	0.078
Parry et al, 2016	CBT vs. Care as usua	balance	0.217	0.113	0.013	-0.005	0.438	1.919	0.055
			0.227	0.081	0.007	0.068	0.386	2.792	0.005



3.4.4.3 Subgroup analysis

3.4.4.3.1 Fear of falling

For the immediate effect, our subgroup analysis (Table 3.3) based on the treatment delivery format (individual vs. group-based intervention) revealed a significant difference for fear of falling (Q=5.082, df=1, p=0.024). Group-based interventions showed an insignificant (p=0.05) small effect size point estimate of 0.18 (95% CI 0.00–0.36), revealing a weaker effect than individual based interventions, which displayed a significant (p<0.001) small to moderate effect size point estimate of 0.47 (95% CI 0.35–0.59). For the retention effect, our subgroup analysis revealed an insignificant difference for fear of falling (Q=2.708, df=1, p=0.10).

3.4.4.3.2 Balance performance

We were unable to conduct the subgroup analysis for balance as only one study (Parry et al., 2016) provided an individual CBT intervention.

Table 3.3 Subgroup analyses

A. Subgroup analysis, immediate effects

Subgroup analysis		Measure	N	g	p-value	95%CI	I^2	Q-statistics
Delivery format	Individual	Fear of falling	2	0.47	0.000	0.35-0.59	52.1	2.09
	Group	Fear of falling	3	0.18	0.05	0.00-0.36	0.000	1.68
	Total between				0.024			5.082

B. Subgroup analysis, retention effects

Subgroup analysis		Measure	N	g	p-value	95%CI	I^2	Q-statistics
Delivery format	Individual	Fear of falling	2	0.49	0.000	0.37-0.61	82.2	5.61
	Group	Fear of falling	2	0.19	0.08	-0.02-0.40	99.6	1.01
	Total between				0.10			2.708

Note: CI = confidence interval; N = number of studies.

3.4.4.4 Sensitivity analysis

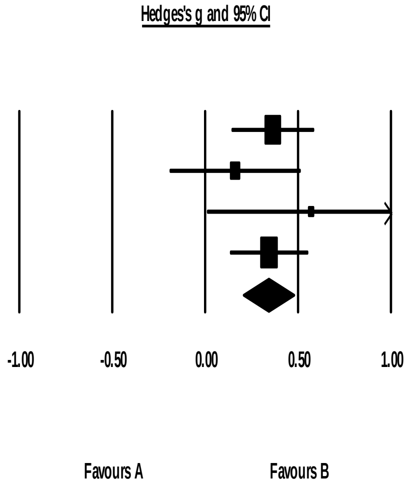
All of the studies included in the between-groups effect size analysis were RCTs with PEDro scores of six or above, thus we performed the sensitivity analysis after removing Liu and Tsui (2014) study (PEDro score=7), which compared exercise with and without CBT. For fear of falling, we found significantly larger effect size point estimates of 0.34 (from g=0.33) (436 participants, fixed effects, 95% CI 0.20–0.48, $p < 0.001$, I^2=0%) and 0.33 (from g=0.30) (412 participants, random effects, 95% CI 0.19–0.47, $p<0.001$, I^2=0%) immediately after the intervention and at follow-up, respectively (Figure 3.4). For balance performance, our sensitivity analysis revealed insignificant smaller effect size point estimates of

0.10 (from g = 0.15) (264 participants, fixed effects, 95% CI -0.07–0.27, p=0.249, $I^{2=}$9%) and 0.21 (from g=0.23) (248 participants, fixed effects, 95% CI 0.03–0.39, p=0.022, I^2=0%) immediately after the intervention and at follow-up, respectively.

Figure 3.4 Sensitivity analysis of (A) 4 studies using CBT for relative efficacy on fear of falling immediately after the interventions ended, (B) 4 studies using CBT for relative efficacy on fear of falling at the last follow-up; (C) 3 studies using CBT for relative efficacy on balance immediately after the interventions ended; and (D) 3 stuides using CBT for relative efficacy on balance at the last follow-up.

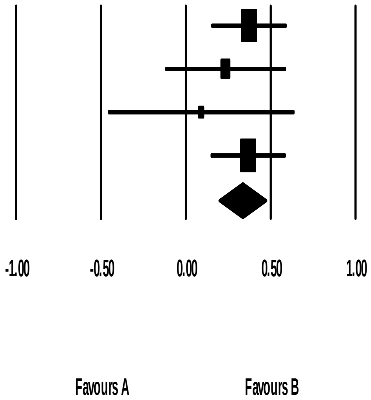
A. Fear of falling, relative efficacy, immediate effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Dorresteijn et al., 2016	CBT vs. Care as usual	Fear of falling	0.364	0.114	0.013	0.140	0.589	3.186	0.001
Huang et al., 2011	CBT vs. Care as usual	Fear of falling	0.162	0.181	0.033	-0.193	0.516	0.893	0.372
Huang et al., 2016	CBT vs. Care as usual	Fear of falling	0.571	0.287	0.082	0.008	1.133	1.988	0.047
Parry et al, 2016	CBT vs Care as usual	Fear of falling	0.344	0.109	0.012	0.131	0.557	3.170	0.002
			0.338	0.070	0.005	0.201	0.475	4.825	0.000



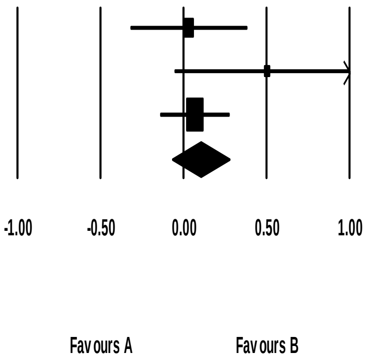
B. Fear of falling, relative efficacy, retention effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Dorresteijn et al., 2016	CBT vs. Care as usual	Fear of falling	0.372	0.114	0.013	0.148	0.597	3.254	0.001
Huang et al., 2011	CBT vs. Care as usual	Fear of falling	0.233	0.182	0.033	-0.123	0.590	1.282	0.200
Huang et al., 2016	CBT vs. Care as usual	Fear of falling	0.091	0.281	0.079	-0.461	0.642	0.323	0.747
Parry et al, 2016	CBT vs. Care as usual	Fear of falling	0.367	0.114	0.013	0.144	0.590	3.229	0.001
			0.331	0.071	0.005	0.191	0.471	4.638	0.000



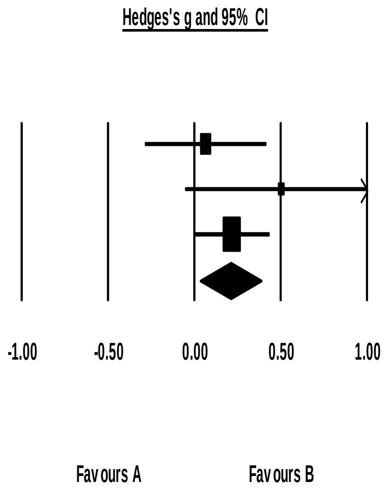
C. Balance, relative efficacy, immediate effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Huang et al., 2011	CBT vs. Care as us	balance	0.033	0.181	0.033	-0.322	0.387	0.180	0.857
Huang et al., 2016	CBT vs. Care as us	balance	0.504	0.286	0.082	-0.056	1.064	1.763	0.078
Parry et al, 2016	CBT vs. Care as us	balance	0.069	0.108	0.012	-0.143	0.280	0.638	0.523
			0.102	0.088	0.008	-0.071	0.274	1.153	0.249



D. Balance, relative efficacy, retention effects

Study name	Comparison	Outcome	Hedges's g	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Huang et al., 2011	CBT vs. Care as usual	balance	0.066	0.181	0.033	-0.289	0.420	0.363	0.716
Huang et al., 2016	CBT vs. Care as usual	balance	0.504	0.286	0.082	-0.056	1.064	1.763	0.078
Parry et al, 2016	CBT vs. Care as usual	balance	0.217	0.113	0.013	-0.005	0.438	1.919	0.055
			0.208	0.091	0.008	0.030	0.386	2.286	0.022

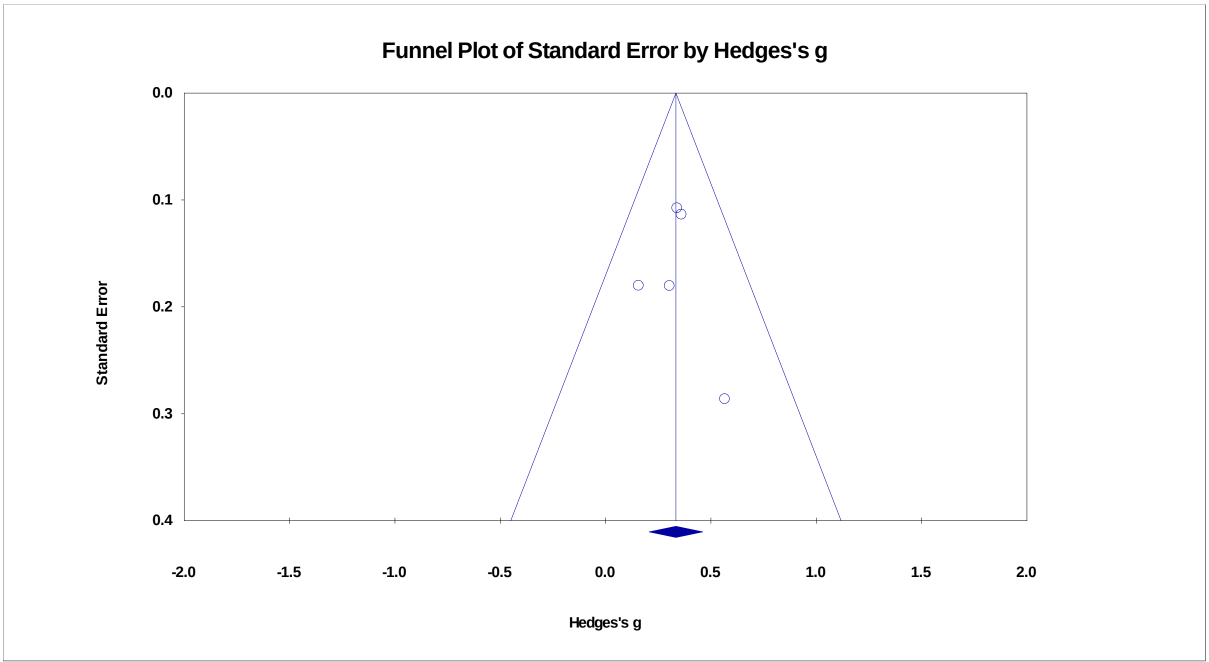


3.4.4.5 Publication bias

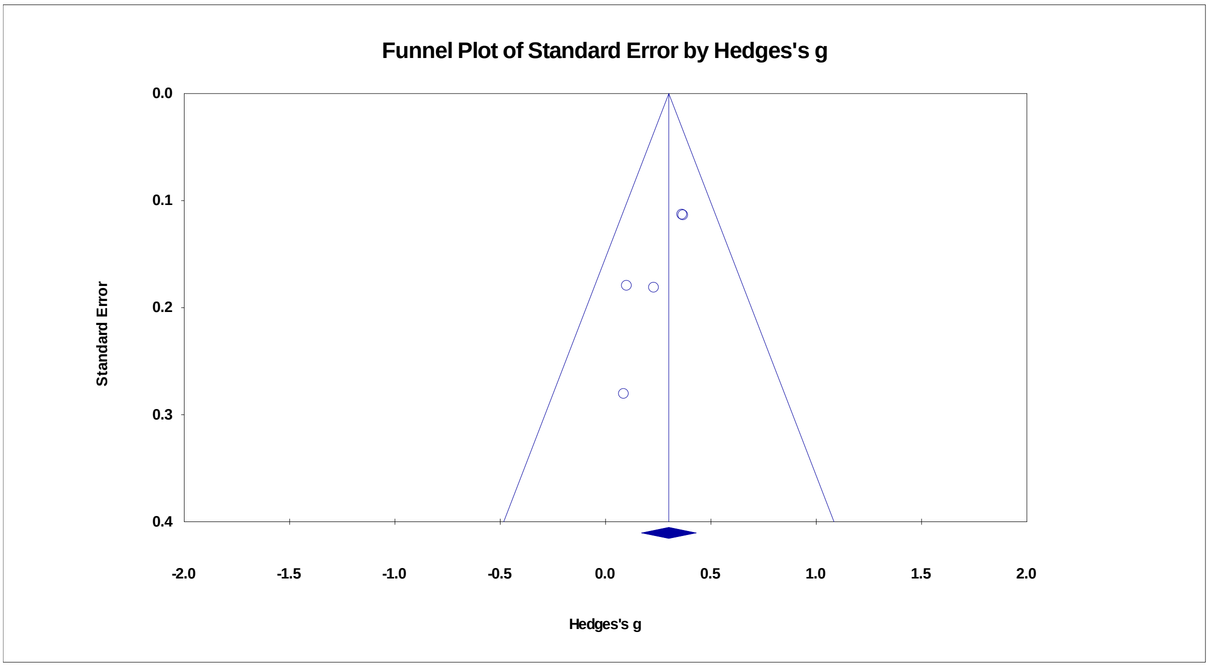
Although the funnel plots (Figure 3.5) did not indicate a publication bias, the Egger's tests (Table 3.4) suggested a possible publication bias across studies comparing CBT and control conditions on the retention effects of fear of falling. However, only a minimal change of less than 0.001 of the mean effect size resulted after adjustment using the trim and fill procedure (from g=0.300 to g=0.30033).

Figure 3.5 Funnel plot of hedges g against standard errors of (A) 5 studies using CBT for relative efficacy on fear of falling immediately after the interventions ended, (B) 4 studies using CBT for relative efficacy on fear of falling at the last follow-up; (C) 4 studies using CBT for relative efficacy on balance immediately after the interventions ended; and (D) 4 stuides using CBT for relative efficacy on balance at the last follow-up.

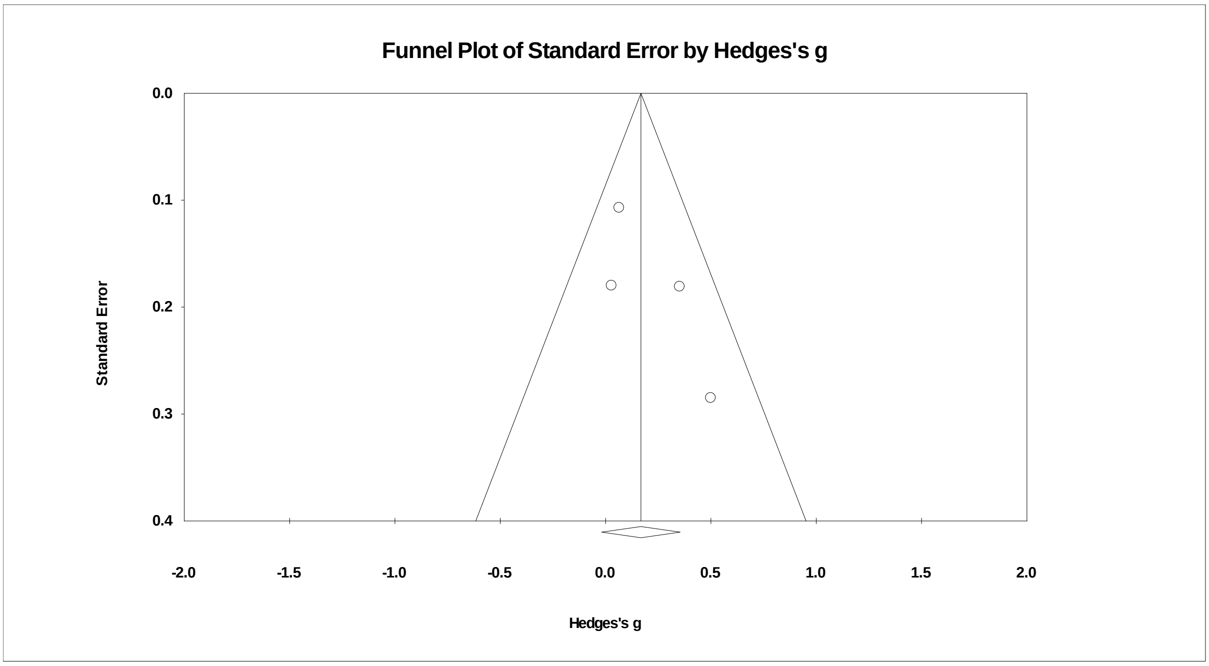
A. Fear of falling, relative efficacy, immediate effects



B. Fear of falling, relative efficacy, retention effects



C. Balance, relative efficacy, immediate effects



D. Balance, relative efficacy, retention effects

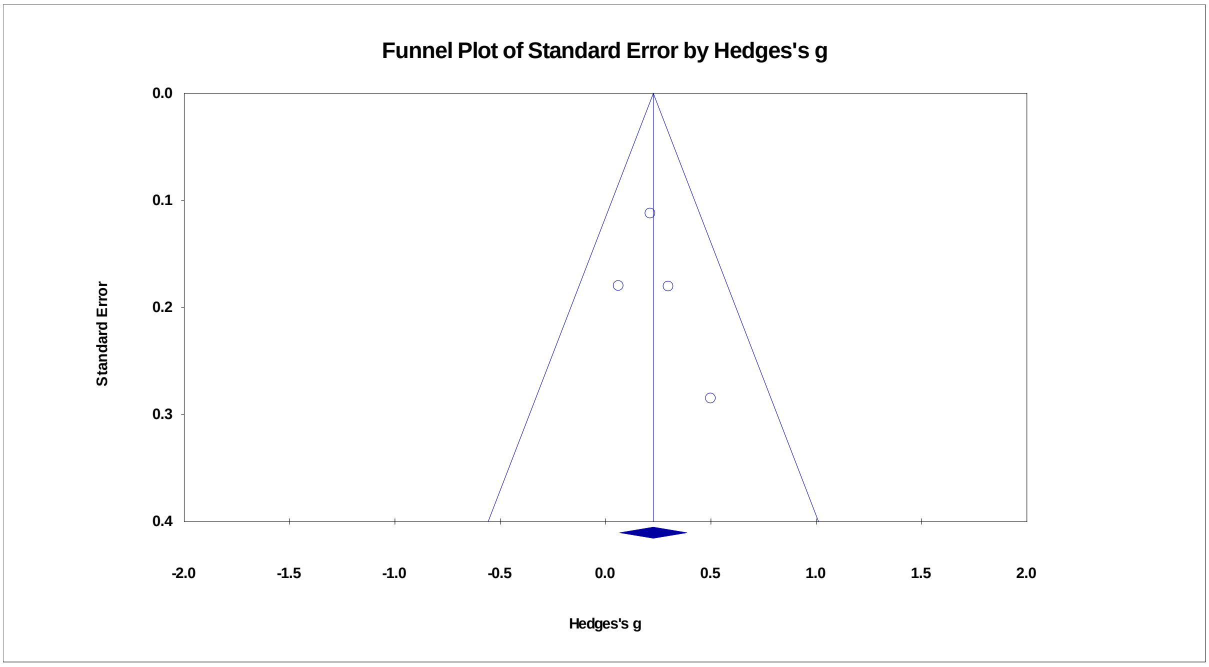


Table 3.4 Egger's tests

Measure		Bias coefficient	95%CI	p-value
Fear of falling	Immediate	0.18	-3.19 – 3.54	0.88
	Retention	-2.13	-4.10 - -0.17	0.04*
Balance	Immediate	2.22	-3.71 – 8.15	0.25
	Retention	1.05	-4.89 – 7.00	0.53

p<0.05

3.5 Discussion

We conducted a systematic review of the literature on CBT interventions for reducing fear of falling or improving balance self-efficacy and improving balance among older adults. Our results suggest that CBT with components of cognitive restructuring, promotion of activities, and goal setting, is generally effective in reducing fear of falling immediately and the effect is retained over time. Compared with control conditions, CBT is also more effective in reducing fear of falling at post-intervention and follow-up assessment. For the effects on enhancing balance, CBT did not demonstrate overall effects at post-intervention and follow-up assessment. It also shows no relative efficacy when compared with control condition at post-intervention. However, it did demonstrate relative efficacy in enhancing balance at follow-up assessment when compared with control conditions.

This is the first meta-analysis to demonstrate the positive effects of CBT in reducing fear of falling or improving balance self-efficacy with immediate and retention effects, and in enhancing balance performance at follow-up. Our findings demonstrate that the immediate effects of CBT on reducing fear of falling (Hedges' g 0.33, 95% CI 0.21–0.46) are comparable to the use of physical training alone found in the meta-analysis by Kumar (2016) (SMD 0.37, 95% CI 0.18–0.56). The retention effect of CBT on reducing fear of falling is superior to the use of physical training alone (SMD 0.17, 95% CI 95% -0.05–0.38) and the effect is statistically significant (Hedges' g 0.42, CI 95%, 0.31–0.52).

The majority of the included studies (Dorresteijn et al., 2016; Huang et al., 2011; Huang et al., 2016; Parry et al., 2016) compared the use of CBT alone with a control condition, and only Liu and Tsui (2014) compared CBT with and without Tai Chi. The positive effects of Tai Chi in reducing fear of falling and improving balance self-efficacy have been demonstrated in several studies (Li, Fisher, Harmer, & McAuley, 2005; Zhang et al., 2006; Sattin, Easley, Wolf, Chen, & Kutner, 2005). Although our sensitivity analysis did not reveal the superiority of combined use of CBT with Tai Chi, it highlighted the need for future trials to examine the efficacy of CBT as an adjunct therapy to customary physical training for reducing fear of falling and enhancing balance.

Our findings also revealed unclear results regarding the effects of CBT on enhancing balance. Our analysis did not demonstrate a statistically significant effect of CBT on enhancing balance immediately after the intervention, although the effect was observed at follow-up. One possible explanation is that one of the objectives of CBT is to safely increase participants' levels of daily activities and physical exercise. Thus, the improvement in balance could not be observed immediately after the intervention but only after a certain period of time after the participants had increased their levels of daily activities and physical exercise.

Another important factor implicated in studies on the fear of falling is fear avoidance behavior, which refers to the behavioral translation of impaired balance self-efficacy. People with fear of falling could thus be further delineated into those with or without such avoidance behavior (Howland et al., 1998; Tinetti et al., 1994; Liu et al., 2015). In view of the potential relationships between fear avoidance behavior, balance, and falls (Delbaere, Crombez, Vanderstraeten, Willems, & Camber, 2004), it is crucial to examine interventions that could reduce fear of falling or improve balance self-efficacy, and reduce fear avoidance behavior. However, only one of the included studies (Dorresteijn et al., 2016) examined the effects of CBT on this crucial aspect, with significant reductions revealed at 5-month follow-up (adjusted mean difference=-2.38, 95% CI $-\infty - -1.12$; p=0.001) and 12-month follow-up (adjusted mean difference=-2.67, 95% CI $-\infty - -1.37$; p=0.001). We recommended that future RCTs with larger sample sizes should investigate this crucial aspect.

3.6 Limitations

Although the synthesized evidence is encouraging, this study has several limitations. At the outcome level, the variance in participant characteristics across studies might have influenced the treatment outcomes. For example, Liu and Tsui (2014) study only recruited participants who had experienced a fall before the study began, while the other studies recruited participants with or without a history of falls. Dorresteijn et al. (2016) recruited participants with at least some concerns about falls and associated activity avoidance, but other studies did not consider this in their inclusion criteria. Furthermore, our review only included studies with older adults and excluded those with specific medical conditions or disorders, thus the results may not be generalizable to frail older adults with chronic illness.

At the study level, as with other similar types of clinical trials, all of the included studies inevitably had a high risk of bias stemming from the lack of blinding of participants and therapists. In addition, two studies had a high risk of bias stemming from incomplete outcome measure data (Dorresteijn et al. (2016) attrition=21% and 25% at post-intervention and last follow-up assessment, respectively; Liu and Tsui (2014) attrition=19% and 21% at post-intervention and last follow-up assessment, respectively) and one study (Parry et al., 2016) with a high risk of bias stemming from a lack of blinding of assessors was included in the meta-analysis.

At the review level, the key search words for intervention were "cognitive behavioral therapy" or "CBT"; therefore, we may have missed studies that adopted a cognitive-behavioral approach without explicitly stating it in the title and abstract. Our literature search was also limited to databases and publications in English peer-reviewed journals, which may have led to some studies being omitted. Although this study confirmed the efficacy of CBT compared with control condition, our subgroup analysis cannot conclude whether the two principal delivery formats, individual versus group, achieved the same magnitude of treatment effects. We are also unable to provide recommendations on the optimal length and contents of CBT interventions due to the limited literature available for review.

3.7 Conclusion

This study is the first systematic review and meta-analysis of the overall effects and relative efficacy of CBT interventions in reducing fear of falling and improving balance among older adults. Despite the small number of studies, our results suggest that CBT interventions have significant immediate and retention effects on reducing fear of falling, and retention effects on enhancing balance among older adults. Our findings are consistent with the previous systematic review, which showed that CBT interventions delivered in either individual or group formats are beneficial for reducing the fear of falling with effects that are comparable to those of physical training. The magnitude of the therapeutic effects and cost benefits of CBT suggest that it could be used as a first-line clinical intervention for older adults with fear of falling.

In view of the evidence synthesized in this study, future research on the use of CBT in reducing fear of falling should include other associated aspects such as fear avoidance behavior and fall risks. In addition, no study has directly compared the effects of group-based and individual CBT, and few studies have compared CBT and CBT with physical training, and hence future studies to compare the effects of individual and group-based CBT and the use of CBT as an adjunct therapy to reduce fear of falling are warranted.

Chapter 4

The predictive roles of fear of falling, fear avoidance behavior and balance in community reintegration of community-dwelling people with stroke

This chapter has been published as below:

- Liu TW, Ng SS, Kwong PW, Ng GY. Fear avoidance behavior, not walking endurance, predicts the community reintegration of community-dwelling stroke survivors. *Archives of Physical Medicine and Rehabilitation* 2015, 96: 1684-90. (Appendix 4.1)

This chapter has been presented in the below conference.

- Liu TW, Ng SS, Kwong PW, Ng GY. Performance of muscle functions, functional mobility and postural stability in stroke survivors with impaired subjective balance confidence. The 9th Pan-Pacific Conference on Rehabilitation cum 21st Annual Congress of Gerontology, Hong Kong, November 29-30, 2014.

- Liu TW, Ng SS, Kwong PW, Ng GY. Fear-avoidance behavior is a good predictor of community integration in patients with stroke. The U.S. – Hong Kong 2015 Conference: Putting Aging Research and Clinical Practice in Cultural Context, Hong Kong, Jan 5-6, 2015.

- Liu TW, Ng SS, Ng GY. Correlates of fear avoidance behaviours among community-dwelling seniors with chronic stroke. The 12th International Symposium on Healthy Aging "Wellness and Longevity: From Science to Service" , Hong Kong, 11-12 March 2017

4.1 Abstract

"Fear avoidance behavior" refers to the restriction of activities induced by a fear of falling (Landers et al., 2011). Although this self-protective measure is intended to prevent falls, excessive fear avoidance behavior could limit activities, restrict social participation and ultimately reduce community reintegration. However, the relationship between fear avoidance behavior and community integration remains uncertain. This study aimed to investigate the relative contributions of walking endurance, subjective balance confidence and fear avoidance behavior to the community reintegration of community-dwelling people with stroke.

Fifty-seven community-dwelling people with stroke aged 50 years or above were recruited. For all participants, the levels of community reintegration and fear avoidance behavior were assessed using the Chinese versions of Community Integration Measure (CIM-C) and the Survey of Activities and Fear of Falling in the Elderly (SAFE-C), respectively. Walking endurance was measured using the distance covered during the 6-Minute Walk test (6MWT), while subjective balance confidence was measured using the Chinese version of the Activities-specific Balance Confidence (ABC-C) scale.

Our correlation analyses revealed that the SAFE-C score, a measure of fear avoidance behavior, exhibited the strongest significant negative correlation with the CIM-C scores among all tested variables. Our regression analyses also revealed that the walking endurance and subjective balance confidence were not significant predictors of CIM-C scores. Our final regression model based on the number of falls during the previous 6 months, Chinese version of the Geriatric Depression Scale (GDS-C) scores, distance covered during the 6MWT, ABC-C score and SAFE-C score predicted 49.7% of the variance in the CIM-C scores.

Our findings suggest that fear avoidance behavior was the only significant predictor of community reintegration in a population of community-dwelling people with stroke, accounting for 11.6% of the variance in this outcome. By contrast, walking endurance and subjective balance confidence were not predictors of community reintegration. Future studies addressing fear avoidance behavior are clearly warranted to improve the level of community reintegration during stroke rehabilitation.

4.2 Introduction

Previous chapter (chapter 3) has synthesized and revealed that cognitive behavioral therapy (CBT) has comparable treatment effects with physical training in reducing fear of falling and improving balance performance among community-dwelling older adults. It sheds the light that CBT could be a potential treatment alternative of reducing fear of falling and improving balance performance among the stroke population.

Reintegration into community is the ultimate aim of stroke rehabilitation. However, the adoption of CBT mainly focuses on reducing fear of falling and fear avoidance behavior, and it does not directly effect on the community reintegration of the stroke population. To hypothesize that the use of CBT could improve the level of community reintegration, we should fill up the research gap regarding the roles the fear of falling and fear avoidance behavior play in community reintegration among the stroke population.

Although previous study had identified that fear of falling played an important predictive role in community reintegration of people with stroke (Carter et al, 2000; Pang et al., 2007), the role of fear avoidance behavior in community reintegration of people with stroke has not been investigated. We expected that with the understanding of the role of fear avoidance behavior in community reintegration, it could help us bridge up the knowledge gap that the combined use of CBT and physical training is a potential treatment alternative to improve the community reintegration of people with stroke with fear of falling and fear avoidance behavior.

Identifying prognostic predictors were important for planning rehabilitative treatment for people with stroke. Previous studies identified several predictors for community reintegration of community-dwelling people with stroke (Carter et al, 2000; Pang et al., 2007). In Carter et al. (2000) of 246 community-dwelling people with stroke, depression (Odds Ratio (OR) 15.2, 95% confidence interval (CI) 2.6-21.2) and functional mobility (OR 15.2, 95% CI 6.4-36.2) were 2 important predictors to community reintegration as measured by the Return to Normal Life Index (RNLI) (Wood-Dauphinee et al, 1988). In another local study of 63 community-dwelling people with stroke, Pang et al. (2007) predictive model reported that balance (R^2=0.10, p=0.03) and balance confidence (R^2=0.07, p=0.01) could account for 10% and 7% respectively of the variance of community reintegration as measured by the RNLI.

Another important predictor of community reintegration after stroke is the subjective balance confidence questionnaire (Powell & Meyers, 1995). The Activities-specific Balance Confidence (ABC) scale is based on the theoretical ground of Bandura's theory of efficacy self-perceptions (Powell & Meyers, 1995; Bandura, 1997). Previous studies revealed that the ABC scale was a stronger predictor than walking speed, walking endurance, or balance performance among people with stroke (Pang et al, 2007) and significantly correlated with level of community reintegration (Schmid et al, 2012).

Fear avoidance behavior is the behavioral translation and reflection of impaired subjective balance confidence (Landers, Durand, Powell, Dibble & Young, 2011). For community-dwelling older adults, fear avoidance behavior has been shown to be associated with fall history (r=0.33), physical frailty (r=0.49), postural control (forward end point excursion, r=0.31), and muscle performance (r=0.037 to 0.44) (Delbaere et al., 2004). In addition, fear avoidance behavior was reported to have a prevalence of up to 54% among community-dwelling older adults (Fletcher & Hirdes, 2004; Zijlstra et al., 2007a).

Although fear avoidance behavior is self-protection in preventing falls, excessive fear avoidance behavior could eventually lead to physical deconditioning and compromise one's community reintegration. The exact mechanism translating fear of falling into behavior is unclear, but it is believed to be associated with catastrophic thinking (Delbaere, Crombez, van Haastregt & Vlaeyen, 2009) that magnifies worries and negatively overstates the consequences of events (Davey &

Levy, 1998). Indeed, those with low subjective balance confidence could be further delineated as having low subjective balance confidence with or without fear avoidance behavior (Howland et al, 1998; Tinetti et al., 1994). These behavioral discrepancies highlight the importance of studying fear avoidance behavior when investigating the impact of fear of falling on community reintegration.

The role of fear avoidance behavior has been explored in community-dwelling older adults and people with other chronic illnesses (eg, Parkinson disease). For community-dwelling older adults, fear avoidance behavior was reported to be a significant independent predictor of disability in activities of daily living (β=0.097, $p<.001$) and poor lower-extremity performance (β=0.143, $p<.001$) (Deshpande et al, 2008). In another study (Rahman, Griffin, Quinn & Jahanshahi, 2011), fear avoidance behavior as measured by the Survey of Activities and Fear of Falling in the Elderly (SAFE) (Lachman et al, 1998) was found to be a significant predictor (β=0.399, p=0.0001) of the quality of life of people with Parkinson disease. However, the role of fear avoidance behavior on community reintegration has not been investigated among people with stroke.

Therefore, this study aimed to determine whether fear avoidance behavior makes an independent contribution to community reintegration; and to quantify its relative contribution to community reintegration when walking endurance and subjective balance confidence were also considered.

4.3 Methods

4.3.1 Study design

This study was a cross-sectional study.

4.3.2 Participants

Community-dwelling people with stroke were recruited from local self-help groups via poster advertisement. Participants were recruited if they aged 50 years, had a stroke at least 12 months previously, were able to understand Cantonese, were able to walk 10m with or without assistance, and were able to score 7 on the Chinese version of the Abbreviated Mental Test (AMT) (Chu, Pei, Ho & Chan, 1995). People were excluded if they had any unstable medical conditions (eg, angina pectoris) or other conditions that might hinder the progress of assessment (eg, dementia). The study protocol was approved by the ethics committee of the administering institution. The study was conducted according to the principles of the Declaration of Helsinki for human experiments. Written informed consent was obtained from all participants prior to the study (Appendix 4.2).

4.3.3 Sociodemographic data

Five types of sociodemographic data were collected during the intake interviews. They consisted of the following: (1) background characteristics, including sex, age, and living arrangements; (2) illness-related variables, including cause of stroke and years since stroke; (3) number of falls in the previous 6 months; (4) mobility related variables, including hemiplegic side, use of walking aids, and time on the timed Up and Go (TUG) test (Podsiadlo & Richardson, 1991); and (5) score on the Chinese version of the AMT (Chu et al, 1995) (an exclusion criterion).

4.3.4 Outcome measures

4.3.4.1 Level of community reintegration

Community reintegration was quantified using scores on the Chinese version of the Community Integration Measure (CIM) (Liu, Ng & Ng, 2014). The Chinese version of the CIM has 10 items with responses on a 5-point scale. The CIM (McColl et al., 2001) has been used on people with brain injury (Reistetter et al., 2005; McColl et al, 2001; Griffen et al., 2010) spinal cord injury (de Wolf et al., 2010), and stroke (Liu et al, 2014). The Chinese version of the CIM has been reported to have good internal consistency (Cronbach alpha=0.84) and good test-retest reliability (intraclass correlation coefficient [ICC]=0.84) on people with stroke (Liu et al, 2014).

4.3.4.2 Fear avoidance behavior

The extent to which activities were being avoided because of fear of falling was assessed using the Chinese version of the SAFE (Chou, Yeung & Wong, 2005). This instrument consists of 22 self-rating items on a 4-point scale. The Chinese version of the SAFE has been reported as having excellent internal consistency (Cronbach alpha=0.95) and construct validity (Rahman et al, 2011).

4.3.4.3 Subjective balance confidence

The original ABC scale was developed to assess self-perceptions of balance efficacy among older adults. It consists of 16 items related to indoor and outdoor activities, with self-ratings from 0% (no confidence) to 100% (complete confidence) on each item. The Chinese version (Mak et al., 2007) has been psychometrically tested on community-dwelling older adults and has been reported as having excellent internal consistency (Cronbach alpha=0.97), excellent test-retest reliability (ICC=0.99), and good interrater reliability (ICC=0.85).

4.3.4.4 Walking endurance

Walking endurance was assessed by the distance covered in the 6MWT, which was originally developed for people with chronic heart failure (Butland, Pang, Gross, Woodcock & Geddes, 1982; Guyatt et al, 1985). The participants walked along a 30-m straight corridor with standardized encouragements given by the assessors at 1, 3, and 5 minutes during the walk (Butland et al, 1982; Guyatt et al, 1985). If needed, standing rest was allowed, and the participant could resume walking when ready within the 6-minute period. The 6MWT distance has demonstrated excellent test-retest reliability (ICC=0.99) and construct validity for people with stroke (Eng et al, 2004).

4.3.4.5 Depressive symptoms

The Geriatric Depression Scale (GDS) containing 30 dichotomous items (yes or no) was initially developed for rating the level of depression in older adults (Yesavage et al, 1982). The GDS was translated into Chinese and psychometrically tested on people with affective disorders and has been reported to have good internal consistency (Cronbach alpha=0.89) and good test-retest reliability (ICC=0.84).

4.3.5 Statistical analysis

The data were analyzed using SPSS version 17.0.The distributions of the responses were checked for normality using the Kolmogorov-Smirnov test. The sociodemographic data were summarized by descriptive statistics, and the relations between the Chinese version of the CIM scores and the other variables were examined using Pearson correlation coefficients. To control for the sociodemographic differences, the number of falls in the previous 6 months and the GDS-C scores, partial correlation coefficients were calculated for the CIM-C scores, with the distances covered in the 6MWT and the scores from the Chinese versions of the GDS and ABC scale scores. Multiple linear regression with a forced entry method was used to determine the relative power of the independent variables for predicting the CIM scores. A confidence level of 0.05 (2 tailed) was adopted for significance testing in this study.

4.3.6 Sample size

The minimum sample size was 50 according to the thumb rule of 10 cases for each predictor variable (Field, 2009).

4.4 Results

4.4.1 Characteristics of participants

Forty men (70%) and 17 women (30%) with different types of stroke (ischemic stroke, n = 29; hemorrhagic stroke, n = 19; unknown or mixed type, n = 9) were recruited. They had a mean age of 61.14±6.66 years and an average of 8.14±4.34 years post-stroke (Table 4.1). Twenty-four suffered from left and 33 from right hemiplegia. Their mean body mass index (BMI) was 24.91±2.96. Fifty (88%) of them lived with others and 51% of the subjects required using a walking aid. They reported a mean fall frequency of 0.44±1.07 over the previous 6 months. The average TUG time was 17.02±6.83 s. The mean GDS-C score was 9.49±6.70 and the mean AMT-C score was 9.35±0.86, suggesting that a group of participants with no to mild depressive symptoms and intact cognition were examined.

Table 4.1: Characteristics of the participants (n = 57)

Characteristics	Value, mean ± SD (range)
Age	61.14±6.66 (50 – 79)
Gender, no.	
Male/Female	40/17
BMI (kg/m^2)	24.91±2.96 (18.24 - 32.24)
Living arrangement, no.	
Along/With family members/carer/friend	7/50
Cause of stroke, no.	
Ischemic	29
Hemorrhagic	19
Unknown or mixed	9
Hemiplegic side, no.	
Left/Right	24/33
Years since stroke	8.144±.34 (1 – 21.75)
No. of falls in past 6 months, no.	0.441±.07 (0 – 6)
Use of walking aids, no. (%)	
Yes/No	29/28
TUG time (s)	17.02±6.83 (4.44 – 40.86)
AMT-C scores	9.35±0.86 (7 – 10)
GDS-C scores	9.496±70 (0 – 28)
6MWT walking distance (m)	248.85±85.06 (78.75 – 452.75)
ABC-C scores	73.99±16.68 (31.25 – 100)
SAFE-C scores	12.68±12.69 (0 – 47)
CIM-C scores	44.754±.94 (29 – 50)

NOTE. Values are mean, SD (range) or n. "C" indicates the Chinese versions of the following: AMT, GDS, ABC, SAFE, and CIM.

4.4.2 Relations between CIM scores and other variables

The mean CIM score was 44.75±4.94, indicating a high level of community reintegration. There were no significant differences in this respect between men and women (t_{55}=0.225), left and right hemiparesis (t_{55}=0.534), needed a walking aid or not (t_{55}=0.047), living alone or with others (t_{55}=0.139), or the types of stroke ($F_{2,54}$=0.551).

There was no significant correlation between the CIM-C scores and age, gender, BMI, living arrangement, chronicity of stroke, affected side, use of walking aids, TUG time or AMT-C score (Table 4.2). The SAFE-C scores had the highest significant negative correlation with the CIM-C scores (r = -0.693, $p \leq 0.001$). Significant correlations were also found between CIM-C scores and GDS-C scores (r = -0.530, $p \leq 0.001$), number of falls in the previous 6 months (r = -0.466, $p \leq 0.001$), ABC-C scores (r = 0.488, $p \leq 0.001$), and distance covered in the 6MWT (r = 0.270, $p \leq 0.05$). After controlling for the number of falls in the previous 6 months and the GDS-C scores, significant partial correlations were found between the CIM-C scores and the ABC-C scores (r = 0.326, $p \leq 0.05$) and SAFE-C scores (r = -0.537, $p \leq 0.001$) (Table 4.3).

Table 4.2 Relationships between the Chinese version of Community Integration Measure (CIM-C) and other variables (n = 57)

Variables	Pearson r correlation with CIM-C scores	p-value
Age	-0.085	0.531
Gender	-0.033	0.809
BMI (kg/m^2)	-0.078	0.565
Living arrangement	-0.019	0.890
Years since stroke	0.211	0.115
Affected side	-0.072	0.596
No. of falls in past 6 months, no.	-0.466	0.000**
Use of walking aids	-0.000	0.963
TUG scores (s)	-0.195	0.147
AMT-C scores	0.198	0.139
GDS-C scores	-0.530	0.000**
6MWT walking distance (m)	0.270	0.042*
ABC-C scores	0.488	0.000**
SAFE-C scores	-0.693	0.000**

*Significant difference at P <0.05
**Significant difference at P <0.01

Table 4.3 Partial correlation coefficients (controlling for number of falls in past six months and GDS-C scores) between CIM-C and other variables (n = 57)

Variables	Partial correlation coefficients with CIM-C score	p-value
6MWT	0.258	0.058
ABC-C	0.326	0.015*
SAFE-C	-0.537	0.000**

*Significant difference at p < 0.05
**Significant difference at p <0.01

4.4.3 Fear avoidance behavior and CIM-C scores

A combined multiple linear regression model including the number of falls in the previous 6 months, GDS-C scores, 6MWT distance, ABC-C scores and SAFE-C scores predicted a total of 49.7% ($F [5, 51] = 12.062$, $p \leq 0.001$) of the variance in the CIM-C scores (Table 4.4). After adjusting for the other variables, the SAFE-C scores remained independently associated with the CIM-C scores, accounting for 11.6% of the variance, and model prediction significantly improved (F change = 12.992, $p \leq 0.001$). The SAFE-C scores were the best predictor of CIM-C scores as indicated by the magnitude of the standardized regression coefficient (ß = -0.520; Model 3 in Table 4.4), and the highest Pearson correlation coefficient ($r = -0.693$, $p \leq 0.001$) (Table 4.2).

Table 4.4 Multiple linear regression analyses (forced entry) relating CIM-C scores with the other variables.

	Independent variables	R^2 (R^2 adj)	R^2 Change	B(S.E.) (Unstandardized coefficient)	β (Standardized coefficient)	p-value
Model 1		0.350 (0.325)	0.325			
	Number of falls in past 6 months			-1.346 (0.562)	-0.291	0.020*
	GDS-C			-0.297 (0.090)	-0.404	0.002**
Model 2		0.425 (.381)	0.056			
	Number of falls in past 6 months			-1.410 (0.541)	-0.305	0.012*
	GDS-C			-0.191 (0.098)	-0.259	0.057
	6MWT			0.006 (0.007)	0.097	0.444
	ABC-C			0.073 (0.042)	0.245	0.093
Model 3		0.542 (.497)	0.116			
	Number of falls in past 6 months			-0.861 (0.511)	-0.186	0.098
	GDS-C			-0.125 (0.090)	-0.170	0.171
	6MWT			0.005 (0.007)	0.083	0.469
	ABC-C			-0.011 (0.045)	-0.036	0.810
	SAFE-C			-0.203 (0.056)	-0.520	0.001**

B, unstandardized regression coefficient; β, standardized regression coefficient.
[a]p<0.01.
[b]p<0.05.

4.5 Discussion

This study is the first study highlighting the contribution of fear avoidance behavior to community reintegration of community-dwelling people with stroke. Our findings add to the current understanding of the role of fear avoidance behavior in healthy older adults and those with stroke.

4.5.1 Community reintegration after stroke

The high CIM-C scores (mean ± S.D, 44.75±4.94) suggest a high level of community reintegration of community-dwelling people with stroke. Our findings are comparable to those of Pang et al. (2007) and Liu et al. (2014) who had studied on Chinese people with stroke. Both groups have reported high average RNLI-C score of 83.1 (S.D. = 13.8) (Pang et al, 2007) and CIM-C score of 43.48 (S.D. = 5.79) (Liu et al, 2014) respectively. However, the present findings are inconsistent with those of other studies that reported RNLI scores of 57.3 to 63.8 (Obembe, Hohnson & Fasuyi, 2002; Murtezani et al, 2009; Obembe et al., 2013) indicating moderate to severe restrictions in self-perceived community reintegration.

There are several reasons which may contribute to the high level of community reintegration among the subjects of the current study. First, their level of physical mobility was high. They had better TUG times (mean ± S.D.; 17.02±6.83) when compared with the subjects of previous studies (20.0-29.1). Second, the subjects were active members of local self-help groups. They actively participated in community activities and volunteered for clinical research. Third, the local environment is not obstructive for people with stroke. The availability of local community centers and easy access to these facilities provide opportunities for social interaction and social participation. Fourth, the majority of the subjects lived with others thus they have either the family or peer support. Fifth, most of the subjects had the habit of regular exercises. As a whole, the subjects' high functional level and their active social participation may account for their self-perceptions of good community reintegration.

4.5.2 Community reintegration and other outcome measures

The correlation analysis revealed that community reintegration was correlated with the number of falls in the previous 6 months (self-reported), walking endurance, depressive symptoms, impaired subjective balance confidence and fear avoidance behavior. The demographic variables, however, were not significantly associated with community reintegration.

Reports on the relationships between community reintegration and demographic variables are inconsistent. Our findings was consistent with that of Pang et al. (2007) and Schmid et al. (2012) which demonstrated no significant correlations of this variable with age, gender, ethnicity, level of education, stroke characteristics, paretic side or post-stroke duration. However, some researchers have reported significant correlations between community reintegration with age ($r = -0.221$, $p \leq 0.05$) and post-stroke duration (Obembe et al., 2002) ($r = 0.604$, $p \leq 0.05$) in other studies.

The mean age of the subjects in this study (61.14±6.66) was comparable to those of Pang et al. (2007) and Schmid et al. (2012) (means of 64.1 and 65.4), but older than those in the study by Obembe et al. (2013) where 62.2% (n = 56) were younger than 60 years. The mean post-stroke duration of our subjects (8.14±4.34 years) is comparable to that of the studies by Pang et al. (2007) and Schmid et al. (2012) but longer than the subjects in the study by Obembe et al. (2002) (1.63 years). These may account for the differences in the relationships between community reintegration and demographics reported across the studies.

As might be expected, a history of fall was found to be associated with activity avoidance among community-dwelling older adults (Delbaere et al, 2009; Howland et al, 1998; Murphy, Williams & Gill, 2002). Although falls and fear of falling are believed to form a “vicious cycle” (Friedman et al, 2002), Delbraere et al. (2009) has suggested that actual falls are indeed the primary cause of fear avoidance behavior. Older adults, especially those with a disabling injury or illness, are more likely to have less confidence in upright balance. For those with impaired subjective balance confidence and catastrophic thinking (Delbaere et al, 2009) about the consequences of falls, we hypothesize that actual falls may raise their concern about falling and induce fear avoidance behavior. The present findings support this hypothesis, and they are consistent with the findings of other studies of community-dwelling older adults (Delbaere et al, 2009; Howland et al, 1998; Murphy et al, 2002). Furthermore, depressive symptoms were also found to be correlated with community reintegration, which is consistent with previous findings (Pang et al, 2007; Obembe et al, 2013).

Our findings also revealed significant correlations between CIM-C scores and the distance covered in the 6MWT, ABC-C scores and SAFE-C scores. Surprisingly, after controlling for GDS-C results and the number of falls in the previous 6 months, 6MWT no longer had significant predictive power. One possible explanation is that over the period of natural recovery, usually 3-6 months (Mayo et al, 1999), people with stroke have reached a plateau of physical recovery. Subjective balance confidence and fear avoidance behavior then come to dominate decisions about daily activities, social interaction and social participation instead of walking endurance.

4.5.3 Fear avoidance behavior independently predicts community reintegration

The final model explained 49.7% of the variance in the community reintegration scores. Fear avoidance behavior was the best independent predictor of the CIM-C and SAFE-C scores, accounting for 11.6% of the variance. Previous studies have investigated the role of subjective balance confidence and the present study further considered its behavioral impact on community reintegration. Our results demonstrate that a higher level of fear avoidance behavior predicts poorer community reintegration of community-dwelling people with stroke.

From the clinical point of view, the current findings are highly relevant to stroke rehabilitation, as this is the first piece of evidence showing that restriction of activity induced by fear of falling is an independent factor influencing community reintegration after stroke. For rehabilitation practice, it is important to identify the basis of patients' fear avoidance behavior in order to specify the training required. In a randomized controlled trial by Zijlstra et al., 2009), improvements in fear of falling and activity avoidance were observed in 196 community-dwelling older adults after an 8-week, multi-component cognitive behavioral group intervention aimed at nurturing realistic and adaptive views of fear of falling and performing activities safely. The effects lasted for 8-14 months and the number of recurrent fallers was still significantly lower than the control group a year after the intervention (Zijlstra et al, 2009). Future studies investigating whether such a multi-component cognitive and behavioral group intervention might be applicable for people with stroke are clearly warranted.

4.5.4 Study Limitations

This study protocol had several limitations. First, the regression model could only account for 49.7% of the total variance in the CIM-C scores and more than half of the variance remained unexplained. Future research should look into other elements such as participation in exercise (Eng et al, 2003) and social support (Glass & George, 1992). Besides, the participants were recruited on a convenience basis through local self-help groups voluntarily. This self-selection may itself reflect limited fear avoidance behavior and self-perceptions of successful reintegration. The fact that our participants had relatively good physical functioning at the beginning of the study could induce a positive bias that they have a stronger sense of community reintegration than those with more severe physical impairment and psychological disturbances.

Of course, no causal relationships among the variables should be inferred based on this cross-sectional study design. Furthermore, the findings should not be generalized to a general stroke population, as the participants were all community-dwelling with relatively good mobility and were socially active.

4.6 Conclusion

Fear avoidance behavior is a better predictor of community reintegration than fall history, depressive symptoms or subjective balance confidence for community-dwelling people with stroke. Fear avoidance behavior is independently related to the level of community reintegration, while walking endurance and subjective balance confidence are not. Fear avoidance behavior is also an independent predictor of CIM-C scores, accounting for 11.6% of the variance. Therefore, the important implication of our findings is that multi-dimensional interventions addressing all the physical, psychological and behavioral factors for stroke rehabilitation should exert the strongest therapeutic effects leading to the maximum level of community reintegration.

Chapter 5

General methodology

This chapter has been published in the below peer-review journals.

- Liu TW, Ng SS. The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly for assessing fear and activity avoidance among stroke survivors. *PLoS ONE* 14(4): e0214796. (Appendix 5.1)

- Liu TW, Ng SS. Assessing fall risks in community-dwelling stroke survivors with Short-form Physiological Profile Assessment (S-PPA). Manuscript has been submitted to peer-review journal *PLoS ONE* (accepted). (Appendix 5.2)

- Liu TW, Ng SS, Ng GY. Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure for use in patients with chronic Stroke. *BioMed Research International* 2014, ID623836, doi: 10.1155/2014/623836. (Appendix 5.3)

- Liu TW, Ng GY, Ng SM. Effectiveness of a combination of cognitive behavioral therapy and task-oriented balance training in reducing the fear of falling in patients with chronic stroke: study protocol for a randomized controlled trial. Trial 2018, 19: 168. /doi.org/10.1186/s13063-018-2549-z. (Appendix 5.4)

This chapter has been presented in the below conferences.

- Liu TW, Ng SS, Ng GY. Translation of Chinese version of Community Integration Measure (CIM) for use in patients with chronic stroke. The 7th World Congress of the International Society of Physical and Rehabilitation Medicine, Beijing, 17-20 June 2013.

- Liu TW, Ng SS, Ng GY. Structural validity of the Chinese (Cantonese) version of the Community Integration Measure (CIM): Evidence from stroke survivors in Hong Kong. The 9th Pan-Pacific Conference on Rehabilitation cum 21st Annual Congress of Gerontology, Hong Kong, November 29-30, 2014.

- Liu TW, Ng SS. The Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) for stroke survivors: Its Internal Consistency and Convergent Validity. The 11th Pan-Pacific Conference on Rehabilitation cum 21st Annual Congress of Gerontology, Hong Kong, November 17-18, 2018.

- Liu TW, Ng SS. Structural validity of the Chinese (Cantonese) version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C): Evidence from Chinese community-dwelling stroke survivors in Hong Kong. Rehabilitation International Asia & Pacific Regional Conference, Macau, June 26-28, 2019.

- Liu TW, Ng SS. Test-retest reliability of the short form Physiological Profile Assessment (S-PPA) for community-dwelling stroke patients. The 6th Annual Public Health Conference, Thailand, July 11-13, 2019 (Pending for acceptance).

5.1 Abstract

As reviewed in Chapter 3, fear of falling can be treated feasibly through physical interventions and cognitive behavioral therapy (CBT). Our results in Chapter 4 also identified fear avoidance behavior as the most potent predictor of community reintegration among people with stroke. Specifically, fear avoidance behavior accounted for 11.6% of the variance in community reintegration as measured using the Community Integration Measure (CIM-C). Based on the reviewed literature and our findings, one could reasonably hypothesize that an effective intervention intended to reduce the fear of falling and fear avoidance behavior could lead to improvements in the community reintegration of people with stroke. In this chapter, we present the general methodology of our main study, including outlines of the trial design, inclusion and exclusion criteria and outcome measures. Additionally, we report 3 cross-sectional studies using community-dwelling people with stroke recruited in 3 different cohorts to examine the psychometric properties of 3 of the adapted outcome measures in our main study. These cross-sectional studies addressed the following topics.

1. The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly (SAFE) for assessing fear and activity avoidance among stroke survivors

The Survey of Activities and Fear of Falling in the Elderly (SAFE) (Lachman et al., 1998) was developed to assess restrictions on activity due to a fear of falling. The utility of this survey has been demonstrated in older adults (Lachman et al., 1998) and people with Parkinson's disease (Masoumeh, Mahdi, Akram & Emad, 2016). Although the SAFE has been translated into Chinese (Cantonese) (as the SAFE-C) (Chou et al., 2005), the psychometric properties of this translated version have not been established in a population of people with stroke. Therefore, this cross-sectional study aimed to validate the SAFE-C (Chou et al., 2005) in community-dwelling people with stroke. Our findings revealed that the psychometric properties of SAFE-C (Chou et al., 2005) are consistent with those reported for the English version and from studies with community-dwelling older adults (Lachman, 1998) and people with Parkinson disease (Masoumeh et al., 2016).

2. Use of the Short-form Physiological Profile Assessment (S-PPA) to assess the fall risks of community-dwelling people with stroke

The Short-form Physiological Profile Approach (S-PPA) (Lord et al, 2003) is a clinical measure used to assess the risk of falling in older adults. This measure has been applied to various populations of older adults (Lord et al, 1991; 1994), including those with chronic illnesses such as stroke (Dean et al, 2012), Parkinson's disease (Paul et al, 2014) and multiple sclerosis (Hoang et al, 2016). However, the psychometric properties of the S-PPA have not been investigated systematically in people with stroke. Therefore, this cross-sectional study aimed to test the psychometric properties of the S-PPA in people with stroke. Our results revealed that the S-PPA is a reliable and valid measure of the fall risks of people with stroke.

3. Translation and initial validation of the Chinese (Cantonese) version of the Community Integration Measure (CIM) for use in people with chronic stroke

The Community Integration Measure (CIM) (McColl et al, 2001) enables a clinical assessment of the level of community reintegration. This measure has been applied widely to people with spinal cord injury (de Wolf, 2010), traumatic brain injury (Griffen et al, 2010) and acquired brain injury (McColl et al, 2013). However, the CIM was not previously translated into Chinese (Cantonese) or validated in people with stroke. Therefore, this study aimed to translate and culturally adapt the 10-item CIM into Chinese (CIM-C) and to evaluate the psychometric properties of this new version. Our findings revealed that the CIM-C provides a reliable, valid and culturally relevant measure of the level of community reintegration in people with stroke in Hong Kong.

5.2 Introduction

Given the feasibility of combining of cognitive behavioral therapy (CBT) and the task-oriented balance training (TOBT), this chapter aimed to present the general methodology of our multi-dimensional rehabilitation programme which aimed at reducing the fear of falling in people with stroke.

5.3 Trial design

This study was a placebo-controlled single-blind parallel group randomized controlled trial (RCT) with a 12-month follow-up, conducted with community-dwelling people with stroke with fear of falling at a university-based neurorehabilitation center. The findings of the trial were reported in accordance with the Consolidated Standards of Reporting Statement (Schulz, Altman & Moher, 2010). A placebo controlled intervention, general health education (GHE), was provided for the control group to help measure the effects of CBT alone. To rule out potential placebo effects such as attention from therapists and knowledge of treatment conditions, the GHE program provided no information related to subjective balance confidence, activity avoidance, falls or physical activity, but only information related to general health issues such as healthy food choices and foot care.

The null hypothesis was that the efficacy of CBT combined with TOBT did not differ significantly from that of GHE combined with TOBT in promoting balance self-efficacy, thus reducing fear avoidance behavior, enhancing balance performance, reducing fall risk, improving community reintegration and health-related quality of life for people with stroke.

5.4 Participants

Study participants were required to meet the following inclusion criteria: (i) aged between 55 and 85, (ii) had been diagnosed with a first unilateral ischemic brain injury or intracerebral hemorrhage by magnetic resonance imaging or computed tomography within 1-6 years post-stroke, (iii) discharged from all rehabilitation services at least 6 months before the program, (iv) able to walk independently for at least 10 meters with or without an assistive device, (v) showing low balance self-efficacy (scoring less than 80 on the Chinese version of the Activities-specific Balance Confidence (ABC-C) Scale (Mark et al., 2007), (vi) scoring higher than 7 out of 10 on the Chinese version of the Abbreviated Mental Test (AMT-C) (Chu et al., 1995) and (vii) able to follow instructions and provide written informed consent. We specified the 1-6 years post-stroke period because the RCT focus on those who were currently undergoing the process of community reintegration with residual deficits (Walsh et al., 2014).

Individuals were excluded if they have any additional medical, cardiovascular, orthopedic or psychiatric or psychological conditions that will hinder proper treatment or assessment, if they present with receptive dysphasia or significant lower limb peripheral neuropathy or if they are involved in drug studies or other clinical trials.

5.5 Outcome measures

The outcome measures adapted in this study included:

Primary Outcome

(i) Subjective balance confidence was measured by the Chinese version of the Activities-specific Balance Confidence scale (ABC-C) (Mak et al., 2007) (Appendix 5.5).

Secondary Outcome

(ii) Fear avoidance behavior was measured by the Chinese version of the Survey of Activities and Fear of Falling (SAFE-C) (Chou et al., 2005) (Appendix 5.6).

(iii) Balance performance was measured using the Berg Balance Scale (BBS) (Berg, 1989) (Appendix 5.7).

(iv) Fall risk was measured by the Short-form Physiological Profile Assessment (S-PPA) (Lord et al., 2003) (Appendix 5.8).

(v) Instrumental activities of daily living were measured by the Chinese version of the Lawton Instrumental Activities of Daily Living Scale (IADL-C) (Tong & Man, 2002) (Appendix 5.9).

(vi) Community reintegration was measured by the Chinese version of the Community Integration Measure (CIM-C) (Liu et al., 2014) (Appendix 5.10).

(vii) Health-related quality of life was measured by the Chinese version of the Short Form General Health Questionnaire (SF36-C) (Lam, Tse, Gandek & Fong, 2005) (Appendix 5.11).

The adoption of these outcome measures were consistent with the International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2001), which classifies functioning in the three domains of (1) body, (2) activities and participation, and (3) contextual factors. Outcome measures (iii) and (iv) were adopted to evaluate the body domain of rehabilitation, whereas the outcome measures (i), (ii), (v) and (vii) were adapted to evaluate the activities and participation domain of rehabilitation.

5.5.1 Primary outcome measures

5.5.1.1 Subjective balance confidence

In this study, fear of falling was not directly evaluated, but through the assessment of subjective balance confidence. This approach to the assessment of fear of falling was consistent with recent literature (Tinetti et al., 1990; Powell & Meyers, 1995) in which fear of falling was operationally defined as ‘low perceived self-efficacy’. It was because of 3 main reasons. Firstly, fear itself implies a psychiatric connotation to phobias which may not be examined accurately (American Psychiatric Association, 1980) without the presence of the real fearful object. Secondly, self-efficacy is the theoretical assumptions of the cognitive process that underlies fear arising from falls, and could be measured in a range of activities using a continuous scale (Tinetti et al., 1990). Thirdly, the evaluation of fear through the examination of subjective balance confidence could expand the measurement from a dichotomous entity (with or without fear) to measurement on continuous scale in which the subjective balance confidence was assessed when undertaking several activities. Although “fear of falling” was operationally defined as subjective balance confidence, this term was continued to be used in this study and recent literature. It was because the construct “fear of falling” not only refers to low balance self-efficacy but also include other falls related belief such as the catastrophizing about the consequences of falls (Delbaere et al., 2009).

The ABC-C (Mak et al., 2007) (Appendix 5.4) consists of 16 items representing specific situations in daily life (e.g., bending over and picking up a slipper from the floor) rated on a scale from 0% (no confidence) to 100% (complete confidence). The original English version of ABC has been validated for use with community-dwelling older adults (Nemmers & Miller, 2008) and people with various medical conditions, such as Parkinson's disease (Bello-Hass, Klassen, Sheppard & Metcalfe, 2011) and stroke (Botner, Miller & Eng, 2005; Salback et al, 2006). The original English version of ABC has been translated into Chinese (Cantonese), and shows an excellent internal consistency (Cronbach's alpha = 0.97) and a high test-retest reliability (intraclass correlation coefficient (ICC) = 0.99) (Mak et al, 2007) in community-dwelling older adults. Although the Fall Efficacy Scale (FES) (Tinetti et al., 1990) was another commonly used clinical instrument, it focuses on assessing the balance efficacy related to indoor activities only. Thus, this study adopted the ABC-C (Mak et al. 2007) which assesses the subjective balance confidence when undertaking both indoor and outdoor activities.

5.5.2 Secondary-outcome measures

5.5.2.1 Fear avoidance behavior

The major adverse consequence of fear of falling is that it can be reflected in the form of self-imposed restrictions on physical activity. That can, of course, lead to various negative health outcomes such as physical deconditioning, decreased competence in engaging the activities of daily living, reduced social participation and eventually a degraded quality of life. However, fear of falling may not necessarily restrict activity (Howland et al., 1998). A study by Howland et al. (1998) found that 55% of 266 community-dwelling older adults reported having fear of falling, but only 56% of them reported associated activity curtailment.

Lachman et al. (1998) developed the Survey of Activities and Fear of Falling in the Elderly (SAFE) intended to evaluate fear avoidance behavior due to fear of falling. The SAFE assesses the level of activity restriction through quantifying self-perceived and observable activities of daily living (ADL) and instrumental ADL (IADL). The original SAFE consisted of 11 items rated on a 4-point scale. It was validated with 270 healthy community-dwelling older people and demonstrated excellent internal consistency (Cronbach's alpha = 0.91) and convergent validity with the FES (r=-0.76). It has also demonstrated criterion validity with quality of life as measured by the Medical Outcome Study Short Form 36 (SF-36) (r=-0.37 to 0.55, $p \leq 0.001$) (Ware, 1993) and discriminant validity in distinguishing those with or without fear of falling (Ware, 1993) in general population and community-dwelling older adults.

5.5.2.1.1 Cross-sectional study 1: The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly for assessing fear and activity avoidance among stroke survivors

Although the SAFE has been translated into Chinese (as the SAFE-C) (Appendix 5.5) and has been reported to have excellent internal consistency (Cronbach's alpha = 0.95) with older adults with depression symptoms (Chou et al., 2005), the utility of SAFE has only be demonstrated among the older adults (Chou et al., 2005) and people with Parkinson's disease (Masoumeh, Laleh, Mahdi, Akram & Emad, 2016). The main objectives of this cross-sectional study were to investigate the internal consistency, test-retest reliability, convergent validity and construct validity of the SAFE-C questionnaire on community-dwelling people with stroke.

5.5.2.1.1.1Methods

Participants

In total, 108 community-dwelling people with stroke were recruited from a local rehabilitation organization in Hong Kong through poster advertising. Their demographics are summarized in Table 5.1. Subjects were recruited if they were at least 50 years old, had suffered a single stroke confirmed by the magnetic resonance imaging or computed tomography at least 1 year before the start of the study, were able to rise from a chair without using any arm support, and had the Chinese version of the Abbreviated Mental Test (AMT-C) (Chu et al., 1995) score of 7 or above. Subjects were excluded if they had any other medical condition that potentially could affect the findings such as chronic knee pain. The Departmental Research Committee of the Hong Kong Polytechnic University has approved the study. Written informed consent was obtained from all of the participants before the study (Appendix 5.12).

Table 5.1 Characteristics of the subjects (n = 108)

Characteristics	Value, mean±SD (range)
Age	60.37±6.30 (50 – 78)
Gender, no.	
Male/Female	71/37
Education, no.	
< Secondary school	23
Secondary school	68
College or above	17
Living, no.	
Alone	6
With family/carer/friend	102
Employment, no.	
Full time	3
Part time	6
Retired	53
Unemployed	46
BMI (kg/m^2)	24.19±3.13 (15.96 – 32.65)
Cause of stroke, no.	
Ischemic	46
Hemorrhagic	62
Hemiplegic side, no.	
Left/Right	55/53
Years since stroke, year	7.64±4.39 (1.65 – 16.90)
No. of falls in past 6 months, no.	
0	85
1	12
$\geq$2	11
Mobility status, no.	
Unaided	27
Stick	52
SBQ	15
LBQ	5
Others	9

Note: no., number; SD, standard deviation; BMI, body mass index; SBQ, small base quadripod; LBQ, large base quadripod.

Outcome Measures

All 108 participants were assessed with three questionnaires, including the SAFE-C, ABC-C and IADL-C, through an individual face-to-face interview in a university-based neurorehabilitation laboratory. Twenty of them were randomly selected by drawing lots for reassessment with SAFE-C after one week to establish test-retest reliability.

- SAFE-C score

The current SAFE-C assesses the level of fear of falling while performing activities such as “go to the store” and “take a tub bath”. There are four response options (0= not all worried; 1 = a little worried; 2 = somewhat worried; 3 = very worried). To assess the level of activity avoidance due to fear of falling, the SAFE uses structured interviewing questions (e.g., “When you go to the store, how worried are you that you might fall?”; “Do you not go to the store because you are very worried that you might fall?” according to the scoring information guide (Appendix 5.13).

- ABC-C score

  Please refer to session 5.5.1.1.

- IADL-C score

  Please refer to session 5.5.2.4.

Data Analysis

The data were analyzed using version 23.0 of the SPSS software suite (IBM, Armonk, NY). The level of confidence for significance was set as $\alpha=0.05$. Internal consistency was evaluated using Cronbach's alpha coefficient. Test-retest reliability was assessed using intra-class correlation coefficients [ICC (3, 1)]. An ICC >0.90 indicates excellent reliability, an ICC of 0.75 to 0.90 indicates good reliability, an ICC of 0.50 to 0.75 indicates moderate reliability, and an ICC <0.50 indicates poor reliability (Koo & Li, 2016). To establish the optimal factor structure for the SAFE-C, principle component analysis (PCA) was performed and scree plots were prepared. Principal axis factoring (PAF) was used for data extraction, followed by promax rotation to enhance the interpretability of the factors. Pearson correlation coefficients were used to establish the convergent validity of the SAFE-C with the ABC-C and IADL-C results. The strength of the correlation was defined as weak (< 0.35), moderate (0.36 to 0.67), or strong (0.68 to 1.0) (Kline, 2000).

Sample size

The minimum sample size was set at 55 for the principal component analysis (PCA) according to the thumb rule of 5 subjects per item (Field, 2009). The sampling adequacy was confirmed by the great (between 0.8 and 0.9) Kaiser-Meyer-Olkin (KMO) value of 0.89 (Kaiser, 1974).

5.5.2.1.1.2 Results

The assessments were performed in a university-affiliated neurorehabilitation laboratory. After providing written consent, the participants completed a demographic data sheet and the ABC-C and IADL-C. Then the participants were interviewed for SAFE-C according to the scoring information guide (Appendix 5.13).

Participants

Total 71 respondents (66 %) were men, and 85 of those (79%) with educational attainment up to secondary school level or above (Table 5.1). Almost all (n=102, 94%) were living with family, a carer or a friend and were unemployed or retired (n=99, 92%). Most had not fallen in the 6 months before the study (n=85, 79%). They had mean a body mass index (BMI) of 24.19±3.13 and 81 (75%) of them relied on a walking aid when walking outdoors. Their mean age was 60.37±6.30 years and the mean years since stroke was 7.64±4.39 years.

The mean scores of all the SAFE-C items and their standard deviations are summarized in Table 5.2. The total mean score was 9.75±7.21. Item 6 (Go out when slippery) had the highest average (1.44±0.95) and item 4 (Get out of bed) the lowest (0.36±0.72).

Table 5.2 Mean and standard deviation (SD) of SAFE – C item scores

Items		Mean	SD
1.	Go to store	0.84	0.93
2.	Prepare simple meals	0.65	0.90
3.	Take a tub bath	1.30	1.06
4.	Get out of bed	0.36	0.72
5.	Take a walk for exercise	0.60	0.85
6.	Go out when slippery	1.44	0.95
7.	Visit a friend or relative	0.73	0.90
8.	Reach over head	0.98	0.94
9.	Go to place with crowds	1.35	0.99
10.	Walk several blocks outside	0.79	1.01
11.	Bend down	0.71	0.95
Total score		9.75	7.21

Note: SAFE-C, the Chinese version of the Survey of Activities and Fear of Falling in the Elderly.

Internal Consistency

The SAFE-C scores had excellent internal consistency with a Cronbach's alpha of 0.90 (Table 5.3). There was moderate to strong item-total correlation ranging from 0.47 to 0.72. Although four of the item-total correlations were < 0.60 (Go to the store, r = 0.59; take a tub bath, r = 0.53; get out of bed, r = 0.47; take a walk for exercise, r = 0.54), there was no item who's deletion improved the overall Cronbach's alpha.

Table 5.3 Internal consistency of the SAFE – C

Item No.	Item	Corrected Item-Total Correlation	Alpha if Item Deleted
1.	Go to the store	0.59	0.89
2.	Prepare simple meals	0.67	0.89
3.	Take a tub bath	0.53	0.90
4.	Get out of bed	0.47	0.90
5.	Take a walk for exercise	0.54	0.89
6.	Go out when slippery	0.65	0.89
7.	Visit a friend or relative	0.67	0.89
8.	Reach over head	0.72	0.88
9.	Go to place with crowds	0.71	0.88
10.	Walk several blocks outside	0.70	0.89
11.	Bend down to get something	0.70	0.89

Note: SAFE-C, the Chinese version of the Survey of Activities and Fear of Falling in the Elderly; Cronbach's α coefficient for the entire SAFE-C is 0.90.

Test-Retest Reliability

Twenty of the 108 respondents were re-assessed after a 1-week interval to quantify the SAFE-C's test-retest reliability. The total SAFE-C score had excellent test-retest reliability after a week, as reflected in an ICC (3, 1) of 0.91 (95% confidence interval (CI) 0.76–0.96) (Table 5.4). Test-retest correlation coefficients for individual items ranged from 0.52 to 0.93, with item 9 [Go to a place with crowds, ICC (2, 1) = 0.93 95% CI 0.83–0.97] indicating the most consistency, and item 1 [Go to the store, ICC (2, 1) = 0.52 95% CI 0.22–0.81] the least. Overall, the ICC (3, 1) of 0.91 indicated good reproducibility for SAFE-C ratings over time.

Table 5.4 Test-retest reliability of the SAFE – C (n=20)

			Test-retest reliability		
	Mean Score			95% CI	
Item	1st	2nd	ICC	Lower	Upper
1.	0.55	0.25	0.52	0.22	0.81
2.	0.30	0.40	0.80	0.48	0.92
3.	1.25	0.95	0.79	0.47	0.92
4.	0.25	0.15	0.92	0.80	0.97
5.	0.25	0.20	0.73	0.32	0.89
6.	1.20	1.20	0.87	0.67	0.95
7.	0.50	0.45	0.81	0.53	0.93
8.	0.85	0.90	0.90	0.74	0.96
9.	1.25	1.20	0.93	0.83	0.97
10.	0.40	0.30	0.84	0.60	0.94
11.	0.60	0.60	0.84	0.59	0.94
Total SAFE – C score	7.40	6.60	0.91	0.76	0.96

Note: SAFE-C, the Chinese version of the Survey of Activities and Fear of Falling in the Elderly; CI, confidence interval.

Convergent Validity

The correlation coefficient relating the SAFE-C and ABC-C results was r = -0.68 (95% CI -0.82 - -0.54), and that relating the SAFE-C and IADL-C results was r = -0.57 (95% CI -0.73 - -0.41). There was moderate to strong negative correlation between the pairs of measures. Both the correlations were statistically significant ($p \leq 0.001$).

Construct Validity

The PCA suggested a 2-factor structure accounting for 54% of the total variance in which each factor with eigenvalue exceeding 1. The Kaiser-Meyer-Olkin (KMO) value of 0.89 indicated sampling adequacy (Kaiser, 1974). Bartlett's test was highly significant (X^2 (55) = 569.30, p≤0.001) suggesting an appropriate use of factor analysis (Field, 2009). Examination of the scree plot suggested that there were 2 or 3 factors above the break point of the data. To avoid under- or over-extraction of the number of factors, we also consider +/- 1 number from the numbers suggested by the scree plot and PCA. Therefore, the numbers of factors used for extraction were 1, 2, 3, and 4. After promax rotation, the loadings of all 11 items were greater than 0.30 (Kaiser, 1974) on the 1-factor structure, ranging from 0.49 to 0.76 with an eigenvalue of 5.50 and 45.2% of the total variance explained (Table 5.5). Although the 2, 3 and 4 factor structures could explain more of the variance, they all have item cross-loadings on more than 1 factor. Thus, the 1-factor structure was adopted.

Table 5.5 Rotated factor matrix of the SAFE-C based on the principal axis factoring with promax rotation

Item		1-factor
(8)	Reach over head	0.76
(9)	Go to place with crowds	0.75
(10)	Walk several blocks outside	0.75
(11)	Bend down	0.74
(2)	Prepare simple meals	0.71
(7)	Visit a friend or relative	0.71
(6)	Go out when slippery	0.69
(1)	Go to store	0.62
(5)	Take a walk for exercise	0.57
(3)	Take a tub bath	0.56
(4)	Get out of bed	0.49
	Eigenvalues	5.50
	Variance explained (%)	45.22

Note: SAFE-C, the Chinese version of the Survey of Activities and Fear of Falling in the Elderly.

5.5.2.1.1.3 Discussion

This study revealed that the SAFE-C has excellent internal consistency, excellent test-retest reliability and concurrent validity with ABC-C and IADLs using people with stroke. The instrument's key construct was identified factor as "fear avoidance circumstances" which takes in common community living activities in which falls usually occur.

The SAFE-C demonstrated excellent internal consistency (Cronbach's alpha of 0.90) which was comparable with that of the original English SAFE (Cronbach's alpha of 0.91) and older adults showing symptoms of depression (Cronbach's alpha of 0.95). It can be inferred that activity restriction arising from fear of falling after a stroke was consistently measured across the 11 items of the SAFE-C.

The SAFE-C showed excellent test-retest reliability [ICC (3, 1) = 0.91, 95% CI 0.76–0.96], suggesting that SAFE-C results are highly reproducible for people with stroke, which is a desirable feature for clinical use. Although item 1 (Go to the store) showed only fair consistency across the 2 measurements, the overall reliability of the measure was not impaired when item 1was retained in the instrument. In addition to real changes in the level of fear of falling while going to the store and its avoidance, several other reasons might contribute to the low repeatability of item 1. Self-perceptions of balance ability might for some reason be particularly inconsistent in the shopping context, or there may have been inconsistent interpretation of the "go to the store" scenario.

Fear of falling is generally quite realistic for cognitively intact and ambulant community-dwelling people with stroke, so SAFE-C results should correlate with balance efficacy as measured by the ABC-C. Indeed, the data show a strong negative correlation (r =-0.68). The strength of correlation between the SAFE-C and IADL-C scores (r = -0.57) was relatively weaker than between the SAFE-C and ABC-C scores (r = -0.68). One possible explanation for the comparatively weaker correlation between the SAFE-C and IADL-C could be explained as the dependency in IADLs was caused by stroke-related physical impairments instead of fear of falling. The study participants were “unable to” rather than “afraid of” carrying out some IADLs. Also, some of the subjects’ fear avoidance behavior was related to social activities, not to typical activities of daily living. It is thus possible that these subjects had little fear avoidance behavior but a high level of dependency, or vice versa. In any case, the correlation between the SAFE-C and the ABC-C results was not close to unity (Field, 2009), which is consistent with the suggestions of previous studies (Howland et al., 1998; Liu et al., 2015) that people with impaired balance may or may not be fearful and may or may not practice avoidance. The correlations between the SAFE-C, the ABC-C and the IADL-C results confirm their convergent validity.

This is the first study to examine the factor structure of the SAFE in population of patients with chronic disabling conditions. The hypothesized 1-factor structure based on fear and avoidance circumstances is consistent with those reported for the Chinese population in Hong Kong with stroke. Although the factor loadings (0.49–0.76) were not similar to those found with healthy older adults in the original study (0.52–0.80) (Lachman et al., 1998), the items on the SAFE constitute a coherent factor structure supporting measurement of the construct among healthy older adults and stroke survivors. That consistency constitutes evidence that fear avoidance behavior is a robust construct. This might be due to similarities in living styles, attitudes towards falls, level of physical activity and beliefs about maintaining balance during activities across the Western population and Hong Kong Chinese population. Based on the validation of the SAFE-C with people with stroke, the present study provides further evidence of the factor structure's applicability. Fear avoidance behavior is a homogeneous construct that can serve as a unidimensional measure. The high consistency of the factor structure suggested that the SAFE-C is a culturally relevant and valid measure of fear avoidance behavior.

It is important to note that this study's participants were recruited by convenience sampling and self-selected. They were relatively young and active with good functional mobility. The findings may not generalize to less able people with stroke, and certainly not to persons not fulfilling the study's inclusion criteria. The sample size of 20 was barely enough for assessing the test-retest reliability. Besides, details of the translation process were not reported in Chou et al. (2005) study in which the SAFE-C was first used in Chinese elderly living in nursing homes. Thus, the discussion of cultural appropriateness is limited in the present study. Note too that no confirmatory factor analysis was conducted to support the recommended 1-factor structure of the SAFE-C. Further investigation of the factor structure and testing of the SAFE-C which involves less able people with stroke are recommended.

5.5.2.1.1.4 Conclusions

Our findings suggested that the psychometric properties of SAFE-C are consistent with those reported for the English version and from studies with community-dwelling older adults (Lachman et al., 1998) and people with Parkinson disease (Masoumeh et al., 2016). Clinicians may choose to incorporate this instrument as their standard for assessing fear avoidance behavior among people with stroke.

5.5.2.2 Balance performance

Balance performance was measured using the Berg Balance Scale (BBS) (Berg et al., 1989) (Appendix 5.6), which was considered a valid measure of functional balance in various populations, such as people with stroke and healthy older adults (Berg, Wood-Dauphine & Williams, 1995). The BBS consists of 14 items, each rated on a 5-point scale: a score of 41-56 indicates the ability to walk independently, 21-40 indicates the ability to walk with assistance and 0-20 indicates wheelchair-bound movement. A higher composite score indicates a better balance performance. In people with stroke, this measure yielded good to excellent test-retest reliability (ICC=0.88–0.92) (Flansbjer, Blom & Brogardh, 2012; Stevenson, 2001) and strong concurrent validity with the Postural Assessment Scale for Stroke Patients (r=0.92–0.95) (Mao, Hsueh, Tang, Sheu & Hsieh, 2002).

5.5.2.3 Fall risk

Fall risk was quantified using the Short-form Physiological Profile Assessment (S-PPA) (Appendix 5.7) which consisted of five tests: a vision test, a proprioception test, a lower extremity muscle force test, a hand reaction time test and a balance test (Lord et al, 2003). Composite scores are measured on a 7-point scale according to the participants' responses to the tests; potential fall risk ranges from -2, representing a very low fall risk, to 4, which represents a very marked fall risk. The S-PPA been applied to populations of older adults (Lord et al., 1991; 1994), including those with various chronic illnesses such as stroke (Dean et al., 2012), Parkinson disease (Paul et al., 2014) and multiple sclerosis (Hoang et al., 2016).

Although several validated measures, such as Balance Master, are applicable for assessing fall risk, they focused on balance parameters, such as centre of pressure and reaction time, and were not direct measures of fall risk. For the S-PPA, it could generate a composite fall risk score indicating the level of fall risk (very low to very marked) of subjects providing both the quantitative and qualitative descriptions of fall risk. Thus, S-PPA was adopted as the outcome measure of fall risk in this study.

5.5.2.3.1 Cross-sectional study 2: Assessing fall risks using the Short-form Physiological Profile Assessment (S-PPA)

The assessment of fall risks and the underlying physiological factors could facilitate fall prevention strategies and rehabilitative training for stroke patients. Although the PPA has been applied to populations of older adults (Lord et al., 1991; 1994), including those with various chronic illnesses such as stroke (Dean et al., 2012), Parkinson disease (Paul et al., 2014) and multiple sclerosis (Hoang et al., 2016), the psychometric properties of the PPA have not been systematically investigated in people with stroke. Therefore, the objectives of this study were to investigate the test-retest reliability, inter-rater reliability, concurrent, convergent and known-group validity and accuracy of the S-PPA (Appendix 5.8) for distinguishing the fall history in people with stroke.

5.5.2.3.1.1 Methods

Participants

One hundred and thirty-seven individuals (70 men, 67 women) with a history of single stroke within 1–6 years, as confirmed by magnetic resonance imaging or computed tomography, were recruited from a local support group through poster advertisements. The inclusion criteria were an age between 50 and 85 years, ability to walk independently for at least 10 meters with or without an assistive device and a score of ≥7/10 on the AMT-C (Che et al, 1995). The exclusion criteria were as follows: any additional medical condition (e.g., angina pectoris), musculoskeletal pain during daily activities or significant lower limb impairment that could affect the assessment (e.g., foot drop).

Twenty-eight consecutive participants were included in the assessment of inter-rater reliability between 2 physiotherapists (raters 1 and 2). These assessments were conducted simultaneously at baseline, with no discussion or disclosure of scores. To determine the test-retest reliability, another 28 consecutive participants not involved in the assessment of inter-rater reliability were re-assessed after a 1-week interval. One of the same physiotherapists (rater 1) conducted this assessment at the same time as the first assessment. The healthy controls completed the demographic data sheet and underwent the S-PPA once as conducted by rater 1.

The assessments were performed in a university-affiliated neurorehabilitation laboratory. After providing written consent, the participants completed a demographic data sheet and the ABC-C. Subsequently, the participants completed the balance tests in random order. These tests were conducted by a physiotherapist with >5 years of clinical experience (rater 1). A resting interval of ≥5 minutes was allowed between each balance test and each S-PPA individual item test. Additional resting time was allowed if needed. All outcome measurements was conducted in random order.

Forty age-matched healthy participants (18 men, 22 women) were recruited at Hong Kong Polytechnic University through poster advertisements. Individuals with any neurological condition (e.g., Parkinson's disease) and an AMT-C score <7 were excluded.

This study was approved by the Ethics Committee of the affiliated institution and was conducted according to the principles of the Declaration of Helsinki regarding human experiments. Informed consent was obtained from the participants prior to the experiment (Appendix 5.14).

Outcome Measures

- S-PPA score

The S-PPA is a physiological-oriented measure of the fall risk that was based on the conceptual model of Lord et al. (2003). The following 5 items were selected to reflect the sensorimotor and balance performance and thus infer the fall risks:

(i) The Melbourne Edge Test was used to assess visual contrast sensitivity (Figure 5.1A). Subjects were required to identify the directions of the low- and high-contrast edges of 20 circular patches (diameter, 25 mm) on a chart. The directions included horizontal, vertical and 45° left and right. The subjects were provided an instructional key card containing the 4 possible directions of the contrasting edges. The correct identification of the lowest contrasting edge was recorded in decibel units (dB).

(ii) The proprioception test was used to assess proprioception (Figure 5.1B). The seated subjects were asked to align their great toes simultaneously on either side of a vertical acrylic-plastic plate (60 cm x 60 cm x 1 cm) without looking at the plate. Any differences in the alignment of the great toes were recorded in degrees.

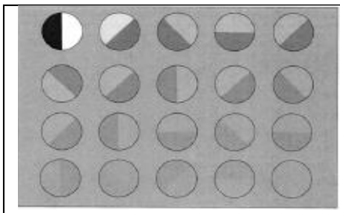
(iii) The hand reaction time test was used to assess the response time (Figure

5.1C). Subjects were required to press the response switch of a modified computer mouse when a red light adjacent to the switch was activated. The reaction time was measured in milliseconds using a built-in timer.

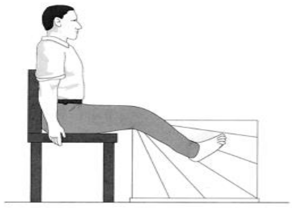
(iv) The knee extension strength test was used to evaluate the strength of the quadriceps muscle in the affected leg (Figure 5.1D). Subjects were required to remain seated while a strap connected to a spring gauge was placed around the leg. The knee extension strength was measured in kilograms using the spring gauge.

(v) The postural sway test was used to assess body displacement (Figure 5.1D). A belt was tied to the subject's waist for 30 seconds. A rod (length, 40 cm) was connected to the belt, and a pen attached to the end of the rod was used to record the subject's body movement on graph paper. The total area traversed by the pen in mm^2 was recorded.

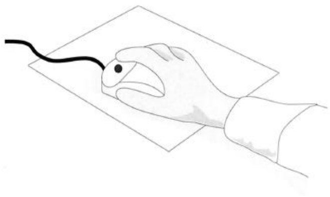
Figure 5.1 Short-form Physiological Profile Approach (S-PPA) of (A) the Melbourne Edge Test Contrast sensitivity, (B) the proprioception test – peripheral sensation; (C) the hand reaction time test; (D) The knee extension strength test; and (E) the postural sway test.



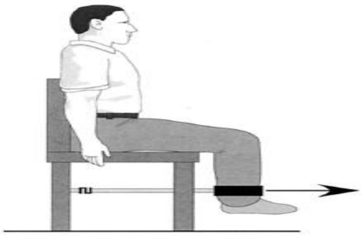
A. The Melbourne Edge Test Contrast sensitivity



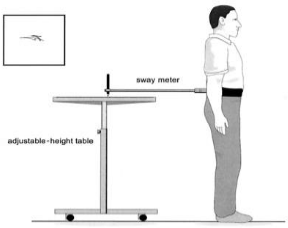
B. The proprioception test – peripheral sensation



C. The hand reaction time test



D. The knee extension strength test



E. The postural sway test

Lord et al. (2003). A physiological profile approach to falls risk assessment and prevention. *Physical Therapy*, 83, 237-252.

The results of each individual item test were input into a Web-based computer software program and converted into individual standardized (z) scores. Next, composite scores were derived through a discriminant function analysis, using reference data from previous studies (Lord et al., 1991; 1994). The composite scores were further converted into standardized (z) 7-point composite fall risk scores of -2 to 4 with reference to a normative database, in which scores of -2 to 0, 0 to 2 and 2 to 4 indicate a very low to low, low to marked and marked to very marked fall risk, respectively. The item tests were administered according to standardized instructions.

- BBS score

Please refer to session 5.5.2.2.

- Functional Reach Test (FRT) score

The FRT was used to evaluate standing balance by measuring the maximum distance the subject could reach forward while standing on a fixed base. In people with stroke, this test yielded excellent test-retest reliability (ICC=0.99) (Wolf et al., 1999) and moderate to strong concurrent validity (r=0.62–0.78) with the BBS (Smith, Hembree & Thompson, 2004; Wolf et al., 1999).

- Timed “Up & Go” (TUG) score

The TUG (Podsiadlo & Richardson, 1991) was used to evaluate functional mobility by measuring the time required by subjects to perform sequential motor tasks, including rising from an armchair, walking 3 m, turning and walking back and sitting down again. In people with stroke, this measure yielded good to excellent test-retest reliability (r=0.87–0.99) (Flansbjer, Holmback, Downham, Patten & Lexell, 2005; Ng, 2005) and excellent concurrent validity (r=0.99) (Ng and Hui-Chan, 2005) with gait velocity.

- ABC-C score

  Please refer to session 5.5.1.1.

Data Analysis

The collected quantitative data were analyzed using SPSS 20.0 software at a significance level of $\alpha = 0.05$. Descriptive statistics were used to summarize the demographic data and variables of interest. The normality of data and homogeneity of the variances were checked using the Shapiro–Wilk test and Levene's test, respectively.

ICCs were used to establish the test-retest reliability and inter-rater reliability, and the equation used to determine this value was selected depending on the intent of the analysis (Rankin & Stokes, 1998). We adopted the ICC (3, 1) to determine the test-retest reliability and generalize the results of our findings to those of other S-PPA raters for clinical practice or research trials. We adopted the ICC (2, 1) to determine inter-rater reliability between the 2 specified raters (raters 1 & 2) (Rankin & Stokes, 1998). ICCs of >0.90, 0.75–0.90, 0.50–0.75 and <0.50 indicate excellent, good, moderate and poor reliability, respectively (Koo & Li, 2016).

To evaluate concurrent validity, the correlations of the S-PPA scores with the, FRT, TUG and BBS scores were examined. Convergent validity was examined using the correlation between the test S-PPA and ABC-C scores. Pearson's r and Spearman's rho analyses were used to analyze the correlations between normally and non-normally distributed variables, respectively. To compare fallers with non-fallers in the stroke group and the stroke group with the healthy group, and assess known-group validity, independent t-tests were applied to parametric data and the Mann–Whitney U test was applied to non-parametric data. Fallers were identified as subjects who had at least one falls in the last 12-month period before data collection. Non-fallers were those with no fall experiences in the 12-month period.

Sample size

The minimum sample size was set at 40 for the interrater and intra-rater reliability, with an alpha level of 0.05 (2-tailed), power of 0.8, and expected reliability at intraclass correlation coefficient (ICC)=0.60 (Portney & Watkins, 2009), allowing for a 30% attrition (Bujang & Baharum, 2017).

5.5.2.3.1.2 Results

Participants

The characteristics of the study participants are summarized in Table 5.6. The stroke group had a mean age of 61.24±7.11 years, and a mean interval of 3.11±1.69 years since the stroke event. Most of the study participants in the stroke group (n=77, 56%) had a hemorrhagic stroke, and nearly all of them (n=126, 92%) lived with family, a caregiver or friend. Seventy-eight (57%) of the patients had 2 or more other chronic comorbidities, such as hypertension and diabetes mellitus, and most of them (n=109, 80%) were taking 2 or more medications (e.g., hypertensive agents). Eighty-three of the patients (61%) had right-side hemiplegia, and the majority required walking aids (stick=106, 77%; small-base quadripod=15, 11%; large-base quadripod=8, 6%) when walking outdoors. Ninety-six (70%), 35 (26%) and 6 patients (4%) had no, 1 or 2 falls during the 12 months before the study began, respectively.

Table 5.6 Demographics of participants

	Stroke group (N=137)	Healthy group (N=40)	t or χ^2 (p-value)
Age (y)	61.24±7.11	62.40±5.07	-0.95 (0.342)
Sex, n (%)			0.36 (0.339)
Female	68 (50)	22 (55)	
Male	69 (50)	18 (45)	
BMI (kg/m^2)	24.2±93.33	23.28±2.71	1.92 (0.058)
Living arrangement., n (%)			
Alone	11 (8)		
With family/carer	126 (92)		
Education., n (%)			
Primary or below	30 (22)		
Secondary	86 (63)		
University or college	21 (15)		
Years since stroke	3.11±1.69		
Cause of stroke, n (%)			
Ischemic	56 (41)		
Hemorrhagic	77 (56)		
Unknown or mixed	4 (3)		
Hemiplegic side, number			
Left/right	54/83		
Number of chronic medical conditions, n (%)			
0	20 (15)		
1	39 (29)		
2	56 (41)		
3 or above	22 (15)		
Number of medication, n (%)			
0 - 1	28 (20)		
2 – 3	65 (47)		
4 or above	44 (33)		
History of falls in past 12 months, n (%)			
0	96 (70)		
1	35 (26)		
2 or above	6 (4)		
Mobility status, number			
Unaided	8 (6)		
Stick	106 (77)		
SBQ	15 (11)		
LBQ	8 (6)		

Note: SD, standard deviation; n, number, BMI, body mass index; SBQ, small base quadripod; LBQ, large base quadripod; t, t test; χ^2, chi-square.

Table 5.7 summarizes the individual test items and S-PPA composite scores of the stroke and healthy groups. The mean S-PPA, FRT, TUG, BBS and ABC-C scores of the stroke group were 1.18±0.94, 20.29±3.04, 17.36±5.11, 49.15±3.82 and 62.46±19.89, respectively. As expected, the healthy group demonstrated better performance on the S-PPA when compared to the stroke group, as demonstrated by the mean composite and individual test item scores.

Table 5.7 S-PPA, BBS, TUG and FRT of the stroke group and healthy group

	Stroke group (N=137)	Healthy group (N=40)
FRT (cm) (higher better)	20.29±3.04	
TUG (s)(lower better)	17.36±5.11	
BBS (lower better)	49.15±3.82	
ABC-C (lower better)	62.461±9.89	
Composite score (lower better)	1.18±0.94	0.22±0.76
Melbourne Edge Test (dB) (higher better)	19.82±1.94	20.20±2.10
Proprioception test (degrees) (lower better)	6.79±3.33	1.99±1.02
Hand reaction time test (ms) (lower better)	283.47±58.78	245.19±41.95
Knee extension strength test (kg) (higher better)	34.21±11.87	49.761±2.34
Postural sway test (mm^2) (lower better)	780.50±666.55	544.70±363.61

Note: values are meanS±D; N, number; FRT, Functional reach test; TUG, Timed “Up & Go”; BBS, Berg Balance Scale; ABC-C, Chinese version of the activities-specific scale; S-PPA, Short –form Physiological Profile Assessment.

Inter-rater Reliability and Test-Retest reliability

The ICCs for the inter-rater reliability and test-retest reliability of the S-PPS composite score were 0.83 (95% CI: 0.67–0.92, p<0.0001) and 0.74 (0.51–0.87, p<0.0001), respectively (Table 5.8). The ICCs for the inter-rater reliability of the S-PPA individual items ranged from 0.56 (95% CI: 0.24–0.77, p=0.001) to 0.87 (95% CI: 0.74–0.94, p<0.0001), and those for the test-retest reliability ranged from 0.58 (95% CI: 0.28–0.78, p<0.0001) to 0.94 (95% CI: 0.87–0.97, p<0.0001).

Table 5.8 Inter-rater and test-retest statistics for S-PPA

	Interrater reliability		Test-retest reliability	
S-PPA section	ICC, Mean (95% CI)	p-value	ICC, Mean (95% CI)	p-value
Melbourne Edge Test	0.87 (0.74-0.94)	<0.0001	0.89 (0.78-0.95)	<0.0001
Proprioception test	0.60 (0.30-0.80)	<0.0001	0.62 (0.32-0.80)	<0.0001
Knee extension strength test	0.86 (0.72-0.93)	<0.0001	0.94 (0.87-0.97)	<0.0001
Hand reaction time test	0.83 (0.67-0.92)	<0.0001	0.89 (0.77- 0.95)	<0.0001
Postural sway test	0.56 (0.24-0.77)	0.001	0.58 (0.28-0.78)	<0.0001
S-PPA composite score	0.83 (0.67-0.92)	<0.0001	0.74 (0.51-0.87)	<0.0001

Note: CI, confidence interval; ICC, intraclass correlation coefficient; S-PPA, Short –form Physiological Profile Assessment.

Concurrent and Convergent Validity

Significant correlations were observed between the S-PPA composite score and various balance measures, including the BBS (rho=-0.70, p<0.0001), FRT (rho=-0.57, p<0.0001) and TUG (rho=0.49, p<0.0001). Furthermore, a significant negative correlation was observed between the S-PPA composite score and ABC-C score (rho=-0.35, p<0.0001).

Known-group Validity

A comparison of fallers and non-fallers in the stroke group revealed significant differences in the S-PPA composite score (*U*=1,495.5, p=0.026) and in the vision test (*U*=1,489.5, p=0.022) (Table 5.9). A comparison of the stroke and healthy control groups revealed significant differences in the S-PPA composite score (*U*=1,166.0, p<0.0001) and most of the individual item scores, including the proprioception test (*U*=551.5, p<0.0001), knee extension strength test (*U*=988.5, p<0.0001), hand reaction time test (*U*=1,532.0, p<0.0001) and postural sway test (*U*=2,100.0, p=0.025).

Table 5.9 Known-group validity of the S-PPA

	Stroke group (N=137) Mean rank	Healthy group (N=40) Mean rank	p-value	Fallers (N=41) Mean rank	Nonfallers (N=96) Mean rank	p-value
Melbourne Edge Test (dB)	86.43	97.81	0.209	57.33	73.98	0.022
Proprioception test (degrees)	104.97	34.29	<0.0001	74.73	66.55	0.269
Knee extension strength test (kg)	76.22	132.79	<0.0001	66.37	70.13	0.612
Hand reaction time test (ms)	97.82	58.80	<0.0001	75.43	66.26	0.216
Postural sway test (mm^2)	93.67	73.00	0.025	78.35	65.01	0.071
S-PPA composite score	100.49	49.65	<0.0001	80.51	64.08	0.026

Note: S-PPA, Short –form Physiological Profile Assessment; n, number.

5.5.2.3.1.3 Discussion

This was the first study to apply the S-PPA to people with stroke and age-matched healthy controls. Our findings revealed that the both S-PPA composite score and individual test scores yielded moderate to good interrater reliability and test-retest reliability in this cohort of ambulant community-dwelling people with stroke. The S-PPA was found to exhibit significant moderate correlations with measures of balance, including the BBS, FRT and TUG, and the ABC-C. Our finding also demonstrated that the S-PPA can distinguish the fall risks of community-dwelling people with stroke and of healthy older adults but limited ability to discriminate between fallers and non-fallers among the included people with stroke.

Our findings regarding test-retest reliability are consistent with those reported by Lord et al. (1994, 2003), who tested samples of community-dwelling older adults. Our findings and those reported by Lord et al. (1994, 2003) revealed that the knee extension strength test had excellent test-retest reliability (ICC=0.97, 95% CI: 0.93–0.98) (Lord et al., 2003), the Melbourne Edge test had good test-retest reliability (ICC=0.81, 95% CI: 0.70–0.88) and the proprioception test (ICC=0.50, 95% CI: 0.15–0.74) (Lord et al., 2003) and postural sway test (ICC=0.68, 95% CI: 0.45–0.84) (Lord et al., 1994) had moderate test-retest reliability. However, our analysis of the test-retest reliability of the proprioception test (ICC=0.62, 95% CI: 0.32–0.80) yielded better results than those obtained by Lord et al. (2003) (ICC=0.50, 95% CI: 0.15–0.74).

One possible explanation for this discrepancy is that our study participants were relatively younger (mean age 61.24 years) than those recruited by Lord et al. (2003) (mean age 80.80 years), and the relatively better peripheral sensation of the younger participants may have yielded more stable scores during repeats of the proprioception test. Indeed, in a study of 550 community-dwelling women aged 20–99 years, Lord et al. (1994) revealed that peripheral sensation, as measured by proprioception, correlated significantly with age ($r=0.20$, $p<0.0001$). Furthermore, the test-retest reliability of the postural sway test was poorer in this study (ICC=0.56–0.58) than the value reported by Lord et al. (2003) (ICC=0.68), consistent with previous studies in which the test-retest reliability of postural sway was comparatively better in healthy adults (test-retest reliability ICC=0.33–0.93) (Leitner et al., 2009; Ford-Smith, Wyman, Fernandez & Newton, 1995) than in populations of people with such as chronic low back pain (ICC=0.26) (Leitner et al., 2007) and transtibial amputation (ICC=0.67) (Jayakaran, Johnson & Sullivan, 2011). Possibly, a post-stroke asymmetric weight-bearing capacity could lead to an increase in postural sway (Marigold et al., 2006), which might thus affected the stability of postural control during repeats of the postural sway test.

We found that among people with stroke in this study, the S-PPA composite score correlated significantly with the balance measures of FRT, TUG and BBS (rho=0.49 to 0.70), but exhibited a comparatively weaker correlation with the ABC-C (rho=-0.35). We believe that the comparatively weaker correlation between the S-PPA and ABC-C can be attributed to the aspects of balance measured by the S-PPA. The S-PPA measures aspects of the physiological profile that contribute to the fall risk, including vision, muscle force, peripheral sensation, reaction time and postural sway. The items on the ABC-C are directly related to daily activities (e.g., getting into or out of frequently used transportation) and functional balance (e.g., distance walking and changing directions), as community-dwelling people with stroke require confidence to perform these activities and functional balance is expected to correlate with the subjective balance confidence. However, the adverse effects of physiological deficits on functional balance could be compensated by external factors, such as the use of walking aids. Thus, this study identified a limited association between the S-PPA and ABC-C.

The known-group validity of the S-PPA was demonstrated by its ability to distinguish people with and without stroke, and those with and without a fall history among people with stroke. As expected, the performances of stroke survivors were worse than those of healthy controls in most of the S-PPA individual item tests, except the Melbourne Edge Test. Among people with stroke, we found that those with a history of fall within a 1-year period before the study began had a poorer S-PPA composite score, but did not receive worse scores on any individual item test. These findings might suggest that for community-dwelling people with stroke with intact cognition, the adoption of fall prevention strategies such as the avoidance of high-risk situations could effectively compensate for the physiological limitations associated with aging and chronic illness. In other words, the S-PPA did not identify notable differences among the physiological deficits in this study.

This study had several major limitations. First, the generalization of our findings is limited to other populations that meet our inclusion and exclusion criteria. Second, this study had a cross-sectional design, and the ability of the S-PPA to identify fallers was analyzed retrospectively. Finally, men might have been underrepresented in our sample of people with stroke as previous evidence revealed that men had higher preponderance rate of people with stroke across age groups in some countries (Foerch, Ghandehari, Xu & Kaul, 2013).

5.5.2.3.1.4 Conclusions

The S-PPA is a valid and reliable measure of the fall risks faced by people with stroke. This measure provides useful information that can be used to personalize physiological treatment regiments to meet the needs of people with stroke with balance disorders.

5.5.2.4 Instrumental ADL

The respondents' engagement in instrumental ADL was measured using the Chinese version of the Lawton Instrumental Activities of Daily Living Scale (IADL-C) (Tong & Man, 2002) (Appendix 5.9). While level of ADLs involved the assessment of functional ability in basic daily activities such as bathing, dressing and going to toilet, level of instrumental ADLs involved the assessment of functional ability in comparatively more complex daily activities such as using the telephone, cooking and using transportation. The original English version of Lawton Instrumental Activities of Daily Living (Lawton IADL) was developed by Lawton and Brody (1969) to assess the instrumental ADL of older adults. It has been translated into Chinese (Cantonese) (Tong & Man, 2002) using institutionalized older adults with excellent inter-rater (ICC = 0.99) and intra-rater reliability (ICC = 0.90) and good internal consistency (Cronbach's alpha = 0.86). The scale's nine items reflect the respondents' level of cognitive or physical function for independence in performing nine instrumental ADL: making telephone calls, using transportation, shopping, cooking, housekeeping, household repair, doing laundry, self-medicating and handling finances. The higher the score represents the higher level of independence in ADLs necessary for living in the community. It has been used in institutionalized older adults (Tong & Man, 2002), older adults with dementia (Cromwell, Eagar & Poulos, 2003) and community-dwelling people with schizophrenia (Huang et al., 2018).

5.5.2.5 CIM

Community reintegration was measured using the Chinese version of the Community Integration Measure (CIM-C) (Liu et al., 2014) (Appendix 5.10). The original English version of the Community Integration Measure (CIM) has been widely used in people with spinal cord injury (de Wolf et al., 2010), traumatic brain injury (Griffen et al., 2010) and acquired brain injury (McColl et al, 2011). However, it has not been translated and culturally adapted into the Chinese

(Cantonese) version.

5.5.2.5.1 Cross-sectional study 3: Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure for use in patients with chronic Stroke

The objectives of this study were to (1) translate and culturally adapt the contents of the English version CIM into Chinese (Cantonese), and (2) to report the results of initial validation of the Chinese (Cantonese) version CIM (CIM-C) including the content validity, internal consistency, test-retest reliability and factor structure in a Chinese setting.

5.5.2.5.1.1 Methods

Translation

Standard translation procedure (forward and backward translation) (Beaton, Bombardier, Guillemin & Ferraz, 2000) was adopted to translate from the English version to Chinese (Cantonese) version of CIM (CIM-C). Two independent bilingual translators whose mother language was Chinese translated the original English version of CIM to the Chinese version. One of them was a professional translator with no background in medicine or rehabilitation and the other was a physiotherapist with more than 3 years of clinical experience. They independently translated the English version CIM into two initial Chinese drafts (D1 & D2). The two initial drafts (D1 & D2) and the original English version CIM were reviewed by the same translators. Any discrepancies identified between D1 and D2 were resolved by discussion to reach a consensus version.

For the backward translation, another 2 independent translators who were blinded to the original CIM were involved. One was a trained translator with no medical or rehabilitation background, and the other was a physiotherapist with more than 3 years of clinical experience. An expert panel consisting of 5 registered physiotherapists (two with 20 years of clinical experience, and three with 3 years of clinical experience in stroke rehabilitation) then evaluated that Chinese version for equivalence of content, semantics, conceptual and for any technical discrepancies with the original English version. The version they produced was named the Chinese-CIM – Pilot and administered to 5 subjects with stroke to ascertain its fluency, clarity and comprehensibility. Their feedback was used to make minor amendments, and the final version, CIM – C, was confirmed.

Assessment Protocol

Sixty-two eligible subjects with stroke were assessed with the CIM-C scale through an individual face-to-face interview. Twenty-five of the subjects were randomly selected by drawing lots for reassessment with CIM-C again after one week to establish test-retest reliability. A 1-week interval was used to minimize chances of subjects' recall of contents from the previous assessment. This period was also considered optimal for avoiding potential occurrences of significant events or changes in their life circumstances that could also impact on their self-perceived balance confidence ratings. Factor structure of CIM-C was assessed by Principal Component Analysis (PCA) on all eligible subjects.

Participants

Sixty-two community-dwelling people with stroke, with a mean of 7.12 years post-stroke, were recruited from among the clients of a local rehabilitation organization in Hong Kong (mean age (SD): 60.71 (6.28) years; 42 men, 20 women) (Table 5.10). Subjects were recruited if they were over 50 years old, had suffered a single stroke at least 1 year before the start of the study, were able to rise from a chair without any arm support, and had an AMT-C score (Chu et al., 1995) of 7 or above. Potential subjects were excluded if they had any other co-morbid neurological disease (e.g. Parkinson's Disease) or an unstable medical condition such as cardiovascular problems that might affect proper assessment.

The subjects were informed about the objectives and procedures of the study and invited to sign a consent form before the experiment. The protocol was approved by the Ethics Committee of the administrative institution and conducted according to the principles of the Declaration of Helsinki for human experiments (Appendix 5.15).

Table 5.10 Characteristics of the subjects (n = 62)

Characteristics	Value, mean±SD (range)
Age	60.71±6.28 (50 – 77)
Gender, no.	
Male/Female	42/20
BMI (kg/m^2)	25.95±3.44 (18.76 – 34.77)
Cause of stroke, no.	
Ischemic	39
Hemorrhagic	22
Unknown or mixed	1
Hemiplegic side, no.	
Left/Right	27/35
Years since stroke	7.12±3.12 (1.95 – 16.86)
No. of falls in past 6 months, no.	
0	62
1	0
≥ 2	0
Use of AFO, no.	2
Mobility status, no.	
Unaided	25
Stick	31
SBQ	5
LBQ	1
Need a companion to walk outside, no.	42
Habit of regular exercise (times/week), no.	
0	2
1 - 3	16
4-6	10
7	34

Note: n, number; SD, standard deviation; BMI, body mass index; AFO, ankle-foot orthosis; SBQ, small base quadripod; LBQ, large base quadripod.

Data Analysis

Quantitative data were analyzed using the Statistical Package for Social Science (SPSS), version 17.0. In the translation process, mode calculation and inter-judge percentage agreement were used to measure agreement in the 4 areas of cultural equivalence. Modification was required if any item failed to reach 70% inter-judge agreement. In the initial validation process, internal consistency was evaluated using Cronbach's α coefficient and item-total correlations. Test-retest reliability was established using the ICC (3, 1). For the examination of factor structure, principal component analysis was adopted to extract the factors as the original study by McColl et al. (2001) and replication study by Reistetter et al. (2005). Scree plot was used to determine the number of factors retained followed by varimax rotation to optimize the loadings of the extracted factors to enhance the interpretability. For the community integration of subjects was characterized using descriptive statistics.

Sample size

The minimum sample size was set at 50 for the PCA according to the thumb rule of 5 subjects per item (Field, 2009). The sampling adequacy was confirmed by the good (between 0.7 and 0.8) KMO value of 0.79 (Kaiser, 1974).

5.5.2.5.1.2 Results

Participants

There were 42 male and 20 female subjects tested. Their mean age was

60.71±6.28) and their mean period since stroke was 7.12±3.12 years. Their mean BMI was 25.95±3.44, and none had a history of falling in the previous 6 months. Thirty-nine of them had ischemic stroke, 22 had hemorrhagic stroke and one with unknown character. The majority of subjects required the use of a walking aid (stick, n = 31; small base quadripod, n = 5; large base quadripod, n = 1), and 42 of them required a companion to walk outdoors (67.74%). Thirty-four claimed to have involved in exercise routinely for 7 times per week (54.9%).

Internal Consistency

The items of the CIM –C demonstrated high internal consistency with a Cronbach's α of 0.84 (Table 5.11). However, the results suggested that deletion of item 5 would increase the overall Cronbach's α of 0.01. The α coefficients of the individual items ranged from 0.28 (item 5) to 0.72 (item 9 and 10).

Table 5.11 Internal consistency of the CIM – C

	Corrected Item-Total Correlation	Alpha if Item Deleted
1. I feel like part of this community, like I belong here.	0.68	0.81
2. I know my way around this community.	0.51	0.83
3. I know the rules in this community and I can fit in with them.	0.43	0.83
4. I feel that I am accepted in this community.	0.60	0.82
5. I can be independent in this community.	0.28	0.85
6. I like where I'm living now.	0.45	0.83
7. There are people I feel close to in this community.	0.38	0.84
8. I know a number of people in *this* community well enough to say hello and have them say hello back.	0.59	0.82
9. There are things that I can do in this community for fun in my free time.	0.72	0.81
10. I have something to do in this community during the main part of my day that is useful and productive.	0.72	0.80

Note: CIM-C, the Chinese version of the Community Integration Measure; Cronbach's α coefficient for the entire CIM – C equals 0.84.

Test-Retest Reliability

Twenty five of the subjects participated in the re-assessment after a 1-week interval. The CIM – C demonstrated good test-retest reliability as reflected in an ICC (3, 1) of 0.84 (95% CI, 0.64–0.93) (Table 5.12). The ICC (3, 1) values for the individual items ranged from 0.34 to 0.88 with item 10 (I have something to do in this community during that main part of my day that is useful and productive) showing the most consistency (ICC = 0.88, 95% CI = 0.73 – 0.95). Item 2 (I know my way around this community) showed the least repeatability (ICC = 0.34, 95% CI = -0.48 – 0.71).

Table 5.12 Test-retest reliability of the CIM – C (n=25)

	Test-retest reliability				
	Mean Score			95% CI	
Item	1st	2nd	ICC	Lower	Upper
1.	4.48	4.44	0.73	0.39	0.88
2.	4.36	4.48	0.34	-0.48	0.71
3.	4.36	4.48	0.51	-0.10	0.78
4.	3.92	4.24	0.72	0.37	0.88
5.	4.00	4.12	0.60	0.11	0.82
6.	4.44	4.36	0.79	0.53	0.91
7.	4.28	4.08	0.83	0.62	0.92
8.	4.48	4.40	0.76	0.47	0.90
9.	4.04	4.20	0.62	0.16	0.83
10.	3.84	4.00	0.88	0.73	0.95
Total CIM – C score	42.20	42.80	0.84	0.64	0.93

Note: CIM-C, the Chinese version of the Community Integration Measure; CI, confidence interval.

Construct Validity

The PCA is a method in clustering variables and explaining the variances of a measure. It was used in the original (McColl et al., 2001) and replication (Reistetter et al., 2005) studies of CIM to examine the construct being measured and which items could be grouped. To compare the present findings with the previous studies, the factor structure of the CIM-C was examined by the PCA with varimax rotation. A 3-factor structure of the CIM-C, including “relationship and engagement”, “sense of knowing” and “independent living”, was revealed in the present study.

The correlation matrix of CIM-C revealed that all 10 items inter-correlated fairly well with correlation coefficients greater than 0.3. The Kaiser-Meyer-Olkin value of 0.79 indicated good sampling adequacy (Kaiser, 1974), and Bartlett's test was highly significant (X^2 (45) = 245.85, p ≤ 0.001), thus PCA was appropriate. After the factor extraction, the number of factors retained was determined by scree plot. It was noted that the extraction of 3 and 4 factors provided very similar estimates of the amount of variance in the indicators accounted for by the construct being measured. In other words, the degree of which a standard score increased in community integration associated with standard score increased in the indicators was very similar in the 3-factor model and 4-factor model. Thus, two, three and four factor solutions were attempted and it was revealed that the 3-factor structure explained the highest percentage of variance and it generated the most meaningful factors (Table 5.13). The loadings of all 10 items in the 3-factor structure exceeded the recommended value 0.4 (Kaiser, 1974) and ranged from 0.64 to 0.84, with 67.2% of the total variance explained.

Table 5.13 Rotated factor matrix of the CIM-C based on the principal component analysis with varimax rotation

Item		Factor 1	Factor 2	Factor 3
8.	I know a number of people well enough to say hello and have them say hello back	0.84		
10.	I have something to do in this community during the main part of my day that is useful and productive	0.73		
7.	There are people I feel close to in this community	0.71		
9.	There are things that I can do in this community for fun in my free time	0.60		
3.	I know the rules in this community and I can fit in with them		0.86	
2.	I know my way around this community		0.74	
1.	I feel like I am part of this community, like I belong here		0.64	
4.	I feel that I am accepted in this community			0.78
6.	I like where I am living now			0.69
5.	I can be independent in this community			0.64
	Eigenvalues	2..72	2.25	1.76
	Variance explained (%)	27.15	22.46	17.55

5.5.2.5.1.3 Discussion

This study has produced the first translation of the CIM into Chinese. It revealed the good internal consistency and excellent test-retest reliability of the Chinese version of CIM. Our final 3-factor structure was comparable to those suggested by Reistetter et al. (2005) for use in people with brain injury, and our model was also consistent with the original theoretical model.

Internal consistency means that the items measure the same traits of the construct and the subjects' responses are consistent across all 10 items. The Cronbach's alpha of 0.84 is consistent with those generated in previous studies of people with acquired brain injury (0.87) (McColl et al, 2001; Griffen et al., 2010). The individual CIM – C items demonstrated acceptable item-total correlations ($r > 0.30$) (McColl et al., 2001), except for item 5 (I can be independent in this community; $r = 0.28$). The greatest increase in Cronbach's alpha would result from deleting item 5, but its removal would increase the alpha by only 0.01. Thus, all individual items were considered worthy of retention.

The excellent test-retest reliability of the CIM – C indicates a high degree of repeatability for clinical use. The 1-week interval was considered appropriate to exclude memory effects while minimizing the possibility of significant events occurring in the interim. Having the same examiner administer the test may have contributed to the excellent test-retest reliability.

Although item 2 (I know my way around this community) showed only fair agreement between the two measurements, retention of item 2 did not impair the overall reliability of the instrument. The item's low apparent repeatability may be due to unspecified measurement error, failure to interpret the concepts "know my way around" and/or "community" consistently, or real changes in the self-perceived level of community integration. Despite the test-retest interval of only one week, one cannot completely exclude the possibility of substantial events affecting an individual's level of community integration. Furthermore, the concepts expressed in item 2 may not have been considered as concrete as other items having high ICC values such as item 7 (there are people I feel close to in this community) and item 10 (I have something to do in this community during the main part of my day that is useful and productive).

In the present study, the PCA revealed a 3-factor structure and the findings were highly consistent with the Model of Community Integration that the original CIM was based on. The high consistency on the Model of Community Integration of CIM across the Western population and Hong Kong Chinese population may suggest that the construct of community integration was comparable between the Western society and Chinese society in Hong Kong. This phenomenon might be due to the multi-cultural environment in Hong Kong. Based on the cross cultural validation for use in people with stroke, the present study could further build up the evidence of the factor structure of CIM-C.

In the present study, the first factor identified was "relationship and engagement" which comprised aspects of social relationships and activities. The first factor consisted of items 7 – 10, in which items 7 and 8 involved aspects of social relationships, and 9 and 10 involved aspects of social activities. Item 9 (There are things that I can do in this community for fun in my free time) and 10 (I have something to do in this community during the main part of my day that is useful and productive) were included under the “occupation” domain in 3-factor structure suggested by Reistetter et al. (2005). However, it would be more appropriate to include both items 9 and 10 in the first factor of the present study (ie, social activity and engagement) due to the cultural differences between these 2 studies. It was because the common concept of people in Hong Kong considered that having interpersonal relationships and meaningful daytime engagement was equivalent to having social support and occupation in the community.

The second and third factors emerged in the present study were “sense of knowing” and “independent living” respectively, which were different from “occupation” and “independence” domains suggested by Reistetter et al. (2005). The second factor (ie, sense of knowing) consisted of items 1 – 3 which involved aspect of “sense of knowing” and belong to the community; while the “occupation” domain suggested by Reistetter et al. (2005) consisted of aspects of productive work and independence. The third factor emerged in this study (ie, independent living) consisted of items 4 – 6 which involved aspects of independence, living situation and sense of being accepted; while the “independence” domain suggested by Reistetter et al. (2005) involved aspects of orientation and independence. Although discrepancies of clustered indicators existed between the present study and those of

Reistetter et al. (2005), all our clustered indicators were consistent with the Model of Community Integration (McColl et al., 2001). Such discrepancies of clustered indicators between different studies could be explained by the fact that factors represented by two or three indicators could be highly unstable across replications (Brown, 2006).

In the present study, the initial psychometric properties of the CIM – C were established using community-dwellers aged over 50 years but with good functional mobility. However, the generalization of the present study was only limited to those fulfilling our inclusion and exclusion criteria. In addition, the sample size of 62 was barely enough for principal component analysis. Further tests of the applicability of the CIM – C to people with other chronic diseases are therefore recommended to further explore the factor structure of the CIM – C.

5.5.2.5.1.4 Conclusions

The findings of the present study showed that the CIM is a culturally relevant, and a reliable and valid instrument for assessing the level of community integration of Chinese population with stroke in Hong Kong. The instrument is user friendly and requires only a basic level of literacy (not to be assumed among elderly

Chinese populations) to conduct, and it could be completed within 3-5 minutes.

5.5.2.6 Health-related quality of life

Health-related quality of life was measured by the Chinese version of the Short Form General Health Questionnaire (SF-36-C) (Lam et al., 2005) (Appendix 5.11). The original English version of the Short Form General Health Questionnaire (SF-36) (Ware et al., 1993) was a self-report 36 items of health-related quality of life measure with a total of 8 subscales in which each subscale consists of 2 to 10 items. It has demonstrated a 2-factor structure, including the physical health summary (PCS) and mental health summary (MCS), in the general population (McHomey, Ware & Raczek, 1993). Two summary scores obtained for the PCS and MCS are converted into a score on a scale from 0 to 100, representing a continuum of disability in which scores of 0 and 100 refer to the maximum and minimum levels of disability, respectively. The original SF-36 has adequate to excellent internal consistency (Cronbach's alpha = 0.70 – 0.80 for each subscale) (Jenkinson, Wright & Coulter, 1994) and adequate to excellent test retest reliability (ICC = 0.60 – 0.81 for each subscale) (Brazier et al., 1992). The SF-36 has been translated into Chinese (Cantonese) (Lam et al., 2005) using general population and demonstrated good internal consistency (Cronbach's alpha = 0.85 – 0.87) for each subscale.

5.6 Therapists and research personnel

Two research assistants with at least 2 years of research experience in the field of physical-exercise training were the assessors of this study. They were given a 1-day training session on obtaining outcome measurements by an experienced physiotherapist before the study. Intensive training was provided in both the theory and practice of conducting assessment with different outcome measures used in this clinical trial. All of the assessors rehearsed the procedure in conducting assessment of all outcome measures with other research team members in order to standardize the assessment. To establish the interrater reliability, the 2 assessors had rated 5 participants and then reviewed for discrepancies, if any.

Two research assistants with the background of exercise sciences were trained by an experienced physiotherapist who have at least 2 years of post-qualification experience as therapists in the field of physical-exercise training. The research assistants were also provided with written progression guidelines in progression of exercises prescription (Table 5.14). A regular review of training records and spot observations were conducted by the experienced physiotherapist to enhance adherence to the written progression guidelines.

The CBT therapists were 3 psychiatric nurses who have qualified as cognitive therapists. They were all have at least 5 years of post-qualification experience with applying CBT clinically. A treatment manual and materials had already been developed with reference to Tennstedt et al. (1998) and Zijlstra et al. (2009) research on fear of falling as experienced by community-dwelling older adults and had been reviewed by the three certified cognitive therapists involved in the study. To ensure treatment integrity, the CBT intervention had already been piloted and audiotaped. Each CBT therapist evaluated the pilot sessions to assess their compliance with the treatment manual, the achievement of session goals and the use of CBT techniques. The GHE intervention was delivered by two research assistants not involved in the assessment or any other part of the intervention, using audio-visual aids and materials that had already been developed.

5.7 Procedure

Participants were recruited from a local self-help group for people with stroke through poster advertisements. On receiving telephone calls from interested parties, our recruitment research assistant performed an initial eligibility screening and offered appointments to gain written informed consent (Appendix 5.16) and completed a baseline assessment. The protocol was approved by the Ethics

Committee of the administrative institution and conducted according to the principles of the Declaration of Helsinki for human experiments (Appendix 5.16).

All of the potential participants were met individually in the study venue to enable the researchers to explain the details of the study, such as its aims, benefits, risks and confidentiality, and then checked the applicants' eligibility against the inclusion and exclusion criteria. If individuals were both interested in joining and eligible to join the clinical trial, written informed consent were obtained before the baseline assessment was conducted. Questionnaires relating to sociodemographic characteristics, variables of interest and physical and functional performance were completed on the same day.

All of the participants were required to undergo five assessments, including, (i) before assessment (baseline treatment); (ii) after 8 sessions of treatment (midway through treatment); (iii) after 16 sessions of treatment (end of treatment); (iv) 12 weeks after treatment (follow-up); (v) and 12 months after treatment (follow-up). All of the assessment procedures were performed by a research assistant blinded to the group allocation and not previously involved in the delivery of the interventions.

5.8 Randomization and blinding

After explaining the study's objectives and obtaining written informed consent, a trained research assistant performed a baseline assessment for all of the outcome measures. An offsite volunteer not involved in the recruitment, intervention or data collection randomly allocated the participants to either the experimental group (EG) or control group (CG) in a 1:1 ratio, using the computer program "Minimise" (Jensen, 1991). The randomization was stratified based on age (55-70 years; 71-85 years), gender (male; female), and level of subjective balance confidence, based on ABC-C scores (<50; 50-80) (Meyers, Fletcher, Myeers & Sherk, 1998). The participants were informed of the results of the group allocation and their resulting training schedule and venue by centralized telephone calls from an offsite volunteer to ensure concealed randomization.

5.9 Sample size

The sample size was calculated using G*Power version 3.1.0, with an alpha level of 0.05 (one-tailed) and a study power of 80%. As no previous studies addressed the effects of CBT in reducing fear of falling in people with stroke, the effect size used to calculate the sample size was the same as that calculated for our pilot sample of 10 subjects (0.26) (five subjects receiving the CBT + TOBT training, and another five subjects receiving the CBT + GHE training) with the use of the ABC-C (Mak et al, 2007) as the primary outcome measure at eight weeks after the end of treatment. The required sample was thus comprised 76 subjects, with 38 per group. With reference to previous clinical trials (Ng & Hui-Chan, 2007; 2009), we expected the dropout rate to be about 15%, requiring an extra six subjects per group to be recruited. Therefore, the planned sample size was 88.

5.10 Data analysis

The data was double entered to enable validation. Simple descriptive statistics were used to summarize the sociodemographic characteristics of the participants and other variables of interest. Normality of data was examined by Kolmogorov-Smirnov test. Between-group comparisons at baseline was performed using *t* tests, Kruskal-Wallis tests, chi-square tests or Fisher's exact test, as appropriate.

To measure the changes over time in variables of interest between the two study arms, mixed-effects models with adjustments for potential confounding variables such as sociodemographic characteristics were used. Mixed-effects models go beyond the customary linear framework by incorporating random effects relating to participants. They account well for intra-correlated repeated measures data and accommodate missing data caused by drop-out, as long as the data are missing at random. Pearson and Spearman's correlation tests, as appropriate, would be used to investigate the correlations between outcome variables. Univariate linear regression analyses were performed to investigate whether the lesion location (left or right hemisphere lesion) predicted the fear of falling and related health outcomes at post-intervention and 12-month follow-up. SPSS 17.0 was used for the remaining statistical analysis, with a 5% level of confidence (two-sided) accepted for significance.

5.11 Intervention

To maintain assessor blinding, the assessment, data entry and data analysis were performed by another full-time trained research assistant, who was blinded to group allocation and not involved in delivering the interventions. The intervention and assessment were physically separated, performed at different sites. The subjects were reminded not to disclose any information on their intervention groups to the assessors. However, it was impossible to blind the therapists and participants to the group allocation.

All of the participants were asked to undertake 16 sessions of training over an 8-week period. The participants in both groups underwent 45-minute sessions of

TOBT in groups of three to five. TOBT is a rehabilitation strategy designed to improve muscle strength in lower limbs and to correct for balance deficits on the paretic side of patients with stroke (Ng & Hui-Chan, 2007; Bayouk, Boucher & Leroux, 2006; Leroux, 2005). Improved strength and balance are gained through the repetition of task-specific functional movements.

The TOBT intervention (Figure 5.2) consisted of five exercises targeting muscle strength in the lower limbs and walking performance: (i) stepping up and down in different directions to strengthen the affected leg muscles and to increase control over shifts in the center of gravity; (ii) heel-raising exercises to strengthen the ankle plantar flexors; (iii) semi-squatting to improve lower limb strength and proprioception in the knees and ankles; (iv) standing on a dura disc to promote static balance; and (v) walking across a surface covered with obstacles to improve dynamic walking balance.

Figure 5.2 Task-oriented balance training (TOBT) of (A) stepping, (B) heel-raising; (C) semi-squatting; (D) standing on dura disc; and (E) walking across obstacles.

 **Figure 6.1 (A) Stepping**	 **Figure 6.1 (B) Heel-raising**	 **Figure 6.1 (C) Semi-squatting**
 **Figure 6.1 (D) Standing on dura disc**	 **Figure 6.1 (E) Walking across obstacles**	

Based on our practical experience of using TOBT in previous studies of patients with stroke (Ng & Hui-Chan, 2007; 2009), the proposed frequency and intensity of treatment were effective and tolerable, providing sufficient stimulation to enhance motor recovery in patients with stroke. In the TOBT sessions, the participants took turns in carrying out one of the TOBT exercises for 8 minutes, followed by at least a 1-minute rest interval and additional resting time was allowed if needed, until the five TOBT exercises completed. All the TOBT were held in the morning, and then the participants attended either the CBT or GHE session on the same day in the afternoon after a two hours lunch break.

Table 5.14 Progression criteria for TOBT

Exercise	Progression criteria	Method of progression
Stepping up and down	Able to complete 50 times	Starting with a 2-inch-high wooden step, then progressing to 4- and 6-inch-high wooden steps after the progression criteria have been met.
Heel-raising exercises	Able to complete 25 times with at least 5 seconds held on each repetition	Starting with a 2-inch-high wooden step, then progressing to 4- and 6-inch-high wooden ramp after the progression criteria have been met.
Semi-squatting	Able to maintain knee flexion angle of 30 degrees without obvious shaking	Starting with a 3-minute rest interval midway through the trials, which is subsequently reduced to 2 minutes, 1 minute and 0 minutes.
Standing on dura disc	Able to stand without external assistance for at least 1 minute (holding handrail or supported by another)	Decrease the base of support.
Walking across obstacles	Able to complete the task within a pre-set duration (20 seconds at the beginning) without knocking down the obstacles	Shorten the pre-set duration and increase number of obstacles.

Note: TOBT, task-oriented balance training

Experimental group (EG)

The EG received bi-weekly CBT sessions for 8 weeks, lasting for 45 minutes per session, in groups of three to five. The CBT sessions were focused on eliminating cognitive and behavioral factors known to generate and aggravate impaired subjective balance confidence and fear-avoidance behavior. Their aims were to increase the self-perception of efficacy regarding falls and the sense of control over falling, to decrease the perception of risk, and to help the participants adopt realistic expectations of the consequences of falls. Each week had a specific theme in the CBT protocol. The main themes and content were summarized in Table 5.15.

Table 5.15 Weekly themes and main content of CBT sessions

Week	Weekly theme
1	Introduction and briefing on the aims of the rehabilitation program • Introduction to group • Introduction of the concept of self-efficacy • Information on post-stroke balance self-efficacy and rehabilitation
2	Understanding the relationships between thoughts, emotions and behavior • Introduction of the CBT model • Understanding fear, fear of falling, fall risks and actual falls • Understanding the automatic thoughts and emotional and behavioral reflection associated with fear of falling
3	Exploring thoughts and maladaptive responses • Identifying maladaptive thoughts leading to physical inactivity • Adapting realistic views of fall risk and the consequences of falls • Recognizing risky behavior • Overcoming barriers to physical activity
4	Exploring adaptive thoughts and behavioral responses • Fall-prevention strategies and safety issues • Recognizing and minimizing fall risk
5	Implementing and reviewing behavioral changes related to ADL • Setting personal goals for ADL • Planning to achieve personal goals by small steps • Recognizing potential hazards and planning for safety
6	Implementing and reviewing behavioral changes related to social activities • Setting personal goals for social activities • Planning to achieve personal goals by small steps • Recognizing potential hazards and planning for safety
7	Reviewing and advancing individual therapeutic goals • Reviewing personal goals for ADL and social activities • Establishing a regular exercise plan
8	Consolidating the experiences of the rehabilitation program • Sharing attitudes and experiences of fear of falling before and after the group • Sharing experiences of applying cognitive-restructuring skills • Establishing the long-term personal goals of regular exercise, ADL independence and social engagement

Note: CBT, cognitive behavior therapy

Weeks 1-2 of the CBT sessions focused on introducing the CBT framework and showing how self-perceived capability and maladaptive thoughts could influence behavioral performance. From week 3 to week 8, two major techniques, cognitive restructuring and behavioral modification, were used in the CBT sessions to achieve participants' personal goals. Cognitive restructuring attains thought alteration in the following four steps: (1) identification of automatic thoughts; (2) examination of cognitive distortion originated by automatic thoughts; (3) disputing the cognitive distortion and automatic thoughts; and (4) developing adaptive beliefs. In the proposed study, these four steps were undertaken in the form of CBT homework assignments (Appendix 5.17) and sharing and discussion during CBT group sessions.

As excessive fear of falling was speculated to stem from the impairment in subjective balance efficacy and distorted cognition regarding falling such as catastrophizing thoughts (Delbaere et al, 2009), the cognitive restructuring and behavioral modification techniques adapted in this study protocol was based on Beck's cognitive model (Beck, 2011). According to the cognitive model proposed by Beck (Beck, 2011), automatic thoughts (i.e., cognition distortion) are at the surface level and directly interact with the environment. They are the rapid thoughts that precede and accompany emotions and behaviors triggered by particular situations. Our cognitive restructuring element mainly target on 3 kinds of automatic thoughts including: (i) catastrophizing which refers to the belief that the consequences of an event will be far worse than the actual outcome, (ii) labeling which refers to the description of one's self-identity based on past imperfections, and (iii) overgeneralization which refers to the development of a general rule based on an isolated incident and the subsequent application of this rule to unrelated situations. For the behavioral modification element, it aimed to equip the participants to identify potential risks and developed behavioral strategies to prepare them to increase their activity levels safely. The combined use of cognitive-restructuring and behavioral-modification techniques was expected to enhance the participants' subjective balance confidence and reduced their fear-related avoidance behavior.

Control group (CG)

The CG attended 16 health talks (two sessions per week, 45 minutes per session) delivered as an inactive attention placebo by a research assistant in groups of three to five. The materials used in the GHE sessions included audio-visual presentations, demonstrations, video clips, mini-games, oral quizzes and posters and pamphlets on various health topics. The GHE sessions were designed to raise awareness of general health issues and increase general health knowledge among an elderly population. The details of the GHE sessions were summarized in Table 5.16.

Table 5.16 Weekly topics of GHE sessions

Week	Topic	Content	Format of Presentation
1.	Home safety	Strategies for removing potential home hazards to prevent residential accidents, such as the proper placement of sharp objects, the safe use of electric appliances and fire safety.	Audio-visual presentation Pamphlets Video clips
2.	Choice of healthy foods	Information on food labels and allergies will be provided to facilitate the choice of healthy foods.	Audio-visual presentation Poster Pamphlets Mini-games Oral quiz
3.	Diet	Tips on healthy diet, such as a food pyramid and healthy recipes, will be introduced to establish a healthy eating style.	Audio-visual presentation Pamphlets Oral quiz
4.	Brain health	Concepts of the mind and memory will be introduced and mini-games relating to brain health will be played to raise awareness of the importance of maintaining brain health.	Audio-visual presentation Mini-games Video clips
5.	Hand care	The importance of hand and wrist care will be	Audio-visual

		emphasized and the appropriate choice and use of hand-care products introduced.	presentation Demonstration
6.	Foot care	The importance of foot and ankle care will be introduced, followed by information on maintaining foot and ankle care.	Audio-visual presentation Video clips
7.	Flu prevention	Health information, including the symptoms, prevention and treatment of flu, will be provided and ways to prevent the flu discussed.	Audio-visual presentation Pamphlets
8.	Handicrafts	The importance of developing hobbies and leisure activities will be discussed, followed by a demonstration of some common handicrafts.	Audio-visual presentation Demonstration Mini-games

Note: GHE, general health education

5.12 Safety and adverse events

CBT is a clinically proven therapeutic intervention with no known associated risks. However, as one of the aims of CBT interventions was to promote independence, the participants were instructed to increase their ADL, physical exercise and social participation. Potential hazards were discussed in the CBT sessions before these behavioral changes were effected. Information on safety precautions was provided, and the participants were aided in the development of strategies to minimize potential hazards and ensure safety. The therapists and research personnel would report any and all adverse events to the Departmental Research Committee of the Hong Kong Polytechnic University.

5.13 Summary

This chapter presented the general methodology, including the trial design, inclusion and exclusion criteria and outcome measures of our main study. Three cross-sectional studies were also conducted and reported here to examine the psychometric properties of the outcome measures adapted in our main study. Details of the implementation of the main study would be presented in next chapter.

Chapter 6

Reducing the fear of falling with cognitive behavioral therapy and task-oriented balance training

This chapter has been published by peer-review journals.

- Liu TW, Ng GY, Chung RC, Ng SS. Decreasing fear of falling in chronic stroke survivors through cognitive behavior therapy and task-oriented training. *Stroke* 2019, 50:148-154. (Appendix 6.1)

This chapter has been presented in the below conference.

- **Liu TW**, Ng SS, Ng GY. Effects of the cognitive behavioural therapy (CBT) on fear of falling with stroke patients: a pilot randomized controlled trial. The 7th World Congress of the International Society of Physical and Rehabilitation Medicine, Beijing, 17-20 June 2013.

6.1 Abstract

Research has shown that balance training is effective for reducing the fear of falling in people with stroke. In this study, we evaluated (1) whether cognitive behavior therapy (CBT) could augment the beneficial effects of task-oriented balance training (TOBT) in reducing the fear of falling in people with stroke and (2) whether it could in turn reduce fear avoidance behavior and improve related health outcomes.

Eighty-nine cognitively intact subjects with stroke were randomized into the following two groups that underwent 90-minute intervention 2 days per week for 8 weeks: (1) CBT + TOBT or (2) general health education (GHE) + TOBT (control). The primary outcome was the fear of falling, and the secondary outcomes were fear avoidance behavior, balance performance, fall risk, independent daily living, community integration, and health-related quality of life. The outcomes were assessed at baseline, after 4 and 8 weeks of intervention, and 3 and 12 months after completing the intervention.

Eighty-two subjects completed the intervention and follow-up assessments. At all assessment time-points, the CBT + TOBT participants reported greater reduction in the fear of falling as measured by the Chinese version of the Activities-specific Balance Confidence scale (ABC-C) (Mak et al., 2007) (mean difference =

0.22, 95% confidence interval (CI) = 0.09 – 0.34, p=0.001) and fear-avoidance behavior as measured by the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) (Chou et al., 2005) (mean difference = -0.07, 95% CI = -0.11 - -0.03, p=0.002), and greater improvements in balance performance as measured by the Berg Balance Scale (BBS) (Berg et al., 1989) (mean difference = 0.03, 95% CI = 0.00 – 0.05, p=0.029) and independent daily living as measured by the Chinese version of the Lawton Instrumental Activities of Daily Living (IADL-C) (mean difference = 0.09, 95% CI = 0.06 – 0.11, p<0.000) than the GHE + TOBT participants. CBT should be considered as an adjuvant therapy to standard physiotherapy for cognitively intact individuals with a history of stroke.

In sum, CBT should be considered as an effective adjuvant therapy to standard physiotherapy for cognitively intact people with stroke to reduce and fear of falling and fear avoidance behavior.

6.2 Introduction

Balance disorders are common in people with stroke, and falls are known to be a major complication following a stroke. For example, after a stroke, falls are reported in 12%–39% of cases in inpatient stroke rehabilitation units (Sze et al., 2001) and in 73%–80% of cases in the community (Forster & Young, 1995). Consistent with this finding, other research has shown that people with stroke have a seven-fold higher risk of experiencing a fracture (Kanis, Oden & Johnell, 2001), especially a hip fracture (Kanis et al, 2001), than healthy individuals.

Fear of falling is a psychological condition associated with balance disorders and fall risks following a stroke. It refers to excessive worrying about losing one's balance. Fear of falling can result in avoidance behavior, leading to inactivity and social isolation, and further exacerbate disability in stroke populations (Hellstrom et al., 2003). In our previous study, we showed that approximately 49% of local community-dwelling people with stroke have a fear of falling (Ng, 2011). Of these, 24% individuals reported falling one to three times in the past 6 months (Ng, 2011).

Consistent with the results of another study on people with stroke (Salbach et al, 2006), our previous research (Ng, 2011) showed that the fear of falling, as measured by the Chinese version of the Activities-specific Balance Confidence (ABC-C) scale (Mak et al., 2007), was an independent and strong predictor of functional mobility in 78 community-dwelling people with stroke, accounting for 17% of the variance in the timed "Up and Go" (TUG) scores in our predictive model (Ng, 2011). Other studies have shown that the level of fear of falling, as measured by the ABC scale, is significantly associated with both functional mobility and community integration in people with stroke (Engberg, Lind, Linder, Nilsson & Sernert, 2008; Liu et al., 2015).

Cognitive behavioral therapy (CBT) is a psychotherapeutic intervention designed to modify unrealistic beliefs that can contribute to negative emotions and behavior. Fear of falling could result from accurate perceptions of impaired balance performance and/or unrealistic beliefs about one's risk of falling. Thus, people with stroke with fear of falling may have (1) impaired balance performance and/or (2) fearful anticipation of falls reflected by an overly pessimistic anticipation of the occurrence of falls. CBT may alter these self-defeating beliefs and thus reduce fear avoidance behavior and the associated adverse consequences, such as limited social participation. Consistent with this idea, one study has shown that CBT is effective in reducing the fear of falling among older adults (Tennstedt et al, 1998).

People with stroke have known stroke-specific impairments, such as muscle weakness, impaired walking ability and excessive fear of falling. Physical exercise, which can improve walking ability (Lord, McPherson, McNaughton, Rouchester & Weatherall, 2008) and balance performance (Lord et al., 2008), has been shown to reduce the fear of falling in people with stroke. Task-oriented balance training (TOBT) is a stroke-specific functional training intervention (Ng & Hui-Chan, 2007) that combines different exercise elements, including strengthening and walking. A recent meta-analysis (Jeon, Kim & Park, 2015) concluded that 2–6 weeks of TOBT can improve lower limb motor function and balance performance in people with stroke.

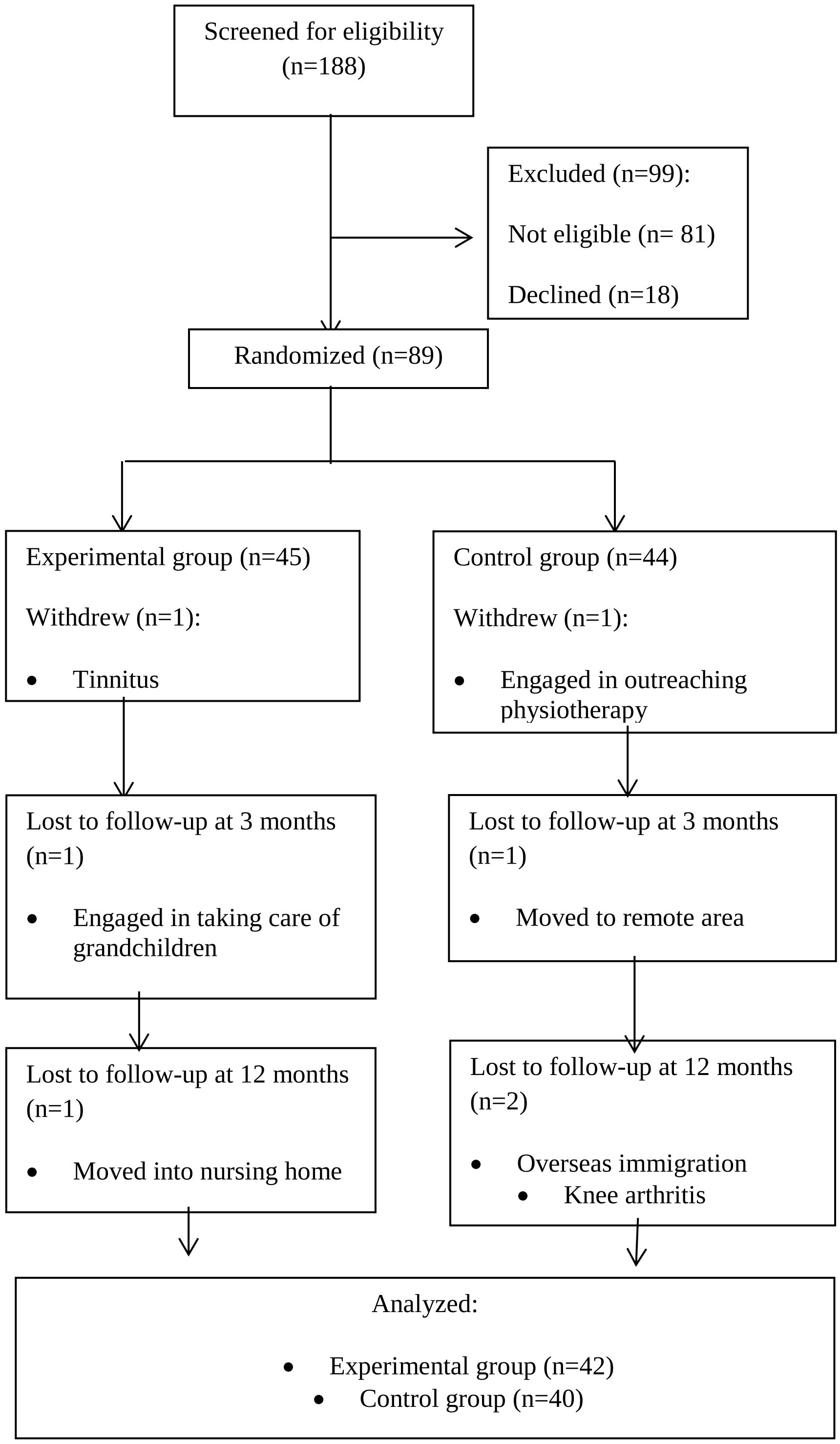
A systematic review (Tang et al., 2015) revealed that physical training is effective (standardized mean difference [SMD]=0.44, 95% confidence interval [CI] 0.11-0.77, p=0.009) in reducing fear of falling among community-dwelling people with stroke. Our recent review in Chapter 3 also revealed that CBT is an effective treatment method (Hedge's g=0.33, 95% CI=0.21-0.46, p<0.001) for fear of falling among older adults (Liu et al., 2018). Besides, our recent study (Liu et al., 2015) found that fear avoidance behavior is a potent independent predictor for the community integration (accounting for 11.6% in the variance as measured by the Chinese version of the Community Integration Measure [CIM-C]) of community-dwelling people with stroke.

Based on the findings of recent literature (Lord et al., 2008; Ng & Hui-Chan, 2007; Jeon et al., 2015) and our findings (Liu et al., 2015; 2018), it is reasonable to expect that the combination of CBT with TOBT will augment the benefits of TOBT in people with stroke. Thus, the aim of this study was to evaluate this possibility. We hypothesized that the combination of CBT with TOBT would result in *earlier* and *greater* benefits than the combination of general health education (GHE) and TOBT in terms of reducing the fear of falling among people with stroke. We also hypothesized that the CBT + TOBT intervention was *superior* to the GHE + TOBT intervention in terms of in reducing fear of falling, reducing fear avoidance behavior, improving balance performance, fall risk, independent daily living, community integration, and health-related quality of life.

6.3 Results

Eighty-nine eligible subjects were enrolled in the study and randomized into two groups: (1) EG that received the combination of CBT and TOBT (CBT + TOBT) and (2) CG that received the combination of GHE and TOBT (GHE + TOBT) (See Figure 6.1).

Figure 6.1 Flow diagram of study



Eighty-nine eligible subjects were enrolled between October 2016 and May 2017. Their characteristics and baseline outcome parameters are summarized in Table 6.1. No significant differences were found in any of the demographic and outcome parameters at baseline.

Table 6.1 Baseline characteristics of participants (n=89)

Characteristics	CBT + TOBT (N=45)	GHE + TOBT (N=44)	t or χ^2 (p-value)
Age (years, meanS±D)*	60.47±5.61	60.46±5.91	-0.01 (0.99)
Sex, n (%)**			0.27 (0.60)
Female	15 (33.3)	17 (38.6)	
Male	30 (66.7)	27 (61.4)	
BMI*	24.83±(3.29)	23.74±3.12	-1.60 (0.11)
Type of stroke, n (%)**			0.04 (0.84)
Ischemic	34 (75.6)	34 (77.3)	
Hemorrhagic	11 (24.4)	10 (22.7)	
Years since stroke (years, mean±SD)*	3.34±1.09	3.78±1.18	1.83 (0.07)
Hemiplegic side, n (%)**			1.42 (0.23)
Left	13 (28.9)	18 (40.9)	
Right	32 (71.1)	26 (59.1)	
History of falls in past 6 months, n (%)**			3.07 (0.55)
No	33 (73.3)	35 (79.5)	
Yes	12 (26.7)	9 (20.5)	
Use of walking aids, n (%)**			0.48 (0.92)
No	4 (8.9)	4 (9.1)	
Yes	41 (9.1)	40 (90.9)	
Outcome measures (mean±SD)			
ABC-C*	58.46±14.88	54.941±4.28	0.35 (0.73)
SAFE-C*	15.60±7.10	15.48±5.13	-0.09 (0.93)
BBS*	43.56±7.24	44.486±.22	0.29 (0.52)
IADL-C*	12.71±2.96	13.05±2.57	0.57 (0.57)
S-PPA*	1.29±0.79	1.26±0.73	-0.19 (0.85)
PCS*	58.34±9.25	58.76±7.75	0.19 (0.82)
MCS*	61.35±8.78	59.21±9.57	0.67 (0.27)
CIM-C*	39.69±6.77	39.61±6.54	-0.05 (0.96)

Note: : n, number; BMI, body mass index; CBT, cognitive behavior therapy; TOBT, task-oriented balance training; GHE, general health education, ABC-C, Activities-specific Balance Confidence Scale (Chinese version); SAFE-C, Survey of Activities and Fear of Falling in the Elderly (Chinese version); BBS, Berg Balance Scale; IADL-C, Lawton Instrumental Activities of Daily Living (Chinese version); S-PPA, Short-form Physiological Profile Assessment; PCS, physical health summary; MCS, mental health summary; CIM-C, Community Integration Measure (Chinese version). p-value: *t-test, **χ^2 test.

Seven participants dropped out of the study because of reasons unrelated to the study, such as tinnitus. Forty-two (93%) and forty (91%) participants in the EG and CG, respectively, completed the training and all assessments with at least 80% attendance.

6.3.1 Effects of CBT + TOBT versus GHE + TOBT

6.3.1.1 Primary outcome: fear of falling

A significant Group × Time interaction effect (mean difference = 0.22, 95% confidence interval (CI) = 0.09 – 0.34, p = 0.001) was observed (see Table 6.2), with the EG demonstrating a greater reduction in the ABC-C mean score than the CG post-intervention (mean difference = 1.77, 95% CI = 0.08 – 3.45, p = 0.04) and up to the 12-month follow-up (3-month follow-up, mean difference = 2.42, 95% CI = 0.42 – 4.42, p = 0.02; 12-month follow-up, mean difference = 2.94, 95% CI = 0.91 – 4.96, p = 0.01) (Table 6.3). Both the EG and CG demonstrated significant improvement in ABC-C mean score between mid-intervention and the 12-month follow-up (for the EG, mean difference = 3.87 – 7.45; for the CG, mean difference = 3.31 – 5.36) (Table 6.4). Significant reduction in maintenance effects were noted in the CG at the

3-month (ABC-C mean difference = −1.56, 95% CI = -2.80 - -0.31, p = 0.02) and 12-month (ABC-C mean difference = −2.05, 95% CI = -3.31 - -0.78, p = 0.002) follow-ups.

Table 6.2 Effects of variables of interests

	Group	Baseline	1 month (midway through treatment)	2 months (end of treatment)	5 months (3 month follow-up)	14 months (12 month follow-up)	Time effect [Mean difference (95% CI), p-value]	Group effect [Mean difference (95% CI), p-value]	Interaction effect [Mean difference (95% CI), p-value]
Primary outcome									
ABC-C (0 to 100, higher better)	CBT + TOBT	53.86 (14.88)	57.44 (12.26)	61.03 (9.45)	60.07 (9.00)	60.11 (8.97)	-0.10(-0.19, -0.01), p=0.032	1.97(0.55, 3.40), p=0.007	0.22(0.09, 0.34), p=0.001
	GHE + TOBT	54.94 (14.28)	58.31 (13.10)	59.92 (10.65)	58.10 (12.78)	57.03 (12.64)			
Secondary outcomes									
SAFE-C (0 to 66, lesser better)	CBT + TOBT	15.60 (7.10)	15.45 (7.14)	13.66 (6.67)	13.70 (6.64)	13.76 (6.71)	-0.03(-0.06, -0.00), p=0.034	-1.18(-1.60, -0.76) p<0.000	-0.07(-0.11, -0.03), p=0.002
	GHE + TOBT	15.48 (5.13)	15.33 (5.13)	14.86 (5.13)	14.95 (5.67)	15.00 (5.96)			
BBS (0 to 56, higher better)	CBT + TOBT	43.56 (7.24)	43.86 (7.20)	44.70 (7.12)	44.49 (7.15)	44.24 (7.31)	-0.00(-0.02, 0.01), p=0.79	0.37 (0.13, 0.61), p=0.003	0.03(0.00, 0.05), p=0.029
	GHE + TOBT	44.48 (6.22)	45.19 (5.77)	45.34 (5.48)	45.17 (5.79)	45.30 (5.90)			
IADL (0 to 18, higher better)	CBT + TOBT	12.71 (2.96)	12.84 (3.09)	14.32 (2.75)	14.23 (2.79)	14.21 (2.87)	-0.02(-0.04, 0.00), p=0.11	1.21(0.90, 1.53), p<0.000	0.09(0.06, 0.11), p<0.000
	GHE + TOBT	13.05 (2.57)	13.20 (2.51)	13.25 (2.64)	13.02 (2.63)	12.83 (2.68)			
PCS (0 to 100, higher better)	CBT + TOBT	61.35 (8.78)	61.43 (8.72)	61.39 (9.01)	61.30 (9.08)	60.98 (9.21)	0.02(-0.02, 0.06), p=0.32	-1.36(-1.91, -0.81), p<0.000	-0.04(-0.09, 0.01), p=0.01
	GHE + TOBT	59.21 (9.57)	60.21 (9.62)	60.97 (10.11)	60.17 (6.57)	60.59 (9.82)			
CIM-C (10 to 50, higher better)	CBT + TOBT	39.69 (6.77)	39.82 (6.18)	40.55 (5.91)	40.42 (5.74)	40.36 (5.79)	0.86(-0.05, -0.00), p=0.02	0.74(0.25, 1.23), p=0.003	0.03(0.01, 0.07), p=0.016
	GHE + TOBT	39.61 (6.54)	39.56 (6.18)	39.65 (6.07)	39.43 (6.03)	38.95 (6.07)			

Note: GHE, general health education; CBT, cognitive behavioral therapy; TOBT, task-oriented balance training; CI, confidence interval; ABC-C, Activities-specific Balance Confidence Scale (Chinese version); SAFE-C, Survey of Activities and Fear of Falling in the Elderly (Chinese version); BBS, Berg Balance Scale; IADL-C, Lawton Instrumental Activities of Daily Living (Chinese version); PCS, physical health summary; CIM-C, Community Integration Measure (Chinese version).

Table 6.3 Between-groups effects of EG and CG

	1 month (mid -training)		2 months (post training)		5 months (3-months follow-up)		14 months (12-month follow-up)	
	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)
Primary outcome								
ABC-C (0 to 100, higher better)	0.02 (0.51)	0.97 (-0.99-1.02)	1.77 (0.85)	0.04 (0.08-3.45)	2.42 (1.01)	0.02 (0.42-4.42)	2.94 (1.02)	0.01 (0.91-4.96)
Secondary outcomes								
SAFE-C (0 to 66, lesser better)	-0.11 (0.16)	0.50 (-0.42-0.21)	-1.43 (0.22)	0.000 (-1.86—1.00)	-1.60 (0.28)	0.000 (-2.16—1.05)	-1.58 (0.36)	0.000 (-2.29—0.87)
BBS (0 to 56, higher better)	-0.03 (0.11)	0.77 (-0.26-0.19)	0.42 (0.13)	0.002 (0.16-0.68)	0.58 (0.16)	0.001 (0.26-0.91)	0.55 (0.19)	0.004 (0.18-0.93)
IADL (0 to 18, higher better)	0.05 (0.11)	0.70 (-0.18-0.27)	1.45 (0.18)	0.000 (1.09-1.80)	1.62 (0.21)	0.000 (1.20-2.03)	1.79 (0.21)	0.000 (1.36-2.22)
CIM-C (10 to 50, higher better)	0.25 (0.22)	0.26 (-0.19-0.69)	0.88 (0.24)	0.000 (0.41-1.36)	0.88 (0.31)	0.01 (0.26-1.50)	1.05 (0.32)	0.002 (0.41-1.69)
PCS (0 to 100, higher better)	0.08 (0.18)	0.64 (-0.28-0.45)	0.20 (0.24)	0.42 (-0.28-0.68)	0.62 (0.40)	0.13 (-0.18-1.42)	0.88 (0.43)	0.04 (0.02-1.73)

Note: EG, experimental group; CG, control group; CI, confidence interval; ABC-C, Activities-specific Balance Confidence Scale (Chinese version); SAFFE-C, Survey of Activities and Fear of Falling in the Elderly (Chinese version); BBS, Berg Balance Scale; IADL-C, Lawton Instrumental Activities of Daily Living (Chinese version); PCS, physical health summary; CIM-C, Community Integration Measure (Chinese version).

Table 6.4 Within-group effects of EG and CG

	1 month (mid -training)		2 months (post training)		5 months (3-months follow-up)		14 months (12-month follow-up)		Carryover effects (3-month follow up vs post training)		Carryover effects (12-month follow up vs post training)	
	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)	Estimate (Standard error)	p-value (95% CI)
Primary outcome ABC-C												
EG	3.87 (0.80)	0.000 (2.28-5.45)	7.45 (0.80)	0.000 (5.87-9.04)	6.68 (0.81)	0.000 (5.09-8.28)	6.91 (0.81)	0.000 (5.31-8.52)	-0.77 (0.81)	0.35 (-2.37-0.83)	-0.54 (0.82)	0.51 (-2.15-1.07)
CG	3.75 (0.62)	0.000 (2.52-4.98)	5.36 (0.62)	0.000 (4.13-6.59)	3.80 (0.63)	0.000 (2.56-5.04)	3.31 (0.64)	0.000 (2.06-4.57)	-1.56 (0.63)	0.02 (-2.80--0.31)	-2.05 (0.64)	0.002 (-3.31--0.78)
Secondary outcome SAFE-C												
EG	-0.23 (0.19)	0.23 (-0.60-0.15)	-2.02 (0.19)	0.000 (-2.39—1.65)	-2.20 (0.19)	0.000 -2.58- -1.83)	-2.30 (0.19)	0.000 (-2.68 --1.93)	-0.18 (0.19)	0.34 (-0.56-0.19)	-0.28 (0.19)	0.14 (-0.66-0.10)
CG	-0.12 (0.16)	0.48 (-0.44-0.20)	-0.58 (0.16)	0.000 (-0.90--0.26)	-0.59 (0.16)	0.000 (-0.91—0.27)	-0.74 (0.17)	0.000 (-1.07—0.42)	-0.01 (0.16)	0.97 (-0.33-0.32)	-0.16 (0.17)	0.34 (-0.49-0.17)
BBS												
EG	0.36 (0.10)	0.000 (0.17-0.56)	1.20 (0.10)	0.000 (1.01-1.40)	1.13 (0.10)	0.000 (0.94-1.32)	1.05 (0.10)	0.000 (0.85-1.24)	-0.07 (0.10)	0.45 (-0.27-0.12)	-0.16 (0.10)	0.12 (-0.35-0.04)
CG	0.38 (0.11)	0.001 (0.16-0.59)	0.73 (0.11)	0.000 (0.51-0.94)	0.52 (0.11)	0.000 (0.31-0.74)	0.50 (0.11)	0.000 (0.28-0.72)	-0.20 (0.11)	0.07 (-0.42-0.02)	-0.22 (0.11)	0.05 (-0.45--0.00)
IADL												
EG	0.20 (0.12)	0.09 (0.03-0.44)	1.68 (0.12)	0.000 1.45-1.91)	1.68 0.12)	0.000 (1.45-1.92)	1.75 (0.12)	0.000 (1.52-1.99)	0.00 (0.12)	0.98 (0.23-0.24)	0.07 (0.12)	0.035 (0.05-0.31)
CG	0.16 (0.11)	0.13 (0.05-0.37)	0.21 (0.11)	0.05 (0.00-0.41)	0.04 (0.11)	0.72 (0.17-0.25)	-0.03 (0.11)	0.81 (-0.19-0.24)	-0.17 (0.11)	0.45 (-0.27-0.12)	-0.23 (0.11)	0.30 (0.02-0.44)
CIM-C												
EG	0.29 (0.17)	0.09 (-0.04-	1.01 (0.17)	0.000 (0.69-1.34)	0.75 (0.17)	0.000 (0.42-1.08)	0.74 (0.17)	0.000 (0.41-1.07)	-0.26 (0.17)	0.12 (-0.59-	0.27 (0.17)	0.011 (0.06-0.60)

			0.61)								0.07)		
	CG	0.04 (0.20)	0.83 (-0.35-0.43)	0.14 (0.20)	0.50 (-0.26-0.53)	-0.10 (0.20)	0.62 (-0.50-0.29)	-0.25 (0.20)	0.23 (-0.65-0.15)	-0.24 (0.20)	0.24 (-0.63-0.16)	-0.38 (0.20)	0.06 (-0.78-0.02)
PCS													
	EG	2.06 (0.23)	0.000 (1.61-2.51)	2.88 (0.23)	0.000 (2.43-3.33)	3.04 (0.23)	0.000 (2.59-3.49)	2.87 (0.23)	0.000 (2.41-3.33)	0.16 (0.23)	0.50 (-0.30-0.61)	-0.01 (0.23)	0.95 (-0.47-0.44)
	CG	1.96 (0.21)	0.000 (1.55-2.38)	2.68 (0.21)	0.000 (2.27-3.10)	2.42 (0.21)	0.000 (2.00-2.84)	1.94 (0.21)	0.000 (1.51-2.36)	-0.27 (0.21)	0.21 (-0.69-0.15)	-0.75 (0.22)	0.001 (-1.17--0.32)

Note: EG, experimental group; CG, control group; CI, confidence interval; ABC-C, Activities-specific Balance Confidence Scale (Chinese version); SAFFE-C, Survey of Activities and Fear of Falling in the Elderly (Chinese version); BBS, Berg Balance Scale; IADL-C, Lawton Instrumental Activities of Daily Living (Chinese version); PCS, physical health summary; CIM-C, Community Integration Measure (Chinese version).

6.3.1.2 Secondary outcomes

Significant Group × Time interaction effects were observed for SAFE-C (mean difference = -0.07, 95% CI = -0.11 - -0.03, $p = 0.002$), BBS (mean difference = 0.03, 95% CI = 0.00 – 0.05, $p = 0.029$), IADL-C (mean difference = 0.09, 95% CI = 0.06 – 0.11, $p < 0.001$), PCS (mean difference = - 0.04, 95% CI = -0.09 – 0.01, $p = 0.01$), and CIM-C (mean difference = 0.03, 95% CI = 0.01 – 0.07, $p = 0.016$) mean scores (Table 6.2). No significant Group × Time interaction effect or time effect was identified for the S-PPA or MCS mean scores (Table 6.5).

Compared with the CG, the EG demonstrated greater improvement with respect to SAFE-C, BBS, IADL-C, and CIM-C mean scores from post-intervention to the 12-month follow-up (Table 6.3) and greater improvement in PCS mean score at the 12-month assessment point (mean difference = 0.88, 95% CI = 0.02-1.73, $p = 0.04$).

Compared with their baseline data, both the EG and CG demonstrated significant reduction in SAFE-C mean score over time from post-intervention to the 12-month follow-up (Table 6.4), and significant improvement in BBS and PCS mean scores starting at mid-intervention. The CG showed significant reductions in maintenance effects on PCS mean score at the 12-month follow-up assessment point (mean difference = -0.75, 95% CI = -1.17 - -0.32, p=0.001). Only the EG group showed significant improvements in IADL-C and CIM-C mean scores from post-intervention to the 12-month follow-up (Table 6.4).

6.3.2 Relationship between the lesion location and intervention response

Our univariate linear regression revealed that the lesion location (left or right hemisphere) was not significantly associated with reduction in the ABC-C mean score and improvements in related health outcomes at postintervention or 12-month following up (Table 6.6)

Table 6.5 Effects of variable of interests, fall risk and psychological function

	Group	Baseline	1 month (midway through treatment)	2 months (end of treatment)	5 months (3 month follow-up)	14 months (12 month follow-up)	Time effect [Mean difference (95% CI), p-value]	Group effect [Mean difference (95% CI), p-value]	Interaction effect [Mean difference (95% CI), p-value]
S-PPA: -2 to 4, lesser better	EG	1.29 (0.79)	1.30 (0.80)	1.29 (0.80)	1.31 (0.80)	1.30 (0.80)	0.00(-0.00, 0.00), p=0.09	-0.01(-0.02, 0.00), p=0.18	-0.00 (-0.00, 0.00), P=0.41
	CG	1.26 (0.73)	1.28 (0.71)	1.28 (0.71)	1.28 (0.72)	1.32 (0.71)			
MCS: 0 to 100, higher better	EG	58.34 (9.25)	60.19 (9.36)	61.02 (9.84)	60.97 (9.88)	60.47 (9.89)	-0.03(-0.06, 0.01), p=0.08	0.46 (-0.07, 0.98), p=0.09	0.06(0.02, 0.11), p=0.10
	CG	58.76 (7.75)	60.66 (7.57)	61.38 (7.45)	61.07 (7.80)	60.32 (7.32)			

Note: EG, experimental group; CG, control group; S-PPA, Short-form Physiological Profile Assessment; MCS, mental health summary.

Table 6.6(A) Regression modeling to determine the effect of lesion location (left-or-right hemisphere) on fear of falling, fear avoidance behavior, balance, fall risk, independent daily living, health-related quality of life and community integration at post intervention.

	B	*P*	*SE*	*β*	R^2(R^2 adjust)
Primary measure					
ABC-C	-4.21	0.09	2.40	-0.26	0.07 (0.05)
Secondary measures					
SAFE-C	0.30	0.51	0.37	0.10	0.01 (-0.01)
BBS	-0.26	0.32	0.25	-0.15	0.02 (0.00)
IADL-C	-0.23	0.46	0.31	-0.12	0.01 (-0.01)
S-PPA	0.02	0.17	0.01	0.21	0.05 (0.02)
CIM-C	-0.19	0.67	0.44	-0.07	0.00 (-0.02)
PCS	0.19	0.60	0.37	0.08	0.01 (-0.02)
MCS	0.79	0.09	0.45	0.26	0.07 (0.05)

Note: ABC-C, Activities-specific Balance Confidence Scale (Chinese version); SAFE-C, Survey of Activities and Fear of Falling in the Elderly (Chinese version); BBS, Berg Balance Scale; S-PPA, Short-form Physiological Profile Assessment; IADL-C, Lawton Instrumental Activities of Daily Living (Chinese version); PCS, physical health summary; MCS, mental health summary; CIM-C, Community Integration Measure (Chinese version).

Table 6.6(B) Regression modeling to determine the effect of lesion location (left-or-right hemisphere) on fear of falling, fear avoidance behavior, balance, fall risk, independent daily living, health-related quality of life and community integration at 12 month follow up.

	B	*P*	*SE*	*β*	R^2(R^2 adjust)
Primary measure					
ABC-C	-3.45	0.21	2.73	-0.20	0.04 (0.01)
Secondary measures					
SAFE-C	0.52	0.38	0.58	0.14	0.02 (-0.01)
BBS	-0.45	0.08	0.25	-0.27	0.08 (0.05)
IADL-C	-0.09	0.81	0.35	-0.04	0.00 (-0.02)
S-PPA	-0.01	0.53	0.02	-0.10	0.01 (-0.02)
CIM-C	-0.27	0.65	0.59	-0.07	0.01 (-0.02)
PCS	-0.46	0.50	0.67	-0.11	0.01 (-0.01)
MCS	0.96	0.06	0.51	0.29	0.08 (0.06)

Note: ABC-C, Activities-specific Balance Confidence Scale (Chinese version); SAFE-C, Survey of Activities and Fear of Falling in the Elderly (Chinese version); BBS, Berg Balance Scale; S-PPA, Short-form Physiological Profile Assessment; IADL-C, Lawton Instrumental Activities of Daily Living (Chinese version); PCS, physical health summary; MCS, mental health summary; CIM-C, Community Integration Measure (Chinese version).

6.4 Discussion

This was the first study to compare the combined effects of CBT and TOBT against those of GHE and TOBT in people with stroke. The CBT protocol was originally developed in a North America fall prevention programme entitled “A matter of balance” (Tennstedt et al., 1998), and was adopted in an European study

(Zijlstra et al., 2009) to work with the fear of falling in the older people. This study modified the original CBT protocol with stroke related contents, and combined with TOBT to work with the fear of falling and related health outcomes in people with stroke. Consistent with the North American and European studies, this study yielded promising results in reducing fear of falling and improving related health outcomes among people with stroke.

Several key findings emerged from this study. First, although earlier improvement was not noted, we found that compared with the GHE + TOBT intervention, the CBT + TOBT intervention produced greater reduction in the fear of falling and fear avoidance behavior and greater improvements in balance performance and independent daily living from immediate post-intervention to 12 months post-intervention. Second, although much of the within-group reduction in the fear of falling was maintained in the EG until 12 months post-intervention, that observed in the CG group dissipated by 3 months post-intervention. Third, the CBT + TOBT intervention improved independent daily living and community integration, with the beneficial effects continuing for 12 months post-intervention. However, no such benefits were observed in the CG.

6.4.1 Effects of CBT and TOBT

Previous studies have shown that TOBT can induce use-dependent plastic changes in the brain of people with stroke (Carey et al, 2004) and improve their lower limb functional performance (Dean, Richard & Malouin, 2000). The findings of the present study are consistent with those of previous studies showing that physical interventions can reduce the fear of falling and improve the balance and quality of life of people with stroke (Tennstedt et al, 1998; Combs et al, 2010).

Our EG demonstrated 13.3%, 12.4%, 12.7%, and 2.6% improvement from the baseline value of the ABC-C, SAFE-C, IADL-C, and BBS, respectively, at post-intervention. Although the improvement in BBS could not reach the minimal detectable change in postural balance (Hiengkaew, Jitaree & Chaiyawat, 2012) of 8% to 12% from baseline on the BBS, our EG showed better improvement than the CG (1.9% improvement from the baseline value) and the stroke subjects of the Holmgren et al. (2010) group who received 5-week high-intensity exercise training (2% improvement from the baseline value). To the best of our knowledge, no minimal detectable change values for the ABC, SAFE, and IADL have been established for comparison at this stage, but the superiority of our EG in these aspects suggests the synergistic effects of CBT and TOBT.

6.4.2 Potential mechanisms of the intervention effects

6.4.2.1 Potential mechanism of the effects of TOBT

Based on Bandura's theory of self-efficacy, an individual's performance is influenced by their perceptions about their ability to engage in the behavior in question. Thus, it hypothesizes that people with stroke perceived balance efficacy can be improved by increasing their sense of mastery, for example, via physical interventions. In the studies on people with stroke by Salbach et al. (2005) and Lord et al. (2008), 6-week task-oriented walking training and community ambulation caused 14% and 26% improvements, respectively, in balance confidence at post-intervention. Our TOBT participants demonstrated approximately 9% improvement in ABC-C post-intervention, which is comparable with the improvement reported by Salbach et al. (2005) but lower than that reported by Lord et al. (2008). The difference could be attributed to the chronicity of illness, as the subjects in Lord et al. (2008) study were in the subacute stage of stroke, whereas those in Salbach et al. (2005) and our study were in the chronic stage of stroke. Overall, these findings suggest that physical intervention is more effective in reducing the fear of falling during the subacute stage than during the chronic stage and that TOBT reduces the fear of falling as measured by the ABC-C by approximately 10% in people with stroke.

Based on the self-efficacy theory, the beneficial effects of TOBT on physical function are more difficult to explain than its effects on the fear of falling and balance performance. Our findings supported the hypothesis that TOBT could improve fear of falling and balance performance through enhanced sense of mastery experiences and in turn leading to the improved physical function of people with stroke. However, the self-efficacy theory could not explain why the benefits of TOBT had significant reduction in carryover effects in physical function (Table 6.7, estimate=-0.75, p=0.001) but remained in balance performance at 12-month follow up. The meta-analysis conducted by Chen and Rimmer (2011) revealed that 10 weeks of physical exercise had a small-to-medium effect on physical function immediately after intervention but not at 12- to 24-weeks post-intervention. Consistent with Chen and Rimmer (2011) findings, the results of our CG revealed that physical exercise alone did not have sustainable effects on physical function. One possible explanation for this finding is that participants did not have sufficient motivation to continue engaging in exercise, thus resulting in a gradual decline in the beneficial effects on general physical function after the intervention ended.

6.4.2.2 Potential mechanism of the effects of combining CBT with TOBT

One strength of this study was its incorporation of a CBT intervention targeting the unrealistic fall beliefs of individuals. Our findings suggest that CBT and TOBT have synergistic effects, as reflected by the greater reductions in the fear of falling and fear avoidance behavior and greater improvements in the related health outcomes compared with those by the combined GHE and TOBT intervention. One probable reason for these synergistic effects could be the improved self-efficacy. According to Bandura, perceived self-efficacy is crucial in chronic illness management, and it could influence motivations and mediate behavior and ultimately determine task performance. Customary physical training predominantly focuses on addressing the physical factors to enhance balance self-efficacy through the sense of mastery, but other sources of self-efficacy, including verbal persuasion, vicarious learning, and learning coping strategies to manage emotional reactions were not addressed. This indicates that further improvement is possible if interventions utilize all sources of self-efficacy as identified by Bandura. In our CBT intervention, the feedback exchange during group sessions and witnessing the success of other group members could enhance self-perceived efficacy of the subjects by verbal persuasion and vicarious learning, respectively. In addition, CBT could reduce psychological responses in people with stroke by identifying and disputing their false beliefs about consequences of falls. Thus, reduced fear of falling could in turn be reflected in daily physical activities, resulting in a reduction in fear-avoidance behavior and improvements in related health outcomes, as identified in our findings.

Our CBT + TOBT intervention was not superior to the GHE + TOBT intervention in enhancing participants' physical function as measured by PCS during the intervention phase, but the within-group benefits in the EG lasted for 12 months, which was longer than those in the CG. Keeping in mind the conclusions from the meta-analysis conducted by Chen and Rimmer (2011), which showed a lack of long-term maintenance of individual improvements from TOBT, the differential effects of the EG intervention on the maintenance effects in the present study suggest that CBT enhanced the maintenance of the benefits of TOBT in physical function. However, neither the CBT+ TOBT nor the GHE + TOBT combination showed significant reduction in fall risk as measured by S-PPA, which was consistent with the results of previous clinical trials on lower limb and balance exercises in community-dwelling older adults (Sherrington et al, 2014; Fair et al, 2014). As fall risk is a complicated and multifactorial domain, our interventions, which mostly target reduction in the fear of falling and improvement in balance, may be insufficient to reduce fall risk or prevent falls. To specially affect fall risk, additional intervention may be needed, such as home safety visits.

Community integration is a comprehensive outcome that reflects the degree of success of rehabilitation interventions in terms of both physical and psychological functions. Although our CBT + TOBT intervention was statistically superior to the GHE + TOBT intervention in enhancing participants' level of community reintegration as measured by CIM-C, this study showed that using the combined CBT and TOBT intervention could not reach clinical significance as only minimal additional improvement revealed. The reasons for these null findings are not entirely clear, but several explanations are possible. For example, our study participants might have reached a plateau of community integration before the study began. Furthermore, our CBT + TOBT intervention might not have adequately supported the participants in translating the reduction in the fear of falling to actual improvements in community integration. Alternatively, improvements in community integration might have been constrained by other factors that could not be addressed by the interventions provided, such as social policy. If the lack of beneficial effects on community integration is due to the lack of efficacy of the combined intervention, modifications in the intervention may be needed for a greater beneficial effect. If this null finding is due to a social policy, then changes in healthcare policy may be needed.

6.4.3 Effects of Lesion Location

Although postural imbalance predominates in cases with lesions in the right hemisphere, the present study revealed that the lesion location (left or right hemisphere) does not play a predictive role in reducing the fear of falling and improving related health outcomes after the CBT + TOBT intervention. This suggests that the associated hemiparesis and the degree of neglect of people with stroke did not affect the benefits of our intervention.

6.4.4 Strength and Limitations

6.4.4.1 Strength of the study

This study had several important strengths. First, the combined intervention offered a treatment (CBT) that was both effective and complementary to physical exercise. Second, a detailed study protocol was published before the study began, allowing replication of the trial in additional populations. Third, one of the goals (and strengths) of CBT is to facilitate ongoing behavioral changes and improvements over time, even after the treatment is completed. We demonstrated the long-term benefits of CBT, when combined with TOBT, for 12 months after completing the treatment.

6.4.4.2 Limitations of the study

The study also had several limitations. First, this study did not record the number of actual falls; thus, the augmenting effects of CBT on fall reduction could not be inferred. We believe that further fall preventive strategies, such as an assistive device and home assessment, are required to transit the effects of CBT in the living environment. Thus, we recommend future studies to investigate the effects of incorporating fall preventive strategies after or together with reduction in the fear of falling. Second, we did not assess two potential confounding factors, depression and fatigue, which could affect the quality of life and could be associated with functional outcomes and mobility in people with stroke. However, we measured another important predictor of the community integration of people with stroke, i.e., the fear-avoidance behavior (Liu et al, 2015), and directly measured the associated health outcomes of fatigue by evaluating the level of independent living and mobility. Third, as with any behavioral study, the study participants were not blinded to their intervention, which might have resulted in increased outcome expectancies in the CBT group. Fourth, the study participants were ambulatory and relatively active and had high educational attainment and socioeconomic status. Thus, the findings may or may not be generalizable to people with stroke who are more disabled and have low educational attainment or low socioeconomic status than those in this study. In addition, an increase in the number of intervention sessions and/or the inclusion of booster sessions may increase the overall efficacy. Fifth, the follow up period of this study was up to 12 months long. We could not exclude the possibility that some of the subjects might have other treatment seeking behavior, especially traditional Chinese medicine, which might confound the follow up assessment.

6.5 Summary and conclusions

Fear of falling could be protective in nature and promote the adoption of fall-protective measures. However, excessive level of this fear can lead to inappropriate defensive behavior, leading to disability and increased fall risks. This study provides important new information regarding the efficacy of an 8-week, 16-session CBT + TOBT intervention that appears to reduce the fear of falling and fear avoidance behavior and improve balance performance and independent daily living, with benefits maintained for 12 months after completing the intervention. CBT appears to be a feasible and effective adjuvant therapy to augment the treatment effects of customary physiotherapy in cognitively intact people with stroke.

Chapter 7

Summary and conclusions of the thesis

7.1 Summary

This thesis began with a review of the recent literature on stroke (Chapter 1), which revealed the nature of stroke as a chronic and disabling disease. Globally, the annual incidence of first-ever stroke is expected to increase to 23 million by 2030. The major impairment after stroke is the sensorimotor impairment, including muscle weakness, spasticity, loss of dexterity, cognitive disorders and mood disturbances, in which the reported prevalence of a fear of falling ranges from 44% to 65% among community-dwelling people with stroke (Schmid et al., 2009; 2011). Previous studies (Holmegren et al., 2010; Hung et al., 2014) suggested that physical training could effectively reduce the fear of falling in stroke survivors. Additionally, cognitive behavioral therapy (CBT) was identified as an alternative treatment intervention for fear of falling in older adults.

In Chapter 2, we identified several gaps in the research regarding the interventions used to treat a fear of falling in people with stroke, as follows:

(1) No previous studies had summarized the ability of CBT to improve the fear of falling and balance;

(2) The effects or independent contributions of fear avoidance behavior on the community reintegration of community-dwelling people with stroke were not systematically investigated in previous studies;

(3) The psychometric properties of several assessment measures, including the Community Integration Measure (CIM) (McColl et al., 2001), Chinese version of the Survey of Activities and Fear of Falling (SAFE-C) (Chou et al., 2005) and Short-form Physiological Profile Assessment (S-PPA) (Lord et al., 2003), had not been tested in people with stroke; and

(4) Previous studies had not investigated the effects of a combination of CBT with task-oriented balance training (TOBT) to reduce the fear of falling and improve the related health outcomes, including fear avoidance behavior, balance performance, fall risks, independent daily living, community reintegration and health-related quality of life.

Our systematic review and meta-analysis (Chapter 3) revealed that CBT can effectively reduce the fear of falling and improve balance performance in older adults. The results of 5 randomized controlled trials including 1,626 subjects demonstrated that a CBT protocol including the components of cognitive restructuring, promotion of physical activities and goal setting yielded significant immediate and retention effects for up to 12 months in terms of reducing the fear of falling. Additionally, this protocol enhanced balance performance among older adults for up to 6 months. The results of our systematic review and meta-analysis also support the use of CBT as an adjunct therapy with physical training to reduce the fear of falling and improve balance performance in people with stroke.

In Chapter 4, we investigated the effect of fear avoidance behavior on the level of community reintegration in people with stroke. Our predictive model including 57 community-dwelling people with stroke explained 49.7% of the variance in community reintegration scores as measured by the Chinese version of the CIM (CIM-C). Fear avoidance behavior was the strongest independent predictor of the level of community reintegration, accounting for 11.6% of variance in the CIM-C scores of cognitively intact ambulant community-dwelling people with stroke in our predictive model. Our findings filled an existing gap in the research and demonstrated that an intervention that targets fear avoidance behavior could potentially improve community reintegration among people with stroke who express a fear of falling.

In Chapter 5, we presented the general methodology of our main study. We reported the findings of three cross-sectional studies related to three of our outcome measures, including the validation of the SAFE-C (Chou et al., 2005) and the S-PPA

(Lord et al., 2003) and the translation and validation of the CIM-C (McColl et al., 2001) for use in people with stroke. Our findings from these three cross-sectional studies suggested that all three measures are reliable and valid for the respective assessments of fear avoidance behavior, fall risks and community reintegration in cognitively intact and ambulant community-dwelling people with stroke.

In Chapter 6, we described a randomized controlled clinical trial (RCT) in which we demonstrated that the combination of CBT + TOBT was superior to the combination of general health education (GHE) + TOBT for reducing the fear of falling and improving some health-related outcomes in people with stroke. Eighty-nine subjects were allocated randomly into either the CBT + TOBT or GHE + TOBT group, and both groups were subjected to 90-min interventions on 2 days per week for 8 weeks. Our findings revealed that the CBT + TOBT intervention led to greater reductions in the fear of falling and fear avoidance behavior and greater improvements in balance performance and independent daily living at 12 months post-intervention when compared to the immediate post-intervention time point. The CBT + TOBT intervention yielded improvements in independent daily living and community integration, the effects of which persisted for 12 months post-intervention. By contrast, no such effects were observed in the GHE + TOBT group. We therefore recommend the consideration of CBT as an adjuvant therapy to standard physiotherapy for cognitively intact people with stroke.

Chapter 6 also provided a possible explanation for the demonstrated synergistic effects of CBT + TOBT, based on Bandura's theory of self-efficacy (1997). Physical training alone, in the form of TOBT, predominantly addresses physical factors with the intent to enhance balance self-efficacy through a sense of mastery. However, this approach does not utilize other sources of self-efficacy, including verbal persuasion, vicarious learning and coping strategies to manage emotional reactions. CBT, as an additional treatment component, could enhance self-efficacy by enabling verbal exchanges and vicarious learning and identifying and disputing false beliefs about falls. Thus, reductions in the fear of falling and fear avoidance behavior may have led to improvements in the identified health outcomes.

7.2 Limitations of the thesis and directions of future research

The findings of this thesis are limited by several factors. First, an 8-week CBT + TOBT group training course might not be sufficient to transmit the beneficial effects of treatment on the fear of falling and balance ability to improvements in psychological function and community reintegration. In other words, the study may have been limited by time and resources. Second, our study participants were relatively ambulant, active and cognitively intact, which may have limited the generalizability of our findings regarding the effects of CBT + TOBT. Third, we have not identified a potential mechanism to explain our observations.

Three priorities for future research have been identified from the findings of this thesis. First, we recommend further psychometric work and the development of an instrument to assess the construct of fear of falling. Although recent studies have applied several instruments, including the Activities-specific Balance Confidence (ABC-C) Scale (Mak et al., 2007) and Falls Efficacy Scale (Tinetti, 1990), these measures aim to assess impaired balance confidence but cannot distinguish whether this factor is adaptive (i.e., leading to the adoption of appropriate fall preventive measures) or maladaptive (i.e., self-imposed limitations on physical activities).

Second, although we attempted to use the theory of self-efficacy (Bandura, 1997) to explain the mechanism by which CBT improves the fear of falling and fear avoidance behavior, we did not address the potential mechanism underlying a fear of falling from a neurophysiological perspective. Therefore, we encourage a future study of the neurophysiological mechanism underlying the fear of falling involving an investigation of how CBT may or may not affect the fear of falling in subjects with and without stroke. For example, a future study might use functional-near-infrared spectroscopy (fNIRS) to examine cerebral blood flow in the prefrontal cortex area in people with or without a fear of falling and to determine the effects of CBT on an excessive fear of falling.

Third, although recent clinical trials have demonstrated the efficacy of physical training and CBT for reducing the fear of falling, this area of research lacks a theoretical model. A future study could use empirical findings to further examine Beck's cognitive model (2011) with respect to the fear of falling. For example, a future study based on the empirical findings of older adults with or without disabling diseases might identify fall-related adaptive and maladaptive automatic thoughts, related contextual factors and associated behavioral responses that could be tested against the hypotheses derived from Beck's cognitive model (2011). The development and testing of a theoretical model of fear avoidance activity due to a fear of falling may provide a framework for the design of future restorative therapies.

7.3 Implications on stroke care practice

Our findings revealed that interventions targeting on fear of falling could in turn leading to the improvement in fear avoidance behavior, balance performance, independent daily living and community reintegration of people with stroke. We suggest that the assessment of fear of falling could be adopted as a routine clinical procedure. People with stroke who are assessed to have appropriate level of fear of falling, the rehabilitative training could be focused on controlling danger (i.e., fall risk) through physical training. For people with stroke who are assessed to have excessive level of fear of falling, the rehabilitative training could be focused on controlling fear (i.e., physical activity avoidance) instead. We recommended that, for future clinical use, a simplified protocol could be developed to facilitate application in practice. We also recommended reduce the number of outcome measures from 7 in this study to 3, including the Chinese version of the Activities-specific Balance Confidence scale (ABC-C), the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) and the Chinese version of the Lawton Instrumental Activity of Daily Living (IADL-C), for future clinical application. Furthermore, given that the intervention for reducing fear of falling is multi-facets in nature, it is expected that a multi-disciplinary approach involving the contributions from physiotherapists, clinical psychologists and nurses could maximize the effects of combined use of CBT and physical training.

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Appendix 3.1 Chapter 3 published on Age and Ageing (Final manuscript)

Cognitive behavioral therapy for fear of falling and balance among older people: A systematic review and meta-analysis

Introduction

Fear of falling refers to the fearful anticipation of falls. It is common among community-dwelling older people with an estimated prevalence of 29% to 76% [1-5]. Excessive fear of falling can lead to reduced balance performance [3, 6], limited activity levels [6, 7], restricted social participation [8, 9], and compromised quality of life [8, 10].

Three recent systematic reviews have provided evidences on interventions aimed at reducing fear of falling among older people [11-13]. Two principal forms of intervention—physiological interventions such as balance exercise, and psychological interventions such as cognitive behavioral therapy (CBT)—were adopted in the reviewed clinical trials. The evidence from these three systematic reviews suggests that it is possible to reduce the fear of falling among older people. However, the effect sizes of the interventions on reducing fear of falling were not synthesized in these reviews.

To provide a precise understanding, Kumar [14] reviewed 25 randomized and quasi-randomized controlled trials with exercise interventions on reducing fear of falling. The synthesized effect sizes were small to moderate (standardized mean difference (SMD) 0.37, 95% CI 0.18–0.56) and the effects did not vary by type, frequency, or duration of intervention. However, effects of psychological interventions aimed at reducing fear of falling among older people, such as CBT, have not been reviewed specifically or synthesized.

CBT is a psychotherapeutic intervention aimed at modifying individuals' thoughts and behavior. People with fear of falling might have self-defeating thinking such as over-pessimistic views regarding the consequences of falls and low fall-related efficacy. CBT could help altering those maladaptive believes and directing to adaptive behaviors such as exercising regularly in safe manners. However, our current state of knowledge about the effects of CBT in reducing fear of falling among older people is limited to the narrative evidence presented in the previous reviews [11–13] in which only included two randomized controlled trials (RCTs) with CBT interventions [15, 16].

Kumar's [14] systematic review and meta-analysis focused on the effects of exercise therapy on reducing fear of falling but the reviewed interventions did not beyond the scope of habitual physiotherapy. The three previous systematic reviews [11 – 13] have reported the effect of interventions on fear of falling, finding that CBT had shown beneficial results, but none has systematically reviewed and synthesized the effect of CBT on improving balance. Thus, we conducted a systematic review and meta-analysis to evaluate and synthesize the effects of CBT for reducing fear of falling and improving balance among older people.

Methods

This review protocol was registered in the PROSPERO database of systematic reviews (registration number CRD42017069111).

Eligibility criteria

Types of participants

Trials with a majority of community-dwelling older people aged >60 were included. The cut-off point of 60 years was determined according to the United Nations definition [17].

Types of interventions

CBT is defined as a psychotherapeutic technique with a cognitive restructuring component with or without behavioral modification procedures.

Types of comparators

Trials compared CBT with an inactive control or compared exercise therapy with and without CBT were included. We defined exercise therapy, with reference to the Medline Subject Heading, as physical activities designed to achieve specific therapeutic goals with the purpose of restoring, maintaining, or improving normal musculoskeletal functions.

Types of outcome measures

Trials with at least one validated measure of either fear of falling or balance at both baseline and post-intervention were included. If more than one validated measure was used, priority was given according to the following rules:

a. For fear of falling, the primary measures were the Falls Efficacy Scale (FES) [18] and the Activities-specific Balance Confidence (ABC) scale [19], then any other validated measure.

b. For balance, the primary measure was the Berg Balance Scale (BBS) [20] and then any other validated measure.

Types of studies

All RCTs published in a peer-reviewed journal were included.

Excluded studies

Studies using a population with a specific disease or condition such as cerebral vascular disease, or psychological treatment that did not include a cognitive restructuring component were excluded.

Data source and searches

In Oct 2017, six electronic bibliographic databases were searched including MEDLINE, CINAHL, PubMed, Web of Science, EMBASE, and Cochrane Library. Combinations of text words and MeSH terms as the search strategy is shown in Supplementary data, Appendix 1, available in Age and Ageing online http://www.ageing.oxfordjournals.org/. We also screened the concurrent clinical trials on the "clinicaltrials.gov" website and reference lists of the selected studies and the previous systematic reviews [11-13]. Forward citation search of selected studies was checked for additional eligible studies.

Study selection

Titles, abstracts and full texts of the selected articles were independently screened by two authors.

Data extraction

Two authors independently extracted data on the methodology and outcome measures using a standardized data extraction sheet.

Methodological quality

The included studies were independently rated by two authors using the Risk of Bias Tool in the Cochrane Handbook for Systematic Reviews of Interventions [21].

Statistical analyses

For the immediate effect, the mean change scores were calculated by subtracting the mean score of the post-intervention CBT group from the mean score of the control group, and then dividing the result by the pooled standard deviation of the two groups with a confidence interval of 95%. For the retention effect, the mean change scores of studies that included short-term follow-up (last follow-up < 6 months or midway follow-up at 6 months) or long-term follow-up (last follow-up > 6 months) were calculated by subtracting the mean score of the CBT group from the mean score of the control group, and then also dividing the result by the pooled standard deviation of the two groups with a confidence interval of 95%.

We used the Comprehensive Meta-Analysis software (version 2.0, Biostat Inc.) to calculate the pooled mean effect sizes. The effect sizes were defined as small (0.2), medium (0.5), or large (> 0.8) [22]. The random effects models were adopted.

Testing homogeneity

Heterogeneity was estimated using I-squared (I2) and Q-statistics. The I2 value of 25%, 50%, and 75% represent low, moderate, and high heterogeneity, respectively.

Subgroup analysis

A predefined subgroup analysis would be conducted if >2 trials available to determine the differences in outcomes between individual CBT and group-based CBT using mixed effects models.

Sensitivity analysis

Sensitivity analyses were conducted to analyze between-groups effect sizes by removing trials that compared exercise with and without CBT.

Risk of bias across studies

We inspected the publication bias using funnel plots and Egger's regression test if >10 trials were identified to ensure power adequacy [23]. The Fail-Safe N analysis would be performed if <10 trials.

Declaration of sources of finding

This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

Results

Study selection

A total of 233 publications were identified from the electronic database of which 24 were removed as duplicates. An additional study [15] was identified in the reference list of a previous review [13]. The full texts of the remaining 10 studies were assessed, of which six were included in our systematic review and five in our meta-analysis.

Study characteristics

The characteristics of the six included studies are summarized in Table 1 (please see Table 1, Appendix 2, in the supplementary data on the journal website (http://www.ageing.oxfordjournals.org/).

Participants.

The 6 reviewed studies included a total of 1,626 participants with mean age of 75.71 (74% female, n=1,208; sample size 80 to 434) mainly recruited from the general community (n = 1,546, 95%). At baseline, one study [24] (n = 122) included subjects with at least one episode of fall in the year before the study. Two studies (n = 266) reported that 18% [25] and 56% [26] of participants had at least one fall episode in the year before the studies began. Two studies reported that 23% [15] and 61% [27] of participants had at least one fall episode three months and six months before the studies began respectively.

Intervention.

Four studies [15, 24-26] adopted group-based interventions and two [27, 28] adopted individual interventions. Five studies [15, 24-26, 28] used face-to-face contact and one study [27] used both face-to-face and telephone contact. The length of intervention ranged from four to 20 weeks, and the number of face-to-face sessions ranged from three to nine with durations of 20 to 120 minutes.

The core components of the CBT interventions included cognitive restructuring, personal goal setting, and promotion of physical activities. The CBT interventions of three studies [25-27] were delivered by nurses.

Comparisons.

Of four studies [15, 24, 27, 28] with two intervention arms, three studies compared CBT with inactive control [15, 27, 28] and one study compared the combined use of CBT and Tai Chi with Tai Chi alone [24]. Two further studies were three-arm trials in which CBT was compared with care-as-usual and CBT with Tai Chi [25, 26]. The mean follow-up period from immediate post-intervention to final measurement was 9.00 + 4.12 months, ranging from four to 12 months.

Outcomes.

Two studies [25, 26] assessed fear of falling by the FES [18]. Another two studies [27, 28] adopted the international version of the FES (FES-I) and another one study [24] adopted the Chinese version of the FES-I. The remaining one study [15] adopted the modified version of the FES. Three studies [25-27] assessed balance by the Tinetti Mobility Scale (TMS) and one [28] used the functional reach test.

Methodological quality

The quality of the included studies varied (please see Table 2, Appendix 3, in the supplementary data on the journal website (http://www.ageing.oxfordjournals.org/). Five studies [24-28] reported adequate random sequence generation, and four [24-27] reported adequate assessor binding. Five studies [15, 24-26, 28] were assessed at low risk of attrition bias. All the six included studies were rated at low risk of reporting bias and other bias. However, all the six included studies had high risk of performance bias due to the lack of blinding between research personnel and participants that probably could lead to overestimation of true effects of CBT.

Quantitative data analyses

Effects of CBT intervention

Fear of falling

Figure 2 summarizes the immediate between-groups effects of CBT compared with control conditions. Our analysis of five studies [24-28] revealed a significant ($p < 0.001$) small effect size of 0.33 (95% CI 0.21–0.46) in favor of CBT compared with control with no significant heterogeneity ($I2 = 0\%$, $p = 0.793$). For the short-term retention effect (<6 months) (please see Figure 3, Appendix 4 in the supplementary data on the journal website (http://www.ageing.oxfordjournals.org/), our analysis ($n = 4$) [24-26, 28] showed a significant ($p = 0.002$) small effect size of 0.25 (95% CI 0.09-0.41) in favor of CBT with no significant heterogeneity ($I2 = 0\%$, $p = 0.679$). For the long-term (>6 months) retention effect, our analysis ($n = 2$) [27, 28] showed a significant ($p < 0.001$) small effect size of 0.37 (95% CI 0.21–0.53) in favor of CBT with no significant heterogeneity ($I2 = 0\%$, $p = 0.975$).

There was no effect of CBT on balance immediately following the trial, but a small effect of 0.18 (95% CI 0.02–0.33, $p = 0.031$) at the short-term (<6 months) follow-up. We did not calculate the long-term (>6 months) effect as only one study [28] with last follow-up >6 months.

Subgroup analysis

Only adequate number of trials ($n = 5$) was available for the subgroup analysis for the immediate effect of fear of falling. Our analysis (please see Table 3, Appendix 5 in the supplementary data on the journal website (http://www.ageing.oxfordjournals.org/) based on the treatment delivery format (individual vs. group-based intervention) revealed a significant difference ($Q = 0.200$, $df = 1$, $p < 0.000$). Group-based interventions showed a significant ($p < 0.000$) small effect size of 0.29 (95% CI 0.00–0.36), revealing a weaker effect than individual based interventions, which displayed a significant ($p = 0.013$) small to moderate effect size of 0.35 (95% CI 0.20–0.51).

Sensitivity analysis

With one trial [24] compared Tai Chi with and without CBT removed, the immediate effect ($g = 0.34$, 95% CI 0.20–0.48, $p < 0.001$) of CBT on fear of falling remained and the short-term (<6 months) retention effect on fear of falling increased from g = 0.25 to g = 0.28 (95% CI 0.10-0.46, p = 0.002). There was no effect on balance immediately following the trial and at the short-term (<6 months) follow-up (please see Figure 3, Appendix 6, in the supplementary data on the journal website (http://www.ageing.oxfordjournals.org/).

Publication bias

Less than 10 trials were identified, thus the Fail-Safe N analysis was performed and indicated that the required number of missing studies to bring the p-value > 0.05 (immediate effect on fear of falling) was 27.

Discussion

Our results suggest that CBT with components of cognitive restructuring, promotion of physical activities, and goal setting, is effective in reducing fear of falling immediately with retention effect up to 12 months. It also demonstrated effects on enhancing balance at <6 months follow-up when compared with control conditions. Subgroup analysis suggested that the effect of group based CBT may be weaker than individual CBT on reducing fear of falling.

Our findings demonstrate that the immediate effects of CBT on reducing fear of falling (Hedges' g 0.33, 95% CI 0.21–0.46) are comparable to the use of exercise therapy alone (SMD 0.37, 95% CI 0.18–0.56) [14]. Besides, the retention effect of CBT on reducing fear of falling is superior to the use of exercise therapy alone at <6 months post-intervention (SMD 0.17, 95% CI 95% -0.05–0.38) and >6 months post-intervention (SMD 0.20, 95% CI -0.01-0.41) as reported in Kumar [14] systematic review and meta-analysis.

The positive effects of Tai Chi in reducing fear of falling and improving balance self-efficacy have been demonstrated in previous studies. However, in Liu study, group of 64 participants received 8 weeks of Tai Chi combined with CBT training did not report better performance in fear of falling (mean difference: -0.46, 95% CI: -2.74-1.81, p = 0.69) and balance (mean difference: 0.58, 95% CI: -0.28-0.49, p = 0.58) than those who received Tai Chi training alone. As the mechanism of CBT is to alter maladaptive believes and direct to adaptive behavioral changes by cognitive restructuring techniques, CBT delivered in form of 10–11 participants per group in Liu study might possibly jeopardize the treatment effects. Findings in Liu study should be interpreted with considerations to the design of training and future trials are needed to re-examine the augmenting effect of CBT as an adjunct therapy to customary exercise.

Our findings also revealed no statistically significant effect of CBT on enhancing balance immediately after the intervention but at <6 months post-intervention. One possible explanation is that one of the objectives of CBT is to safely increase participants' level of daily activities. It is different from ordinary health promotion techniques focusing on information giving in which the treatment effect is expected to diminish over time. Instead, CBT emphasizes on establishing habitual behavioral patterns. Thus, the improvement in balance could only be observed after a certain period of time after the participants had increased their levels of daily activities. However, one of the larger trials [27] in our analysis did not have six months post-intervention follow-up information and all the five included studies did not have >6 post-intervention follow-up information on balance improvement. It could have limited our findings if the effect of CBT on improving balance occurs at later stage after intervention.

Another important factor implicated in studies on the fear of falling is fear avoidance behavior, which refers to the restriction of physical activities due to impaired confidence in maintaining balance during physical activities. However, only one of the included studies examined the effects of CBT on this aspect, with significant reductions revealed at 5-month follow-up (adjusted mean difference = -2.38, 95% CI $-\infty$ − -1.12; $p = .001$) and 12-month follow-up (adjusted mean difference = -2.67, 95% CI -∞ − -1.37; p = .001). We recommended that future RCTs with larger sample sizes should investigate this aspect.

Limitations

This study has several limitations. Our review only included studies with older adults and excluded those with specific medical conditions or disorders, and all the included studies excluded participants with impaired cognitive function. Thus, the results may not be generalizable to frail older adults with impaired cognitive function and/or chronic illness. The findings of this study might also have been affected by high risk of performance bias due to the infeasibility of blinding participants and therapists owing to the nature of intervention, and high risk of publication bias due to the small number of included studies for statistical analysis by funnel plots and Egger's regression test. Moreover, the differences among CBT treatments might have contributed to clinical heterogeneity even though statistical homogeneity of effect size was suggested by homogeneity testing (I2 and Q-statistics). Although the core CBT element, cognitive restructuring, was embedded, the CBT interventions varied across studies in terms of the number and duration of sessions, delivery format, treatment contents and therapists' background. Furthermore, we may have missed studies that did not explicitly stating "CBT" or "cognitive behavioral therapy" in the title and abstract. In addition, before we did the meta-analysis, we did not consider to adjust the p-values under the false discovery rate method with Bonferroni correction or compute the power level of all included studies which was equal to 1 – Type II error that might result in high false positive rate (Type I error). In other words, the power of some included studies may be too low to detect the true underlying significant effect of intervention and this might affect the validity of our meta-analytic results. Finally, given the vulnerability of overall effect size revealed by the Fail-Safe N test, a small number of future studies with null effect might alter the findings of this study and we may have overestimated the intervention effects due to the small number of trials included [29].

Conclusion

This study is the first systematic review and meta-analysis of CBT on reducing fear of falling and improving balance among older people. Our results suggest that CBT interventions have significant immediate and retention effects up to 12 months on reducing fear of falling, and six months post-intervention effect on enhancing balance among older people. Based on our findings, a sample size of at least 190 participants is recommended for future research with three-arm comparisons of CBT, exercise therapy and CBT with exercise therapy.

Ethical approval

Ethical approval was not required.

Conflict of interest

The authors declare that they have no financial or other conflict of interest.

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Appendix 3.2 Search strategies of randomized controlled trials

1. Search strategy for Medline (1965-present) vis EBSCOhost

(MH "Cognitive Therapy+") OR "CBT"	27,508
(MH "Cognitive Therapy+") OR "cognitive behavioral therapy"	24630
1 or 2	8,270
(MH "Aged+") OR (MH "Frail Elderly/PX") OR "elderly"	2,775,109
"fear of falling"	1255
"balance confidence"	638
(MH "Self Efficacy") OR "balance efficacy"	16,024
5 or 6 or 7	17,651
3 and 4 and 8	47

MH: MeSH term

2. Search strategy for CINAHL Complete via EBSCOhost (CINAHL)

(MH "Cognitive Therapy") OR "cognitive behavioral therapy"	15,738
CBT	3565
1 or 2	16,473
(MH "Aged") OR "elderly" OR (MH "Frail Elderly") OR (MH "Geriatric Functional Assessment")	634,795
Fear of falling	850
Balance confidence	462
(MH "Self-Efficacy") OR "balance efficacy"	15,267
Falls efficacy	293
5 or 6 or 7 or 8	16,498
3 and 4 and 9	78

MH: MeSH term

3. Search strategy for PubMed via EBSCOhost

Cbt [All Fields]	8349
"cognitive therapy"[MeSH Terms] OR cognitive behavioral therapy[Text Word]	24663
1 or 2	27308
("fear"[MeSH Terms] OR "fear"[All Fields] OR "fear of"[All Fields]) AND ("accidental falls"[MeSH Terms] OR ("accidental"[All Fields] AND "falls"[All Fields]) OR "accidental falls"[All Fields] OR "falling"[All Fields])	1,555
("Balance"[Journal] OR "balance"[All Fields]) AND confidence[All Fields]	3,713
("Balance"[Journal] OR "balance"[All Fields]) AND efficacy[All Fields]	7,184
("accidental falls"[MeSH Terms] OR ("accidental"[All Fields] AND "falls"[All Fields]) OR "accidental falls"[All Fields] OR "falls"[All Fields]) AND efficacy[All Fields]	2,223
4 or 5 or 6 or 7	13079
"aged"[MeSH Terms] OR elderly[Text Word]	2777514
older[All Fields] AND ("persons"[MeSH Terms] OR "persons"[All Fields] OR "person"[All Fields])	264426
9 or 10	2866813
3 and 8 and 11	45

4. Search strategy for Web of Science

#1 cbt or cognitive behavioral therapy	27,231
#2 elderly or older people or older person or aging	2,672,786
#3 balance confidence or balance efficacy or falls efficacy or fear of falling	27,057
1 and 2 and 3	51

5. Search strategy for Embase

“elderly” ab, ti or “older people” ab, ti or “aging” ab, ti or “older person” ab, ti	472,096
“fear of falling” ab, ti or “balance confidence” ab, ti or “balance efficacy” ab, ti or “falls efficacy” ab, ti	2,782
“cognitive behavioral therapy” ab, ti or “cbt”	16,637
2 and #3 and 4	4

Ab: abstract; ti: title.

6. Search strategy for Cochrane Library (limited to trials)

(MH "Cognitive Therapy+") OR "CBT" OR “cognitive behavioral therapy”	9,581
“elderly” OR “older people” OR “aging” OR “older person”	40,556
“fear of falling” OR “balance efficacy” OR “falls efficacy” OR “balance confidence”	5,671
1 AND 2 AND 3	212
limit 4 to trials	8

MH: MeSH term

Appendix 4.1 Chapter 4 published on Archives of Physical Medicine and Rehabilitation (Final manuscript)

Fear avoidance behavior, not walking endurance, predicts the community reintegration of community-dwelling stroke survivors

INTRODUCTION

Stroke is an age-related, disabling and burdensome global disease[1]. With an aging population, it is estimated that the number of strokes will reach 23 million[2] in 2030 causing more than 7 million deaths worldwide annually[3]. After stroke, most people are left with some level of dependency in their activities of daily living[4] and thus restriction of social participation[1] resulting from sensorimotor impairment[5] and perhaps psychological disturbances[6]. For stroke recovery, community reintegration is the ultimate goal of rehabilitation aiming at reducing handicap and enhancing quality of life.

Community reintegration is the process of promoting those impaired after disabling injuries or illnesses to re-accommodate into society[7-10]. Previous studies on satisfaction with community reintegration following stroke revealed inconsistent findings[11-13]. For example, Carter reported[11] 55% of 182 patients with sub-arachnoid hemorrhage had reintegrated to their previous lifestyle satisfactorily as measured by the Reintegration to Normal Life Index (RNLI)[14], while Pang reported[12] only 11 % of 63 community-dwelling stroke survivors were fully satisfied with their level of community reintegration as measured by the Chinese version of the RNLI[15].

Identifying predictors of community reintegration is important in stroke rehabilitation. Several studies have explored predictive models of community reintegration to provide insight for stroke rehabilitation[11, 12]. Some studies suggest that the distance covered in the six-minute walk test (6MWT)[16,17] is the best predictor of community reintegration for people suffering from respiratory problems[16], cardiovascular diseases[17] and chronic stroke[5].

Another important predictor of community reintegration after stroke is the subjective balance confidence test[18]. The Activities-specific Balance Confidence (ABC) scale was based on the theoretical ground of Bandura's theory of efficacy self-perceptions[18, 19]. Previous studies revealed that ABC was a stronger predictor than walking speed, walking endurance or balance performance among stroke patients[12] and significantly correlated with level of community reintegration[20]. However, fear avoidance behavior (FAB) has not been addressed.

FAB is the behavioral translation and reflection of impaired subjective balance confidence[21]. For community-dwelling older adults, FAB has been shown to be associated with fall history (*r* = 0.33), physical frailty (*r* = -0.49), postural control (forward endpoint excursion, *r* = -0.31) and muscle performance (*r* = -0.37 to -0.44)[22]. In addition, FAB was reported to have a prevalence of up to 54% among community-dwelling older adults[23, 24].

Although FAB is self-protective in preventing falls, excessive FAB would eventually lead to physical deconditioning and compromised one's community reintegration. The exact mechanism translating fear of falling into behavior is unclear, but it is believed to be associated with catastrophic thinking[25] that magnifies worries and negatively overstates the consequences of events[26]. Indeed, those with low subjective balance confidence could be further delineated as having low subjective balance confidence with or without FAB[27, 28]. These behavioral discrepancies highlight the importance of studying FAB when investigating the impact of fear of falling on community reintegration.

The role of FAB has been explored in community-dwelling older adults and patients with other chronic illnesses such as Parkinson's disease. For community-dwelling older adults, FAB was reported to be a significant independent predictor of disability in the activities of daily living and of poor lower extremity performance[29]. In another study[30], FAB as measured by the Survey of Activities and Fear of Falling in the Elderly (SAFE)[31] was found to be a significant predictor of the quality of life of patients with Parkinson's disease. However, the role of FAB has not been investigated among patients with stroke. Thus, this study aimed at (1) determining whether FAB makes an independent contribution to community reintegration; and (2) quantifying its relative contribution to community reintegration when walking endurance and subjective balance confidence were also considered.

METHODS

Participants

Community-dwelling stroke survivors were recruited from local self-help groups via poster advertisement. Participants were recruited if they aged 50 or above, had a stroke at least 12 months previously, were able to understand Cantonese, were able to walk 10 m with or without assistance, and were able to score 7 or above on the Chinese version of the Abbreviated Mental Test (AMT-C)[32].

People were excluded if they had any unstable medical condition such as angina pectoris, or other conditions that might hinder the progress of assessment such as dementia. The study protocol was approved by the Ethics Committee of the administering institution. The study was conducted according to the principles of the Declaration of Helsinki for human experiments. Written informed consent was obtained from all participants prior to the study.

Socio-demographic data

Five types of socio-demographic data were collected during the intake interviews. They consisted of: (1) background characteristics including gender, age and living arrangements; (2) illness-related variables including cause of stroke and years since stroke; (3) number of falls in previous 6 months; (4) mobility-related variables including hemiplegic side, use of walking aids and the time on the Timed "Up & Go" (TUG)[33] test; and (5) AMT-C[32] score (an exclusion criterion).

Outcome Measures

Level of Community reintegration:

Community integration was quantified using scores on the Chinese version of the Community Integration Measure (CIM-C)[10]. The CIM-C has 10 items with responses on a 5-point scale. The CIM[34] has been used on people with brain injury[34-36], spinal cord injury[37] and chronic stroke[10]. The CIM-C has been reported to have good internal consistency (Cronbach's α of 0.84) and good test-retest reliability (ICC = 0.84) on people with stroke[10].

Fear avoidance behavior:

The extent to which activities were being avoided due to fear of falling was assessed using the Chinese version of Survey of Activities and Fear of Falling in the Elderly (SAFE-C)[38]. This instrument consisted of 22 self-rating items on a 4-point scale. The SAFE-C has been reported as having excellent internal consistency (Cronbach's α of 0.95) and construct validity[30].

Subjective balance confidence:

The original Activities-specific Balance Confidence Scale was developed to assess self-perceptions of balance efficacy among older adults[18]. It consisted of 16 items related to indoor and outdoor activities with self-ratings from 0 (no confidence) to 100% (complete confidence) on each item. The Chinese version[39] had been psychometrically tested on community-dwelling older adults and reported as having excellent internal consistency (Cronbach's α of 0.97), excellent test-retest reliability (ICC = 0.99) and good inter-rater reliability (ICC = 0.85).

Walking endurance:

Walking endurance was assessed by the distance covered in the six-minute walk test (6MWT) which was originally developed for patients with chronic heart failure[16, 17]. The participants walked along a 30-m straight corridor with standardized encouragements given by the assessors at 1, 3, and 5 minutes during the walk[16, 17]. If needed, standing rest was allowed and the participant could resume walking when ready within the 6 minute period. The 6MWT distance has demonstrated excellent test-retest reliability (ICC = 0.99) and construct validity for patients with chronic stroke[40].

Depressive symptoms:

The Geriatric Depression Scale (GDS) containing 30 dichotomous items (yes or no) was initially developed for rating the level of depression in the elderly[41]. The GDS was translated into Chinese and psychometrically tested on patients with affective disorders[42] and was reported to have good internal consistency (Cronbach's α of 0.89) and good test-retest reliability (ICC = 0.84).

Statistical analysis:

The data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 17.0 and the distributions of the responses were checked for normality using Kolmogorov-Smirnov test. The socio-demographic data was summarized by descriptive statistics and the relationships between the CIM-C scores and the other variables were examined using Pearson correlation coefficients. To control for the socio-demographic differences, partial correlation coefficients were calculated for the distances covered in 6MWT, the GDS-C and ABC-C scores. Multiple linear regression with forced entry method was used to determine the relative power of the independent variables for predicting the CIM-C scores. A confidence level of 0.05 (2 tailed) was adopted for significance testing in this study.

RESULTS

Characteristics of participants

Forty men (70%) and 17 women (30%) with different types of stroke (ischemic stroke, *n* = 29; hemorrhagic stroke, *n* = 19; unknown or mixed type, *n* = 9) were recruited. They had a mean age of 61.14 years (S.D. = 6.66) and an average of 8.14 years (S.D. = 4.34) post-stroke (Table 1). Twenty-four suffered from left and 33 from right hemiplegia. Their mean body mass index (BMI) was 24.91 (S.D. = 2.96). Fifty (88%) of them lived with others and 51% of the subjects required using a walking aid. They reported a mean fall frequency of 0.44 (S.D. = 1.07) over the previous 6 months. The average TUG[34] time was 17.02 s (S.D. 6.83). The mean GDS-C score was 9.49 $\pm$ 7.60 and the mean AMT-C score was 9.35 $\pm$ 0.86, suggesting that a group of participants with no to mild depressive symptoms and intact cognition were examined.

As actual fall is closely related to fear of falling, 12 subjects were categorized into the group with fall history group and 45 subjects to the group without fall history based on the number of falls in the previous 6 months. Homogeneity of variances was analyzed by Leven's test. For the age, BMI, years since stroke, TUG time, distance covered by 6MWT, AMT-C score, GDS-C score and ABC-C score, the variances were equal between the two groups. However, the variances of SAFE-C ($F(1, 55) = 15.77$, $p<.000$) score and CIM-C ($F(1, 55) = 14.56$, $p<.000$) score were significantly different between the two groups. To compare the baseline characteristics, a secondary analysis was performed and revealed that there were no significant differences between the two groups although equal variances not assumed in the SAFE-C and CIM-C scores (Table 2).

Relationships between CIM-C scores and other variables

The mean CIM-C score was 44.75 (S.D. = 4.94), indicating a high level of community reintegration. There were no significant differences in this respect between males and females (t (55) = 0.225), left and right hemiparesis (t (55) = 0.534), needed a walking aid or not (t (55) = 0.047), living alone or with others (t (55) = 0.139), or the types of stroke (F (2, 54) = 0.551).

There was no significant correlation between the CIM-C scores and age, BMI, chronicity of stroke, TUG time, AMT-C score or distance covered in the 6MWT (Table 3). The SAFE-C scores had the highest significant negative correlation with the CIM-C scores (r = -0.693, $p \leq 0.001$). Significant correlations were also found between CIM-C scores and GDS-C scores ($r = -0.530$, $p \leq 0.001$), number of falls in the previous 6 months ($r = -0.466$, $p \leq 0.001$), ABC-C scores ($r = 0.488$, $p \leq 0.001$), and distance covered in the 6MWT ($r = 0.270$, $p \leq 0.05$). After controlling for the number of falls in the previous 6 months and the GDS-C scores, significant partial correlations were found between the CIM-C scores and the ABC-C scores ($r = 0.326$, $p \leq 0.05$) and SAFE-C scores ($r = -0.537$, $p \leq 0.001$) (Table 4).

Fear avoidance behavior and CIM-C scores

A combined multiple linear regression model including the number of falls in the previous 6 months, GDS-C scores, 6MWT distance, ABC-C scores and SAFE-C scores predicted a total of 49.7% (F [5, 51] = 12.062, $p \leq 0.001$) of the variance in the CIM-C scores (Table 5). After adjusting for the other variables, the SAFE-C scores remained independently associated with the CIM-C scores, accounting for 11.6% of the variance, and model prediction significantly improved (F change = 12.992, $p \leq 0.001$). The SAFE-C scores were the best predictor of CIM-C scores as indicated by the magnitude of the standardized regression coefficient (ß = -0.518; Model 3 in Table 4), and the highest Pearson correlation coefficient (r = -0.693, $p \leq 0.001$) (Table 2).

DISCUSSION

There has not been any study highlighting the contribution of FAB to community reintegration of community-dwelling chronic stroke survivors. Our findings add to the current understanding of the role of FAB in healthy older adults and those with chronic stroke.

Community reintegration after stroke

The high CIM-C scores (mean $\pm$ S.D, 44.75 $\pm$ 4.94) suggest a high level of community reintegration of community-dwelling persons with chronic stroke. Our findings are comparable to those of Pang[12] and Liu[10] who had studied on Chinese stroke survivors. Both groups have reported high average RNLI-C score of 83.1 (S.D. = 13.8)[12] and CIM-C score of 43.48 (S.D. = 5.79)[10] respectively. However, the present findings are inconsistent with those of other studies that reported RNLI scores of 57.3 to 63.8[13,43,44] indicating moderate to severe restrictions in self-perceived community reintegration.

There are several reasons which may contribute to the high level of community reintegration among the subjects of the current study. First, their level of physical mobility was high. They had better TUG times (mean $\pm$ S.D.; 17.02 $\pm$ 6.83) when compared with the subjects of previous studies (20.0-29.1). Second, the subjects were active members of local self-help groups. They actively participated in community activities and volunteered for clinical research. Third, the local environment is not obstructive for survivors of chronic stroke. The availability of local community centers and easy access to these facilities provide opportunities for social interaction and social participation. Fourth, the majority of the subjects lived with others thus they have either the family or peer support. Fifth, most of the subjects had the habit of regular exercises. As a whole, the subjects' high functional level and their active social participation may account for their self-perceptions of good community reintegration.

Community reintegration and other outcome measures

The correlation analysis revealed that community reintegration was correlated with the number of falls in the previous 6 months (self-reported), walking endurance, depressive symptoms, impaired subjective balance confidence and FAB. The demographic variables, however, were not significantly associated with community reintegration.

Reports on the relationships between community reintegration and demographic variables are inconsistent. Our findings echo that of Pang[12] and Schmid[20] who found no significant correlations of this variable with age, gender, ethnicity, level of education, stroke characteristics, paretic side or post-stroke duration. However, some researchers have reported significant correlations between community reintegration with age[44] (r = -0.221, $p \leq 0.05$) and post-stroke duration[13] (r = 0.604, $p \leq 0.05$) in other studies.

The mean age of the subjects in this study (61.14 ± 6.66) was comparable to those of Pang[12] and Schmid[20] (means of 64.1 and 65.4), but older than those in the study by Obembe[44] where 62.2% (n = 56) were younger than 60 years. The mean post-stroke duration of our subjects (4.33-8.14 years) is comparable to that of the studies by Pang[12] and Schmid[20] but longer than the subjects in the study by Obembe[13] (1.63 years). These may account for the differences in the relationships between community reintegration and demographics reported across the studies.

As might be expected, a history of fall was found to be associated with activity avoidance among community-dwelling older people[25, 27, 45]. Although falls and fear of falling are believed to form a “vicious cycle”[46], Delbraere[25] has suggested that actual falls are indeed the primary cause of FAB. Older adults, especially those with a disabling injury or illness, are more likely to have less confidence in upright balance. For those with impaired subjective balance confidence and catastrophic thinking[25] about the consequences of falls, we hypothesize that actual falls may raise their concern about falling and induce FAB. The present findings support this hypothesis, and they are consistent with the findings of other studies of community-dwelling elderly persons[25, 27, 45]. Furthermore, depressive symptoms were also found to be correlated with community reintegration, which is consistent with previous findings[12,44].

Our findings also revealed significant correlations between CIM-C scores and the distance covered in the 6MWT, ABC-C scores and SAFE-C scores. Surprisingly, after controlling for GDS-C results and the number of falls in the previous 6 months, 6MWT no longer had significant predictive power. One possible explanation is that over the period of natural recovery, usually 3-6 months[5], stroke survivors have reached a plateau of physical recovery. Subjective balance confidence and FAB then come to dominate decisions about daily activities, social interaction and social participation instead of walking endurance.

Fear avoidance behavior independently predicts community reintegration

The final model explained 49.7% of the variance in the community reintegration scores. FAB was the best independent predictor of the CIM-C and SAFE-C scores, accounting for 11.6% of the variance. Previous studies have investigated the role of subjective balance confidence and the present study further considered its behavioral impact on community reintegration. Our results demonstrate that a higher level of FAB predicts poorer community reintegration of community-dwelling chronic stroke patients.

From the clinical point of view, the current findings are highly relevant to stroke rehabilitation, as this is the first piece of evidence showing that restriction of activity induced by fear of falling is an independent factor influencing community reintegration after stroke. For rehabilitation practice, it is important to identify the basis of patients' FAB in order to specify the training required. In a randomized controlled trial by Zijlstra et al[47, 48], improvements in fear of falling and activity avoidance were observed in 196 community-dwelling older persons after an 8-week, multi-component cognitive behavioral group intervention aimed at nurturing realistic and adaptive views of fear of falling and performing activities safely. The effects lasted for 8-14 months and the number of recurrent fallers was still significantly lower than the control group a year after the intervention[48]. Future studies investigating whether such a multi-component cognitive and behavioral group intervention might be applicable for patients with chronic stroke are clearly warranted.

Study Limitations

This study protocol had several limitations. First, the regression model could only account for 49.7% of the total variance in the CIM-C scores and more than half of the variance remained unexplained. Future research should look into other elements such as participation in exercise[49] and social support[50].

Secondly, the participants were recruited on a convenience basis through local self-help groups voluntarily that could limit the representativeness of our sample. This self-selection may itself reflect limited FAB and self-perceptions of successful reintegration. The fact that our participants had relatively good physical functioning at the beginning of the study could induce a positive bias that they have a stronger sense of community reintegration than those with more severe physical impairment and psychological disturbances. The small sample size also limited the power of the regression analysis of this study.

Of course, no causal relationships among the variables should be inferred based on this cross-sectional study design and future studies based on longitudinal design are recommended to develop the prediction model of community reintegration of stroke patients. Furthermore, the findings should not be generalized to a general stroke population, as the participants were all community-dwelling with relatively good mobility and were socially active.

CONCLUSION

In contrast with previous studies, our study reveals that FAB is a better predictor of community reintegration than fall history, depressive symptoms or subjective balance confidence for community-dwelling people with chronic stroke. It is possible that the FAB is a more sensitive measure of community reintegration as it is the behavioral translation of impaired subjective balance confidence induced by actual falls and catastrophic thinking associated with depressive symptoms. FAB is independently related to the level of community reintegration while walking endurance and subjective balance confidence are not. FAB is also an independent predictor of CIM-C scores, accounting for 11.6% of the variance. Therefore, multi-dimensional interventions addressing all the physical, psychological and behavioral factors for stroke rehabilitation may have the strongest therapeutic effects leading to the maximum level of community reintegration.

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Appendix 4.2 Information sheet, consent form and ethical approval of study of Identification of predictor

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

<u>Title:</u> Correlates of fear avoidance behaviours among community-dwelling seniors with chronic stroke.

The Department of Rehabilitation Sciences of The Hong Kong Polytechnic University is now undergoing a research titled 'Correlates of fear avoidance behaviours among community-dwelling seniors with chronic stroke'. The purpose of this research is to explore the factors correlated with fear avoidance behavior among community-dwelling seniors with chronic stroke. This study has been approved by the Departmental Research Committee (HSESC) of The Hong Kong Polytechnic University. (HSESC reference number: HSEARS20140129003)

Research personnel of the department will invite you to come to the laboratory of the Department of Rehabilitation Sciences of The Hong Kong Polytechnic University to complete a socio-demographic sheet, the 6 Minutes Walk Test (6MWT), the Chinese version of the Geriatric Depression Scale (GDS-C), the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C), the Chinese version of the Activities-specific Balance Confidence scale (ABC-C) and the Chinese version of the Community Integration Measure (CIM-C). The whole assessment procedure will last for 45 minutes.

The major benefit from participating in this study is that you can know your fear avoidance behavior and correlates. The results could provide scientific evidence in supporting the clinicians in understanding the correlates of fear avoidance behavior in people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Your participation in this research is strictly voluntary, and you can withdraw from this research at any time without giving explanations, and it will not lead to any punishment or prejudice against you. Your personal information will not be disclosed to people who are not related to this study and your name or photo will not appear on any publications resulted from this study.

Questions regarding this study will be answered by the chief investigator, Mr. LIU Tai Wa, who can be reached by telephone at 2768- . If you have complaints related to the investigators, you can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- .

Thank you for participating in this study.

Mr. LIU Tai Wa
PhD student
Department of Rehabilitation Sciences
The Hong KongPolytechnicUniversity

Hung Hom Kowloon Hong Kong 香港九龍紅磡
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THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

研究課題　　社區居住中風病人的恐懼迴避行為的相關因數。
理工大學康復治療科學系現正進行一項有關長社區居住中風病人的恐懼迴避行為的相關性的研究。是項研究旨在探索中風病人的恐懼迴避行為的相關因數。本研究已通過理工大學康復治療科學系科研委員會 (HSESC) 的審批 (HSESC 參考號碼: HSEARS20140129003)。

本學系的研究人員將邀請閣下參與填寫一份社會人口資料、四份問卷，包括長者恐懼跌倒調查表、活動平衡信心評分表、老年抑鬱量表和社區整合量法日常家居及社區活動能力評估，及六分鐘步行測試。整個測試程序，需時約 45 分鐘。

參與此研究的主要好處是參與研究者可以了解自己的恐懼迴避行為。研究結果將為中風病人提供恐懼跌倒迴避行為相關因數的參考資料。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

您有權在任何時候、無任何原因之情況下放棄參與此次研究, 而此舉將不會導致您受到任何懲罰或不公平的對待。您的資料也不會洩露予與此研究無關的人員，您的名字或相片亦不會出現在任何出版物上。

如閣下需要更多有關此項研究的資料，可以致電 2768　　　來聯繫此次研究的負責人，廖泰華先生。若您對此研究的科研人員有任何投訴，亦可以聯絡鍾小姐 (部門科研委員會秘書)，電話：2766　　　。

多謝閣下參予此項研究。

廖泰華先生

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The Hong Kong Polytechnic University

Department of Rehabilitation Sciences

<u>Research Project Informed Consent Form</u>

Project entitled: Correlates of fear avoidance behaviours among community-dwelling seniors with chronic stroke

Investigator: Mr. LIU Tai Wa

Purpose:

Explore the factors correlated with fear avoidance behavior among community-dwelling seniors with chronic stroke.

Methods:

All participants with stroke will be required to complete a socio-demographic sheet, the 6 Minutes Walk Test (6MWT), the Chinese version of the Geriatric Depression Scale (GDS-C), the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C), the Chinese version of the Activities-specific Balance Confidence scale (ABC-C) and the Chinese version of the Community Integration Measure (CIM-C). The whole assessment procedure will last for 45 minutes.

Potential Risks and Benefits:

The major benefit from participating in this study is that you can know your fear avoidance behavior and correlates. The results could provide scientific evidence in supporting the clinicians in understanding the correlates of fear avoidance behavior in people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Informed Consent

I, ____, understand the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name will not appear on any publications resulted from this study.

I can contact the chief investigator, Mr. LIU Tai Wa, at telephone 2768- for any questions regarding this study. If I have complaints related to the investigators, I can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- . I know I will be given a signed copy of this consent form.

Signature (subject): ______________________________ Date: _______________

Signature (Witness): ______________________________ Date: _______________

香港理工大學康復治療科學系研究同意書

項目名稱: 社區居住中風病人的恐懼迴避行為的相關因數。

科研人員: 廖泰華先生

研究目的及內容:

探索中風病人的恐懼迴避行為的相關因數。

研究方法:

所有參與研究者將被安排填寫一份社會人口資料、四份問卷，包括長者恐懼跌倒調查表、活動平衡信心評分表、老年抑鬱量表和社區整合量法日常家居及社區活動能力評估，及六分鐘步行測試。整個測試程序，需時約 45 分鐘。

潛在風險及得益:

參與此研究的主要好處是參與研究者可以了解自己的恐懼迴避行為。研究結果將為中風病人提供恐懼跌倒迴避行為相關因數的參考資料。整個檢查程序都己經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

同意書:

本人 ____ 已瞭解此次研究的具體情況。本人願意參加此次研究。本人有權在任何時候、無任何原因的情況下放棄參與此次研究，而此舉不會導致本人受到任何懲罰或不公平的對待。本人明白參加此研究的潛在風險，以及本人的資料將不會泄露給與此研究無關的人員，我的名字或相片也不會出現在任何的出版物上。

本人可致電 2768 與此研究的負責人廖泰華先生聯絡。若本人對研究人員有任何投訴，可聯絡鍾小姐（部門科研委員會秘書），電話：2766 。本人亦明白，參與此研究需要本人簽署一分同意書。

簽名 (參加者): ______________________________ 日期: __________________

簽署 (見證人): ______________________________ 日期: __________________

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

To	Ng Sheung Mei Shamay (Department of Rehabilitation Sciences)
From	TSANG Wing Hong Hector, Chair, Departmental Research Committee
Email	rshtsang@ Date 17-Feb-2014

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 17-Feb-2014 to 17-Feb-2016:

Project Title:	Fear of falling: Its prevalence and correlation with stroke-specific impairments, motor functions, quality of life and community integration in patients with stroke in Hong Kong.
Department:	Department of Rehabilitation Sciences
Principal Investigator:	Ng Sheung Mei Shamay
Reference Number:	HSEARS20140129003

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

You will receive separate email notification should you be required to obtain fresh approval.

TSANG Wing Hong Hector

Chair

Departmental Research Committee

Appendix 5.1 Cross-sectional study 1 published on PLoS ONE (Final manuscript)

The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly for assessing fear and activity avoidance among stroke survivors

Introduction

Fear of falling is a common psychological trait among stroke survivors, with self-reported prevalence rate high up to 49% among those resided in the community [1]. The major adverse consequence is that fear of falling can be reflected in the form of self-imposed restrictions on physical activity. That can of course lead to various negative health outcomes such as physical deconditioning [2], decreased competence in the activities of daily living [3], limited social participation [4] and eventually a degraded quality of life [5]. Fear of falling may not necessarily restrict activity, however [6, 7]. A study by Howland [7] found that 55% of 266 community-dwelling elderly adults reported fear of falling, but only 56% of them reported associated activity curtailment. Advanced age, female gender, impaired vision, poor perceived health, lack of support and a history of multiple falls are risk factors for activity restriction due to fear of falling [3,8].

Despite fear avoidance behavior having been studied among community-dwelling healthy older adults, most previous studies [6, 9] have used questions such as "Do you avoid certain activities due to concerns about falling" [9] or "Has fear of falling made you avoid any activities?" [6] to classify people as with or without activity restriction due to fear of falling. The use of a single dichotomous question makes for easy categorization for research purposes, but it provides insufficient information for clinicians to address rehabilitation needs. Lachman [10] developed the Survey of Activities and Fear of Falling in the Elderly (SAFE) intended to evaluate fear avoidance behavior due to fear of falling. The SAFE assesses the level of activity restriction through quantifying self-perceived and observable activities of daily living (ADL) and instrumental ADL (IADL). The original SAFE consisted of 11 items rated on a 4-point scale. It was validated with 270 healthy community-dwelling older people and demonstrated excellent internal consistency (Cronbach's alpha = 0.91) and convergent validity with the Falls Efficacy scale (FES) (r=-0.76). It has also demonstrated criterion validity with quality of life as measured by the Medical Outcome Study Short Form 36 (SF-36) (r=-0.37 to 0.55) [11] and discriminant validity in distinguishing those with or without fear of falling [10]. The Persian version of the SAFE [12] has been shown to have excellent test-retest reliability (Intra-class correlation coefficient = 0.97), and good correlation with Activities-specific Balance Confidence (ABC) scale ratings [13] (r=-0.87) among older people with Parkinsonism. The SAFE has been translated into Chinese (as the SAFE-C) and has been reported to have excellent internal consistency (Cronbach's alpha = 0.95) with older people with depression symptoms [14].

Although improving functional status is an important focus of stroke rehabilitation, activity restriction can jeopardize clinicians' efforts, as fear avoidance behavior may hinder stroke survivors' performing physical and independent living activities. Despite the fact that the SAFE has been used with community-dwelling older people and elderly people with Parkinson's disease, its psychometric properties have not been established for stroke survivors. This study was therefore designed to validate the SAFE among community-dwelling people after a stroke. Its objectives included investigating the instrument's internal consistency, test-retest reliability, convergent validity and construct validity as well as the level of fear avoidance behavior manifested by community-dwelling stroke survivors.

Materials and Methods

Participants

In total, 108 community-dwelling stroke survivors were recruited from a local rehabilitation organization in Hong Kong through poster advertising. Their demographics are summarized in Table 1. Subjects were recruited if they were at least 50 years old, had suffered a single stroke confirmed by the magnetic resonance imaging or computed tomography at least 1 year before the start of the study, were able to rise from a chair without using any arm support, and had an Abbreviated Mental Test [15] score of 7 or above. Subjects were excluded if they had any other medical condition that potentially could affect the findings such as chronic knee pain. The Departmental Research Committee of the Hong Kong Polytechnic University has approved the study. Written informed consent was obtained from all of the participants before the study.

Outcome Measures

All 108 participants were assessed with three questionnaires through an individual face-to-face interview in a university-based neurorehabilitation laboratory during April to May 2018. 20 of the subjects (19%) were randomly selected by drawing lots for reassessment with SAFE-C after one week to establish test-retest reliability.

SAFE-C score

The current SAFE [10] has 11 self-rated items with a one-factor structure assessing the level of fear of falling while performing activities such as “go to the store” and “take a tub bath”. There are four response options (0= not all worried; 1 = a little worried; 2 = somewhat worried; 3 = very worried). To assess the level of activity avoidance due to fear of falling, the SAFE uses structured interviewing questions (e.g., “When you go to the store, how worried are you that you might fall?”; “Do you not go to the store because you are very worried that you might fall?” according to the scoring information guide. The Chinese version (SAFE-C) [14] is a translation of the original version in which 22 items were included. The SAFE-C had been demonstrated to have excellent internal consistency 0.95 (Cronbach’s alpha = 0.95) [14].

Activities-specific Balance Confidence score

Fear of falling was also measured using the ABC-C [16], a Chinese translation of the 16-item Activities Balance Confidence Scale. Respondents rate indoor and outdoor functional activities from 0% (no confidence) to 100% (complete confidence) representing their subjective confidence about maintaining their balance. The ABC-C [16] has been used with healthy older people and those with chronic disease such as stroke.   It had been demonstrated to have excellent internal consistency of 0.97 (Cronbach's alpha = 0.97) [16]. As the FES, which was adopted in the development study of original SAFE, focused on assessing the balance efficacy related to indoor activities only, this study adopted the ABC-C to assess the fear of falling related to both indoor and outdoor activities.

Lawton Instrumental Activities of Daily Living score

Level of independence in daily living was assessed using the IADL-C [17], a Chinese translation of the Lawton Instrumental Activities of Daily Living questionnaire. Respondents rate their perceptions of their independence in 9 daily household or community functions using a 3-point Likert scale (0 = unable to do, 1 = with assistance, 2 = independent). The IADL-C has been validated with institutionalized older adults and reported to have good internal consistency (Cronbach's alpha = 0.86) and excellent inter-rater (ICC = 0.99) and test-retest (ICC = 0.90) reliability [17].

Data analysis

The data were analyzed using version 23.0 of the SPSS software suite (IBM, Armonk, NY). The level of confidence for significance was set as $\alpha=0.05$. Internal consistency was evaluated using Cronbach's alpha coefficient. Test-retest reliability was assessed using intra-class correlation coefficients (ICCs). An ICC >0.90 indicates excellent reliability, an ICC of 0.75 to 0.90 indicates good reliability, an ICC of 0.50 to 0.75 indicates moderate reliability, and an ICC <0.50 indicates poor reliability [18]. To establish the optimal factor structure for the SAFE-C, principle component analysis (PCA) was performed and scree plots were prepared. Principal axis factoring (PAF) was used for data extraction, followed by promax rotation to enhance the interpretability of the factors. Pearson correlation coefficients were used to establish the convergent validity of the SAFE-C with the ABC-C and IADL-C results. The strength of the correlation was defined as weak (< 0.35), moderate (0.36 to 0.67), or strong (0.68 to 1.0) [19].

Results

The assessments were performed in a university-affiliated neurorehabilitation laboratory. After providing written consent, the participants completed a demographic data sheet and the ABC-C and IADL-C. Then the participants were interviewed for SAFE-C according to the scoring information guide.

Characteristics of the subjects

Most of the 108 respondents were men (n=71, 66%) with educational attainment up to secondary school level (n=68, 63%) (see Table 1). Almost all (n=102, 94%) were living with family, a carer or a friend and were unemployed or retired (n=99, 92%). Most had not fallen in the 6 months before the study (n=85, 79%). They had mean a body mass index (BMI) of 24.19 (SD 3.13) and 81 (75%) of them relied on a walking aid when walking outdoors. Their mean age was 60.37 years (SD 6.30) and the mean years since stroke was 7.64 years (SD 4.39).

The mean scores of all the SAFE-C items and their standard deviations are summarized in Table 2. The total mean score was 9.75 (SD 7.21, range from 0 to 28). Item 6 (Go out when slippery) had the highest average (1.44 $\pm$ 0.95) and item 4 (Get out of bed) the lowest (0.36 $\pm$ 0.72).

Internal consistency

Taken together, the items of the SAFE-C had excellent internal consistency with a Cronbach's alpha of 0.90 (see Table 3). There was moderate to strong item-total correlation ranging from 0.47 to 0.72. Although four of the item-total correlations were < 0.60 (Go to the store, r = 0.59; take a tub bath, r = 0.53; get out of bed, r =

0.47; take a walk for exercise, r = 0.54), there was no item who's deletion improved the overall Cronbach's alpha.

Test-retest reliability

Twenty of the 108 respondents were reassessed after a 1-week interval to quantify the SAFE-C's test-retest reliability. The total SAFE-C score had excellent test-retest reliability after a week as reflected in an ICC of 0.91 (95% confidence interval (CI) 0.76–0.96) (see Table 4). Test-retest correlation coefficients for individual items ranged from 0.52 to 0.93, with item 9 (Go to a place with crowds, ICC = 0.93 95% CI 0.83–0.97) indicating the most consistency, and item 1 (Go to the store, ICC = 0.52 95% CI 0.22–0.81) the least. Overall, the 0.91 ICC indicated good reproducibility for SAFE-C ratings over time.

Convergent validity

The correlation coefficient relating the SAFE-C and ABC-C results was r = -0.68 (95% CI -0.82 to -0.54), and that relating the SAFE-C and IADL-C results was r = -0.57 (95% CI -0.73 to -0.41). There was moderate to strong negative correlation between the pairs of measures. Both the correlations were statistically significant ($p \leq 0.001$).

Construct validity

The PCA suggested a 2-factor structure accounting for 54% of the total variance in which each factor with eigenvalue exceeding 1. The Kaiser-Meyer-Olkin (KMO) value of 0.89 indicated sampling adequacy [20]. Bartlett's test was highly significant (X^2 (55) = 569.30, $p \leq 0.001$) suggesting an appropriate use of factor analysis [21]. Examination of the scree plot suggested that there were 2 or 3 factors above the break point of the data. To avoid under- or over-extraction of the number of factors, we also consider +/- 1 number from the numbers suggested by the scree plot and PCA. Therefore, the numbers of factors used for extraction were 1, 2, 3, and 4. After promax rotation, the loadings of all 11 items were greater than 0.30 [22] on the 1-factor structure, ranging from 0.49 to 0.76 with an eigenvalue of 5.50 and 45.2% of the total variance explained (see Table 5). Although the 2, 3 and 4 factor structures could explain more of the variance, they all have item crossloadings on more than 1 factor. Thus, the 1-factor structure was adopted.

Discussion

This is the first study designed to investigate the psychometric properties of the SAFE-C using people with chronic stroke. It revealed the excellent internal consistency and excellent test-retest reliability of the SAFE-C. It also revealed its concurrent validity, as it showed significant correlation with ABC-C and IADL-C results. The instrument's key construct was identified factor as "fear avoidance circumstances" which takes in common community living activities in which falls usually occur. That 1-factor structure is consistent with those suggested by Lachman [10] for use with community-dwelling and healthy older adults.

Previous studies using dichotomous "yes/no" questions revealed that around 41% of healthy older adults had fear avoidance behavior [8]. The main limitations of using a dichotomous "yes/no" question are that it cannot (i) inform about the overall level of fear of falling during activities, (ii) reflect what kinds of physical activity are being restricted, and (iii) provide enough information to estimate whether or not the fear is excessive. A strength of this study is the use of a validated instrument to unravel which daily physical activities most influence fear of falling. The overall mean item score of 9.75 indicates significant activity restriction due to fear of falling. The 3 least fear-inducing daily activities—getting out of bed, taking a walk for exercise and preparing simple meals—are all necessary for wholesome independent living. The low level of activity restriction associated with those three items may indicate only minimal impact of fear of falling on self-care and on maintaining healthy habits.

On the other hand, the 3 most fearful daily activities—going out when it's slippery, going to places with crowds and taking a tub bath—are indeed common fall settings with alternatives which allow them to be avoided. Recognizing the fall risks in these circumstances could be interpreted as wise wariness. It does not necessarily entail activity curtailment. After all, walking several blocks outside and go to the store induced minimal fear of falling. Thus, it is reasonable to infer that the study participants knew they had alternatives. If so, the findings could be interpreted as confirming that the avoidance measured is neither restrictive nor excessive, but rather protective instead.

The validation results reveal that the SAFE-C has excellent internal consistency (Cronbach's alpha of 0.90) comparable with that of the original English SAFE (Cronbach's alpha of 0.91). The SAFE-C has also been assessed with older adults showing symptoms of depression where it yielded a Cronbach's alpha of 0.95. It can be inferred that activity restriction arising from fear of falling after a stroke was consistently measured across the 11 items of the SAFE-C.

The SAFE-C showed excellent test-retest reliability (ICC = 0.91, 95% CI 0.76–0.96), though it was slightly lower than that reported for the Persian version assessed using people with Parkinson's disease (ICC = 0.97, minimum detectable change at the 95% confidence level of 5.28). The excellent test-retest reliability suggests that SAFE-C results are highly reproducible for people with stroke, which is a desirable feature for clinical use. Although item 1 (Go to the store) showed only fair consistency across the 2 measurements, the overall reliability of the measure was not impaired when item 1was retained in the instrument. In addition to real changes in the level of fear of falling while going to the store and its avoidance, several other reasons might contribute to the low repeatability of item 1. Self-perceptions of balance ability might for some reason be particularly inconsistent in the shopping context. Or there may have been inconsistent interpretation of the “go to the store” scenario.

Fear of falling is generally quite realistic for such subjects, so SAFE-C results should correlate with balance efficacy as measured by the ABC-C. Indeed, the data show a strong negative correlation (r = -0.68). A similar correlation was found among people with Parkinsonism (r = -0.87) [12] and among healthy older adults with poor balance as measured using the Falls Efficacy Scale (r = -0.76) [10].

The strength of correlation between the SAFE-C and IADL-C scores (r = -0.57) was relatively weaker than between the SAFE-C and ABC-C scores (r = -0.68). That would be explained if some of the subjects’ dependency in daily living was due to stroke-related physical impairments but not to fear of falling. Also, some of the subjects' fear avoidance behavior was related to social activities, not to typical activities of daily living. It is thus possible that these subjects had little fear avoidance behavior but a high level of dependency, or vice versa. In any case, the correlation between the SAFE-C and the ABC-C results was not close to unity [21], which is consistent with the suggestions of previous studies [4, 7] that people with impaired balance may or may not be fearful and may or may not practice avoidance. The correlations between the SAFE-C, the ABC-C and the IADL-C results confirm their convergent validity.

This is the first study to examine the factor structure of the SAFE in population of patients with chronic disabling conditions. The hypothesized 1-factor structure based on fear and avoidance circumstances is consistent with those reported for the Chinese population in Hong Kong with chronic stroke. Although the factor loadings (0.49–0.76) were not similar to those found with healthy older adults in the original study (0.52–0.80) [10], they constitute a coherent factor structure supporting measurement of the construct among healthy older adults and stroke survivors. That consistency constitutes evidence that fear avoidance behavior is a robust construct. This might be due to similarities in living styles and level of physical activity across the Western population and Hong Kong Chinese population. As Hong Kong Chinese people is living in a multicultural environment and having westernized living styles, it is understandable that their beliefs about maintaining balance during activities and attitudes towards falls should be similar to those of the Westerners. Based on the validation of the SAFE-C with stroke survivors, the present study provides further evidence of the factor structure's applicability. Fear avoidance behavior is a homogeneous construct that can serve as a unidimensional measure. The high consistency of the factor structure suggested that the SAFE-C is a culturally relevant and valid measure of fear avoidance behavior.

It is important to note that this study's participants were recruited by convenience sampling and self-selected. They were relatively young and active with good functional mobility. The findings may not generalize to less able stroke survivors, and certainly not to persons not fulfilling the study's inclusion criteria. The sample size of 20 was barely enough for assessing the test-retest reliability. Besides, details of the translation process were not reported in Chou [14] study in which the SAFE-C was first used in Chinese elderly living in nursing homes. Thus, the discussion of cultural appropriateness is limited in the present study. Note too that no confirmatory factor analysis was conducted to support the recommended 1-factor structure of the SAFE-C. Further investigation of the factor structure and testing of the SAFE-C which involves less able stroke survivors are recommended.

Conclusions

Although the cultural appropriateness is not explored the present study, our results support the validity and reliability of the SAFE-C. It's psychometric properties are consistent with those reported for the English version and from studies with community-dwelling older people [10] and individuals with Parkinson disease [12]. The results also suggest that the activities of community-dwelling stroke survivors are only mildly restricted by fear of falling as evidenced by the reported SAFE-C item mean scores (0.71-1.44, indicating "not all worried" to "a little worried")." They have alternatives which they can turn to in high fall risk situations. Clinicians may choose to incorporate this instrument as their standard for assessing fear avoidance behavior among stroke survivors. The findings will also help clinicians consider the therapeutic interventions such as cognitive-behavioral therapy to reduce fear of falling and activity avoidance.

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Appendix 5.2 Cross-sectional study 2 submitted to PLoS One (Accepted)

Assessing the fall risks of community-dwelling stroke survivors using the Short-form Physiological Profile Assessment (S-PPA)

Introduction

Stroke survivors frequently experience falls, with reported fall rates as high as 12–39% in inpatient settings and 73–80% in community settings [1]. Stroke survivors are also more susceptible than healthy individuals to serious physical injuries after falls, and particularly face a 7-fold higher risks of hip fracture [2]. Therefore, a valid, reliable, and quantitative measure of the fall risk is needed to provide insights into fall prevention and direct interventions to the underlying physiological factors of falls in stroke survivors.

Reasons of increased post stroke fall risks are multifactorial, and a recent systematic review [3] revealed that sensorimotor impairment such as balance and mobility problems, cognitive impairment, depression, self-care dependence, taking medications and history of falling are associated fall risk factors in community stroke survivors. Previous studies [4-9] have used balance measures, such as the Berg Balance Scale (BBS) [4-8] and Mini-Balance Evaluation Systems Test (Mini-BESTest) [9], and generic fall risk measures (e.g., history of previous falls) [10] to evaluate fall risks among stroke survivors. However, these balance measures have some limitations with regard to their psychometric properties and insights into fall prevention and rehabilitative interventions. For example, either a single-task balance measure, such as the Functional Reach Test (FRT) [11], or a multi-task balance measure, such as the Berg Balance Scale (BBS) [12], could be used to capture underlying physiological factors, such as vision [13] and peripheral sensation [14], that contribute to the fall risk. Although Smith and colleagues [10] tested STRATIFY [15], a generic fall risk measure, this tool was revealed to have limited ability in predicting falls (sensitivity, 11.3%; specificity, 89.5%) in stroke survivors. Furthermore, Breisinger and colleagues [16] developed a disease-specific measure of the fall risk, the Stroke Assessment of Fall Risk (SAFR), which included test items intended to assess the risk factors for falling (impulsivity and hemi-neglect) and functional balance test items (e.g., transfer) adopted from the Functional Independence Measure. Although this scale was reported to yield accurate predictions (area under the receiver operating characteristic (ROC) curve, 0.73; sensitivity, 78%; specificity, 63%) in an inpatient setting, it was unable to reveal the underlying physiological factors. Furthermore, the SAFR was not tested among community-dwelling stroke survivors and provided limited insights relevant to long-term rehabilitative planning.

Lord and colleagues [14] developed the Physiological Profile Approach (PPA) to assess the fall risks of older adults. The main advantage of this approach is the conceptualization of the fall risk as an interaction of multiple sensorimotor factors, rather than only the individual's balance performance, the presence of demographic risk factors (e.g., age) or clinical characteristics (e.g., use of medication). Rather, the PPA assesses 5 physiological factors, including vestibular function, peripheral sensation, muscle force, vision and reaction time, contributing to the balance and mobility performance which are associated with the fall risk factors common to both the older adults and stroke survivors (3, 14)

Long and short forms of the PPA are available. The long form includes 13 individual test items, including 3 vision tests (high- and low-contrast visual acuity, contrast sensitivity and visual field dependence), 3 peripheral sensation tests (tactile sensitivity, vibration sense and proprioception), 3 muscle force tests (knee flexion, knee extension and ankle dorsiflexion), 2 reaction time tests (hand and foot) and 2 postural sway tests (standing on the floor and standing on a foam rubber mat with or without eyes closed). The long form requires a total of 45 minutes to complete.

However, the short form (S-PPA), which retains 5 of the 13 individual item tests on the long-form PPA, was developed to reduce the administrative time for screening purposes [14]. These 5 retained individual test items, namely the Melbourne Edge Test, proprioception test, knee extension muscle strength test, hand reaction time test and postural sway test, exhibited moderate to excellent test-retest reliability (r=0.50–0.97) in community-dwelling older people [14]. These 5 tests could also correctly distinguish 75–79% of older adults with or without a fall history in institutional [17] and community settings [18].

The assessment of fall risks and the underlying physiological factors could facilitate fall prevention strategies and rehabilitative training for stroke patients. Although the PPA has been applied to populations of older adults [17, 18], including those with various chronic illnesses such as stroke [19, 20], Parkinson disease [21] and multiple sclerosis [22], the psychometric properties of the PPA have not been systematically investigated in stroke survivors. Therefore, the objectives of this study were to investigate the inter-rater and intra-rater reliability, concurrent, convergent and known-group validity and accuracy of the S-PPA for distinguishing the fall history in chronic stroke survivors.

Materials and Methods

Subjects

One hundred and thirty-seven individuals (70 men, 67 women) with a history of single stroke within 1–6 years, as confirmed by magnetic resonance imaging or computed tomography, were recruited from a local support group through poster advertisements. The inclusion criteria were an age between 50 and 85 years, ability to walk independently for at least 10 meters with or without an assistive device and a score of ≥7/10 on the Chinese version of the Abbreviated Mental Test (AMT-C) [23]. The exclusion criteria were as follows: any additional medical condition (e.g., angina pectoris), visual impairment not correctable by glasses, musculoskeletal pain during daily activities or significant lower limb impairment that could affect the assessment (e.g., foot drop).

Forty age-matched healthy participants (18 men, 22 women) were recruited at Hong Kong Polytechnic University through poster advertisements. Individuals with any neurological condition (e.g., Parkinson’s disease) and an AMT-C score <7 were excluded.

This study was approved by the Ethics Committee of the affiliated institution and was conducted according to the principles of the Declaration of Helsinki regarding human experiments. Informed consent was obtained from the participants prior to the experiment.

Outcome Measures

Short-form Physiological Profile Assessment (S-PPA)

The S-PPA is a physiological-oriented measure of the fall risk consisting of 5 sensorimotor and balance performance items:

(vi) The Melbourne Edge Test was used to assess visual contrast sensitivity. Subjects were required to identify the directions of the low- and high-contrast edges of 20 circular patches (diameter, 25 mm) on a chart. The directions included horizontal, vertical and 45° left and right. The subjects were provided an instructional key card containing the 4 possible directions of the contrasting edges. The correct identification of the lowest contrasting edge was recorded in decibel units (dB). This test yielded good test-retest reliability (intraclass correlation coefficient (ICC)=0.81, 95% CI: 0.70–0.88) in community-dwelling older adults[14].

(vii) The proprioception test was used to assess proprioception. The seated subjects were asked to align their great toes simultaneously on either side of a vertical acrylic-plastic plate (60 cm x 60 cm x 1 cm) without looking at the plate. Any differences in the alignment of the great toes were recorded in degrees. This test yielded moderate test-retest reliability (ICC=0.50, 95% CI: 0.15–0.74) [14].

(viii) The hand reaction time test was used to assess the response time. Subjects were required to press the response switch of a modified computer mouse when a red light adjacent to the switch was activated. The reaction time was measured in milliseconds using a built-in timer. This test yielded moderate test-retest reliability (ICC=0.69, 95% CI: 0.45–0.84) [14].

(ix) The knee extension strength test was used to evaluate the strength of the quadriceps muscle in the affected leg. Subjects were required to remain seated while a strap connected to a spring gauge was placed around the leg. The knee extension strength was measured in kilograms using the spring gauge. This test yielded excellent test-retest reliability (ICC=0.97, 95% CI: 0.93–0.98) [14].

(x) The postural sway test was used to assess body displacement. A belt was tied to the subject's waist for 30 seconds. A rod (length, 40 cm) was connected to the belt, and a pen attached to the end of the rod was used to record the subject's body movement on graph paper in mm^2. This test yielded moderate test-retest reliability (ICC=0.68, 95% CI: 0.45–0.82) [14].

The results of each individual item test were input into a Web-based computer software program and converted into individual standardized (z) scores and composite score. Using reference data from previous studies [17, 18], the composite scores were further converted into standardized (z) 7-point composite fall risk scores of -2 to 4, in which scores of -2 to 0, 0 to 2 and 2 to 4 indicate a very low to low, low to marked and marked to very marked fall risk, respectively. The item tests were administered according to standardized instructions.

Berg Balance Scale (BBS)

The BBS is a 14-item measure used to evaluate functional balance on a 5-point scale. A higher composite score indicates a better balance performance. In stroke survivors, this measure yielded good to excellent test-retest reliability (ICC=0.88–0.92) [24, 25] and strong concurrent validity with the Postural Assessment Scale for Stroke Patients (r=0.92–0.95) [26].

Functional Reach Test (FRT)

The FRT was used to evaluate standing balance by measuring the maximum distance the subject could reach forward while standing on a fixed base. In stroke survivors, this test yielded excellent test-retest reliability (ICC=0.99) [27] and moderate to strong concurrent validity (r=0.62–0.78) with the BBS [8, 27].

Timed "Up & Go" (TUG)

The TUG [28] was used to evaluate functional mobility by measuring the time required by subjects to perform sequential motor tasks, including rising from an armchair, walking 3 m, turning and walking back and sitting down again. In stroke survivors, this measure yielded good to excellent test-retest reliability (r=0.87–0.99) [29, 30] and excellent concurrent validity (r=0.99) [30] with gait velocity.

The Chinese version of the activities-specific balance confidence scale (ABC-C)

The ABC-C [31] is a 16-item measure used to assess a subject's subjective balance confidence (0%, no confidence; 100%, complete confidence) in specific daily life situations, such as "getting into or out of a commonly used form of transportation". In stroke survivors, the ABC yielded good test-retest reliability (ICC=0.85) and moderate concurrent validity with the TUG (r=0.48), 10-meter walk test (10MWT) (r=0.52) and 6-minute walk test (r=0.45) [32].

Data collection

The assessments were performed in a university-affiliated neurorehabilitation laboratory. After providing written consent, the participants completed a data extraction form, including demographic data, history of falls in the past 12 months, types of medications and co-morbid conditions, and the ABC-C. Subsequently, the participants completed the balance tests in random order. These tests were conducted by a physiotherapist with >5 years of clinical experience (rater 1).

Experimental protocol

A resting interval of ≥5 minutes was allowed between each balance test and each S-PPA individual item test. Additional resting time was allowed if needed. The measurements were conducted according to the following procedure:

(i) TUG: subjects were allowed 1 practice trial and then completed 3 test trials. The average time of the 3 test trials was used.

(ii) FRT: subjects were allowed 2 practice trials and then completed 3 test trials. The average distance of the 3 test trials was used.

(iii) BBS: subjects were asked to complete 1 BBS trial. Instructions were provided by rater 1.

(iv) S-PPA: subjects were asked to complete 1 trial of the Melbourne Edge Test and 1 trial of the postural sway test. Instructions were provided by rater 1. The subjects were allowed 1 practice trial for the proprioception, and 5 pre-practice tests and 5 practice for the hand reaction time tests, respectively, after instructions were provided by rater 1. Next, the participants were asked to complete 5 trials of the proprioception test and 10 trials of the hand reaction time test, respectively. For the knee extension strength test, subjects were asked to complete 3 trials after instructions were provided by rater 1, and the average weight lifted in the 3 trials was calculated.

Twenty-eight consecutive participants were included in the assessment of inter-rater reliability between 2 physiotherapists (raters 1 and 2). These assessments were conducted simultaneously at baseline, with no discussion or disclosure of scores. To determine intra-rater reliability, another 28 consecutive participants not involved in the assessment of inter-rater reliability were re-assessed according to the S-PPA experimental protocol after a 1-week interval. One of the same physiotherapists (rater 1) conducted this assessment at the same time as the first assessment. The healthy controls completed the demographic data sheet and underwent the S-PPA once as conducted by rater 1.

Data analysis

The collected quantitative data were analyzed using SPSS 20.0 software at a significance level of α = 0.05. Descriptive statistics were used to summarize the demographic data and variables of interest. The normality of data and homogeneity of the variances were checked using the Shapiro–Wilk test and Levene's test, respectively.

ICCs were used to establish test-retest reliability, and the equation used to determine this value was selected depending on the intent of the analysis [33]. We adopted the ICC (2, 1) to determine inter-rater reliability and generalize the results of our findings to those of other S-PPA raters for clinical practice or research trials. We adopted the ICC (3, 1) to determine intra-rater reliability between the 2 specified raters (raters 1 & 2) [33]. ICCs of >0.90, 0.75–0.90, 0.50–0.75 and <0.50 indicate excellent, good, moderate and poor reliability, respectively [34].

To evaluate concurrent validity, the correlations of the S-PPA scores with the, FRT, TUG and BBS scores were examined. Convergent validity was examined using the correlation between the test S-PPA and ABC-C scores. Pearson's r and Spearman's rho analyses were used to analyze the correlations between normally and non-normally distributed variables, respectively. To compare fallers with non-fallers in the stroke group and the stroke group with the healthy group and assess known-group validity, independent t-tests were applied to parametric data and the Mann–

Whitney U test was applied to non-parametric data. Fallers were identified as subjects who had at least one falls in the last 12-month period before data collection. Non-fallers were those with no fall experiences in the 12-month period.

A receiver operating characteristic (ROC) curve analysis and areas under the curve (AUCs) were used to determine the cutoff point of the S-PPA composite score. AUC values of ≤0.5, 0.5 to <0.7, 0.7 to <0.8, 0.8 to <0.9 and ≥0.9 indicate no, poor, acceptable, excellent and outstanding discrimination, respectively [35]. The cutoff score was determined using the Youden index at the point where both the sensitivity and specificity values were maximized.

Results

Characteristics of the subjects

The stroke group had a mean age of 61.2 years, and a mean interval of 3.1 years since the stroke event (Table 1). Seventy-eight (57%) of the patients had 2 or more other chronic comorbidities, such as hypertension, and most of them (n=109, 80%) were taking 2 or more medications (e.g., hypertensive agents). Eighty-three of the patients (61%) had right-side hemiplegia, and the majority (n=129, 94%) required walking aids when walking outdoors. The majority of the patients (n=96, 70%) had no history of fall during the 12 months before the study began.

Table 2 summarizes the individual test items and S-PPA composite scores of the stroke and healthy groups. The mean S-PPA, FRT, TUG, BBS and ABC-C scores of the stroke group were 1.2, 20.3, 17.2, 49.2 and 65.1, respectively. As expected, the healthy group demonstrated better performance on the S-PPA when compared to the stroke group, as demonstrated by the mean composite and individual test item scores.

Reliability

The ICCs for the inter-rater and intra-rater reliability of the S-PPA composite score were 0.83 (95% CI: 0.67–0.92, $p<0.0001$) and 0.74 (0.51–0.87, $p<0.0001$), respectively (Table 3). The ICCs for the inter-rater reliability of the S-PPA individual items ranged from 0.56 (95% CI: 0.24–0.77, $p=0.001$) to 0.87 (95% CI: 0.74–0.94, $p<0.0001$), and those for the intra-rater reliability ranged from 0.58 (95% CI: 0.28–0.78, $p<0.0001$) to 0.94 (95% CI: 0.87–0.97, $p<0.0001$).

Concurrent and convergent validity

Significant correlations were observed between the S-PPA composite score and various balance measures, including the BBS (rho=-0.70, p<0.0001), FRT (rho=-0.57, p<0.0001) and TUG (rho=0.49, p<0.0001). Furthermore, a significant negative correlation was observed between the S-PPA composite score and ABC-C score (rho=-0.35, p<0.0001).

Known-group validity

A comparison of fallers and non-fallers in the stroke group revealed significant differences in the S-PPA composite score (*U*=1,495.5, p=0.026) and in the vision test (*U*=1,489.5, p=0.022) (Table 4). A comparison of the stroke and healthy control groups revealed significant differences in the S-PPA composite score (*U*=1,166.0, p<0.0001) and most of the individual item scores, including the proprioception test (*U*=551.5, p<0.0001), knee extension strength test (*U*=988.5, p<0.0001), hand reaction time test (*U*=1,532.0, p<0.0001) and postural sway test (*U*=2,100.0, p=0.03).

ROC curve analysis

Table 5 summarizes the results of the ROC curve analysis of the fall risk screening tests. A S-PPA cutoff score of 0.87 was identified between fallers and non-fallers in the stroke group, and the ROC curve yielded an AUC of 0.62 (95% CI: 0.52–0.72), sensitivity of 39% and specificity of 81%. Among the 4 tests used to screen the fall risk, only the BBS demonstrated an acceptable ability to differentiate participants with stroke who did or did not have a history of falls (AUC=0.77, 95% CI: 0.67–0.86). The remaining 3 screening tests of fall risk, namely the S-PPA, FRT and TUG, had a poor discriminative ability to distinguish participants with stroke who did or did not have a history of falls (AUC=0.62–0.64). The AUCs of the balance measures are illustrated in Fig. 1.

Table 5 Ability of BBS, FRT, S-PPA and TUG to distinguish stroke survivors with or without fall history

Fall risk screening tests	AUC	95%CI	Cutoff point	Sensitivity % (95% CI)	Specificity % (95% CI)
BBS	0.77	0.67-0.86	47.5	68 (52-80)	86 (77-91)
FRT	0.62	0.52-0.72	21.5	36 (27-47)	81 (68-89)
S-PPA	0.62	0.52-0.72	0.87	39 (29-50)	82 (71-90)
TUG	0.64	0.55-0.73	14.21	41 (31-51)	95 (84-99)

Note: AUC, area under the characteristic; CI, confidence interval; BBS, Berg Balance Scale; FRT, Functional reach Test; S-PPA, Short –form Physiological Profile Assessment; TUG, Timed “Up & Go”.

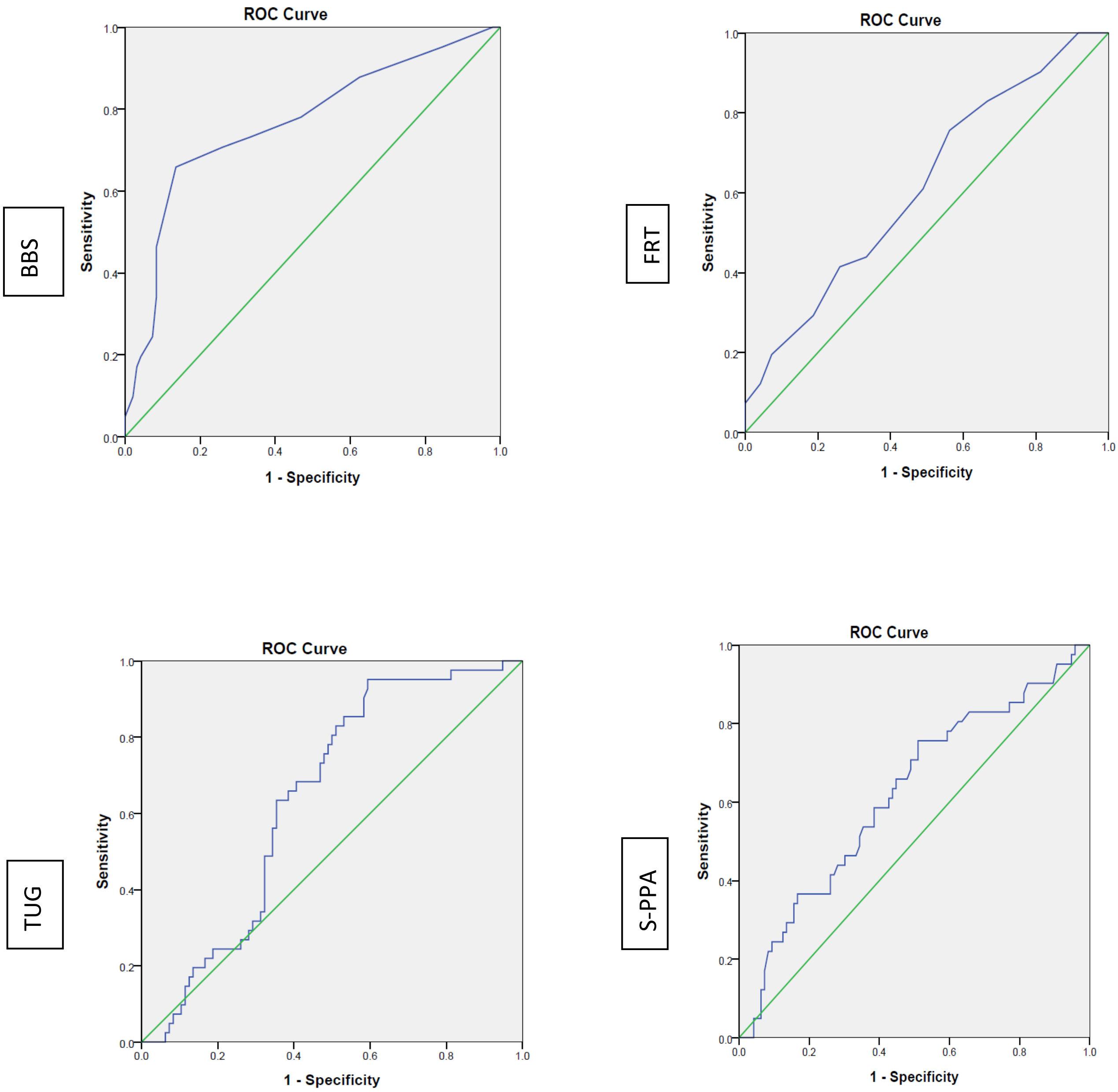

Figure 1 Receiver operator characteristic (ROC) curves of the Berg Balance Scale (BBS), Functional reach test (FRT), Timed “Up & Go” (TUG) and Short-form Physiological Profile Assessment (S-PPA) to distinguish stroke subjects with or without a history of fall (N = 137)

Discussion

This was the first study to apply the S-PPA to stroke survivors and age-matched healthy controls. All of the participants were able to complete the S-PPA, indicating that this fall risk measure could be feasibly applied to stroke survivors with intact cognition (AMT score ≥7) and mild balance impairments. Our findings revealed that the both S-PPA composite score and individual test scores yielded moderate to good interrater and intra-rater reliability in this cohort of ambulant community-dwelling stroke survivors. The S-PPA was found to exhibit significant moderate correlations with measures of balance, including the BBS, FRT and TUG, and the ABC-C. Our finding also demonstrated that the S-PPA can distinguish the fall risks of community-dwelling chronic stroke survivors and of healthy older adults. However, the S-PPA composite score had a limited ability to discriminate between fallers and non-fallers among the included stroke survivors.

Our findings regarding test-retest reliability are consistent with those reported by Lord and colleagues [14, 18], who tested samples of community-dwelling older adults. Our findings and those reported by Lord and colleagues [14, 18] revealed that the knee extension strength test had excellent test-retest reliability (ICC=0.97, 95% CI: 0.93–0.98) [14], the Melbourne Edge test had good test-retest reliability (ICC=0.81, 95% CI: 0.70–0.88) and the proprioception test (ICC=0.50, 95% CI:

0.15–0.74) [14] and postural sway test (ICC=0.68, 95% CI: 0.45–0.84) [18] had moderate test-retest reliability. However, our analysis of the test-retest reliability of the proprioception test (inter-rater reliability, ICC=0.60, 95% CI: 0.30-0.80; intra-rater reliability, ICC=0.62, 95% CI: 0.32–0.80) yielded better results than those obtained by Lord and colleagues [14] (ICC=0.50, 95% CI: 0.15–0.74). One possible explanation for this discrepancy is that our study participants were relatively younger (mean age: 61±7 years) than those recruited by Lord and colleagues (mean age: 81±3 years) [14], and the relatively better peripheral sensation of the younger participants may have yielded more stable scores during repeats of the proprioception test. Indeed, in a study of 550 community-dwelling women aged 20–99 years, Lord and colleagues [18] revealed that peripheral sensation, as measured by proprioception, correlated significantly with age ($r=0.20$, $p<0.0001$). Furthermore, the test-retest reliability of the postural sway test was poorer in this study (ICC=0.56–0.58) than the value reported by Lord and colleagues [14] (ICC=0.68), consistent with previous studies in which the test-retest reliability of postural sway was comparatively better in healthy adults (test-retest reliability ICC=0.33–0.93) [36-38] than in populations of patients with such as chronic low back pain (ICC=0.26) [36] and transtibial amputation (ICC=0.67) [39]. Possibly, a post-stroke asymmetric weight-bearing capacity could lead to an increase in postural sway [40], which might thus affected the stability of postural control during repeats of the postural sway test. Our findings also revealed that the S-PPA composite score has a higher degree of inter-rater reliability (ICC=0.83) than intra-rater reliability (IC=0.74). One possible explanation is that there may be unspecified measurement error between raters such as the height of the adjustable table used for recording the subject's body movement during postural sway test. Of course, despite the test-retest interval of only one week, we cannot completely exclude the possibility that the study participants' physiological factors were improved or deteriorated.

We found that among stroke survivors in this study, the S-PPA composite score correlated significantly with the balance measures of FRT, TUG and BBS (rho=-0.49 to 0.70), but exhibited a comparatively weaker correlation with the ABC-C (rho=-0.35). This finding is inconsistent with previous findings that the subjective balance confidence, as measured by the ABC, correlates with several balance measures, including the TUG (r=-0.48), 10MWT (r=-0.52) and 6-minute walk test (r=0.45) [32]. We believe that this discrepancy can be attributed to the different aspects of balance measured by these instruments. Whereas the TUG, 10WMT and 6-minute walk test are measures of the functional balance performance, the S-PPA measures aspects of the physiological profile that contribute to the fall risk, including vision, muscle force, peripheral sensation, reaction time and postural sway. The items on the ABC-C are directly related to daily activities (e.g., getting into or out of frequently used transportation) and functional balance (e.g., distance walking, changing directions and transit postures), as community-dwelling stroke survivors require confidence to perform these activities and functional balance is expected to correlate with the subjective balance confidence. However, the adverse effects of physiological deficits on functional balance could be compensated by external factors, such as the use of walking aids or walking with a companion. In summary, this study identified a limited association between the S-PPA and ABC-C.

The known-group validity of the S-PPA was demonstrated by its ability to distinguish people with and without stroke and those with and without a fall history among stroke survivors. Our findings are consistent with the findings of Lorbach and colleagues [41], who reported that the S-PPA composite score can effectively distinguish between people with and without Alzheimer's disease. As expected, the performances of stroke survivors were worse than those of healthy controls in most of the S-PPA individual item tests, except the Melbourne Edge Test. Among stroke survivors, we found that those with a history of fall within a 1-year period before the study began had a poorer S-PPA composite score but did not receive worse scores on any individual item test. These findings might suggest that for community-dwelling stroke survivors with intact cognition, the adoption of fall prevention strategies such as the avoidance of high-risk situations could effectively compensate for the physiological limitations associated with aging and chronic illness. In other words, the S-PPA did not identify notable differences among the physiological deficits in this study.

Our ROC curve analysis revealed findings consistent with those reported by Tsang and colleague [9], who stated that the BBS was best able to distinguish stroke survivors who did and did not have a history of falls (AUC=0.72, 95% CI: 0.61–0.83) when compared with the FRT and TUG. In contrast to previous prospective studies demonstrating the good predictive ability of the PPA among older adults with or without a fall history, our retrospective findings suggested that the S-PPA had a poor ability to distinguish stroke survivors with and without a fall history. The inconsistencies between the studies by Lord and colleagues [17, 18] and our findings may be explained by differences in the study population; the former included older adults who resided in an intermediate care institution and hostel for aged persons. Although the participants generally exhibited independence in activities of daily living, their participation in social activities may have been comparatively limited and their living environments might have been altered to reduce fall hazards. By contrast, our study participants were community-dwelling and participated actively in exercise and social activities. Therefore, the falls experienced by our study participants were more likely attributable to external risk factors, compared to those of older adults who resided in more structured living environments.

As reviewed by Xu and colleagues [3], sensorimotor performance is one of the fall risk factors of community-dwelling people with stroke. Together with Xu and colleagues [3] and our findings, we inferred that the S-PPA could reliably assess one of the risk factors leading to increased fall risks, namely the impacts of physiological factors on sensorimotor performance.   However, S-PPA's ability to screen for overall fall risks of community-dwelling people with stroke is limited.

This study had several major limitations. First, the generalization of our findings is limited to other populations that meet our inclusion and exclusion criteria. Second, this study had a cross-sectional design, and the ability of the S-PPA to identify fallers was analyzed retrospectively. Finally, men might have been underrepresented in our sample of stroke survivors as previous evidence revealed that men had higher preponderance rate of stroke survivors across age groups in some countries [42].

Conclusions

The S-PPA is a valid and reliable measure of the fall risks faced by chronic stroke survivors. Although this measure demonstrated a limited ability to discriminate between stroke survivors with and without a history of falling, it was found to exhibit moderate concurrent validity with several balance measures, including the BBS, FRT and TUG, and moderate convergent validity with the ABC-C. The S-PPA is advantageous because it used simple equipment to assess the physiological factors that might contribute to the fall risks of stroke survivors. Therefore, this measure provides useful information that can be used to personalize physiological treatment regiments to meet the needs of for stroke survivors with balance disorders. Further studies of patients with a variety of stroke-specific impairments present at several levels of severity would provide additional data for validation and generalizability.

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Appendix 5.3 Cross-sectional study 3 published on BioMed Research International (Final manuscript)

Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure (CIM) for use in patients with chronic stroke

INTRODUCTION

Community integration involves promoting interactions with society for those who would otherwise find themselves isolated from it [1- 3]. It is the ultimate goal of physical, mental and drug rehabilitation [4]. After disabling injury or illness it means return to a "normal" lifestyle, and it relates closely to the quality of life of people with chronic illness. For example, a retrospective study by Huebner's group of 45 Americans with traumatic brain injury [5] revealed that increased community participation as measured by the Community Integration Questionnaire (CIQ)[6] significantly correlated (r = 0.61, $P \leq 0.01$) with better quality of life. In another study with Chinese population [7], Kwok and his colleagues interviewed 500 subjects at 3 months post-stroke and another 433 subjects at 12 months post-stroke found that community participation as measured by the Chinese version of the London Handicap Scale (LHS) [8] was a stronger predictor of community integration than either functional status or post-stroke depression, or quality of life.

In 2001 the WHO published its International Classification of Functioning, Disability and Health (ICF)[9], which classifies functioning in the three domains of (1) body, (2) activities and participation, and (3) contextual factors. The body domain looks at changes in body function and structures; the activities and participation domain looks at the capacity to perform and performance of tasks; and the contextual factors domain looks at environmental and personal factors that influence functioning and disability. Activities and participation are emphasized as the major classification components.

There are several existing measures aiming to capture the multiple facets of community integration and measuring different aspects of the construct. They include the 11-item Reintegration to Normal Living Index (RNLI) [4], the 27 – item Craig Handicap Assessment and Reporting Tool (CHART) [10] and the Community Integration Questionnaire (CIQ) [6]. Although these measures all have sound psychometric properties, each is grounded on the developer's concept of community integration. For example, the CHART and CIQ were developed using a concept of "handicap" based on the WHO's International Classification of Impairments, Disabilities, and Handicap published in 1980[11], while the RNLI was derived from the views of consumers, family members and health care professionals.

In view of the lack of consistent definition of community integration, McColl et al. [12] had attempted to develop a theoretical model of community integration, the Model of Community Integration, from the view of people with brain injuries. Under the notion of this model, community integration was conceptualized to comprise four factors, including “assimilation”, “support”, “occupation” and “independent living”, and each had specific indicators consistent with the ICF’s concept of “activities and participation”. Based on the Model of Community Integration, McColl et al. developed the original Community Integration Measure (CIM) [13].

The CIM has 10 items with each item soliciting a rating on a five-point scale, giving a minimum score of 10 to a maximum of 50. The CIM has demonstrated good psychometric properties with good internal consistency (Cronbach’s alpha = 0.87) [13, 14], and good convergent validity [13] in distinguishing acquired brain injury survivors from healthy adults. The CIM scores also have significant positive correlations with various validated measures including the Community Integration Questionnaire [6], the Satisfaction With Life Scale (SWLS) [15], the Social Provision Scale (SPS) [16] and the perceived mental health quality of life composite score of the SF-12 Health Survey (SF-12) [17]. However, the test-retest reliability of the CIM has not yet been established.

For the factor structure, the original CIM [13] revealed a 1-factor structure measuring a unidimensional construct of community integration. In a replication study, Reistetter et al. [3] reported a 3-factor structure, namely the “support”, “occupation” and “independence” factors, and the indicators were clustered differently from the original theoretical model. The discrepancy between the identified factor structures in previous studies warrants for a re-visit of the underlying dimensionality that the CIM intended to capture.

Clinicians need a reliable and valid measure consistent with the ICF model to document the most substantive outcome of rehabilitation —community integration— particularly for patients with stroke. Chinese stroke survivors, in particular, are poorly served in this respect. Although the CIM is now widely used with survivors of brain injury [3, 13, 14] and spinal cord injury [18], it has not yet been translated from English into any other languages. Thus, the objectives of this study were to (1) translate and culturally adapt the contents of the English version CIM into Chinese (Cantonese), (2) to report the results of initial validation of the Chinese (Cantonese) version CIM (CIM-C) including the content validity, internal consistency, test-retest reliability and factor structure in a Chinese setting, and (3) to use the CIM-C to investigate the level of community integration of stroke survivors living in Hong Kong.

METHODS

Translation

The translation and cross-cultural adaptation of the CIM involved the following six steps.

Step 1. An expert panel consisting of 5 registered physiotherapists (two with 20 years of clinical experience, and three with 3 years of clinical experience in stroke rehabilitation) was set up.

Step 2. The English version of the CIM was translated into Chinese by 2 independent bilingual translators whose mother language was Chinese. One of them was a professional translator with no background in medicine or rehabilitation and the other was a physiotherapist with more than 3 years of clinical experience. They independently translated the English version CIM into two initial Chinese drafts (D_1 & D_2).

Step 3. The two initial drafts (D_1 & D_2) and the original English version CIM were reviewed by the same translators involved in step 2. Any discrepancies identified between D_1 and D_2 were resolved by discussion to reach a consensus version (D_{1-2}).

Step 4. For the backward translation, another 2 independent translators who were blinded to the original CIM were involved. One was a trained translator with no medical or rehabilitation background, and the other was a physiotherapist with more than 3 years of clinical experience. Each translated D_{1-2} into English independently. As no conceptual discrepancies could be identified in the back translation, D_{1-2} was adopted as a Chinese version of the CIM.

Step 5. The expert panel then evaluated that Chinese version for equivalence of content, semantics, conceptual and for any technical discrepancies with the original English version. The version they produced was named the Chinese-CIM – Pilot.

Step 6: The Chinese-CIM – Pilot was administered to 5 subjects with stroke to ascertain its fluency, clarity and comprehensibility. Their feedback was used to make minor amendments, and the final version, CIM – C, was confirmed. (See Appendix I)

Subjects

Sixty-two community-dwelling stroke survivors, with a mean of 7.12 years post-stroke, were recruited from among the clients of a local rehabilitation organization in Hong Kong (mean age (SD): 60.71 (6.28) years; 42 men, 20 women) (Table 1). Subjects were recruited if they were over 50 years old, had suffered a single stroke at least 1 year before the start of the study, were able to rise from a chair without any arm support, and had an Abbreviated

Mental Test score [19] of 7 or above. Potential subjects were excluded if they had any other co-morbid neurological disease (e.g. Parkinson's Disease) or an unstable medical condition such as cardiovascular problems that might affect proper assessment.

The subjects were informed about the objectives and procedures of the study and invited to sign a consent form before the experiment. The protocol was approved by the Ethics Committee of the administrative institution and conducted according to the principles of the Declaration of Helsinki for human experiments.

Test-Retest Reliability and factor structure

All 62 subjects with chronic stroke were assessed with the CIM-C scale through an individual face-to-face interview. Twenty-five of the subjects (40.3%) were randomly selected by drawing lots for reassessment with CIM-C again after one week to establish test-retest reliability. A 1-week interval was used to minimize chances of subjects' recall of contents from the previous assessment. This period was also considered optimal for avoiding potential occurrences of significant events or changes in their life circumstances that could also impact on their self-perceived balance confidence ratings. Factor structure of CIM-C was assessed by Principal Component Analysis (PCA) on all 62 subjects.

Data analysis

Quantitative data were analyzed using the Statistical Package for Social Science (SPSS), version 17.0. In the translation process, mode calculation and inter-judge percentage agreement were used to measure agreement in the 4 areas of cultural equivalence. Modification was required if any item failed to reach 70% inter-judge agreement. In the initial validation process, internal consistency was evaluated using Cronbach's α coefficient and item-total correlations. Test-retest reliability was established using the intraclass correlation coefficients (ICCs). For the examination of factor structure, principal component analysis was adopted to extract the factors as the original study by McColl et al. [3] and replication study by Reistetter et al. [13]. Scree plot was used to determine the number of factors retained followed by varimax rotation to optimize the loadings of the extracted factors to enhance the interpretability. For the community integration of subjects was characterized using descriptive statistics.

RESULTS

Characteristics of the subjects

There were 42 male and 20 female subjects tested. Their mean age was 60.71 (SD = 6.28) and their mean period since stroke was 7.12 years (SD = 3.12). Their mean BMI was 25.95 (SD = 3.44), and none had a history of falling in the previous 6 months. Thirty-nine of them had ischemic stroke, 22 had hemorrhagic stroke and one with unknown character. The majority of subjects required the use of a walking aid (stick, n = 31; small base quadripod, n = 5; large base quadripod, n = 1), and 42 of them required a companion to walk outdoors

(67.74%). Thirty-four claimed to have involved in exercise routinely for 7 times per week (54.9%).

Internal Consistency

The items of the CIM –C demonstrated high internal consistency with a Cronbach's α of 0.84 (Table 2). However, the results suggested that deletion of item 5 would increase the overall Cronbach's α of 0.01. The α coefficients of the individual items ranged from 0.28 (item 5) to 0.72 (item 9).

Test-Retest Reliability

Twenty five of the subjects participated in the re-assessment after a 1-week interval. The CIM – C demonstrated good test-retest reliability as reflected in an ICC of 0.84 (95% confidence interval, 0.64 – 0.93) (see Table 3). The ICC values for the individual items ranged from 0.34 to 0.88 with item 10 (I have something to do in this community during that main part of my day that is useful and productive) showing the most consistency (ICC = 0.88, 95% CI = 0.73 – 0.95). Item 2 (I know my way around this community) showed the least repeatability (ICC = 0.34, 95% CI = -0.48 – 0.71).

Factor structure

The Principal Component Analysis (PCA) is a method in clustering variables and explaining the variances of a measure [20]. It was used in the original [13] and replication [3] studies of CIM to examine the construct being measured and which items could be grouped. To compare the present findings with the previous studies, the factor structure of the CIM-C was examined by the PCA with varimax rotation. A 3-factor structure of the CIM-C, including “relationship and engagement”, “sense of knowing” and “independent living”, was revealed in the present study.

The correlation matrix of CIM-C revealed that all 10 items inter-correlated fairly well with correlation coefficients greater than 0.3. The Kaiser-Meyer-Olkin value of 0.79 indicated good sampling adequacy [21], and Bartlett’s test was highly significant (X^2 (45) = 245.85, $P \leq 0.001$), thus PCA was appropriate. After the factor extraction, the number of factors retained was determined by scree plot. It was noted that the extraction of 3 and 4 factors provided very similar estimates of the amount of variance in the indicators accounted for by the construct being measured. In other words, the degree of which a standard score increased in community integration associated with standard score increased in the indicators was very similar in the 3-factor model and 4-factor model. Thus, two, three and four factor solutions were attempted and it was revealed that the 3-factor structure explained the highest percentage of variance and it generated the most meaningful factors (Table 4). The loadings of all 10 items in the 3-factor structure exceeded the recommended value 0.4 [22] and ranged from 0.64 to 0.84, with 67.17% of the total variance explained.

Community integration of stroke survivors in Hong Kong

Table 5 shows the mean score for each item in the CIM – C and its standard deviation. The CIM-C ratings ranged from 28 to 50, and the mean score was 43.48 (SD = 5.79). The item with the highest score (4.58 $\pm$ 0.66) was item 3 (I know the rules in this community and I can fit in with them) and the item with the lowest score (3.93 $\pm$ 1.14) was item 10 (I have something to do in this community during the main part of my day that is useful and productive).

Table 6 compares the mean CIM-C scores of subjects with different selected characteristics. Independent t-tests revealed no significant difference in the overall CIM-C scores of subjects with different gender, right or left side hemiplegia, with or without ankle-foot orthoses, or requiring or not requiring a companion to walk outdoors.

DISCUSSION

This study has produced the first translation of the CIM into Chinese. It revealed the good internal consistency and excellent test-retest reliability of the Chinese version of CIM. In addition, this study extended the findings of previous investigations on the level of community integration of people with various chronic illnesses, including acquired brain injury [13], traumatic brain injury [14] and spinal cord injury [18], by investigating the level of community integration of Chinese stroke survivors in Hong Kong using a measure coherent with the ICF model. Our final 3-factor structure was comparable to those suggested by Reistetter and colleagues [3] for use in patients with brain injury, and our model was also consistent with the original theoretical model. The people with chronic stroke living in Hong Kong were reported to have high level of community integration (mean (SD): 43.48 (5.79)).

Internal Consistency

Internal consistency means that the items measure the same traits of the construct and the subjects' responses are consistent across all 10 items. The Cronbach's alpha of 0.84 is consistent with those generated in previous studies of people with acquired brain injury (0.87) [13, 14]. The individual CIM – C items demonstrated acceptable item-total correlations ($r > 0.30$) [23], except for item 5 (I can be independent in this community; $r = 0.28$). The greatest increase in Cronbach's alpha would result from deleting item 5, but its removal would increase the alpha by only 0.01. Thus, all individual items were considered worthy of retention.

Test-Retest Reliability

The excellent test-retest reliability of the CIM – C indicates a high degree of repeatability for clinical use. The 1-week interval was considered appropriate to exclude memory effects while minimizing the possibility of significant events occurring in the interim. Having the same examiner administer the test may have contributed to the excellent test-retest reliability.

Although item 2 (I know my way around this community) showed only fair agreement between the two measurements, retention of item 2 did not impair the overall reliability of the instrument. The item's low apparent repeatability may be due to unspecified measurement error, failure to interpret the concepts "know my way around" and/or "community" consistently, or real changes in the self-perceived level of community integration. Despite the test-retest interval of only one week, one cannot completely exclude the possibility of substantial events affecting an individual's level of community integration. Furthermore, the concepts expressed in item 2 may not have been considered as concrete as other items having high ICC values such as item 7 (there are people I feel close to in this community) and item 10 (I have something to do in this community during the main part of my day that is useful and productive).

Factor structure

In the present study, the PCA revealed a 3-factor structure and the findings were highly consistent with the Model of Community Integration that the original CIM [13] was based on. The high consistency on the Model of Community Integration of CIM across the Western population and Hong Kong Chinese population may suggest that the construct of community integration was comparable between the Western society and Chinese society in Hong Kong. This phenomenon might be due to the multi-cultural environment in Hong Kong. Based on the cross cultural validation for use in patients with stroke, the present study could further build up the evidence of the factor structure of CIM-C.

In the present study, the first factor identified was “relationship and engagement” which comprised aspects of social relationships and activities. The first factor consisted of items 7 – 10, in which items 7 and 8 involved aspects of social relationships, and 9 and 10 involved aspects of social activities. Item 9 (There are things that I can do in this community for fun in my free time) and 10 (I have something to do in this community during the main part of my day that is useful and productive) were included under the “occupation” domain in 3-factor structure suggested by Reistetter et al. [3]. However, it would be more appropriate to include both items 9 and 10 in the first factor of the present study (ie, social activity and engagement) due to the cultural differences between these 2 studies. It was because the common concept of people in Hong Kong considered that having interpersonal relationships and meaningful daytime engagement was equivalent to having social support and occupation in the community.

The second and third factors emerged in the present study were “sense of knowing” and “independent living” respectively, which were different from “occupation” and “independence” domains suggested by Reistetter et al. [3]. The second factor (ie, sense of knowing) consisted of items 1 – 3 which involved aspect of “sense of knowing” and belong to the community; while the “occupation” domain suggested by Reistetter et al. [3] consisted of aspects of productive work and independence. The third factor emerged in this study (ie, independent living) consisted of items 4 – 6 which involved aspects of independence, living situation and sense of being accepted; while the “independence” domain suggested by Reistetter et al. [3] involved aspects of orientation and independence. Although discrepancies of clustered indicators existed between the present study and those of Reistetter et al. [3], all our clustered indicators were consistent with the Model of Community Integration [12]. Such discrepancies of clustered indicators between different studies could be explained by the fact that factors represented by two or three indicators could be highly unstable across replications [24].

Level of community integration of Hong Kong stroke survivors

Our results showed that the overall level of community integration (mean (SD): 43.48 (5.79)) was comparable to those reported among people with spinal cord injury (SCI) [18] (mean

(SD): 42.50 (5.80)) but higher than those of people with traumatic brain injury (TBI) (mean (SD): 39.40 (8.10)) [14] and acquired brain injury (ABI) (mean (SD): 28.80 (7.70)) [13]. The study found that people with stroke, like those with SCI, have a high level of community integration as measured by the CIM. The high CIM scores in our subjects could be explained by several reasons. Fifty-five percent of our subjects claimed to exercise 7 times per week, and this group of patients would be more active to join the community activities. In De Wolf's study [18], 60% of the subjects with SCI had a low impairment levels (tetraplegia ASIA D or paraplegia), and all the subjects in our present study had high level of functional mobility. In addition, the functional mobility of our subjects with stroke, similar to those of patients with SCI, can mostly be compensated for by efficient use of assistive devices, walking aids and/or a wheelchair. For people with brain injuries, the impaired cognition and emotional and personality changes following traumatic brain injuries may underlie their low average CIM scores. Associated memory loss, problem solving skill deficits, impaired social relationship skills, emotional distresses and impaired self esteem could lower their CIM scores in the habits of living and self-evaluation aspects.

Limitations

In the present study, the initial psychometric properties of the CIM – C were established using community-dwellers aged over 50 years but with good functional mobility. However, the generalization of the present study was only limited to those fulfilling our inclusion and exclusion criteria. In addition, the sample size of 62 was barely enough for principal component analysis. Further tests of the applicability of the CIM – C to people with other chronic diseases are therefore recommended to further explore the factor structure of the CIM – C.

CONCLUSIONS

Assessing the level of community integration is essential in evaluating rehabilitation outcomes for people with chronic disease. Cross-cultural adaptation of a validated instrument for quantifying community integration can help to build up an internationally comparable body of scientific knowledge. The findings of the present study showed that the CIM is a culturally relevant, and a reliable and valid instrument for assessing the level of community integration of Chinese population with stroke in Hong Kong. The instrument is user friendly and requires only a basic level of literacy (not to be assumed among elderly Chinese populations) to conduct, and it could be completed within 3-5 minutes.

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Appendix 5.4 Research protocol published on Trial (Final manuscript)

Effectiveness of a combination of cognitive behavioral therapy and task-oriented balance training in reducing the fear of falling in patients with chronic stroke: Study protocol for a randomized controlled trial

Background

Fear of falling (FoF) is one of the most common post-stroke complications, and is widely acknowledged as part of a vicious circle[1] leading to actual falls.[2] It is a debilitating post-fall syndrome stemming from low balance self-efficacy and the fearful anticipation of falling.[3, 4] The reported prevalence of FoF varies between post-stroke stages, ranging from 54% before discharge[5] from an acute unit to 44% at 6 months after stroke[6] and 58% among community-dwelling patients with stroke.[7] If no action is taken, FoF spirals into a loss of physical function, dependency on others for assistance with activities of daily living (ADL), restrictions on daily activities[4] and a higher fall rate, [8] eventually compromising community integration.[9]

Two recent systematic reviews synthesized the findings of interventions targeting FoF. Bula's (2011)[10] review of 46 randomized controlled trials (RCTs) with 6,794 community-dwelling elderly persons revealed that the majority of the reviewed studies (n = 38) focused on fall prevention and balance improvement, with FoF regarded as a secondary outcome. In the eight studies directly addressing the "fear of fearing," the use of physiological interventions such as tai chi,[11] strengthening, balance and walking exercises,[12] psychological interventions such as cognitive behavioral therapy (CBT)[13, 14] and guided relaxation and exercise imagery[15] was reported to help reduce FoF among community-dwelling older people.

In another systematic review, Tang (2015)[16] examined 19 clinical trials addressing FoF among people with stroke. Despite its significant influence on stroke rehabilitation, FoF was regarded only as a secondary target in the studies reviewed. Tang's (2015)[16] meta-analysis of 15 clinical trials with 627 participants revealed that the use of intensive exercise-based physiological interventions, such as gait training,[17-20] exergaming,[21] yoga[22] and a combination of fitness, mobility and functional exercises,[23, 24] can reduce FoF with a medium effect size (standardized mean difference: 0.44; 95% confidence interval (0.11-0.77); p = 0.009). No improvements were noted in the four reviewed studies using psychological interventions (motor imagery)[25-28], and no retention effect was noted in the studies with follow-up assessment. However, the effectiveness of CBT as a psychological intervention in reducing the FoF of stroke patients has not been examined.

CBT is a psychotherapeutic approach that redirects negative cognitive, emotional or behavioral responses to help people develop coping mechanisms and self-confidence.[29]

For example, people with FoF originating from impaired balance self-efficacy can use CBT to change their self-defeating beliefs, improve their balance self-efficacy and replace their unrealistic anticipation of falls and magnified fear of fall consequences with a realistic, positive perspective on falls, in turn reducing their fear avoidance.

As summarized by Bula (2011)[10] and Tang (2015),[16] studies have shown that physical exercise can reduce FoF in older people and people with stroke as either a primary or a secondary outcome. As psychological interventions offer another possible means of reducing FoF, we aim to examine the effectiveness of a combination of CBT and task-oriented balance training (TOBT) in reducing the FoF of people with stroke. TOBT will be used in the proposed study because it targets stroke-specific impairments and has been clinically proved to improve the balance performance of people with stroke.[30, 31] The inclusion of CBT in our treatment arm is based on our hypothesis that CBT is an adjunct therapy capable of optimizing the treatment effects of exercise in reducing FoF. It is expected to tackle FoF directly through the promotion of balance self-efficacy, and its indirect effects will be mediated by repeated exercise and reduced fear avoidance behavior, further enhancing balance performance and ADL and thereby improving community integration. The combined effects of CBT and TOBT in reducing FoF are expected to improve patients' balance, reduce their risk of fall, increase their independence and thereby promote their community integration. Indeed, in Huang's (2016)[32] recent RCT with elderly persons, CBT with an exercise intervention (n = 27) performed better than both CBT alone (n = 27) and treatment as usual (n = 26) in reducing FoF and depression and enhancing mobility and muscle strength, with retention effects observed up to 5 months later. Therefore, the proposed study aims to determine whether combining CBT with TOBT augments the latter's positive treatment effects on FoF, and thus fear-avoidance behavior, balance ability, fall risk, independent living, enhancing community integration and health-related quality of life among community-dwelling seniors with stroke.

To develop an intervention for clinical use, a protocol is necessary to ensure the consistency of implementation and ease of replication. Therefore, the objective of this paper is to report the details of a protocol for combining CBT and TOBT to reduce FoF among people with stroke.

Methods

Trial design

The proposed study will be a placebo-controlled single-blind parallel group RCT with a 12-month follow-up, conducted with community-dwelling chronic stroke survivors with FoF at a university-based rehabilitation center. The findings of the trial will be reported in accordance with the Consolidated Standards of Reporting Statement.[33]

Choice of comparator

A placebo control intervention, general health education (GHE), will be provided for the control group to help measure the effects of CBT alone. To rule out potential placebo effects such as attention from therapists and knowledge of treatment conditions, the GHE program will provide no information related to subjective balance confidence, activity avoidance, falls or physical activity, but only information related to general health issues such as healthy food choices and foot care.

Null hypothesis

The null hypothesis will be that the efficacy of CBT combined with TOBT does not differ significantly from that of GHE combined with TOBT in promoting balance self-efficacy, thus reducing fear-avoidance behavior, enhancing balance ability, reducing fall risk, improving community reintegration and health-related quality of life for people with stroke.

Participants

Prospective participants will be required to meet the following inclusion criteria: (i) aged between 55 and 85, (ii) diagnosed with a first unilateral ischemic brain injury or intracerebral hemorrhage by magnetic resonance imaging or computed tomography within 1-6 years post-stroke, (iii) discharged from all rehabilitation services at least 6 months before the program, (iv) able to walk independently for at least 10 meters with or without an assistive device, (v) showing low balance self-efficacy (scoring less than 80 on the Chinese version of the Activities-specific Balance Confidence [ABC-C] Scale, [34] (vi) scoring higher than 7 out of 10 on the Chinese version of the Abbreviated Mental Test[35] and (vii) able to follow instructions and provide written informed consent.

Individuals will be excluded if they have any additional medical, cardiovascular, orthopedic or psychiatric or psychological conditions that will hinder proper treatment or assessment, if they present with receptive dysphasia or significant lower limb peripheral neuropathy or if they are involved in drug studies or other clinical trials.

Therapists and research personnel

Two research assistants with at least 2 years of research experience in the field of physical-exercise training will be the assessors of this study. They will be given a 1-day training session on obtaining outcome measurements by an experienced physiotherapist before the study. Training will be provided in both the theory and practice of using the outcome measures. All of the assessors will rehearse the outcome measures with the research-team personnel to standardize the assessment. To establish the interrater reliability, the 2 assessors will rate 5 participants and then review for discrepancies if any.

Two TOBT therapists will have been trained by an experienced physiotherapist and have at least 2 years of post-qualification experience as therapists in the field of physical-exercise training. The 2 TOBT therapists will also be provided with written progression guidelines

(Table 1). A regular review of training records and spot observations will be conducted by the experienced physiotherapist to enhance adherence to the written progression guidelines. The CBT therapists will be 3 psychiatric nurses who have qualified as cognitive therapists. They will all have at least 5 years of post-qualification experience with applying CBT clinically. A treatment manual and materials have already been developed with reference to Tennstedt's (1998)[13] and Zijlstra's (2009)[14] research on FoF as experienced by community-dwelling older adults and reviewed by the three certified cognitive therapists involved in the study. To ensure treatment integrity, the CBT intervention has already been piloted and audiotaped. Each CBT therapist evaluated the pilot sessions to assess their compliance with the treatment manual, the achievement of session goals and the use of CBT techniques. The GHE intervention will be delivered by two research assistants not involved in the assessment or any other part of the intervention, using audio-visual aids and materials that have already been developed.

Procedure

Participants will be recruited from a local self-help group for people with stroke through poster advertisements. On receiving telephone calls from interested parties, our recruitment research assistant will perform an initial eligibility screening and offer appointments to gain written informed consent and complete a baseline assessment.

All of the potential participants will meet individually in the study venue to enable the researchers to explain the details of the study, such as its aims, benefits, risks and confidentiality, and then check the applicants' eligibility against the inclusion and exclusion criteria. If individuals are both interested in joining and eligible to join the clinical trial, written informed consent will be obtained before the baseline assessment is conducted. Questionnaires relating to sociodemographic characteristics, variables of interest and physical and functional performance will be completed on the same day.

Measurements

All of the participants will be required to undergo five sets of measurements: (i) before assessment (baseline treatment); (ii) after 8 sessions of treatment (midway through treatment); (iii) after 16 sessions of treatment (end of treatment); (iv) 12 weeks after treatment (follow-up); (v) and 12 months after treatment (follow-up). All of the assessment procedures will be performed by a research assistant blind to the group allocation and not previously involved in the delivery of the interventions.

Randomization and blinding

Figure 2 [see Additional file 2] presents an overview of the study. After explaining the study's objectives and obtaining written informed consent, a research assistant will perform a baseline assessment for all of the outcome measures. An offsite volunteer not involved in the recruitment, intervention or data collection will randomly allocate the participants to either the EG or CG in a 1:1 ratio, using the computer program "Minimise".[36] The randomization will be stratified based on age (55-70 years; 71-85 years), gender (male; female), and level of subjective balance confidence, based on ABC-C scores (<50; 50-80).[37] The participants will be informed of the results of the group allocation and their resulting training schedule and venue by centralized telephone calls from an offsite volunteer to ensure concealed randomization.

To maintain assessor blinding, the assessment, data entry and data analysis will all be performed by another full-time research assistant blind to group allocation and not involved in delivering the interventions. The intervention and assessment will be physically separate, performed at different sites. The subjects will be reminded not to disclose any information on their intervention groups to the assessors. However, it will be impossible to blind the therapists and participants to the group allocation.

All of the participants will be asked to undertake 16 sessions of training over an 8-week period. The participants in both groups will undergo 45-minute sessions of TOBT in groups of three to five. TOBT is a rehabilitation strategy designed to improve muscle strength in lower limbs and to correct for balance deficits on the paretic side of patients with stroke.[30, 38, 39] Improved strength and balance are gained through the repetition of task-specific functional movements.

The TOBT intervention will consist of five exercises targeting muscle strength in the lower limbs and walking performance: (i) stepping up and down in different directions to strengthen the affected leg muscles and to increase control over shifts in the center of gravity; (ii) heel-raising exercises to strengthen the ankle plantar flexors; (iii) semi-squatting to improve lower limb strength and proprioception in the knees and ankles; (iv) standing on a dura disc to promote static balance; and (v) walking across a surface covered with obstacles to improve dynamic walking balance.

Based on our practical experience of using TOBT in previous studies of patients with chronic stroke, [30, 40] the proposed frequency and intensity of treatment will be effective and tolerable, providing sufficient stimulation to enhance motor recovery in patients with stroke. In the TOBT sessions, the participants will take turns in carrying out one of the TOBT exercises for 8 minutes, followed by a 1-minute rest interval, until the five TOBT exercises have been completed. All the TOBT will be held in the morning, and then the participants attend either the CBT or GHE session on the same day in the afternoon after a two hours lunch break.

Experimental group

The EG will receive bi-weekly CBT sessions for 8 weeks, lasting for 45 minutes per session, in groups of three to five. The CBT sessions will be focused on eliminating cognitive and behavioral factors known to generate and aggravate impaired subjective balance confidence and fear-avoidance behavior. Their aims will be to increase the self-perception of efficacy regarding falls and the sense of control over falling, to decrease the perception of risk and to help the participants adopt realistic expectations of the consequences of falls. Each week will have a specific theme in the CBT protocol. The main themes and content are summarized in Table 2.

Weeks 1-2 of the CBT sessions will focus on introducing the CBT framework and showing how self-perceived capability and maladaptive thoughts can influence behavioral performance. From week 3 to week 8, two major techniques, cognitive restructuring and behavioral modification, will be used in the CBT sessions to achieve participants' personal goals. Cognitive restructuring attains thought alteration in the following four steps: (1) identification of automatic thoughts; (2) examination of cognitive distortion originated by automatic thoughts; (3) disputing the cognitive distortion and automatic thoughts; and (4) developing adaptive beliefs. In the proposed study, these four steps will be undertaken in the form of CBT homework assignments and sharing and discussion during CBT group sessions.

After effecting cognitive restructuring, the CBT group sessions will target behavioral modification, another crucial component of the intervention. The participants will be equipped to identify potential risks and develop behavioral strategies to prepare them to increase their activity levels safely. The CBT sessions will also serve as a platform for vicarious learning, social persuasion and social modeling for the participants through group discussion and observing the success of others. In addition, mastery experiences can be gained through the successful application of CBT in daily situations. Indeed, according to Bandura (1997),[41] this is the major source of self-efficacy. Therefore, the use of cognitive-restructuring and behavioral-modification techniques is expected to enhance the participants' subjective balance confidence and reduce their fear-related avoidance behavior.

Control group

The CG will attend 16 health talks (two sessions per week, 45 minutes per session) delivered as an inactive attention placebo by a research assistant in groups of three to five. The materials used in the GHE sessions will include audio-visual presentations, demonstrations, video clips, mini-games, oral quizzes and posters and pamphlets on various health topics. The GHE sessions will be designed to raise awareness of general health issues and increase general health knowledge among an elderly population. The details of the GHE sessions are summarized in Table 3.

Safety and adverse events

CBT is a clinically proven therapeutic intervention with no known associated risks. However, as one of the aims of CBT interventions is to promote independence, the participants will be instructed to increase their ADL, physical exercise and social participation. Potential hazards will be discussed in the CBT sessions before these behavioral changes are effected. Information on safety precautions will be provided, and the participants will be aided in the development of strategies to minimize potential hazards and ensure safety. The therapists and research personnel will report any and all adverse events to the Departmental Research Committee of the Hong Kong Polytechnic University.

Outcome measures

Primary outcome measure

Balance confidence

Our primary outcome of interest is FoF that will be measured using the Chinese version of the ABC-C.[34] The ABC-C consists of 16 items representing specific situations in daily life rated on a scale from 0% (no confidence) to 100% (complete confidence). The ABC has been validated for use with community-dwelling elderly[42] and people with various medical conditions, such as Parkinson's disease[43] and stroke.[44, 45] The ABC has also been translated into Chinese (Cantonese), and shows an excellent internal consistency (Cronbach's alpha = .97) and a high test-retest reliability (intraclass correlation coefficient = .99).[34]

Secondary-outcome measures

Fear-avoidance behavior

The participants' engagement in fear-avoidance behavior will be assessed using the Chinese version of the Survey of Activities and Fear of Falling (SAFFE-C).[46] The SAFFE-C is a self-reported inventory designed to measure the restriction on respondents' activity created by FoF. The SAFFE-C consists of 22 items measuring the extent of individuals' worry over performing 22 activities representing ADLs, mobility and social activity on a 4-point Likert scale (0 = not at all worried, 1 = a little worried, 2 = somewhat worried and 3 = very worried). The Chinese translation of the SAFFE shows excellent internal consistency (Cronbach's alpha = .95).[46]

Balance

Balance ability will be measured using the Berg Balance Scale (BBS),[47] which is considered a valid measure of functional balance in various populations, such as stroke survivors and healthy older adults.[48] The BBS consists of 14 items, each rated on a 5-point scale: a score of 41-56 indicates the ability to walk independently, 21-40 indicates the ability to walk with assistance and 0-20 indicates wheelchair-bound movement.

Fall risk

Fall risk will be quantified using the Short-form Physiological Profile Assessment (S-PPA) which consists of five tests: a vision test, a proprioception test, a lower extremity muscle force test, a hand reaction time test and a balance test.[49] Composite scores are measured on a 7-point scale according to the participants' responses to the tests; potential fall risk ranges from -2, representing a very low fall risk, to 4, which represents a very marked fall risk. The S-PPA has been shown to effectively distinguish recurrent fallers from non-fallers among community-dwelling older adults.[50]

ADL

The respondents' engagement in ADL will be measured using the Chinese version of the Lawton Instrumental Activities of Daily Living Scale.[51] The scale's nine items reflect the respondents' level of independence in performing nine instrumental ADL: making telephone calls, using transportation, shopping, cooking, housekeeping, household repair, doing laundry, self-medicating and handling finances.

Community reintegration

Community reintegration will be measured using the Chinese version of the Community Integration Measure (CIM-C).[52] The CIM-C consists of 10 items on a 5-point scale representing the respondents' self-reported sense of community reintegration. The CIM has been used for patients with various chronic illnesses, such as acquired brain injury[53] and stroke.[52]

Health-related quality of life

Quality of life will be assessed using the Chinese version of the Short Form General Health Questionnaire (SF36-C).[54] The SF36 consists of self-reported items related to physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning and emotional well-being. Two summary scores obtained for a physical-component scale (PCS) and a mental-component scale (MCS) are converted into a score on a scale from 0 to 100, representing a continuum of disability in which scores of 0 and 100 refer to the maximum and minimum levels of disability, respectively.

Data analysis

The data will be double entered to enable validation. Simple descriptive statistics will be used to summarize the sociodemographic characteristics of the participants and other variables of interest. Normality of data will be examined by Kolmogorov-Smirnov test. Between-group comparisons at baseline will be performed using *t* tests, Kruskal-Wallis tests, chi-square tests or Fisher's exact test, as appropriate.

To measure the changes over time in variables of interest between the two study arms, mixed-effects models with adjustments for potential confounding variables such as sociodemographic characteristics will be used. Mixed-effects models go beyond the customary linear framework by incorporating random effects relating to participants. They account well for intra-correlated repeated measures data and accommodate missing data caused by drop-out, as long as the data are missing at random. Pearson and Spearman's correlation tests, as appropriate, will be used to investigate the correlations between outcome variables. SPSS 17.0 will be used for the remaining statistical analysis, with a 5% level of confidence (two-sided) accepted for significance.

Sample size

The sample size has been calculated using G*Power version 3.1.0, with an alpha level of 0.05 (one-tailed) and a study power of 80%. As no previous studies have addressed the effects of CBT in reducing fear of falling on stroke populations, the effect size used to calculate the sample size is the same as that calculated for our pilot sample of 10 subjects (0.26) (five subjects receiving the CBT + TOBT training, and another five subjects receiving the CBT + GHE training) with the use of the ABC-C[34] as the primary outcome measure at eight weeks after the end of treatment. The required sample will thus comprise 76 subjects, with 38 per group. With reference to previous clinical trials,[30, 40] we expect the dropout rate to be about 15%, requiring an extra six subjects per group to be recruited. Therefore, the planned sample size is 88.

Discussion

FoF and actual falls create a vicious cycle with devastating consequences for patients with chronic stroke. More than half of the patients with stroke in the community under study experience impaired subjective balance confidence and have suffered at least one fall since discharge. Interventions for fall prevention have focused on balance training, leaving the FoF of stroke survivors under-addressed. The aim of the proposed clinical trial is to evaluate the effectiveness of a combination of TOBT and CBT in reducing FoF, and in turn reducing fear-avoidance behavior, increasing balance, enhancing engagement in ADL, decreasing fall risk, promoting community reintegration and enhancing the quality of life of patients with chronic stroke.

CBT is a form of clinically proved psychotherapeutic intervention designed to shape patients' thinking and actions to achieve therapeutic goals. Research has shown that multidimensional programs with CBT components provide an effective means of treating FoF and reducing the incidence of fall among healthy older adults. This sheds light on the effects on stroke recovery of CBT combined with customary physical training. The inclusion of CBT with customary physical training will help to break the vicious cycle of FoF and actual falls and thus enhance the rehabilitative outcomes of patients with chronic stroke.

One of the limitations of this study is not collecting the actual fall data. However, the main purpose of this study is to evaluate the augmenting effects of CBT on existing physiotherapy in enhancing subjective balance confidence. The occurrence of post-stroke falls is a complex issue involving the interplay between physical, psychological, behavioral and environmental factors. Future studies could further examine the roles of subjective balance confidence in developing fall prevention strategies for patients with stroke. Besides, this study may involve community-dwelling stroke patients with a range of balance ability level. Thus, the use of BBS may not be adequately sensitive to capture the balance improvement among subjects with mildly affected balance ability.

It is hoped that the results of this study will provide scientific evidence supporting the use of CBT to augment the effects of physiotherapy in enhancing subjective balance confidence and thus stroke rehabilitation. If effective, our intervention will offer a safe, cost-effective and readily transferrable therapeutic approach to clinical practice that reduces fear avoidance behaviors and fall risk, improves balance and level of independence, enhances health-related quality of life and decreases associated healthcare costs.

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Appendix 5.5 The Chinese version of the Activities-specific Balance Confidence scale (ABC-C)

0% 10 20 30 40 50 60 70 80 90 100%

無信心 絕對信心

當你做下面嗰啲活動嘅時候，你有幾多信心你可以保持平衡同埋穩定

	活動項目	分數
1.	喺屋裡面行嚟行去	
2.	上落樓梯	
3.	“嗚”低身喺地下度執起隻拖鞋	
4.	喺個架度，攞一個擺喺你頭咁高嘅罐頭	
5.	趷高腳，去攞高過你頭頂啲嘢	
6.	企喺櫈上面攞嘢	
7.	掃地	
8.	行出屋企，去附近搭車	
9.	上落你搭慣嘅交通工具	
10.	穿過停車場去商場	
11.	行上或者行落條短斜坡	
12.	喺一個好迫，同埋周圍啲人又行得好快嘅商場裡面行	
13.	喺商場度行嘅時候，俾人撞落你度	
14.	捉住條扶手，踏入或者踏出扶手電梯	
15.	拎住啲嘢，手又冇得扶住，踏入或者踏出扶手電梯	
16.	行出出便，濕滑嘅地面	

Appendix 5.6 The Chinese version of the Survey of Activities and Fear of Falling (SAFE-C)

你對這些日常活動恐懼跌倒程度有多少?

日常生活	對這項目恐懼跌倒 (0=沒有, 1=小小, 2=有點, 3=十分害怕)
1. 行商店	0 1 2 3
2. 清潔房間	0 1 2 3
3. 預備用膳	0 1 2 3
4. 看醫生或看牙醫	0 1 2 3
5. 沖浴缸浴	0 1 2 3
6. 沖花灑浴	0 1 2 3
7. 自行如廁 (大小二便)	0 1 2 3
8. 起床	0 1 2 3
9. 行路運動	0 1 2 3
10. 路面濕滑時仍外出	0 1 2 3
11. 上落樓梯	0 1 2 3
12. 乘搭公共交通工具	0 1 2 3
13. 出入汽車	0 1 2 3
14. 探訪朋友或親戚	0 1 2 3

15. 社交活動	0 1 2 3
16. 穿衣解履	0 1 2 3
17. 接觸過頭的東西	0 1 2 3
18. 去人多擠迫的地方	0 1 2 3
19. 自己在自住大廈內或居所內走動	0 1 2 3
20. 自行行幾條街	0 1 2 3
21. 屈身執拾東西	0 1 2 3
22. 去看電影或看表演	0 1 2 3

Appendix 5.7 The Berg Balance Scale (BBS)

1. ***SITTING TO STANDING***
   INSTRUCTIONS: Please stand up. Try not to use your hands for support.

   ( ) 4 able to stand without using hands and stabilize independently
   ( ) 3 able to stand independently using hands
   ( ) 2 able to stand using hands after several tries
   ( ) 1 needs minimal aid to stand or to stabilize
   ( ) 0 needs moderate or maximal assist to stand

2. ***STANDING UNSUPPORTED***
   INSTRUCTIONS: Please stand for two minutes without holding.

   ( ) 4 able to stand safely 2 minutes
   ( ) 3 able to stand 2 minutes with supervision
   ( ) 2 able to stand 30 seconds unsupported
   ( ) 1 needs several tries to stand 30 seconds unsupported
   ( ) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. **SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL**
   INSTRUCTIONS: Please sit with arms folded for 2 minutes.

   ( ) 4 able to sit safely and securely 2 minutes
   ( ) 3 able to sit 2 minutes under supervision
   ( ) 2 able to sit 30 seconds
   ( ) 1 able to sit 10 seconds
   ( ) 0 unable to sit without support 10 seconds

4. **STANDING TO SITTING**

INSTRUCTIONS: Please sit down.

( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. **TRANSFERS**

INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cueing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. **STANDING UNSUPPORTED WITH EYES CLOSED**

INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.

( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays steady
( ) 0 needs help to keep from falling

7. **STANDING UNSUPPORTED WITH FEET TOGETHER**

INSTRUCTIONS: Place your feet together and stand without holding.

( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently and to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. **REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING**

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently >25 cm (10 inches)
( ) 3 can reach forward >12.5 cm safely (5 inches)
( ) 2 can reach forward >5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/ requires external support

9. **PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION**

INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. **TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING**

INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right.
(Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. **TURN 360 DEGREES**

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only in 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cueing
( ) 0 needs assistance while turning

12. **PLACING ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED**

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps >20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete >2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. **STANDING UNSUPPORTED ONE FOOT IN FRONT**

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT)

Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. **STANDING ON ONE LEG**

INSTRUCTIONS: Stand on one leg as long as you can without holding.

( ) 4 able to lift leg independently and hold >10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or >3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assist to prevent fall

ITEM	DESCRIPTION	SCORE (0-4)
1.	Sitting to standing	_____
2.	Standing unsupported	_____
3.	Sitting unsupported	_____
4.	Standing to sitting	_____
5.	Transfers	_____
6.	Standing with eyes closed	_____
7.	Standing with feet together	_____
8.	Reaching forward with outstretched arm	_____
9.	Retrieving object from floor	_____
10.	Turning to look behind	_____
11.	Turning 360 degrees	_____
12.	Placing alternate foot on stool	_____
13.	Standing with one foot in front	_____
14.	Standing on one foot	_____
	TOTAL (maximum 56)	_____

0–20, wheelchair bound
21–40, walking with assistance
41–56, independent

Appendix 5.8 The Short-form Physiological Profile Assessment (S-PPA)

1. **Edge contrast sensitivity**

score:_______

2. **Reaction time – hand (millisecond)**

Pre-practice 5 times	Practice	Test
N.A.	1.	1.
	2.	2.
	3.	3.
	4.	4.
	5.	5.
	N.A	6.
		7.
		8.
		9.
		10.

3. **Proprioception**

Difference (in degree)	Score
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.

4. **Knee extension strength**

Score:______ kg

5. **Balance (Performance = sway area = AP x lateral)(Staple the graph paper with the assessment form, then calculate and score on the table)**

Eye open – floor	Antero-posterior	Medio-lateral

Appendix 5.9 The Chinese version of the Lawton Instrumental Activities of Daily Living Scale (IADL-C)

No	ITEM	Score
1.	"你能唔能夠自己用電話呢?" 包括找電話號碼，打及接聽電話 不需要任何幫助 需要一些幫忙 完全不能自己做	**2** **1** **0**
2.	"你能唔能夠自己搭車呢？" 包括自己上到正確的車，俾車錢/買車票，上/落車(假設你必須要搭交通工具去一個遠的地方例如探朋友/睇醫生) 不需要任何幫助 需要一些幫忙 完全不能自己做	**2** **1** **0**
3.	你能唔能夠自己買嘢呢？包括自己揀貨品、俾錢及攞番屋企 (假設你必須要到附近商店買食物或日用品) 不需要任何幫助 需要一些幫忙 完全不能自己做	**2** **1** **0**
4.	你能唔能夠自己煮食呢？包括自已諗食乜、準備材料、煮熟食物及放入碗碟裡(假設你必須要自己準備兩餐) 不需要任何幫助 需要一些幫忙 完全不能自己做	**2** **1** **0**
5.	你能唔能夠自己做家務呢？包括簡單家務(如抹檯、執床、洗碗) 及較重的家務(如抹地/窗) 假設你必須要自己做家務 不需要任何幫助 需要一些幫忙 完全不能自己做	**2** **1** **0**
6.	你能唔能夠應付簡單的家居維修呢? 例如換燈泡、縫修檯及上緊螺絲等 (假設你必須要自己做家務) 不需要任何幫助 需要一些幫忙 完全不能自己做	**2** **1** **0**

7.	你能唔能夠自己洗衫呢? 包括清洗及曬自己的衫、被、床單等（假設你必須要洗自己的衫、被、床單等） 不需要任何幫助 需要一些幫忙 完全不能自己做	 **2** **1** **0**
8.	你能唔能自己服用藥物呢？包括能依照指示在正確的時間內服用正確的份量(假設你必須要查藥油或藥等) 不需要任何幫助 需要一些幫忙 完全不能自己做	 **2** **1** **0**
9.	你能唔能夠處理自己的財務呢? 包括日常錢銀的找續、交租／水電費及到銀行提款(假設你必須要買嘢、自己交租／水電費及有將錢放在銀行) 不需要任何幫助 需要一些幫忙 完全不能自己做	 **2** **1** **0**
	總分**:**	

Appendix 5.10 The Chinese version of the Community Integration Measure (CIM-C)

For each of the following statements, please indicate whether you agree or disagree:

在下列的問題裡，請選擇同意或不同意

1. I feel like part of this community, like I belong here.

我覺得我是這個社會的一部分，我屬於這個社會

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

2. I know my way around this community.

我清楚我在這個社會的方向

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

3. I know the rules in this community and I can fit in with them.

我知道在這個社會的規則，我可以適應它

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

4. I feel that I am accepted in this community.

我覺得我被這個社會所接納的

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

5. I can be independent in this community.

我可以在這個社區獨立

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

6. I like where I'm living now.

我喜愛我現在居住的地方

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

7. There are people I feel close to in this community.

在這個社會裡有我相熟的人

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

8. I know a number of people in *this* community well enough to say hello and have them say hello back.

在*這個*社會裡我認識一了些朋友會跟我打招呼的

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

9. There are things that I can do in this community for fun in my free time.

在這個社會裡我可以在空餘時間做自己喜歡的事

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

10. I have something to do in this community during the main part of my day that is useful and productive.

在這個社會裡，我每天都可以做到一些有用和有生產力的事

[ ] 經常同意 Always agree

[ ] 有時同意 Sometimes agree

[ ] 中立 Neutral

[ ] 有時不同意 Sometimes disagree

[ ] 經常不同意 Always disagree

Appendix 5.11 The Chinese version of the Short Form General Health Questionnaire (SF-36-C)

<u>for SF-36 Healthy Survey (Chinese version)</u> 簡明健康狀況調查表（SF-36）

說明：這項調查是詢問您對自己健康狀況的了解。此項資料記錄您的自我感覺和日常生活的情況。請您按照說明回答下列問題。如果您對某一個問題不能做出肯定的回答，請按照您的理解選擇最合適的答案。

1． 總括來說，您認為您的健康狀況是：

（只圈出一個答案）

極好	--	1
很好	--	2
好	--	3
一般	--	4
差	--	5

2． <u>和一年前相比較</u>，您認為您<u>目前</u>全面的健康狀況如何？

（只圈出一個答案）

比一年前好多了	--------------------------------	1
比一年前好一些	--------------------------------	2
和一年前差不多	--------------------------------	3
比一年前差一些	--------------------------------	4
比一年前差多了	--------------------------------	5

下列各項是您日常生活中可能進行的活動。以您目前的健康狀況，您在進行這些活動時，有沒有受到限制？如果有的話，程度如何？（每項只圈出一個答案）

活動	有很大限制	有一點限制	沒有任何限制
3．劇烈活動，比如跑步，搬重物，或參加劇烈的體育活動	1	2	3
4．中等強度的活動，比如搬桌子，使用吸塵器清潔地面，玩保齡球或打太極拳	1	2	3
5．提起或攜帶蔬菜，食品或雜貨	1	2	3
6．上幾層樓梯	1	2	3
7．上一層樓梯	1	2	3
8．彎腰，跪下，或俯身	1	2	3
9．步行十條街以上（一公里）	1	2	3
10．步行幾條街（幾百米）	1	2	3
11．步行一條街（一百米）	1	2	3
12．自己洗澡或穿衣服	1	2	3

在過去四個星期裏，您在工作或其它日常活動中，會不會因為身體健康的原因而遇到下列的問題？
（每項只圈出一個答案）

	會	不會
13．　減少了工作或其它活動的時間	1	2
14．　實際做完的比想做的要少	1	2
15．　工作或其它活動的種類受到限制	1	2
16．　進行工作或其它活動時有困難（比如覺得更為吃力）	1	2

在過去的四個星期裏，您在工作或其它日常活動中，會不會由於情緒方面的原因（比如感到沮喪或焦慮）遇到下列的問題？　　（每項只圈出一個答案）

	會	不會
17．　減少了工作或其它日常活動的時間	1	2
18．　實際做完的比想做的要少	1	2
19．　工作時或從事其它活動時不如往常細心了	1	2

20.在過去四個星期裏，您的身體健康或情緒問題在多大程度上妨礙了您與家人、朋友、鄰居或社團的日常社交活動？

（只圈出一個答案）

毫無妨礙	------------------------------------	1
有很少妨礙	------------------------------------	2
有一些妨礙	------------------------------------	3
有較大妨礙	------------------------------------	4
有極大妨礙	------------------------------------	5

21.在過去四個星期裏，您的身體有沒有疼痛？如果有的話，疼痛到什麼程度？

（只圈出一個答案）

完全沒有	--	1
很輕微	--	2
輕微	--	3
有一些	--	4
劇烈	--	5
非常劇烈	--	6

22. 在過去四個星期裏，您身體上的疼痛對您的日常工作（包括上班和家務）有多大影響？

（只圈出一個答案）

毫無影響	------------------------------------	1
有很少影響	------------------------------------	2
有一些影響	------------------------------------	3
有較大影響	------------------------------------	4
有極大影響	------------------------------------	5

下列問題是有關您在過去四個星期裏您覺得怎樣和您其它的情況。針對每一個問題，請選擇一個最接近您的感覺的答案。

在過去四個星期裏有多少時間：（每項只圈出一個答案）

	常常 如此	大部分時間	相當多時間	有時	偶爾	從來 沒有
23．您覺得充滿活力？	1	2	3	4	5	6
24．您覺得精神非常緊張？	1	2	3	4	5	6
25．您覺得情緒低落，以致於沒有任何事能使您高興起來？	1	2	3	4	5	6
26．您感到心平氣和？	1	2	3	4	5	6
27．您感到精力充足？	1	2	3	4	5	6
28．您覺得心情不好，悶悶不樂？	1	2	3	4	5	6
29．您感到筋疲力盡？	1	2	3	4	5	6
30．您是個快樂的人？	1	2	3	4	5	6
31．您覺得疲倦？	1	2	3	4	5	6

32．在過去四個星期裏，有多少時間由於您的身體健康或情緒問題妨礙了您的社交活動（比如探親、訪友等）？

（只圈出一個答案）

常常有妨礙 ------------------------------------ 1

大部分時間有妨礙 -------------------------------- 2

有時有妨礙 ------------------------------------ 3

偶爾有妨礙 ------------------------------------ 4

完全沒有妨礙 ------------------------------------ 5

如果用下列的句子來形容您，您認為有多正確？

（每項只圈出一個答案）

	肯定對	大致對	不知道	大致不對	肯定不對
33．您好像比別人更容易生病	1	2	3	4	5
34．您好像所有您認識的人一樣健康	1	2	3	4	5
35．您覺得自己的身體狀況會變壞	1	2	3	4	5
36．您的健康極好	1	2	3	4	5

Appendix 5.12 Information sheet, consent form and ethical approval of cross-sectional study 1

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

<u>**Title:**</u> **The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) for assessing fear and activity avoidance among stroke survivors**

The Department of Rehabilitation Sciences of The Hong Kong Polytechnic University is now undergoing a research titled 'The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) for assessing fear and activity avoidance among stroke survivors'. The purpose of this research is to determine the internal consistency, test-retest reliability, convergent validity and construct validity of the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C). This study has been approved by the Departmental Research Committee (HSESC) of The Hong Kong Polytechnic University. (HSESC reference number: HSEARS20140129003)

Research personnel of the department will invite you to come to the laboratory of the Department of Rehabilitation Sciences of The Hong Kong Polytechnic University to complete a socio-demographic sheet, the SAFE-C, the Chinese version of the Activities-specific Balance Confidence scale (ABC-C) and the Chinese version of the Lawton Instrumental Activity of Daily Living scale (IADL-C). The whole assessment procedure will last for 30 minutes.

The major benefit from participating in this study is that you can know your fear avoidance behavior. The results could provide scientific evidence in supporting the clinicians in using the SAFE-C in assessing the fear avoidance behavior in people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures. The testing procedures have been well proved to be safe.

Your participation in this research is strictly voluntary, and you can withdraw from this research at any time without giving explanations, and it will not lead to any punishment or prejudice against you. Your personal information will not be disclosed to people who are not related to this study and your name or photo will not appear on any publications resulted from this study.

Questions regarding this study will be answered by the chief investigator, Mr. LIU Tai Wa, who can be reached by telephone at 2768- . If you have complaints related to the investigators, you can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- .

Thank you for participating in this study.

Hung Hom Kowloon Hong Kong 香港九龍紅磡

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香港理工大學

研究課題 長者恐懼跌倒調查表於評估中風病人的信效度。

理工大學康復治療科學系現正進行一項有關長者恐懼跌倒調查表於評估中風病人的信效度研究。是項研究旨在研究長者恐懼跌倒調查表評估中風病人的內部一致性、再測信度、聚合效度和建構效度。本研究已通過理工大學康復治療科學系科研委員會 (HSESC) 的審批 (HSESC 參考號碼: HSEARS20140129003)。

本學系的研究人員將邀請閣下參與填寫一份社會人口資料和三份問卷，包括長者恐懼跌倒調查表、活動平衡信心評分表和日常家居及社區活動能力評估。整個測試程序，需時約 30 分鐘。

參與此研究的主要好處是參與研究者可以了解自己的懼恐懼跌倒迴避行為。研究結果將為中風病人提供恐懼跌倒迴避行為參考資料。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

您有權在任何時候、無任何原因之情況下放棄參與此次研究，而此舉將不會導致您受到任何懲罰或不公平的對待。您的資料也不會洩露予與此研究無關的人員，您的名字或相片亦不會出現在任何出版物上。

如閣下需要更多有關此項研究的資料，可以致電 2768 來聯繫此次研究的負責人，廖泰華先生。若您對此研究的科研人員有任何投訴，亦可以聯絡鍾小姐 (部門科研委員會秘書)，電話：2766 。

多謝閣下參予此項研究。

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廖泰華先生

香港理工大學康復治療科學系博士研究生

The Hong Kong Polytechnic University

Department of Rehabilitation Sciences

Research Project Informed Consent Form

Project entitled: The reliability and validity of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C) for assessing fear and activity avoidance among stroke survivors

Investigator: Mr. LIU Tai Wa

Purpose:

Determine the internal consistency, test-retest reliability, convergent validity and construct validity of the Chinese version of the Survey of Activities and Fear of Falling in the Elderly (SAFE-C).

Methods:

All participants with stroke will be required to complete a socio-demographic sheet, the SAFE-C, the Chinese version of the Activities-specific Balance Confidence scale (ABC-C) and the Chinese version of the Lawton Instrumental Activity of Daily Living scale (IADL-C). The whole assessment procedure will last for 30 minutes.

Potential Risks and Benefits:

The major benefit from participating in this study is that you can know your fear avoidance behavior. The results could provide scientific evidence in supporting the clinicians in using the SAFE-C in assessing the fear avoidance behavior in people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Informed Consent

I, ____, understand the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name will not appear on any publications resulted from this study.

I can contact the chief investigator, Mr. LIU Tai Wa, at telephone 2768- for any questions regarding this study. If I have complaints related to the investigators, I can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- . I know I will be given a signed copy of this consent form.

Signature (subject): ________________________________ Date: ______________

Signature (Witness): _______________________________ Date: _______________

香港理工大學康復治療科學系研究同意書

項目名稱: 長者恐懼跌倒調查表於評估中風病人的信效度。

科研人員: 廖泰華先生

研究目的及內容:

研究長者恐懼跌倒調查表評估中風病人的內部一致性、再測信度、聚合效度和建構效度。

研究方法:

所有參與研究者將被安排填寫一份社會人口資料和三份問卷，包括長者恐懼跌倒調查表、活動平衡信心評分表和日常家居及社區活動能力評估。整個測試程序，需時約 30 分鐘。

潛在風險及得益:

參與此研究的主要好處是參與研究者可以了解自己的恐懼跌倒迴避行為。研究結果將為中風病人提供恐懼跌倒迴避行為參考資料。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

同意書:

本人 ____ 已瞭解此次研究的具體情況。本人願意參加此次研究。本人有權在任何時候、無任何原因的情況下放棄參與此次研究，而此舉不會導致本人受到任何懲罰或不公平的對待。本人明白參加此研究的潛在風險，以及本人的資料將不會泄露給與此研究無關的人員，我的名字或相片也不會出現在任何的出版物上。

本人可致電 2768 與此研究的負責人廖泰華先生聯絡。若本人對研究人員有任何投訴，可聯絡鍾小姐（部門科研委員會秘書），電話：2766 。本人亦明白，參與此研究需要本人簽署一分同意書。

簽名 (參加者): ______________________________ 日期: __________________

簽署 (見證人): ______________________________ 日期: __________________

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To	Ng Sheung Mei Shamay (Department of Rehabilitation Sciences)		
From	TSANG Wing Hong Hector, Chair, Departmental Research Committee		
Email	rshtsang@	Date	17-Feb-2014

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 17-Feb-2014 to 17-Feb-2016:

Project Title:	Fear of falling: Its prevalence and correlation with stroke-specific impairments, motor functions, quality of life and community integration in patients with stroke in Hong Kong.
Department:	Department of Rehabilitation Sciences
Principal Investigator:	Ng Sheung Mei Shamay
Reference Number:	HSEARS20140129003

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

You will receive separate email notification should you be required to obtain fresh approval.

TSANG Wing Hong Hector

Chair

Departmental Research Committee

Appendix 5.13 Scoring information guide

Activity Questionnaire

A. Do you currently:	1. Go to the store? 1. NO ↓ GO TO C 2. YES ↓ GO TO B	2. Prepare simple meals? 1. NO ↓ GO TO C 2. YES ↓ GO TO B
B. When you........, how worried are you that you might fall?	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F
C. Do you not [ACTIVITY] because you are......... that you might fall?	1. Very worried 2. Somewhat worried → 3. A little worried GO TO D Or 4. Not at all worried → GO TO E	1. Very worried 2. Somewhat worried → 3. A little worried GO TO D Or 4. Not at all worried → GO TO E
D. Are there other reasons that you do not........	1. NO 2. YES → SPECIFY:________ ________________ ________________ GO TO F	1. NO 2. YES → SPECIFY:________ ________________ ________________ GO TO F
E. What are the reasons that you do not........	SPECIFY:______________ ________________ ________________ GO TO F	SPECIFY:______________ ________________ ________________ GO TO F
F. Compared to 5 years ago, would you say that you........	1. More than you used to, 2. About the same, or 3. Less than you used to.	1. More than you used to, 2. About the same., or 3. Less than you used to.

A. Do you currently:	3. Take a tub bath? 1. NO ↓ GO TO C 2. YES ↓ GO TO B	4. Get out of bed? 1. NO ↓ GO TO C 2. YES ↓ GO TO B
B. When you........, how worried are you that you might fall?	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F
C. Do you not [ACTIVITY] because you are......... that you might fall?	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E
D. Are there other reasons that you do not........	1. NO 2. YES → SPECIFY:__________ ______________________ ______________________ GO TO F	1. NO 2. YES → SPECIFY:__________ ______________________ ______________________ GO TO F
E. What are the reasons that you do not........	SPECIFY:________________ ______________________ ______________________ GO TO F	SPECIFY:________________ ______________________ ______________________ GO TO F
F. Compared to 5 years ago, would you say that you........	1. More than you used to, 2. About the same, or 3. Less than you used to.	1. More than you used to, 2. About the same, or 3. Less than you used to.

A. Do you currently:	5. Take a walk for exercise? 1. NO ↓ GO TO C 2. YES ↓ GO TO B	6. Go out when it is slippery? 1. NO ↓ GO TO C 2. YES ↓ GO TO B
B. When you........, how worried are you that you might fall?	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F
C. Do you not [ACTIVITY] because you are......... that you might fall?	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E
D. Are there other reasons that you do not........	1. NO 2. YES → SPECIFY:__________ ______________________ ______________________ GO TO F	1. NO 2. YES → SPECIFY:__________ ______________________ ______________________ GO TO F
E. What are the reasons that you do not........	SPECIFY:________________ ______________________ ______________________ GO TO F	SPECIFY:________________ ______________________ ______________________ GO TO F
F. Compared to 5 years ago, would you say that you.....	1. More than you used to, 2. About the same, or 3. Less than you used to.	1. More than you used to, 2. About the same., or 3. Less than you used to.

A. Do you currently:	7. Visit a friend or relative? 1. NO ↓ GO TO C 2. YES ↓ GO TO B	8. Reach for something over your head? 1. NO ↓ GO TO C 2. YES ↓ GO TO B
B. When you........, how worried are you that you might fall?	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F
C. Do you not [ACTIVITY] because you are......... that you might fall?	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E
D. Are there other reasons that you do not....	1. NO 2. YES → SPECIFY:_________ ____________________ ____________________ GO TO F	1. NO 2. YES → SPECIFY:_________ ____________________ ____________________ GO TO F
E. What are the reasons that you do not........	SPECIFY:________________ ________________________ ________________________ GO TO F	SPECIFY:________________ ________________________ ________________________ GO TO F
F. Compared to 5 years ago, would you say that you.....	1. More than you used to, 2. About the same, or 3. Less than you used to.	1. More than you used to, 2. About the same., or 3. Less than you used to.

A. Do you currently:	9. Go to a place with crowds? 1. NO ↓ GO TO C 2. YES ↓ GO TO B	10. Walk several blocks outside? 1. NO ↓ GO TO C 2. YES ↓ GO TO B
B. When you........, how worried are you that you might fall?	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F
C. Do you not [ACTIVITY] because you are......... that you might fall?	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E
D. Are there other reasons that you do not....	1. NO 2. YES → SPECIFY:__________ ____________________ ____________________ GO TO F	1. NO 2. YES → SPECIFY:__________ ____________________ ____________________ GO TO F
E. What are the reasons that you do not........	SPECIFY:__________________ ____________________ ____________________ GO TO F	SPECIFY:__________________ ____________________ ____________________ GO TO F
F. Compared to 5 years ago, would you say that you.....	1. More than you used to, 2. About the same, or 3. Less than you used to.	1. More than you used to, 2. About the same., or 3. Less than you used to.

A. Do you currently:	11. Bend down to get something? 1. NO ↓ GO TO C 2. YES ↓ GO TO B
B. When you........, how worried are you that you might fall?	1. Very worried 2. Somewhat worried 3. A little worried, or 4. Not at all worried GO TO F
C. Do you not [ACTIVITY] because you are......... that you might fall?	1. Very worried 2. Somewhat worried → GO TO D 3. A little worried Or 4. Not at all worried → GO TO E
D. Are there other reasons that you do not....	1. NO 2. YES → SPECIFY:________ ________________ ________________ GO TO F
E. What are the reasons that you do not........	SPECIFY:____________ ________________ ________________ GO TO F
F. Compared to 5 years ago, would you say that you.....	1. More than you used to, 2. About the same, or 3. Less than you used to.

Appendix 5.14 Information sheet, consent form and ethical approval of cross-sectional study 2

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

Title: Assessing fall risks using the Short-form Physiological Profile Assessment (S-PPA)

The Department of Rehabilitation Sciences of The Hong Kong Polytechnic University is now undergoing a research titled 'Assessing fall risks using the Short-form Physiological Profile Assessment (S-PPA)'. The purpose of this research is to investigate the test-retest reliability, inter-rater reliability, concurrent, convergent and known-group validity and accuracy of the S-PPA for distinguishing the fall history in people with chronic stroke. This study has been approved by the Departmental Research Committee (HSESC) of The Hong Kong Polytechnic University. (HSESC reference number: HSEARS20140129003)

Research personnel of the department will invite you to come to the laboratory of the Department of Rehabilitation Sciences of The Hong Kong Polytechnic University to complete a socio-demographic sheet, the Chinese version of the Activities-specific Balance Confidence scale (ABC-C), Berg Balance Scale, Functional Reach Test (FRT), Timed "Up & Go" (TUG) and the S-PPA. Participants will be required to complete the test twice within 7 days apart.

The major benefit from participating in this study is that you can know your fall risk. The results could provide scientific evidence in supporting the clinicians in using the S-PPA in assessing the fall risk of people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures. The testing procedures have been well proved to be safe.

Your participation in this research is strictly voluntary, and you can withdraw from this research at any time without giving explanations, and it will not lead to any punishment or prejudice against you. Your personal information will not be disclosed to people who are not related to this study and your name or photo will not appear on any publications resulted from this study.

Questions regarding this study will be answered by the chief investigator, Mr. LIU Tai Wa, who can be reached by telephone at 2768- . If you have complaints related to the investigators, you can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- .
Thank you for participating in this study.

Mr. LIU Tai Wa

PhD student
Department of Rehabilitation Sciences
The Hong KongPolytechnicUniversity

Hung Hom Kowloon Hong Kong 香港九龍紅磡

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THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

<u>研究課題</u>　　使用簡短生理輪廓評定評估跌倒風險。

理工大學康復治療科學系現正進行一項有關使用簡短生理輪廓評定評估跌倒風險研究。是項研究旨在調查簡短生理輪廓評定評估中風病人的再測信度、施測者間信度、同時效度、收斂效度、區辨效度及分辨中風病人跌倒歷史的準確性。本研究已通過理工大學康復治療科學系科研委員會 (HSESC) 的審批 (HSESC 參考號碼: HSEARS20140129003)。

本學系的研究人員將邀請閣下參與填寫一份社會人口資料、活動平衡信心評分表、伯格平衡量表、功能範圍測試、定時並去測試和進行簡短生理輪廓評定。整個測試程序，需時約 45 分鐘。

參與此研究的主要好處是參與研究者可以了解自己的跌倒風險。研究結果將為中風病人提供跌倒風險參考資料。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

您有權在任何時候、無任何原因之情況下放棄參與此次研究, 而此舉將不會導致您受到任何懲罰或不公平的對待。您的資料也不會洩露予與此研究無關的人員，您的名字或相片亦不會出現在任何出版物上。

如閣下需要更多有關此項研究的資料，可以致電 2768　　　來聯繫此次研究的負責人，廖泰華先生。若您對此研究的科研人員有任何投訴，亦可以聯絡鍾小姐(部門科研委員會秘書)，電話：2766　　。

多謝閣下參予此項研究。

廖泰華先生

香港理工大學康復治療科學系博士研究生

Hung Hom Kowloon Hong Kong 香港九龍紅磡

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Email 電郵 polyu@polyu.edu.hk

Website 網址 www.polyu.edu.hk

The Hong Kong Polytechnic University

Department of Rehabilitation Sciences

<u>Research Project Informed Consent Form</u>

Project entitled: Assessing fall risks using the Short-form Physiological Profile Assessment (S-PPA)

Investigator: Mr. LIU Tai Wa

Purpose:

Investigate the test-retest reliability, inter-rater reliability, concurrent, convergent and known-group validity and accuracy of the S-PPA for distinguishing the fall history in people with chronic stroke.

Methods:

All participants with stroke will be required to complete a socio-demographic sheet, the Chinese version of the Activities-specific Balance Confidence scale (ABC-C), Berg Balance Scale, Functional Reach Test (FRT), Timed "Up & Go" (TUG) and the S-PPA.

Potential Risks and Benefits:

The major benefit from participating in this study is that you can know your fall risk. The results could provide scientific evidence in supporting the clinicians in using the S-PPA in assessing the fall risk of people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Informed Consent

I, ____, understand the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name will not appear on any publications resulted from this study.

I can contact the chief investigator, Mr. LIU Tai Wa, at telephone 2768-   for any questions regarding this study. If I have complaints related to the investigators, I can contact Ms. Chung, secretary of Departmental Research Committee, at 2766-   . I know I will be given a signed copy of this consent form.

Signature (subject): ________________________________ Date: ______________

Signature (Witness): _______________________________ Date: _______________

香港理工大學康復治療科學系研究同意書

項目名稱: 使用簡短生理輪廓評定評估跌倒風險。

科研人員: 廖泰華先生

研究目的及內容:

調查簡短生理輪廓評定評估中風病人的再測信度、施測者間信度、同時效度、收斂效度、區辨效度及分辨中風病人跌倒歷史的準確性。

研究方法:

所有參與研究者將被安排填寫一份社會人口資料、活動平衡信心評分表、伯格平衡量表、功能範圍測試、定時並去測試和進行簡短生理輪廓評定。整個測試程序，需時約 45 分鐘。

潛在風險及得益:

參與此研究的主要好處是參與研究者可以了解自己的跌倒風險。究結果將為中風病人提供跌倒風險參考資料。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

同意書:

本人 ____ 已瞭解此次研究的具體情況。本人願意參加此次研究。本人有權在任何時候、無任何原因的情況下放棄參與此次研究，而此舉不會導致本人受到任何懲罰或不公平的對待。本人明白參加此研究的潛在風險，以及本人的資料將不會泄露給與此研究無關的人員，我的名字或相片也不會出現在任何的出版物上。

本人可致電 2768 與此研究的負責人廖泰華先生聯絡。若本人對研究人員有任何投訴，可聯絡鍾小姐（部門科研委員會秘書），電話：2766 。本人亦明白，參與此研究需要本人簽署一分同意書。

簽名 (參加者): ______________________________ 日期: __________________

簽署 (見證人): ______________________________ 日期: __________________

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

To	Ng Sheung Mei Shamay (Department of Rehabilitation Sciences)
From	TSANG Wing Hong Hector, Chair, Departmental Research Committee
Email	rshtsang@ Date 17-Feb-2014

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 17-Feb-2014 to 17-Feb-2016:

Project Title:	Fear of falling: Its prevalence and correlation with stroke-specific impairments, motor functions, quality of life and community integration in patients with stroke in Hong Kong.
Department:	Department of Rehabilitation Sciences
Principal Investigator:	Ng Sheung Mei Shamay
Reference Number:	HSEARS20140129003

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

You will receive separate email notification should you be required to obtain fresh approval.

TSANG Wing Hong Hector

Chair

Departmental Research Committee

Appendix 5.15 Information sheet, consent form and ethical approval of cross-sectional study 3

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

<u>Title:</u> Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure for use in patients with chronic Stroke

The Department of Rehabilitation Sciences of The Hong Kong Polytechnic University is now undergoing a research titled 'Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure for use in patients with chronic Stroke (CIM-C)'. The purpose of this research is to translate and culturally adapt the contents of the English version CIM into Chinese (Cantonese), and report the results of initial validation of the Chinese (Cantonese) version CIM (CIM-C) including the content validity, internal consistency, test-retest reliability and factor structure in a Chinese setting. This study has been approved by the Departmental Research Committee (HSESC) of The Hong Kong Polytechnic University. (HSESC reference number: HSEARS20140129003)

Research personnel of the department will invite you to come to the laboratory of the Department of Rehabilitation Sciences of The Hong Kong Polytechnic University to complete a socio-demographic sheet and the Chinese version of the Community Integration Measure (CIM-C). The whole assessment procedure will last for 10 minutes.

The major benefit from participating in this study is that you can know your level of community reintegration. The results could provide scientific evidence in supporting the clinicians in using the CIM-C in assessing the level of community reintegration of people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures. The testing procedures have been well proved to be safe.

Your participation in this research is strictly voluntary, and you can withdraw from this research at any time without giving explanations, and it will not lead to any punishment or prejudice against you. Your personal information will not be disclosed to people who are not related to this study and your name or photo will not appear on any publications resulted from this study.

Questions regarding this study will be answered by the chief investigator, Mr. LIU Tai Wa, who can be reached by telephone at 2768- . If you have complaints related to the investigators, you can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- .

Thank you for participating in this study.

Mr. LIU Tai Wa

PhD student
Department of Rehabilitation Sciences
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THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

研究課題 翻譯及初步驗證社區整合量法於中風病人。

理工大學康復治療科學系現正進行一項有關社區整合量法調查表於評估中風病人的翻譯及初步驗證研究。是項研究旨在翻譯及研究社區整合量法調查表評估中風病人的內容效度、內部一致性、再測信度和因素結構。本研究已通過理工大學康復治療科學系科研委員會 (HSESC) 的審批 (HSESC 參考號碼: HSEARS20140129003)。

本學系的研究人員將邀請閣下參與填寫一份社會人口資料和社區整合量法問卷。整個測試程序，需時約 10 分鐘。

參與此研究的主要好處是參與研究者可以了解自己的社區整合程度。研究結果將為中風病人提供社區整合程度參考資料。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

您有權在任何時候、無任何原因之情況下放棄參與此次研究, 而此舉將不會導致您受到任何懲罰或不公平的對待。您的資料也不會洩露予與此研究無關的人員，您的名字或相片亦不會出現在任何出版物上。

如閣下需要更多有關此項研究的資料，可以致電 2768 來聯繫此次研究的負責人，廖泰華先生。若您對此研究的科研人員有任何投訴，亦可以聯絡鍾小姐(部門科研委員會秘書)，電話：2766 。

多謝閣下參予此項研究。

廖泰華先生
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Website 網址 www.polyu.edu.hk

The Hong Kong Polytechnic University

Department of Rehabilitation Sciences

<u>Research Project Informed Consent Form</u>

Project entitled: Translation and initial validation of the Chinese (Cantonese) version of Community Integration Measure for use in patients with chronic Stroke

Investigator: Mr. LIU Tai Wa

Purpose:

Translate and culturally adapt the contents of the English version CIM into Chinese (Cantonese), and report the results of initial validation of the Chinese (Cantonese) version CIM (CIM-C) including the content validity, internal consistency, test-retest reliability and factor structure in a Chinese setting.

Methods:

All participants with stroke will be required to complete a socio-demographic sheet and the CIM-C. The whole assessment procedure will last for 10 minutes.

Potential Risks and Benefits:

The major benefit from participating in this study is that you can know your level of community reintegration. The results could provide scientific evidence in supporting the clinicians in using the CIM-C in assessing the level of community reintegration in people with stroke. The testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Informed Consent

I, ____, understand the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name will not appear on any publications resulted from this study.

I can contact the chief investigator, Mr. LIU Tai Wa, at telephone 2768- for any questions regarding this study. If I have complaints related to the investigators, I can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- . I know I will be given a signed copy of this consent form.

Signature (subject): ________________________________ Date: ______________

Signature (Witness): _______________________________ Date: _______________

香港理工大學康復治療科學系研究同意書

項目名稱: 翻譯及初步驗證社區整合量法於中風病人。

科研人員: 廖泰華先生

研究目的及內容:

翻譯及研究社區整合量法調查表評估中風病人的內容效度、內部一致性、再測信度和因素結構。

研究方法:

所有參與研究者將被安排填寫一份社會人口資料和社區整合量法問卷。整個測試程序，需時約 10 分鐘。

潛在風險及得益:

參與此研究的主要好處是參與研究者可以了解自己的社區整合程度。究結果將為中風病人提供社區整合程度參考資料。整個檢查程序都己經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

同意書:

本人 ____ 已瞭解此次研究的具體情況。本人願意參加此次研究。本人有權在任何時候、無任何原因的情況下放棄參與此次研究，而此舉不會導致本人受到任何懲罰或不公平的對待。本人明白參加此研究的潛在風險，以及本人的資料將不會泄露給與此研究無關的人員，我的名字或相片也不會出現在任何的出版物上。

本人可致電 2768　　　與此研究的負責人廖泰華先生聯絡。若本人對研究人員有任何投訴，可聯絡鍾小姐（部門科研委員會秘書），電話：2766　　　。本人亦明白，參與此研究需要本人簽署一分同意書。

簽名 (參加者): ______________________________ 日期: __________________

簽署 (見證人): ______________________________ 日期: __________________

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To	Ng Sheung Mei Shamay (Department of Rehabilitation Sciences)
From	TSANG Wing Hong Hector, Chair, Departmental Research Committee
Email	rshtsang@ Date 17-Feb-2014

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 17-Feb-2014 to 17-Feb-2016:

Project Title:	Fear of falling: Its prevalence and correlation with stroke-specific impairments, motor functions, quality of life and community integration in patients with stroke in Hong Kong.
Department:	Department of Rehabilitation Sciences
Principal Investigator:	Ng Sheung Mei Shamay
Reference Number:	HSEARS20140129003

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

You will receive separate email notification should you be required to obtain fresh approval.

TSANG Wing Hong Hector

Chair

Departmental Research Committee

Appendix 5.16 Information sheet, consent form and ethical approval of the randomized controlled trial

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

<u>**Title:**</u> **Randomised controlled trial – combined use of task-oriented balance training and cognitive behavioral therapy in reducing fear of falling, fear avoidance behavior, balance performance in people with chronic stroke**

The Department of Rehabilitation Sciences of The Hong Kong Polytechnic University is now undergoing a research titled 'Assessing fall risks using the Short-form Physiological Profile Assessment (S-PPA)'. The purpose of this research is to investigate the test-retest reliability, inter-rater reliability, concurrent, convergent and known-group validity and accuracy of the S-PPA for distinguishing the fall history in people with chronic stroke. This study has been approved by the Departmental Research Committee (HSESC) of The Hong Kong Polytechnic University. (HSESC reference number: HSEARS2013012002-01)

Research personnel of the department will invite you to come to the laboratory of the Department of Rehabilitation Sciences of The Hong Kong Polytechnic University. All eligible subjects will be randomly assigned into 2 groups: (1) cognitive behavioral therapy and task-oriented balance training (CBT + TOBT) and (2) general health education and task-oriented balance training (GHE + TOBT) respectively for 8 weeks, 2 times a week (total 16 treatment sessions). Subjects will be assessed on improvement of fear of falling, fear avoidance behavior, balance performance, independent daily living, fall risk, health-related quality of life and community reintegration.

The major benefit from participating in this study is that you can know your fear of falling, fear avoidance behavior, balance performance, independent daily living, fall risk, health-related quality of life and community reintegration. The results could provide scientific evidence in supporting the clinicians in planning a rehabilitative program for reducing the fear of falling in people with stroke. The intervention and testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Your participation in this research is strictly voluntary, and you can withdraw from this research at any time without giving explanations, and it will not lead to any punishment or prejudice against you. Your personal information will not be disclosed to people who are not related to this study and your name or photo will not appear on any publications resulted from this study.
Questions regarding this study will be answered by the chief investigator, Mr. LIU Tai Wa, who can be reached by telephone at 2768- . If you have complaints related to the investigators, you can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- .

Thank you for participating in this study.

Mr. LIU Tai Wa

PhD student
Department of Rehabilitation Sciences
The Hong KongPolytechnicUniversity

Hung Hom Kowloon Hong Kong 香港九龍紅磡

Tel 電話(852) 2766 5111 Fax 傳真(852) 2784 3374

Email 電郵 polyu@polyu.edu.hk

Website 網址 www.polyu.edu.hk

研究課題 隨機安慰劑對照臨床試驗——平衡訓練課程配合認知行為療法以善慢性中風病人有關怕跌程度、因怕跌而避免活動的程度、平衡能力及運動現。

理工大學康復治療科學系現正進行一項有關衡訓練課程配合認知行為療法以改善慢性中風病人有關怕跌程度、因怕跌而避免活動的程度、平衡能力及運動表現研究。是項研究旨在調查認知行為療法(CBT)配合平衡訓練是否比一般健康講座(GHT)配合平衡訓練或只進行平衡訓練更能有效地改善慢性中風病人之平衡力的自我有效度、平衡能力及運動表現。本研究已通過理工大學康復治療科學系科研委員會 (HSESC) 的審批 (HSESC 參考號碼: HSEARS20140129003)。

本學系的研究人員將隨機將所有合適的研究參加者分成兩組，分別接受: (1) 認知行為療法(CBT)及任務導向平衡能力訓練; (2) 一般健康講座(GHT) 及任務導向平衡能力訓練。所有參加者將按組別接受一個半小時復康訓練。若閣下參加第一組治療，你將須接受四十五分鐘的認知行為療法(CBT)及四十五分鐘的任務導向平衡能力訓練，上述復康訓練每星期兩天，並且將持續八個星期。若閣下參加第二組，則須接受四十五分鐘的一般健康講座及四十五分鐘的任務導向平衡能力訓練，每星期兩天，並且將持續八個星期。

參與此研究的主要好處是參與研究者可以了解自己的平衡力的自我有效度、因有關怕跌而避免活動的程度、平衡能力及活動能力表現，此外亦能提供重要數據幫助設計給曾中風長者改善平衡力的自我有效度、平衡能力、活動能力以及生活質素的康復治療。可以了解自己的跌倒風險。整個檢查程序都已經過驗證，證明過程十分安全。唯期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

您有權在任何時候、無任何原因之情況下放棄參與此次研究, 而此舉將不會導致您受到任何懲罰或不公平的對待。您的資料也不會洩露予與此研究無關的人員，您的名字或相片亦不會出現在任何出版物上。

如閣下需要更多有關此項研究的資料，可以致電 2768 來聯繫此次研究的負責人，廖泰華先生。若您對此研究的科研人員有任何投訴，亦可以聯絡鍾小姐 (部門科研委員會秘書)，電話：2766 。

多謝閣下參予此項研究。

廖泰華先生
香港理工大學康復治療科學系博士研究生

Hung Hom Kowloon Hong Kong 香港九龍紅磡

Tel 電話(852) 2766 5111 Fax 傳真(852) 2784 3374

Email 電郵 polyu@polyu.edu.hk

Website 網址 www.polyu.edu.hk

The Hong Kong Polytechnic University

Department of Rehabilitation Sciences

Research Project Informed Consent Form

Project entitled: Randomised controlled trial – combined use of task-oriented balance training and cognitive behavioral therapy in reducing fear of falling, fear avoidance behavior, balance performance in people with chronic stroke

Investigator: Dr. Shamay NG, Mr. LIU Tai Wa

Purpose:

Investigate whether the combined use of cognitive behavioral therapy and task-oriented balance training is superior to the combined use of general health education and task-oriented balance training in improving fear of falling, fear avoidance behavior, balance performance, independent daily living, fall risk, health-related quality of life and community reintegration.

Methods:

All participants will be randomly assigned into 2 groups: (1) cognitive behavioral therapy and task-oriented balance training (CBT + TOBT) and (2) general health education and task-oriented balance training (GHE + TOBT) respectively for 8 weeks, 2 times a week (total 16 treatment sessions). Subjects will be assessed on improvement of fear of falling, fear avoidance behavior, balance performance, independent daily living, fall risk, health-related quality of life and community reintegration.

Potential Risks and Benefits:

The major benefit from participating in this study is that you can know your fear of falling, fear avoidance behavior, balance performance, independent daily living, fall risk, health-related quality of life and community reintegration. The results could provide scientific evidence in supporting the clinicians in planning a rehabilitative program for reducing the fear of falling in people with stroke. The intervention and testing procedures have been well proved to be safe and used with negligible side effects, both clinically and experimentally. A few subjects may feel some exhaustion during assessment and therefore rest will be allowed between assessment procedures.

Informed Consent

I, ____, understand the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name will not appear on any publications resulted from this study.

I can contact the chief investigator, Mr. LIU Tai Wa, at telephone 2768- for any questions regarding this study. If I have complaints related to the investigators, I can contact Ms. Chung, secretary of Departmental Research Committee, at 2766- . I know I will be given a signed copy of this consent form.

Signature (subject): ________________________________ Date: _______________

Signature (Witness): _______________________________ Date: ________________

香港理工大學康復治療科學系

病人參加研究計劃同意書

計劃名稱: 隨機安慰劑對照臨床試驗——平衡訓練課程配合認知行為療法以改善慢性中風病人有關怕跌程度、因怕跌而避免活動的程度、平衡能力及運動表現。

負責人: 伍尚美博士, 廖泰華先生

研究目的: 研究認知行為療法(CBT)配合平衡訓練是否比一般健康講座(GHT)配合平衡訓練或只進行平衡訓練更能有效地改善慢性中風病人之平衡力的自我有效度、平衡能力及運動表現。

研究方法: 所有合適的研究參加者將隨機分成兩組，分別接受: (1) 認知行為療法(CBT)及任務導向平衡能力訓練; (2) 一般健康講座(GHT) 及任務導向平衡能力訓練。所有參加者將按組別接受一個半小時復康訓練。若閣下參加第一組治療，你將須接受四十五分鐘的認知行為療法(CBT)及四十五分鐘的任務導向平衡能力訓練，上述復康訓練每星期兩天，並且將持續八個星期。若閣下參加第二組，則須接受四十五分鐘的一般健康講座及四十五分鐘的任務導向平衡能力訓練，每星期兩天，並且將持續八個星期。

所有參加者將會於每個月接受一次有關怕跌程度、因怕跌而避免活動的程度、平衡能力及運動表現平衡能力之檢查（共需檢查四次）。

檢查內容包括：怕跌程度之問卷、因有關怕跌而避免活動之問卷、平衡能力和活動功能表現，以及生活質素之問卷。每節檢查需時六十分鐘。

好處及風險: 參與此研究的好處是：參加者可以了解自己的平衡力的自我有效度、因有關怕跌而避免活動的程度、平衡能力及活動能力表現，此外亦能提供重要數據幫助設計給曾中風長者改善平衡力的自我有效度、平衡能力、活動能力以及生活質素的康復治療。

認知行為療法(CBT) 、任務導向平衡能力訓練及整個檢查程序都經過驗證，證明過程十分安全，不論在臨床上或實驗上，其副作用都可以忽略，唯測試期間小部份參與人士可能會感到少許疲倦，參加者可按需要於測試期間作中段休息。

資料保密: 所有參加者均屬自願性質，並於療程中段可隨時退出此項研究，而不會受到任何處罰。是項研究並已獲得香港理工大學的安全審批。研究結果將提供數據，反映給予中風病人改善平衡能力及活動能力的康復治療的效能。是項研究所收集的一切個人資料均絕對保密，參加者的身份將不會在本研究之任何相關的通訊中被識別出來。

查詢: 如閣下需要更多有關此項研究的資料，可以致電 2768 來聯繫此次研究的負責人，廖泰華先生。若您對此研究的科研人員有任何投訴，亦可以聯絡鍾小姐 (部門科研委員會秘書)，電話：2766 。

同意書:

本人 ________________________________ 已瞭解此次研究的具體情況。本人願意參加此次研究。本人有權在任何時候、無任何原因的情況下放棄參與此次研究，而此舉不會導致本人受到任何懲罰或不公平的對待。本人明白參加此研究的潛在風險，以及本人的資料將不會泄露給與此研究無關的人員，我的名字或相片也不會出現在任何的出版物上。

本人可致電 2768　　　與此研究的負責人廖泰華先生聯絡。若本人對研究人員有任何投訴，可聯絡鍾小姐（部門科研委員會秘書），電話：2766　　　。本人亦明白，參與此研究需要本人簽署一分同意書。

簽名 (參加者): ________________________ 日期: ______________

簽署 (見證人): ________________________ 日期: ______________

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To	Ng Sheung Mei Shamay (Department of Rehabilitation Sciences)
From	TSANG Wing Hong Hector, Chair, Departmental Research Committee
Email	rshtsang@ Date 05-Dec-2016

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 01-Feb-2015 to 31-Jan-2019:

Project Title:	Effects of a community rehabilitation programme for enhancing subjective balance confidence in patients with chronic stroke: A randomized, controlled trial
Department:	Department of Rehabilitation Sciences
Principal Investigator:	Ng Sheung Mei Shamay
Project Start Date:	01-Feb-2015
Reference Number:	HSEARS20131012002-01

Please note that it is the University's policy that all new research/teaching projects involving tests/trials on human subjects are required to take out appropriate insurance if deemed necessary by the Human Subjects Ethics Sub-committee. For such cases, investigators are not allowed to start any research/teaching projects involving tests/trials on human subjects if no appropriate insurance is or can be arranged.

You will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Human Subjects Ethics Sub-committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

TSANG Wing Hong Hector

Chair

Departmental Research Committee

Appendix 5.17 Cognitive behavioral therapy (CBT) homework

<u>認知行為小組作業</u>

在過去的一週中, 有遇到令你擔心 (害怕)跌倒或實際跌倒的情形嗎?

事件	情緒	想法	行為

Appendix 6.1 Chapter 6 published on Stroke

Decreasing fear of falling in chronic stroke survivors through cognitive behavior therapy and task-oriented training

Introduction

Balance disorders are common in individuals with a history of stroke, and falls are known to be a major complication following a stroke. For example, after a stroke, falls are reported in 12%–39% of cases in inpatient stroke rehabilitation units[1] and in 73%–80% of cases in the community[2]. Consistent with this finding, other research has shown that individuals with a history of stroke have a 7-fold higher risk of experiencing a fracture[3], especially a hip fracture[3], than healthy individuals.

Fear of falling is a psychological condition associated with balance disorders and fall risks following a stroke. It refers to excessive worrying about losing one's balance. Fear of falling can result in avoidance behavior, leading to inactivity and social isolation, and further exacerbate disability in stroke populations. In our previous study, we showed that approximately 49% of local community-dwelling stroke survivors have a fear of falling[4]. Of these, 24% individuals reported falling one to three times in the past 6 months[4].

Consistent with the results of another study on stroke survivors[5], our previous research[4] showed that the fear of falling, as measured by the Chinese version of the Activities-specific Balance Confidence (ABC-C) scale[6], was an independent and strong predictor of functional mobility in 78 community-dwelling stroke survivors, accounting for 17% of the variance in the timed “Up and Go” scores in our predictive model[4]. Other studies have shown that the level of fear of falling, as measured by the ABC scale, is significantly associated with both functional mobility and community integration in patients with a history of stroke[7, 8].

Cognitive behavior therapy (CBT) is a psychotherapeutic intervention designed to modify unrealistic beliefs that can contribute to negative emotions and behavior. Fear of falling could result from accurate perceptions of impaired balance ability and/or unrealistic beliefs about one’s risk of falling. Thus, stroke survivors with fear of falling may have (1) impaired balance ability and/or (2) fearful anticipation of falls reflected by an overly pessimistic anticipation of the occurrence of falls. CBT may alter these self-defeating beliefs and thus reduce fear-avoidance behavior and the associated adverse consequences, such as limited social participation. Consistent with this idea, one study has shown that CBT is effective in reducing the fear of falling among older individuals[9].

People with a history of stroke have known stroke-specific impairments, such as muscle weakness and excessive fear of falling. Physical exercise, which can improve walking ability[10] and balance performance[11], has been shown to reduce the fear of falling in people with a history of stroke. Task-oriented balance training (TOBT) is a stroke-specific functional training intervention[12] that combines different exercise elements, including strengthening and walking. One meta-analysis[13] concluded that 2–6 weeks of TOBT can improve lower limb motor function and balance performance in individuals with a history of stroke.

Based on the findings of these studies, it is reasonable to expect that the combination of CBT with TOBT will augment the benefits of TOBT in individuals with chronic stroke. Thus, the aim of this study was to evaluate this possibility. We hypothesized that the combination of CBT with TOBT would result in greater benefits than the combination of general health education (GHE) and TOBT in terms of reducing the fear of falling among people with chronic stroke. We also expected that the CBT + TOBT intervention would show better results than the GHE + TOBT intervention in terms of additional outcomes related to the fear of falling, including fear-avoidance behavior, balance, fall risk, independent daily living, community integration, and health-related quality of life.

Methods

The data that support the findings of this study are available from the corresponding author upon reasonable request. The Departmental Research Committee of the Hong Kong Polytechnic University approved the research protocol (HSEARS20131012002–01). Written informed consent was obtained from all participants before starting the study.

Study Design

This study was a single-blind randomized controlled trial. We used the effect size from a pilot study of 10 subjects (d = 0.26)[14] to calculate the sample size necessary to detect a significant between-group difference in the fear of falling because no previous study has investigated the effects of combining CBT with physical exercise for reducing the fear of falling in people with stroke. Thus, we determined that a sample size of 76 (38 per group), with an alpha of 0.05 and a power of 0.80, was required to detect a significant between-group difference. A total sample size of 88 (76 + 12) was planned to allow for an anticipated 15% dropout rate[12, 15]. The protocol for this study was pre-registered (NCT02937532) and published elsewhere[14].

Randomization

After obtaining informed consent and performing baseline assessments, an offsite research assistant randomized the subjects, stratified by age (55–70 years vs. 71–85 years), sex, and balance efficacy based on ABC-C scores (<50; 50–80)[16] using Minimize[17] software. Allocation concealment was attained by centralized phone calls.

Participants

Eighty-nine eligible subjects aged between 55 and 85 years were enrolled in the study. They (1) had a single stroke within 1–6 years before the study, as confirmed by magnetic resonance imaging or computed tomography scan; (2) could independently walk at least 10 m, with or without an assistive device; (3) scored $\geq$7 out of 10 on the Chinese version of the Abbreviated Mental Test; and (4) had low balance confidence (ABC-C score < 80)[16] (see Figure 1). Potential participants who were involved in drug studies or other clinical trials or had receptive dysphasia, cognitive impairment that could hinder the process of the study, any comorbid orthopedic or pain conditions that could impede the assessment and intervention (e.g., low back pain and osteoarthritis), any visual impairment that could not be corrected by glasses, or any additional significant medical condition, such as angina pectoris, were excluded. Eligible subjects were randomized into two groups: (1) an experimental group that received the combination of CBT and TOBT (CBT + TOBT) and (2) a control group that received the combination of GHE and TOBT (GHE + TOBT).

Intervention

The subjects attended 8 weeks of bi-weekly sessions of 90 min each in our neurorehabilitation laboratory. The CBT + TOBT subjects attended 45 min of group-based CBT followed by 45 min of TOBT, whereas the control group attended 45 min of GHE followed by 45 min of TOBT. Both the CBT and GHE interventions were performed in the morning session, and the TOBT intervention was performed in the afternoon session on the same day.

The CBT sessions aimed to enhance the subjects' balance efficacy using two main strategies, namely cognitive restructuring and behavioral modification. The TOBT sessions comprised five progressive muscle-strengthening and balance exercises, such as heel raises. An experienced physiotherapist and two trained research assistants with exercise or sports science backgrounds conducted the TOBT sessions. Further details on the CBT and TOBT sessions have been published previously[14].

The control (GHE + TOBT) group received 45 min of the same TOBT bi-weekly for 8 weeks. However, for these participants, the TOBT treatment was followed by 45 min of group-based GHE as an attention control. The GHE intervention was delivered by two research assistants not involved in the assessment or any other intervention in this study. Various information materials, such as audio-visual presentations, were used with varying weekly themes of general health knowledge not related to balance confidence and falls.

Measures

Primary outcome

Balance confidence was the primary outcome variable and was measured using the 16-item ABC-C[6]. The items reflect the participant's level of confidence in maintaining balance during daily functional activities. The ABC-C demonstrated excellent internal consistency (Cronbach's alpha = 0.97) and high test–retest reliability [intraclass correlation coefficient (ICC) = 0.99] in healthy older adults in the measure development study[6]. In the current sample, internal consistency values (Cronbach's alphas) ranged from 0.93 to 0.94 across the five assessment points, indicating good to excellent reliability.

Secondary outcomes

Fear-avoidance behavior was assessed using the Chinese version of the 22-item Survey of Activities and Fear of Falling in the Elderly (SAFE-C)[18]. The SAFE-C items assess the level of worry associated with performing activities of daily living. It has exhibited excellent internal consistency (Cronbach's alpha = 0.95) in older people[18]. The internal consistency values (Cronbach's alphas) of the SAFE-C in the current study ranged from 0.80 to 0.81 across the five assessment points, indicating good reliability.

The 14-item Berg Balance Scale (BBS) was used to assess balance ability. The scale has shown excellent test–retest reliability (ICC = 0.95–0.97) in stroke survivors[19]. Its internal consistency values (Cronbach's alphas) in the current study ranged from 0.91 to 0.92 across the five assessment points, indicating excellent reliability.

The Short-form Physiological Profile Assessment (S-PPA)[20] was used to assess fall risk. S-PPA scores can range from −2 to 4, indicating a very low to very high fall risk. The S-PPA comprises five measurements, namely a vision test, proprioception, a lower extremity muscle force test, a reaction time test, and a balance test. It has demonstrated ICC values ranging from 0.57 to 0.97 in older people[20], indicating poor to excellent test–retest reliability.

The Chinese version of the 9-item Lawton Instrumental Activities of Daily Living scale[21] was used to evaluate the level of independence in normal daily activities. This scale has demonstrated good internal consistency (Cronbach's alpha = 0.86) and excellent test–retest reliability (ICC = 0.90) in institutionalized older people[21]. Its internal consistency values (Cronbach's alphas) in the current study ranged from 0.88 to 0.90 across the five assessment points, indicating good reliability.

The 10-item Chinese version of the Community Integration Measure (CIM-C)[22] was used to assess the level of community integration. The CIM-C items reflect the respondent's perceptions of their ability to fit into the community. It has shown good internal consistency (Cronbach's alpha = 0.84) and good test–retest reliability (ICC = 0.84) in people with chronic stroke[22]. Its internal consistency values (Cronbach's alpha) in the current study ranged from 0.85 to 0.86 across the five assessment points, indicating good reliability.

The Chinese version of the Short-Form General Health Questionnaire (SF-36-C)[23] was used to measure the self-perceived health-related quality of life. The SF-36-C can be used to generate scores for both physical health summary (PCS) and mental health summary (MCS), both of which demonstrated good internal consistency (Cronbach's alpha = 0.85 and 0.87, respectively) in healthy adults[23]. The internal consistency values (Cronbach's alpha) of the PCS and MCS in the current study ranged from 0.83 to 0.84 and 0.82 to 0.83, respectively, across the five assessment points, indicating good reliability.

Data analysis

SPSS 23.0 (IBM, Armonk, NY) was used to test the study hypotheses. An experiment-wise p value of <0.05 (two-sided) was used to indicate that a finding was statistically significant. The subjects' characteristics were summarized using descriptive statistics, and independent *t*-tests and chi-square tests were used for between-group baseline comparisons.

As planned *a priori*[14], linear mixed-effects modeling (MEM) was used to evaluate the intervention effects. An intention-to-treat analysis was used. MEM was repeated across the four time points (time effect) and two groups (group effect) to determine the between- and within-group differences for post-hoc analyses. The maintenance effects were analyzed by comparing the post-intervention and follow-up assessment results using the same MEM approach. Univariate linear regression analyses were performed to investigate whether the lesion location (left or right hemisphere lesion) predicted the fear of falling and related health outcomes at post-intervention and 12-month follow-up.

Results

Eighty-nine eligible subjects were enrolled between October 2016 and May 2017. Their characteristics are summarized in Table 1, and the baseline outcome parameters are summarized in Table I in the online-only Data Supplement. No significant differences were found in any of the demographic and outcome parameters at baseline.

Effects of CBT + TOBT versus GHE + TOBT

Primary outcome: fear of falling

A significant Group × Time interaction effect (mean difference: 0.22; $p = 0.001$) was observed (see Table 2), with the CBT + TOBT group demonstrating a greater reduction in the fear of falling than the GHE + TOBT group post-intervention (mean difference = 1.77, $p = 0.04$) and up to the 12-month follow-up (3-month follow-up, mean difference = 2.42, $p = 0.02$; 12-month follow-up, mean difference = 2.94, $p = 0.01$) (see Table II in the online-only Data Supplement). Both the CBT + TOBT and GHE + TOBT groups demonstrated significant reduction between mid-intervention and the 12-month follow-up (see Table III in the online-only Data Supplement). Significantly reduced maintenance effects were noted in the GHE + TOBT group at the 3-month (mean difference = −1.56, $p = 0.02$) and 12-month (mean difference = −2.05; $p = 0.002$) follow-ups.

Secondary outcomes

No significant Group × Time interaction effect or time effect was identified for fall risk or psychological function (See Table IV in the online-only Data Supplement). Significant Group × Time interaction effects were observed for fear-avoidance behavior, balance, independent daily living, physical function, and community integration (Table 2). Compared with the GHE + TOBT group, the CBT + TOBT group demonstrated better outcomes with respect to fear-avoidance behavior, balance, independent daily living, and community integration from post-intervention to the 12-month follow-up (See Table II in the online-only Data Supplement) and greater improvement in physical function at the 12-month assessment point. Compared with their baseline data, both the CBT + TOBT and GHE + TOBT groups demonstrated significant reduction in fear-avoidance behavior over time from post-intervention to the 12-month follow-up (See Table III in the online-only Data Supplement) and significant improvement in balance and physical function starting at mid-intervention. The GHE + TOBT group showed significant reductions in maintenance effects on physical function at the 12-month follow-up assessment point. Only the CBT + TOBT group showed significant improvements in independent daily living and community integration from post-intervention to the 12-month follow-up.

Relationship between the lesion location and intervention response

Our univariate linear regression revealed that the lesion location (left or right hemisphere) was not significantly associated with reduction in the fear of falling and improvements in related health outcomes at post-intervention or 12-month follow-up (See Table V in the online-only Data Supplement).

Discussion

This was the first study to compare the combined effects of CBT and TOBT against those of GHE and TOBT in people with a history of stroke. Several key findings emerged from this study. First, we found that compared with the GHE + TOBT intervention, the CBT + TOBT intervention produced greater reduction in the fear of falling and fear-avoidance behavior and greater improvements in balance ability and independent daily living from immediate post-intervention to 12 months post-intervention. Second, although much of the within-group reduction in the fear of falling was maintained in the CBT + TOBT group until 12 months post-intervention, that observed in the GHE + TOBT group dissipated by 3 months post-intervention. Third, the CBT + TOBT intervention improved independent daily living and community integration, with the beneficial effects continuing for 12 months post-intervention. However, no such benefits were observed in the GHE + TOBT group.

Previous studies have shown that TOBT can induce use-dependent plastic changes in the brain of stroke survivors[24] and improve their lower limb functional performance[25]. The findings of the present study are consistent with those of previous studies showing that physical interventions can reduce the fear of falling and improve the balance and quality of life of people with a history of stroke[9, 26].

Our CBT + TOBT group demonstrated 13.3%, 12.4%, 12.7%, and 2.6% improvement from the baseline value of the fear of falling, fear avoidance behavior, independent living, and balance, respectively, at post-intervention. Although the improvement in balance could not reach the minimal detectable change in postural balance[27] of 8% to 12% from baseline on the BBS, our CBT + TOBT group showed better improvement than the GHE + TOBT group (1.9% improvement from the baseline value) and the stroke subjects of the Holmgren[28] group who received 5-week high-intensity exercise training (2% improvement from the baseline value). To the best of our knowledge, no minimal detectable change values for the fear of falling, fear-avoidance behavior, and independent living have been established for comparison at this stage, but the superiority of our CBT + TOBT group in these aspects suggests the synergistic effects of CBT and TOBT.

Based on Bandura's theory of self-efficacy, an individual's performance is influenced by their perceptions about their ability to engage in the behavior in question. Thus, it hypothesizes that stroke survivors' perceived balance efficacy can be improved by increasing their sense of mastery, for example, via physical interventions. In the studies on stroke patients by Salbach[11] and Lord[10], 6-week task-oriented walking training and community ambulation caused 14% and 26% improvements, respectively, in balance confidence at post-intervention. Our TOBT participants demonstrated approximately 9% improvement in balance confidence post-intervention, which is comparable with the improvement reported by Salbach[11] but lower than that reported by Lord[10]. The difference could be attributed to the chronicity of illness, as the subjects in Lord's[10] study were in the subacute stage of stroke, whereas those in Salbach's[11] and our study were in the chronic stage of stroke. Overall, these findings suggest that physical intervention is more effective in reducing the fear of falling during the subacute stage than during the chronic stage and that TOBT reduces the fear of falling by approximately 10% in chronic stroke patients.

Based on the self-efficacy theory, the beneficial effects of TOBT on physical function are more difficult to explain than its effects on the fear of falling and balance ability. The meta-analysis conducted by Chen[29] revealed that 10 weeks of physical exercise had a small-to-medium effect on physical function immediately after intervention but not at 12- to 24-weeks post-intervention. Consistent with Chen's[29] findings, the results of our control group (GHE + TOBT) revealed that physical exercise alone did not have sustainable effects on physical function. One possible explanation for this finding is that participants did not have sufficient motivation to continue engaging in exercise, thus resulting in a gradual decline in the beneficial effects on general physical function after the intervention ended.

One strength of this study was its incorporation of a CBT intervention targeting the unrealistic fall beliefs of individuals. Our findings suggest that CBT and TOBT have synergistic effects, as reflected by the greater reductions in the fear of falling and fear-avoidance behavior and greater improvements in the related health outcomes compared with those by the combined GHE and TOBT intervention. One probable reason for these synergistic effects could be the improved self-efficacy. According to Bandura, perceived self-efficacy is crucial in chronic illness management, and it could influence motivations and mediate behavior and ultimately determine task performance. Customary exercise therapy predominantly focuses on addressing the physical factors to enhance balance self-efficacy through the sense of mastery, but other sources of self-efficacy, including verbal persuasion, vicarious learning, and learning coping strategies to manage emotional reactions were not addressed. This indicates that further improvement is possible if interventions utilize all sources of self-efficacy as identified by Bandura. In our CBT intervention, the feedback exchange during group sessions and witnessing the success of other group members could enhance self-perceived efficacy of the subjects by verbal persuasion and vicarious learning, respectively. In addition, CBT could reduce psychological responses in stroke survivors by identifying and disputing their false beliefs about consequences of falls. Thus, reduced fear of falling could in turn be reflected in daily physical activities, resulting in a reduction in fear-avoidance behavior and improvements in related health outcomes, as identified in our findings.

Our CBT + TOBT intervention was not superior to the GHE + TOBT intervention in enhancing participants' physical function during the intervention phase, but the within-group benefits in the CBT + TOBT group lasted for 12 months, which was longer than those in the GHE + TOBT group. Keeping in mind the conclusions from the meta-analysis conducted by Chen[29], which showed a lack of long-term maintenance of individual improvements from TOBT, the differential effects of the CBT + TOBT intervention on the maintenance effects in the present study suggest that CBT enhanced the maintenance of the benefits of TOBT in physical function. However, neither the CBT+ TOBT nor the GHE + TOBT combination showed significant reduction in fall risk, which was consistent with the results of previous clinical trials on lower limb and balance exercises in community-dwelling older adults[30, 31]. As fall risk is a complicated and multifactorial domain, our interventions, which mostly target reduction in the fear of falling and improvement in balance, may be insufficient to reduce fall risk or prevent falls. To specially affect fall risk, additional intervention may be needed, such as home safety visits.

Community integration is a comprehensive outcome that reflects the degree of success of rehabilitation interventions in terms of both physical and psychological functions. This study showed only minimal additional improvement in this domain using the combined CBT and TOBT intervention. The reasons for these null findings are not entirely clear, but several explanations are possible. For example, our study participants might have reached a plateau of community integration before the study began. Furthermore, our CBT + TOBT intervention might not have adequately supported the participants in translating the reduction in the fear of falling to actual improvements in community integration. Alternatively, improvements in community integration might have been constrained by other factors that could not be addressed by the interventions provided, such as social policy. If the lack of beneficial effects on community integration is due to the lack of efficacy of the combined intervention, modifications in the intervention may be needed for a greater beneficial effect. If this null finding is due to a social policy, then changes in healthcare policy may be needed.

Although postural imbalance predominates in cases with lesions in the right hemisphere, the present study revealed that the lesion location (left or right hemisphere) does not play a predictive role in reducing the fear of falling and improving related health outcomes after the CBT + TOBT intervention. This suggests that the associated hemiparesis and the degree of neglect of stroke patients did not affect the benefits of our intervention.

This study had several important strengths. First, the combined intervention offered a treatment (CBT) that was both effective and complementary to physical exercise. Second, a detailed study protocol was published before the study began, allowing replication of the trial in additional populations. Third, one of the goals (and strengths) of CBT is to facilitate ongoing behavioral changes and improvements over time, even after the treatment is completed. We demonstrated the long-term benefits of CBT, when combined with TOBT, for 12 months after completing the treatment.

The study also had several limitations. First, this study did not record the number of actual falls; thus, the augmenting effects of CBT on fall reduction could not be inferred. We believe that further fall preventive strategies, such as an assistive device and home assessment, are required to transit the effects of CBT in the living environment. Thus, we recommend future studies to investigate the effects of incorporating fall preventive strategies after or together with reduction in the fear of falling. Second, we did not assess two potential confounding factors, depression and fatigue, which could affect the quality of life and could be associated with functional outcomes and mobility in stroke survivors. However, we measured another important predictor of the community integration of stroke survivors, i.e., the fear-avoidance behavior[8], and directly measured the associated health outcomes of fatigue by evaluating the level of independent living and mobility. Third, as with any behavioral study, the study participants were not blinded to their intervention, which might have resulted in increased outcome expectancies in the CBT group. Fourth, the study participants were ambulatory and relatively active and had high educational attainment and socioeconomic status. Thus, the findings may or may not be generalizable to individuals with a history of stroke who are more disabled and have low educational attainment or low socioeconomic status than those in this study. In addition, an increase in the number of intervention sessions and/or the inclusion of booster sessions may increase the overall efficacy.

Summary and conclusions

Fear of falling could be protective in nature and promote the adoption of fall-protective measures. However, excessive level of this fear can lead to inappropriate defensive behavior, leading to disability and increased fall risks. This study provides important new information regarding the efficacy of an 8-week, 16-session CBT + TOBT intervention that appears to reduce the fear of falling and fear avoidance behavior and improve balance and independent daily living, with benefits maintained for 12 months after completing the intervention. CBT appears to be a feasible adjuvant therapy to augment the treatment effects of customary physiotherapy in cognitively intact people with a history of stroke.

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