The Implementation of Cognitive Stimulation Therapy Hong Kong Version (CST-HK) for Promoting Cognitive Functioning and Psychosocial Well-being of People with Dementia

Research Protocol
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Investigators
Gloria Hoi Yan WONG
Assistant Professor
Department of Social Work and Social Administration
The University of Hong Kong
Email: ghywong@hku.hk
Tel: (852) 3917 2074

Yui Ching CHUNG
Physiotherapist
Elderly Service Department
Hong Kong Young Women's Christian Association

Wai Chi CHAN
Clinical Associate Professor
Department of Psychiatry
The University of Hong Kong

Yan ZHANG
PhD Candidate
Department of Social Work and Social Administration
The University of Hong Kong

Background

Dementia is a group of disorders characterized by cognitive impairments that affect a person's everyday functional ability, causing disability and poor quality of life. It affects 46.8 million people worldwide in 2015, and the number is expected to reach 74.7 million in 2030 and 131.5 million in 2050 (Prince et al., 2015). The World Health Organization has announced it as a public health priority since 2012 (World Health Organization, 2012). In Hong Kong, the number of people with dementia is projected to increase two-fold from 103,433 in 2009 to 332,688 in 2039 (Yu et al., 2012). There is currently no cure for the condition.

Non-pharmacological interventions such as cognitive training, cognitive rehabilitation, and cognitive stimulation aim at slowing down the cognitive decline experienced by a person with dementia (Bahar-Fuchs, Clare, & Woods, 2013). Cognitive stimulation involves a range of group activities and discussions to enhance general cognitive and social functioning. A meta-analysis of 15 studies with a total of 718 persons with dementia showed evidence of benefits of cognitive stimulation on cognitive function, quality of life, and self-reported well-being of the people with dementia (Orrell et al., 2017). The benefits appeared to add on to medication effects (Aguirre, Woods, Spector, & Orrell, 2013). The clinical improvements in verbal and visual memory, orientation, and auditory comprehension after cognitive stimulation appeared to be able to translate into improvements in real world activity (Hall, Orrell, Stott, & Spector, 2013), as seen in enhancement of the communication and social interaction of persons with dementia (Woods, Aguirre, Spector, & Orrell, 2012).

In view of the current evidence, cognitive stimulation is recommended by the National Institute for Health and Clinical Excellence and the Alzheimer's Disease International as an evidence-based, non-pharmacological intervention to be offered to all people with mild-to-moderate dementia (National Institute for Health and Clinical Excellence [NICE], 2007; Prince, Bryce, & Ferri, 2011). A standard protocol of cognitive stimulation therapy with evidence is a 7-week intervention developed by Spector and her colleagues (Spector et al., 2003). It is a series of standardized, well-structured stimulating activities, implemented in a sensitive, respectful and person-centered manner. Group CST typically involves 14 sessions of 45-minute group activities that required cognitive processing delivered over a 7-week period (2 sessions per week, with approximately 45 mins per session) (Aimee Spector et al., 2003). The group size was standardized to be 6 to 8 persons (Orrell et al., 2017). People with dementia would participate in each of the 14 designated theme activities during each session. The activities aimed at stimulating and engaging persons with dementia in an active way, and providing an optimal learning environment and the positive social benefits of group therapy (National Institute for Health and Clinical Excellence [NICE], 2007). Cognitive stimulation therapy can be delivered by non-specialist healthcare workers with minimum training (Khan, Corbett, & Ballard, 2014; Paddick, 2015; Aimee Spector et al., 2003). This allows CST to be used in low-resource environment (Paddick, 2015). Manuals in different languages had been published for the group leaders to follow. Due to this advantage of high reproducibility with high quality evidence support, CST was widely adopted in over 20 countries (Orrell et al., 2017).

In Hong Kong, there is currently no recommendations or routine provision of cognitive stimulation. In 2015, the standard group CST protocol was culturally adapted for and tested in Chinese people with dementia in Hong Kong (CST-HK) (Wong et al., 2017). The observed improvements in cognitive outcome was in line with that of overseas studies (Hall et al., 2013; Aimee Spector, Orrell, & Woods, 2010). The protocol appeared to be feasible and acceptable

to Hong Kong Chinese, with high attendance rate (92%) and low attrition rate (13%). Cultural issues identified in the pilot have been published and recommendations were made in adapting the protocol to the Hong Kong cultural settings (Wong et al., 2017). A Hong Kong Chinese version of the manual for CST group leaders has been published in 2017 (Spector, Thorgrimsen, Woods, & Orrell, 2017).

This healthcare promotion project aims to enhance the quality of life and cognition of people with mild-to-moderate cognitive impairment through the use of CST-HK delivered by trained non-professional group leaders. As part of project evaluation, we aim to test the effectiveness of CST-HK compared with a wait-list control group who will receive care as usual during the waiting period.

Research Objectives

The research aims to investigate the effectiveness of CST-HK among people with mild-to-moderate cognitive impairment in Hong Kong in a larger scale across service settings. We also aim to explore the effectiveness of CST-HK delivered by non-professional staff, as a possible solution to address the shortage of specialized healthcare manpower and increasing demands of non-pharmacological interventions for people with dementia.

Hypotheses

We hypothesized that, compared with the wait-list control group, the group who have received a 7-week (14-session) CST-HK intervention delivered by trained non-professional staff will show greater improvement or maintenance of (1) quality of life; and (2) cognitive performance.

Research Design

This is a cluster randomized wait-list control study.

Study Sample

A total of 128 older persons with mild to moderate cognitive impairment will be recruited from nine service units of Hong Kong Young Women's Christian Association, including two residential care units and seven community care units. This sample size is calculated based on the primary outcomes of quality of life and cognitive function. Repeated measure analysis of variance (ANOVA), between factors will be used. Assuming a medium effect size (f = 0.25), 80% power and 5% significance level, with two groups and two time points (calculated using G*Power 3.1.9.2), a total of 98 participants are required. We propose a sample size of 128 to accommodate for a 30% attrition rate.

Inclusion and exclusion criteria are:

- A clinical diagnosis of mild-to-moderate dementia, or a cognitive assessment result suggestive of mild-to-moderate cognitive impairment;
- Be able to communicate and understand Cantonese;
- Be able to hear and see well enough to participate in the cognitive stimulation activities;
- No major illness that would affect participation (including clinically significant depressive symptoms or acute psychotic disorders);
- No behavioural problems (e.g., aggression, inappropriate sexual behaviors) or psychotic symptoms (e.g., hallucination, delusion) that would interfere with participation in the intervention;
- A caregiver who is able to give joint informed consent.

Intervention and Procedures

A briefing session will be provided to participants and their family caregivers by the staff of Hong Kong Young Women's Christian Association for recruitment. Upon giving written consent, participants will be randomized into intervention group (n=64) or waitlist control group (n=64) in groups of eight. Two randomization lists will be generated by HKU researchers, one each for residential care units and community care units. Hong Kong Young Women's Christian Association will be informed about the group allocation upon successful recruitment of eight eligible participants. The intervention group will receive the14-session group CST-HK (45 minutes per session, two times a week, for 7 weeks in total) provided by trained facilitators. The wait-list control group will receive usual care in the service units they are attach to and will start their CST-HK programme after an 8-week delay.

A total of 40 CST-HK facilitators without specialized healthcare background will be recruited by Hong Kong Young Women's Christian Association. They are required to attend two 4-hour workshops to acquire the knowledge and skills for delivering CST-HK. The knowledge and skills include the guiding principles, and the theme of each training session. After the workshops, the facilitators will be designated to nine elderly service units mentioned above and practice their learnt knowledge and skills in delivering CST-HK under the supervision of experienced CST-HK interventionists with specialized healthcare background in Hong Kong Young Women's Christian Association. At the end of the practicum, the trainees will be evaluated to ensure the fidelity of CST-HK.

The person with dementia and their caregivers will undergo an interview at study baseline and 7 weeks. A service assistant blind to the group allocation will conduct the interviews. The interview will last for approximately 45 minutes for the person with dementia and the caregiver, respectively. A post-intervention assessment will be conducted in the wait-list control group upon completion of the delayed intervention.

Measurements for Primary Outcomes

The primary outcome of CST-HK, quality of life, will be measured using the Quality of Life in Alzheimer's Disease scale (Chan, Chu, Lee, Li, & Yu, 2011; Logsdon, Gibbons, McCurry, & Teri, 2002). Self-rating of the persons with dementia would be used in this study using the patient version of this tool.

Cognitive function will be measured using the Alzheimer's Disease Assessment Scale-Cognitive Subscale test (Chu et al., 2000). No deterioration in cognition is defined as a change in the score of ≥0 point in ADAS-Cog, and clinically meaningful improvement a change in score of ≥4 points, in the post-intervention assessment compared with baseline score.

Data Analysis

Intention-to-treat analysis will be conducted. For the main outcome measures of quality of life and cognition, ANOVA will be used to assess changes from baseline to 7 weeks after between the intervention group and the wait-list control group. Further analysis will be conducted by ANCOVA controlling for baseline differences in age, gender, education level, type of care setting, AChEI use (using random effects) and baseline cognition and quality of life. As a sensitivity analysis, we will also conduct exploratory analysis including the post-intervention data from the wait-list control group.

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