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Effects of a family caregiver-delivered multi-sensory cognitive stimulation intervention for older people with dementia during COVID-19: A randomized controlled trial

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Abstract

Background and Objectives: Many community dementia services such as home-visiting services and center-based activities were suspended during the COVID-19 pandemic. This study investigated the efficacy of a caregiver-delivered cognitive stimulation therapy (CDCST) on people with dementia during the pandemic.

Research Design and Methods: This was a two-arm randomized controlled trial involving 241 patient-caregiver dyads assigned to a 15-week CDCST or control group (usual care). We hypothesized that CDCST would facilitate significant improvements among people with dementia (cognition, behavioral/psychiatric symptoms, quality of life) and their caregivers (caregiving appraisal, attitudes, psychological well-being) at post-intervention (T1) and at the 12-week follow-up (T2). Generalized estimating equations evaluated the study outcomes.

Results: A total of 230 dyads completed the study, with good program adherence (93%). Participants in the CDCST showed significant improvements in cognition ($p < .001$), behavioral and psychiatric symptoms ($p = .027$), and quality of life ($p = .001$) at the 3-month follow-up period. Family caregivers had improved positive aspects of caregiving ($p = .008$; $p = .049$) and decreased negative attitudes toward people with dementia ($p = .013$; $p < .001$) at both T1 and T2. There were non-significant changes in the caregivers' perceived burden, distress, and psychological well-being.

Discussion and Implications: Family caregivers could be trained to provide cognitive stimulation at home for people with dementia, which could benefit both parties. CDCST could manage to improve the cognition, neuropsychiatric symptoms, and quality of life of people with dementia, while also improving caregiving appraisal and negative attitudes among family caregivers.

Clinical Trial Registration Number: NCT03803592

Keywords: caregiver-led interventions; cognitive impairment; neuropsychiatric symptoms

Introduction

People with dementia experience progressive cognitive decline leading to a loss of self-caring ability and poor quality of life (Alzheimer's Disease International, 2018). Uncertainty about the progression of the disease, the various caregiving tasks, and the responsibilities would result in a high level of stress and burden among family caregivers (Edwards et al., 2018). Moreover, up to 97% of affected individuals present behavioral and psychological symptoms of dementia (BPSD), such as emotional outbursts, wandering, and anxiety/depression, which would further aggravate the physical and mental suffering of their family caregivers (Cloak & Al Kahlili, 2022). Non-pharmacological interventions, which are recommended as a first-line approach to managing people with dementia, have been found to reduce BPSD and slow down cognitive decline (de Oliveira et al., 2015).

Cognitive stimulation therapy (CST) is an evidence-based non-pharmacological intervention for people with mild to moderate dementia (Woods et al., 2012). It offers a range of group-based activities intended to stimulate several domains, such as learning, memory, and concentration (Spector et al., 2003). Recent reviews have provided evidence of the effectiveness of cognitive stimulation in improving the cognition and quality of life of people with dementia (Chen, 2022; Saragih et al., 2022). However, similar articles noted that the effects of cognitive stimulation on BPSD cannot be confirmed due to inadequate evidence from previous trials. Notably, most pooled studies in the two previous meta-analyses have small sample sizes, so there is a need to further investigate the potential multi-domain effects of this widely used intervention for people with dementia.

Previous studies implementing CST were delivered by professional staff, and people with dementia were required to visit community-based centers or outpatient departments to attend the sessions. However, as dementia is a chronic condition, it is imperative to explore other means to continuously facilitate therapeutic interventions for people with dementia. The

experience from the COVID-19 pandemic has also highlighted the need for easily accessible and low-cost interventions for people with dementia, who are part of the vulnerable population during the quarantine and post-pandemic period (Alves et al., 2020). Hence, it has been suggested that home-based CST delivered by caregivers be implemented. According to Milders et al. (2013), appropriate training could equip family caregivers with the knowledge and skills to deliver cognitive stimulation to people with dementia, allowing the program to continue without provider supervision. Compared to center-based interventions, the caregiver-delivered approach may be independently carried out anywhere at any time but still provide patients with meaningful opportunities for engagement (Toh et al., 2016).

Apart from managing the cognitive and neuropsychiatric symptoms of people with dementia, promoting the well-being of caregivers should be considered when designing home-based interventions. In their review, Leung et al. (2017) developed a framework to suggest that involving caregivers in cognitive-based interventions could improve their quality of life, depressive symptoms, and relationship with people with dementia (Figure 1). The binding ties theory (Townsend & Franks, 1995), enrichment process theory (Cartwright et al., 1994), and scaffolding process theory (Cavanaugh et al., 1989) underpin the model. Particularly, involving caregivers in cognitive-based interventions could (1) widen the understanding of interpersonal interactions among patient-caregiver dyads; (2) promote reciprocal sharing of meaningful and pleasurable activities; and (3) provide caregiver-initiated cognitive support, which is subsequently related to caregiver well-being. The dyadic interpersonal processes are interrelated such that caregivers may experience several positive experiences during their interactions, which further mediate improvements in their psychological well-being.

Nevertheless, the number of high-quality trials examining the feasibility and efficacy of caregiver-led CST on both people with dementia and caregivers are limited (Leung et al.,

2017). There is also scarce evidence of the long-term effects of CST on people with dementia, with most studies lacking post-trial follow-ups. Our literature review revealed only two studies from the UK (Orgeta et al., 2015; Orrell et al., 2017) that investigated the effects of one-on-one CST delivered by caregivers for 25 weeks. Both studies found that the caregiver-delivered CST had no significant effects on the cognition and quality of life of people with dementia, although there was some evidence of positive changes in the caregiver-recipient relationship and the caregiver's quality of life. While caregivers in these studies reported adequate knowledge of and confidence in delivering the CST, they had low intervention adherence rates (with < 50% completing the minimum required number of sessions), which might have contributed to the non-significant results on the target outcomes. As the traditional CST originated in the UK (Spector et al., 2003), most studies investigating this intervention and its modifications have been conducted in Western countries (Toh et al., 2016) such as the UK, the US, Italy, France, and Spain (Saragih et al., 2022; Ward et al., 2022). Thus, their generalizability to the Asian context constitutes an existing research gap. There were a few small pilot studies of CST in Asian populations, such as Japan (Yamanaka et al., 2013), which examined the feasibility of the CST Japanese version in improving the cognition and mood of people with dementia. Another small-scale trial in Taiwan (Yang et al., 2016) compared CST with reminiscence and aromatherapy, noting that aromatherapy could be more effective in alleviating the agitation and depressive mood of people with dementia. In Hong Kong, Wong et al. (2017) noted that a culturally-adapted version of the traditional CST was feasible and several cultural aspects, such as collectivism, filial piety, and pragmatism (i.e., a preference for practical engagement rather than for abstract theorization), could influence the implementation of caregiver-delivered CST in Chinese communities (Wong et al., 2017). There is a need to conduct large-scale RCTs to further

examine the utility and efficacy of CST among Asian populations, despite having the largest number of people with dementia (Alzheimer's Disease International, 2020).

Recently, we found that a home-based, multisensory, caregiver-delivered CST (CDCST) is feasible among family caregivers of people with dementia, with low attrition and high adherence rates (Kor et al., 2022). Hence, it is imperative to investigate the outcomes of this new intervention through an adequately powered randomized controlled study to provide evidence of its efficacy. The present study aims to assess the efficacy of a home-based CDCST for people with dementia and their caregivers. We hypothesized that people with dementia would have significant improvements in cognition, quality of life, and BPSD; while family caregivers would have positive changes in their caregiving appraisal, relationship with people with dementia, psychological well-being (depression, anxiety, stress), caregiving burden, distress, and quality of life after the intervention and at the 12-week follow-up, versus the control group.

Methods

Design

A prospective, two-armed, randomized, single-blinded, parallel clinical trial design was adopted. People with dementia and their family caregivers were randomized to either the intervention group (CDCST) or the control group (usual care). The report was in accordance with the CONSORT 2010 Statement (Schulz et al., 2010). The study was approved by the Hong Kong Polytechnic University (HSEARS20180911004) and was registered at ClinicalTrials.gov (NCT03803592).

Settings and participants

The participants were community-dwelling patient-caregiver dyads from five community centers providing services for older people. We recruited participants through convenience sampling from March 2020 to December 2021. We included patient-caregiver dyads based on the following criteria:

- a) People with dementia: (1) aged ≥ 65 years; (2) diagnosed with any type of dementia as defined by The International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10); and (3) in the early to moderate stage of dementia, namely, stages 4-6 according to the Global Deterioration Scale.
- b) Family caregivers: (1) aged ≥ 18 years; (2) related by blood or marriage (e.g., a spouse, sibling, child, or grandchild) to the person with dementia, and has been assuming caring responsibilities ranging from providing physical aid, emotional support, assisting with transportation, finances, personal hygiene, and decision-making; and (3) has been providing most of the daily care/support (daily contact for at least four hours).

We excluded people with dementia and caregivers who had been diagnosed with a physical or mental condition in an acute phase (e.g., bipolar disorder, schizophrenia, cancer, or acute stroke) that might affect their ability to participate in the program.

Sample size

The sample size estimation was based on our previous pilot study (Kor et al., 2022). Considering the effect size of (Cohen's d) 0.29 on the BPSD and 0.511 on the Positive Aspect of Caregiving, we adopted a conservative effect size of 0.3 for the sample size estimation. With the 20% attrition rate from our prior study, 230 participants were required to detect mean differences between the intervention and control groups at a power of 80% and a two-sided significance level of 5%.

Randomization, allocation, and blinding

Using computer-generated randomization (Stata version 13), an independent statistician randomized the participants into the intervention and control groups (1:1 ratio). Written consent for participation was collected from both family caregivers and people with dementia. We followed the ethics of dementia research guidelines published by Alzheimer Europe (2011) on obtaining consent from people with dementia. We carefully explained the study to the prospective participants and helped the people with dementia go through the process of deciding whether they should take part in the study. Some negative responses (e.g., crying) were also regarded as a sign of refusal to join. After the baseline assessment, the participants received notice of their group allocation in an opaque sealed envelope on the first day of the intervention. The group allocation lists were concealed from the researchers, community center staff, and outcome assessors.

Intervention

The intervention protocol was developed based on the implementation guidelines for cognitive stimulation and sensory activities for people with dementia (Aguirre et al., 2014; Spector et al., 2003; Vozzella, 2007). The CDCST included various tasks, such as compiling photograph albums and garnishing fruits/vegetables, as well as multisensory activities such as tasting fruits, singing, and dancing. The aims were: (1) to stimulate different cognitive domains and senses through enjoyable activities; and (2) to promote interaction and collaboration between people with dementia and their caregivers. After balancing the intervention dosage and considering issues of feasibility, duration, and number of sessions from similar studies on CST and multisensory activities (Kim et al., 2017; Strøm et al., 2016), we decided that the CDCST should consist of 45 sessions held over 15 weeks. For face validity, the intervention protocol was reviewed by a group of experts that included nurses, social workers, occupational therapists, and clinical psychologists.

To implement the CDCST, the caregivers received 12 hours of training, including two sessions (2 hours each) provided by nurses and social workers, and self-directed learning/practice through a booklet in between the sessions. The booklet included manual instructions for each activity and guidelines on using the 4F cycle (Facts, Feelings, and Finding the future) (Greenaway, 1992) to review and reflect on what they had gained and understood after the intervention. The caregivers were also provided with a “Five Senses Box,” which included such items as photographs and cards, supplemented for some activities by items from daily life provided by the caregivers (e.g., fruits, snacks). After the training, the caregivers were asked to deliver the CDCST at home 3 times per week for 45 minutes each time. In the first 10 minutes of each session, the caregiver was instructed to follow the booklet and the cards in the “Five Senses Box” to provide the person with a reality orientation, such as ensuring that the participant was aware of the day, date, and weather, followed by the main activities (Table 1). A weekly telephone follow-up was provided by research assistants to monitor the caregivers’ progress and to address any difficulties during implementation. Caregivers were also actively encouraged throughout to contact the team via a phone hotline for any queries. We followed the guidelines from the NIH Behavior Change Consortium to facilitate treatment fidelity. The outline of the CDCST and its intervention fidelity components were previously published (Kor et al., 2022) and are detailed in Supplementary Table 1 in the Online Supplementary Material.

Control group

Participants in the control group received the usual care services for older people in the community centers. These services included brief education sessions on caregiving skills, meal delivery, and financial assistance whenever necessary.

Measurement

Participants completed several outcome measures via telephone, online, or mail (telephone for people with dementia; online and mail response for caregivers) at baseline (T0), immediately after the intervention (T1), and 3 months after the intervention (T2). Other information and the psychometric properties of the measures are given in Supplementary Table 2:

- a) For people with dementia, cognitive function was assessed via the Montreal Cognitive Assessment 5-minute protocol (MoCA-5-min) (Wong et al., 2015). Higher scores in the MoCA 5-min, indicate better cognitive performance. Meanwhile, BPSD were assessed through the Chinese version of the Neuropsychiatric Inventory-Questionnaire (NPI-Q), with higher ratings indicating increased symptom severity (Wong et al., 2014). Quality of life was evaluated through the Chinese version of the Quality of Life in Alzheimer's disease scale (QoL-AD) (Yu et al., 2013).
- b) For family caregivers, caregiving appraisal was measured through the Positive Aspect of Caregiving scale (PAC) (Lou et al., 2015). Meanwhile, the extent of the caregivers' negative attitudes toward family members with dementia was assessed through the Family Attitude Scale (FAS) (Yu et al., 2016). Caregivers' perceived stress, anxiety, and depression were identified through the 21-item Depression, Anxiety, and Stress Scale (DASS 21) (Yu et al., 2016). Caregiving burden was measured via the Zarit Burden Interview (ZBI) (Chan et al., 2005). Caregiver distress associated with BPSD was identified through the second part of the NPI-Q (Wong et al., 2014). Higher scores in all the mentioned measures indicate a higher occurrence of the target outcomes. Meanwhile, higher FAS scores indicate more negative attitudes toward people with dementia.

Data analysis

Data analysis was conducted using SPSS version 26.0. Descriptive statistics were used to present the participants' characteristics. The baseline outcome variables and socio-demographic characteristics of the CDCST and control groups were compared using the Chi square exact test (for categorical data), the Mann-Whitney U test, and the independent t-test (for continuous data). Generalized estimating equations (GEE) were adopted to examine the group effect (intervention vs. control), time effect (T0, T1, T2), and interaction effect (group x time) for the outcome measures. Missing data were accommodated within the GEE to facilitate the intention-to-treat analysis. For the analysis of outcomes on people with dementia, sociodemographic variables, such as age, sex, cognitive stage, and baseline MoCA, were controlled. For the caregivers, the analysis was adjusted for their age, sex, education, income, living arrangement with the people with dementia, duration of care provided, and the degree of dependence of the people with dementia. The level of significance of all statistical tests was at 0.05.

Results

Characteristics of the participants

Two hundred and forty-one dyads from five community centers joined the study and were allocated to either the intervention (n = 121) or control group (n = 120) (Figure 2). The mean age of the caregivers was 63.0 (*SD* = 11.3) and that of people with dementia was 83.0 (*SD* = 8.0). Most caregivers (61.0%) were spouses or children in-law of the care recipients (Table 1).

Attrition, completion, and duration of practice

The attrition rate of the CDCST group was 5.8%, and the main reasons for dropping out were related to health problems of people with dementia (e.g., upper respiratory tract infection), which were unrelated to the intervention. The completion rate (conducted 80% or

more of the CDCST sessions) was 87.6%. The average duration of conducting CDCST was also recorded between T0 – T1 and T1 – T2 (Table 3).

Effects on people with dementia

Participants in the CDCST group did not demonstrate significant changes in their outcome measures immediately after the intervention (T1). Results showed that the intervention group had significantly greater improvements than the control at T2 (3-month follow-up) in global cognition ($\beta = 2.80$, 95% CI [1.92, 3.68], $p < .001$). Significant improvements at T2 were also noted in BPSD ($\beta = -1.38$, 95% CI [-2.61, -0.15], $p = .027$) and quality of life ($\beta = 2.56$, 95% CI [1.07, 4.05], $p = .001$).

Effects on family caregivers

Family caregivers in the CDCST group experienced significant improvements in the positive aspects of caregiving (T1: $\beta = 3.29$, 95% CI [0.87, 5.71], $p = .008$; T2: $\beta = 2.84$, 95% CI [0.02, 5.67], $p = .049$) and negative attitudes toward people with dementia (T1: $\beta = -3.91$, 95% CI [-6.98, -0.83], $p = .013$; T2: $\beta = -7.29$, 95% CI [-11.60, -2.99], $p < .001$) after the intervention and at the 3-month follow-up (Table 2). However, the effects of the intervention on caregiver burden, caregiver distress, depression, anxiety, and stress levels were not confirmed at either time point.

Discussion

This study provided evidence of the efficacy of a caregiver-led cognitive stimulation program for people with dementia and their caregivers. With the social gathering restrictions and limited center-based programs during the COVID-19 pandemic, this study showed that a home-based approach could facilitate cognitive stimulation for people with dementia and benefit their caregivers. Our results indicated that CDCST enhanced the global cognition,

BPSD, and quality of life of people with dementia. Meanwhile, positive improvements were seen in the caregivers' caregiving appraisals and reductions in their negative attitudes. Hence, the study showed that CDCST, which can be implemented without healthcare-provider supervision in community settings, could benefit patient-caregiver dyads.

Results showed that CDCST has the potential to improve the global cognition of people with dementia. These findings are supported by recent reviews (Chen et al., 2022; Saragih et al., 2022), suggesting that CST delivered by healthcare and other professionals could improve the cognition of people with dementia. The program's multicomponent nature might have contributed to the significant findings. For instance, each CDCST session started with a reality orientation, enabling the participants to familiarize themselves with time, place, and people. The completion of various activities (e.g., creating handicrafts, garnishing fruits/vegetables, compiling photograph albums, and engaging in horticulture) was aimed at stimulating attention, executive function, and visuospatial skills. Guessing songs, singing/dancing to musical instruments, and compiling photographs could have contributed to reinforcing memory. Accordingly, multisensory involvement from cognitively stimulating activities could activate neuronal pathways among people with dementia (Saragih et al., 2022). The delivery of CDCST by caregivers also facilitated communication and collaboration with people with dementia, which had protective effects on cognition (Morese & Palermo, 2022). While group CST could offer more social engagement than the one-on-one approach, the patient-caregiver dyad interaction could support an atmosphere of trust and relaxation, as the cognitive stimulation was facilitated by someone familiar with the person with dementia (Fauth et al., 2012).

However, the findings should be interpreted with caution. First, the intervention group had relatively higher baseline MoCA scores than the control group, which might have contributed to their better performance in the cognitive tests at follow-up. Higher MoCA

scores may reflect a higher cognitive reserve, facilitating better responses to cognitively stimulating activities (Kang et al., 2018). Moreover, the cognitive benefits of CDCST were not immediately detected after the intervention but were perceived at the 3-month follow-up. This contrasts with previous reviews in which positive changes in the cognition and quality of life of people with dementia were demonstrated immediately after the CST (Chen, 2022; Saragih et al., 2022). Compared to the CDCST, the traditional CST adopted a group-based approach, through which different social activities can be offered to people with dementia, with additional cognitive and psychosocial stimulation (e.g., interaction with peers). Participating in CST in a group context could enhance the neuroplasticity of older adults, which mediates positive changes in the quality of life and psychosocial functioning of people with dementia (McDonough et al., 2015; Woods et al., 2012). The CDCST adopted a one-to-one approach with group-based activities, which might explain the non-significant effects at T1. A longer intervention duration might be needed to provide adequate stimulation. For example, previous trials facilitated caregiver-led CST for 25 weeks (Orgeta et al., 2015; Orrell et al., 2017). However, these trials had low intervention adherence rates, leading to non-significant changes in the cognitive outcomes. Future studies of CDCST could explore the feasibility and efficacy of extended trial periods for people with dementia and their caregivers.

Compared to the participants in the control arm, those in the CDCST group experienced less progression in BPSD and better improvements in quality of life during the 3-month follow-up. These findings are noteworthy as there is limited evidence of the effects of CST in reducing the neuropsychiatric symptoms of dementia (Chen, 2022; Saragih et al., 2022). Since traditional/group CST dominates the pooled information in such reviews, our study provides insights into the potential advantage of a caregiver-delivered CST in managing BPSD. Caregivers facilitating cognitively stimulating activities could promote

positive interactions with people with dementia, reducing the latter's behavioral/psychological symptoms and improving their personhood (Carbone et al., 2021). Meanwhile, as cognitive deficits and neuropsychiatric changes among people with dementia impact their quality of life, encouraging them to participate in activities that require decision-making and individual interactions would be beneficial (Holopainen et al., 2019). This is in line with the goal of CDCST. Similar to the cognitive outcomes, improvements in the participants' BPSD and quality of life were noted during the follow-up rather than immediately post-intervention. Apart from the need to explore longer delivery periods for CDCST, supporting caregivers to sustain its implementation is important to establish its effects on BPSD and quality of life in future studies.

The study provided evidence that CDCST could also benefit its facilitators, who are the caregivers of people with dementia. Participants reported having more positive caregiving experiences and lesser negative attitudes toward their family members with dementia. Remarkably, there is a paucity of evidence on the effects of CST on caregivers. In a review of 10 trials, Pinto et al. (2019) found inconsistent outcomes of CST toward family caregivers, with only two studies involving caregiver-delivered approaches. For example, Orgeta et al. (2015) found that a caregiver-led CST did not enhance the caregivers' resilience or relationship with people with dementia, although their quality of life improved after the intervention. Another study noted that the caregivers' health status and psychological well-being did not change after implementing CST, but their quality of life improved and their care recipients perceived better relationships with them (Orrell et al., 2017). In this study, accomplishing the CDCST activities facilitated collaboration between people with dementia and their caregivers, and each session ended with an open discussion of one's positive/negative perceptions of performing the activities. These aspects might have contributed to the improvements in the caregivers' role appraisal and attitudes toward people

with dementia. It was suggested that improved dyadic relationships could delay cognitive decline, lessen BPSD, and improve well-being among people with dementia, while also reducing the caregiving burden and improving role satisfaction among caregivers (Fauth et al., 2012). However, a review of cross-sectional studies found weak evidence of the effects of dyadic relationship quality toward the health outcomes of people with dementia (Edwards et al., 2018), suggesting the need for quality studies on this topic. While our current study did not aim to explore associations between patient-caregiver outcomes, this could be a valuable aim for future studies evaluating caregiver-delivered interventions.

Meanwhile, CDCST did not facilitate significant changes in caregiver burden, caregiver distress, depression, anxiety, or stress levels. These findings were consistent with the review of Pinto et al. (2019), which evaluated the effects of professional- and caregiver-delivered CST on caregivers of people with dementia. Two pilot studies, one from Portugal (Alves et al., 2014) and another from Tanzania (Paddick et al., 2017) found that CST delivered by professionals may reduce the caregiver burden, anxiety, and caregiver distress, but these studies were too underpowered ($N < 30$) to provide robust evidence. Currently, our CDCST protocol only covers practical techniques to deliver the intervention. We recommend that future trials of CDCST could combine some components for managing caregiver burden and distress, such as provision of ad-hoc support sessions and information for the caregivers to access support groups (Burgdorf et al., 2022). The weekly telephone follow-up in the CDCST protocol, which was intended to assist participants in implementing the intervention, could also be maximized as a platform for supporting the caregivers' emotional and practical needs. Notably, Rice et al. (2022) observed that these components can effectively improve caregiving burden and the psychological well-being of caregivers.

It is possible that CST might not be able to provide immediate health outcomes to caregivers, but may aid in improving their caregiving appraisal and relationship quality with

people with dementia, which could eventually influence their perceived caregiving burden/distress or psychological well-being. In a cross-sectional study in China, Wang et al. (2022) found that caregiving appraisal mediated the relationships between the caregivers' knowledge/attitudes toward dementia and their psychological well-being. Future studies may fill this gap by exploring potential relationships among these outcomes to better support caregivers in facilitating interventions for people with dementia. While our analysis controlled for several covariates, other factors could have influenced the caregivers' negative experiences and psychological status, such as the severity of the patient's cognitive/functional decline, the unpredictable behaviors of people with dementia, the number of helpers, the caregiver's personality, and perceived self-efficacy (Edwards et al., 2018). These variables may need to be considered in future studies to determine the types of caregivers who could benefit most from delivering CST to people with dementia.

While CDCST was proposed to manage the cognitive and neuropsychiatric symptoms of people with dementia, the aim was also to improve caregiver role appraisal, attitudes toward people with dementia, and psychological well-being. The Chinese culture stresses that caring for older/sick family members is a filial responsibility, which could help to embed the CDCST as a home-based intervention for people with dementia. However, support measures must be readily available to avoid overburdening the caregivers, who are also responsible for extending physical, psychosocial, and medical assistance to their care recipients. As our society enters the post-pandemic period, caregivers may also begin to assume more responsibilities outside the home. To reduce the caregivers' workload and maximize the potential benefits of cognitive stimulation to both caregivers and recipients, CDCST could be combined with traditional center-based CST. This would enable the caregivers to learn more techniques for facilitating CST at home, while also giving them a respite from their caregiving roles. Future studies could also explore the feasibility of providing the CDCST

training to caregivers through a virtual mode, which could promote accessibility and convenience to the participants, despite potential social mobility restrictions or lockdowns.

Study limitations

This study has some limitations. First, we only recruited people with mild to moderate dementia, meaning that patients in the advanced stages of dementia were not represented. Potential selection bias due to convenience sampling may also limit the generalizability of the results to other eligible populations. Since the study was conducted in Hong Kong, where concepts of filial piety permeate the culture, the CDCST may have been more easily facilitated. This approach may be perceived differently in other cultures; hence, future studies could explore the potential utility of the CDCST in other communities or settings. Despite upholding various aspects of fidelity in the study, the assessment of intervention delivery was self-reported, which might have influenced the caregivers to perceive that they had facilitated the CDCST as they had been trained to do, but without validation from a reliable observer. Objective measures of fidelity, such as observations by the researchers or audio/video recordings of sessions, would be valuable in future trials. Since the study was conducted during the COVID-19 pandemic, outcome assessments were not completed via the traditional in-person method. Research assistants were adequately experienced and trained to facilitate data collection, but the possible effect of contextual factors (e.g., timing, mood, health status when answering the assessment tools) in assessing outcomes cannot be ruled out. Meanwhile, there are limitations to using the MoCA 5-min to evaluate some specific cognitive domains of people with dementia. Future studies may consider adopting multiple and robust assessment tools to investigate the effects of CDCST on different cognitive functions.

Although this study demonstrated that CDCST is feasible, the intervention was conducted during the COVID-19 outbreak, when most caregivers had more time because of

the government's stay-at-home guidelines. Given the intensity of training (12 hours) and frequency of intervention delivery (thrice per week) of the CDCST, there may be concerns about its feasibility as society begins to return to normal living conditions. In future trials of CDCST, its feasibility in the post-pandemic period should be examined, and consideration given to reducing the number of training hours or implementation frequency. Lastly, the study compared the efficacy of the CDCST to the usual care received by people with dementia in community centers. Having a more active control condition (e.g., a group/center-based CST) would be vital to determine whether the caregiver-delivered intervention is comparable to traditional CST approaches.

Conclusion

CDCST is a multisensory and home-based approach that can benefit both people with dementia and family caregivers. CDCST could enhance the global cognition and quality of life of people with dementia, while also assisting in reducing the progression of neuropsychiatric symptoms after 3 months of follow-up. Meanwhile, caregivers had a more positive caregiving appraisal and experienced a reduction in negative attitudes toward their family members with dementia after delivering the intervention. However, the impact of CDCST on the caregivers' perceived burden, distress, and psychological well-being (i.e., depression, anxiety, stress) was limited, and requires further investigation. A longer implementation period may be needed to establish its immediate and long-term effects on people with dementia and their caregivers.

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Conflict of Interest

None

Data Availability

The study protocol has been pre-registered in ClinicalTrials.gov (NCT03803592). The conditions of our ethics approval do not allow us to publicly archive or share the study data with non-members of the research team. To seek access to the data, analytic methods, and materials related to this study, interested readers should contact the corresponding author (Dr. Patrick Kor) to discuss data sharing agreement.

Trial Registration

This trial was registered with the US National Institutes of Health (ClinicalTrials.gov) under the number # NCT03803592

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Tables

Table 1. Demographic Characteristics of the Participants at Baseline

Characteristics	Total (N=241)	Intervention (n=121)	Control (n=120)	$\chi^2/Z/t$	p-value
People with dementia					
Age (Mean, SD) (Range 60-102)	83.0 (8.0)	82.8 (7.8)	83.3 (8.1)	-0.45 ^a	0.651
Sex (n, %) [^]					
Male	98 (40.8)	49 (40.8)	49 (40.8)	0.00 ^b	1.000
Female	142 (59.2)	71 (59.2)	71 (59.2)		
Marital status (n, %)					
Single	1 (0.4)	-	1 (0.8)	1.45 ^b	0.485
Married	130 (53.9)	63 (52.1)	67 (55.8)		
Divorced/Widowed	110 (45.6)	58 (47.9)	52 (43.3)		
Self-care abilities (n, %)					
Severe/total dependence	47 (19.5)	19 (15.7)	28 (23.3)	5.60 ^b	0.133
Moderate dependence	73 (30.3)	34 (28.1)	39 (32.5)		
Mild dependence	79 (32.8)	41 (33.9)	38 (31.7)		
Total independence	42 (17.4)	27 (22.3)	15 (12.5)		
Outcome measures (Mean, SD)					
MoCA Total (R: 0-30)	11.64 (5.59)	12.45 (5.40)	10.82 (5.69)	-2.58	0.010 [*]
NPI-Q: Severity (R: 0-36)	10.06 (6.52)	9.65 (6.30)	10.47 (6.74)	-0.78	0.433
Quality of life-Alzheimer's Disease (R: 13-52)	31.51 (6.55)	32.25 (7.22)	30.77 (5.72)	-1.46	0.144
Family caregivers					
Age (Mean, SD) (Range 31-90)	63.0 (11.3)	63.6 (11.1)	62.5 (11.6)	0.71 ^a	0.479
Sex (n, %)					
Male	49 (20.3)	21 (17.4)	28 (23.3)	1.33 ^b	0.249
Female	192 (79.7)	100 (82.6)	92 (76.7)		
Marital status (n, %) [^]					
Single	66 (27.5)	37 (30.8)	29 (24.2)	2.07 ^b	0.355
Married	158 (65.8)	77 (64.2)	81 (67.5)		
Divorced/Widowed	16 (6.6)	6 (5.0)	10 (8.3)		
Educational level (n, %) [^]					
No formal education	5 (2.1)	3 (2.5)	2 (1.7)	1.23 ^b	0.746
Primary	52 (21.7)	23 (19.0)	29 (24.4)		
Secondary	106 (44.2)	56 (46.3)	50 (42.0)		
College or above	77 (32.1)	39 (32.2)	38 (31.9)		
Employment status (n, %) [^]					
Unemployed	25 (10.4)	10 (8.3)	15 (12.5)	1.37 ^b	0.503
Retired	148 (61.7)	74 (61.7)	74 (61.7)		
Employed	67 (27.9)	36 (30.0)	31 (25.8)		
Monthly household income (n, %) ^{^c}					
Less than 2,000 HKD	23 (9.7)	12 (10.0)	11 (9.3)	0.31 ^b	0.960

2,000 – 9,999 HKD	110 (46.2)	56 (46.7)	54 (45.8)		
10,000 – 19,999 HKD	51 (21.4)	24 (20.0)	27 (22.9)		
20,000 HKD or above	54 (22.7)	28 (23.3)	26 (22.0)		
Relationship with people with dementia (n, %)					
Spouse	82 (34.0)	44 (36.4)	38 (31.7)	0.61 ^b	0.895
Children/in-laws	147 (61.0)	71 (58.7)	76 (63.3)		
Grandson/daughter	8 (3.3)	4 (3.3)	4 (3.3)		
Sibling/other relatives	4 (1.7)	2 (1.7)	2 (1.7)		
Living arrangement with people with dementia (n,%)					
Same household	171 (71.0)	90 (74.4)	81 (67.5)	1.38 ^b	0.239
Different household	70 (29.0)	31 (25.6)	39 (32.5)		
Duration of care provided to people with dementia, in hours/week (Mean, SD)					
	50.2 (38.0)	50.5 (38.4)	50.0 (37.7)	0.10 ^a	0.921
Outcome measures (Mean, SD)					
Positive Aspect of Caregiving (R: 9-45)	29.81 (11.30)	30.53 (12.33)	29.09 (10.16)	-1.65 ^c	0.099
Family Attitude Scale (R: 0-120)	61.18 (13.24)	61.20 (14.29)	61.17 (12.14)	-0.29 ^c	0.771
Zarit Burden Interview (R: 0-88)	37.44 (14.43)	36.33 (13.45)	38.57 (15.33)	-1.02 ^c	0.309
NPI-Q: Caregiver distress (R: 0-45)	10.40 (9.44)	10.16 (9.31)	10.64 (9.61)	-0.45 ^c	0.652
DASS-21: Depression (R: 0-21)	5.53 (7.25)	5.43 (7.50)	5.63 (7.01)	-0.61 ^c	0.539
DASS-21: Anxiety (R: 0-21)	5.26 (6.76)	5.65 (7.33)	4.87 (6.14)	-0.56 ^c	0.575
DASS-21: Stress (R: 0-21)	10.14 (9.05)	10.17 (9.23)	10.12 (8.92)	-0.09 ^c	0.930

^aMissing data: For family caregivers – Marital status (n=1, 0.4%); Religion (n=2, 0.8%); Education (n=1, 0.4%); Employment status (n=1, 0.4%); Monthly household income (n=3; 1.2%); Attendance in training related to dementia care (n=4, 1.6%); For people with dementia – Sex (n=1, 0.4%); Cognitive stage (n=1, 0.4%)

Notes: χ^2 = Chi-square test; Z = Mann-Whitney U-test; t = Independent t-test; N = Total participants; SD = Standard deviation; MoCA = Montreal Cognitive Assessment; NPI-Q = Neuropsychiatric Inventory-Questionnaire; DASS-21= Depression Anxiety Stress Scale 21; HKD = Hong Kong Dollars

Superscripts: ^aIndependent t-test; ^bChi-square test; ^cMann-Whitney U-Test; ^dUS\$1= HK\$7.8

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Table 2. GEE Analysis of the Comparison of Outcomes Between the Control and Intervention Groups

Measures	Intervention Group (n=121)	Control Group (n=120)	Group-by-Time interaction effects		Effect size (T0-T1; T0-T2)
PEOPLE WITH DEMENTIA					
MoCA 5-min	Mean (SD)	Mean (SD)	β (95% CI)	<i>p</i>	<i>d</i>
T0	12.45 (5.38)	10.82 (5.67)			
T1	12.83 (6.07)	10.51 (6.23)	0.69 (-0.12, 1.51)	0.097	0.11
T2	13.39 (6.51)	8.96 (5.41)	2.80 (1.92, 3.68)	<0.001*	0.47
NPI-Q: Severity					
T0	9.64 (6.27)	10.48 (6.69)			
T1	9.44 (5.86)	11.25 (6.56)	-0.97 (-2.02, 0.08)	0.071	0.16
T2	9.00 (6.46)	11.22 (6.75)	-1.38 (-2.61, -0.15)	0.027*	0.21
QoL-AD					
T0	32.25 (7.19)	30.78 (5.70)			
T1	32.73 (6.91)	30.03 (5.38)	1.23 (-0.06, 2.51)	0.062	0.20
T2	33.52 (6.70)	29.49 (5.82)	2.56 (1.07, 4.05)	0.001*	0.41
FAMILY CAREGIVERS					
PAC					
T0	30.53 (12.28)	29.09 (10.12)			
T1	34.71 (8.12)	29.98 (9.56)	3.29 (0.87, 5.71)	0.008*	0.37
T2	33.45 (11.52)	29.17 (9.95)	2.84 (0.02, 5.67)	0.049*	0.26
FAS					
T0	61.20 (14.23)	61.17 (12.09)			
T1	57.63 (15.61)	61.51 (14.53)	-3.91 (-6.98, -0.83)	0.013*	0.26
T2	54.14 (20.45)	61.40 (17.42)	-7.29 (-11.60, -2.99)	0.001*	0.38
ZBI					
T0	36.33 (13.40)	38.57 (15.27)			
T1	35.81 (13.42)	37.80 (15.40)	0.24 (-1.94, 2.42)	0.828	0.02
T2	35.48 (14.70)	38.88 (16.03)	-1.16 (-3.69, 1.37)	0.369	0.08
NPI-Q: Caregiver distress					
T0	10.36 (9.37)	10.47 (9.54)			
T1	10.02 (8.69)	10.62 (8.88)	-0.49 (-1.91, 0.93)	0.501	0.06
T2	10.39 (10.57)	10.87 (10.40)	-0.36 (-2.15, 1.43)	0.692	0.04
DASS 21: Depression					
T0	5.50 (7.49)	5.63 (6.98)			
T1	5.50 (7.35)	5.19 (6.89)	0.45 (-0.66, 1.55)	0.431	0.06
T2	6.25 (7.90)	6.64 (7.41)	-0.26 (-1.56, 1.05)	0.698	0.03
DASS 21: Anxiety					
T0	5.65 (7.30)	4.87 (6.11)			
T1	5.27 (6.49)	4.17 (6.09)	0.31 (-0.83, 1.45)	0.591	0.05
T2	5.55 (6.66)	5.34 (6.66)	-0.58 (-1.78, 0.63)	0.350	0.09
DASS 21: Stress					
T0	10.17 (9.19)	10.12 (8.87)			
T1	10.05 (8.87)	9.73 (8.15)	0.26 (-1.21, 1.74)	0.726	0.03
T2	10.78 (9.36)	10.67 (9.76)	0.06 (-1.49, 1.62)	0.935	0.01

Notes: GEE = Generalized estimating equations; n = number of participants; T0 = baseline; T1 = immediate post-intervention; T2 = 12-week follow-up; SD = Standard deviation; β = Beta coefficient; CI = confidence interval; *p* = level of significance; *d* = effect size; MoCA 5-min = Montreal Cognitive Assessment 5-minute protocol; NPI-Q = Neuropsychiatric Inventory-Questionnaire; QoL-AD = Quality of Life in Alzheimer's Disease; PAC = Positive Aspects of Caregiving; FAS = Family Attitudes Scale; ZBI = Zarit Burden Interview; DASS-21 = Depression Anxiety Stress Scale-21

Table 3. Duration of the Conducting CDCST between T0 and T1 and T1 and T2

Average duration of CDCST per week (minutes)	Between T0 and T1 Number of subjects (%)	Between T1 and T2 Number of subjects (%)
<59.9	7 (6.14)	12 (10.71)
60–120	30 (26.32)	42 (37.50)
120–150	69 (60.52)	56 (50.0)
>150	8 (7.02)	2 (3.03)
Total	114 (100)	112 (1.79)

Notes: CDCST = Caregiver-delivered cognitive stimulation therapy; T0 = baseline; T1 = immediate post-intervention; T2 = 12-week follow-up; ^aMissing data were replaced by “zero,” indicating that the participants did not perform the CDCST.

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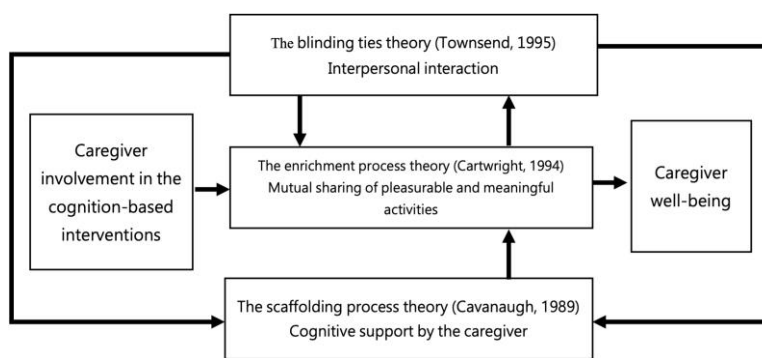
Figures

Figure 1. *Theoretical Framework Explaining the Effects of Caregiver Involvement in Cognition-Based Interventions on Their Well-Being (Leung et al., 2017)*

Figure 2. *Study Flow Diagram*

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Figure 1



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Figure 2

