Study Protocol and Statistical Analysis Plan

Full Title of the Study

Cognitive Stimulating Play Intervention for Dementia: A Feasibility Randomized Controlled Trial

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Introduction

Around 47 million people worldwide are affected by dementia, and the number is projected to triple in 2050.[1] Treatment that reverse the pathological changes in the brain is not available currently, but cognition of People with Dementia (PWD) could be improved through intervention. Among the three major approaches in cognitive intervention for PWD, namely cognitive training, cognitive rehabilitation, and cognitive stimulations,[2] cognitive stimulation was the one that recommended for enhancing the cognitive functions of PWD by the UK's National Institute for Health and Clinical Excellence.[3] Therefore, this study will apply an adapted intervention targeting on stimulating cognitive function of PWD—the Cognitive Stimulating Play Intervention (CoS-Play)—that involves the six mind-body functional domains advocated for enhancing cognition of PWD by Wong and colleagues in 2014.[4] They include auditory music and rhythm, visuospatial and fine motor skills, language and verbal skills, executive functions, kinesthetic and gross motor skills, and social functioning. The CoS-Play Intervention will address the shortcoming of the heavy reliance on language of conventional cognitive stimulation programs, and focus on the application of play. Some evidence from the literature demonstrated that playing games is beneficial to PWD's self-confidence, social engagement with other participants, cognition and behavioural symptoms, but the methodological quality of some studies were found to be generally inadequate and not anchored in a conceptual framework.[5-6] This study will address theses knowledge gaps using a randomized controlled trial and employing both quantitative measures and qualitative interviews to evaluate the feasibility and preliminary efficacy of the intervention.

Objectives of the Study

By carrying out the intervention in local day-care centers in Hong Kong alongside a wait-list control group, the study aimed at exploring the feasibility of the Cognitive Stimulating Play Intervention (CoS-Play) as a means of cognitive stimulation for people with early to moderate dementia, and examining its preliminary effects on the cognitive functions.

Study Design and Procedures

Design

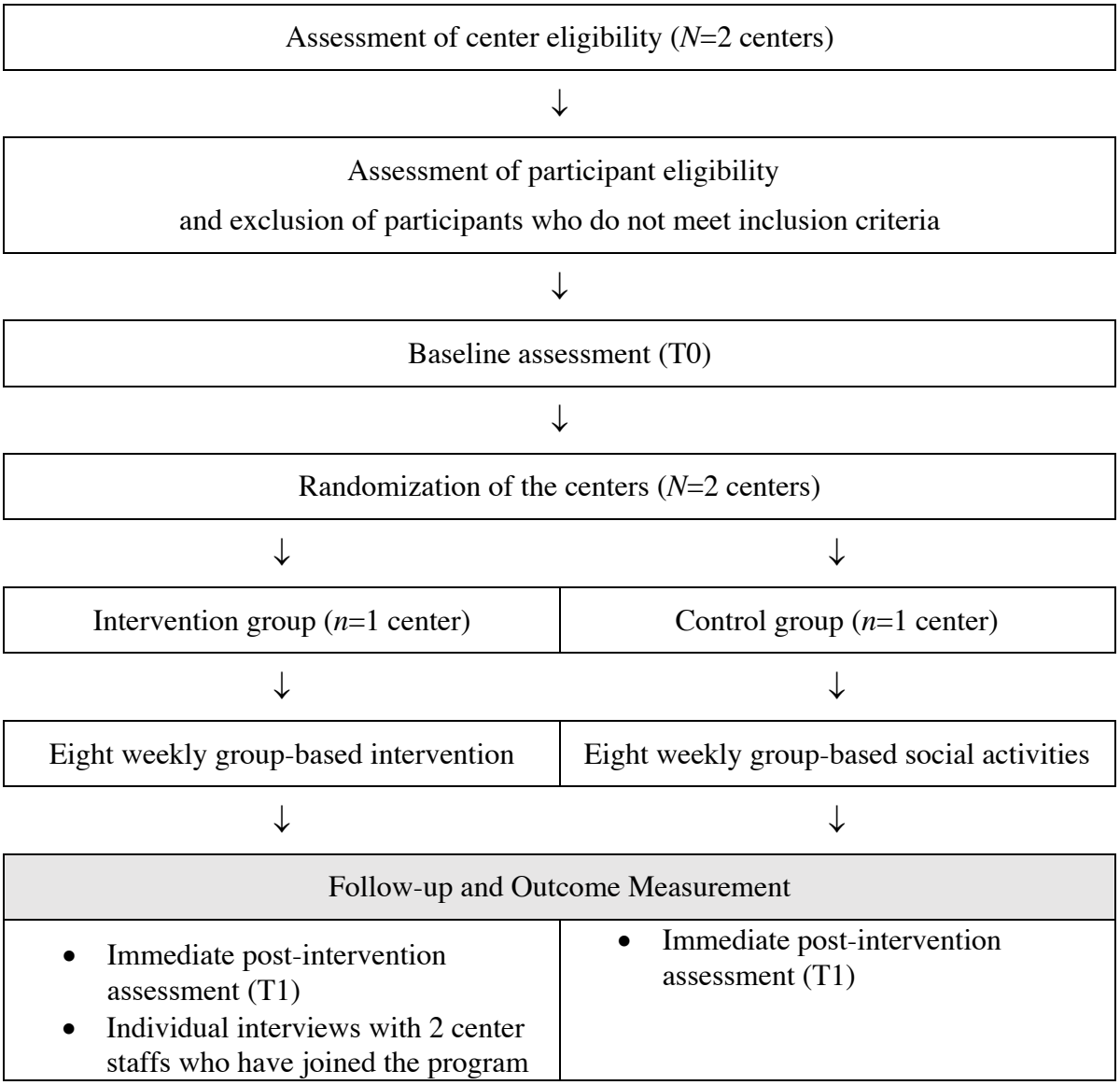
This is a randomized controlled trial employing quantitative pre-intervention and post-intervention assessment of participants, as well as qualitative interviews with staff members of 2 community day-care centers to evaluate the feasibility and preliminary efficacy of the

intervention. This design allows us to reflect on the utility of the intervention in real practice, which is particularly important during the developmental stage of a complex intervention.[7]

Population

Eligible participants will be community dwelling adults aged 60 or above with a medically confirmed diagnosis of any type of dementia (such as Alzheimer disease, vascular dementia, etc). Those who will be included as participants are people at the stage of early to moderate dementia (stages 4-6 according to the Global Deterioration Scale[8]), able to sit independently, and physically stable. Those with acute physical or mental illnesses will be excluded. Center staffs who will be assisting in the CoS-Play will be invited to take part in interviews so that their opinions on the implementation of the program could be solicited

Procedures



Study Outcomes

Quantitative outcomes

A trained research assistant who will be blinded to the group allocation will assess the cognitive functions of the participants using the Montreal Cognitive Assessment (MoCA), the Fuld Object Memory Evaluation (FOME), and the Modified Verbal Fluency test (embedded in the FOME), at baseline (T0), and immediately postintervention (T1).

a. ***Montreal Cognitive Assessment (MoCA).*** The Hong Kong version of the MoCA will be used to measure the global cognitive functions of the participants.[9] This instrument has high internal consistency (Cronbach a α = .767), excellent inter-rater reliability (Intra-class Correlation Coefficient [ICC] = 0.987), and good construct validity as compared with the Mini Mental State Examination and Global Deterioration Scale.[9] It consists of 11 items, and lower total scores refer to lower levels of cognitive function.
b. ***Fuld Object Memory Evaluation (FOME).*** Participants' memory will be evaluated using the FOME.[10] The participants will be asked to memorise and recall 10 items across 5 recall trials and a delayed recall trial. The instrument has been validated in the Hong Kong Chinese population and found to have better construct validity than the Mini Mental State Examination (r = 0.69-0.74), and to have test–retest reliability (ICC = 0.91-0.96).[11] Three FOME scores, namely total storage (possible range of 0-50), total retrieval (possible range of 0-50), and delayed recall (0-10) will be derived. Total storage represents the encoding function, while total retrieval and delayed recall refer to the retrieval function. Higher scores represent better memory.
c. ***Modified fluid verbal fluency test***. Verbal fluency will be assessed using the Modified Fuld Verbal Fluency test,[12] which was modified from the original Fuld Verbal Fluency test embedded in the FOME as a distraction task. Participants will be asked to name animals, fruits, and vegetables in 1 minute or 30 seconds. The construct validity was acceptable as compared with the Mini Mental State Examination (r = 0.76), and the test had good test–retest reliability (r = 0.74).[12] Total scores are the sum of the items being recalled, with higher total scores referring to better verbal fluency.

Qualitative outcomes

The staff will be interviewed about their perceptions of: (a) the acceptability of the program, (b) the feasibility of integrating the program to the usual service operations of the center, (c) the practicality of the program, and (d) the effects of the program on participants.

The guiding questions will be as follows:

a. **Acceptability**.
   What do you think about the acceptability or satisfaction of the intervention to people with moderate dementia?
b. **Integration**.
   What would you think if the intervention were to be integrated into the normal routine of your center?
c. **Practicality**.
   What are the practical concerns regarding the CoS-Play?
d. **Efficacy**.
   What changes did you observe in the participants after they had participated in the CoS-Play?

Statistical Analysis Plan

Quantitative analysis

SPSS Statistics 23 will be used for all analyses. Data collection and entry will be conducted by a research assistant who will be blinded to the group allocations. The demographic data and the participants' performance at baseline will be compared with Fisher exact test for categorical data, and with the Mann-Whitney U test for continuous data to detect differences between intervention and control groups. Intention-to-treat methods will be used for all analyses. Missing values will be imputed with the last observation carried forward approach. Analysis of covariance (ANCOVA) will be used to examine whether there are significant differences between groups on the outcome measures after 8 weeks of the intervention, using its baseline measures as a covariate. A 2-sided significance test ($P < .05$) will be applied. The magnitude of the effects between the intervention and control groups will be displayed as a partial η^2 effect size.[13]

Qualitative analysis

A deductive content analysis approach will be used to analyze the transcribed interview verbatim in relation to the feasibility of the intervention, which is considered suitable for a detailed analysis of the 4 indicators of the feasibility of the intervention—acceptability, integration, practicality, and effects.[14] The principle investigator and a trained research assistant will first immerse themselves in the data, decide on the analysis of manifest content together before coding the transcripts individually. After that, both of them will discuss discrepancies in the coding and will reach a consensus on the categories that will be generated.

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