



Implementing Cognitive Training Research in Older Adults: Randomized Controlled Trial, Ground Issues, and Considerations

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Abstract

With the global surge in aging population, there is increasing attention to develop and utilize evidence-based cognitive training programs as potential tools to slow down the age-related cognitive decline. Employing a randomized controlled trial design, we evaluated the efficacy of a pen-paper-based cognitive intervention program on three different cognitive profiles (i.e., cognitively healthy, mild cognitive impairment, and dementia) of older adults in Singapore. This program, namely, Active Brain Learning, was modified from the original cognitive intervention program known as Learning Therapy in Japan. The training components consist of simple arithmetic calculation and reading aloud which were adapted and contextualized to suit the local older adults. Historical influences and sociocultural contexts played significant roles in the development and implementation of the Active Brain Learning program. In this case, we discuss the research and methodological approaches as well as the issues and challenges of evaluating the efficacy of the Active Brain Learning program on cognition and general well-being of older adults within the community and in senior daycare facilities. Concerted effort from all stakeholders would be essential toward bridging the gap between research implementation and the ground realities to meet the changing needs of the aging population.

Learning Outcomes

By the end of this case, students should be able to

- Design a simple experimental study using randomized controlled trial (RCT)
 - Understand the intricacies and need to consider local or contextual factors in research
 - Appreciate the potential issues and challenges in research implementation on the ground
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Overview and Context

In our cognitive training research, we have conducted a series of experimental studies in older adults from both healthy and clinical populations in Singapore. As our research center has existing collaboration with Professor Ryuta Kawashima, a renowned neuroscientist from Tohoku University in Japan, we adopted and applied his cognitive training principles and methods to the local population. The intervention takes the form of both pen-paper-based and brain-training-games approach. In this case, we focus the case discussion on the pen-paper-based intervention across three studies done in continuity.

The impacts of aging are multi-dimensional. Much of the research effort has been directed at the prevention goal to delay cognitive decline, such as cognitive training and stimulation to enhance cognitive and social functioning. Although Prof. Kawashima's intervention approach

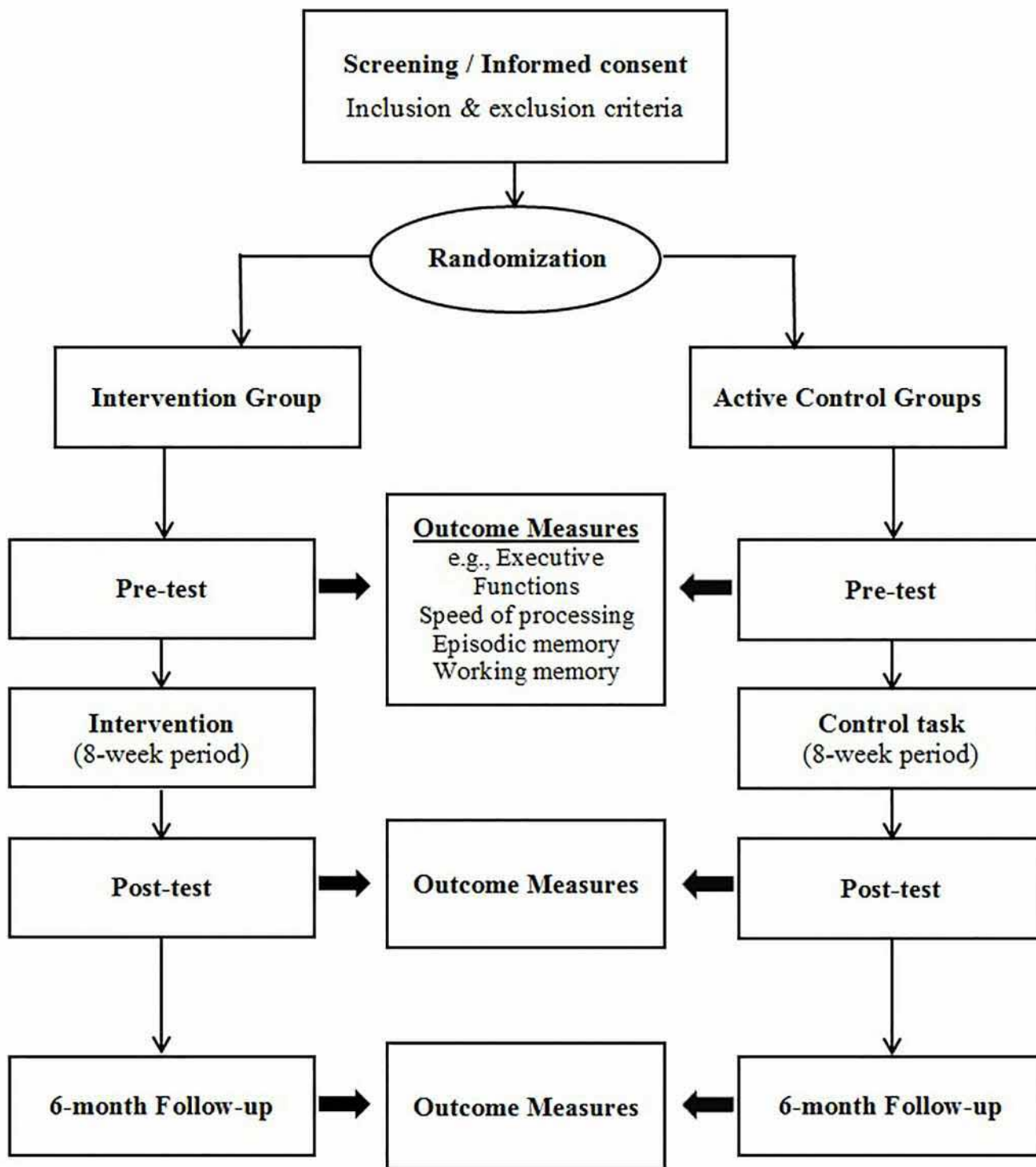
has been widely adopted in Japan, it is necessary to consider the local context, such as the unique profile of the current cohort of older adults in Singapore of whom a significant proportion are illiterate or have low level of education due to missed opportunity for schooling during the wartime.

Apart from showing that a training program works to improve cognitive outcome in the trained cognitive domains, there has been a focus of transferability to other (untrained) cognitive domains as well, preferably to meaningful everyday life functioning. Of interest, Prof. Kawashima has developed a pen-paper-based cognitive training program called “Learning Therapy” (LT) that has shown some beneficial effects in Japan. LT consists of two tasks, namely, reading aloud and simple arithmetic calculation, both of which have been shown to activate the prefrontal cortex and engage numerous cognitive processes (Uchida & Kawashima, 2008). The simplicity of the pen-paper-based intervention is well-suited to the local seniors without the technological complexities.

Research Design

A typical cognitive training study design is based on randomized controlled trial (RCT). An RCT aims to reduce any experimental bias while evaluating the efficacy of an intervention program. Participants are randomly allocated into either the intervention group (i.e., the group that received the training program) or the control group (i.e., the comparison group that does not receive the training) (e.g., [Figure 1](#)). The control group could either be a passive, no-contact group (i.e., no intervention) at a minimum, or more ideally an active control group (performing a generic task during the intervention period). For cognitive research, an active control group is preferred over passive group because it controls certain aspects of attention, time, or expectation associated with the intervention group (Kinser & Robins, 2013).

Figure 1. Example of study flowchart of an 8-week cognitive intervention study in healthy older adults.



In addition, all participants would undergo a pre-test to establish some baseline measures, followed by an intervention period and a post-test (same measures as pre-test) to examine changes (if any). RCT is the gold standard to tease apart and validate the causal effects of an intervention, though other alternative approach known as realist evaluation has also been

proposed for more complex, multi-componential, and contextually synergistic social interventions in situations when forcing an RCT design might not be feasible (Bonell, Fletcher, Morton, Lorenc, & Moore, 2012). A transfer effect is present when the training leads to significant improvement to untrained cognitive domains or other domains on psycho-social aspects and/or everyday life functioning.

Research Practicalities

Discussed below are a series of three pen-paper-based (i.e., Active Brain Learning [ABLE] program) intervention studies conducted in Singapore on healthy as well as clinical populations (i.e., mild cognitive impairment [MCI] and dementia). ABLE program is adapted from LT to suit the needs of local adults. As Prof. Kawashima's LT intervention requires a certain degree of literacy, it necessitates some adaptations to suit the current cohort of seniors in Singapore, especially those with low level of literacy coupled with language barriers (as majority are dialect-speaking), which also poses a challenge to conventional cognitive assessments. In this case, we describe the common and unique issues as well as the learning points from our experiences in conducting this line of research in the local context.

Study 1. Cognitive Training for Older Adults: ABLE Intervention Study (Simple Arithmetic Calculation & Reading Aloud)

We started off with the first study on older adults with healthy cognition primarily recruited from our educational institution (with a small proportion from members of the public), and thus the sample would not be representative of the local population but the aims were oriented toward hypothesis testing. A total of 92 participants aged 50 and above were recruited for this cognitive intervention study (which entailed completing the training worksheets for 5 days a week, 15-20 min a day, over 8 weeks). To assess the impact of ABLE on cognition, we had three parallel groups: an ABLE group and two active control groups (see [Figure 1](#) for the study flowchart). The first control group comprised the same training materials as the ABLE group, but different training instruction (i.e., specifically no time pressure compared to the intervention group, to tease apart if speed was critical). The second control group had to do 6 × 6 Sudoku and spot-the-difference games. Participants were randomly assigned to each of the training groups.

Instead of a passive control group, we used an active control group to account for the potential confounds that resulted from practice effects, experimenter bias, and placebo or social-motivational effects. To provide compelling evidence on the training effects, the experimental design should ideally incorporate the criteria of double-blind, placebo-controlled, and random assignment (Simons et al., 2016).

A double-blind design, however, could be largely resource-dependent. In this study, we had the support of an administrative coordinator to help manage the participants (e.g., giving out weekly training worksheets, etc). Although the participants could be blinded to the conditions of the study (with an active control design), in reality, some of the participants might still inadvertently divulge to the experimenters their assigned group when they talked about their training materials in their visits, so a strictly double-blind design remains a challenge. In comparison, in a single-blind design, participants are blinded to the conditions of the study and presumably have no reasons to be led to expect the different outcomes. Arguably, unlike a laboratory controlled study (e.g., pharmacological study), it is oftentimes impractical for social interventions to be double-blinded (Bonell et al., 2012). Nonetheless, in situations when the participants would be aware of the experimental conditions and thus form certain expectations on the outcomes, the researchers might take into consideration how to design the study in a manner that both groups would have comparable expectations for improvements (Simons et al., 2016).

In this first study, however, we soon realized that the primarily convenient sample that consisted of mostly active, motivated, highly educated, and high-functioning participants from an educational institution was not favorable to test the hypotheses. Among the several cognitive domains that were included as outcome measures, the intervention group outperformed the control groups at post-test in the domain of processing speed. This finding was consistent with previous research in Japan which found a benefit of LT on processing speed. However, this improvement was only seen in one of the three tests that were used to measure processing speed. Thus, the benefit shown was limited.

Indeed, one of the possible reasons for the partial, limited training effects observed in this study could be due to the fact that the baseline cognitive performances were very good to begin with. Some participants already attained the (near) maximum score for certain cognitive measures (i.e., ceiling effect). In such cases, it would not be possible to improve any further (also considering the limitation of the test batteries). As argued, most of the participants were staff members working in the educational setting, who were relatively well-educated and still actively working in the academic institution during their involvement in the project. These active lifestyles were likely contributors to mental stimulation as well. Thus, the effects of any additional mental training program would be minimal. Hence, the sampling of participants is an important consideration, and so, further investigation is needed to extend the study to a broader spectrum of participants with varying degrees of cognitive functioning.

Study 2. ABLE Intervention Study (Simple Arithmetic Calculation Component Only) in Clients With MCI in a

Senior Daycare Center

As discussed, due to the poor literacy that is characteristic of the current cohort of older adults in Singapore, it was necessary to modify and simplify the training materials. Most of the clients were non-English speaking. Although many of the Chinese clients speak mandarin dialect, a majority do not know how to read. In view of the language barrier, this project could only examine the efficacy of the simple arithmetic calculation component of ABLE on cognition and general well-being of clients with MCI. Another issue that we faced was the broad range of cognitive measures used in the first study in healthy older adults would no longer be feasible for this cohort of seniors with low literacy compounded by cognitive impairment. Therefore, there were only limited measures to be chosen from.

In this pilot study, 24 clients aged 65 and above with MCI were recruited and randomized into two groups, experimental or control group. In consideration of the limited resources (e.g., manpower from the center to support individualized daily training and to conduct pre- and post-assessments, availability of eligible clients, etc.), we had to settle for a small but minimally viable number of 24 participants (12 per group; following a recommended sample size for pilot study, Julious, 2005). The assigned care staff received training on administering the assessments and daily training protocol, as the care staff would have greater rapport with the clients with MCI under their care and were able to converse in dialects. Crucially, they were able to gauge the time window of the day when the clients were in a more receptive and alert state to do the training worksheets. The experimenters would visit the senior daycare center from time to time to check in with the care staff. In this case, the care staff played the critical role of tester and training administrator. One limitation is the potential experimenter variability in administering the assessments, or experimenter-expectancy bias. Therefore, the planning of the study should factor in adequate time for training of “people on the ground” involved in the research, and in our case the care staff (who had no research experience), which could also be a challenge due to the center’s competing resources or other demands.

A delayed intervention paradigm (wait-list control) was modeled in this study to assess the training efficacy. After pre-test, participants in the experimental group embarked on ABLE for 4 weeks, whereas those in the control group had no training (i.e., delayed). An active control task was not put in place as the control participants would carry out their routine activities at the center (“treatment as usual”) and to avoid placing additional demand on the staff. At mid-test, the efficacy of 4 weeks of ABLE training as compared with control was assessed. Subsequently, participants in the experimental group continued training for another 4 weeks, whereas those in the control group commenced the 4-week ABLE training. At post-test, the efficacy of 8-week versus 4-week ABLE training was assessed.

As with past studies, global cognition tends to be consistent across times and would not change much (except for dementia with a downward trajectory), and thus the domain-specific cognitive functions should be targeted. In this study, however, we only had one domain-specific cognitive test on processing speed, but unexpectedly, many of the clients were unable to complete the simple task, so analysis could not be performed on the limited data points. In retrospect, it would be useful to include a broader range of cognitive measures and to test the feasibility of the measures on a small subset of sample, before deciding on the test batteries to use. In this pilot study, the only significant finding was the improvement in general well-being of the participants but the plausible social-motivational effects could not be ruled out from the training effects due to the additional individualized attention received by the clients.

In this project, the center's management was supportive of the study, that translated to their care staff who made it possible by taking charge of administering the training materials and assessments on their respective clients. In our earlier efforts to reach out to some other stakeholders, however, it has not been always well-received without obstacles or rejections due to a lack of open-mindedness toward research, though this seems to be changing with increasing interest given to evidence-based training programs.

In conducting a research project as such, support from the right partner and "people on the ground" is crucial to a successful implementation of the intervention study, but we also recognize the inherent challenges as discussed.

Study 3. A Multisite Cognitive Intervention Project to Evaluate the Efficacy of ABLE Program to Improve Cognition and Well-Being of Persons With Dementia (Currently Ongoing With Results Expected by End 2017)

Following the pilot study on clients with MCI, the service provider was keen to roll out ABLE on a larger scale to 12 of their senior daycare centers, involving clients with mild to moderate dementia. Drawing from the experience from the pilot study, we aimed to further adapt, formalize, and validate a new set of training materials customized for the clients with dementia. This involved contextualizing the arithmetic worksheets to simulate real-life scenarios, such as buying things (rather than presenting in pure mathematical equations), to make it more appealing to the seniors. The worksheets had various difficulty levels to suit participants with different arithmetic abilities. Other modifications included longer training period, more outcome measures, and larger sample size (with multiple centers). The outcome measures chosen are generally easy to administer and have been reportedly tested with persons with dementia (PWD).

With the involvement of multiple centers, it is possible to consider a cluster RCT design as there are readily identifiable groups. In a cluster RCT, the centers (rather than individual participants) are randomized. As participants in the same center will receive the same treatment, contamination between individuals assigned to different treatments is unlikely to occur. Nonetheless, due to the stakeholder's decision to roll out the training program to all centers, a simple RCT was adopted. This means each of the centers would have equal number of clients in both intervention and control groups.

For randomization, we applied block design randomization using a computer-generated sequence and matched to the clients' age and educational level. The other potential but realistic issues to anticipate include drop out or attrition due to various reasons such as relocation, client's hospitalization and withdrawal, etc. Such impact would be especially greater for study with a small sample size.

Similar to the pilot study, the implementation of the training program and administration of cognitive assessments depend crucially on the support from the center staff involved in the study. With the larger trial, a more practical and manageable approach to implementing the project is to have staggered starts for the centers according to their geographical cluster. The researchers would go down to each cluster and conduct briefing and training sessions to the center staff on the training materials and protocol as well as cognitive assessments. The center's arrangement was to assign a few dementia clients under each care staff involved, who would conduct the daily training and pre- and post-assessments on their respective clients. Regular monitoring throughout the study by researchers would be crucial to ensure consistent implementation of the training program, especially for multisite studies involving several center staff. Although the center care staff received training to run the study, it was a challenge as most were new to research. The potential biases that might arise from experimenter variability and expectations could only be minimized, though could not be entirely accounted for.

Our next phase is to bring the ABLE program to PWD into their own home, of which caregiver's support is critical. This is a new challenge considering caregiver's burden or those without caregiver's support. There is no easy solution, but there remains the potential for new ideas to be developed outside the existing paradigm.

Practical Lessons Learned

In the case discussion, we have shared a few lessons learned that span across three studies. First, it is important to consider the right sample and the profile of the participants that could have an unintended bearing on the outcomes. For example, the high-functioning sample of

participants might translate to limited margin for improvement. In our other study on brain training games in older adults, the right sample to consider might be those who belong to the “Fitbit” group (i.e., more receptive to technology) or smart phone users. This also shows the multi-pronged intervention approach is essential to cater to the varying needs of older adults across a spectrum of functioning.

Second, it might be necessary to localize and contextualize the training and assessment methods. In the case study, we highlighted the unique profile of the current cohort of local seniors in Singapore with very different educational and cultural background. Taking this into consideration might require modifying the training materials and the careful selection of the appropriate test instruments.

Third, we need to consider the most appropriate research design for the study’s purpose, and this could mean striving for a judicious balance between ideal versus practical in its implementation, while not compromising the rigor of the research.

Fourth, one of the main goals of cognitive intervention programs is to demonstrate transfer effects as meaningful gains in daily life or delay in cognitive decline. Therefore, careful thought needs to be given to the selection of the right measures to capture the target core cognitive processes and relevant dimensions, while taking into account the contextual factors.

Fifth, the key to implementing a research program on the ground necessarily depends largely on “people on the ground.” This is one of the greatest challenges, so finding the right stakeholders to work with and getting the support from the people on the ground is critical to ensure the smooth execution of the research program and valid results.

In conclusion, it has been a learning experience through “trial and error” in some way in the efforts to bridge the gap between science and practice to implementation on the ground. In our conversations with others in the field, we realize that much of the issues and other considerations discussed are more common than uniquely ours. We hope that our sharing could be of benefit to the readers as well as to stimulate more critical thinking and discussions on how we can do better as we learn from each other.

Exercises and Discussion Questions

- 1.What is (are) the key difference(s) between a randomized controlled trial (RCT) versus a non-experimental design?
- 2.Why is an active control group more preferred over passive control?
- 3.If you plan to replicate an intervention study, what are some of the local or contextual

factors that might be influential to your study outcome, which you need to take into consideration in designing the study?

4. What are some of the issues to be anticipated as you work with the stakeholders to implement and execute your intervention study on the ground?

Further Reading

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