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The effects of cognitive training in healthy community residing Thai elderly: a randomized controlled trial.092022 V.1

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**Keywords:** cognitive functions, community, elderly, healthy, randomized controlled trial, global cognitive function in healthy thai, cognitive training intervention, cognitive training in healthy community, thai mental state examination, cognitive training session, cognitive training, mean number of cognitive training session, risk reduction of dementia, dementia, cti in old age, healthy thai, residing thai, global cognitive function, technology cti in community, tmse score among cti, treatment effect by examination, bangkok, controlled intervention trial, senior society, technology cti, significant treatment effect for improvement, senior society on the edge, cti group, cti, intervention trial

#### Disclaimer

The authors declare that they have no conflicts of interest.



## Abstract

Aim: Cognitive training intervention (CTI) in the elderly is associated with a risk reduction of dementia; however, the effects of interactive computerized-CTI in old ages have been inconclusive. The present study aimed to determine the effects of low-technology CTI in community-based populations.

Methods: The study was a 2-arm parallel single-blinded randomized controlled intervention trial. The primary endpoint assessed the treatment effect by examination of global cognitive function, utilizing the Thai Mental State Examination (TMSE), at the 12th week (T1), while the secondary endpoint evaluated the carry-over effect at the 24th week (T2).

Results: Eighty-six eligible participants were recruited from a senior society on the edge of Bangkok. At baseline (T0), the mean age and TMSE score among CTI (n=44) and wait-list (n=42) groups were similar (age; 66.66±5.52) and 67.52±6.46; TMSE; 28.84±1.38 and 28.83±1.12, respectively). For the CTI group, the mean number of cognitive training sessions was 14.82±7.62. By using intention-to-treat analysis at the primary endpoint, the mean difference score of TMSE in the CTI groups was significantly higher than the wait-list group (ΔTMSEbetween group at T1-T0=0.57; 95%CI=0.07 to 1.08.; p = 0.026) while the effect size was 0.48. At the secondary endpoint, there was no significant difference observed between the CTI and wait-list groups (ΔTMSEbetween group at T2-T0=0.33; 95%CI= -0.23 to 0.88; p = 0.248) while the effect size was 0.25.

Conclusions: CTI showed a significant treatment effect for improvement in global cognitive function in healthy Thai elderly but did not demonstrate a carryover effect.

#### **Attachments**



ProtocolRCTCogTrainE...

441KB

## **Guidelines**

The cognitive training intervention (CTI) is referred to as a non-pharmacological intervention that involves a kind of restorative strategy to improve cognitive performance in the healthy elderly. The exercises in the CTI for this study combined six cognitive functions (i.e. complex attention, executive function, learning and memory, language, visuoconstruction-perceptual ability, and social cognition). The CTI was implemented twice per week with 30 minutes allocated to each session (24 sessions in 12 weeks). The sessions were led by the author who quided the participants through each activity systematically. Each session comprised eight three-minute sections and followed the same format: 1) check-in and introduction, 2) cognitive domain practices (6 sections), and 3) summary and feedback section. There was a one-minute break after each section to enable participants to recover. The CTI was run by an audio-visual digital video disk created by the authors which explained instruction and demonstration in each lesson and involved an individual paper-pencil workbook. The CTI employed speed tests, matching activities, gap completion, and short-answer questions.



#### **Materials**

#### 1. Materials for primary outcome

The primary outcome was the evaluation of global cognitive function with the use of Thai Mental Status Examination (TMSE)<sup>12</sup>, of which total score is 30 and is divided into six categories: orientation (score of 6), registration (3), attention (5), calculation (3), language (10), and recall (3). The average total score among Thai elderlies (60-70 years old) who are free from underlying diseases and psychoactive substances is 27.38±2.02. According to this examination, elderlies who scored higher than 23 were considered normal.

### 2. Materials for secondary outcome

The secondary outcome consisted of three components:

2.1 Evaluation of cognitive function was performed in merely five from the total of six subdomains by using a neuropsychological assessment battery.

Attention-concentration with Digit Span ForwardWorking memory with Digit Span Backward

- Secondary verbal memory with Word List Learning in Alzheimer's Disease Assessment Scale — cognitive subscale (ADAS-cog)13

- Psychomotor speed with Trail-Making Test A- Executive function with Trail-Making Test B

- Delayed recall memory with Word Recall in Alzheimer's Disease Assessment Scale — cognitive subscale (ADAS-cog)<sup>13</sup>

- Visuoconstructional-perceptional ability with Constructional praxis in Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog)
- Language fluency with Letter and Category Fluency Test
- 2.2 Assessment of Elderlies' Quality of Life was composed of
- Thai Geriatric Depression Scale-15 (TGDS-15)
- Older People's Quality of Life Questionnaire (OPQOL-Brief)

#### References



References.pdf

# **Troubleshooting**

# Safety warnings



No safety warnings



## Before start

#### - Target Population

Thai elderly people with the minimum age of 55 years in the elderly center or the Center of the Development of Quality of Life for the Elderly who were not diagnosed with dementia or mild cognitive impairment (MCI)

#### - Population to be studied

Thai elderly people with the minimum age of 55 years in the elderly center or the Center of the Development of Quality of Life for the Elderly who were literate and not diagnosed with dementia or MCI and participate in activities held by the elderly center.

#### - Sample

Thai elderly people with the minimum age of 55 years who joined activities at the elderly center showed interest and willingness in being part of the study. Criteria for sample selection are as follows.

#### Inclusion criteria

- 1. Those who are ≥ 55 years old.
- 2. Those who are members of the elderly center/club.
- 3. Those who show a willingness to participate in the study.

#### Exclusion criteria

- 1. Those whose education level is lower than six years of education.
- 2. Those who have a visual disorder cannot see with glasses on.
- 3. Those who even with hearing aids have hearing difficulties that impair their communication.
- 4. Those who have been a member of the elderly center/ club for shorter than three months.
- 5. Those who have compromised intellect and possess the Thai Mental Status Examination (TMSE)8 score of < 24.
- 6. Those who are diagnosed with dementia based on DSM-54 and the National Institute on Aging5 and have Clinical Dementia Rating Scale (CDR) ≥ 1.
- 7. Those who are diagnosed with MCI based on DSM-54 and the National Institute on Aging7 and have Clinical Dementia Rating Scale (CDR) of 0.5.
- 8. Those who are currently diagnosed with all substance use disorders except tobacco and caffeine use disorder based on DSM-5.
- 9. Those who are diagnosed with neurological disorders are stroke, epilepsy, and Parkinson's disease.
- 10. Those who are diagnosed with major psychiatric disorders, for instance, psychotic disorders, bipolar disorders, and major depressive disorders are based on DSM-5.
- 11. Those who use benzodiazepine every day
- 12. Those who use anticholinergics every day
- 13. Those who use Acetylcholinesterase inhibitor (AChEI) every day.



14. Those who use N-methyl D-aspartate (NMDA) receptor antagonists every day.

#### Criteria for Setting

Eligible participants were recruited at the Senior Society of Nonthaburi Municipality, Bangkok, Thailand due to its following qualities:

- 1. It was a place established to improve the quality of life and promote the career of the Thai elderly.
- 2. It was located in the area of Bangkok Metropolitan or its vicinity.
- 3. It had approximately 200 members who were at least sixty years old. This number was sufficient for the volunteer recruitment in this study. (Based on the participation rate at 50%)
- 4. It had an activity room that could accommodate at least 50 people.

#### - Sample size

The sample size was estimated using a 1:1 ratio 2–sample parallel RCT with a continuous outcome.

The statistical significance level of  $\alpha = 0.05$ 

The power ( $\beta$ ) was set at 0.80

When values were substituted in the formula,  $\mu$ \_con, the mean of TMSE in normal elderlies obtained from the literature review, was 27.80 and  $\sigma$  was 1.57.

The effect size was set at 1.0 (difference of the mean of TMSE between the treatment and control group). According to this formula, the number of each arm was 39; however, the author prevented the loss of follow-ups on the participants by increasing the sample size by 10 percent. As a result, the final sample size per arm was 44.

## 1. Materials for primary outcome

The primary outcome was the evaluation of global cognitive function with the use of the Thai Mental Status Examination (TMSE), of which total score is 30 and is divided into six categories: orientation (score of 6), registration (3), attention (5), calculation (3), language (10), and recall (3). The average total score among Thai elderlies (60-70 years old) who are free from underlying diseases and psychoactive substances is 27.38±2.02. According to this examination, elderlies who scored higher than 23 were considered normal.

## 2. Materials for secondary outcome

The secondary outcome consisted of three components:

- 2.1 Evaluation of cognitive function was performed in merely five from the total of six subdomains by using a neuropsychological assessment battery.
- Attention-concentration with Digit Span Forward
- Working memory with Digit Span Backward
- Secondary verbal memory with Word List Learning in Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog)13
- Psychomotor speed with Trail-Making Test A
- Executive function with Trail-Making Test B
- Delayed recall memory with Word Recall in Alzheimer's Disease Assessment Scale cognitive subscale (ADAScog)13



- Visuoconstructional-perceptional ability with Constructional praxis in Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog)
- Language fluency with Letter and Category Fluency Test
- 2.2 Assessment of Elderlies' Quality of Life was composed of
- Thai Geriatric Depression Scale-15 (TGDS-15)
- Older People's Quality of Life Questionnaire (OPQOL-Brief)
- Identification of the Study End Point

This project lasted 24 weeks (6 months) with two points of time when the outcome was investigated.

- 1. In the 12th week of the study, when the participants in the control group received their last CTs, both primary and secondary outcomes were measured to point out their immediate effect.
- 2. In the 24th week when the participants in the treatment group received their last CT, both primary and secondary outcomes are examined to see it sustain effect of CT. However, between the 12th and the 24th week, no CTs were arranged.
- Statistical method
- 1. Data analysis with descriptive statistics was implemented to analyze the participants' personal data, which were frequency and percent. In case the data showed normal distribution, mean, standard deviation (SD), 95% confidence interval (95% CI) were applied; whereas when the data were irregularly distributed, median and interquartile range (IQR) were used instead.
- 2. Comparative analysis of primary outcome and secondary outcome in the treatment and control group was carried out using an independent sample t-test because the study aimed to measure the resulting mean of the cognitive function of the two groups: the treatment group who received CT and the wait-list control group.
- 3. The comparison between the primary and secondary results was performed twice, in the third and sixth month, to examine the treatment effect (immediate effect) and carryover effect (sustained effect) respectively.
- 4. When some participants terminated their participation or missed their follow-ups or appointments, Intention-To-Treat (ITT) analysis was carried out in comparison with Per-Protocol analysis (PP) based on the data of all participants who passed the screening and were selected as the control group regardless of their study protocol completion.



# Study design

- 1:1 ratio 2-arm parallel single-blinded intervention randomized controlled trial study design (RCT) with a single-blinded assessor.
  - All cognitive function outcomes were assessed by trained blinded psychologists not involved in the recruitment process and experimental phase.
  - Study Endpoint Classification: Efficacy Study
  - Intervention Model: Parallel
  - Number of Arms: 2

## 1.1 Allocation

- Randomized controlled trial, Block of four techniques

#### 1.2 **Arm 1**

- Intervention Name: Cognitive training program + usual recreational group activities
- Type: Experimental
- Classification: Cognitive + behavioral intervention
- Descriptions: The CTI referred to a non-pharmacological intervention that involved a kind of restorative strategy to improve cognitive performance in healthy elderly. The exercises in the CTI for this study combined 6 cognitive functions (i.e. complex attention, executive function, learning and memory, language, visuoconstruction-perceptual ability, and social cognition). The CTI was implemented twice per week with 30 minutes allocated to each session (24 sessions in 12 weeks). The sessions were led by the author who guided the participants through each activity systematically. Each session comprised of 8 sections of 3-minutes each following the same format:1) check-in and introduction, 2) cognitive domain practices (6 sections), and 3) summary and feedback section. There was a 1-minute break after each section ended to enable participants to recover. The CTI was run by an audio-visual digital video disk created by the authors which explained instruction and demonstration in each lesson and involved an individual paper-pencil workbook. The CTI employed speed tests, matching activities, gap completion, and short-answer questions.

#### 1.3 **Arm 2**

- Intervention Name: Wait-list group
- Type: Usual recreational group activities
- Classification: Behavioral intervention
- Descriptions: Wait-list groups voluntarily attended additional activities following a regular schedule at the elderly center such as aerobic exercises, ballroom dance, folk Thai dance, fitness drills, yoga, Tai Chi, Karaoke, musical instrument lessons, Mandarin-Chinese or English lessons, and practice with dharma and meditation.

## 1.4 Objectives/ Hypothesis/ Assumption



Primary objective: To investigate how cognitive training intervention affects cognitive function in the elderly with normal cognitive function.

Hypothesis: The elderly whose cognitive function is normal and undergoes cognitive training possess more competent cognitive function performance than those with normal cognitive function but receive no cognitive training.

#### Assumption:

- 1. All participants understand and sincerely answer all questions.
- 2. The present study determines that a cognitive training program (CT) is the only available restorative strategy.

#### 2 -Investigational product, dosage & route of administration

The CTI is referred to as a non-pharmacological intervention that involves a kind of restorative strategy to improve cognitive performance in the healthy elderly. The exercises in the CTI for this study combined six cognitive functions (i.e., complex attention, executive function, learning and memory, language, visuoconstructionperceptual ability, and social cognition ).

The CTI was implemented twice per week with 30 minutes allocated to each session (24 sessions in 12 weeks).

The sessions were led by the author who guided the participants through each activity systematically.

Each session comprised eight three-minute sections and followed the same format:1) check-in and introduction, 2) cognitive domain practices (6 sections), and 3) summary and feedback section. There was a one-minute break after each section to enable participants to recover. The CTI was run by an audio-visual digital video disk created by the authors which explained instruction and demonstration in each lesson and involved an individual paper-pencil workbook. The CTI employed speed tests, matching activities, gap completion, and short-answer questions.

#### -Comparator, dosage & mode of administration

The comparator was the participants in the control group who were also in the waitlist control group. While on the waitlist, the participants in the control group were still able to join all the activities held by the elderly club.

Introduction (3 minutes): - Check-in and instuction - Breathing exercise and grounding Cognitive domain practices (24 minutes): comprised of 6 sections, 3 minutes per section and 1-minute break after each section; 1) complex attention  $\Rightarrow$  break  $\Rightarrow$  2) executive function  $\Rightarrow$  break  $\Rightarrow$  3) learning and memory ightarrow break ightarrow 4) language ightarrow break ightarrow 5) visuoconstructional-perceptual ability ightarrow break ightarrow6) social cognition Wrap-up and Feedback (3minutes)

Figure 2 Cognitive training intervention (CTI) protocol.

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Cognitive training intervention (CTI) protocol.

А	В
Cognitive functions	Exercises
1. complex attention	· Speed tests, catching the errors
2. executive function	· Problem-solving task, matching game

1



А	В
3. learning and memory	· Match-up game, gap completion
4. language	· Reading short passages and answering the questions
5. visuoconstruction- perceptual ability	· Counting cube
6. social cognition	· Topic discussion

The exercises targeted 6 cognitive functions

#### 3 Sample size

The sample size was estimated using a 1:1 ratio 2-sample parallel RCT with the continuous outcome; 2 tailed test.

The statistical significance level of  $\alpha = 0.05$ 

The power ( $\beta$ ) was set at 0.80

When values were substituted in the formula, the mean of TMSE in normal elderlies obtained from the literature review, was 27.80 and SD was 1.57.

The effect size was set at 1.0 (difference of the mean of TMSE between the treatment and control group). According to this formula, the number of each arm was 39; however, the author prevented the loss of follow-ups on the participants by increasing the sample size by 10 percent. As a result, the final sample size per arm was 44.

#### 4 **Conceptual Framework**



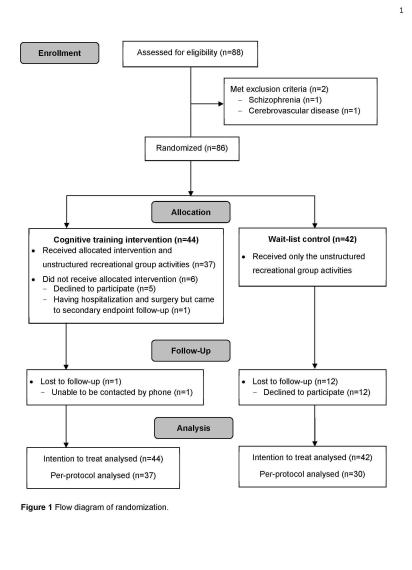
Conceptual Framework Healthy Elderly Cognitive training program (CT) Post-test\*\* at 3<sup>rd</sup> month Post-test\*\* at 6th month Demographic characteristic: age, sex, education etc. Cognitive function Cognitive function Cognitive function Instrumental Activities of daily living (IADL) (R\* Clinical characteristic: Underling diseases, Medication Instrumental Activities of daily living (IADL) • Instrumental Activities of daily living (IADL) Wait-list Quality of life (QoL) control (WC) Quality of life (QoL) Quality of life (QoL)

Remark \* R. Block of four randomization; \*\* 1:1 ratio 2-arm parallel single-blinded intervention RCT (All cognitive function outcomes were assessed by trained blinded psychologists not involved in the recruitment process and experimental phase.)

## Conceptual Framework

# **Enrollment**

#### 5 **Assessed for eligibility**



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Flow diagram of randomization.

#### 5.1 Inclusion criteria

- 1. Those who are  $\geq$  55 years old.
- 2. Those who are members of the elderly center/club.
- 3. Those who show a willingness to participate in the study.

#### 5.2 Exclusion criteria

- 1. Those whose education level is lower than six years of education.
- 2. Those who have a visual disorder cannot see with glasses on.



- 3. Those who even with hearing aids have hearing difficulties that impair their communication.
- 4. Those who have been a member of the elderly center/ club for shorter than three months.
- 5. Those who have compromised intellect and possess the Thai Mental Status Examination (TMSE) score of < 24.
- 6. Those who are diagnosed with dementia based on DSM-5 and the National Institute on Aging and have clinical Dementia Rating Scale (CDR)  $\geq$  1.
- 7.Those who are diagnosed with MCI based on DSM-5 and the National Institute on Aging 7 and have Clinical Dementia Rating Scale (CDR) 6 of 0.5.
- 8. Those who are currently diagnosed with all substance use disorders except tobacco and caffeine use disorder based on DSM-5<sup>9,10</sup>.
- 9. Those who are diagnosed with neurological disorders are stroke, epilepsy, and Parkinson's disease.
- 10.Those who are diagnosed with major psychiatric disorders, for instance, psychotic disorders, bipolar disorders, and major depressive disorders are based on DSM-5<sup>9</sup>.
- 11. Those who use benzodiazepines every day
- 12. Those who use anticholinergics every day
- 13. Those who use Acetylcholinesterase inhibitor(AChEI) every day.
- 14. Those who use N-methyl D-aspartate (NMDA) receptor antagonists every day.

## 5.3 Criteria for Setting

Eligible participants were recruited at the Senior Society of Nonthaburi Municipality, Bangkok, Thailand due to its following qualities:

- 1.It was a place established to improve the quality of life and promote the career of the Thai elderly.
- 2. It was located in the area of Bangkok Metropolitan or its vicinity.
- 3.It had approximately 200 members who were at least sixty years old. This number was sufficient for the volunteer recruitment in this study. (Based on the participation rate at 50%)
- 4.It had an activity room that could accommodate at least 50 people.

# **Expected results**

## 6 Expected results

In this research study, two outcomes were identified: primary and secondary outcome with the use of several tools as follows.



- 1) The primary outcome measured global cognitive function by employing the Thai Mental State Examination (TMSE), a neuropsychiatric test for standard mental status examinations for the Thai elderly. The total score of the TMSE is 30 points and the cut-off point for the diagnosis of normal (healthy) Thai elderly is over 23 points.

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#### 2) The secondary outcomes:

a. Eight cognitive subdomains: the neuropsychological assessment battery was used to evaluate the 8 cognitive subdomains

Cognitive subdomain	Test	Instruction	
1. Attention-concentration	Digit Span Forward	"I am going to say some numbers and when I am through, repeat them to me	
		exactly as I said them".	
		Example:	
		3-8-6	
		5-1-2	
		3-4-1-7	
		6-1-5-8	
		8-4-2-3-9	
2. Working memory	Digit Span Backward	"I am going to say some more numbers, but when I am through you must repeat	
		them to me in the backward order."	
		Example:	

## Outcome measurements (1)

		5-1
		2-8
		9-4-6
		7-3-5
		8-3-5-9
3. Verbal memory	Word List Learning of	The subject is given three trials to learn a list of high-frequency, high imagery
	Alzheimer's Disease	nouns. The 10 words are printed in block letters on white cards.
	Assessment Scale —	Use the word cards that match the word list for each visit. The word list should
	cognitive subscale (ADAS-	be identified prior to each visit by reviewing the study case report forms.
	cog): Thai version	For each word, indicate on the case report form if the subject did or did not
		remember it.
		At the start of the first trial, the tester gives the following instructions verbatim:
		"I am going to show you some words printed on these cards one at a time.
		Please read each word out loud and try to remember it, because later I will ask
		you to try to remember all of the words I have shown you. Ready? Read the
		word and try to remember it."
		After the presentation, the tester asks the subject to try to recall as many of the
		words as possible by saying: "Good, now tell me all the words you can
		remember."
		Two more learning and recall trials follow.
		Example: เลือด ค่าย ถ้าถี ไฟ ดีก

## Outcome measurements (2)

		At the end of the third trial, inform the subject that (s)he will be asked to reca these words again by saying, "I will ask you to recall those words again at the end of the test."	
4. Psychomotor speed	Trail-Making Test A	"Please draw a line, going from a number to a number in ascending order.  Begin here [point to (1)] and to the end. End here [point to (8)]  Example:  7  8  13119711  4  3	
5. Executive function	Trail-Making Test B	"Please draw a line, going from a number to a letter in ascending order. Be here [point to (1)] and draw a line from 1 then to 0 then to 2 and so on. En here [point to (4)] Example:	

# Outcome measurements (3)

		্র ক্রমণার নি ক্রমণার নি ক্রমণার বা
Visuoconstructional- perceptional ability	Constructional praxis of Alzheimer's Disease Assessment Scale — cognitive subscale (ADAS- cog)	This test assesses the subject's ability to copy 4 geometric forms ranging from a very simple one (circle) to a fairly difficult one (cube).  The forms should be presented one at a time in the following order. Circle → Two Overlapping → Rectangles Diamond (Rhombus) → Cube  The tester should give the subject a lead pencil with an eraser along with the first drawing.  The tester says the following instructions verbatim to the subject: "On this piece of paper is a shape. Try to draw another one that looks just like this, somewhere on the page." (Tester may point to the shape.)  The figures must be presented one at a time. At the completion of each drawing, remove the completed form from the table and then present the next figure to the subject.  Figures:

# Outcome measurements (4)



7. Delayed recall memory Word List Learning of The examiner gives the following instruction: "You read some words earlier. Alzheimer's Disease which I asked you to remember. Tell me as many of those words as you can Assessment Scale remember. cognitive subscale (ADAScog): Thai version 8. Language fluency Letter "S "Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns, numbers, or words that begin with the same sound but have a different suffix. I will tell you to stop after one minute. Now, tell me as many words as you can think of that begin with the letter S. .... [time for 60 sec]....Stop.3

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## Outcome measurements (5)

## 6.1 -Primary outcome

The primary outcome was the evaluation of global cognitive function with the use of Thai Mental Status Examination (TMSE), of which total score is 30 and is divided into six categories: orientation (score of 6), registration (3), attention (5), calculation (3), language (10), and recall (3). The average total score among Thai elderlies (60-70 years old) who are free from underlying diseases and psychoactive substances is 27.38±2.02. According to this examination, elderlies who scored higher than 23 were considered normal.

## 6.2 -Secondary outcome

The secondary outcome consisted of three components:

- 1.Evaluation of cognitive function was performed in merely five from the total of six subdomains by using a neuropsychological assessment battery.
- 1.1 Attention-concentration with digit Span Forward
- 1.2 Working memory with digit Span Backward
- 1.3 Secondary verbal memory with word List Learning in Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog)
- 1.4Psychomotor speed with trail-Making Test A
- 1.5 Executive function with trail-Making Test B



- 1.6 Delayed recall memory with word Recall in Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog)
- 1.7 Visuoconstructional-perceptional ability with Constructional praxis in Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-cog)
- 1.8 Language fluency with letter and Category Fluency Test

## 6.3 Assessment of Elderlies' Quality of Life was composed of

- Thai Geriatric Depression Scale-15 (TGDS-15)
- Older People's Quality of Life Questionnaire (OPQOL-Brief)

6

#### b. Psychosocial outcomes

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Secondary outcomes: Psychosocial outcome measurements

## 7 Identification of the Study End Point

This project lasted 24 weeks (6 months) with two points of time when the outcome was investigated.

- 1. In the 12th week of the study, when the participants in the control group received their last CTs, both primary and secondary outcomes were measured to point out their immediate effect.
- 2. In the 24<sup>th</sup> week when the participants in the treatment group received their last CT, both primary and secondary outcomes are examined to see it sustain effect of CT. However, between the 12<sup>th</sup> and the 24<sup>th</sup>week, no CTs were arranged.



37

ตารางที่ 2 ขั้นตอนการดำเนินการศึกษาทดลอง

Visit ที่ 1; Wk ที่ 0	Pre-test ได้แก่ TMSE, L-IAD	DL, TGDS และ OPQOL-Brief	
	Randomization		
เริ่มการทดลอง	กลุ่ม Intervention	กลุ่ม Control	
Visit ที่ 2; Wk ที่ 1	CTI	WC	
Visit ที่ 3; Wk ที่ 1	CTI	WC	
Visit ที่ 4; Wk ที่ 2	CTI	WC	
Visit ที่ 5; Wk ที่ 2	CTI	WC	
Visit ที่ 6; Wk ที่ 3	СТІ	WC	
Visit ที่ 7; Wk ที่ 3	CTI	WC	
Visit ที่ 8; Wk ที่ 4	CTI	WC	
Visit ที่ 9; Wk ที่ 4	CTI	WC	
Visit ที่ 10; Wk ที่ 5	CTI	WC	
Visit ที่ 11; Wk ที่ 5	CTI	WC	
Visit ที่ 12; Wk ที่ 6	CTI	WC	
Visit ที่ 13; Wk ที่ 6	CTI	WC	
Visit ที่ 14; Wk ที่ 7	CTI	WC	
Visit ที่ 15; Wk ที่ 7	CTI	WC	
Visit ที่ 16; Wk ที่ 8	СТІ	WC	
Visit ที่ 17; Wk ที่ 8	CTI	WC	
Visit ที่ 18; Wk ที่ 9	CTI	WC	
Visit ที่ 19; Wk ที่ 9	CTI	WC	
Visit ที่ 20; Wk ที่ 10	CTI	WC	
Visit ที่ 21; Wk ที่ 10	CTI	WC	
Visit ที่ 22; Wk ที่ 11	CTI	WC	
Visit ที่ 23; Wk ที่ 11	CTI	WC	
Visit ที่ 24; Wk ที่ 12	CTI	WC	
Visit ที่ 25; Wk ที่ 12	CTI	WC	
Visit ที่ 26; Wk ที่ 12	1 <sup>st</sup> End Point TMSE, Neurops	ychological assessment, TGDS	
	และ OPQOL-Brief		
ระหว่าง Wk ที่ 13 – 23	ไม่ได้รับ CTI แต่เข้าร่วม	เข้าร่วมกิจกรรมในชมรม	
	กิจกรรมในชมรมผู้สูงอายุ	ผู้สูงอายุตามปกติ	
	ตามปกติ		
Visit ที่ 27; Wk ที่ 24	2 <sup>nd</sup> End Point TMSE, Neuropsychological assessment		
		OL-Brief	

หมายเหตุ CTI = Cognitive training intervention;

WC = Wait-list control เข้าร่วมกิจกรรมในชมรมผู้สูงอายุตามปกติระหว่างสัปดาห์ที่ 1-12

Experimental phase, Primary and Secondary Endpoint Measurement