THE EFFECTS OF THE ORAL EXERCISES ON THE ORAL FUNCTION OF PEOPLE WITH DEMENTIA

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ผลของการออกกำลังในช่องปากต่อการทำหน้าที่ในช่องปากของผู้ที่มีภาวะสมองเสื่อม

น.ส.ขวัญฤทัย สมศักดิ์

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ขวัญฤทัย สมศักดิ์ : ผลของการออกกำลังในช่องปากต่อการทำหน้าที่ในช่องปากของผู้ที่มีภาวะสมองเสื่อม. (THE EFFECTS OF THE ORAL EXERCISES ON THE ORAL FUNCTION OF PEOPLE WITH DEMENTIA) อ.ที่ปรึกษาหลัก : รศ. ทญ. ดร.อรพินท์ โคมิน, อ.ที่ปรึกษาร่วม : รศ. นพ.สุขเจริญ ตั้งวงษ์ไชย

การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาผลของการออกกำลังในช่องปากที่บ้านต่อการทำหน้าที่ในช่องปากของผู้ที่มีภาวะสมองเสื่อมระดับเล็กน้อยถึงปานกลาง โดยผู้ป่วยที่มีภาวะสมองเสื่อมระดับเล็กน้อยถึงปานกลาง ณ โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย ที่ได้รับการสุ่มให้อยู่ในกลุ่มทดลอง (11 คน) ได้รับคำสั่งให้ออกกำลังในช่องปากที่บ้าน 3 อย่าง เป็นเวลา 3 เดือน ในขณะที่กลุ่มควบคุม (11 คน) ไม่ได้ออกกำลังในช่องปากใด ๆ อาสาสมัครได้รับการประเมินการทำหน้าที่ในช่องปาก อันได้แก่ ความดันลิ้นสูงสุด อัตราการขยับลิ้นและริมฝีปากหรืออัตราออรัล ไดอะโดโคไคนีซิส (โอดีเค) การกลืนและความชื้นในช่องปาก ก่อนเริ่มการศึกษาและเมื่อสิ้นสุด 1, 2 และ 3 เดือน นอกจากนี้ อาสาสมัครยังได้รับการประเมินภาวะโภชนาการ อันได้แก่ การวัดเส้นรอบวงแขน เส้นรอบวงน่อง ดัชนีมวลกาย และแบบคัดกรองภาวะโภชนาการฉบับย่อ ก่อนเริ่มการศึกษาและภายหลัง 3 เดือน จากนั้นทำการวิเคราะห์ทางสถิติโดยใช้ข้อมูลของอาสาสมัคร 19 คน (กลุ่มทดลอง 10 คน และกลุ่มควบคุม 9 คน) ที่ได้รับการประเมินครั้งสุดท้ายอย่างครบถ้วน ผลการศึกษาพบว่า ความดันลิ้นสูงสุดและอัตราการขยับลิ้นและริมฝีปากในกลุ่มทดลองมีค่าเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติหลังจากออกกำลังในช่องปากเป็นเวลา 3 เดือนและพบอิทธิพลปฏิสัมพันธระหว่างเวลาและการออกกำลัง อย่างไรก็ตาม ไม่พบอิทธิพลปฏิสัมพันธต่อความชื้นในช่องปาก และการกลืนในทั้ง 2 กลุ่มไม่เปลี่ยนแปลงตลอดการศึกษา นอกจากนี้ ยังพบว่าเส้นรอบวงแขน เส้นรอบวงน่อง และดัชนีมวลกายในกลุ่มทดลองมีค่าเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติหลังจาก 3 เดือนและพบอิทธิพลปฏิสัมพันธระหว่างเวลาและกลุ่ม ความร่วมมือในการออกกำลังโดยรวมคิดเป็นร้อยละ 96.5 โดยความร่วมมือในการออกกำลังมีความสัมพันธ์แบบแปรผกผันกับอายุอย่างมีนัยสำคัญทางสถิติ และไม่พบการรายงานผลข้างเคียงที่สำคัญจากการศึกษา การศึกษานี้สรุปได้ว่า การออกกำลังในช่องปากที่บ้านสามารถเพิ่มความแข็งแรงของลิ้นและการเคลื่อนไหวของลิ้นและริมฝีปากในผู้ที่มีภาวะสมองเสื่อมระดับเล็กน้อยถึงปานกลาง โดยผู้ดูแลที่ได้รับการสอนให้ควบคุมการออกกำลังมีความสำคัญอย่างมากต่อการประสบผลสำเร็จของการออกกำลังในช่องปาก

สาขาวิชา ทันตกรรมประดิษฐ์ ลายมือชื่อนิสิต .....

ปีการศึกษา 2564 ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

ลายมือชื่อ อ.ที่ปรึกษาร่วม .....

6076051232 : MAJOR PROSTHODONTICS

KEYWORD: ORAL EXERCISE / ORAL FUNCTION / DEMENTIA

Kwanrutai Somsak : THE EFFECTS OF THE ORAL EXERCISES ON THE ORAL FUNCTION OF PEOPLE WITH DEMENTIA. Advisor: Assoc. Prof. ORAPIN KOMIN, D.D.S., Ph.D. Co-advisor: Assoc. Prof. SOOKJAROEN TANGWONGCHAI, M.D.

The objective of this study was to examine the effects of the home-based oral exercises on the oral function in people with mild to moderate dementia. The patients with mild to moderate dementia at King Chulalongkorn Memorial Hospital, who were randomly allocated to an experimental group (n = 11), were asked to perform 3 home-based oral exercises for 3 months while those in a control group (n = 11) did not do any oral exercises. The oral function including maximum tongue pressure (MTP), oral diadochokinesis (ODK) rates of /ta/, /ka/, /pa/, swallowing function (modified water swallowing test: MWST), and oral moisture were evaluated at baseline and at the end of the 1st, 2nd, and 3rd months. In addition, the nutritional status including the mid-upper arm circumference (MUAC), calf circumference (CC), body mass index (BMI), and the Mini Nutritional Assessment-Short Form were evaluated as consequences of changed oral function at baseline and after 3 months. The data of 19 participants (10 in the experimental group and 9 in the control group), who were completely evaluated at the end-point visit, were analyzed. The results showed that the MTP and ODK rates of /ta/, /ka/, and /pa/ in the experimental group improved significantly after the 3-month program, with notable interaction effects between time and intervention. Nevertheless, there was no significant interaction effect on the oral moisture, and the MWST scores in two groups were unchanged. Furthermore, after 3 months, the MUAC, CC, and BMI in the experimental group increased significantly, with notable interaction effects between time and groups. The total exercise compliance rate was 96.5%. The compliance was significantly negatively correlated with age. There was no reported serious adverse event. In conclusion, the home-based oral exercises performed in this study could improve the tongue strength and motor function of tongue and lips in people with mild to moderate dementia. The caregivers, who were trained to control the exercises, were crucial to the success of the oral exercises.

Field of Study: Prosthodontics

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Student's Signature .....

Advisor's Signature .....

Co-advisor's Signature .....

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Kwanrutai Somsak

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LIST OF ABBREVIATIONS

(Sorted in alphabetical order)

AD	-	Alzheimer's disease
ADL	-	Activities of daily living
BAI	-	Barthel Activity of Daily Living Index
BMI	-	Body mass index
BPSD	-	Behavioral and psychological symptoms of dementia
CC	-	Calf circumference
CDR	-	Clinical Dementia Rating
DLB	-	Dementia with Lewy bodies
EAT-10	-	10-item Eating Assessment Tool
FTD	-	Frontotemporal dementia
GEE	-	Generalized Estimating Equation
ICC	-	Intraclass Correlation Coefficient
JOF	-	Jaw-opening force
JSG	-	Japanese Society of Gerodontology
MCI	-	Mild cognitive impairment
MMSE	-	Mini-Mental State Examination
MNA®	-	Mini Nutritional Assessment

MNA®-SF	-	Mini Nutritional Assessment-Short Form
MoCA	-	Montreal Cognitive Assessment
MTP	-	Maximum tongue pressure
MUAC	-	Mid-upper arm circumference
ODK	-	Oral diadochokinesis
OHRQoL	-	Oral health-related quality of life
PDD	-	Parkinson’s disease with dementia
TCI	-	Tongue Coating Index
TP	-	Tongue pressure
VaD	-	Vascular dementia

CHAPTER I
INTRODUCTION

Background and Rationale

Nowadays, the number of elders in populations has been increasing dramatically.[1] In 2020, older people aged 60 years and older was 14% of the global population.[2] In Thailand, the Situation of the Thai Elderly 2020 presented that older people aged 60 years and older were 18.1% of total Thai population.[2] This data indicates that Thailand has become an aging society and will be an aged society in the near future.

Elderly people have faced several health problems. One of them is cognitive impairment or dementia. Neurodegenerative diseases are the most common causes of dementia, which leads to the problems in memory, thinking, cognitive function, capacity to perform activities in daily life, and behavior.[3-8]

People with dementia could have decreased oral function. Therefore, they can have eating, swallowing, and nutritional problems.[9] The consequences are general health problems (e.g., aspiration pneumonia), nutritional problems, low quality of life, and the needs of long-term nursing care.[10-12] People with dementia or cognitive impairment could have decreased oral function, such as decreased swallowing function, salivary gland function, maximum bite force, and tongue-lip motor function.[9, 13-15] Moreover, it was presented that cognitive function was related to some oral functions, such as maximum tongue pressure (MTP), maximal occlusal force, motor function of tongue, and masticatory ability.[15-18] The oral function can be evaluated by assessing the MTP, swallowing function, occlusal force, tongue-lip motor function, masticatory function, oral hygiene, and oral moisture.[12]

The structure which is very important in the processes of mastication, swallowing, and speech, is the tongue.[19, 20] The movement of the tongue is activated by intrinsic tongue muscles, extrinsic tongue muscles, and suprahyoid muscles.[21] The tongue function, including tongue strength, movement, and coordination, is important in the masticatory process.[22] It should be evaluated for maintaining the eating ability and swallowing rehabilitation.[23] The assessment of the tongue function includes tongue strength, speed, endurance, and power.[21] The most common assessment is the tongue pressure (TP) which quantifies the tongue strength. The TP influences the oral function, swallowing, and dysphagia.[24, 25]

The swallowing problem solving might be alternation of nutritional intake methods (e.g., enteral tube feedings), or modification of diet texture (e.g., pureed foods or thickened liquids).[26, 27] However, those methods could negatively affect the patients' quality of life. Some of them did not like the feel and taste of thicken liquids (e.g., thickened water, thickened coffee, and thickened juice) and felt that their thirst is not quenched.[26] They were likely to inadequate fluid intake, dehydration, and inadequate nutritional intake.[26, 28] Therefore, there are attempts to discover the treatment which can improve the swallowing without those modification. It was shown that oral exercises could provide the improvement of oral function.[29] At present, there are no established standard protocols for the oral exercises. Several studies determined the influences of the oral exercise on the oral function with varied training protocols.[21, 28-61] Unfortunately, almost half of these studies excluded the people with cognitive problems or dementia. The researchers considered that people with cognitive problems or dementia could not follow the exercise protocols due to their cognitive problems.[30, 45] When considering the other half of these studies, some of them were conducted in healthy young adults or healthy seniors who did not suffer from dementia. This evidence indicated that the

people with dementia might lack opportunities to get the effective oral exercises in order to improve their decreased oral function.

To the best of the researcher's knowledge, there are two research evaluated the effects of oral exercise on the oral function in patients with cognitive impairment or dementia. One of them did not present significant changes in oral function after training.[59] The other one showed significant improvement in MTP after training.[49] However, that study lacked a control group, and the exercise consisted of face-to-face training sessions administered by the professional and used a special device.[49] Hence, the people might not be able to perform that exercise regularly in daily lives.

Therefore, this research was conducted to examine the effects of home-based oral exercises on the oral function in people with mild to moderate dementia in the aspects of MTP, tongue-lip motor function, swallowing function, and oral moisture. In addition, the history of swallow and nutritional status were evaluated as consequences of changed oral function.

Research Questions

Do the home-based oral exercises improve the oral function in people with mild to moderate dementia?

Research questions	Oral function
Primary research question	MTP
Secondary research questions	Tongue-lip motor function
	Swallowing function
	Oral moisture

Research Objectives

To examine the effects of the home-based oral exercises on the oral function in people with mild to moderate dementia.

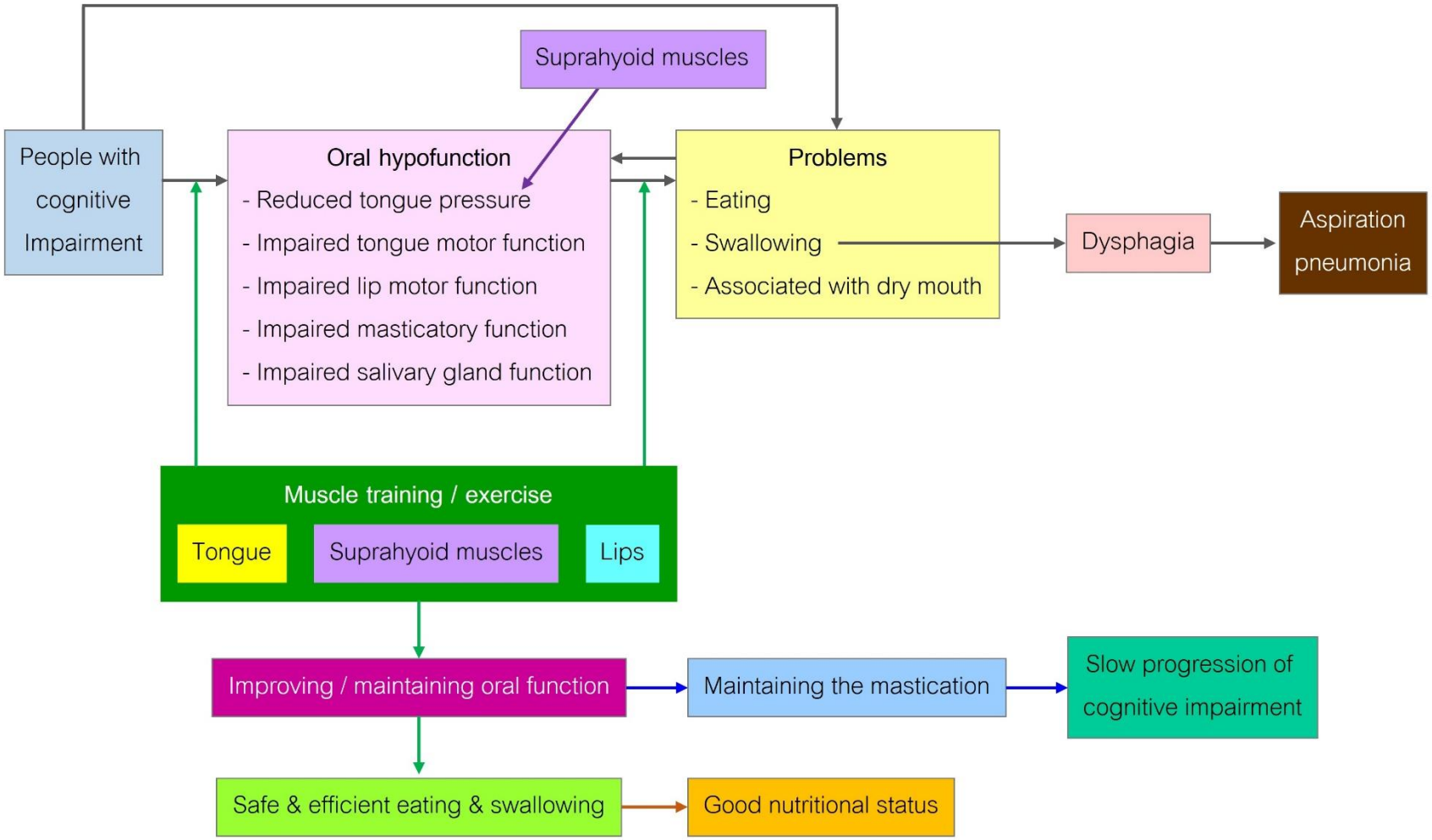
Research objectives	Oral function
Primary research objective	MTP
Secondary research objectives	Tongue-lip motor function
	Swallowing function
	Oral moisture

Research Hypotheses

The home-based oral exercises improve the oral function in people with mild to moderate dementia.

Research hypotheses	Oral function
Primary research hypothesis	MTP
Secondary research hypotheses	Tongue-lip motor function
	Swallowing function
	Oral moisture

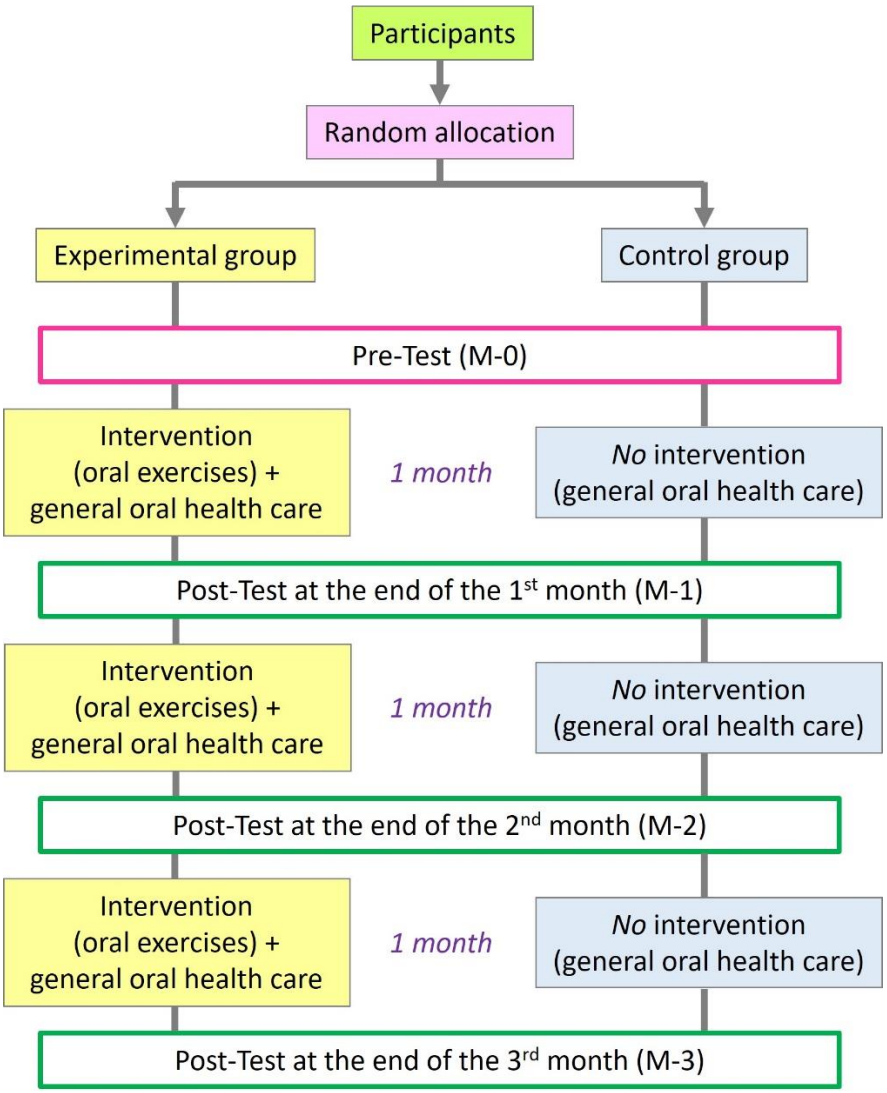
Conceptual Framework



Research Design

Experimental study

Randomized controlled trial (RCT)



Expected Outcomes of Research

1. The protocol of home-based oral exercises for improving the oral function of people with mild to moderate dementia would be recommended.

2. The oral function of people with mild to moderate dementia would be improved. The occurrence of oral hypofunction in this population would be postponed. These people with dementia would have safe and efficient eating and swallowing, and the chance of aspiration pneumonia would be reduced. Finally, these people would have good quality of life.

3. The results of this study would reveal the status of oral function of people with mild to moderate dementia in Thailand.

4. The professionals and related persons would know the factors affecting oral function of people with mild to moderate dementia.

5. The results of this study might shed light on the useful information to develop and improve the policy, strategy, and treatment plan in order to enable people with dementia to have good oral function. The consequences are safe and efficient eating and swallowing, and good quality of life.

6. The results of this study would be useful for future studies.

CHAPTER II
LITERATURE REVIEW

1. Elderly Population

Globally, the number of elders in populations has been increasing dramatically.[1] In 2020, older people aged 60 years and older was 14% of the global population.[2] This proportion will rise to 16% in 2050.[62] The key drivers of population aging are increasing life expectancy and falling fertility rates.[63] The United Nations (UN) predicted that life expectancy at birth will rise from 64.2 years in 1990 to 72.6 years in 2019, and could rise to 77.1 years in 2050.[62]

In Thailand, the number of elders has grown rapidly.[64] In 2021, the Situation of the Thai Elderly 2020 reported that people aged 60 years and older were 18.1% of total Thai population.[2] This data indicates that Thailand has become an aging society. In this aging population, the percentage of elderly aged 60-69 years, 70-79 years, and at least 80 years was 60.3, 28.1, and 11.6, respectively.[2] When we look back on the previous to the recent national data in 2017, it was found that the number of elderly had increased continuously. The percentage of older people in 1994, 2002, 2007, 2011, 2014 and 2017 were 6.8, 9.4, 10.7, 12.2, 14.9, and 16.7, respectively.[65] It was predicted that the number of elders will rise to over 30% of the population by 2035.[64] This indicates that Thailand will soon become an aged society. The United Nations (UN) predicted that life expectancy at birth of Thai people will rise from 75.6 years in 2015-2020 to 77.5 years in 2025-2030, 81.2 years in 2045-2050, and could rise to 87.8 years in 2095-2100.[66]

2. Dementia

Cognitive impairment is one of the most common health issues faced by the elders worldwide. The prevalence of cognitive impairment increases with age. The cognitive decline in elderly adults could be classified into four states: normal cognitive decline related to aging, subjective cognitive impairment (complaint of cognitive impairment, but normal result of cognitive screening test), mild cognitive impairment (MCI), and dementia.[67]

Neurodegenerative diseases are the most common causes of dementia, which lead to declines in memory, thinking, cognitive function, capacity to perform activities in daily life, and behavior.[3-8] Furthermore, dementia is one of the leading causes of dependency and disability of the seniors.[4] People with dementia have difficulties in independent living, occupational functioning, and social functioning.[68] However, dementia is not a normal part of aging although the biggest risk factor for dementia is age.[4, 69]

2.1 Situation of Dementia

Globally, the prevalence of dementia has increased due to the expansion of elderly population.[5, 70] The total number of people who suffer from dementia in 2010, 2015, and 2017 were 35.6, 46, and 50 million, respectively. It was predicted to increase to 82 million in 2030 and 152 million in 2050.[3] Sixty-three percent of people with dementia live in low-middle-income countries while 37% of them live in high income countries. The incidence of dementia has increased with increasing age. It is from 3.1 in 1000 people aged 60-64 years to 175 in 1000 people aged 95 years and over.[71] There are over 10 million new cases each year. In other words, one new case occurs every 3.2 seconds.[72]

In 2016, dementia was the 5th leading cause of death worldwide and in upper-middle-income countries. Furthermore, it was the 3rd leading cause of death in high-income countries.(73)

In Thailand, the prevalence of Thai people with dementia increases with increasing age. According to the 5th Thai National Health Examination Survey in 2014, Thai people with dementia was 8.1% of total aging population. The prevalence of Thai elderly with dementia is shown in Table 1.(74)

Table 1 The prevalence of Thai elderly with dementia in 2014(74)

Age (years)	Prevalence (%)		
	Male	Female	Total
60-69	5.2	4.5	4.8
70-79	7.1	8.2	7.7
≥ 80	13.6	28.5	22.6
Total	6.8	9.2	8.1

In 2021, the Situation of the Thai Elderly 2020 reported that the predicted number of Thai people who suffer from dementia will increase from 651,950 people in 2020 to 1,396,472 people in 2040. The percentage of persons with dementia and the predicted number of persons with dementia in Thailand are shown in Table 2.(2)

Table 2 The percentage of persons with dementia and the predicted number of persons with dementia in Thailand[2]

Age (years)	Persons with dementia (%)		The predicted number of persons with dementia (x1,000)			
			2020		2040	
	Female	Male	Female	Male	Female	Male
60-64	1.8	1.7	40	32	45	39
65-69	3.0	2.6	53	36	76	55
70-74	5.1	4.0	62	34	127	74
75-79	9.0	6.2	74	32	183	79
80-84	15.9	9.8	81	26	217	65
85-89	27.2	15.0	77	19	197	38
≥ 90	54.9	26.4	73	12	182	19

2.2 The Dementia

Dementia is not a disease.[75] It is a chronic, slow, and progressive syndrome.[3, 4, 68, 76] Dementia leads to declines in memory, thinking, cognitive function, capacity to perform activities in daily life, and behavior.[3-8, 68] It affects the patients' memory, orientation, thinking, judgement, problem solving, comprehension, learning capacity, calculation, language, communication, behavior, personality, emotional control, motivation, sleep, daily activities (e.g., eating, drinking and swallowing), and abilities of independent living.[3-8, 68, 75, 76] Generally, it starts with slight memory problems and finishes with severe brain damage.[76]

The risk factors of dementia are multifactorial.[75] The followings are the risk factors of dementia;

- *Age*[3, 4, 68, 76] : The greatest risk factor for dementia is age.[4] Dementia mainly affects the people over the age of 65 years, especially over 80 years.[3, 68] The risk

of dementia increases with age.[76] People under the age of 60 are at a lower risk.[3] However, the onset of dementia could be as early as 35 years old.[76]

- *Genetic factors*[3, 76] : There might be a powerful family link with dementia in some families.[76] This risk factor is more likely in people who are younger than 70 years old.[3]

- *Less educational level in early life*[75, 77, 78] : High educational level in early life and lifelong high educational accomplishment are a protective factor of dementia.[75, 77] High education in early life can delay the onset of dementia for many years.[75]

- *Hypertension*[3, 4, 75, 77, 78] : Midlife hypertension might increase the risk of dementia in late life. It is recommended that systolic blood pressure of midlife people should be controlled to 130 mmHg or lower for preventing or delaying the dementia.[77]

- *Hearing impairment*[77, 79] : Hearing impairment might cause cognitive decline by the way of decreased cognitive stimulation.[77] The cognitive performance would decrease with every 10 decibels decrease in hearing.[79] However, hearing aid use could decrease the risk of dementia from hearing loss.[77]

- *Smoking*[3, 4, 75, 77, 80] : Midlife heavy smoking could double the risk of dementia, Alzheimer's disease, and vascular dementia in more than 20 years later.[80]

- *Traumatic brain injury*[76-78] : Moderate, severe, or repeated head injury might be a risk factor of dementia.[76-78]

- *Other factors*[3, 4, 75-78] : Diabetes, hyperlipidemia, excessive alcohol consumption, obesity, lack of regular exercise, depression, sleep disturbance, unhealthy diet, low social activity, air pollution, etc.[3, 4, 75-78]

2.3 Signs and Symptoms of Dementia

The signs and symptoms of dementia vary among individuals[3, 4], depending on the influence of disease and the people's personality before being dementia.[4] The signs and symptoms can be categorized into three stages;[3, 4, 8, 68, 76, 81]

1) *Mild (early) stage:*
    - Gradual forgetfulness which interferes the daily activities, especially the learning of new material
    - Time disorientation
    - Getting lost in familiar places
    - Impaired daily performances (The patients cannot do more complicate daily activities.)

2) *Moderate (middle) stage (the longest stage):*
    - Clearer memory loss, especially the new information, such as recent events, place, people's names and faces (Only very familiar or highly learned material is retained.)
    - Getting lost at home
    - Serious handicap to independent living and needing help for personal care
    - Behavioral changes (e.g., wandering, repeated questioning, restlessness, moody)
    - Difficulties in communication (speech and language), attention, and problem solving
    - Confusion in routine activities
    - Having balance problems

3) *Severe (late) stage:*

- Serious memory loss and inability to remember new information
- Severe difficulties in recognizing close relatives and friends
- Unaware of the time and place
- Near absolute inactivity and dependence
- Behavioral changes (e.g., anger and aggressiveness)
- Difficulties in walking and communicating
- Increasing need for assisted self-care
- No response to the surroundings

Moreover, behavioral and psychological symptoms of dementia (BPSD) of all phases are abnormal motor behavior, aggression, agitation, anxiety, indifference, sleep changes, delusions, depression, etc.[3, 82]

2.4 Types of Dementia

2.4.1 Alzheimer's disease (AD)

AD is the most common type of dementia (50-75%).[3, 4, 68, 83] It is a slowly progressive illness with insidious onset. People with AD have normal attention, but impaired memory and difficulties in learning and retaining new material.[68, 83] The behavioral disorders of people with AD are depression, apathy, aggression, agitation, inappropriate language, and behavior of sexuality.[68, 83] In the severe stage, patients may have akinesia, seizures, myoclonus, and aphasia. Finally, they might die because of systemic infections related to severe incapacity.[83]

2.4.2 Vascular dementia (VaD)

VaD is the second most common type of dementia (20-30%).[3, 68] It is caused by lacking of blood supply to the brain related to thromboembolism, hemorrhage, or ischemia. It affects multiple areas of the brain, so there is variability in clinical presentation. VaD is more common among elderly patients with vascular diseases, especially in those with diabetes and high blood pressure.[3, 83] The clinical characteristics of VaD are impaired memory (but less affected than AD), depression, apathy, mood fluctuation, and stepwise deterioration of physical frailty.[68, 83]

2.4.3 Frontotemporal dementia (FTD)

FTD is found about 5-10% of dementia cases.[68] It is a slowly progressive illness with insidious onset. Its onset is earlier than AD. FTD results from atrophy of frontal and temporal lobes of the brain.[3, 83] The clinical characteristics of FTD are language difficulty, speech impairment and loss, personality and behavioral changes, lack of social tact, poor hygiene, sexual disinhibition, hyperorality or oral exploration of eatable and uneatable objects, inability to refrain from touching objects, aberrant motor behaviors, depression, apathy, and mood changes.[3, 68, 83] However, in contrast to AD, memory loss is not FTD's main characteristics. The people with FTD might have intact calculation and visuospatial skills.[3, 83]

2.4.4 Dementia with Lewy bodies (DLB)

DLB is found less than 5 percent of dementia cases.[68] It is caused by abnormal proteins (Lewy bodies) in the brain cells. The characteristics of DLB are fluctuating cognition, spontaneous motor features of parkinsonism, rigidity, tremor, bradykinesia, difficulties in executive function, attention disorganization, and visual hallucinations.[3, 68, 83]

2.4.5 Parkinson's disease with dementia (PDD)

The patients with Parkinson's disease might suffer from PDD. Its symptoms are quite similar to those of DLB.[3]

2.4.6 Mixed dementia

Mixed dementia is caused by more than one cause of dementia, usually AD and VaD.[3] It is more common in elderly people aged 90 years and older.[77]

2.5 Cognitive Screening Tests for Dementia

The cognitive screening tests for dementia are used to measure the cognitive function. Globally, the Mini-Mental State Examination (MMSE) is the most widely and frequently used cognitive screening test.[84-87] It was published in 1975, and has been translated into many languages.[85-88] The MMSE is one of the cognitive tests recommended by the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) to verify the clinical diagnosis of probable AD.[86] On the average, it takes about 5-10 minutes to administer.[85, 86] It may need less time for the healthy and young elderly people with intact cognition, and require more time for the very old persons with dementia.[85]

The MMSE covers 7 cognitive domains or function, which are orientation to time, orientation to place, registration, attention and calculation, recall, language, and visual construction.[86] Its maximum score is 30 points, and the cut-off score for dementia is less than 24 points.[85, 86]

The MMSE scores are influenced by age, education level, literacy, cultural background, language, and social class.[84-87] The patients with young age, high

education, or initial abnormality can show a ceiling effect, leading to the false negatives.[84, 87] On the other hand, the patients with old age, low education, different culture, and sensory impairment can create the false positives.[84] Therefore, the MMSE has to adjust the cut-off score for age, educational level, literacy, and language.[84, 85]

The MMSE has acceptable psychometric properties.[85] Its sensitivity and specificity are 80% and 86%, respectively.[87] However, the MMSE has poor sensitivity to MCI.[86, 88] It cannot discriminate the patients with MCI from those with dementia[87], and those with mild AD from normal patients[86].

2.6 Staging the Severity of Dementia

According to the article of Morris and John[6], the Clinical Dementia Rating (CDR) is used for staging the severity of dementia. The CDR was developed by Hughes et al. in 1982.[89] After that, in 1993, Morris and John added some information that are mostly used currently. The needed information for evaluating the CDR is from the semi-structure interview with the patients and informants, such as caregivers and relatives. The CDR evaluates the impairment in 6 cognitive categories (memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care) on a 5-point scale. The severity of dementia is categorized into five stages;[6]

- Global CDR score = 0 : No dementia
- Global CDR score = 0.5 : Questionable dementia (roughly equivalent to MCI[90])
- Global CDR score = 1 : Mild dementia
- Global CDR score = 2 : Moderate dementia
- Global CDR score = 3 : Severe dementia

The global CDR score can be determined by using the Washington University CDR-assignment algorithm via https://biostat.wustl.edu/~adrc/cdrpgm/index.html.

Furthermore, the CDR sum of boxes score, which is the more quantitative version of CDR score, can be used. It can be calculated by summing the scores from 6 categories.[6, 91, 92] Its maximum score is 18 (6x3).[91]

In Thailand, Thai version of the CDR was developed by Associate Professor Dr. Solaphat Hemrungrojn, Department of Psychiatry, Faculty of Medicine, Chulalongkorn University.

The CDR is usually used in clinical practice and research.[92] It is beneficial because of the following reasons. Firstly, it is clinically based. Secondly, all 6 categories link to the validated clinical diagnostic criteria for dementia directly.[6] Lastly, its validity and reliability is high.[6, 93]

However, it was reported that the CDR has limitation because it needs a considerable amount of data from the patient and related informant. If a trustworthy and well-informed caregiver is not available, there will be problems.[94] Therefore, Perneczky et al.[94] proposed that the MMSE can be used as a substituted method for staging the severity of dementia. Their results are presented in Table 3.[94]

Table 3 The relationship between the CDR and the MMSE scores according to the study of Perneczky et al.[94]

CDR scores	MMSE scores
0	30
0.5	26-29
1	21-25
2	11-20
3	0-10

Moreover, Feldman et al.[95] exhibited the approximate range of MMSE scores for staging the dementia severity. In their article, the people with mild, moderate, and severe dementia usually have the MMSE score of 18–26, 10–18, and 0-10, respectively.[95]

3. Oral Function of Elderly People

The oral function refers to the function of masticatory system, speaking, and psychosocial well-being.[96, 97] Its efficacy decreases with age.[29] There are several factors affecting the oral function, such as TP, the number of functional teeth, oral moisture, tongue-lip motor function, dental prostheses, degree of swallowing, temporomandibular function, and degree of mouth opening.[12, 96] The oral function can be evaluated by assessing the MTP, swallowing function, occlusal force, tongue-lip motor function, masticatory function, oral hygiene status, and oral moisture.[12]

In elderly people, one of the inevitable problems is reduction in physical abilities. Moreover, declines in motivation and interest in oral health might occur. Therefore, they could not take care of their oral health properly and effectively. The consequences are several oral problems. The oral problems commonly faced by elders are tooth loss, dental caries, periodontal disease, xerostomia, and oral precancer or oral cancer.[98-101] Therefore, ***declines in oral function*** *or* ***oral frailty***, which is frailty which shows in the oral cavity, can be found in older people. The oral frailty includes slight choking or spillage while eating, difficulty in chewing, increased number of unchewable foods, and decreased articulation.[12, 102] The oral frailty can progress to the ***oral hypofunction***, which includes decreased TP, decreased swallowing function, decreased occlusal force, decreased tongue-lip motor function,

decreased masticatory function, poor oral hygiene, and oral dryness (hyposalivation). The oral hypofunction can progress to the ***oral dysfunction***, which consists of eating, swallowing, and mastication disorders. The older people with oral dysfunction need the nursing care. The oral dysfunction is irreversible while the oral hypofunction and oral frailty can be restored back to the previous stage (Figure 1).[12]

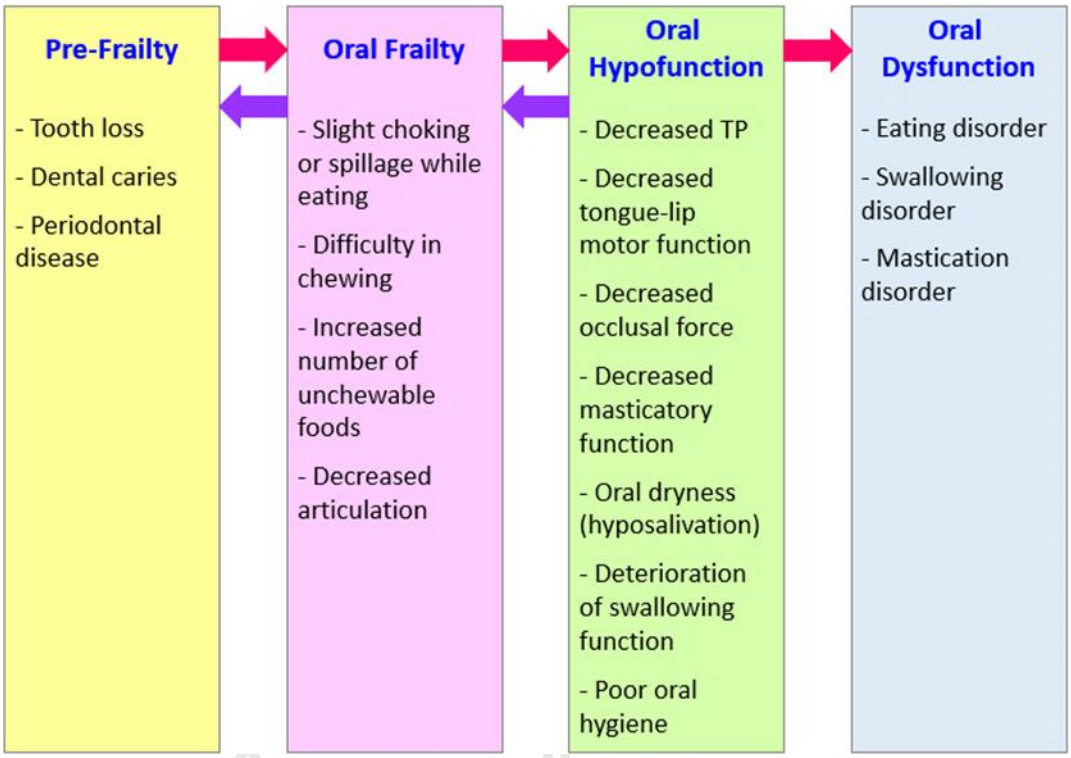


Figure 1 Stages of the oral function in elderly people[12]

The early detection of decreased oral performance and intervention may prevent the oral frailty.[102] The oral exercise, training, or intervention is important for restoring the oral hypofunction back to the oral frailty. Moreover, the education, awareness, and treatment of pre-frailty, oral frailty, oral hypofunction, and oral dysfunction are considerable to prevent the oral function from becoming irreversible and requiring the nursing care.[12] Maintaining oral function is important for maintaining and improving masticatory function and quality of life in elders.[29, 102, 103]

Table 4 shows the signs, symptoms, measurement, and diagnostic criteria of the oral hypofunction recommended by the Japanese Society of Gerodontology (JSG).[12] If at least three diagnostic criteria are met, the oral hypofunction will be defined.[12]

Table 4 The signs, symptoms, measurement, and diagnostic criteria of the oral hypofunction recommended by the Japanese Society of Gerodontology (JSG)[12]

Signs and symptoms	Measurement	Diagnostic criteria
Decreased TP	MTP	< 30 kPa
Decreased tongue-lip motor function	Oral diadochokinesis (ODK) rate (the number of /pa/, /ta/ or /ka/ produced per second)	< 6 times/second
Decreased occlusal force	- Occlusal force - The number of natural teeth	< 200 N < 20
Decreased masticatory function	- Glucose concentration from chewed gummy jelly - Visual reference material	< 100 mg/dl < 2
Oral dryness (hyposalivation)	- Oral moisture checker - Saxon test	< 27.0 ≤ 2 g/2 min
Deterioration of swallowing function	10-item Eating Assessment Tool (EAT-10)	≥ 3
Poor oral hygiene	- Total number of microorganisms - Tongue Coating Index (TCI)	≥ 106.5 CFU/ml ≥ 50%

There are studies indicated that decreased TP was associated with age.[104-107] Furthermore, the study of Iyota et al.[107] revealed that decrease in oral function was correlated with age. The TP, tongue motor function of both anterior and posterior regions, occlusal force, and masticatory function decreased significantly in people aged 70-79 years and over, 60-69 years and over, 70-79 years, and 40-49 years and over, respectively. On the other hand, in older people aged 80 years and over, the degree of tongue coating increased significantly. However, the results of that study showed no differences in the oral moisture and swallowing function among people aged 20-29, 40-49, 50-59, 60-69, 70-79, and 80 years and older.[107]

4. Oral Function of People with Dementia

Decreased mastication was related with cognitive impairment.[108] While cognitive impairment progress, the level of oral hygiene care, motor skill, and oral health care attendance decrease. Therefore, the oral health problems could occur.[10, 109] Some oral functions are affected in the people who have cognitive impairment. The reduced oral function may concur with the early stage of cognitive declination.[17] The people with dementia may have eating, swallowing, and nutritional problems.[9] The consequences are problems in general health (e.g., aspiration pneumonia), needs of long-term care, and low quality of life.[10-12]

The people with dementia had decreases in unstimulated salivary flow, salivary gland function, occlusal area, the number of present teeth, maximum bite force, and mastication ability.[9, 13, 15, 109, 110] The elders with AD had TMJ abnormalities (e.g., osteoarthrosis in TMJ, osteoarthritis in TMJ, and arthralgia in TMJ), orofacial pain, and low stimulated submandibular salivary flow.[111, 112] The decreased salivary flow rate can cause difficulties in eating, swallowing, communication, dental caries,

inflammation of mucosa, candidiasis, frictional lesion in denture wearers, and halitosis.[113]

Swallowing impairment or dysphagia is one of the oral function problems in the people with dementia.[96, 111, 114] The risk of dysphagia increases with age. Dysphagia can cause malnutrition, dehydration, functional decline, weight loss, fear of drinking and eating, low quality of life, aspiration pneumonia, and death.[111, 114] The aspiration pneumonia is one of the major causes of death in old people. In people with dementia, the relative risk of pneumonia is high.[115] The prevalence of dysphagia in people with dementia ranges from 13 to 57 percent.[96, 114] It varies according to the different types and severity of dementia.[114, 116] The common symptoms of dysphagia are difficulties in mastication, difficulties in swallowing, coughing or choking with fluid or food, and pocketing of food in the mouth.[114] The reduced force of tongue or TP and hyposalivation are concerned as causes of dysphagia.[111, 114] The severity of AD might be related to the dysphagia severity. People with severe AD showed greater pharyngeal swallowing delay than people with mild and moderate AD.[111] It was reported that reduction in cognitive function might be a predictor of dysphagia.[117]

Considering the relationship between oral function and cognitive function in elders, the cognitive function was associated with the MTP[16, 18], ODK rate[16], masticatory function[15, 118], maximal occlusal force[17], chewing ability[119, 120], and number of teeth[18]. Decreased TP and ODK might cause cognitive decline.[16] Reduced cognition was associated with reduced masticatory function in elderly people with dementia.[118]

It was recommended that the professionals should try to stimulate and maintain the mastication in elders with dementia to preserve the cognition.[118] The reason is that mastication could affect the brain in the regions which are vital in

memory and learning.[108, 121, 122] Furthermore, chewing and clenching can increase cerebral blood flow.[123] Therefore, preservation of normal chewing and retention of teeth may prevent degeneration of the brain, and decrease the risk of cognitive impairment.[118, 120, 124]

5. Tongue and Related Muscles

5.1 Tongue

The masticatory process involves the rhythmic opening and closing of the jaw. It requires coordination of tongue, cheeks, lips, and mandible movements.[22] The masticatory performance is affected by oral functions which are tongue muscle force (MTP)[103, 125, 126], speed of the tongue movement (ODK of /ta/[103, 126, 127] and /ka/[126]), lip function (ODK of /pa/)[126], cheek pressure[125], maximum occlusal force[127, 128], occlusal contact area[129], mandibular movement[130], and the number of occluding pairs[128].

The tongue is very important in the processes of mastication, swallowing, speech, and respiration.[19, 20] The functions of tongue in the masticatory and swallowing processes are bolus formation, placement, and manipulation. After that, the tongue will transfer the bolus from the oral cavity to the pharynx by a driving force at the base of the tongue.[23]

The tongue is a muscular hydrostat. The movable structure comprises almost fully of muscle and does not move around a joint. The movement of the tongue is activated by intrinsic tongue muscles, extrinsic tongue muscles, and suprahyoid muscles.[21] The tongue movement could be roughly divided into two types: anterior and posterior parts of the tongue. The functions of the anterior part are bolus formation, placement, and manipulation, while those of the posterior part (base of

the tongue) are bolus containment and transferring the bolus into the pharynx.[131, 132] Impaired tongue function is one of major causes of dysphagia. The impairment of the tongue base can cause the decreased bolus clearance through the pharynx, leading to residue in the pharynx and aspiration.[25]

The tongue function, including tongue strength, movement, and coordination, is important in the masticatory process.[22] It should be evaluated for maintaining the eating ability and swallowing rehabilitation.[23] The assessment of the tongue function includes tongue strength (the muscle fibers' ability to produce or resist force), tongue speed (the contraction velocity), tongue endurance (the muscle's ability to sustain force over time or across multiple repetitions), and tongue power (the ability to contract muscles forcefully and quicky).[21] The most common assessment is the TP which quantifies the tongue strength, followed by tongue speed represented by the ODK rates of /ta/ and /ka/.

The TP is important in the evaluation of swallowing function and might be an indicator of dysphagia because it influences the oral function, swallowing, and dysphagia.[24, 25] The TP was associated with swallowing function, oral and pharyngeal transit time, and the percentage of oral residue. Decreased TP causes problems of chewing, swallowing, ingesting, speech, and poor nutrition.[102] In persons with impaired TP, liquids might spill into the pharynx before the airway protection occurs, or impaired clearance of bolus might occur, leading to pharyngeal residue. The consequence is aspiration.[28] It was suggested that improving tongue function (e.g., training of oral motor function) and providing the prostheses might restore the masticatory performance in older people.[22]

The MTP was associated with aging[104, 105, 133, 134], sarcopenia[104, 105], masticatory performance[133], maximum occlusal force[133], the activity of suprahyoid muscle[135], tongue muscle thickness[134], the number of teeth[102], tooth loss[133],

MMSE scores[16], Montreal Cognitive Assessment (MoCA) scores[18], Barthel Index scores[105], Mini Nutritional Assessment-Short Form (MNA®-SF) scores[105], body mass index (BMI)[133], activities of daily living (ADL)[136], grip strength[24], walking speed[24], muscle index[102], back muscle strength[137], and trunk muscle mass index[134].

According to the study of Utanohara et al.[106], the average MTP of Japanese healthy seniors aged 60-69 and 70-79 years were 37.6 ± 8.8 and 31.9 ± 8.9 kPa, respectively. The MTP of males was not statistically different from those of females. In the male group, elderly aged 60-69 years had lower MTP than people aged 20-39 years, and elders aged 70-79 years had lower MTP than people aged 20-49 years significantly. In the female group, elderly aged 70-70 years had lower MTP than people aged 20-69 years significantly.[106] The expected MTP of older people aged 60-69 years and at least 70 years are 30 kPa and 20 kPa, respectively.

The MTP is measured by using the tongue pressure measurement device. One of the devices commonly used is the JMS tongue pressure measuring instrument (JMS Co., Ltd., Japan). The patients are instructed to sit in the relaxed and upright position, then slightly bite the device with their upper and lower central incisors and close their lips.[104, 106, 126, 133, 138] The tongue bulb is placed between anterior region of the tongue and the anterior part of hard palate.[139] Thereafter, they are requested to raise their tongue and compress the tongue bulb onto the palate as hard as they could for 7 seconds.[104, 106, 126, 138] Measurements are taken 3 times, and the mean value is calculated.[104, 106, 133, 138]

The process of producing TP by pushing the tongue against the palate composes of lifting the tongue muscle via the intrinsic and extrinsic tongue muscles, and elevating the floor of mouth via the contraction of the suprahyoid muscles.[45]

5.2 Suprahyoid Muscles

Suprahyoid muscles are important in the masticatory process. As stated above, the movement of tongue and the producing TP (by pushing the tongue against the palate) are activated by the tongue muscles and the suprahyoid muscles.[21, 45] Moreover, the suprahyoid muscle is greatly important in swallowing. It is crucial in hyoid elevation and upper esophageal sphincter (UES) opening.[24, 45] Decreased strength of suprahyoid muscle causes decreased hyoid elevation and insufficient UES opening, resulting in pharyngeal residue and aspiration after swallowing.[140] Furthermore, suprahyoid muscle plays a role in jaw opening.[55]

The indicator of suprahyoid muscle strength is the jaw-opening force (JOF). It is measured by using the jaw-opening sthenometer (Livt, Inc., Tokyo, Japan). The patients are instructed to sit comfortably without a back in a neutral position.[140] Then, they are asked to open the jaw as hardly as possible. Measurements are repeated 3 times, and the average value is calculated.[140, 141] The JOF is associated with aging[104], sarcopenia[104], MTP[135], sex[134, 142], neck circumference[142], grip strength[24], and trunk muscle mass index[134].

6. Oral Exercises

Since the elders' oral function, masticatory function, and swallowing function decreases as reported above, there are attempts to improve decreased oral function for maintaining the good quality of life and preventing the needs of long-term nursing care in the elders. The oral exercises are recommended to improve and maintain the oral function.[29]

As stated earlier, dysphagia can cause malnutrition, dehydration, asphyxia, poor quality of life, aspiration pneumonia, and death.[111, 114] The swallowing problem solving might be alternation of nutritional intake methods (e.g., enteral tube feedings), or modification of diet texture (e.g., pureed foods or thickened liquids).[26, 27] However, those methods can negatively affect the patients' quality of life. Some of them did not like the feel and taste of thicken liquids (e.g., thickened water, thickened coffee, and thickened juice) and felt that their thirst is not quenched.[26] They were likely to inadequate fluid intake, dehydration, and inadequate nutritional intake.[26, 28]

Therefore, there are attempts to discover the treatment which can improve the swallowing without those modification. Several studies showed that oral exercises could provide the improvement of oral function and masticatory function.[28-58] Therefore, the oral exercise is highly recommended. The exercises of tongue muscles and suprahyoid muscles are recommended in several studies.[28-58] However, it was suggested that, to prevent dysphagia, older people should exercise the tongue muscles, rather than the suprahyoid muscles, in order to increase or maintain the muscle strength.[141]

6.1 Tongue Exercises

Since the tongue is important in mastication and swallowing, it is the most common target of oral exercises.

6.1.1 Tongue resistance-strengthening exercise

The tongue resistance-strengthening exercise is a common method to improve the tongue strength represented by TP. The method is pushing the tongue

upward, forward, or to the left and right sides against the immovable load or resistance, and hold for a few seconds. Its objectives are to improve the tongue strength and oral function (bolus formation, holding, propulsion, and mastication).[19]

The tongue can be roughly divided into two parts: anterior and posterior parts. The target of anterior elevation exercise is placing the tongue tip against the palate behind the alveolar ridge while the target of posterior elevation exercise is placing the tongue dorsum against the junction between hard palate and soft palate.[143] The tip of the tongue is important in swallowing, so the exercise which improves the strength of the anterior part of the tongue is useful, especially in the patients with dysphagia in the oral preparation and oral stages. It was presented that the anterior and medial parts of the tongue were the most responsive parts to the tongue resistance-strengthening exercises.[132] Furthermore, it was revealed that anterior tongue-strengthening exercise could enhance anterior and posterior MTP in healthy young adults.[36]

The benefits of the tongue strengthening exercises stated in the previous studies include significant increases in MTP[28, 33, 41-47, 49-53], swallowing TP[28, 42, 43], tongue speed (ODK rate of /ta/ and /ka/)[45], tongue volume[42], tongue thickness[33, 46], suprahyoid muscle strength[33, 46], suprahyoid muscle thickness[33, 46], swallowing function[47, 52], UES opening width[45], anterior and superior movement of hyoid bone[45], quality of life[43], cheek pressure[53], body weight[60], albumin[60], protein[60], energy[60], and protein intake[60]. Moreover, the benefits were significant decreases in pharyngeal transition time[45], penetration aspiration[28, 45], airway invasion for liquid[43], and post-swallow vallecular residue with thin liquid[51].

The methods of tongue strengthening vary. The majority is pushing the tongue against the palate as hard as possible[41, 45-47, 50, 52, 60] or compressing the

air-filled bulb of the tongue pressure measuring instrument[21, 28, 33, 42-44, 49, 51] for a few seconds. In addition, some protocols ask the patients to push the sides of the tongue against the tongue blade[41], push the tongue forward against the tongue blade[19], pull the tongue back against the pulling force given by the professionals[19], or chew the hard gum[53].

The **"Peko Panda"** (JMS Co., Ltd., Japan) is one of the devices used for tongue-strengthening training.[19] It was developed by Dr.Takeshi Kikutani at the Oral Rehabilitation Tama Clinic, Nippon Dental University, Japan.[144] It is made by thermoplastic elastomer resin[145]. The Peko Panda has five levels of hardness, so it can be chosen depending on the patients' abilities, and provides a gradual increase in the exercise load (Figure 2 and Table 5).[19, 144]

Figure 2 Peko Panda (JMS Co., Ltd., Japan)

Table 5 Peko Panda's levels of hardness

Hardness	Color	Resistance pressure (kPa)
Super soft (SS)	Blue	5
Soft (S)	Pink	10
Medium-Soft (MS)	Purple	15
Medium (M)	Green	20
Hard (H)	Yellow	30

Each Peko Panda comprises of three sections; pressure against section, bite position section, and handle section (Figure 4).[19] The pressure against section, which is hollow hemisphere, is for training. It is compressible when the people push the tongue against the device, then return to the original shape when the force is released. The bite position section is for positioning. The people's anterior teeth slightly bite this section to position the training section. The handle section is for handling. The people or caregiver put a finger in this hole to prevent the accidental swallowing of the device. [144]

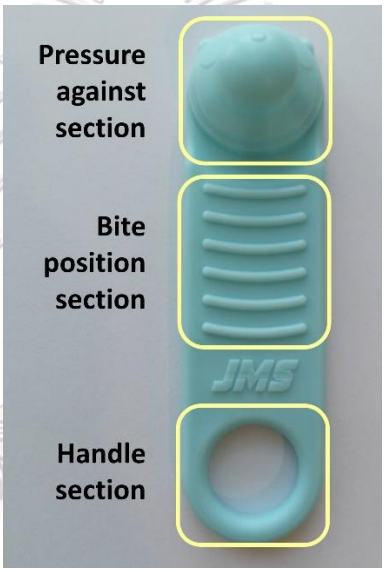


Figure 3 Peko Panda's sections

The users are instructed to place the Peko Panda between the tongue and the palate, with the projection part contacting the tongue dorsum, then slightly bite at the bite position section with their anterior teeth. They are asked to push the tongue upward against the Peko Panda and hold for a few seconds.[19, 146]

The advantages of the Peko Panda are simple, convenient, and easy to use. It can boost an understanding of the training methods, and encourage the patients to exercise willingly.[144, 147]

To the best of the researcher's knowledge, there are a few studies using Peko Panda for tongue strengthening exercise. Tsuga (abstract)[148] reported that tongue exercise with Peko Panda could increase or keep the TP in 12 of 18 elderly participants, and improve the subjective salivation in some participants. Nakao et al. (case report)[149] showed that tongue exercise with Peko Panda could enhance the TP and swallowing function in a patient with dentatorubral-pallidoluysian atrophy (DRPLA). Shindo et al. (abstract)[150] presented that tongue exercise with Peko Panda could increase the TP and improve the skilled activities of the tongue and lips in edentulous patients. Tamura and Kikutani[147] stated that tongue exercise with Peko Panda could improve the swallowing function in a 8-year-old boy with Down syndrome. Sato et al. (abstract)[145] exhibited that tongue exercise with Peko Panda could be used in the patients who cannot sit vertically.

6.1.2 Tongue speed exercise

The tongue speed exercise is used for improving tongue speed. The patients are asked to produce /ta/ repeatedly as fast as they could for 10 seconds.[21] The syllable /ta/ is used to train the motor function of the anterior part of the tongue.

6.1.3 Tongue range-of-motion exercise

The tongue range-of-motion exercise is used for improving oral transit including bolus formation, holding, propulsion, and mastication. This exercise consists of tongue elevation, lateralization, protrusion, and retraction exercises.[19]

6.2 Suprahyoid Muscle Exercises

In the process of swallowing, the tongue is pushed up against the palate, and the hyoid bone is elevated by the suprahyoid muscles.[102] Therefore, the exercise of suprahyoid muscles is essential for improving the swallowing function. Moreover, the training might help to produce the TP because the suprahyoid muscle plays a role in tongue elevation and movement.[21, 45]

6.2.1 Head-Lifting Exercise (Shaker Exercise)

The head-lifting exercise or Shaker exercise is one of the famous training methods for the people who have dysphagia due to abnormal UES opening.[151] The objective of this exercise is to improve the hyolaryngeal antero-superior movement by improving the suprahyoid muscle strength.[19] The patients are instructed to lie in the supine position on the floor or bed without pillow under their heads, then raise their heads high and forward to see their toes, but not raise their shoulders off the floor or bed, and hold for 1 minute. This action is repeated 3 times with a rest of 1 minute between repetitions. Afterwards, the patients are asked to perform 30 consecutive repetitions of head raise without rest.[19, 151]

However, the Shaker exercise has limitations. It causes a strain on the sternocleidomastoid muscles. The patients with ambulatory problems, cervical spine deficits/injuries, limited neck mobility, a history of radical neck dissection involving the sternocleidomastoid muscles, and tracheostomy tube placement are limited to perform this exercise.[19, 54, 56]

6.2.2 Jaw-Opening Exercise

The objective of the jaw-opening exercise is to improve UES opening during swallowing.[19] The patients are asked to open their jaws as wide as they can and hold for 10 seconds with a rest of 10 seconds between each exercise.[19, 54] However, the patients with a history of TMJ dislocation, degeneration of the articular disc of the TMJ, and mandibular arthritis should not perform this exercise.[19, 54]

Furthermore, there are other exercises of suprahyoid muscles presented in some studies including high-speed jaw-opening exercise[55], resistance-based chin-to-chest exercise[56], and swallow exercise aid[57].

The benefits of the suprahyoid muscle exercises include significant increases in UES opening width[54, 55, 151], anterior laryngeal excursion[151], vertical position at rest of the hyoid bone [55], upward and forward movement of hyoid bone[54], hyoid bone elevation during swallowing[55], velocity of hyoid bone's movement during swallowing[55], suprahyoid muscle volume[57], activation in the hyolaryngeal musculature[56], jaw opening strength[57], TP[57], and maximum mouth opening[57]. In addition, other benefits are significant decreases in pharyngeal transit time[54, 55] and duration of hyoid bone elevation[55].

6.3 Other Oral Exercises

The examples of other oral exercises are tongue-holding swallow exercise (Masako Maneuver) and lip exercise. The objective of Masako Maneuver is to improve the contraction of posterior pharyngeal muscles. The patients are asked to put the tongue out and gently hold it between the anterior teeth or gums, then swallow. The objective of lip exercise is to improve oromotor functional control of lips. The patients are asked to protrude and retract their lips.[19]

6.4 Training Protocols

At present, there are no established standard protocols for the oral exercises. However, the factors affecting the success of the exercises which should be considered are timing (when to begin exercise), intensity (the amount of force resistance during exercise), repetition (the number of exercise's sets per day), frequency (the number of days per week) and duration (the length of training program).[143] In 2011, the American College of Sports Medicine recommended the guideline for the exercises.[152] For example, the resistance exercises are recommended to be performed 2-3 days/week, with the rest of at least 48 hours between sessions and the rest intervals of 2-3 minutes between sets.[152]

The training protocols of oral exercises varied in several studies.[21, 28-61] Almost all studies presented the significant improvement of oral function within three months. However, the study of Morisaki[29] reported that a significant increase of TP was not found at three months, but six months. His study was conducted in Japanese dependent elders aged at least 65 years in nursing facilities with the need for care ranging from the lightest to the most serious need.[29] It was stated that the patients with chronic and longer duration of swallowing problems might require longer duration to show positive changes in swallowing outcomes.[153]

Nevertheless, some studies did not show significant improvement of oral function. For example, the study of Kikutani et al.[60] presented that the MTP of the old people in long-term care setting did not significantly change after doing the oral exercises including the exercises of tongue, lips, cheeks, soft palate, and neck. Moreover, the study of Kawano et al.[59] revealed that the oral function of the elders

with dementia did not significantly change after doing the candy-sucking exercise for six months.

Unfortunately, almost half of the previous studies determining the effects of oral exercise on the oral function excluded the patients with cognitive deficit or dementia. The researchers considered that the people with dementia were not able to follow the exercise protocols due to their cognitive problems.[30, 45] When considering the other half of these studies, some of them were conducted in healthy young adults or healthy seniors who did not suffer from dementia. This evidence indicated that people with dementia might lack opportunities to get the effective oral exercises in order to improve their decreased oral function.

To the best of the researcher's knowledge, there are two research evaluated the effects of oral exercise on the oral function in the patients with cognitive impairment or dementia. The first one is the study of Kawano et al.[59] which aimed to evaluate the influence of dysphagia training on the oral function of elders with dementia. The participants in that study were 25 elders with dementia living in one nursing home. The intervention was the lollipop sucking training. All participants were asked to continuously suck the strawberry flavored lollipop for 10 minutes per day without biting or taking out of the mouth, three days per week for six months. However, the results presented that the participants' oral function did not significantly change after the 6-month training. Moreover, the lollipop sucking training might provide the risk of aspiration pneumonia because the subjects had to continuously swallow during this 10-minute training.[59]

The other one is the study of Namasivayam-MacDonald et al.[49] which was conducted to define the effects of the tongue-strengthening exercise on the MTP of the elderly with cognitive impairment. The participants in their study were seven dependent elders aged 84-99 years who had mild to moderately severe cognitive

impairment and lived in the long-term care facilities. The intervention, which was a tongue pressure strength and accuracy training (TPSAT) with the accuracy targets of 25-85% of baseline MTP, was conducted two days per week (in the morning) for two months. The exercise was a face-to-face therapy managed by a speech-language pathologist with the use of a tongue pressure measurement device. The results presented that both anterior and posterior MTP increased significantly.[49] However, that study had some limitations. Firstly, that study had a small number of subjects with no explanation of the sample size calculation. Secondly, the subjects had a wide variety of cognitive diagnosis (3 subjects had borderline cognitive performance, 2 subjects had moderate cognitive impairment, and the other 2 subjects had moderately severe cognitive impairment). Their MTP might be the effect of the cognitive impairment severity.[49] Thirdly, that study did not have the control group. Therefore, the results might not completely confirm the effects of the intervention on the participants' MTP.

According to the earlier points, people with dementia have decreased oral function that might lead to eating problems, swallowing problems, nutritional problems, general health problems, low quality of life, and needs of long-term care. Several studies determining the influences of the oral exercise on the oral function excluded the patients with cognitive deficit or dementia. Therefore, these suffered people were neglected and lacked opportunities to get the effective oral exercises to improve their problems. To the best of the researcher's knowledge, there are two research determining the effects of the oral exercise on the oral function of the patients with cognitive impairment or dementia. On top of that, one of them did not show the significant changes of the oral function after oral exercise. The other one presented the improvement of MTP, but that study had some limitations. Moreover, the exercise in that study was a face-to-face therapy which had to use a special

device managed by a professional. Hence, the people might not be able to perform that exercise regularly in daily lives.

Therefore, this research was conducted to examine the effects of home-based oral exercises on the oral function in people with mild to moderate dementia in the aspects of MTP, tongue-lip motor function, swallowing function, and oral moisture. In addition, the history of swallow and nutritional status were evaluated as consequences of changed oral function.

CHAPTER III

RESEARCH METHODOLOGY

1. Population and Sample

1.1 Target population

People with mild to moderate dementia

1.2 Study population

People with mild to moderate dementia at the Dementia Day Center and the Psychiatric outpatient clinic, King Chulalongkorn Memorial Hospital

1.3 Inclusion criteria

Male and female subjects with

- age of 50 years and over
- physician's diagnosis of dementia / mild dementia / moderate dementia (AD, VaD, FTD, or Mixed dementia of AD, VaD and FTD)
- CDR scale of 1 or 2 (mild or moderate dementia)[6]
- capability to perform some basic ADL which represented by the Barthel Activities of Daily Living Index (BAI) score of 5 and over[154]
- good vision and hearing
- capability to speak Thai
- orally nutritional intake
- upper and lower natural or artificial central incisors (to stabilize the device in the process of MTP measurement)
- abilities to elevate the tongue to the palate

- acceptable retention and stability of removable dentures (in case of wearing removable dentures)
- abilities to follow the research methods
- caregiver who had capabilities to speak, read, and write in Thai

  (The caregiver had to take care of the people with dementia for at least 3 hours/day, more than 3 months, and be with the people with dementia in the past 3 days.)

1.4 Exclusion criteria

Subjects with

- bedrest or bedridden
- terminal illness
- current oral exercises
- history of glossectomy
- head and neck cancer
- history of head and neck radiation therapy
- Sjögren's syndrome
- alternative routes of nutrition support (e.g., tube feeding)

1.5 Sample

People with mild to moderate dementia at the Dementia Day Center and the Psychiatric outpatient clinic, King Chulalongkorn Memorial Hospital who met the eligibility criteria and were willing to participate in this study

1.6 Sample size determination

The sample size was calculated using the G*Power Software, Version 3.1.9.2 (Kiel University, Kiel, Germany) with an effect size of 1.15 (for the MTP as the primary

outcome), an α of 0.05, and a power of 0.8. The used effect size was between the effect size of two studies which were similar to this study. The first one was the study of Namasivayam-MacDonald et al.[49] which showed the effect size of 2.31. Another one was the study of Park et al.[46] which showed the effect size of 1.06. The required sample size was calculated to be 9 people per group. After adjusting for dropouts of 20%, the sample size would be 11 people per group.

1.7 Approach to participants

The information of patients (e.g., age and diagnosis of dementia) was assessed by two clinical psychologists at the Dementia Day Center, King Chulalongkorn Memorial Hospital. The information of the patients who met the aforementioned criteria was approved by a physician. After that, the researcher met the patients to explain the information of this study and invited them and their caregivers to participate in this study. The caregivers also were the participants in this study because they had to be interviewed in some questionnaires.

1.8 Random allocation

The patients were not randomized to participate in this study, but all patients who met the aforementioned criteria were invited. Afterwards, the subjects were randomly allocated to an experimental group (n = 11) or a control group (n = 11). The experimental group consisted of the participants with odd identification numbers, and the control group consisted of those with even numbers.

1.9 Dropout criteria

1) The participants passed away.
2) The participants did not have abilities to follow the research methods.
3) The participants were seriously ill and could not do the oral exercises.

4) The participants' compliance was less than 75% of prescribed exercise protocol.

5) The participants felt discomfort or pain in the TMJ.

6) The participants wanted to drop out of this study.

2. Observation and Measurement

2.1 Independent variables

The independent variables in this study were 3 home-based oral exercises including the tongue-strengthening exercise, ODK exercise, and mouth-opening exercise.

2.2 Dependent variables

The major dependent variables in this study and their measurement are shown in Table 6. In addition, the minor dependent variables were the TCI score, history of swallowing, and nutritional status.

Table 6 The major dependent variables and measurement

Dependent variables	Measurement
MTP *(Primary outcome)*	Tongue pressure measuring instrument (JMS tongue pressure measuring instrument, TPM01, JMS Co., Ltd., Japan)
Tongue-lip motor function (ODK rates of /ta/, /ka/, and /pa/)	Automatic counter (KENKOKUN HANDY, T.K.K.3351, Takei Scientific Instruments Co., Ltd., Japan)
Swallowing function	Modified Water Swallowing Test (MWST)
Oral moisture	Oral moisture checker (Mucus, Life Co., Ltd., Japan)

The details of methods of measurement are shown in the part of Materials and Methods.

3. Intervention

3.1 The intervention

In this study, the intervention for the subjects in the experimental group was 3 home-based oral exercises including the tongue-strengthening exercise, ODK exercise, and mouth-opening exercise. All exercises were recommended to be performed 3 days/week, on nonconsecutive days. This study focused on the home-based oral exercises since the subjects could perform these exercises anywhere and at any time. Moreover, these exercises were practicable during the COVID-19 situation because the patients and caregivers were not required to go to the hospital to receive a face-to-face training.

The details of these oral exercises are shown in the part of Materials and Methods.

3.2 Strategies for improving the participants' compliance in this study

1) The participants and caregivers got clear explanation about the objectives, benefits, and exercise protocol.
2) The participants and caregivers in the experimental group got a pamphlet showing all oral exercises.
3) The participants and caregivers got a pamphlet containing the information of general oral health care.
4) The caregivers in the experimental group got reminder messages on training days.

5) The researcher contacted the participants and caregivers by phone call every week.
6) The participants and caregivers could contact the researcher all the time.
7) The participants and caregivers could manage the oral exercises themselves.

3.3 Compliance monitoring

1) The caregivers in the experimental group received a record sheet for recording the exercise performance and were informed to submit the record sheet every two weeks.
2) The researcher contacted the participants and caregivers by phone call every week.

4. Materials and Methods

4.1 Questionnaire and chart development

1) The researcher developed the following questionnaires and charts:
   - the questionnaire about the general data, medical history, physical exercise practices, social activities, and related conditions of the participants.
   - the chart for recording the oral function, the number of functional natural teeth, and the history of swallowing and choking
   - the chart for recording the nutritional status
   - the COVID-19 screening questionnaire
   - the record sheet for the caregivers in the experimental group (The caregivers were informed to record the subjects' exercise progress in this sheet.)
   - the chart for recording the problems or adverse events

2) These questionnaires and charts were sent to the experts to improve clarity, face validity, and content validity. After that, the researcher adjusted them in accordance with the experts' feedback.

3) The researcher contacted the copyright owner, Thai developer, or organization to ask for the permission to use the Thai version of the MMSE, CDR Scale, BAI, and MNA®-SF.

4.2 Researcher's training

The researcher was trained for assessing the cognitive function using the MMSE by a clinical psychologist at the Dementia Day Center, King Chulalongkorn Memorial Hospital. Furthermore, the researcher passed the Brief Training & Reliability Protocol for the CDR via the on-line training system at knightadrc.wustl.edu and got the on-line certificate as a CDR rater from the Knight Alzheimer's Disease Research Center of Washington University School of Medicine, St. Louis, Missouri, USA.

In addition, the researcher evaluated the intra-examiner reliability of assessing the MTP, all ODK rates, swallowing function, oral moisture value, and TCI score using the Intraclass Correlation Coefficient (ICC). Five participants at the Dementia Day Center, King Chulalongkorn Memorial Hospital were assessed the MTP, ODK rates, MWST score, oral moisture value, and TCI score two times with the time interval of approximately one week. The ICC were 0.99 which indicated excellent reliability.[155]

4.3 Ethical approval

In the informed consent process, since the participants in this study were the patients with dementia, their legal guardians were requested to read and sign the informed consent form together with theses vulnerable participants. Moreover, the

caregivers were also requested to sign the informed consent form because they were interviewed in some questionnaires.

This research was conducted with the respect of three basic ethical principles;

1) Respect for person

The researcher explained the entire information clearly. The participants, legal guardians, and caregivers had autonomy of thought and intentionality when making decision. Their decision making for participation in this study was free of compulsion and persuasion.

2) Beneficence and non-maleficence

The participants got the benefits. Their oral function would be improved, and the occurrence of oral hypofunction would be postponed. They would have safe and efficient eating and swallowing, and the chance of aspiration pneumonia might be reduced. Therefore, these subjects would have good quality of life. Furthermore, the subjects and caregivers were asked to stop the mouth-opening exercise if the subjects felt discomfort or pain at the TMJ during the exercise. However, the researcher basically examined the subjects' TMJ and took a history of TMD before starting this study. Moreover, the researcher protected the participants' confidential information. There were no subjects' names or any identifiers in all recording charts.

3) Justice

This research had clear inclusion and exclusion criteria. Furthermore, the intervention's benefits and risks were equally distributed by random allocation.

The protocol of this study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (IRB No. 484/63), in compliance

with the International guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS guidelines and International Conference on Harmonization in Good Clinical Practice (ICH-GCP). The researcher got the authorization for conducting this study in the King Chulalongkorn Memorial Hospital. Moreover, this research project was reviewed and approved by the Thai Clinical Trials Registry (TCTR20210810004).

4.4 Inform consent process

The researcher explained the information of this study to the patients who met the aforementioned criteria, as well as their caregivers, and their legal guardians, then gave them the information document and the informed consent forms. The patients, caregivers, and legal guardians were informed that the data would be collected at the hospital on their regular appointment date, or at the patients' houses. It depended on their convenience. This was a strategy for facilitating the participants. After that, these patients, caregivers, and legal guardians were invited to participate in this study. If they accepted, they were requested to sign the informed consent forms.

4.5 Random allocation

The subjects were randomly allocated to an experimental group or a control group. The experimental group consisted of the subjects with odd identification numbers, and the control group consisted of those with even numbers. The subjects in the experimental group were asked to do home-based oral exercises for three months and got the general oral hygiene instruction, but the subjects in the control group got the general oral hygiene instruction only.

4.6 Data collection before the intervention (M-0)

1) The researcher assessed the subjects' cognitive status using Thai version of the MMSE (MMSE-Thai 2002), the severity of dementia using the CDR scale, and the abilities to perform basic daily activities using the BAI. If the patients' global CDR scores were not 1 or 2, or the BAI scores were less than 5, they would be excluded from this study.

2) The researcher interviewed the subjects and caregivers about the subjects' general data, medical history, physical exercise practices, social activities, and related conditions, as well as the history of swallowing and choking.

3) The researcher assessed the subjects' nutritional status using the Mini Nutritional Assessment-Short Form (MNA®-SF) and anthropometric measurements.

3.1) MNA®-SF

The MNA®-SF is a validated and efficient screening tool for assessing nutritional status and identifying elders who are malnourished or at risk of malnutrition.[156-160] It was developed by Laurence et al. in 2001[161], and revised by Kaiser et al. in 2009.[162] The MNA®-SF is a short form of the Mini Nutritional Assessment (MNA®).[157, 158, 161] It is widely used because it is simple, easy to use, inexpensive, non-invasive, and time saving (less than 5 minutes).[156, 157, 159-162] It does not need laboratory investigation.[159] The MNA®-SF has high sensitivity, specificity, and positive predictive value.[157] Moreover, it has high diagnostic accuracy and high correlation with the original MNA®.[161]

The MNA®-SF comprises 6 questions about food intake, weight loss, mobility, serious psychological stress or acute disease,

neuropsychological problems, and body mass index (BMI).[157, 159, 161, 162] All questions can be answered by the caregivers or checked in the medical record.[159] The MNA®-SF does not consist of the questions on self-opinion about the nutritional and health status as shown in the original MNA®. Therefore, it was chosen to be a tool for evaluating the nutritional status in this study because the impairment of cognition and memory in the subjects with dementia might affect the accuracy of self-reported answers.[163]

The maximum score of the MNA®-SF is 14 points. The scores of 0-7, 8-11, and 12-14 points represents malnourished, at risk of malnutrition, and normal nutritional status, respectively.[154]

In the process of using the MNA®-SF, the researcher asked the subjects' caregivers in the 1st to 5th questions. The BMI in the 6th question was determined by the researcher.

- The subjects were measured weight using a digital scale (Shaper®, Ek-Chai Distribution System Co., Ltd, Thailand). They were instructed to remove shoes, socks, and heavy cloths, and void urine before weighing.[164, 165]

- The subjects were measured height using a height measuring scale (OST Overseas Co., Ltd, Thailand) attached to a wall and a 90° headboard size of at least 6 cm wide.[166] The subjects were asked to remove shoes, socks, and accessory on head or hair. They were informed to stand up straight with their heels together, and their shoulders, buttocks, and heels touching the wall.[159, 164, 166] They were requested to hang their arms freely,

with palms facing thighs. After that, the researcher lowered a headboard until it contacted with the top of the head.[159, 166]

- The researcher determined the BMI (kg/m^2) by dividing the weight (kg) by the height (m) squared.[159]

3.2) *Anthropometric measurements*

Anthropometric measurements are generally used for evaluating nutritional status.[164, 167-170] They are easy to use, non-invasive, inexpensive, and time-saving methods.[164, 167, 170]

i. *Mid-upper arm circumference (MUAC)*

The MUAC is used to identify moderate and severe malnutrition (underweight or thinness) in adults.[168] The subjects were asked to bend their left arm at the elbow. The researcher measured a distance between the upper shoulder's bony protrusion and the elbow's bony point, then marked the mid-point. After that, the subjects were informed to hang the arm freely by their side. The researcher measured the MUAC by positioning a flexible and non-elastic measuring tape perpendicular to the long axis of arm at the marked mid-point, and tightening the tape snugly without compressing the skin.[165, 166, 171, 172] If the left arm could not be used because of some health problems, the right arm might be used. The cut-off point is less than 21.[171]

ii. *Calf circumference (CC)*

The CC is used to evaluate low or loss of muscle mass (underweight or thinness) in elderly population.[168] The World Health Organization (WHO) recommended that CC is the most sensitive measurement of muscle mass and total body muscle loss in older people.[168, 172] Furthermore, CC has great correlation with nutritional protein.[173] The participants were informed to sit on the chair, and hang the left leg freely. The researcher measured the CC by positioning a flexible and non-elastic measuring tape perpendicular to the long axis of leg at the widest part of calf, and tightening the tape snugly without compressing the skin. After that, the researcher measured above and below the point to confirm the widest point. If the left leg could not be used because of some health problems, the right leg might be used.[159, 170, 172] The cut-off point is less than 31.[159, 171]

iii. *BMI* (mentioned above)

4) The researcher measured the participants' oral moisture at the dorsum of the tongue[12, 174-180] using an oral moisture checker (Mucus, Life Co., Ltd., Japan) shown in Figure 4. To eliminate the stimulant effects (e.g., conversation, water, food, and tension), the researcher asked the participants to relax for about 5 minutes prior to the evaluation.[175-177, 180] The subjects were requested to put their tongue out, then the researcher placed the sensor covered by a disposable cover at the center of lingual mucosa about 1 cm from the tip of

tongue.[174-176, 178-180] The researcher measured the oral moisture three times and used the median value as oral moisture value.[175, 176, 178, 180, 181]

Figure 4 Oral moisture checker (Mucus, Life Co., Ltd., Japan)

5) The researcher measured the participants' MTP using a tongue pressure measuring instrument (JMS tongue pressure measuring instrument, TPM01, JMS Co., Ltd., Japan), shown in Figure 5, by asking them to relax and sit in an upright position, then slightly bite the plastic pipe of the probe with their upper and lower central incisors and close their lips.[23, 104, 106, 139, 182] (In case the subjects did not have natural central incisors and could not stabilize the plastic pipe, they had to wear the removable dentures during the measurement.) The balloon (tongue bulb) was placed between anterior regions of the tongue and hard palate.[139] Thereafter, the subjects were requested to raise the tongue and compress the balloon as hard as they could for 7 seconds.[104, 106, 126, 138] The researcher measured the MTP three times, with resting intervals of about 30 seconds, and calculated the average value of the measurements. [104, 106, 133, 138]

Figure 5 Tongue pressure measuring instrument
(JMS tongue pressure measuring instrument, TPM-01, JMS Co., Ltd., Japan)

6) The researcher evaluated the enrolled subjects' ODK rates, which represents motor speed and dexterity of tongue and lips, using an automatic counter (KENKOKUN HANDY, T.K.K.3351, Takei Scientific Instruments Co., Ltd., Japan) shown in Figure 6. The researcher asked the subjects to repeat monosyllables of /ta/, /ka/, and /pa/ as fast as they could for 5 seconds. The syllables /ta/, /ka/, and /pa/ are used to assess the motor speed and dexterity of the anterior region of the tongue, posterior region of the tongue, and lips, respectively.[12, 14, 126, 183, 184] The researcher gave a demonstration before the test.[184]

Figure 6 Automatic counter
(KENKOKUN HANDY, T.K.K.3351, Takei Scientific Instruments Co., Ltd., Japan)

7) The researcher evaluated the swallowing function using a MWST by placing 3 ml of cold water on the subjects' floor of mouth with a 5-ml syringe (NIPRO, NIPRO (Thailand), Co., Ltd., Thailand). After that, the researcher asked the subjects to swallow the water, then swallow the saliva (dry swallow) twice. The scores of swallow are shown in Table 7.[23, 185, 186] If the score was 1-3, the test would be stopped. If the score was 4 or 5, the process was repeated twice, and the lowest score was used.[23, 185, 186] The cut-off score of this test was 3.[23, 185] The score of 1-3 indicates a greater risk of dysphagia.

Table 7 Scores for a Modified Water Swallowing Test (MWST)

Scores	Characteristics
1	Inability to swallow with cough and/or breathing changes (e.g., frequent breathing)
2	Successful swallowing with changes in breathing (e.g., frequent breathing), without coughing
3	Successful swallowing with cough and/or wet-hoarse voice, without breathing changes
4	Successful swallowing with normal breathing, without cough and wet-hoarse voice
5	Score 4, plus ≥ 2 additional dry swallows within 30 seconds

The MWST is commonly used because it is easy and simple. Moreover, it is safe since the small volume of water (3 ml) is used.[23, 185, 186] The previous studies of Sato et al.[185] and Hoshino et al.[187] used this test to assess the swallowing function of elderly people with mild to severe dementia.

8) The researcher used the TCI, which represents the tongue coating status, to evaluate the participants' oral hygiene by dividing the tongue surface into nine parts. Each part was scored: score 0 = no visible tongue coating, score 1 = thin tongue coating with visible tongue papillae, and score 2 = very thick tongue coating without visible tongue papillae.[188, 189] The TCI score (%) was calculated by summing the scores from nine parts, then dividing by 18, and multiplying by 100.[188, 189]

9) The researcher counted the number of functional natural teeth under a flashlight. The number of natural teeth was recommended by the JSG to be an alternative method for determining the occlusal force.[12] A decreased occlusal force is diagnosed when there are 0-19 natural teeth (except retained roots and teeth that have mobility 3) in the mouth.[12] In this study, the number of functional natural teeth was counted according to the following inclusion and exclusion criteria. The inclusion criteria included sound teeth, teeth with restoration, and teeth with pathology that could be restored. The exclusion criteria included retained roots and very loose teeth that need to be extracted.

4.7 Advising the oral exercises to the participants in the "experimental group"

For three months of this study, all home-based oral exercises were led and controlled by the caregivers who were trained by the researcher. The subjects and caregivers got a pamphlet showing all oral exercises and a record sheet. The caregivers were asked to document the exercise progress and submit these records two times per month:

1) *At the end of the 2nd week:* The researcher contacted the caregivers by phone call and asked how many times the subjects did the oral exercises in the past two weeks.

2) *At the end of the 4th week:* The researcher got the record sheet back by herself.

Furthermore, the researcher contacted the subjects by phone call once a week to observe the problems and exercise compliance, and encourage them. It was recommended that the tongue exercise and the ODK exercise should be conducted before meals.[190]

4.7.1 Tongue-strengthening exercise

The objective of the tongue-strengthening exercise was to improve the tongue strength represented by MTP. The Peko Panda (JMS Co., Ltd., Japan), shown in Figure 7, was used for tongue-strengthening exercise in this study. It has five levels of hardness (Figure 8 and Table 8) which could be chosen depending on the subjects' MTP. The subjects could get a gradual increase in the exercise load (intensity).[19, 144] In the process of tongue-strengthening exercise, the subjects were asked to push their tongues upward against the training section of Peko Panda and hold for 3 seconds.

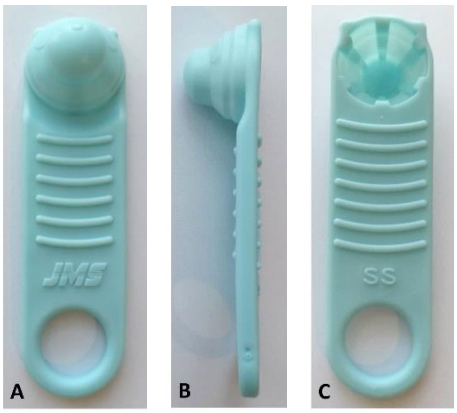


Figure 7 Peko Panda's front (A), side (B), and back (C) views

Figure 8 Five levels of Peko Panda's hardness

Table 8 Five levels of Peko Panda's hardness

Hardness	Color	Resistance pressure (kPa)
Super soft (SS)	Blue	5
Soft (S)	Pink	10
Medium-Soft (MS)	Purple	15
Medium (M)	Green	20
Hard (H)	Yellow	30

The advantages of the Peko Panda are simple, convenient, and easy to use. It can boost an understanding of the training methods, and encourage the patients to exercise willingly.[144, 147] Moreover, the caregivers could detect the subjects' exercise performance by sensing the vibration at the finger in Peko Panda's hole.

Exercise protocols

The researcher set the exercise load at 60% of the MTP at baseline for the 1st week of exercise program, and at 80% of the MTP at baseline for the 2nd week to the end of the 1st month. Afterwards, the researcher set the exercise load at 80% of the new MTP for the 2nd and 3rd months. Each participant's MTP was remeasured at the end of the 1st and 2nd months, and the 80% of the new MTP was recalculated (Table

9). These exercise loads were modified from the Guidance for Prescribing Exercise of the American College of Sports Medicine[152] and the previous study[42].

Table 9 Schedule of the exercise load

Time	Exercise load
The 1st week	60% of the MTP at baseline
The 2nd week to the end of the 1st month	80% of the MTP at baseline
The 2nd month	80% of the MTP measured at the end of 1st month
The 3rd month	80% of the MTP measured at the end of 2nd month

Because the resistance pressure of Peko Panda is a constant value that cannot be changed, the Peko Panda was selected corresponding to the calculated value, or to be close to but not exceed the calculated value.

In the process of training, the caregivers were instructed to place a finger in the Peko Panda's hole and place the Peko Panda between the anterior part of the tongue and the palate of the subjects. The projection section of the tool had to contact the tongue dorsum. The subjects were asked to slightly bite at the bite position section of the tool with their anterior teeth, then push the tongue upward against the Peko Panda and hold for 3 seconds. In case the subjects did not have natural anterior teeth and could not stabilize the Peko Panda, they must wear their removable dentures during the exercise.

According to the Guidance for Prescribing Exercise of the American College of Sports Medicine[152], this exercise was recommended to be performed

- 10 times/set, with the resting intervals of about 3 seconds between times
- 3 sets/day, with the resting intervals of about 2-3 minutes between sets
- 3 days/week, on nonconsecutive days

The caregivers were informed to wash the Peko Panda with water and let it air dry after use. Moreover, they must check the fissure on the Peko Panda before use. If there were any fissures, the tool could not be used.[191]

However, if the subjects felt pain in the oral cavity during the exercise, they would be instructed to stop this exercise for one day and restart the exercise on the following day.

4.7.2 ODK exercise

The objective of the ODK exercise was to improve the motor function of tongue and lips in the aspects of speed and dexterity.

Exercise protocols

The subjects were asked to repeat the pronunciations of /ta/, /ka/, and /pa/ as fast as they could for 10 seconds. The syllables /ta/, /ka/, and /pa/ were used to train the motor function of the anterior region of the tongue, posterior region of the tongue, and lips, respectively.[12, 14, 126, 183] According to the Guidance for Prescribing Exercise of the American College of Sports Medicine[152] and the previous study[21], this exercise was recommended to be performed

- 5 times of repeated pronunciation of /ta/ as fast as possible for 10 seconds, with the resting intervals of approximately 10 seconds between times
- 5 times of repeated pronunciation of /ka/ as fast as possible for 10 seconds, with the resting intervals of approximately 10 seconds between times
- 5 times of repeated pronunciation of /pa/ as fast as possible for 10 seconds, with the resting intervals of approximately 10 seconds between times
- with the resting intervals of about 2-3 minutes between sets of /ta/, /ka/, and /pa/
- 3 days/week, on nonconsecutive days

4.7.3 Mouth-opening exercise

The objective of the mouth-opening exercise was to improve the strength of suprahyoid muscles.

Exercise protocols

The subjects were asked to open their mouth as wide as they could for 10 seconds. The subjects with complete dentures were recommended to remove their dentures during this exercise. According to the Guidance for Prescribing Exercise of the American College of Sports Medicine[152] and the previous study[54], this exercise was recommended to be performed

- 3 times/set, with the resting intervals of about 10 seconds between times
- 3 sets/day, with the resting intervals of about 2-3 minutes between sets
- 3 days/week, on nonconsecutive days

However, if the participants felt discomfort or pain in the TMJ during this exercise, they were asked to stop.

In accordance with the patients' behaviors, the researcher allowed the caregivers to manage the exercises independently, that is, the researcher allowed the caregivers to pause the exercises when the participants refused to continue the exercises. The exercises would go on when the participants were willing or ready. However, the exercises had to be completed on the same day.

4.7.4 General oral health care

In addition to the oral exercises mentioned previously, the participants and caregivers got the general oral hygiene instructions and a pamphlet containing the information.

General oral health care

- Brush teeth and tongue dorsum surface twice daily with a soft-bristle toothbrush and a toothpaste containing fluoride for 2 minutes.[9, 192-194]
- Clean between teeth (interdental cleaning) with interdental cleaning devices (e.g., floss and interdental brush) once a day.[192, 193]
- Gently clean the residual ridge with washcloth or soft-bristle toothbrush.
- Coat lips with moisturizer.

Removable denture care

- Clean the dentures by brushing with a denture brush or soft-bristle toothbrush, and a nonabrasive denture cleanser, soap or dishwashing liquid.[195, 196]
- Remove the dentures at bedtime.[194, 196] The dentures should not be worn 24 hours/day to avoid denture stomatitis.[196]
- Store the dentures in water when they are not being worn in the oral cavity to avoid denture distortion.[195, 196]
- Do not place the dentures in hot or boiling water to avoid denture distortion.[195, 196]
- Remove the denture adhesive from the dentures and oral cavity daily, in case of using denture adhesive.[195, 196]

4.8 Advising the general oral health care to the participants in the "control group"

The subjects and their caregivers got the general oral hygiene instructions and a pamphlet containing the information mentioned in 4.7.4.

4.9 Data collection at the end of the 1st month (M-1)

4.9.1 Experimental group

1) The researcher evaluated the MTP, ODK rates, swallowing function, oral moisture value, and TCI score of the subjects.
2) The subjects and their caregivers were interviewed about swallowing and choking.
3) The researcher calculated 80% of the measured MTP, then select the new Peko Panda for the 2nd month.
4) The researcher reviewed all exercise protocols and general oral hygiene instructions to the subjects and caregivers, and gave them a new record sheet for the 2nd month.

4.9.2 Control group

1) The researcher evaluated the MTP, ODK rates, swallowing function, oral moisture value, and TCI score of the subjects.
2) The subjects and their caregivers were interviewed about swallowing and choking.
3) The researcher reviewed the general oral hygiene instructions to the subjects and caregivers.

4.10 Data collection at the end of the 2nd months (M-2)

4.10.1 Experimental group

1) The researcher evaluated the MTP, ODK rates, swallowing function, oral moisture value, and TCI score of the subjects.
2) The subjects and their caregivers were interviewed about swallowing and choking.
3) The researcher calculated 80% of the measured MTP, then select the new Peko Panda for the 3rd month.

4) The researcher reviewed all exercise protocols and general oral hygiene instructions to the subjects and caregivers, and gave them a new record sheet for the 3rd month.

4.10.2 Control group

1) The researcher evaluated the MTP, ODK rates, swallowing function, oral moisture value, and TCI score of the subjects.
2) The subjects and their caregivers were interviewed about swallowing and choking.
3) The researcher reviewed the general oral hygiene instructions to the subjects and caregivers.

4.11 Data collection at the end of the 3rd months (M-3)

1) The researcher evaluated the MTP, ODK rates, swallowing function, oral moisture value, TCI score, and nutritional status (MUAC, CC, BMI, and MNA®-SF score) of all subjects in both groups.
2) All subjects and their caregivers were interviewed about swallowing and choking.

Note: The processes in the 4.6 to 4.11 topics were conducted in a private room.

4.12 Exercise compliance calculation

The caregivers were asked to note the subjects' exercise progress in the record sheets after completion of each exercise on training days. The researcher collected the exercise compliance from the record sheets documented by the caregivers and calculated the exercise compliance:

$$\text{Exercise compliance (\%)} = \frac{\text{The total number of documented exercise performances}}{\text{The total number of recommended exercises}} \times 100$$

4.13 Management during the COVID-19 crisis

1) The researcher screened all subjects and caregivers before conducting on each visit. The subjects and their caregivers were asked about the history of COVID-19 infection of them and their family members; the history of travelling to - or returning from the high-risk countries or areas; the history of visiting public places or attending large gatherings; the history of contacting with COVID-19 patients or respiratory secretion of COVID-19 patients; and the occupation. Moreover, they were taken the temperature with an infrared thermometer, and were asked about the symptoms of fever, cough, sore throat, runny nose, altered or poor smell, altered or poor taste, difficult breathing or shortness of breath, headache, and muscular pain.[197]

2) The subjects and caregivers were asked to wear mask.[198]

3) The subjects and caregivers were asked to clean their hands with 70-80% alcohol-based hand sanitizer.[198]

4) The subjects and caregivers were instructed to avoid touching teeth, gum, dentures, oral cavity, and nasal cavity. If they contacted with oral and nasal secretion, they would be asked to immediately clean their hands with 70-80% alcohol-based hand sanitizer.[198]

5) The researcher wore a surgical mask and/or N95 respirator all the time. Furthermore, she wore eyeglasses, face shield, hair net, disposable gloves, waterproof coat, and waterproof leg covers.[198]

6) The researcher placed waste contaminated with oral secretion in plastic bags, then tightened the bags.[198]

However, these strategies were adapted depending on the situation of COVID-19 pandemic.

5. Data Analysis

The data was analyzed using the Statistics Package for the Social Sciences (SPSS), version 28.0. Statistical significance was set at $p < 0.05$. The Fisher's Exact Test was used to compare the nominal variables between 2 groups (experimental group and control group). The Mann-Whitney U Test was used to compare the quantitative variables between 2 groups. The Spearman's correlation was used to determine the association between the oral function and other variables. The univariable and multivariable (Stepwise method) linear regression were used to determine the factors influencing oral function at baseline. The generalized estimating equation (GEE) analysis was performed to examine the effects of home-based oral exercises on the oral function (MTP, ODK rates, MWST score, and oral moisture) and nutritional status.

Because 3 subjects dropped out of this study due to behavioral issues and serious COVID-19 situation, the data of 19 subjects (10 in the experimental group and 9 in the control group) who were completely assessed the data at the end-point visit were analyzed in this study.

CHAPTER IV
RESULTS

1. The participants' characteristics

The participants consisted of 16 females (84.2%) and 3 males (15.8%). The age of participants ranged from 61 to 87 years old with a mean age (± SD) of 74.5 ± 6.3 years. Thirteen subjects (68.4%) were from the Psychiatric outpatient clinic while 6 subjects (31.6%) were from the Dementia Day Center. The average score of BAI was 16.8 ± 2.9. About half of the participants (52.6%) were widowed or divorced. Nearly all of them (94.7%) were literate. The most common type of dementia in this study was AD (52.6%), followed by VaD (42.1%), and mixed dementia (5.3%). Most of them (73.7%) suffered from mild dementia while 26.3% suffered from moderate dementia. The average scores of CDR sum of box and MMSE were 7.5 ± 2.1 and 15.8 ± 3.3, respectively. Seven participants (36.8%) had only one chronic disease while 12 participants (63.2) had at least two chronic diseases. The most common disease was hyperlipidemia (63.2%), followed by hypertension (57.9%), cardiovascular disease (42.1%), and diabetes mellitus (26.3%). The average numbers of taken medication and medication-induced hyposalivation/xerostomia were 7.3 ± 3.4 and 1.7 ± 1.5, respectively. Most of the participants (84.2%) visited the dentists when having oral problems only while 15.8% regularly visited the dentists. Table 10 presents the general characteristics, dementia status, medical history, and related conditions of the participants. All data, except BAI score and the number of medication-induced hyposalivation/xerostomia, in the experimental group were not significantly different from those in the control group.

Table 10 General characteristics, dementia status, medical history, and related conditions of the participants at baseline

Characteristics	Total (N = 19)	Experimental group (N = 10)	Control group (N = 9)	p-value
Sex *[n (%)]*				
Female	16 (84.2)	7 (70.0)	9 (100.0)	0.211†
Male	3 (15.8)	3 (30.0)	0 (0.0)	
Age (years) *[mean ± SD]*	74.5 ± 6.3	74.1 ± 7.3	75.0 ± 5.4	0.711‡
Source of participants *[n (%)]*				
Psychiatric outpatient clinic	13 (68.4)	5 (50.0)	8 (88.9)	0.141†
Dementia Day Center	6 (31.6)	5 (50.0)	1 (11.1)	
BAI score *[mean ± SD]*	16.8 ± 2.9	15.6 ± 3.1	18.1 ± 2.1	0.047‡
Marital status *[n (%)]*				
Widowed / Divorced	10 (52.6)	6 (60.0)	4 (44.4)	0.656†
Married	6 (31.6)	2 (20.0)	4 (44.4)	
Single	3 (15.8)	2 (20.0)	1 (11.1)	
Literacy *[n (%)]*				
Literate	18 (94.7)	9 (90.0)	9 (100.0)	1.000‡
Ability to write the name only	1 (5.3)	1 (10.0)	0 (0.0)	
Type of dementia *[n (%)]*				
AD	10 (52.6)	3 (30.0)	7 (77.8)	0.070†
VaD	8 (42.1)	6 (60.0)	2 (22.2)	
Mixed dementia	1 (5.3)	1 (10.0)	0 (0.0)	
Severity of dementia *[n (%)]*				
Mild (CDR 1)	14 (73.7)	6 (60.0)	8 (88.9)	0.165‡
Moderate (CDR 2)	5 (26.3)	4 (40.0)	1 (11.1)	
CDR sum of box score *[mean ± SD]*	7.5 ± 2.1	8.1 ± 2.2	6.9 ± 1.8	0.201‡
MMSE score *[mean ± SD]*	15.8 ± 3.3	15.6 ± 3.3	16.1 ± 3.4	0.742‡
The number of diagnosed chronic diseases (excluded dementia) *[n (%)]*				
1	7 (36.8)	3 (30.0)	4 (44.4)	0.650†
≥ 2	12 (63.2)	7 (70.0)	5 (55.6)	

Table 10 General characteristics, dementia status, medical history, and related conditions of the participants at baseline (continued)

Characteristics	Total (N = 19)	Experimental group (N = 10)	Control group (N = 9)	p-value
Diagnosed chronic diseases *[n (%)]*				
Hyperlipidemia	12 (63.2)	5 (50.0)	7 (77.8)	0.350†
Hypertension	11 (57.9)	6 (60.0)	5 (55.6)	1.000†
Cardiovascular disease	8 (42.1)	6 (60.0)	2 (22.2)	0.170†
Diabetes Mellitus	5 (26.3)	4 (40.0)	1 (11.1)	0.303†
Other diseases	7 (36.8)	4 (40.0)	3 (33.3)	1.000†
The number of taken medication *[mean ± SD]*	7.3 ± 3.4	7.9 ± 3.1	6.7 ± 3.8	0.565‡
The number of medication-induced hyposalivation/xerostomia *[mean ± SD]*	1.7 ± 1.5	2.4 ± 1.5	0.9 ± 1.1	0.027‡
Frequency of visiting the dentist *[n (%)]*				
Sometimes (visiting the dentist when having oral problems)	16 (84.2)	10 (100.0)	6 (66.7)	0.087†
Regularly (≥ once a year)	3 (15.8)	0 (0.0)	3 (33.3)	

† Fisher's Exact Test; ‡ Mann-Whitney U Test

BAI: Barthel Activities of Daily Living Index, AD: Alzheimer's disease, VaD: Vascular dementia,

CDR: Clinical Dementia Rating, MMSE: Mini-Mental State Examination

2. Physical exercise practices and social activities of the participants

The participants spent 3.5 ± 3.2 hours/week for physical exercising. The most common exercise was walking (73.7%), followed by stretching and/or moving arms and legs (36.8%), yoga (26.3%), aerobic dance (10.5%), cycling (5.3%), and walking in water (5.3%). In addition, they spent 10.1 ± 11.1 hours/week for joining social activities. The most common social activity was talking with neighborhoods (47.4%), followed by joining group activities (36.8%), meeting with friends (21.1%), and meeting with family (15.8%). Table 11 shows the physical exercise practices and social activities of the participants. All data in the experimental were not significantly different from those in the control group.

Table 11 Physical exercise practices and social activities of the participants

Activities	Total (N = 19)	Experimental group (N = 10)	Control group (N = 9)	p-value
Physical exercise practices *[n (%)]*				
Walking	14 (73.7)	7 (70.0)	7 (77.8)	1.000†
Stretching and/or moving arms and legs	7 (36.8)	4 (40.0)	3 (33.3)	1.000†
Yoga	5 (26.3)	3 (30.0)	2 (22.2)	1.000†
Aerobic dance	2 (10.5)	1 (10.0)	1 (11.1)	1.000†
Cycling	1 (5.3)	0 (0.0)	1 (11.1)	0.474†
Walking in water	1 (5.3)	1 (10.0)	0 (0.0)	1.000†
The number of hours/week of physical exercise practices *[mean ± SD]*	3.5 ± 3.2	3.5 ± 3.4	3.5 ± 3.1	0.967‡
Social activities *[n (%)]*				
Talking with neighborhoods	9 (47.4)	6 (60.0)	3 (33.3)	0.370†
Joining group activities	7 (36.8)	5 (50.0)	2 (22.2)	0.350†
Meeting with friends	4 (21.1)	3 (30.0)	1 (11.1)	0.582†
Meeting with family	3 (15.8)	1 (10.0)	2 (22.2)	0.582†
Other activities	2 (10.5)	1 (10.0)	1 (11.1)	1.000†
The number of hours/week of social activities *[mean ± SD]*	10.1 ± 11.1	11.6 ± 8.7	8.6 ± 13.6	0.153‡

† Fisher's Exact Test; ‡ Mann-Whitney U Test

3. Oral function and nutritional status at baseline

The oral function of the subjects was evaluated in six aspects: 1) tongue strength represented by MTP; 2) tongue-lip motor function represented by ODK rates of /ta/, /ka/, and /pa/; 3) swallowing function represented by MWST score; 4) oral moisture; 5) oral hygiene represented by TCI score; and 6) occlusal force represented by the number of functional natural teeth. The average MTP (± SD) of the subjects was 24.3 ± 3.6 kPa. The average values of ODK rates of /ta/, /ka/, and /pa/ were 4.5 ± 0.7, 4.2 ± 0.8, and 4.7 ± 0.9 times/second, respectively. The median MWST score (IQR) was 5 (5-5). The mean oral moisture value was 24.4 ± 3.5. The mean TCI score was 37.4 ± 15.4 percent. The mean number of functional natural teeth was 14.4 ± 10.5 teeth.

In addition, the participants and caregivers were interviewed about the history of choking while eating and problems in drug swallow in the participants' daily lives. Fourteen subjects (73.7%) could eat without choking while 5 subjects (26.3%) had sometimes choking. The causes of choking were fast eating, soup or water, spicy food, and dry food. Considering drug swallow, 17 subjects (89.5%) could swallow drugs normally while 2 subjects in the experimental group (10.5%) had problems in drug swallow.

The nutritional status of the participants was assessed using the MNA®-SF, MUAC, CC, and BMI. The mean MUAC, CC, and BMI were 28.5 ± 2.8 cm, 33.7 ± 2.9 cm, and 24.6 ± 4.3 kg/m^2, respectively. The mean MNA®-SF score was 11.9 ± 1.2.

Table 12 shows the oral function, history of swallow, and nutritional status of the participants. All data, except ODK rates of /ta/ and /pa/, in the experimental group were not significantly different from those in the control group.

Table 12 Oral function, history of swallow, and nutritional status of the participants at baseline

	Total (N = 19)	Experimental group (N = 10)	Control group (N = 9)	p-value
Oral function				
MTP (kPa) *[mean ± SD]*	24.3 ± 3.6	23.6 ± 4.2	25.2 ± 2.8	0.540‡
ODK rate of /ta/ (times/second) *[mean ± SD]*	4.5 ± 0.7	4.1 ± 0.6	4.9 ± 0.5	0.015‡
ODK rate of /ka/ (times/second) *[mean ± SD]*	4.2 ± 0.8	3.9 ± 0.5	4.6 ± 0.9	0.099‡
ODK rate of /pa/ (times/second) *[mean ± SD]*	4.7 ± 0.9	4.3 ± 0.6	5.1 ± 0.9	0.040‡
MWST score *[median (IQR)]*	5 (5-5)	5 (5-5)	5 (5-5)	0.292‡
Oral moisture *[mean ± SD]*	24.4 ± 3.5	23.2 ± 4.4	25.6 ± 1.8	0.967‡
TCI score (%) *[mean ± SD]*	37.4 ± 15.4	41.7 ± 17.2	32.7 ± 12.2	0.232‡
The number of functional natural teeth *[mean ± SD]*	14.4 ± 10.5	15.6 ± 10.7	13.1 ± 10.9	0.743‡
History of sometimes choking while eating *[n (%)]*	5 (26.3)	3 (30.0)	2 (22.2)	1.000†
Causes of choking *[n (%)]*				
Fast eating	1 (5.3)	0 (0.0)	1 (11.1)	0.474†
Soup/water	2 (10.5)	1 (10.0)	1 (11.1)	1.000†
Spicy food	1 (5.3)	1 (10.0)	0 (0.0)	1.000†
Dry food	1 (5.3)	1 (10.0)	0 (0.0)	1.000†
History of problems in drug swallow *[n (%)]*	2 (10.5)	2 (20.0)	0 (0.0)	0.474†
Nutritional status *[mean ± SD]*				
MUAC (cm)	28.5 ± 2.8	28.6 ± 3.1	28.3 ± 2.5	0.870‡
CC (cm)	33.7 ± 2.9	34.2 ± 3.3	33.1 ± 2.5	0.462‡
BMI (kg/m^2)	24.6 ± 4.3	25.7 ± 5.2	23.4 ± 2.8	0.369‡
MNA®-SF score	11.9 ± 1.2	12.2 ± 1.1	11.6 ± 1.2	0.212‡

† Fisher's Exact Test; ‡ Mann-Whitney U Test

MTP: Maximum tongue pressure, ODK: Oral diadochokinesis, MWST: Modified water swallowing test,

TCI: Tongue Coating Index, MUAC: Mid-upper arm circumference, CC: Calf circumference, BMI: Body mass index,

MNA®-SF: Mini Nutritional Assessment-Short Form

When comparing the oral function between the participants with regular and sometimes visiting the dentist, it was found that the MTP of the participants with regular visits was significantly higher than those with sometimes visits. Table 13 shows the comparisons of oral function between participants with regular and sometimes visiting the dentist.

Table 13 Comparisons of oral function between participants with regular and sometimes visiting the dentist

Oral function	Regular visiting the dentist (N = 3)	Sometimes visiting the dentist (N = 16)	p-value
MTP (kPa) *[mean ± SD]*	28.1 ± 1.3	23.7 ± 3.4	0.034*
ODK rate of /ta/ (times/second) *[mean ± SD]*	4.7 ± 0.5	4.4 ± 0.7	0.430
ODK rate of /ka/ (times/second) *[mean ± SD]*	4.4 ± 1.1	4.2 ± 0.7	0.753
ODK rate of /pa/ (times/second) *[mean ± SD]*	5.3 ± 0.8	4.6 ± 0.8	0.196
MWST score *[median (IQR)]*	5 (5-5)	5 (5-5)	0.665
Oral moisture *[mean ± SD]*	24.8 ± 2.7	24.3 ± 3.8	0.737
TCI score (%) *[mean ± SD]*	38.9 ± 14.7	37.2 ± 15.9	0.735
The number of function natural teeth *[mean ± SD]*	21.3 ± 4.5	13.1 ± 10.9	0.263

* $p < 0.05$ by Mann-Whitney U Test

MTP: Maximum tongue pressure, ODK: Oral diadochokinesis, MWST: Modified water swallowing test,

TCI: Tongue Coating Index

When comparing the oral function and nutritional status between the participants with mild and moderate dementia, it was found that the MTP of the participants with mild dementia was significantly higher than those with moderate dementia. Table 14 shows the comparisons of oral function and nutritional status between participants with mild and moderate dementia.

Table 14 Comparisons of oral function and nutritional status between participants with mild and moderate dementia

Oral function / Nutritional status	Mild dementia (N = 14)	Moderate dementia (N = 5)	p-value
Oral function			
MTP (kPa) *[mean ± SD]*	25.9 ± 2.5	20.1 ± 2.6	0.003*
ODK rate of /ta/ (times/second) *[mean ± SD]*	4.5 ± 0.7	4.4 ± 0.6	0.744
ODK rate of /ka/ (times/second) *[mean ± SD]*	4.2 ± 0.8	4.2 ± 0.6	0.852
ODK rate of /pa/ (times/second) *[mean ± SD]*	4.7 ± 0.9	4.6 ± 0.8	0.744
MWST score *[median (IQR)]*	5 (5-5)	5 (5-5)	0.550
Oral moisture *[mean ± SD]*	24.3 ± 3.4	24.4 ± 4.4	0.711
TCI score (%) *[mean ± SD]*	35.3 ± 12.6	43.3 ± 22.0	0.483
The number of functional natural teeth *[mean ± SD]*	12.9 ± 9.8	18.8 ± 12.6	0.178
Nutritional status *[mean ± SD]*			
MUAC (cm)	28.8 ± 2.9	27.5 ± 2.3	0.354
CC (cm)	33.5 ± 2.7	34.2 ± 3.9	0.817
BMI (kg/m^2)	25.0 ± 4.5	23.4 ± 3.7	0.405
MNA®-SF score	11.9 ± 1.2	11.8 ± 1.3	0.807

* $p < 0.05$ by Mann-Whitney U Test

MTP: Maximum tongue pressure, ODK: Oral diadochokinesis, MWST: Modified water swallowing test,

TCI: Tongue Coating Index, MUAC: Mid-upper arm circumference, CC: Calf circumference, BMI: Body mass index,

MNA®-SF: Mini Nutritional Assessment-Short Form

When comparing the oral function and nutritional status between the participants with AD and VaD, it was found that the ODK rates of /ta/, /ka/ and /pa/ of the participants with AD were significantly higher than those with VaD. Table 15 shows the comparisons of oral function and nutritional status between participants with AD and VaD.

Table 15 Comparisons of oral function and nutritional status between participants with Alzheimer's disease (AD) and vascular dementia (VaD)

Oral function / Nutritional status	AD (N = 10)	VaD (N = 8)	p-value
Oral function			
MTP (kPa) *[mean ± SD]*	23.8 ± 3.4	25.2 ± 4.0	0.266
ODK rate of /ta/ (times/second) *[mean ± SD]*	4.8 ± 0.5	4.0 ± 0.6	0.009*
ODK rate of /ka/ (times/second) *[mean ± SD]*	4.7 ± 0.8	3.8 ± 0.4	0.014*
ODK rate of /pa/ (times/second) *[mean ± SD]*	5.1 ± 0.8	4.2 ± 0.7	0.040*
MWST score *[median (IQR)]*	5 (5-5)	5 (5-5)	0.371
Oral moisture *[mean ± SD]*	24.9 ± 2.9	23.7 ± 4.5	0.790
TCI score (%) *[mean ± SD]*	38.9 ± 16.1	34.0 ± 15.3	0.590
The number of function natural teeth *[mean ± SD]*	12.2 ± 10.7	16.8 ± 11.1	0.423
Nutritional status *[mean ± SD]*			
MUAC (cm)	27.7 ± 2.3	29.0 ± 3.1	0.593
CC (cm)	33.0 ± 2.4	34.0 ± 3.4	0.722
BMI (kg/m^2)	22.6 ± 2.4	26.4 ± 5.1	0.062
MNA®-SF score	11.7 ± 1.3	12.0 ± 1.2	0.609

* $p < 0.05$ by Mann-Whitney U Test

MTP: Maximum tongue pressure, ODK: Oral diadochokinesis, MWST: Modified water swallowing test,

TCI: Tongue Coating Index, MUAC: Mid-upper arm circumference, CC: Calf circumference, BMI: Body mass index,

MNA®-SF: Mini Nutritional Assessment-Short Form

When analyzing with Spearman's correlation to determine the association between oral function and other variables at baseline, it was found that the MTP was significantly positively correlated with the BAI score but significantly negatively correlated with the CDR sum of box score. The ODK rates of /ta/, /ka/, and /pa/ were found to be correlated significantly. The ODK rates of /ta/ and /pa/ were significantly positively correlated with the BAI score but significantly negatively correlated with the number of medication-induced hyposalivation/xerostomia. The TCI score was significantly negatively correlated with the oral moisture and age. The number of functional natural teeth was significantly negatively correlated with age. Furthermore, it was found that the BAI score was significantly negatively correlated with the CDR sum of box score and the number of medication-induced hyposalivation/xerostomia. Table 16 shows the Spearman's correlation coefficient (rho) for the oral function and related variables at baseline.

When analyzing with univariable linear regression, it was found that the MTP was significantly positively related to the BAI score but significantly negatively related to the CDR sum of box score. The ODK rates of /ta/ and /pa/ were significantly positively related to the BAI score but significantly negatively related to the number of medication-induced hyposalivation/xerostomia. In addition, the results of the multivariable linear regression presented that the MTP was significantly negatively related to the CDR sum of box score. The ODK rate of /ta/ was significantly negatively related to the number of medication-induced hyposalivation/xerostomia, but significantly positively related to the BAI score and the number of hours/week spent on social activities. The ODK rate of /pa/ was significantly negatively related to the number of medication-induced hyposalivation/xerostomia. Table 17 shows the results of linear regression analysis for the factors influencing the oral function at baseline.

Table 16 Spearman's correlation coefficient (rho) for the oral function and related variables at baseline

	MTP	ODK /ta/	ODK /ka/	ODK /pa/	MWST score	Oral Moisture	TCI score	NT	CDR S score	BAI score	Age	Med xeros
MTP	1.000											
ODK /ta/	-0.058	1.000										
ODK /ka/	-0.178	0.891**	1.000									
ODK /pa/	0.014	0.887**	0.862**	1.000								
MWST score	0.086	0.022	-0.022	0.065	1.000							
Oral Moisture	0.062	0.030	-0.163	-0.191	0.086	1.000						
TCI score	-0.273	-0.010	0.082	0.070	0.065	-0.474*	1.000					
NT	-0.270	-0.154	-0.205	-0.226	0.345	0.078	0.423	1.000				
CDR S score	-0.705**	-0.238	-0.214	-0.233	0.000	-0.108	0.129	0.303	1.000			
BAI score	0.573*	0.551*	0.417	0.595**	-0.044	0.091	0.120	-0.226	-0.751**	1.000		
Age	-0.133	0.059	-0.045	0.033	-0.390	-0.019	-0.470*	-0.553*	0.243	-0.131	1.000	
Med xeros	-0.136	-0.609**	-0.400	-0.578**	0.309	-0.262	0.233	0.418	0.143	-0.572*	-0.420	1.000

* $p < 0.05$, ** $p < 0.01$

MTP: Maximum tongue pressure, ODK /ta/: Oral diadochokinesis rate of /ta/, ODK /ka/: Oral diadochokinesis rate of /ka/, ODK /pa/: Oral diadochokinesis rate of /pa/,

MWST: Modified water swallowing test, TCI: Tongue Coating Index, NT: The number of functional natural teeth, CDR S: Clinical Dementia Rating sum of box,

BAI: Barthel Activities of Living Index, Med xeros: The number of medication-induced hyposalivation/xerostomia

Table 17 Results of linear regression analysis for the factors influencing the oral function at baseline

Oral function	Univariable regression					Multivariable regression				
	Factors	B	SE	ß	p-value	Factors	B	SE	ß	p-value
MTP	- CDR sum of box score	-1.357	0.265	-0.779	< 0.001*	CDR sum of box score	-1.357	0.265	-0.779	< 0.001*
	- BAI score	0.684	0.252	0.551	0.015*					
ODK rate of /ta/	- The number of medication-induced hyposalivation/xerostomia	-0.290	0.085	-0.636	0.003*	- The number of medication-induced hyposalivation/xerostomia	-0.248	0.085	-0.544	0.011*
	- BAI score	0.148	0.045	0.626	0.004*	- BAI score	0.093	0.042	0.392	0.046*
	- The number of hours/week of social activities	0.009	0.015	0.154	0.530	- The number of hours/week of social activities	0.023	0.010	0.369	0.036*
ODK rate of /pa/	- BAI score	0.159	0.062	0.530	0.020*	The number of medication-induced hyposalivation/xerostomia	-0.320	0.117	-0.554	0.014*
	- The number of medication-induced hyposalivation/xerostomia	-0.320	0.117	-0.554	0.014*					

* $p < 0.05$

MTP: Maximum tongue pressure, ODK: Oral diadochokinesis, CDR: Clinical Dementia Rating, BAI: Barthel Activities of Daily Living Index

4. Oral exercise compliance of the participants

Through the end of 3 months, all subjects in the training group could perform the home-based oral exercises continuously without any reported serious adverse effects. The mean percentage of oral exercise compliance of the 1st month, 2nd month, 3rd month, and total compliance were 97.9%, 96.7%, 95.3%, and 96.5%, respectively. When analyzing with Spearman's correlation, it was found that the total exercise compliance was significantly negatively correlated with age, that is, the older the subjects are, the lower their compliance. However, when comparing the exercise compliance between the subjects with mild and moderate dementia, there was no significant difference between both groups (p = 0.122 by Mann-Whitney U Test).

5. Oral function through the end of 3 months and the effects of home-based oral exercises on the oral function

Table 18 presents the results of GEE analysis when time, groups (intervention), and interaction between time and groups were used as the factors, and the oral functions were used as the dependent variables.

Table 18 Results of generalized estimating equation (GEE) analysis when the oral functions were used as the dependent variables

Oral function	Time			Groups			Time X Groups		
	χ^2	df	p-value	χ^2	df	p-value	χ^2	df	p-value
MTP	159.98	3	< 0.001*	14.16	1	< 0.001*	155.69	3	< 0.001*
ODK rate of									
/ta/	68.16	3	< 0.001*	0.24	1	0.625	113.32	3	< 0.001*
/ka/	48.29	3	< 0.001*	0.16	1	0.688	61.77	3	< 0.001*
/pa/	17.53	3	< 0.001*	0.08	1	0.775	49.81	3	< 0.001*
Oral moisture	8.07	3	0.045*	0.62	1	0.431	3.33	3	0.344

* p < 0.05, MTP: Maximum tongue pressure, ODK: Oral diadochokinesis

5.1 MTP

Table 19 shows the MTP from baseline through the end of 3 months. In the experimental group, the MTP of the participants improved significantly after performing the oral exercises. The MTP at M-1, M-2, and M-3 were significantly higher than at M-0, and the MTP at M-2 and M-3 were significantly higher than at M-1. On the other hand, the MTP of the participants in the control group slightly increased after 3 months. Furthermore, when comparing between two groups, the MTP in the experimental group were significantly higher than in the control group at M-1, M-2, and M-3. The results of GEE analysis showed significant interaction effects between time and groups, significant differences between groups, and significant effects of time when the MTP was used as the dependent variable (Table 18).

5.2 ODK rate of /ta/

Table 19 shows the ODK rate of /ta/ from baseline through the end of 3 months. In the experimental group, the ODK rate of /ta/ of the participants improved significantly after performing the oral exercises. The ODK rates of /ta/ at M-1, M-2, and M-3 were significantly higher than at M-0. On the other hand, in the control group, the ODK rate of /ta/ of the participants decreased significantly after 3 months. The ODK rates of /ta/ at M-2 and M-3 were significantly lower than at M-0. The results of GEE analysis showed significant interaction effects between time and groups and significant effects of time when the ODK rate of /ta/ was used as the dependent variable (Table 18).

Table 19 The oral function from baseline through the end of 3 months of the participants

	Experimental group				Control group			
	M-0	M-1	M-2	M-3	M-0	M-1	M-2	M-3
MTP (kPa) *[mean ± SD]*	23.6 ± 4.2	33.5 ± 6.5 $^{§, \#}$	36.9 ± 6.7 $^{§, ¶, \#}$	37.8 ± 6.7 $^{§, ¶, \#}$	25.2 ± 2.8	25.1 ± 3.1 $^{\#}$	25.1 ± 2.9 $^{\#}$	25.5 ± 3.5 $^{\#}$
ODK rate of /ta/ (times/second) *[mean ± SD]*	4.1 ± 0.6	5.0 ± 0.7 §	5.1 ± 0.8 §	5.2 ± 0.7 §	4.9 ± 0.5	4.8 ± 0.6	4.6 ± 0.7 §	4.6 ± 0.7 §
ODK rate of /ka/ (times/second) *[mean ± SD]*	3.9 ± 0.5	4.8 ± 0.8 §	5.0 ± 0.7 $^{§, ¶}$	4.9 ± 0.7 $^{§, ¶}$	4.6 ± 0.9	4.5 ± 0.9	4.5 ± 0.9	4.5 ± 0.9 §
ODK rate of /pa/ (times/second) *[mean ± SD]*	4.3 ± 0.6	5.1 ± 0.8 §	5.2 ± 0.8 §	5.3 ± 0.9 $^{§, ¶}$	5.1 ± 0.9	4.9 ± 0.8 §	4.7 ± 0.8 $^{§, ¶}$	4.8 ± 0.8 §
MWST score *[median (IQR)]*	5 (5-5)	5 (5-5)	5 (5-5)	5 (5-5)	5 (5-5)	5 (5-5)	5 (5-5)	5 (5-5)
Oral moisture *[mean ± SD]*	23.2 ± 4.4	25.8 ± 4.1 §	26.1 ± 3.2 §	26.1 ± 3.4 §	25.6 ± 1.8	26.1 ± 2.8	26.4 ± 3.2	26.4 ± 1.4 §

§ $p < 0.05$ by GEE analysis: Difference in a comparison to M0

¶ $p < 0.05$ by GEE analysis: Difference in a comparison to M1

$^{\#}$ $p < 0.05$ by GEE analysis: Difference between experimental and control groups

M-0: At baseline, M-1: At the end of the 1st month, M-2: At the end of the 2nd month, M-3: At the end of the 3rd month

MTP: Maximum tongue pressure, ODK: Oral diadochokinesis, MWST: Modified water swallowing test

5.3 ODK rate of /ka/

Table 19 shows the ODK rate of /ka/ from baseline through the end of 3 months. In the experimental group, the ODK rate of /ka/ of the participants improved significantly after performing the oral exercises. The ODK rates of /ka/ at M-1, M-2, and M-3 were significantly higher than at M-0, and the rates at M-2 and M-3 were significantly higher than at M-1. On the other hand, in the control group, the ODK rate of /ka/ of the participants decreased significantly after 3 months. The ODK rate of /ka/ at M-3 was significantly lower than at M-0. The results of a GEE analysis showed significant interaction effects between time and groups and significant effects of time when the ODK rate of /ka/ was used as the dependent variable (Table 18).

5.4 ODK rate of /pa/

Table 19 shows the ODK rate of /pa/ from baseline through the end of 3 months. In the experimental group, the ODK rate of /pa/ of the participants improved significantly after performing the oral exercises. The ODK rates of /pa/ at M-1, M-2, and M-3 were significantly higher than at M-0, and the rate at M-3 was significantly higher than at M-1. On the other hand, in the control group, the ODK rate of /pa/ of the participants decreased significantly after 3 months. The ODK rates of /pa/ at M-1, M-2, and M-3 were significantly lower than at M-0, and the rate at M-2 was significantly lower than at M-1. The results of GEE analysis showed significant interaction effects between time and groups and significant effects of time when the ODK rate of /pa/ was used as the dependent variable (Table 18).

5.5 Swallowing function

Table 19 shows the MWST score from baseline through the end of 3 months. Throughout this study, the MWST scores of the subjects in experimental and control groups were unchanged.

5.6 Oral moisture

Table 19 shows the oral moisture from baseline through the end of 3 months. In the experimental group, the oral moisture value of the participants improved significantly after performing the oral exercises. The oral moisture values at M-1, M-2, and M-3 were significantly higher than at M-0. However, in the control group, the oral moisture of the participants also increased significantly after 3 months. The oral moisture value at M-3 was significantly higher than at M-0. The results of a GEE analysis showed only significant effects of time when the oral moisture was used as the dependent variable (Table 18).

Furthermore, when considering the TCI score after receiving the general oral hygiene instruction, the TCI scores of the participants in the experimental group decreased from 41.7 ± 17.2 percent at baseline to 37.8 ± 18.5 percent after 3 months, and the TCI scores in the control group also decreased from 32.7 ± 12.2 percent at baseline to 30.2 ± 15.0 percent after 3 months. This indicated that the tongue coating of the participants in both groups decreased after receiving the general oral hygiene instruction.

When analyzing with Spearman's correlation to determine the association between the changes of oral function and other variables in the experimental group, it was found that the mean differences of the ODK rates of /ta/, /ka/, and /pa/ were found to be significantly correlated and were significantly negatively correlated with the MMSE score. Moreover, the mean difference of the ODK rate of /ka/ was significantly positively correlated with the number of hours/week of physical exercise practices. Table 20 shows the Spearman's correlation coefficient (rho) for the changes of ODK rates and related variables in the experimental group.

Table 20 Spearman's correlation coefficient (rho) for the changes of ODK rates and related variables in the experimental group

	Δ ODK rate of /ta/	Δ ODK rate of /ka/	Δ ODK rate of /pa/	MMSE score	The number of hours/week of physical exercise practices
Δ ODK rate of /ta/	1.000				
Δ ODK rate of /ka/	0.684*	1.000			
Δ ODK rate of /pa/	0.959**	0.815**	1.000		
MMSE score	-0.762*	-0.691*	-0.806**	1.000	
The number of hours/week of physical exercise practices	0.404	0.673*	0.481	-0.425	1.000

* p < 0.05, ** p < 0.01, Δ Mean difference

ODK: Oral diadochokinesis, MMSE: Mini-Mental State Examination

Furthermore, when analyzing with Spearman's correlation to determine the association between the changes of oral function and other variables in the control group, it was found that the mean difference of MTP was significantly positively correlated with the MMSE score but significantly negatively correlated with the CDR sum of box score. Table 21 shows the Spearman's correlation coefficient (rho) for the changes of MTP and related variables in the control group.

Table 21 Spearman's correlation coefficient (rho) for the changes of MTP and related variables in the control group

	Δ MTP	MMSE score	CDR sum of box score
Δ MTP	1.000		
MMSE score	0.711*	1.000	
CDR sum of box score	-0.672*	-0.487	1.000

* p < 0.05, ** p < 0.01, Δ Mean difference

MTP: Maximum tongue pressure, CDR: Clinical Dementia Rating

6. History of swallow after doing oral exercises

In the experimental group, the history of choking while eating and problems in drug swallow in daily lives of the participants were likely to improve. At M-3, the number of participants with sometimes choking decreased from 3 to 1 participant. Only one participant in the experimental group sometimes choked while eating spicy food. In addition, at M-3, the number of participants with problems in drug swallow decreased from 2 to no participants. On the other hand, the number of participants with sometimes choking in the non-training group increased from 2 to 3 participants. Table 22 shows the history of choking while eating and problems in drug swallow from baseline to three months later.

Table 22 The history of choking while eating and drug swallow at baseline through the end of 3 months of the participants

	Experimental group				Control group			
	M-0	M-1	M-2	M-3	M-0	M-1	M-2	M-3
History of sometimes choking while eating [n (%)]	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	2 (22.2)	2 (22.2)	3 (33.3)	3 (33.3)
Causes of choking [n (%)]								
Fast eating	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)	2 (22.2)	2 (22.2)
Soup/water	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (11.1)	1 (11.1)	1 (11.1)
Spicy food	1 (10.0)	1 (10.0)	1 (10.0)	1 (10.0)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)
Dry food	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
History of problems in drug Swallow [n (%)]	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

M-0: At baseline, M-1: At the end of the 1st month, M-2: At the end of the 2nd month, M-3: At the end of the 3rd month

7. Nutritional status after 3 months

Table 23 presents the results of GEE analysis when time, groups, and interaction between time and groups were used as the factors, and the nutritional parameters were used as the dependent variables.

Table 23 Results of generalized estimating equation (GEE) analysis when the nutritional parameters were used as the dependent variables

Nutritional parameters	Time			Groups			Time X Groups		
	χ^2	df	p-value	χ^2	df	p-value	χ^2	df	p-value
MUAC	1.58	1	0.209	0.61	1	0.435	13.82	1	< 0.001*
CC	5.45	1	0.020*	1.33	1	0.249	7.46	1	0.006*
BMI	0.38	1	0.537	2.43	1	0.119	14.71	1	< 0.001*
MNA®-SF score	1.34	1	0.247	2.50	1	0.114	0.28	1	0.595

* $p < 0.05$

MUAC: Mid-upper arm circumference, CC: Calf circumference, BMI: Body mass index,

MNA®-SF: Mini Nutritional Assessment-Short Form

7.1 MUAC

Table 24 shows the MUAC at baseline and at the end of 3 months. In the experimental group, the MUAC of the participants increased significantly after 3 months. The MUAC at M-3 was significantly higher than at M-0. On the other hand, the MUAC of the participants in the control group decreased after 3 months. The results of GEE analysis showed significant interaction effects between time and groups when the MUAC was used as the dependent variable (Table 23).

Table 24 The nutritional parameters at baseline and at the end of 3 months of the participants

	Experimental group			Control group		
	M-0	M-3	p-value	M-0	M-3	p-value
MUAC (cm) *[mean ± SD]*	28.6 ± 3.1	29.5 ± 3.2	0.001*	28.3 ± 2.5	27.9 ± 2.7	0.055
CC (cm) *[mean ± SD]*	34.2 ± 3.3	34.9 ± 3.6	0.002*	33.1 ± 2.5	33.0 ± 2.7	0.728
BMI (kg/m^2) *[mean ± SD]*	25.7 ± 5.2	26.2 ± 5.1	0.003*	23.4 ± 2.8	23.0 ± 2.8	0.016*
MNA®-SF score *[mean ± SD]*	12.2 ± 1.1	12.5 ± 1.0	0.138	11.6 ± 1.2	11.7 ± 1.2	0.703

* $p < 0.05$ by GEE analysis: Difference between M0 and M3

M-0: At baseline, M-3: At the end of the 3rd month

MUAC: Mid-upper arm circumference, CC: Calf circumference, BMI: Body mass index, MNA®-SF: Mini Nutritional Assessment-Short Form

7.2 CC

Table 24 shows the CC at baseline and at the end of 3 months. In the experimental group, the CC of the participants increased significantly after 3 months. The CC at M-3 was significantly higher than at M-0. On the other hand, the CC of the participants in the control group slightly decreased after 3 months. The results of GEE analysis showed significant interaction effects between time and groups and significant effects of time when the CC was used as the dependent variable (Table 23).

7.3 BMI

Table 24 shows the BMI at baseline and at the end of 3 months. In the experimental group, the BMI of the participants increased significantly after 3 months. The BMI at M-3 was significantly higher than at M-0. On the other hand, the BMI of the participants in the control group decreased significantly after 3 months. The BMI at M-3 was significantly lower than at M-0. The results of GEE analysis showed significant interaction effects between time and groups when the BMI was used as the dependent variable (Table 23).

7.4 MNA®-SF score

Table 24 shows the MNA®-SF score at baseline and at the end of 3 months. The MNA®-SF score of the participants in both experimental and control groups increased after 3 months. The results of GEE analysis did not show any significant effects when the MNA®-SF score was used as the dependent variable (Table 23).

CHAPTER V
DISCUSSION

This study evaluated the oral function of people with mild to moderate dementia in six aspects, which were tongue strength represented by MTP; tongue-lip motor function represented by ODK rates of /ta/, /ka/, and /pa/; swallowing function represented by MWST score; oral moisture; oral hygiene represented by TCI score; and occlusal force represented by the number of functional natural teeth. The measurements of tongue strength, tongue-lip motor function, oral moisture, oral hygiene, and occlusal force in this study followed the recommendations of the JSG[12]. It was presented that decreased TP, decreased tongue-lip motor function, oral dryness, poor oral hygiene, and decreased occlusal force will be diagnosed when the MTP is less than 30 kPa, the ODK rate is less than 6 times/second, the oral moisture is less than 27.0, the TCI score is at least 50%, and there were less than 20 natural teeth (without retained roots and mobility 3) in the mouth, respectively.[12] In this study, the baseline values of MTP, ODK rates of /ta/, /ka/, and /pa/, oral moisture, TCI score, and the number of functional natural teeth were lower than the diagnostic values of oral hypofunction proposed by the JSG[12]. This indicated that, at baseline, the subjects had decreased TP, decreased tongue-lip motor function, oral dryness, and decreased occlusal force, but did not have poor oral hygiene. However, although the JSG suggested measuring the swallowing function by using the EAT-10,[12] the researcher decided to use the MWST, which is safe, simple, and easy[23], to evaluate the swallowing function in this study because the EAT-10 requires self-reported answers from the subjects, and the impairment of cognition and memory in the subjects with dementia might affect the accuracy of these self-reported answers.[163] The median MWST score at baseline of the subjects was 5, indicating no obvious swallowing problems.

Considering the oral function of the subjects at baseline, it was found that the MTP of the subjects who regularly visited the dentists was significantly higher than those visited the dentists only when they had oral problems. It might be because the subjects who regularly visit the dentists could get the oral care properly. If the dentists noticed any oral problems, they would provide recommendations and treatments as soon as possible. Therefore, people with dementia should be encouraged to have regular dental checkups. Moreover, the ODK rates of /ta/, /ka/, and /pa/ which represent the motor function of tongue and lips of the subjects with VaD were significantly lower than those with AD. This was probably because the VaD is more common in patients with stroke, that could impair their motor function.[3, 199]

The MTP of the subjects with mild dementia was found to be significantly higher than those with moderate dementia. This finding is consistent with other findings in this study which showed a significantly negative relation between MTP and CDR sum of box score which represents the severity of dementia, that is, the more severe the dementia, the lower the tongue strength. Furthermore, the MTP and ODK rates of /ta/ and /pa/ were found to be significantly positively related to the BAI score, that is, the more functional dependence, the lower tongue strength and tongue-lip motor function. For example, some subjects with low BAI scores might require assistance in eating due to their impaired tongue strength and motor function of tongue and lips. In addition, the ODK rate of /ta/ was significantly associated with the number of hours/week spent on social activities (e.g., talking with neighborhoods, meeting with friends and family). The movements of tongue while speaking could be a probable explanation of this finding. Therefore, people with dementia should be encouraged to participate in the social activities that they enjoy. This is beneficial to their oral function as well as other aspects.

The TCI score was found to be significantly negatively related to the oral moisture value, that is, the more tongue coating, the less oral moisture. This finding

is consistent with Watanabe's as cited in Funahara et al's study, which presented that tongue coating was associated with dry mouth.[200] Moreover, the number of functional natural teeth in this study was found to be significantly negatively related with age. This finding is consistent with a previous study which presented an association between age and the number of natural teeth.[201]

When considering the oral function after performing a package of three home-based oral exercises and the influences of the training on oral function, the results showed that the home-based oral exercises performed in this study could significantly improve tongue strength and motor function of tongue and lips in people with mild to moderate dementia. However, it did not affect the swallowing function and oral moisture.

The results of MTP in this study are consistent with the previous research which were conducted in various groups of people[30-33, 37, 40]. Moreover, the mean difference of the MTP in the control group was significantly positively correlated with the MMSE score but significantly negatively correlated with the CDR sum of box score. This indicated that, in people with mild to moderate dementia who did not perform any oral exercises, changes in tongue strength were associated with their cognitive function and severity of dementia.

The results of tongue-lip motor function in this study are consistent with a previous study which showed significant improvement in the alternating motion rate (AMR) of /t**ə**/ after the training of tongue strength.[37] However, the results in this study are not in agreement with a previous research which did not show significant changes in the ODK rates of /pa/, /ta/ ,and /ka/ after the exercise of pronouncing the syllables pa-ta-ka and other trainings.[61] When considering the changes in the ODK rates of /ta/, /ka/, and /pa/ in the experimental group, the mean differences of all ODK rates were found to significantly negatively related to the MMSE score. This indicated that, in people with mild to moderate dementia who performed oral

exercises, changes in tongue-lip motor function were associated with their cognitive function. Furthermore, the mean difference of the ODK rate of /ka/ was significantly positively related to the number of hours/week spent on physical exercise practices (e.g., walking, stretching and/or moving arms and legs, and aerobic dance). Therefore, people with dementia should be encouraged to perform the non-harmful physical exercises that they enjoy because it is beneficial to their health as well as their oral function.

Regarding the swallowing function, the MWST scores of all subjects in two groups did not change through the end of 3 months. This indicated that all subjects in this study swallowed the water in the MWST safely during the 3-month period, as evidenced by the MWST scores of 4 or 5.

By the way, previous research found the association between the strength of swallowing-related muscles and whole body. For examples, the TP which represents tongue strength was significantly related to walking speed[24], grip strength[24], and back muscle strength[137], and the JOF which represents suprahyoid muscle strength was significantly related to neck circumference[142] and grip strength[24]. Therefore, the evaluation of tongue and swallowing-related muscle strength could include oral area and entire body.

In this study, the oral moisture values of the subjects in both groups increased significantly after 3 months. This could be explained that the exercises conducted in this study might not directly affect the changes in oral moisture. However, the oral exercises might be a quick way to improve oral moisture because, when compared to baseline, the oral moisture values in the training group increased significantly after 1, 2, and 3 months of training, while those in the control group increased significantly after 3 months. The people with dementia who did not perform any oral exercises might take longer to significantly increase their oral moisture value due to some limitations.

After finishing the exercise program, the nutritional parameters consisting of MUAC, CC, and BMI were significantly higher than at baseline. These results indicated that the oral exercises performed in this study improved oral function, that is, the participants could eat more as a result of improved oral function after completing oral exercises. However, these people should be focused on maintaining muscles. They should eat proper and healthy foods, such as proteins, lean meats, fish, eggs, dairy products, vegetables, beans, fruits, and berries, while reducing the proportions of carbohydrates and fats, as well as avoiding foods high in saturated fats.[202, 203] However, people who have underlying diseases should eat foods that are appropriate for their diseases. Moreover, these people should perform physical exercises that they enjoy regularly.[203] In addition, the history of choking while eating and problems in drug swallow in daily lives of the participants in the experimental group were likely to improve after doing oral exercises. After 1, 2, and 3 months of training, the number of trained participants with history of choking while eating and problems in drug swallow decreased. Only one participant in the experimental group sometimes choked while eating spicy food. Nonetheless, coughing while eating spicy food may not be unusual, as capsaisin, the pungent agent in chili peppers, has been reported as a cough stimulant.[204]

In this study, the subjects could perform the home-based oral exercises continuously throughout this 3-month training, without any reported serious adverse events. The overall exercise compliance rate was 96.5 percent, which resulted in the significant improvements in tongue strength and motor function of tongue and lips. The exercise compliance of the subjects with mild dementia was not significantly different from those with moderate dementia. This indicated that the exercise compliance might not depend on the severity of dementia. However, the exercise compliance was significantly negatively associated with age, that is, the older the people with dementia are, the lower their compliance. The key person of doing the

home-based oral exercises was the caregivers who were instructed to lead and control these exercises. Therefore, the caregivers should be educated on the decreased oral function, the consequences of decreased oral function, and the benefits of oral exercises. If they completely understand, they will have a positive attitude toward these oral exercises and will do the best in administering these exercises, resulting in high exercise compliance and improved oral function.

This study did not evaluate the oral health-related quality of life (OHRQoL) of the subjects because the OHRQoL indices require self-reported answers from the subjects, and the impairment of cognition and memory in the subjects with dementia might affect the accuracy of these self-reported answers.[163] However, according to a previous study, the older people should keep at least 5 natural teeth in order to have better OHRQoL.[205] In this study, the mean number of functional natural teeth was 14.4 teeth. This probably indicated that the subjects' OHRQoL was not bad.

The researcher suggested the health professionals, caregivers, and families who take care of people with dementia to add this oral exercise protocol as a part of dementia management in order to enable the people with dementia to have improved oral function, resulting in safe and efficient eating for as long as possible. In addition, the people with dementia should be encouraged to participate in social activities and perform non-harmful physical exercises regularly because these activities would be beneficial to their oral function as well as other aspects. The Dementia Day Center at King Chulalongkorn Memorial Hospital is a good model for the care centers since it offers a variety of activities, including mental activities, social activities, and exercise practices, to the people with dementia and their caregivers.

By the way, a relatively small sample size is a limitation in this study. There were differences in a few parameters between the experimental and control groups at baseline. Increasing the sample size in the future might help to resolve these findings. However, the sample size in this study met the minimum requirement.

Furthermore, because there was only one examiner in this study, the examiner was not blinded. However, the examiner attempted to conduct this study without bias. The further study should be conducted in the larger sample size with more than one examiner. In addition, other aspects of oral function in people with dementia should be examined in order to shed light on the useful information in this field.

CHAPTER VI
CONCLUSION

The home-based oral exercises in this study could significantly improve tongue strength and motor function of tongue and lips in people with mild to moderate dementia. The changes in tongue-lip motor function of the participants in the training group were significantly correlated with their cognitive function and physical exercise practices. The consequences of improved oral function were significant increases in nutritional parameters, indicating that these people could eat more. The subjects in this study could perform the home-based oral exercises continuously throughout this 3-month training without any serious reported adverse events, and the overall compliance was great. Their exercise compliance was significantly negatively associated with age and did not depend on their severity of dementia. The caregivers, who were trained to lead and control these exercises, were crucial to the success of the exercise. They should have a positive attitude toward oral exercises after learning about the consequences of decreased oral function and benefits of oral exercises. The researcher suggested the health professionals, caregivers, and families who take care of people with dementia to add this oral exercise protocol as a part of dementia management in order to enable the people with dementia to have improved oral function, resulting in safe and efficient eating for as long as possible.

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